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-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.

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ARTICLE WRITING

Clinically relevant scientific advances during recent years include the 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 rigour of the 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 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.

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Review articles: The format for reviews substantially differ 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 that 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 with 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.

-Keywords : 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.



INSTRUCTIONS to AUTHORS

The first paragraph should introduce the general topic or problem and emphasize 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 the 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 historical 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 be 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 describe 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 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 belong. 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 something else (different in what way? the reader may 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.

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Book chapter:

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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 a historical precedent. Instead, indicate the point in the manuscript by providing citation by superscribing.

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6. Parenthetically refer to tables and figures and avoid statements in which a table of the 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 significance 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

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INSTRUCTIONS to AUTHORS

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

1. Morphometric analysis

Anesthesiology

Animal study

Basic Science

- 1. Biology
- 2. Biochemistry
- 3. Biomaterials

4. Bone mechanics

5. Bone regeneration

- 6. Bone graft
- 7. Bone graft substitutes
- 8. Drugs

Disc

- 1. Disc Degeneration
- 2. Herniated Disc
- 3. Disc Pathology
- 4. Disc Replacement
- 5. IDET

Disease/Disorder

- 1. Congenital
- 2. Genetics
- 3. Degenerative disease
- 4. Destructive (Spinal Tumors)
- 5. Metabolic bone disease
- 6. Rheumatologic

Biomechanics Cervical Spine

- 1. Cervical myelopathy
- 2. Cervical reconstruction
- 3. Cervical disc disease
- 4. Cervical Trauma
- 5. Degenerative disease

Complications

- 1. Early
- 2. Late
- 3. Postoperative

Deformity

- 1. Adolescent idiopathic scoliosis
- 2. Kyphosis
- 3. Congenital spine
- 4. Degenerative spine conditions

Diagnostics

- 1. Radiology
- 2. MRI
- 3. CT scan
- 4. Others



Pain

Epidemiology Etiology Examination **Experimental study** Fusion 1. Anterior 2. Posterior 3. Combined 4. With instrumentation Infection of the spine Surgery 1. Postoperative 2. Rare infections 3. Spondylitis 4. Spondylodiscitis 5. Tuberculosis Instrumentation **Meta-Analysis** Osteoporosis 1. Bone density Trauma 2. Fractures 3. Kyphoplasty 4. Medical Treatment 5. Surgical Treatment Outcomes 1. Conservative care 2. Patient Care 3. Primary care 4. Quality of life research Tumors 5. Surgical 1. Chronic pain 3. Primary malign tumors 2. Discogenic pain

3. Injections 4. Low back pain 5. Management of pain 6. Postoperative pain 7. Pain measurement **Physical Therapy** 1. Motion Analysis 2. Manipulation 3. Non-Operative Treatment 1. Minimal invasive 2. Others 3. Reconstructive surgery **Thoracic Spine Thoracolumbar Spine Lumbar Spine** Lumbosacral Spine Psychology 1. Fractures 2. Dislocations Spinal cord 1. Spinal Cord Injury **Spinal stenosis** 1. Cervical 2. Lumbar 3. Lumbosacral 1. Metastatic tumors 2. Primary benign tumors



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EDITORIAL

Dear Colleagues,

Once again, I want to say that I feel privileged to be the person who disseminates our professional journal to you, and it is with great honor and humility that I share this, the 2nd issue this year, with you. I am deeply grateful to all the authors, reviewers, assistant editors, secretaries, and the Galenos publishing team for the efforts they contributed to getting it published. We are very happy to announce that JTSS is currently indexed in ten indices; Scopus, Ulakbim, Türkiye Atıf Dizini, Index Copernicus, J-Gate, Europub, Proquest, Gale Cengage learning, Ebsco Host and recently China Knowledge Resource Integrated.

In this issue, there are seven clinical research studies. The first is a retrospective clinical study examining, "The Effect of Chronic Kidney Disease in Patients with Spontaneous Spondylodiscitis". The second is a clinical study discussing "The Neurologic Deficit Risk of Three Different Kinds of Spinal Osteotomies and Perioperative Management". The third is a clinical study entitled, "Comparison of Subpedicular and Kambin's Triangle Approaches in Transforaminal Epidural Injection Applications in Case of Lumbar Disc Hernia". The fourth article is about "Evaluation of the Efficacy of Percutaneous Caudal and Combined Caudal/Transforaminal Neuroplasty-Adesiolysis in the Treatment of Symptomatic Lumbar Spinal Stenosis". The authors of the fifth study looked at "Surgical Treatment of Latrogenic Pseudomeningoceles". The sixth study is about "Comparing Results of Posterior Cervical Facet Joint Cage Stabilization with Lateral Mass Fixation in Cervical Foraminal Stenosis" while, in the seventh, the authors Evaluated "Conservative Treatment of Acute Low Back Pain: Acetaminophen Combined with Etodolac or Diclofenac A Comparative Study of 67 patients".

I hope that each of you value the information in these articles, and that you apply it to your daily practices. Our goal is to provide you with whatever insights we can to insure that you are on the cutting edge of all the latest developments in your respective fields. It is my sincere hope that this newsletter helps achieve these objectives.

With kindest regards,

Editor in Chief Metin Özalay, M.D., Prof.

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THE EFFECT OF CHRONIC KIDNEY DISEASE IN PATIENTS WITH SPONTANEOUS SPONDYLODISCITIS

Fikret Şahintürk¹, Erkin Sönmez¹, Selim Ayhan¹, Deniz Ustaoğlu², Salih Gülşen¹, Cem Yılmaz¹

¹Başkent University Faculty of Medicine, Department of Neurosurgery, Ankara, Turkey ²Başkent University Faculty of Health Sciences, Department of Management of Health Institutions, Ankara Turkey

Objective: Spontaneous spondylodiscitis is a rare but serious infectious disease of the vertebral column that can lead to permanent neurological deficits. We investigated the differences during follow-up of this pathology, which is more common in patients undergoing hemodialysis (HD) treatment for chronic kidney disease (CKD), compared with the general population.

Materials and Methods: The data of patients who were treated for spontaneous spondylodiscitis between 2016-2021 at the Başkent University Department of Neurosurgery were used retrospectively. The patients were divided into 2 groups according to the diagnosis of CKD. Demographic data of the patients, biochemical values at the time of diagnosis (C-reactive protein, sedimentation, leukocyte, lymphocyte), microbiological and pathological examination results, and treatment method (surgical, medical) applied after diagnosis was obtained from the medical records. The effects of CKD presence and treatment methods on patient survival were investigated.

Results: Of the 49 patients included in the study, 57.1% were female and the mean age was 66 years. Twenty-four of the patients were chronic HD patients. The microbiological examination of the samples taken determined that the causative pathogen could be produced in the cultures of 21 (42.8%) patients. According to the results of the pathological examination, signs of infection were detected in 24 (48.9%) patients. It was determined that 27 of the patients were operated. There was a central venous catheter in 20 of the patients. There was no statistically significant difference in survival between the groups that were operated on for instability and those that were not operated on. However, chronic renal failure and the presence of central venous catheters increased mortality statistically significantly.

Conclusion: In the presence of back pain in chronic HD patients, spondylodiscitis should be suspected and diagnosed at an early stage, even if there is no fever or high infection parameters. Finally, great emphasis on disinfection procedures and aseptic techniques in patients with central venous catheters protected from these serious infectious complications.

Keywords: Spondylodiscitis, kidney failure, hemodialysis

INTRODUCTION

Spinal infections are a disease characterized by delays in diagnosis and treatment due to their silent clinics. Neurological deficits, sepsis, and even mortality may develop due to delays in treatment. Its incidence has increased recently. Parallel to the newly developed antibiotics, the development of resistance in microorganisms and the fact that stabilization techniques have become more sophisticated day by day have made it mandatory for professionals interested in this subject to keep their knowledge up-to-date⁽¹⁾.

In spontaneous spondylodiscitis, the causative microorganisms reach the vertebrae and intervertebral disks by bacteremia, retrograde infection from the urinary tract, and direct invasion from adjacent tissues. The incidence of vertebral osteomyelitis is estimated to be 2.4/100,000 on average. Its incidence increased with age. While it is 0.3/100,000 in the population under the age of 18, it increased to 6.5/100,000 in the population over the age of $70^{(2)}$. Hemodialysis (HD) patients have additional

risk factors compared with the normal population. These are repeated vascular interventions, the presence of a long-term catheter, and contamination of the dialysis water treatment system. The features and clinical course of spontaneous spondylodiscitis in patients with HD patients may differ from those in the general population⁽²⁾.

Case studies of spontaneous spondylodiscitis in patients with HD patients can be found in the literature. However, the outcomes of patients are not well defined^(3,4). This study determines the prognostic factors of spontaneous spondylodiscitis, its clinical course, and its effect on survival in patients with HD patients.

MATERIALS AND METHODS

This study was approved by the Başkent University Institutional Review Board (project no: KA22/190) and supported by the Başkent University Research Fund. For the study, the data of patients who were treated for spontaneous spondylodiscitis

Address for Correspondence: Erkin Sönmez, Başkent University Faculty of Medicine, Department of Neurosurgery, Ankara, Turkey Phone: +90 532 621 25 14 E-mail: erkinso@gmail.com Received: 11.10.2022 Accepted: 17.01.2023 ORCID ID: orcid.org/0000-0002-5693-3542



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between 2016-2021 at the Başkent University Department of Neurosurgery were used retrospectively. The patients were divided into 2 groups according to the diagnosis of chronic kidney disease (CKD). Demographic data of the patients, biochemical values at the time of diagnosis [C-reactive protein (CRP), sedimentation, leukocyte, lymphocyte], microbiological and pathological examination results, and treatment method (surgical, medical) applied after diagnosis was obtained from the medical records. The effects of CKD presence and treatment methods on patient survival were investigated.

Statistical Analysis

As descriptive statistics in the study, frequency (n) and percentage (%) values are given in the evaluation of categorical variables. The Shapiro-Wilk normality test was used for the conformity of the numerical variables to the normal distribution, and the median (minimum-maximum) values were given as the descriptive statistics for the variables whose normal distribution assumption was provided, for those whose mean ± standard deviation was not normally distributed. Student t-test, Mann-Whitney U test, and Welch t-test were used to examine the differences between groups in terms of numerical variables. The pearson chi-square test and Fisher's Exact test were used to examine the relationship between categorical variables. The log-rank test was used to compare survival times according to the status of being operated, the presence of corticotropin releasing factor, and the status of receiving antibiotic treatment. Type I error probability was taken as α =0.05 in all hypothesis tests, and the Statistical Package Social Science v25.0 package program was used for statistical evaluations.

RESULTS

Of the 49 patients included in the study, 57.1% were female and the mean age was 66 years. Twenty-four of the patients were chronic HD patients. It was determined that 35 of the patients had infected vertebrae in the lumbar region, 8 in the thoracic region, 3 in the thoracolumbar junction, and 3 in the cervical region (Table 1). The microbiological examination of the samples taken determined that the causative pathogen could be produced in the cultures of 21 (42.8%) patients. Staphylococcus aureus (S. aureus) (n=10, 47.6%) was found to be the most common agent. Other causative microorganisms detected are Staphylococcus epidermidis (n=6, 28.5%), pseudomonas (n=2, 9.5%), coagulasenegative Staphylococcus (n=2, 9.5%), and Staphylococcus lugdenesis (n=1, %4.7) was found (Table 2). According to the results of the pathological examination, signs of infection were detected in 24 (48.9%) patients. It was determined that 27 of the patients were operated on. The management of a total of 49 patients with spontaneous spondylodiscitis is shown in Table 3. There was a central venous catheter in 20 of the patients (Table 1). The mortality rate was 22.4% (n=11). According to the statistical analysis performed by comparing the chronic HD patients and the patients without CKD, no significant difference was found in gender, (p=0.33) age, (p=0.33) and preoperative biochemical parameter values (CRP, sedimentation, leukocyte, lymphocyte) (p=0.33, p=0.0.55, p=0.73, p=0.73). There was no statistically significant difference in survival between the groups that were operated on for instability and those that were not operated on (p=0.77). However, chronic renal failure and the presence of central venous catheters increased mortality statistically significantly (p=0.002). Pictures of operations performed due to instability developing after spondylodiscitis are shown in Figure 1.

Table	1.	Summary	of	characteristics	of	patients	with
spontaneous spondylodiscitis (n=49)							

spontaneous sponaytouisettis	(1112)
Variable	Value
Mean age in years	66
Sex	
Males	21 (42.9%)
Females	28 (57.1%)
Levels involved vertebra	
Cervical	3 (6.1%)
Thoracic	8 (16.3%)
Thoracolumbar Junction	3 (6.1%)
Lumbar	35 (71.4%)
Management	
Operated + medical treatment	27 (55.1%)
Medical treatment	22 (44.8%)
Central venous catheter	
Yes	20 (40.8%)
No	29 (50.1%)
Chronic kidney disease	
Yes	24 (48.9%)
No	25 (51.02%)
Mortality	
Yes/(operated/non-operated)	11/(6/5)
No	38
Cultures	
(+)	21 (42.8%)
(-)	28 (57.1%)
Pathological examination	
(+)	24 (48.9%)
(-)	25 (51.02%)

 Table 2. Microorganism species detected in the microbiological examination

Causative organism	
S. aureus	10 (47.6%)
Staphylococcus epidermidis (n=6, 28.5%)	6 (28.5%)
Pseudomonas (n=2, 9.5%)	2 (9.5%)
Coagulase-negative Staphylococcus (n=2, 9.5%)	2 (9.5%)
Staphylococcus lugdenesis (n=1,4.7%)	1 (4.7%)
S. aureus: Staphylococcus aureus	









Figure 1. A) Preop MRI image of vertebral defect due to spondylodiscitis in the lumbar region B) Postoperative CT image C) Preop MRI image of vertebral defect due to spondylodiscitis in the thoracic region D) Postoperative CT image MRI: Magnetic resonance imaging, CT: Computed tomography

DISCUSSION

Spontaneous spondylodiscitis is a rare disease that can be fatal due to low treatment efficacy. It is more common in patients with dialysis patients recently. Frequent vascular interventions and the presence of a central venous catheter pose a risk of bacteremia. The resulting bacteremia involves the pathogen in the intervertebral disks in 50.8% of the cases⁽⁵⁾.

In our study, we investigated the effects of prognostic factors, clinical course, and survival on chronic dialysis patients to compare the results of infectious spondylodiscitis compared with the group without CKD.

Consistent with previous studies, we also found in our study that spondylodiscitis developing in chronic dialysis patients was more mortal than in the group without renal failure⁽⁶⁾. Because of the microbiological examination performed in our

study, 42.8% of the causative microorganisms were shown. The inability to identify the causative microorganism causes difficulty in choosing the right antibiotic therapy. This result was found to be consistent with previous studies^(7,8). Consistent with the literature, we identified *S. aureus* as the most common cause of spondylodiscitis, which is responsible for bacteremia in the HD group. Repeated vascular interventions are the reason for this. Zhang et al.⁽⁹⁾ Although a lower rate of *S. aureus* bacteremia was shown in patients using an arteriovenous fistula, the rate was found to be higher than that in the general population. In our study, we found *S. aureus* to be the most common factor in HD patients with central venous catheters, and we showed that mortality was higher in the catheter group. According to these results, it is important for patients on HD to perform HD with an arteriovenous fistula as soon as possible instead of a central venous catheter for a long time and to comply with antisepsis rules for patient survival. In a study by Lu et al.⁽¹⁰⁾ involving



1,550 HD patients, it was determined that approximately 10% of the patients had a central venous catheter, and the biofilm layer formed on the catheter was responsible for spondylodiscitis. Additionally, spondylodiscitis should be kept in mind in case of new-onset back pain in patients with permanent central venous catheters other than HD patients.

Surgery is the preferred treatment option in cases of epidural abscess compressing the spinal cord or nerve roots, progressive or acute neurological deficit, spinal instability, or deformity. The primary goal of surgical treatment is tissue culture, drainage of the abscess, and debridement of non-viable tissue. Because of the study by Tschöke et al.⁽¹¹⁾, they suggested that debridement and use of appropriate antibiotics according to the results of microbiological examination of the tissue taken could provide the cure. Additionally, long-term bed rest required during antibiotic treatment of patients with impaired vertebral structure to spondylodiscitis causes many complications. In our study, there was no statistically significant difference between the operated and non-operated groups in terms of survival. However, our opinion is that even though there is no difference in mortality, patients who underwent surgery have a good quality of life, even due to early mobilization. We think that the high mortality rate in our study is due to the late diagnosis of spondylodiscitis in patients with HD patients. There are delays in the diagnosis because the infection parameters are higher in the group with chronic disease than in the healthy group, and the fever in the group with indwelling catheters is primarily attributed to the catheter infection. This delay causes more serious damage to the spine. In this group with a comorbid disease, the difficulty of surgical treatment, duration of treatment, and risk of mortality increase due to the delay. Identifying the causative microorganism as soon as possible and early treatment is critical for the prognosis of the infective condition in patients.

Study Limitations

This study has limitations. Cases were reviewed retrospectively so that only associations between spondylodiscitis and mortality could be detected, whereas causal associations could not be clearly identified. Because the prevalence of infectious spondylodiscitis was low, the number of cases was limited, reducing our ability to detect significance in variables. Despite these limitations, the clinical course, prognostic factors for patients with infectious spondylodiscitis were determined.

CONCLUSION

In the presence of back pain in patients with chronic HD patients, spondylodiscitis should be suspected and diagnosed at an early stage, even if there is no fever or high infection parameters. Finally, great emphasis on disinfection procedures and aseptic techniques in patients with central venous catheters protected from these serious infectious complications.

Ethics

Ethics Committee Approval: This study was approved by the Başkent University Institutional Review Board (project no: KA22/190, date: 12.04.2022)

Informed Consent: Retrospective study.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: F.Ş., E.S., S.A., S.G., C.Y., Concept: F.Ş., E.S., S.A., Design: F.Ş., E.S., Data Collection or Processing: F.Ş., D.U., Analysis or Interpretation: F.Ş., D.U., Literature Search: F.Ş., E.S., S.A., Writing: F.Ş., E.S., S.A.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study received no financial support.

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ORIGINAL ARTICLE

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THE NEUROLOGIC DEFICIT RISK OF THREE DIFFERENT KINDS OF SPINAL OSTEOTOMIES AND PERIOPERATIVE MANAGEMENT

¹Liv Hospital Ulus, Clinic of Orthopedics and Traumatology, İstanbul, Turkey ²Atlas University Faculty of Medicine, Department of Orthopedics and Traumatology, İstanbul, Turkey ³Liv Hospital Vadistanbul, Clinic of Orthopedics and Traumatology İstanbul, Turkey

Objective: We reported intraoperative and early postoperative new neurologic deficits and acute management of this problem in patients who underwent correction surgery with spinal osteotomies [posterior vertebral column resection (PVCR), pedicle subtraction osteotomy (PSO), and Smith-Peterson osteotomy (SPO)] for complex spinal deformity, and we secondarily compared osteotomies in terms of observing neurologic deficits.

Materials and Methods: Between 2017 and 2021 were retrospectively reviewed from our medical records. A total 83 patients who underwent correction of severe spine deformity with various spinal osteotomies were included in the study.

Results: In total, 3 patients with SPO (2 perioperative and 1 postoperative) and 2 patients with PVCR (both postoperative) had a new neurologic deficit. From these 5 patients, 3 of them had adult deformity and 2 had pediatric congenital kyphoscoliosis. Three patients had no intraoperative signal loss and were normal postoperatively, but they gradually lost motor power in their legs within 6 h of surgery.

Conclusion: We did not observe any neurologic event perioperatively and postoperatively in patients who underwent PSO, and the neurologic complication rate was slightly higher in patients who underwent PVCR. Intraoperative neuromonitoring should be used in every spinal deformity correction surgery even if false-negative results can occur. Perioperative signal loss should be taken seriously, and a necessary management protocol should start immediately. The last check of neuromonitoring should be done before waking up, and a routine neurologic exam must be carried out during hospitalization time. Because of postoperative neurologic deficits can occur.

Keywords: Spine osteotomy, neurologic deficits, scoliosis, khyposis

INTRODUCTION

The rate of new neurologic deficits associated with spine surgery was reported as 1% based on data from the Scoliosis Research Society on 108,419 adult patients with a primary diagnosis of degenerative disease⁽¹⁾. A new neurologic deficit is one of a devastating complications of severe spine deformity surgery. This may occur intraoperatively or in the early postoperative period⁽²⁾. Neuromonitoring is an essential tool used during spine deformity surgery to detect any potential neurologic deficit early⁽³⁾. Intraoperative signal loss may occur unilaterally or bilaterally. In addition, false-negative and false-positive instances may occur during surgery. The signal loss could be due to a direct mechanical injury to the cord or nerve root, vascular compromise, or inadequate decompression of the dura or nerve roots after osteotomies⁽⁴⁾. Vale et al.⁽⁵⁾ demonstrated that patients with an acute neurologic deficit or injury could improve when mean arterial pressure (MAP) is maintained

above 85 mmHq. Unfortunately, given the paucity of data on delayed neurologic deficits, there are no existing guidelines for the treatment of this relatively rare phenomenon⁽⁵⁾. Wang et al.⁽⁶⁾ reported that patients with higher ratios of coronal and sagittal angulation were at risk of spinal cord monitoring events and new neurologic deficits. The authors evaluated the patients who only underwent posterior vertebral column resection (PVCR) for deformity correction⁽⁶⁾. Alternatively, Trobisch et al.⁽⁷⁾ reported the outcomes of pedicle subtraction osteotomy (PSO) for the deformity correction without neuromonitoring, and the authors discovered similar neurologic complications compared to previous studies. We hypothesized that intraoperative neuromonitoring, which should be performed during complex spinal deformities that require spinal osteotomies, could detect similar signal losses, independent of the type of corrective spinal osteotomy. Therefore, we reported intraoperative and early postoperative new neurologic deficits, as well as acute management of this problem in patients who underwent

Address for Correspondence: Gökhan Kürşat Kara, Liv Hospital Ulus, Clinic of Orthopedics and Traumatology, İstanbul, Turkey Phone: +90 532 376 01 62 E-mail: drkursatkara@yahoo.com Received: 20.12.2022 Accepted: 16.03.2023 ORCID ID: orcid.org/0000-0002-2058-6534



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correction surgery with spinal osteotomies for complex spinal deformity, and we secondarily compared osteotomies in terms of observing neurologic deficits.

MATERIALS AND METHODS

Study Population

This retrospective study was approved by the İstinye University Ethical Review Board (3/2022.K-34) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all the patients. Data of patients who underwent corrective spinal surgery between 2017 and 2021 were retrospectively reviewed from our medical records. Patients who underwent correction of spine deformity with various spinal osteotomies were included in the study. Patients with preoperative neurological deficits and those who underwent revision surgeries were excluded.

Surgical Technique and Neuromonitoring

All surgeries were performed by a spine surgeon with over 25 years of experience and the senior author of this study. PVCR, PSO, the and Smith-Peterson osteotomy (SPO) were performed if needed. No preoperative halo traction or intraoperative traction was used. Intraoperative neuromonitoring was performed with transcranial motor-evoked potentials (MEP), somatosensory-evoked potentials (SSEP), free-run electromyography (EMG), and pedicle screw stimulation EMG under total intravenous anesthesia. No intraoperative wakeup test was used routinely. All cases followed MEP and SSEP neuromonitoring modalities during the operation. Immediate action was taken for those who lost signals intraoperatively with normalization of blood pressure (systolic pressure to 100 mmHg and above), normalization of PO2 (100), removal of rod, loosening of correction, and further decompression of dura and nerve roots. The signals returned to normal within 15 min after necessary interventions in all patients. After the normalization of the MEP and SSEP signals, re-correction of the deformity was performed uneventfully.

Statistical Analysis

Data analysis was performed using SPSS (IBM, Armonk, NY, USA). Chi-square test was used to compare neurologic deficit risk for osteotomy groups. A p value of <0.05 was considered statistically significant.

RESULTS

This study included 83 patients (52 female, 31 male) with a mean age of 32 years (range; 6-53 years old) (29 pediatric and 54 adult patients). The mean coronal Cobb's angle was 98° (range; 60-100°), and the mean sagittal Cobb's angle was 78° (range; 55-95°). PVCR was performed in 35 patients, PSO was performed in 20 patients, and SPO was performed in 28 patients for rigid deformity correction (Table 1). We encountered intraoperative

signal loss in two patients on one side after the affected side had been instrumented and corrected. Immediate action was performed in these patients, as previously described (Figure 1). Three patients had no intraoperative signal loss and were normal postoperatively, but they gradually lost motor power in their leqs within 6 h of surgery. These patients had postoperative bilateral neurologic deficits, so we started to apply a high dose of steroid protocol. Immediate computed tomography and magnetic resonance imaging were also conducted. These patients underwent immediate exploratory surgery, and we applied necessary decompression of the dura and nerve roots. In two of the three patients, there was no evidence of hardware malposition, hematoma, or obvious cord compression. All patients hgb levels were above 10 g/dL. In total, three patients with SPO (two perioperative and one postoperative) and two patients with PVCR (both postoperative), had a new neurologic deficit (Table 2). Four of these patients recovered completely within six months postoperatively, and one patient remained Frankel grade C at two years postoperatively. Of these five patients, three had adult spinal deformity, and two had pediatric congenital kyphoscoliosis. There was no statistically significant difference between the osteotomy groups for neurological deficit risk (p>0.05).

DISCUSSION

The most important finding of this study was observing two perioperative signal losses during spine deformity surgery; however, we also observed three early postoperative neurologic deficits despite having normal signals during surgery. Intraoperative signal loss and postoperative early and late new neurological deficits are the most significant complications of spine deformity surgery. Therefore, intraoperative neuromonitoring is used as a tool to recognize possible new neurologic deficits. Based on several studies, neuromonitoring is significantly effective in reducing the incidence of new neurologic deficits^(3,8,9). However, some other studies have also reported false-negative results^(10,11). The MAP has a significant effect on the SSEP results. If MAP drops below 60 mmHg,significant changes in SSEP may occur^(12,13).Mentioned

Table 1. Demographic variables					
Gender	52 female, 31 male				
Age	32 у (бу-53у)				
Coronal Cobb	98° (60-100°)				
Sagital Cobb	78° (55-95°)				
Pediatric patients	29 patients				
Adult patients	54 patients				
SPO	28 patients				
PSO	20 patients				
PVCR	35 patients				

PVCR: Posterior vertebral column resection, PSO: Pedicle subtraction osteotomy, SPO: Smith-Peterson osteotomy





Figure 1. a) After a pedicle screw, b) osteotomy and correction, left lower extremity signal loss, c) after the standard protocol, signal recovery, d) final

Table 2. Neurologic deficit			
Neurologic deficit	SPO	PSO	PVCR
Intraoperative	2	0	0
Postoperative	1	0	2

PVCR: Posterior vertebral column resection, PSO: Pedicle subtraction osteotomy, SPO: Smith-Peterson osteotomy

that high lability in MAP usually results in false-positive results⁽¹³⁾. The authors did not observe any false-negative results, but they remarked that postoperative neurologic status could not be predicted by neuromonitoring changes⁽¹³⁾. Raynor et al.⁽¹⁰⁾ reported 0.36% (45 patients) false-negative outcomes out of 12,375 spine surgeries. Among this group, only two had permanent new neurologic deficits. In this study, we observed three postoperative neurologic deficits out of 83 patients (3.6%) that could not be detected intraoperatively, which can be considered a false-negative result. Among the three patients, only one had a permanent neurologic deficit (1.2%). According to our experience, we observed two perioperative signal losses during spinal correction surgery managed by a standard protocol as follows:

1. We increased the systolic blood pressure above 100 mmHg. 2. We increased the PO, to 100%.

3. We started to replace the estimated blood loss.

4. We removed the rod and reduced the correction.

5. We checked all implants using anterior-posterior and lateral views with an image intensifier.

6. We checked with a second look for nerve roots and dura, and if needed, enlarged the decompression.

7. If the signal returned to normal within 30 min, we replaced the rod and reperformed the correction.

8. We checked neuromonitoring before wound closure. 9. If the signals did not return, we started the wake-up test. Another devastating problem after deformity correction surgery is an early postoperative neurologic deficit despite stable intraoperative monitoring and postoperative normal neuro exam. This may occur within hours or even days after surgery⁽¹⁴⁾. The main reason for this type of event is usually delayed ischemic injury of the spinal cord or compression of the cord because of inadequate decompression, specifically after osteotomies or even postoperative hematoma development⁽¹⁴⁾. According to our results, we had three new neurologic deficits within 6 h postoperatively. All patients underwent computed tomography and magnetic resonance imaging to rule out the malposition of screws, inadequate decompression, or postoperative hematoma. All patients received a high dose of steroid protocol for 24 h after the first detection of neurologic decline with full monitorization of blood pressure (systolic above 100 mmHq), setting oxygenation PO_{γ} to 100%, and setting hemoglobin level above 10 mg/dL. The same management was also been recommended by Auerbach et al.^(14,15). After this systematic approach, all patients underwent an immediate exploration of the surgical field. All necessary spinal cord decompression was performed. Two of them returned to normal within three months. After two years, one patient improved neurologically, but is still in Frankel grade C. Our study also compared the neurologic deficits in terms of the type of corrective osteotomy performed during surgery. We encountered perioperative signal loss in two patients who underwent SP osteotomy and three with postoperative neurologic deficits (one SP osteotomy and two PVCR). We did not observe any neurologic event perioperatively or postoperatively in patients who underwent



PSO, and the neurologic complication rate was slightly higher in those who underwent PVCR. Wang et al.⁽⁶⁾ evaluated 202 consecutive pediatric and adult spine deformities who underwent PVCR. The authors observed 140 signal losses without neurologic deficits and 36 (17.8%) true-positive results, and the overall neurologic deficit ratio was 8/202 (4%)⁽⁶⁾. Daubs et al.⁽¹⁶⁾ reported a 6% neurologic deficit in 84 patients who underwent PSO at a tertiary spine center. In their systematic review and meta-analysis, Liu et al.⁽¹⁷⁾ discovered a higher risk of permanent neurologic deficit in SPO than in PSO (6% vs 5%). Our overall neurologic deficit rate was 3.6%, and our overall permanent neurologic deficits can be explained by the use of intraoperative neuromonitoring and early management of the signal losses.

Study Limitations

The main limitation of our study is that it is a retrospective analysis of a relatively small number of a heterogeneous patient population that contains both pediatric and adult spine deformities. However, we performed a retrospective analysis of a prospectively monitored patient group treated by a single surgeon using the same approaches. Besides, our osteotomy groups had a relatively similar patient number, allowing us to compare neuromonitoring results and neurologic deficits. This study focused on intra and postoperative neurological deficit risk and manegement for spinal osteotomies. Therefore type and level of curvature, curve flexibility, correction rate, comorbidities, intraoperative blood loss, and operation time were ignored. The main strength of our study is that it is the first research to report neuromonitoring results and the management of neurologic events in patients with SPO, PSO, and PVCR.

CONCLUSION

We did not observe any neurological event perioperatively and postoperatively in patients who underwent PSO, and the neurologic complication rate was slightly higher in patients who underwent PVCR. According to the results acquired from this study, intraoperative neuromonitoring should be used in every spinal deformity correction surgery, even if false-negative results occur. Perioperative signal loss should be taken seriously, and the necessary management protocol should be started immediately. The last check should be performed before waking up, and a routine neurologic exam must be conducted during hospitalization.

Ethics

Ethics Committee Approval: This retrospective study was approved by the İstinye University Ethical Review Board (3/2022.K-34, date: 06.09.2014) and conducted in accordance with the Declaration of Helsinki.

Informed Consent: Written informed consent was obtained from all the patients.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: G.K.K., Ç.Ö., U.A., Concept: G.K.K., K.T., Y.Ç., Ç.Ö., U.A., Design: G.K.K., K.T., Y.Ç., Ç.Ö., U.A., Data Collection or Processing: G.K.K., K.T., Y.Ç., Analysis or Interpretation: G.K.K., Y.Ç., Ç.Ö., U.A., Literature Search: G.K.K., Y.Ç., Writing: G.K.K., K.T., Y.Ç.

Conflict of Interest: The authors have no conflicts of interest to declare.

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ORIGINAL ARTICLE

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COMPARISON OF SUBPEDICULAR AND KAMBIN'S TRIANGLE APPROACHES IN TRANSFORAMINAL EPIDURAL INJECTION APPLICATIONS IN CASE OF LUMBAR DISC HERNIA

Bilal Aykaç, Abdullah Küçükalp

Private Hayat Hospital, Clinic of Orthopedics and Traumatology, Bursa, Turkey

Objective: The lumbar transforaminal epidural steroid injection (LTFESI) procedure has been used safely in patients with radiculopathic pain secondary to lumbar disc herniation, who did not respond to conservative treatment for many years. In this study, we show that the approach using the Kambin's triangle area is an effective and reliable method of application, as an alternative to the subpedicular approach commonly used in LTFESI.

Materials and Methods: Between 2017-2021, 79 patients with symptoms of radiculopathy due to lumbar disc herniation, confirmed by clinical and radiological diagnosis, were included in the study. To the patients: In the operating room, Kambin's triangle in 43 patients and subpedicular approaches in 36 patients were performed with LTFESI, accompanied by scopy image. For radiculopathic pai, Numerical Rating Scale (NRS) and functionally Oswestry Disability Index (ODI) scores were statistically compared in two different approaches before the procedure, at the 2nd week and 3rd month after the procedure.

Results: There was no significant difference between the two groups in pre-procedural NRS (p=0.240) and ODI (p=0.517) scoring. It was determined that the change observed in NRS and ODI measurements over time in both approaches showed a statistically significant difference in response to treatment (NRS; p=0.008, ODI; p=0.016). There was no significant difference between the two groups after the procedure, between the NRS (p=0.523) and ODI (p=0.617) scores at the 2nd week and the NRS (p=0.058) and ODI (p=0.056) scores at the 3rd month. Relative treatment effects were found to be similar in the subpedicular and Kambin's triangle groups.

Conclusion: It has been shown that the Kambin's triangle area, which is poorer in terms of neurovascular structures, can be used effectively and safely as an alternative to the subpedicular area in LTFESI applications.

Keywords: Transforaminal injection, Kambin's triangle, subpedicular area, lumbar disc herniation

INTRODUCTION

In cases of lumbar disc herniation, leg pain is one of the most common complaints because of the pressure on the herniated disc material on the nerve roots. Additionally, numbness and loss of strength can be seen in the dermatomes and myotomes of the relevant nerve roots in the lower extremities⁽¹⁾. Although this may adversely affect the quality of life of patients, they can create great burdens for national economies. The first choice in treatment is conservative treatment methods^(2,3).

In cases where conservative treatment is ineffective, minimally invasive interventional treatments have been used more and more frequently. Among them, the transforaminal epidural steroid injection (TFESI) procedure has been used for many years for treating radiculopathy secondary to lumbar disc herniation⁽²⁾. These procedures are effective and safe in relieving pain. Indications, evidence, and safety considerations for the technique have been identified⁽⁴⁾.

The most commonly used method in lumbar TFESI (LTFESI) is the subpedicular approach. In the subpedicular approach, cases of spinal cord infarction secondary to neurovascular injury, which is a rare but catastrophic complication, have been reported⁽⁵⁾. The Kambin's triangle approach is as effective as the subpedicular approach and offers significant advantages in terms of avoiding neurovascular complications⁽⁶⁾.

In this study, we show that the Kambin's triangle approach, which uses the Kambin's triangle area, which is defined as the safe zone, is an effective and reliable application method as an alternative to the subpedicular approach, which is open to complications in LTFESI.

MATERIALS AND METHODS

Study Group

Ethics committee approval was obtained for this study, dated 16.06.2021 and numbered 2011-KAEK-26/383 of the Bursa

Address for Correspondence: Bilal Aykaç, Private Hayat Hospital, Clinic of Orthopedics and Traumatology, Bursa, Turkey Phone: +90 505 622 99 85 **E-mail:** draykac@gmail.com **Received:** 09.01.2023 **Accepted:** 23.02.2023 **ORCID ID:** orcid.org/0000-0002-6180-2467



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Uludağ University Ethics Committee. All the patients were selected from patients who had previously received medical treatment and/or physical therapy protocol treatment, but did not have a clinical response. Patients with a history of previous lumbar surgery, degenerative spinal stenosis, surgical indication, bleeding diathesis, morbid obesity (body mass index over 40), local skin lesion, previous history of LTFESI, and patients under 18 years of age were excluded from the study. Between 2017 and 2021, 84 patients, who were confirmed by clinical and radiological diagnosis, had lumbar disc herniation in magnetic resonance imaging taken at least 3 months before the procedure, had radiculopathy symptoms due to lumbar disc herniation, had no acute neurological symptoms, and motor loss, were followed up and scored. (Two patients without follow-up and 3 patients with more than one level of LTFESI were excluded from the study) 79 patients were included in the study.

Process Preparation and Technique

Informed consent forms were obtained from all patients before the LTFESI procedure. Level detection was performed in the operating room, on the surgical table, by monitoring, in the prone position, under scopy control. After sterilization of the area to be injected, 5 cc of 2% prilocaine hydrochloride was injected as a local anesthetic. Subsequently, the posterolateral transforaminal area was accessed with a 22 gauge spinal needle under scopy control, accompanied by antero-posterior (AP) and lateral (L) scopy images. By determining the Kambin (Figure 1A) in 43 patients, the subpedicular area (Figure 1B) in 36 patients, and controlling the needle position with L images (Figure 2) to prevent needle trauma to the root and disc after AP, 1 cc opaque material was again accompanied by AP scopy image. Iohexol was diluted with 5 cc of isotonic solution and approximately 1.5-2 cc was injected for confirmation (Figure 3). After defining the dural border (descending root), foramen, and root structures emerging from the foramen in the medial, a total of 5 cc was applied by mixing 1 cc betamethasone and 4 cc 2% prilocaine hydrochloride (Figure 4). During the procedure,



active foot movements were checked for severe leg pain and possible motor deficit, keeping in contact with the patient. After the procedure, the patients were followed up for at least 3 h, and they were mobilized and discharged after the motor-sensory block was completely over. Numerical Rating Scale (NRS) scores for pain level and Oswestry Disability Index (ODI) scores for functional evaluation were examined before the procedure, at the 2nd week and at the 3rd month after the procedure, from the files of the patients who underwent LTFESI. Considering the anatomical limits of the patients, according to the injection application area: They were collected in two different groups, namely the Kambin's triangle and the subpedicular area, and their scores were compared.

Statistical Analysis

The distributions of age, NRS, and ODI were examined using Shapiro-Wilk's tests, normality plots, and skewness/kurtosis statistics. Since none distributed normally, they were provided by a median [interquartile range (IQR): 1st quartile-3rd quartile]. Mean ± standard deviation was also reported for NRS and ODI. Frequency and proportion were given for sex.

The age and sex of the patients were compared between application groups by Mann-Whitney U test and Pearson chisquare test, respectively. NRS and ODI were compared between application groups at each evaluation period by Mann-Whitney U test, as well. The changes in NRS and ODI measurements across time were compared between application groups by F1-LD-F1 design. ANOVA type test statistics, the degree of freedom, and p-values were reported for the overall time effect and group*time interaction effects. Relative treatment effects (RTEs) were provided with 95% confidence interval by graphs. A p-value<0.05 was considered as statistically significant. Descriptive statistics were calculated using IBM SPSS Statistics 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). The F1-LD-F1 design was performed using the RStudio software (v.1.4.1106)⁽⁷⁾ and the nparLD package⁽⁸⁾ in the R v.4.1 programming language⁽⁹⁾.



Figure 1. Application areas accompanied by AP scope; **A)** Kambin's triangle area, **B)** Subpedicular area AP: Antero-posterior



RESULTS

Seventy nine patients who met the criteria and followed up were included in the study. The median age of the patients was 46 years (IQR: 35-61) in the group in which the Kambin's triangle approach was applied, while it was 48 years (IQR: 39-61) in the subpedicular approach group. 53.5% (n=23) of the group in which the Kambin's triangle approach was applied and 63.9% (n=23) of the group in which the subpedicular approach was applied were women. There was no statistically significant difference between the two groups in terms of age and gender (p=0.668 for age, p=0.351 for gender).

When the pain and disability levels of the patients were examined, the median NRS was 8 (IQR: 7-8) before treatment for both groups. The median NRS was determined as 2 (IQR: 1-3) at weeks 2 and 2 (IQR: 0-3) at 3 months in the group in which the Kambin's triangle approach was applied. In the subpedicular approach group, the median NRS was 2



Figure 2. The position of the needle in the scope image in the Kambin area



Figure 3. AP image with opaque material injection AP: Antero-posterior

(IQR: 1-4) at the 2nd week and 3rd month (Table 1). There was no significant difference between the pre-procedural NRS (p=0.240) and ODI (p=0.517) scores between the two groups. The change observed in NRS and ODI scores over time showed a statistically significant difference in both approaches; a significant improvement was observed in NRS pain (Figure 5) and ODI functional (Figure 6) scoring (NRS; p-value=0.008 ODI; p-value=0.016). When both groups were compared: There was no significant difference between the NRS (p=0.523) and ODI (p=0.617) scores at the post-procedure 2nd week, and the NRS (p=0.058) and ODI (p=0.056) scores at the 3rd month (Table 2). When RTEs were examined, it was found that both pain and disability levels decreased significantly in the 2nd week, but increased slightly in the 3rd month in the subpedicular group; in the Kambin's triangle group, it was observed that the decrease in the level of pain and disability continued, albeit slightly, at the 3rd month. However, the RTEs of the two groups at each time point were similar (Figure 7).

DISCUSSION

TFESI has been used for many years for treating radiculopathy caused by lumbar disc herniation⁽²⁾. LTFESI is a targeted therapy tool for lumbar radiculopathy with up to 80% immediate response⁽¹⁰⁾. There is strong evidence to support the use of lumbar TFESI in patients with acute to subacute, unilateral radicular pain caused by herniated nucleus pulposus^(11,12). The most commonly used approach for transforaminal injections is the subpedicular application technique⁽¹³⁾, first described by Bogduk and Endres⁽¹⁴⁾. Some authors are; declaring that the subpedicular approach to transforaminal epidural injections is actually unsafe, he believes that when administering LTFESI, they should be made in the lower part of the foramen, known as the Kambin's triangle, where the vascular and nerve structures are less dense⁽¹⁵⁾. In our study, the subpedicular area was determined in 36 patients and LTFESI was applied. To



Figure 4. After the application of opaque material, local anesthetic and steroid injection and spread image in the AP plane AP: Antero-posterior



minimize possible complications and considering the literature supporting this study, LTFESI was applied to 43 patients with the Kambin's triangle approach. In the two patient groups (Table 2), in which there was no significant difference between preprocedural NRS and ODI scores, NRS and ODI scores decreased significantly at the 2nd week and 3rd month after the procedure (Figures 5, 6).

Sencan et al.⁽¹⁶⁾, in their study on 61 patients, applied subpedicular injection to the patients. They measured the NRS scores of patients who had a mean NRS of 8 before the procedure at the 1st week, 2nd week, and 3rd month after the procedure, respectively, as 0.3,3. Likewise, they measured their ODI score, which was 48 before the procedure, to 26, 22, 22 at the 1st week, 2nd week, and 3rd month after the procedure, respectively. They obtained significant statistical data toward improvement in NRS and ODI scores in subpedicular area applications and as a result; They stated that the application of subpedicular LTFESI is an effective and safe method for radiculopathy. In our study, we applied subpedicular LTFESI to 36 of 79 patients. In our evaluation: In patients with a mean NRS score of 8 before

the procedure, the postoperative 2^{nd} week and 3^{rd} month scores were found to be 2.2, respectivel; similarly, in patients with a pre-procedural ODI score of 71, the postoperative 2^{nd} week and 3^{rd} month scores were 14.19, respectively found.

Ghai et al.⁽¹⁷⁾ applied subpedicular to 38 of 75 patients and Kambin to 37 of them in their randomized controlled study; when they compared both groups, they found statistically similar results in NRS and ODI scores at 2nd week, 1st month, and 3rd month and stated that both applications could be used safely for radiculopathy. In our study, in patients with similar demographic data, pain and functional score before the procedure; we observed that both treatments were effective in terms of improvement in pain and functional scores, and the RTS values were similar.

Complications from these procedures result from needle insertion and/or drug administration. Potential risks include infection, hematoma, intravascular drug injection, direct nerve trauma, subdural drug injection, air embolism, disc space entry, urinary retention, and hypersensitivity reactions⁽¹²⁾.

Table 1. Patients' pain and disability levels through time with respect to the application						
	Application					
	Kambin's triangle (n=43)	Subpedicular (n=36)				
NRS [median (IQR)]						
Baseline	8 (7-8)	8 (7-8)				
2 nd week	2 (1-3)	2 (1-4)				
3 rd month	2 (0-3)	2 (1-4)				
ODI [median (IQR)]						
Baseline	77 (67-78)	71 (67-77)				
2 nd week	14 (12-28)	14 (10-33)				
3 rd month	14 (4-26)	19 (9-40)				

NRS: Numeric Rating Scale for pain, ODI: Oswestry Disability Index, IQR: Interquartile range, 1st quantile-3rd quantile



Figure 5. Distribution of NRS values within each application NRS: Numerical Rating Scale



Figure 6. Distribution of ODI values within each application ODI: Oswestry Disability Index



	Application		
	Kambin's triangle (n=43)	Subpedicular (n=36)	p-value
NRS			
Baseline	7.81±15.62 8 (7-8)	7.56±15.30 8 (7-8)	0.240
2 nd week	2.26±1.51 2 (1-3)	2.53±1.75 2 (1-4)	0.523
3 rd month	2.07±2.02 2 (0-3)	3.00±2.27 2 (1-4)	0.058
ODI			
Baseline	74.42±7.44 77 (67-78)	72.81±7.62 71 (67-77)	0.517
2 nd week	18.93±14.45 14 (12-28)	22.81±17.45 14 (10-33)	0.617
3 rd month	18.12±19.55 14 (4-26)	27.06±22.60 19 (9-40)	0.056

Table 2. Patients' pain and disability levels through time with respect to the application

NRS: Numeric Rating Scale for pain, ODI: Oswestry Disability Index, SD: Standard deviation NRS and ODI were reported as mean \pm SD and median (IQR)



Figure 7. Relative treatment effect of pain and disability levels based on application

RTE: Relative treatment effect, ODI: Oswestry Disability Index

Windsor et al. ⁽¹⁸⁾ reported that severe infections are rare with an incidence of 0.1-0.01% of all spinal injections. Cases of meningitis, epidural abscess, osteomyelitis, and discitis have been reported. *Staphylococcus aureus* is the most common organism. It is believed to be administered through the skin through the pinhole. Although these risks are valid for both application areas, no complications related to infection were observed in our series. The incidence of epidural hematoma is estimated to be less than 1 in 150,000 epidural applications⁽¹⁹⁾. Damage to the underlying vessels can lead to hematomas that cannot be visualized with conventional fluoroscopy⁽¹²⁾. However, Murthy et al.⁽²⁰⁾ reported that the Adamkiewicz artery (AKA) passes through the safe triangle and that the injection applied to this region may directly damage the vein. In the study, 97% of the AKA foramen were located in the upper half (88% in the upper third, 9% in the middle third) and 2% in the lower third. He reported that AKA was never seen in the lower fifth of the foramen. Glaser and Shah⁽¹⁵⁾ stated that AKA can enter any middle thoracic, lower thoracic, or lumbar foramen, and the exact level cannot be known by the procedural specialist. The authors reported that the subpedicular approach to transforaminal epidural injections is unsafe and stated that injury to the AKA may cause paraplegia. Therefore, they argued that as an alternative to subpedicular administration, catastrophic injury could be avoided and transforaminal injections should be made in the lower part of the foramen known as the Kambin's triangle.

Direct trauma with the needle to the spinal nerve or dorsal root ganglion is another complication of accidental needle insertion, particularly when performing TFESI. Severe pain occurs with this trauma, and it is important not to over-sedation in order not to mask the complication⁽¹⁴⁾. For this reason, we performed the procedures by keeping in touch with the local application, without applying sedation to our patients during the application. Neurological complications were not observed in any of our patients.

It is important to recognize the pattern of subdural and subarachnoid contrast diffusion during the application of the LTFESI procedure⁽²¹⁾. If local anesthetics are injected intrathecally, blockade of neural elements may cause the central canal, cauda equina, and conus medularis syndromes depending on penetration and level of blockage. The transient



respiratory depression increased weakness/sensory loss, apnea, and loss of consciousness may also occur, and these are said to be associated with increased subdural spread of anesthetics^(21,22). Other complications include persistent paresthesias, arachnoiditis, and meningitis. The amount of local anesthetic (6-8 mL) typically used in lumbar epidural injections is usually not sufficient to cause respiratory depression. However, a greater volume in the subdural space can rapidly increase in the head direction, causing serious cardiovascular and respiratory effects^(22,23). In this study, a contrast material spread pattern was observed in scopy vision in all patients, and LTFESI was applied after ensuring that there was no intrathecal spread, and the mentioned complications were not observed in either group.

Levi et al.⁽²⁴⁾ in their review study including the Kambin's triangle application, they reported that 12 of 257 patients had intradiscal injections, 8 had intrathecal injections, and 17 had vascular injections, and they stated that there were no neurological complications in any patient. Ghai et al.⁽¹⁷⁾ in their randomized controlled study, they reported that 7 of 37 patients who underwent the Kambin's triangle approach developed intravascular access and 7 developed needle paresthesia. They reported that 4 of 38 patients who underwent a subpedicular approach developed intravascular access and 6 developed needle paresthesia. In our study, no complications were observed in either group. We believe that the LTFESI application was applied to a selected patient group, sedation was not given during the application, repetitive scopy imaging in both planes during needle placement, and contrast material administration helped us avoid related complications.

Complications from lumbar epidural injections are extremely rare. Many, if not all, complications can be avoided with the utmost attention to sterility, correct needle placement, and a thorough understanding of the involved anatomy and contrast medium diffusion on fluoroscopic imaging.

Study Limitations

In this study; the limitations of the study are the lack of a sufficient number of patients for evaluating disc degeneration, the inability to measure the amount of radiation exposed in fluoroscopy-guided practice, and the lack of long-term follow-up.

CONCLUSION

In our study, it was observed that the Kambin's triangle application can be applied as effectively and safely as the subpedicular application. Case reports reporting that the subpedicular area, which is commonly used in LTFESI applications, is open to complications, have been presented in the literature. These complications arise from the anatomically rich area of neurovascular structures. Although complications were not observed in either group in our study, we think that the anatomically defined Kambin's triangle area, which is poorer in terms of neurovascular structures, can be used safely as an alternative.

Ethics

Ethics Committee Approval: Ethics committee approval was obtained for this study, dated 16.06.2021 and numbered 2011-KAEK-26/383 of the Bursa Uludağ University Ethics Committee. **Informed Consent:** Informed consent forms were obtained from all patients before the LTFESI procedure.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: B.A., Concept: B.A., A.K., Design: B.A., A.K., Data Collection or Processing: B.A., A.K., Analysis or Interpretation: B.A., A.K., Literature Search: B.A., Writing: B.A., A.K.

Conflict of Interest: The authors have no conflicts of interest to declare.

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ORIGINAL ARTICLE

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EVALUATION OF THE EFFICACY OF PERCUTANEOUS CAUDAL AND COMBINED CAUDAL/TRANSFORAMINAL NEUROPLASTY-ADESIOLYSIS FOR TREATING SYMPTOMATIC LUMBAR SPINAL STENOSIS

Mehmet Osman Akçakaya¹, Alparslan Aşır², Savaş Çömlek³

¹Demiroğlu Bilim University Faculty of Medicine, Department of Neurosurgery, İstanbul, Turkey ²Ataşehir Florence Nightingale Hospital, Clinic of Neurosurgery, İstanbul, Turkey ³Gayrettepe Florence Nightingale Hospital, Clinic of Anesthesiology and Reanimation, İstanbul, Turkey

Objective: Lumbar spinal stenosis (LSS) is a narrowing of the canal diameter due to degenerative changes, particularly in elderly individuals. This narrowing sometimes accompanies foraminal stenosis. The aim of this study was to investigate the efficacy of caudal and combined caudal/transforaminal adhesiolysis for treating symptomatic LSS patients.

Materials and Methods: Patients between the ages of 48-74, whose diagnosis was confirmed by magnetic resonance imaging were included in the study. The gender distribution was kept the same in both groups. The procedure was initially performed through the caudal way in all patients. Patients, with no evidence of foraminal passage in epidurography were categorized in group 2 as a combined caudal and transforaminal adhesiolysis groups. A total of 80 patients (40 patients in each group) were included in this study. Pain relief was evaluated using the walking distance, visual analog scale (VAS), and Oswestry Disability Index (ODI) before the procedure (baseline) and at the second week, the third and the sixth months after the procedure.

Results: Baseline VAS values were found to be at least 5 and higher in the patients without foraminal passage by epidurography. These values were present in 35% of the patients in the caudal group. The increase in walking distance was similar in both groups (72.5% in the caudal group and 75% in the combined group). The improvement in VAS was significant in the combined group, and was observed in 39 of 40 patients. The improvement in ODI was 97.5% in both groups. No complications were encountered during and after the procedures.

Conclusion: Caudal neuroplasty adhesiolysis is an effective method for treating chronic low back pain due to symptomatic LSS and its effectiveness is increased when adding a transforaminal procedures in cases with no foraminal passage in epidurography.

Keywords: Symptomatic lumbar spinal stenosis, neurogenic claudication, percutaneous neuroplasty, adhesiolysis, caudal, transforaminal, hyaluronidase, hypertonic sodium chloride solution

INTRODUCTION

Lumbar spinal stenosis (LSS) is defined as narrowing of the anterior posterior diameter of the spinal canal, nerve root canals (lateral recess), and intervertebral foramen^(1,2). This entity occurs due to hypertrophy of the ligamentum flavum and facet joints, osteophytic protrusions, and intervertebral disc herniations because of acquired degeneration of the spine⁽¹⁻⁶⁾. Although the cause of this situation has not been fully understood, it can also be seen in asymptomatic individuals⁽⁷⁻⁹⁾. Symptoms generally vary according to the location of the neural compression. Neurogenic claudication is typically found in central canal stenosis, whereas lateral recess and foraminal stenosis are associated with radicular pain. Neurogenic

claudication is a feeling of pain and weakness in the legs, which worsens in walking or prolonged standing and improves with rest or flexion of the lower back⁽¹⁾. This results in patients to have decreased mobility and function, and eventually even simple tasks such as standing upright or picking up objects may become difficult to perform and necessitate some degree of help from others. Initially symptomatic LSS patients are treated with various conservative treatment modalities, whereas unresponsive cases are candidates for decompressive spinal surgery. Meanwhile, the importance of epidural procedures as a pre-surgical treatment method is increasing. However, the limited effectiveness of epidural steroid therapy, especially in the presence of neural compression, has brought new searches to the agenda^(1,10). Racz and Holubec⁽¹¹⁾ described

Address for Correspondence: Mehmet Osman Akçakaya, Demiroğlu Bilim University Faculty of Medicine, Department of Neurosurgery, İstanbul, Turkey Phone: +90 532 255 77 74 E-mail: moakcakaya@gmail.com Received: 04.01.2023 Accepted: 14.03.2023 ORCID ID: orcid.org/0000-0001-8617-202X



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percutaneous epidural neuroplasty-adhesiolysis in 1989. This method, also known as the Racz method, is gaining popularity and used reliably and effectively for treating different spinal pathologies⁽¹²⁾. In this study, it was aimed to investigate the efficacy of caudal and combined caudal/transforaminal adhesiolysis for treating symptomatic LSS patients.

MATERIALS AND METHODS

A total of 80 patients aged between 48 and 74 years with neurological claudication and diagnosis of symptomatic spinal stenosis confirmed by neurologic examination and radiographic evidence [plain films of the lumbar spine and magnetic resonance imaging (MRI)] were included. The study was conducted with the approval of the Demiroğlu Bilim University Ethics Committee (no: 44140529, date: 23.06.2020). An informed consent form of the procedure was obtained from all patients. The patient gender distribution was kept the same in both groups. The neuroplastic procedure was initiated caudally in all patients. Patients whose anteroposterior (AP) and lateral fluoroscopy could not show radiopaque material passing through the foramen were included in the combined caudal/transforaminal neuroplastic adhesiolysis group, which was designed as a second group. Forty patients were included in each group. In the follow-up of the patients, walking distance, visual analogue scale (VAS), and Oswestry Disability Index (ODI) scores were measured at four different times, including baseline, two weeks, three and six months. Patients with unclear or suspicious symptoms, spondylolisthesis findings on MRI imaging, or a history of previous spinal surgery were excluded from the study. In addition, patients with uncontrolled psychiatric disorders, bleeding disorders, sepsis, skin infection at the entry point, spinal infection, previous spinal surgeries with implants, and the patients who cannot lie in the prone position, those who are pregnant or breastfeeding, and the patients with a history of allergy to possible drugs to be used were also excluded from the study.

Procedures

All the procedures were performed in the operating room under anesthesia with necessary monitoring and fluoroscopy. The patients were placed in the prone position with local area cleaning and sterile isolation. A specially designed 16 gauge RX Coude® needle and a Racz® catheter (Epimed International Inc., Johnstown, NY) were used for caudal neuroplasty intervention and Couda Blunt Needle (Epimed International Inc., Johnstown, NY) for transforaminal neuroplasty. Neuroplasty was initiated caudally in all patients. The Racz® catheter was placed with minimal manipulation in the position closest to the desired level and side (ventral lateral epidural area) for neuroplasty. Neuroplastia-adhesiolysis was only caudally performed in the patients who has passage of radiopaque through the desired foramen. The transforaminal procedure was also added to the caudal approach in cases with no radiopaque material passage through the desired foramen. The study was designed as two groups. The first group was composed of the patients who underwent caudal intervention alone, and the second group included patients who underwent both caudal and transforaminal procedures. Serum sale (10%) was administered caudally alone. Patients who could not obtain sufficient volume or were treated as risky by clinical and radiological evaluation were excluded from the study. All patients were included in the post-procedure exercise program.

Caudal Approach

The sacral hiatus is defined and entered by lateral fluoroscopic guidance after the skin Infiltration with local anesthetic. When the skin is passed, the epidural needle (16-gauge RX Coudé®) is advanced so that it remains below the level of the S3 foramen. After being understood with negative aspiration, that we are in the epidural space, an epidurogram is performed by giving 10 cc of omnipaque. The presence of filling defects was evaluated. Then, under continuous AP fluoroscopic guidance, the tip of the catheter is advanced into the ventral lateral epidural space at the desired level (matching the filling defect) (Figure 1). Under real-time fluoroscopy, an additional 2-3 cc of contrast is injected through the catheter to see whether the radiopaque transition through the neural foramen responsible for spinal stenosis; (Figure 1 and 2). When the transition is satisfactory, the procedure is continued with a slow injection of 1500 U of hyaluronidase in 10 cc 0.5% lidocaine. Then, 3 cc of 10 cc local anesthetic/steroid solution containing 0.5% lidocaine and 80 mg methylprednisolone (Depo-Medrol) is given as a test dose. Five minutes later, if there isnot any evidence of intrathecal or



Figure 1. Lateral fluoroscopic view showed the needle positioned in the neural foramen following caudal injection and just before performing the transforaminal injection



intravascular passage, the remaining 7 cc is injected. Subdural or subarachnoidal passage carries the risk of motor block. So, the patients are followed up in the recovery room for 20-60 min to be sure if there is any sign of motor block. Then, 10 cc of 10% hypertonic saline solution is given by slow infusion. The catheter was removed 30 minutes later. The entrance area on the skin is covered with a sterile dressing, and the patient is transferred to his room after the recovery period.

Combined Caudal and Transforaminal Approach

In cases where the target level could not be reached with the caudal approach (no contrast passage through the foramen), a second catheter was placed in the ventral epidural space through the transforaminal way. For this purpose, the target level is defined in AP fluoroscopy. The vertebral endplate were superimposed on top of each other. The AP angle at this point is typically 15 to 20 degrees in the caudocephalad direction. Then, the fluoroscopy is rotated obliquely about 15 degrees to the targeted foramen side. In this position, the spinous process overlaps the contralateral superior articular process (SAP). The target point is at the very end of the SAP, also known as the Scottish dog's ear. The SAP forms the inferoposterior part of the target foramen and should be superimposed with the disc in an oblique view. This will create a secure bony target to pass behind the nerve root. The skin is passed with an 18 gauge needle, and then the 15-16 gauge RX Coude Blunt Needle, whose chuck is removed and replaced, is advanced until it contacts the medial SAP. The tip of the needle is turned 180 degrees laterally, and after 5 mm is advanced so that the bone tissue is bypassed, it is rotated 180 degrees medially again and proceeded slowly. It can be clearly felt that the tip of the needle crosses the intertransverse ligament. In lateral fluoroscopy, the tip of the needle should be anterior to the SAP in the posterior foramen



Figure 2. AP fluoroscopic view of a caudal injection AP: Anteroposterior

(Figure 3 and 4). Preferably, in lateral fluoroscopy, radiopaque material is given to investigate if there is a venous spread or subarachnoidal passage. Then, 5 mL of 1% lidocaine containing 750 units of hyaluronidase and 40 mg of triamcinolone is



Figure 3. The lateral fluoroscopic view of a patient following caudal and transforaminal injections. Note that the contrast medium is radiated both in the neural foramen and downwards in the central canal



Figure 4. AP fluoroscopic view of a transforaminal injection in a patient in the combined injection group AP: Anteroposterior



injected into the targeted areas. During the follow-up period, no caudal, interlaminar, or transforaminal epidural steroid injections were made. Pain levels were evaluated with VAS and ODI scores before the procedures as a baseline and after two weeks, three and six months, and a year. Walking distance was defined as the distance until the initiation of neurological claudication that inhibits the walking of the patient and it was specified in five categories, which is initiation between 0-50 meters, 50-150 meters, 150-350 meters, 350-750 meters, and above 750 meters.

Statistical Analysis

The normality of data distrubition was verified with Skewness and Kurtosis tests. Student's t-test was used for comparing the findings between the two groups and pairedsamples t-test for each group. Chi-square test was administered for categorical variables and the Wilcoxon signed-rank test for evaluating differences in walking distance. All statistical analyses were conducted using SPSS v20.0. A p-value of less than 0.05 was considered statistically significant.

RESULTS

According to the procedures administered, the patients were divided into two equal groups. Each group consisted of 23 female and 17 male patients (F/M: 1.35). Mean age was 58.98±6.51 years. The group in which the caudal approach was executed to the patients was named as group 1 and the group in which a combined approach was executed to the patients as group 2. Tables 1 and 2 summarize results for each group. The mean VAS score was 7.78±1.12 in group 1 and 7.78±1.14 in group 2. The mean ODI score was 38±3.6 in group 1 and 34.8±4.81 in group 2. After the procedures, the mean VAS scores at all three control examinations were 3.65±1.64, 3.38±1.41 and 3.4±1.65 in group 1 and all results showed statistical significance comparing the first evaluation (p<0.001 for all results). Also, the mean ODI scores were 24.55±6.25, 20.9±6.01 and 19.68±5.88 and the results had statistical significancy (p<0.001 for all results). When inspecting the results of group 2, similar significant findings were maintained as in group 1. The mean VAS scores were 3.35±1.37, 3±1.2 and 2.93±1.29 and the mean ODI scores were 23.3±5.09, 18.45±5.85, and 18.25±5.61 respectively (Figures 5 and 6). All results were statistically significant compared to the preoperative evaluation (p<0.001 for all results). The walking distances of the patients was evaluated according to the scale given above. An increase in walking distance was evaluated for each group and both group revealed a difference beginning from the first evaluation after the procedure. Distance scores of group 1 and group 2 had statistical significancy compared to the preoperative evaluation (p<0.001 for all results). After the last evaluation in the sixth month, 10 patients were need to have an additional injection treatment in group 1 and six patients in group 2 when individually observed that their pain improvements were unsatisfactory. Comparing the two groups, the treatment modalities did not showed a statistical significance if we consider the need for additional intervention as treatment failure (p=0.264).

DISCUSSION

LSS was first described by Arnoldi et al.⁽¹³⁾ in 1976 as the narrowing of the spinal canal, nerve root canals, or intervertebral foramen. This narrowing is due to degenerative changes in the lumbar spine. These degenerative changes include hypertrophy of the ligamentum flavum and facet joints, osteophyte formation, decreased intervertebral disc height and bulging, and herniations of the lumbar disks^(1,2,4,5,14-16). LSS may remain asymptomatic or present with neurogenic claudication and/or radicular pain in affected patients. Neurogenic claudication is the most common symptom. Because of venous hypertension, ischemia in the nerve roots and neurogenic claudication occur as a result. Neurogenic claudication is defined as pain that worsens with walking and radiates to the legs. Pain is generally relieved by leaning forward and sitting^(1,17-21). Over time, the emergence of neurogenic claudication occurs at shorter distances, and vital activities are increasingly restricted⁽¹⁾. The source of radicular pain in patients is usually stenosis in the lateral canal (foraminal and/or subarticular). It often presents with sciatic pain defined as low back, hip, and leg pain, and follows a dermatoma^(4,14,22-26). If a good result cannot be obtained with conservative methods in the treatment, epidural steroids and local anesthetics are administered via the caudal, interlaminar, or foraminal routes⁽²⁷⁾. It is known that corticosteroids exert their effects by inhibiting the synthesis of a group of pro-inflammatory agents⁽²⁷⁻²⁹⁾. Local anesthetics may also help relieve symptoms in the short or long term, and they show this effect by suppressing nociceptive discharge, blocking the sympathetic reflex arc, inhibiting axonal transport of nerve fibers, and by their anti-inflammatory effects^(27,30-35). However, the recurrence of symptoms necessitated the development of new treatment modalities that can be applied before surgery. For this purpose, epidural adhesiolysis, also known as epidural neuroplasty, has been defined⁽³⁶⁾. The treatment spectrum of epidural adhesiolysis, which was initially developed for treating epidural fibrosis secondary to surgery, expanded in time to include spinal stenosis and gained popularity⁽³⁷⁾. Although there are various variations in this process, the technique on which it is based is the one defined by the Texas Tech Health Sciences Pain Center and was published in 1989⁽³⁶⁾. In the original procedure, the epidural catheter had to remain in place for 3 days to administer different drugs each day. Today, however, the procedure has turned into an outpatient procedure since the catheter was withdrawn after the combination of steroids, local anesthetic, hyaluronidase, and hypertonic saline was applied^(14,36,38,39). Epidural adhesiolysis was first defined by Racz and Holubec⁽¹¹⁾ in 1989. That time the procedure have differences such as the local anesthetic dose or absence of hyaluronidase. In their study in 1994 (28 patients



Table 1. Shows characteristics and results of caudal injection group

				2 nd	2 nd		3 rd	6 th	6 th	
A = =	Candan	Baseline	Baseline	week	week	3 rd month	month	month	month	Additional
Age	Gender	VAS		VAS		VAS	75	VAS	77	injection
5/	г г	0	40	4	40	2	20	0	10	+
22	г г	1	40 7F	2 7	24	Z	20	2	10	
60	г г	0	20 70	2 7	20	2	20	2	10	
00		/	20 77	2 2	20	2	10	Z	14	
0/	N	0 7	27	Z	24	Z	20	7	10	
54		1	44	2	20	5	20	5	18	
64 FF		0	57	Z	24	5	54 10	4	5U 1.0	+
20		9	42	2	24	2 7	10	2	10	
/0		8	45	4	20	5	20	2	10	
68		9	44	5	28	5	18	5	14	
66	F	/	36	2	18	2	16	2	16	
60	M	8	40	3	1/	3	15	3	15	
61	F	9	43	6	32	4	18	4	18	
64	-	6	3/	/	35	5	35	/	33	+
62	F	10	42	/	28	3	28	5	28	+
56		9	45	6	22	6	22	6	20	+
57	F	8	33	5	20	5	18	5	18	+
54	F	7	38	4	20	4	18	5	22	+
52	F	6	39	3	30	3	20	3	16	
54	М	8	40	4	20	4	18	2	18	
53	М	9	36	5	18	3	18	3	18	
61	F	7	38	3	29	3	22	3	20	
73	М	8	38	2	19	2	14	2	14	
74	М	6	34	6	15	5	14	2	14	
48	F	8	32	1	22	1	18	1	18	
52	F	7	34	2	15	2	14	2	14	
54	М	8	38	2	20	2	18	2	16	
60	М	9	37	3	22	3	22	3	22	
59	F	7	31	4	18	4	18	2	18	
58	F	8	37	2	20	2	16	2	16	
57	F	7	36	3	26	3	22	3	22	
56	М	8	34	3	23	3	20	3	20	
55	F	7	38	4	27	4	21	4	14	
54	М	8	39	2	36	2	30	5	30	+
53	М	6	42	2	22	2	18	2	16	
52	М	9	34	3	23	3	18	3	18	
51	F	10	38	6	26	6	22	6	22	
54	F	9	36	8	36	8	36	8	36	+
61	F	9	34	4	26	4	26	5	24	+
73	М	8	36	4	30	3	26	4	22	

F: Female, M: Male, VAS: Visual analog scale score, ODI: Oswestry Disability Index





Table 2. Shows characteristics and results of combined (transformainal + caudal) injection group											
					2 nd	2 nd	3 rd	3 rd			
A = =	Candan	TFI level/	Baseline	Baseline	week	week	month	month	6 th month	6 th month	Additional
Age	Gender	side	VAS		VAS	20	VAS	10	VAS	10	injection
5/			/	42	4 	20	2	10	2	10	
55			8	58	2	24	2	16	2	14	
60	-	L2/R	/	40	2	22	2	14	3	16	
65	F	L3/R	6	32	3	23	2	1/	2	14	
67	М	L3/L	7	20	2	14	2	12	2	12	
54	М	L3/L	8	42	2	22	3	18	3	18	
64	М	L3/R	9	42	2	32	3	34	3	30	+
55	F	L4/L	6	36	3	21	3	16	2	14	
70	М	L5/R	7	37	4	24	2	18	2	16	
68	М	L5/L	5	31	3	26	3	17	3	14	
66	F	L5/R	7	32	2	16	2	14	2	16	
60	М	L5/L	8	31	3	17	3	15	3	15	
61	F	L5/L	9	33	5	31	4	18	2	14	
64	F	L4/R	8	43	6	32	3	35	5	33	+
62	F	L4/R	9	34	7	27	3	20	3	14	
56	F	L3/R	8	32	5	21	4	22	3	14	
57	F	L5/R	8	28	5	20	3	16	5	18	
54	F	L4/R	9	27	4	22	4	14	3	12	
52	F	L5/L	7	30	3	28	3	18	3	16	
54	М	L5/R	6	27	3	22	4	16	2	18	
53	М	L3/R	8	35	5	18	3	18	3	18	
61	F	L3/L	8	36	3	29	3	22	3	20	
73	М	L2/R	7	34	2	19	2	14	2	14	·
74	М	L2/L	8	35	4	14	3	14	2	14	
48	F	L1/R	9	37	1	22	1	18	1	18	
52	F	L2/L	6	30	2	15	2	14	2	14	
54	М	L3/R	9	40	2	20	2	18	2	16	
60	М	L3/L	8	33	3	22	3	16	3	22	
59	F	L2/R	7	31	4	18	4	18	2	18	
58	F	L1/L	9	37	2	18	2	16	2	16	
57	F	L4/L	7	36	3	26	3	14	3	22	
56	М	L4/R	8	34	3	23	3	16	3	20	
55	F	L4/L	9	40	4	27	3	14	2	14	
54	М	L5/L	8	39	2	34	2	28	5	30	+
53	M	15/R	6	40	2	27	2	14	2	16	
52	M	15/1	9	34	3	23	3	16	3	18	
51	F	15/R	10	38	5	26	6	14	3	27	
54	F	15/1	9	36	6	30	8	36	8	36	+
61	F	14/R	9	34	4	26	4	26	5	74	+
73	M		8	34	4	20	τ ζ	20	5	27	+
15	IVI	L4/L	0	50	4	20	5	24	J	22	

F: Female, M: Male, VAS: Visual analog scale score, ODI: Oswestry Disability Index, TFI: Transforaminal injection, R: Right, L: Left



series), Stolker et al.⁽⁴⁰⁾ administered only hyaluronidase to their patients without hypertonic saline solution, and they described more than 50% reduction in pain in 64% of the patients at the end of the first year. Based on this result, they argued that the main effect of adhesiolysis is through hyaluronidase. Heavner et al.⁽⁴¹⁾ performed lesion-specific adhesiolysis in 59 patients with chronic intractable low back pain in their prospective randomized study and grouped the patients into four groups; 1) hyperyonic saline + hyaluronidase, 2) hypertonic saline, 3) isotonic saline, 4) isotonic saline + hyaluronidase. The need for additional interventions for pain control was found the lowest in the hypertonic saline + hyaluronidase group.

In 2004, Manchikanti et al.⁽⁴²⁾ implemented a one-day adhesiolysis protocol (targeting with epidurography) in patients with chronic low back and/or leg pain. The first of the 3 separate

groups they formed was defined as the control group, and adhesiolysis was not applied. Adhesiolysis was applied to the targets determined in the second and third groups. 0.9% normal saline was given to the second group and 10% hypertonic saline to the third group. At the end of the 12-month followup, a 50% improvement was reported in 72% of the patients in the third group, and this rate was reported as 60% in the saline group⁽³⁶⁾. Our study was composed of two groups. Those who had the caudal approach were included in group 1, and the patients whose fluoroscopy did not reveal any contrast passage through the foramen were placed in the combined caudal/ transforaminal adhesiolysis group (group 2). A significant improvement (p<0.001 for all results) was observed in the walking distance of the patients in both groups, and this rate constituted 72.5% (29 patients) and 75% (30 patients) of the













Figure 6. Graphs show changes in ODI scores before and after injection in both the caudal and combined injection groups ODI: Oswestry Disability Index

patients in group 1 and group 2, respectively. The improvement in walking distance means that the limitations in the daily life of the patients are reduced. This was also observed in the ODI results, which inquire about personal care, sleep, social life, and traveling. The improvement in ODI values at the sixth month was 97.5% in both groups (p<0.001 for all results). When the duration of the symptoms is long, central stenosis becomes severe and mainly in these patients, the contrast medium does not reach the root, so the outcome after the caudal approach alone is likely to be poor⁽⁴³⁾. Similarly, in our study, radicular pain was more prevalent in this group of patients before the procedure. However, our study design does not allow those patients to be treated with the caudal approach alone, and therefore, we did not find any significant differences between these two groups. On the other hand, although there is no statistically significant difference between those two groups, we found a tendency of recurrence and the need of an additional injection in the group 2. We consider that it is related to severe anatomical changes in these patients. Our study showed that a combined caudal and transforaminal approach may result in considerable good results in the vast majority of patients even in the presence of foraminal stenosis. As mentioned above, epidural adhesiolysis by the caudal approach is a proven and safe method that has been in use over the last three decades. It is a relatively easy technique to acquire, that enables catheter insertion and performing epiduroscopy, which gives an overall



view, assessment, and continuous treatment (if needed) option for the stenotic vertebral level. Adding transforaminal injection is always possible when necessary. Both approaches provide similar results for the control of radiating pain in case of foraminal stenosis⁽⁴⁴⁾. A recent meta-analysis showed slightly better results in favor of transforaminal injection; however, the level of evidence was found to be low and therefore, transforaminal injections could be only weekly recommended over caudal injections⁽⁴⁵⁾. The transforaminal injection is also a safe and efficient method in the management of radiating pain due to foraminal stenosis. However, it does not have similar effects on the pain-related central canal stenosis. In most of the patients, not an isolated foraminal or isolated central canal stenosis is encountered, it is mostly a combination of both clinical conditions. Therefore, we found it rationale to perform first a caudal injection and then adding transforaminal injection in case needed.

Study Limitations

This study has some limitations due to the study design. We do not have a control group in case of foraminal stenosis, that inhibits contrast medium passage, where the patients were treated with the caudal approach only since it is known that is associated with poor outcome. We used the caudal approach to distinguish patients with foraminal stenosis. This resulted in automatically grouped patients, and group 2 consisted of patients with some anatomical disadvantage. Therefore, the comparison between these two patient groups can be criticized by this means.

CONCLUSION

Caudal neuroplasty adhesiolysis is an effective method for treating chronic low back pain due to symptomatic LSS, and the addition of the transforaminal neuroplasty adhesiolysis to the caudal approach increases the success in cases where foraminal contrast passage is not observed in epidurography.

Ethics

Ethics Committee Approval: The study was conducted with the approval of the Demiroğlu Bilim University Ethics Committee (no: 44140529, date: 23.06.2020).

Informed Consent: An informed consent form of the procedure was obtained from all patients.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: M.O.A., S.Ç., Concept: M.O.A., A.A., S.Ç., Design: M.O.A., A.A., S.Ç., Data Collection or Processing: A.A., S.Ç., Analysis or Interpretation: M.O.A., A.A., S.Ç., Literature Search: M.O.A., A.A., Writing: M.O.A., A.A., S.Ç.

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ORIGINAL ARTICLE

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SURGICAL TREATMENT OF IATROGENIC PSEUDOMENINGOCELES

¹Çukurova University Faculty of Medicine, Department of Neurosurgery, Adana, Turkey ²Gaziantep Medical Point Hospital, Clinic of Radiology, Gaziantep, Turkey ³Acıbadem Ankara Hospital, Clinic of Neurosurgery, Ankara, Turkey ⁴Bahçeşehir University Faculty of Medicine, Department of Neurosurgery, İstanbul, Turkey

Objective: Pseudomeningocele that develops after spinal surgery is a rare complication that should be well-guided by surgeons. In the absence of proper treatment, it may increase the morbidity of the patients.

Materials and Methods: The medical records of 13 patients with iatrogenic pseudomeningocele who underwent primary dura repair with myofascial flap support and lumbar subarachnoid drainage, were retrospectively reviewed.

Results: There were four female (31%) and 9 male (69%) patients in the study cohort. The mean age of the patients was 45 years (2-68 years). Six patients had decompression with implanted fusion, 5 patients had microdiscectomy, 1 patient had untethering for tethered cord syndrome and 1 patient had intradural extramedullary tumor excision as the first operation. One patient had a pseudomeningocele at the cervical region and the other patients' lesions were at the lumbar region. Revision microdiscectomies were performed in 5 patients with recurrent/residual disc herniations, and abscess drainage was performed in 1 patient with an abscess at the operation site. Infected cases were consulted in the infectious diseases department, and antibiotherapy was given for appropriate periods. None of the patients had any additional complications and persistence or recurrence of the pseudomeningocele following dura repair and lumbar subarachnoid drainage. The complaints of all the patients were resolved.

Conclusion: Although there are cases with iatrogenic pseudomeningoceles who present spontaneous recovery in the literature, most of these cases require surgical exploration and primary repair. Surgical repair with myofascial flap support and lumbar subarachnoid drainage seems to be an effective option in patients with iatrogenic pseudomeningoceles.

Keywords: Spine surgery, complications, pseudomeningocele, lumbar subarachnoid drainage, duraplasty

INTRODUCTION

Spinal pseudomeningocele is an extradural cerebrospinal fluid (CSF) collection because of dural defects. The difference between the pseudomeningocele and congenital meningoceles is that there is no real arachnoid membrane in the pseudomeningocele. Therefore, they are called pseudomeningoceles. They may present as congenital, traumatic, or postoperative complications^(1,2). The most common type is the iatrogenic pseudomeningocele after spinal surgeries. These types of pseudomeningoceles are complications that should be well-guided by surgeons and increase morbidity. The incidence of pseudomeningocele in the literature was between 0.068% and $2\%^{(1,3,4)}$. There is no consensus in the literature regarding the treatment of the spinal pseudomeningocele. This study evaluated 13 patients who had iatrogenic pseudomeningocele and their primary treatments.

MATERIALS AND METHODS

The medical records of 13 patients who presented with iatrogenic pseudomeningocele at 2 neurosurgery clinics between January 2013 and January 2020 and underwent primary dura repair with myofascial flap support and lumbar subarachnoid drainage, were retrospectively reviewed. All study protocols were performed in accordance with the ethical rules proposed in the Helsinki Declaration. Ethics committee approval was received from the Çukurova University Non-Interventional Scientific Research Ethics Committee (126/13, date: 07.10.2022). Patient demographics and medical records, including age, gender, clinical symptoms, preoperative and postoperative neurological status, and visual analog scores, first-session operative indications and applied surgeries, hospitals of first-session surgery, radiological diagnoses, treatment modalities, and postoperative complications were gathered. Contrast-enhanced spinal magnetic resonance

Address for Correspondence: Kadir Oktay, Çukurova University Faculty of Medicine, Department of Neurosurgery, Adana, Turkey Phone: +90 506 256 51 76 E-mail: drkadiroktay@hotmail.com Received: 05.11.2022 Accepted: 16.03.2023 ORCID ID: orcid.org/0000-0003-2420-2734



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imaging (MRI) was performed on all patients before surgery (Figure 1). The treatment plans of the patients who were investigated for infection were made according to the scans and opinions of the specialist in infectious disease. Before surgery, 1 gram of ampicillin-sulbactam was administered, and 1 gram of ampicillin-sulbactam was administered four times daily for three days postoperatively. Tissue and fluid samples were obtained from all the patients. Antibiotherapies were arranged by the department of infectious diseases according to their isolation and identification. Lumbar subarachnoid drainage was applied in all patients. CSF drainage was achieved in the range of 50-120 mL daily for a total of 5-7 days. After ensuring that the wound was closed, the drainage systems were pulled out under sterile conditions and the drainage sites were sutured.

Statistical Analysis

The SPSS 25.0 (IBM Corporation, Armonk, New York, United States) program was used to analyze the variables. The Mann-Whitney U test was used with the Monte Carlo results to compare the categorical variables quantitatively. The quantitative variables were described as mean \pm standard deviation, the median range (maximum-minimum), and categorical variables as n (%). The variables were examined at a 95% confidence level, and p<0.05 was considered significant.

RESULTS

Patient Profile

There were four female (31%) and 9 male (69%) patients in the study cohort. The mean age of the patients was 45 years (2-68 years). The first operations of 4 patients were performed at our center and 9 in another neurosurgery clinic. Six patients had decompression with implanted fusion, 5 patients had microdiscectomy, 1 patient had untethering for tethered



Figure 1. Sagittal and axial T2-weighted lumbar magnetic resonance images of the fifth patient revealed a giant lumbosacral iatrogenic pseudomeningocele

cord syndrome and 1 patient had intradural extramedullary tumor excision as the first operation. One patient had a pseudomeningocele at the cervical region and the other patients at the lumbar region (Table 1). All the patients underwent multiple lumbar punctures before the surgical treatment of pseudomeningoceles. However, the resolution of the pseudomeningoceles could not be achieved with lumbar punctures.

Patients Symptoms and Neuroimaging

The most common symptoms were wound swelling and intracranial hypotension symptoms (such as headache, nausea, vertigo, dizziness, blurry vision, diplopia, unsteady gait) (69%) (Figure 2). Other symptoms identified were lumbar back pain (46%), radiculopathy symptoms (38%), wound leakage (15%), and fever (7%), respectively (Table 1). Contrast-enhanced MRI was performed for all the patients, and pseudomeningocele sacs were identified in all patients (Figure 1). Two patients had an infection in the operation region, and 1 patient had developed an abscess formation (Table 1).

Surgery

All the patients underwent primary dura repair with myofascial support and lumbar subarachnoid drainage. Dura repair was performed by primary suturation with 4/0 silk sutures. Fullthickness pedicular muscle and fascia flaps were applied for myofascial support. Revision microdiscectomies were performed in 5 patients with recurrent/residual disc, and abscess drainage was performed in one patient with an abscess. Infected cases were consulted the infectious disease clinics, and antibiotherapy was given for appropriate periods. CSF drainage was achieved in the range of 50-120 mL daily for a total of 5-7 days. In the patient who had a pseudomeningocele in the cervical region, CSF drainage was ensured in a controlled manner from lumbar drainage and not to exceed 50 ml per day. In the literature, because of the progression to herniation in such a case, CSF drainage was performed with close followup⁽⁵⁾. The patient had pseudomeningocele repair without any additional problems. None of the patients had any additional complications or recurrence of the pseudomeningocele following dura repair and lumbar subarachnoid drainage (Table 1). The complaints of all the patients improved. All the patients were discharged after an uneventful postoperative period.

DISCUSSION

Spinal pseudomeningocele is an extradural CSF collection without an arachnoid membrane due to a small defect in the dura. It was first described as an extradural cyst by Hyndman and Gerber⁽⁶⁾ in 1946. However, they classified the spinal pseudomeningocele as iatrogenic and traumatic in 2 groups. Miller and Elder⁽⁷⁾ divided this pathology into 3 groups in 1968, and it was finally classified as congenital, iatrogenic, and traumatic. Congenital pseudomeningoceles are usually detected in patients with neurofibromatosis and Marfan



Table 1. Demographic characteristics of the patients

Patient	Age/ gender	Symptoms	First session pathology / treatment modality	Neuroimaging	The first operation center	Treatment modality	Complication
1	50/M	Wound swelling + intracranial hypotension	L4-5 microdiscectomy	Lumbar pseudomeningocele	AND	Dura repair + microdiscectomy + LSD	-
2	56/M	Wound leakage + lumbar back pain + left radiculopathy	L3-5 decompression with implanted fusion + implant removal	Lumbar pseudomeningocele + abscess	AND	Dura repair + abscess drainage + LSD + antibiotherapy	-
3	28/M	Wound swelling + intracranial hypotension	L1 fracture / T11-L3 implanted fusion	Lumbar pseudomeningocele	AND	Dura repair + LSD	-
4	35/F	Wound swelling + right radiculopathy + intracranial hypotension	L2-3 + L3-4 microdiscectomy	Lumbar pseudomeningocele	OD	Dura repair + microdiscectomy + LSD	-
5	39/M	Wound swelling + intracranial hypotension	L4-S1 decompression with implanted fusion	Lumbar pseudomeningocele	AND	Dura repair + implant removal + LSD	-
6	66/M	Lumbar back pain + left radiculopathy + fever	L4-5 microdiscectomy	Lumbar pseudomeningocele + infection in the operation region	AND	Dura repair + LSD + antibiotherapy	-
7	2/M	Wound swelling	Untethering for tethered cord syndrome	Lumbar pseudomeningocele	AND	Dura repair + LSD	-
8	44/F	Wound swelling + intracranial hypotension	Cervical intradural extramedullary tumor excision	Cervical pseudomeningocele	OD	Dura repair + LSD	-
9	68/F	Lumbar back pain + intracranial hypotension	L1-S1 decompression with implanted fusion	Lumbar pseudomeningocele	AND	Dura repair + LSD + implant revision + L1-L2 decompression	-
10	57/F	Wound leakage + intracranial hypotension + lumbar back pain + left radiculopathy	L3-4 + L4-5 microdiscectomy	Lumbar pseudomeningocele	OD	Dura repair + microdiscectomy + LSD	-
11	56/M	Wound swelling + lumbar back pain + intracranial hypotension	L4-5 microdiscectomy	Lumbar pseudomeningocele	AND	Dura repair + LSD	-
12	38/M	Wound swelling + intracranial hypotension	L3-5 decompression with implanted fusion	Lumbar pseudomeningocele	AND	Dura repair + LSD	-
13	45/M	Wound swelling + lumbar back pain + left radiculopathy	L4-S1 decompression with implanted fusion	Lumbar pseudomeningocele + infection in the operation region	OD	Dura repair + LSD + antibiotherapy	-

'Implant removal was performed in a second session.

M: Male, F: Female, AND: Another neurosurgery department, OD: Our department, LSD: Lumbar subarachnoid drainage





Figure 2. Peroperative images of the same patient. (a) Cerebrospinal fluid collection under the skin incision. (b) Drainage of the high-pressured collection. (c) Pseudomeningocele pouch. (d) The small defect of the dura was causing cerebrospinal fluid leakage

syndrome. They are usually located in the thoracic region and the thoracolumbar junction^(4,6). Traumatic pseudomeningoceles are the rarest forms and are usually located in the cervical and thoracic regions because of distraction injuries^(8,9). The most common forms are iatrogenic types, and they are identified as postoperative complications after spinal surgeries^(2-4,10-13). latrogenic pseudomeningoceles are most commonly detected in the lumbar region.

Spine surgery is linked to a wide range of intraoperative complications, including wrong-level surgery, nerve root lesions, vascular injury, and dural tearing. Dural injury is not uncommon, with reported incidence rates of 1-17.4%⁽¹³⁻¹⁵⁾. The rates of dural injury vary according to the types of surgeries. The rates were found to be 1.8% in microdiscectomies, 5.3% in laminectomies, and 17.4% in revision surgeries⁽¹⁶⁻¹⁸⁾. The rate of detection of iatrogenic pseudomeningoceles in the literature is in the range of 0.068-2%^(1,3,4). The iatrogenic pseudomeningoceles are classified as large (greater than 5 cm), and giant (larger than 8 cm) pseudomeningoceles due to their size^(3,4,19). latrogenic pseudomeningoceles can be asymptomatic or may present with clinical symptoms including back pain, radicular pain, cauda equina syndrome, or signs of intracranial hypotension, such as postural headache, dizziness, neck pain, tinnitus, vision problems, and nausea, and vomiting^(1,10-13,20). In cases where the pressure in the pseudomeningocele sac is high, leakage from the incision may be observed. In cases with excess pouch size, herniation of neural tissues into the sac can be observed. In particular, herniations are observed in the sac after pseudomeningoceles in the thoracic and lumbar region^(1,8,9,11,12). In the literature, there are cases of decerebrate rigidity or herniation symptoms because of CSF leakage^(5,21). A case of hydronephrosis induced by a pseudomeningocele extending to the retroperitoneal region was also been presented in the literature⁽²²⁾. There is no consensus on the treatment of iatrogenic pseudomeningoceles in the literature. Although some cases spontaneously recovered, surgical repair is usually required⁽²⁾. Treatment modalities of pseudomeningoceles include conservative methods, epidural blood-patch applications, primary dura repair with surgical excision of the pseudomeningocele, and drainage catheters placed at the subarachnoid space^(1,4,20). Conservative methods include bed rest, prevention of leakage from the skin incision, and repetitive punctures applied to the sac⁽¹⁾. In patients with spontaneous CSF leakage, the epidural blood-patch application is performed⁽²³⁾. However, in patients with failure of conservative methods, intracranial hypotension symptoms, progressive myelopathy or cauda equina syndrome, and infection, surgical interventions are required^(1,20).

Surgical excision of the pseudomeningocele and primary dura repair is the definitive treatment method. In patients with large dural defects, duraplasty with fascia grafts or synthetic dura grafts can be applied. Fibrin glue and myofascial flaps are also among the methods applied to provide support to the repaired dura^(16,19). After the repair, only the use of Jackson-Pratt drain or lumbar subarachnoid drainage are options for the drainage. In the literature, although it was shown that good results were obtained with the prolonged use of Jackson-Pratt drains instead of subarachnoid drainage, the general opinion is that better results are obtained with external subarachnoid drainage^(5,24,25). In this study, we performed pseudomeningocele excision, primary dura repair with myofascial flap support, and lumbar subarachnoid drainage. We did not apply any foreign material such as a dura graft or fibrin glue in any patient. In cases with large dura defects, we performed duraplasty with autologous fascia grafts and obtained positive results.

Study Limitations

There are certain limitations to this study. The main limitations are the retrospective nature of the study and the relatively small sample size (13 patients). There is also a lack of pediatric patients (only 1 patient) in this study group.

CONCLUSION

In the literature, there are some cases with iatrogenic pseudomeningoceles that present spontaneous recovery. However, most of these cases require surgical exploration and primary repair. In this study, 13 patients who were diagnosed with iatrogenic pseudomeningoceles and underwent surgery are presented. All the patients underwent pseudomeningocele excision, primary dura repair with myofascial flap support, and lumbar subarachnoid drainage. Good results were obtained in all the patients. It is important to perform the surgeries as soon as possible to reduce the risk of infection. Surgical repair and lumbar subarachnoid drainage seem to be favorable options for patients with iatrogenic pseudomeningoceles.

Ethics

Ethics Committee Approval: Ethics committee approval was received from the Çukurova University Non-Interventional Scientific Research Ethics Committee (126/13, date: 07.10.2022). **Informed Consent:** Retrospective study.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: K.O., A.G., Concept: K.O., A.G., Design: K.O., A.G., Data Collection or Processing: E.G., M.A., O.B., Analysis or Interpretation: K.O., U.E., Literature Search: K.O., M.A., O.B., Writing: K.O., U.E.

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COMPARING RESULTS OF POSTERIOR CERVICAL FACET JOINT CAGE STABILIZATION WITH LATERAL MASS FIXATION IN CERVICAL FORAMINAL STENOSIS

Aykut Sezer¹, Mesut Uluöz², Can Sezer³

¹Dr. Ersin Arslan Training and Research Hospital, Clinic of Neurosurgery, Gaziantep, Turkey ²University of Health Sciences Turkey, Adana City Training and Research Hospital, Clinic of Orthopedics, Adana, Turkey ³University of Health Sciences Turkey, Adana City Training and Research Hospital, Clinic of Neurosurgery, Adana, Turkey

Objective: Although neck and arm pain are the most common symptoms of cervical foraminal stenosis, neuromotor deficits are also observed. The most common surgical treatment for cervical foraminal stenosis is cervical decompression and fusion. This process is difficult and invasive. The study evaluates the effectiveness and results of posterior cervical facet cages (PCFC) operation in cervical foraminal stenosis. **Materials and Methods:** In this study, 80 patients who underwent PCFC operation and 70 patients who underwent decompression with lateral mass screw fixation (LMSF) between May 2016 and May 2021 were evaluated. Clinical information, laboratory results, and radiological findings were reviewed retrospectively. The patients were divided into two groups PCFC -applied patients in group 1 and LMSF- applied

patients in group 2. Pain complaints of the patients were evaluated using a visual analog scale (VAS). Posterior disc height (PDH) (mm) and foraminal height (FH) (mm) were used for radiological evaluation. **Results:** The mean hospitalization time of the patients was 27 h in group 1 and 92 h in group 2. There was a statistically significant difference between the groups in terms of mean hospitalization time (p<0.001). The mean preoperative and postoperative VAS scores in group 1 were 6.8 and 2.9 for neck pain, and 7.1 and 2.6 for arm pain, respectively. Mean preoperative and postoperative VAS scores in group 2 were 6.7 and 3.8

for neck pain, respectively. There was a statistically significant difference between the groups in terms of a decrease in VAS scores (p<0.001). PDH in group 1 was 2.3 mm preoperatively and 2.6 mm postoperatively. The FH was 10.2 mm preoperatively and 10.5 mm postoperatively. In group 2, PDH was 2.4 mm preoperatively and 2.3 mm postoperatively. FH was 10.6 mm preoperatively, and no postoperative change was detected. There was a statistically significant difference between groups 1 and 2 in terms of PDH and FH (p<0.001).

Conclusion: It shows that minimally invasive facet cages can be considered as a safe alternative method for root decompression and spinal fusion in cervical foraminal stenosis.

Keywords: Cervical disc degeneration, cervical spondylosis, posterior cervical facet cages, lateral mass screw fixation

INTRODUCTION

ORIGINAL ARTICLE

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Foraminal stenosis is the most important pathology that occurs because of cervical intervertebral disc degeneration or spondylosis. The clinical presentation of this condition manifested as radiculopathy. Although the most predominant symptom is neck and arm pain in patients with foraminal stenosis, neuromotor deficits are also observed^(1,2). In radiculopathy caused by degenerative disc disease or spondylosis, posterior decompression with lateral mass screw fixation (LMSF) together with cervical laminectomy is a standard method considered an effective treatment. The surgical aim is to decompress the nerve with foraminotomy. Minor laminotomy is typically performed. With foraminotomy, the affected nerve root is decompressed. Posterior stabilization should be performed to prevent instability after decompression. For this purpose, posterior lateral mass screw fixation is applied⁽³⁻⁷⁾. Although this treatment modality has a lower risk of dysphagia than anterior intervention, it typically requires nerve root manipulation and bone resection⁽⁸⁾.

In the LMSF method: The risk of neurological complications, osteophytes, kyphosis, muscle atrophy, and disc fusion with reconstruction is high. After the excision of the ligamentum flavum, the dura mater emerges, and consequently the risk of damage to the dura mater increases^(4,9). With minimally invasive cervical posterior surgery, recovery and hospitalization times are shortened due to a significant reduction in intraoperative blood loss and tissue damage⁽¹⁰⁻¹²⁾. Recently, posterior cervical facet cages (PCFC) have been developed as a percutaneous system with minimal incisions in the posterior cervical approach^(10,13). In cervical stenosis-related radiculopathy, positive results after

Address for Correspondence: Can Sezer, University of Health Sciences Turkey, Adana City Training and Research Hospital, Clinic of Neurosurgery, Adana, Turkey Phone: +90 532 232 73 89 E-mail: mdcansezer@gmail.com Received: 26.12.2022 Accepted: 01.04.2023 ORCID ID: orcid.org/0000-0003-0776-9421



[©]Copyright 2023 by the Turkish Spine Society / The Journal of Turkish Spinal Surgery published by Galenos Publishing House. Licensed by Creative Commons Attribution-NonCommercial 4.0 International (CC BY-NC-ND 4.0). surgery with minimally invasive implants placed between the facet joints have been reported for up to two years as an alternative to LMSF. However, few publications are compared the biomechanical effects between LMSF and PCFC^(14,15). Our aim in our study was to compare the clinical and radiological results of a Posterior Cervical Facet Cage Technique with the posterior lateral mass screw fixation technique in cervical foraminal stenosis.

MATERIALS AND METHODS

Between May 2016 and May 2021, 150 patients who were operated on with the diagnosis of C5-6 segment cervical stenosis were included in the study. Eighty patients underwent the PCFC method (group 1) and 70 patients underwent the LMSF method (group 2). A patient's data, including the clinical course, neurological findings, laboratory results, and neuroimaging findings, were reviewed retrospectively. Inclusion criteria were: 1) patients aged between 18 and 75 years, 2) patients who received radiculopathy due to foraminal stenosis and underwent PCFC or LMSF, 3) patients who received an epidural steroid injection and/or who failed at least 6 weeks of conservative treatment. Exclusion criteria were: 1) cervical myelopathy, 2) spondylolisthesis greater than 3.5 mm, 3) cervical kyphosis, 4) metabolic or connective tissue disease, 5) osteoporosis, 6) pregnancy or breastfeeding, 7) systemic inflammatory disease, 8) facet joint pathology. We followed up on 150 patients' clinical information, laboratory results, and radiological findings obtained retrospectively from hospital medical records for 2 weeks, 6 weeks, 3 months, 6 months, and 12 months. In the PCFC application, after the patient is fixed in the prone position



and the shoulders are pulled back. Simultaneous lateral and anteroposterior (AP) images were taken using two C-arms. The facet joint to which PCFC will be applied is confirmed by entering with a spinal needle. After the skin incision, Access Chisel is advanced under fluoroscopic guidance until the bone is reached. The Access Chisel is used to locate and cut the tip of the joint capsule. The Access Chisel is advanced into the facet joint space. Decortication Trephine is delivered through the Access Chisel to the distal end of the bone. The Guide Tube is advanced into the facet joint space through the Fork Mallet. Decortication Rasp is advanced. The Guide Tube is locked with the quide tube holder and Rasped up to the upper handle of the decortication. The PCFC cervical cage transport device is advanced into the guide tube until it locks with the guide tube. AP and lateral fluoroscopy were used to confirm the proper placement of the cage. The bone graft material was placed in the upper part of the guide tube. After the cage is confirmed by final AP and lateral fluoroscopy, it is placed in the facet joint space (Figure 1). In the LMSF application group, after the patient was fixed in the prone position, bilateral paravertebral muscles were peeled open to expose the spinous process, bilateral laminae, and lateral mass. The needle insertion point and angle were determined according to the Magerl technique. The lateral mass screw was inserted after sounding. After the screw position was confirmed to be good by fluoroscopy, posterior resection of the posterior wall of the spinal canal at the corresponding segment was performed, paying attention to the protection of the lateral mass bone. The vertebral plate was completely removed to completely decompress the spinal canal. After traction by the contact cranial ring arch, a prebent titanium rod was linked to the screw. All patients were



Figure 1. The PCFC process application is shown in **A**) The incision site is planned for the PCFC procedure. **B**, **C**) Chisel is advanced under fluoroscopic guidance until the bone is reached. **D**, **E**) PCFC is placed in the facet joint space with guidance. **F**, **G**) The AP and lateral fluoroscopic images of the PCFC cage placed in the facet joint space are shown. **H**) It has been shown that minimal entry space is required for its application

PCFC: Posterior cervical facet cages, AP: Anteroposterior



routinely given postoperative nonopioid analgesic medication. pain complaints of the patients were evaluated using a visual analog scale (VAS). VAS is 0 to 10-point scale. On the VAS, 0 represents the absence of pain, and 10 represents the worst pain the patient can imagine⁽¹⁶⁾. For neck pain and arm pain in both group, VAS was evaluated on the day of surgery and at the 2nd week, 6th week, 3rd month, 6th month, and 12th month postoperatively. Preoperative and postoperative radiological images were analyzed in both groups, and posterior disc height (PDH) (mm) and foraminal height (FH) (mm) were measured. For our study, ethics committee approval was received for this study from Sanko University, Sanko Hospital Clinical Research Ethics Committee (decision no: 2022/04-01, date: 24.02.2022), and was performed out following the Declaration of Helsinki. Written informed consent was obtained from all the participants.

Statistical Analysis

In comparisons between the 2 study groups: Student's t-test was used for Gaussian continuous variables, the Mann-Whitney U test was used for non-gaussian non-continuous variables, and χ^2 was used for categorical variables. A value of p<0.05 was considered statistically significant. All analyses were performed using R Statistical Software Version 3.3.2.

RESULTS

Seventy nine (53%) male and 71 (47%) female patients were included in the study. The mean age of the patients was 62.3 (25-73) years. The demographic and characteristic features of

 Table 1. Demographic and characteristics of the patients

the patients are given in Table 1. There was no statistically significant difference between the two groups in terms of age and gender. Fifty five (69%) patients in group 1 had a previous operation history. In these patients, the most common operation was anterior cervical discectomy in 39 (71%) patients, anterior cervical fusion surgery in 11 (20%) patients, and posterior cervical fusion surgery combined with laminectomy in 5 (9%) patients. In group 2, 39 (55%) patients had a history of surgery, and posterior decompression surgery was found in these patients. The most frequently affected level was the C5-C6 level in both groups. Then, in the order of frequency in both groups, it was C6-C7, C4-5, and C3-4. The mean hospitalization time was 27.1 h in group 1 and 52.6 h in group 2. There was a statistically significant difference in hospitalization time between the groups (p<0.001).

In group 1, preoperative and postoperative VAS scores were 6.8 and 2.9 for neck pain and 7.1 and 2.6 for arm pain, respectively. There was an increase in arm pain in 2 patients and an increase in the neck and arm pain in 1 patient. This was reflected in the VAS scores. There was no change in the neck and arm pain in the four patients. There was a statistically significant difference in VAS reduction (p<0.001). The follow-up periods of the patients in group 1 are given in Table 2. In group 2, preoperative and postoperative VAS were 6.7 and 3.8 for neck pain and 6.9 and 2.9 for arm pain. There was an increase in arm pain in 3 patients. Although neck and arm pain increased in 23 patients in the early postoperative period, neck and arm pain increased in only 8 patients during follow-up. There was no change in

Table 1. Demographic and characteristics of the patients								
Characteristics	Grup 1 (n=80)	Grup 2 (n=70)	p value					
Age (years)	61	63	0.72					
Male, n (%)	43 (54)	36 (51)	0.56					
Prior cervical spine surgery, n (%)	-	-	0.068					
Yes	55 (69)	39 (55)	-					
No	25 (31)	31 (45)	-					
Cage placement, n (%)	-	-	<0.001					
Unilateral	7 (9)	0	-					
Bilateral	73 (91)	70 (100)	-					
Cage segment, n (%)	-	-	0.84					
C3-4	6 (7)	7 (10)	-					
C4-5	17 (21)	13 (18)	-					
C5-6	35 (44)	32 (46)	-					
C6-7	22 (28)	18 (26)	-					
Postoperative complications, n (%)	-	-	<0.001					
Spinal cord injury	0	2 (3)	-					
Vertebral artery injury	0	1 (2)	-					
CSF leak	0	6 (9)	-					
Wound infection	1 (1)	5 (7)	-					
Meningitis	0	2 (3)	-					
CSF: Cerebrospinal fluid								

the neck and arm pain of 5 patients. Although there was no significant decrease in VAS during the early postoperative period, a statistically significant difference was found in the postoperative VAS reduction (p<0.001). The follow-up periods of the patients in group 2 are given in Table 3. When the VAS between group 1 and group 2 was evaluated, a statistically significant difference was found in the decrease in VAS of the patients in group 1 (p<0.001). The PDH (mm) in group 1 was 2.3 mm preoperatively and 2.6 mm postoperatively. FH (mm) was 10.2 mm preoperatively and 10.5 mm postoperatively. In group 2, the PDH (mm) was 2.4 mm preoperatively and 2.3 mm postoperatively. FH (mm) was 10.6 mm preoperatively, and no postoperative change was detected. There was a statistically significant difference between groups 1 and 2 in terms of PDH and FH (p<0.001). Wound infection was detected in only 1 (1%) patient as a postoperative complication in patients in group 1. In group 2, cerebrospinal leakage (CSF) in 6 (9%) patients, wound infection in 5 (7%) patients, spinal cord injury in 2 (3%) patients, meningitis in 2 (3%) patients, and 1 (2%) patients vertebral artery damage was revealed. When postoperative complications were evaluated, a statistically significant difference was found between group 1 and group 2 (p<0.001). There was no reoperation or readmission in any group.

DISCUSSION

The surgical approach in the surgical treatment of cervical intervertebral disc degeneration or spondylosis can be anterior, posterior, and combined. The most commonly preferred approach is posterior. The choice of the surgical approach is influenced by factors such as the location of pathology, the number of levels, and the degree of the clinical picture. Although cervical laminectomy and foraminotomy effectively decompress neurogenic structures, they can cause segmental instability, kyphosis, and neurologic deficits as well as technical difficulties. LMSF is also added to the decompression to prevent these complications⁽¹⁷⁻²²⁾. LMSF with laminectomy is effective for cervical mononeuropathy, along with the advantage of preserving stability^(6,23).

Table 2. Group 1 scores

Time	VAS for neck	VAS for arm	PDH	FH
DC	(0	71	2.7	10.2
05	0.0	/.1	2.5	10.2
2 weeks	4.1	3.6	2.6	10.5
6 weeks	3.3	2.8	-	-
3 months	2.4	2.3	-	-
6 months	2.2	2.4	2.4	10.4
12 months	2.3	2.2	-	-

VAS: Visual analog scale, PDH: Posterior disc height (mm), FH: Foraminal height (mm), DS: The day of surgery, 2 weeks: The control visit 2 weeks after surgery and the VAS score at subsequent visits



Despite this, the risk of damage to neurogenic structures and surrounding muscle and bone structures increases. The risk of adjacent segment degeneration is also increased⁽¹⁾. PCFC performs root decompression and fusion by opening the neuronal foramen in the cervical facet with minimally invasive intervention, without damaging the paraspinal muscles, with negligible bleeding. Due to the increased tissue damage in group 2, additional pain occurs postoperatively in patients depending on the severity of the pain, even if the neurogenic pathology disappears. In our study, this explains the fact that group 2 early postoperative VAS did not decrease as much as in group 1. Minimally invasive percutaneous intervention in group 1 increases the postoperative comfort of the patients due to less tissue damage and shortens the hospitalization period of the patients. PCFC is less invasive, requires a shorter hospital stay, and has fewer potential complications^(24,25). Efficacy data thus far has shown PCFC to be comparable to LMSF for radicular pain, with multiple studies demonstrating significant improvement in symptoms in 95% of patients^(26,27). The favorable outcomes of this study add to the growing literature supporting PCFC as a low-morbidity, high-efficacy alternative for cervical radicular symptoms.

In the study of Maulucci et al.⁽²⁸⁾ 2 mm facet cage and LMSF surgeries detected an increase in FH and stability, but could not detect statistically significant results in kinematic results. Kasliwal et al.⁽²⁹⁾ found significant improvements in VAS for the pain neck and arm in a 20-month follow-up study of 19 patients who underwent revision surgery for pseudoarthrosis. However, they did not detect any significant change in cervical lordosis. Other studies in the literature have demonstrated similar stability with PCFC to traditional open LMSF surgery^(30,31). Despite similar stability, it provides decompression of neuropathic structures because of a statistically significant increase in disc height and FH in group 1 compared to group 2. This explains that the decrease in VAS in group 1 is more pronounced than the decrease in VAS in group 2. The study by McCormack et al.⁽¹⁰⁾ including 60 patients who underwent PCF, reported that there was no vertebral artery injury or damage to neural structures and that no patient required reoperation. In our study, wound infection developed in only one patient in group 1, which is consistent with low complication

Table 3. Group 2 scores

Time	VAS for neck pain	VAS for arm pain	PDH	FH
DS	6.7	6.9	2.4	10.6
2 weeks	6.1	3.8	2.3	10.6
6 weeks	4.3	3.1	-	-
3 months	3.4	2.6	-	-
6 months	2.9	2.5	2.3	10.5
12 months	2.6	2.7	-	-

VAS: Visual analog scale, PDH: Posterior disc height (mm), FH: Foraminal height (mm), DS: The day of surgery, 2 weeks: The control visit 2 weeks after surgery and the VAS score at subsequent visits





rates. However, in the seven-month follow-up of the study by Siemionow et al.⁽³²⁾ In 89 patients, the postoperative complication rate of LMSF was found to be 4.3%. The authors reported neurological complications related to C5 palsy in one patient and spinal cord irritation in one patient. The findings of this study evidence the safety of PCFC, and its potential as a low-morbidity alternative to LMSF for radiculopathy. The procedures took an average of 27.1 h and on average required a 52.6-hour hospital stay. In comparison, one study looking at LMSF found an average length of procedure of 204±59 min and an average length of stay of 47.5±38.4 h with LMSF⁽²⁵⁾. The authors also reported postoperative parietal stroke in one patient and atrial fibrillation in one patient. The authors found the complication rate to be 3.4% in patients who used a posterior cervical cage. The reason why the complication rates in this study were higher than that in our study may be that our patient exclusion criteria were wider.

Complications included dysphagia, hematoma, worsening myelopathy, recurrent laryngeal nerve palsy, cerebrospinal fluid leaks, wound infection, increased radiculopathy, Horner's syndrome, respiratory insufficiency, esophageal perforation, and instrument failure^(24,33). In the LMSF group, CSF in 6 (9%) patients, wound infection in 5 (7%) patients, spinal cord injury in 2 (3%) patients, meningitis in 2 (3%) patients, and 1 (2%) patients vertebral artery damage was revealed. There were no spinal cord injury, CSF leak, meningitis, and vertebral artery damage in the PCFC group (p<0.001). This demonstrates the significantly higher morbidity with LMSF, with most of these complications being avoided with PCFC given the minimally invasive posterior approach.

Study Limitations

This study has limitations. It is retrospective and the study is limited to one year. Longer follow-up and analyzes must understand the effects in the adjacent segment and to understand the long-term effects.

CONCLUSION

Surgical treatment options for cervical intervertebral disc degeneration or spondylosis remain largely invasive. The PCFC technique is a minimally invasive approach that provides a clinically significant improvement in the presence of clinical and radiological findings in patients with cervical radiculopathy. This technique can be considered as a safe alternative to surgical treatment in patients with spinal stenosis, particularly those with comorbidities.

Ethics

Ethics Committee Approval: The study, ethics committee approval was received for this study from Sanko University, Sanko Hospital Clinical Research Ethics Committee (decision

no: 2022/04-01, date: 24.02.2022), and was performed out following the Declaration of Helsinki.

Informed Consent: Written informed consent was obtained from all the participants.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: A.S., Concept: A.S., M.U., C.S., Design: M.U., Data Collection or Processing: A.S., M.U., C.S., Analysis or Interpretation: A.S., M.U., C.S., Literature Search: A.S., M.U., C.S., Writing: A.S., C.S.

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ORIGINAL ARTICLE-

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CONSERVATIVE TREATMENT OF ACUTE LOW BACK PAIN: ACETAMINOPHEN COMBINED WITH ETODOLAC OR DICLOFENAC A COMPARATIVE STUDY OF 67 PATIENTS

Celaleddin Bildik¹, Tuna Pehlivanoğlu^{2,3}

¹Ataşehir Florence Nightingale Hospital, Department of Orthopedic Surgery and Traumatology, İstanbul, Turkey ²Liv Hospital Ulus, Department of Orthopedic Surgery and Traumatology, İstanbul, Turkey ³İstinye University Faculty of Medicine, Department of Orthopaedic Surgery and Traumatology, İstanbul, Turkey

Objective: Acute low back pain (LBP) is the leading cause of disability worldwide, whereas the ideal initial treatment protocol is still under debate. The aim of this study was to question, whether acetaminophen combined with etodolac or diclofenac could provide efficient ease of symptoms in patients with acute LBP and to assess whether one combination could be superior compared to the other in terms of clinical and functional outcomes, with health-related quality of life.

Materials and Methods: A retrospective, comparative study of 67 patients with acute, non-radicular, and non-traumatic LBP was undertaken. Patients were assessed in two groups, whereas daily, group one [34 patients, mean age of 47.1 (range 24-56)] received 4x500 mg acetaminophen combined with 2x400 mg etololac and the group two [33 patients, mean age of 44.8 (range 26-53)] received 4x500 mg acetaminophen combined with 2x75 mg diclofenac, for one week. Patients' pre-treatment and post-treatment visual analog scale (VAS), Oswestry Disability Index (ODI), and Roland-Morris Disability Questionnaire (RMDQ) scores were recorded and compared.

Results: Group 1-2 had a pre-treatment mean VAS back score of 7.4-7.1, ODI score of 76.2-75.8 and RMDQ score of 18.2-19.4 improved to 1.4-1.3, 16.1-16.4, and 5.8-6.2 at the end of 1st week (p<0.001 for all), which further improved to 1.1-1.2, 15.8-15.3, and 3.3-3.2 (p<0.001 for all) at the end of 12th week. Intergroup comparison yielded no statistically significant data (p>0.05 for all).

Conclusion: Daily 2000 mg acetaminophen combined with 800 mg etodolac or 150 mg diclofenac could provide effective and sustained pain relief, with significant clinical and functional amelioration resulting in significant improvements in health-related quality of life, if applied under strict indication criteria to patients with acute non-traumatic and non-radicular LBP.

Keywords: Acute low back pain, acetaminophen, non-steroidal anti-inflammatory drugs, etodolac, diclofenac, health-related quality of life, visual analog scale, Oswestry Disability Index, Roland Morris Disability Questionnaire

INTRODUCTION

Low back pain (LBP) is on the most prevalent global health problem^(1,2), with a global point prevalence ranging between 18 to 33%^(3,4). It was reported, that over 80% of the population had at least one episode of acute LBP in their lifetime. Even with proper management, LBP was reported to cause a tremendous economical burden, while over 50 billion United States Dollars was reported as the estimated total costs associated with LBP in the United States⁽⁵⁾ and 3.5 billion Euros in the Netherlands⁽⁶⁾. Acute LBP was defined as pain originating between the lower border of the scapula and upper gluteal folds and lasting shorter than 12 weeks frequently attributed to non-specific causes without any certain etiology^(7,8). Patients with acute, new - onset LBP were reported to have a favorable prognosis with complete resolution of pain in 80% of patients, while up

to 20% of patients might experience moderate to severe pain 3 months later and 30% of them were noted to have LBP-related functional impairment^(9,10).

Current guidelines recommend acetaminophen as the first line of analgesic treatment^(11,12), while it was neither based on strong evidence^(3,13), nor on its analgesic efficacy in patients with acute LBP, but on a relatively superior safety profile compared to other non-steroidal anti-inflammatory drugs (NSAIDs)⁽⁸⁾. However, because of the lack of symptomatic efficacy as monotherapy, acetaminophen was recommended to be used along with other NSAIDs^(14,15).

The aim of this study was to question, whether acetaminophen combined with etodolac or diclofenac could provide efficient ease of symptoms in patients with acute LBP and to assess whether one combination could be superior compared to the other by comparing the pre- and post-treatment results of

Address for Correspondence: Tuna Pehlivanoğlu, Liv Hospital Ulus, Department of Orthopedic Surgery and Traumatology, İstanbul, Turkey Phone: +90 533 393 66 00 E-mail: dr.tuna@hotmail.com Received: 13.01.2023 Accepted: 03.04.2023 ORCID ID: orcid.org/0000-0001-8886-7538



[©]Copyright 2023 by the Turkish Spine Society / The Journal of Turkish Spinal Surgery published by Galenos Publishing House. Licensed by Creative Commons Attribution-NonCommercial 4.0 International (CC BY-NC-ND 4.0). Roland-Morris Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI), and visual analog scale (VAS) back scores.

MATERIALS AND METHODS

After obtaining institutional review board approval (Florence Nightingale Hospital, FNG-A 710), a retrospective, comparative study was performed on assessing consecutive patients in 2022 (January to November), who received conservative treatment with acute LBP. One hundred forty three consecutive patients were identified. The following inclusion criteria were applied: (1) having a new episode of LBP (defined as pain between the 12th rib and gluteal crease), (2) having LBP of less than 6 weeks of duration preceded by a painless period for at least 1 month, (3) being 18-60 years old, (4) having been treated with acetaminophen combined with etodolac or diclofenac, and (5) being willing to participate in the study. The following exclusion criteria were applied: (1) having radicular pain, (2) having a history of trauma, malignancy or metabolic bone disease, (3) having a diagnosis of spinal infection, fracture or neoplasm, (4) having a history of spinal surgery, (5) using any type of analgesic drug before the initiation of the current treatment regimen, (6) using any type of psychotropic drug currently, (7) having applied conservative treatment other than acetaminophen combined with etodolac or diclofenac due to any reason (allergy, contraindication, physician's preference), (8) being younger than 18, older than 60 years of age, and (9) being unwilling to participate in the study (Table 1). Because of the aforementioned criteria, 76 patients were excluded (16: radicular pain, 14: history of trauma, malignancy or metabolic bone disease, 12: having an age >60, 11: diagnosis of spinal infection, fracture or neoplasm, 9: usage of analgesic drug(s)



before the initiation of the treatment, 7: having applied other drug(s) combination as conservative treatment, 4: being unwilling to participate, 3: usage of psychotropic drug(s) before the initiation of the treatment) (Table 2). The remaining 67 patients were included in the study.

The study was approved by the Demiroğlu Bilim University Ethics Committee (decision no: 24345, date: 17.01.2023).

Treatment Protocol

All patients were prescribed a daily dosage of 4x500 mg acetaminophen combined with 2x400 mg etodolac or 2x75 mg diclofenac taken orally in addition to advice and reassurance regarding the course of the acute LBP underlining remaining active, avoiding bed rest and resuming normal movement as soon as possible.

Clinical Outcome Parameters (COP)

As the patient reported outcome questionnaires ODI scores,VAS back scores were applied to evaluate the clinical and functional outcomes. RMDQ, which is 24 point-scale, was applied to evaluate LBP and related functional impairment in terms of disability. The aforementioned scores were applied before the initiation of the treatment and at 1st, 2nd, 4th, 6th, 8th and 12th week after the initiation of the medical treatment.

Information of Informed Consent

All patients were taken informed consent, so that their pre-, intra-, and post-operative data could be used for publication by hiding their identity.

Statistical Analysis

For the statistical analysis, SPSS software (Version 22.0; SPSS Inc, Chicago, IL, USA) was used. Data are expressed as mean +/- standard deviation. The chi-square test and Fisher's exact

Table 1. Inclusion and exclusion criteria		
Inclusion criteria	Exclusion criteria	
Having a new episode of LBP (defined as pain between the $12^{\rm th}$ rib and gluteal crease)	Having radicular pain	
Having LBP of less than 6 weeks of duration preceded by a painless period for at least 1 month	Having a history of trauma, malignancy, or metabolic bone disease	
Being 18-60 years old, (4) having been treated with acetaminophen combined with etodolac (2x400 mg) or diclofenac (2x75 mg)	Having a diagnosis of spinal infection, fracture or neoplasm	
Having been treated with acetaminophen combined with etodolac or ketorolac	Having a history of spinal surgery	
Being willing to participate in the study	Using any type of analgesic drug before the initiation of the current treatment regimen	
-	Using any type of psychotropic drug currently	
-	Having applied conservative treatment other than acetaminophen combined with etodolac or diclofenac due to any reason (allergy, contraindication, physician's preference)	
-	Being younger than 18, older than 60 years of age	
-	Being unwilling to participate in the study	
L PD: Low back pain		

LBP: Low back pain



test were used for the analysis of categorical variables and to compare different time points where appropriate. Oneway analysis of variance (ANOVA) was used to determine a significant difference at various time points. A p-value less than 0.05 was considered as statistically significant.

RESULTS

Sixty seven consecutive patients (52 females, 15 males) with acute LBP, which was treated with a daily dosage of 4x500 mg acetaminophen combined with 2x400 mg etodolac or 2x75 mg diclofenac taken orally for one week were enrolled. Patients were divided into two groups, which were comparable in terms of their demographic values and pre-treatment clinical and functional scores Table 3. Group 1 was applied 4x500 mg acetaminophen combined with 2x400 mg etodolac for one week. It comprised 34 patients with a mean age of 47.1 (range 24-56). Group 1 had a pre-treatment mean VAS back score of 7.4 (range 5-9), ODI score of 76.2 (range 72-81), and mean RMDQ

score of 18.2 (range 14-23). At the 1st week follow-up, group 1 had a mean VAS back score of 1.4 (range 0-2), ODI score of 16.1 (range 15-21), and mean RMDQ score of 5.8 (range 0-13) (p<0.001 for all). At the 12th week follow-up, group 1 had a mean VAS back score of 1.1 (range 0-2), ODI score of 15.8 (range 15-18), mean RMDQ score of 3.3 (range 0-9) (p<0.001 for all). It was detected, that the treatment protocol was yielding remarkable improvements regarding the clinical and functional outcomes with high statistical significance from pre-treatment to the 1st week post-treatment, and from 1st week post-treatment to 12th week post-treatment. Group 2 was applied 4x500 mg acetaminophen combined with 2x75 mg diclofenac for one week. It comprised 33 patients with a mean age of 44.8 (range 26-53). Group 2 had a pre-treatment mean VAS back score of 7.1 (range 5-9), ODI score of 75.8 (range 71-80), and mean RMDQ score of 19.4 (range 13-22). At the 1st week follow-up, group 2 had a mean VAS back score of 1.3 (range 0-2), ODI score of 16.4 (range 15-21), and mean RMDQ score of 6.2 (range 2-15)

Consecutive Patients with acute Low Back Pain (Assessed for eligibility) n = 143 (79 females, 64 males)	 Patients were excluded from the study: n = 76 (27 females, 49 males) 16: radicular pain 14: history of trauma, malignancy, or metabolic bone disease 12: having an age >60 11: diagnosis of spinal infection, fracture or neoplasm
v	 initiation of the treatment 7:having applied other drug(s) combinations as conservative treatment 4: being unwilling to participate 3: usage of psychotropic drug(s) before the initiation of the treatment
Patients included in the study and randomized by computer software n = 67 (52 females, 15 males)	

Table 2. Flowchart of the study population

 Table 3. Demographic data, pre-treatment clinical and functional scores

5 1 /1				
	Group 1	Group 2	p-value	
Number	34	33	0.34	
Age	47.1 (range 24-56)	44.8 (range 26-53)	0.47	
Treatment protocol	4x500 mg acetaminophen + 2x400 mg etodolac	4x500 mg acetaminophen + 2x75 mg diclofenac	N/A	
Mean VAS back score	7.4 (range 5-9)	7.1 (range 6-9)	0.24	
Mean ODI score	76.2 (range 72-81)	75.8 (range 71-80)	0.39	
Mean RMDQ	18.2 (range 14-23)	19.4 (range 13-22)	0.27	
VAS-Visual analogue scale ODI: Oswestry Disability Index, RMDO: Roland-Morris Disability Questionnaire				



Table 4. Comparison of Post-treatment cunicat and functional scores				
	Group 1	Group 2	p-value	
Post-treatment 1 st week				
Mean VAS back score	1.4 (range 0-2)	1.3 (range 0-2)	0.41	
Mean ODI score	16.1 (range 15-21)	16.4 (range 15-21)	0.24	
Mean RMDQ	5.8 (range 0-13)	6.2 (range 2-15)	0.27	
Post-treatment 12 th week				
Mean VAS back score	1.1 (range 0-2)	1.2 (range 0-2)	0.39	
Mean ODI score	15.8 (range 15-18)	15.3.(range 15-20)	0.27	
Mean RMDQ	3.3 (range 0-9)	3.2 (range 0-11)	0.34	

 Table 4. Comparison of Post-treatment clinical and functional scores

VAS: Visual analogue scale, ODI: Oswestry Disability Index, RMDQ: Roland-Morris Disability Questionnaire

(p<0.001 for all). At the 12th week follow-up, group 2 had a mean VAS back score of 1.2 (range 0-2), ODI score of 15.3 (range 15-20), and mean RMDQ score of 3.2 (range 0-11) (p<0.001 for all). It was detected, that the treatment protocol was yielding remarkable improvements regarding the clinical and functional outcomes with high statistical significance from pre-treatment to the 1st week post-treatment, and from 1st week posttreatment to 12th week post-treatment similar to the results of group 1. Intergroup comparison of clinical-functional outcomes recorded in post-treatment periods yielded no statistical significance (p>0.05 for VAS, ODI and RMDQ scores at all times) attributed to equal treatment efficacy and success of both treatment combinations Table 4. In groups 1 and 2 following adverse events were reported: Gastrointestinal problems including diarrhea (2-1) (p=0.26) and dizziness (1-2) (p=0.34). Patients in both groups were detected to have relatively low rates of complications, underlining the safety of the treatment protocols.

DISCUSSION

This study reported that 2000 mg acetaminophen combined with either 800 mg etodolac or 150 mg diclofenac could provide effective clinical and functional recovery together with successful pain relief in the short term in patients with acute nontraumatic, non-radicular LBP. However, no clinically significant difference regarding the clinical and functional outcomes between the two two treatment protocols were detected. The literature is highly conflicting regarding the ideal treatment of acute LBP. Recent clinical guidelines prepared for the initial treatment of acute LBP recommend the use of acetaminophen as the first line of medical treatment and NSIADs as the second line of treatment, which could be added to acetaminophen in addition to general recommendations including staying active, avoiding rest, and returning to daily activities as soon as possible^(1,11). The PACE study, as a double-blind randomized study regarding the efficacy of acetaminophen for acute LBP, reported, that neither regular, nor as-needed usage of acetaminophen as a standalone treatment for acute LBP provided improved recovery, as compared to placebo⁽⁸⁾. In addition, they also noted, that acetaminophen as a standalone treatment for acute LBP had no effect on function, pain, quality of life, disability, sleep, and global symptom change⁽⁸⁾. In conjunction with the aforementioned study, we seldom prescribe acetaminophen as the initial standalone treatment for patients with acute LBP. However, acetaminophen was reported to be ineffective if used as the standalone treatment⁽¹⁴⁾. Therefore, NSAIDs were recommended to be added to acetaminophen to provide superior pain management for patients with acute LBP^(10,15). Plapler et al.⁽¹⁶⁾ reported in their double-blind, randomized study, that ketorolac could provide faster pain relief compared with naproxen in patients with acute LBP. Irizarry et al.⁽¹⁵⁾ reported in their randomized controlled trial conducted to compare the efficacy of ibuprofen versus ketorolac versus diclofenac, that ketorolac resulted in better pain relief and less gastric irritation compared with ibuprofen. However, there is a lack of data in the current literature regarding the efficacy of etodolac versus diclofenac combined with acetaminophen for acute LBP. This is why we also preferred to compare etodolac or diclofenac combined with acetaminophen to assess the efficacy of pain management, which was equally successful in both groups. The ideal treatment combination of LBP still constitutes a controversy. Acetaminophen was determined to have a safer profile in terms of adverse effects, as compared to NSAIDs, leading to the recommendation of it as the first -line treatment^(10,17). We similarly reported rates of adverse effects in both groups of patients, while non of them necessitated any change in the treatment protocol. Opposed to our findings, Friedman et al.⁽¹⁰⁾ reported, that when combined with an NSAID, acetaminophen had no additional benefit in acute LBP. Another double blind-randomized study, conducted by Ridderikhof et al.⁽¹⁷⁾ reported that 50 mg diclofenac combined with 1000 mg acetaminophen was not superior compared to diclofenac alone, while similar to our study, both treatments provided efficient pain relief after 3 days. A Cochrane review concluded that, NSAIDs were marginally better than placebo for acute LBP, whereas a combination with acetaminophen was not assessed⁽¹⁸⁾.

Study Limitations

This study has some limitations. First, it is a retrospective study with a limited number of patients, which is owed to strict



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inclusion criteria to have less biased data with homogenous patient groups. Another limitation is having no placebo group because of the retrospective nature of the study. Another limitation is, that despite the fact, that patients were strictly advised to stick to the drugs, that were prescribed by their physician, they might still take additional analgesics and did not inform their physician about that confounding the data provided for the study.

This study also possesses some strength. First, it is best to our knowledge the first study in the literature comparing the treatment efficacy of etodolac versus diclofenac combined with paracetamol in a highly selective group of patients with acute, non-traumatic, and non-radicular LBP, which is the leading cause of disability worldwide with no clear guideline for ideal treatment⁽¹⁹⁾. Another strength is, that it is a comparative study providing concrete data with good evidence.

CONCLUSION

This study concluded, that daily 2000 mg acetaminophen combined with 800 mg etodolac or 150 mg diclofenac could provide effective and sustained pain relief, with significant clinical and functional amelioration resulting in significant improvements in health-related quality of life, if applied under strict indication criteria to patients with acute non-traumatic and non-radicular LBP.

Ethics

Ethics Committee Approval: The study was approved by the Demiroğlu Bilim University Ethics Committee (decision no: 24345, date: 17.01.2023).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: C.B., T.P., Concept: C.B., T.P., Design: C.B., T.P., Data Collection or Processing: C.B., T.P., Analysis or Interpretation: C.B., T.P., Literature Search: C.B., T.P., Writing: C.B., T.P.

Conflict of Interest: The authors have no conflicts of interest to declare.

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