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About Us

Journal of Turkish Spinal Surgery (www.jtss.org), is the official publication of the Turkish Spinal Surgery Society. First journal was printed on January, in 1990. It is a double-blind peer-reviewed multidisciplinary journal for the physicians who deal with spinal diseases and publishes original studies which offer significant contributions to the development of the spinal knowledge. The journal publis¬hes original scientific research articles, invited reviews and case reports that are accepted by the Editorial Board, in English.

The journal is published once in every three months and a volume consists of four issues. Journal of Turkish Spinal Surgery is published four times a year: on January, April, July, and October.

Journal of Turkish Spinal Surgery is indexed in TÜBİTAK ULAKBİM TR Index, EBSCO, J-Gate, GALE, ProQuest, Türkiye Atıf Dizini, Index Copernicus and Europub.

The Turkish Spinal Surgery Society was established in 1989 in Izmir (Turkey) by the pioneering efforts of Prof. Dr. Emin Alıcı and other a few members. The objectives of the society were to: - establish a platform for exchange of information/ experience between Orthopedics and Traumatology Specialists and Neurosurgeons who deal with spinal surgery - increase the number of physicians involved in spinal surgery and to establish spinal surgery as a sophisticated medical discipline in Turkey - follow the advances in the field of spinal surgery and to communicate this information to members - organize international and national congresses, symposia and workshops to improve education in the field - establish standardization in training on spinal surgery - encourage scientific research on spinal surgery and publish journals and books on this field - improve the standards of spinal surgery nationally, and therefore make contributions to spinal surgery internationally.

The main objective of the Journal is to improve the level of knowledge and experience among Turkish medical society in general and among those involved with spinal surgery in particular. Also, the Journal aims at communicating the advances in the field, scientific congresses and meetings, new journals and books to its subscribers. Journal of Turkish Spinal Surgery is as old as the Turkish Spinal Surgery Society.

The first congress organized by the Society took place in Çeşme, Izmir, coincident with the publication of the first four issues. Authors were encouraged by the Society to prepare original articles from the studies presented in international congresses organized by the Society every two years, and these articles were published in the Journal. The Journal publishes clinical or basic research, invited reviews, and case presentations after approval by the Editorial Board. Articles are published after at least two reviewers review them. Editorial Board has the right to accept, to ask for revision, or to refuse manuscripts.

The Journal is issued every three months, and one volume is completed with every four issue. Associate Editors and Editor in Chief are responsible in reviewing and approving material that is published. Responsibility for the problems associated with research ethics or medico-legal issues regarding the content, information and conclusions of the articles lies with the authors, and the editor or the editorial board bears no responsibility. In line with the increasing expectations of scientific communities and the society, improved awareness about research ethics and medico-legal responsibilities forms the basis of our publication policy.

Citations must always be referenced in articles published in our journal. Our journal fully respects to the patient rights, and therefore care is exercised in completion of patient consent forms; no information about the identity of the patient is disclosed; and photographs are published with eye-bands. Ethics committee approval is a prerequisite. Any financial support must clearly be disclosed. Also, our Journal requests from the authors that sponsors do not interfere in the evaluation, selection, or editing of individual articles, and that part or whole of the article cannot be published elsewhere without written permission.

Journal of Turkish Spinal Surgery is available to the members of the society and subscribers free of charge. Membership fees, congresses, and the advertisements appearing in the journal meet the publication and distribution costs.

The advertisement fees are based on actual pricing. The Editorial Board has the right for signing contracts with one or more financial organizations for sponsorship. However, sponsors cannot interfere in the scientific content and design of the journal, and in selection, publication order, or editing of individual articles.

Journal of Turkish Spinal Surgery agrees to comply with the "Global Compact" initiative of the UN, and this has been notified to the UN. Therefore, VI our journal has a full respect to human rights in general, and patient rights in particular, in addition to animal rights in experiments; and these principles are an integral part of our publication policy.

Recent advances in clinical research necessitate more sophisticated statistical methods, well-designed research plans, and more refined reporting. Scientific articles, as in other types of articles, represent not only an accomplishment, but also a creative process.

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The quality of a report depends on the quality of the design and management of the research. Well-designed questions or hypotheses are associated with the design. Well-designed hypotheses reflect the design, and the design reflects the hypothesis. Two factors that determine the efficiency of a report are focus and shortness. Drawing the attention to limited number of subjects allows the author to focus on critical issues. Avoidance from repetitions (apart from a few exceptions), a simple language, and correct grammar are a key to preparing a concise text. Only few articles need to exceed 3000 words, and longer articles may be accepted when new methods are being reported or literature is being reviewed.

Although authors should avoid complexity, the critical information for effective communication usually means the repetition of questions (or hypotheses or key subjects). Questions must be stated in Abstract, Introduction and Discussion sections, and the answers should be mentioned in Abstract, Results, and Discussion sections. Although many journals issue written instructions for the formatting of articles, the style of the authors shows some variance, mainly due to their writing habits.

Journal of Turkish Spinal Surgery adopts the AMA style as a general instruction for formatting. However, not many authors have adequate time for learning this style. Thus, our journal is tolerant to personal style within the limitations of correct grammar and plain and efficient communication.

JOURNAL OF TURKISH SPINAL SURGERY

Instructions to Authors

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PEER REVIEW

Article is reviewed by secretaries of the journal after it is uploaded to the web site. Article type, presence of the all sections, suitability according to the number of words, name of the authors with their institutions, corresponding address, mail addresses, telephone numbers and ORCID numbers are all evaluated and shortcomings are reported to the editor. Editor request the all defect from the authors and send to vice editors and native English speaker editor after completion of the article. Vice editors edit the blinded article and this blinded copy is sent to two referees. After reviewing of the article by the referees in maximum one month, the review report evaluating all section and his decision is requested, and this blinded report is sent to the author. In fifteen days, revision of the article is requested from the authors with the appreciate explanation. Revised blinded copy is sent to the referees for the new evaluation. Editor if needed may sent the manuscript to a third referee. Editorial Board has the right to accept, revise or reject a manuscript.

-Following types of manuscripts related to the field of "Spinal Surgery" with English Abstract and Keywords are accepted for publication: I- Original clinical and experimental research studies; II- Case presentations; and III- Reviews.

AUTHOR'S RESPONSIBILITY

The manuscript submitted to the journal should not be previously published (except as an abstract or a preliminary report) or should not be under consideration for publication elsewhere. Every person listed as an author is expected to have been participated in the study to a significant extent. All authors should confirm that they have read the study and agreed to the submission to Journal of Turkish Spinal Surgery for publication. This should be notified with a separate document as shown in the "Cover Letter" in the appendix. Although the editors and referees make every effort to ensure the validity of published manuscripts, the final responsibility rests with the authors, not with the Journal, its editors, or the publisher. The source of any financial support for the study should be clearly indicated in the Cover Letter.

It is the author's responsibility to ensure that a patient's anonymity be carefully protected and to verify that any experimental investigation with human subjects reported in the manuscript was performed upon the informed consent of the patients and in accordance with all guidelines for experimental investigation on human subjects applicable at the institution(s) of all authors.

Authors should mask patients' eyes and remove patients' names from figures unless they obtain written consent to do so from the patients; and this consent should be submitted along with the manuscript.

CONFLICTS OF INTEREST

Authors must state all possible conflicts of interest in the manuscript, including financial, institutional and other relationships that might lead to bias or a conflict of interest. If there is no conflict of interest, this should also be explicitly stated as none declared. All sources of funding should be acknowledged in the manuscript. All relevant conflicts of interest and sources of funding should be included on the title page of the manuscript with the heading "Conflicts of Interest and Source of Funding".

ARTICLE WRITING

Clinically relevant scientific advances during recent years include use of contemporary outcome measures, more sophisticated statistical approaches, and increasing use and reporting of well-formulated research plans (particularly in clinical research).

Scientific writing, no less than any other form of writing, reflects a demanding creative process, not merely an act: the process of writing changes thought. The quality of a report depends on the quality of thought in the design and the rigor of conduct of the research. Well-posed questions or hypotheses interrelate with the design. Well-posed hypotheses imply design and design implies the hypotheses. The effectiveness of a report relates to brevity and focus. Drawing the attention to a few points will allow authors to focus on critical issues. Brevity is achieved in part by avoiding repetition (with a few exceptions to be noted),

clear style, and proper grammar. Few original scientific articles need to be longer than 3000 words. Longer articles may be accepted if substantially novel methods are reported, or if the article reflects a comprehensive review of the literature.

Although authors should avoid redundancy, effectively communicating critical information often requires repetition of the questions (or hypotheses/key issues) and answers. The questions should appear in the Abstract, Introduction, and Discussion, and the answers should appear in the Abstract, Results, and Discussion sections.

Although most journals publish guidelines for formatting a manuscript and many have more or less established writing styles (e.g., the American Medical Association Manual of Style), styles of writing are as numerous as authors. Journal of Turkish Spinal Surgery traditionally has used the AMA style as a general guideline. However, few scientific and medical authors have the time to learn these styles. Therefore, within the limits of proper grammar and clear, effective communication, we will allow individual styles.

Permissions: As shown in the example in the appendix (Letter of Copyright Transfer) the authors should declare in a separate statement that the study has not been previously published and is not under consideration for publication elsewhere. Also, the authors should state in the same statement that they transfer copyrights of their manuscript to our Journal. Quoted material and borrowed illustrations: if the authors have used any material that had appeared in a copyrighted publication, they are expected to obtain written permission letter and it should be submitted along with the manuscript.

Review articles: The format for reviews substantially differs from those reporting original data. However, many of the principles noted above apply. A review still requires an Abstract, an Introduction, and a Discussion. The Introduction still requires focused issues and a rationale for the study. Authors should convey to readers the unique aspects of their reviews which distinguish them from other available material (e.g., monographs, book chapters). The main subject should be emphasized in the final paragraph of the Introduction. As for an original research article, the Introduction section of a review typically need not to be longer than four paragraphs. Longer Introductions tend to lose focus, so that the reader may not be sure what novel information will be presented. The sections after the Introduction are almost always unique to the particular review, but need to be organized in a coherent fashion. Headings (and subheadings when appropriate) should follow parallel construction and reflect analogous topics (e.g., diagnostic categories, alternative methods, alternative surgical interventions). If the reader considers only the headings, the logic of the review (as reflected in the Introduction) should be clear. Discussion synthesizes the reviewed literature as a whole coherently and within the context of the novel issues stated in the Introduction.

The limitations should reflect those of the literature, however, rather than a given study. Those limitations will relate to gaps in the literature which preclude more or less definitive assessment of diagnosis or selection of treatment, for example. Controversies in the literature should be briefly explored. Only by exploring limitations will the reader appropriately place the literature in perspective. Authors should end the Discussion by abstract statements similar to those which will appear at the end of the Abstract in abbreviated form.

In general, a review requires a more extensive literature review than an original research article, although this will depend on the topic. Some topics (e.g., osteoporosis) could not be comprehensively referenced, even in an entire monograph. However, authors need to ensure that a review is representative of the entire body of literature, and when that body is large, many references are required.

Original Articles: Original articles should contain the following sections: “Title Page”, “Abstract”, “Keywords”, “Introduction”, “Materials and Methods”, “Results”, “Discussion”, “Conclusions”, and “References”. “Keywords” sections should also be added if the original article is in English.

- Title (80 characters, including spaces): Just as the Abstract is important in capturing a reader’s attention, so is the title. Titles rising or answering questions in a few brief words will far more likely do this than titles merely pointing to the topic. Furthermore, such titles as “Bisphosponates reduce bone loss” effectively convey the main message and readers will more likely remember them. Manuscripts that do not follow the protocol described here will be returned to the corresponding author for technical revision before undergoing peer review. All manuscripts in English, should be typed double-spaced on one side of a standard typewriter paper, leaving at least 2.5 cm. margin on all sides. All pages should be numbered beginning from the title page.

- Title page should include: a) informative title of the paper, b) complete names of each author with their institutional affiliations, c) name, address, fax and telephone number, e-mail of the corresponding author, d) address for the reprints if different from that of the corresponding author, e) ORCID numbers of the authors. It should also be stated in the title

page that informed consent was obtained from patients and that the study was approved by the ethics committee.

The "Level of Evidence" should certainly be indicated in the title page (see Table-1 in the appendix). Also, the field of study should be pointed out as outlined in Table-2 (maximum three fields).

- Abstract: A150 to 250 word abstract should be included at the second page. The abstract should be written in English and for all articles. The main topics to be included in Abstract section are as follows: Background Data, Purpose, Materials- Methods, Results and Conclusion. The Abstract should be identical in meaning. Generally, an Abstract should be written after the entire manuscript is completed. The reason relates to how the process of writing changes thought and perhaps even purpose. Only after careful consideration of the data and a synthesis of the literature can author(s) write an effective abstract. Many readers now access medical and scientific information via Web-based databases rather than browsing hard copy material. Since the reader's introduction occurs through titles and abstracts, substantive titles and abstracts more effectively capture a reader's attention regardless of the method of access. Whether reader will examine an entire article often will depend on an abstract with compelling information. A compelling Abstract contains the questions or purposes, the methods, the results (most often quantitative data), and the conclusions. Each of these may be conveyed in one or two statements. Comments such as "this report describes…" convey little useful information.

-Key Words: Standard wording used in scientific indexes and search engines should be preferred. The minimum number for keywords is three and the maximum is five.

- Introduction (250 – 750 words): It should contain information on historical literature data on the relevant issue; the problem should be defined; and the objective of the study along with the problem solving methods should be mentioned.

Most studies, however, are published to: (1) report entirely novel findings (frequently case reports, but sometimes substantive basic or clinical studies); (2) confirm previously reported work (eg, case reports, small preliminary series) when such confirmation remains questionable; and (3) introduce or address controversies in the literature when data and/or conclusions conflict. Apart from reviews and other special articles, one of these three purposes generally should be apparent (and often explicit) in the Introduction.

The first paragraph should introduce the general topic or problem and emphasized its importance, a second and perhaps a third paragraph should provide the rationale of the study, and a final paragraph should state the questions, hypotheses, or purposes.

One may think of formulating rationale and hypotheses as Aristotelian logic (a modal syllogism) taking the form: If A, B, and C, then D, E, or F. The premises A, B, and C, reflect accepted facts whereas D, E, or F reflect logical outcomes or predictions. The premises best come from published data, but when data are not available, published observations (typically qualitative), logical arguments or consensus of opinion can be used. The strength of these premises is roughly in descending order from data to observations or argument to opinion. D, E, or F reflects logical consequences. For any set of observations, any number of explanations (D, E, or F) logically follows. Therefore, when formulating hypotheses (explanations), researchers designing experiments and reporting results should not rely on a single explanation.

With the rare exception of truly novel material, when establishing rationale authors should generously reference representative (although not necessarily exhaustive) literature. This rationale establishes novelty and validity of the questions and places it within the body of literature. Writers should merely state the premises with relevant citations (superscripted) and avoid describing cited works and authors` names. The exceptions to this approach include a description of past methods when essential to developing rationale for a new method, or a mention of authors` names when important to establish historic precedent. Amplification of the citations may follow in the Discussion when appropriate. In establishing a rationale, new interventions of any sort are intended to solve certain problems. For example, new implants (unless conceptually novel) typically will be designed according to certain criteria to eliminate problems with previous implants. If the purpose is to report a new treatment, the premises of the study should include those explicitly stated problems (with quantitative frequencies when possible) and they should be referenced generously.

The final paragraph logically flows from the earlier ones, and should explicitly state the questions or hypotheses to be addressed in terms of the study (independent, dependent) variables. Any issue not posed in terms of study variables cannot be addressed meaningfully. Focus of the report relates to focus of these questions, and the report should avoid questions for which answers are well described in the literature (e.g., dislocation rates for an implant designed to minimize stress shielding). Only if there are new and unexpected information should data reported apart from that essential to answer the stated questions.

- Materials - Methods (1000-1500 words): Epidemiological/ demographic data regarding the study subjects; clinical and radiological investigations; surgical technique applied; evaluation methods; and statistical analyses should be described in detail.

In principle, the Materials and Methods should contain adequate detail for another investigator to replicate the study. In practice, such detail is neither practical nor desirable because many methods will have been published previously (and in greater detail), and because long descriptions make reading difficult. Nonetheless, the Materials and Methods section typically will be the longest section. When reporting clinical studies authors must state approval of the institutional review board or ethics committees according to the laws and regulations of their countries. Informed consent must be stated where appropriate. Such approval should be stated in the first paragraph of Materials and Methods. At the outset the reader should grasp the basic study design. Authors should only briefly escribe and reference previously reported methods. When authors modify those methods, the modifications require additional description.

In clinical studies, the patient population and demographics should be outlined at the outset. Clinical reports must state inclusion and exclusion criteria and whether the series is consecutive or selected; if selected, criteria for selection should be stated. The reader should understand from this description all potential sources of bias such as referral, diagnosis, exclusion, recall, or treatment bias. Given the expense and effort for substantial prospective studies, it is not surprising that most published clinical studies are retrospective.

Such studies often are criticized unfairly for being retrospective, but that does not negate the validity or value of a study. Carefully designed retrospective studies provide most of the information available to clinicians. However, authors should describe potential problems such as loss to follow-up, difficulty in matching, missing data, and the various forms of bias more common with retrospective studies.

If authors use statistical analysis, a paragraph should appear at the end of Materials and Methods stating all statistical tests used. When multiple tests are used, authors should state which tests are used for which sets of data. All statistical tests are associated with assumptions, and when it is not obvious the data would meet those assumptions, the authors either should provide the supporting data (e.g., data are normally distributed, variances in gro-ups are similar) or use alternative tests. Choice of level of significance should be justified. Although it is common to choose a level of alpha of 0.05 and a beta of 0.80, these levels are somewhat arbitrary and not always appropriate. In the case where the implications of an error are very serious (e.g., missing the diagnosis of a cancer), different alpha and beta levels might be chosen in the study design to assess clinical or biological significance.

- Results (250-750 words): "Results" section should be written in an explicit manner, and the details should be described in the tables. The results section can be divided into sub-sections for a more clear understanding.

If the questions or issues are adequately focused in the Introduction section, the Results section needs not to be long. Generally, one may need a paragraph or two to persuade the reader of the validity of the methods, one paragraph addressing each explicitly raised question or hypothesis, and finally, any paragraphs to report new and unexpected findings. The first (topic) sentence of each paragraph should state the point or answer the question. When the reader considers only the first sentence in each paragraph in Results, the logic of the authors` interpretations should be clear. Parenthetic reference to all figures and tables forces the author to textually state the interpretation of the data; the important material is the authors` interpretation of the data, not the data.

Statistical reporting of data deserves special consideration. Stating some outcome is increased or decreased(or greater or lesser) and parenthetically stating the p (or other statistical) value immediately after the comparative terms more effectively conveys information than stating something is or is not statistically significantly different from so-mething else (different in what way? the readermay ask). Additionally, avoiding the terms 'statistically different' or 'significantly different' lets the reader determine whether they will consider the statistical value biologically or clinically significant, regardless of statistical significance.

Although a matter of philosophy and style, actual p values convey more information than stating a value less than some preset level. Furthermore, as Motulsky notes, "When you read that a result is not significant, don't stop thinking... First, look at the confidence interval... Second, ask about the power of the study to find a significant difference if it were there." This approach will give the reader a much greater sense of biological or clinical significance.

- Discussion (750 - 1250 words): The Discussion section should contain specific elements: a restatement of the problem or question, an exploration of limitations and as-sumptions, a comparison and/or contrast with information (data, opinion) in the literature, and a synthesis of the comparison and the

author's new data to arrive at conclusions. The restatement of the problem or questions should only be a brief emphasis. Exploration of assumptions and limitations are preferred to be next rather than at the end of the manuscript, because interpretation of what will follow depends on these limitations. Failure to explore limitations suggests the author(s) either do not know or choose to ignore them, potentially misleading the reader. Exploration of these limitations should be brief, but all critical issues must be discussed, and the reader should be persuaded they do not jeopardize the conclusions.

Next the authors should compare and/or contrast their data with data reported in the literature. Generally, many of these reports will include those cited as rationale in the Introduction. Because of the peculiarities of a given study the data or observations might not be strictly comparable to that in the literature, it is unusual that the literature (including that cited in the Introduction as rationale) would not contain at least trends. Quantitative comparisons most effectively persuade the reader that the data in the study are "in the ballpark," and tables or figures efficiently convey that information. Discrepancies should be stated and explained when possible; when an explanation of a discrepancy is not clear that also should be stated. Conclusions based solely on data in the paper seldom are warranted because the literature almost always contains previous information.

Finally, the author(s) should interpret their data in the light of the literature. No critical data should be overlooked, because contrary data might effectively refute an argument. That is, the final conclusions must be consistent not only with the new data presented, but also that in the literature.

- Conclusion: The conclusions and recommendations by the authors should be described briefly. Sentences containing personal opinions or hypotheses that are not based on the scientific data obtained from the study should be avoided.

- References: References are numbered (Arabic numerals) consecutively in the order in which they appear in the text (note that references should not appear in the abstract) and listed double-spaced at the end of the manuscript. The preferred method for identifying citations in the text is using within parentheses. Use the form of the "Uniform Requirements for Manuscripts" (http://www.icmje.org/about-icmje/faqs/icmje-recommendations/). If number of authors exceeds seven, list first 6 authors followed by et al.

Use references found published in peer-reviewed publications that are generally accessible. Unpublished data, personal communications, statistical programs, papers presented at meetings and symposia, abstracts, letters, and manuscripts submitted for publication cannot be listed in the references. Papers accepted by peer-reviewed publications but not yet published ("in press") are not acceptable as references.

Journal titles should conform to the abbreviations used in "Cumulated Index Medicus".

Please note the following examples of journal, book and other reference styles:

Journal article:

1. Berk H, Akçalı Ö, Kıter E, Alıcı E. Does anterior spinal instrument rotation cause rethrolisthesis of the lower instrumented vertebra? J Turk Spinal Surg. 1997;8 (1):5-9.

Book chapter:

2. Wedge IH, Kirkaldy-Willis WH, Kinnard P. Lumbar spinal stenosis. Chapter 5. In: Helfet A, Grubel DM (Eds.). Disorders of the Lumbar Spine. JB Lippincott, Philadelphia 1978;pp:61-8.

Entire book:

3. Paul LW, Juhl IH (Eds.). The Essentials of Roentgen Interpretation. Second Edition, Harper and Row, New York 1965; pp:294-311.

Book with volume number:

4. Stauffer ES, Kaufer H, Kling THF. Fractures and dislocations of the spine. In: Rock-wood CA, Green DP (Eds.). Fractures in Adults. Vol. 2, JB Lippincott, Philadelphia 1984;pp:987-1092.

Journal article in press:

5. Arslantaş A, Durmaz R, Coşan E, Tel E. Aneurysmal bone cysts of the cervical spine. J Turk Spinal Surg. (In press).

Book in press:

6. Condon RH. Modalities in the treatment of acute and chronic low back pain. In: Finnison BE (Ed.). Low Back Pain. JB Lippincott (In press).

Symposium:

7. Raycroft IF, Curtis BH. Spinal curvature in myelomeningocele: natural history and etiology. Proceedings of the American Academy of Orthopaedic Surgeons Symposium on Myelomeningocele, Hartford, Connecticut, November 1970, CV Mosby, St. Louis 1972;pp:186- 201.

Papers presented at the meeting:

8. Rhoton AL. Microsurgery of the Arnold-Chiari malformation with and without hydromyelia in adults. Presented at the

Annual Meeting of the American Association of Neuro-logical Surgeons, Miami, Florida, April 7, 1975.

-Tables: They should be numbered consecutively in the text with Arabic numbers. Each table with its number and title should be typed on a separate sheet of paper. Each table must be able to stand alone; all necessary information must be contained in the caption and the table itself so that it can be understood independent from the text. Information should be presented explicitly in "Tables" so that the reader can obtain a clear idea about its content. Information presented in "Tables" should not be repeated within the text. If possible, information in "Tables" should contain statistical means, standard deviations, and t and p values for possibility. Abbreviations used in the table should be explained as a footnote.

Tables should complement not duplicate material in the text. They compactly present information, which would be difficult to describe in text form. (Material which may be succinctly described in text should rarely be placed in tables or figures.) Clinical studies for example, often contain complementary tables of demographic data, which although important for interpreting the results, are not critical for the questions raised in the paper. Well focused papers contain only one or two tables or figures for every question or hypothesis explicitly posed in the Introduction section. Additional material may be used for unexpected results. Well-constructed tables are self-explanatory and require only a title. Every column contains a header with units when appropriate.

- Figures: All figures should be numbered consecutively throughout the text. Each figure should have a label pasted on its back indicating the number of the figure, an arrow to show the top edge of the figure and the name of the first author. Black-and-white illustrations should be in the form of glossy prints (9x13 cm). The letter size on the figure should be large enough to be readable after the figure is reduced to its actual printing size. Unprofessional typewritten characters are not accepted. Legends to figures should be written on a separate sheet of paper after the references.

The journal accepts color figures for publication if they enhance the article. Authors who submit color figures will receive an estimate of the cost for color reproduction. If they decide not to pay for color reproduction, they can request that the figures be converted to black and white at no charge. For studies submitted by electronic means, the figures should be in jpeg and tiff formats with a resolution greater than 300 dpi. Figures should be numbered and must be cited in the text.

- Style: For manuscript style, American Medical Association Manual of Style (9th edition). Stedman's Medical Dictionary (27th edition) and Merriam Webster's Collegiate Dictionary (10th edition) should be used as standard references. The drugs and therapeutic agents must be referred by their accepted generic or chemical names, without abbreviations. Code numbers must be used only when a generic name is not yet available. In that case, the chemical name and a figure giving the chemical structure of the drug should be given. The trade names of drugs should be capitalized and placed in parentheses after the generic names. To comply with trademark law, the name and location (city and state/country) of the manufacturer of any drug, supply, or equipment mentioned in the manuscript should be included. The metric system must be used to express the units of measure and degrees Celsius to express temperatures, and SI units rather than conventional units should be preferred.

The abbreviations should be defined when they first appear in the text and in each table and figure. If a brand name is cited, the manufacturer's name and address (city and state/country) must be supplied.

The address, "Council of Biology Editors Style Guide" (Council of Science Editors, 9650 Rockville Pike, Bethesda, MD 20814) can be consulted for the standard list of abbrevia-tions.

-Acknowledgments: Note any non-financial acknowledgments. Begin with, "The Authors wish to thank…" All forms of support, including pharmaceutical industry support should also be stated in Acknowledgments section.

Authors are requested to apply and load including the last version of their manuscript to the manuscript submission in the official web address (www.jtss.org). The electronic file must be in Word format (Microsoft Word or Corel Word Perfect). Authors can submit their articles for publication via internet using the guidelines in the following address: www.jtss.org.

- Practical Tips:

1. Read only the first sentence in each paragraph throughout the text to ascertain whether those statements contain all critical material and the logical flow is clear.

2. Avoid in the Abstract comments such as, "… this report describes…" Such statements convey no substantive information for the reader.

3. Avoid references and statistical values in the Abstract.

4. Avoid using the names of cited authors except to establish historical precedent. Instead, indicate the point in the manuscript by providing citation by superscripting.

5. Avoid in the final paragraph of the Introduction purposes such as, "… we report our data…" Such statements fail to focus

the reader's (and author's!) attention on the critical issues (and do not mention study variables).

6. Parenthetically refer to tables and figures and avoid statements in which a table of figure is either subject or object of a sentence. Parenthetic reference places interpretation of the information in the table or figure, and not the table or figure.

7. Regularly count words from the Introduction through Discussion.

TABLE-1. LEVELS OF EVIDENCE

LEVEL- I .

1) Randomized, double-blind, controlled trials for which tests of statistical significance have been performed

2) Prospective clinical trials comparing criteria for diagnosis, treatment and prognosis with tests of statistical significance where compliance rate to study exceeds 80%

3) Prospective clinical trials where tests of statistical ignificance for consecutive subjects are based on predefined criteria and a comparison with universal (gold standard) reference is performed

4) Systematic meta-analyses which compare two or more studies with Level I evidence using pre-defined methods and statistical comparisons.

5) Multi-center, randomized, prospective studies

LEVEL –II.

1) Randomized, prospective studies where compliance rate is less than 80%

2) All Level-I studies with no randomization

3) Randomized retrospective clinical studies

4) Meta-analysis of Level-II studies

LEVEL– III.

1) Level-II studies with no randomization (prospective clinical studies etc.)

2) Clinical studies comparing non-consecutive cases (without a consistent reference range)

3) Meta-analysis of Level III studies

LEVEL- IV.

1) Case presentations

2) Case series with weak reference range and with no statistical tests of significance

LEVEL – V.

1) Expert opinion and review articles

2) Anecdotal reports of personal experience regarding a study, with no scientific basis

TABLE-2. CLINICAL AREAS

Anatomy

Morphometric analysis

Anesthesiology

Animal study

Basic Science

Biology

Biochemistry

Biomaterials

Bone mechanics

Bone regeneration

Bone graft

Bone graft sustitutes

Drugs

Disc

Disc Degeneration

Herniated Disc

Disc Pathology

Disc Replacement

IDET

Disease/Disorder

Congenital

Genetics

Degenerative disease

Destructive (Spinal Tumors)

Metabolic bone disease

Rheumatologic

Biomechanics Cervical Spine

Cervical myelopathy

Cervical reconstruction

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Cervical disc disease
Cervical Trauma
Degenerative disease
Complications
Early
Late
Postoperative
Deformity
Adolescent idiopathic scoliosis
Kyphosis
Congenital spine
Degenerative spine conditions
Diagnostics
Radiology
MRI
CT scan
Others
Epidemiology
Etiology
Examination
Experimental study
Fusion
Anterior
Posterior
Combined
With instrumentation
Infection of the spine
Postoperative
Rare infections
Spondylitis
Spondylodiscitis
Tuberculosis
Instrumentation
Meta-Analysis
Osteoporosis
Bone density
Fractures
Kyphoplasty
Medical Treatment
Surgical Treatment
Outcomes
Conservative care
Patient Care
Primary care
Quality of life research
Surgical
Pain
Chronic pain
Discogenic pain
Injections
Low back pain
Management of pain
Postoperative pain
Pain measurement
Physical Therapy
Motion Analysis
Manipulation
Non-Operative Treatment
Surgery
Minimal invasive
Others
Reconstructive surgery
Thoracic Spine
Thoracolumbar Spine
Lumbar Spine
Lumbosacral Spine
Psychology
Trauma

Fractures

Dislocations

Spinal cord

Spinal Cord Injury

Spinal stenosis

Cervical

Lumbar

Lumbosacral

Tumors

Metastatic tumors

Primary benign tumors

Primary malign tumors

APPLICATION LETTER EXAMPLE:

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JOURNAL OF TURKISH SPINAL SURGERY

Dear Colleagues,

Once again, it is my pleasure and privilege to be publishing this, the 2nd issue, of our professional journal this year. I am pleased to inform you that we have changed our system, and have joined the Journal Agent Online Article Processing System (LookUs Scientific). This system is user friendly and you can easily submit an article to our system. We continue to work harmoniously with our publisher-Galenos Publishing House.

This issue includes seven clinical research studies and one case report. I hope that each of you will review this issue carefully, and incorporate whatever you find useful into your daily practices.

The first study is a Retrospective Clinical Study about the Clinical and Radiological Results of Laminectomy and Posterolateral Screw Fixation in the Treatment of Cervical Spondylotic Myelopathy. The second article is a study Comparing Two Posterior Instrumentation Techniques in Multilevel Cervical Spondylotic Myelopathy Treatment: Lateral Mass Screw Fixation vs Pedicle Screw Fixation. The third is a clinical study, entitled Evaluation of the Effectiveness and Reliability of Low-dose Tranexamic Acid Used in Adolescent Idiopathic Scoliosis Surgery. The fourth article is a study entitled the reliability and accuracy of radiographs in the assessment of pedicle screw placement; a comparison with computerized tomography. The authors of the fifth study discuss whether Radiofrequency Ablation, in Conjunction with Vertebral Augmentation, is an Effective Option in Painful Spinal Metastasis. The sixth article is about Meralgia Paresthetica Caused by Thoracolumbar Brace in Conservatively Treated Thoracolumbar Fractures while, in the seventh, the authors evaluated the Efficiency of Silver-coated Titanium Alloy Screws in the Prevention of Implant-associated Infections. The eighth article is a case report about Horner's Syndrome in a Congenital Scoliosis Patient: A Complication Related to Internal Jugular Vein Catheterization or Prone Position?

I hope that you, our readers, appreciate the work that goes into the writing and compilation of these articles, and that you take the time to read and absorb the vital information contained herein. As always, it's our goal to provide you with the most current research available, and information on cutting edge practices and methodology. Our mission is to guarantee that we remain at the forefront of all the latest developments, and this issue is intended to further that goal.

With kindest regards,

Editor in Chief

Metin Özalay, M.D.

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CLINICAL AND RADIOLOGICAL RESULTS OF LAMINECTOMY AND POSTEROLATERAL SCREW FIXATION IN THE TREATMENT OF CERVICAL SPONDYLOTIC MYELOPATHY

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ABSTRACT

Objective: The purpose of this study was to evaluate clinical and radiological findings related to the treatment of the patients with cervical spondylotic myelopathy (CSMP) in our medical center who underwent posterior cervical laminectomy and posterolateral fusion surgery with lateral mass screw fixation (LMSF).

Materials and Methods: In this study, the postoperative clinical and radiological results of 30 patients who underwent posterior laminectomy and posterolateral fusion surgery by a single spinal surgeon with the diagnosis of cervical spondylosis in our medical center between 2015 and 2019 were retrospectively evaluated.

Results: In total, 30 patients [23 males (76.7%) and 7 females (23.3%)] were included in the study, and the follow-up period was 6 to 44 months with an average of 21.2 months. In total, 91 laminectomies were performed on the cervical vertebrae of our patients. The mean diameter of the spinal canal in the narrowest place was 5.80 mm (9.6, 2.5) in the preoperative period, and 11.16 mm (13.6-9.4) in the postoperative period. In the postoperative period, an average of 1.35 mm (0.4-3.1) spinal cord shift was observed. The mean modified Japanese Orthopedic Association scores of all patients increased postoperatively to 15.2 (8-18) from the preoperative values of 12 (6-16). While mean preoperative Cobb angle in Group A was - 23.5° (-45°/-10°), mean postoperative Cobb angle was -9.8° (-34°/+15°). While mean preoperative Cobb angle in Group B was +13.8° (+3°/+33°), mean postoperative Cobb angle was +13.3° (+32°/-5°).

Conclusion: In the treatment of patients with CSMP, adequate spinal canal decompression is created with posterior laminectomy and the LMSF technique, and these provide sufficient neurological recovery and stability. Posterolateral stabilization can preserve cervical alignment in patients with lordotic spine alignment and prevent progressive kyphosis after laminectomy; however, if anterior osteophytosis is present in patients with a preoperative loss of lordosis or kyphotic alignment, this technique may not be suitable for ideal lordotic alignment.

Keywords: Cervical spondylotic myelopathy, posterolateral fusion, cervical alignment

INTRODUCTION

Degeneration of vertebrae, discs, uncinate, and facet joints in the cervical region with aging is called cervical spondylosis (CS). While narrowing in the spondylotic cervical canal statically damages neural structures and glial cells, axons become more vulnerable to secondary injury with repeated flexion and extension movement[1]. In addition, in the spondylotic process that develops with age, vertebral artery, anterior spinal artery, and radicular artery blood flows may decrease due to compression and cause ischemic damage[2,3]. CS myelopathy (CSMP) is the most common cause of non-traumatic spinal cord dysfunction in adults[4]. Although it has a wide clinical spectrum, limited spontaneous recovery is observed in patients, while a gradual clinical deterioration is generally observed[5,6]. The Nurick scale[5], the Harsh scale[7], the Cooper scale[8], the Prolo scale[9], and the Japanese Orthopedic Association (JOA)/modified JOA (mJOA) scales[10,11] can be used for clinical evaluations of CSMP patients.

Surgical treatment aims to correct spinal compression, correct sagittal alignment and stabilize the spine[12]. The preoperative cervical sagittal alignment, the location of the spinal cord compression, the number of compressing segments, and the comorbidities present in the patient are important in determining which surgical approach to use[12,13]. In patients with cervical disc hernia, osteophytes, or ossification of the posterior longitudinal ligament, anterior surgical approaches can be preferred because they facilitate the correction of kyphotic spine segments and result in less postoperative pain[12].

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However, if the myelopathy is caused by the compression of multiple spinal segments, posterior surgical approaches are more attractive because decompressing of three or more segments using long-level anterior corpectomies may lead to increased complication risks and fusion problems[14].

The purpose of our study was to evaluate clinical and radiological findings related to the treatment of CSMP patients in our medical center who underwent posterior cervical laminectomy and posterolateral fusion surgery with lateral mass screw fixation (LMSF).

MATERIALS AND METHODS

Study Population

This study was conducted upon receiving approval from the Ethics Committee for Clinical Studies of Ordu University (number: 2020/161). In this study, postoperative clinical and radiological findings of patients who underwent posterior laminectomy and fusion surgery by a single spinal surgeon in our hospital between 2015 and 2019 were retrospectively evaluated. Cases of CS with two or more levels of disc herniation from the anterior of the spinal cord and posterior longudinal ligament calcification as well as signs of compression of the spinal cord from the posterior were included in the study. At least two levels of laminectomy and three levels of lateral mass screws were applied to patients with kyphotic or lordotic spine alignment. Patients who underwent posterior decompression and fusion due to trauma or tumor were excluded from the study. In total, 30 patients (23 males, 7 females) were included in the study, and the follow-up period was 6 to 44 months (mean: 21.2 months). Informed consent was obtained from our patients for our study.

Surgical Technique

All cases were operated on in the prone position with a head holder after intubation. Paravertebral muscles were lateralized after the midline skin incision. A C arm was used for distance determination in operation. Then, the screws were placed at the required level using the Magerl technique (Osimplant, Turkey). Next, an extended laminectomy was performed using 1 and 2 mm Kerrison rongeurs, and the medial edges of the facet joints and neural foramen were decompressed (Figure 1). The lordotic inclined rods and screws were bilaterally stabilized. For fusion to the posterolateral side, the bones revealed by spinous process excision and laminectomy were mixed with synthetic graft and placed on the lateral side of the rods after decortication of the lateral masses. The wound was closed in layers in accordance with the anatomical position, and the patients were mobilized at the sixth postoperative hour. A cervical neck collar was used for six weeks.

Evaluations

Radiological Measurements

Neutral radiographs, dynamic radiographs, cervical computerized tomography (CT), and cervical magnetic resonance imaging (MRI) examinations were used for radiological evaluation. Cervical spine alignments were evaluated in terms of the Cobb angle. The calculations were obtained from vertical lines connecting the parallels drawn to the inferior end-plates of the C2 and C7 corpus (Figure 2). Lordotic angle values were evaluated as negative (-), and kyphotic angle values were evaluated as positive (+). Postoperative screw malpositions were evaluated with cervical CT. A mid-sagittal T2 cervical MRI was used for the narrowest location of the preoperative cervical canal and for postoperative enlargement of this region and enlargement of the anterior epidural space (Figure 3). In addition, each patient's lumbar spinal MRI was evaluated.

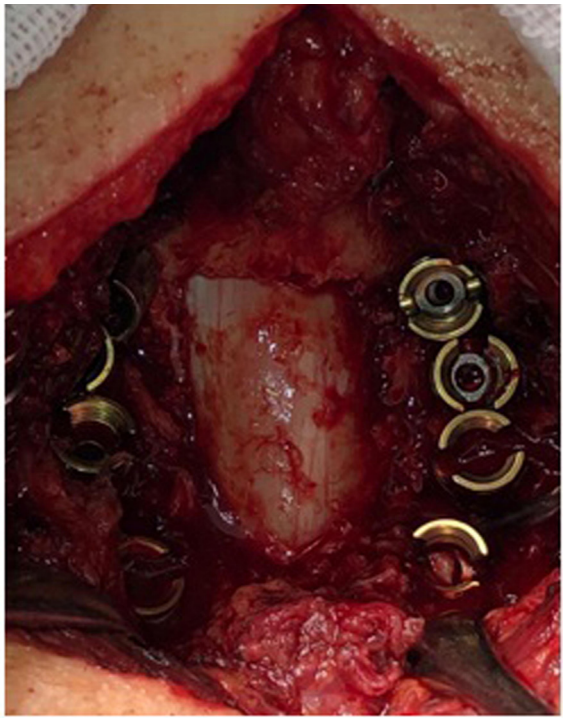

Figure 1. C4-C7 stabilization and decompressive laminectomy view

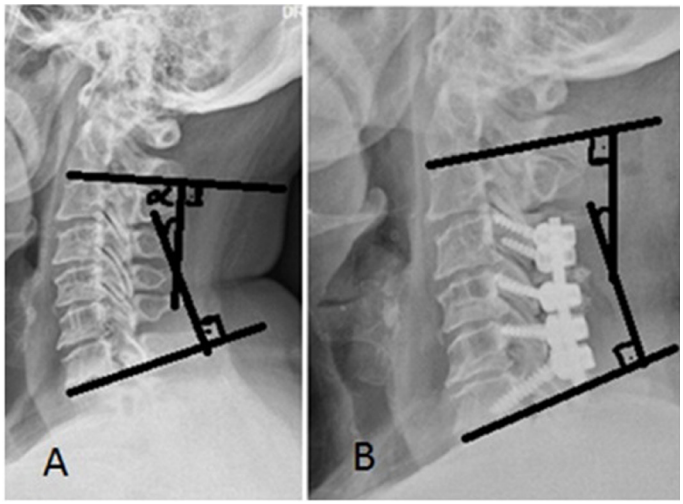

Figure 2A, B. Preoperative and postoperative Cobbs angle measurement method

Clinical Assessments

Clinical evaluations of the patients were compared according to the results of the mJOA (Table 1) and Nurick scales (Table 2) preoperatively and sixth months postoperatively. mJOA score improvements were calculated using the Hirabayashi method as follows: [(postoperative score - preoperative score)/(18-preoperative score)]x100.

Classifications

Those with preoperative lordotic spine alignment were classified as Group A, and those with kyphotic alignment were classified as Group B. Both groups were classified according to their postoperative cervical alignment, and these groups are indicated in Table 3.

Statistical Analysis

The data were analyzed statistically using the Statistical Package for the Social Sciences (IBM SPSS for Windows, V.24). Descriptive statistics for continuous variables, including mean and standard deviation, were calculated. Statistical analysis of all data was performed using the paired sample t-test. Continuous variables were presented as mean differences and 95% confidence intervals.

RESULTS

Patient Distribution Results

In total, 30 patients - 23 males (76.7%) and 7 females (23.3%) were included in the study, and the follow-up period was 6 to 44 months with an average of 21.2 months. The patients were between 40 and 80 years old (mean: 58.9), and 50% were between 50 and 59 years old. In total, 91 laminectomies were performed on the cervical vertebrae of our cases. The highest number of laminectomies were performed on the C5 vertebrae (27 cases) (Table 4).

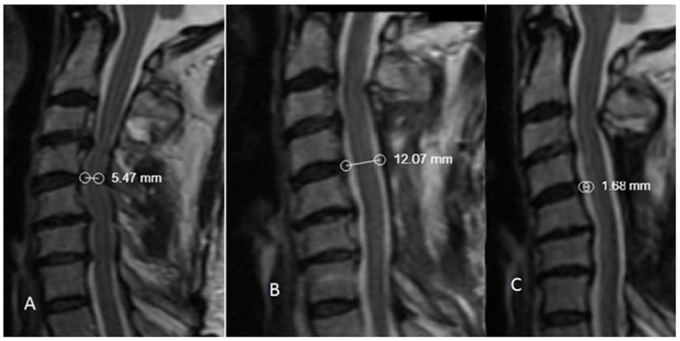

Figure 3. A) Narrowest canal diameter measurement in sagittal T2 MRI examination. **B)** Measurement of spinal canal diameter in postoperative sagittal T2 MRI examination. **C)** Measurement of the epidural distance formed in the postoperative sagittal T2 MRI examination.

Table 1. mJOA scale

Evaluation of upper extremities	
0	No movement in your hands
1	It moves your hands but cannot eat with a spoon
2	You can eat using it with a spoon, but it cannot button the dress buttons
3	Dress can button buttons with great difficulty
4	Dress can button buttons with slight difficulty
5	Normal, no disturbances
Motor-sensory evaluation of sub extremities	
0	Complete loss of motor and sensory functions
1	Sensory functions are preserved, but they cannot move their feet
2	It can move your feet but can't walk
3	Walking on flat ground with the help of a support (cane or walker)
4	With a support, the ladder can go up and down
5	There is moderate or severe instability during the walk, but the stairs can go up and down without support
6	It has a slight instability while walking, but it can walk without help
7	No dysfunction
Sensory evaluation of upper extremities	
0	Complete loss of sensation in the hands
1	There is severe sensory loss or pain description
2	Slight loss of sensation
3	Sensory loss does not describe
Evaluation of the sfincter function	
0	Not being able to urinate voluntarily
1	Significant difficulty in urinating
2	Mild or moderate difficulty urinating
3	Normal

mJOA: Modified Japanese Orthopedic Association

Table 2. Nurick scale

Grade 0	No myelopathy, minimal radiculopathy
Grade 1	There is myelopathy, walking is normal
Grade 2	There is mild to moderate myelopathy, walking is affected, it can work
Grade 3	Moderate myelopathy, impaired walking, independent at home but unable to work
Grade 4	There is moderate to severe myelopathy, the walker and someone's support are required
Grade 5	There is severe myelopathy, in a wheelchair

Results Associated with Sagittal Alignment

While the preoperative was -23.5º (-45º and -10º), the postoperatively mean angle was -9.8º (-34º and +15º). Postoperatively, 12 cases (70.6%) had lordotic cervical alignment, and 5 cases (29.4%) had kyphotic cervical alignment. In Group A, the diameter of the spinal canal measured from the narrowest part of the spinal cord was 5.3 mm (2.5-7.3 mm) on average. This value was measured as an average of 11.3 mm (10-12.9 mm) in Group AL and an average of 11.3 mm (9.7-13.6 mm) in Group AK (Table 5). The spinal canal diameters increased in both groups. An epidural cerebrospinal fluid gap was observed in postoperative MRI examination due to an average of 1.3 mm (0.4-3.1 mm) spinal cord displacement.

While the preoperative Cobb angle in Group mean B was +13.8º (+3º and +33º), the postoperative angle mean was +13.3º (+32º and -5º). Kyphotic alignment continued in 11 cases (84.6%), and lordotic alignment developed in 2 cases (15.4%). In Group B, the diameter of the spinal canal measured from the narrowest part of the spinal cord was 6.5 mm (4.9-9.6 mm) on average. This value was measured as an average of 11.5 mm (9.4-13.6 mm) in Group BL and an average of 10.9 mm (9.5-12.9 mm) in Group BK (Table 5). The spinal canal diameters increased in both groups. An epidural cerebrospinal fluid gap was observed in postoperative MRI examination due to an average of 1.4 mm (0.4-2.8 mm) spinal cord displacement.

While the mean diameter of the spinal canal in the narrowest place was 5.80 mm (9.6, 2.5) in the preoperative period, and 11.16 mm (13.6-9.4) in the postoperative period (p<0.001). In the postoperative period, an average of 1.35 mm (0.4-3.1) spinal cord shift was observed (p<0.001).

The cervical CT and dynamic radiographs of all cases showed that posterolateral fusion developed in the sixth postoperative month.

Table 3. Classifications of group A and B according to postoperative alignment

	Postoperative lordotic alignment	Postoperative kyphotic alignment
Group A	AL	AK
Group B	BL	BK

Table 4. Distribution of cases by age, gender and level of laminectomy

	n	%
Gender		
Male	23	76.7
Female	7	23.3
Age range		
40-49	4	13.3
50-59	15	50
60-69	6	20
70 ve >	5	5
Vertebral level undergoing laminectomy		
C1	1	3.3
C2	1	3.3
C3	14	46.7
C4	21	70
C5	27	90
C6	24	80
C7	3	10
Distribution of screws		
C1	2	0.8
C2	2	0.8
C3-6	211	80.8
C7	38	14.5
T1	6	2.3
T2	2	0.8

Clinical Evaluation

The mean mJOA scores of all cases increased postoperatively to 15.2 (8-18) from the preoperative values of 12 (6-16). The increase in the postoperative mJOA scores was statistically significant (p<0.001). The improvement in the mJOA scores was average 63.8 (17-100). The Nurick score for all patients was on average 2.4 (0-5) in the preoperative period, and this score decreased to an average of 1.1 (0-4) in the postoperative period (p<0.001).

The mean preoperative mJOA scores of 14 patients with postoperative lordotic sequence increased from 11.4 (6-16) to postoperative 14.7 (9-18). Improvement in the mJOA scores in these patients was average 64.8 (25-100). While the preoperative Nurick values of these cases were average 2.8 (0-5), they decreased to postoperatively to 1.4 (0-4) (Table 6).

Table 5. Preoperative and postoperative cobbs angle changes and spinal canal diameters of cases

	Preoperative		Postoperative			
Group	A	B	AL	AK	BL	BK
n, (%)	17 (56.7)	13 (43.3)	12 (70.1)	5 (29.4)	2 (15.4)	11 (84.6)
Cobbs angle	- 45°,-10°	+3°,+33°	-34°,-5°	+2°,+15°	-5°,-5°	+3°,+32°
Mean	-23.5°	+13.8°	-17.3°	+8.2°	-5°	+16.6°
Spinal canal diameter (mm)*	2.5-7.3	4.9-9.6	10-12.9	9.7-13.6	9.4-13.6	9.5-12.9
Mean	5.3	6.5	11.3	11.3	11.5	10.9

*= It is the diameter measured preoperatively and postoperatively from the narrowest segment of the spinal canal

Table 6. mJOA score, improvement in JOA score and nurick score according to the postoperative sagittal alignment

	Preoperative mJOA (mean)	Postoperative mJOA (mean)	Improvement %	Preoperative Nurick	Postoperative Nurick
Postoperative lordotic alignment (n=14)	11.4	14.7	64.8	2.8	1.4
Postoperative kyphotic alignment (n=16)	12.5	15.7	62.5	2.1	0.8

mJOA: Modified Japanese Orthopedic Association, JOA: Japanese Orthopedic Association

The preoperative mJOA scores of 16 patients with postoperative kyphotic alignment were average 12.5 (6-16). This value increased to 15.7 (8-18) in the postoperative period. The improvement in the JOA scores was average 62.5 (17-100). The preoperative Nurick values of this group decreased from 2.1 (1-5) to 0.8 (0-4) in the postoperative period (Table 6).

Complications

C5 nerve palsy was observed in two cases; the functional loss in shoulder abduction observed in these cases improved with physical therapy at the postoperative three-months control. Postoperative wound infection was seen in one case; the infection resolved with appropriate antibiotic therapy, and reoperation was not needed. As the left C5 lateral mass was broken while applying the lateral mass screw in one case, a screw was placed in that segment from one side. There was no problem in applying screws to the vertebrae above and below the fracture on the same side. No additional procedure other than synthetic graft was used for fusion. A unilateral C7 transpedicular screw was directed to the lateral of the vertebral corpus in two cases and to the spinal canal in one case. In one case, a unilateral T1 transpedicular screw was directed to the lateral of the vertebral corpus. Vertebral artery injury or loss of neurological function due to screw application were not observed in any of our patients. Therefore, no patients were reoperated on due to screw malposition.

A total of 261 screws were applied to the patients: 2 lateral mass screws to C1, 2 transpedicular screws to C2, 211 lateral mass screws to C3-6, 38 transpedicular screws to C7, 6 transpedicular screws to T1, and 2 transpedicular screws to T2 (Table 4). Lumbar spondylosis were accompanied in 21 cases (70%).

DISCUSSION

In the treatment of CSMP caused by the cervical narrow canal, it is essential to relax the spinal cord by expanding the spinal canal. Anterior, posterior, and combined approaches have been described for the surgical treatment of CSMP. Generally, the anterior approach is preferred in kyphotic cases, while the posterior approach is preferred in lordotic cases[12]. However, in some cases it may not be clear which surgical approach will be appropriate. As in all degenerative spine diseases, multilevel stenosis is observed in cases of CSMP; multilevel decompression with the posterior approach is becoming more common in these cases. Likewise, multilevel decompression with an anterior approach, especially in corpectomy operations, may not provide sufficient stability even if stabilization is included, and a need for posterior stabilization arises[14].

With the posterior surgical approach in CSMP treatment, adequate decompression can be achieved by performing posterior stabilization/fusion or laminoplasty after single-level multilevel laminectomies. Laminoplasty would be a good choice for multilevel CSMP cases with lordotic alignment[12,14,15]. Although laminoplasty provides adequate decompression in patients with kyphotic cervical spine alignment, it is not recommended because it cannot correct spine alignment. It has been reported that more kyphotic deformity develops in patients who underwent laminoplasty compared to patients operated on with an anterior approach[13,16,17]. Kim and Dhillan[18] proposed the application of fusion to reduce the risk of postoperative kyphotic deformity in patients with a loss of lordosis or kyphotic curvature. On the other hand, denervation, which occurs due to the stripping of deep extensor muscles, which is performed to provide the necessary surgical area for these approaches, is one of the common causes of a loss of lordosis after laminoplasty[19,20].

While adequate spinal canal decompression occurs with the posterior surgical approach, decompression only with laminectomy may cause segmental instability, kyphotic deformity, the emergence of perineural adhesions, and late neurological deterioration. Similarly, according to a study by Kaptain et al.[16], kyphosis may develop in 21% of patients undergoing laminectomy for CSMP, and pre- and postoperative alignment is not associated with clinical outcomes. On the other hand, adequate spinal canal decompression occurs with the posterior surgical approach, while the release of the posterior tension band increases the risk of kyphotic deformity depending on factors such as age, osteoporosis, degree of decompression, affected spine levels, and underlying pathological processes[21]. In addition, a postoperative loss of lordosis is due in part to straightening the neck during preoperative positioning. In order to prevent these adverse effects that may occur during the postoperative period, the application of fusion after posterior laminectomy has been recommended[22]. Stabilization created with posterior cervical screw fixation after laminectomy helps neurological recovery, and a cervical loss of lordosis can be

prevented by strengthening the posterior tension band[23]. In addition, the large screw heads of the screws used in stabilization may prevent the necessary repositioning to ensure intraoperative sagittal alignment[24].

Posterior cervical screw fixation can be applied as transpedicular or LMSF[25-27]. It has been reported that with the application of cervical transpedicular screw fixation, the impaired cervical lordotic alignment will be improved by biomechanically stronger transpedicular screws[28]. However, the placement of transpedicular screws in the cervical region, the anatomically thin structure of the pedicles, their neurovascular neighbourhood, especially the need for an orientation of up to 45°, requires significant experience or technological support such as navigation guidance[29]. Neurovascular injury and other complications limit the use of this technique[30]. Although intraoperative CT applications have been described to reduce the complication rates of cervical transpedicular screw application, an increased cost and a high exposure to radiation are other important disadvantages[31,32].

Despite the biomechanical weaknesses of the LMSF technique compared to the stabilization systems made with transpedicular screws, it has also been reported that lordosis is preserved, especially in patients with lordotic spine sequences, and kyphotic deformity can be significantly reduced in patients with mild kyphotic sequences[33-35]. On the other hand, for the treatment of CSMP patients with advanced kyphotic angulation, fusion can be applied with multilevel corpectomy and/or decompression provided by osteotomies, which can be performed with combined anterior and posterior approaches. Although successful neurological recovery can be achieved with a combined approach, implant-related complication rates are especially high[36]. Cabraja et al.[24] found no difference in clinical improvement after anterior and posterior cervical decompression but reported less sagittal improvement in the posterior procedure than in the anterior procedure. From a clinical standpoint, it has been reported that better results were obtained in cases that included stabilization, regardless of the anterior or posterior approach[37].

It is known that the cervical spine undergoes a loss of lordosis during the degenerative process. This process, loss of disc height, osteophyte protrusions, arthrosis of facet joints, which turn into a vicious cycle in a cause-effect relationship, becomes relatively stable, and cervical spinal stenosis also occurs. However, the emerging spondylotic cervical spine, especially the strong fusion of spondylotic osteophytes located in the anterior area, may not be possible with a posterior approach alone to provide sagittal alignment with a stabilization application[3,38]. Therefore, although corpectomy/osteotomy techniques are recommended for better lordotic alignment, it should be known that the complication rates of these techniques are high. On the other hand, stabilization of the spine has been suggested for successful clinical results, regardless of the approach used[37]. Cheung et al.[39] demonstrated that the improvement in mean JOA scores was statistically significant after the third postoperative month, and the scores decreased in the sixth month. In our study, it was observed that the preoperative mean JOA score of our patients increased from 12 to 15.2 in the sixth postoperative month. It was seen that there was an average of 63.8% improvement in the JOA score. It was observed that the Nurick score of our patients decreased from 2.4 in the preoperative period to 1.1 postoperatively. Regardless of postoperative kyphotic or lordotic alignment, clinical improvement was observed in both conditions.

It has been reported that there is a relationship between clinical results and the ability to provide anterior and posterior subarachnoid distances in the sagittal MRI scans of patients who underwent laminoplasty[1]. Similarly, sagittal alignment can be corrected with LMSF after laminectomy, and excellent neurological recovery can be achieved by the posterior displacement of the spinal cord[27]. In our patients, it was observed that the spinal canal diameter expanded from 5.8 mm to 11.2 mm in the narrowest place after laminectomy, and sufficient decompression was observed. In addition, postoperative cervical MRI revealed an average epidural CSF distance of 1.35 mm in the anterior epidural space. Posterolateral bone fusion was observed in all our cases in the sixth postoperative month. No permanent neurological damage or vascular injury was observed due to the application of lateral mass or transpedicular screws. In our clinical follow-up, no increase in kyphotic deformities was observed.

In our study, it was observed that the lordotic alignment was preserved in 70.6% of the patients with preoperative lordotic spine alignment, and postoperative kyphotic alignment developed in 29.4% of the patients. In addition, it was observed that 84.6% of our patients with preoperative kyphotic spine alignment continued to have kyphotic alignment, and postoperative lordotic alignment was achieved in 15.4% of these patients. Although lordotic alignment could not be achieved in these cases, it was observed that there was no increase in kyphotic angulation in the clinical follow-up.

There are several possible reasons why lordotic alignment was not achieved in our patients with kyphosis. In the presence of anterior fusion caused by anterior osteophytosis accompanying kyphotic deformity, adequate correction strength may not be obtained with LMSF application. In addition, preoperative positioning to facilitate surgical exploration could not be corrected sufficiently postoperatively. The absence of lordotic alignment might have also been caused by the large screw heads preventing the manipulation required to insert the lordotic curved rod.

Study Limitations

This study has some limitations. Its retrospective nature and relatively low number of participants may decrease the scientific value of the study. In addition, this study was carried out by a single surgical team, and we only selected patients from our medical center. Therefore, prospective, large-scale, multicenter clinical trials are needed to further validate our results.

CONCLUSION

In the treatment of CSMP cases, adequate spinal canal decompression is created with posterior laminectomy and the LMSF technique, and these provide sufficient neurological recovery and stability. Posterolateral stabilization can preserve cervical alignment in patients with lordotic spine alignment and prevent progressive kyphosis after laminectomy; however, if anterior osteophytosis is present in patients with a preoperative loss of lordosis or kyphotic alignment, this technique may not be suitable for ideal lordotic alignment.

Ethics

Ethics Committee Approval: This study was conducted upon receiving approval from the Ethics Committee for Clinical Studies of Ordu University (number: 2020/161).

Informed Consent: Informed consent was obtained from our patients for our study.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Concept: A.D., Design: A.D., Data Collection or Processing: D.O.K., Analysis or Interpretation: D.O.K., Literature Search: D.O.K., A.D., Writing: D.O.K.

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ORIGINAL ARTICLE
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COMPARISON OF TWO POSTERIOR INSTRUMENTATION TECHNIQUES IN MULTILEVEL CERVICAL SPONDYLOTIC MYELOPATHY TREATMENT: LATERAL MASS SCREW FIXATION VS PEDICLE SCREW FIXATION

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ABSTRACT

Objective: In this study we compared the clinical results of two posterior instrumentation methods in surgical treatment of multilevel cervical spondylotic myelopathy (CSM) and we aimed to share the clinical outcomes.

Materials and Methods: This study was a retrospective analysis of patients with multilevel CSM disease who underwent decompression and posterior internal fixation with lateral mass screw (LMS) or pedicle screw (PS). The study included 63 patients and the patients were divided into two groups. The LMS group comprised 32 patients and the PS group included 31 patients. C2-7 cervical lordosis, modified Japanese Orthopedic Association (mJOA) scores, neck disability index (NDI) and visual analog scale (VAS) assessments of the groups were compared. Complications were noted and analyzed in detail.

Results: In the PS group, change in C2-7 lordosis was found to be significantly higher than the LMS group ($p<0.001$). Changes in quality of life indices (mJOA, NDI and VAS) in the postoperative period did not show a significant difference between LMS and PS groups ($p=0.608$, $p=0.224$ and $p=0.296$). In the study group, 10 complications were observed in 63 patients (10/63, 15.8%). Implant related complication ratio was found to be significantly higher in the LMS group.

Conclusion: Both of the posterior instrumentation methods revealed similar results in terms of quality of life indices. In this study, better results were obtained in the PS group in terms of C2-7 lordosis and implant-related complications. We think that both methods can be used in CSM treatment, however PS fixation is technically challenging with a long learning curve. Therefore, we have the opinion that it can be applied in selected patients by trained and experienced surgeons.

Keywords: Cervical spondylotic myelopathy, lateral mass screw, pedicle screw

INTRODUCTION

Cervical spondylotic myelopathy (CSM) is a spinal cord disease that causes limitation of movement and poor quality of life in the elderly population. Spinal cord compression develops as secondary to joint, and ligament hypertrophy generally occurs progressively, surgical treatment is recommended in cases with severe myelopathy to stop clinical deterioration[1]. Laminectomy with decompression and fusion is generally recommended in patients with axial neck pain and involving the multilevel spinal cord (level 3 and above) disease[2]. Lateral mass screwing (LMS) is commonly used for posterior fixation. LMS was first applied in 1979 by Roy-Camille and quickly gained widespread popularity in the spine community[3]. The most important advantage is that it provides an effective fixation and low neurovascular injury rate[3-5]. However, the fact that the screw placed in the lateral mass has a short bone-screw purchase worries clinicians about implant failure[6-8]. Another posterior instrumentation method, pedicle screwing (PS), was first used by Abumi et al.[9] in trauma surgery in 1990. By this method, screws are placed to the pedicles, the strongest part of the vertebra and a strong anchor is created as in the thoracic and lumbar region. The point that major concern of most surgeons is the risk of vertebral artery injury and root damage[10,11]. Therefore, it is not preferred as widely as LMS.

In this study, we examined the clinical results of two posterior instrumentation methods in multilevel CSM surgical treatment

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in terms of radiological, quality of life indices and complications, and we aimed to share the clinical results.

MATERIALS AND METHODS

This study had been carried out in accordance with principles of the Declaration of Helsinki and approved by Ethics Committee of Adana City Training and Research Hospital. Informed patient consent was obtained from all individuals.

Patient Population

This study was a retrospective analysis of patients with multilevel CSM disease who underwent decompression with total laminectomy and posterior internal fixation with LMS or PS fixation in the period January 2014 to February 2019. The inclusion criteria were: in at least 3 consecutive levels of spinal cord compression in magnetic resonance imaging (MRI), hyperintense changes in T2 sequence consistent with myelopathy, accompanying neck pain, neurological examination findings consistent with myelopathy. Exclusion criteria were; previous anterior/posterior decompression or fusion and signs of pointing a motor neuron disease or polyneuropathy in electromyography.

The study included 63 cases, and the patients were divided into two groups. The cases in which preoperative cervical lordosis was preserved were included in the LMS group, while patients whose cervical lordosis deteriorated were included in the PS group. The LMS group comprised 32 patients, and the PS group included 31 patients.

Surgical Procedures

All operations were performed by the same senior spine surgeon. LMS was performed following posterior midline incision, bilateral subperiosteal muscle dissection and facet joints were exposed. The superior lateral ventral corner parallel to the facet joints was targeted by entering a 2 mm high-speed burr drill from the midpoint of the lateral mass. Screws (PIRON/IZMIR/TURKEY) were all 4 mm in diameter and 10-14 mm in length. Cobalt chromium (Co-Cr) rods were preferred.

PS fixation were performed with free-hand technique under fluoroscopy guidance and the screw entry point is identified as Abumi et al.[12] defined. PS (PIRON/IZMIR/TURKEY) diameters were 4 mm in size, length of screws ranged between 24-38 mm and Co-Cr rods were preferred.

All patients underwent total laminectomy in selected levels. While performing decompression in the LMS group, care was taken that the facetectomy should not exceed 50% of facet joints to not cause further instability[13,14]. In the PS group, 2-level ponte osteotomy was performed at C4-5 and C5-6 levels for prophylactic foraminotomy[15]. C5 roots were widely decompressed. This procedure was performed to prevent the development of postoperative C5 palsy.

Following screw fixation, posterior cortex of lateral masses were decorticated and fusion with autografts (harvested from lamina) performed. While rods were placed in both groups, the head side of the operating table was raised, and rods were placed on the screw heads under compressive force to create a lordotic posture to neck. Neurological damage was tried to be prevented by checking the simultaneous intraoperative neuromonitorisation (IONM) recording.

IONM was used in both LMS and PS groups to detect spontaneous physiological changes by recording during the surgical period.

Radiological Assessment

All patients had symptomatic multilevel CSM with neck pain, confirmed by MRI. Computerised tomography imaging, cervical hyperflexion-hyperextension radiographs and anteroposterior and lateral radiographs were performed preoperatively. Only the preoperative and final postoperative radiographs were included for evaluation due to the length of the follow-up time. Radiographic parameters included C2-7 lordosis.

Clinical Outcomes

Modified Japanese Orhtopedic Association (mJOA) score, neck disability index (NDI) and visual analog scale (VAS) assessments were performed to patients preoperatively and postoperatively to assess the health-related quality indices and patient comfort. We compared the results of mJOA, NDI and VAS scores preoperatively and the last follow-up postoperatively due to the length of the study.

Apart from surgical complications such as infection and postoperative haematoma, implant related mechanical complications (screw pull-out, screw loosening, screw breakage, rod breakage) and neurovascular injury were assessed and compared. Patients without mechanical complication were considered in favor of fusion.

Statistical Analysis

Statistical evaluation was performed using the Statistical Package for Social Sciences (SPSS) for Windows 20 (IBM SPSS Inc., Chicago, IL) program. The normal distribution of the data was evaluated with the Kolmogorov-Smirnov test. Normally distributed numerical variables were shown as mean ± standard deviation, while numerical variables not showing normal distribution were shown as median (minimum, maximum). Categorical variables were expressed as numbers and percentages. Student t-test was used for comparing numerical variables showing normal distribution between the two groups, and Mann-Whitney U test was used for comparing numerical variables that did not show normal distribution. Chi-square and Fisher's exact Chi-square test were used for comparison of categorical data. For the comparison of pre- and postoperative changes, repeated mixed model analysis was used. The relationship between the postoperative change percentages (%) of radiographic parameters and quality of life indices was evaluated with Spearman correlation analysis.

RESULTS

Sixty-three CSM patients with 32 LMS and 31 PS screws were included in the study population. The mean age of the patients

was 62.2±8.6, 57.2% (n=37) were male, 42.8% (n=26) were female. The median follow-up interval of the patients was 26 (17-46) months. The demographic characteristics, preoperative radiological findings and quality of life indices of the patients are shown in detail in Table 1.

In PS group, C2-7 lordosis change was found to be significantly high with respect to LMS group (p<0.001) (Table 2).

Significant improvement was found in C2-7 lordosis and quality of life indices (mJOA, NDI and VAS) postoperatively in all patients (Table 2).

Changes in quality of life indices (mJOA, NDI and VAS) postoperatively did not differ significantly between the LMS and PS groups (p=0.608, p=0.224, p=0.296) (Table 2).

In the study group, complications were observed in 10 patients with a ratio of 15.8% (10/63). Screw loosening was seen in 4 patients (12.5%) in the LMS group, these patients underwent revision surgery and revised with PS's. In LMS group no screw or rod fracture was observed. Upon the development of superficial wound infection in 1 patient (3.1%), debridement was performed under local anesthesia and antibiotherapy was applied according to the wound culture result. Direct neurovascular injury was not observed. C5 palsy was observed in 2 patients (6.2%) after the second postoperative day. Complete recovery was achieved at the end of the first month following the physical therapy and rehabilitation programme.

No screw loosening, screw or rod fracture was observed in the PS group. C5 palsy was observed in 2 patients (6.4%) after the second postoperative day. With appropriate physiotherapy, complete recovery was achieved in the patients within 1 month. One patient underwent debridement due to superficial wound infection. Implant-related revision surgery was not performed. Vertebral artery injury or spinal cord direct injury was not found. In LMS group, implant related complications are found to be significantly high with respect to PS group (p<0.05) Table 3.

DISCUSSION

CSM is a progressive disease that causes spinal cord dysfunction, causing gait disorders and weakness in the upper and lower extremities. In this clinical status where medical treatment is not effective, surgical strategies are applied. The main purpose of surgical treatment is to stop progression of disease and provide an effective decompression[16]. General opinion in decompression surgery is such that if the spinal cord is compressed from the anterior, it is usually relieved from pressure anteriorly, if the compression is from the

Table 1. Distribution of demographic and clinical findings

Variables	All population (n=63)	LMS (n=32)	PS (n=31)	p
Age, years				
Mean ± SD	62.2±8.6	63.9±8.8	62.5±7.6	0.693
Min-max	49-77	49-72	49-77	
Gender, n (%)				
Female	27 (42.8)	16 (50.0)	9 (29)	0.324
Male	36 (57.2)	16 (50.0)	22 (71)	
Follow-up period (m)				
Median	26	26.5	25	0.116
Min-max	17-46	24-46	17-33	
Preoperative C2-7 lordosis (°)				
Median	2	3	0	0.019
Min-max	(-10)-10	(0)-10	(-10)-3	
mJOA				
Mean ± SD	9.1±2.5	9.2±2.5	9.0±1.4	0.824
Min-max	7-13	7-13	7-13	
VAS				
Mean ± SD	8.2±0.8	7,9±0.9	8.3±0.8	0.327
Min-max	6-9	6-9	7-9	
NDI				
Median	30	28	30	0.817
Min-max	20-38	20-38	21-38	

Numerical variables with normal distribution were shown as mean ± SD.
Numerical variables that do not show normal distribution are shown as median.
Categorical variables were shown as numbers (%).
LMS: Lateral mass screw, PS: Pedicle screw, mJOA: Modified Japanese Orthopedic Association, VAS: Visual analog scale, NDI: Neck disability index, SD: Standard deviation, Min: Minimum, Max: Maximum

Table 2. Postoperative change of radiographic parameters and quality of life indices

Variables	All population (n=63)		p	LMS (n=32)		p	PS (n=31)		p	Δp
	Preoperative	Postoperative		Preoperative	Postoperative		Preoperative	Postoperative		
C2-7 (°)										
Median	2	10	<0.001*	3	6	<0.001*	0	9	<0.001*	<0.001*
Min-max	(-10)-10	0-18		(0)-10	0-16		(-10)-3	3-18		
mJOA										
Mean ± SD	9.1±2.5	13.3±1.3	<0.001*	9.2±2.5	13.1±1.1	<0.001*	9.0±1.4	13.4±1.5	<0.001*	0.608
Min-max	7-13	11-16		7-13	11-16		7-13	11-16		
VAS										
Mean ± SD	8.2±0.8	3.4±1.3	<0.001*	7,9±0.9	3.5±1.3	<0.001*	8.3±0.8	3.6±1.3	<0.001*	0.296
Min-max	6-9	2-6		6-9	2-6		7-9	2-6		
NDI										
Median	30	17	<0.001*	28	18	<0.001*	30	15	<0.001*	0.224
Min-max	20-38	8-34		20-38	8-34		21-38	8-34		

Numerical variables with normal distribution were shown as mean ± SD.
Numerical variables that do not show normal distribution are shown as median.
*p<0.05 shows statistical significance.
Δp shows statistical significance of preoperative and postoperative differences between groups (ΔMASS vs ΔPedicule)
LMS: Lateral mass screw, PS: Pedicle screw, mJOA: Modified Japanese Orthopedic Association, VAS: Visual analog scale, NDI: Neck disability index, SD: Standard deviation, Min: Minimum, Max: Maximum

Table 3. Evaluation of complications between groups

	Implant related complications (screw loosening) (%)	Infection (%)	C5 palsy (%)
LMS (n=32)	4 (12.5)	1 (3.1)	2 (6.2)
PS (n=31)	0 (0)	1 (3.2)	2 (6.4)
p-value	p<0.05	p>0.05	p>0.05

p<0.05 shows statistical significance.
LMS: Lateral mass screw, PS: Pedicle screw

posterior, the spinal cord is decompressed from the posterior. However, this is not always the case. Posterior approaches are generally preferred in cases with multi-level spinal cord compression[2]. While deciding on a posterior approach, detailed questioning of the need for instrumentation is important to prevent complications such as instability and postlaminectomy kyphosis. More complex surgical procedures may be required if postlaminectomy kyphosis occurs in patients with spinal cord dysfunction[17,18].

Laminoplasty, one of the cervical posterior instrumentation methods, can be used in cases where cervical lordosis is preserved[19,20]. However, in cases with neutral or kyphotic cervical curvature, additional fusion is recommended if there is accompanying neck pain[2]. The two effective methods at this point are LMS and PS[2,6,21,22]. LMS is the most preferred posterior instrumentation method preferred by spinal surgeons. Fixation is provided by screws placed in the lateral mass of the cervical vertebra (Figure 1). The risk of nerve root damage and vertebral artery injury is low[3-5]. The main concern with LMS is related to the strength of the screw[7,23]. This situation causes weakness in

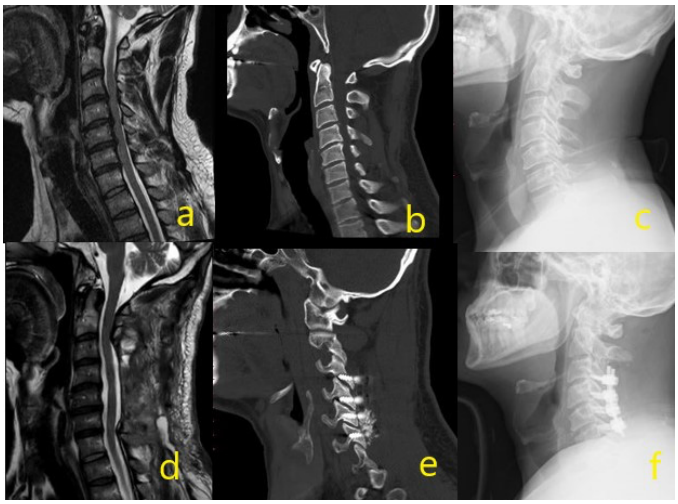

Figure 1. Radiological images of the 58-year-old male patient with CSM who underwent total laminectomy with decompression + lateral mass fixation between C3-6 are shown above. Preoperative magnetic resonance, computed tomography, and lateral X-ray images are demonstrated between a-c). In d-f) images, postoperative images are displayed on MRI, CT and direct lateral radiography, respectively.

CSM: Cervical spondylotic myelopathy, MRI: Magnetic resonance imaging, CT: Computed tomography

pathologies that require rigid fixation. PS, on the other hand, provides strong anchor strength and stabilization by reaching the anterior of the vertebra through the pedicle[24] (Figure 2). Its major disadvantage is the risk of nerve root injury and vertebral artery injury[6].

In this study, we examined the clinical results of both methods in terms of cervical lordosis, quality of life indices and complications. In the study of Sielatycki et al.[25], decompression and fusion with LMS were applied to 45 patients with CSM, and as a result of the study, a significant 3.6° improvement was found in the C2-7 cobb angle[25]. In another study, Abumi et al.[24] reported the results of cervical kyphosis treatment with PS's, and kyphosis was divided into 2 groups as flexible and rigid/fixed. The kyphosis angle was measured radiologically, and approximately 23° correction was obtained postoperatively. In our study, we obtained similar results parallel to the literature mentioned above. Radiologically, there was a significant improvement in C2-7 lordosis values in both groups. When compared between the groups, the improvement was better in the PS group. We attribute this to the ponte osteotomies we performed for prophylactic foraminotomy. It can be explained why the improvement in C2-7 lordosis is better in the PS group with this process, which provides a gain of approximately 5° at each level. Another reason may be that when performing decompression in the LMS group, care was taken that facetectomies did not exceed 50% in order to not to increase instability (Table 4).

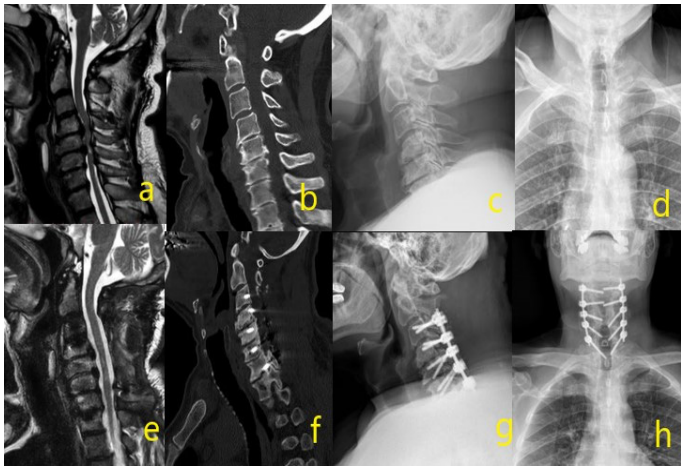

Figure 2. A 61-year-old male patient with multilevel CSM underwent decompression + PS fixation between C3-7. Preoperative MRI, CT and direct x-ray images are seen on images between a-d). Postoperative images are seen in images between e-h). e) MRI shows that the spinal cord compression has disappeared completely.

CSM: Cervical spondylotic myelopathy, PS: Pedicle screw, MRI: Magnetic resonance imaging, CT: Computed tomography

Table 4. Levels and numbers of total laminectomy and ponte osteotomy

Levels	Total laminectomies	Ponte osteotomy
C2-3	78	-
C3-4	81	-
C4-5	63	31
C5-6	63	31
C6-7	21	-
Total	306	62

Several studies have been published reporting improvement in quality of life after fusion with laminectomy in multilevel CSM treatment[25-28]. In the study of Sielatycki et al.[25], 45 patients underwent laminectomy with decompression and fusion with the lateral mass, and at the end of 1 year, significant improvement was obtained in NDI and mJOA scores. In the study conducted by Blizzard et al.[28] where they compared laminoplasty with laminectomy + fusion (LMS) in patients with CSM, 31 patients were applied laminectomy + fusion, and it was reported that there was a significant improvement in JOA and VAS scores[28]. In the study of Du et al.[29], 41 patients with multilevel cervical degenerative myelopathy were evaluated. The study, which reported a mean follow-up of 2.8 years, found significant improvement in JOA and VAS scores in patients who underwent laminectomy with fusion (LMS). In another study reporting 18 months follow-up results of 48 patients, Chang et al. applied posterior instrumentation (LMS) with laminectomy a significant improvement was observed in JOA score. Kotil et al.[30] found a significant improvement in Nurick scores in the study in which patients with CSM have applied decompression with posterior fixation (PS). In another study, Abumi et al.[32] reported the results of one-stage surgery with PS in patients with myelopathy. Neurological status evaluation was made according to Frankel staging and no worsening was observed in the postoperative period in any patient, while improvement was detected in 26 of 46 patients. In this study, considering the literature data reported above, we think that the results obtained in both groups are satisfactory in terms of quality of life scores. When we compared the results of both groups in terms of mJOA, NDI and VAS, we could not find a significant difference. We think the reason for this is the sufficient stability was accomplished and adequate decompression had been provided.

Some complications were encountered in the study cohort. Screw loosening was seen as an implant-related complication in 4 patients in the LMS group, and these patients underwent revision surgery by placing PS's. There were no implant-related complications in the PS group. In the biomechanical study of Johnston et al.[23], LMS and PS were compared, while the percentage of loosening in the bone-screw interface of PS's was found to be low, the strength was found to be higher in the fatigue test. In the biomechanical study of Ito et al.[8], LMS and PS were compared under the effect of torsion and flexion-extension forces. PS's were found to have 4 times stronger pullout strength in the torsion group and 2 times stronger in the flexion-extension group. In this study, a result supporting the above literature was obtained. While no pull-out or loosening was observed in the PS group, 4 patients in the LMS group had screw loosening.

Superficial wound infection developed in both groups in 2 patients and they were given medical treatment with locally administered surgical debridement. No vertebral artery damage or direct root injury was observed in both groups. There were no neurological deficits due to spinal cord injury however C5

palsy was observed both in 2 patients in LMS and PS group postoperatively 48 hours. We do not know the exact cause of C5 palsy, but we think that the tension in the root due to spinal cord shift after decompression caused this situation. Many articles have reported the development of C5 palsy as a result of posterior cervical surgery, and the rate for this has been reported as 5-14%[33,34]. In this study, this rate was found to be 6.4%. Considering the current literature data, our C5 palsy complication rate is parallel to the literature.

Study Limitations

There are many limitations to this study. The first one of these is the retrospective design. Secondly, radiographic parameters could be analyzed in more detail and their correlation with quality of life indices could be questioned. The strength of the study is that it analyzed two different posterior fixation techniques demographically, radiologically and clinically in similar patient groups.

CONCLUSION

Both posterior instrumentation methods showed similar results in terms of quality of life indices. In this study, better results were obtained in the PS group in terms of C2-7 lordosis and implant-related complications. We think that both methods can be used in CSM treatment, but the PS application technically difficult and has a long learning curve. Therefore, we believe that it can be applied by skilled and experienced surgeons in selected cases.

Ethics

Ethics Committee Approval: This study had been carried out in accordance with principles of Declaration of Helsinki and approved by Ethics Committee of Adana City Training and Research Hospital (date: 15.01.2020, decision no: 690).
Informed Consent: Informed consent was obtained from all individual participants included in the study.
Peer-review: Internally peer-reviewed.

Authorship Contributions

Concept: S.K.O., A.A., S.B.K., V.A., B.A., Y.G., A.İ.Ö., Design: S.K.O., A.A., S.B.K., V.A., B.A., Y.G., A.İ.Ö., Data Collection or Processing: A.A., S.K.O., S.B.K., V.A., B.A., Y.G., A.İ.Ö., Analysis or Interpretation: A.A., S.K.O., S.B.K., V.A., B.A., Y.G., A.İ.Ö., Literature Search: S.K.O., A.A., S.B.K., V.A., B.A., Y.G., A.İ.Ö., Writing: S.K.O., A.A., S.B.K., V.A., B.A., Y.G., A.İ.Ö.

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EVALUATION OF THE EFFECTIVENESS AND RELIABILITY OF LOW-DOSE TRANEXAMIC ACID USED IN ADOLESCENT IDIOPATHIC SCOLIOSIS SURGERY

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ABSTRACT

Objective: Tranexamic acid (TXA) is an antifibrinolytic drug that is frequently used in pediatric spinal fusion surgery to prevent bleeding. In recent publications, TXA was used in very high doses, but there is no consensus about the dosage of TXA in adolescent idiopathic scoliosis (AIS) surgeries. Our aim was to investigate the effectiveness and safety of a low-dose regimen on perioperative bleeding in AIS surgery.

Materials and Methods: A total of 25 patients diagnosed as having AIS were reviewed retrospectively. We retrieved demographic and intraoperative data, and bleeding related outcomes of the patients from their medical records. The primary outcomes were estimated blood loss and the transfusion requirements.

Results: Twenty-two (88%) of the patients were women. The mean age was 13.72 years. The mean number of vertebrae fused was 11.79. Estimated blood loss was 616 mL, and intraoperative mean red blood cell unit transfusion was determined as 0.8 units. No adverse event was observed related to TXA usage.

Conclusion: The use of low-dose TXA is a reliable and efficient method to reduce bleeding in AIS surgery.

Keywords: Tranexamic acid, adolescent idiopathic scoliosis, blood loss

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity involving the sagittal, horizontal, and frontal planes, and affecting 1-3% of the child population aged 10-16 years. Although the pathogenesis is not clearly explained, hereditary factors are in the foreground[1]. Posterior spinal fusion (PSF) surgery is the preferred type of surgery in these patients, but long surgical time and extensive dissections can cause significant blood loss. In addition, multiple osteotomies and wide muscle dissections performed during surgery, preoperative high Cobb angle, and increased number of vertebrae requiring fusion, cause an increase in the amount of bleeding[2]. Due to allogeneic blood transfusion performed after severe bleeding; transfusion reactions and blood-borne pathogen transmission increase the risk of morbidity and mortality[3]. Therefore, besides techniques such as hypotensive anesthesia, acute normovolemic hemodilution, preoperative autologous donation, there are also pharmacological agents used to prevent bleeding[4,5].

Tranexamic acid (TXA) is an antifibrinolytic drug that is a synthetic lysine analog. It prevents fibrin degradation by preventing the conversion of plasminogen to plasmin[6]. TXA is frequently used in major surgery with bleeding, and its effectiveness in pediatric spinal fusion surgery has been reported many times in the literature[7-9].

Although TXA is used in different doses in the literature, we have been using it in our clinic, in the surgery of AIS cases with a loading dose of 10 mg/kg and a maintenance dose of 1 mg/kg/h since 2015. In this retrospective study, our aim is to investigate the effect and safety of this low-dose regimen on perioperative bleeding applied in AIS patients with PSF between 2015-2020.

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MATERIALS AND METHODS

This retrospective study was approved by Başkent University Instutional Review Board (KA21/29). After the approval of the ethics committee, 25 consecutive patients with American Society of Anesthesiologists (ASA) risk classification I-III, between the ages of 12-15, who underwent PSF surgery with spinal cord monitoring, in our hospital between the years 2015-2020, were evaluated. Patients with a diagnosis of neuromuscular or congenital scoliosis, patients who underwent anterior revision, or lengthening spinal surgery, and patients with incomplete data were excluded from the study. The patients' information was obtained from archived files, anesthesia records, and the medical data system used in our hospital.

Patients' age, gender, weight, height, body mass index, preoperative hemoglobin levels, and preoperative Cobb angle were obtained from pre-anesthesia records. From the intraoperative records, operation time, fusion levels, estimated blood loss (EBL), and the amount of erythrocyte used [red blood cell unit (RBC)] were obtained. Then postoperative hemoglobin value, amount of RBC used, postoperative Cobb angle, hospital stay, and complications were obtained from the postoperative records.

Anesthesia Management

All patients were sedated with 0.05 mg/kg midazolam (Dormicum® 5 mg/5 mL ampoule, Deva, Istanbul/Turkey) 15 minutes before the operation, and taken to the operating room. In anesthesia management, after standard anesthesia monitoring, anesthesia induction was applied with Propofol (2-3 mg/kg, Propofol® 1% 200 mg/20 mL ampoule, Fresenius Kabi, Austria), Fentanyl (2 µg/kg Fentanyl® 0,05 mg/mL ampoule, Johnson&Johnson, Istanbul/Turkey) and Rocuronium Bromide (0.3 mg/kg Esmeron® 50 mg/5 mL ampoule, Merck Sharp Dohme, Istanbul/Turkey). After intubation, invasive arterial catheterization from the radial artery, and central venous catheterization from the right internal jugular vein, were performed. Additionally, an oral temperature probe, bladder catheterization, and 2 peripheral vascular access were provided. After the patients were positioned properly in the prone position, baseline electrophysiological values were obtained for neurophysiological monitoring. For the maintenance of anesthesia, 50% nitric oxide, 50% oxygen, and total intravenous anesthesia (propofol-remifentanil infusion; 4-6 mg/kg/st - 1-2 µg kg/h) was applied. To reduce blood loss, controlled hypotension was applied with an average arterial pressure of 60-65 mmHg. Acid-base balance and hemoglobin levels were monitored with periodic blood gas sampling. During the anesthesia, besides hemodynamic data and bleeding, temperature and external warming were performed. Neurophysiological monitoring was performed with all patients to monitor all stages of surgery. TXA (Transamine® 50 mg/mL ampoule, Istanbul/Turkey) was administered immediately after the induction of anesthesia at a dose of 10 mg/kg in 100 mL isotonic for 15 minutes. Its maintenance dose was started before the skin incision as 1 mg/kg/h, and continued intraoperatively. It was stopped at the end of the surgery. The amount of intraoperative bleeding was determined by the pad-sponge count and the amount of blood accumulated in the suction tanks. The irrigation fluid and the amount of blood in the collection jars were carefully calculated by the nurse. The amount of blood in the pads and sponges was determined by making an estimated calculation according to the blood saturation. RBC suspension was given when the hemoglobin level was 9 gr dL^{-1} in blood gas monitoring. During the closure phase of the surgery, 0.15 mg/kg intravenous morphine and 15 mg/kg paracetamol were applied to all patients. Patients without hemodynamic problems and acid-base imbalances were extubated and taken to the recovery room. Patients who started morphine administration with a patient-controlled analgesia device, and whose pain control was provided, were sent to the orthopedics service for postoperative follow-up. Patients with an estimated amount of bleeding more than 30% of their total blood volume, those who developed metabolic or respiratory acidosis, those who were hemodynamically unstable, and those who received inotrope/vasopressor support were referred to the intensive care unit for a closer postoperative follow-up.

Surgical Technique

Posterior surgery was performed in all patients in the prone position. The skin and subcutaneous tissue were passed through a midline incision. The paraspinal muscles were stripped subperiosteally then polyaxial pedicle screws were placed at specified levels using the appropriate technique. The curvatures were corrected by derotation, compression, and distraction maneuvers over the rod. After the instrumentation was completed, the posterior elements were decorticated, and bony areas for fusion were created using allografts. Additional osteotomies were not performed for any patient. Following bleeding control and wound washing, vancomycin powder was applied over the implants and the surgical site. Postop wound drainage was followed by the hemovac drainage system. The hemovac drain was withdrawn on the first postoperative day and the patients were mobilized.

Statistical Analysis

The analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS) for Windows 21 (Chicago IL., USA) package program. For continuous variables, descriptive statistics are used as the mean and standard deviation, or minimum-maximum, and the categorical variables were shown as the number of cases and percentage (%).

RESULTS

Twenty-five consecutive patients who were operated on, in our hospital, with a diagnosis of AIS were included in the study. The mean age of the patients was 13.72 (minimum-maximum: 13-15) and 22 (88%) of them were women. In the preoperative

anesthesia evaluation of patients, 72% ASA I, 24% ASA II, of the ASA II patients (n=6); 4 had mild asthma, 1 had diabetes mellitus, and 1 had epilepsy. One patient with ASA III had a diagnosis of 2/4 mitral insufficiency. The average weight of the patients was 40.8 kg (32-58) and their average height was 151 cm (140-176). The mean preoperative hb value of all cohort was 13.3 g dL^{-1} (11.7-16.9), and the preoperative Cobb angles averaged 51°(40-65°) (Table 1).

Patients were instrumented between T1-L5 levels, and the mean number of vertebrae fused was 11.79 (7-16). The mean operation time was 213 minutes (120-300 min), and the average hospital stay of the whole patient group was 5.48 days (3-8). Considering the complications of the whole study group, instrumentation was extended from T10 to T2 due to increased thoracic curvature after 2 years in one patient, and debridement was applied 2 days after surgery due to early wound infection in another patient. However, no complications related to the use of TXA were observed (Table 2).

Considering the results related to bleeding, the mean EBL of the whole study group was 616 mL (250-1100), and intraoperative mean RBC transfusion was determined as 0.8 units (0-2). When the blood transfusions given to the patients during surgery were examined, it was determined that 9 (36%) patients did not receive a transfusion, 12 (48%) patients received 1 unit and 4 (16%) patients received 2 units of red blood cells. In the postoperative period, mean RBC transfusion was determined as 0.5 units (0-2). In this period, 13 (52%) patients had no transfusion, while 10 (40%) patients received 1 unit and 2 (8%) patients received 2 units. The total transfusion mean was 1.36 units (0-3). The postoperative mean hemoglobin value was 11.24 g dL^{-1} (Table 2). All of the patients were followed up in the orthopedics ward, and none of them needed intensive care.

Table 1. Mean demographics of the patients

Age (y)	13.72±0.79
Gender (Male/female) n	3/22
ASA physical status (I/II/III) n	18/6/1
Weight (kg)	40.8±7.74
Height (cm)	151±7.71
BMI	17.7±2.49
Preoperative hb (g dL^{-1})	13.3±1.02
Preoperative Cobb angle (°)	51.0±8.33

Data is given as numbers for gender and ASA, otherwise mean ± standard deviation.
n: Number, ASA: American Society of Anesthesiologists, BMI: Body mass index

Table 2. Operation related factors, bleeding related outcomes, hospitalization time and complications

Postoperative Cobb angle (°)	8.36±6.70
Number of levels fused	11.79±2.93
Operation time (minutes)	213.60±54.61
Estimated blood loss (mL)	616±228.54
Intraoperative transfusion (unit)	0.80±0.70
Postoperative transfusion (unit)	0.56±0.65
Total transfusion (unit)	1.36±1.03
Postoperative hb (g dL^{-1})	11.24±1.16
Hospitalization time (days)	5.48±1.04
Complications (n)	2

Data is given as numbers for complications otherwise mean ± standard deviation

DISCUSSION

In this retrospective study, it was shown that low-dose TXA administered at a dose of 10 mg/kg loading, and 1 mg/kg/h maintenance, in AIS patients who underwent PSF, decreased intraoperative bleeding and the need for transfusion.

In the literature, the use of TXA in heart, liver, trauma, and solid organ surgery is very common and has been shown to reduce bleeding and the need for transfusion[10,11]. Also, there is an increasing number of publications on its use in pediatric scoliosis surgery[12–14]. In a meta-analysis of 581 patients, including AIS patients, the usage of TXA was shown to reduce bleeding and the need for transfusion[15]. In another meta-analysis including 2500 AIS patients, TXA has been shown to reduce the duration of surgery without increasing complications, as well as reducing the estimated intraoperative blood loss and blood transfusion need[16].

In recent publications, it is seen that TXA is used in very different loading and maintenance doses in AIS surgeries[17–21]. The loading doses of 20, 50, and 100 mg/kg used in these studies are high. In our study, a low dose protocol was applied with a loading dose of 10 mg/kg, and a maintenance dose of 1 mg/kg. In our study, an average of 11 vertebrae were fused and the average EBL was 616 mL. In a study where the mean vertebrae fusion numbers were similar to our study, but the dose of TXA used was 10 times higher (loading 100 mg/kg maintenance 10 mg/kg), the EBL was found to be 619 mL, similar to our study[18]. In another study in which a 50 mg/kg loading and 5 mg/kg maintenance dose was administered in AIS patients, an average of 10 levels were fused, and the EBL in this study was found to be 695 mL, once again, similar to our study[17]. However, compared to our study, the amount of RBC units used intraoperatively was found to be lower in this study (0.8 vs 0.3). Our transfusion strategy may also play a role in explaining this difference. In our study, 9 patients (36%) did not receive a transfusion in the intraoperative period, while 12 patients (48%) received 1 unit and 4 patients (16%) received 2 units of RBC transfusion. In all our scoliosis surgeries, we accepted the threshold hb level as 10 g dL^{-1} to preserve the perfusion of the spinal cord. We performed transfusion at levels below these values, and also in cases of severe hemodynamic disturbances and hypotension, that could not be explained by other factors. This situation can be attributed to the differences

in the transfusion protocol between clinics, and consequently the differences in the results of the studies can be explained.

In a study in which 100 mg/kg loading and 10 mg/kg/h maintenance doses of TXA were used in AIS surgery, it was reported that intraoperative blood loss was significantly decreased compared to the placebo group (800 mL vs 1376 mL respectively). However, transfusion volumes were similar[19]. This is attributed by the authors to the lack of published standard criteria for blood transfusion thresholds, as in our study. In addition to hemoglobin and hemodynamic parameters, it was also emphasized that blood transfusion can be performed in order to be one step ahead of bleeding, depending on the previous experience of the anesthesiologists. Similarly, Sethna et al.[12], using TXA at a 100 mg/kg loading and 10 mg/kg/h maintenance dose, found a 41% reduction in blood los, but reported that the amount of transfused blood was not different from the placebo group. There are two randomized controlled trials that applied and evaluated the low dose TXA regimen we used. One of these studies reported a 30% reduction in the number of blood products transfused and no difference in blood loss[13], while the other reported a significant reduction in intraoperative EBL and total drained blood, similar to our study[7].

The recent studies, using very different and high dose schemes, have not been planned in accordance with the pharmacokinetics of TXA. Johnson et al.[17] emphasized that guidelines should be created using pharmacokinetic data and modeling, to increase the effectiveness of TXA, reduce the side effects and find the minimum effective dose. Goobie and Faraoni.[22] conducted a study about pharmacokinetic modeling and simulations for TXA. They recommended the loading dose as 10-30 mg/kg, and maintenance as 5-10 mg/kg/h, for pediatric trauma and pediatric non-cardiac surgery. Apparently, in line with these recommendations, it has been revealed that very high doses were used in many recent studies.

Very high doses of TXA may be associated with serious undesirable side effects. Nausea, vomiting, diarrhea, deep vein thrombosis, pulmonary embolism, myocardial infarction, hypersensitivity reaction, renal failure, and seizures may be seen[9,23,24]. A TXA-related seizure is an important side effect of TXA, and its incidence has been reported to be more frequent than originally thought. Seizures usually occur in the early postoperative period after surgery, and are due to the fast entrance of TXA into the central nervous system in high concentrations. The administration of the lowest effective loading dose to prevent seizures has emphasized the need for dose adjustment in patients with renal dysfunction, a history of seizures, or any other reason for impaired blood-brain barrier[25]. With the occurrence of seizures during recovery, it can be concluded that the effect of potential seizures, in studies with high doses, was attenuated or some of them were overlooked, due to the residual effect of anesthesia. In addition, cases with anaphylactic reactions related to TXA use have also been reported[26,27]. Although the number of patients in our study was small, we did not encounter any side effects related to the use of TXA at the doses we used. Surgical complications which developed in two patients were resolved by debridement and extension of the system to higher levels.

The retrospective nature of our study, the absence of a control group, and the small number of patients are important limitations. However, even with these limitations, it is important to note that we have seen low blood loss with low dose TXA protocol, in long segment fusion, which is close to high dose studies in the literature.

CONCLUSION

The use of low-dose TXA with minimal adverse effects would be a reliable method to reduce bleeding in AIS surgery until an effective pharmacokinetic study specific to the pediatric spinal surgery population has been performed, and a minimum effective dose is found in the future.

Ethics

Ethics Committee Approval: This retrospective study approved by Başkent University Instutional Review Board (KA21/29) and supported with materials by Başkent University Research Fund.
Informed Consent: Retrospective study.

Authorship Contributions

Concept: Ç.B., Ü.Ö.G., Design: Ç.B., Ü.Ö.G., Data Collection or Processing: Ü.Ö.G., Analysis or Interpretation: Ç.B., Literature Search: Ç.B., Ü.Ö.G., Writing: Ç.B., Ü.Ö.G.

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THE RELIABILITY AND ACCURACY OF RADIOGRAPHS IN THE ASSESSMENT OF PEDICLE SCREW PLACEMENT; A COMPARISON WITH COMPUTERIZED TOMOGRAPHY

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ABSTRACT

Objective: The purpose of this study was to evaluate the reliability and accuracy of radiographic assessment of pedicle screw placement, using computed tomography (CT) as the reference standard.

Materials and Methods: Fifteen patients who underwent posterior spinal fusion were retrospectively reviewed. Pedicle screw position was rated using postoperative anteroposterior and lateral radiographs by two independent spinal surgeons twice at least four weeks apart. CT was rated by two other spinal surgeons collectively and reached a consensus decision. Kappa analysis was used to measure the relative agreement between radiographic ratings and CT evaluation.

Results: A total of 367 screws were evaluated. According to CT evaluation, 69 (18.8%) pedicle screws were determined as malpositioned. However, in plain radiographs, 53 (14.4%) pedicle screws were rated as malpositioned. The intraobserver reliability of radiographic ratings was almost perfect for both observers at both times (ICC=0.833 and 0.817). On the other hand, the interobserver reliability was substantial at both occasions (ICC=0.722 and 0.808). The agreement between radiographic ratings and CT evaluation (reference standard) was substantial (kappa=0.686, 95% confidence interval=0.586-0.785). The sensitivity and specificity of radiographs to detect a malpositioned screw were 65.2% and 97.3%, respectively.

Conclusion: Radiographic ratings showed substantial and almost perfect agreement among observers. However, the accuracy of radiography was low compared to CT evaluation. In case of suspicion, CT should be the choice of the imaging modality to decide on a malpositioned screw.

Keywords: Screw malposition, plain radiographs, CT reconstruction, accuracy

INTRODUCTION

Pedicle screws have become the gold standard fixation method in spinal surgery due to their various advantages, such as greater rotational stability, the possibility of instrumentation in the absence of posterior elements, diminished number of levels required for stability, avoidance of neural dissection, and shorter operation time[1]. However, these screws are not entirely secure and might result in severe neurovascular and visceral injuries in case of extra-pedicular placement[2,3]. Although various assistive methods are used to increase the accuracy of screw position, the pedicle screw malposition still remains a significant problem. In a recent metanalysis that examined 51,161 pedicle screws, the accuracy of pedicle screws ranged between 61.3% to 100% using different guided techniques[4].

In general, five different incorrect screw placements can occur. The first one is the perforation of the anterior cortex. In this malposition, mortal injuries may occur because the tip of the screw might damage the vascular and visceral organs lying anterior to the vertebral corpus[5-7]. The second is the perforation of the medial wall of the pedicle. In this case, the neural structures are under the risk of injury. Another malposition is perforation of the lateral pedicular wall. Lateral perforations may result in root injuries or visceral injuries such as pneumothorax in the thoracal spine[8]. In addition, screws can penetrate the superior or inferior disc space, which may cause chronic pain. All these incorrect screw placements not only result in significant injuries but also cause decreased fixation strength, insufficient deformity correction and screw pull-out, as the stability is also impaired[9,10].

Computerized tomography (CT) is currently accepted as the gold-standard method to evaluate the position of the pedicle screws in post operative imaging. However, post operative radiographs are the first-line imaging modality in evaluating pedicle screw placement which is both practical, inexpensive, and safe. Due to the complexity of the spine anatomy, it is not always easy

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to decide on the placement of a pedicle screw on radiographs. Few studies in the literature examine the reliability and accuracy of radiological evaluation of pedicle screw placement. We hypothesized that radiographic evaluation underestimates the pedicle screws' malposition and cannot precisely diagnose screw malposition. This study aimed to test the reliability of the radiological criteria used in the assessment of the pedicle screw placement and compare it with the gold standard CT examination.

MATERIALS AND METHODS

Study Population

This study was performed on patients who underwent posterior spinal fusion using pedicle screw instrumentation between 2018 and 2020 in authors' institutions. Patients who had both postoperative anteroposterior (AP) and lateral spinal radiographs (scoliosis view) and CT were identified and included in the study. CT is not a routine imaging method used for postoperative radiological evaluation in our clinic. CT is ordered only in suspicious cases, such as the development of a postoperative neurological deficit or suspicious direct radiographic findings compatible with screw malposition. Clinical and demographic data were obtained from institutional medical records, and imaging studies were obtained from the picture archiving and communication system (PACS). This study was carried out in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments, and the Institutional Review Board approved the study protocol (approval date/issue: 04.03.2021/1-45).

Sample Size Calculation

The sample size was calculated to detect a difference in the Cohen's kappa statistics between minimum acceptable kappa ($\kappa 0$):0.8 and expected kappa ($\kappa 1$):0.7 at a two-tailed p=0.05 significance level (α error) and with 80% power (1-β error), assuming that two observers (κ=2) rated each pedicle screw. A minimum number of 283 ratings (pedicle screws) were required[11]. Among eligible patients, 15 patients with 367 pedicle screws were randomly selected and included in the study to obtain sufficient statistical power.

Plain Radiographic Assessments

Two independent spinal surgeons (Observer A & Observer B) with at least five years of experience in spinal surgery took part in the study. Each observer independently rated radiographs on two separate occasions (t1 and t2), at least four weeks apart. Observers were blinded to their previous readings. The order of the X-rays was randomized using a sequential, random number generator to prevent possible recall. All assessments were performed on digital radiographs that were stored in PACS using the software program Sectra IDS7 (Ver. 18.2., Sectra AB, Sweden) on the digital workstation. Five previously described criteria were used to evaluate the malposition of the pedicle screws (Figure 1)[12,13]. Pedicle screws that met

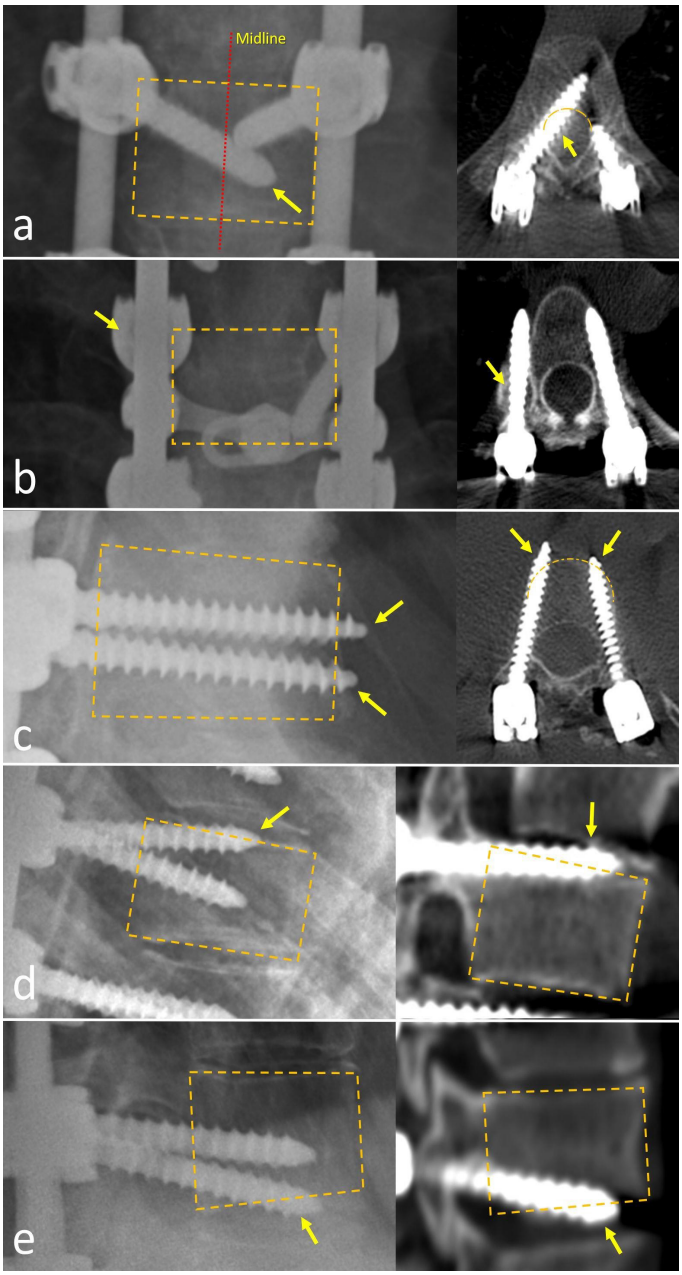

Figure 1. Five criteria used to assess the pedicle screw malposition on AP and lateral radiographs and representative CT images. **a)** Medial perforation. The pedicle screw should be within the elliptic pedicle image and the tip of the screw should not pass beyond the midline. **b)** Lateral perforation. The tip of the pedicle screws should stay within the rectangle forming vertebral body and shouldn't deviate abnormally in the lateral direction (Yellow rectangle shows the vertebral corpus). **c)** Anterior cortical penetration. In the lateral radiography screws should stay within the borders of rectangle forming vertebral body and tip of the screws shouldn't exceed anterior cortex of vertebral corpus. **d)** Superior penetration. In the lateral radiography screws should stay within the borders of rectangle forming vertebral body and tip of the screws shouldn't exceed superior cortex of vertebral corpus. **e)** Inferior penetration. In the lateral radiography screws should stay within the borders of rectangle forming vertebral body and tip of the screws shouldn't exceed inferior cortex of vertebral corpus.

any of these criteria were considered incorrectly placed. After the completion of ratings, the observers reached a consensus through discussion on their disagreements. The joint decision on radiographic ratings was used for comparison to CT ratings.

CT Assessments

Since CT is the best available imaging technique for assessing the pedicle screw placement, the CT was used as a reference standard. CT evaluation was performed by two different observers (Observer C and observer D), except for those who evaluated direct radiography. These observers were also spinal surgeons. Both observers evaluated the CT collectively and reached a consensus decision. During the CT evaluation, they used the axial sections and the coronal and the sagittal views to improve accuracy. Besides, they performed multiplanar reconstruction (MPR) in suspicious screws. Similar criteria were used for CT ratings. Observers determined whether the screw was correctly positioned and if the screw was malpositioned, they also decided on the direction of the breach. The study design is illustrated in Figure 2.

Statistical Analysis

Statistical analysis was performed using SPSS Statistics Base v.23 for Windows. Descriptive statistics of the continuous and categorical data were presented as mean ± standard deviation, range, and frequency distribution. Kappa statistics were used to establish a relative level of agreement on the categorical variables. Interpretation of the data was performed according to Landis and Koch[14]. Agreement was graded as slight (κ=0-0.2), fair (κ=0.21-0.40), moderate (κ=0.41-0.60), substantial (κ=0.61-0.80), and almost perfect (κ=0.81-1).

RESULTS

There were 15 patients (3 male, 12 female) with a mean age of 29.2±19.9 years (range: 13-73). The etiologies were adolescent idiopathic scoliosis (n=4), adult scoliosis (n=5), neuromuscular scoliosis (n=2), Scheuermann kyphosis (n=2), and adult degenerative scoliosis (n=2). An average of 15 segments (range: 10-17) was instrumented, ranging from T3 to L5. All pedicle screws were inserted using the fluoroscopy-assisted free-hand

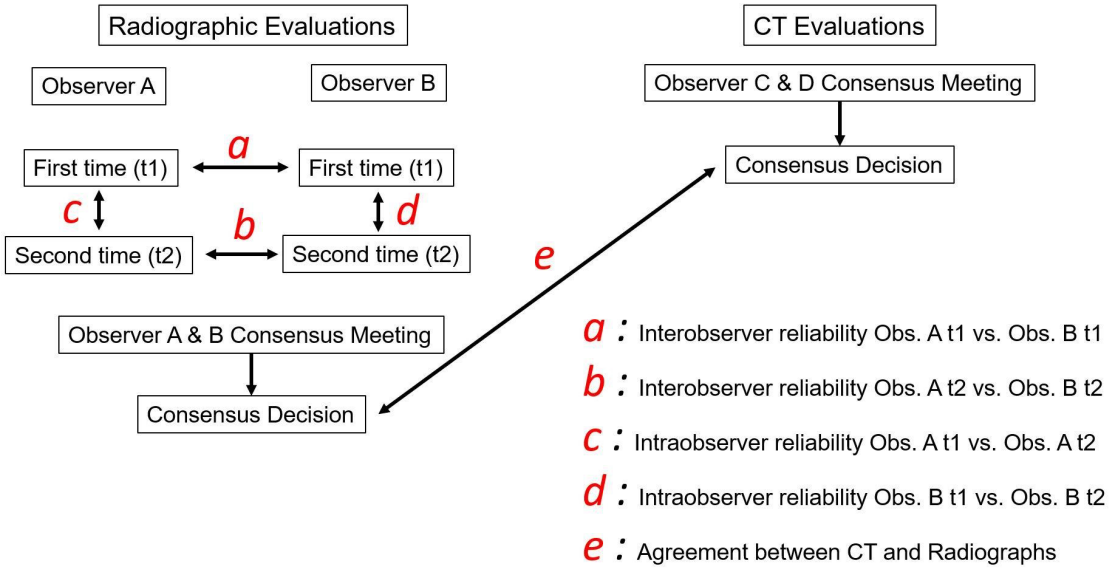

Figure 2. Diagram showing study design and statistical comparisons
CT: Computerized tomography, Obs.: Observer

Table 1. The number of pedicle screws and their direction in consensus decision with plain radiographs and CT

	Consensus CT ratings	Consensus radiographic ratings	Accuracy
Correct (n, %)	298 (81.2%)	314 (85.6%)	290 True rating (97.3%)
Medial (n, %)	43 (11.7)	33 (9%)	29 True rating (67.4%)
Lateral (n, %)	16 (4.4%)	12 (3.3%)	11 True rating (68.7%)
Superior (n, %)	1 (0.3%)	3 (0.8%)	1 True rating (100%)
Inferior (n, %)	-	3 (0.8%)	0 True rating (0%)
Anterior (n, %)	9 (2.5%)	2 (0.5%)	2 True rating (22.2%)
Total (n, %)	367 (100%)	367 (100%)	333 True rating (90.7%)

technique. None of the patients had neurovascular or visceral complications.

A total of 367 screws were evaluated. According to CT evaluation, 69 (18.8%) pedicles screws were determined as malpositioned. However, in plain radiographs, 53 (14.4%) pedicle screws were rated as malpositioned (Table 1). The intra-observer reliability of radiographic ratings was almost perfect for both observers at both times. On the other hand, the interobserver reliability was substantial on both occasions (Table 2). The agreement between radiographic ratings and CT evaluation (reference standard) was substantial (kappa=0.686, 95% confidence interval=0.586-0.785). The sensitivity and specificity of radiographs to detect a malpositioned screw were 65.2% and 97.3%, respectively (Table 3).

DISCUSSION

The current study tested the intra and interobserver reliability of radiographic evaluation to detect pedicle screw malposition and its accuracy using CT as the reference standard. Reliability analysis showed an almost perfect intra-observer agreement; however, the interobserver agreement was under acceptable limits (kappa<0.800). More importantly, there was a significant discrepancy between radiographic ratings and CT. The sensitivity of radiographs to detect a malpositioned pedicle screw was 65.2%. In other words, radiographs cannot diagnose one of every three malpositioned pedicle screws. Anterior cortical penetration and medial wall violation are the most common inaccurate ratings with radiographic evaluation. Although radiographic ratings were reliable, they were not entirely accurate. Thus, in case of suspicion, CT should be taken for confirmation. It should be kept in mind that both clinical and imaging findings should be evaluated together to decide on revision surgery. Many authors have reported that a slight breach on the pedicle wall is entirely asymptomatic. However, screw malposition can cause serious complications such as new radicular pain, weakness, sensory loss, more seriously, complete paralysis.

Considerably variable results regarding the reliability of conventional radiography and CT have been reported in current literature.

A possible explanation for achieving such variable results is that there is no consensus on the gold standard evaluation and/or classification method for the screw position. In a recent systematic review, Aoude et al.[15] examined 68 articles that evaluated the reliability of either conventional radiography (4 papers) or CT (64 papers). They concluded that there was no standardized method to determine the accuracy of pedicle screw position, and many of these authors did not describe their evaluation criteria[15]. Unlike these studies, the current study was conducted using predefined criteria for ratings, which was the most important strength of our study[12,13]. In addition, the direction of the malpositioned screw was included in the assessment, apart from general considerations such as “in” or “out”.

The most critical weakness of the current study was the use of CT as a reference standard. It has been reported that the accuracy of CT is also controversial in cadaver studies since the

Table 2. Intra and interobserver reliability of radiographic evaluations

	Kappa	95% CI	Interpretation
Intra-observer reliability			
Obs. A t_1 vs. Obs. A t_2	0.833	(0.814-0.951)	Almost perfect
Obs. B t_1 vs. Obs. B t_2	0.817	(0.732-0.901)	Almost perfect
Interobserver reliability			
Obs. A t_1 vs. Obs. B t_1	0.722	(0.622-0.821)	Substantial
Obs. A t_2 vs. Obs. B t_2	0.808	(0.721-0.894)	Substantial

Obs.: Observer, t_1: First time, t_2: Second time, CI: Confidence interval, vs.: Versus

Table 3. Agreement between consensus radiographic ratings and consensus CT findings

		Consensus CT		
		Correct	Malposition	Total
Consensus X-ray	**Correct**	290	24	314
	Malposition	8	45	53
	Total	298	69	367
Kappa (95% CI)		0.686 (0.586-0.785)		
Interpretation		Substantial		
Sensitivity		65.2%		
Specificity		97.3%		

CT: Computerized tomography, CI: Confidence interval

exact placement of the screw is determined by direct visual and tactile dissection[16-22]. Therefore, cadaver studies provide more reliable information regarding the accuracy of the imaging studies (Table 4). Learch et al.[16] reported that the sensitivity of conventional radiographs to detect a malpositioned screw was 63%, and the CT was 87%. Ferrick et al.[20] reported that the accuracy varied between 73% to 83% depending on surgeon experience based on the classification of screw position to be inside or outside. Choma et al.[21] found that the sensitivity of the radiographic technique was 70.1% and specificity was 83.0%, whereas sensitivity for CT scans was 84.7% and specificity was 89.7%. Brooks et al.[22] showed that the sensitivity of radiographs, CT, and combined use of modalities were 93.9%, 94%, and 98.7%, respectively, while the specificity was 12.5%, 36.7%, and 40.7%, respectively. They suggested that routine evaluation of pedicle screw postoperatively can be reliably obtained with plain radiographs, while patients who present with significant complaints of pain and/or neurologic deficits, the best way to detect correctly placed screws is with the combination of CT and plain radiography[22]. In our study, with reference to CT, the agreement between the observers was acceptable in radiological evaluation (kappa=0.722, 0.808). In addition, the sensitivity and specificity of the radiography were 65.2% and 97.3%, respectively.

The use of intraoperative fluoroscopy and postoperative plain radiographs is currently the standard for screw assessment in many centers. Because, considering severe complications related to the screw malposition, intraoperative accurately determining the anatomical location of the screw provides important information to the surgeon in deciding whether the screw placement needs to be revised. However, many studies did not report their criteria for evaluating intraoperative or postoperative radiography so far. Kim et al.[12] described retrospectively based on postoperative CT to establish reliable and accurate criteria for intraoperative evaluating screw position. They suggest that Intraoperative plain radiographs alone using three radiographic criteria were very sensitive and accurate to detect lateral wall pedicle screw violations and also extremely specific and accurate for assessing for medial wall violations in scoliotic and kyphotic spinal deformities[12]. Weinstein et al.[23], in which the screw position in the thoracic spine was evaluated by plain radiography, reported that 21% had medial cortical perforation, and of those 92% were in the spinal canal. They showed that the interobserver agreement was 74%, the sensitivity was 31% for the radiographic evaluation of perforation, and the specificity was 90%. In addition, they reported that the false-negative evaluation was 14.5%, and the incorrect grading was approximately 60%[23].

The role of the lateral radiographs in the evaluation of screw position is controversial[24]. A true lateral radiograph alone was inaccurate to determine the penetration of the anterior cortex by the pedicle screw. Whitecloud et al.[25] examined the accuracy of the lateral radiographs in a cadaver study. To detect an anterior cortical penetration on a lateral radiograph, the X-ray tube should be angled 5° in the coronal plane for T12 - L3 levels and 10° for L4 - S1 levels. They recommended additional oblique views to determine accurate screw penetration[25]. The findings in this study are consistent with our results. The anterior cortical penetration could be detected in two screws out of nine (22.2%), since only true lateral radiographs were used in the current study.

Table 4. Previously published cadaver studies reporting the reliability of pedicle screw position ratings using direct radiography and CT

Author	Year	Case/screw		X-ray	CT	Combined
Weinstein et al.[23]	1988	8/124	Sensitivity	31%	-	-
			Specificity	90%	-	-
Yoo et al.[17]	1997	6/36	Accuracy	-	Cobalt Chroma screws, 68% Titanium screws, 87%	-
Ferrick et al.[20]	1997	4/48	Accuracy	73%	83%	-
Rao et al.[19]	2003	12/NR	Inter-observer reliability		Moderate Titanium screws, kappa: 0.53 Stainless-steel screws kappa=0.44	-
			Intra-observer reliability		Substantial Titanium screw kappa=0.63 Stainless-steel screws kappa=0.62	-
Learch et al.[16]	2004	3/30	Accuracy	63 %	87%	-
Choma et al.[21]	2006	5/120	Sensitivity	70.1%	84.7%	-
			Specificity	83.0%	89.7%	
Brooks et al.[22]	2007	18/180	Accuracy	79.4%	84.4%	90 %
			Sensitivity	93.9%	94%	98.7%
			Specificity	12.5%	36.7%	40.7%

CT: Computerized tomography, NR: Not reported

Study Limitations

There are some strengths and limitations of this study. The most important weakness of the current study was the use of CT as a reference standard, which may not reflect the correct position. Although two observers collectively rated CT scans using advanced imaging techniques, some of the screws might be incorrectly evaluated on the CT. The second limitation is the inclusion of a heterogeneous group of patients with different etiologies. Determination of the midline of the vertebrae might be faulty in patients with rotational deformity.

CONCLUSION

In the evaluation of postoperative pedicle screw placement, plain AP and lateral radiographs may be insufficient, particularly determination of medial and anterior violation. Although the agreement of observers was within the acceptable limits, the accuracy was low compared to CT evaluation. CT should be used to evaluate the accuracy of screw position in cases such as patients with postoperative neurological deficits.

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ORIGINAL ARTICLE
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IS RADIOFREQUENCY ABLATION IN CONJUNCTION WITH VERTEBRAL AUGMENTATION AN EFFECTIVE OPTION IN PAINFUL SPINAL METASTASIS?

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ABSTRACT

Objective: Patients with metastatic tumors are most frequently expressed with painful spinal lesions. However, effective palliative treatment is still controversial. The aim of this study is the assessment of the efficacy and safety of vertebral augmentation in conjunction with radiofrequency ablation (RFA) of painful spinal metastases.

Materials and Methods: Twenty-six patients with metastatic spine tumors treated with RFA in conjunction with cement augmentation between June 2014 and December 2019 were retrospectively analyzed. The patients were followed up for an average of 25.2±13.8 months. Evaluation of efficacy is performed based on tumor pain, pain disability, functional activities, quality of life, neurological status, and tumor progression. Reliability evaluation was made based on complications and side effects.

Results: The mean age was 64.4±12.6 years. The female to male ratio was 14:12. RFA with augmentation was successfully performed on all patients. No major complications developed in these patients. Primary tumors were observed to be more breast (38%), renal (23%) and multiple myeloma (12%). Visval analogue Scale scores decreased after the procedure and improvement continued in every period of follow-up (from 8.2±1 months preoperatively to 3.5±1.6 months postoperatively p<0.005). The patients discontinued painkiller use after one month. On the Oswestry dysability scale score, significant improvement was observed in the first month (41.8±15.1 vs 82.6±9.1, p<.005). Tumor progression was observed in different regions in 10 patients and we lost those patients in the follow-up.

Conclusion: In painful spinal metastases with preserved posterior wall and pedicle integrity, the combination of RFA in conjunction with vertebroplasty can be safely implemented for pain palliation and local tumor control.

Keywords: Spine, neoplasm metastasis, palliative, radiofrequency ablation, vertebral augmentation

INTRODUCTION

Spine involvement is known to be about 40% in patients with the metastatic bone disease[1]. Clinically, this problem, which may lead to severe pain, pathological fractures and neuromuscular dysfunction, causes the patient to become immobile and leads to a deterioration in the quality of life[2-4]. Palliative treatment in these patients poses major challenges and calls for a comprehensive, multidisciplinary approach[5]. In painful metastatic lesions, radiofrequency ablation (RFA) therapy has begun to be used as a micro-invasive process, which disrupts intraosseous nerve fibres, reduces lesion volume, reduces osteoclastic activity, and prevents pain transmission by disrupting tumor cells that produce nerve stimulating cytokines[6,7].

At the same time, the combined use of cement to increase the resistance of the spine to compressive loads can increase the quality of life of the patients and prevent complications that may lead to neurological damage resulting from pathological fractures[8,9].

This study aimed to investigate the effect of combined treatment of percutaneous RFA and vertebral augmentation on the quality of life of patients with spinal metastasis.

MATERIALS AND METHODS

After the approval of the University of Health Sciences Turkey, Antalya Training and Research Hospital Clinical Research Ethics Committee (date: 22.12.2020, number: 20/23), the data of patients who underwent RFA and vertebral augmentation for painful metastatic spine disease in our clinic between 2014 and 2019 were retrospectively analyzed. The database included the patien's age, gender, primary tumor histology, level of the treated spine, the location and volume of the lesion in the involved spine, the number and duration of ablations performed

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and the patient's history of radiotherapy in the previous six weeks. After a complete description of the study to the subjects, written informed consent was obtained. The Declaration of Helsinki were taken into account during the present study.

Patients undergoing RFA and vertebroplasty were selected according to the decision of the council consisting of a spine surgeon and medical oncologist. Patients who have pain that leads to decreased quality of life and could not be controlled with conventional analgesics, localized tumors in two or three adjacent vertebrae and persistent and recurrent pain despite radiation therapy were included in the study. Patients with osteoblastic lesions, spinal instability and cord compression due to metastatic mass were excluded from the study.

After the patients were turned to the prone position under superficial sedation, the surgical area was disinfected with Betadine solution and prophylactic antibiotic treatment was administered before and after the procedure (cefazoline IV, 1 g x 4/12 hours). Local anaesthetic infiltration was applied, starting from the skin area, including the vertebral periosteum to be treated. The unilateral or bilateral transpedicular guide was placed under the guidance of fluoroscopy (Figure 1)[10]. A transpedicular biopsy was performed before performing RFA as a routine protocol and the results were recorded on the patient chart (Figure 2). After the procedure, analgesic treatment was ordered by the routine protocol of the clinic. Patients were evaluated at the first week and the first, third, and sixth months in the postoperative period with the Visual analogue scale (VAS) and the Oswestry disability index (ODI) for the assessment of the quality of life, and as well as with an magnetic resonance imaging in terms of recurrence.

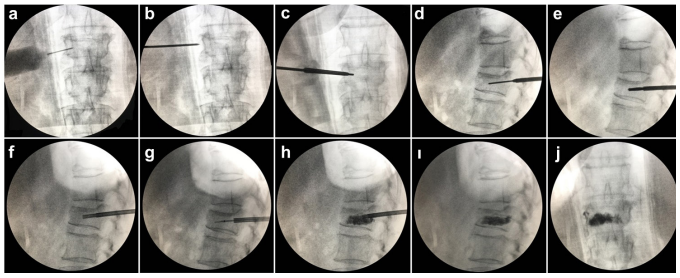

Figure 1. Percutaneous RFA and vertebroplasty procedure. The anteroposterior and lateral projection on fluoroscopy shows the position of the needles (a, b, c, d, e, f), vertebral lesions treated with RFA (g); distribution of the cement through the entire vertebral body (h, i, j)

RFA: Radiofrequency ablation

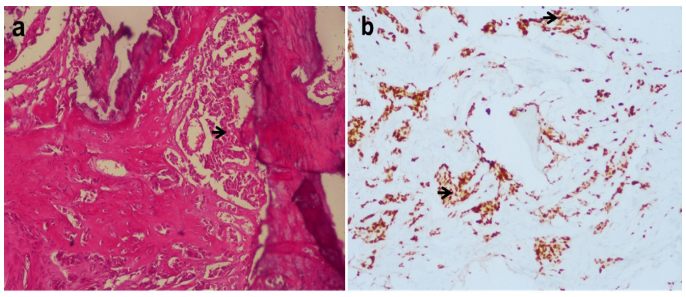

Figure 2. Breast tumor cells with pleomorphic, large hyperchromatic nucleous, eosinophilic cytoplasm (black arrow), consisting of small acinar structures in bone and chondroid matrix. H&E,10x (a) and ER nuclear positive, 10x (b)

RESULTS

Data of 26 patients with painful spinal metastases who met the inclusion criteria were retrospectively analyzed. The mean age of the patients was 64.4±12.6 years. Female to male ratio was 14:12. The demographic characteristics of the patients are presented in Table 1. The most common primary tumor was Breast Ca, followed by Renal Ca and Multiple Myeloma. It was observed that the treated metastatic spine disease was in the thoracic region in 35% of the cases and the lumbar

Table 1. Demographic data and function outcome scores of the patients

Patients	Data
Age (year)	64.4±12.6
Gender	
Female	14
Male	12
Primary lesion	
Breast	10
Renal cell	6
Multiple myeloma	3
Gastric Ca	2
Lung	2
Liver	2
Colon	1
Lymphoma	1
Cervix Ca	1
Treated vertebral level	
One	22
Two or more	4
Lentgh of operation (minute)	42.9±11
Hospital stay (days)	1.3±1.4
Follow-up (month)	25.2±13.8
VAS scores	
Preoperative	8.2±1.0
Postoperative first day	4.6±1.6
Postoperative first month	3.8±1.5
Postoperative three month	3.7±1.3
Postoperative six month	3.5±1.6
ODI	
Preoperative	82.6±9.1
Postoperative one month	41.8±15.1

VAS: Visual analogue scale, ODI: Oswestry dysability scale, Ca: Cancer

region in 65%. RFA with vertebroplasty was successfully performed on all patients (Figure 3 and 4). Cement leakage was not observed. No other complications occurred during the procedure. There was a significant decrease in the VAS scale after the procedure, indicating a decrease in pain intensity and a significant difference in each post-procedure compared to the pre-procedure. The evaluation of the ODI at 1 month compared with before the procedure also showed significant improvement in all domains (Table 1). Analgesic doses were reduced in all patients 24 hours after the procedure, and one month later all patients had greatly improved their quality of life and stopped the analgesic because there was no significant pain that would affect functional activity. Nine of the 26 patients (34.6%) enrolled in the study had tumor progression in different regions, and all of these patients died during a mean follow-up period of 19 months (range: 6-40 mos.). No local recurrence was observed in the radiographic examinations performed during the controls of the patients.

DISCUSSION

In this study, we retrospectively evaluated the efficacy and safety of RFA in conjunction with vertebral augmentation in pain palliation in painful spinal metastases. As a result of the evaluation, we determined that this treatment approach is effective and safe. During the follow-up period, no recurrences, major side effects, or complications were observed, and

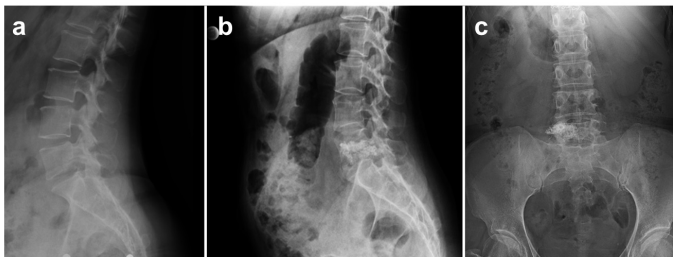

Figure 3. A 46-year-old female patient with metastatic breast cancer to the L5 vertebra. Preoperative (a) and 12-month follow-up radiographs (b, c). Patient's pain decreased from 9/10 to 4/10 after treatment and at the last follow-up

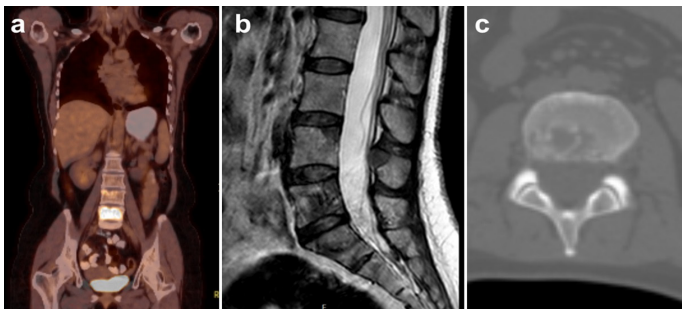

Figure 4. Preoperative PET (a) and sagittal T1-weighted MR imaging showing the level (L5) of spinal metastasis (b), Preoperative axial CT showing the osteolytic metastatic tumor (c)

MR: Magnetic resonance, CT: Computed tomography, PET: Positron emission tomography

secondary surgical interventions were not required. All pain was effectively controlled using only analgesics. The patients' quality of life improved. This study supported the use of RFA in conjunction with vertebroplasty as a viable, minimally invasive spinal approach for the treatment of patients with thoracolumbar vertebral metastasis. Our findings were supported by the literature.

Since RFA was first carried out of in conjunction with vertebroplasty there has been an increase in the literature investigating its role in painful spinal metastases[11]. It has been emphasized that this treatment approach can be used not only for pain palliation but also for local tumor control. In the guidelines published by the Metastatic Spine Working Group, patients with asymptomatic spinal metastases, uncomplicated painful metastases, and stable pathological vertebral fractures and with a life expectancy of more than six months can safely have RFA and vertebral augmentation performed for pain palliation and local tumor control[12]. In their study, Hoffman et al.[13] demonstrated that the application of vertebral augmentation with RFA had a 100% pain-relieving effect within the first 24 hours, and they found that the combined procedure had a synergistic effect. It was shown that VAS scores significantly decreased from 7.2/10 before the procedure to 3.4/10 after the procedure[13]. Reyes et al.[14] reported significant improvement in palliation of pain and level of function with combined RFA and vertebroplasty in their multicenter retrospective study of 49 patients with 72 painful vertebral metastases. In the studies, the most important common findings, apart from pain palliation, was that no treatment-related complications occurred during the procedure and follow-up.

In research studies, many reasons have been shown why RFA should be performed before vertebroplasty[15]. The most often reason given for this sequence is reducing the potential for distal metastasis in the venous system by changing the location of tumor cells, preventing complications associated with embolization by causing thrombosis of the vertebral venous plexus, and ensuring a more equal distribution of cement to provide better stability to the spine[16]. In addition, radiographic local control rates of combined RFA and vertebroplasty were reported as 89% (41/46) and 70% (21/30) after three months and one year, respectively[17].

Nakatsuka et al.[18] reported serious complications such as paraparesis and severe pain in up to 25% of patients after the RFA treatment for spinal metastases, but they stated that most of the patients they treated had a posterior wall and pedicle invasion and as a result related complications occurred at a high rate[18]. They reported that the symptoms disappeared during the follow-up. In our study, we did not see any major complications in the patients, since the spinal metastases did not destruct the posterior wall and the pedicles. We observed a significant improvement in pain and quality of life using the VAS and ODI scores that can accurately evaluate the refractory pain and quality of life of the patients. A limited number of patients, the absence of a control group, and a short follow-up

period are the limitations of our study. However, the emergence of many metastases in the follow-up of the patients poses a serious difficulty in the long-term follow-up to determine the recurrence and survival of these patients.

CONCLUSION

RFA with combined cement injection is safe and effective in the palliative treatment of patients with painful metastatic spine tumors.

Ethics

Ethics Committee Approval: The study approved by University of Health Sciences Turkey, Antalya Training and Research Hospital Clinical Research Ethics Committee (date: 22.12.2020, number: 20/23).

Informed Consent: The informed consent was obtained.

Authorship Contributions

Surgical and Medical Practices: Ö.F.K., S.A., Concept: Ö.F.K., S.A., Design: Ö.F.K., Data Collection or Processing: Ö.F.K., A.K., Analysis or Interpretation: Ö.F.K., S.A., Literature Search: Ö.F.K., V.N., Writing: Ö.F.K., A.K., V.N., S.A.

Conflict of Interest: The authors declare that they have no conflict of interest.

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MERALGIA PARESTHETICA CAUSED BY THORACOLUMBAR BRACE IN CONSERVATIVELY TREATED THORACOLUMBAR FRACTURES

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ABSTRACT

Objective: Lateral femoral cutaneous neuropathy or meralgia paresthetica (MP) occurs for various reasons. MP developing after spine surgery is not uncommon and is mostly due to the prone position during surgery or iliac graft harvesting. However, it is usually overlooked due to mild symptoms and a self-limiting course. The purpose of this study was to present a case series of five patients who were followed up with conservative treatment for vertebral fractures and developed MP after prolonged use of lumbar braces.

Materials and Methods: The sample comprised five patients with thoracolumbar fractures who did not meet the surgical criteria of the Thoracolumbar Injury Classification and Severity score and who were advised to use lumbar braces for 8 weeks and to return to the outpatient department. These patients did not present for follow-up due to the coronavirus disease-2019 (COVID-19) pandemic and continued to use the lumbar brace for more than the advised 8 weeks. A retrospective evaluation of age, sex, body mass index (BMI), comorbidities, and duration of brace use was conducted.

Results: Three of the five patients were male with an average age of 61±18 years, average BMI of 29.3±4.8 kg/m^2, (after excluding the young and normal-weight patient, the average age and BMI increased to 70±5 years and 31.6±1.5 kg/m^2, respectively), and an average brace use duration of 18.4±3.2 weeks. Three patients presented with MP on the left side.

Conclusion: Although tight-fitting pants/corsets/belts/body armor can cause MP, no cases of MP caused by lumbar braces used for conservative treatment of vertebral fractures have been reported. This case series arose from the effects of COVID-19, as the patients wanted to stay home.

Keywords: Meralgia paresthetica, brace, COVID-19, fracture, vertebra

INTRODUCTION

Meralgia paresthetica (MP) was first defined by Bernhardt and Roth in 1895 as a neurological disorder causing pain or dysesthesia in the anterolateral aspect of the thigh caused by compression of the lateral femoral cutaneous nerve (LFCN). A Dutch population study reported an incidence rate of MP of 0.43 per 10,000 person-years, whereas an older study reported 3 per 10,000 general clinic patients, with a predominance between the ages of 30 and 50 years[1].

The LFCN courses through the pelvis adjacent to the lateral side of the iliopsoas muscle and enters the thigh through or under the inguinal ligament close to the anterior superior iliac spine where entrapment occurs most frequently. As the nerve is purely sensory, symptoms relating to sensorial dysfunction, such as burning, tingling, or pins, are the most frequent clinical findings[2]. MP predominantly arises from mechanical entrapment of the LFCN, and causes include trauma, tight-fitting pants/corsets/belts/body armor, compression from carrying heavy objects supported on the thigh, and use of a wallet. Iatrogenic causes have been reported due to iliac bone grafting, prolonged lithotomy and the prone spine positions, injury while performing inguinal herniorrhaphy, and retractor compression during gastroplasty[2]. Obesity, pregnancy, and diabetes mellitus are risk factors[1]. However, two thin pediatric patients with MP have also been reported[3].

The diagnosis is mostly clinical due to an unpleasant feeling at the site innervated by the LFCN. Physicians may employ electrophysiological testing but the reliability of somatosensory-evoked potentials (SSEPs) in MP is controversial[4].The Thoracolumbar Injury Classification and Severity score (TLICS) was designed to take into account the morphology of the fracture, posterior ligamentous complex integrity, and neurological status to allow for better categorization and communication among surgeons[5]. The AO Spine Injury Classification system establishes subgroups from the original Magerl AO concept but uses three main injury categories[6]. Although various

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approaches exist to determine whether a conservative or surgical treatment course is appropriate, the overall agreement is to follow-up patients with a thoracolumbosacral orthosis (TLSO) brace for 8-12 weeks in neurologically intact cases that do not meet the instability criteria[7].

MATERIALS AND METHODS

The study was performed in agreement with the ethical standards specified in the Declaration of Helsinki and was accepted by the Research Ethics Committee of Çankırı Karatekin University (No: 464/010321). Approval from the Ministry of Health in regards to studies involving Coronavirus disease-2019 (COVID-19) cases was obtained (2021-01-11T14_56_04). A written informed consent from each patient approving for images and clinical information regarding to their case be reported in a medical publication was obtained. Patients with thoracolumbar fractures due to trauma who applied for follow-up after the COVID-19 pandemic began were analyzed. Patients who did not meet the surgical criteria, who were advised to use a TLSO for 8 weeks, and who were followed up with neurological and radiological evaluations were included. All corsets were provided by the same supplier, who was experienced and the only supplier in the city. The patients were checked for proper usage after the TLSO was applied. They were advised to use diclofenac potassium 50 mg/day for persistent pain. All patients that delayed their follow-up examination and continued to use the TLSO and presented with a tingling, burning, or a numbness sensation in the anterolateral aspect of the thigh were included.

Outcome Measures

Demographic information was obtained along with the TLICS score, AO spine injury classification, BMI, comorbidities, duration of TLSO usage, and the side of MP.

RESULTS

Five patients presented with dysesthesia in the anterolateral aspect of the thigh after the COVID-19 pandemic began and who used the TLSO for 18.4±3.2 weeks instead of the advised 8 weeks. The patients had an average age of 61±18 years and an average BMI of 29.3±4.8 kg/m^2. However, when the young and otherwise healthy patient no. 2 was excluded, the average age and BMI increased to 70± 5 years and 31.6±1.5 kg/m^2, respectively. Three patients had hypertension, and two patients had been diagnosed with type 2 diabetes previously. Three patients had a type A1 AO classification of vertebral fracture along with a TLICS score of 1, and the other two had type A3 and a score of 1. None of the patients were indicated for surgery at the time of the diagnosis or after their follow-up examination. All patients presented to the emergency ward after trauma with isolated vertebral fractures but only patients no. 1 and no. 4 presented with scalp abrasions and sutured lacerations due to high-energy traffic accidents.

All patients complained of aggravated symptoms at noon, particularly while standing, and symptoms were relieved after removing the brace before going to bed. The patients were relieved of their MP symptoms for an average of 5 days after discontinuing the TLSO. Only patient no. 1 had continuing symptoms and was prescribed 75 mg pregabalin twice daily for 28 days, which was discontinued after the symptoms disappeared. The patients' characteristics are summarized in Table 1. The computed tomography findings of each patient are shown in Figures 1-5.

DISCUSSION

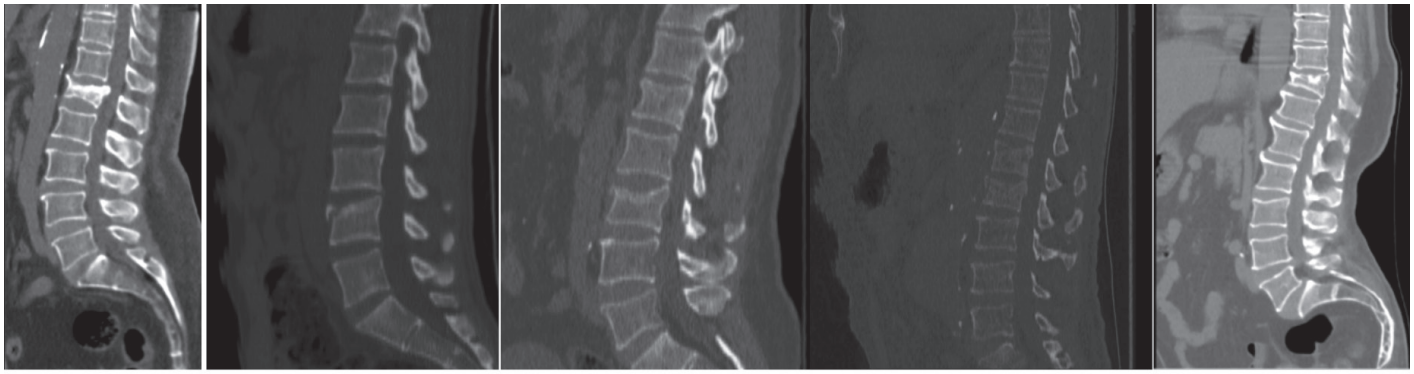
A case series of five patients with thoracolumbar fractures who were treated conservatively with bracing are reported. These patients used the braces longer than the advised 8 weeks due to the COVID-19 pandemic. They were diagnosed with MP based on sensory deficit symptoms in the distribution area of the LFCN without motor deficits. Although the use of tight-fitting pants, corsets, belts, and body armor can cause MP, a literature review did not yield any reports of MP associated with thoracolumbar bracing.

MP is a purely sensory disorder involving the LFCN derived from the L2-L3 nerve root. The most common compression site is where the nerve passes through or under the inguinal

Table 1. List of patients and attributes

No	Sex	Age	Pathology	TLICS score	AO class	BMI (kg/m^2)	Co-morbidity	Duration (weeks)	MP side
1	F	69	L1 burst fracture	2	A3	32.8	Hypertension, asthma	24	Left
2	M	25	L4 compression fracture	1	A1	20.1	None	16	Left
3	M	62	L3 compression fracture	1	A1	30.1	Atherosclerotic heart disease, dyslipidemia	15	Left
4	M	74	L2 burst fracture	2	A3	30.2	Hypertension, diabetes mellitus type 2	17	Right
5	F	76	T11 compression fracture	1	A1	33.6	Hypertension, osteoporosis, diabetes mellitus type 2	20	Right

TLICS: Thoracolumbar Injury Classification and Severity score, BMI: Body mass index, MP: Meralgia paresthetica



1 2 3 4 5

Figure 1-5. The sagittal reconstructed view of thoracolumbar CT findings as discussed in Table 1
CT: Computed tomography

ligament. Obesity or tight-fitting clothes and belts are risk factors for mechanical compression. The patients in this case series fit the diagnosis of MP, but no nerve conduction study was ordered due to low reliability[8]. Four of the five patients in this case series had an average BMI of 31.6 kg/m^2 (type 1 obesity). Two of the four patients were also diagnosed with type 2 diabetes. Both obesity and type 2 diabetes are risk factors for MP[1]. However, one of the patients had a BMI of 20.1 kg/m^2, which is close to the lower level of normal weight. Although a low BMI is not a known risk factor, two thin pediatric patients with MP have been reported[3]. Relatively thin people lack extra subcutaneous adipose tissue, allowing superficial nerves to course without extra protection, which would make them vulnerable to trauma and chronic compression.

The one factor that all patients had in common was the use of a TLSO. Although bracing is a low-risk and cost-effective method for treating thoracolumbar fractures, it does have limitations. Pressure sores due to rigid braces, non-compliance, diminished pulmonary capacity, and weakening of the load-bearing musculature are known complications[9]. The brace itself is a compressing factor around the abdomen and at the superior edge of the pelvis. While standing, the inferior border of the brace corresponds roughly to the superior one-third of the inguinal ligament, where the LFCN courses. While sitting with the brace, the inferior border completely rests on the waistline and the inguinal region. This may have caused compression of the LFCN and the symptoms. The patients in this case series were examined after the use of a TLSO and were properly trained to remove the appliance while lying down. However, no emphasis was placed on the significance of protecting the iliac wing and axilla from pressure, which should have been mentioned along with tips to protect against sores. The patients felt increased dysesthesia while standing upright, which exacerbates this syndrome[10]. The patients were unable to recall the exact timing of the symptoms, as most of them did not complain in the beginning. The suggested time frame for a TLSO is 8-12 weeks. The patients in this case series used the brace for an average of 18.4 weeks. Four of the five patients in this case series were obese, which would make a difference. Patient no. 2 was thin, which allowed the brace's compressive force to directly press on the LFCN. In addition to these factors, the COVID-19 pandemic restricted social life and increased stay-at-home policies; thus, more sedentary time was spent at home with increased sitting time. This may be another contributing factor.

The patients in this case series were not evaluated via electromyography, as confounding results have been reported with this procedure. Although a study evaluating SSEPs between 20 patients and 22 healthy controls concluded that SSEPs are a diagnostic aid, another study demonstrated that SSEPs produce abnormal readings in the case of very serious nerve damage[1]. Performing electromyography is difficult in obese patients; thus, it should not be routinely employed or required for diagnosing MP but rather used to eliminate other differential diagnoses[2].

CONCLUSION

Bracing is the proper approach to follow up a thoracolumbar fracture when surgery is not indicated. Previous data have revealed similar outcomes compared with surgical intervention. This study of five patients describes a complication of lumbar bracing that has not been reported previously. Perhaps a cotton coating on the inferior edge of the brace would help diminish this effect.

Although this is a case series of five patients who developed MP after prolonged use of a TLSO due to a thoracolumbar fracture, it provides evidence of an additional cause of MP that has not been reported. This report serves as a reminder to all physicians that the impact of the COVID-19 pandemic is much more prominent than anticipated, affecting the habits of all patients. The follow-up can be facilitated by phone calls. This case series of five patients had the limitations of being a retrospective analysis that was prone to selection bias and lacked a control arm.

Ethics

Ethics Committee Approval: The study was performed in agreement with the ethical standards specified in the Declaration of Helsinki and was accepted by the Research Ethics Committee of Çankırı Karatekin University (number: 464/010321).

Informed Consent: A written informed consent from each patient approving for images and clinical information regarding to their case be reported in a medical publication was obtained.

Peer-review: Internally peer-reviewed.

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EFFICIENCY OF SILVER-COATED TITANIUM ALLOY SCREWS IN THE PREVENTION OF IMPLANT-ASSOCIATED INFECTIONS

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ABSTRACT

Objective: Instrumentation is used for treating spinal fractures. Degenerative and neoplastic spine diseases have gradually increased in recent years because of advancements in spine surgery. The major disadvantage of instrumentation is implant-associated infections that result in morbidity and mortality, in addition to considerable financial losses because of increased treatment costs. This study examined the effectiveness of Ti alloy screws coated with Silver (Ag) ion nanoparticles in preventing infection in the rat spine.

Materials and Methods: In this study, 24 male, six-month-old white Sprague-Dawley rats were used. The animals were divided into three groups, each with an equal number of animals. A pedicle screw of appropriate size was placed in the lumbar vertebrae of animals and inoculated with a 1 million CFU/10 microliter Staphylococcus Aureus ATCC 29213 strain. A Ti alloy microscrew with a surface area of 25 mm^2 was placed in the first group, Ag-coated Ti alloy microscrew with a surface area of 25 mm^2 was placed in the second group, and a Ag-coated Ti alloy microscrew with a surface area of 50 mm^2 was placed in the third group.

Results: Screw and tissue samples were taken and microbiologically examined. After microbiological evaluation, no statistically significant difference was reported between these groups in terms of the number of microorganisms growing on the screw and tissue.

Conclusion: Because of the difficulties and financial burdens that arise after the occurrence of an infection, the importance and necessity of developing anti-infective biomaterials are very clear. No anti-infective effect was observed in the Ag-coated pedicle screws in our study. Solution-focused studies are required for developing implants with better biocompatibility, lower infection rates, and lower costs in the following years.

Keywords: Spinal infection, implant associated infections, surgical site infection, silver ions

INTRODUCTION

Beyond enabling daily basic functions of patients with the aim of a painless and disability-free life, in recent years, the aim has been to have patients recover to an extent that enables them to have a comfortable social life. Therefore, surgical techniques based on preserving the biodynamic properties of the spine are being developed. With new developments in spine surgery and advances in the instrumentation industry, the use of implants in surgical treatment has gradually increased. In addition to the remarkable advantages of implants in the treatment of spinal diseases, they have considerable disadvantages such as neural injury, host incompatibility with foreign body, technical failures in implant application, high postoperative infection rates, and increased treatment costs. Among these, one of the most common implant-associated complications is implant-associated infection[1,2]. The literature review shows that this rate varies between 1% and 8.5% in large case series[3-5]. These types of infections can cause considerable morbidity and even mortality[6]. The treatment of implant-associated infections requires intensive antibiotherapy and impairs patients' quality of life as a result of removal of the implant, long hospital-stay, and long periods of immobilization[7]. The use of prophylactic systemic antibiotics is insufficient in combating these types of infections[8]. The risk of serious toxicity arises because of the use of high doses in treatment with systemic antibiotics, and local administration involves technical difficulties[9]. Consequently, medical treatment is insufficient for such infections because there is a different mechanism originating from biomaterials in the development of implant-associated infections. Based on the available information, it was considered that shaping the implant surface in a manner that prevents bacterial adhesion may reduce implant-associated infection[10]. Based on this view, in our study, titanium alloy screws (Ti6Al4V), which are frequently used today in spinal surgery, and Ti alloy screws with a Silver (Ag)-coated surface of different sizes were compared by creating an experimental model in the rat spine to test their effect on bacteria.

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MATERIALS AND METHODS

The microscrews used Ti6A14V alloy microscrews with a surface area of 25 mm^2 were used in the first group (Normed, Germany). Ti6A14V alloy microscrews with a surface area of 25 mm^2, which were coated in Ag using the sol-gel method, were used in the second group (Tasarımmed, Turkey). In the third group, Ti6A14V alloy microscrews with a surface area of 50 mm^2, which were coated in Ag using the sol-gel method, were used (Tasarımmed, Turkey). In this study, the *Staphylococcus aureus* ATCC 29213 strain, which was previously shown to cause osteomyelitis in the rat spine, was used.

Preparation of Animals and Surgical Intervention

This research was approved by Bakırköy Prof. Dr. Mazhar Osman Training and Research Hospital, Clinic of Psychiatry, Neurology and Neurosurgery Ethics Board (2012-47773). In this study, 24 male, white six-month-old Sprague Dawley rats weighing between 300 and 350 g were used. Each group was maintained in two separate cages. Moreover, each animal was observed in a separate cage on the first postoperative day. The animals were randomly numbered, and three different groups of eight were formed. The animals that were planned to undergo surgery were separated from the group one day before the operation, and their lumbar back region was shaved with the help of a depilatory cream (Figure 1). The instruments to be used in the surgery were sterilized in a steam autoclave (Amsco, USA) at 134 °C the night before. After being sedated with sevoflurane (Sevorane, Abbott, USA), the animals were taken in for surgery under general anesthesia induced with a 60 mg/kg intraperitoneal injection of ketamine hydrochloride (Ketalar®, Pfizer, USA). The animals were secured to the operating table in prone position (Figure 1).

At the start of the surgery, the incision area was cleaned with povidone-iodine and covered with sterile fabric. A vertical skin-subcutaneous incision of 1.5-2 cm length was made in the lumbar region (approximately the L3-4 region) with a no. 11 scalpel (Figure 2A).

The fascia was seen and opened in a vertical plane with a new no. 11 scalpel parallel to the skin incision (Figure 2A). The paravertebral muscles were stripped from the unilateral spinous process and laminae. The lamina and facet joints were seen (Figure 2B). The surface of lamina was decorticated with a no. 11 scalpel. A screw insertion slot was opened with a 20-gauge needle in a lateral direction to the junction point of the lamina and facet joint (Figure 3A). In the slot on the lamina, Ti alloy microscrews with a surface area of 25 mm^2 was inserted in the first group; Ti alloy microscrews with a surface area of 25 mm^2 that are coated with 5 to 8 mcm-thick silver layer were inserted in the second group; and Ti alloy microscrews with a surface area of 50 mm^2 that are coated with 5 to 8 mcm-thick silver layer were inserted in the third group; and the inserted screws were tightened with a screwdriver (Figure 3B). For consistent growth of both soft tissue and implant infection, inoculation with 105 CFU was required[11]. Bacterial solutions in a volume of 10 µl were applied onto the screw in the surgical field using a 50 µl micropipette in all groups, and the fascia was closed. Note that follow-up was performed for 21 days. During the follow-up period, the animals were closely followed up to monitor their feeding, behaviors and wounds (redness and discharge), and the changes were noted on a daily basis.

The incision sites of animals had the same characteristics for all groups. In 90% of all groups, skin rash and swelling were present at the wound site; however, there was no discharge in any of the animals. When the swelling was palpated, it was hard to touch and fixed under the skin (Figure 4A, B).

There were no neurological complications developed in any of the animals. Two animals died in the preoperative period because of respiratory failure caused by anesthesia, and one

Figure 1. The thoracolumbar region of the animal was shaved and cleaned with povidone-iodine, and it was placed on the operating table in prone position.

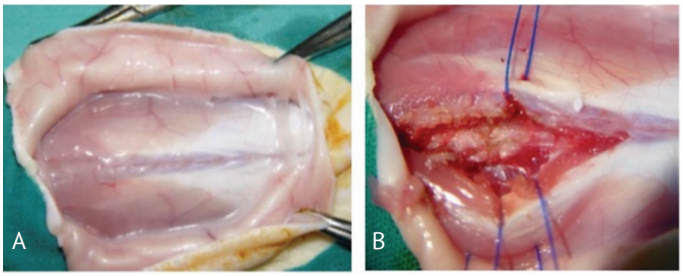

Figure 2. A) Paravertebral muscles of the thoracolumbar region and the lumbar fascia are seen following the skin incision (left image), B) Paravertebral muscles are stripped away, and the lamina and facet joints are exposed (right image).

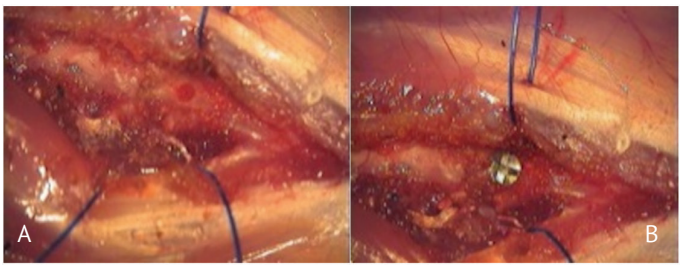

Figure 3. A) The screw entry slot that has been opened can be seen in the image on the left, B) The screw has been placed through the slot that was opened, as seen in the image on the right.

animal died in the early postoperative period because of respiratory failure caused by anesthesia. The animals that died were replaced with new animals.

Statistical Analysis

The NCSS (Number Cruncher Statistical System) 2015 and PASS (Power Analysis and Sample Size) 2015 Statistical Software (Utah, USA) were used for statistical analysis when evaluating the results obtained from the study. The study data were assessed using descriptive statistical methods (mean and standard deviation). Moreover, for comparing quantitative data, the Kruskal-Wallis test was used for inter-group comparison of parameters that did not show a normal distribution, and the Mann-Whitney U test was used to determine the group causing the difference. The Spearman's correlation analysis was used to evaluate the relations between parameters. P values of <0.05 were considered to be statistically significant.

RESULTS

Method and Follow-up Duration

Three animals died on the postoperative day zero because of anesthesia-associated complication. All three animals were replaced with new animals on the same day. No other animal died during the 21-day follow-up period. The body weight and body temperature of the animals were measured on days 0, 3, 7, 15 and 21. No changes were detected in the body weight and body temperature in any of the animals.

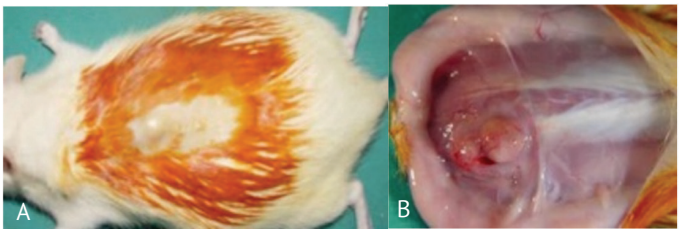

Figure 4. A) The stage of obtaining a sample from an animal in the first group after sacrification. The incision and abscess formation under the skin in the incision area is seen in the image. B) The skin-subcutaneous tissue has been cut through and the fascia and paravertebral muscles are exposed, as seen in the image. There is an abscess formation extending from the paravertebral muscles to the subcutaneous area in the surgical site.

Evaluation of Infection

Bone-related infection developed in all groups that were inoculated with bacteria. Bacterial growth occurred in all of the screws and bone samples. All animals had swelling that was palpable on the skin. When an incision was made on this swelling, purulent effusion was observed in three animals in the first group, four animals in the second group, and three animals in the third group. A stiffer and more organized tissue was encountered in other animals. The number of microorganisms that grew on the screw and in the tissue was then statistically compared (Table 1).

Microbiological Evaluation

Bone samples taken from each animal under aseptic conditions were placed in sterile falcon tubes. The bones were then weighed in a precision balance (Shimadzu, Libror AEG-120, Japan) and mechanically homogenized in 10 mL of serum in a sterile mortar. After homogenization, the samples were spread on tryptic soy agar after serial dilution. After 24 h of incubation at 37 °C, the bacterial count was quantitatively determined (CFU/g). The presence of growth on screws was investigated by placing the screws in 0.5 mL of TSB and vortexing it and then inoculating that onto TSA growth medium. No bacteria other than *Staphylococcus aureus* was detected in the inoculated media (Table 2).

Comparison of groups revealed no statistically significant difference between the number of microorganisms on the screw ($p=0.968>0.05$). Paired comparisons between these groups did not reveal any statistically significant difference in terms of the number of microorganisms on the screw ($p>0.05$). Comparison of the number of microorganisms per gram in tissue revealed no statistically significant difference between the groups ($p=0.403>0.05$). Paired comparisons did not reveal any statistically significant difference between these groups in terms of the number of microorganisms per gram in tissue ($p>0.05$).

Table 1. Number of microorganisms that grew on the screws

	Ti alloy microscrew with a surface area of 25 mm^2	Ti alloy Ag-coated microscrew with a surface area of 25 mm^2	Ti alloy Ag-coated microscrew with a surface area of 50 mm^2
n=1	2,100	2,725	81
n=2	235	2,800	1,970
n=3	3,900	7,020	3,440
n=4	1,280	5,792	3,100
n=5	3,193	1,620	1,930
n=6	3,365	2,110	1,680
n=7	5,497	2,200	6,400
n=8	2,480	1,800	4,890

Table 2. Number of microorganisms per gram in bone tissue

	The group in which a Ti alloy microscrew with a surface area of 25 mm^2 was placed	The group in which a Ti alloy Ag-coated microscrew with a surface area of 25 mm^2 was placed	The group in which a Ti alloy Ag-coated microscrew with a surface area of 50 mm^2 was placed
n=1	66,877	53,611	184,872
n=2	6,486	1,713,910	139,024
n=3	121,132	414,787	331,250
n=4	175,291	278,422	223,502
n=5	322,656	243,983	98,918
n=6	171,755	279,117	770,718
n=7	287,577	183,457	333,512
n=8	250,555	315,080	304,550

DISCUSSION

In the last two decades, rapid advances have been made in general medicine, as well as in the field of spine surgery in terms of diagnosing and treating diseases. Because of the developments in biomaterial technology and nanotechnology, considerable changes have been achieved in the implants used in spine surgery. These developments significantly increased the number of surgeries using biomaterials, and consequently brought about biomaterial-associated problems. In particular, in spine instrumentation, there are many complications arising from the most frequently used metal alloy screws. Among these complications, implant-associated infections are most common. While the infection rate is ~1% in the interventions where metal implants are not used in spinal surgery, this rate varies between 1% and 8.5% in cases where metal implants are used[3-5,12,13]. Implants act as passive surfaces prone to bacterial adhesion and biofilm formation. A recent study reported an infection rate as high as 21% after complex adult spine deformity surgery where the operation duration was long[14]. Antibiotherapy alone is insufficient in the presence of implants infection, and revision surgery is inevitable in patients who do not respond to medical treatment and especially in late-onset infection[15]. In addition to the medical and social problems caused by all these situations, the financial burden that arises is a serious problem[16].

Staphylococcus epidermidis and *S. aureus* are most commonly isolated in biomaterial-associated infections[17,18]. Although less frequently, other microorganisms that are isolated include *E. coli*, *Peptococcus*, *Pseudomonas aeruginosa*, *Proteus mirabilis* and *group A beta hemolytic streptococci*[19]. The major pathogenic cause of biometal, bone, joint and soft tissue infections is *S. aureus*[20]. Therefore, in this study, a *S. aureus* ATCC 29213 strain, which is known to lead to the development of osteomyelitis, was used.

In recent years, Ti alloy metal implants have frequently been preferred in surgical instrumentation. Greater bone adhesion and a more stable structure is achieved with Ti implants compared to other metals. Their better adhesion to bone and stable structure have made Ti implants become more preferable[21]. Placement of implants into tissue causes certain changes in the natural response that normally occurs in a damaged tissue[22]. Therefore, the implant surface provides a suitable surface for bacteria to settle and colonize and paves the way for infection by disrupting the host defence mechanisms.

It was thought that coating the surface of biomaterials with antibacterial agents to prevent them from constituting a ground for bacterial settlement and biofilm formation could be a solution, and many materials were used for this purpose. One of these materials is Ag, which has been known since ancient times to have an anti-infective effect and is used in many areas today for its anti-infective characteristic. The first written document on the antiseptic effect of Ag is the book of King Menes of Egypt that dates back to around 3600 B.C.[23]. Ag is a noble metal that lies in Group 1B with the atomic number 47 in the periodic table[24]. It has the highest electrical and thermal conductivity compared to other metals and is resistant to corrosion. It is known that both its free form and Ag salts have an antimicrobial effect[25]. However, many studies have shown that Ag exhibits its antiseptic effect best in its oxidative state, which is the +1 ion form[26]. Moreover, the dimensions of nanoparticles are of great importance in antibacterial efficacy. As the particle size gets smaller, the antibacterial efficacy increases. Several studies have shown that Ag nanoparticles have antimicrobial efficacy[27-30]. Ag exhibits antibacterial activity through its oligodynamic properties. Ag ions coming out of metallic Ag with the oligodynamic effect are adsorbed by bacterial cells and this leads to a toxic effect and activates its antibacterial efficacy[31]. Ag ions liberated from metallic Ag are positively charged. The electronegative surface of bacteria attracts positively charged Ag ions. Positively charged Ag ions have an affinity to negatively charged sulfhydryl groups in the enzyme system of the cell wall. By binding these groups, they prevent the transmembranous energy transfer and electron transport of bacteria. Moreover, they inhibit the formation of a protective film[32].

In the literature, Ag compounds and salts in various forms and different chemical structures such as impregnation and coating

are used with many different medical products. Silver nitrate and silver sulfadiazine are among the ones that are used most frequently[33,34]. Antimicrobial activity is related to the method in which Ag is used and the number of ions released as a result[35]. Most *in vitro* tests performed have yielded positive results[36,37]. *In vivo* studies, however, have revealed that the results can take a very different shape within the organism. Clinical studies have been conducted, especially with arterial grafts, central venous catheters, urinary catheters and ventricular drainage catheters. Ag has been used for antibacterial efficacy not only in medical interventional applications but also in many other fields. It has been used in fabrics because it can prevent nosocomial infections and its bactericidal effects have been demonstrated as a result[38]. Moreover, its antiseptic effects have been shown in environmental cleaning and cleaning of dishwater[39].

In the study where Secinti et al.[40] used Ag-coated metal alloy implants, it is reported that these implants had antibacterial efficacy. Direct electrical current was applied to the implants in the same study; it was shown that the ion release and antibacterial effect increased significantly. It was reported that uncoated metal alloy screws to which direct current was applied had significant antibacterial efficacy compared to the ones to which current was not applied[40]. The long-term protective effects of Ti implants coated with Ag ion-doped ceramic nanopowder against antibacterial activity have been shown in an *in vivo* experimental study by Kose et al.[41]. In a clinical study by Riley et al.[42] that included 1309 patients, it was found that silver oxide-coated urinary catheters increased bacteriuria. Silver acetate-coated arterial grafts were prophylactically used in 430 patients in the study by Larena-Avellaneda et al.[43], and no difference was observed compared with the control group. In the experimental study by Schneider et al.[44] where they performed vascular grafts, no difference was observed between silver-coated and rifampin-impregnated grafts. In the study by Camargo et al.[45] where they performed on 109 patients hospitalized in the intensive care unit, no significant difference was reported in Ag-coated central venous catheters in terms of infection compared with the control group. When applied locally and topically on the body surface, many different forms of Ag such as silver sulfadiazine, silver hydroalginate, silver-coated silicon and silver nitrate have been shown to have antibacterial efficacy at various levels in clinical studies with large case series and meta-analyses[46-49].

There are two handicaps to using Ag in implants. The first handicap is that the presence of ions is temporary depending on the amount of material. The other handicap is the risk of toxicity. It has been stated in the literature that no toxic effects were observed in the amounts used in many experimental and clinical studies[50]. However, different results were obtained in the clinical study by Massè et al.[51] in which they placed 50 Ag-coated stainless steel screws and 56 uncoated stainless steel screws in the lower extremities of 106 patients. Although there was no statistically significant difference between the screws in terms of culture positivity, the study was terminated because of a significant increase in the serum Ag levels[51]. *In vivo* study by Hazer et al.[52] Ag nanoparticle coated Ti screws were shown to have antimicrobial effect. However, in our study comparing Ag coated Ti screws with Ti screws, there was no significant difference between the groups[52]. The silver +1 nanoparticle count is the primary factor that provides antibacterial efficacy; however, the implant surface area is the main factor that affects the number of ions that are released. Therefore, Ag-coated microscrews with two different surface areas, one with a 25 mm^2 and the other with a 50 mm^2 surface area, were used in our study. However, no difference was reported between these two microscrews, and antibacterial efficacy could not be demonstrated. It is understood that although the release of nanoparticles from Ag-coated implant surfaces does mostly provide antibacterial efficacy in *in vitro* tests performed with proper solutions; this effect is not at the desired level in the body where there is an environment that is dense with electrolytes. It is thought that this may be related to the fact that the oxidation of silver and the release of nanoparticles in the body does not occur in the same way as it does under in vitro conditions. Furthermore, the nanoparticle release takes place in a limited time in relation to the amount of coating that is present.

CONCLUSION

Today, implant-related infections remain as a serious problem and the financial losses in addition to medical and social losses that occur as a result cannot be underestimated. It is of great importance to develop biomaterials that can prevent infection. Ag-coated Ti alloy microscrews with two different surface areas and uncoated standard Ti alloy microscrews were used in our study. When compared with the other group that was implanted uncoated titanium alloy screws, the two groups that were implanted with Ag-coated screws revealed no statistically significant difference, and no anti-infection effect was observed. Considering the difficulties and financial burdens that arise after the occurrence of an infection, the importance and necessity of developing anti-infective biomaterials are very clear today. Solution-focused further studies are required for developing implants with better biocompatibility, lower infection rates and lower costs in the following years.

Ethics

Ethics Committee Approval: This research was approved by Bakırköy Prof. Dr. Mazhar Osman Training and Research Hospital, Clinic of Psychiatry, Neurology and Neurosurgery Ethics Board (2012-47773).

Informed Consent: Experimental study.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: N.A.K., Concept: N.A.K., A.E.O., Design: N.A.K., A.E.O., Data Collection or Processing: M.Ü.,

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CASE REPORT
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HORNER'S SYNDROME IN A CONGENITAL SCOLIOSIS PATIENT: A COMPLICATION RELATED TO INTERNAL JUGULER VEIN CATHETERISATION OR PRONE POSITION?

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ABSTRACT

Horner's syndrome (HS) is a rare complication after anterior cervical discectomy and it is characterized by ipsilateral ptosis, miosis and fascial anhidrosis. Here, we described transient postoperative HS in a patient with congenital scoliosis who underwent posterior T7 hemivertebra excision. Fortunately, HS resolved completely after 3 months of follow-up. One must consider internal jugular vein catheterization or prone position as the cause of postoperative HS in non-cervical surgeries.

Keywords: Horner's syndrome, jugular vein catheterization, prone position, congenital scoliosis

INTRODUCTION

Postoperative Horner's syndrome (HS) is a rare complication characterized by ipsilateral ptosis, miosis and facial anhidrosis. It is the result of direct or indirect compression or tension of oculosympathetic fibers[1]. Anterior cervical discectomy and fusion surgery is the most common cause of direct trauma[2]. Additionally, the syndrome can occur as a result of recurrent attempts of needle damage during internal jugular vein (IJV) catheterization. In our case, we reported postoperative HS in a congenital scoliosis patient who underwent posterior T7 hemivertebra excision with a history of IJV catheterization.

CASE REPORT

The 12-year-old-girl patient underwent posterior T7 hemivertebra excision and posterior instrumentation and fusion between T1 and T10 levels. After uneventful anesthesia induction, the correct head position was given, and landmark method is used for right IJV catheterization. We succeeded IJV catheterization after three unsuccessful attempts. After standard monitoring and arterial monitoring, the patient was turned to the prone position. Operation time was 240 minutes; the patient was extubated uneventfully.

At the postoperative 1st day, we recognized that the right site pupil was smaller than the left one. On physical examination, we detected ptosis and miosis on the right site, and HS was diagnosed. Neurology consultation was done. Bilateral light reaction and cranial nerve examination were normal. No pathologic finding was detected in her cervical magnetic resonance imaging study. There was no cervical hematoma, and her range of motion was normal. No medication was given to the patient. The HS resolved completely after 3 months follow-up.

DISCUSSION

HS is the result of the interruption of an oculosympathetic pathway to the eye with different causes. Sympathetic preganglionic fibers exit from high centers like the hypothalamus and spinal cord and descend across the neck with cervical sympathetic chain. After they make synapse with superior cervical ganglion at the back site of carotis artery, postganglionic fibers enter the orbita next to the internal carotis artery.

IJV is located at anterolateral site of cervical sympathetic chain in normal anatomy. Because of the close relationship during IJV catheterization, injection damage or hematoma compression

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caused by unexpected puncture of carotis, it can effect cervical sympathetic branches and stellate ganglion[3]. Damage risk is high with recurrent unsuccessful attempts. Anatomic variations and with turning the head over 40° makes IJV and carotis artery to overlap, so the risk of artery puncture and damage to sympathetic brunch increase[4]. At this point, ultrasonography usage increases the success of the process, and unnecessary arterial puncture and hematoma formation and damage of sympathetic brunches are prevented. In the literature, there are case reports in which complications reported despite ultrasonography usage[3]. Other cause of direct trauma is surgery. Cervical spinal surgery and carotis endarterectomy are high-risk ones but it can occur in other surgeries involving cervical area[2,5].

Lubelski et al.[6] performed a retrospective systemic review including 1,116 patients who passed anterior cervical spinal surgery. Because of the anatomic location of sympathetic brunches, C4-5 and C5-6 levels were the most common surgical levels causing HS. They reported higher incidence than the literature reported[6]. Generally, local anesthetic diffusion after brachial plexus blockage or high levels in lumbar/thoracal epidural anesthesia are the examples of postoperative HS due to anesthesia applications. These are generally transient cases[7].

HS can occur in decubitus and supine positions where the neck position is not in neutral position[8]. Here the mechanism is excess stretching of sympathetic chain with exaggerated positions and resulting with secondary ischemia. HS in the prone position was also reported in the literature[9]. In one study, the authors presented a patient who underwent a 6-hour abdominoplasty and liposuction surgery and developed postoperative HS. Surgery had three phases, and the first phase lasted for two hours in the prone position. Authors related this complication to stretching and compression of the oculosympathetic pathway in the upper part of the thorax during the prone position. In a prone position, there is prolonged excessive pressure on the thorax and with abduction of the arms, greater pressure exerted on the thorax[9]. Prolonged operation time may be the other additional cause.

CONCLUSION

There is no specific treatment of HS so prevention is so important. Recurrent attempts with landmark method, excess rotation of the head to the left site, exaggerated positions, fluid-drug extravasations or hematoma due to carotis puncture are the risk factors for HS. In our case, cause of the HS can be direct puncture of the needle due to recurrent attempts or prone position in a long operation surgery.

One must consider IJV catheterization as the cause of postoperative HS in non-cervical surgeries.

Ethics

Informed Consent: Informed consent was obtained from the patient.

Peer-review: Internally peer-reviewed.

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