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Bağcılar Tıp Bülteni

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The journal is published quarterly in March, June, September and December.

English Title: Bagcilar Medical Bulletin

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T.C.Sağlık Bakanlığı Sağlık Bilimleri Üniversitesi, İstanbul Bağcılar Eğitim ve Araştırma Hastanesi adına Başhekim Doç. Dr. Ozan Beytemür. (Türkiye Cumhuriyeti Sağlık Bakanlığı Sağlık Bilimleri Üniversitesi, İstanbul Bağcılar Eğitim ve Araştırma Hastanesi, Ortopedi ve Travmatoloji Kliniği, İstanbul, Türkiye).

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The journal is published quarterly in March, June, September and December.

Original clinical and experimental articles,interesting case studies, and literature reviews made from relevant authors in their brancheswill be accepted for evaluation in BMB.

Bagcilar Medical Bulletin is indexed in **TÜBİTAK/ULAKBİM, EBSCO, Gale, Türk Medline, Turkey Citation Index, Index Copernicus, ProQuest, J-Gate** and **ScopeMed.**

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Bağcılar Tıp Bülteni/Bagcilar Medical Bulletin (BTB), Sağlık Bilimleri Üniversitesi, İstanbul Bağcılar Eğitim ve Araştırma Hastanesi'nin süreli bilimsel yayınıdır. Uluslararası, hakem değerlendirmeli, İngilizce ve açık erişim olarak yılda 4 sayı (Mart, Haziran, Eylül, Aralık) yayınlanan bilimsel bir dergi olup, tıbbın tüm alanlarındaki bilgi birikiminin uluslararası bilimsel platformda yayılabilmesini amaçlamaktadır. Bu amaçla tıbbın her alanında yapılmış orijinal klinik ve deneysel çalışmalar ve ilginç olgu sunumları ile konusunda uzman yazarların yaptığı literatür derlemeleri yayın için değerlendirmeye alınır.

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Derginin editöryal ve yayın süreçleri ile etik kuralları International Committee of Medical Journal Editors (ICMJE), World Association of Medical Editors (WAME), Council of Science Editors (CSE), Committee on Publication Ethics (COPE), European Association of Science Editors (EASE), ve National Information Standards Organization (NISO) gibi uluslararası kuruluşların kurallarına uygun olarak şekillenmektedir. Dergimiz, şeffaf olma ilkeleri ve "Akademik Yayıncılıkta En İyi Uygulamalar İlkeleri" ile uyum içindedir.

Bağcılar Tıp Bülteni, **TÜBİTAK/ULAKBİM, EBSCO, Gale, Türk Medline, Türkiye Atıf Dizini, Index Copernicus, ProQuest, J-Gate** ve **ScopeMed** tarafından indekslenmektedir.

Dergi Adı (İngilizce): Bagcilar Medical Bulletin

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Açık Erişim Politikası

Bu dergi, araştırmaları kamuya ücretsiz olarak sunmanın daha büyük bir küresel bilgi alışverişini desteklediği ilkesine dayanarak içeriğine anında açık erişim sağlar.

Yazarlar ve telif hakkı sahipleri, Bağcılar Tıp Bülteni'nde yayınlanan makaleler için tüm kullanıcılara ücretsiz olarak erişim sağlar. Makaleler kaynak gösterilmek şartıyla kullanıma açıktır.

Açık Erişim Politikası, Budapeşte Açık Erişim Girişimi'nin (BOAI) kurallarına dayanmaktadır. "Açık erişim" ile, onun ücretsiz erişilebilirliğini kastedilmektedir. Herhangi bir kullanıcının bu makalelerin tam metinlerini okumasına, indirmesine, kopyalamasına, dağıtmasına, yazdırmasına, aramasına veya bağlantı vermesine, indeksleme için taramasına, yazılıma veri olarak iletmesine veya başka herhangi bir yasal amaç için internetin kendisine erişim elde etmekten ayrılamaz olanlar dışında finansal, yasal veya teknik engeller olmadan kullanmasına izin verir. Çoğaltma ve dağıtım üzerindeki tek kısıtlama ve bu alandaki telif hakkının tek rolü, yazarlara çalışmalarının bütünlüğü üzerinde kontrol ve uygun şekilde tanınma ve alıntılanma hakkı vermek olmalıdır.

Gönderim, değerlendirme ve yayın sürecinde yazarlardan herhangi bir ücret talep edilmez.

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Description

Bagcilar Medical Bulletin is a peer-reviewed English journal aiming to publish original research, current review articles, case reports and letters related to all medical fields. The journal is currently published quarterly as an online publication. The articles will become freely available to all readers in pdf format as soon as they have been accepted after peer review. Accepted articles will immediately appear as a part of the issue belonging to that publication period. The journal uses EjManager online manuscript submission, review and tracking system .

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The editorial and publication process of the Journal of the Turkish Academy of Dermatology are shaped in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE), World Association of Medical Editors (WAME), Council of Science Editors (CSE), Committee on Publication Ethics (COPE), European Association of Science Editors (EASE), and National Information Standards Organization (NISO). The journal is in conformity with the Principles of Transparency and Best Practice in Scholarly Publishing.

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Authors have to confirm in the section "Materials and Methods" that study has been conducted in compliance to above mentioned principles, approvals have been obtained from related institutional ethical committees and informed consents were collected.

When reporting experiments on animals, authors should indicate whether the institutional and national guides for the care and use of laboratory animals were followed as in "Guide for the Care and Use of Laboratory Animals" and approval from ethical committee should be taken. The editor and the publisher do not guarantee or accept responsibility for the published features or definitions of commercial products. If there is direct or indirect grant support, it should be acknowledged in the section titled "declaration of interest" and should include the full name of the sponsor and grant number. Existence or lack of sponsorship of any kind as well as the type of sponsorship (consulting etc.) has to be acknowledged, as well.

Adopts WAME's definition which states that conflict of interest exists when author, peer reviewer or editor has a competing interest that could unduly influence (or be reasonably seen to do so) his or her responsibilities in the publication process. The types of competing interests that should be declared include financial ties, academic commitments, personal relationships, political or religious beliefs, institutional affiliations. The conflict of interest is to be acknowledged in the manuscript.

All manuscripts submitted to the journal for publication are checked by Crossref Similarity Check powered by "iThenticate" software for plagiarism. If plagiarism is detected, relevant institutions may be notified. In this case, the authors might be asked to disclose their raw data to relevant institutions.

Language

The language of the Bagcilar Medical Bulletin is American English. In addition, abstracts of the articles are published in both English and Turkish, and abstracts in both languages are requested from the authour(s).

Manuscript Organization And Format

All correspondence will be sent to the first-named author unless otherwise specified. Papers should be accompanied by a cover letter indicating that the paper is intended for publication and specifying for which section of the Journal it is being submitted (i.e., original research article,brief research article, review article, case report or letter to the editor). In addition, a Copyright Transfer Form, Author Contribution Form and ICJME Form for Disclosure of Potential Conflicts of Interest must be submitted. Authors will be notified of the receipt of their paper and the number assigned to it. The number should be included in all further correspondence. All parts of the manuscript, including case reports, quotations, references, and tables, must be double-spaced throughout. All four margins must be at least 2.5 cm. The manuscript should be arranged in the following order, with each item beginning a new page: 1) title page, 2) abstract, 3) text, 4) acknowledgement 5) references, and 6) tables and/or figures. All pages must be numbered consecutively.

Title Page

On the title page, include full names of authors, academic or professional affiliations, and complete address with phone, fax number(s) and e-mail address (es) of the corresponding author. Acknowledgments for personal and technical assistance should be indicated on the title page.

Abstract and Keywords

Title of the manuscript in English should be written in English abstract, and a Turkish title must be for Turkish abstract.. All articles should include abstract and keywords. For abstracts are most distinct parts of an article and take place on the electronic databases, author should be sure that abstract represents the content of the article accurately. Abstract should inform about the basis of the study and include the purpose, basic procedures (selection of cases and laboratory animals, observatory and analytical methods), key findings and conclusions. New and significant apects of the study or observations should be stated. Up to 3-10 key words in English and in Turkish should be in accordance with National Library of Medicine's Medical Subjects Subheadings (MeSH).

Manuscript Types

Original Research

Original research articles report substantial and original scientific results within the journal scope. Original research articles comprised of Abstract, Key Words, Introduction, Material and Methods, Results, Discussion, Conclusion, References and Table/ Figures. The abstract should be structured as the following.

INSTRUCTIONS TO AUTHORS

Abstract

The abstract should be no longer than 500 words and structured as follows: objective, method, results, and conclusions. Objective -the primary purpose of the article; Material and Method(s) -data sources, design of the study, patients or participants, interventions, and main outcome measures; Results -key findings; Conclusions -including direct clinical applications.

Keywords

Up to 3-10 key words in English and in Turkish should be in accordance with National Library of Medicine's Medical Subjects Subheadings (MeSH).

Introduction

This section should contain a clear statement of the general and specific objectives as well as the hypotheses which the work is designed to test. It should also give a brief account of the reported literature. The last sentence should clearly state the primary and secondary purposes of the article. Only, the actual references related with the issues have to be indicated and data or findings related with the current study must not be included in this section.

Material and Methods

This section should contain explicit, concise descriptions of all procedures, materials and methods used in the investigation to enable the reader to judge their accuracy, reproducibility, etc. This section should include the known findings at the beginning of the study and the findings during the study must be reported in results section. Ethics Committee Approval of the research and written Informed Consent obtained from the participants should be indicated.

The selection and description of the participants

The election, source of population, inclusion and exclusion criteria of the people who participate to experimental or clinical study must be clearly defined in this section. The particular study sample must be explained by the authors (i.e., why the study is performed in a definite age, race or sex population, etc.)

Technical information

The methods, apparatus (the manufacturer's name and address in parentheses), and procedures in sufficient detail must be defined to allow others to reproduce the results. References to established methods, including statistical methods (see below) must be given and brief descriptions for methods that have been published but are not well-known must be provided; new or substantially modified methods must be described, the reasons for using them must be given, and their limitations of the methods must be evaluated. The all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration must be identified. Authors submitting review manuscripts should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

Statistics

The statistical methods must be described with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. If possible, findings should be quantified and presented with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Relying solely on statistical hypothesis testing, such as P values, which fail to convey important information about effect size must be avoided. References for the design of the study and statistical methods should be to standard works when possible (with pages stated). Define statistical terms, abbreviations, and most symbols. The computer software used must be specified.

Results

The results should be presented in logical sequence in the text, tables, and illustrations, giving the main or most important findings first. The all the data in the tables or illustrations should not be repeated in the text; only the most important observations must

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be emphasized or summarized. Extra or supplementary materials and technical detail can be placed in an appendix where they will be accessible but will not interrupt the flow of the text, or they can be published solely in the electronic version of the journal.

Discussion

The findings of the study, the findings and results which support or do not support the hypothesis of the study should be discussed, results should be compared and contrasted with findings of other studies in the literature and the different findings from other studies should be explained. The new and important aspects of the study and the conclusions that follow from them should be emphasized. The data or other information given in the Introduction or the Results section should not be repeated in detail.

Conclusions

Conclusions derived from the study should be stated. For experimental studies, it is useful to begin the discussion by summarizing briefly the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for future research and for clinical practice. The conclusions should be linked with the goals of the study but unqualified statements and conclusions not adequately supported by the data should be avoided. New hypotheses should be stated when warranted, but should be labeled clearly as such.

Tables, Graphics and Illustrations

Tables, graphics and illustrations should be numbered in Arabic numerals in the text. The places of the illustrations should be signed in the text. Detailed information is under the related heading in below.

Brief Research

Brief researches are similar to original research in that they follow the same format and guidelines, but they consider small-scale research or research that is in early stages of development. These may include preliminary studies that has a simple research design or a small sample size and that have produced limited pilot data and initial findings that indicate need for further investigation. Brief researches are much shorter than manuscripts associated with a more advanced, larger-scale research project. They are not meant to be used for a short version of an article about research that would otherwise qualify for a full original research manuscript or for publishing material on research that lacks significance, is not rigorous or, if expanded, would not qualify for a full article or for research.

Case Report

Case reports consider new, interesting and intriguing case studies in detail. They should be unique and present methods to overcome any health challenge by use of novel tools and techniques and provide a learning source for the readers. Case reports comprise of: Abstract (unstructured summary), Key-words, Introduction, Case Report, Discussion, Reference, Tables and Figures. Written informed consent of the patient should be obtained and indicated in the manuscript.

Review

Review articles are written by individuals who have done substantial work on the subject or are considered experts in the field. The Journal invites authors to write articles describing, evaluating and discussing the current level of knowledge regarding a specific subject in the clinical practice.

The manuscript should have an unstructured abstract representing an accurate summary of the article, key words, introduction, conclusion. Authors submitting review article should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

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Letter to the Editor

Letter to the Editor is short and decisive manuscript. They should be preferably related to articles previously published in the Journal or views expressed in the Journal. The letter should not include preliminary observations that need a later study for validation.

Tables

Tables capture information concisely and display it efficiently; they also provide information at any desired level of detail and precision. Including data in tables rather than text frequently makes it possible to reduce the length of the text. Each table should be typed or printed with double spacing on a separate sheet of paper. The tables should be numbered consecutively in the order of their first citation in the text and a brief title for each table should be supplied. Any internal horizontal or vertical lines should not be used and a short or an abbreviated heading should be given to each column. Authors should place explanatory matter in footnotes, not in the heading. All nonstandard abbreviations should be explained in footnotes, and the following symbols should be used in sequence: *,†,‡,§,ǁ,¶,**,††,‡‡. The statistical measures of variations, such as standard deviation and standard error of the mean should be identified. Be sure that each table is cited in the text. If you use data from another published or unpublished source, obtain permission and acknowledge that source fully. Additional tables containing backup data too extensive to publish in print may be appropriate for publication in the electronic version of the journal, deposited with an archival service, or made available to readers directly by the authors. An appropriate statement should be added to the text. Such tables should be submitted for consideration with the paper so that they will be available to the peer reviewers.

Illustrations (Figures)

Figures should be either professionally drawn and photographed, or submitted as digital prints in photographic-quality. In addition to requiring a version of the figures suitable for printing, authors are asked for electronic files of figures in a format (for example, JPEG or GIF) that will produce high-quality images in the Web version of the journal; authors should review the images of such files on a computer screen before submitting them to be sure they meet their own quality standards. For x-ray films, scans, and other diagnostic images, as well as pictures of pathology specimens or photomicrographs, sharp, glossy, black-and-white or color photographic prints should be sent, usually 127 x 173 mm. Letters, numbers, and symbols on figures should therefore be clear and consistent throughout, and large enough to remain legible when the figure is reduced for publication. Figures should be made as self-explanatory as possible, since many will be used directly in slide presentations. Titles and detailed explanations belong in the legends--not on the illustrations themselves. Photomicrographs should have internal scale markers. Symbols, arrows, or letters used in photomicrographs should contrast with the background. Photographs of potentially identifiable people must be accompanied by written permission to use the photograph. Figures should be numbered consecutively according to the order in which they have been cited in the text. If a figure has been published previously, the original source should be acknowledged and written permission from the copyright holder should be submitted to reproduce the figure. Permission is required irrespective of authorship or publisher except for documents in the public domain. Accompanying drawings marked to indicate the region to be reproduced might be useful to the editor. We publish illustrations in color only if the author pays the additional cost.

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The legends for illustrations should be typed or printed out using one spacing, starting on a separate page, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, each one clearly should be identified and explained in the legend. The internal scale should be explained and the method of staining in photomicrographs should be identified.

Units of Measurement

Measurements of length, height, weight, and volume should be reported in metric units (meter, kilogram, or liter) or their decimal multiples. Temperatures should be in degrees Celsius, blood pressures should be in millimeters of mercury. Authors must consult the Information for Authors of the particular journal and should report laboratory information in both local and International

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System of Units (SI). Drug concentrations may be reported in either SI or mass units, but the alternative should be provided in parentheses where appropriate.

Abbreviations and Symbols

Use only standard abbreviations; use of nonstandard abbreviations can be confusing to readers. Avoid abbreviations in the title of the manuscript. The spelled-out abbreviation followed by the abbreviation in parenthesis should be used on first mention unless the abbreviation is a standard unit of measurement.

Acknowledgement(s)

All forms of support, including individual technical support or material support must be acknowledged in the author's footnote before references.

Case Reports and Word Limitation

Original papers and reviews have no specific word limitation. A case report must be strictly limited to 1000 words excluding abstract and have minimal figures, tables, and references. Letters to the Editor (maximum of 500 words, including references; no tables or figures) will be considered if they include the notation "for publication." A letter must be signed by all of its authors. Letters critical of an article published in the journal must be received within 12 weeks.

Preparation of Manuscripts

The Bagcilar Medical Bulletin follows the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals". Upon submission of the manuscript, authors are to indicate the type of trial/research and provide the checklist of the following guidelines when appropriate:

CONSORT statement for randomized controlled trials (Moher D, Schultz KF, Altman D, for the CONSORT Group. The CONSORT statement revised recommendations for improving the quality of reports of parallel group randomized trials. JAMA 2001; 285: 1987-91),

PRISMA for preferred reporting items for systematic reviews and meta-analyses (Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 2009; 6(7): e1000097.),

STARD checklist for the reporting of studies of diagnostic accuracy (Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al, for the STARD Group. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. Ann Intern Med 2003;138:40-4.),

STROBE statement-checklist of items that should be included in reports of observational studies,

MOOSE guidelines for meta-analysis and systemic reviews of observational studies (Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting Meta-analysis of observational Studies in Epidemiology (MOOSE) group. JAMA 2000; 283: 2008-12).

CARE guidelines are designed to increase the accuracy, transparency, and usefulness of case reports. (Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D; the CARE Group. The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development.)

References

Although references to review articles can be an efficient way to guide readers to a body of literature, review articles do not always reflect original work accurately. Readers should therefore be provided with direct references to original research sources whenever possible. On the other hand, extensive lists of references to original work on a topic can use excessive space on the printed page. Small numbers of references to key original papers often serve as well as more exhaustive lists, particularly since references can

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now be added to the electronic version of published papers, and since electronic literature searching allows readers to retrieve published literature efficiently. Using abstracts as references should be avoided.

References to papers accepted but not yet published should be designated as "in press" or "forthcoming"; authors should obtain written permission to cite such papers as well as verification that they have been accepted for publication. Information from manuscripts submitted but not accepted should be cited in the text as "unpublished observations" with written permission from the source. Citing a "personal communication" should be avoided unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text. For scientific articles, written permission and confirmation of accuracy from the source of a personal communication must be obtained.

Reference Style and Format

The Uniform Requirements style for references is based largely on an American National Standards Institute style adapted by the National Library of Medicine for its databases. Authors should consult NLM's Citing Medicine for information on its recommended formats for a variety of reference types. References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure. The titles of journals should be abbreviated according to the style used in the list of Journals in National Library of Medicine sources. Accuracy of citation is the author's responsibility. All references should be cited in text. Type references in the style shown below. If there are more than 6 authors, list them followed by et al. Abbreviations of journal names should conform to the style used in National Library of Medicine. If a journal is not indexed in National Library of Medicine's MEDLINE/PubMed, it should not be abbreviated.

Examples for References:

1. For articles in journals:

For the published article from the journal which placed and abbreviated in MEDLINE:

Crow SJ, Peterson CB, Swanson SA, Raymond NC, Specker S, Eckert ED, et al. Increased mortality in bulimia nervosa and other eating disorders. Am J Psychiatry 2009;166(12):1342-1346.

For the published article from the journal which is not placed and is not abbreviated in MEDLINE:

Sevinçer GM, Konuk N. Emotional eating. Journal of Mood Disorders 2013;3:171-178.

2. For the supplement:

For the published article from the journal which placed and abbreviated in MEDLINE:

Sharan P, Sundar AS. Eating disorders in women. Indian J Psychiatry 2015:57(Suppl 2):286-295.

For the published article from the journal which is not placed and is not abbreviated in MEDLINE:

Maner F. Yeme bozukluklarının tedavisi. Anadolu Psikiyatri Dergisi 2009;10(Ek 1):55-56.

3. For articles in press:

Cossrow N, Pawaskar M, Witt EA, Ming EE, Victor TW, Herman BK, et al. Estimating the prevalence of binge eating disorder in a community sample from the United States: comparing DSM-IV-TR and DSM-5 criteria. J Clin Psychiatry, 2016. (in press).

4. For the citations from books:

Books edited by one editor:

McKnight TL. Obesity Management in Family Practice. 1st ed., NewYork: Springer, 2005:47-51.

For the citation from a section of book edited by editor(s):

Jebb S, Wells J. Measuring body composition in adults and children. In Clinical Obesity in Adults and Children, Copelman P, Caterson I, Dietz W (editors). 1st ed., London: Blackwell Publishing, 2005:12-18.

If the authors of the cited section are the editors of the book:

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Eckel RH (editor). Treatment of obesity with drugs in the new millennium. In Obesity Mechanisms and Clinical Management. First ed., Philadelphia: Lippincott Williams & Wilkins, 2003:449-476.

For the citation from a translated book:

McGuffin P, Owen MJ, Gottsman II. Psikiyatri Genetiği ve Genomiği. Abay E, Görgülü Y (Çevirenler) 1st ed., Istanbul: Nobel Tıp Kitabevleri, 2009:303-341.

5. For the citation from thesis:

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6. For the citation from posters:

Akbaş Öncel D, Akdemir A. Üniversite öğrencilerinde diyet, beden algısı ve kendilik algısı arasındaki ilişkiler. 47. Ulusal Psikiyatri Kongresi Özet Kitabı, 26-30 Ekim 201, Antalya, 2011:102.

7. Online Article:

Kaul S, Diamond GA. Good enough: a primer on the analysis and interpretation of noninferiority trials. Ann Intern Med [Internet]. 2006 Jul 4 [cited 2007 Jan 4];145(1):62-9. Available from:http://www.annals.org/cgi/reprint/145/1/62.pdf

SUBMISSION TO JOURNAL

All new manuscripts must be submitted through the Bagcilar Medical Bulletin online manuscript submission and peer review system. Complete instructions are available at the website (). A cover letter should accompany with manuscripts, including the knowledge of:

•The findings of previous same studies should be informed and should be cited. The copies of previous same studies should be sent with manuscripts that might help to the editor in the decision process.

•The knowledge of "all authors have read and accepted the study in its form, all authors meet the criteria for being in authorship" should be stated.

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SUBMISSION CHECKLIST

It is hoped that this list will be useful during the final checking of an article prior to sending it to the journal's editor for review. Please consult this Guide for Authors, for further details of any item.

Ensure that the following items are present:

• Cover letter to the editor

- The category of the manuscript
- Acknowledgement of "the paper is not under consideration for publication in another journal"
- Disclosure of any commercial or financial involvement
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Copyright Transfer Form

Author Contribution Form

ICJME Form for Disclosure of Potential Conflicts of Interest

-Permission of previous published material if used in the present manuscript

-Acknowledgement of the study "in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of in 2000.

-Statement that informed consent was obtained after the procedure(s) had been fully explained.

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-Indicating whether the institutional and national guide for the care and use of laboratory animals was followed as in “Guide for the Care and Use of Laboratory Animals”.

-Title page

-The title of the manuscript both in Turkish and in English

-All authors and their affiliations

-All authors’ e-mail address, full postal address, GSM phone, business telephone and fax numbers

-Abstracts (400-500 words) Both in Turkish and in English

-Keywords: 3 to 10 words (in Turkish and in English)

-Body text

-Acknowledgement

-Reference

-All tables (including title, description, footnotes)

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Peer Review, Publication Ethics and Malpractice Statement

Peer- Review

Submission is considered on the conditions that papers are previously unpublished and are not offered simultaneously elsewhere; that authors have read and approved the content, and all authors have also declared all competing interests; and that the work complies with the ethical approval requirements and has been conducted under internationally accepted ethical standards. If ethical misconduct is suspected, the Editorial Board will act in accordance with the relevant international rules of publication ethics (i.e., COPE guidelines).

Editorial policies of the journal are conducted as stated in the rules recommended by the Council of Science Editors and reflected in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. Accordingly, authors, reviewers, and editors are expected to adhere to the best practice guidelines on ethical behavior contained in this statement.

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For the experimental, clinical, and drug human studies, approval by the ethical committee and a statement on the adherence of the study protocol to the international agreements (World Medical Association of Helsinki "Ethical Principles for Medical Research Involving Human Subjects," amended October 2013) are required. In experimental animal studies, the authors should indicate that the procedures followed were by animal rights (Guide for the care and use of laboratory animals), and they should obtain animal ethics committee approval. The Ethics Committee approval document should be submitted to the Bagcilar Medical Bulletin together with the manuscript.

The approval of the ethics committee; a statement on the adherence to international guidelines mentioned above; and proof that the patient's informed consent is obtained should be indicated in the `Material and Method` section. These items are required for case reports whenever data/media could reveal the identity of the patient.

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The editor of the journal strives to meet the needs of readers and authors, and to provide a fair and appropriate peer-review process. The editor is also responsible for deciding which articles submitted to the journal should be published and guided by the policies subjected to legal requirements regarding libel, copyright infringement, and plagiarism. The editor might discuss such policies, procedures, and responsibilities with reviewers while making publication decisions. The editor is responsible for the contents and overall quality of the publication.

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Reviewers evaluate manuscripts without regard for the origin, gender, sexual orientation, or political philosophy of the authors. Reviewers also ensure a fair, blind peer review of the submitted manuscripts for evaluation.

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Contribution to editor

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Reviewers offer objective judgments and evaluations. The reviewers express their views clearly with appropriate supporting arguments.

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Reviewers ought to identify a relevant published study that the authors have not cited. Reviewers also call to the editor's attention any substantial similarity or overlap between the manuscript and any other published paper of which they have personal knowledge.

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Authors must ensure that their study is entirely original. References to the literature should be appropriately cited.

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Acknowledgement to the workof others must be given. Authors should cite publications of relevance to their own study. All of the sources for the author’s study should be noted.

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Authorship of a Paper

Authorship of a paper ought to be limited to those who have made a noteworthy contribution to the study. If others have participated in the research, they should be listed as contributors. Authorship also includes a corresponding author who is in communication with the editor of a journal. The corresponding author should ensure that all appropriate co-authors are included in a paper.

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YAZARLARA BİLGİ

Hakem Değerlendirmesi, Yayın Etiği ve Kötüye Kullanım

Hakem Değerlendirmesi

Makalelerin daha önce yayınlanmamış olması ve aynı anda başka bir yere gönderilmemiş olması koşuluyla başvuru kabul edilir; yazarlar, içeriği okuduğunu, onayladığını, tüm yazarların çıkar çatışmalarını beyan ettiğini, çalışmanın etik onaya uygun olduğunu ve uluslararası kabul görmüş etik standartlarda yürütüldüğünü kabul eder. Etik suistimalden şüphelenilmesi durumunda, Yayın Kurulu ilgili uluslararası yayın etiği kurallarına (COPE yönergelerine) uygun olarak hareket edecektir.

Derginin yayın politikaları, Bilim Konseyi Editörleri tarafından önerilen kurallarda belirtildiği gibi yürütülür ve ICMJE Biyomedikal Dergilere Gönderilen Makaleler için Tekdüzen Gereklilikler: Biyomedikal Yayın için Yazma ve Düzenleme'de yansıtılır. Buna göre yazarlar, gözden geçirenler ve editörlerin bu bildirimde yer alan etik davranışa ilişkin en iyi uygulama kılavuzlarına uymaları beklenmektedir.

Gönderilen yazılar çift-kör hakem değerlendirmesine tabi tutulur. Dergide yayımlanacak yazıların seçimine rehberlik eden bilim kurulu, derginin seçilmiş uzmanlarından ve gerekirse ilgili araştırma alanında ulusal ve uluslararası uzmanlardan seçilmiş uzmanlardan oluşur. Tüm yazılar editör, bölüm yardımcı editörleri ve en az üç dahili ve harici uzman hakem tarafından incelenir. Tüm araştırma makaleleri de bir istatistik editörü tarafından yorumlanır.

İnsan ve Hayvan Araştırmaları

Deneysel, klinik, ilaç ve insan çalışmaları için, etik kurul onayı ve çalışma protokolünün uluslararası anlaşmalara uygunluğuna dair bir beyan (World Medical Association of Helsinki "Ethical Principles for Medical Research Involving Human Subjects," Ekim 2013) gereklidir. Deneysel hayvan çalışmalarında yazarlar, izlenen prosedürlerin hayvan haklarına uygun olduğunu (Laboratuvar Hayvanlarının Bakım ve Kullanım Kılavuzu) belirtmeli ve hayvan Etik Kurul Onayı almalıdır. Etik Kurul Onayı belgesi, makale ile birlikte Bağcılar Tıp Bülteni'ne gönderilmelidir.

Etik Kurul Onayı ile yukarıda belirtilen uluslararası kılavuzlara uyum ve hastanın aydınlatılmış onamının alındığına dair beyan "Materyal ve Yöntem" bölümünde belirtilmeli ve kullanılan veri/medyanın hastanın kimliğini ortaya çıkarabileceği durumlarda vaka raporları gerekmektedir. Yazarlar, kurumlar arasında çıkar çatışması beyanı, herhangi bir mali veya maddi desteğin kabulünün belirtilmesi makale gönderen yazarlar için zorunludur ve bu açıklama makalenin sonunda yer almalıdır. Hakemler, yazarlar veya kurumlar ile aralarında herhangi bir potansiyel çıkar çatışması varsa, bunu rapor etmelidir.

18 yaşın altındaki kişiler için, her iki ebeveynin veya kişinin yasal vasisi veya velisinin imzasını içeren bir onay formu gönderilmelidir.

İntihal ve Etik Suistimal

Bağcılar Tıp Bülteni, tüm makaleleri yayınlanmadan önce "iThenticate" kullanarak intihal taramasına tabi tutar. Dergi, iThenticate raporlarına göre benzerlik oranı %15'in üzerinde olan makaleleri kabul etmemektedir.

Yazarların aşağıda yazılanlar gibi her türlü intihal ve etik suistimalden kaçınmaları önemlidir:

İntihal: Başka bir yazarın yayınındaki bir içeriğin tamamını veya bir kısmını kaynak göstermeden yeniden yayınlamak.

Fabrikasyon (Uydurma): Var olmayan veri ve bulguları/sonuçları yayınlamak.

Çoğaltma: Bir makalenin farklı dillerde yeniden yayınlanmasını içeren başka bir yayından alınan verileri kullanmak.

Dilimleme (Salamizasyon): Bir çalışmanın sonuçlarını bölerek birden fazla yayın oluşturma.

Veri Manipülasyonu/Yanlışlığı: Yanlış bir izlenim vermek için araştırma verilerini manipüle etmek veya kasıtlı olarak çarpıtmak.

İntihal, fabrikasyon, çoğaltma, veri manipülasyonu ve dilimleme gibi etik olmayan uygulamaları ve yazarlık hediye etme, uygunsuz teşekkür ve COPE akış şemalarına uygun olmayan referanslar gibi uygulamalarla inceleme sürecini etkilemeye yönelik çabaları onaylamıyoruz.

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Gönderilen yazılar ayrıca otomatik yazılım tarafından intihal ve yayın değerlendirmesine tabi tutulur. Yazarlar, çalışma sonuçlarını tamamen veya kısmen özet şeklinde yayınlayıp yayınlamadıklarını bildirmekle yükümlüdür.

A. YAYINCININ GÖREVLERİ:

Etik Olmayan Yayınlama Davranışının Ele Alınması

Yayıncı, iddia edilen veya kanıtlanmış bilimsel suistimal, hileli yayın veya intihal durumlarında, söz konusu makaleyi editörlerle yakın iş birliği içinde değiştirmek için tüm uygun önlemleri alacaktır. Bu, en ciddi durumda, etkilenen çalışmanın bir yanlışlık sonucu yayınlanmasını, ifşa edilmesini veya geri çekilmesini içerir. Yayıncı, editörlerle birlikte, araştırma suistimalinin meydana geldiği makalelerin yayınlanmasını tespit etmek ve önlemek için makul adımları atacak ve hiçbir koşulda bu tür kötüye kullanımın gerçekleşmesine teşvik etmeyecek veya bilerek izin vermeyecektir.

Editöryal Özerklik

Bağcılar Tıp Bülteni, herhangi birinin veya ticari ortakların etkisi olmaksızın editöryal kararların özerkliğini sağlamayı taahhüt eder.

Fikri Mülkiyet ve Telif Hakkı

Bağcılar Tıp Bülteni, dergide yayınlanan makalelerin mülkiyetini ve telif haklarını korur ve her makalenin yayınlanmış kaydını tutar. Dergi, yayınlanan her makalenin bütünlüğünü ve şeffaflığını sağlar.

Bilimsel Suistimal

Bağcılar Tıp Bülteni'nin yayıncısı, hileli yayın veya intihal ile ilgili gerekli tüm önlemleri almaktadır.

B. EDİTÖRLERİN GÖREVLERİ:

Yayın Kararı ve Sorumluluğu

Dergi editörü, dergideki her şeyi kontrol altında tutar, okuyucuların ve yazarların ihtiyaçlarını karşılamaya çalışır. Editör ayrıca dergiye gönderilen makalelerin hangilerinin yayınlanması gerektiğine karar vermekten ve hakaret, telif hakkı ihlali ve intihal ile ilgili yasal gerekliliklere tabi politikalar tarafından yönlendirilmekten sorumludur. Editör, yayın kararları verirken hakemlerle tartışabilir. Yayının içeriğinden ve genel kalitesinden editör sorumludur. Editör, adil ve uygun bir hakemlik süreci sağlamalıdır.

Nesnellik

Dergiye gönderilen makaleler her zaman önyargısız olarak değerlendirilir.

Gizlilik

Editör, gönderilen bir makaleyle ilgili herhangi bir bilgiyi, editör kadrosu, hakemler ve yayıncı dışında hiç kimseye açıklamamalıdır.

Çıkar Çatışmaları ve İfşa

Bağcılar Tıp Bülteni, yazarlar, hakemler ve editörler gibi taraflar arasında herhangi bir çıkar çatışmasına izin vermez. Gönderilen bir makaledeki yayınlanmamış materyaller, yazarın açık izni olmaksızın hiç kimse tarafından kullanılmamalıdır.

Yayımlanan Eserlerde Temel Hatalar

Yazarlar, yayınlanan çalışmada önemli hatalar veya yanlışlıklar tespit edilirse, derhal dergi editörlerini veya yayıncısını bilgilendirmek ve makaleyi düzeltmek veya geri çekmek üzere onlarla iletişim sağlamakla yükümlüdür. Editörler veya yayıncı, yayınlanan bir çalışmanın önemli bir hata veya yanlışlık içerdiğini üçüncü bir taraftan öğrenirse, yazarlar makaleyi derhal düzeltmeli, geri çekmeli veya dergi editörlerine makalenin doğruluğuna dair kanıt sağlamalıdır.

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C. HAKEMLERİN GÖREVLERİ:

Değerlendirme

Hakemler, yazarların kökeni, cinsiyeti, cinsel yönelimi veya politik felsefesini gözetmeksizin yazıları değerlendirir. Hakemler ayrıca değerlendirme sırasında gönderilen yazılar için adil bir kör hakem incelemesi sağlar.

Gizlilik

Gönderilen makalelerle ilgili tüm bilgiler gizli tutulur. Hakemler, editör tarafından izin verilmedikçe başkalarıyla tartışılmamalıdır.

Çıkar Çatışmaları ve İfşa

Hakemlerin yazarlar, fon sağlayıcılar, editörler vb. taraflarla ilgili herhangi bir çıkar çatışması yoktur.

Editöre Katkı

Hakemler, editöre karar vermede ve makaleyi geliştirmede yardımcı olabilir.

Nesnellik

Daima objektif bir değerlendirme yapılır. Hakemler görüşlerini uygun destekleyici argümanlarla açıkça ifade eder.

Kaynakların Onaylanması

Hakemler, yazarların atıfta bulunmadığı ilgili yayınlanmış bir çalışmayı tanımlamalıdır. Hakemler ayrıca, makale ile kişisel bilgilerine sahip oldukları diğer yayınlanmış makaleler arasındaki önemli benzerlikleri veya örtüşmeleri editörün dikkatine sunarlar.

D. YAZARLARIN GÖREVLERİ:

Raporlama Standartları

Gönderilen bir makale orijinal olmalı ve yazarlar, makalenin daha önce herhangi bir dergide yayınlanmamış olmasını sağlamalıdır. Araştırmanın verileri makalede tam anlamıyla sunulmalıdır. Bir makale, başkalarının çalışmayı yeniden kopyalamasına izin vermek için gerekli ayrıntı ve referansları içermelidir.

Özgünlük

Çalışmalarını dergiye göndermek isteyen yazarlar, çalışmalarının tamamen özgün olduğundan emin olmalıdır. Literatürden alınan kelime ve cümleler uygun şekilde alıntılanmalıdır.

Çoklu Yayınlar

Yazarlar, aynı çalışmayı başka bir dergide yayınlanmak veya değerlendirilmek üzere göndermemiş olmalıdır. Aynı çalışmanın birden fazla dergiye aynı anda gönderilmesi kabul edilemez ve etik dışı bir davranış olarak nitelendirilir.

Kaynakların Belirtilmesi

Başkalarının çalışmalarının uygun bir şekilde alıntılanması gerekir. Yazarlar, çalışmayı belirlemede etkili olan yayınlara atıfta bulunmalıdır. Çalışmanın sürecini kapsayan tüm kaynaklar belirtilmelidir.

Makale Yazarlığı

Bir makalenin yazarlığı, çalışmaya kayda değer bir katkı yapmış olanlarla sınırlı olmalıdır. Başkaları araştırmaya katılmışsa, katkıda bulunanlar olarak listelenmelidir. Yazarlık aynı zamanda bir derginin editörü ile iletişim halinde olan bir sorumlu yazarı da içerir. Sorumlu yazar, tüm uygun ortak yazarların bir makaleye dahil edilmesini sağlamalıdır.

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Çıkar Çatışmaları ve İfşa

Tüm finansal destek kaynakları açıklanmalıdır. Tüm yazarlar, çalışmalarını oluşturma sürecinde (varsa) çıkar çatışmasını ifşa etmelidir. Gönderilen bir çalışma için bireylerden veya kurumlardan alınan mali yardımlar veya diğer destekler, Bağcılar Tıp Bülteni Yayın Kurulu'na açıklanmalıdır. ICMJE Potansiyel Çıkar Çatışması Bildirim Formu, olası bir çıkar çatışmasını açıklamak için katkıda bulunan tüm yazarlar tarafından doldurulmalı ve gönderilmelidir. Derginin Yayın Kurulu, editörler, yazarlar veya hakemler arasında olası bir çıkar çatışması durumlarında COPE ve ICMJE yönergeleri kapsamında hareket eder.

Mali veya şahsi fayda sağlayan koşullar, bir çıkar çatışması doğurur. Bu durum, bilimsel sürecin ve yayınlanan makalelerin güvenilirliği, bilimsel çalışmaların planlanması, uygulanması, yazılması, değerlendirilmesi, düzenlenmesi ve yayınlanması sırasında çıkar çatışmalarının objektif olarak ele alınması ile doğrudan ilişkilidir.

Finansal ilişkiler en kolay tespit edilen çıkar çatışmalarıdır ve derginin, yazarların ve bilimin güvenilirliğini zedelemesi kaçınılmazdır. Bu çatışmalara bireysel ilişkiler, akademik rekabet veya entelektüel yaklaşımlar neden olabilir. Yazarlar, çalışmanın tüm verilerine ulaşmalarını veya makalelerini analiz etme, yorumlama, hazırlama ve yayınlama olanaklarını kısıtlayan kâr veya başka bir avantaj elde etme düşüncesiyle sponsorlarla anlaşmalardan mümkün olduğunca kaçınmalıdır. Editörler, çalışmaları değerlendirirken aralarında ilişki olabilecek kişileri bir araya getirmekten kaçınmalıdır. Makaleler hakkında nihai kararı verecek olan editörlerin, karar verecekleri konulardan hiçbiriyle kişisel, mesleki veya mali bağı olmamalıdır. Yazarlar, makalelerinin bağımsız bir değerlendirme süreci ile etik ilkeler çerçevesinde değerlendirilmesini sağlamak için olası çıkar çatışmalarını yayın kuruluna bildirmelidir.

Editörlerden birinin herhangi bir yazıda yazar olması durumunda editör, makale değerlendirme sürecinden çıkarılır. Herhangi bir çıkar çatışmasını önlemek için makale değerlendirme süreci çift kör olarak yapılmaktadır. Çift kör değerlendirme sürecinden dolayı Baş Editör dışında hiçbir yayın kurulu üyesine, uluslararası danışma kurulu üyesine veya hakemlere, makalenin yazarları veya yazarların kurumları hakkında bilgi verilmemektedir.

Yayın ekibimiz tüm bu durumları göz önünde bulundurarak değerlendirme sürecinin tarafsız bir şekilde yürütülmesi için özveriyle çalışmaktadır.

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Bağcılar Tıp Bülteni (Bagcilar Medical Bulletin), tıbbın her alanında araştırma makalelerini, güncel derleme yazılarını, olgu sunumlarını ve editöre mektupları İngilizce tam metin ve Türkçe özle yayınlayan hakemli bir dergidir. Dergi online olarak yılda 4 sayı yayınlanmaktadır. Tüm makaleler kabul edilir edilmez, online olarak pdf formatında bu web sitesinde, o dönemdeki sayının bir makalesi olarak yer alacaktır. Dergi Galenos Yayınevi tarafından yayımlanmaktadır.

Editoryal Politikalar ve Hakem Süreci

Yayın Politikası

Bağcılar Tıp Bülteni, yayınlanmak üzere gönderilen yazıları aşağıda belirtilen şekillerde kabul eder:

-Orijinal araştırmalar,

-Kısa araştırmalar,

-Olgu sunumları,

-Derlemeler,

-Editöre mektup

Dergi, Türkiye'de yapılan araştırmaların uluslararası bilim arenasına duyurulması, uluslararası bilim çevrelerince paylaşılması ve bu bağlamda Türkiye'nin tanıtılmasına katkıda bulunmayı misyon edindiğinden özellikle orijinal araştırma niteliğindeki yazıları yayınlamaya öncelik vermektedir. Dergide yayınlanacak derleme türündeki yazılar editör tarafından konu ile ilgili çalışan yetkin kişilere hazırlatılmaktadır.

Genel İlkeler

Daha önce yayınlanmamış ya da yayınlanmak üzere başka bir dergide halen değerlendirmede olmayan ve her bir yazar tarafından onaylanan makaleler dergide değerlendirilmek üzere kabul edilir. Yayın kurulu, yazarların iznini alarak yazıda değişiklikler yapabilir. Editör ve dil editörleri dil, imlâ ve kaynakların National Library of Medicine MEDLINE/PubMed Resources'da belirtildiği gibi yazılmasında ve ilgili konularda tam yetkilidir.

Eğer makalede daha önce yayınlanmış alıntı yazı, tablo, resim vs. mevcut ise makale yazarı, yayın hakkı sahibi ve yazarlarından yazılı izin almak ve bunu makalede belirtmek zorundadır. Gerekli izinlerin alınıp alınmadığından yazar(lar) sorumludur.

Bilimsel toplantılarda sunulan özet bildiriler, makalede belirtilmesi koşulu ile kaynak olarak kabul edilir. Editör, dergiye gönderilen makale biçimsel esaslara uygun ise, gelen yazıyı yurtiçinden ve/veya yurtdışından en az iki hakemin değerlendirmesinden geçirtir, hakemler gerek gördüğü takdirde yazıda istenen değişiklikler yazarlar tarafından yapıldıktan sonra yayınlanmasına onay verir. Makale yayınlanmak üzere dergiye gönderildikten sonra yazarlardan hiçbirinin ismi, tüm yazarların yazılı izni olmadan yazar listesinden silinemez ve yeni bir isim yazar olarak eklenemez ve yazar sırası değiştirilemez. Yayına kabul edilmeyen makale, resim ve fotoğraflar yazarlara geri gönderilmez.

Yazar Hakları

Makalelerinin telif haklarını dergiye devreden yazarlar, yayınladıkları yazıdaki yazılarını diğer çalışmalarında kısmen veya tamamen, herhangi bir revizyon veya değişiklik yapmadan kullanma ve uygun gördükleri takdirde kitap haline getirme hakkını saklı tutarlar. Dergideki, CC BY-NC-ND 4.0 Lisansıvnda ve derginin Açık Erişim politikasında belirtildiği gibi açıkça yayınlanmalıdır. Makale, yazar tarafından bir kitap bölümü olarak veya bir koleksiyonda veya derlemede yeniden kullanılacaksa veya ticari amaçlarla bir kitap haline getirilecekse, atama veya feragat etme hakkını saklı tutan Dergi'den izin alınması gerekir. Bu yeniden kullanım için bedel ve dergide asıl yayına açıkça verilmek üzere uygun bir atıf yapılması gerekmektedir.

Yazarların Soru mluluğu

Makalelerin bilimsel ve etik kurallara uygunluğu yazarların sorumluluğundadır. Yazar makalenin orijinal olduğu, daha önce başka bir yerde yayınlanmadığı ve başka bir yerde, başka bir dilde yayınlanmak üzere değerlendirmede olmadığı konusunda teminat

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sağlamalıdır. Uygulamadaki telif kanunları ve anlaşmaları gözetilmelidir. Telife bağlı materyaller (örneğin tablolar, şekiller veya büyük alıntılar) gerekli izin ve teşekkürle kullanılmalıdır. Başka yazarların, katkıda bulunanların çalışmaları ya da yararlanılan kaynaklar uygun biçimde kullanılmalı ve referanslarda belirtilmelidir.

Gönderilen makalede tüm yazarların akademik ve bilimsel olarak doğrudan katkısı olmalıdır, bu bağlamda "yazar" yayınlanan bir araştırmanın kavramsallaştırılmasına ve desenine, verilerin elde edilmesine, analizine ya da yorumlanmasına belirgin katkı yapan; yazının yazılması ya da bunun içerik açısından eleştirel biçimde gözden geçirilmesinde görev yapan; yazının yayınlanmak üzere nihai halini onaylayan ve çalışmanın herhangi bir bölümünün doğruluğuna ya da bütünlüğüne ilişkin soruların uygun şekilde soruşturulduğunun ve çözümlendiğinin garantisini vermek amacıyla çalışmanın her yönünden sorumlu olmayı kabul eden kişi olarak görülür. Fon sağlanması, ya da araştırma grubunun genel süpervizyonu tek başına yazarlık hakkı kazandırmaz. Yazar olarak gösterilen tüm bireyler sayılan tüm ölçütleri karşılamalıdır ve yukarıdaki ölçütleri karşılayan her birey yazar olarak gösterilebilir. Çok merkezli çalışmalarda grubun tüm üyelerinin yukarıda belirtilen şartları karşılaması gereklidir. Yazarların isim sıralaması ortak verilen bir karar olmalıdır. Tüm yazarlar yazar sıralamasını Telif Hakkı Devir Formunda imzalı olarak belirtmek zorundadırlar. Yazarların tümünün ismi yazının başlığının altındaki bölümde yer almalıdır.

Yazarlık için yeterli ölçütleri karşılamayan ancak çalışmaya katkısı olan tüm bireyler Teşekkür (Acknowledgement) kısmında sıralanmalıdır. Bunlara örnek olarak ise sadece teknik destek sağlayan, yazıma yardımcı olan ya da sadece genel bir destek sağlayan kişiler verilebilir. Finansal ve materyal destekleri de belirtilmelidir.

Yazıya materyal olarak destek veren ancak yazarlık için gerekli ölçütleri karşılamayan kişiler "klinik araştırıcılar" ya da "yardımcı araştırıcılar" gibi başlıklar altında toplanmalı ve bunların işlevleri ya da katılımları "bilimsel danışmanlık yaptı", "çalışma önerisini gözden geçirdi", "veri topladı" ya da "çalışma hastalarının bakımını üstlendi" şeklinde belirtilmelidir. Teşekkür (Acknowledgement) kısmında belirtilen bu ifadeler için bu bireylerden de yazılı izin alınması gerekmektedir.

Bütün yazarlar, araştırmanın sonuçlarını ya da bilimsel değerlendirmeyi etkileyebilme potansiyeli olan finansal ilişkiler, çıkar çatışması ve çıkar rekabetini beyan etmelidirler. Bir yazar kendi yayınlanmış yazısında belirgin bir hata ya da yanlışlık tespit ederse, bu yanlışlıklara ilişkin düzeltme ya da geri çekme için yayın yönetmeni ile hemen temasa geçme ve işbirliği yapma sorumluluğunu taşır. Yazarların katkısını belirten Yazar Katkı Formu ve çıkar çatışması olup olmadığını belirten ICMJE Potansiyel Çıkar Çatışması Beyan Formu makale ile birlikte gönderilmelidir. Yazarların görevleri ve sorumlulukları ICMJE yönergelerine dayandırılmaktadır.

Editör ve Hakem Sorumlulukları ve Değerlendirme Süreci

Editörler, makaleleri, yazarların etnik kökeninden, cinsiyetinden, cinsel yöneliminden, uyruğundan, dini inancından ve siyasi felsefesinden bağımsız olarak değerlendirirler. Yayına gönderilen makalelerin adil bir şekilde çift taraflı kör hakem değerlendirmesinden geçmelerini sağlarlar. Gönderilen makalelere ilişkin tüm bilginin, makale yayınlanana kadar gizli kalacağını garanti ederler. Editörler içerik ve yayının toplam kalitesinden sorumludurlar. Gereğinde hata sayfası yayınlamalı ya da düzeltme yapmalıdırlar.

Genel Yayın Yönetmeni; yazarlar, editörler ve hakemler arasında çıkar çatışmasına izin vermez. Hakem atama konusunda tam yetkiye sahiptir ve Bağcılar Tıp Bülteni'nde yayınlanacak makalelerle ilgili nihai kararı vermekle yükümlüdür. Dergide yayın etiği hususunda COPE yönergeleri izlenmektedir.

Hakemler makaleleri, yazarların etnik kökeninden, cinsiyetinden, cinsel yöneliminden, uyruğundan, dini inancından ve siyasi felsefesinden bağımsız olarak değerlendirirler. Araştırmayla ilgili, yazarlarla ve/veya araştırmanın finansal destekçileriyle çıkar çatışmaları olmamalıdır. Değerlendirmelerinin sonucunda tarafsız bir yargıya varmalıdırlar. Hakemler yazarların atıfta bulunmadığı konuyla ilgili yayınlanmış çalışmaları tespit etmelidirler. Gönderilmiş yazılara ilişkin tüm bilginin gizli tutulmasını sağlamalı ve yazar tarafında herhangi bir telif hakkı ihlali ve intihal fark ederlerse Genel Yayın Yönetmeni`ne raporlamalıdırlar. Hakem, makale konusu hakkında kendini vasıflı hissetmiyor ya da zamanında geri dönüş sağlaması mümkün görünmüyorsa, Baş Editör`e bu durumu bildirmeli ve hakem sürecine kendisini dahil etmemesini istemelidir.

Editör makalelerle ilgili bilgileri (makalenin alınması, içeriği, gözden geçirme sürecinin durumu, hakemlerin eleştirileri ya da varılan sonuç) yazarlar ya da hakemler dışında kimseyle paylaşmaz.

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Değerlendirme sürecinde editör hakemlere gözden geçirme için gönderilen makalelerin, yazarların özel mülkü olduğunu ve bunun imtiyazlı bir iletişim olduğunu açıkça belirtir. Hakemler ve yayın kurulu üyeleri topluma açık bir şekilde makaleleri tartışamazlar. Hakemlerin kendileri için makalelerin kopyalarını çıkarmalarına izin verilmez ve editörün izni olmadan makaleleri başkasına veremezler. Hakemler gözden geçirmelerini bitirdikten sonra makalenin kopyalarını yok etmeli ya da editöre göndermelidirler. Dergimiz editörü de reddedilen ya da geri verilen makalelerin kopyalarını imha etmelidir.

Yazarın ve editörün izni olmadan hakemlerin gözden geçirmeleri basılamaz ve açıklanamaz. Hakemlerin kimliğinin gizli kalmasına özen gösterilmelidir. Bazı durumlarda editörün kararıyla, ilgili hakemlerin makaleye ait yorumları aynı makaleyi yorumlayan diğer hakemlere gönderilerek hakemlerin bu süreçte aydınlatılması sağlanabilir. Değerlendirme süreciyle ilgili COPE yönergeleri izlenmektedir.

Açık Erişim İlkesi

Açık erişimli bir yayın olan Bağcılar Tıp Bülteni dergisinin tüm içeriği okura ya da okurun dahil olduğu kuruma ücretsiz olarak sunulur. Okurlar, yayıncı ya da yazardan izin almadan dergi makalelerinin tam metnini okuyabilir, indirebilir, kopyalayabilir, dağıtabilir, basabilir, arayabilir ve link sağlayabilir.

Yayın Etiği

İlke ve Standartlar

Bağcılar Tıp Bülteni yayın etiğinde en yüksek standartlara bağlıdır ve Committee on Publication Ethics (COPE), Council of Science Editors (CSE), World Association of Medical Editors (WAME) ve International Committee of Medical Journals (ICJME) tarafından geliştirilen yayın etiği ilkelerini ve tavsiyelerini gözetir.

Gönderilen tüm makaleler orijinal, yayınlanmamış (konferans bildirilerindeki tam metinler de dahil) ve başka bir dergide değerlendirme sürecinde olmamalıdır. Her bir makale editörlerden biri ve en az iki hakem tarafından çift kör değerlendirmeden geçirilir. Gönderilen makaleleri intihal yazılımı ile denetleme hakkımız haklıdır. İntihal, veride hile ve tahrif (araştırma verisi, tabloları ya da imajlarının manipülasyonu ve asılsız üretimi), insan ve hayvanların araştırmada uygun olmayan kullanımı konuları denetimden geçmektedir. Bu standartlara uygun olmayan tüm makaleler yayından çıkarılır. Buna yayından sonra tespit edilen olası kuraldışı, uygunsuzluklar içeren makaleler de dahildir. Yayın etiği kurallarına bağlı olarak, intihal şüphesini ve duplikasyon durumlarını rapor edeceğimizi belirtiriz. Olası bilimsel hatalı davranışları ve yayın etiği ihlali vakalarını ele alırken COPE Ethics Flowcharts izlenir.

İnsan ve Hayvan Hakları, Bilgilendirilmiş Olur, Çıkar Çatışması

Bağcılar Tıp Bülteni, yayınladığı makalelerin ticarî kaygılardan uzak ve konu ile ilgili en iyi etik ve bilimsel standartlarda olması şartını gözetmektedir. Makalelerin etik kurallara uygunluğu yazarların sorumluluğundadır.

Bağcılar Tıp Bülteni, 2013 yılında revize edilen Helsinki Deklarasyonu “Ethical Principles for Medical Research Involving Human Subjects”e ve 2006 yılında revize edilen WMA Statement on Animal Use in Biomedical Research’e uymayı prensip edinmiştir. Bu yüzden dergide yayınlanmak üzere gönderilen yazılarda, klinik deneylere katılan denekler ile ilgili olarak yukarıda belirtilen etik standartlara uyulduğunun mutlaka belirtilmesi gerekmektedir. Ayrıca deneyin türüne göre gerekli olan yerel veya ulusal etik komitelerden alınan onay yazıları yazı ile birlikte gönderilmelidir. Bununla birlikte deneye katılan kişi/hastalardan, hastalar eğer temyiz kudretine sahip değilse vâsilerinden yazılı bilgilendirilmiş onam alındığını belirten bir yazı ile beraber tüm yazarlar tarafından imzalanmış bir belgenin editöre gönderilmesi gerekmektedir.

Hastalardan izin alınmadan mahremiyet bozulamaz. Hastaların ismi, isimlerinin baş harfleri ya da hastane numaraları gibi tanımlayıcı bilgiler, fotoğraflar ve soy ağacı bilgileri vb. bilimsel amaçlar açısından çok gerekli olmadıkça ve hasta (ya da anne-baba, ya da vâsisi) yazılı bilgilendirilmiş onam vermedikçe basılmazlar. Özellikle olgu bildirimlerinde, çok gerekli olmadıkça hasta ile ilgili tanımlayıcı ayrıntılar çıkarılmalıdır. Örneğin, fotoğraflarda göz bölgesinin maskelenmesi kimliğin gizlenmesi için yeterli değildir. Eğer veriler kimliğin gizlenmesi için değiştirildiyse yazarlar bu değişikliklerin bilimsel anlamı etkilemediği konusunda güvence vermelidirler. Olgu sunumlarında yer verilen hastalardan bilgilendirilmiş onam alınmalıdır. Bilgilendirilmiş onam alındığı da makalede belirtilmelidir.

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Bu tip çalışmaların varlığında yazarlar, makalenin YÖNTEM(LER) bölümünde bu prensiplere uygun olarak çalışmayı yaptıklarını, kurumlarının etik kurullarından ve çalışmaya katılmış insanlardan "bilgilendirilmiş onam" aldıklarını belirtmek zorundadırlar.

Çalışmada "hayvan" kullanılmış ise yazarlar, makalenin YÖNTEM(LER) bölümünde "Guide for the Care and Use of Laboratory Animals" doğrultusunda çalışmalarında hayvan haklarını koruduklarını ve kurumlarının etik kurullarından onay aldıklarını belirtmek zorundadırlar. Hayvan deneyleri rapor edilirken yazarlar, laboratuvar hayvanlarının bakımı ve kullanımı ile ilgili kurumsal ve ulusal rehberlere uyup uymadıklarını yazılı olarak bildirmek zorundadırlar.

Editör ve yayıncı, reklâm amacı ile dergide yayınlanan ticari ürünlerin özellikleri ve açıklamaları konusunda hiçbir garanti vermemekte ve sorumluluk kabul etmemektedir. Eğer makalede doğrudan veya dolaylı ticarî bağlantı veya çalışma için maddî destek veren kurum mevcut ise yazarlar; kaynak sayfasında, kullanılan ticarî ürün, ilaç, ilaç firması vb. ile ticari hiçbir ilişkisinin olmadığını veya varsa nasıl bir ilişkisinin olduğunu (konsültan, diğer anlaşmalar) bildirmek zorundadır.

Buna göre, yazar, hakem ya da editör sorumluluklarını aşırı düzeyde ve/veya haksızlığa yol açabilecek düzeyde etkileyebilecek ya da etkileyebileceği olası bir çıkar rekabeti içindeyse, çıkar çatışması söz konusudur ve bunun açıklanması gerekir. Açıklanması öngörülen çıkar çatışması tipleri, finansal bağlar, akademik taahhütler, kişisel ilişkiler, politik ya da dini inançlar, kurumsal bağlantılardır. Çıkar çatışması söz konusuysa bu makalede açıklanmalıdır.

Dergiye yayımlanmak üzere gönderilen tüm yazılar editör ve hakemlerin uzmanlığı ile Crossref Similarity Check "iThenticate" programı ve internet üzerinden arama motorlarında taranarak, intihal kontrolünden geçmektedir. İntihal taraması sonucuna göre yazılar reddedilebilir. İntihal tespit edilmesi halinde, ilgili kurumlara yazarlar hakkında ihbar yapılabilir. Bu durumda yazarlar sorumlu kurumlara çalışmalarının ham sonuçlarını teslim etmek zorunda kalabilir.

Dil

Bağcılar Tıp Bülteni`nin yayın dili Amerikan İngilizcesi'dir. Ayrıca makalelerin özleri hem İngilizce, hem Türkçe yayınlanır. Her iki dildeki özler yazarlardan istenir.

Yazıların Hazırlanması

Aksi belirtilmedikçe gönderilen yazılarla ilgili tüm yazışmalar ilk yazarla yapılacaktır. Gönderilen yazılar, yazının yayınlanmak üzere gönderildiğini ve Bağcılar Tıp Bülteni`nin hangi bölümü (Orijinal Araştırma, Kısa Araştırma, Olgu Sunumu, Derleme, Editöre Mektup) için başvurulduğunu belirten bir mektup, yazının elektronik formunu içeren Microsoft Word 2003 ve üzerindeki versiyonları ile yazılmış elektronik dosya ile tüm yazarların imzaladığı 'Telif Hakkı Devir Formu' , Yazar Katkı Formu ve ICMJE Potansiyel Çıkar Çatışması Beyan Formu eklenerek gönderilmelidir. Yazıların alınmasının ardından yazarlara makalenin alındığı, bir makale numarası ile bildirilecektir. Tüm yazışmalarda bu makale numarası kullanılacaktır. Makaleler sayfanın her bir kenarından ,5 cm kenar boşluğu bırakılarak ve çift satır aralıklı yazılmalıdır. Makalelerde aşağıdaki sıra takip edilmelidir ve her bölüm yeni bir sayfa ile başlamalıdır: 1) başlık sayfası, 2) öz, 3) metin, 4) teşekkür / 5) kaynaklar ve 6) tablo ve/veya şekiller. Tüm sayfalar sırayla numaralandırılmalıdır.

Başlık

Başlık sayfasında, yazarların adları, akademik ünvanları ve yazışılacak yazarın tam adres, telefon ve faks numaraları ile e-mail adresi mutlaka bulunmalıdır. Yazıların Türkçe özlerinde mutlaka Türkçe başlık da yer almalıdır.

Öz ve Anahtar Sözcükler

Makalenin İngilizce başlığı İngilizce özde, Türkçe başlığı da Türkçe özde yer almalıdır. Bütün makaleler öz ve anahtar kelime içermelidir. Özler bir makalenin birçok elektronik veri tabanında yer alan en belirgin kısmı olduğundan, yazarlar özün makalenin içeriğini doğru olarak yansıttığından emin olmalıdır. Öz çalışmanın temeliyle ilgili bilgi vermeli ve çalışmanın amacını, temel prosedürleri (olguların ya da laboratuvar hayvanlarının seçimi, gözlemsel ve analitik yöntemler), ana bulguları (mümkünse özgül etki büyüklüklerini ve istatistiksel anlamlılıklarını vererek) ve temel çıkarımları içermelidir. Çalışmanın ya da gözlemlerin yeni ve önemli yönleri belirtilmelidir. Anahtar sözcükler, her türlü yazıda Türkçe ve İngilizce özlerin altındaki sayfada 3-10 adet

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verilmelidir. Anahtar sözcük olarak National Library of Medicine'ın Tıbbi Konu Başlıkları'nda (Medical Subject Headings, MeSH) yer alan terimler kullanılmalıdır. MeSH'de yer alan terimlerin Türkçe karşılıklarına Türkiye Bilim Terimleri'nden erişilebilir.

Makale Türleri

Orijinal Araştırma

Orijinal araştırma makaleleri derginin kapsamına uygun konularda önemli, özgün bilimsel sonuçlar sunan araştırmaları raporlayan yazılardır. Orijinal araştırma makaleleri, Öz, Anahtar Kelimeler, Giriş, Yöntem ve Gereçler, Bulgular, Tartışma, Sonuçlar, Kaynaklar bölümlerinden ve Tablo, Grafik ve Şekillerden oluşur. Öz bölümü araştırma yazılarında aşağıda belirtilen formatta yapılandırılmış olmalıdır.

Öz

Araştırma yazılarında Türkçe ve İngilizce özler en fazla 500 kelime olmalı ve şu şekilde yapılandırılmalıdır: Amaç/Objective: Yazının birincil ve asıl amacı; Yöntem ve Gereçler/Material and Method(s): Veri kaynakları, çalışmanın iskeleti, hastalar ya da çalışmaya katılanlar, görüşme/değerlendirmeler ve temel ölçümler; Bulgular/Results: Ana bulgular; Sonuç(lar)/Conclusion(s):Doğrudan klinik uygulamalar, çıkartılacak sonuçlar belirtilmelidir.

Anahtar Kelimeler

National Library of Medicine'ın Tıbbi Konu Başlıkları'nda (Medical Subject Headings, MeSH) yer alan terimler kullanılmalıdır, en az üç anahtar kelime belirtilmelidir.

Giriş

Giriş/Introduction bölümünde konunun önemi, tarihçe ve bugüne kadar yapılmış çalışmalar, hipotez ve çalışmanın amacından söz edilmelidir. Hem ana hem de ikincil amaçlar açıkça belirtilmelidir. Sadece gerçekten ilişkili kaynaklar gösterilmeli ve çalışmaya ait veri ya da sonuçlardan söz edilmemelidir.

Yöntem ve Gereçler

Yöntem ve Gereçler/Material and Methods bölümünde, veri kaynakları, hastalar ya da çalışmaya katılanlar, ölçekler, görüşme/değerlendirmeler ve temel ölçümler, yapılan işlemler ve istatistiksel yöntemler yer almalıdır. Yöntem bölümü, sadece çalışmanın planı ya da protokolü yazılırken bilinen bilgileri içermelidir; çalışma sırasında elde edilen tüm bilgiler bulgular kısmında verilmelidir. Yöntem ve Gereçler bölümünde olguların seçimi ve tanımlanması hakkında bilgi, teknik bilgi ve istatistik hakkında bilgi yer almalıdır. Araştırmanın Etik Kurul Onayı ve katılımcılardan alınan yazılı Bilgilendirilmiş Onam belirtilmelidir.

Olguların Seçimi ve Tanımlanması

Gözlemsel ya da deneysel çalışmaya katılanların (hastalar, hayvanlar, kontroller) seçimi, kaynak popülasyon, çalışmaya alınma ve çalışmadan dışlanma ölçütleri açıkça tanımlanmalıdır. Yaş ve cinsiyet gibi değişkenlerin çalışmanın amacıyla olan ilişkisi her zaman açık olmadığından yazarlar çalışma raporundaki kullanımlarını açıklamalıdır; örneğin yazarlar niçin sadece belli bir yaş grubunun alındığını ya da neden kadınların çalışma dışında bırakıldığını açıklamalıdır. Çalışmanın niçin ve nasıl belli bir şekilde yapıldığı açık bir şekilde belirtilmelidir. Yazarlar etnisite ya da ırk gibi değişkenler kullandıklarında bu değişkenleri nasıl ölçtüklerini ve geçerliklerini açıklamalıdır.

Teknik Bilgi

Diğer çalışmacıların sonuçları yineleyebilmesi için yöntem ve kullanılan araçlar (üretici firma ve adres paragraf içinde belirtilerek) ayrıntılı bir şekilde belirtilmelidir. Önceden kullanılan bilinen yöntemler için (istatistiksel yöntemler dahildir) kaynak gösterilmeli, basılmış ama iyi bilinmeyen bir yöntem için kaynak verilmeli ve yöntem açıklanmalıdır. Aynı şekilde yeni ya da belirgin olarak modifiye edilmiş yöntemler tanımlanmalı ve kullanılma nedenleri belirtilip kısıtlılıkları değerlendirilmelidir. Kullanılan tüm ilaç ve

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kimyasallar doğru olarak tanımlanıp jenerik isimleri, dozları ve kullanım biçimleri belirtilmelidir. Gözden geçirme yazısı gönderen yazarlar veriyi bulma, seçme, ayırma ve sentezleme yöntemlerini belirtmelidir. Bu yöntemler aynı zamanda özde de yer almalıdır.

İstatistik

İstatistiksel yöntem, orijinal veriye erişebilecek bilgili bir okuyucunun rapor edilen sonuçları onaylayabileceği bir ayrıntıda belirtilmelidir. Mümkünse, bulgular niceliksel hale getirilmeli ve hata ölçümleri (güvenlik aralıkları gibi) sunulmalıdır. Etki büyüklüğünü vermeyen, p değerlerinin kullanımı gibi, salt istatistiksel hipotez sınamasına dayanılmamalıdır. Çalışma deseni ve istatistiksel yönteme dair kaynaklar sayfalar belirtilerek mümkün olduğu sürece standart kaynaklar olmalıdır. İstatistiksel terimler, kısaltmalar ve semboller tanımlanmalıdır. Kullanılan bilgisayar programı belirtilmelidir.

Bulgular

Ana bulgular istatistiksel verilerle desteklenmiş olarak eksiksiz verilmeli ve bu bulgular uygun tablo, grafik ve şekillerle görsel olarak da belirtilmelidir. Bulgular yazıda, tablolarda ve şekillerde mantıklı bir sırayla önce en önemli sonuçlar olacak şekilde verilmelidir. Tablo ve şekillerdeki tüm veriyi yazıda vermemeli, sadece önemli noktaları vurgulanmalıdır. Ekstra materyal ve teknik bilgi ek kısmında verilerek yazının akışının bozulmaması sağlanmalı, alternatif olarak bunlar sadece elektronik versiyonda yer almalıdır.

Tartışma

Tartışma/Discussion bölümünde o çalışmadan elde edilen veriler, kurulan hipotez doğrultusunda hipotezi destekleyen ve desteklemeyen bulgular ve sonuçlar irdelenmeli ve bu bulgu ve sonuçlar literatürde bulunan benzeri çalışmalarla kıyaslanmalı, farklılıklar varsa açıklanmalıdır. Çalışmanın yeni ve önemli yanları ve bunlardan çıkan sonuçları vurgulanmalıdır. Giriş ya da sonuçlar kısmında verilen bilgi ve veriler tekrarlanmamalıdır.

Sonuçlar

Sonuçlar/Conclusions bölümünde çalışmadan çıkarılan sonuçlar sıralanmalıdır. Deneysel çalışmalar için tartışmaya sonuçları kısaca özetleyerek başlamak, daha sonra olası mekanizmaları ya da açıklamaları incelemek ve bulguları önceki çalışmalarla karşılaştırmak, çalışmanın kısıtlılıklarını özetlemek, gelecekteki çalışmalar ve klinik pratik için uygulamalarını belirtmek faydalıdır. Varılan sonuçlar çalışmanın amacıyla karşılaştırılmalı, ancak elde edilen bulgular tarafından yeterince desteklenmeyen çıkarımlardan kaçınılmalıdır. Yazarlar, eğer elde ettikleri veriler ekonomik veri ve analizler içermiyorsa, ekonomik çıkar ya da faydalarla ilgili yorumlardan özellikle kaçınılmalıdır. Gerektiğinde yeni hipotezler ortaya konmalı, ancak bunların yeni hipotezler olduğu belirtilmelidir.

Tablo, Grafik ve Şekiller

Yazı içindeki grafik, şekil ve tablolar Arap sayıları ile numaralandırılmalıdır. Şekillerin metin içindeki yerleri belirtilmelidir. Ayrıntılı bilgi aşağıda ilgili başlık altında yer almaktadır.

Kısa Araştırma

Kısa Araştırma makaleleri tarz ve format açısından Orijinal Araştırma makaleleri gibidir; ancak daha küçük ölçekli araştırmaları ya da geliştirme çalışmasının erken aşamalarında olan araştırmaları ele alır. Basit araştırma tasarımı kullanan ön çalışmalar, sınırlı pilot veri sağlayan küçük örnek kitle ile yapılan çalışmalar, ileri araştırma gereksinimine işaret eden başlangıç bulguları bu tür araştırmalar kapsamında sayılabilir. Kısa Araştırma makaleleri, büyük ölçekli gelişkin araştırma projelerini konu alan Orijinal Araştırma makalelerinden daha kısadır. Ancak Kısa Araştırma, Orijinal Araştırma makalesi olabilecek kalitede bir araştırma makalesinin kısa versiyonu olarak anlaşılmamalıdır; önem derecesi düşük, titizlikle yapılmamış bir araştırma hakkında bir yayın malzemesi hazırlamak için kullanılmamalıdır ya da genişletildiğinde Orijinal Araştırma makalesi ya da araştırma niteliği kazanmayacak bir içeriği değerlendirecek bir makale türü olarak anlaşılmamalıdır.

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Olgu Sunumu

Olgu sunumu makaleleri özgün vakaları rapor eden yazılardır. Derginin kapsamına giren konulara ilişkin bir problemin üstesinden gelen tedaviyle ilgili, yeni araçlar, teknikler ve metotlar göstererek okuyucular için bilgilendirme sağlamalıdır. Olgu sunumu yazıları Öz (özün araştırma makalesinde olduğu gibi belli bir formatta yapılandırılmış olması gerekmiyor), Anahtar Kelimeler, Giriş, Olgu Sunumu, Tartışma, Referanslar, gerekirse Tablo ve açıklayıcı bilgilerden oluşur. Olgu sunumunda yazılı bilgilendirilmiş onam alınmalı ve makalede belirtilmelidir.

Derleme

Derleme makaleleri alanında zengin birikime ve atıf alan çalışmalara sahip uzman kişilerce yazılan yazılardır. Klinik pratiğe ilişkin bir konuda mevcut bilgiyi tanımlayan, değerlendiren ve tartışan; geleceğe ilişkin çalışmalara yol gösteren derleme yazıları yazmaları için dergi belirlediği yazarlara davet gönderir. Derleme makaleleri, Öz (özün, araştırma makalesinde olduğu gibi belli bir formatta yapılandırılmış olması gerekmiyor), Anahtar Kelimeler, Giriş, Sonuç bölümlerinden oluşur. Derleme makale gönderen yazarların, makalede kullandıkları verinin seçimi, alınması, sentezi için kullandıkları yöntemleri tanımlayan bir bölüme de makalede yer vermeleri gerekir. Bu yöntemler Öz bölümünde de belirtilmelidir.

Editöre Mektup

Editöre Mektup, kısa ve net görüş bildiren yazılardır. Dergide daha önce yayınlanmış olan makalelerle ilgili olarak ya da dergide ifade edilmiş görüşlerle ilgili olarak yazılmış olması tercih edilir. Editöre Mektup yazıları, daha sonra yeni bir yazı ile geçerlilik ispatı gerektirebilecek ön görüş bildiren yazılar olmamalıdır.

Tablolar

Tablolar bilgileri etkin bir şekilde gösterir ve ayrıca bilginin istenen tüm ayrıntı seviyelerinde verilmesini sağlar. Bilgileri metin yerine tablolarda vermek genelde metnin uzunluğunu kısaltır.

Her tablo ayrı bir sayfaya çift aralıklı olarak basılmalıdır. Tablolar metindeki sıralarına göre numaralanıp, her birine kısa bir başlık verilmelidir. MS Word 2003 ve üstü versiyonlarında otomatik tablo seçeneğinde "tablo klasik 1" ya da "tablo basit 1" seçeneklerine göre tablolar hazırlanmalıdır. Başlık satırı ve tablo alt üst satırları dışında tablonun içinde başka dikey ve yatay çizgiler kullanılmamalıdır. Her sütuna bir başlık verilmelidir. Yazarlar açıklamaları başlıkta değil, dipnotlarda yapmalıdır. Dipnotlarda standart olmayan tüm kısaltmalar açıklanmalıdır. Dipnotlar için sırasıyla şu semboller kullanılmalıdır: (*,†,‡,§,ǁ,¶,**,††,‡‡).

Varyasyonun standart sapma ya da standart hata gibi istatistiksel ölçümleri belirtilmelidir. Metin içinde her tabloya atıfta bulunulduğuna emin olunmalıdır. Eğer yayınlanmış ya da yayınlanmamış herhangi başka bir kaynaktan veri kullanılıyorsa izin alınmalı ve onlar tam olarak bilgilendirilmelidir. Çok fazla veri içeren tablolar, çok yer tutar ve sadece elektronik yayınlar için uygun olabilir ya da okuyuculara yazarlar tarafından doğrudan sağlanabilir. Böyle bir durumda uygun bir ifade metne eklenmelidir. Bu tip tablolar, hakem değerlendirmesinden geçmesi için makaleyle beraber gönderilmelidir.

Şekiller

Şekiller ya profesyonel olarak çizilmeli ve fotoğraflanmalı ya da fotoğraf kalitesinde dijital olarak gönderilmelidir. Şekillerin basıma uygun versiyonlarının yanı sıra JPEG ya da GIF gibi elektronik versiyonlarda yüksek çözünürlükte görüntü oluşturacak biçimlerde elektronik dosyaları gönderilmeli ve yazarlar göndermeden önce bu dosyaların görüntü kalitelerini bilgisayar ekranında kontrol etmelidir.

Röntgen, CT, MRI filmleri ve diğer tanısal görüntülemeler yüksek kalitede basılmış olarak gönderilmelidir. Bu nedenle şekillerin üzerindeki harfler, sayılar ve semboller açık ve tüm makalede eşit ve yayın için küçültüldüklerinde bile okunabilecek boyutlarda olmalıdır. Şekiller mümkün olduğunca tek başlarına anlaşılabilir olmalıdır. Fotomikrografik patoloji preparatları iç ölçekler içermelidir. Semboller, oklar ya da harfler fonla kontrast oluşturmalıdır. Eğer insan fotoğrafı kullanılacaksa, ya bu kişiler fotoğraftan tanınmamalıdır ya da yazılı izin alınmalıdır (Etik bölümüne bakınız).

Şekiller metinde geçiş sıralarına göre numaralandırılmalıdır. Eğer önceden yayınlanmış bir şekil kullanılacaksa, yayın hakkını elinde bulunduran bireyden izin alınmalıdır. Toplum alanındaki belgeler hariç yazarlığa ve yayıncıya bakılmadan bu izin gereklidir.

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Basılacak bölgeyi gösteren ek çizimler editörün işini kolaylaştırır. Renkli şekiller editör gerekli gördüğünde ya da sadece yazar ek masrafı karşılarsa basılır.

Şekillerin Dipnotları

Ayrı bir sayfadan başlayarak şekiller için tablo başlıkları ve dipnotları tek aralıklı olarak ve Arap sayıları ile hangi şekle karşı geldikleri belirtilerek yazılmalıdır. Semboller, oklar, sayılar ya da harfler şeklin parçalarını belirtmek için kullanıldığında, dipnotlarda her biri açıkça tanımlanmalıdır. Fotomikrografik patoloji preparatlarında iç ölçek ve boyama tekniği açıklanmalıdır.

Ölçüm Birimleri

Uzunluk, ağırlık ve hacim birimleri metrik (metre, kilogram, litre) sistemde ve bunların onlu katları şeklinde rapor edilmelidir. Sıcaklıklar Celsius derecesi, kan basıncı milimetre civa cinsinden olmalıdır. Ölçü birimlerinde hem lokal hem de Uluslararası Birim Sistemleri (International System of Units, SI) kullanılmalıdır. İlaç konsantrasyonları ya SI ya da kütle birimi olarak verilir, alternatif olarak parantez içinde de verilebilir.

Kısaltmalar ve Semboller Sadece standart kısaltmaları kullanın, standart olmayan kısaltmalar okuyucu için çok kafa karıştırıcı olabilir. Başlıkta kısaltmadan kaçınılmalıdır. Standart bir ölçüm birimi olmadıkça kısaltmaların uzun hali ilk kullanılışlarında açık, kısaltılmış hali parantez içinde verilmelidir.

Teşekkür(ler)

Yazının sonunda kaynaklardan önce yer verilir. Bu bölümde kişisel, teknik ve materyal yardımı gibi nedenlerle yapılacak teşekkür ifadeleri yer alır.

Kelime Sayısı Sınırlandırması

Türkçe ve İngilizce özler en fazla 500 kelime olmalıdır. Orijinal makaleler ve derleme yazılarında özel bir kelime sayısı sınırlandırması yoktur. Olgu sunumları öz /abstract hariç 1000 kelime ile sınırlandırılmalı ve en az sayıda şekil, tablo ve kaynak içermelidir. Editöre mektuplar (en fazla 1000 kelime, tablosuz ve şekilsiz) olmalı ve mektup, tüm yazarlar tarafından imzalanmış olmalıdır. Bağcılar Tıp Bülteni`nde yayınlanmış olan bir yazı ile ilgili eleştiri ya da değerlendirme niteliğindeki mektuplar sözü edilen yazının yayınlanmasından sonraki 12 hafta içinde alınmış olmalıdır.

Makale Hazırlığı

"Bağcılar Tıp Bülteni", Tıp Dergilerinde Bilimsel Çalışmaların Yürütülmesi, Raporlanması, Düzenlenmesi ve Yayınlanmasına İlişkin Yönergeleri takip eder "(Uluslararası Tıp Dergisi Editörleri Komitesi ICMJE). Makalenin sunulması üzerine, yazarlar deneme/araştırma türünü belirtmeli ve uygun olduğunda aşağıdaki kuralların kontrol listesini sağlamalıdır:

Randomize çalışmalar için CONSORT beyanı (CONSORT Grubu için Moher D, Schultz KF, Altman D. CONSORT beyanı paralel grup randomize çalışmaların raporlarının kalitesini iyileştirmek için önerileri gözden geçirdi. JAMA 2001; 285: 1987-91),

Sistematik gözden geçirmeler ve meta-analizler için tercih edilen raporlama maddeleri için PRISMA (Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Grubu. Sistematik İncelemeler ve Meta-Analizler için Tercih Edilen Raporlama Maddeleri: PRISMA Beyanı. PLoS Med 2009; 6 (7): e1000097.),

Tanısal doğruluk çalışmalarının raporlanması için STARD kontrol listesi (Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, vd, STARD Grubu için. Teşhis doğruluğu çalışmalarının eksiksiz ve doğru raporlanmasına yönelik: STARD girişimi, Ann Intern Med 2003; 138: 40-4.),

STROBE gözlemsel çalışma raporlarında yer alması gereken maddelerin kontrol listesi,

Gözlemsel çalışmaların meta-analizi ve sistemik incelemeleri için MOOSE yönergeleri (Stroup DF, Berlin JA, Morton SC, vd.) Epidemiyolojideki gözlemsel çalışmaların meta-analizi: Epidemiyoloji (MOOSE) grubundaki gözlemsel çalışmaların Meta-analizini bildirme önerisi JAMA 2000; 283: 2008-12),

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CARE kuralları, vaka raporlarının doğruluğunu, şeffaflığını ve kullanışlılığını artırmak için tasarlanmıştır. (Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D; CARE Grubu. CARE Yönergeleri: Konsensüs Tabanlı Klinik Vaka Raporlama Rehberinin Geliştirilmesi).

Kaynaklar

Kaynaklarla İlgili Genel Konular

Gözden geçirme yazıları okuyucular için bir konudaki kaynaklara ulaşmayı kolaylaştıran bir araç olsa da, her zaman orijinal çalışmayı doğru olarak yansıtmaz. Bu yüzden mümkün olduğunca yazarlar orijinal çalışmaları kaynak göstermelidir. Öte yandan, bir konuda çok fazla sayıda orijinal çalışmanın kaynak gösterilmesi yer israfına neden olabilir. Birkaç anahtar orijinal çalışmanın kaynak gösterilmesi genelde uzun listelerle aynı işi görür. Ayrıca günümüzde kaynaklar elektronik versiyonlara eklenebilmekte ve okuyucular elektronik literatür taramalarıyla yayınlara kolaylıkla ulaşabilmektedir.

Özler kaynak olarak gösterilmemelidir. Kabul edilmiş ancak yayınlanmamış makalelere atıflar "basımda" ya da "çıkacak" şeklinde verilmelidir; yazarlar bu makaleleri kaynak gösterebilmek için yazılı izin almalıdır ve makalelerin basımda olduğunu ispat edebilmelidir. Gönderilmiş ancak yayına kabul edilmemiş makaleler, "yayınlanmamış gözlemler" olarak gösterilmeli ve kaynak yazılı izinle kullanılmalıdır. Genel bir kaynaktan elde edilemeyecek temel bir konu olmadıkça "kişisel iletişimlere" atıfta bulunulmamalıdır. Eğer atıfta bulunulursa parantez içinde iletişim kurulan kişinin adı ve iletişimin tarihi belirtilmelidir. Bilimsel makaleler için yazarlar bu kaynaktan yazılı izin ve iletişimin doğruluğunu gösterir belge almalıdır.

Referans Stili ve Formatı

Tek tip kurallar esas olarak National Library of Medicine, tarafından uyarlanmış olan bir ANSI standart stilini kabul etmiştir. Kaynak atıfta bulunma örnekleri için yazarlar NIH Samples of Formatted References for Authors of Journal Articles sitesine başvurabilirler. Dergi isimleri National Library of Medicine kaynağında yer alan şekilleriyle kısaltılmalıdır. Kaynaklar yazının sonunda (Kaynaklar/References) başlığı altında metindeki geçiş sırasına göre numaralandırılıp dizilmelidir. Metin içinde ise parantez içinde belirtilmelidir. Kaynakların listesiyle metin içinde yer alış sırası arasında bir uyumsuzluk bulunmamalıdır.

Kaynaklar yazının sonunda (Kaynaklar/References) başlığı altında metindeki geçiş sırasına göre numaralandırılıp dizilmelidir. Metin içinde ise () şeklinde parantez içinde referans numarası belirtilmelidir. Kaynakların listesiyle metin içinde yer alış sırası arasında bir uyumsuzluk bulunmamalıdır.

Kaynakların doğruluğundan yazar(lar) sorumludur. Tüm kaynaklar metinde belirtilmelidir. Kaynaklar aşağıdaki örneklerdeki gibi gösterilmelidir. Altı yazardan fazla yazarı olan çalışmalarda ilk altı yazar belirtilmeli, sonrasında "ve ark." ya da "et al." ibaresi kullanılmalıdır. Kaynak dergi adlarının kısaltılması National Library of Medicine'de belirtilen kısaltmalara uygun olmalıdır. National Library of Medicine'da indekslenmeyen bir dergi kısaltılmadan yazılmalıdır.

Kaynaklar için örnekler aşağıda belirtilmiştir:

1. Dergilerdeki makaleler için örnekler: MEDLINE'da yer alan ve kısaltması MEDLINE'a göre yapılan dergi makalesi için: Crow SJ, Peterson CB, Swanson SA, Raymond NC, Specker S, Eckert ED, et al. Increased mortality in bulimia nervosa and other eating disorders. Am J Psychiatry 2009;166(12):1342-1346.

MEDLINE'da yer almayan ve kısaltması olmayan dergi makalesi için: Sevinçer GM, Konuk N. Emotional eating. Journal of Mood Disorders 2013;3:171-178.

2. Ek sayı için: MEDLINE'da yer alan ve kısaltması MEDLINE'a göre yapılan dergi makalesi için: Sharan P, Sundar AS. Eating disorders in women. Indian J Psychiatry 2015:57(Suppl 2):286-295.

MEDLINE'da yer almayan ve kısaltması olmayan dergi makalesi için: Maner F. Yeme bozukluklarının tedavisi. Anadolu Psikiyatri Dergisi 2009;10(Ek 1):55-56.

3. Baskıdaki makale için: Cossrow N, Pawaskar M, Witt EA, Ming EE, Victor TW, Herman BK, et al. Estimating the prevalence of binge eating disorder in a community sample from the United States: comparing DSM-IV-TR and DSM-5 criteria. J Clin Psychiatry, 2016. (in press).

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4. Kitaptan alıntılar:

Tek yazarlı kitaptan alıntı için:

McKnight TL. Obesity Management in Family Practice. 1st ed., New York:Springer, 2005:47-51.

Kitaptan bir bölüm için, editör(ler) varsa:

Jebb S, Wells J. Measuring body composition in adults and children. In Clinical Obesity in Adults and Children, Copelman P, Caterson I, Dietz W (editors). 1st ed., London: Blackwell Publishing, 2005:12-18.

Editörler aynı zamanda kitabın içindeki metin ya da metinlerin yazarı ise: Önce alınan metin ve takiben kitabın ismi yine kelimeler büyük harfle başlatılarak yazılır.

Eckel RH (editor). Treatment of obesity with drugs in the new millennium. In Obesity Mechanisms and Clinical Management. 1st ed., Philadelphia: Lippincott Williams & Wilkins, 2003:449-476.

Çeviri Kitaptan Alıntı için:

McGuffin P, Owen MJ, Gottsman II. Psikiyatri Genetiği ve Genomiği. Abay E, Görgülü Y (translation editors) 1st ed., Istanbul: Nobel Tıp Kitabevleri, 2009:303-341.

5. Tezden alıntı için: Keçeli F. Yeme bozukluğu hastalarında obsesif kompulsif bozukluk ve kişilik bozukluğu. Thesis, T.C. Sağlık Bakanlığı Bakırköy Prof. Dr. Mazhar Osman Ruh Sağlığı ve Sinir Hastalıkları Eğitim ve Araştırma Hastanesi, Istanbul:2006.

6. Kongre bildirileri için: Akbaş Öncel D, Akdemir A. Üniversite öğrencilerinde diyet, beden algısı ve kendilik algısı arasındaki ilişkiler. 47. Ulusal Psikiyatri Kongresi Özet Kitabı, 26-30 Ekim 201, Antalya, 2011:102.

7. Online Makale:

Kaul S, Diamond GA. Good enough: a primer on the analysis and interpretation of noninferiority trials. Ann Intern Med [Internet]. 4 Temmuz 2006 [Atıf tarihi:4 Ocak 2007];145(1):62-9. Erişim adresi:http://www.annals.org/cgi/reprint/145/1/62.pdf

Makalenin Dergiye Gönderilmesi

Çevrimiçi gönderim (online submission) ile birlikte Bağcılar Tıp Bülteni web sitesinin (www.ijfed.org) ilgili kısımlarındaki talimatlara uyarak makale gönderilebilmekte, hakem süreçleri de bu yolla yapılabilmektedir.

Makalelere eşlik eden ve aşağıdaki bilgileri içeren bir kapak mektubu olmalıdır.

• Aynı ya da çok benzer çalışmadan elde edilen raporların daha önce yayına gönderilip gönderilmediği mutlaka belirtilmelidir. Böyle bir çalışmaya özgül olarak atıfta bulunulmalı ve ayrıca yeni makalede de eskisine atıfta bulunulmalıdır. Gönderilen makaleye bu tip materyalin kopyaları da eklenerek editöre karar vermesinde yardımcı olunmalıdır.

• Eğer makalenin kendisinde ya da yazar formunda belirtilmemişse çıkar çatışmasına neden olabilecek mâli ya da diğer ilişkileri belirten bir ifade olmalıdır.

• Makalenin tüm yazarlar tarafından okunup kabul edildiğini, önceden belirtilen şekilde yazarlık ölçütlerinin karşılandığını, her yazarın makalenin dürüst bir çalışmayı yansıttığına inandığını belirten bir ifade olmalıdır. Mektup editöre yardımcı olabilecek tüm diğer bilgileri içermelidir. Eğer makale önceden başka bir dergiye gönderilmişse önceki editörün ve hakemlerin yorumları ve yazarların bunlara verdiği cevapların gönderilmesi faydalıdır. Editör, önceki yazışmaların gönderilmesini hakem sürecini dolayısıyla yazının yayınlanma sürecini hızlandırabileceğinden istemektedir.

Yazarların makalelerini göndermeden önce bir eksiklik olmadığından emin olmalarını sağlamak için bir kontrol listesi bulunmaktadır. Yazarlar derginin kontrol listesini kullanıp gönderilerini kontrol etmeli ve makaleleri ile birlikte bu formu göndermelidirler.

YAZARLARA BİLGİ

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• Editöre sunum sayfası

- Makalenin kategorisi

- Başka bir dergiye gönderilmemiş olduğu bilgisi

- Sponsor veya ticari bir firma ile ilişkisi (varsa belirtiniz)

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- İngilizce yönünden kontrolünün yapıldığı

- Telif Hakkı Devir Formu

- Yazar Katkı Formu

- ICMJE Potansiyel Çıkar Çatışması Beyan Formu

• Daha önce basılmış materyal (yazı-resim-tablo) kullanılmış ise izin belgesi

• İnsan öğesi bulunan çalışmalarda "gereç ve yöntemler" bölümünde Helsinki Deklarasyonu prensiplerine uygunluk, kendi kurumlarından alınan etik kurul onayının ve hastalardan "bilgilendirilmiş olur (rıza)" alındığının belirtilmesi

• Hayvan öğesi kullanılmış ise "gereç ve yöntemler" bölümünde "Guide for the Care and Use of Laboratory Animals" prensiplerine uygunluğunun belirtilmesi

• Kapak sayfası

- Makalenin Türkçe ve İngilizce başlığı (tercihen birer satır)

- Yazarlar ve kurumları

- Tüm yazarların yazışma adresi, iş telefonu, faks numarası, GSM, e-posta adresleri

• Özler (400-500 kelime) (Türkçe ve İngilizce)

• Anahtar Kelimeler: 3-10 arası (Türkçe ve İngilizce)

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Bağcılar Tıp Bülteni

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ORIGINAL RESEARCH

Bagcilar Med Bull 2022;7(4):292-301
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Evaluation of Anesthesia Methods in Patients Undergoing Percutaneous Kyphoplasty: A Prospective Study

Perkütan Kifoplasti Uygulanan Hastalarda Anestezi Yöntemlerinin Değerlendirilmesi: Prospektif Bir Çalışma

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Abstract

Objective: The aim of this research is to examine the effects of the anesthesia method and preoperative characteristics on postoperative results and complications in patients who underwent percutaneous kyphoplasty (PKP).

Method: Patients were put into three groups according to the anesthesia methods used: (1) General anesthesia (sedation), (2) Central block (spinal and epidural anesthesia), (3) Peripheral block (erector spina plane block, and paravertebral block). Patients' pain values, hemodynamic parameters, additional need for sedation, and perioperative and postoperative complications were recorded prospectively together with visual pain scales (VAS).

Results: There were 22 individuals in group 1, 20 individuals in group 2, and 24 individuals in group 3. The average paracetamol and tramadol doses, postoperative VAS scores, and additional need for sedation were statistically significantly higher in group 1 (for all p<0.001) compared to other groups. Postoperative time to first mobilization and discharge were significantly lower in group 3 (for both, p<0.001). Patient satisfaction in group 3 was found to be significantly higher than that in group 1 (p<0.001). The rate of post-anesthesia care unit was higher in group 1 and lower in group 3 (p<0.001) and the rate of perioperative nausea rate was statistically significantly lower (p=0.008). The research samples did not differ statistically significantly from one another with regard to mean arterial pressure, heart rate, SpO_2, operation time, perioperative, and postoperative complication rates.

Conclusion: We think that central and especially peripheral block methods might be preferred because anesthesia methods in PKP surgery

Öz

Amaç: Bu çalışmanın amacı perkütan kifoplasti (PKP) cerrahisi uygulanan hastalarda uygulanan anestezi yöntemi ile preoperatif özelliklerinin, postoperatif sonuçlar ve komplikasyonlar üzerindeki etkisini incelemektir.

Yöntem: Anestezi yöntemlerine göre hastalar; 1: Genel anestezi (sedasyon), 2: Santral blok (spinal ve epidural anestezi), 3: Periferik blok (erector spina düzlem bloğu ve paravertebral blok) şeklinde 3 gruba ayrıldı. Hastaların preoperatif özellikleri, belirlenen zamanlarda visual ağrı skalası (VAS) ile kaydedilen ağrı değerleri, hemodinamik parametreleri, ek sedasyon gereksinimi, perioperatif ve postoperatif komplikasyonları prospektif olarak kaydedildi.

Bulgular: Grup 1'de 22, grup 2'de 20 ve grup 3'te 24 hasta yer aldı. Grup 1'de ortalama parasetamol, tramadol dozları, postoperatif VAS skorları ve ek sedasyon ihtiyacı, diğer gruplara göre istatistiksel olarak anlamlı derecede daha yüksek düzeyde bulundu (tümü için p<0,001). Postoperatif ilk mobilizasyon ve taburculuk zamanı grup 3'te diğer gruplara kıyasla istatistiksel olarak anlamlı düzeyde daha düşük izlendi (her ikisi için de p<0,001). Grup 3'te hasta memnuniyeti grup 1'e göre istatistiksel olarak anlamlı düzeyde daha yüksek gözlendi (p<0,001). Postoperatif bakım ünitesi oranı grup 1'de diğer gruplara göre daha yüksek ve grup 3'te diğer gruplara kıyasla anlamlı düzeyde daha düşüktü (p<0,001). Perioperatif bulantı oranı ise istatistiksel olarak anlamlı düzeyde daha düşük gözlendi (p=0,008). Çalışma grupları ile ortalama arter basıncı, kalp atış hızı, SpO_2, operasyon süresi, perioperatif ve postoperatif komplikasyon oranları bakımından istatistiksel olarak anlamlı bir fark görülmedi.

Sonuç: İleri yaş ve komorbiditeleri çok olan hastalarda PKP cerrahilerinde anestezi yöntemi olarak santral ve özellikle periferik blok yöntemlerinin

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are safer and they provide satisfaction in patients with advanced age and various comorbidities.

Keywords: Erector spina plane block, paravertebral block, percutaneous kyphoplasty, sedoanalgesia, vertebroplasty

daha güvenle ve daha yüksek hasta memnuniyeti ile tercih edilebileceğini düşünmekteyiz.

Anahtar kelimeler: Erektör spina plan bloğu, paravertebral blok, perkütan kifoplasti, sedoanaljezi, vertebroplasti

Introduction

Trauma, osteoporosis, malignancy-related metastases, and hemangiomas can all cause vertebral compression fractures (VCF), especially in the advanced age group (1). While VCF can cause chronic pain, if not treated adequately, it can lead to nerve damage, psychiatric problems, bed dependency, kyphosis that reduces the quality of life (2-4), aim to provide pain relief and deformity correction quickly and safely (5). Percutaneous kyphoplasty (PKP) has been performed for earlier anatomical and symptomatic treatment, life of patient, and decreased mortality and morbidity (6).

In a meta-analysis (7), PKP was shown to have greater efficiency compared to PVP. PKP is a method applied in the form of injections into the volume obtained using an inflatable balloon in the bone to restore the low-pressure cement and vertebral body height (1).

PKP is a treatment method that is thought to reduce the quality of life and reduces morbidity and mortality, especially in the geriatric age group, for VCF patients who cannot endure pain or do not benefit enough from conservative treatment (8). The prone position of the patient in PKP surgery may cause increased cardiopulmonary risk and difficulty in airway management. Although general anesthesia provides a comfortable surgical procedure, it is associated with life-threatening problems, anesthetic side effects, prolonged hospital stay, and an increase in the cost, especially among the elderly with comorbidities (9). Local anesthesia, which is frequently preferred, may be insufficient in adequate analgesic activity alone. Pain during surgery, difficulty in intervention, and the possibility of patient dissatisfaction generally cause other anesthesia methods to be preferred (10). Despite the growing number of studies regarding the therapeutic efficacy, surgical technique, and adverse effects of those various treatments, it remains unclear which type of anesthesia is best for PKP. Our goal was to carry out a prospective research comparing the effects of preoperative patient characteristics and different anesthesia methods applied during PKP in our clinic on perioperative results, complications, postoperative mobilization and discharge time, and patient satisfaction.

Materials and Methods

Study Design

Data on demographic characteristics [body mass index, gender, age, ASA use, preoperative pain value (VAS0)], analgesic use habits, anesthesia technique chosen by anesthesiologist blind to the study, perioperative hemodynamic parameters, additional opioid during surgery, analgesic or anesthetic need, and perioperative complications (patients who willingly stopped the procedure during the intervention, moaning, hypotension, hypertension, bradycardia, respiratory depression, desaturation and need for mask ventilation) were taken from the records of the individuals with the treatment of PKP between 01 January-28 June 2022 after the approval of the University of Health Sciences Turkey, Bursa High Specialization Training and Research Hospital Ethics Committee (2021-KAEK-25 2021/12-09), clinical trials number NCT05526794 and the patient's consent. Inclusion criteria were determined as being aged 18-100 years, being scheduled for kyphoplasty surgery, and giving written consent to participate in the study. Exclusion criteria were unwillingness to participate in the study, major bleeding on surgery, presence of communication and perception problems, not knowing Turkish, previous cerebrovascular disease and personal dysfunction (Figure 1). In addition, the first mobilization time, additional analgesic need, total amount of analgesic used in 24 hours, discharge time, VAS values at 2 (VAS1), 6 (VAS2), 12 (VAS3), and 18 (VAS4) hours, and complications (nausea, vomiting, pain, delirium, respiratory insufficiency, infection, deep vein thrombosis, pulmonary embolus, need for re-operation, need for intensive care or mechanic ventilator) were also recorded. 1 gr intravenous (iv) paracetamol was applied for all patients with a VAS value of 2 or 3; 1 mg/kg iv tramadol was administered additionally for those with a VAS value of 4 and over. Also, on the day of discharge, the satisfaction level of the patients with the anesthetic method was recorded as satisfied, not satisfied, or undecided.

Anesthesia Method

After standard monitoring, all anesthesia methods [general anesthesia, sedation, spinal anesthesia, epidural

anesthesia, erector spina plane block (ESPB), paravertebral block (PVB)], drug doses used, and additional analgesic or anesthetic needed during surgery were recorded by the blind anesthesiologist and surgeon, within the patient's knowledge. Patients were in the prone position during surgery. Necessary intervention (such as oxygen support, increased fluid replacement, ephedrine, or vasoactive drug application) was made in case of any complication. The patients were separated into three groups: (1) General anesthesia and sedation, (2) spinal and epidural anesthesia, and (3) ESPB and PVB. Central and peripheral regional anesthesia methods were planned for the patients one level below the surgical site.

Sedation and general anesthesia: Patients were monitored and peripheral vascular access was opened. While they were in a prone position, 1-2 mg midazolam and 1 µg/kg fentanyl and 4 Lt/min mask O_2 support were started. In case of desaturation, it was planned to correct the position of the patients, curarize them, and switch to orotracheal intubation.

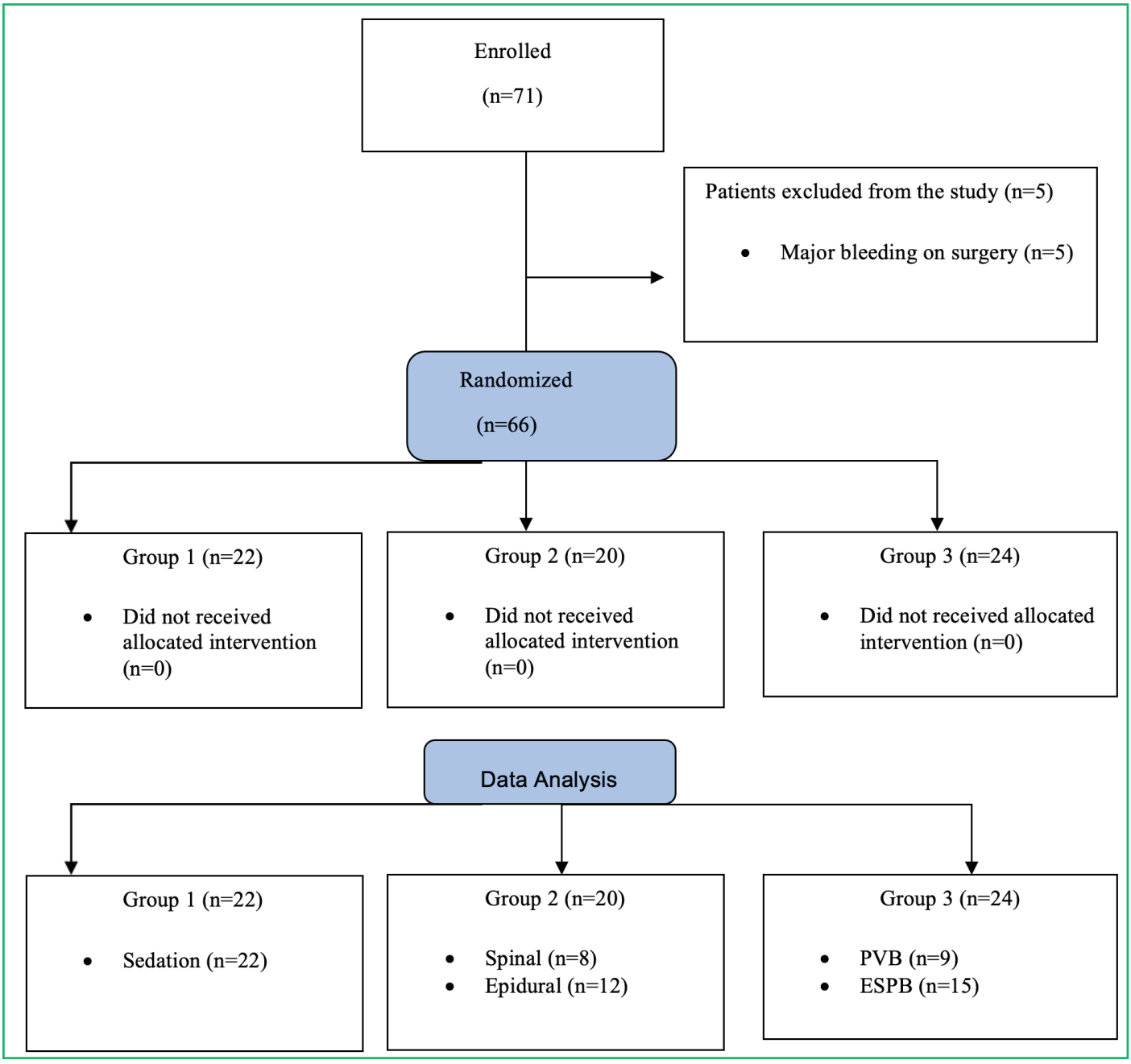

Figure 1. Flow chart of procedure

Spinal anesthesia: In a monitored sitting or reclining position, 1.5 mL of 1% isobaric bupivacaine (Marcaine® 0.5% vial, Eczacıbaşı) and 3.5 mL of a mixture of distilled water as 4.5 mg were given to the selected intrathecal area under sterile conditions. When it was ensured that adequate sensory blockade was achieved approximately 10 min after the procedure, surgery was allowed in the prone position.

Epidural anesthesia: After the individual was monitored, the epidural space was entered sterile conditions at the level determined by the surgery in a sitting position. When negative pressure was felt, 10 mL of 0.5% bupivacaine, 2 mL of fentanyl, and 8 mL of saline mixture were administered through an epidural catheter. Surgery was allowed when the adequate sensory blockade was achieved.

ESPB: The same skilled anesthesiologist who was blind to the study conducted bilateral ESPB with ultrasonography (USG) in the prone position. The process was carried out with the in-plane technique by means of a linear probe (6-13 MHz). A block needle of 22G (100 mm, Germany, B-braun) was applied bilaterally at the level determined according to the location of the fracture, lateral to the spinous process by 3 cm. By moving the needle in the craniocaudal direction, erector muscle was separated from transverse process with the help of 1-2 mL of SF. When the correct site was followed, 20 mL of 0.25% bupivacaine and 50 mg of 0.2% lidocaine were aspirated. The process was repeated on the opposite side in the same way.

PVB: After the patient was monitored, PVB was applied at the level determined by USG in the prone position. The process was carried out with the in-plane technique by means of a linear probe (6-13 MHz). After observing the transverse process and pleura, 20 mL of 0.5% bupivacaine in total was applied bilaterally by aspiration into the paravertebral area, which was seen as a triangle. When sensory blockade occurred, surgery was started.

Surgical Procedure

Experienced surgeons performed all PKP procedures. The patient was positioned face down. To complete entire PKP, a unilateral transverse process-pedicle technique was used. Under pinhole fluoroscopy, it was carried out via the anterior portion of the vertebrae. A balloon was then placed on the vertebral body and expanded. Lastly, lateral fluoroscopy was used to guide the injection of bone cement into the vertebral body. The anatomical level at which surgery was performed was recorded. The surgical technique was applied similarly to that in the literature (11).

Visual Analogue Scale (VAS)

VAS is a real-time, non-invasive, rapidly responding, patient-to-patient, and easy-to-apply pain assessment scale (12). No pain was scored with 0 point, and very severe pain with 10 points.

The Universe of the Study and the Sample

The population of the study consisted of male/female patients aged 18-100 years, who underwent PKP surgery in our hospital between January and July 2022.

Sample calculation was not made for the study, and 66 patients were included in the study, except for 5 patients who had major bleeding during surgery. After the study was completed, a post-hoc power analysis was conducted to examine whether the power of the study was sufficient. In the analyses made for pain scores, discharge and mobilization times, which constituted the main hypothesis of the study, the power level was found above 99.8% for all three parameters, showing that the study sample was sufficient for the study. Power analyses were performed with the G*Power 3.1 program.

Statistical Analysis

In the study, descriptive data are shown as percentages and numbers, and measurement data are shown as median (minimum-maximum) values. In the comparison of categorical data, the chi-square and Fisher tests were used where appropriate. The Kolmogorov-Smirnov tests were used to analyze the normal distribution of measurements. The Kruskal-Wallis test was employed to compare the measurements since the data did not exhibit a normal distribution. The value of $p<0.05$ was accepted for statistical significance. Bonferroni correction was applied for p-values in post-hoc analysis. All analyses were performed with the SPSS 20 program.

Results

No statistically significant difference was observed with regard to gender, ASA use, smoking, comorbidities, mobilization levels, level of surgery, need for preoperative analgesic use, and baseline VAS values in a total of 66 patients, 38 of whom were female and 28 were male (Table 1). As the anesthesia method, sedation was applied in 22 patients, central block in 20 patients (spinal anesthesia in 8 patients, epidural anesthesia in 12 patients), and peripheral block in 24 patients (PVB in 9 patients, ESPB in 15 patients).

The rate of need for additional sedation, VAS scores at all postoperative measured times, and paracetamol and

tramadol doses were found to be statistically significantly higher in group 1 than in group 2 and group 3 (for all, p<0.001). No statistically significant difference was found among the study groups and heart rate, peripheral oxygen saturation (SpO_2), operation time, mean arterial pressure (MAP), and perioperative complication rates (Table 2).

Postoperative time to first mobilization and discharge was longer in group 1 than in other samples. It was significantly shorter in group 3 than in other samples (for both, p<0.001). The patient satisfaction rate in group 3 was statistically significantly higher than in group 1 (p<0.001). The rate of PACU was higher in group 1 than in other groups, and significantly lower in group 3 than in other groups (p<0.001). Postoperative complication rates were found to be statistically similar in the study groups (p>0.50) (Table 3). When the postoperative complications were examined, patients in group 1 and group 3 had nausea and vomiting, 2 patients had hypotension (starting with mobilization), and 1 patient had respiratory distress. Prolongation of sensory blockade was observed in 1 patient in group 2 and 3.

Perioperative nausea rate was found statistically significantly lower in group 3 than in group 1 and group 2 (p=0.008). The rates of perioperative hypotension, arrhythmia, and desaturation were found to be statistically similar in the study samples (p>0.05) (Table 4).

Discussion

Since spine augmentation procedures include the injection of needles with different diameters into the vertebral body, they are associated with significant pain.

Table 1. Assessment of demographic data according to study groups

		Group 1	Group 2	Group 3	p
Med (Min-max)		Med (Min-max)	Med (Min-max)		
Age		73.5 (65.0-81.0)	72.5 (66.0-83.0)	71.0 (66.0-82.0)	0.897[a]
Gender	Female	13 (59.1)	13 (65.0)	12 (50.0)	0.596[b]
	Male	9 (40.9)	7 (35.0)	12 (50.0)	
ASA		3.0 (2.0-3.0)	3.0 (2.0-3.0)	3.0 (2.0-3.0)	0.970[a]
Level	Thoracal	14 (63.6)	10 (50.0)	11 (45.8)	0.457[b]
	Lumbar	8 (36.4)	10 (50.0)	13 (54.2)	
Analgesic	Yes	22 (100.0)	20 (100.0)	24 (100.0)	*
	No	0 (0.0)	0 (0.0)	0 (0.0)	
Mobilization	Self-sufficient	5 (22.7)	5 (25.0)	5 (20.8)	0.880[c]
	Only meet his/her needs such as toilette	10 (45.5)	10 (50.0)	10 (41.7)	
	Bed-ridden, able to stand up with support	6 (27.3)	4 (20.0)	9 (37.5)	
	Immobilized	1 (4.5)	1 (5.0)	0 (0.0)	
HT	Yes	10 (45.5)	12 (60.0)	10 (41.7)	0.452[b]
	No	12 (54.5)	8 (40.0)	14 (58.3)	
DM	Yes	13 (59.1)	13 (65.0)	13 (54.2)	0.767[b]
	No	9 (40.9)	7 (35.0)	11 (45.8)	
HR	Yes	13 (59.1)	11 (55.0)	15 (62.5)	0.881[b]
	No	9 (40.9)	9 (45.0)	9 (37.5)	
Obesity	Yes	5 (22.7)	2 (10.0)	8 (33.3)	0.184[c]
	No	17 (77.3)	18 (90.0)	16 (66.7)	
Tobacco	Yes	5 (22.7)	7 (35.0)	7 (29.2)	0.680[b]
	No	17 (77.3)	13 (65.0)	17 (70.8)	
Other	Yes	8 (36.4)	8 (40.0)	10 (41.7)	0.933[b]
	No	14 (63.6)	12 (60.0)	14 (58.3)	
VAS 0		7.0 (6.0-9.0)	7.5 (6.0-9.0)	7.5 (6.0-9.0)	0.770[a]

Med: Median, k.: Met, *Not calculated, [a]: Kruskal-Wallis test, [b]: Chi-square test, [c]: Fisher test VAS0: Preoperative VAS, HT: Hypertension, DM: Diabetes mellitus, HR: Heart rate, VAS: Visual pain scales

Table 2. Assessment of perioperative data according to study groups

Median (Min-max)		Group 1	Group 2	Group 3	p
		Median (Min-max)	Median (Min-max)		
MAP1		65.0 (57.0-98.0)	65.5 (55.0-86.0)	67.0 (58.0-96.0)	0.747[a]
MAP2		63.0 (40.0-92.0)	59.5 (48.0-80.0)	64.5 (55.0-84.0)	0.296[a]
MAP3		60.0 (44.0-86.0)	57.0 (45.0-79.0)	60.5 (48.0-80.0)	0.167[a]
MAP4		60.5 (48.0-80.0)	60.0 (51.0-78.0)	60.5 (52.0-82.0)	0.842[a]
HR1		80.5 (67.0-102.0)	79.0 (67.0-98.0)	79.5 (60.0-98.0)	0.931[a]
HR2		79.5 (65.0-98.0)	79.5 (70.0-112.0)	79.5 (65.0-98.0)	0.756[a]
HR3		78.0 (68.0-108.0)	79.0 (69.0-112.0)	78.0 (65.0-112.0)	0.430[a]
HR4		77.5 (67.0-90.0)	77.5 (67.0-98.0)	75.5 (68.0-109.0)	0.830[a]
SpO_2-1		96.0 (92.0-98.0)	97.0 (95.0-98.0)	96.0 (94.0-98.0)	0.500[a]
SpO_2-2		96.0 (86.0-98.0)	97.0 (92.0-98.0)	97.0 (94.0-98.0)	0.110[a]
SpO_2-3		96.0 (86.0-98.0)	96.0 (88.0-98.0)	97.0 (86.0-98.0)	0.154[a]
SpO_2-4		96.0 (90.0-98.0)	97.0 (95. 0-98.0)	97.0 (92.0-98.0)	0.428[a]
Additional dose	Yes	18 (81.8)	6 (30.0)	5 (20.8)	**<0.001[b*]**
	No	4 (18.2)	14 (70.0)	19 (79.2)	
Operation time (dk)		55.0 (40.0-70.0)	47.5 (35.0-75.0)	47.5 (35.0-65.0)	0.346[a]
Perioperative complication	Yes	9 (40.9)	10 (50.0)	7 (29.2)	0.365[b]
	No	13 (59.1)	10 (50.0)	17 (70.8)	

[a]: Kruskal-Wallis test, [b]: Chi-square test, *p<0.001, MAP1: MAP at the 15. min of operation, MAP2: MAP at the 30. min of operation MAP3: MAP at the 45. min of operation, MAP4: MAP at the 60. min of operation, HR1: HR at the 15. min of operation, HR2: MAP at the 30. min of operation, HR3: HR at the 45. min of operation, HR4: MAP at the 60. min of operation, SpO_2-1: SpO_2 at the 15. min of operation, SpO_2-2: SpO_2 at the 30. min of operation, SpO_2-3: SpO_2 at the 45. min of the operation, SpO_2-4: SpO_2 at the 60.min of the operation, HR: Heart rate, MAP: Mean arterial pressure

In group 1, the need for additional sedation was observed to be significantly higher in VAS scores, paracetamol and tramadol doses at all postoperative measurement times compared to other groups. Perioperative nausea, PACU need, postoperative first mobilization and discharge times were lower in group 3 than in other groups. The time to discharge and mobilization was highest in group 1, and the patient satisfaction rate was highest in group 3.

Regardless of which anesthesia method is preferred, it is important to provide a good depth of anesthesia at a level that will prevent spinal cord or nerve damage and prevent needle malposition. Poor perioperative pain management was linked to higher rates of morbidity and death as well as worse levels of patient satisfaction, particularly in patients with comorbid conditions. The pain is correlated with increased arrhythmia, hypertension, and cranial bleeding, especially in patients with underlying cardiovascular comorbidities (13). An increase in opioid associated complications (such as consciousness, respiratory depression, hypotension, vomiting, and nausea) may be observed with an opioid preference for perioperative pain control (14). Although many methods such as local, general (sedoanalgesia), regional and peripheral block are applied in PKP surgery, there is still no consensus on the ideal method. In the older age group, any of these options can be problematic.

Although local anesthesia is preferred in PKP surgery, it may not be satisfactory for both the surgeon and the patient if it cannot provide adequate analgesia, especially balloon inflation. In a study in the literature, individuals were separated into 2 groups as local and general anesthesia groups. Both local and general anesthesia might be used in PKP. However, it is stated that local anesthesia is less costly and more effective, and safe with bearable pain compared to general anesthesia (15). Although local anesthesia and sedation provide adequate surgical conditions in studies, surgeons find general anesthesia to be more reliable and comfortable for this procedure (16,17). In these patients with various comorbidities, general anesthesia poses more risks and is linked to longer hospital stays and stays in the PACU as well as a higher frequency of postoperative pulmonary problems (18). In a similar study, local, general and monitoring anesthesia methods were compared. In this study, local anesthesia was performed in ropivacaine (n=55), iv anesthesia with dexmedetomidine (n=55) and general anesthesia with fentanyl/propofol/sevoflurane (n=55). Better sedation and analgesia, shorter operation time, better cooperation with patients, and fewer

Table 3. Assessment of postoperative data according to study groups

Median (Min-max)		Group 1	Group 2	Group 3	p
		Median (Min-max)	Median (Min-max)		
Postop VAS1		4.0 (2.0-6.0)	2.0 (1.0-4.0)	2.0 (0.0-4.0)	**<0.001**[**a]
Postop VAS2		4.0 (2.0-5.0)	2.0 (1.0-4.0)	2.0 (0.0-4.0)	**<0.001**[**a]
Postop VAS3		4.0 (2.0-5.0)	2.0 (1.0-4.0)	2.0 (0.0-4.0)	**<0.001**[**a]
Postop VAS4		4.0 (2.0-4.0)	2.0 (1.0-4.0)	2,0 (0.0-4.0)	**<0.001**[**a]
Postop time to first mobilization		10.0 (8.0-14.0)	8.5 (6.0-12.0)	6.0 (4.0-8.0)	**<0.001**[**a]
Discharge		26.0 (18.0-48.0)	20.0 (14.0-30.0)	16.0 (10.0-30.0)	**<0.001**[**a]
Satisfaction	Satisfied	9 (40.9)	12 (60.0)	21 (87.5)	**0.010**[*b]
	Uncertain	11 (50.0)	7 (35.0)	3 (12.5)	
	Unsatisfied	2 (9.1)	1 (5.0)	0 (0.0)	
Postop complication	Yes	6 (27.3)	1 (5.0)	1 (4.2)	0.055[b]
	No	16 (72.7)	19 (95.0)	23 (95.8)	
PACU	Yes	19 (86.4)	9 (45.0)	3 (12.5)	**<0.001**[**c]
	No	3 (13.6)	11 (55.0)	21 (87.5)	
Paracetamol dose (mg)		3.000 (1.000-3.000)	1.000 (0-3.000)	0 (0-3.000)	**<0.001**[**a]
Tramadol dose (mg)		250 (0-300)	0 (0-200)	0 (0-200)	**<0.001**[**a]

[a]: Kruskal-Wallis test, [b]: Fisher test, [c]: Chi-square test, *p<0.05, **p<0.001, VAS1: Postoperative 2. hour, VAS2: postoperative 6. hour, VAS3: Postoperative 12. hour, VAS4: Postoperative 18. hour, PACU: Postanesthesia care unit

Table 4. Assessment of perioperative complications according to study groups

Median (Min-max)		Group 1	Group 2	Group 3	p
		Median (Min-max)	Median (Min-max)		
Periop hypotension	Yes	5 (22.7)	7 (35.0)	2 (8.3)	0.097[a]
	No	17 (77.3)	13 (65.0)	22 (91.7)	
Periop arrhythmia	Yes	6 (27.3)	7 (35.0)	5 (20.8)	0.576[b]
	No	16 (72.7)	13 (65.0)	19 (79.2)	
Periop nausea	Yes	8 (36.4)	10 (50.0)	2 (8.3)	**0.008**[*b]
	No	14 (63.6)	10 (50.0)	22 (91.7)	
Periop desaturation	Yes	7 (31.8)	7 (35.0)	2 (8.3)	0.072[b]
	No	15 (68.2)	13 (65.0)	22 (91.7)	

[a]: Fisher test, [b]: Chi-square test, *p<0.05

perioperative side effects were observed in monitoring anesthesia with dexmedetomidine (19). In a study, patients were put into the conventional group (0.5% local anesthesia with lidocaine (1); n=42), the prevention group [(1) + celecoxib 200 mg orally the night before surgery and iv 40 mg parecoxib sodium 1 hour before surgery (2); n=43] and the combined group [(1) + (2) + additional intraoperative dexmedetomidine 0.5 µg/kg/hour intravenously; n=43]. For kyphoplasty under local anesthesia, it was observed that combined intraoperative sedation gave better results with preemptive analgesia in reducing intraoperative pain and preventing intra and postoperative hemodynamic changes compared to extra preemptive analgesia or local anesthetic alone (20).

In our study, 81.8% of the patients in group 1 required additional perioperative anesthesia. Ketamine, midazolam, and fentanyl weighted sedation were added. While the average postoperative VAS values were 4 at all measurement times, the average time to the first mobilization and discharge were 10 hours and 26 hours, respectively. While 40.9% of patients were satisfied with anesthesia, 86.4% of the patients needed PACU. We can attribute the general reason for dissatisfaction with pain during surgery, increased nausea due to additional intraoperative sedation, and high

rates of PACU hospitalization. Postoperative complications such as the need for reoperation, bleeding, surgical site infection, and pain were seen in 27.3% of the patients. The average postoperative paracetamol dose was 3 gr, while average tramadol dose was 200 mg. Nausea, desaturation, arrhythmia and hypotension were observed in patients preoperatively, respectively. We associate desaturation with respiratory depression caused by anesthetics; and others with both hypotension caused by anesthetics and changes in the prone position.

Although it is not very common, there have been recent publications in the literature about the utilization of spinal anesthesia for kyphoplasty. In a study (21), a case in which low-dose spinal anesthesia with low dose sedation was applied to patients. It was stated that although there was an adequate sensory blockade, some of the pain control could be achieved by co-administration of iv fentanyl and propofol. It was emphasized that although spinal anesthesia was effective in pain control, attention should be paid in terms of hemodynamic instability and cardiovascular complications that might develop due to local anesthesia baricity (14). In a similar study, the experience of spinal anesthesia in 11 patients who underwent kyphoplasty was published (22). Despite the fact that spinal anesthetic and local anesthetic infiltrations were employed, it was noted that 4 individuals felt discomfort throughout the surgery. Selecting the baricity of the local anesthetic to be injected intrathecally was another difficulty for them. They used hyperbaric lidocaine in the first 6 individuals, but changes to isobaric lidocaine because of a high incidence of hemodynamic instability; they suggested that there is an increase in complications, probably due to more cephalic spread of hyperbaric lidocaine on prone. The third constraint they noted was the unexpected prolongation of the procedure and inability to extend block time, especially if more level of vertebrae was included in the surgery (23). In another study on subarachnoid anesthesia for kyphoplasty, patients were given intrathecal hyperbaric or plane bupivacaine with or without fentanyl. It was stated that 5 individuals had pain while having the surgery and additional iv analgesia was needed. Other patients were comfortable, except that one patient felt pain pressure on the ribs. No patient had respiratory distress or the need for deep sedation. As a result of the study, it was stated that for kyphoplasty, subarachnoid anesthesia might be a suitable method (24).

According to some reports in the literature, segmental epidural anesthesia is superior to general anesthesia with regard to analgesic consumption, postoperative analgesia, and speed of treatment in patients with PKP. However, it should be noted that epidural anesthetic leakage into the subarachnoid space could be resulted in total spinal anesthesia (1). In our study, 30% of patients in group 2 needed additional need for sedation. Additional ketamine and midazolam were administered. The average VAS values in the first 12 hours after surgery were around 2. The average time to the first mobilization and discharge were 8.5 hours and 20 hours, respectively. While the average need for paracetamol was 2 gr postoperatively, that was 0 for tramadol. While 60% of the patients were satisfied with anesthesia, 45% needed PACU. Reoperation was required in 1 patient due to postoperative bleeding complications. The most common perioperative complication was nausea, which we associated with sympathetic blockade and opioid use. Postoperative complications were hypotension, arrhythmia, and desaturation similar to other groups.

It has been shown that good acute or chronic pain control at the cervical, thoracic and lumbar levels are achieved with ESPB, which has recently become widespread in PKP (10,25,26). In a study in which ESPB-related motor weakness was reported, ESPB was shown as a piece of multimodal analgesia (27). In a similar study performed on patients who underwent kyphoplasty with local anesthesia and ESPB, postoperative analgesia was required in all of the patients operated under local anesthesia and in 22.7% of the patients who underwent ESPB. In the ESPB group, no additional sedation was needed during the intraoperative procedure (28). In the case reports, the view that ESPB offers comfortable anesthesia management for PKP was supported by the possibility of anesthesia maintenance without the need for any additional intraoperative sedation (28,29).

In our study, the need for additional sedation in group 3 was seen the least with 20.8% compared to other groups. Perioperative complications were observed in 29.2% of patients. While the average measured postoperative VAS value was 2, the need for paracetamol and tramadol use was significantly lower than in other groups. The average times to first mobilization and discharge were 6 and 16 hours, respectively, and were significantly lower compared to other groups. 12.5% of patients needed PACU. We think that this group has the highest satisfaction rate with 87.5% due to more comfort and early recovery. Only 1 patient had postoperative sensory blockade for a long time. This resulted in patient dissatisfaction, delay in mobilization,

and prolonged discharge time. Perioperative nausea, hypotension, arrhythmia and desaturation were observed significantly less than in other groups.

Study Limitations

The limitations of our study were the low number of cases due to rarity of the surgeries, surgeon satisfaction and inability to look for their effects on long-term chronic pain. Also, in order to obtain statistical data, combining small groups and examining them in 3 main groups prevented the investigation of the effectiveness of different methods.

Conclusion

We observed that patients who underwent peripheral block in anesthesia management in kyphoplasty surgery had fewer intraoperative complications, need for additional sedation and PACU, shorter postoperative mobilization and discharge time, lower VAS values at specified measurement times, and increased patient satisfaction. We think that peripheral anesthesia methods, especially ESPB and PVB, can be safely preferred by experienced people in these surgeries, where anesthesia management is risky due to advanced age, increased co-morbidities, and the preferred prone position during surgery.

Ethics

Ethics Committee Approval: Were taken from the records of the individuals with the treatment of PKP between July 01 and 22, 2022 after the approval of the University of Health Sciences Turkey, Bursa High Specialization Training and Research Hospital Ethics Committee (2021-KAEK-25 2021/12-09), clinical trials number NCT05526794.

Informed Consent: Patient signed consent was obtained.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: T.O., Design: T.O., Data Collection or Processing: T.O., Ü.K., Analysis or Interpretation: T.O., A.D., Ü.K., Drafting Manuscript: T.O., A.D., Critical Revisation of Manuscript: A.O., Ü.K., Ş.E.Ö., Final Approval and Accountability: Ş.E.Ö., A.O., Technical and Material Support: A.D., A.O., Supervision: T.O., Ş.E.Ö., Writing: T.O.

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ORIGINAL RESEARCH

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Evaluation of Anesthesia Administrations in Electroconvulsive Therapy in the COVID-19 Pandemic Process

COVID-19 Pandemi Sürecinde Elektrokonvülsif Tedavilerde Anestezi Uygulamalarının Değerlendirilmesi

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Abstract

Objective: The aim of this study is to evaluate the approach of anesthesiology physicians to electroconvulsive therapy (ECT) in the Coronavirus disease-2019 (COVID-19) pandemic process, the protective safety measures taken before and during ECT, and their approach to the use of personal protective equipment (PPE).

Method: A questionnaire form including questions about changes in ECT treatments, use of PPE, employee and patient safety during the pandemic process was prepared. Anesthesiology lecturers, specialist doctors and research assistants throughout Turkey were invited to participate in the research by sending the link of the questionnaire form via either the online social network application WhatsApp, or emails through the Turkish Society of Anesthesiology and Reanimation.

Results: The forms of 130 participants who responded were analyzed. Of the participants, 43.8% (n=25) were specialist physician, 36.9% (n=57) were research assistant, and 19.2% (n=48) were lecturers. The distribution of the institutions where the participants worked was university hospitals at the rate of 43.8% (n=57), training and research hospitals at the rate of 47.7% (n=67), and private and public hospitals at the rate of 8.5% (n=11). Among the participants, 63.8% (n=83) stated that they continued to perform ECT, while 76.9% (n=100) stated that the number of ECT performed in their hospital decreased. The number of people in the room during ECT was four or less in 73.8% (n=96) of the participants, the rate of the participants who practiced more than 30 min waiting interval between ECTs was 9.2% (n=12). It was found that the rate of high-efficiency particulate air filter application to the anesthesia device was 93.8%, the rate of preoxygenation application was 85.4%, and

Öz

Amaç: Koronavirüs hastalığı-2019 (COVID-19) pandemisi sürecinde anesteziyoloji hekimlerinin elektrokonvülsif tedavi (EKT) uygulamasına yaklaşımı, EKT sırasında alınan koruyucu güvenlik önlemleri, kişisel koruyucu ekipman (KKE) kullanımı, anestezi uygulamaları ile ilgili durum ve yaklaşımlarını değerlendirmektir.

Yöntem: Türkiye genelindeki anestezi öğretim görevlisi, uzman doktor ve araştırma görevlileri, pandemi sürecinde EKT uygulamalarındaki değişiklikler, KKE kullanımı, çalışan ve hasta güvenliği ile ilgili soruları içeren anket formu online ve Türk Anesteziyoloji ve Reanimasyon Derneği aracılığıyla gönderilerek araştırmaya katılmaya davet edildi.

Bulgular: Çalışmaya 130 kişi yanıt verdi, yanıt verenlerin sonuçları analiz edildi. Katılımcıların %43,8'ü (n=25) uzman hekim, %36,9'u (n=57) araştırma görevlisi, %19,2'si (n=48) öğretim görevlisiydi. Hastane dağılımı %43,8 (n=57) üniversite, %47,7 (n=67) eğitim araştırma, %8,5 (n=11) özel ve devlet hastanesi idi. Pandemide EKT uygulamaya devam ettiğini belirtenlerin oranı %63,8 (n=83) iken %76,9'u (n=100) hastanelerinde EKT uygulama sayılarında azalma olduğunu söylemişlerdir. EKT sırasında odada bulunan kişi sayısı katılımcıların %73,8'inde (n=96) 4 ve altında, EKT arası 30 dakika üzerinde bekleme süresi uygulayan katılımcıların oranı %9,2 (n=12) idi. Anestezi cihazı ekshalasyon valfine hepafiltre uygulama oranı %93,8; preoksijenizasyon uygulama oranı %85,4; balon maske ventilasyon uygulama oranı %77,7 olarak bulundu. EKT uygulaması sırasında katılımcıların %45'i her zaman KKE kullandığını, %10'u hiçbir uygulamada KKE kullanmadığını belirtti. KKE kullanım oranlarına bakıldığında sırasıyla %93,1'inde N95 (FFP2/FFP3), %50,8'inde tek kat eldiven, %50,8'inde boks gömleği ve %49'unda cerrahi maske kullanıldığı

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the rate of applying bag mask ventilation was 77.7%. Forty-five percent of the participants indicated that they always used PPE, 10% stated not to use PPE in any treatment. It was determined that the most commonly used PPEs were N95 (FFP2 or higher) (93.1%), single-layer glove (50.8%), box apron (50.8%), and surgical mask (49%), respectively. The rate of participants who stated that they experienced no difficulty in procuring PPE was 53.8%, whereas 29.2% indicated that they had difficulty in procuring N95 (FFP2 or higher). Of the participants, 66.9% reported that a COVID-19 polymerase chain reaction (PCR) test was performed within 24-48 hours before ECT, 8.5% stated that patients did not undergo COVID-19 PCR testing. It was detected that 14.6% of the participants performed ECT to COVID-19 positive patients and 9.2% had COVID-19 infection after the treatment.

Conclusion: ECT treatments have decreased to a great extent during the pandemic process. We wanted to draw attention to procedures that would cause aerosolization in ECT, the importance of PPE use and the differences in practice with questions toward the level of knowledge in line with the recommendations of the guidelines on this subject. We are of the opinion that it will be important to know and implement the guidelines in terms of employee and patient safety in the presence of a possible pandemic.

Keywords: Anesthesia, approach, COVID-19, electroconvulsive therapy, personal protective equipment, treatment

görüldü. Katılımcıların %53,8'i KKE temininde zorluk çekmediğini belirtirken, %29,2'si N95 (FFP2/FFP3) temininde zorluk yaşadıklarını belirtmişlerdir. EKT öncesi 24-48 saat içinde COVID polimereaz zincir reaksiyon (PCR) testine bakılma oranı %66,9 olarak bulunurken; katılımcıların %8,5'i hastalara COVID PCR testi yapılmadığını belirtmiştir. Katılımcıların %14,6'sı ise COVID-19 pozitif hastalara EKT uyguladığını söylemiştir. Uygulama sonrası hekimlerden %9,2'sinin COVID-19 enfeksiyonu geçirdiği saptanmıştır.

Sonuç: Pandemi sürecinde EKT uygulamaları büyük oranda azalmıştır. EKT'de aerosol oluşumuna sebep olacak uygulamalara, KKE kullanımının önemine ve bu konuda kılavuzların önerileri doğrultusunda bilgi düzeylerine yönelik sorular ile uygulama farklılıklarına dikkat çekmek istedik. Olası bir pandemi varlığında çalışan ve hasta güvenliği açısından, kılavuzların bilinmesi ve uygulanmasının önemli olacağı kanısındayız.

Anahtar kelimeler: Anestezi, COVID-19, elektrokonvülsif tedavi, kişisel koruyucu ekipman, yaklaşım

Introduction

Healthcare workers (HCWs) may be exposed to many adverse conditions such as infection, radiation, and chemical and physical risks while providing diagnostic and therapeutic healthcare services in hospitals (1). Among these, the most common cause of morbidity and mortality is constituted by infection based on the margin of exposure. Protective measures, including vaccination, if possible, change the risk of infection, depending on the extent to which they are implemented in the working environment. Among the protective measures to be taken during the pandemic process, complying with national and international guidelines and using personal protective equipment (PPE) have an important place. HCWs should use special clothes and additional protective equipment determined with regard to the unit where they work in addition to gloves and masks to protect themselves and patients while providing healthcare services (2).

The novel Coronavirus disease-2019 (COVID-19), which emerged in December 2019 in Wuhan, China, was recognized as a pandemic in January 2020 by the World Health Organization (WHO). This virus, which transmits through close contact and droplets and causes COVID-19, has caused serious changes in the global economy and health systems all over the world (3). In anesthesia administrations during the COVID-19 pandemic, many difficulties may be encountered due to infection transmission, such as aerosol exposure in the first place. Along with the patient's respiratory activity, some medical interventions may also produce aerosols. These aerosols include particles that can travel longer distances and remain in the air longer; however, their potential to infect is unclear (4).

Anesthesiologists and intensive care physicians are among the highest risk group with a high probability of encountering patients diagnosed and suspected with COVID-19 since they provide consultation services in many areas of hospitals such as operating room, intensive care unit, code blue, magnetic resonance imaging, electroconvulsive therapy (ECT), and endoscopy unit (5,6).

ECT is an urgent and life-saving treatment for patients diagnosed with depression and other serious psychiatric illnesses that require a rapid therapeutic response such as suicidality and catatonia. The meeting of the increasing intensive care needs during COVID-19 has been hindered all over the world because the risk of transmission during the COVID-19 pandemic, the inadequacy of information about COVID-19, and the unavailability of vaccination measures for a period have restricted the working areas of anesthesiologists (7).

In the present study, we aimed to have an idea about the approach to ECT, the protective safety precautions taken during ECT, working conditions, and anesthesia applications in hospitals throughout Turkey during the COVID-19 pandemic.

Materials and Methods

The study was carried out in accordance with the principles of the Declaration of Helsinki after obtaining approvals from the Local Ethics Committee of University of Health Sciences Turkey, Bursa High Specialization Training and Research Hospital (2011-KAEK-25 2020/11-11) and the Ministry of Health Scientific Research Platform (2020-11-02T21_10_33). A cross-sectional online survey was conducted with anesthesiologists working throughout Turkey. For this purpose, using Google forms, a questionnaire consisting of a total of 27 questions was created, two of the questions were open-ended and twenty-five were close-ended. The participants were invited to the study by sending a form link by means of the social network application WhatsApp and e-mail through the Turkish Society of Anesthesiology and Reanimation.

The participants were physicians who worked in university, public, and private hospitals throughout Turkey as anesthesiology and reanimation lecturers, specialists, and research assistants. Physicians working or receiving education abroad and those who did not actively work were excluded from the study. The questionnaire was prepared within a certain system using the multiple-choice question technique. The principles of impartiality and not directing the answers of the participants were followed in the question choices. Following the informed consent, the participants were asked to fill out the questionnaire form without providing identifiable information such as name, surname and the name of the institution where they worked. The information script about the purpose of the survey was presented to the participants in the introduction section. The questions in the questionnaire were about demographic characteristics, clinical and anesthesia approach in performing ECT, changes occurred in the pandemic process, use of PPE, employee and patient safety, and catching COVID-19 disease.

Statistical Analysis

In the study, the descriptive data were presented as numbers. In the comparison of categorical data, the chi-square and Fisher tests were used where appropriate. $p<0.05$ was accepted for statistical significance. Bonferroni correction was applied for the p-values in post-hoc analyses. All statistical analyses were performed using the IBM SPSS 20 software package.

Results

The forms of 130 participants who were agreed to participate in our study were statistically evaluated. Of the participants, 74 (56.9%) were female, 56 (43.1%) were male, and the majority (n=59, 45.4%) were in the 26-35 year age group. Among the participants enrolled in the study, 43.8% were specialist physicians, 36.9% were research assistants, and 19.2% were lecturers. Those with a working experience of less than 5 years (n=42, 32.3%) based on their years in the profession and those working in a training and research hospital (n=62, 47.7%) were in the majority. The demographic characteristics of the participants are shown in Table 1.

While the rate of participants who performed ECT to less than 50 patients per month was 82.3% before the pandemic period, it reached 92.3% during the pandemic. Of the participants, 63.8% continued to perform ECT during the pandemic process, whereas 76.9% indicated that there was a decrease in the number of patients who underwent ECT in their hospitals (Table 2).

When examining the data regarding the preparations for the ECT during the pandemic process according to the health institutions where the physicians worked, it was found that there were significant differences between the hospitals where the participants worked in terms of the number of people present in the ECT room and whether the ECT room was within the operating room. According to the post-hoc analysis results, performing ECT in the room with the presence of five or more people was determined

Table 1. Demographic characteristics of the participants

		n	(%)
Age (years)	26-35	59	(45.4)
	36-45	43	(33.1)
	46-55	28	(21.5)
Gender	Female	74	(56.9)
	Male	56	(43.1)
Title	Lecturer	25	(19.2)
	Specialist	57	(43.8)
	Research assistant	48	(36.9)
Year in the profession	<5	42	(32.3)
	5-10	34	(26.2)
	11-15	22	(16.9)
	16-20	14	(10.8)
	>20	18	(13.8)
Institution	University hospital	57	(43.8)
	Training and research hospital	62	(47.7)
	Other (state hospital, private hospital)	11	(8.5)

to be significantly higher in training and research hospitals than in university hospitals and other hospitals (state and private hospitals) (p<0.001). The rate of the presence of ECT room within the operating room in university hospitals was statistically significantly higher than in the training and research hospitals and other hospitals (p<0.001). No statistically significant differences could be detected between the institutions they worked in terms of applying COVID-19 PCR test before ECT, the status of performing ECT to COVID-19 PCR positive patients, and other ECT precautions during the pandemic process (Table 3).

During the pandemic process, the number of people in the ECT room was four or less in 73.8% of the participants. The waiting interval for the next patient to be admitted for ECT was 30 minutes or more in 9.2% of the hospitals, whereas 12.3% of the participants stated that they continued the application without any waiting interval. Soda lime replacement following anesthesia application was daily in 36.9% of the hospitals, and once a week in 32.3%. While 36.9% of the participants stated that they changed the anesthesia breathing circuit after each patient, the rate of high-efficiency particulate air (HEPA) filter between the reservoir bag-anesthesia circuit and between mask-anesthesia circuit was 93.8%. It was found that the rate of preoxygenation before anesthesia induction was 86.9%, and the rate of bag mask ventilation (BMV) was 77.7%.

The rate of box apron use in the participants working in university hospitals was found to be statistically significantly lower than in those working in training and research hospitals and other hospitals (p=0.005). There was no statistically significant difference between the institutions worked in terms of preferring surgical mask, N95 (FFP2/FFP3), eye goggles, face shields, overalls, box apron, single-layer gloves, double-layer gloves, overshoe covers, bonnet and boots as PPEs or not preferring to use any PPE (Table 4). When asked about difficulty experienced in procuring PPE, 53.8% of the participants indicated that they had no difficulty at all, and 29.2% stated that they had difficulty in obtaining N95 (FFP2/FFP3).

Table 2. Data on ECT application before and during the pandemic

		n	(%)
Number of ECT BP (per month)	<50	107	(82.3)
	50-100	18	(13.8)
	>100	5	(3.9)
Number of ECT DP (per month)	<50	120	(92.3)
	50-100	9	(6.9)
	>100	1	(0.8)
Continuing to perform ECT (DP)	Yes	83	(63.8)
	No	47	(36.2)
ECT application DP	Decrease	100	(76.9)
	Same	21	(16.2)
	Increase	9	(6.9)

Median (minimum-maximum) values are presented. BP: Before the pandemic, DP: During the pandemic, ECT: Electroconvulsive therapy

Discussion

As a result of our study, it was observed that ECT treatment continued in most of the hospitals throughout Turkey, but the number of monthly ECT performed decreased by more than half during pandemic process. The number of people in the room during ECT was four or less in 73.8% of the participants. The rate of the participants who waited more than 30 min between ECTs was quite low. It was determined that about one-third of the participants changed their breathing circuit after each patient, the rate of HEPA filter application to the anesthesia device was 93.8%. The rate of preoxygenation application before anesthesia induction was found to be 85.4%, whereas the rate of applying BMV was 77.7%. Forty-five percent of the participants stated that they used PPE during performing ECT. When the PPE use of the participants examined that there was no significant difference between the hospitals in terms of PPEs used except for box apron. It was detected that 73.8% of the participants changed only their gloves before each ECT.

ECT therapy is lifesaving for many patients with psychosis and/or major depression (8,9). Adopting the view that ECT is not an elective procedure (9,10), the American Psychiatric Association recommends its use to be continued during the pandemic in the treatment of critically ill patients who cannot be managed medically (11). The decision to continue/suspend/terminate ECT treatment should be taken after considering the potential risks and benefits in the current pandemic situation (11,12). The studies in the literature show that many health centers have limited the number of patients to be admitted per day during the pandemic between three and six (11,13), and have also recommended that the frequency of sessions for a patient be twice a week (13-16). However, the determination of the seizure threshold with respect to age to reduce the number of ECT sessions can be one of the substantial factors (17). In studies conducted, it has been reported that some centers terminated performing ECT treatments due to fear of spreading COVID-19 during the pandemic and major hurdles in the provision of ECT services that include

the lack of anesthetists and the assignment of COVID-19 patients to intensive care units for their treatment. Unlike these centers, it was determined in our study that 63.8% of the participants continued ECT treatments by taking the necessary precautions.

Considering the measures taken in the literature before ECT in patients hospitalized in the clinic during pandemic, symptom monitoring for each patient, intranasal cleaning with povidone-iodine wipes and mouth wash with hydrogen peroxide to reduce viral load, wearing a surgical mask before the procedure and ensuring hand hygiene of patients before the procedure are seen to be performed (18). In our study, when the protective measures applied while bringing patients from the clinic were questioned, 89.2% of the participants stated that patients came to the room where ECT would be applied wearing surgical masks, 52.3% stated that daily symptom monitoring was conducted and 40% stated that patients' fever was measured. On the other hand, it was seen that povidone-iodine nasal wipes and hydrogen peroxide mouthwash were applied in none of the hospitals where the participants worked.

Since ECT treatment is a procedure that creates aerosols, it is advised to minimize the number of personnel in the room to prevent cross-infection risk (19). This is of importance for both the safety of HCWs and the continuity of the procedure. In studies conducted, ECT treatment, which was performed with seven people in the pre-pandemic period, has been proposed to be performed with a maximum of four people in the pandemic (7,19). Considering studies in the literature regarding this issue, the presence of less than five personnel in the ECT room during the pandemic period is important for the safety of the patient and HCWs (7). In our study,

Table 3. Measures taken in ECTs during the pandemic process by the institutions

		University		Training and research		Other		Total		p
		n	(%)	n	(%)	n	(%)	n	(%)	
Number of people in the room where ECT was applied	2-4 people	49	(86.0)	36	(58.1)	11	(100.0)	96	(73.8)	<0.001[C]
	>5 people	8	(14.0)	26	(41.9)	0	(0.0)	34	(26.2)	
Waiting interval between ECTs	None or waiting under 30 min	50	(87.7)	58	(93.5)	10	(90.9)	118	(90.8)	0.548[C]
	>30	7	(12.3)	4	(6.5)	1	(9.1)	12	(9.2)	
Soda lime replacement interval between ECTs	End of day or more frequent	24	(42.1)	26	(41.9)	6	(54.5)	56	(43.1)	0.724[C]
	Less frequent	33	(57.9)	36	(58.1)	5	(45.5)	74	(56.9)	
Breathing circuit change between ECTs	Yes	19	(33.3)	22	(35.5)	7	(63.6)	48	(36.9)	0.154[C]
	No	38	(66.7)	40	(64.5)	4	(36.4)	82	(63.1)	
HEPA filter application to the anesthesia device	Yes	56	(98.2)	56	(90.3)	10	(90.9)	122	(93.8)	0.119[F]
	No	1	(1.8)	6	(9.7)	1	(9.1)	8	(6.2)	
Application of bag mask ventilation (BMV)	Yes	47	(82.5)	46	(74.2)	8	(72.7)	101	(77.7)	0.512[C]
	No	10	(17.5)	16	(25.8)	3	(27.3)	29	(22.3)	
Preoxygenation application	Yes	47	(82.5)	54	(87.1)	10	(90.9)	111	(85.4)	0.668[C]
	No	10	(17.5)	8	(12.9)	1	(9.1)	19	(14.6)	
Presence of ECT room within the operating room	Yes	39	(68.4)	11	(17.7)	3	(27.3)	53	(40.8)	<0.001[C]
	No	18	(31.6)	51	(82.3)	8	(72.7)	77	(59.2)	
Availability of negative pressure system in the room where ECT is performed	Yes	6	(10.5)	6	(9.7)	2	(18.2)	14	(10.8)	0.760[F]
	No	46	(80.7)	47	(75.8)	8	(72.7)	101	(77.7)	
	Participant did not know	5	(8.8)	9	(14.5)	1	(9.1)	15	(11.5)	
Chest X-ray before ECT	Yes	33	(57.9)	30	(48.4)	5	(45.5)	68	(52.3)	0.521[C]
	No	24	(42.1)	32	(51.6)	6	(54.5)	62	(47.7)	
Performing ECT to COVID PCR positive patients	Yes	10	(17.5)	8	(12.9)	1	(9.1)	19	(14.6)	0.668[C]
	No	47	(82.5)	54	(87.1)	10	(90.9)	111	(85.4)	
Applying COVID PCR test before ECT	Yes	50	(87.7)	58	(93.5)	11	(100.0)	119	(91.5)	0.438[F]
	No	7	(12.3)	4	(6.5)	0	(0.0)	11	(8.5)	

[C]: Chi-square test, [F]: Fisher's test, COVID: Coronavirus, PCR: Polymerase chain reaction, ECT: Electroconvulsive therapy, HEPA: High-efficiency particulate air

similar to other studies, 73.8% of the participants indicated that the number of people in the room was four or less. On the other hand, it was detected that there were five or more people in the room in training and research hospitals. In line with the literature, most of the participants performed the treatment with five or less personnel.

During the pandemic, it is emphasized that the room should be thoroughly disinfected at the end of each ECT treatment and that there should be an interval of at least 30 minutes between patients, depending on the room air exchange rate (20). In similar studies, it is recommended to increase the interval between ECTs from 10 minutes to 30 minutes (7), or to close the doors and windows during ECT and to open them for 15 minutes after the patient is taken to the recovery room, or to use two rooms alternately. In our study, this interval was 30 min or longer in 9.2% of the hospitals, whereas 12.3% of the participants stated that they continued to perform ECT without waiting. We attribute the fact that ECT is performed without giving any interval to not investigating conducted studies and lack of information.

In routine anesthesia practice, it is proposed that the carbon dioxide absorber (soda lime) is generally replaced if it turns to violet color. An alternative to decide when to replace the absorber is to monitor the end-tidal CO_2, and it is recommended it be replaced when its level reaches approximately 5 torr or 0.05% (21). Other studies (22,23) suggest the replacement of the soda lime after each patient in cases with possible/definite COVID-19 diagnosis during the pandemic process. Of the participants in our study,

Table 4. Analysis of the use and preferences of PPE during ECT in the pandemic period by the institution worked

		University		Training and research		Other		Total		p
		n	(%)	n	(%)	n	(%)	n	(%)	
PPE use during ECT	Always	39	(68.4)	47	(75.8)	9	(81.8)	95	(73.1)	0.871[F]
	Sometimes	12	(21.1)	9	(14.5)	1	(9.1)	22	(16.9)	
	Never	6	(10.5)	6	(9.7)	1	(9.1)	13	(10.0)	
PPE preference: Surgical mask	Yes	29	(50.9)	26	(41.9)	3	(27.3)	58	(44.6)	0.298[C]
	No	28	(49.1)	36	(58.1)	8	(72.7)	72	(55.4)	
PPE preference: N95 (FFP2/FFP3)	Yes	52	(91.2)	57	(91.9)	11	(100.0)	120	(92.3)	0.894[F]
	No	5	(8.8)	5	(8.1)	0	(0.0)	10	(7.7)	
PPE preference: Goggles	Yes	13	(22.8)	18	(29.0)	3	(27.3)	34	(26.2)	0.739[C]
	No	44	(77.2)	44	(71.0)	8	(72.7)	96	(73.8)	
PPE preference: Face shields	Yes	18	(31.6)	28	(45.2)	3	(27.3)	49	(37.7)	0.236[C]
	No	39	(68.4)	34	(54.8)	8	(72.7)	81	(62.3)	
PPE preference: Overalls	Yes	5	(8.8)	7	(11.3)	0	(0.0)	12	(9.2)	0.485[C]
	No	52	(91.2)	55	(88.7)	11	(100.0)	118	(90.8)	
PPE preference: Box apron	Yes	20	(35.1)	38	(61.3)	8	(72.7)	66	(50.8)	0.005[C]
	No	37	(64.9)	24	(38.7)	3	(27.3)	64	(49.2)	
PPE preference: Single-layer glove	Yes	26	(45.6)	31	(50.0)	6	(54.5)	63	(48.5)	0.816[C]
	No	31	(54.4)	31	(50.0)	5	(45.5)	67	(51.5)	
PPE preference: Double-layer glove	Yes	12	(21.1)	20	(32.3)	2	(18.2)	34	(26.2)	0.313[C]
	No	45	(78.9)	42	(67.7)	9	(81.8)	96	(73.8)	
PPE preference: Overshoe cover	Yes	6	(10.5)	12	(19.4)	1	(9.1)	19	(14.6)	0.342[C]
	No	51	(89.5)	50	(80.6)	10	(90.9)	111	(85.4)	
PPE preference: Bonnet	Yes	29	(50.9)	33	(53.2)	3	(27.3)	65	(50.0)	0.280[C]
	No	28	(49.1)	29	(46.8)	8	(72.7)	65	(50.0)	
PPE preference: Boot	Yes	0	(0.0)	1	(1.6)	0	(0.0)	1	(0.8)	>0.999[F]
	No	57	(100.0)	61	(98.4)	11	(100.0)	129	(99.2)	
PPE preference: None	Yes	1	(1.8)	0	(0.0)	0	(0.0)	1	(0.8)	0.523[F]
	No	56	(98.2)	62	(100.0	11	(100.0)	129	(99.2)	

ECT: Electroconvulsive therapy, [C]: Chi-square test, [F]: Fisher's test, PPE: Personal protective equipment

36.9% stated that they replaced the soda lime every day, while the rate of those stating that they performed soda lime replacement after each patient was 6.2%. It has been indicated that the anesthesia procedure should be adjusted in a way that prevents contamination of patients and HCWs, following published consensus guidelines (24). As with most respiratory viruses, the disease is most contagious when the patient is symptomatic, but there are studies in the literature demonstrating that severe acute respiratory syndrome-coronavirus-2 is transmitted also by asymptomatic individuals (25). It can be usually difficult to identify and isolate infected patients; for this reason, it is recommended that measures be taken during the airway management of all patients (26), and that disposable airway equipment be used as much as possible (23). It was stated by 93.8% of the physicians participated in our study that they applied HEPA filter between the anesthesia device and the exhalation valve and between the mask and breathing circuit. The rate of the participants who changed the breathing circuit after each patient was found to be 36.9%. Although the HEPA filter application rate was determined to be high as suggested in the literature, we consider less replacement of the breathing circuit to be associated with cost.

Because some patients may carry the virus asymptomatically (27), it is proposed to avoid aerosol-forming procedures such as high flow nasal oxygen, mechanical ventilation, tracheal aspiration and BMV and to perform preoxygenation with oxygen flow below 5 L/min via closed circuit (28). Similarly, in our study, the rate of performing pre-oxygenation to the patients before anesthesia induction was 85.4%, whereas 77.7% of the participants used the BMV that might create aerosols. The reason for this may be the inability to go out of routine practice during ECT procedures and the lack of command over the guidelines' recommendations on this subject. Many studies have emphasized that ideally patients are needed to be treated in negative pressure rooms, if available (20,26,28,29). In our study, the rate of the participants stating that ECT treatment was performed in a negative pressure room was 10.8%. We think that this low rate may be linked to the fact that the ECT rooms were outside the operating room in 59.2% of the participants and/or the absence of negative pressure systems. It has been proposed in a study that a routine chest radiography should be taken along with the PCR test for each patient who will undergo ECT. Half of the participants in our study indicated that a routine chest radiography of the patient was taken before ECT.

Although the WHO recommends the use of surgical masks, gloves, long sleeved box aprons, eye protections (goggles or face shields) as a choice of PPE in aerosol-generating procedures in non-COVID patients (30), during the pandemic period, all ECT centers worldwide have adopted a policy of universal safety precautions, regardless of PCR test results, due to possible false negative test results and asymptomatic carriers (7). N95/FFP2 (or higher) masks, face shields, eye goggles, liquid resistant long sleeve aprons and double-layer gloves are recommended to be used as full PPE for all members actively involved in ECT treatment (11-15,17,20). In addition, it is advised that after each patient, outer layer gloves should be changed and eye goggles/face shields should be cleaned against the possible secretion contact (7). Of the participants in our study, 45.4% stated that they always used PPE during ECT procedure, while 10% stated that they never used PPE in any ECT procedure. The most commonly used PPEs were observed to be N95 (FFP2/FFP3) (93.1%), single-layer glove (50.8%), box apron (50.8%) and surgical mask (49%), respectively. After each patient, 15.4% of the participants changed all PPEs, whereas as suggested in the literature (7), 73.8% changed only gloves. It was determined that the recommended full personal protection was not always implemented by all participants. We can relate this situation to the fact that the participants felt safer themselves with the administration of both inactivated and mRNA vaccines to HCWs during the 3-month period when the study was carried out. The rate of the participants who did not experience difficulty in procuring PPE was 53.8%, on the other hand, 29.2% of the participants stated to have difficulty in obtaining N95. We are of the opinion that the low rate of PPE use is mostly associated with the hospitals with difficulty in procurement. These data draw attention to the importance of correct and effective use of PPE.

COVID-PCR test has been recommended to be applied within 24-48 hours before performing ECT procedure in pandemic process, and the recommendations in the guidelines published in Turkey are also in this direction (18,31). In our study, 66.9% of the participants indicated that COVID-PCR test was performed within 24-48 hours before ECT, 8.5% stated that no PCR test was applied to patients. Moreover, 14.6% of the participants specified that they applied ECT to COVID-19 positive patients. A study conducted in Italy found the rate of HCWs who had COVID-19 infection to be 9% (32). Similarly, it was detected that 9.2% of the physicians participated in our study had COVID-19 infection; however, it was not questioned whether the cause of the infection was the patient, work environment, or society.

Study Limitations

The limitations of our study include the facts that the study covered a short period (July-September 2021) during the pandemic period when vaccine administrations were also performed, that the vaccination status of the participants was not questioned, and that the number of people who participated in the survey of this study was low due to the large number of survey studies conducted in this period.

Conclusion

During the pandemic process, ECT applications and frequency have undergone a change according to the patient's condition. When applying anesthesia in ECT, we wanted to draw attention to procedures that would cause aerosolization, the importance of PPE use and the differences in practice with questions toward the level of knowledge about the use of guidelines in this issue. We are of the opinion that the appropriate and correct implementation of the recommendations given in the guidelines should be attached importance and known in terms of employee and patient safety in the presence of a possible pandemic.

Ethics

Ethics Committee Approval: The study was carried out in accordance with the principles of the Declaration of Helsinki after obtaining approvals from the Local Ethics Committee of University of Health Sciences Turkey, Bursa High Specialization Training and Research Hospital (2011-KAEK-25 2020/11-11) and the Ministry of Health Scientific Research Platform (2020-11-02T21_10_33).

Informed Consent: Before answering the questions in the questionnaire made via google forms, the consent of the participants to participate in the study was obtained online.

Peer-review: Internally and externally peer-reviewed.

Authorship Contributions

Concept: A.D., T.O., Design: A.D., T.O., Data Collection or Processing: A.D., A.N.B., Analysis or Interpretation: A.N.B., Drafting Manuscript: T.O., A.D., Critical Revision of Manuscript: Ş.E.Ö., A.D., Final Approval and Accountability: Ş.E.Ö., T.O., Technical or Material Support: A.N.B., T.O., Supervision: Ş.E.Ö., Writing: A.D., A.N.B., Ş.E.Ö., T.O.

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ORIGINAL RESEARCH

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The Relationship of Job Satisfaction with Nomophobia and Social Media Addiction in Healthcare Professionals: A Cross-sectional Study

Sağlık Çalışanlarında İş Doyumunun Nomofobi ve Sosyal Medya Bağımlılığı ile İlişkisi: Kesitsel Çalışma

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Abstract

Objective: The purpose of this study was to investigate the relationships between the levels of psychological health, nomophobia, and social media addiction and the job satisfaction levels of health workers.

Method: An observational (cross-sectional) study was designed between September 15th and December 15th, 2020, with 591 volunteer healthcare providers (HCPs) working in the period of pandemic in University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital. In a constructed questionnaire including socio-demographic data, Minnesota job satisfaction scale, nomophobia scale, Bergen social media addiction scale, and psychological health assessment questions were applied.

Results: A total of 182 male (30.8%) and 409 (69.2%) female HCPs with a mean age of 30.25±7.04 years were examined. Job satisfaction distribution rates were 1.2% (n=7) for low level, 83.6% (n=494) for moderate level, and 15.2% (n=90) for high level. The frequency of probable depression was found to be 46.4% (n=274) and the presence of nomophobia was 97.5% (n=579) in all. It was observed that higher job satisfaction was related to less time spent on social media, social media addiction and depression levels significantly (p=0.039 r=-0.086; p=0.040 r=-0.085; p=0.000 r=-0.314, respectively). Those with high job satisfaction had a significantly younger age (p=0.002), less work experience (p=0.001), more time spend on social media (p=0.004), lower social media addiction (p=0.005), less depression (p=0.000), and less nomophobia (p=0.042) levels compared to those with low and moderate satisfaction levels. Risk factors were evaluated by linear regression test and depression score was found as an independent risk factor affecting job satisfaction (F=8.826, p=0.000, R^2=0.111).

Öz

Amaç: Bu çalışmanın amacı sağlık çalışanlarının iş tatmin düzeyine göre psikolojik sağlık, nomofobi ve sosyal medya bağımlılık durumları arasındaki ilişkileri incelemektir.

Yöntem: 15 Eylül-15 Aralık 2020 tarihleri arasında Sağlık Bilimleri Üniversitesi, Gaziosmanpaşa Eğitim ve Araştırma Hastanesi'nde pandemi döneminde çalışan 591 gönüllü sağlık çalışanı ile gözlemsel (kesitsel) bir çalışma tasarlanmıştır. Sosyo-demografik verileri içeren yapılandırılmış bir ankette Minnesota iş tatmin ölçeği, nomofobi ölçeği, Bergen sosyal medya bağımlılığı ölçeği ve psikolojik sağlık değerlendirme soruları yer almıştır.

Bulgular: Araştırmaya yaş ortalaması 30,25±7,04 yıl olan 182 erkek (%30,8) ve 409 (%69,2) kadın sağlık çalışanı dahil edildi. İş tatmin düzeyi dağılımı %1,2 (n=7) düşük, %83,6 (n=494) orta, %15,2 (n=90) yüksek düzey olarak saptandı. Katılımcılarda olası depresyon sıklığı %46,4 (n=274) ve nomofobi görülme sıklığı %97,5 (n=579) olarak bulundu. İş doyumunun artmasıyla birlikte sırasıyla sosyal medyada geçirilen süre, sosyal medya bağımlılığı ve depresyon düzeylerinin anlamlı düzeyde azaldığı gözlendi (sırasıyla p=0,039 r=-0,086; p=0,040 r=-0,085; p=0,000 r=-0,314). Yüksek düzey iş tatminine sahip olanların düşük ve orta tatmin düzeyi olanlara göre anlamlı düzeyde daha genç yaşta (p=0,002) oldukları, daha az çalışma tecrübesi olduğu (p=0,001), sosyal medyada daha fazla zaman geçirdiği (p=0,004) ancak sosyal medya bağımlılık düzeylerinin daha düşük (p=0,005) olduğu, daha az depresif (p=0,000) ve daha az nomofobik (p=0,042) oldukları gözlendi. İş doyumu üzerinde etkili faktörler lineer regresyon ile değerlendirildiğinde depresyon düzeyinin bağımsız risk faktörü olduğu görüldü (F=8,826, p=0,000, R^2=0,111).

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Conclusion: Only one out of every six HCPs expressed high job satisfaction. Half of all were found to be depressed and almost all were nomophobic. Our study contributed to the literature, especially in showing that HCPs need support for mental health and professional support.

Keywords: Depression, job satisfaction, nomophobia, social media

Sonuç: Her altı sağlık çalışanından sadece bir kişi yüksek iş tatmini ifade ederken, yarısı depresif, tamamına yakını nomofobik bulunmuştur. Özellikle sağlık çalışanlarının ruh sağlığı ile mesleki doyuma yönelik desteğe ihtiyacı olduğunu göstermesi açısından çalışmamız literatüre katkıda bulunmuştur.

Anahtar kelimeler: Depresyon, iş tatmini, nomofobi, sosyal medya

Introduction

Job satisfaction is defined as any combination of psychological and environmental conditions that cause the employee to comment "I am satisfied with my job" (1). Job satisfaction has an unusually large impact on employee motivation and increases productivity (2,3). As a result of increasing cases and deaths during the pandemic period, individuals experience various psychological problems such as depression, anxiety and stress disorder, fear of death, post-traumatic stress disorders, burnout, and increase in addictions (4). Considering that there are 59 million health workers all over the world and the pandemic continues, all studies examining job satisfaction and effective factors as a factor that will increase productivity in the field of health are important (5,6).

The World Health Organization has declared that the world is facing two major health threats as "pandemic and information epidemic" (7). During pandemic, it has been observed that the use of the internet, tele-medicine applications, and social media has increased rapidly for both patients and employees, both for information purposes and protection from the epidemic (8). In addition, increasing usage trend has emerged as increasing addictions such as social media addiction, internet addiction, and mobile phone addiction through different social media applications (9). Nomophobia refers to the individual's fear of not being able to communicate via cell phone or internet and is derived from the abbreviation of the words "no mobile phobia" (10,11). Nomophobia is remarkable, especially in preventing the misuse of mobile phones, which can easily cause distraction and, therefore, irreversible errors in the clinical environment (12).

This study is based on the hypothesis of a possible relationship between the job satisfaction levels, psychological health, nomophobia, and social media addiction status of HCPs during the pandemic period. It has aimed to question the job satisfaction levels and risk factors.

Materials and Methods

The main population of the study included 2.200 healthcare workers in the hospital, and a pilot study was conducted with a group of 50 health professionals who volunteered to participate before the study. In the analysis performed with the G-Power program based on type 1 error of 0.05 and a 95% power, it was found appropriate to work with at least 574 cases, with preliminary job satisfaction points of nomophobia groups (3.02±0.64 for severe nomophobia and 2.84±0.55 for moderate nomophobia) explaining a 0.301 effect size for the study sample formula.

An online questionnaire including an online consent form at the first page was used to collect data. The health professionals who did not want to give consent did not participate in the study. Research data were collected through an online questionnaire after interviewing 591 healthcare professionals working at University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital and volunteering to participate in this study, between 15 September 2020 and 15 December 2020, after obtaining their consent. In the questionnaire, socio-demographic information, Minnesota job satisfaction scale (MSQ), nomophobia scale (NMP-Q), Bergen social media addiction scale (BSMAS), and psychological health assessment (PHQ-9) questions were applied.

The MSQ is a 20-item five-point Likert-type (with a score ranging from 1 to 5) instrument with features that reveal intrinsic and extrinsic satisfaction factors. While the scale expresses low, medium and high level of job satisfaction over the total score, values above 3 points on average can also be interpreted in favor of high satisfaction. The scale was firstly developed by Weiss et all. (13) and validated to Turkish language by Baycan (14).

The NMP-Q was developed by Yildirim and Correia (15). It is a 4-factor scale and consists of 20 questions. All 20 questions in NMP-Q were prepared in a 7-point Likert scale and rated from 1 to 7, with 1 corresponding to "strongly disagree" and 7 to "strongly agree". A score below 20 is

considered normal, 20-60: Mild nomophobia, 60-100: Moderate, 100 and over as severe nomophobia (15).

The BSMAS was developed by Schou Andreassen et al. (16) and its Turkish validity and reliability study was conducted by Demirci (17). It is a five-point Likert-type scale consisting of 6 questions questioning the use of social media (Facebook, Instagram, Twitter, etc.) by considering the last year. There is no specific cut-off value.

The Turkish validity and reliability study of the Patient Health Questionnaire (PHQ-9) was performed by Sarı et al. (18). The evaluation of the scale is done as follows; 0-4 points are grouped as no depression, 5-9 points as mild depression, 10-14 points as moderate, 15-19 points as moderate-severe, and 20 and above points as severe depression. A PHQ-9 score of 10 points and above has 88% sensitivity and 88% specificity for major depression (19).

Ethical Approval

This observational and cross-sectional study was approved by University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital Clinical Research Ethics Committee (decision no: 151, date no: 02.09.2020). Informed consent forms were obtained from the participants before the procedure.

Statistical Analysis

Descriptive analyses was given using the mean and standard deviation for normally distributed variables, and the median and interquartile range for non-normally distributed variables. Ordinal and nominal variables were given as numbers (n) and percent (%). Comparisons between the groups were analyzed using the Mann-Whitney U test and Kruskal-Wallis test. The chi-square test was used to examine the difference between categorical variables. The relationship between the variables was examined with the Spearman Correlation analysis. The Lineer regression analysis was performed to explain the factors affecting the MSQ score. The total type-1 error level was determined as 5% for statistical significance.

Results

A total of 591 healthcare professionals, including 182 men (30.8%) and 409 (69.2%) women, participated in this study. The mean age of the cases was 30.25±7.04 years and the mean working period was 7.37±5.35 years. According to the Minnesota scale job satisfaction levels, normal-moderate job satisfaction was 1.2% (n=7), moderate level job satisfaction was 83.6% (n=494), and high-level job satisfaction was 15.2% (n=90) of all. The rate of those who were possibly depressed was found to be 46.4% (n=274). The incidence of nomophobia was found to be 97.5% (n=579). Nomophobia was observed at mild level in 34.5% (n=204), moderate level in 45.5% (n=239), and extreme level in 20% (n=18). The mean scores of the scales used are shown in Table 1.

In Table 2, it was observed that gender (p=0.945), marital status (p=0.757), income status (p=0.232), and smoking (p=0.920) or alcohol use (p=0.072) did not make a significant difference in terms of job satisfaction. According to occupation group comparisons, health officers/medical secretaries had a significantly higher job satisfaction than other HCPs (p=0.001), and the lowest satisfaction was in the midwife/nurse group.

As shown in Table 3, those with high job satisfaction versus others had a significantly younger age (p=0.002), less work experience (p=0.001), and more time spend on social media (p=0.004) but lower social media addiction levels (p=0.005), and had less depression (p=0.000), less nomophobia (p=0.042).

In Table 4, the relationship between job satisfaction score and all scale scores in the study was demonstrated. It was observed that time on social media, social media addiction score and depression score had negative correlations with job satisfaction (p=0.039 r=-0.086; p=0.040 r=-0.085; p=0.000 r=-0.314, respectively).

In Table 5, the predictors of HCPs' job satisfaction were evaluated by linear regression. Age, work experience, time spent on social media, social media addiction score, nomophobia score and depression score were evaluated in the model, and the high level of depression was found to be an independent risk factor for low job satisfaction (F=8.826, p=0.000, R^2=0.111).

Table 1. The score values of the main scales and subgroup scales used in the study

Variable	X ± SD	Minimum-maximum
Minnesota job satisfaction scale total score	3.03±0.73	1.00-6.55
Bergen social media addiction scale score	14.41±6.02	0-30
Nomophobia scale total score	72.70±28.86	0-140
Patient health questionnaire total score	9.82±5.18	0-24

X ± SD: Mean ± standard deviation

Table 2. Evaluation of the differences between the variables of socio-demographic characteristics and job satisfaction

Socio-demographical characteristics	n (%)	Minnesota job satisfaction scale total score	
		Median (Minimum-M-maximum)	Test values (Z/X^2; p)
Gender			
Female	409 (69.2%)	3.10 (1.00-5.00)	Z=-0.069
Male	182 (30.8%)	3.38 (1.00-6.55)	p=0.945
Marital status			
Single	334 (56.5%)	3.10 (1.00-6.55)	Z=-0.310
Married	257 (43.5%)	3.10 (1.00-5.00)	p=0.757
Occupation			
Doctor	292 (49.4%)	3.05 (1.00-4.60)	X^2=18.324
Midwife/nurse	99 (16.8%)	3.00 (1.00-4.80)	**p=0.001**
Health officer/ medical secretary	65 (11.0%)	(1.35-6.55)	
Health technicians	35 (5.9%)	3.05 (1.85-4.30	
Others	100 (16.9%)	3.35 (1.00-5.00)	
Income level			
Low	135 (22.8%)	2.98 (1.00-4.95)	X^2=2.920
Moderate	302 (51.1%)	3.10 (1.00-6.55)	p=0.232
High	154 (26.1%)	3.15 (1.40-4.95)	
Smoking			
Never	417 (70.6%)	3.10 (1.00-6.55)	X^2=0.167
Smoker	140 (23.7%)	3.05 (1.00-5.00)	p=0.920
Ex-smoker	34 (5.8%)	2.93 (0.30-4.40)	
Alcohol use			
No	440 (74.5%)	3.10 (1.00-6.55)	Z=-1.801
Yes	151 (25.5%)	3.10 (1.00-5.00)	p=0.072
Mobile phone usage frequency for business			
Rare	123 (20.8%)	3.15 (1.00-4.95)	X^2=3.599
Often	312 (52.8%)	3.05 (1.00-6.55	p=0.165
Everytime	156 (26.4%)	3.05 (1.00-5.00)	

Z/KW: Mann-Whitney U test/Kruskal-Wallis test values, p: Statistical significance

Table 3. Comparison of age, years of employment, and time spent on social media between low, moderate and high job satisfaction level groups according to the Minnesota job satisfaction scale score

Variables	Job satisfaction levels by Minnesota job satisfaction scale score			
	[a]Low (n=7, 1.2%)	[b]Moderate (n=494, 83.6%)	[c]High (n=90, 15.2%)	Test value
	X ± SD	X ± SD	X ± SD	X^2, p
Age (year)	31.66±7.97	29.92±7.55	28.67±6.82	**X^2=13.081 p=0.002 p^{a-b}=0.016 p^{a-c}=0.019 p^{b-c}=0.048**
Job experience (year)	8.26±5.66	7.25±5.18	6.21±4.55	**X^2=12.342 p=0.001 p^{a-b}=0.055 p^{a-c}=0.006 p^{b-c}<0.001**
Time spent browsing the media (hour)	2.44±1.76	3.16±1.84	3.92±2.68	**X^2=45.639 p=0.004 p^{a-b}: 0.042 p^{a-c}: 0.005 p^{b-c}:** 1.000
Nomophobia score	107.43±37.48	73.33±27.58	70.44±29.85	**X^2=6.326 p=0.042 p^{a-b}: 0.046 p^{a-c}: 0.036 p^{b-c}:** 1.000
Bergen social media addiction score	20.57±63	14.65±5.91	13.10±5.99	**X^2=10.615 p=0.005 p^{a-b}:** 0.079 **p^{a-c}: 0.014 p^{b-c}: 0.048**
PHQ-9 score	14.86±6.39	10.26±5.05	7.82±4.78	**X^2=** 21.978 **p=0.000 p^{a-b}:** 0.055 **p^{a-c}: 0.006 p^{b-c}<0.001**

X ± SD: Mean ± standard deviation, X^2: Kruskal-Wallis test value, p: Statistical significance, [a]: Low satisfaction group, [b]: Moderate satisfaction group, [c]: High satisfaction group

Discussion

In this study, which was conducted to evaluate the job satisfaction level, psychological health, social media addiction and nomophobia of the HCPs were investigated and it was seen that half of the participants were likely to be depressed and almost all of them were nomophobic. The presence of depression was found to be an independent risk factor for job dissatisfaction. It was determined that with the increase in the level of depression, job dissatisfaction, social media addiction, nomophobia level and the time spent in social media via phone would increase.

In the study of Dağdeviren et al. (20), it was observed that the job satisfaction of the instructors was at a moderate level of 85.4%. While no difference was found in job satisfaction according to gender, it was observed that age and duration of professional experience period were significant factors that changed the level of job satisfaction (20). In our study, age and experience were not significant and the job satisfaction of the HCPs was similar, and moderate level of job satisfaction was observed in 83.6% of HCPs. In the study conducted in Egypt during the pandemic period, job satisfaction of nurses was found at 51% (21).

Table 4. Correlation analyses

		Age	Time spent on social media	Job experience	Bergen social media addiction scale score	Nomophobia total score	Patient health questionnaire total score	Minnesota job satisfaction scale total score
Age	r	-	-0.338	0.716	-0.251	-0.164	-0.156	-0.077
	p	.-	0.000	0.000	0.000	0.000	0.000	0.063
Time spent on social media	r	-0.338	-	-0.209	0.478	0.309	0.175	-0.086
	p	0.000	-.	0.000	0.000	0.000	0.000	0.039
Job experience	r	0.716	-0.209	-	-0.154	-0.150	-0.113	-0.051
	p	0.000	0.000	-.	0.000	0.000	-0.051	0.223
Bergen social media addiction scale score	r	-0.251	0.478	-0.154	-	0.519	*0.040	-0.085
	p	0.000	0.000	0.000	.-	0.000	0.000	0.040
Nomophobia total score	r	-0.164	0.309	-0.150	0.519	-	0.247	-0.040
	p	0.000	0.000	0.000	0.000	-.	0.000	0.332
Patient health questionnaire total score	r	-0.156	0.175	-0.113	0.268	0.247	-	-0.314
	p	0.000	0.000	0.006	0.000	0.000	-.	0.000
Minnesota job satisfaction scale total score	r	-0.077	-0.086	-0.051	-0.085	-0.040	-0.314	-
	p	0.063	*0.039	0.223	0.040	0.332	0.000	.

Table 5. Evaluation of the factors affecting general job satisfaction in healthcare workers by linear regression

	B	t	p
Factors affecting Minnesota job satisfaction scale score			
Age	-0.011	-1.749	0.081
Job experience (year)	-0.000	-0.022	0.982
Time spent on social media by phone daily	-0.020	-1.227	0.220
Bergen social media addiction score	-0.006	-0.911	0.363
PHQ-9 patient health questionnaire score	-0.045	-7.626	0.000
Nomophobia total score	0.001	0.575	0.565
F=8.826. p=0.000 R^2=0.111			

PHQ-9: Psychological health assessment

In another study conducted among nurses caring for older adults, job dissatisfaction was found in 68% of nurses, and it was observed that physical conditions of working areas and salary were negative determinants (22). In another study conducted with HCPs in emergency department, the mean job satisfaction score was 3.18±0.71 points (23) and it was observed to be close to the value of 3.03±0.73 in our study. In our study sample consisting of all subgroups of HCPs, the lowest satisfaction level was observed in the midwife/nurse group, while the highest satisfaction level was observed in medical secretaries. This result supports the high dissatisfaction rates in nursing studies. In a study conducted with nurses and medical secretaries, the average job satisfaction was reported as 3.16 and 3.32 points, respectively, and it was observed that medical secretaries had a higher job satisfaction (24). In the study of Ghawadra et al. (25), the nurses who were dissatisfied were found to be significantly associated with a high level of stress and depression. Similarly, our study found that depression score predicted job dissatisfaction of HCPs.

Balcı and Baloğlu (26) found a positive significant correlation between social media addiction and depression. Participants with severe depression symptoms have higher social media addiction scores than those with normal and mild depression (26). However, Emirza et al. (27) showed that there was a positive linear relationship between the level of social media use and job satisfaction, too. In the epidemic process, societies can see information and communication technologies as "saviors". This technology made it possible to reach and share information about the epidemic with large population segments. On the other hand, behaviors such as gambling, playing video games, watching TV series, using social media, or surfing the internet may be exhibited to reduce stress and anxiety and/or alleviate depressive mood due to the epidemic (28). According to the results of an international study, when the use of media at home during the worldwide Coronavirus disease-2019 pandemic was examined, it was found that 67% of individuals watched more news broadcasts, 45% spent longer on messaging services, 44% spent longer on social media, and 36% spent more time on computer/video games (29). Bunch video app had 1 million downloads in just seven days, and House party, a social video, and gaming app, showed a 70% increase in monthly signups (30). In the study conducted

by Alaika et al. (31), the BSMAS of the participants was 18 points, and above, 68.8% of them spent more than 4 hours a day browsing social media, and the most used applications were Facebook and WhatsApp. In the study of Balcı et al. (32) with healthcare professionals, the most used social media tools were reported to be Instagram, Facebook, and WhatsApp, respectively. In terms of social media addiction, the addiction level of healthcare professionals who use Instagram more in daily life is higher than those who use WhatsApp (32). In our study, it was observed that the most frequently used social media application was the Instagram application at the rate of 79.2%. It was thought that high rate of Instagram use might be one of the reasons of social media addiction among HCPs in our study sample.

Kuscu et al. (33) demonstrated that anxiety and depression symptoms were correlated with nomophobia. Therefore, nomophobia was questioned as it could be a symptom of depression. Correlations of high nomophobia scores versus high depression and low satisfaction scores in our study have shown that nomophobia level is an important sign of job dissatisfaction. In our study, the use of social media by the participants via mobile phones was questioned, and their nomophobia levels were compared in terms of inappropriate use. In the study conducted by Kaviani et al. (34), 37.3% of the participants had mild nomophobia, 48.7% moderate, and 13.2% extreme. In the study of Bartwal and Nath (35) 15.5% of the students had nomophobia. In terms of nomophobia level, 67.2% of them experienced moderate nomophobia, while 17.3% were found to be extremely nomophobic (35). A recent study by Gurbuz and Ozkan (36) in Bursa in our country has shown that 8.5% of young people are severely nomophobic, 71.5% are moderately and 20.0% are low nomophobic. While there was no statistically significant difference between gender, working status and nomophobia level, age was found to be significant. As young people's age increased, the levels of nomophobia decreased. Although nomophobia, which was at a higher level in high school years, decreased slightly in university years, the nomophobia levels of students were observed to be higher than graduates and working youth (36). In our study, it was observed that 34.5%, 45.5%, and 20% of the participants were mildly, moderately, and severely nomophobic, respectively, and they were generally moderately nomophobic according to the nomophobia score.

In the study conducted by Demirci (17), the time spent on social media daily varied between 1 and 12 hours, and a significant relationship was found between the level of social media addiction and anxiety, depression symptoms, and time spent on social media. Andreassen et al. (37) argued that the use of social networks in the workplace would impair job performance as it caused distraction while doing work. Some studies argue the opposite. Andreassen et al. (37) expressed the use of social networks, benefits such as increased job satisfaction that individuals obtained through sources such as emotional support from their social relationships and interactions, new ideas, and access to seemingly unnecessary information. However, in our study, it was observed that job dissatisfaction, depression, and nomophobia increased with the increase in time spent on social media.

Conclusion

In our study, very dramatic results were obtained. Especially PHQ-9 score and the MSQ scores were important. It was seen that only one out of every six health workers had high job satisfaction, and at least half of them were possibly depressed. The fact that almost all of the participants were nomophobic was attributed to the increase in the use of mobile phone applications both in in-hospital services and as a communication tool regarding the pandemic. The fact that entertainment platforms such as Instagram are mostly used shows that healthcare professionals try to achieve satisfaction through entertainment and socialization. Depression as an independent predictive factor for job dissatisfaction shows that HCPs need support for their mental health and job satisfaction. Additionally, all volunteers participating in the study were able to monitor their results and answers online.

Ethics

Ethics Committee Approval: Ethics committee approval was obtained with the official letter dated 02.09.2020 numbered 151 from the University of Health Sciences Turkey, Gaziosmanpaşa Training and Research Hospital Clinical Research Board of the Ministry of Health Provincial Health Directorate.

Informed Consent: All participants were informed about the study and their consent was obtained.

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Authorship Contributions

Concept: A.F.A., M.M.B., O.B., Design: A.F.A., M.M.B., O.B., Data Collection or Processing: A.F.A., M.M.B., O.B., Analysis or Interpretation: M.M.B., Technical or Material Support: A.F.A., M.M.B., O.B., Final Approval and Accountability: A.F.A., M.M.B., O.B., Writing: A.F.A., M.M.B., O.B.

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ORIGINAL RESEARCH

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Clinical Practice Data of Robot-assisted Gait Therapy After Stroke: A Retrospective Study

İnme Sonrası Robot Yardımlı Yürüme Terapisinin Klinik Verileri: Retrospektif Bir Çalışma

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Abstract

Objective: Patients with stroke are often exposed to significant levels of disability resulting in long-term functional limitations. Robot-assisted gait therapy in stroke rehabilitation is a novel modality for improving walking ability and balance. In this retrospective study, we aimed to assess the outcomes of robot-assisted gait training (RAGT) in patients with stroke.

Method: Forty-nine post-stroke patients (mean post-stroke duration 10.82±14.12 months; mean age 57.06±14.73 years; 34 males; 15 females), who underwent RAGT device plus therapeutic exercise (multiple robot-assisted therapy sessions; mean number of sessions 42.37±25.68), were included in this study. The patients' pre- and post-therapy Brunnstrom lower extremity motor staging (Brunnstrom), functional ambulation scale (FAS), Ashworth spasticity scale (Ashworth), and Barthel index (BI) of activities of daily living scores were obtained from medical records and computerized database. Besides, speed and distance improvement were recorded for each patient by RAGT device.

Results: Post-stroke patients experienced statistically significant gains in Brunnstrom, FAS, BI, RAGT device speed and distance outcomes when compared to baseline values ($p<0.05$). There was a moderate positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and $p<0.05$). Additionally, there was a moderate correlation between RAGT device speed improvement value and post-therapy Brunnstrom value ($r=+0.353$; $p<0.05$).

Conclusion: Our study results suggest that robot-assisted gait therapy appears to be effective for facilitating returns including motor function, ambulation, and daily living skills in post-stroke patients. This study also demonstrates that the better the functional status of the patient at baseline, the better the improvement in walking speed with the RAGT

Öz

Amaç: İnmeli hastalar, sıklıkla uzun-dönem fonksiyonel kısıtlılık ile sonuçlanan anlamlı düzeyde özürlülüğe maruz kalırlar. İnme rehabilitasyonunda robot yardımlı yürüme yeteneği ve dengenin daha iyi hale getirilmesinde yeni bir yöntemdir. Bu retrospektif çalışmada, inmeli hastalarda robot-yardımlı yürüme terapisinin (RAGT) sonuçlarını değerlendirmeyi amaçladık.

Yöntem: Bu çalışmada, (RAGT) artı terapötik egzersiz (çok sayıda RAGT; ortalama seans sayısı 42,37±25,68) uygulanan kırt dokuz kronik inme hastası (ortalama inme sonrası süre 10,82±14,12 ay; ortalama yaş 57,06±14,73 yıl; 34 erkek; 15 kadın) yer aldı. Hastaların tedavi öncesi ve tedavi sonrası Brunnstrom alt ekstremite motor evreleme değerleri (Brunnstrom), fonksiyonel ambulasyon skalası (FAS), Ashworth spastisite skalası (Ashworth) ve Barthel indeks (BI) günlük yaşam aktivite skorları, medikal kayıtlardan ve bilgisayar veritabanından sağlandı. Bunun yanında, her hasta için hız ve mesafede iyileşme verileri, RAGT cihazı ile kaydedildi.

Bulgular: İnme sonrası RAGT ve egzersiz tedavisi alan hastalarda başlangıç değerlerine kıyasla Brunnstrom, FAS, BI, RAGT cihazı hız ve mesafe ölçüm değerlerinde istatistiksel olarak anlamlı iyileşme gözlendi ($p<0,05$). RAGT cihazı hızda iyileşme değerleri ile başlangıç Brunnstrom-FAS-BI değerleri arasında orta pozitif korelasyon gözlendi (r değerleri sırasıyla +0,408; +0,371; +0,367 ve $p<0,05$). Ek olarak, RAGT cihazı hız iyileşme değerleri ile çalışma sonu Brunnstrom değerleri arasında orta düzeyde bir korelasyon vardı ($r=+0,353$; $p<0,05$).

Sonuç: Çalışma bulgularımız inme sonrası RAGT uygulanmasının inme hastalarında motor fonksiyon, ambulasyon, günlük yaşam aktivitelerinde iyileşmeyi kolaylaştırmada etkili olduğunu göstermiştir. Bu çalışma, aynı zamanda başlangıçta daha iyi fonksiyonel durumu olan inme hastalarında, RAGT cihazı ile yürüme hızında daha fazla iyileşme ve daha

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device and the higher the success of the treatment. The authors think that correlation between post-stroke patients' baseline values and output data by RAGT device is an important indicator for prognosis.

Keywords: Activities of daily living, stroke, rehabilitation, robotics

yüksek tedavi başarısı göstermiştir. Yazarlar, inme hastalarının başlangıç değerleri ve RAGT cihazı çıkış verileri arasındaki korelasyonun prognoz açısından önemli bir belirteç olduğunu düşünmektedir.

Anahtar kelimeler: Günlük yaşam aktiviteleri, inme, rehabilitasyon, robot teknolojisi

Introduction

Robot-assisted gait training (RAGT) for regaining and improving walking ability has been developed in order to automate locomotor training of post-stroke patients as a novel neurorehabilitation technique (1-5).

In the area of stroke rehabilitation, balance, gait and neural plasticity improvements are in favor of RAGT (6-19). Independent from stroke etiology-hemorrhagic or ischemic- RAGT therapy could improve the patients' gait in a similar proportion (12). RAGT can be used as a therapeutic approach not only for stroke patients, but also for other neurological patients, such as spinal cord injury and multiple sclerosis patients with promising results (18-21).

RAGT is consistent with the patient-centered therapy according to individual's needs of locomotion (6). Main advantage of RAGT is the quantifiability of locomotor ability of the patient at baseline, after the sessions with a computer screen attached to the device itself. Besides, it lightens the load of the therapist because it involves a programmable task-oriented device (9,13,14).

In the light of the foregoing grounds, in this retrospective study, we aimed to assess functional outcomes of robot-assisted gait therapy in patients with stroke.

Materials and Methods

Study Design and Population

In this retrospective study, forty-nine post-stroke patients (mean post-stroke duration 10.82±14.12 months; mean age 57.06±14.73 years; 34 males; 15 females), who underwent robot-assisted gait therapy (Lokomat® Robotic gait training; Hocoma AG, Zurich, Switzerland) plus therapeutic exercise, were included. Inclusion and exclusion criteria were specified according to the patients' database. Clinical data and functional indexes of seventy patients were assessed from their medical files and computerized database. Patients with conditions that could affect study results such as comorbidities that could affect balance and lower extremity functions (e.g., other neurological diseases, hip or knee replacement, advanced vision and vestibular disorders), poor cognitive skills (mini-mental state examination <24), and poor cooperation were excluded from the study. The patients whose data were included in the study were informed and their consents were obtained. The study was approved by the Local Ethics Committee of Memorial Hospital (approval no: 12.11.2021/007).

Interventions

Lokomat® (Hocoma AG, Zurich, Switzerland) used in the therapy as a robotic device has three parts: Computer-operated robotic exoskeleton, a treadmill and a body-weight support system (5,22,23). It is adjustable to patient's size and form (23). Besides, treatment parameters such as speed, walking distance, walking duration, body weight support, and guidance forces can be defined and recorded by the device (24-28). During therapy sessions, velocity of the treadmill was fixed at 1.5 km/hr and at the beginning, approximately 50% of each subject's body weight was supported. During the following sessions, the bodyweight support was reduced to the minimum as tolerated without substantial knee buckling or toe drag. Guidance force was maintained at 100% during all sessions (10,28). Speed and distance improvement were recorded for each patient.

In the treatment, the therapeutic exercises based on Bobath and Brunnstrom methods were set individually according to the patient's status, consisting of posture, balance, and gait. The procedure focused on gait and balance in order to raise awareness about trunk stability-symmetry and body weight support on the affected leg. Each exercise session was conducted for half an hour.

Clinical Assessment Scales

All patients were clinically assessed by the Brunnstrom motor staging (Brunnstrom) (29), functional ambulation scale (FAS) (30), Ashworth spasticity scale (Ashworth) (31), and Barthel index (BI) of activities of daily living (32) at baseline and at the end of therapy (multiple Lokomat® plus therapeutic exercise sessions; mean number of sessions 42.37±25.68).

The Brunnstrom was used for motor function of the post-stroke survivors. This system contains 6 stages, in which 1 represents "flaccidity" (no movement on the affected

lower limb), 2 represents "appearing of spasticity", 3 represents "increase in spasticity", 4 represents "decrease in spasticity", 5 represents "minimal spasticity", and 6 represents "disappearance of spasticity and coordination reappears" (29).

FAS was utilized for ambulation capability. It is a 6-item scale, in which 0 stands for "can't walk", 1 stands for "dependent walk in the form of continuous manual contact", 2 stands for "dependent walk in the form of continuous or intermittent manual contact", 3 stands for "dependent walk in the form of verbal guarding", 4 stands for "independent walk freely on level surfaces only", and 5 stands for independent walk freely on any surface" (30).

The Ashworth was applied for spasticity. This index consists of 5 stages, in which 0 means "no increase in muscle tone", 1 means "slight increase in muscle tone", 2 means "more marked increase in muscle tone through most limb easily flexed", 3 means "considerable increase in muscle tone, passive movement difficult", and 4 means "rigidity of limb in flexion or extension" (31).

BI was used for independency of daily activities. This examination tool has 10 items including feeding, moving from wheelchair, personal cleaning (washing face, combing hair, shaving, cleaning teeth), getting on and off toilet, bathing himself/herself, walking on level surface, ascending and descending stairs, dressing, bowel control, and bladder control. The score for each item is calculated according to independent action or action with help. Higher scores mean more independence (32).

Statistical Analysis

The data were analyzed using GNU Project-PSPP software version 1.6.2 for statistical analysis and Microsoft Excel computer programs. Descriptive statistical methods including frequency, percentage, mean, and standard deviation were used. The Kolmogorov-Smirnov test was applied for testing normality of the data. The Wilcoxon test was used to compare pre- and post-treatment results. The relationship between variables was investigated by the Pearson's correlation coefficient. The results were evaluated at 95% confidence interval, and $p<0.05$ was considered statistically significant.

Results

Forty-nine patients' data (34 males; 15 females; mean age 57.06±14.73 years) were included in this study. As shown in Table 1, the mean time after stroke was 10.82±14.12 months, and participants had either hemorrhagic (34.7%) or ischemic (65.3%) stroke as an etiology. All post-stroke patients had multiple robot-assisted gait therapy sessions, and the mean number of these sessions was 42.37±25.68 (Table 1).

Table 2 shows the results for RAGT speed and distance improvement after therapy. After 42.37±25.68 sessions of RAGT plus therapeutic exercise, the participants had RAGT speed improvement of 23.27±21.25, and RAGT distance improvement of 53.98±77.11 (Table 2).

Table 3 displays motor, functional ambulation, spasticity, and activities of daily living measures (Brunnstrom, FAS, Ashworth, and BI respectively). When compared to the pre-treatment value, all participants had statistically significant improvement in the Brunnstrom, FAS, and BI index ($p=0.0001$ for all, Table 3).

We also analyzed the correlation between RAGT parameters (speed distance improvement) and outcome measures including the Brunnstrom, FAS, Ashworth, and BI. Table 4 and Table 5 describe the Pearson's correlation results. There was a moderate positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and $p<0.05$). Additionally, there was a moderate positive correlation between RAGT device speed improvement value

Table 1. Demographic characteristics of post-stroke patients

		n	%
Gender	Male	34	69.4
	Female	15	30.6
Affected side	Right	24	49.0
	Left	25	51.0
Etiology	Hemorrhagic stroke	17	34.7
	Ischemic stroke	32	65.3
		Mean ± SD	**Min-max**
Age (year)		57.06±14.73	23-85
Post-stroke duration (months)		10.82±14.12	1-72
Number of RAGT + therapeutic exercise sessions		42.37±25.68	10-100

SD: Standard deviation. RAGT: Robot-assisted gait therapy

Table 2. RAGT improvement of post-stroke patients

	Mean ± SD	Min-max
RAGT speed improvement	23.27±21.25	-19-71
RAGT distance improvement	53.98±77.11	-94-311

SD: Standard deviation. RAGT: Robot-assisted gait therapy

and Brunnstrom value at the end of the therapy (r=+0.353; p<0.05) (Table 4). Besides, a strong positive correlation was observed between post-treatment and pre-treatment values of outcome measures of the participants (Table 5).

Discussion

The findings of this retrospective, cross-sectional clinical trial show that the use of robot-assisted gait therapy elicited significant gains in motor function, ambulation and daily living skills in post-stroke patients. This study also demonstrates that the better the functional status of the patient at baseline, the higher the success of the treatment.

A recent update of a Cochrane database review, published in 2020, analyzed 62 randomized, controlled trials with a total of 2440 post-stroke patients (age range 47-76 years) by comparing the effects of RAGT versus conventional training. The authors concluded that RAGT in combination with therapeutic exercise after stroke was effective for independent walking, and increasing walking speed when compared to conventional training (33). Similar to the results of Cochrane database (33), walking speed of our trial population was ameliorated after robot-assisted gait therapy. Specifically, the mean RAGT speed improvement after the treatment (mean number of treatment sessions 42.37±25.68, minimum: 10 maximum: 100) was 23.27±21.25 in our study.

Table 3. Motor, functional ambulation, spasticity, and activities of daily living measures at baseline and at the end of the therapy

		Baseline		After RAGT + therapeutic exercise (mean number of sessions= 42.37±25.68)		
		Mean ± SD	**Min-max**	**Mean ± SD**	**Min-max**	
Brunnstrom lower extremity motor staging (Brunnstrom) (29)		2.33±1.01	1-6	3.22±0.85	1-6	**0.0001**
FAS (30)		1.1±1.16	0-4	2.35±1.25	0-5	**0.0001**
		Count	**%**	**Count**	**%**	
FAS (30)	Score 0- non-functional ambulator (cannot walk)	20	40.82	2	4.08	**0.0001**
	Score 1- dependent ambulator who requires assistance from another person in the form of continuous manual contact	13	26.53	13	26.53	
	Score 2- dependent ambulator who requires assistance from another person in the form of continuous or intermittent manual contact	8	16.33	11	22.45	
	Score 3- dependent ambulator who requires assistance from another person in the form of verbal supervision/guarding	7	14.29	14	28.57	
	Score 4-independent ambulator who can walk freely on level surfaces only	1	2.04	7	14.29	
	Score 5-independent ambulator who can walk freely on any surface			2	4.08	
		Mean ± SD	**Min-max**	**Mean ± SD**	**Min-max**	
Ashworth spasticity scale (Ashworth) lower extremity (31)		1.33±1.36	0-4	1.51±1.08	0-4	0.117
		Count	%	Count	%	
Ashworth spasticity scale (Ashworth) lower extremity (31)	Score 0-no increase in muscle tone	21	42.86	8	16.33	0.117
	Score 1-slight increase in muscle tone	7	14.29	20	40.82	
	Score 2-more marked increase in muscle tone through most limb easily flexed	7	14.29	11	22.45	
	Score 3-considerable increase in muscle tone, passive movement difficult	12	24.49	8	16.33	
	Score 4-limb rigid in flexion or extension	2	4.08	2	4.08	
		Mean ± SD	**Min-max**	**Mean ± SD**	**Min-max**	
BI of activities of daily living (32)		33.78±21.54	5-75	55.71±26.65	5-100	**0.0001**

SD: Standard deviation, RAGT: Robot-assisted gait therapy, FAS: Functional ambulation scale, BI: Barthel index

Table 4. Correlation of RAGT improvement parameters and outcome measures

r*	RAGT speed improvement	RAGT distance improvement
Baseline value of Brunnstrom lower extremity motor staging (Brunnstrom)	**0.408****	0.212
The study end value of Brunnstrom lower extremity motor staging (Brunnstrom)	**0.353****	0.212
Baseline value of FAS	**0.371****	0.220
The study end value of FAS	0.203	0.040
Baseline value of Ashworth spasticity scale (Ashworth)	0.055	-0.090
The study end value of Ashworth spasticity scale (Ashworth)	0.085	-0.085
Baseline value of BI of activities of daily living	**0.367****	0.072
The study end value of BI of activities of daily living	0.267	-0.022

* Pearson correlation, **p<0.05, SD: Standard deviation, RAGT: Robot-assisted gait therapy, FAS: Functional ambulation scale, BI: Barthel index

Table 5. Correlation of the participants

Paired samples correlations	r*
Brunnstrom-baseline & Brunnstrom-therapy end	**0.765****
FAS-baseline & FAS-therapy end	**0.794****
Ashworth-baseline & Ashworth-therapy end	**0.804****
Barthel index-baseline & Barthel index-therapy end	**0.774****

* Pearson correlation, **p<0.05

Neuromuscular and motor impairment in stroke patients can cause muscle weakness, deterioration of motor function, ambulation, and activities of daily living. Besides, the level of impairment in these subjects differs individually (34). In our trial, we found that there was a moderate positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and p<0.05). Additionally, there was a moderate correlation between RAGT device speed improvement value and Brunnstrom value at the end of the therapy (r=+0.353; p<0.05). We consider that correlation between post-stroke patients' baseline values and output data by RAGT device is an important indicator for medical prognostication. Also, our study shows that good motor function, ambulation and activity levels of the patients at the beginning of the treatment increase the success of the treatment.

The results reported here support the earlier findings of randomized controlled trials that studied gait ability or independence in activity of daily living by RAGT, and concluded improvements in locomotor milepost in post-stroke patients (2-5,16,26). Mustafaoglu et al. (2) investigated the effects of RAGT in 51 stroke patients. One of the outcomes in their study was BI of activities of daily living. After 6 weeks of therapy, they found that RAGT plus therapeutic exercise (TE) improved BI index significantly when compared to TE alone, or RAGT alone (p<0.016) (2). Moreover, Li et al. (3), published an article about a new RAGT model, called the BEAR-H1 (Shenzhen milebot robot technology). In their multi-center study of 130 stroke patients, they investigated the effectiveness of RAGT. FAS for ambulation was one of the outcomes in the study. They reported that patients had amelioration in FAS score after 4 weeks of rehabilitation (3). Aprile et al. (26) also highlighted the fact that RAGT as a neurorehabilitation tool promoted ambulation (FAS) significantly. Likewise, in the present study, we used the Brunnstrom for motor function (29), FAS for ambulation (30), Ashworth for spasticity (31), and BI for activities of daily living (32). We observed significant improvement after robot-assisted gait therapy in motor, ambulation, and activities of daily living except spasticity (p=0.117 for spasticity index of Ashworth, and p=0.0001 for the rest).

Actually, Morone et al. (35-37) pointed out that baseline ambulation status played an important role to interpret post-stroke patients who might have more gains from RAGT. In their three studies through short-term and long-term follow-up of stroke patients who had RAGT, they reported that when baseline ambulation score was low, the benefit from RAGT would be to a greater extent (35-37). Contrary to these studies, in this study, there was a positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and p<0.05). Patients with high functional and ambulation levels had more gains from robot-assisted therapy.

Interestingly, there is a long-term study examining efficaciousness of RAGT versus conventional therapy in stroke during 5-year follow-up (38). In this randomized, controlled study of 63 post-stroke patients, it was concluded that conventional therapy was better than RAGT in terms of walking and endurance. More long-term studies are needed to generate well-defined scientific data.

Study Limitations

Our study has some limitations as well. First, retrospective design and the absence of a control group are major limitations in our study. Second, the number of therapy

sessions was different for each patient. Third, the small number of patients can potentially lead to interpret findings cautiously.

Conclusion

In conclusion, our study results showed that robot-assisted gait therapy had a positive effect on motor recovery, ambulation status, and daily living skills in post-stroke patients. Besides, there is positive correlation between robotic speed improvement parameter and baseline outcome measures of therapy including motor function, ambulation, and daily living skills. The authors think that correlation between post-stroke patients' baseline values and output data of speed improvement is an important indicator for prognosis. The better the functional status of the patient at baseline, the higher the success of the treatment. Nonetheless, there is a need for further studies with higher patient numbers to confirm these beneficial effects in post-stroke patients.

Ethics

Ethics Committee Approval: The study is in accordance with the Declaration of Helsinki. The Local Ethics Committee of Memorial Hospital approved this trial protocol at 12/11/2021 with a number of 007.

Informed Consent: Informed consent was obtained from participants participating in the study in this article.

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Authorship Contributions

Concept: İ.S., E.Ç., Design: İ.S., Data Collection or Processing: E.T., Y.T.Y., Analysis or Interpretation: İ.S., E.Ç., Drafting Manuscript: İ.S., Y.T.Y., E.T., Critical Revision of Manuscript: E.Ç., Final Approval and Accountability: E.Ç., İ.S., E.T., Y.T.Y.

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ORIGINAL RESEARCH

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Prevalence of Obesity in Rheumatologic Diseases and Its Relationship with Disease Activity

Romatolojik Hastalıklarda Obezite Prevalansı ve Hastalık Aktivitesi ile İlişkisi

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Abstract

Objective: Obesity is a common health problem and a complex disease that is defined as overly fat deposition in adipotic tissue. Studies conducted in our country (Turkey) have reported prevalence of obesity between 12 and 22 percent. Obesity has been shown to be associated with several rheumatic diseases and inflammation. The aim of this study is to assess the prevalence of obesity in rheumatologic diseases, and possible relationships between disease activity and accompanying obesity.

Method: A total of 1064 newly patients diagnosed with osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis (AS), systemic lupus erythematosus (SLE), fibromyalgia (FM), gout, Behçet's disease (BD), vasculitis, polymyalgia rheumatica (PMR), Sjögren's syndrome (SS), Familial Mediterranean fever, polymyositis, and systemic sclerosis (SSc) were included in the study. Age, gender, disease activity scores, and laboratory and clinical findings were all recorded.

Results: Obesity incidences were found to be 4.5% in RA, 3.2% in SLE, 1.6% in AS, 40.1% in OA, 11.2% in FM, 19.7% in gout, 1.8% in BD, 15% in vasculitis, 13.7% in PMR, 8% in SS, and 8.3% in SSc. Obesity and OA were revealed to have a statistically significant association. Disease activity scores were statistically significantly higher in obese FM patients compared to non-obese patients ($p<0.001$). We found a low rate of obesity in inflammatory rheumatic diseases, and we could not find a relationship between obesity and disease activity.

Öz

Amaç: Obezite adipoz dokuda fazla yağ depolanması olarak tanımlanan kompleks bir hastalık ve genel sağlık sorunudur. Ülkemizde yapılan araştırmalarda obezite prevelansı %12-22 olarak bildirilmiştir. Obezitenin çeşitli romatizmal hastalıklar ve enflamasyonla ilişkisi gösterilmiştir. Bu çalışmanın amacı romatolojik hastalıklarda obezite prevelansını ve hastalık aktivitesi ile ilişkisini araştırmaktır.

Yöntem: Çalışmaya yeni osteoartrit (OA), romatoid artrit (RA), ankilozan spondilit (AS), sistemik lupus eeritamatosus (SLE), fibromiyalji (FM), gut, Behçet hastalığı (BH), vaskülit, polimiyalji romatika (PMR), Sjögren sendromu (SS), Ailevi Akdeniz ateşi, polimiyozit ve sistemik skleroz (SSc) tanısı almış 1064 romatoloji hastası dahil edilmiştir. Hastaların yaş, cinsiyet, hastalık aktivite skorları, laboratuvar ve klinik bulguları kaydedilmiştir.

Bulgular: Obezite insidansları RA'da %4,5, SLE'de %3,2, AS'de %1,6, OA'de %40,1, FM'de %11,2, gutta %19,7, BH'de %1,8, vaskülitte %15, PMR'de %13,7, SS'de %8, ve SSc'de %8,3 olarak tespit edildi. Obezite ve OA arasında istatistiksel olarak kuvvetli ilişki saptandı. Hastalık aktivite skorları ise obez FM hastalarında obez olmayanlara göre istatistiksel olarak anlamlı düzeyde yüksek bulundu ($p<0,001$). Enflamatuvar romatizmal hastalıklarda obezite oranı düşük bulunurken, obezite ile hastalık aktivitesi arasında bir ilişki bulunmadı.

Sonuç: Yapılan son çalışmalarda obezite ve enflamasyon arasında ilişki gösterilse de bizim çalışmamızda ilginç olarak obezitenin OA ve FM hastalarıyla ilişkisi ortaya konmuş ancak enflamatuvar romatizmal

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Conclusion: While recent studies have associated obesity with inflammation, interestingly, in our study, obesity was found to be related to OA and FM, but was not associated with inflammatory rheumatic diseases. The relationship with OA may be explained by mechanical factors, but more comprehensive studies are needed on the relationship with obesity and inflammatory rheumatic diseases.

Keywords: Ankylosing spondylitis, disease activity, obesity, osteoarthritis, rheumatoid arthritis, rheumatological diseases

hastalıklar ile arasında ilişki gösterilememiştir. OA ve obezite arasındaki ilişki mekanik faktörlerle açıklanabilir, ancak FM ve diğer enflamatuvar romatizmal hastalıklar ve obezite ilişkisini açıklayabilmek için daha kapsamlı ileri çalışmalara ihtiyaç duyulmaktadır.

Anahtar kelimeler: Ankilozan spondilit, hastalık aktivitesi, obezite, osteoartrit, romatoid artrit, romatizmal hastalıklar

Introduction

Inflammatory rheumatic diseases (IRD) which comprise diverse conditions are chronic inflammatory diseases that usually affect the musculoskeletal system, and also cause systemic involvement (1). Obesity is described as a systemic disease with known metabolic and cardiovascular complications, but also has a role in the development of inflammatory diseases and reported to be highly prevalent in IRD (2).

The assumed mechanisms for the relationship between pain and obesity include mechanical, structural, metabolic and behavioral changes, and most likely the combination of factors is effective and can contribute differently depending on the disorder. Increased pressure on the joints from the increase of body weight, various metabolic alterations, and lifestyle changes due to restricted movements may facilitate diseases characterized by pain, and they may worsen the existing diseases of obese people. A positive correlation has been found between musculoskeletal system disorders and obesity grades (3). Studies in the literature have demonstrated that obesity is associated with low back and neck pain, fibromyalgia (FM), osteoarthritis (OA), some soft tissue diseases (carpal tunnel syndrome, plantar fasciitis), and connective tissue disease, such as gout and rheumatoid arthritis (RA) (4).

Obesity is also associated with inflammation (5). The link between obesity and inflammation was explained by the release of bioactive proteins named adipokines from white adipose tissue, which are potential mediators playing a role in the modulation of inflammatory response (6). Adipokines, and the leptin and adiponectin hormones, promote metabolic homeostasis and play a role in the release of inflammatory factors such as IL-12p40 and IL-16 (5,6).

The relationship between obesity and rheumatologic diseases has been defined in the literature, and studies have shown the relationship between obesity and OA, RA, systemic lupus erythematosus (SLE), gout, and FM (2). However, studies showing the relationship between obesity and ankylosing spondylitis (AS), polymyalgia rheumatica (PMR), Sjogren disease (SSc) and vasculitis, have been limited. Similarly, there have been no adequate studies on the relationship between obesity and systemic sclerosis (SS), Behçet's disease (BD) and Familial Mediterranean fever (FMF). Our study is the first to demonstrate the prevalence of obesity and its relation to disease activity within a wide range of rheumatologic diseases.

The aim of this study is to assess the prevalence of obesity in rheumatologic diseases, and possible relationships between disease activity and accompanying obesity.

Materials and Methods

Our study had cross-sectional design, our study group consisted of 1,064 patients of rheumatic disease with or without obesity. The study was carried out between 01.01.2015 and 31.12.2015 by scanning the patient files. These patients were diagnosed with rheumatologic diseases according to the relevant criteria. Body weight was measured in kilograms (kg) with a scale, and height was evaluated in meters (m). Body mass index (BMI) was computed by dividing the body weight (kg) by the square of the height (m^2). A BMI ≥30 kg/m^2 was considered to be obese. Exclusion criteria included psychosomatic/psychiatric disorders and the use of psychotropic drugs or alcohol/substance abuse, previously steroid use, thyroid dysfunction and infection, other autoimmune and/or chronic diseases affecting metabolism.

Age, gender, disease activity scores, positive antinuclear antibody (ANA), C-reactive protein (CRP) values, and erythrocyte sedimentation rate (ESR), and the persistence of arthritis, fatigue, and Reynaud's syndrome, were collected through patient recordings.

For disease activity scores, the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) for OA, the disease activity score-28 (DAS-28) for RA, the Bath AS disease activity index for AS, the fibromyalgia impact

questionnaire (FIQ) for FM, the SLE disease activity index for SLE, and the BD current activity form for BD were used (7-12).

The Local Ethics Committee (University of Health Sciences Turkey, Erzurum Regional Training and Research Hospital, Clinical Research Ethics Committee; confirmation number: 2015/8-56; date: 21.04.2015) approved the study, which was carried out in accordance with the principles of the Helsinki Declaration.

Statistical Analysis

We conducted the statistical analyses using SPSS for Windows, version 17.0. When not otherwise specified, results were stated as means ± standard deviation or median (minimum-maximum) according to their distribution. Normality tests were used. We used the independent-sample t-test or Mann-Whitney U test between two subject groups, and used the Spearman correlation test or Pearson correlation test, when applicable. Comparison between categorical variables was done with the chi-square test. The statistical significance level of the results was taken as $p<0.05$ at the 95% confidence interval.

Results

Nine of 197 RA patients (4.5%), 2 of 62 SLE patients (3.2%), 2 of 119 AS patients (1.6%), 67 of 167 OA patients (40.1%), 33 of 293 FM patients (11.2%), and 1 of 53 BD patients (1.8%) were diagnosed as obese. The age, gender, laboratory findings, and disease activity scores of obese and non-obese patients are given in Table 1.

Disease activity scores were statistically significantly higher in obese FM patients compared to non-obese patients ($p<0.001$). The mean age was higher in obese FM patients than in non-obese FM patients ($p<0.001$). There was no statistically significant difference between obese and non-obese groups in terms of age, gender, ESR, CRP, or disease activity scores for OA, RA, AS, SLE, and BD.

One of 12 SSc patients (8.3%) and 3 of 20 vasculitis patients (15.0%) were obese. The age, gender, and laboratory and clinical findings of obese and non-obese patients are shown in Table 2. No significant difference was found between obese and non-obese vasculitis patients in terms of age, gender, or laboratory and clinical findings. Positive ANA was more common in non-obese SSc patients, whereas the incidence of Reynaud's syndrome was statistically higher in obese patients ($p<0.001$ and $p=0.024$, respectively).

Four of 29 PMR patients (13.7%) and 14 of 71 gout patients (19.7%) were obese. The age, gender, and laboratory and clinical findings of obese and non-obese patients are given in Table 3.

Arthritis was common in both groups, while fatigue was the most common symptom in non-obese patients with gout ($p<0.001$). Fatigue was significantly higher in obese patients, while arthritis was more common in non-obese PMR patients ($p=0.001$ and $p<0.001$, respectively). No significant difference was found between both groups in terms of age, gender, CRP, or ESR values.

Two of 25 SS patients (8.0%) were obese. The age, gender, and laboratory and clinical findings of obese and non-obese patients are given in Table 4. Both ANA positivity and Reynaud's syndrome and sun sensitivity findings were significantly higher in non-obese patients than in obese SS patients ($p<0.001$, $p=0.024$, and $p=0.001$, respectively). Dry eyes and dry mouth findings, on the other hand, were more common in obese SS groups ($p<0.001$).

One of 2 PMR patients (50.0%) met the obesity criteria.

No obese patients were found among the 14 FMF patients. When somatic symptoms of obese FMF patients were analyzed, we found high values, as presented in Table 5.

Significant somatic symptoms found in FM patients included fatigue (87.0%), irritable bowel syndrome (57.0%), dyspepsia (51.0%), and constipation (27.0%). These symptoms were followed by paraesthesia (10.0%) and sun sensitivity (9.0%). Other accompanying symptoms included dry mouth, Reynaud's syndrome, and diarrhoea.

The distribution of obesity in rheumatic diseases is shown in Table 6. While the relationship between OA and obesity was statistically significant, we observed an inverse relationship in most other IRD.

Discussion

Different prevalences in different countries have been reported for obesity, which is a common health problem. Studies conducted in our country (Turkey) have reported prevalences between 12 and 22% for obesity (13). Obesity has been associated with several rheumatic diseases and inflammation (1). Since rheumatic diseases usually progress with inflammation, we thought that defining the presence of accompanying obesity and related factors could contribute to disease management. The incidence of obesity has been reported in about 12-17% of patients with RA (14). There are no published data demonstrating

the relationship between obesity and RA in the Turkish population. In our study, we found the incidence of obesity to be 4.5% in Turkish RA patients. Our obesity prevalence was found to be lower than in previous investigations. Similarly, the obesity prevalence was low in SLE patients in our study (3.2%). Several studies have reported the incidence of obesity of 27-39% in SLE patients (11). Confirming the results of previous studies (15), we observed no association between obesity and a higher degree of disease activity for RA and SLE. Likewise, there was no association between the presence of obesity and disease activity scores for AS and OA. In a study from the literature, BMI was found to be associated with disease activity (16), while another study from our country, consistent with this study, reported no significant difference between AS and control groups in terms of BMI and disease activity (17). In our study, the incidence of obesity was found as high as 40.1% but was not correlated with disease activity in OA patients. Previous studies found the incidence of obesity to be 83% for knee OA and 25% for hip OA; no increased incidence was reported for hand OA (18). WOMAC scores were found to be high in hip OA patients with higher BMI (19). For OA, the main weakness of our study was the inability to search the relationship between obesity and OA because the disease was not classified according to the region such as hip, knee, or hand OA.

We found the prevalence of obesity in 11.2% of FM patients. This prevalence was not consistent with the literature, although high FIQ scores and mean age were consistent (20). In this research, we queried many somatic symptoms that were comorbid with FM, such as abdominal pain, fatigue, gastric disturbance, irritable bowel syndrome, oral ulcers, constipation, diarrhoea, Reynaud's syndrome, sun sensitivity, dry eyes, dry mouth, urticaria, and paraesthesia. Higher prevalances of these symptoms support the severity of FM.

Because this was the first study, investigating the prevalence of obesity in patients with SSc, vasculitis, SS, PMR, and BD may increase the robustness of our study. The main weakness of the study was the inability to investigate the relationship between obesity and these diseases due to the scarce number of patients. Obesity was found in 3 cases (15%) with vasculitis and in 1 case (8.3%) with SSc. One study in the literature demonstrated that vascular inflammation neutrophil infiltration was higher in people with higher BMI values (21). In a study with SSc patients, BMI was found to be significantly lower compared to the controls (22). In the study, we found the prevalence of obesity to be 8% in SS

Table 1. Age, gender ratio, laboratory investigations and disease activities of rheumatic patients with(out) obesity

		Age	Gender (female/male)	CRP	ESR	Disease activity scores¶
RA n=197	Obesity (+)	53.2±8.9	9/0 (100.0%)	12 (3-33.3)	39 (5-80)	4.4±1.1
	Obesity (-)	52.3±13.3	149/39 (79.0%)	3.5 (0.34-739)	18 (1-255)	4.2±1.4
	p	**0.398**	**0.101**	**0.137**	**0.130**	**0.158**
SLE n=62	Obesity (+)	43.5±24.7	2/0 (100.0%)	8.8 (3.6-14)	23 (16-30)	7±2.8
	Obesity (-)	38.2±13.9	60/0 (100.0%)	4.7 (3-618)	23.5 (3-160)	6.5±2.6
	p	**0.633**		**0.294**	**0.623**	**0.196**
AS n=119	Obesity (+)	56±9.8	2/56 (3.0%)	12.5 (4-21)	35 (10-60)	4.2±1
	Obesity (-)	39.5±11.8	0/61 (0%)	3.8 (2-135)	16 (1-255)	5.3±1.5
	p	**0.250**	**0.146**	**0.638**	**0.866**	**0.384**
OA n=167	Obesity (+)	62.8±10.2	63/4 (94.0%)	3.4 (3-24)	12 (2-70)	47.3±5.6
	Obesity (-)	61.8±12.4	90/10 (90.0%)	3.4 (1-124)	12 (2-80)	47.7±6.4
	p	**0.508**	**0.150**	**0.229**	**0.623**	**0.694**
BD n=53	Obesity (+)	37±12.3	1/0 (100.0%)	3.4 (2-25)	20 (15-29)	2±0.8
	Obesity (-)	36.2±11.1	21/31 (40.0%)	11.65 (1.2-158)	25 (3.5-130)	2±0.6
	p	**0.452**	**0.586**	**0.729**	**0.762**	**0.540**
FM n=293	Obesity (+)	50.5±10.7	33/0 (100.0%)	3.4 (3-72)	14 (4-54)	4 (3-50)
	Obesity (-)	41.2±11.3	252/8 (96.0%)	3.4 (1-67)	14 (1-76)	4.5 (0.8-65)
	p	**0.000***	**0.149**	**0.862**	**0.348**	**0.000***

¶: DAS-28 for RA, SLEDAI for SLE, BASDAI for AS, WOMAC for OA, BDCAF for BD, FIQ for FM

*: p<0.005, RA: Rheumatoid arthritis, SLE: Systemic lupus erythematosus, AS: Ankylosing spondylitis, OA: Osteoarthritis, BD: Behçet's disease, FM: Fibromyalgia, CRP: C-reactive protein, DAS-28: Disease activity score-28, WOMAC: Western Ontario and McMaster Universities Osteoarthritis index, FIQ: Fibromyalgia impact questionnaire, ESR: Erythrocyte sedimentation rate

Table 2. Age, gender ratio, laboratory investigations and clinic features of rheumatic patients with(out) obesity

	SSc patients, n=12			Vasculitis patients, n=20		
	Obesity (+)	Obesity (-)	p	Obesity (+)	Obesity (-)	p
Age	48.8±15.7	50.7±19.7	**0.348**	55±17.4	37.9±11.8	**0.495**
Gender (female/male)	1/0 (100.0%)	10/1 (90.0%)	**0.273**	3/0 (100.0%)	11/6 (64.0%)	**0.345**
CRP	48.5	10.8 (2.7-80)	**0.157**	6.1 (3-254)	9.7 (3.4-16)	**0.724**
ESR	40	30 (8-110)	**0.240**	22 (1-113)	14 (12-16)	**0.664**
ANA	0/1 (0%)	5/6 (45.0%)	**0.000**			
Fatigue	0/1 (0%)	3/8 (27.0%)	**0.605**	1/2 (3.03%)	5/12 (29.0%)	**0.898**
Arthritis	0/1 (0%)	8/3 (72.0%)	**0.813**	2/1 (66.0%)	8/9 (47.0%)	**0.556**
Reynaud's syndrome	1/0 (100.0%)	8/3 (72.0%)	**0.024**	0/3 (0%)	4/13 (23.0%)0	**0.374**

*: p<0.005 (none for this table), SSc: Systemic sclerosis, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate, ANA: Antinuclear antibody

Table 3. Age, gender ratio, laboratory investigations and clinic features of rheumatic patients with(out) obesity

	Gout patients, n=71			PMR patients, n=29		
	Obesity (+)	Obesity (-)	p	Obesity (+)	Obesity (-)	p
Age	56.9±1.,9	**57.4±15.7**	0.916	74.2±8.9	72.8±12	**0.821**
Gender (female/male)	3/11 (21.0%)	**17/40 (29.0%)**	0.531	3/1 (75.0%)	18/7 (72.0%)	**0.920**
CRP	6.9 (3.4-51)	**12.6 (0.34-739)**	0.274	3.3 (3.1-8.4)	10 (3-144)	**0.197**
ESR	25 (4-70)	**23 (2-99)**	0.650	36 (12-70)	34 (2-84)	**0.514**
Fatigue	0/14 (0%)	**3/54 (5.0%)**	0.000*	1/3 (25.0%)	3/22 (12.0%)	**0.001***
Arthritis	13/1 (92.0%)	**53/4 (92.0%)**	0.000*	3/1 (75.0%)	25/0 (100.0%)	**0.000***

*: p<0.005, PMR: Polymyalgia rheumatica, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate

Table 4. Age, gender ratio, laboratory investigations and clinic features of rheumatic patients with(out) obesity

	SS patients, n=25		
	Obesity (+)	Obesity (-)	p
Age	55±7	51.7±10.7	**0.685**
Gender (female/male)	2/0 (100.0%)	22/1 (95.0%)	**0.760**
CRP	4.2 (3-5.4)	3.5 (2.7-218)	**0.665**
ESR	47 (34-60)	22 (6-99)	**0.410**
ANA	1/1 (50.0%)	16/7 (69.0%)	**0.000***
Fatigue	0/2 (0%)	11/12 (47.0%)	**0.207**
Arthritis	0/2 (0%)	8/15 (34.0%)	**0.332**
Reynaud's syndrome	0/2 (0%)	6/17 (27.0%)	**0.024***
Dry eyes	2/0 (100.0%)	17/ (73.0%)	**0.000***
Dry mouth	2/0 (100.0%)	20/3 (86.0%)	**0.000***
Sun sensitivity	0/2 (0%)	9/14 (39.0%)	**0.001***

*: p<0.005, SS: Sjögren's syndrome, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate, ANA: Antinuclear antibody

Table 5. Somatic symptoms of obese FM patients

	Existence/ non-existence	%
Fatigue	29/4	(87.0%)
Dry eyes	0/33	(0%)
Dry mouth	1/32	(3.0%)
Sun sensitivity	3/30	(9.0%)
Reynaud's syndrome	2/31	(6.0%)
Diarrhoea	1/32	(3.0%)
Constipation	9/24	(27.0%)
Dyspepsia	17/16	(51.0%)
Paraesthesia	3/30	(10.0%)
Irritable bowel syndrome	19/14	(57.0%)

Somatic symptoms of obese patients on FM are given as a percentage (%), FM: Fibromyalgia

and 13.7% in PMR. One study demonstrated that there was no correlation between PMR and BMI (23). The prevalence of obesity in patients with these diseases was not different from the normal population. In these patients, we did not find a strong and consistent relationship between obesity and clinical features (e.g., arthritis, fatigue, or Renaud's syndrome) and laboratory findings (ESR, CRP, or ANA). Similarly, one obese patient (1.8%) was found among 53 BD patients, and no relationship was observed between obesity and disease activity.

Similar to the results of a previous study, we found the second highest prevalence of obesity after OA in patients

with gout in our study group (19.7%). The association between gout and obesity may confirm that they are a part of the metabolic syndrome (24,25).

Table 6. Distribution according to disease types of rheumatic patients with(out) obesity

	Obesity (+)	Obesity (-)	p
RA	9	188	0.000*
SLE	2	60	0.02*
AS	2	124	0.000*
OA	67	59	0.000*
BD	1	52	0.01*
FM	33	260	0.41
SSc	1	11	0.65
Vaskulitis	3	17	0.7
Gout	14	57	0.037*
PMR	4	25	0.84

*: p<0.05, RA: Rheumatoid arthritis, SLE: Systemic lupus erythematosus, AS: Ankylosing spondylitis, OA: Osteoarthritis, BD: Behçet's disease, FM: Fibromyalgia, SSc: Systemic sclerosis, PMR: Polymyalgia rheumatica

Study Limitations

Our study had the limitation that it was planned as a cross-sectional study.

Conclusion

In this study, the highest incidence of obesity among rheumatologic diseases was found to be 40.1% in OA patients, followed by gout as 19.7%. We believe that these higher rates might be associated with mechanical and metabolic factors. In FM, on the other hand, we observed higher disease activity in obese patients. Despite recent studies that have underlined the relationship between obesity and inflammation, in general, we found a lower rate of obesity in IRD, and we did not find a relationship between obesity and disease activity.

Further studies are needed to better understanding the prevalence and related features of concomitant obesity in rheumatic disease. Thus, future studies should seek to identify other possible factors liable for obesity in rheumatologic disease, beyond those set forth above. Age-matched case-control studies would help to better understand the background prevalence of obesity.

Ethics

Ethics Committee Approval: The Local Ethics Committee (University of Health Sciences Turkey, Erzurum Regional Training and Research Hospital-Clinical Research Ethics Committee; confirmation number: 2015/8-56; date: 21.04.2015) approved the work, carried out in accordance with the principles of the Helsinki Declaration.

Informed Consent: Informed consent was obtained.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Concept: S.H., A.Ç., H.U., A.A., Y.Y., Design: S.H., A.Ç., H.U., A.A., Y.Y., Data Collection or Processing: S.H., A.Ç., H.U., A.A., Y.Y., Analysis or Interpretation: S.H., A.Ç., H.U., A.A., Y.Y., Final Approval and Accountability: S.H., A.Ç., H.U., A.A., Y.Y., Critical Revision of Manuscript: S.H., A.Ç., H.U., A.A., Y.Y., Writing: S.H., A.Ç., H.U., A.A., Y.Y.

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ORIGINAL RESEARCH

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Depression and Anxiety in Mothers of Children Hospitalized for COVID-19 Infection

COVID-19 Enfeksiyonu Nedeniyle Hastaneye Yatırılan Çocukların Annelerinde Depresyon ve Anksiyete

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Abstract

Objective: Coronavirus disease-2019 (COVID-19) infection and the pandemic process have become crucial public health problems with devastating effects on the psychological, social, and economic aspects of society. This study aimed to examine the emotional state of the mothers of the children diagnosed with this disease, to investigate the symptoms of depression and anxiety, and to reveal the situations that might affect these due to the COVID-19 pandemic, which is a crucial source of stress.

Method: We included mothers of 50 pediatric patients (under 18 years old) hospitalized for COVID-19 infection proven by severe acute respiratory syndrome-coronavirus-2 polymerase chain reaction test, and mothers of 50 patients hospitalized with other diagnoses except for COVID-19. We evaluated mothers with the hospital anxiety and depression scale (HAD).

Results: We assessed the relationship between education level and anxiety/depression in mothers of children diagnosed with COVID-19. A negative correlation was found between education level and HAD anxiety subscale (p=0.049, r=-0.280). The mean HAD anxiety score of mothers of COVID-19 positive children was statistically significantly higher than in the control group (p=0.001). The incidence of depression in the study population was almost equal, and there was no statistically significant difference between the groups (p=0.839). According to the total HAD scale score, the mean score of the mothers of the COVID-19 group had statistically significantly higher scores than the control group (p=0.043).

Conclusion: Although two years have passed since the pandemic started, COVID-19 is still a source of anxiety and stress for parents. In addition, socio-demographic factors affecting the psychological health of parents may further increase this burden.

Keywords: Anxiety, children, COVID-19, depression, mothers, socio-demographic factors

Öz

Amaç: Koronavirüs hastalığı-2019 (COVID-19) enfeksiyonu ve pandemi süreci, toplumun psikolojik, sosyal ve ekonomik yönleri üzerinde yıkıcı etkileri olan çok önemli halk sağlığı sorunu haline gelmiştir. Bu çalışmada, bu hastalık tanısı alan çocukların annelerinin duygusal durumlarının incelenmesi, depresyon ve anksiyete belirtilerinin araştırılması ve çok önemli bir stres kaynağı olan COVID-19 pandemisi nedeniyle bunları etkileyebilecek durumların ortaya konulması amaçlanmıştır.

Yöntem: Çalışmaya şiddetli akut solunum sendromu-koronavirüs-2 polimeraz zincir reaksiyon testi ile kanıtlanmış COVID-19 enfeksiyonu nedeniyle hastaneye yatırılan 50 pediyatrik hastanın (18 yaş altı) annelerini ve COVID-19 tanısı hariç diğer tanılarla hastanede yatan 50 hastanın annelerini dahil ettik. Anneler hastane anksiyete ve depresyon ölçeği (HAD) ile değerlendirildi.

Bulgular: COVID-19 tanısı alan çocukların annelerinde eğitim düzeyi ile anksiyete ve depresyon arasındaki ilişki değerlendirildi. Eğitim düzeyi ile HAD anksiyete alt ölçeği arasında negatif korelasyon (p=0,049, r=-0,280) saptandı. COVID-19 pozitif çocukların annelerinin HAD anksiyete puan ortalaması kontrol grubuna göre istatistiksel olarak anlamlı derecede yüksekti (p=0,001). Çalışma popülasyonunda depresyon insidansı neredeyse eşitti ve gruplar arasında istatistiksel olarak anlamlı bir fark yoktu (p=0,839). Toplam HAD ölçek skoruna göre COVID-19 tanısı alan gruptaki annelerin puan ortalamaları kontrol grubuna göre istatistiksel olarak anlamlı derecede yüksekti (p=0,043).

Sonuç: Pandeminin başlamasından bu yana iki yıl geçmesine rağmen, COVID-19 hala ebeveynler için bir anksiyete ve stres kaynağıdır. Ayrıca ebeveynlerin psikolojik sağlığını etkileyen sosyo-demografik faktörler bu yükü daha da artırabilir.

Anahtar kelimeler: Anksiyete, anneler, COVID-19, çocuklar, depresyon, sosyo-demografik faktörler

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Introduction

The Coronavirus disease-2019 (COVID-19) infection, which started in China in December 2019 and spread rapidly around the world, was declared a pandemic by the World Health Organization on March 11, 2020 (1). COVID-19 infection and the pandemic process have become crucial public health problems with devastating effects on the psychological, social, and economic aspects of society (2).

During the COVID-19 pandemic, many precautions have been taken in our country as the rest of the world. These precautions included the transition to online education and work instead of face-to-face teaching and working, quarantine, and curfews during the pandemic (3). Studies have shown that the COVID-19 pandemic process affects the mental health of parents and children (4,5). In a study conducted in China, where the pandemic first started, it was emphasized that more than half of adult people had anxiety symptoms during this process (6). Studies conducted during previous epidemics have also shown an increase in psychiatric diseases, especially anxiety, depression, and post-traumatic stress disorder (2,7).

In children infected with COVID-19, the hospitalization process is stressful for children and their parents. The main factors that cause stress and anxiety among parents are those related to the child's health conditions and environmental, administrative, and socio-economic factors, and are in parallel with an increasing number of cases and deaths, scarcity of hospital beds, risk of infection due to close contact with the patient, other family members. Worrying about health, fear of death, the sadness of losing loved ones, and economic recession are some of the other causes that can worsen the situation by increasing psychological stress (2). Studies have also emphasized that psychiatric symptoms occur in children hospitalized for COVID-19 and their parents (8-10). A study conducted in our country has stated that the age of the parents, education level, and economic level are socio-economic variables that may affect the mental health of both families and children (3).

There are limited studies on how the mental health of mothers of children hospitalized with the diagnosis of COVID-19 infection is affected (2,9). This study aimed to examine the emotional state of the mothers of the children diagnosed with this disease, to investigate the symptoms of depression and anxiety, and to reveal the situations that may affect these due to the COVID-19 pandemic, which is a crucial source of stress. Also, our study aimed to understand and address the needs of children and their mothers and to prevent psychiatric disorders that might occur by developing action plans or training programs for this.

Materials and Methods

We conducted this study in University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital between April 2022 and June 2022. We included the mothers of 50 pediatric patients (under 18 years old) hospitalized in the Clinic of Pediatric Infectious Diseases due to COVID-19 infection proven with severe acute respiratory syndrome-coronavirus-2 polymerase chain reaction test and the mothers of 50 patients hospitalized with other diagnoses except for COVID-19 diagnosis. Our study was approved by the Ethics Committee of University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital on March 30, 2022, with the decision number 2022/514/222/45, and performed in accordance with the Declaration of Helsinki. We would need a sample size of 45 in each group to reliably (with a probability greater than 0.8) detect an effect size of $0.6 \geq d$, assuming a two-sided criterion for detection that allowed for a maximum type I error rate of $a=0.05$. We added five more patients to each patient group for possible data loss problems in the study. We used a stratified random sampling method for the control group and designed the study as a prospective, cross-sectional case-control study.

We included patients after they were informed about the study and obtained their written consent. All the participant children's conditions were stable. We excluded mothers if their children had poor general conditions (respiratory distress, cardiovascular dysfunction, neurologic disorder, malignancy), psychiatric disease, used psychiatric drugs, or they did not want to participate in the study. We conducted all interviews on the 2nd day of hospitalization (24 hours after hospitalization). We uploaded all data we collected to a database and kept monitored records. Interviews with the mothers lasted about half an hour, with personal protective equipment and masks.

First, we asked questions to the participant mothers about their age, educational status, occupation, marital status, average monthly income, having a history of a psychiatric disease, having a child loss before, and whether the inpatient child had a chronic disease or not, and we recorded obtained data on an interview form.

After that, we assessed hospital anxiety and depression scale (HAD). Zigmond and Snaith (11) developed this scale, and the validity and reliability were proven in our country

by Aydemir et al. (12). The questionnaire contains a total of 14 questions which consists of two subscales, including anxiety (HAD-A) and depression (HAD-D). Odd numbers measure anxiety, and even numbers estimate depression. Each item has different scoring values. Answer options in questions 1, 3, 5, 6, 8, 10, 11, and 13 have decreasing scores from A to D (from 3 to 0). On the other hand, answer options of the 2nd, 4th, 7th, 9th, 12th, and 14th questions have increasing scores (from 0 to 3). The total scores of the subscales are obtained by summing these item scores. For the anxiety subscale, the 1st, 3rd, 5th, 7th, 9th, 11th, and 13th items; for the depression subscale, the scores of the 2nd, 4th, 6th, 8th, 10th, 12th, and 14th items are summed. We took the cut-off score as 10 for the anxiety subscale and 7 for the depression subscale following the literature (12). We considered the mothers as the under-risk group, who had scale scores above these cut-off points, and evaluated the results in this context.

Statistical Analysis

We expressed normally distributed quantitative variables as mean ± standard deviation. We used the Student's t- and Mann-Whitney U tests to compare two groups with normally and non-normally distributed data with a p-value of <0.05, respectively. We assessed correlation coefficients in non-normally distributed data with the Spearman's correlation test, and used the chi-square test to compare two groups with categorical data. We used SPSS 25 software (IBM SPSS Statistics, New York) for statistical calculations.

Results

A total of 100 mothers, including 50 mothers of COVID-19-positive children and 50 mothers of COVID-19-negative children, were included in the study. The median age of mothers of COVID-19-positive patients participating in this study was 33.16±5.18 years (Table 1). Nine (18%) of these mothers had primary school graduates, while 21 (42%) had high school, 16 (32%) had a university, and 4 (8%) had master's degree graduates (Table 1). The financial situations of 20 (40%) patients were low, 22 (44%) of them were moderate, and 8 (16%) of them were good (Table 1). While 47 of the mothers were married, 3 of them were divorced (Table 1). When we compared the socio-demographic data according to the groups, there was no statistical difference (Table 2). We assessed the relationship between education level and anxiety/depression in mothers of children diagnosed with COVID-19. A negative correlation was found between education level and HAD anxiety subscale (p=0.049, r=-0.280). There was no significant relationship between education level and HAD depression subscale. There was no correlation between age (r=-0.042, p=0.775) and mean monthly income (r=-0.133, p=0.358) and HAD anxiety subscale. Also, HAD depression subscale did not correlate with age (r=-0.133, p=0.433) and monthly income (r=-0.152, p=0.293) (Table 3). In addition, HAD anxiety and HAD depression subscale scores were high in divorced or separated mothers p=0.008; p=0.016).

According to the HAD anxiety subscale, 42% of the mothers of children diagnosed with COVID-19 had anxiety symptoms, and 58% did not. On the other hand, 20%

Table 1. Socio-demographic data of the mothers

	COVID-19-positive group	COVID-19-negative group	p
Age (years)			
Mean ± SD	33.16±5.18	33.0±5.35	0.895*
(min-max)	(21-45)	(20-44)	
Educational status n (%)			0.968**
Primary school	9 (18)	8 (16)	
High school	21 (42)	22 (44)	
University	16 (32)	17 (34)	
Master's degree	4 (8)	3 (6)	
Marital status n (%)			0.695**
Married	47 (94)	46 (92)	
Single	3 (6)	4 (8)	
Job n (%)			0.977**
Housewife	27 (54)	25 (50)	
Official	17 (34)	17 (34)	
Employee	3 (6)	4 (8)	
Business	3 (6)	4 (8)	
Average monthly income n (%) Turkish liras (TL)			0.914**
<5000	20 (40)	19 (38)	
5000-10000	22 (44)	24 (48)	
>10000	8 (16)	7 (14)	

*Student's t-test, **chi-square test, SD: Standard deviation, COVID-19: Coronavirus disease-2019

Table 2. Comparison of groups according to HAD scale scores

		Anxiety	Depression	Total
COVID-19 (+)	Mean ± SD	10.36±4.62	7.5±4.7	17.8±8.4
	(min-max)	(3-20)	(0-20)	(3-40)
COVID-19 (-)	Mean ± SD	7.62±3.3	7.3±2.9	14.96±5.35
	(min-max)	(1-16)	(1-13)	(2-24)
p*		0.001	0.839	0.043

*Student's t-test, SD: Standard deviation, COVID-19: Coronavirus disease-2019, HAD: Hospital anxiety and depression scale

of mothers of COVID-19-negative children had anxiety symptoms, whereas 80% did not. According to the HAD depression subscale, 28% of the mothers of COVID-19-diagnosed children had significant depression symptoms, whereas 72% did not. On the other hand, 22% of mothers of COVID-19-negative children had depression symptoms, whereas 78% did not. The mean HAD anxiety score of mothers of COVID-19-positive children was statistically significantly higher than the control group (p=0.001). The incidence of depression in the study population was almost equal, and there was no statistically significant difference between the groups (p=0.839). According to the total HAD scale score, the mean score of the mothers of the COVID-19 diagnosed group had statistically significantly higher scores than the control group (p=0.043) (Table 4).

Table 3. Correlation between the socio-demographic data of the mothers of the COVID-19-positive group and HAD scale scores

	Anxiety		Depression	
	r	p	r	p
Age	-0.042	0.775	-0.113	0.433
Education level	-0.280*	**0.049**	-0.124	0.390
Average monthly income	-0.133	0.358	-0.152	0.293

*Spearman's correlation test, COVID-19: Coronavirus disease-2019, HAD: Hospital anxiety and depression scale

Table 4. Anxiety and depression results regarding marital status in COVID-19 group

	Married	Separated	p
Anxiety	9 (7-12)	19 (18-19.5)	**0.008**
Depression	6 (4-10)	17 (14-18.5)	**0.016**

*Mann-Whitney U test, COVID-19: Coronavirus disease-2019

Discussion

Studies conducted in previous outbreaks and during the COVID-19 pandemic showed a significant increase in psychiatric diseases, especially generalized anxiety disorder, depression, and post-traumatic stress disorder, in infected people or in those under infection risk (2,7). In this study, we tried to find the main factors contributing to the rate of anxiety and depression and psychiatric findings in mothers of hospitalized children with a positive diagnosis of COVID-19. Although the mean anxiety score of mothers of COVID-19-positive children was significantly higher than the control group, the depression score was almost equal in both groups.

The mean anxiety score of COVID-19-positive children's mothers was significantly higher than the control group in the Yuan study (9). However, contrary to our study, the depression score was higher in the COVID-19-positive group (9). Anxiety was observed in 42% of mothers of COVID-19-positive children, while depression was seen in 48% (9). Similarly, in a study conducted with the mothers of 150 children hospitalized for COVID-19 in India in 2020, the anxiety rate was 35%, and depression was 38% (2). Studies stated that psychological vulnerability and uncertainty factors might play a role as the cause of anxiety developing during pandemic processes (13-15). However, in our study, depression symptoms were not high, contrary to the literature. But these studies were conducted in the early period of the COVID-19 pandemic. The world was unprepared for this pandemic, and death rates were higher than nowadays. We can attribute this to heavy quarantine conditions, economic problems, and people facing uncertainty.

Different studies have been conducted to date to evaluate the psychological impact of the COVID-19 pandemic on individuals. In Zhao et al.'s (16) meta-analysis, which included 74 studies examining the psychiatric effects of COVID-19 and SARS on society, the mean prevalence of depression was 23.9% during the COVID-19 outbreak in 21 of 36 studies about COVID-19. In addition, the mean prevalence of anxiety was 23.4% in 24 studies. Another study conducted with 7143 people in China during the pandemic reported the anxiety symptom rate as 25% (17). The results obtained in these studies were similar to the results of the mothers of our COVID-19-negative patients. Hospitalization of children with COVID-19 positivity during the pandemic period is a risk factor affecting the mental health of the children's parents. Therefore, the stress, anxiety, and depression levels of the parents whose children were admitted due to COVID-19 infection were higher than the control group, as stated in the above studies, which is also consistent with the results of our study.

In our study, we also aimed to reveal the importance of the psychological impact of socio-demographic factors on the study population, and we found that mothers with lower education levels showed higher anxiety symptoms. However, there was no significant correlation between education level and depression. Studies conducted during and before the pandemic investigated the protective effect of education levels against psychological problems (3,18). These results suggested that people with high education level could develop effective mechanisms for

offering solutions to psychological problems by accessing information during the pandemic.

Arıkan and Acar (3), who included approximately 247 parents from our country in their study, reported that age was a risk factor for depression. However, we did not find a significant relationship between age and depression. Some studies suggested that depression was less in older individuals than in younger adults (19). Our results were different, and we think that it is because the mean age of our individuals was high, and the other studies were conducted in the early period of the COVID-19 pandemic.

In addition, we found that anxiety and depression were significantly higher in divorced mothers or mothers separated from their spouses in our study. A study emphasized that spousal support is crucial for coping with the anxiety and stress that occur during the struggle with health problems (20). In addition, studies report the protective effect of the cohabitation of spouses on depression (21).

Study Limitations

We conducted the research in a single center with limited participants, including only the mothers of the inpatients, due to circumstances. However, the results may differ in studies with larger populations, so larger-scale epidemiological assessments are needed in this area.

Conclusion

As a result, although two years have passed since the pandemic started, COVID-19 is still a source of anxiety and stress for parents. In addition, socio-demographic factors affecting the psychological health of parents may further increase this burden. Large-scale studies on this subject may boost awareness of parents' mental situation and evaluate parents' psychological status on time, which may result in early interventions for necessary circumstances.

Ethics

Ethics Committee Approval: Our study was approved by the Ethics Committee of University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital on March 30, 2022, with the decision number 2022/514/222/45, and performed in accordance with the Declaration of Helsinki.

Informed Consent: We included patients after they were informed about the study and obtained their written consent.

Peer-review: Internally and externally peer-reviewed.

Authorship Contributions

Concept: M.T.K., E.K., Y.A., Design: M.T.K., E.K., Y.A., Data Collection or Processing: M.T.K., A.K., A.E., Analysis or Interpretation: M.T.K., E.K., C.Ç., Z.V.P., Drafting Manuscript: M.T.K., E.K., Z.V.P., A.E., Critical Revision of Manuscript: E.K., A.K., C.Ç., Y.A., Final Approval and Accountability: M.T.K., A.K., E.K., C.Ç., Z.V.P., A.E., Y.A., Technical or Material Support: E.K., Z.V.P., A.E, Supervision: M.T.K., A.K., Y.A., Writing: M.T.K., A.K., E.K., C.Ç., Z.V.P., A.E., Y.A.

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ORIGINAL RESEARCH

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Non-invasive Assessment of Insulin Resistance and Diabetes Risk with FINDRISC Score Among Physicians in a Tertiary Care Hospital

Üçüncü Basamak Bir Hastanede Hekimler Arasında İnsülin Direnci ve Diyabet Riskinin FINDRISK Skoru ile Değerlendirilmesi

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Abstract

Objective: To assess insulin resistance (IR) and diabetes risk levels with Finnish diabetes risk score (FINDRISC) questionnaire in physicians from a tertiary care hospital.

Method: A cross-sectional study was carried out on 200 physicians working in a tertiary hospital. Data were collected using the FINDRISC tool, "fasting blood glucose", and "fasting insulin". "The homeostatic model assessment of insulin resistance" (HOMA-IR) was calculated. FINDRISC is an eight-question score. FINDRISC scores and 10-year diabetes mellitus risk rates are; <7 points (low) and 1%, 7-11 points (mild/slightly elevated) and 4%, 12-14 points (moderate) and 16%, 15-20 points (high) and 33%, 21-26 points (very high) and 50% (respectively).

Results: The FINDRISC categories were low in 16.0%, mild (slightly elevated) in 36.5%, moderate in 23.5%, high in 18.5%, and very high in 5.5%. HOMA-IR was high in 49.5%, while impaired fasting glucose (IFG) was present in 24% of the doctors. The majority of the physicians (n=155) had a body mass index of ≥25 kg/m^2, did not exercise regularly (n=178), did not consume daily vegetables and/or fruits (n=125), and had diabetic relatives (n=144). The relationships of the FINDRISC score with IFG, the presence of daily fruit/vegetable in-take and regular physical activity were significant (p=0.001). Although the association of FINDRISC score with HOMA-IR was insignificant, the risk of the development of new

Öz

Amaç: Üçüncü basamak bir hastanede çalışan doktorlarda insülin direncini (IR) ve diyabet risk düzeylerini Finlandiya Diyabet Risk skor (FINDRISK) anketi ile değerlendirmek amaçlanmıştır.

Yöntem: Çalışmamız üçüncü basamak bir hastanede çalışan 200 hekim üzerinde kesitsel olarak gerçekleştirilmiştir. Çalışmamızda FINDRISK, açlık kan şekeri ve açlık insülini kullanıldı. IR HOMA-IR ile hesaplandı. FINDRISK sekiz sorudan oluşan, 10 yıllık diyabet riskini belirleyen bir ölçektir. FINDRISK puanları ve 10 yıllık diabetes mellitus risk oranları; <7 puan (düşük) ise % 1, 7-11 puan (hafif) ise % 4, 12-14 puan (orta) ise % 16, 15-20 puan (yüksek) ise % 33, 21-26 puan (çok yüksek) ise % 50 (sırasıyla).

Bulgular: Çalışmaya dahil edilen sağlık çalışanlarının FINDRISK skorları % 16'sında düşük, % 36,5'inde hafif, % 23,5'inde orta, % 18,5'inde yüksek ve % 5,5'inde çok yüksekti. Doktorların %49,5'inde HOMA-IR ve % 24'ünde bozulmuş açlık glukozu (BAG) mevcuttu. Katılımcıların 155'inin vücut kitle indeksi ≥25 kg/m^2 idi, 178'i düzenli egzersiz yapmıyordu, 125'i günlük sebze ve/veya meyve tüketmiyordu ve 144'ünün diyabetik akrabaları mevcuttu. FINDRISK skoru ile BAG, günlük sebze/meyve tüketimi ve düzenli egzersiz yapmak arasında istatistiksel olarak ileri düzeyde anlamlı ilişki bulundu (p=0,001). FINDRISK skoru ile HOMA-IR arasında anlamlı ilişki saptanmamakla birlikte, HOMA-IR yüksek

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onset diabetes for patients with high HOMA-IR was low in 8.1%, mild in 32.3%, moderate in 33.3%, high in 20.2%, and very high in 6.1%. The risk of diabetes (FINDRISC) was higher among the consultants compared to the residents (p=0.001), which persisted even after controlling for age.

Conclusion: FINDRISC scores showed weak but highly significant positive correlations with insulin, glucose, and HOMA-IR levels. Age groups and job position revealed that even after adjustment for age, the job position was high risk (2.9 fold) for diabetes. Diabetes is more prevalent among hypertensive physicians. The FINDRISC assessment may be used in the screening of physicians for diabetes in Turkey.

Keywords: Diabetes mellitus type 2, FINDRISC insulin resistance, occupational health, physicians

görülen olguların % 8,1'inin diyabet riski düşük, % 32,3'ünün hafif, % 33,3'ünün orta, %20,2'sinin yüksek ve %6,1'inin çok yüksek saptandı. Yaş düzenlendikten sonra bile uzmanlarda diyabet riski asistanlara göre daha yüksek bulundu (p=0,001).

Sonuç: FINDRISK skoru, insülin, glukoz ve HOMA-IR seviyeleri ile anlamlı pozitif korelasyon göstermektedir. Yaş grupları ve iş pozisyonu, yaşa göre ayarlama yapıldıktan sonra bile, iş pozisyonunun diyabet için yüksek risk (2,9 kat) oluşturduğunu ortaya koymaktadır. Ayrıca hipertansif hekimler arasında diyabet riski daha yüksek saptanmıştır. Bulgularımız, FINDRISK değerlendirmesinin Türkiye'deki tıp doktorlarında diyabet taraması için kullanılabileceğini düşündürmektedir.

Anahtar kelimeler: İnsüline bağımlı olmayan diabetes mellitus, FINDRISK insülin direnci, iş sağlığı, tıp doktorları

Introduction

Type 2 Diabetes Mellitus (T2DM) is the most common endocrinological disease in the world as well as in Turkey, with a rising frequency day by day. According to the data of the International Diabetes Federation (IDF), the worldwide number of diabetic people aged 20-79 years old was 463 million in 2019 and is estimated to reach 700 million in 2045 (1). According to the IDF, Turkey has the third highest diabetes rate in Europe with a prevalence of 11.1% in 2019 (1).

The Framingham heart study indicated that the impact of parental diabetes on the development risk of diabetes in an offspring is similar to that of genetic risk. However, the role of metabolic risk factors, diet, physical activity and genetic on the risk of offspring diabetes is not adequately understood, which reflects the influence of familial factors other than genetic background.

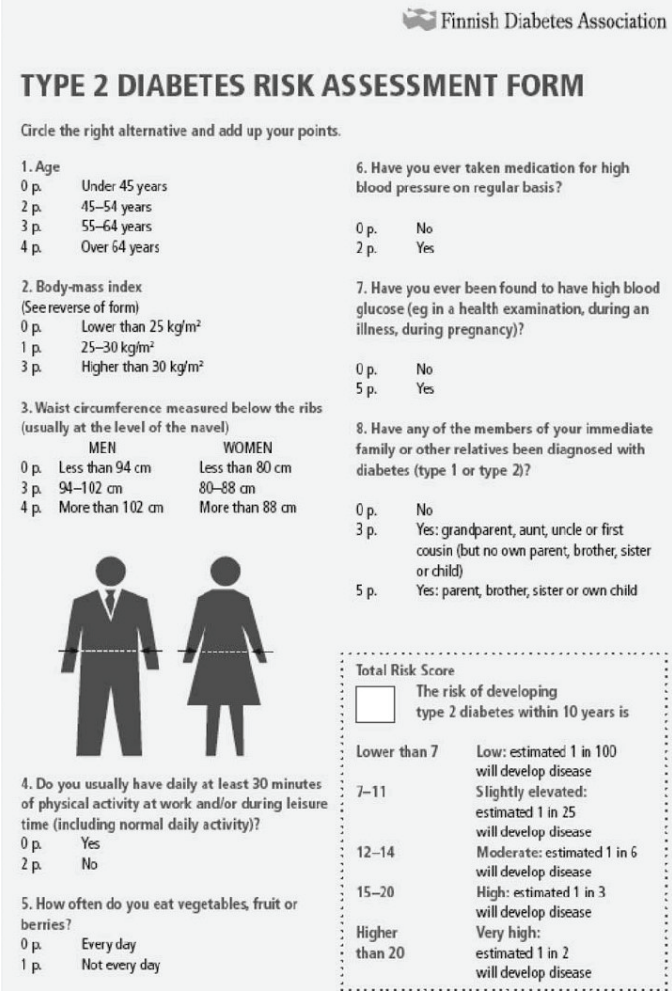
It is essential to define and manage the risk groups on an individualized basis. A two-step approach is recommended, where first a risk score is calculated, followed by confirmatory tests such as fasting blood glucose (FBG), hemoglobin A1c, and oral glucose tolerance test (2).

The Finnish diabetes risk score (FINDRISC) T2DM risk assessment form has traditionally been used as a predictor of type 2 diabetes (3). It takes into account the usual clinical characteristics, such as age, body mass index (BMI), waist circumference (WC), physical activity, dietary consumption of fruits, vegetables, and berries, use of antihypertensive medication, history of high blood glucose, and family history of diabetes. Brodovicz et al.'s (4) study showed that FINDRISC was associated with insulin sensitivity. In the Lima-Martínez et al.'s (5) study, BMI, WC, plasma insulin concentration, and HOMA-IR index were higher in the high-risk group compared to subjects in the low-moderate risk group according to the FINDRISC. FINDRISC is one of the tools referred by Turkish scholars in screening T2DM. This tool is based on demographic data, clinical information, and modifiable lifestyle factors, such as diet and physical activity, requiring no blood tests. Therefore, it is cheap and easy to apply, especially in areas where fasting glucose tests or other blood markers are not available (6).

Materials and Methods

This cross-sectional study was approved by the Local Ethics Committee of the Ethics Committee of University of Health Sciences Turkey, İstanbul Bağcılar Training and Research Hospital (IRB number: GOKAEK/2013-120). Written informed consent was provided from all participants. A total of 260 consultants and 189 residents were actively working in the hospital during the study time. Of the 449 medical doctors in the hospital, 220 were randomly (selected using the list of employees based on random numbers tables) invited to participate in the study. Two-hundred seven of the invited physicians agreed to participate in this study. Participants were asked about their medical history, and seven participants diagnosed with diabetes were excluded. The physicians with DM, hypothyroidism, malignancy, pregnancy and use of medications for hypertension and diabetes (oral antidiabetic drug or insulin) were excluded.

FINDRISC is a non-invasive screening tool to identify individuals at high risk for diabetes and pre-diabetes, and consists of eight questions. It collects data on sex, age, BMI, WC, physical activity level, daily consumption of vegetables, fruits or berries, history of antihypertensive drugs, history of increased FBG, and family history of DM (7). The primary outcome of the study was to determine FINDRISC scores (Figure 1) (8). FINDRISC scores and 10-year DM risk rates are <7 points (low) and 1%, 7-11 points (mild/slightly elevated) and 4%, 12-14 points (moderate) and 16%, 15-20 points (high) and 33%, 21-26 points (very high), and 50% (respectively) (Table 1) (9,10).



Finnish Diabetes Association

TYPE 2 DIABETES RISK ASSESSMENT FORM

Circle the right alternative and add up your points.

1. Age
0 p. Under 45 years
2 p. 45–54 years
3 p. 55–64 years
4 p. Over 64 years

2. Body-mass index
(See reverse of form)
0 p. Lower than 25 kg/m²
1 p. 25–30 kg/m²
3 p. Higher than 30 kg/m²

3. Waist circumference measured below the ribs (usually at the level of the navel)

	MEN	WOMEN
0 p.	Less than 94 cm	Less than 80 cm
3 p.	94–102 cm	80–88 cm
4 p.	More than 102 cm	More than 88 cm

4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?
0 p. Yes
2 p. No

5. How often do you eat vegetables, fruit or berries?
0 p. Every day
1 p. Not every day

6. Have you ever taken medication for high blood pressure on regular basis?
0 p. No
2 p. Yes

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?
0 p. No
5 p. Yes

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?
0 p. No
3 p. Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)
5 p. Yes: parent, brother, sister or own child

Total Risk Score
The risk of developing type 2 diabetes within 10 years is

Lower than 7	Low: estimated 1 in 100 will develop disease
7–11	Slightly elevated: estimated 1 in 25 will develop disease
12–14	Moderate: estimated 1 in 6 will develop disease
15–20	High: estimated 1 in 3 will develop disease
Higher than 20	Very high: estimated 1 in 2 will develop disease

Figure 1. Type 2 diabetes risk assessment form

Table 1. The determination of 10-year risk and risk class according to the FINDRISC score

Total FINDRISC score	10-year risk	Risk class
<7 points	1%	Low
7-11 points	4%	Slightly elevated/mild
0-14 points	1-17%	Moderate
15-20 points	33%	High
21-26 points	50%	Very high

FINDRISC: Finnish diabetes risk score

The formula is BMI=weight (kg)/height² (m²) where kg is a person's weight in kilograms and m² is his/her height in meters squared.

Additionally, demographic features were recorded, anthropometric measurements were performed and FBG and fasting insulin were tested. Blood samples were collected after 12 hours of fasting. Blood glucose was measured by the photometric method using the Siemens Advia 1800 device. The insulin levels were analyzed by the chemiluminescence immunoassay method in a Siemens Advia Centaur device. The Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) was calculated as "glucose x insulin/405" (11). Insulin resistance was defined as a HOMA-IR ≥2.5 (11).

Power analysis determined a sample size of 200 participants to reach 95% confidence interval.

Statistical Analysis

Data were analyzed using the SPSS for Windows 15.0 computer program (release 22.0; SPSS Inc. Chicago, IL, USA). Descriptive data were expressed as mean ± standard deviation. Differences between categorical variables were compared by the chi-square test. The Pearson correlation analysis was used to evaluate the correlation of variables. The combined effects of age and job category on increased FINDRISC were evaluated by performing logistic regression analysis. Based on the percentage measurement values that were observed in the literature review, the total sample size should be 200 using the G-POWER program with a 0.3 (cohen) effect size, 97.5% power and 0.05 margin of error. A p-value <0.05 was considered to be statistically significant.

Results

Data of 200 participants were analyzed. In our study, 58.0% of the participants were males. Half of the participants were residents, while the remaining were consultant physicians with more experience, but also higher working years (12).

While the BMI was below 25 kg/m² in 45 physicians, it was between 25 and 29.9 kg/m² in 117, and above 30 kg/m² in 38. High or very high WC was found in 76% of the participants. Only 11% of the participants exercised at least 30 minutes a day, and only 37.5% consumed daily vegetables and/or fruits. The rate of smoker participants was 58.0%. Of the physicians, 19.5% were previously diagnosed with high blood pressure, and 17% had been told that their blood glucose level was high or borderline. While 28% of the cases had no diabetes in their family, 47% had second-degree relatives with T2DM, and 25% had first degree relatives with DM. A total of 72% had genetic predisposition. The risk of diabetes was low in only 16.0%. On the other hand, FBG levels were below 100 mg/dL in most cases, while HOMA-IR was determined positive in 49.5% of the physicians. The proportion of moderate to very high-risk diabetes according to the FINDRISC categorization was 47.5% (Table 2).

Table 2. Descriptive findings of the study

		n	%
Age	<45 y	169	84.5
	45-54 y	29	14.5
	55-64 y	2	1.0
Body mass index (BMI) (kg/m²)	Normal <25	45	22.5
	Overweight 25-29.9	117	58.5
	Obese ≥30	38	19.0
Waist circumference (WC)	Normal (m: <94 cm, f: <80 cm)	48	24.0
	High (m: 94-102 cm, f: 80-88 cm)	99	49.5
	Very high (m: >102 cm, f: >88 cm)	53	26.5
Physically active (at least 30 min per day)	Yes	22	11.0
	No	178	89.0
Consumption of fruits and vegetables (at least one portion per day)	Every day	75	37.5
	Not every day	125	62.5
Antihypertensive treatment	No	161	80.5
	Yes	39	19.5
History of high blood glucose	No	166	83.0
	Yes	34	17.0
Family history of type 2 diabetes mellitus	No	56	28.0
	Yes (second degree-relatives)	94	47.0
	Yes (first degree-relatives)	50	25.0
FINDRISC category	Low	32	16.0
	Mild	73	36.5
	Moderate	47	23.5
	High	37	18.5
	Very high	11	5.5
Fasting blood glucose (FBG) (mg/dL)	<100	153	76.5
	100-125 (IFG)	45	22.5
	≥126	2	1.0
Insulin resistance (HOMA-IR)	Yes	99	49.5
	No	101	50.5
Daily smoking	Yes	64	32.0
	No	136	68.0

High HOMA-IR was observed in almost equal ratios of residents and consultants. However, increased HOMA-IR was significantly more common among males, people with IFG, higher BMI groups, larger WC, and participants with a history of hypertension (Table 3).

FINDRISC scores showed weak but highly significant positive correlations with insulin (r=0.278, p<0.001), glucose (r=0.256, p<0.001), and HOMA-IR (r=0.283, p<0.001) levels (Table 4, 5). There is a statistically significant relationship between fruit and vegetable consumption and FINDRISC, but not with HOMA-IR (p<0.01) (Table 6). There is a statistically significant correlation between regular exercise and FINDRISC (p<0.01) (Table 7).

The independent effects of age and job position in the FINDRISC category were evaluated by constructing a logistic regression profile, where age groups and job position were used as independent variables, which revealed that even after adjustment for age, the job position was a 2.9 fold high risk for diabetes (Table 8) (3). Consultants had significantly higher diabetes as defined by the FINDRISC categories, compared to the resident doctors (p<0.001).

Discussion

This study demonstrated significantly high diabetes risk among medical doctors in a tertiary care hospital in Turkey. As to the FINDRISC categories, 84% of the participants had mild to very high risk of DM. Furthermore, the HOMA-IR was above the threshold in almost half of the doctors. The risk of diabetes was higher among the consultants, which persisted even after controlling for age.

Multiple approaches have been recommended for population-based screening, and various risk scores have been proved to be useful for identifying high-risk populations (13). FINDRISC is an established risk prediction tool, which is widely employed in Europe with an accuracy of 85% (14).

The epidemiological data have demonstrated that hypertension and T2DM are commonly related conditions, and their concordance is expanded in populations. Hypertension affects up to 40% or more of diabetic patients (15). In our study, values of HOMA-IR were significantly different in patients with and without a history of hypertension. Our findings demonstrate that higher HOMA-IR plays a role in the development of hypertension. A 3-year follow-up study by Baghbani-Oskouei et al. (16) found that, independent of BMI and multiple variables, fasting insulin and IR index parameters were strong risk factors for the development of hypertension in normotensive healthy adults without diabetes.

Additionally, the study of Brodovicz et al. (4) has confirmed that the FINDRISC is associated with IR. Furthermore, the FINDRISC modified for Latin America significantly correlated with IR in obese subjects (5), and FINDRISC has been shown to predict impairments in insulin sensitivity and insulin secretion, the conversion to T2DM, drug-treated hypertension, cardiovascular events, as well as total

Table 3. Comparison of the studied variables according to the HOMA-IR categories

		HOMA-IR category					
		<2.5		2.5 and above			
		n	%	n	%	χ^2	p
Sex	Male	47	40.5	69	59.5	11.01	**0.001**
	Female	54	64.3	30	35.7		
Age groups	<45 y	84	52.8	75	47.2	1.68	0.194
	45 y and above	17	41.5	24	58.5		
Impaired fasting glucose (IFG)	No	90	59.2	62	40.8	19.22	**<0.001**
	Yes	11	22.9	37	77.1		
Body mass index (BMI) groups (kg/m²)	<25	36	80.0	9	20.0	28.99	**<0.001**
	25-29.9	57	48.7	60	51.3		
	≥30	8	21.1	30	78.9		
Waist circumference (WC)	Normal (m: <94 cm, f: <80 cm)	35	72.9	13	27.1	20.13	**<0.001**
	High (m: 94-102 cm, f: 80-88 cm)	51	51.5	48	48.5		
	Very high (m: >102 cm, f: >88 cm)	15	28.3	38	71.7		
Daily min. 30 m exercise	Yes	14	63.6	8	36.4	1.70	0.191
	No	87	48.9	91	51.1		
Fruit/vegetable consumption	Daily	40	53.3	35	46.7	0.38	0.535
	Not daily	61	48.8	64	51.2		
Hypertension history	No	89	55.3	72	44.7	7.54	**0.006**
	Yes	12	30.8	27	69.2		
History of high blood glucose	No	81	48.8	85	51.2	1.13	0.287
	Yes	20	58.8	14	41.2		
Family history of diabetes mellitus	No	34	60.7	22	39.3	3.68	0.158
	Yes (first degree)	20	42.6	27	57.4		
	Yes (second degree)	47	48.5	50	51.5		
Position	Resident	51	51.0	49	49.0	0.02	0.888
	Consultant	50	50.0	50	50.0		
Smoking	No	68	50.0	68	50.0	0.04	0.837
	Yes	33	51.6	31	48.4		

HOMA-IR: Homeostatic model assessment of insulin resistance

Table 4. The classification of HOMA-IR positive patients according to the FINDRISC scores

	FINDRISC scores	n	%
HOMA-IR positive patients (n=99)	Low	8	8.1
	Mild	32	32.3
	Moderate	33	33.3
	High	20	20.2
	Very high	6	6.1

Chi-square test, p<0.01, FINDRISC: Finnish diabetes risk score, HOMA-IR: Homeostatic model assessment of insulin resistance

Table 5. The classification of patients with impaired fasting glucose according to the FINDRISC scores

		Impaired fasting glucose		p
		Yes n (%)	No n (%)	
FINDRISC scores	Low	2 (4.2%)	31 (20.4%)	**0.001****
	Mild	13 (27.1%)	61 (40.1%)	
	Moderate	14 (29.2%)	35 (23.1%)	
	High	13 (27.1%)	20 (13.1%)	
	Very high	6 (12.4%)	5 (3.3%)	

Chi-square test, ** p<0.01, FINDRISC: Finnish diabetes risk score

mortality. In current study, according to FINDRISC logistic regression model created to control the independent effects of age and job position on the FINDRISC category, when the job position was used as independent variable, which revealed that even after adjustment for age, the job position was a 2.9 fold risk for high risk or T2DM. It

seems likely that age and workplace factors such as heavy working conditions may hinder optimal self-management and contribute to high risk of diabetes. While the rates of incidence increase until the age of 65 years, the incidence and prevalence levels remain constant after the age of 65 years (17).

The American Diabetes Association recommends T2DM testing from those at the age of 45 years to adults who are overweight or obese and have any risk factors for T2DM (18). The high risk (mild to very high risk of DM: 84%) and relatively young age (84.5% below 45 years) of our sample suggests that screening blood checks should be considered even at an earlier age.

Table 6. Diabetes risk and HOMA-IR relationship by fruits and vegetables intake

		Fruits and vegetables intake (consumption) (at least one portion per day)		p
		Every day	Not every day	
		n (%)	n (%)	
FINDRISC scores	Low	22 (29.3%)	11 (8.8%)	0.001**
	Mild	28 (37.3%)	46 (36.8%)	
	Moderate	17 (22.7%)	32 (25.6%)	
	High	6 (8%)	27 (21.6%)	
	Very high	2 (2.6%)	9 (7.2%)	
HOMA-IR	Yes	35 (46.7%)	64 (51.2%)	0.535
	No	40 (53.3%)	61 (48.8%)	

Chi-square test, ** p<0.01, FINDRISC: Finnish diabetes risk score, HOMA-IR: Homeostatic model assessment of insulin resistance

Table 7. Diabetes risk assessment according to exercise status

		Exercise status		p
		Yes n (%)	No n (%)	
FINDRISC scores	Low	10 (45.5%)	23 (12.9%)	0.001**
	Mild	8 (36.4%)	66 (37.2%)	
	Moderate	3 (13.6%)	46 (25.8%)	
	High	1 (4.5%)	32 (17.9%)	
	Very high	0 (0%)	11 (6.2%)	

Chi-square test, ** p<0.01, FINDRISC: Finnish diabetes risk score

Type 2 diabetes mellitus' onset in individuals develops especially during working life. The highest level of incidence is observed in the first four decades of life. Stress sources, such as job stress and working in shifts, may predispose to the development of T2DM by increased cortisol production as a result of overactivation of the hypothalamic-pituitary-adrenal axis (19).

Implementation studies have proven that lifestyle interventions followed by organized physical activity sessions combined with counseling to increase physical activity in the prevention of T2DM can be effective. Hellgren et al.'s (20) study aimed to explore the feasibility and effect of an intervention in clinical practice with isolated physical activity in individuals with IGT, recruited by the FINDRISC questionnaire. The authors showed that focusing on solitary physical activity inevitably led to changes in diet with weight loss and significant improvement of essential risk factors. The FINDRISC score was not significantly associated with physical activity in Roşescu et al.'s (21) study. Moreover, they found that patients who rarely exercised had a moderate-high risk of developing diabetes in the next ten years (21). Hamilton et al.'s (22) study showed that low physical activity compared to a sedentary lifestyle contributed to reducing the incidence of DM. Only 11% of the physicians included in our study were exercising at least 30 minutes a day, which might be the result of a busy life.

Irregular intake of vegetables and fruits, increased WC, and increased BMI were identified as leading risk factors of T2DM development. In our study, only 37.5% of the patients consumed vegetables and fruits every day. Variations in the glycemic index/glycemic load ratio of consumed vegetables and fruits did not count for the relationship of specific fruits with risk of T2DM, but the glycemic index/glycemic load ratio of fruits did not seem to be the fact that specified their relationship with T2DM.

Positive family history is another accepted risk factor for diabetes. Around 40% of people with a positive family history

Table 8. Logistic regression analysis to determine the risk of the development of diabetes

					95% CI for EXP (B)	
	B	Wald	Sig.	Exp (B)	Lower	Upper
Age groups (45 y and above vs. <45 y)	2.123	13.062	<0.001	8.355	2.642	26.418
Experience (resident vs. consultant)	1.096	10.127	0.001	2.993	1.524	5.881
Constant	0.615	4.616	0.032	1.850		

CI: Confidence interval

might have moderate to high risk for developing diabetes (23). However, although 72% (n=144) of our participants had some family history of DM, we could not demonstrate a statistically significant relationship between HOMA-IR and family history. However, studies on this subject are still unclear (24). Walker et al. (25) demonstrated that there was no association between genetic predisposition and insulin sensitivity but there was an association with insulin secretion.

According to 2019 Diabetes Atlas (1), 2 in 3 people with DM live in urban areas, and 1 in 13 adults has IGT. Our sample consisted of doctors living in an urban city in a developing country. Thus, our figures of 22.5% IFG can be regarded as relatively high. On the other hand, senior doctors had a higher risk compared to the relatively younger residents. More years spent under heavy working conditions can be a factor increasing the incidence of DM. Since the consultants have a busier work schedule and the risk persisted after adjustment for age, this finding can be attributed to work stress, which requires further verification.

Study Limitations

Our study has some limitations. This study was conducted in a single-center on a representative sample for the studied population. Although it demonstrates the diabetes-related risk of the participants, caution is warranted for generalizing the findings.

Conclusion

The FINDRISC tool can cover the need for cost-effective and evidence-based solutions to struggling with DM. Medical doctors are significantly prone to diabetes, possibly due to their lifestyles lacking exercise and regular consumption of fruits and vegetables. Strenuous, stressful, and long working hours may contribute to the increased DM risk, too. Hypertension is common among physicians with high insulin resistance, probably related to similar pathogenetic mechanisms involved in both disorders.

We suggest using FINDRISC as one of the tools used in the screening of medical doctors for diabetes in Turkey. Furthermore, projects are needed to modify the reversible diabetes risk factors among medical doctors.

Ethics

Ethics Committee Approval: The study was approved by the Ethics Committee of University of Health Sciences Turkey, İstanbul Bağcılar Training and Research Hospital (IRB number: 2013/120, date: 18 February 2013).

Informed Consent: Informed consent form (BGOF) has been signed.

Peer-review: Internally and externally peer-reviewed.

Authorship Contributions

Concept: E.S., S.Y., B.A., H.K., S.P., D.Ş., Design: E.S., S.Y., B.A., H.K., S.P., D.Ş., S.Yı., Data Collection or Processing: E.S., S.Y., B.A., H.K., D.Ş., Analysis or Interpretation: E.S., S.Y., H.K., S.P., D.Ş., Drafting Manuscript: H.K., S.Y., S.P., S.Yı., D.Ş., Final Approval and Accountability: E.S., H.K., B.A., Critical Revision of Manuscript: E.S., D.Ş., S.Yı., B.A., Writing: E.S., H.K., B.A., Supervision: E.S., S.Y., S.Yı., D.Ş.

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ORIGINAL RESEARCH

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Outcomes of Hospitalized Patients with Infective Endocarditis: A Tertiary Center Experience

Enfektif Endokardit Bulgularımız: Üçüncü Basamak Merkez Deneyimi

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Abstract

Objective: The purpose of this study is to report our experience with a comprehensive view of patients hospitalized in tertiary level center with a diagnosis of infective endocarditis (IE).

Method: Medical records of patients who were hospitalized with a diagnosis of IE between January 2017 and December 2019 were retrospectively reviewed by using hospital database. Two groups were generated as survivors and non-survivors. Surgical intervention, occurrence of complications, and in-hospital and 30-day mortality data were noted.

Results: A total of 53 patients (58.5% male) were included in this single-center retrospective study. Native valve endocarditis was more common (86.8%) and located in mitral position. Seven patients had mechanical prosthetic valve infection, those were also in mitral position. Most of the patients (92.4%) had vegetation size greater than 10 mm. Thirty-one patients (58.5%) had culture negative endocarditis while *Staphylococcus aureus* was the most common (9.4%) cultured organism. In-hospital or 30-day mortality was found 35.8%. The rate of embolism was 45.3%. Risk factors associated with mortality included advanced age, lower body mass index, being in NYHA III/IV status, development of acute renal failure and embolic phenomenon, septic shock, congestive heart failure, and presence of tricuspid regurgitation higher than moderate degree. Early valve surgery seems to improve the prognosis of IE according to our findings.

Conclusion: Advanced age, lower BMI, being in NYHA III/IV status, previous history of hypertension, presence of tricuspid valve regurgitation higher than moderate degree, occurrence of acute renal failure, embolic phenomenon, septic shock, and congestive heart failure was found as risk factors for mortality. Early valve surgery may improve prognosis of IE according to our study.

Keywords: Heart valve disease, infective endocarditis, prognosis

Öz

Amaç: Bu çalışmada, Türkiye'de üçüncü basamak bir hastanede enfektif endokardit (EE) tanısı ile yatan ve tedavi gören hastaların kapsamlı değerlendirilmesi ve mortalite ilişkili faktörlerin ortaya çıkarılması amaçlanmıştır.

Yöntem: EE tanısı ile Ocak 2017 ve Aralık 2019 tarihleri arasında hastanemize yatırılan hastaların tıbbi kayıtları hastane veri tabanı kullanılarak retrospektif olarak incelendi. Ölen ve sağ kalan olarak iki grup oluşturularak cerrahi müdahale, komplikasyon oluşumu, hastane içi ve 30 günlük mortalite verileri kaydedildi.

Bulgular: Tek merkezli bu çalışmaya retrospektif olarak toplam 53 hasta (%58,5 erkek) dahil edildi. Hastaların %86,8'i doğal kapak endokarditi olup en sık tutulan kapak mitral kapaktı. Yedi hastada protez kapak enfeksiyonu saptanmış olup, bunlar da mitral lokalizasyondaydı. Hastaların %92,4'ünde 10 mm'den büyük vejetasyon gözlendi. Otuz bir hastada (%58,5) kültür negatif endokardit bulunurken, üreme olduğunda en sık izole edilen mikroorganizma *Staphylococcus aureus* idi. Hastane içi veya 30 günlük mortalite oranı %35,8 ve emboli oranı %45,3 idi. Mortalite ile ilişkili risk faktörleri ileri yaş, düşük vücut kitle indeksi, NYHA III/IV statüsünde olma, akut böbrek yetmezliği, embolik olay gelişimi, septik şok, konjestif kalp yetmezliği ve orta dereceden fazla triküspit yetersizliği olarak tespit edildi.

Sonuç: İleri yaş, düşük vücut kitle indeksi, NYHA III/IV statüsünde olmak, önceden hipertansiyon öyküsü, orta dereceden fazla triküspit kapak yetersizliği varlığı, akut böbrek yetmezliği oluşumu, embolik olay, septik şok ve konjestif kalp yetmezliği mortalite için risk faktörleri olarak saptandı. Çalışmamıza göre erken kapak cerrahisi uygulanan hastalarda mortalite daha düşüktür ve erken cerrahi EE'nin prognozunu iyileştiriyor gibi görünmektedir.

Anahtar kelimeler: Enfektif endokardit, kalp kapak hastalığı, prognoz

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Introduction

Despite advances in diagnosis and medical/surgical treatment in cardiology, infective endocarditis (IE) is still a life-threatening condition with a mortality rate approaching 34% (1). With the decreasing incidence of rheumatic fever and advances in interventional valvular heart disease therapies, the epidemiology of IE has shifted from younger patients with rheumatic fever to older subjects with multiple diseases. While the percentage of patients newly diagnosed with IE remained the same as in the past two decades (2), ten new cases of IE were reported per 100,000 population year in the Western population (3).

Heart failure, systemic embolization, cardiogenic shock and stroke, disseminated infection, abscess formation and arrhythmias including complete heart block are well-defined complications and the type of infecting pathogen, duration of infectious state prior to therapy, accompanying comorbidities, the localization and size, and mobility of vegetation are known risk factors for complications. Antibiotic regimen, timing of surgery and management of complications have been explained in detail in the European Society of Cardiology Guidelines (4).

In this study, we aimed to describe our experience with a comprehensive view of patients hospitalized in tertiary level center with a diagnosis of IE. The primary outcome of this study was to evaluate factors associated with in-hospital and 30-day mortality in patients hospitalized with IE.

Materials and Methods

Patients who were diagnosed and hospitalized with the International Classification of Diseases code for IE (I33.0) in our tertiary center hospital between January 2017 and December 2019 were included in this retrospective study. Seventy-seven patients matched with this code were evaluated and diagnosis was made based on Duke's criteria as defined in the current guidelines (4) and 53 patients (58.5% male) who meet Duke's criteria were included. The remaining 24 patients were excluded due to lack of echocardiographic findings or unproven minor criterion. Medical records were reviewed for patients' demographic information, medical history, predisposing conditions (intravenous drug use, poor dental health, immunocompromised condition due to organ transplantation or autoimmune disease etc. and rheumatic heart disease), laboratory results, blood culture findings and clinical characteristics of endocarditis by using hospital database. Antibiotic regimen decision and timing of surgery were applied according to current guidelines in our tertiary center hospital. Surgical intervention, occurrence of complications, and in-hospital and 30-day mortality data were noted. Echocardiography views were reviewed to define the location, size, and mobility of vegetation.

This study was approved by the Ethics Committee of University of Health Sciences Turkey, İstanbul Bağcılar Training and Research Hospital was obtained (date: 05/07/2022, number: 2022/07/03/003). Human Studies and Research Committee of our institution and patient consent was waived accordingly.

Statistical Analysis

The Statistical Package for the Social Sciences 25.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Categorical data were expressed as number (n) and percentages (%). Continuous variables were expressed as mean ± standard deviation. Variables having linear correlation were evaluated by using the Pearson's correlation test and non-linear variables were evaluated by using the Spearman's correlation test. Independent variables of in-hospital and 30-day mortality were identified by using binary logistic regression analysis. The groups were compared in terms of in-hospital and 30-day mortality occurrence by the Mann-Whitney U test. The chi-square test was used to assess differences in categorical variables between groups. Significance was presumed at a 2-sided $p<0.05$.

Results

Clinical Findings

The patients with a matched code for IE were reassessed for the Duke's criteria (5) and 53 patients (58.5% male) were included in this single-center retrospective study. The mean age of patients was 56.9±16.7 years and the mean body mass index was 25.7±4.3. Diabetes mellitus (DM) was present in 24.5% of patients while hypertension (HT) was in 39.6%. There were 3 patients (5.7%) with a diagnosis of coronary artery disease (CAD), 2 (3.8%) with chronic obstructive pulmonary disease (COPD), and 2 (3.8%) with immunocompromised situation. In the study group, 5.7% of patients were current smokers. Nine (17%) patients were in atrial fibrillation rhythm. When the patients were evaluated according to the symptoms at presentation, fever (94.3%) and chills (94.3%) were the most common symptoms, followed by dyspnea (92.5%), palpitation (79.2%), syncope (26.4%), and chest pain (11.3%). Most of the patients (75.5%) were in NYHA III/IV class (Table 1).

Table 1. Demographic, clinical data of patients and complications during follow-up

Variables	All patients (n=53)	Survivors (n=34)	Non-survivors (n=19)	p
Age , years	56.9±16.7	53.3±14.9	63.6±18.1	**0.031**
Male, n (%)	31 (58.5)	21 (48.4)	10 (52.6)	0.570
Body mass index (kg/m²)	25.7±4.3	27.1±4.3	23.2±3.03	**0.001**
Smoking, n (%)	3 (5.7)	1 (33.4)	2 (66.6)	0.290
Chronic obstructive pulmonary disease, n (%)	2 (3.8)	-	2 (100)	0.124
Coronary artery disease, n (%)	3 (5.7)	2 (66.6)	1 (33.4)	0.710
Hypertension, n (%)	21 (39.6)	9 (42.8)	12 (57.1)	**0.018**
Diabetes mellitus, n (%)	13 (24.5)	7 (53.8)	6 (46.2)	0.285
Hyperlipidemia, n (%)	1 (1.9)	1 (100)	-	0.642
Chronic renal failure, n (%)	8 (15.1)	3 (37.5)	5 (62.5)	0.098
Immunsupresive condition, n (%)	2 (3.8)	-	2 (100)	0.124
Malignancy, n (%)	1 (1.9)	-	1 (100)	0.358
Atrial fibrillation, n (%)	9 (17)	4 (44.4)	5 (55.5)	0.165
Symptoms at presentation				
Chest pain, n (%)	6 (11.3)	4 (66.6)	2 (33.3)	0.634
Dyspnea, n (%)	49 (92.5)	31 (63.2)	18 (36.7)	0.547
NYHA III/IV, n (%)	40 (75.5)	21 (51.5)	19 (47.5)	**0.001**
Paipitation, n (%)	42 (79.2)	24 (51.2)	18 (42.8)	**0.036**
Fever, n (%)	50 (94.3)	31 (62)	19 (38)	0.255
Dizziness, n (%)	50 (94.3)	31 (62)	19 (38)	0.255
Syncope, n (%)	14 (26.4)	6 (42.8)	8 (57.1)	0.055
Complications				
Leaflet perforation, n (%)	10 (18.9)	8 (80)	2 (20)	0.217
Chordal rupture, n (%)	10 (18.9)	7 (70)	3 (30)	0.484
Pseudoanevrisma	6 (11.3)	6 (100)	-	**0.059**
Severe valvular dysfunction	48 (90.6)	29 (60.4)	19 (39.6)	**0.097**
Major embolic events	24 (45.3)	11 (45.8)	13 (54.2)	0.012
Renal	4 (7.5)	4 (100)	-	0.158
Cerebral	14 (26.4)	5 (35.7)	9 (64.3)	0.013
Peripheric extremity	3 (5.7)	3 (100)	-	0.250
Splenic	5 (9.4)	3 (60)	2 (40)	0.596
Acute renal failure, n (%)	10 (18.8)	2 (20)	8 (80)	**0.002**
Acute heart failure, n (%)	17 (32.07)	2 (11.7)	15 (88.2)	**<0.0001**
Septic shock, n (%)	18 (33.9)	2 (11.1)	16 (88.8)	**<0.0001**
Total length of hospital stay, n (days)	33 (22.5-84)	36.2±10.6	25.6±19.5	**0.014**
Surgery, n (%)	37 (69.8)	30 (81.1)	7 (18.9)	**<0.0001**

NYHA: New York Heart Association

Laboratory and Echocardiographic Findings

With regards to echocardiographic data, 15 patients had vegetations greater than 20 mm, 34 patients had vegetations between 10 and 20 mm in diameter and 4 had less than 10 mm. Native valve endocarditis was more common (86.8%) and vegetations were in the mitral valve position in 34 (64.2%) patients, aortic valve position in 25 (47.2%) patients, and both aortic and mitral valve positions in 9 of these patients. Seven patients have mechanical prosthetic valve infection, 6 of them were localized in mitral position and 1 patient had a bioprosthetic valve infection that was also in mitral position (Table 2).

A total of 22 (41.5%) patients had a positive blood culture pre-operatively, with *Staphylococcus aureus* being the most cultured organism (15.1%). Coagulase negative *Staphylococci* was cultured in 5 (9.4%) and group B

Streptococcus in 4 patients (7.5%). Thirty-one patients (58.5%) had culture negative endocarditis (Table 2). In-hospital or 30-day mortality was found in 35.8% (19 patients). In addition, the rate of acute renal failure was 18.8%, the rate of acute decompensated heart failure was 32.07%, and the rate of septic shock was 33.9% in this study. The localization of embolization was defined according to clinical and radiological findings. A total of 24 patients (45.3%) experienced major embolic events; fourteen patients experienced cerebral embolism while 3 patients had peripheral arterial embolism, 5 patients had splenic embolism and 4 patients had renal embolism (Table 1).

Table 2. Laboratory and echocardiographic data of patients

Variables	All patients (n=53)	Survivors (n=34)	Non-survivors (n=19)	p
Laboratory findings				
Haemoglobin (g/dL)	9.5±1.6	10.02±1.7	8.68±1.25	**0.005**
Platelet ($10^3/\mu L$)	250±139	292±115	176±150	**0.003**
White blood cell ($10^3/\mu L$)	11.7±4.6	11.4±4.9	12.3±4.2	0.526
Neutrophil ($10^3/\mu L$)	6.01±5.5	6.7±3.03	6.8±3.5	0.798
Lymphocyte ($10^3/\mu L$)	1.06 (0.12-11.92)	0.87 (0.55-7.63)	1.06 (0.12-11.92)	0.675
Creatinine (mg/dL)	0.9 (0.43-6.85)	0.92 (0.49-5.48)	0.91 (0.43-6.85)	0.697
Glomerular filtration rate (mL/dk/1.73 m^2)	95±29.02	88.8±28.7	85.9±30.3	0.375
C-reactive protein (mg/L)	107.8±74.9	86.9±58.8	145.2±86.9	**0.005**
NT-pro-BNP (ng/mL)	1473.3 (124-35000)	480 (124-18400)	19800 (9602-35000)	**<0.0001**
Erytrocite sedimentation rate	61.6±29.7	61.5±28.9	62±31.7	0.951
Procalcitonin (ng/mL)	7.58 (0.64-36.9)	0.84 (0.73-36.9)	13.2 (0.92-33.1)	**0.001**
Troponin-I (pg/mL)	38 (4-3963)	32.6 (41.-709)	57.6 (16-3963)	0.084
Blood culture analysis				
Staphylococcus aureus	8 (15.1)	2	6	
Coagulase negative *Staphyloccus*	5 (9.4)	3	2	
Streptococcus mutans	4 (7.5)	4	-	
HACEK	1 (1.9)	-	1	
Enterococcus foecallis	2 (3.8)	1	1	
Candida albicans	1 (1.9)	-	1	
Brucellacae	1 (1.9)	1	-	
Culture negative	31 (58.5)	22	9	
Echocardiographic findings				
Ejection fraction, (%)	59.1±6.7	58.2±6.7	57.8±6.9	0.862
Left ventricular end-diastolic diameter, (mm)	49.2±5.7	50.8±5.9	50.1±5.6	0.646
Left ventricular end-systolic diameter, (mm)	31.7±6.1	34.5±6.1	34.7±6.2	0.904
Left atrium, (mm)	42.4±5.1	42.2±5.6	42.7±4.2	0.736
TAPSE, (mm)	18.1±3.2	18±3.6	17.7±2.3	0.734
Effected valves, n (%)				
Native valves	46 (86.8)	30 (65.2)	16 (34.7)	0.491
Prosthetic valves	7 (13.2)			
Metalic	6 (11.3)		3 (50)	0.491
Bioprothesis	1 (1.9)	3 (50)	1 (100)	0.358
Aortic	25 (47.2)	-	9 (36)	0.604
Mitral	34 (64.2)		12 (35.3)	0.570
Aortic and mitral	13 (24.5)	16 (64)	5 (38.5)	0.536
Tricuspide	3 (5.6)	22 (64.7)	3 (100)	0.765
		8 (61.5)		
		-		
Vegetation area, (mm^2)	137 (15-686)	118 (15-686)	167 (44.1-478)	0.525
Tricuspide regurgitation (>2)	20 (37.7)	8 (40)	12 (60)	**0.007**

HACEK: *Haemophilus species, Aggregatibacter species, Cardiobacterium hominis, Eikenella* corrodens, and *Kingella* species; NT-proBNP: N-terminal prohormone of brain natriuretic peptide; TAPSE: Tricuspid annular plane systolic excursion

Findings According to Mortality

We further divided 53 patients into survivor and non-survivor groups. Both groups were similar in terms of gender, smoking, DM, immunocompromised condition, COPD, CAD, CRF, and history of malignancy. However, age and HT were significantly higher in the non-survivor group (63.6±18.1 vs. 53.3±14.9, p=0.031; 57.1% vs. 42.8%, p=0.018, respectively). Moreover, body mass index was significantly lower in the non-survivor group (23.2±3.03 vs. 27.1±4.3, p=0.001). The presence of tricuspid regurgitation higher than moderate degree was also higher in the non-survivor group (60% vs. 40%; p=0.007). In terms of laboratory markers, NT-pro-BNP [19800 (9602-35000) vs. 480 (124-18400); p<0.0001], C-reactive protein (CRP) (145.2±86.9 vs. 86.9±58.8; p=0.005), procalcitonin [13.2 (0.92-33.1) vs. 0.84 (0.73-36.9); p=0.001] were significantly higher and hemoglobin (8.68±1.25 vs. 10.02±1.7; p=0.005), platelet counts (176718.4±150446.7 vs. 292344.1±115628; p=0.003) were significantly lower in the non-survivor group. Furthermore, acute renal failure (80% vs. 20%, p=0.002), major embolic events (54.2% vs. 45.8%, p=0.012), decompensated heart failure (88.2% vs. 11.7%, p<0.0001), and septic shock (88.8% vs. 11.1%, p<0.0001) occurred more common in the non-survivor group. When major embolic events were detailed, it was observed that cerebral embolism (64.3% vs. 35.7%, p=0.013) was significantly higher. According to treatment data, 81.1% of patients in the survivors and 18.9% of non-survivors underwent surgery (p<0.0001). Early surgery was performed within 1-6 days of hospitalization to prevent embolism, heart failure and uncontrolled infection. Patients with high risk of surgery (e.g., high intracranial bleeding risk in patients with cerebral embolism or patients in septic shock) did not undergo early surgery. Laboratory and clinical data of the groups are presented in detail in Tables 1, 2.

Discussion

This study was designed to evaluate hospitalized patients with a diagnosis of IE in our institution. Several features were identified that are compatible with previous literature. Risk factors associated with mortality were advanced age, lower BMI, being in NYHA III/IV status, previous history of HT, occurrence of acute renal failure, embolic phenomenon (especially cerebral embolism), septic shock, congestive heart failure, and presence of tricuspid valve regurgitation higher than moderate degree. Regarding laboratory markers, higher NT-proBNP, CRP, procalcitonin values and lower hemoglobin and platelet counts were detected as associated factors with mortality. Early valve surgery may improve the prognosis of IE according to our findings.

According to blood culture results, *Staphylococcus aureus* was the most common cultured organism (15.1%). Our patients were usually referred from other clinics and the blood cultures were taken under antibiotic treatment. This resulted as high prevalence (58.5%) of negative blood culture in our study. *Staphylococcus aureus* is also the most common organism in IE patients in the literature; however, microbiologic shift to *Streptococcus* and HACEK (*Haemophilus* species, *Aggregatibacter* species, *Cardiobacterium hominis, Eikenella corrodens* and *Kingella*) organisms was reported (6,7).

There are conflicting data regarding early surgery in the literature. In a randomized study, early surgery was shown to significantly reduce morbidity and embolic events especially in patients with large left-sided lesions (>10 mm), whereas some studies have failed to show survival benefit of early surgery with native valve endocarditis (8-10). Another indication for early surgery is uncontrolled infection. This was supported by several retrospective cohort studies showing that locally aggressive infection was associated with a higher mortality rate (11,12). Early surgery is recommended for patients with heart failure and high-risk lesions to prevent embolization and for those with uncontrolled infection according to current guidelines (4). The presence of congestive heart failure has been defined as the most consistent predictor of mortality in previous studies (13,14). Congestive heart failure was found to be an independent predictor of mortality in our study, as well. In our analysis, mortality was significantly lower in patients who underwent surgery in the acute phase of endocarditis. The incidence of embolic events was 33% and the brain was the most common embolism site (15). Similarly, embolic events were found to be significantly associated with mortality; however, they were not defined as independent predictors of mortality. We detected a higher rate of embolism (45.3%) and the most common embolism site was the brain due to the impairment in the middle cerebral artery and its branches. Haemorrhagic transformation occurred in 5 patients (35.7%) and surgery was postponed. The high rate of embolic complications may be explained via relatively larger vegetation size, since 92.4% of patients had a vegetation size greater than 10 mm according to our echocardiographic findings. History of hypertension, presence of syncope, occurrence of congestive heart failure during the disease course, higher erythrocyte sedimentation rate and procalcitonin levels

were documented to be associated risk factors with embolic events.

Patients with comorbidities, history of valvular heart disease or mechanical heart valve, being underwent more invasive medical procedures, less likely to undergo heart surgery and advanced age have been shown to be independent risk factors for mortality in IE (3,16,17). Advanced age was detected as a risk factor for mortality. Although, an overestimation of male gender has been reported (18), the risk of acquiring fatal IE was found similar in both genders in our study

Study Limitations

This analysis should be interpreted in terms of its retrospective design, low number of patients, and lack of long-term follow-up. However, controlled studies are not applicable due to the nature of the disease. Further statistical analyses were not performed due to small sample size and lower number of patients in subgroups. It would be more informative to compare two groups with the same level disease to define predictors of mortality; however, this could not be applied due to the small sample size.

Conclusion

The mortality and morbidity of IE remains high despite advances in treatment. Risk factors associated with mortality according to our small study group were advanced age, lower BMI, being in NYHA III/IV status, previous history of HT, presence of tricuspid valve regurgitation higher than moderate degree, occurrence of acute renal failure, embolic phenomenon (especially cerebral embolism), septic shock, and congestive heart failure. Regarding laboratory markers, higher NT-proBNP, CRP, procalcitonin values and lower hemoglobin and platelet counts were detected as the factors associated with mortality. Early valve surgery may improve the prognosis of IE according to our study.

Highlights

• The morbidity/mortality associated with IE is still high.

• Since most of the patients were referred from other clinics, clinical suspicion is essential.

• Early surgery seems to improve prognosis.

Ethics

Ethics Committee Approval: This study was approved by Ethics Committee of University of Health Sciences Turkey, İstanbul Bağcılar Training and Research Hospital was obtained (date: 05/07/2022, number: 2022/07/03/003).

Informed Consent: Patient consent waived due to retrospective design.

Peer-review: Internally and externally peer-reviewed.

Authorship Contributions

Concept: S.Ö., E.D., İ.Ş., E.O., Design: S.Ö., E.D., İ.Ş., E.O., Data Collection or Processing: S.Ö., E.D., O.İ., E.H., E.M.F., Analysis or Interpretation: S.Ö., E.D., O.İ., E.H., E.M.F., Literature Search: S.Ö., E.D., O.İ., E.H., E.M.F., Writing: S.Ö., E.D., İ.Ş., E.O.

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ORIGINAL RESEARCH

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Outcomes of Femoral Neck Fracture Surgery Compared Elective Total Hip Arthroplasty: Evaluation of 340 Patients

Elektif Total Kalça Artroplastisi ile Karşılaştırıldığında Femur Boyun Kırığı Cerrahisi Sonuçları: 340 Hastanın Değerlendirilmesi

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Abstract

Objective: This study aims to determine the frequency of total hip arthroplasty and hemiarthroplasty in patients with femoral neck fractures (FNF); and to identify whether there is a difference between patients who underwent hip arthroplasty with the diagnosis of femoral neck fracture and hip osteoarthritis in terms of demographic characteristics such as age, gender, comorbid diseases and surgical procedures, need for intensive care and mortality.

Method: This retrospective study included 340 patients who underwent hip arthroplasty in Antalya Atatürk State Hospital Clinic of Orthopaedics and Traumatology. The patients were first divided into two groups as those who underwent hip arthroplasty due to FNF and due to hip osteoarthritis, and were then compared in terms of study parameters.

Results: The mean age of patients operated on due to FNF and hip osteoarthritis was 77.2±10.7 years and 57±13.3 years, respectively. 98.3% of patients underwent unilateral hip replacement (HR) and 97.8% of them partial HR; 83.5% unilateral and 100% total HR due to FNF and hip osteoarthritis, respectively (all p<0.001). Length of hospital stay was found to be statistically significantly higher in patients operated for hip osteoarthritis (p=0.005), while the need for intensive care unit admission (p<0.001) and mortality rate (p=0.011) was higher in FNF patients.

Conclusion: Almost all of patients who underwent hip arthroplasty due to FNF received partial HR. Patients with FNFs appear to be at higher risk in terms of mortality and morbidity due to their demographic and clinical characteristics, in addition to comorbidities and also hemodynamic disorders that may occur secondary to trauma. It is, therefore, necessary to contribute to reducing morbidity and mortality by taking preoperative and postoperative precautions and maintaining careful follow-up care.

Keywords: Arthroplasty, femoral neck fractures, hip, osteoarthritis, replacement

Öz

Amaç: Bu araştırmada, femur boyun kırığı olan hastalarda total kalça artroplastisi ve hemiartroplasti tercih sıklığının belirlenmesi; femur boyun kırığı ve kalça osteoartriti tanılarıyla kalça artroplasti ameliyatı yapılan hastalar arasında yaş, cinsiyet, komorbid hastalıklar gibi demografik özellikler, yapılan cerrahi işlem ve özellikleri ile yoğun bakım ihtiyacı ve mortalite açısından bir fark olup olmadığının araştırılması amaçlanmıştır.

Yöntem: Retrospektif araştırmaya Antalya Atatürk Devlet Hastanesi Ortopedi ve Travmatoloji Kliniği'nde kalça artroplasti ameliyatı yapılan toplam 340 hasta dahil edildi. Hastalar femur boyun kırığı ve kalça osteoartriti nedeniyle kalça artroplasti ameliyatı yapılanlar olmak üzere iki gruba ayrıldı ve çalışma parametreleri açısından karşılaştırıldı.

Bulgular: Femur boyun kırığı ve kalça osteoartriti tanısıyla opere edilen hastaların yaş ortalaması sırasıyla 77,2±10,7 ve 57±13,3 yıl olarak hesaplandı. Her iki grupta da hastaların istatistiksel olarak anlamlı bir bölümünü kadınlar oluşturuyordu. Femur boyun kırığı tanısı olan hastaların %98,3'üne (p<0,001) tek taraflı ve %97,8'ine parsiyel (p<0,001); kalça osteoartriti tanısı olan hastaların %83,5'ine (p<0,001) tek taraflı ve %100'üne total (p<0,001) kalça protezi uygulandı. Hastanede yatış süresi kalça osteoartriti tanısıyla opere edilenlerde (p=0,005), yoğun bakım ihtiyacı (p<0,001) ve mortalite oranı (p=0,011) ise femur boyun kırığı tanısıyla opere edilenlerde istatistiksel olarak anlamlı düzeyde daha fazla bulundu.

Sonuç: Kliniğimizde femur boyun kırığı tanısıyla kalça artroplasti yapılan hastaların neredeyse tamamına yakınında parsiyel kalça protezi tercih edildiği saptandı. Hastaların demografik, klinik ve laboratuvar özellikleri ile eşlik eden komorbiditeler ve travmaya sekonder ortaya çıkabilecek hemodinamik bozukluklar nedeni ile femur boyun kırığı olan hastaların mortalite ve survey açısından daha fazla risk altında olduğu görülmektedir. Preoperatif ve postoperatif alınacak önlemlerle, takipte dikkatli olunarak morbidite ve mortalitenin düşürülmesine katkı sağlanmalıdır.

Anahtar kelimeler: Artroplasti, femur boyun kırıkları, kalça, kalça protezi, osteoartrit

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Introduction

Osteoarthritis (OA) is a leading cause of pain and disability, and reason for using healthcare services among adults (1). According to 2019 data, an estimated 240 million people worldwide have symptomatic and activity-limiting OA (2). After the knee, the hip is the second largest joint most commonly affected by OA (1). Several professional organizations have developed guidelines for the treatment and management of OA. In general, these guidelines recommend that patients with OA should be offered a range of non-pharmacological interventions, including relevant training, dietary weight management (for those who are overweight), and structured exercise programmes (3-7). Paracetamol, oral NSAIDs, topical NSAIDs, duloxetine, opioids, intra-articular (IA) corticosteroid, and IA hyaluronic acid are often preferred in pharmacological treatment in addition to supportive/complementary treatments in the conservative treatment of hip OA (3-7). However, surgical treatment is indicated in advanced-stage cases that have failed to respond to medical and supportive treatments. In the earlier stages, on the other hand, joint sparing procedures such as pelvic osteotomy or hip arthroscopy may be considered, depending on patients' underlying diagnosis. However, these procedures do not generally suffice in patients with severe degenerative changes. It is, therefore, of fundamental importance to consider hip resurfacing or total hip replacement (THR) options for patients with advanced joint damage (1).

Femoral neck fracture (FNF), on the other hand, is an important health condition in older age due to its frequent occurrence especially in elderly patients (accounting for approximately 3.6% of adult fractures) (8), leading to high mortality and morbidity. All over the world, hip fractures have been reported to be among the top 10 causes of disability in adults (9). Total hip arthroplasty (THA), hemiarthroplasty (HA) or internal fixation techniques can be utilized in the surgical treatment of FNFs. It is still controversial whether hip replacement should be performed in THA surgery or HA surgery for patients with FNFs (8,9). In addition to studies suggesting that THA provides better functional outcomes compared to HA in selected and active elderly patients (10), there is also evidence for clinically insignificant improvement in function and quality of life at long-term follow-up (9). However, over the years, there has been a remarkable increase in the use of THA, with significant variations across all geographical regions and locations (11).

In the relevant literature, there are studies comparing the results of THA surgery in patients with FNFs or hip OA (12-14) and the results of THA and HA surgeries in patients with FNFs (8,9,15). With the aim of drawing attention to the fact that the surveys of the patients with FNFs and hip OA may present serious differences due to different demographic and clinical characteristics, this study attempted to investigate whether there was a difference in terms of the demographic characteristics such as age, gender, and comorbidities of the patients who underwent surgeries due to two different indications, as well as the surgical procedures and their features, the need for intensive care and mortality among such patients, and to determine the preferences for either THA or HA surgery in patients with FNFs.

Materials and Methods

Study Design and Participants

The population of the retrospective study consisted of 381 patients who underwent hip arthroplasty surgery in Antalya Atatürk State Hospital at the Orthopedics and Traumatology Clinic between 2017 and 2020. The patients who underwent revision hip arthroplasty and patients with missing data were excluded from the study, which continued with 340 patients.

The patients were divided into 2 groups as those who underwent hip arthroplasty surgery for FNFs and those who underwent elective THA due to hip OA, and were compared in terms of study parameters.

Data Collection and Laboratory Measurements

Demographic characteristics such as age and gender, as well as comorbidities, clinical features, treatment and outcome data of the patients in the study sample were obtained from electronic medical records and patients' surgery notes.

Ethical Approval

Prior to the study, necessary ethical approval was obtained from the Clinical Research Ethics Committee of University of Health Sciences Turkey, Antalya Training and Research Hospital with the decision number 16/2 dated 25 August 2022. The study was conducted in accordance with the Declaration of Helsinki.

Statistical Analysis

Statistical analysis was made using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY, USA). The Shapiro-Wilk test was used to test the normality of the data. Descriptive analyses were presented using mean ± standard deviation, median (IQR) or n (%), when appropriate.

Categorical data were analyzed by the Pearson's chi-squared or Fisher's Exact test. The Mann-Whitney U test and Student's t-test were used for the analysis of non-normally and normally distributed numerical data, respectively. Two-sided p-value less than 0.05 was considered statistically significant.

Results

The mean age of the patients who underwent hip arthroplasty due to FNFs was 77.2±10.7 years, and the mean age was 57±13.3 years in those operated on due to hip OA (p<0.001). Women accounted for a significantly higher proportion in OA group than FNF group (p=0.016). Comorbid diseases were found to be statistically significantly more common in patients who underwent surgery due to FNFs (p<0.001). The most common comorbidities were hypertension (HT), cardiovascular diseases, and diabetes mellitus (DM) in patients who were operated on due to FNFs, whereas such comorbidities included DM, HT and chronic kidney failure in patients who underwent arthroplasty due to hip OA. In addition, anemia was found to accompany 63.6% of the patients who underwent hip arthroplasty due to FNFs and 36.7% of them who underwent surgery due to hip OA (p<0.001) (Table 1).

Of all the patients who underwent hip arthroplasty due to FNFs, it was clear that the preferred surgical procedure was HA (p<0.001) for 97.8% of them, while it was unilateral surgery for 98.3% (p<0.001). On the other hand, 83.5% (p<0.001) of them who underwent surgery due to hip OA received a unilateral procedure, whereas 100% (p<0.001) of them underwent total unilateral hip replacement. The cementless fixation technique was used in 99.1% of the patients who were operated on due to hip OA and the cemented fixation technique in 68% of those who underwent arthroplasty due to FNFs (p<0.001). The length of hospital stay was statistically significant in patients operated on due to hip OA (p=0.005), and likewise, the need for ICU admission (p<0.001) as well as in-hospital (p=0.011) and 1-year (p<0.001) mortality rates in patients operated on due to FNFs were statistically significant (Table 2).

Table 1. Comparison of demographic characteristics of patients with hip arthroplastysurgery due to FNFs and hip OA

Variables	Patients with hip arthroplasty due to FNFs (n=231)	Patients with hip arthroplasty due to hip OA (n=109)	p-values
Age (years)	77.2±10.7	57±13.3	**<0.001**
Female	77.1±10.6	57.1±13.7	**<0.001**
Male	77.4±10.9	56.9±12.4	**<0.001**
Gender			
Female	141 (61)	81 (74.3)	**0.016**
Male	90 (39)	28 (25.7)	
Comorbidities	209 (90.5)	50 (45.9)	**<0.001**
HT	113 (48.9)	8 (7.3)	**<0.001**
DM	44 (19)	12 (11)	**0.062**
CVD	59 (25.5)	1 (0.9)	**<0.001**
COPD	20 (8.7)	1 (0.9)	**0.012**
CRF	13 (5.6)	2 (1.8)	**0.191**
Anemia	147 (63.6)	40 (36.7)	**<0.001**

Results are presented as mean ± standard deviation, median (interquartile range) or n (%). Student's t-test, Mann-Whitney U test, Pearson chi-square test. FNF: Femoral neck fracture, OA: Osteoarthritis, HT: Hypertension, DM: Diabetes mellitus, CVD: Cardiovascular diseases, COPD: Chronic obstructive pulmonary disease, CRF: Chronic renal failure

Discussion

It was revealed that HA was the preferred surgical procedure in almost all of the patients with FNFs who underwent hip arthroplasty surgery in our clinic, with the length of hospital stay being statistically significantly higher in the patients who were operated on due to hip OA, while the need for

Table 2. Comparison of follow-up and treatment characteristics of patients with hiparthroplasty surgery due to FNFs and hip OA

Variables	Patients with hip arthroplasty due to FNFs (n=231)	Patients with hip arthroplasty due to hip OA (n=109)	p-values
Body side			
Unilateral	227 (98.3)	91 (83.5)	**<0.001**
Bilateral	4 (1.7)	18 (16.5)	
Partial/total			
Partial	226 (97.8)	0 (0)	**<0.001**
Total	5 (2.2)	109 (100)	
Use of cement			
Cementless	74 (32)	108 (99.1)	**<0.001**
Cemented	157 (68)	1 (0.9)	
Length of hospital stay	4 (3-6)	7 (6-10)	**<0.001**
Ward only	6 (4-10)	7 (6-10)	**0.005**
Ward + ICU	3 (3-5)	3 (3-3)	0.213
ICU admission	135 (58.4)	7 (6.4)	**<0.001**
Length of ICU stay	1 (1-1)	1 (1-1)	0.174
In-hospital mortality	16 (6.9)	0 (0)	**0.011**
1-year mortality	42 (18.18)	1 (0.92)	**<0.001**

Results are presented as mean ± standard deviation, median (interquartile range) or n (%). Student's t-test, Mann-Whitney U test, Pearson chi-square test. FNF: Femoral neck fracture, OA: Osteoarthritis, ICU: Intensive care unit

ICU admission and mortality rates were statistically higher in patients operated on due to FNFs.

In the literature, there are studies comparing the results of THA in patients with FNFs or hip OA (12,13) and the results of THA and HA in patients with FNFs (8,9,14). With the aim of emphasizing the fact that the surveys of the patients with FNFs and hip OA may present notable differences depending on different demographic and clinical characteristics, this study attempted to investigate whether there was a statistical significance in terms of the demographic characteristics such as age, gender, and comorbidities of the patients who underwent surgeries due to two different indications, as well as the surgical procedures and their features, the need for intensive care and mortality among such patients, and to determine the preferences for either THA or HA surgery in patients with FNFs.

The results of our study regarding the surgical procedure used in patients with FNFs undergoing hip arthroplasty indicated that THA was much less preferred in our clinic when compared to the results reported in the literature. For example, a study examining the variations in treatment choices for patients with FNFs over the years by utilizing the data obtained from the American Board of Orthopaedic Surgery database and evaluating approximately 20,000 FNF cases reported that the THA preference rate, which was 0.7% in 1999, increased to 7.7% in 2011, and that the rate of preference for HA decreased from 67.1% to 63.1% in the same period. In the same study, the remaining part of the rates belonged to the internal fixation technique (15). Gausden et al. (10) also investigated the contemporary reasons for any THA failures in patients with FNFs and followed those with FNF who underwent arthroplasty for an average of 6 years between 2000 and 2017. In that study, THA was reported to be the preferred technique for 9.6% of the patients who underwent hip arthroplasty due to FNFs, whereas it was HA in 91.4% of them in the same period (10). Although we neither examined the variations in treatment choices in FNF patients over the years, nor included any patients who underwent internal fixation technique in our study, it was found that the rate of THA among patients who underwent hip arthroplasty was lower than what was reported in the literature, with a rate of 2.2%. The tendency of orthopedic surgeons to shorten the operation time, the poor general condition of patients, and the faster provision of medical supplies for partial prosthesis due to the fact that patients are operated under emergency conditions can be considered as the factors influencing the preference of HA as a surgical procedure in patients with FNFs in our clinic, when compared to the literature. As reported by Li and Luo (8) in their review, we also agree that many aspects such as the age of the patients, whether or not they have osteoporosis, the type of FNF preoperative reduction, and the needs of the patient should be taken into account in the selection of surgical methods for FNFs in elderly patients in our clinic.

In one of the studies comparing the early postoperative results of patients who underwent THA for FNFs and hip OA, Charette et al. (16) evaluated the 2008-2016 database of the American National Surgical Quality Improvement Program, and reported an increased risk of postoperative complications, such as increased mortality and major morbidity, re-operation, prolonged operative time, increased length of hospital stay, and reduced likelihood of being discharged home in the patients who underwent THA due to FNFs compared to those operated due to OA. Another study comparing the patients, who underwent THA surgery due to FNFs and hip OA diagnoses, by evaluating a very large series reported that perioperative mortality and pulmonary embolism rates were statistically significantly higher in the group operated due to FNFs (17). Likewise, another review of a large patient series reported that the prevalence of complications was 3 times higher in a group of trauma patients and, unlike our study, the duration of hospital stay was found to be longer in those operated due to FNFs. The same study mentioned that patients with FNFs, in general, were an extremely fragile group of patients requiring additional perioperative and postoperative care (12). Due to the small number of patients who underwent THA due to FNFs in our study, we could not make a statistically significant comparison of their results with those of the patients who underwent THA due to hip OA; nevertheless, we found that 2 (of 5 patients) (40%) of the patients who underwent THA due to FNFs developed the need for ICU hospitalization, yet without any in- hospital or one-year mortality, and that 7 (6.4%) of the patients (109 patients) who underwent THA due to hip OA required ICU admission, yet with no mortality rates. Still, as mentioned earlier, the number of patients who underwent THA due to FNFs in our clinic was only 5 (2.2%), which does not allow a sound statistical evaluation.

Moreover, the study of Yoo et al. (18), evaluating more than 6,000 FNF patients who underwent HA, reported mortality rates of 3.08% in the 65-79 age group, and 5.28% in the 80-99 age group. In the same study, the length of hospital stay was found to be 35.08 (±37.72) days in the 65-79 age

group, and 35.33 (±36.98) days in the 80-99 age group (18). The study of Chammout et al. (19) focusing on the results of primary HA in elderly patients with cognitive dysfunction and displaced FNFs reported the one-year mortality rate as quite high as 31%. It was also mentioned in the same study that at least one third of patients with hip fractures had impaired cognitive status at levels that could complicate their postoperative rehabilitation, emphasizing that this condition would result in inadequate rehabilitation when observed in all patients included in their study (19). In our study, in-hospital mortality rate was 2.65% and one-year mortality rate was 18.58% in all age groups of 226 FNF patients with a mean age of 77 (minimum: 49, maximum: 99) years, who underwent HA, whereas the average length of hospital stay was 5.59 days, which is quite low compared to the results reported in the literature.

The most similar study to ours in general was the one conducted by Le Manach et al. (20) in France, with nearly 700,000 patients from 864 medical centers. In that study, a relatively larger proportion of patients who underwent elective total hip replacement (THR) were male compared to those who underwent hip fracture surgery, and that they had developed less comorbidity. The study further reported that ICU admission was 1.28% after hip fracture surgery and 0.37% after elective THR, with the in-hospital mortality rate being 3.42% after hip fracture surgery and 0.18% after elective THR (20). Our study found that a statistically significant proportion of patients who underwent both hip fracture surgery and elective THR surgery were women. In addition, similar to the study of Le Manach et al. (20), our study revealed that comorbid diseases were found to be statistically significantly more common in patients who underwent hip fracture surgery compared to those who underwent elective THR surgery. In our study, on the other hand, the rate of ICU stay was 58.4% after hip fracture surgery, 6.4% after elective THR, while the in-hospital mortality rate was found to be 2.59% and 0%, respectively. The reason why the mortality rate was generally found to be quite low compared to the literature may be that especially advanced elderly FNF patients with comorbidities were followed in the ICU on the 1st post-operative day, and of course, all patients in need were followed up in the ICU for as long as necessary, which also explains the high ICU hospitalization rates.

In the practical application of the Anesthesia and Reanimation Clinic in our hospital, ICU follow-up after FNF has become almost standard. We believe that this practice significantly reduces the in-hospital mortality rate compared to the literature. This is a result that can be obtained as a suggestion from our research. This can be considered as one of the strengths of our research. On the other hand, the number of studies conducted to determine HA and THA preference rates in FNF cases is limited in our country. In this sense, we believe that our research will contribute to the literature. And this is another strength of our research.

Study Limitations

The fact that HA was preferred in almost all of the FNF patients in our clinic did not allow for a statistically sound comparison between THA and HA in terms of parameters such as hospital stay, ICU admission rate, and mortality rate, which is considered as one of the important limitations of our study.

Conclusion

In our clinic, it was determined that partial hip replacement was the preferred surgical procedure for almost all patients who underwent hip arthroplasty due to FNFs. Although partial and THR surgeries performed for FNF and hip OA indications are similar in terms of operation techniques and endoprostheses used, it is believed that patients with FNFs are more at risk in terms of mortality and survey because of the demographic, clinical and laboratory characteristics of the patients, accompanying comorbidities, and hemodynamic disorders that may occur secondary to trauma. Therefore, regardless of any indication and/or technique, every patient who has undergone hip arthroplasty should be evaluated as a whole, and careful follow-up should contribute to reducing morbidity and mortality along with preoperative and postoperative measures such as anemia treatment as well as blood pressure/blood sugar regulation.

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Ethics

Ethics Committee Approval: The ethical approval for the study was obtained from the University of Health Sciences Turkey, Antalya Training and Research Hospital, Clinical Research Ethics Committee with the decision number 16/2 dated 25 August 2022.

Informed Consent: Since it was a retrospective file scanning study, informed consent was not obtained from the patients.

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ORIGINAL RESEARCH

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Increased Serum Met-enkephalin Level in Patients with Intrahepatic Cholestasis of Pregnancy

Gebeliğin İntrahepatik Kolestazı Olan Hastalarda Artmış Serum Met-enkefalin Seviyesi

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Abstract

Objective: To evaluate met-enkephalin levels in women with intrahepatic cholestasis of pregnancy (ICP) by comparison to healthy controls and to compare the pregnancy outcomes.

Method: This cross-sectional study was conducted in 43 pregnant women with ICP and 40 randomly selected healthy pregnant women, who formed the control group. Serum met-enkephalin concentrations were measured using an enzyme-linked immunosorbent assay. The patients' age, body mass index (BMI), gestational week, fasting serum bile acid, serum parameters, birth week, and APGAR scores at 1st and 5th minutes were recorded.

Results: Maternal age, BMI and gestational age at blood sampling were similar between the two groups. Considering the pregnancy outcomes, birth week was significantly lower in the ICP group than in the control group (37 vs. 38 weeks, respectively; p<0.001). The median met-enkephalin level was significantly higher in the ICP group compared to the control group (273 vs. 121.5, respectively; p<0.001). A significant negative correlation was observed between met-enkephalin level and birth week (r=-0.33; p=0.002). The area under the curve was 91% for the cut-off point 145 of met-enkephalin (p<0.001). The specificity and sensitivity were 77.5% and 79%, respectively. A significant effect of met-enkephalin on the diagnosis of cholestasis was observed (odds ratio: 1.01, p<0.001, 95% confidence interval: 1.007-1.02)

Conclusion: Serum met-enkephalin levels were increased in patients with gestational cholestasis compared to healthy controls. Based on this, opioid receptor antagonists may be a promising treatment alternative.

Keywords: Bile acids, cholestasis, opioid, pregnancy, pruritus

Öz

Amaç: Gebeliğin intrahepatik kolestazı (GİK) olan gebelerde serum met-enkefalin düzeylerini sağlıklı kontrollerle karşılaştırarak değerlendirmek ve gebelik sonuçlarını karşılaştırmaktır.

Yöntem: Bu kesitsel çalışma, GİK 43 gebe ve kontrol grubunu oluşturan rastgele seçilmiş 40 sağlıklı gebe ile yürütüldü. Serum met-enkefalin konsantrasyonları, enzime bağlı immünosorbent testi kullanılarak ölçüldü. Hastaların yaşı, vücut kitle indeksi (VKİ), gebelik haftası, açlık serum safra asidi, serum parametreleri, doğum haftası, 1. ve 5. dakika APGAR skorları kaydedildi.

Bulgular: Anne yaşı, VKİ ve gebelik yaşı iki grup arasında benzerdi. Gebelik sonuçları dikkate alındığında, doğum haftası GİK grubunda kontrol grubuna göre anlamlı olarak daha düşüktü (sırasıyla 37 ve 38 hafta; p<0,001). Medyan met-enkefalin düzeyi, kontrol grubuna kıyasla kolestaz grubunda anlamlı olarak daha yüksekti (sırasıyla 273'e 121,5; p<0,001). Met-enkefalin düzeyi ile doğum haftası arasında anlamlı negatif korelasyon gözlendi (r=-0,33; p=0,002). Met-enkefalinin kesme noktası 145 için eğri altında kalan alan %91 idi (p<0,001). Özgüllük ve duyarlılık sırasıyla %77,5 ve %79 idi. Met-enkefalin düzeyinin kolestaz tanısı koymada anlamlı etkisi gözlendi (olasılık oranı: 1,01, p<0,001, %95 güven aralığı: 1,007-1,02).

Sonuç: Serum Met-enkefalin düzeyi gebelik kolestazı olan hastalarda sağlıklı kontrollere göre anlamlı olarak artmış izlenmiştir. Buna dayanarak, Met-enkefalin gestasyonel kolestaz tanısında yeni bir belirteç olarak düşünülebilir ve ayrıca opioid reseptör antagonistleri umut verici bir tedavi alternatifi olabilir.

Anahtar kelimeler: Gebelik, kaşıntı, kolestaz, opioid, safra asitleri

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Introduction

Intrahepatic cholestasis of pregnancy (ICP) is defined as the presence of gestational pruritus along with increased serum bile acids and aminotransferase levels, which are observed through the second or third trimester of pregnancy (1). The incidence of ICP is reported as 0.1-2% in all pregnant women worldwide, and it can be complicated by an increased risk of preterm labor, fetal distress, meconium-stained amniotic fluid, fetal bradycardia, and sudden fetal demise (2,3). A variety of factors such as genetic, ethnic, deteriorations in the hepatocellular transport cycles, hormonal factors, and environmental contributors are accused in the pathogenesis of the disease (4).

Since it may complicate pregnancies, there are still no reliable markers to predict the risk of ICP. The maternal serum bile acid level above 40 µmol/L is the most commonly preferred marker used in the prediction of obstetrical outcomes so far (5). Aside from bile acid levels, pregnancy-associated plasma protein-A (PAPP-A), aspartate aminotransferase (AST) to platelet ratio, and oxidative markers, and inflammatory molecules have been investigated to predict early onset of ICP (4-6).

The etiology of ICP is still unclear and it was reported that increased levels of endogenous opioid met-enkephalin could cause cholestasis in the general population (7). The pentapeptide met-enkephalin is known as an inhibitory growth factor that has functions in cell development, tissue renewal, wound healing, angiogenesis, and inhibition of DNA synthesis in fetal cells (8). Chronic exposure to met-enkephalin could also cause detrimental effects on pregnancy outcomes and it could harm brain, kidney, liver, and lung functions (8). To date, no studies have evaluated the relationship between met-enkephalin levels and pregnancies complicated with ICP.

This study aimed to evaluate met-enkephalin levels in women with ICP by comparison to healthy controls.

Materials and Methods

This cross-sectional study was carried out in 83 pregnant women between March 2021 and September 2021 at a tertiary referral center. University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital Ethics Committee's approval was obtained before the study was undertaken (2021/171). Helsinki guidelines regarding ethical considerations on human subjects were followed. Informed consent was obtained from all of the participants.

Maternal demographic and clinical features, laboratory parameters, serum met-enkephalin levels, and delivery outcomes of the participants were recorded. All patients were evaluated with a complete obstetric examination and transabdominal ultrasound.

For the study group, the diagnosis of ICP in a pregnant woman was based on the clinical presentation of widespread itching involving palms and soles without rash, accompanied by either elevated serum liver enzymes and/or elevated serum TBA levels (>10 µmol/L) in the absence of other possible etiologies (9). Any patients with hematological or liver disorders, viral hepatitis, autoimmune diseases, malignancy, dermatological pathology, medications affecting liver enzymes and bile acids, risk factors for preeclampsia or gestational diabetes, and patients with a history of poor obstetric outcomes were excluded.

Age, gestational week and body mass index (BMI)- matched healthy pregnant women were included as healthy controls. All patients with complete clinical follow-up data were recruited into the study.

Met-enkephalin Measurement

Venous blood samples were obtained from the antecubital vein of the patients after overnight fasting period. The samples were kept for 2 hours at room temperature at 2-8 °C before centrifugation for 15 min at 1000×g. The supernatant was stored at -80 °C until use. The serum concentration of met-enkephalin was evaluated by the enzyme-linked immunosorbent assay (ELISA) technique using an ELISA kit (Cat no: E-EL-0020) purchased from Elabscience (USA) following the manufacturer's instructions and were expressed in pg/mL. The detection range was 125.00-8000 pg/mL for met-enkephalin and coefficient of variation was <10%.

Statistical Analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). The Shapiro Wilk test was used to evaluate the distribution of the continuous data. Descriptive data were expressed in median and interquartile ranges. The Mann-Whitney U test was used to compare the quantitative data of control and ICP groups. The Spearman correlation analysis was performed to assess the relationship between met-enkephalin levels and age, BMI, bile acid level, and birth week.

The optimal cut-off value of the met-enkephalin to detect ICP was determined using receiver operating characteristic (ROC) curves and Youden's index. A logistic regression

analysis was performed to assess the adjusted effect of met-enkephalin on ICP. A value of p<0.05 was considered statistically significant.

Results

Fourty-three women with ICP and 40 healthy pregnant control were involved in the study. The median age of the patients was 30.5 years in the control group, whereas it was 29 years in the ICP group and no significant difference was observed between the two groups. As expected, serum AST, alanine aminotransferase, total bilirubin, and bile acid levels were significantly higher in the ICP group compared to the control group (p<0.05 for all comparisons). However, no significant difference was observed regarding the gestational week, BMI and GGT levels between the study and control groups. The median met-enkephalin level was significantly higher in the ICP group compared to the control group (273 pg/mL vs. 121.5 pg/mL, respectively; p<0.001).

Considering the obstetric outcomes, the birth week was significantly lower in the ICP group than in the control group (37 vs. 38 weeks, respectively; p<0.001). No significant difference was observed regarding 1st and 5th minutes APGAR scores between the study groups (Table 1).

Table 1. Comparison of control and ICP groups regarding basic characteristic, laboratory parameters and fetal outcomes

	Control (n=40)	ICP (n=43)	p-value
	Median (IQR)	Median (IQR)	
Age (years)	30.5 (6)	29 (16)	0.58
Gravidity	3 (1.75)	2 (2)	**<0.001**
Parity	1.5 (1)	0 (1)	**<0.001**
BMI (kg/m²)	27.2 (2.3)	28.9 (5.1)	0.16
Gestational week	33 (4.75)	3 3(6)	0.53
AST (IU/L)	24.5 (8)	93 (118)	**<0.001**
ALT (IU/L)	35 (10.75)	159 (192)	**<0.001**
GGT (IU/L)	29 (10.75)	3 1(8)	0.65
Total bilirubin (mg/dL)	0.55 (0.3)	1.1 (0.5)	**<0.001**
Bile acid (μmol/L)	4 (2.75)	40 (31)	**<0.001**
Birth week	38 (1)	37 (2)	**<0.001**
APGAR 1 min	7 (1.75)	7 (1)	0.55
AGGAR 5 min	9 (1.5)	9 (1)	0.48
Met-enkephalin (pg/mL)	121.5 (36)	273 (247)	**<0.001**

IQR: Interquartile range, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, BMI: Body mass index, ICP: Intrahepatic cholestasis of pregnancy

A significant positive correlation was observed between met-enkephalin level and BMI (r=0.3; p=0.005). On the other hand, a significant negative correlation was observed between met-enkephalin level and birth week (r=-0.33; p=0.002) (Table 2).

ROC analysis revealed an AUC of 91% for the cut-off point 145 pg/mL of met-enkephalin (p<0.001). The specificity and sensitivity were 77.5% and 79%, respectively (Figure 1, Table 3).

Since BMI had a significant correlation with met-enkephalin levels, we further performed a logistic regression analysis to achieve the adjusted effect of met-enkephalin. A significant effect of met-enkephalin on ICP was observed (odds ratio: 1.01, p<0.001, 95% confidence interval: 1.007-1.02) (Table 4).

Discussion

This study revealed that met-enkephalin could increase in patients with ICP compared to controls. A cut-off level above 145 pg/mL could be used in the diagnosis of ICP.

The opioid peptide levels and opioidergic neurotransmission are increased in cases with cholestasis and pruritus (10,11). Besides, increased plasma met-enkephalin level was considered as a predictor of reduced survival marker in patients with primary biliary cirrhosis (7). These findings confirmed the relationship between opioid peptides and the pruritus of cholestasis (12). In experimental cholestasis models, it was reported that met-enkephalin immunoreactivity could be observed in the liver tissue, particularly in cholangiocytes (10). Moreover, the administration of opioid receptor antagonists such as naloxone and nalmefene to patients with primary biliary cirrhosis improved plasma bilirubin levels (7). In our study, at the same line with the previously reported studies, significantly increased met-enkephalin levels were detected in patients suffering ICP compared to controls. We may speculate that met-enkephalin could be associated with pruritus and increased risk of cholestasis due to the effect on the hepatobiliary system.

Previous studies also tried to find out a marker to predict ICP in early stages of gestation. Tolunay et al. (4) evaluated AST to platelet ratio index (APRI) for that purpose. They revealed a sensitivity of 86.5% and specificity of 77.3% for an optimal cut-off value of 0.57. The authors concluded that a liver-specific enzyme to platelet ratio could be used to determine ICP from blood tests obtained in the first trimester (4). Another study evaluated- serum Tyrosine (Y), Lysine (K),

Table 2. Spearman correlation analysis of met-enkephalin and age, BMI, bile acid, and birth week

	Age (years)		BMI (kg/m²)		Bile acid (µmol/L)		Birth week	
	r	p	r	p	r	p	r	p
Met-enkephalin (pg/mL)	-0.02	0.98	0.3	**0.005**	0.61	**<0.001**	-0.33	**0.002**

BMI: Body mass index

Table 3. ROC analysis of met-enkephalin levels in prediction of ICP

	AUC	Specificity	Sensitivity	PPV	NPV	LR+	LR-	p-value	95% CI	
									Lower	Upper
Met-enkephalin (145 pg/mL)	91%	77.5%	79%	21%	77%	3.5	0.3	**<0.01**	85%	96%

ROC: Receiver operating characteristic, ICP: Intrahepatic cholestasis of pregnancy, AUC: Area under the curve, CI: Confidence interval

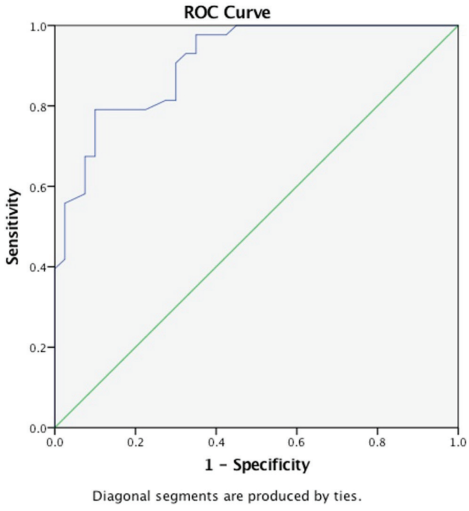

Figure 1. ROC analysis of met-encephalin levels in prediction of ICP

ROC: Receiver operating characteristic, ICP: Intrahepatic cholestasis of pregnancy

Table 4. Logistic regression analysis of met-enkephalin levels and cholestasis considering BMI levels

	B	p-value	Exp (B)	95% CI	
				Lower	Upper
BMI (kg/m²)	0.11	0.33	1.1	0.9	1.3
Met-enkephalin (pg/mL)	0.01	**<0.001**	1.01	1.007	1.02

Constant (-5.72). BMI: Body mass index, CI: Confidence interval

and Leucine (L)- YKL-40 levels in pregnant women with ICP and concluded that YKL-40 levels were significantly higher with a 40% sensitivity and 93% specificity for serum YKL-40 concentration of 84.80 ng/mL (13). The studies focusing on inflammatory and immunological theories also investigated pro-inflammatory cytokines (14,15) and found increased levels of IL-6 and IL-17 in patients with ICP (13). Moreover, the lipid peroxidation markers such as Gpx and plasma 8-iso-PGF2α level were also investigated (6). Hu et al. (6) reported that lower levels of these markers could be used in predicting the risk of perinatal complications. Regarding the studies mentioned above, inflammation and oxidative processes could be accused in ICP pathogenesis. Still, no utilization of these markers is yet available in clinical practice, and these theories are far away from explaining the pruritus seen in ICP.

Another issue of concern in ICP is poor obstetric outcomes and postnatal complications (16,17). A meta-analysis evaluating ICP and its relationship with adverse perinatal risks showed that an increased risk could be observed when bile acids were over 40 µmol/L (18). However, another study concluded that the threshold of bile acids should be 100 µmol/L to predict poor prenatal outcomes. The authors concluded that different levels could be associated with various methods in the analysis (1). The postnatal complications include sweating and fever, decreased sleep periods, jaundice, sepsis, seizures, increased muscle tone, continuous high-pitched crying, gastrointestinal dysfunction, vomiting, and sudden death (18). There was no significant difference regarding 1st and 5th minutes of APGAR scores between ICP and control groups in our study. However, the birth week was significantly less in the ICP group compared to the control group. The risk of increased fetal demise or poor obstetric outcomes could lead the obstetricians to early induce labor.

Study Limitations

The limitation of our study is its small sample size and the lack of more comprehensive follow-up data. However, this is the first study in the literature including a prospective cohort of age-matched pregnant women with and without ICP. Although the OR is too close to the upper confidence interval level; there is still a prominent significant P value. This is probably related to the significant difference in the big gap of met-enkephalin levels and the distribution

of the met-enkephalin levels at the upper border of the confidence interval in the study group. The area under curve 91% clarifies that our results are promising in the diagnosis of ICP.

Conclusion

Met-enkephalin could increase patients with ICP compared to controls, and opioid receptor antagonists may be a promising treatment alternative. However, our study findings need to be confirmed in larger populations from different ethnicities.

Ethics

Ethics Committee Approval: Ethics approval to carry out the study was provided by Clinical Research Ethics Committee of University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital, (date: 15.03.2021, no: 2021.06.47, protocol :2021/171).

Informed Consent: Informed consent was obtained from all of the participants.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Concept: S.S.Ç., Design: S.S.Ç., Data Collection or Processing: M.E., Analysis or Interpretation: M.E., Final Approval and Accountability: M.E., Drafting Manuscript: S.S.Ç., Critical Revision of Manuscript: S.S.Ç., M.E., Writing: S.S.Ç., M.E.

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ORIGINAL RESEARCH

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Evaluation of the Effects of Ondansetron Administration in the ERAS Protocol on Regional Anesthesia in Cesarean Surgeries: A Prospective Randomized Study

Sezaryen Ameliyatlarında ERAS Protokolünde Ondansetron Uygulamasının Rejyonal Anestezi Üzerine Etkilerinin Değerlendirilmesi: Prospektif Randomize Bir Çalışma

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Abstract

Objective: The enhanced recovery after surgery protocol has been applied more frequently in cesarean surgeries, and regional anesthesia is the first choice because of its postoperative advantages. Hypotension and bradycardia are common side effects of spinal anesthesia. Bezold Jarisch reflex, which occurs by the stimulation of 5-HT3 receptors, is thought to be effective. This study was planned as a prospective randomized study to investigate the effect of ondansetron, a 5-HT3 receptor antagonist, on hemodynamics in pregnant women undergoing cesarean section under spinal anesthesia.

Method: Seventy-eight pregnant women scheduled for elective cesarean section with spinal anesthesia were included in the study. Patients were randomly divided into two groups; group 1 (n=38) received ondansetron 4 mg intravenously before spinal anesthesia, and group 2 (n=40) did not receive ondansetron. Blood pressure, peak heart rate, and vasopressor requirements were evaluated in both groups.

Results: The reductions in the mean arterial pressure were significantly lower in group 2 than in group 1 at 2 and 4 minutes (p<0.05). Patients in group 1 had a lower need for vasopressors (p=0.001) and a significantly lower incidence of nausea and vomiting (p=0.01).

Conclusion: When ondansetron was used before spinal anesthesia in pregnant women undergoing elective cesarean section, hemodynamics were more stable, vasopressor use was reduced, and nausea and vomiting were reported to be less.

Keywords: ERAS, nausea, ondansetron, spinal anesthesia, vomiting

Öz

Amaç: Cerrahi sonrası hızlandırılmış iyileşme protokolü sezaryen ameliyatlarında daha sık uygulanmaya başlanmış olup, postoperatif avantajlarından dolayı rejyonel anestezi ilk tercihtir. Spinal anestezinin yan etkileri arasında hipotansiyon ve bradikardi sık görülmektedir. 5-HT3 reseptörlerinin uyarılmasıyla meydana gelen Bezold Jarisch refleksinin etkili olduğu düşünülmektedir. Bu çalışma spinal anestezi altında sezaryen yapılan gebelerde 5-HT3 reseptör antagonisti olan ondansetron uygulamasının hemodinamiye etkisini araştırmak amacıyla planlanmıştır.

Yöntem: Spinal anestezi ile elektif sezaryen planlanan 78 gebe çalışmaya dahil edildi. Hastalar rastgele iki gruba ayrılarak; spinal anesteziden önce grup 1 (n=38) 4 mg intravenöz ondansetron almış, grup 2 (n=40) ise ondansetron almamıştır. Her iki gruptaki hastaların kan basıncı, kalp tepe atımı ve vazopressör gereksinimleri değerlendirilmiştir.

Bulgular: Ortalama arter basıncındaki düşüşler grup 2'de 2. ve 4. dakikalarda grup 1'e göre anlamlı olarak daha düşüktü (p<0,05). Grup 1'deki hastaların vazopressör ihtiyacı (p=0,001) ve bulantı- kusma insidansı anlamlı olarak daha düşüktü (p=0,01).

Sonuç: Elektif sezaryen uygulanan gebelerde spinal anestezi öncesi ondansetron kullanıldığında hemodinami daha stabil olup, vazopressör kullanımı azalmış ve bulantı-kusmanın daha az olduğu görülmüştür.

Anahtar kelimeler: ERAS, kan basıncı, kusma, ondansetron, spinal anestezi

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Introduction

The enhanced recovery after surgery (ERAS) is a standardized care program that includes preoperative, intraoperative and postoperative processes in colorectal, urological, gynecological and hepatobiliary surgery. ERAS has been shown to reduce the length of hospital stay, complications, readmissions, and cost (1). ERAS protocol is more frequently preferred in elective cesarean deliveries, which is one of the surgical procedures (2). According to this protocol, in planned births, follow-up is started between 10 and 20 weeks of gestation, while trying to optimize patient comorbidities. In unplanned or emergency situations, it is appropriate within 30-60 minutes of birth (3). This protocol involves preoperative thromboprophylaxis, antibiotic prophylaxis, ensuring perioperative fluid balance and normothermia, preventing postoperative nausea, early removal of urinary catheters, and effective pain relief (4). Thus, regional anesthesia in cesarean sections is preferred because it provides many advantages such as easier patient management, safety and low cost compared to general anesthesia in cesarean section surgeries (5).

In spinal anesthesia, hypotension may develop due to a decrease in systemic vascular resistance (SVR) and cardiac output due to sympathetic blockade (6,7). Hypotension is observed more frequently, especially in obstetric patients (8). Mechanisms causing hypotension include sympatholysis and the Bezold-Jarisch reflex (BJR). As a result of sympatholysis, venous return flow to the right atrium decreases and "5-hydroxytryptamine3" sensitive (5-HT3, serotonin) chemoreceptors (Bezold-Jarisch reflex) in the heart wall are stimulated. Vasodilatation, bradycardia and hypotension occur due to the release of serotonin (9-11). There are many studies evaluating 5-HT3 receptor antagonists to prevent spinal anesthesia-induced hypotension. Some studies have shown that administering a 5-HT3 receptor antagonist (ondansetron) before spinal anesthesia limits the decrease in blood pressure due to spinal anesthesia and reduces the incidence of hypotension (11-15). In a study by Chooi et al. (16), ondansetron administration was more effective in preventing hypotension and bradycardia requiring treatment.

Our study aimed to evaluate the effect of ondansetron (5-HT3 receptor antagonist) administration on hemodynamics before spinal anesthesia in elective cesarean deliveries.

Materials and Methods

After Ethics Committee approval of the University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital (protocol no: 2019/523, date: 09.12.2019) was obtained, a total of 80 patients aged 18-45 years in the American Society of Anesthesiologists (ASA) II anesthesia risk group, who agreed to undergo cesarean section with spinal anesthesia between December 2019 and April 2020, were included in this study. The study was planned in accordance with the Helsinki Declaration. Written informed consent was obtained from all patients prior to the enrollment in the study. Type I error level (alpha level) was 0.2, number of patients per group was taken as 23 to obtain a statistical power of 80%. The number of patients was considered as 40 to add to the possibility of their possible separation. We created two patient groups of the same size according to the treatment: Group 1 (ondansetron group) and group 2 (ondansetron-free group). Patients above ASA III, those who were pregnant before 32 weeks of gestation, those who did not accept spinal anesthesia, and those who were randomized to general anesthesia perioperatively were excluded from the study. Two patients were excluded because they were switched to general anesthesia perioperatively. Patients included in the study were routinely given a supine position in the operation room according to the ASA standard, and heart rate (HR), pulse oximetry (SpO_2), and non-invasive blood pressure monitoring were provided. All patients were preloaded with 5 mL/kg^{-1} crystalloid solution. Group 1 received 4 mg ondansetron intravenous (IV) push. After being positioned in a sitting position, the patient was positioned in a supine position after hyperbaric bupivacaine + 10 µg fentanyl was administered in a total volume of 2 mL-2.5 mL (according to the patient's height) at a rate of 10 seconds following CSF inflow with a 25 G Quinke-type needle through the L3-L4 or L4-L5 interspinous space. A roller was placed under the pregnant woman's thigh for the left lateral decubitus position. The T6 dermatome block level was confirmed before the skin incision. Perioperative mean blood pressure below 60 mmHg or more than a 25% decrease from baseline was considered hypotension. If the heart rate dropped below 55 beats/min-1, 0.5 mg atropine IV was administered. IV ephedrine was administered to patients who developed hypotension. Demographic data of the patients, the total amount of fluids, ephedrine and oxytocin administered perioperatively, and atropine and methylazine requirements were recorded. Peak heart rate (HR) and mean blood pressure (MAP) values were recorded at the beginning of spinal anesthesia (T1), 2^{nd} (T2), 4^{th} (T3), 6^{th} (T4), 8^{th} (T5), 10^{th} (T6), 15^{th} (T7) higher at the end of the operation were discharged to the outpatient clinic.

Statistical Analysis

Analyses were performed using NCSS 11 (Number Cruncher Statistical System, 2017 Statistical Software). In our study, frequency and percentage values were given for the variables. Mean, standard deviation, median, minimum and maximum values were given for continuous variables. The normal distribution test of continuous variables was performed with the Kolmogorov-Smirnov test. The chi-square analysis was used for the relationships between categorical variables. Categorical variables were assessed with the Fisher's Exact test and Fisher-Freeman-Halton test when appropriate.

Independent sample t-test was used to compare two groups in continuous independent variables with normal distribution. The Mann-Whitney U test was used in the comparison of two independent groups for the variables that did not meet the assumption of normal distribution. For dependent variables that did not have normal distribution, the Wilcoxon signed-rank test was employed for comparisons between two groups. $P<0.05$ was considered statistically significant.

Results

Seventy-eight patients who underwent cesarean section under spinal anesthesia were included in the study. They were divided into the Ondansetron-treated group (group 1, n=38) and the ondansetron-free group (group 2, n=40).

Demographic data of the patients, duration of operation, the total amount of fluid, ephedrine and oxytocin are given in Table 1. The mean age of the patients was 29.1±4.8/29.6±5.7 years (group 1/group 2). ASA score, body mass index, perioperative bleeding and the total amount of fluid were similar in both groups. In group 2, the used amount of oxytocin and ephedrine was higher, and the operation time was longer ($p<0.05$) (Table 1). Nausea and vomiting were observed less in group 1 ($p<0.05$). Both groups had no statistically significant difference in atropine use and methylation requirement (Table 1). The patients' heart rates were similar in both groups (Figure 1). When the mean blood pressure was evaluated, it was statistically significantly lower in group 2 at 2nd and 4th minutes. The mean blood pressures of the patients before the spinal procedure (beginning) and at the end of the operation (ending) were similar (Figure 2).

Discussion

In this study, hypotension and nausea-vomiting were less common, and perioperative hemodynamics were more stable in the ondansetron group in patients undergoing cesarean section under spinal anesthesia. The used amount of ephedrine was also less than in the control group.

Hypotension due to peripheral vasodilation is common in cesarean surgeries performed with spinal anesthesia. Many studies investigate the effect of 5 HT-3 receptor antagonists on hypotension. Causes of hypotension include decreased SVR due to sympathetic blockade and BJR. As a result

Table 1. Comparison of group 1 (ondansetron) and group 2 (ondansetron free) among demographic data of patients, duration of operation, amount of fluid and medication used perioperatively

	Group 1 n (38)	Group 2 n (40)	p
Age	29.1±4.8	29.6±5.7	0.6
ASA n (%)			
II	31 (81.6)	32 (80)	0.86
III	7 (18.4)	8 (20)	
BMI, kg.m^2	32.4±2.9	32.8±2.8	0.89
Presence of nausea and vomiting	5 (13.2)	15 (37.5)	**0.01**
Amount of bleeding (mL)	545.5±79.5	551.2±76.3	0.67
Fluid intake, mL	1378±78.9	1908±543	0.3
Amount of oxytocin, unite	31.5±0.8	36.7±1.4	**0.004**
Amount of ephedrine, mg	5.4±1.19	12.6±1.4	**0.001**
Duration of operation, min	50 (28-85)	55 (30-86)	**0.02**
Atropine use	1 (2.6)	5 (12.5)	0.1
Methylergonovine use	3 (7.9)	8 (20)	0.12

Categorical variables were shown as numbers (%). Numerical variables with normal distribution were shown as mean ± standard deviation. Numerical variables that do not show normal distribution are shown as median (minimum-maximum). $p<0.05$ shows statistical significance, BMI: Body mass index, ASA: American Society of Anesthesiologists

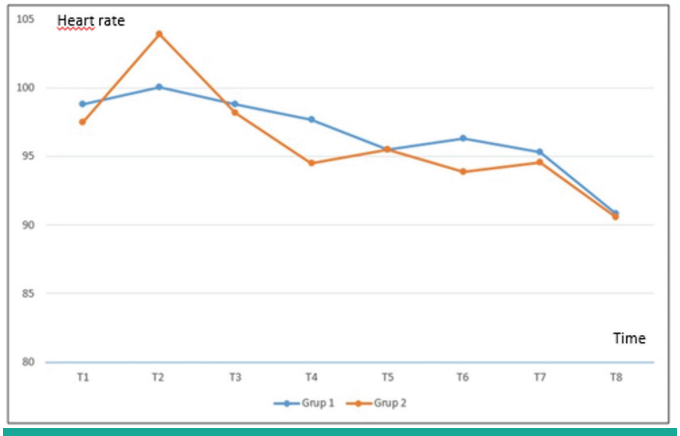

Figure 1. Comparison of perioperative heart rate

T1: The beginning of spinal anesthesia, T2: 2nd heart rate, T3: 4th heart rate, T4: 6th heart rate, T58th heart rate, T6: 10th heart rate, T7: 15th heart rate and T8: The end of the operation

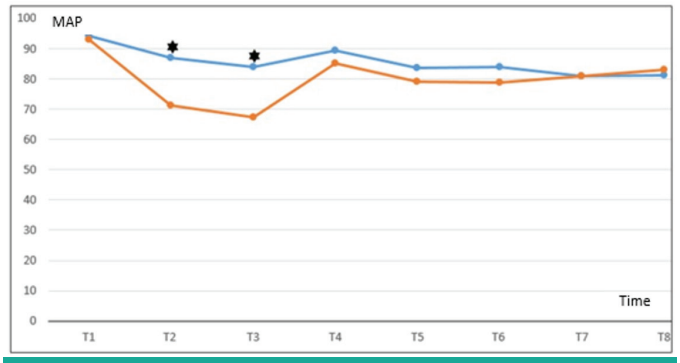

Figure 2. Comparison of perioperative mean arterial pressure (MAP)

T1: The beginning of spinal anesthesia, T2: 2nd heart rate, T3: 4th heart rate, T4: 6th heart rate, T58th heart rate, T6: 10th heart rate, T7: 15th heart rate minutes and T8: The end of the operation

of stimulation of chemoreceptors (5-HT3, serotonin) in the heart wall with a decreased venous return to the right heart, BJR is activated; vasodilatation, bradycardia and hypotension occur (5). Accordingly, ondansetron is thought to inhibit BJR by binding to 5HT-3 receptors and preventing hypotension (6,7). There are studies suggesting that prophylactic ondansetron reduces hypotension and vasopressor use (8-13), and our results are similar to these studies. However, studies also support that ondansetron does not affect the risk of hypotension (14,15). Therefore, the mechanism by which ondansetron causes the observed effects on hypotension and vasopressor requirement is not fully understood.

Due to hypotension, uterine blood flow decreases and fetomaternal circulation is disrupted (11). Ephedrine, an alpha and beta agonist in treating hypotension related to neuraxial anesthesia, is preferred in obstetric anesthesia because it increases uterine blood flow (17). Thus, the side effects of hypotension are prevented by maintaining uterine blood flow. We believe that uteroplacental blood flow was well preserved in the ondansetron group, in which the requirement of hypotension and vasopressor (ephedrine) were less.

Prevention of nausea-vomiting in the ERAS protocol is essential for patient satisfaction, recovery and early discharge (1,15,16). In spinal anesthesia, cerebral blood flow decreases due to hypotension, and the vomiting center is stimulated, splanchnic blood flow decreases and serotonin release from the gastrointestinal system increases. Accordingly, nausea and vomiting are frequently observed (17). In cesarean deliveries, intraoperative nausea-vomiting increases with perioperative antibiotic use, pain, uterotonic drug use, removal of the uterine outside the abdomen and peritoneal irrigation in addition to hypotension due to spinal anesthesia (18,19). In addition, hypotension may trigger nausea and vomiting and may pose serious risks for the mother (loss of consciousness, pulmonary aspiration) and the baby (hypoxia, acidosis, neurologic damage) (20). Studies have shown less nausea and vomiting with perioperative ondansetron use in cesarean surgeries (21,22). Our study also supports the findings.

Study Limitations

The limitation of this study is that a fixed dose of ondansetron was used. Borgeat et al. (23) compared the effect of different doses of ondansetron on hypotension. Another limitation of our study is that only ondansetron was used among the 5 HT-3 receptor antagonists. Many studies evaluated the effects of ondansetron and granisetron on hemodynamics, and different results were found (13,24,25). Therefore, further studies with larger samples and different 5HT3 receptor antagonists are needed.

According to a Cochrane study, IV fluid loading, IV ephedrine or phenylephrine administration in caesarian sections have been shown to reduce spina anesthesia-related hypotension (26). However, studies have reported that prophylactic IV ondansetron effectively reduces the incidence of hypotension and vasopressor need due to spinal anesthesia in pregnant women undergoing cesarean section, and may even be an effective alternative to ephedrine (24,27,28).

Conclusion

We believe that ondansetron administration will be beneficial in preventing hypotension and nausea due to spinal anesthesia's effect and decrease the need for vasopressors in cesarean deliveries.

Ethics

Ethics Committee Approval: After Ethics Committee approval of the University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital (protocol no: 2019/523, date: 09.12.2019) was obtained.

Informed Consent: Written informed consent was obtained from all patients in this study prior to the enrollment in the study.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: N.A., Concept: N.A., Design: N.A., P.K.E., İ.P., Data Collection or Processing: N.A., D.A.,

P.K.E., Analysis or Interpretation: N.A., D.A., P.K.E., Literature Search: N.A., D.A., İ.P., Writing: N.A., D.A., İ.P.

Conflict of Interest: No conflict of interest was declared by the authors.

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CASE REPORT

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Giant Pulmonary Abscess After COVID-19 Pneumonia: A Case Report

COVID-19 Pnömonisi Sonrası Dev Pulmoner Apse: Olgu Sunumu

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Abstract

The Coronavirus disease-2019 (COVID-19) in children is more likely to be asymptomatic or to have mild-to-moderate symptoms; however, severe cases have also been reported. A 10-year-old boy previously diagnosed with pontocerebellar hypoplasia presented with respiratory distress after 2 days of fever. He underwent tracheal intubation. He was COVID-19 positive. On day 10, a cystic area was observed in his chest radiography and thorax computer tomography also showed a thick-walled pulmonary abscess. Percutaneous empyema drainage was performed. On day 20, an open surgical tracheotomy was performed. On day 25, the percutaneous drainage catheter was removed. On day 55, he was discharged on the home ventilator and his chest radiography was normal. Children with COVID-19 may develop a pulmonary abscess secondary to superinfections during intensive care follow-up.

Keywords: Child, COVID-19, pulmonary abscess, superinfections

Öz

Çocukların Koronavirüs hastalığı-2019 (COVID-19) asemptomatik, hafif veya şiddette hastalık olarak geçirme olasılığı daha yüksektir, ancak ciddi olgular da bildirilmektedir. Daha önce bilinen pontoserebellar hipoplazi tanısı olan 10 yaşında erkek hasta iki günlük ateş sonrası solunum sıkıntısı ile başvurdu. Solunum sıkıntısı nedeniyle entübe edildi. COVID-19 pozitifti. On gün sonra çekilen akciğer grafisinde kistik bir alan gözlendi ve toraks bilgisayarlı tomografisinde kalın duvarlı bir akciğer apsesi görüldü. Perkütan ampiyem drenajı yapıldı. Bu çalışmada COVID-19 pozitif çocukların yoğun bakım takibi sırasında süperenfeksiyonlara sekonder akciğer apsesi gelişebileceğini bildirmek istedik.

Anahtar kelimeler: Akciğer apsesi, COVID-19, çocuk, süperenfeksiyon

Introduction

Severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) causes Coronavirus disease-2019 (COVID-19) and has caused substantial morbidity and mortality in adults. Although children with COVID-19 are more likely to be asymptomatic or have a mild to moderate disease course, severe cases were reported (1). Here, we present a child who had a pulmonary abscess associated with superinfection after COVID-19 pneumonia.

Case Report

A 10-year-old boy, previously diagnosed with pontocerebellar hypoplasia, developed bilateral femoral fractures after falling off. His both legs were placed in a cast and he was discharged on the same day. Two days later, he presented with respiratory distress and fever ongoing since discharge. He was transferred to our pediatric intensive care unit due to his worsening dyspnea/hypoxia and underwent tracheal intubation. On physical examination,

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he was unconscious and in poor general condition. His blood pressure was 102/63 mmHg, heart rate was 142/min, body temperature was 38 °C, SpO_2 was 79%, and respiratory rate was 25/min. Chest examination revealed a reduced chest expansion, bilateral widespread crackles, and decreased breath sounds. His chest X-ray and computed tomography (CT) revealed diffuse ground-glass opacity bilaterally and peripheral zone consolidation (Figure 1). SARS-CoV-2 reverse transcription-polymerase chain reaction (RT-PCR) was positive on the nasopharyngeal swab. Laboratory parameters are shown in Table 1. Favipiravir, ceftriaxone, and azithromycin were initiated. He also received intravenous immunoglobulin (immunoglobulin G: 300 mg/dL) therapy. He required invasive mechanical ventilation for 10 days. On day 10, a cystic area was observed on his chest X-ray and thorax CT revealed a thick-walled pulmonary abscess accompanied by a consolidation and atelectasis zone in the lower lobe of the right lung (Figure 1). Percutaneous empyema drainage was performed by interventional radiology. His antimicrobial treatment was switched to vancomycin, meropenem, metronidazole, and liposome amphotericin B. On day 20 of intubation, an open surgical tracheotomy was performed. All of the bacterial cultures (hemocultures, tracheal aspirate, urine, and abscess drainage fluid), aspergillus serology, and antigen were negative. On day 25, the percutaneous drainage catheter was removed. On day 55, he was discharged on the home ventilator and his chest radiography was normal. The written informed consent to publication has been obtained from the parents on behalf of the patient.

Discussion

We presented a 10-year-old boy who developed a pulmonary abscess that had an air-fluid level, associated with superinfection after COVID-19 pneumonia. Our patient was immobilized and had poor oral hygiene. Superinfections and

Table 1. Serial laboratory results of the patient

Variables	HD 1	HD3	HD 6	HD 8	HD 10	HD 12	HD 14	HD 16	HD 18	HD 20	HD 24	HD 28
White blood cell count, $\times10^3/\mu L$	25.2	4.63	10.3	12.1	15.7	28.2	11.1	11.6	7.7	13.3	13.7	8.2
Neutrophil, $\times10^3/\mu L$	20.5	8.7	7.5	8.3	11.6	23.4	6.6	7.6	3.6	6.7	7.9	4.9
Lymphocyte, $\times10^3/\mu L$	2.7	3.9	1.3	2.4	3.7	2.4	3.4	2.8	2.9	4.3	3.1	1.8
Hemoglobulin, g/dL	9.5	9.8	11.1	12.4	12.4	11.4	8.1	9.3	8.9	9.8	7.2	10.9
Platelets, $\times10^3/\mu L$	219	137	136	178	310	512	380	332	391	330	125	174
Glucose, mg/dL	235	115	172	116	108	107	70	337	80	65	86	89
BUN, mg/dL	6	8	27	17	25	18	16	12	17	23	18	9
Creatinine, mg/dL	0.13	0.11	0.27	0.16	0.22	0.18	0.13	0.29	0.15	0.29	0.1	0.1
Total bilirubin, mg/dL	0.24	0.91	3.08	1.96	0.98	1.4	0.78	0.58	0.66	0.53	0.57	0.81
AST, U/L	66	89	101	197	145	134	118	112	140	316	149	106
ALT, U/L	129	77	84	67	43	40	36	33	35	82	47	30
Uric acid, mg/dL	5	6.7	8.8	2	3.9	4.2	5.2	5.7	7.8	8.5	7.1	2.4
CK, U/L	119	1496	768	48	48	165	52	83	57	41	46	47
ALP, U/L	150	67	69	110	82	114	136	156	160	261	140	121
LDH, U/L	482	646	1990	1277	1414	1294	733	649	539	667	650	752
Sodium, mmol/L	140	149	148	148	151	149	160	153	160	142	142	138
Potassium, mmol/L	2.9	3.2	4.3	3.85	4.2	2.9	4.17	6.85	3.00	3.67	4.46	2.7
Total protein, g/dL	5.2	6.5	8.7	7.4	7.5	7.6	5.5	5.1	6.1	6.3	5.1	5.3
Albumin, g/dL	3.1	4.8	3.6	3.2	3.4	3.9	2.8	2.5	3.4	3.4	2.7	3.2
CRP, mg/L	117	209	475	153	54	84	116	114	93	67	102	128
Pro-Calcitonin, ng/mL	0.7	2.3	25.9	10.1	6.8	1.5	0.8	0.6	0.3	0.7	0.7	1.7
PT, sec	26.3	19.1	18.9	17.7	16.7	16.1	16.3	17.9	15.9	15.3	-	15.2
PT INR	2.1	1.5	1.5	1.4	1.3	1.3	1.3	1.4	1.2	1.2	-	1.2
aPTT, sec	42.3	36.6	39.8	39.6	42	36.5	36.8	43.4	42.9	44.3	-	40.4
D-dimer, µg/mL (FEU)	1.0	0.85	3.93	-	-	5.26	3.18	2.95	2.82	-	-	-

CPR: C-reactive protein, aPTT: Activated partial thromboplastin time, INR: International normalized ratio, LDH: Lactate dehydrogenase, AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, FEU: Fibrinogen equivalent units, CK: Creatine kinase, BUN: Blood urea nitrogen, HD: Hospital day

co-infections have been reported associated with COVID-19 during the pandemic. The study by Garcia-Vidal et al. (2) described the epidemiology and outcome of co-infections and superinfections accompanying hospitalized patients with COVID-19. In this study, co-infection with COVID-19 was uncommon and mainly related to bacterial infections. The most common bacteria isolated were *S. pneumoniae* and *S. aureus*. Although superinfections were rare, they had a worse outcome. The most frequently isolated bacteria were *P. aeruginosa* and *E. coli*. Our patient received antibiotic therapy in the pediatric intensive care unit admission; therefore, we did not isolate a pathogenic bacterium.

Renaud-Picard et al. (3) reported a 59-year-old woman with a pulmonary abscess. The case was the only COVID-19-associated pulmonary abscess reported in the literature so far. This case developed a pulmonary abscess while she was SARS-CoV-2 RT-PCR negative on nasopharyngeal swab on admission and 24 days later. Our patient developed a giant pulmonary abscess on day 10 of hospitalization while SARS-CoV-2 RT-PCR was still positive. Abscesses occurring in different regions have been reported during the COVID-19 pandemic (4,5). We think that our case report holds significance since it is the first child in the literature to have a pulmonary abscess linked to COVID-19.

We observed a superinfection of COVID-19 pneumonia. The reason for the development of a pulmonary abscess in our patient may be inadequate oral care and low immunoglobulin levels. The widespread use of antibiotics in COVID-19 pneumonia may exacerbate antimicrobial resistance and may increase morbidity and mortality.

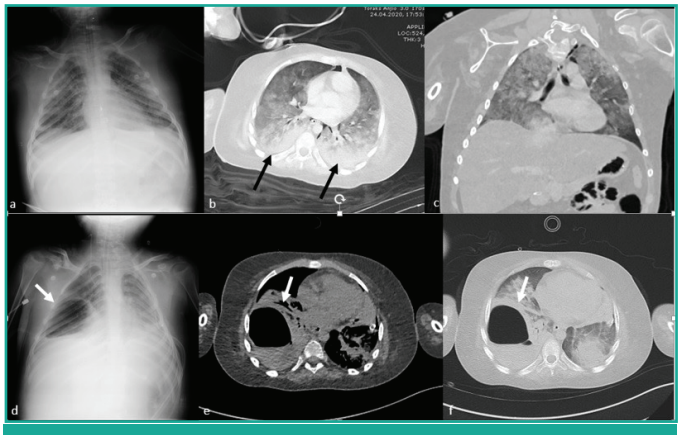

Figure 1. Increased widespread density in both lungs was observed in the chest X-ray (a). In Thorax CT, consolidation was more pronounced at the bases and diffuse ground-glass densities were detected in both lungs (b,c). Ten days later, a thick-walled cavitary lesion in the middle-lower zone of the right lung was observed in PA chest X-ray (d). Thorax CT examination: A thick-walled pulmonary abscess accompanied by consolidation and atelectasis was observed in the lower lobe of the right lung (e,f)

CT: Computed tomography

Ethics

Informed Consent: The written informed consent to publication has been obtained from the parents.

Peer-review: Internally and externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: N.A., A.İ.S., M.O., Concept: N.A., M.E.M., A.İ.S., M.O., F.B.P., Design: N.A., M.E.M., A.İ.S., E.Ş., Data Collection or Processing: N.A., M.O., E.Ş., Analysis or Interpretation: N.A., M.E.M., F.B.P., Literature Search: N.A., F.B.P., Writing: N.A., E.Ş.

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Main Points

- This case highlights that superinfection, although rare, can cause a giant pulmonary abscess that may develop after a Coronavirus disease-2019 (COVID-19) infection.
- The widespread use of antibiotics in COVID-19 pneumonia may exacerbate antimicrobial resistance and may increase morbidity and mortality
- We recommend following precautions for infection control and reviewing factors that may cause superinfection.

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CASE REPORT

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A Rare Case of McCune-Albright Syndrome in Association with Acromegaly: Treatment Options and a Review of the Literature

Akromegali ile İlişkili Nadir Bir McCune-Albright Sendromu Olgusu: Tedavi Seçenekleri ve Literatürün Gözden Geçirilmesi

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Abstract

McCune-Albright syndrome constitutes of fibrous dysplasia, café-au-lait macules, and various endocrinopathies such as thyroid, cortisol, prolactin and growth hormone hypersecretion. Growth hormone excess as a manifestation of endocrine hyperfunction is uncommon. We present a case of McCune-Albright syndrome with compressive optic neuropathy due to fibrous dysplasia and acromegaly which was resistant to different therapies. A 33-year-old male patient was admitted to our center due to loss of vision and a progressively growing mass in the right parietal region. Magnetic resonance image yielded a contrast enhanced lesion, measuring 10x15 cm in size. The patient underwent decompression surgery due to optic nerve and chiasm compression and the histopathologic evaluation was compatible with fibrous dysplasia. The patient was diagnosed with acromegaly after laboratory evaluation. Surgical treatment was not preferred. Medical therapy with octreotide LAR 10 mg once a month was recommended. Cabergoline was added to his therapy and the doses of these two medicines were gradually escalated. Pegvisomant therapy was planned because IGF-1 level was not normalized. As a rarely encountered syndrome, it is important to recognize this syndrome and evaluate for a wide range of endocrinopathies. There are various treatment options and further research is still warranted.

Keywords: Acromegaly, cabergoline, fibrous dysplasia, McCune-Albright syndrome, pegvisomant, somatostatin receptor analogues

Öz

McCune-Albright sendromu, fibröz displazi, café-au-lait lekeleri ile tiroid, kortizol, prolaktin ve büyüme hormonu hipersekresyonu gibi çeşitli endokrinopatilerden oluşur. Endokrin hiperfonksiyonunun bir belirtisi olarak büyüme hormonu fazlalığı nadirdir. Makalemizde farklı tedavilere dirençli akromegali ve fibröz displazi nedeniyle kompresif optik nöropatisi olan bir McCune-Albright sendromu olgusunu sunuyoruz. Otuz üç yaşında erkek hasta, görme kaybı ve sağ parietal bölgede giderek büyüyen kitle nedeniyle merkezimize başvurdu. Manyetik rezonans görüntülemede 10x15 cm boyutlarında kontrast tutan bir lezyon izlendi. Optik sinir ve kiazma basısı nedeniyle dekompresyon cerrahisi uygulanan olguda histopatolojik değerlendirme fibröz displazi ile uyumlu bulundu. Hastaya laboratuvar değerlendirmesinin ardından akromegali tanısı konuldu. Cerrahi tedavi tercih edilmedi. Ayda bir kez 10 mg oktreotid LAR ile medikal tedavi önerildi. Tedavisine kabergolin eklendi ve bu iki ilacın dozları yavaş yavaş artırıldı. IGF-1 düzeyi normale dönmediği için pegvisomant tedavisi planlandı. Nadir görülen bir sendrom olarak, bu sendromu tanımak ve eşlik edebilecek çeşitli endokrinopatileri değerlendirmek önem arz eder. Tedavi seçenekleri çok çeşitli olup ileri araştırmalara ihtiyaç mevcuttur.

Anahtar kelimeler: Akromegali, fibröz displazi, kabergolin, McCune-Albright sendromu, pegvisomant, somatostatin reseptör analoğu

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Introduction

Fibrous dysplasia (FD) is a congenital disease which is characterized with the replacement of medullary bone with fibrous tissue. It may cause pain, fractures and deformities in the affected bones. It presents in various clinical settings including monostotic form (solitary bone lesion), polyostotic form (multiple bone lesion), and uncommonly McCune-Albright syndrome (MAS). MAS constitutes of FD, café-au-lait macules, and different endocrinopathies such as thyroid, cortisol, prolactin (PRL) and growth hormone (GH) hypersecretion (1). GH excess as a manifestation of endocrine hyperfunction is uncommon. We presented a case of MAS with compressive optic neuropathy due to FD in association with acromegaly which was resistant to different therapies and we aimed to highlight the therapeutical challenges.

Case Report

A 33-year-old male patient was admitted to the otorhinolaryngology outpatient clinic in 2009 due to loss of vision and a progressively growing mass in the right parietal region. The mass was present since childhood. Magnetic resonance image (MRI) yielded a contrast enhanced lesion, measuring 10x15 cm in size, which invaded the sphenoid sinus, frontal sinus, and nasal cavity, compressed the cavernous sinus, displaced the clivus, extended toward optic chiasm, suprasellar region, and diploic space, expanded the midline bones (Figure 1). The patient underwent decompression surgery due to optic nerve and optic chiasm compression. The histopathologic evaluation was compatible with FD. The patient was consulted by endocrinology department with regard to associated syndromes and pituitary hormones.

He complained headache, increased sweating, and weakness. He noticed growth in hands and increase in shoe size. He was 187 cm in height and weighed 89 kg (body mass index: 25.5 kg/m^2). His blood pressure was 140/80 mmHg. His past medical history was only significant for hypertension for one year. On physical examination, prognathism, acral growth, chin asymmetry and temporal swelling were noted. Laboratory data are shown in Table 1. GH and insulin like growth hormone (IGF)-1 was elevated. Therefore, GH response during oral glucose tolerance test was evaluated. GH was not suppressed and the patient was diagnosed with acromegaly. Acromegaly along with FD was compatible with MAS. However, we did not observe any skin lesion. Skeletal survey was done. Lesions of FD were noted in the mandible, right iliac crest, acetabulum, femur head bilaterally, and proximal right tibia and fibula (Figure 2). Vertebrae were not involved. Neither osteopenia nor osteoporosis was detected on dual energy X-ray absorptiometry. Medical therapy with octreotide LAR 10 mg once a month and calcium and vitamin D supplementation were recommended. The patient was lost in the follow-up after 3 months of the treatment.

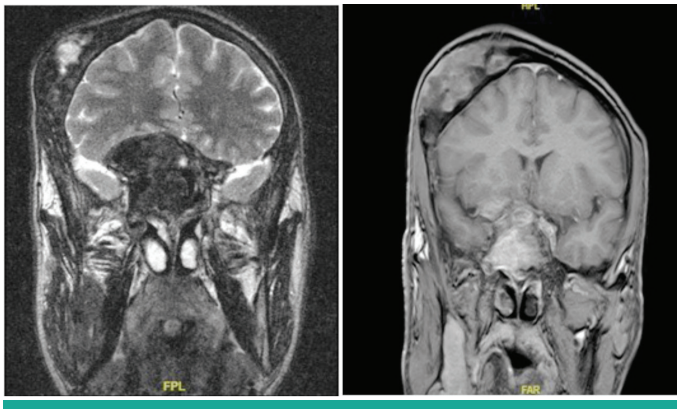

Figure 1. Magnetic resonance image of the patient

Table 1. Laboratory findings

Biochemical features	Results	Normal range
Fasting plasma glucose	79	70-110 mg/dL
Urea	33	10-50 mg/dL
Creatinine	0.8	0.6-1.3 mg/dL
Alanine transaminase	16	3-55 U/L
Aspartate transaminase	20	5-34 U/L
Sodium	140	136-145 mmol/L
Potassium	3.5	3.5-5.1 mmol/L
Calcium	9.1	8.8-10.6 mg/dL
Phosphorus	2.8	2.4-4.4 mg/dL
Parathyroid hormone	86.7	15-68.3 pg/mL
25 (OH) vitamin D	4	15-50 µg/L
Thyroid stimulating hormone	0.719	0.35-4.94 µLU/mL
Free triiodothyronine	2.9	2.6-4.3 pg/mL
Free	0.75	0.7-1.48 ng/dL
Adrenocorticotropic hormone	73.71	7.2-63.3 pg/mL
Cortisol	18	6.0-19.0 µg/dL
Follicle stimulating hormone	3.16	1.37-13.58 mLU/mL
Luteinizing hormone	2.2	0.57-12.07 mIU/mL
Total testosterone	2.25	2.4-8.7 ng/mL
Prolactin	45.26	2.58-18.12 ng/mL
Growth hormone	7.6	0.06-5.00 ng/mL
Insulin-like growth factor-1	825	115-307 ng/mL
Low dose dexamethasone suppression test	0.8	1.8 µg/dL>

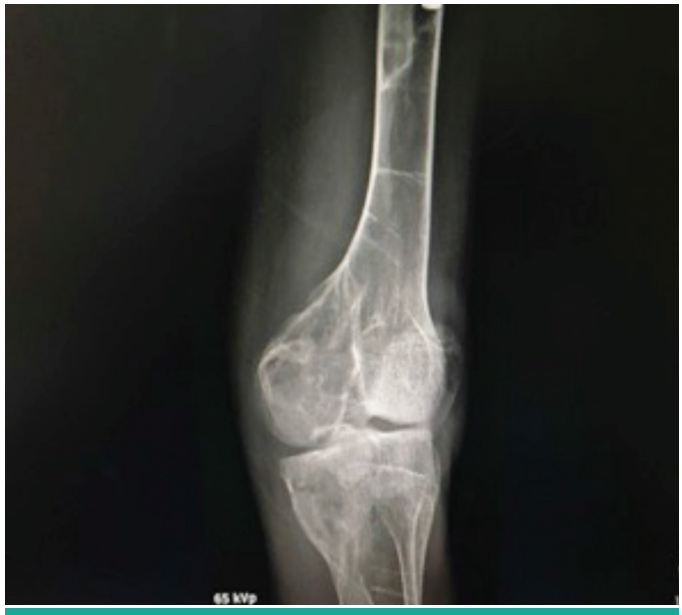

Figure 2. X-ray of the femur, tibia, and fibula

The patient was readmitted to the endocrinology unit after 2 years with the same complaints. He quitted octreotide and calcium-vitamin D in that timespan. Laboratory studies revealed GH: 6.70 ng/mL, IGF-1: 1057 ng/mL, and PRL: 42.89 ng/mL. Although thyroid function tests were within normal limits, multiple hypoechoic nodules, the largest one being 16x8 mm in size with microcalcifications, were detected on ultrasound (USG). Echocardiography revealed left atrial and ventricular enlargement, hypokinetic areas in apicolateral segments, ejection fraction of 35%. Cardiomyopathy was diagnosed. No polyps were detected on colonoscopic examination. Scrotal USG yielded normal features.

Visual field test revealed right sided temporal hemianopsy. The bone lesion was persistent on sellar MRI. Because of extensive involvement and close relation to vital structures, surgical treatment was not preferred. Therefore, octreotide 20 mg once a month was initiated again. Cabergoline 0.5 mg twice a week was added to the treatment. Octreotide dose was gradually escalated up to 40 mg and cabergoline to 1 mg twice a week. PRL level was significantly decreased. Although IGF-1 level was not normalized, it decreased significantly to 368 ng/mL. As an adverse effect of octreotide treatment, we did not detect glucose intolerance and cholelithiasis at the fifth year of therapy. Since IGF-1 level was not normalized, pegvisomant therapy was planned.

Discussion

MAS is a rare disease with an estimated prevalence of 1/100.000-1/1.000.000. Its clinical triad is composed of FD, café-au-lait skin lesions, and various endocrinopathies. It is caused by the stimulation of G protein α subunit due to activating mutations of *GNAS1* gene located on the long arm of chromosome 20 (2). The stimulation of G protein α subunits results in hyperfunctional endocrinopathies. Puberty precox is the most common endocrinopathy seen in MAS. Information regarding puberty was unclear in our patient; therefore, we could not rule out puberty precox. Although short stature is expected in puberty precox, concomitant gigantism may cover its effect on height. Other endocrinopathies constitute of acromegaly, hyperprolactinemia, hyperthyroidism, hypercortisolism, and hypophosphatemic rickets or osteomalacia. The incidence of GH excess among patients with MAS is approximately 20% (3). Chanson et al. (3) evaluated the association of acromegaly and MAS in 112 patients and they reported that the mean age at diagnosis was 24.4 (3-64) years and male was the preponderant gender (4). Our patient was diagnosed with MAS in his 30s due to the signs of GH excess and acromegaly. Acromegaly associated with MAS differs from classical acromegaly in that it is accompanied by hyperprolactinemia in 80-85% of cases and pituitary adenomas are not always detectable on imaging (2). Mechanism about discrepancy between laboratory and imaging is unclear and there are various hypotheses. A study which investigated laboratory data of 12 patients with MAS found a significant association between PRL and IGF-1 levels (5). Radiologic findings were present in 50% of MAS associated acromegaly, while the findings were present in 80% of classical acromegaly (2).

It is thought that there is no autonomy because of hypersecretion without pituitary lesion and response to somatostatin analogues. Supporting this hypothesis, mammosomatotroph hyperplasia in pituitary biopsies were shown in a study (6). A wide range of pituitary pathology may be explained by embryonic differentiation and abnormal hypothalamic regulation (7). Our case presented with elevated levels of GH, IGF-1, and PRL which decreased after cabergoline and octreotide combination therapy and absence of pituitary lesion.

Hyperthyroidism with MAS usually presents as subclinical hyperthyroidism and/or thyroid gland abnormalities on USG (8). In some cases, overt hyperthyroidism may be present, so they should be followed with thyroid function tests periodically. Although thyroid cancer is rare in MAS, considering increased malignancy risk with acromegaly, it would be judicious to monitor periodically with USG (9). Our patient was euthyroid at the time of diagnosis and

hyperthyroidism did not ensue during follow-up. Thyroid USG showed multinodular goiter. Fine needle aspiration biopsy of the suspect nodules was done and it was reported as benign. We did not observe growth in nodules.

Hypercortisolemia and adrenal hyperplasia has been reported in the literature. Cushing syndrome with MAS may undergo spontaneous remission. It is recommended to search for Cushingoid features and screen the suspected cases (10). We applied 1 mg dexamethasone suppression test to evaluate hypercortisolism and it was suppressed to less than 1.8 mcg/dL. Therefore, Cushing syndrome was ruled out.

FD is not as rare as MAS. It represents 7% of all benign bone lesions. Polyostotic involvement is evident in 30% of cases, while monostotic involvement is more common. Differentiation and abnormal proliferation of bone marrow stromal cell derived from medullary cavity give rise to FD lesions and the lesions expands exophytic masses with intact cortical bone (11). Although specific findings on imaging are generally enough for diagnosis, bone biopsy can be performed in case of indeterminant feature (1). FD in MAS mostly manifests as painless craniofacial lesions causing facial asymmetry. Cranial nerve compression, visual loss, and hearing impairment may be observed. Optic nerve may remain unaffected for years, although it is surrounded by the lesion. Ophthalmologic examination and tests for hearing loss should be done initially at diagnosis and annually thereafter (12).

Computed tomography is the most effective imaging modality for detecting craniofacial FD, but MRI is superior in detecting soft tissue and cranial nerve involvement (4). In our case, apparent craniofacial involvement caused progressive visual loss due to optic nerve compression visible on MRI scan, but hearing loss was absent. Axial and appendicular skeleton involvement may arise over time and plain films are usually enough for diagnosis (2). Vitamin D deficiency in MAS is common likewise normal population. Evaluation of vitamin D deficiency and treatment when necessary is advised.

Management of MAS is multimodal and tailored for each patient. Operation is generally ill-advised except for progressive visual and hearing loss in case of craniofacial FD (2). Transcranial surgery is the preferred method because of altered sphenoid sinus anatomy due to bone thickening. Radiotherapy has risk for sarcomatous transformation in FD, thus it is preferred only in patients who are amenable to operation and refractory to medical treatment (3). Although somatostatin receptor analogues significantly decrease GH and IGF-1 levels, remission can be achieved only in 30% of patients (13). Bromocriptin, a dopamine receptor agonist, has become a less favorable option nowadays (3). There are reports of success with combination therapy of another dopamine receptor agonist cabergoline and somatostatin receptor analogues. Akintoye et al. (5) showed good response with the use of this combination therapy in 6 out 7 patients. Combination therapy is recommended in case of inadequate control with monotherapy (5). Pegvisomant, a GH receptor antagonist, is another option in unresponsive cases (14). Our patient showed poor response to low dose octreotide and hormone levels kept increasing under therapy with intermediate dose of octreotide and cabergoline. We considered the addition of pegvisomant.

In conclusion, as a rarely encountered syndrome, it is important to recognize MAS and evaluate for a wide range of endocrinopathies in addition to lesions of FD. There are various treatment options and further research is still warranted.

Ethics

Informed Consent: Written informed consent received from the patient.

Peer-review: Internally and externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: O.E., Concept: H.P., O.E., Design: H.P., O.E., Data Collection or Processing: O.E., Analysis or Interpretation: H.P., Final Approval and Accountability: H.P., Writing: O.E.

Conflict of Interest: No conflict of interest was declared by the authors.

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