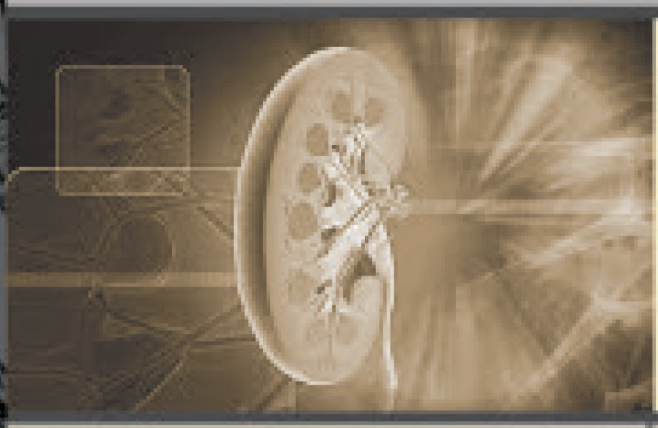
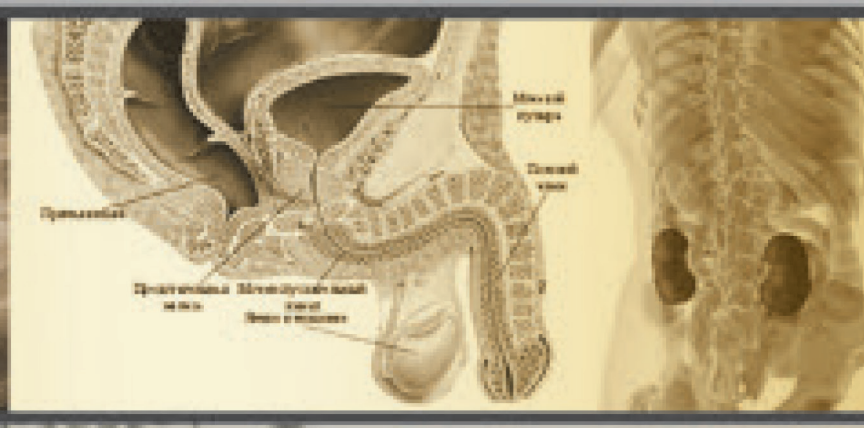
2010
Society of Urological Surgery in Turkiye

E-ISSN 2148- 9580

JOURNAL OF UROLOGICAL SURGERY

Volume 9 / Issue 1 / March 2022 www.jurolsurgery.org





galenos yayinevi

Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

EDITORIAL BOARD

Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

galenos yayınevi

Galenos Publishing House
Owner and Publisher
Derya Mor
Erkan Mor
Publication Coordinator
Burak Sever
Web Coordinators
Fuat Hocalar
Turgay Akpınar
Graphics Department
Ayda Alaca
Çiğdem Birinci
Gülay Saday
Gülşah Özgül
Finance Coordinator
Sevinç Çakmak

Project Coordinators
Aysel Balta
Duygu Yıldırım
Gamze Aksoy
Gülay Akın
Hatice Sever
Melike Eren
Özlem Çelik Çekil
Pınar Akpınar
Rabia Palazoğlu
Research&Development
Melisa Yiğitoğlu
Nihan Karamanlı
Digital Marketing Specialist
Ümit Topluoğlu

Publisher Contact
Address: Molla Gürani Mah. Kaçamak Sk. No: 21/1 34093 İstanbul, Turkiye
Phone: +90 (212) 621 99 25 **Fax:** +90 (212) 621 99 27
E-mail: info@galenos.com.tr/yayin@galenos.com.tr
Web: www.galenos.com.tr
Publisher Certificate Number: 14521

Publication Date: March 2022

E-ISSN: 2148- 9580
International scientific journal published quarterly.

Reviewing the articles' conformity to the publishing standards of the Journal, typesetting, reviewing and editing the manuscripts and abstracts in English and publishing process are realized by Galenos.

Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

ABOUT US

Journal of Urological Surgery is the official open access scientific publication organ of the Society of Urological Surgery. Journal of Urologic Surgery is being published in İstanbul, Turkiye. It is a double peer-reviewed journal published quarterly in March, June, September and December.

Journal of Urological Surgery is indexed in Web of Science-Emerging Sources Citation Index (ESCI), DOAJ, EBSCO, CINAHL, Research Bib-Academic Resource Index, Root Indexing, TUBITAK/ULAKBIM Turkish Medical Database, TurkMedline, Turkiye Citation Index.

The target audience of the journal includes physicians working in the fields of urology and all other health professionals who are interested in these topics.

The editorial processes of the journal are shaped in accordance with the guidelines of the international organizations such as the International Council of Medical Journal Editors (ICMJE) (http://www.icmje.org) and the Committee on Publication Ethics (COPE) (http://publicationethics.org).

All manuscripts should be submitted through the journal's web page at www.jurolsurgery.org. Instructions for authors, technical information, and other necessary forms can be accessed over this web page. Authors are responsible for all content of the manuscripts.

Our mission is to provide practical, timely, and relevant clinical and basic science information to physicians and researchers practicing the urology worldwide. Topics of Journal of Urological Surgery include;

Pediatric urology,

Urooncology,

Andrology,

Functional urology,

Endourology,

Transplantation,

Reconstructive surgery,

Urologic pathology,

Urologic radiology,

Basic science,

General urology.

Special features include rapid communication of important timely issues, surgeon' workshops, interesting case reports, surgical techniques, clinical and basic science review articles, guest editorials, letters to the editor, book reviews, and historical articles in urology.

Open Access Policy

This journal provides immediate open access to its content on the principle that making research freely available to the public supports a greater global exchange of knowledge.

Open Access Policy is based on rules of Budapest Open Access Initiative (BOAI). http://www.budapestopenaccessinitiative.org/ By "open access" to [peer-reviewed research literature], we mean its free availability on the public internet, permitting any users to read, download, copy, distribute, print, search, or link to the full texts of these articles, crawl them for indexing, pass them as data to software, or use them for any other lawful purpose, without financial, legal, or technical barriers other than those inseparable from gaining access to the internet itself. The only constraint on reproduction and distribution, and the only role for copyright in this domain, should be to give authors control over the integrity of their work and the right to be properly acknowledged and cited.

Address for Correspondence

Ali Tekin

Mehmet Ali Aydınlar Acıbadem Üniversitesi Atakent Hastanesi

Turgut Özal Bulvarı No: 16 34303 Kucukcekmece-Istanbul, Turkiye

Issuing Body

Galenos Yayınevi Tic. Ltd. Şti.

Molla Gürani Mahallesi Kaçamak Sokak No: 21/1 34093 Fındıkzade, İstanbul, Turkiye

Phone : +90 212 621 99 25

Fax : +90 212 621 99 27

E-mail : info@galenos.com.tr

Instructions to Authors

Introductions for authors are published in the journal and on the web page http://jurolsurgery.org

Material Disclaimer

The author(s) is (are) responsible from the articles published in the The Journal of Urological Surgery. The editor, editorial board and publisher do not accept any responsibility for the articles.

Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

INSTRUCTIONS TO AUTHORS

Journal of Urological Surgery is the official publication of Society of Urological Surgery. The publication languages of the journal are English and Turkish.

Journal of Urological Surgery does not charge any fee for article submission or processing. Also manuscript writers are not paid by any means for their manuscripts.

The journal should be abbreviated as "J Urol Surg" when referenced.

The Journal of Urological Surgery accepts invited review articles, research articles, brief reports, case reports, letters to the editor, and images that are relevant to the scope of urology, on the condition that they have not been previously published elsewhere. Basic science manuscripts, such as randomized, cohort, cross-sectional, and case control studies, are given preference. All manuscripts are subject to editorial revision to ensure they conform to the style adopted by the journal. There is a single blind kind of reviewing system.

The Editorial Policies and General Guidelines for manuscript preparation specified below are based on "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations)" by the International Committee of Medical Journal Editors (201, archived at http://www.icmje.org/).

Editorial Process

Following receiving of each manuscript, a checklist is completed by the Editorial Assistant. The Editorial Assistant checks that each manuscript contains all required components and adheres to the author guidelines, after which time it will be forwarded to the Editor in Chief. Following the Editor in Chief's evaluation, each manuscript is forwarded to the Associate Editor, who in turn assigns reviewers. Generally, all manuscripts will be reviewed by at least three reviewers selected by the Associate Editor, based on their relevant expertise. Associate editor could be assigned as a reviewer along with the reviewers. After the reviewing process, all manuscripts are evaluated in the Editorial Board Meeting.

The Journal of Urological Surgery's editor and Editorial Board members are active researchers. It is possible that they would desire to submit their manuscript to the Journal of Urological Surgery. This may be creating a conflict of interest. These manuscripts will not be evaluated by the submitting editor(s). The review process will be managed and decisions made by editor-in-chief who will act independently. In some situation, this process will be overseen by an outside independent expert in reviewing submissions from editors.

Preparation of Manuscript

Manuscripts should be prepared according to ICMJE guidelines (http://www.icmje.org/).

Original manuscripts require a structured abstract. Label each section of the structured abstract with the appropriate subheading (Objective, Materials and Methods, Results, and Conclusion). Case reports require short unstructured abstracts. Letters to the editor do not require an abstract. Research or project support should be acknowledged as a footnote on the title page.

Technical and other assistance should be provided on the title page.

Title Page

Title: The title should provide important information regarding the manuscript's content.

The title page should include the authors' names, degrees, and institutional/professional affiliations, a short title, abbreviations, keywords, financial disclosure statement, and conflict of interest statement. If a manuscript includes authors from more than one institution, each author's name should be followed by a superscript number that corresponds to their institution, which is listed separately. Please provide contact information for the corresponding author, including name, e-mail address, and telephone and fax numbers.

Running Head: The running head should not be more than 40 characters, including spaces, and should be located at the bottom of the title page.

Word Count: A word count for the manuscript, excluding abstract, acknowledgments, figure and table legends, and references, should be provided not exceed 3000 words. The word count for an abstract should be not exceed 250 words.

Conflict of Interest Statement: To prevent potential conflicts of interest from being overlooked, this statement must be included in each manuscript. In case there are conflicts of interest, every author should complete the ICMJE general declaration form, which can be obtained at: http://www.icmje.org/coi_disclosure.pdf

Abstract and Keywords: The second page should include an abstract that does not exceed 250 words. For manuscripts sent by authors in Turkiye, a title and abstract in Turkish are also required. As most readers read the abstract first, it is critically important. Moreover, as various electronic databases integrate only abstracts into their index, important findings should be presented in the abstract.

Turkish abstract texts should be written in accordance with the Turkish Dictionary and Writing Guide of the Turkish Language Association.

Abstract

Objective: The abstract should state the objective (the purpose of the study and hypothesis) and summarize the rationale for the study.

Materials and Methods: Important methods should be written respectively.

2010 Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

INSTRUCTIONS TO AUTHORS

Results: Important findings and results should be provided here.

Conclusion: The study's new and important findings should be highlighted and interpreted.

Other types of manuscripts, such as case reports, reviews and others will be published according to uniform requirements. Provide at least 3 keywords below the abstract to assist indexers. Use terms from the Index Medicus Medical Subject Headings List (for randomized studies a CONSORT abstract should be provided (http://www.consort-statement.org).

After keywords in original research articles there must be a paragraph defining "What is known on the subject and what does the study add".

Original Research

Abstract length: Not to exceed 250 words. "What is known on the subject and what dos the study add" not exceed 100 words.

Article length: Not to exceed 3000 words.

Original researches should have the following sections:

Introduction: The introduction should include an overview of the relevant literature presented in summary form (one page), and whatever remains interesting, unique, problematic, relevant, or unknown about the topic must be specified. The introduction should conclude with the rationale for the study, its design, and its objective(s).

Materials and Methods: Clearly describe the selection of observational or experimental participants, such as patients, laboratory animals, and controls, including inclusion and exclusion criteria and a description of the source population. Identify the methods and procedures in sufficient detail to allow other researchers to reproduce your results. Provide references to established methods (including statistical methods), provide references to brief modified methods, and provide the rationale for using them and an evaluation of their limitations. Identify all drugs and chemicals used, including generic names, doses, and routes of administration. The section should include only information that was available at the time the plan or protocol for the study was devised on STROBE (http://www.strobe-statement.org/).

Statistics: Describe the statistical methods used in enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. Statistically important data should be given in the text, tables and figures. Provide details about randomization, describe treatment complications, provide the number of observations, and specify all computer programs used.

Results: Present your results in logical sequence in the text, tables, and figures. Do not present all the data provided in the tables and/or figures in the text; emphasize and/or summarize only important findings, results, and observations in the text. For clinical studies provide the number of samples, cases, and controls included in the study. Discrepancies between the planned number and obtained number of participants should be explained. Comparisons, and statistically important values (i.e. p value and confidence interval) should be provided.

Discussion: This section should include a discussion of the data. New and important findings/results, and the conclusions they lead to should be emphasized. Link the conclusions with the goals of the study, but avoid unqualified statements and conclusions not completely supported by the data. Do not repeat the findings/results in detail; important findings/results should be compared with those of similar studies in the literature, along with a summarization. In other words, similarities or differences in the obtained findings/results with those previously reported should be discussed.

Study Limitations: Limitations of the study should be detailed. In addition, an evaluation of the implications of the obtained findings/results for future research should be outlined.

Conclusion: The conclusion of the study should be highlighted.

References

Cite references in the text, tables, and figures with numbers in parentheses. Number references consecutively according to the order in which they first appear in the text. Journal titles should be abbreviated according to the style used in Index Medicus (consult List of Journals Indexed in Index Medicus). Include among the references any paper accepted, but not yet published, designating the journal and followed by, in press. Authors are solely responsible for the accuracy of all references.

Examples of References:

1. List All Authors

Ghoneim IA, Miocinovic R, Stephenson AJ, Garcia JA, Gong MC, Campbell SC, Hansel DE, Fergany AF. Neoadjuvant systemic therapy or early cystectomy? Singlecenter analysis of outcomes after therapy for patients with clinically localized micropapillary urothelial carcinoma of the bladder. Urology 2011;77:867-870.

2. Organization as Author

Yaycioglu O, Eskicorapci S, Karabulut E, Soyupak B, Gogus C, Divrik T, Turkeri L, Yazici S, Ozen H; Society of Urooncology Study Group for Kidney Cancer Prognosis. A preoperative prognostic model predicting recurrence-free survival for patients with kidney cancer. Jpn J Clin Oncol 2013;43:63-68.

3. Complete Book

Wein AJ, Kavoussi LR, Novick AC, Partin AW, Peters CA. Campbell-Walsh Urology, 10th ed. Philadelphia, Elsevier&Saunders, 2012.

4. Chapter in Book

Pearle MS, Lotan Y Urinary lithiasis: etiology, epidemiology, and pathogenesis. In: Wein AJ, Kavoussi LR, Novick AC, Partin AW, Peters CA. Campbell-Walsh Urology, 10th ed. Philadelphia, Elsevier&Saunders, 201, pp 1257-1323.

Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

INSTRUCTIONS TO AUTHORS

5. Abstract

Nguyen CT, Fu AZ, Gilligan TD, Kattan MW, Wells BJ, Klein EA. Decision analysis model for clinical stage I nonseminomatous germ cell testicular cancer. J Urol 2008;179:495a (abstract).

6. Letter to the Editor

Lingeman JE. Holmium laser enucleation of the prostate-If not now, when? J Urol 2011;186:1762-1763.

7. Supplement

Fine MS, Smith KM, Shrivastava D, Cook ME, Shukla AR. Posterior Urethral Valve Treatments and Outcomes in Children Receiving Kidney Transplants. J Urol 2011;185(Suppl):2491-2496.

Case Reports

Abstract length: Not to exceed 100 words.

Article length: Not to exceed 1000 words.

Case Reports can include maximum 1 figure and 1 table or 2 figures or 2 tables.

Case reports should be structured as follows:

Abstract: An unstructured abstract that summarizes the case.

Introduction: A brief introduction (recommended length: 1-2 paragraphs).

Case Presentation: This section describes the case in detail, including the initial diagnosis and outcome.

Discussion: This section should include a brief review of the relevant literature and how the presented case furthers our understanding to the disease process.

Review Articles

Abstract length: Not to exceed 250 words.

Article length: Not to exceed 4000 words.

Review articles should not include more than 100 references. Reviews should include a conclusion, in which a new hypothesis or study about the subject may be posited. Do not publish methods for literature search or level of evidence. Authors who will prepare review articles should already have published research articles on the relevant subject. There should be a maximum of two authors for review articles.

Images in Urological Surgery

Article length: Not to exceed 500 words.

Authors can submit for consideration an illustration and photos that is interesting, instructive, and visually attractive, along with a few lines of explanatory text and references. Images in Urology can include no more than 500 words of text, 5 references, and 3 figure or table. No abstract, discussion or conclusion are required but please include a brief title.

Urological Pathology

Article length: Not to exceed 500 words.

Urological pathology can include no more than 500 words of text, 5 references, and 3 figure or table. No abstract, discussion or conclusion are required but please include a brief title.

Letters to the Editor

Article length: Not to exceed 500 words.

Letters can include no more than 500 words of text, 5-10 references, and 1 figure or table. No abstract is required, but please include a brief title.

How I do?

Unstructured abstract: Not to exceed 50 words.

Article length: Not to exceed 1500 word.

Urologic Survey

Article length: Not to exceed 250 words.

Tables, Graphics, Figures, and Images

Tables: Supply each table on a separate file. Number tables according to the order in which they appear in the text, and supply a brief caption for each. Give each column a short or abbreviated heading. Write explanatory statistical measures of variation, such as standard deviation or standard error of mean. Be sure that each table is cited in the text.

Figures: Figures should be professionally drawn and/or photographed. Authors should number figures according to the order in which they appear in the text. Figures include graphs, charts, photographs, and illustrations. Each figure should be accompanied by a legend that does not exceed 50 words. Use abbreviations only if they have been introduced in the text. Authors are also required to provide the level of magnification for histological slides. Explain the internal scale and identify the staining method used. Figures should be submitted as separate files, not in the text file. High-resolution image files are not preferred for initial submission as the file sizes may be too large. The total file size of the PDF for peer review should not exceed 5 MB.

Authorship

Each author should have participated sufficiently in the work to assume public responsibility for the content. Any portion of a manuscript that is critical to its main conclusions must be the responsibility of at least 1 author.

Contributor's Statement

All submissions should contain a contributor's statement page. Each manuscript should contain substantial contributions to idea and design,

2010 Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

INSTRUCTIONS TO AUTHORS

acquisition of data, or analysis and interpretation of findings. All persons designated as an author should qualify for authorship, and all those that qualify should be listed. Each author should have participated sufficiently in the work to take responsibility for appropriate portions of the text.

Acknowledgments

Acknowledge support received from individuals, organizations, grants, corporations, and any other source. For work involving a biomedical product or potential product partially or wholly supported by corporate funding, a note stating, "This study was financially supported (in part) with funds provided by (company name) to (authors' initials)", must be included. Grant support, if received, needs to be stated and the specific granting institutions' names and grant numbers provided when applicable.

Authors are expected to disclose on the title page any commercial or other associations that might pose a conflict of interest in connection with the submitted manuscript. All funding sources that supported the work and the institutional and/or corporate affiliations of the authors should be acknowledged on the title page.

Ethics

When reporting experiments conducted with humans indicate that the procedures were in accordance with ethical standards set forth by the committee that oversees human experimentation. Approval of research protocols by the relevant ethics committee, in accordance with international agreements (Helsinki Declaration of 197, revised 2013 available at http://www.wma.net/e/policy/b3.htm, "Guide for the Care and use of Laboratory Animals" www.nap.edu/catalog/5140.html/), is required for all experimental, clinical, and drug studies. Studies performed on human require ethics committee certificate including approval number. It also should be indicated in the "Materials and Methods" section. Patient names, initials, and hospital identification numbers should not be used. Manuscripts reporting the results of experimental investigations conducted with humans must state that the study protocol received institutional review board approval and that the participants provided informed consent.

Non-compliance with scientific accuracy is not in accord with scientific ethics.

Plagiarism: To re-publish whole or in part the contents of another author's publication as one's own without providing a reference. Fabrication: To publish data and findings/results that do not exist.

Duplication: Use of data from another publication, which includes re-publishing a manuscript in different languages.

Salamisation: To create more than one publication by dividing the results of a study preternaturally.

We disapproval upon such unethical practices as plagiarism, fabrication, duplication, and salamisation, as well as efforts to influence the review process with such practices as gifting authorship, inappropriate acknowledgements, and references. Additionally, authors must respect participant right to privacy.

On the other hand, short abstracts published in congress books that do not exceed 400 words and present data of preliminary research, and those that are presented in an electronic environment are not accepted pre-published work. Authors in such situation must declare this status on the first page of the manuscript and in the cover letter. (The COPE flowchart is available at: http://publicationethics.org).

We use iThenticate to screen all submissions for plagiarism before publication.

Conditions of Publication

All authors are required to affirm the following statements before their manuscript is considered:

1. The manuscript is being submitted only to The Journal of Urological Surgery

2. The manuscript will not be submitted elsewhere while under consideration by The Journal of Urological Surgery

3. The manuscript has not been published elsewhere, and should it be published in the Journal of Urological Surgery it will not be published elsewhere without the permission of the editors (these restrictions do not apply to abstracts or to press reports for presentations at scientific meetings)

4. All authors are responsible for the manuscript's content

5. All authors participated in the study concept and design, analysis and interpretation of the data, drafting or revising of the manuscript, and have approved the manuscript as submitted. In addition, all authors are required to disclose any professional affiliation, financial agreement, or other involvement with any company whose product figures prominently in the submitted manuscript.

Authors of accepted manuscripts will receive electronic page proofs and are responsible for proofreading and checking the entire article within two days. Failure to return the proof in two days will delay publication. If the authors cannot be reached by email or telephone within two weeks, the manuscript will be rejected and will not be published in the journal.

Copyright

At the time of submission all authors will receive instructions for submitting an online copyright form. No manuscript will be considered for review until all authors have completed their copyright form. Please note, it is our practice not to accept copyright forms via fax, e-mail, or postal service unless there is a problem with the online author accounts that cannot be resolved. Every effort should be made to use the online copyright system. Corresponding authors can log in to the submission system at any time to check the status of any co-author's copyright form. All accepted

Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

INSTRUCTIONS TO AUTHORS

manuscripts become the permanent property of the Journal of Urological Surgery and may not be published elsewhere in whole or in part without written permission.

If article content is copied or downloaded for non-commercial research and education purposes, a link to the appropriate citation [authors, journal, article title, volume, issue, page numbers, digital object identifier (DOI)] and the link to the definitive published version should be maintained. Copyright notices and disclaimers must not be deleted.

Note: We cannot accept any copyright that has been altered, revised, amended, or otherwise changed. Our original copyright form must be used as is.

Copyright Transfer Form

Abbreviations and Symbols

Use only standard abbreviations. Avoid abbreviations in the title and abstract. The full term for an abbreviation should precede its first use in the text, unless it is a standard abbreviation. All acronyms used in the text should be expanded at first mention, followed by the abbreviation in parentheses; thereafter the acronym only should appear in the text. Acronyms may be used in the abstract if they occur 3 or more times therein, but must be reintroduced in the body of the text. Generally, abbreviations should be limited to those defined in the AMA Manual of Style, current edition. A list of each abbreviation (and the corresponding full term) used in the manuscript must be provided on the title page.

Online Article Submission Process

The Journal of Urological Surgery uses submission software powered by Online Article Submission articles the website for submissions to the Journal of Urological Surgery is http://submitjurolsurgery.org. This system is quick and convenient, both for authors and reviewers.

The Review Process

Each manuscript submitted to the Journal of Urological Surgery is subject to an initial review by the editorial office in order to determine if it is aligned with the journal's aims and scope, and complies with essential requirements. Manuscripts sent for peer review will be assigned to one of the journal's associate editors that has expertise relevant to the manuscript's content. All manuscripts are single-blind peer reviewed. All accepted manuscripts are sent to a statistical and English language editor before publishing. Once papers have been reviewed, the reviewers' comments are sent to the Editor, who will then make a preliminary decision on the paper. At this stage, based on the feedback from reviewers, manuscripts can be accepted, rejected, or revisions can be recommended. Following initial peer-review, articles judged worthy of further consideration often require revision. Revised manuscripts generally must be received within 3 months of the date of the initial decision. Extensions must be requested from the Associate Editor at least 2 weeks before the 3-month revision deadline expires; the Journal of Urological Surgery will reject manuscripts that are not received within the 3-month revision deadline. Manuscripts with extensive revision recommendations will be sent for further review (usually by the same reviewers) upon their re-submission. When a manuscript is finally accepted for publication, the Technical Editor undertakes a final edit and a marked-up copy will be e-mailed to the corresponding author for review and to make any final adjustments.

English Language Editing

All manuscripts are professionally edited by an English language editor prior to publication.

Subscription Information

Address: Angora Cad. 2007 Sokak Vadikent 90 sit. No: 41 Beysukent/ANKARA
Telephone: +90 312 236 18 55
Fax: +90 312 236 27 69
Online Submission: submitjurolsurgery.org
Web page: jurolsurgery.org
E-mail: info@jurolsurgery.org

Correspondence

All correspondence should be directed to the journal's editorial.
Editor-in-chief: Ali Tekin
Mehmet Ali Aydınlar Acıbadem Üniversitesi Atakent Hastanesi
Turgut Özal Bulvarı No: 16 34303 Kucukcekmece-Istanbul, Turkiye

Society of Urological Surgery

JOURNAL OF UROLOGICAL SURGERY

CONTENTS

ORIGINAL RESEARCH
Endourology

Doi: 10.4274/jus.galenos.2021.2021.0048
J Urol Surg, 2022;9(1):1-8

The Comparison of Conventional and Retzius-Sparing Robot-Assisted Radical Prostatectomy for Clinical, Pathological, and Oncological Outcomes

Nejdet Karşıyakalı[1], Mahir Bülent Özgen[1], Bora Özveren[1], Haydar Durak[2], Yeşim Sağlıcan[3], Levent Türkeri[1]

[1]Acıbadem Mehmet Ali Aydınlar University, Altunizade Hospital, Clinic of Urology, İstanbul, Turkiye
[2]Acıbadem Mehmet Ali Aydınlar University, Altunizade Hospital, Clinical Pathology Laboratory, İstanbul, Turkiye
[3]Acıbadem Mehmet Ali Aydınlar University, Maslak Hospital, Clinic of Pathology, İstanbul, Turkiye

What's known on the subject? and What does the study add?

Initial description of the surgical technique involves the dissection of the Retzius space after dropping the bladder from the anterior abdominal wall which is now considered as the "conventional" method of robot-assisted radical prostatectomy (cRARP). Retzius-sparing RARP (RsRARP; Bocciardi approach) was initially introduced by Galfano et al. in 2010 and it is one of the most innovative surgical approaches which allows preservation of deep dorsal venous complex and anatomical structures responsible for urinary continence such as urinary sphincter, endopelvic fascia, and puboprostatic ligaments. RsRARP appears to have superior early continence recovery and similar oncologic outcomes when compared to cRARP. Studies of direct comparison of cRARP with RsRARP in the hands of the same surgeon(s) are still limited. In this study we presented our single-center, single-surgeon, long-term experience by comparing cRARP and RsRARP in terms of perioperative clinical, pathological, and oncological outcomes. One of the main emerging findings of this study was a shorter surgical time with RsRARP. RsRARP becomes prominent with a shorter surgery duration and similar complication rates when compared to cRARP in patients with higher ASA class scores even if they had higher cT stages and D'Amico clinical risk group in the preoperative evaluation indicating a safe surgical approach.

Abstract

Objective: This study aimed to assess and compare the conventional and Retzius-sparing robot-assisted radical prostatectomy (cRARP and RsRARP) in term of perioperative clinical, pathological, and oncological outcomes.

Materials and Methods: This study included 238 consecutive male patients who underwent RARP between May 2008 and November 2020. RARP operations were performed by a single-surgeon. Patients were divided into groups according to the surgical approach and were statistically compared in terms of perioperative clinical, final pathological, and oncological outcomes.

Results: The mean age of patients was 64±7 years. cRARP was performed in 134 (56.3%) patients, whereas RsRARP in 104 (43.7%). The frequency of patients with the American Society of Anesthesiologists Class-2 score was higher in the RsRARP group ($p<0.001$). The median surgery duration was 300 (270-360) min. The median surgery duration was shorter in RsRARP group (290 vs. 330 minute) ($p<0.001$). No difference was found between the groups in terms of estimated blood loss and postoperative complication rates ($p=0.112$ and $p=0.182$, respectively). No difference was found between the groups when they were compared for surgical margin positivity ($p=0.453$). Although not statistically significant, the frequency of surgical margin positivity with pT3a/pT3b disease was higher in patients who underwent cRARP ($p=0.412$ and $p=0.261$, respectively). At a median follow-up of 13 (6-36) months, no difference was found between the groups in terms of biochemical recurrence at months -3,-6,-9,-12,-18,-24, and -30, respectively ($p>0.05$, for each).

Conclusion: RsRARP allows a safe operation with a shorter surgical time and similar surgical margin positivity, oncological outcomes, and complication rates compared to cRARP.

Keywords: Retzius-sparing, robot-assisted radical prostatectomy, radical prostatectomy, robotics, prostate cancer

Correspondence: Nejdet Karşıyakalı MD, Acıbadem Mehmet Ali Aydınlar University, Altunizade Hospital, Clinic of Urology, İstanbul, Turkiye
Phone: +90 505 865 24 63 **E-mail:** nkarsiyakali@hotmail.com **ORCID-ID:** orcid.org/0000-0002-0709-0331
Received: 04.04.2021 **Accepted:** 14.05.2021

Cite this article as: Karşıyakalı N, Özgen MB, Özveren B, Durak H, Sağlıcan Y, Türkeri L. The Comparison of Conventional and Retzius-Sparing Robot-Assisted Radical Prostatectomy for Clinical, Pathological, and Oncological Outcomes. J Urol Surg, 2022;9(1):1-8.

Introduction

Radical prostatectomy (RP) is the recommended definitive surgical treatment modality for patients who had organ-confined prostate cancer (PCa) and are eligible for radical surgery with a life expectancy of at least 10 years (1). In 2000, robot-assisted RP (RARP) was reported for the first time as a consequence of technological advances in the field of medicine (2,3). Subsequent experience identified RARP as a minimally invasive surgical technique with proven advantages, such as reduced perioperative bleeding and blood transfusion, reduced postoperative pain, and reduced length of hospital stay compared to open RP (4,5). The initial description of the surgical technique involves the dissection of the Retzius space after dropping the bladder from the anterior abdominal wall, which is now considered as the "conventional" method of RARP (cRARP) (3,6). Several modifications in the surgical technique, such as restoration of the posterior aspect of rhabdosphincter, periurethral suspension stitch, total anatomic reconstruction, etc., were described to provide better functional outcomes (7-9). Retzius-sparing RARP (RsRARP; Bocciardi approach) was initially introduced by Galfano et al. (10) in 2010 and is one of the most innovative surgical approaches, which preserves the deep dorsal venous complex and anatomical structures responsible for urinary continence, such as urinary sphincter, endopelvic fascia, and puboprostatic ligaments.

Subsequent studies revealed that RsRARP has superior early continence recovery and similar oncologic outcomes compared to cRARP (11-14). However, studies that directly compare cRARP with RsRARP in the hands of the same surgeon(s) are still limited. Therefore, this study aimed to present our single-center, single-surgeon, and long-term experience by comparing cRARP and RsRARP in terms of perioperative clinical, pathological, and oncological outcomes to contribute to the cumulative body of knowledge on this topic.

Materials and Methods

Study Population and Surgical Approach

We retrospectively reviewed the medical records of male patients who underwent PCa surgery in Acıbadem Mehmet Ali Aydınlar University, Altunizade and Kadiköy Hospitals, Clinics of Urology between May 2008 and November 2020. The study included patients who were diagnosed with PCa and treated with RARP and with sufficient clinical information in their medical records. The Local Institutional Ethics Committee (IRB No: 2020-26/09) approved this study and all steps were planned and conducted following the Declaration of Helsinki and its later amendments. Written informed consent on admittance to the hospital was obtained from all individuals, which permitted the use of respective medical information in clinical studies.

Demographic and preoperative clinical characteristics of patients, perioperative surgical parameters, such as duration of surgery, estimated blood loss, postoperative complications according to the Clavien-Dindo (C-D) surgical complication classification (15), length of hospital stay, and catheterization duration, as well as pathological findings of both prostate biopsy and prostatectomy specimens, were recorded in detail for each patient. Clinically significant PCa was defined as the presence of the Gleason score of >6 or Gleason score of 6 diseases and tumor volume >0.5 cm^3 for prostatectomy specimens as previously reported by Epstein et al. (16). Prostate-specific antigen (PSA) levels were recorded for patients who continued their outpatient clinic follow-ups. Biochemical recurrence (BCR) was defined as PSA levels of 0.2 ng/mL or higher, which was confirmed by a repeat measurement at 2 weeks.

Patients who underwent open RP (n=3), whose Gleason score could not be evaluated in prostatectomy specimen due to neoadjuvant docetaxel chemotherapy (n=2), and those with missing clinical data (n=20) were excluded from the study. Patients were divided into two groups according to the surgical approach (cRARP and RsRARP groups).

A single-surgeon (L.T.) with experience in robotic surgery performed all RARP operations using DaVinci® Si or Xi Surgical Systems (Intuitive Surgical, Sunnyvale, CA, USA). cRARP operations were performed as previously described by Rocco et al. (7), while RsRARP operations were performed as described by Galfano et al. (10), with minor modifications in both operations. During RsRARP, the selection of fascial planes for dissection and transition from one plane to another was performed based on preoperative imaging and anatomical findings during surgery to achieve negative surgical margins. The surgical duration was described as the time interval between the first trocar insertion and suture closure of the last port site. All prostatectomy specimens were evaluated by two dedicated uro-pathologists (H.D. & Y.S.) following the latest International Society of Urologic Pathology (ISUP) criteria (17).

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences version 22.0 software (IBM Corp., Armonk, NY, USA). The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to check the normality of data for quantitative variables. Continuous variables were expressed in mean ± standard deviation and median and interquartile range, whereas categorical variables were expressed in number and frequency. The Pearson chi-square, Fisher Exact, Student t-test, and Mann-Whitney U tests were used wherever possible. A two-sided p-value of <0.05 was considered statistically significant.

Results

This study included 238 male patients. The mean age of patients was 64±7 years and the mean prostate volume was 52.34±22.55 mL. The median preoperative PSA level was 6.40 (4.60-10.00) ng/mL (Table 1). cRARP was performed in 134 (56.3%) patients, whereas RsRARP in 104 (43.7%). The frequency of patients with the American Society of Anesthesiologists (ASA) class-1 was higher in the cRARP group while the frequency of patients with ASA class-2 was higher in the RsRARP group (p<0.001) (Table 1). No difference was found between cRARP and RsRARP in terms of PSA levels and prostate volume (p=0.735 and p=0.283, respectively). The frequency of patients with cT1c disease, patients who had ISUP-grade group (GG)-1 in prostate biopsy specimens, and patients with the clinical low-risk group were higher in the cRARP group compared to the RsRARP group (p=0.024, p=0.003, and p=0.001, respectively) (Table 1).

The median surgery duration was 300 (270-360) min. The median estimated blood loss during the surgery was 50 (50-100) mL. The median length of hospital stay and catheterization duration was 2 (2-3) and 7 (7-9) days, respectively. The median follow-up was 13 (6-36) months (Table 2).

pT2, pT3a, pT3b, and pT4 disease were observed in 148 (62.2%), 59 (24.8%), 30 (12.6%), and 1 (0.4%) patients, respectively.

Table 1. Preoperative clinical characteristics of patients and pathological findings of prostate biopsy specimens and comparison of patients according to surgical approach in terms of preoperative clinical characteristics and pathological findings of prostate biopsy specimens

			Surgical approach		
		All patients (n=238, 100%)	**Conventional (n=134, 56.3%)**	**Retzius-sparing (n=104, 43.7%)**	
		n, %	**n, %**	**n, %**	**p-value$^{\Psi}$**
Age at surgery (year) (mean ± SD)		64±7	64±7	64±7	[a]0.470
Body mass index (kg/m^2) (mean ± SD)		26.68±3.44	26.91±3.64	26.53±3.33	[a]0.508
ASA-class	ASA class-1	84 (37.0%)	61 (49.6%)	23 (22.1%)	[b]<0.001*
	ASA class-2	139 (61.2%)	59 (48.0%)	80 (76.9%)	
	ASA class-3	4 (1.8%)	3 (2.4%)	1 (1.0%)	
Diabetes mellitus (yes)		36 (15.1%)	18 (13.4%)	18 (17.3%)	[c]0.408
Hypertension (yes)		91 (38.2%)	38 (28.4%)	53 (51.0%)	[c]<0.001*
Coronary artery disease (yes)		33 (13.9%)	19 (14.2%)	14 (13.5%)	[c]0.874
Chronic obstructive pulmonary disease (yes)		9 (3.8%)	5 (3.7%)	4 (3.8%)	[b]1.000
Digital rectal examination	Benign	199 (83.6%)	118 (88.1%)	81 (77.9%)	[c]0.035
	Suspicious	39 (16.4%)	16 (11.9%)	23 (22.1%)	
Preoperative PSA level (ng/mL) [median (IQR)]		6.40 (4.60-10.00)	6.40 (4.70-9.60)	6.34 (4.60-11.00)	[d]0.735
Prostate volume (cc) (mean ± SD)		52.34±22.55	53.75±21.24	50.56±24.08	[a]0.283
Clinical (c) T-stage	cT1a	2 (0.8%)	0	2 (2.1%)	[b]0.024*
	cT1b	3 (1.3%)	2 (1.5%)	1 (1.0%)	
	cT1c	194 (81.5%)	116 (86.6%)	78 (75.0%)	
	cT2a	10 (4.2%)	3 (2.2%)	7 (6.7%)	
	cT2b	25 (10.5%)	13 (9.7%)	12 (11.5%)	
	cT2c	4 (1.7%)	0	4 (3.8%)	
Prostate biopsy ISUP-grade group	ISUP-1	75 (31.5%)	56 (41.8%)	19 (18.3%)	[c]0.003*
	ISUP-2	88 (37.0%)	44 (32.8%)	44 (42.3%)	
	ISUP-3	44 (18.5%)	20 (14.9%)	24 (23.2%)	
	ISUP-4	16 (6.7%)	6 (4.5%)	10 (9.6%)	
	ISUP-5	15 (6.3%)	8 (6.0%)	7 (6.7%)	
D'Amico clinical risk group	Low-risk	56 (23.5%)	43 (32.1%)	13 (12.5%)	[c]0.001*
	Intermediate-risk	142 (59.7%)	73 (54.5%)	69 (66.3%)	
	High-risk	40 (16.8%)	18 (13.4%)	22 (21.2%)	

$^{\Psi}$: P-values describe the comparison of Conventional and Retzius-Sparing RARP groups, [a]: Student t-test, [b]: Fisher's Exact test, [c]: Pearson chi-square test, [d]: Mann-Whitney U test, *: p<0.05, IQR: Interquartile Range, SD: Standard deviation, ASA: American Society of Anesthesiologists, PSA: Prostate-specific antigen, ISUP: International Society of Urologic Pathology

Extended pelvic lymph node dissection was performed in 139 (58.4%) patients according to the European Association of Urology guideline recommendations (1). The mean total number of lymph nodes that are dissected in extended pelvic lymph node dissection and the median number of lymph nodes with metastatic deposits were 15±8 and 0 (0-0), respectively. Lymph node metastasis was observed in 13 (5.5%) patients and clinically significant PCa was observed in 220 (92.4%) patients. Positive surgical margin (PSM) was observed in 44 (18.5%) patients (Table 2). The rate of PSM increased by the pT stage (10.1% for pT2 and 32.6% for pT3 disease). Although not statistically significant, PSM frequency was higher in patients with pT3a and pT3b disease who underwent cRARP compared to RsRARP (p=0.412 and p=0.261, respectively) (Table 3). The median number of PSM areas was 1 (1-2) in the cRARP group and 2 (1-2) in the RsRARP group (p=0.534). PSM in prostate apex was observed in 15/134

Table 2. Perioperative surgical features and pathological findings of the prostatectomy specimens and the comparison of patients according to surgical approach in terms of perioperative clinical characteristics and pathological findings of the prostatectomy specimens

			Surgical Approach		
		All patients (n=238, 100%)	**Conventional (n=134, 56.3%)**	**Retzius-sparing (n=104, 43.7%)**	
		n, %	**n, %**	**n, %**	**p-value$^{\Psi}$**
Surgery duration (min) [median (IQR)]		300 (270-360)	330 (270-390)	290 (240-345)	[a]<0.001*
Estimated blood loss during surgery (mL) [median (IQR)]		50 (50-100)	50 (50-125)	100 (50-100)	[a]0.112
Length of hospital stay (day) [median (IQR)]		2 (2-3)	2 (2-3)	2 (2-3)	[a]0.774
Catheterization duration (day) [median (IQR)]		7 (7-9)	7 (7-8)	8 (7-10)	[a]<0.001*
Prostatectomy ISUP-grade group	ISUP-1	25 (10.5%)	20 (14.9%)	5 (4.8%)	[b]0.003*
	ISUP-2	112 (47.1%)	67 (50.0%)	45 (43.3%)	
	ISUP-3	70 (29.4%)	33 (24.6%)	37 (35.6%)	
	ISUP-4	6 (2.5%)	0	6 (5.8%)	
	ISUP-5	25 (10.5%)	14 (10.4%)	11 (10.6%)	
Pathological (pT) stage	pT2	148 (62.2%)	88 (65.7%)	60 (57.7%)	[c]0.425
	pT3a	59 (24.8%)	30 (22.4%)	29 (27.9%)	
	pT3b	30 (12.6%)	16 (11.9%)	14 (13.5%)	
	pT4	1 (0.4%)	0	1 (1.0%)	
Extended pelvic lymph node dissection (ePLND) (yes)		139 (58.4%)	69 (51.5%)	70 (67.3%)	[b]0.014*
Total number of lymph node excised in ePLND (mean ± SD)		15±8	15±7	15±8	[d]0.840
Number of metastatic lymph node [median (IQR)]		0 (0-0)	0 (0-0)	0 (0-0)	[a]0.815
Lymph node metastasis (yes)		13 (5.5%)	6 (4.5%)	7 (6.7%)	[b]0.792
Clinically significant prostate cancer (yes)		220 (92.4%)	120 (89.6%)	100 (96.2%)	[b]0.056
Surgical margin (positive)		44 (18.5%)	27 (20.1%)	17 (16.3%)	[b]0.453
Tumor volume (mL) [median (IQR)]		3.20 (1.50-6.50)	3.00 (1.24-6.00)	3.25 (1.90-7.00)	[a]0.213
Tumor volume ratio (%) [median (IQR)]		7.00 (2.70-14.00)	6.40 (2.00-13.90)	7.55 (3.10-14.55)	[a]0.070
Postoperative complication (yes)		13 (5.5%)	5 (3.7%)	8 (7.7%)	[b]0.182
Postoperative complication time	Early	12 (92.3%)	4 (80.0%)	8 (100.0%)	[c]0.385
	Late	1 (7.7%)	1 (20.0%)	0	
Clavien-Dindo (C-D) grade	C-D-1	3 (1.3%)	2 (1.5%)	1 (1.0%)	[c]0.244
	C-D-2	1 (0.4%)	1 (0.7%)	0	
	C-D-3A	4 (1.7%)	1 (0.7%)	3 (2.9%)	
	C-D-3B	5 (2.1%)	1 (0.7%)	4 (3.8%)	
Clavien-Dindo subgroups	C-D-2 and lower	4 (1.7%)	3 (2.2%)	1 (1.0%)	[c]0.077
	C-D-3 and upper	9 (3.8%)	2 (1.5%)	7 (6.7%)	
Follow-up (month) [median (IQR)]		13 (6-36)	30 (12-60)	8 (3-13)	[a]<0.001*

$^{\Psi}$: P-values describe the comparison of Conventional and Retzius-Sparing RARP groups, [a]: Mann-Whitney U test, [b]: Pearson chi-square test, [c]: Fisher's Exact test, [d]: Student t-test, *p<0.05, ISUP: International Society of Urologic Pathology, SD: Standard deviation

(11.2%) patients in the cRARP group and 9/104 (8.7%) patients in the RsRARP group (p=0.865).

No intraoperative complication was observed in any patients while postoperative complications were observed in 13 (5.5%) patients. According to C-D surgical complication classification, C-D grade-I, C-D grade-II, C-D grade-IIIa, and C-D grade-IIIb complication rates were 3 (1.3%), 1 (0.4%), 4 (1.7%), and 5 (2.1%), respectively (Table 2). Details of postoperative complications are summarized in Supplementary Table 1.

The comparison in terms of the perioperative clinical features revealed a significantly shorter duration of surgery in the RsRARP group (p<0.001). Contrarily, no difference was found between the groups in terms of estimated blood loss (p=0.112). Additionally, no difference was found between the groups when they were compared for hospital stay duration, while the catheterization duration was longer (median 7 days vs. 8 days) in the RsRARP group (p=0.774 and p<0.001, respectively) (Table 2).

The frequency of ISUP-GG-1 disease was higher in the cRARP group while the frequency of ISUP-GG-4 disease was higher in the RsRARP group in prostatectomy specimens (p=0.003) (Table 2). However, no difference was found between the cRARP and RsRARP groups when they were compared for other pathological outcomes, such as pT stage, clinically significant PCa, lymph node metastasis, number of metastatic lymph nodes, PSM, tumor volume, and tumor volume ratios (p>0.05, for each) (Table 2).

No difference was found between the groups in terms of postoperative complications, C-D subgrades of surgical complications, and major complication (≥C-D grade-3) rates (p=0.182, p=0.244, and p=0.077, respectively) (Table 2). The rate of ≥C-D grade-3 complications increased by D'Amico risk groups (3.6%, 4.2%, and 5.0% for low-, intermediate-, and high-risk patients, respectively), without difference between the clinical risk groups in terms of postoperative complications (p=0.824).

There was no difference between the groups in terms of BCR at months -3, -6, -9, -12, -18, -24, and -30, respectively (p=1.000, p=1.000, p=0.273, p=0.190, p=1.000, p=0.240, and p=1.000, respectively). BCR rates of patients whose PSA levels were available in the medical records at the stated date according to surgical approach are summarized in Table 4.

Discussion

This study presented our single-center, single-surgeon, and long-term experience for cRARP and RsRARP and compared these surgical techniques in terms of perioperative clinical, pathological, and oncological outcomes. One of the main emerging findings of our study was a shorter surgical time with RsRARP. Patients in the RsRARP group had higher anesthesia risk scores according to the ASA Classification. Therefore, RsRARP becomes prominent with shorter surgery duration and similar complication rates compared to cRARP in patients with higher ASA Class scores even with higher cT stages and D'Amico clinical risk group in the preoperative evaluation, which indicate a safe surgical approach.

Recently, various RARP forms became a widely utilized approach in the surgical treatment of localized PCa (18). A large prospective, single-center, single-surgeon, consecutive case series, by Sayyid et al. (11) compared patients who underwent cRARP (n=100) and RsRARP (n=100) for early operative outcomes. Similar to our study results, no differences for intra- or postoperative complication rates and length of hospital stay were revealed for cRARP and RsRARP groups. Additionally, the authors revealed a significantly less console time for the RsRARP group (11). The most current systematic review, which compares cRARP and RsRARP, revealed that RsRARP was associated with shorter surgical duration (19). In this review, similar to our findings, no significant difference was reported in terms of estimated blood loss and for overall complication rates between the cRARP and RsRARP groups (19). Moreover, Phukan et al. (20) revealed similar overall and major complication (C-D grade ≥3) rates for cRARP and RsRARP in their systematic review and meta-analysis. Contrarily, Dalela et al. (12) revealed higher postoperative complication rates for RsRARP compared to cRARP in patients with low- and intermediate-risk PCa according to the National Comprehensive Network guideline (18% vs. 12%, respectively).

Table 3. The distribution of surgical margin positivity frequency according to surgical approach and prostatectomy pT stage

Pathological (p) T-stage		Surgical approach		
		Conventional (n=134, 56.3%)	Retzius-sparing (n=104, 43.7%)	p-value
		n, %	n, %	
pT2 (n=148, 62.2%)	Surgical Margin (positive)	9 (10.2%)	6 (10.0%)	[a]0.964
pT3a (n=59, 24.8%)	Surgical Margin (positive)	9 (30.0%)	6 (20.7%)	[a]0.412
pT3b (n=30, 12.6%)	Surgical Margin (positive)	9 (56.3%)	5 (35.7%)	[a]0.261
pT4 (n=1, 0.4%)	Surgical Margin (positive)	0	0	-

[a]: Pearson chi-square test

Table 4. The comparison of patients according to surgical approach in terms of biochemical recurrence

Biochemical Recurrence	Surgical approach		
	Conventional (n=134, 56.3%)	Retzius-sparing (n=104, 43.7%)	
	Ψn, %	Ψn, %	p-value
Month 3 (yes)	3/87 (3.4%)	2/60 (3.3%)	[a]1.000
Month 6 (yes)	1/60 (1.7%)	1/31 (3.2%)	[a]1.000
Month 9 (yes)	0/48 (0%)	1/18 (5.6%)	[a]0.273
Month 12 (yes)	1/69 (1.4%)	2/27 (7.4%)	[a]0.190
Month 18 (yes)	1/33 (3.0%)	0/11 (0%)	[a]1.000
Month 24 (yes)	1/48 (2.1%)	1/7 (14.3%)	[a]0.240
Month 30 (yes)	2/26 (7.7%)	0/3 (0%)	[a]1.000
Month 36 (yes)	3/41 (7.3%)	-	-
Month 48 (yes)	4/28 (14.3%)	-	-
Month 60 (yes)	2/24 (8.3%)	-	-
Month 72 (yes)	1/11 (9.1%)	-	-
Month 84 (yes)	1/11 (9.1%)	-	-
Month 96 (yes)	1/3 (33.3%)	-	-
Month 108 (yes)	0/2 (0%)	-	-
Month 120 (yes)	0/1 (0%)	-	-
Month 132 (yes)	0/1 (0%)	-	-
Month 144 (yes)	0/1 (0%)	-	-

[a]: Fisher's Exact test,Ψ: The first number before the brackets indicates the patients with biochemical recurrence and the second number after the brackets indicates the patients whose prostate-specific antigen levels are available in medical records at the stated date

Our study cohort revealed that neither the overall nor C-D grade of ≥3 complication rates were significantly different between the groups. Complications were infrequent in both cohorts. Additionally, RsRARP may be beneficial by shortening the surgical duration in patients with high ASA Class scores. Lim et al. (21) also compared cRARP and RsRARP patients in terms of perioperative clinical and oncologic outcomes, and similar to our findings, they revealed a significantly shorter console time and oncologically safe procedure with acceptable PSM rates with RsRARP.

The status of surgical margins is important in terms of oncological control after RP. However, conflicting results were published from different institutions regarding RsRARP. Galfano et al. (14) revealed their first oncological results for RsRARP in 200 consecutive patients with a prospective, non-controlled case series study. The authors evaluated the learning-curve effect for the RsRARP outcomes. PSM for the first 100 and remaining 100 patients was reported as 22.4% and 10.1% for pT2 disease, respectively (14). Contrarily, Dalela et al. (12) reported higher PSM for RsRARP compared to cRARP (25% vs. 13%). A systematic review by Checcucci et al. (19) also revealed a lower likelihood of PSM for cRARP. Level 1 evidence is rare in this context and in the first randomized controlled trial that compares cRARP and RsRARP. Menon et al. (22) revealed "non-focal" PSM as 8.3% and 11.7% for cRARP and RsRARP groups, respectively. Our study did not observe any difference between the cRARP and RsRARP groups in terms of PSM focality and apical PSM. A recent retrospective study revealed 42% PSM with RsRARP in patients who had locally advanced PCa (13). Our study cohort revealed an overall PSM in 16.3% of patients who underwent RsRARP, and similar to previous publications, it was 10% in patients who had pT2 disease. Performing RsRARP after an initial robotic experience in cRARP might be one of the reasons for lower PSM in the RsRARP group in our study cohort. This situation could also explain the importance of the learning-curve effect for better outcomes in robotic surgery. Increased PSM rates were reported for the pT3 stage relative to the pT2 stage (11). Contrarily, RsRARP did not alter both pT2 and pT3 PSM rates compared to cRARP in a systematic review and meta-analysis (20). However, the rate of PSM in patients with pT3 disease was lower in the RsRARP group compared to cRARP in our study cohort. This may be an important observation when taken together in patients who underwent RsRARP with statistically significantly higher cT stage, prostate biopsy ISUP-GG, and D'Amico clinical risk group in the preoperative evaluation. Our study cohort revealed lower PSM in the RsRARP group compared to the cRARP group. The level of surgical experience may explain some of the observed differences in various studies as suggested by Galfano et al. (14). Moreover, the transition between the layers of fascial planes, as we routinely performed, to adjust the limits of dissection according to the site and extent of disease may further improve the surgical margin clearance. Our study cohort included patients from all D'Amico clinical risk groups and intra-, inter-, or extrafascial dissections utilized during the operation interchangeably for PSM prevention.

Galfano et al. (14) revealed 1-year biochemical disease-free survival rates as 89% and 92% for the first and second 100 cases, respectively, in patients who underwent RsRARP. Chang et al. (23) reported similar BCR rates at 1-year for cRARP and RsRARP (16.7% vs. 13.3%, respectively). Similarly, Dalela et al. (12) reported the probability of BCR-free survival as 0.91 vs. 0.91 for cRARP and RsRARP, respectively. Menon et al. (22) also reported similar BCR-free survival probability for two RARP techniques (0.93 vs. 0.84, for cRARP and RsRARP, respectively) in patients with low-intermediate PCa at 12 months. Our study revealed quite lower BCR rates in both cRARP and RsRARP groups compared to the aforementioned studies at 12 months.

Study Limitations

This study has some limitations. The major limitation is its retrospective nature, which might have introduced a selection

bias for an accurate comparison of each group. Additionally, long-term follow-up for PSA levels and BCR status is lacking for some patients, which limits the validity of long-term-oncological outcomes. Currently, the collection of data for both long-term functional and oncological outcomes of patients is an ongoing project at our institution. However, two key strengths of the present study that are worth mentioning include the presence of a control group, which includes the patients who underwent cRARP, and performance of all surgeries by the same surgeon in both groups, which eliminate most of the operator-related variables. Another important aspect is the inclusion of patients with all D'Amico clinical risk groups, which reflects our routine Uro-oncology practice.

Conclusion

The present study suggests that RsRARP can be safely performed with similar oncological efficacy and complication rates with a significantly shorter surgical time compared to cRARP even in patients with higher ASA Class scores, higher cT stages, and D'Amico clinical risk group. Further well-designed, large-scale, multi-center, prospective studies are required to confirm these findings.

Ethics

Ethics Committee Approval: The Local Institutional Ethics Committee (IRB No: 2020-26/09) approved this study and all steps were planned and conducted following the Declaration of Helsinki and its later amendments.

Informed Consent: Written informed consent on admittance to the hospital was obtained from all individuals, which permitted the use of respective medical information in clinical studies.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Y.S., L.T., Concept: B.Ö., L.T., Design: B.Ö., L.T., Data Collection or Processing: N.K., M.B.Ö., H.D., Analysis or Interpretation: N.K., M.B.Ö., Y.S., L.T., Literature Search: N.K., Writing: N.K., M.B.Ö., L.T.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Mottet N, van den Bergh RCN, Briers E, Cornford P, De Santis M, Fanti S, Gillessen S, Grummet J, Henry AM, Lam TB, Mason MD, van der Poel HG, van der Kwast TH, Rouvière O, Schoots I, Tilki D, Wiegel T. EAU - ESTRO - ESUR - SIOG Guidelines on Prostate Cancer 2020. European Association of Urology Guidelines. 2020 Edition., Vol presented at the EAU Annual Congress Amsterdam 2020. Arnhem, The Netherlands, European Association of Urology Guidelines Office, 2020.
2. Abbou CC, Hoznek A, Salomon L, Lobontiu A, Saint F, Cicco A, Antiphon P, Chopin D. Prostatectomie radicale laparoscopique réalisée à distance par robot. A propos d'un cas [Remote laparoscopic radical prostatectomy carried out with a robot. Report of a case]. Prog Urol 2000;10:520-523.
3. Binder J, Kramer W. Robotically-assisted laparoscopic radical prostatectomy. BJU Int 2001;87:408-410.
4. Yaxley JW, Coughlin GD, Chambers SK, Occhipinti S, Samaratunga H, Zajdlewicz L, Dunglison N, Carter R, Williams S, Payton DJ, Perry-Keene J, Lavin MF, Gardiner RA. Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study. Lancet 2016;388:1057-1066.
5. Ilic D, Evans SM, Allan CA, Jung JH, Murphy D, Frydenberg M. Laparoscopic and robotic-assisted versus open radical prostatectomy for the treatment of localised prostate cancer. Cochrane Database Syst Rev 2017;9:CD009625.
6. Tewari A, Peabody J, Sarle R, Balakrishnan G, Hemal A, Shrivastava A, Menon M. Technique of da Vinci robot-assisted anatomic radical prostatectomy. Urology 2002;60:569-572.
7. Rocco F, Carmignani L, Acquati P, Gadda F, Dell'Orto P, Rocco B, Bozzini G, Gazzano G, Morabito A. Restoration of posterior aspect of rhabdosphincter shortens continence time after radical retropubic prostatectomy. J Urol 2006;175:2201-2206.
8. Patel VR, Coelho RF, Palmer KJ, Rocco B. Periurethral suspension stitch during robot-assisted laparoscopic radical prostatectomy: description of the technique and continence outcomes. Eur Urol 2009;56:472-478.
9. Menon M, Shrivastava A, Bhandari M, Satyanarayana R, Siva S, Agarwal PK. Vattikuti Institute prostatectomy: technical modifications in 2009. Eur Urol 2009;56:89-96.
10. Galfano A, Ascione A, Grimaldi S, Petralia G, Strada E, Bocciardi AM. A new anatomic approach for robot-assisted laparoscopic prostatectomy: a feasibility study for completely intrafascial surgery. Eur Urol 2010;58:457-461.
11. Sayyid RK, Simpson WG, Lu C, Terris MK, Klaassen Z, Madi R. Retzius-Sparing Robotic-Assisted Laparoscopic Radical Prostatectomy: A Safe Surgical Technique with Superior Continence Outcomes. J Endourol 2017;31:1244-1250.
12. Dalela D, Jeong W, Prasad MA, Sood A, Abdollah F, Diaz M, Karabon P, Sammon J, Jamil M, Baize B, Simone A, Menon M. A Pragmatic Randomized Controlled Trial Examining the Impact of the Retzius-sparing Approach on Early Urinary Continence Recovery After Robot-assisted Radical Prostatectomy. Eur Urol 2017;72:677-685.
13. Nyarangi-Dix JN, Görtz M, Gradinarov G, Hofer L, Schütz V, Gasch C, Radtke JP, Hohenfellner M. Retzius-sparing robot-assisted laparoscopic radical prostatectomy: functional and early oncologic results in aggressive and locally advanced prostate cancer. BMC Urol 2019;19:113.
14. Galfano A, Di Trapani D, Sozzi F, Strada E, Petralia G, Bramerio M, Ascione A, Gambacorta M, Bocciardi AM. Beyond the learning curve of the Retzius-sparing approach for robot-assisted laparoscopic radical prostatectomy: oncologic and functional results of the first 200 patients with ≥1 year of follow-up. Eur Urol 2013;64:974-980.
15. Dindo D, Clavien PA. What is a surgical complication? World J Surg 2008;32:939-941.
16. Epstein JI, Walsh PC, Carmichael M, Brendler CB. Pathologic and clinical findings to predict tumor extent of nonpalpable (stage T1c) prostate cancer. JAMA 1994;271:368-374.
17. Epstein JI, Egevad L, Amin MB, Delahunt B, Srigley JR, Humphrey PA; Grading Committee. The 2014 International Society of Urological Pathology (ISUP) Consensus Conference on Gleason Grading of Prostatic Carcinoma: Definition of Grading Patterns and Proposal for a New Grading System. Am J Surg Pathol 2016;40:244-252.

18. Agarwal G, Valderrama O, Luchey AM, Pow-Sang JM. Robotic-Assisted Laparoscopic Radical Prostatectomy. Cancer Control 2015;22:283-290.

19. Checcucci E, Veccia A, Fiori C, Amparore D, Manfredi M, Di Dio M, Morra I, Galfano A, Autorino R, Bocciardi AM, Dasgupta P, Porpiglia F. Retzius-sparing robot-assisted radical prostatectomy vs the standard approach: a systematic review and analysis of comparative outcomes. BJU Int 2020;125:8-16.

20. Phukan C, Mclean A, Nambiar A, Mukherjee A, Somani B, Krishnamoorthy R, Sridhar A, Rajan P, Sooriakumaran P, Rai BP. Retzius sparing robotic assisted radical prostatectomy vs. conventional robotic assisted radical prostatectomy: a systematic review and meta-analysis. World J Urol 2020;38:1123-1134.

21. Lim SK, Kim KH, Shin TY, Han WK, Chung BH, Hong SJ, Choi YD, Rha KH. Retzius-sparing robot-assisted laparoscopic radical prostatectomy: combining the best of retropubic and perineal approaches. BJU Int 2014;114:236-244.

22. Menon M, Dalela D, Jamil M, Diaz M, Tallman C, Abdollah F, Sood A, Lehtola L, Miller D, Jeong W. Functional Recovery, Oncologic Outcomes and Postoperative Complications after Robot-Assisted Radical Prostatectomy: An Evidence-Based Analysis Comparing the Retzius Sparing and Standard Approaches. J Urol 2018;199:1210-1217.

23. Chang LW, Hung SC, Hu JC, Chiu KY. Retzius-sparing Robotic-assisted Radical Prostatectomy Associated with Less Bladder Neck Descent and Better Early Continence Outcome. Anticancer Res 2018;38:345-351.

Supplementary Table 1. Details of overall complications according to Clavien-Dindo surgical complication classification

Grade-I (n= 3, 1.3%)	**Grade-II (n=1, 0.4%)**	**Grade-IIIa (n=4, 1.7%)**	**Grade-IIIb (n=5, 2.1%)**
Conservatively managed hematuria [1 (0.4%)]	Postoperative fever treated with antibiotic	Delayed anastomosis healing and re-catheterization under local anesthesia [2 (0.8%)]	Bleeding required re-operation [2 (0.8%)]
Conservatively managed delayed anastomosis healing [1 (0.4%)]	-	Percutaneous abscess drainage under local anesthesia [1 (0.4%)]	Re-operation for anastomosis repair [2 (0.8%)]
Urinary retention required re-catheterization [1 (0.4%)]	-	Percutaneous intra-abdominal urine drainage under local anesthesia [1 (0.4%)]	Hernioraphy due to incisional hernia [1 (0.4%)]

ORIGINAL RESEARCH
Urooncology

Doi: 10.4274/jus.galenos.2021.2021.0065
J Urol Surg, 2022;9(1):9-19

The Effect of Postoperative Early Mobilization on the Healing Process and Quality of Life Following Radical Cystectomy and Ileal Conduit: A Randomized Prospective Controlled Trial

Sevgi Vermişli[1], Özgür Çakmak[2], Talha Müezzinoğlu[3], Güven Aslan[4], Hakan Baydur[5]

[1]Republic of Turkey Ministry of Health, Bornova Türkan Özilhan State Hospital, İzmir, Turkiye
[2]Medicana International İzmir Hospital, Clinic of Urology, İzmir, Turkiye
[3]Manisa Celal Bayar University, Hafsa Sultan Hospital, Clinic of Urology, Manisa, Turkiye
[4]Dokuz Eylül University Training and Research Hospital, Clinic of Urology, İzmir, Turkiye
[5]Manisa Celal Bayar University Faculty of Health Sciences, Manisa, Turkiye

What's known on the subject? and What does the study add?

Early and organized mobilization after surgery is in the context of enhanced recovery after surgery interventions. However, there is no clear data about the time of early mobilization. This mobilization procedure can be performed safely. Early mobilization could be safely performed in the patients who underwent radical cystectomy and ileal diversion in accordance with following the standard procedure and it, which has positively contributed to the healing process and improved their quality of life.

Abstract

Objective: This study aimed to evaluate the effect of postoperative early mobilization in patients who underwent radical cystectomy (RC) and ileal conduit in terms of the healing process and quality of life (QoL).

Materials and Methods: This multicenter prospective randomized controlled study included 40 patients who were randomly divided into two groups. The intervention group was mobilized within the first 16 h postoperatively following the mobilization procedure, which was determined according to the literature. Data were collected using the case report form, hospital anxiety and depression scale, and 36-Item Short Form Survey (SF-36) QoL scale.

Results: Postoperative hospitalization, narcotic analgesic administration duration, first oral food intake, flatus, defecation, and nasogastric tube termination time were shorter in the intervention group. Additionally, blood glucose and pulse values were higher in the control group after mobilization. SF-36 physical function, physical role difficulty, and general perception of health subscales were higher in the intervention group at the postoperative first and third months ($p<0.05$).

Conclusion: Early mobilization positively contributed to the healing process and improved the QoL in patients who underwent RC and ileal conduit surgery.

Keywords: Early mobilization, radical cystectomy, ileal conduit, quality of life

Introduction

Radical cystectomy (RC) is considered a standard treatment option for invasive and high-risk recurrent non-invasive bladder cancer (1). RC is one of the most traumatic cancer surgeries in terms of psychological stress and lifestyle change (2).

Today, interest is growing in quality of life (QoL) studies that evaluated the symptomatic effects of oncological surgical modalities considering the patients' subjective statements (1). Negative changes are observed regarding urinary, rectal, and sexual functions and in the perception of body image in patients undergoing RC and urinary diversion (3). Minimizing the loss

Correspondence: Ph.D., RN Sevgi Vermişli, Republic of Turkey Ministry of Health, Bornova Türkan Özilhan State Hospital, İzmir, Turkiye
Phone: +90 533 224 00 43 **E-mail:** sevgi0535@yahoo.com **ORCID-ID:** orcid.org/0000-0002-5306-6519
Received: 24.05.2021 **Accepted:** 01.08.2021

Cite this article as: Vermişli S, Çakmak Ö, Müezzinoğlu T, Aslan G, Baydur H. The Effect of Postoperative Early Mobilization on the Healing Process and Quality of Life Following Radical Cystectomy and Ileal Conduit: A Randomized Prospective Controlled Trial. J Urol Surg, 2022;9(1):9-19.

of function as a result of surgical intervention is possible with evidence-based treatments (4).

Most of the enhanced recovery after surgery (ERAS) protocols are physiologically based on preoperative, operative, and postoperative procedures that can be adapted to a specific problem (5). Early and organized mobilization after surgery is in the context of ERAS interventions (6). Nowadays, ERAS is still limited in clinical practice despite the evidence of its efficacy in patients who underwent RC and urinary diversion (7,8). In their meta-analysis, Cerantola et al. (9) revealed that the evidence of the effectiveness of many ERAS components on RC treatment is insufficient. Early mobilization has been provided for patients who received RC treatment; however, standard mobilization procedure was not defined in the ERAS protocol studies (10,11). To our knowledge, our study is the first prospective randomized controlled study that evaluated the effect of early mobilization on clinical outcomes and QoL in patients who underwent RC and urinary diversion. This study aimed to investigate the effects of early mobilization on the postoperative healing process and QoL in patients who underwent RC and ileal conduit surgery due to bladder cancer. This study highlights the need to increase the healthcare professionals' awareness of the importance of ERAS protocol and ERAS components on the healing process of patients who received RC and ileal loop.

Materials and Methods

Design

A prospective randomized controlled study.

Research Model

This study was conducted between March 2015 and April 2017 as multicenter research within the body of the Urooncology Association at an educational research hospital and two university hospitals serving in the Aegean region of Turkey. The sampling was determined following the study conducted by Porserud et al. (10), which was conducted with two groups consisting of 20 individuals by block randomization. The sample size of the study was determined by power analysis following Porserud et al. (10). According to the power analysis results, 40 patients were included in the study and were divided into two groups of 20 patients by block randomization, as intervention and control groups. Patients who were hospitalized to receive RC and ileal loop treatments were included in the study; the individuals were aged 50-75 years, literate, and open to communicate and cooperate, without sensory loss or comorbidity that could hinder mobilization and history of radiotherapy and chemotherapy and were in American Society of Anesthesiologists I-II risk groups, and did not have any mental and psychiatric disorders. Those who signed the informed consent form were included in the study. During the study, 2 patients could not be followed due to communication problems, 3 patients developed intolerance symptoms during mobilization, and 12 patients underwent additional surgical procedures; a total of 17 patients were excluded from the study. Patient recruitment went on until the number of sampling was reached. After exclusion of 17 patients, the study was ended when a total of 40 patients (intervention: 20, control group: 20) were reached.

Surgical Procedure

Surgical operations were performed by three surgeons, one in each center. A vertical midline incision that does not extend above the umbilicus was performed. The ileal conduit was preferred as the diversion technique and extended lymph node dissection was also performed. Apart from early mobilization, ERAS protocols, as applied in clinical practice, were performed in all study participants from all three centers (intervention and control groups) as follows: Preoperative counseling and training, preoperative medical optimization, oral mechanical bowel preparation, preoperative diet, epidural analgesia, antimicrobial prophylaxis, and skin preparation, standard anesthesia protocol, preoperative liquid diet 8 h before surgery, urinary drainage, and postoperative multimodal analgesia practices (patient-controlled analgesia was not performed in postoperative pain control). No postoperative complications were observed that might necessitate the patients to have an additional operation, as well as surgical mortality.

Mobilization Procedure

The patients were mobilized following the assessment of their suitability for mobilization as shown in Figure 1. Analgesic treatments were applied before the mobilization as prescribed by clinicians. The patients were mobilized under the supervision of researchers in accordance with the mobilization procedure in Figure 2. The exact definition of "early mobilization" in terms of the period after RC with ileal diversion is not reported in the literature. Therefore, the most appropriate time for mobilization was determined as the beginning of the next workday (on the first day after surgery), considering the factors, such as the time and length of operation, and the fact that the postoperative process coincided with the time of shift change, and the number of health personnel working in the clinic at night shift sufficient for safe mobilization. This period included the first 16 h after surgery assuming a normal operating procedure, and the period after 17 h was considered as late mobilization. Patients in the intervention group were mobilized within the 16 h postoperatively, whereas the mobilization of the control group was carried out after 17 h postoperatively.

Data Collection Method

The case report form (CRF) and hospital anxiety and depression scale (HADS) were completed by the researchers using the face-to-face interview method and the 36-Item Short Form Survey (SF-36) QoL scale was filled by patients 1 day before surgery. Vital signs and peripheral blood glucose levels of patients before and after mobilization were recorded. HADS and SF-36 scales were applied after mobilization at the first and third months after surgery.

Data Collection Tools

CRF: This form consists of 14 questions that are related to sociodemographic and clinical features of patients, information about the operation process and postoperative healing process, and data on the patient's vital signs before and after mobilization.

HADS: The validity and reliability of the Turkish version of the HADS scale were developed in 1983 and tested by Aydemir et al. (12). The scale is used to measure the level and severity of anxiety and depression and determine the risk of anxiety and depression. There are, in total, 14 questions on the 4-point Likert scale; the odd numbers measure anxiety and the even numbers measure depression. The cut-off point of the scale is considered as 10/11 for the anxiety subscale and 7/8 for the depression subscale; those having higher scores are considered at risk.

SF-36 Quality of Life Scale: The SF-36 scale consists of 36 items and eight dimensions as follows: physical function, social functioning, role limitations due to physical problems, role

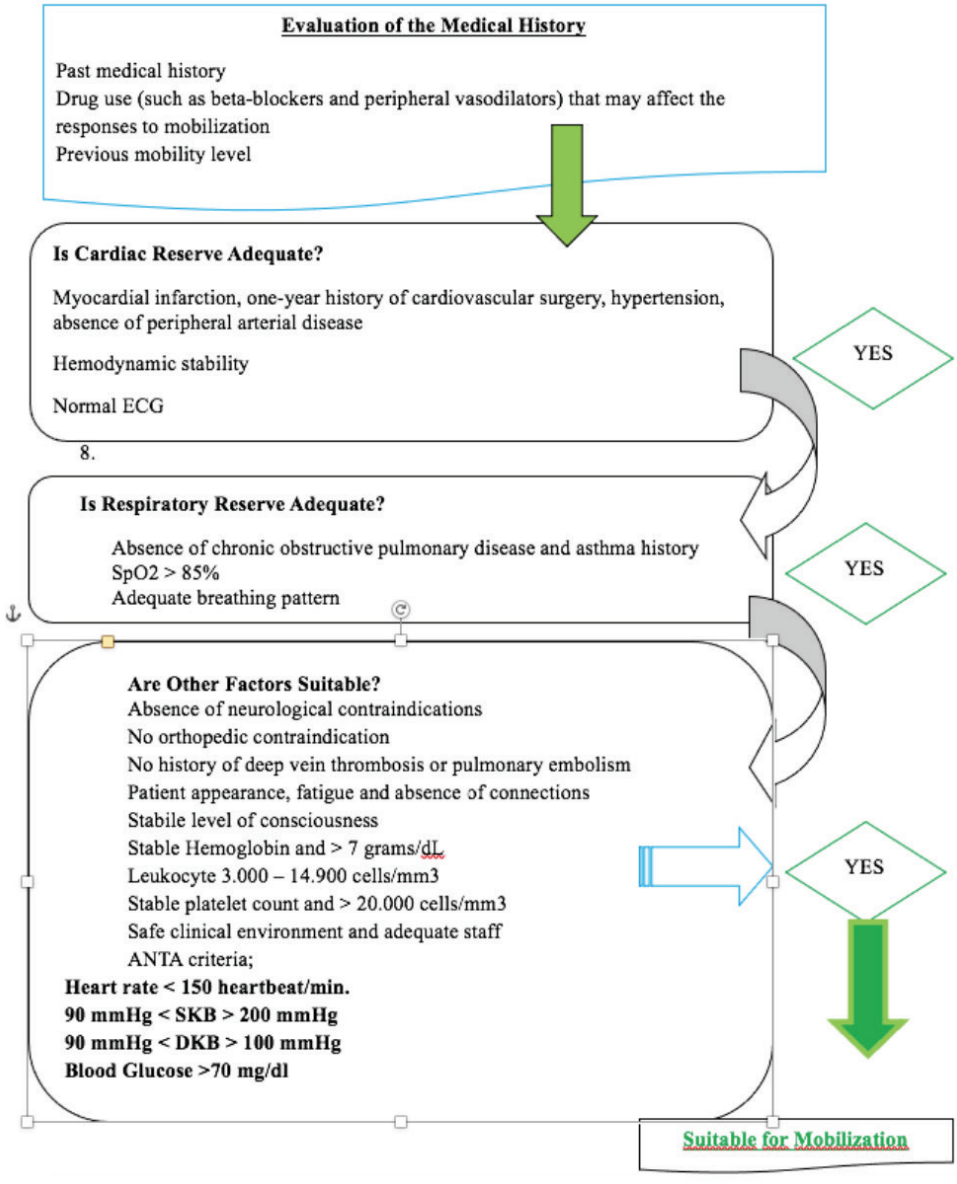


Figure 1. Mobilization suitability assessment guide

limitations due to emotional problems, mental health, energy/vitality, pain, and general perception of health. Zero-point from the subdimensions represent the worst health status, whereas 100 points show the best health status. Turkish validity and reliability test of The SF-36 scale was made by Kocyigit et al. (13).

Ethical Considerations

Written permission was obtained from the research centers before the research. The local ethics committee approval was obtained (İzmir Tepecik Training and Research Hospital, approval number: 14/2, date: 30.10.2014). Written and verbal informed consent of patients was also obtained using an informed volunteer consent form.

Statistical Analysis

The Statistical Package for Social Sciences (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) package program was used to evaluate the research data. The Shapiro-Wilk test was used to determine the normally distributed data. The descriptive statistics, Student t-test, and Mann-Whitney U test were used to analyze the data. The accepted level of significance was considered as $p<0.05$.

Results

The mean age of the patients was 64.8±10.3 [minimum-maximum (min-max): 48.0-80.0) years in the intervention group and 65.8±7.2 (min-max: 52-80] years in the control group. No significant difference was found between the groups in terms of sociodemographic characteristics, such as age, gender, smoking, and chronic disease ($p>0.05$). Previous surgical history was present in 75% (n=15) of the intervention group, whereas 40% (n=8) of the control group ($p=0.027$). Postoperative complications were recorded according to the Clavien-Dindo classification system and were similar in frequency and incidence between the two groups. Complications, which were seen in both group participants, were limited to requiring medical interventions, such as antiemetics, analgesics, or antibiotics, according to the Clavien-Dindo classification system (Table 1).

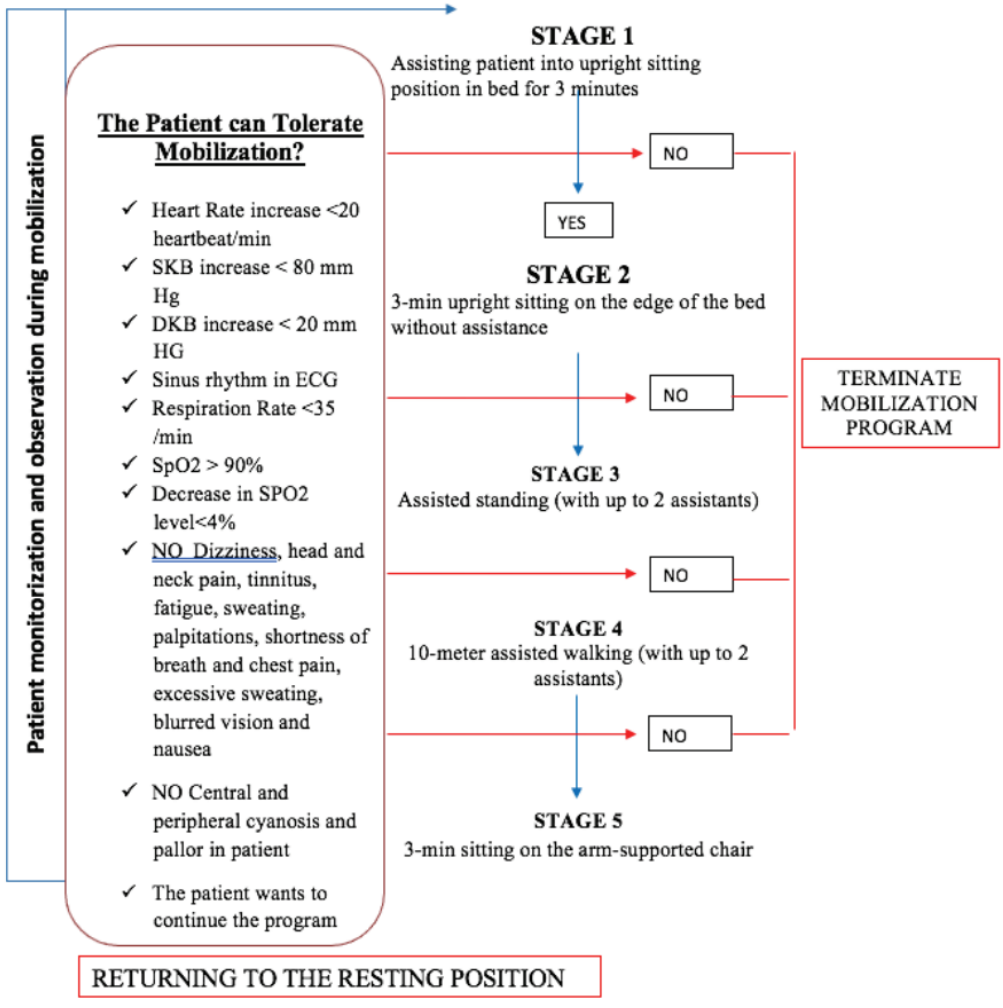


Figure 2. Mobilization application procedure

The mean length of total hospital stay was 15.6±3.9 (min-max: 10.0-25.0) days and 19.7±5.9 (min-max: 10.0-31.0) days in the intervention and control groups, respectively (p=0.013). The mean duration of postoperative narcotic analgesic administration time was 4.3±3.8 (min-max: 1.0-18.0) days in the intervention group, which was shorter than in the control group with statistically significant difference (p=0.026). The mean first oral food intake, flatus, defecation, and nasogastric (NG) tube termination times in group 2 were 3.2±1.1 (min: 1.0-max: 6.0) days, 3.4±1.4 (min: 2.0-max: 6.0) days, 4.4±1.5 (min: 3.0-max: 8.0) days, and 2.7±1.3 (min: 1.0-max: 5.0) days, respectively, which were earlier than the control group with statistically significant difference (p=0.026, p=0.013, p=0.023, and p=0.013). In the intervention group, the mean mobilization time in the first 24 h after surgery was 70.5±20.1 (min: 40.0-max: 105.0) min, with statistically significant difference (p<0.01) (Table 2).

The mean pulse rate after mobilization was 101.3±15.3 (min: 76.0-max: 137.0) min in the control group and the mean value of SPO2 without oxygen support was 96.1%±2.3% (min-max: 92.0-100.0) in the intervention group, which were statistically significantly higher (p=0.036 and p=0.001).The mean blood glucose value after mobilization was 109.8±24.3 (min: 90.0-max: 176.0) mg/dL in the intervention group and 139.3±41.7 (min: 92.0-max: 234.0) mg/dL in the control group, which was statistically significantly lower in the intervention group as shown in Table 3 (p=0.009).

No significant difference was found between the groups in terms of SF-36 quality of life and HADS scale scores preoperatively (p>0.05) (Table 4). The SF-36 subscale scores of physical function, physical role difficulty, and general perception of health were significantly higher in the intervention group in the first postoperative month (p=0.016, p=0.041, and p=0.001). The mean of SF-36 vitality, mental health, social functioning, and general perception of health subscale scores were statistically significantly higher in the third postoperative month (p<0.01, p<0.01, p=0.013, and p<0.01) (Table 5).

Discussion

ERAS protocols do not only increases patient satisfaction and QoL but also improve clinical outcomes (14). The results related to sociodemographic variables, such as age and gender participants, were consistent with the literature (7,15-18). Considering the effects of sociodemographic and clinical characteristics on QoL and postoperative healing process, homogeneity of the research sample is of importance to not affect the results biasedly.

Table 1. Sociodemographic characteristics

Variable		Intervention (n=20)		Control (n=20)		Test statistics		Variable		Intervention (n=20)		Control (n=20)		Test statistics	
		(n)	(%)	(n)	(%)	z	p			(n)	(%)	(n)	(%)	z	p
Age groups	18-65 years	9	45.0	11	55.0	-0.624	0.532[b]	Gender	Male	19	95.0	19	95.0	0.000	1.000[b]
	66-80 years	11	55.0	9	45.0				Female	1	5.0	1	5.0		
Marital status	Married	17	85.0	16	80.0	-0.411	0.681[b]	Previous any surgical experience	Yes	15	75.0	8	40.0	-2.211	0.027[b]
	Single	3	15.0	4	20.0				No	5	25.0	12	60.0		
Educational background	Literate	4	20.0	7	35.0	-0.452	0.651[b]	Preoperative training	Yes	11	55.0	10	50.0	-0.313	0.755[b]
	Primary education	9	45.0	6	30.0				No	9	45.0	10	50.0		
	High school	4	20.0	3	15.0			Postoperative complication	Yes	4	20.0	3	15.0	-0.411	0.681[b]
	Graduate and postgraduate	3	15.0	4	20.0				No	16	80.0	17	85.0		
Body mass index	Normal weight	9	45.0	6	30.0	-0.805	0.421[b]	Intensive care monitoring	Yes	4	20.0	7	35.0	-1.049	0.294[b]
	Overweight	6	30.0	6	40.0				No	16	80.0	13	65.0		
Smoking	Smokes	7	35.0	4	20.0	-1.049	0.294[b]			Intervention		Control (n=20)		Test statistics	
	Gave up	13	60.0	16	80.0										
HT	Yes	7	35.0	8	40.0	-0.322	0.747[b]			Mean ± SD (min-max)		Mean ± SD (min-max)		t	p
	No	13	65.0	12	60.0										
Diabetes	Yes	5	25.0	4	20.0	-0.374	0.708[b]	Age/Year		64.8±10.3 (48.0-80.0)		65.8±7.2 (52.0-80.0)		-0.375	0.710[a]
	No	15	75.0	16	80.0										

[a]: Student t-test, [b]: Mann-Whitney U test, SD: Standard deviation, Min: Minimum, Max: Maximum, HT: Hypertension

Preoperative anxiety, which negatively affects the QoL, is more common in patients with previous surgical experience (3). Patients' expectations for the healing process also affect the QoL (6,19). Our study revealed that the status of having previous surgical experience was higher in the intervention group; however, the expectations for recovery time, SF-36, and HADS scores were similar in both groups.

ERAS components have been reported to decrease the length of postoperative hospital stay (7,16,20). Similar to the literature, our study revealed a significantly shorter length of postoperative and total hospital stay in the intervention group. However, the total hospital stay in our study was longer than in the literature (7,17,20). In Turkey, government health payments cover the entire treatment process without being affected by the length of hospital stay. Therefore, most physicians prefer to follow the recovery process in the hospital. Additionally, as the sample of the study was 60 years or older, the anesthesia preparation process was conducted in the hospital. Therefore, preoperative hospital stay was higher in both groups compared to the literature (15,18,21). Early mobilization may play a significant role in decreasing postoperative and total hospital stays.

Djaladat et al. (5) revealed that the complication incidence decreased in parallel with the length of hospital stay in patients who underwent ERAS. Moreover, Rivas et al. (21) revealed that the length of hospital stay was shortened without the risk of postoperative complications. The current study revealed no significant difference between the groups in terms of complication incidence rate. ERAS components that are jointly applied in research groups are thought to cause similarities between the groups.

Table 2. Clinical features and data on the postoperative healing process

Variables	Intervention (n=20)	Control (n=20)	Test statistics	
	Mean ± SD (min-max)	Mean ± SD (min-max)	z	p
Length of operation/hour	5.6±1.7 (3.0-8.0)	6.4±1.8 (3.0-9.0)	-1.346	0.178[a]
Preoperative hospital stay/day	5.2±3.6 (2.0-16.0)	7.3±5.1 (1.0-18.0)	-1.906	0.057[a]
Postoperative hospital stay/day	10.4±2.8 (6.0-16.0)	12.4±3.3 (6.0-19.0)	-2.199	0.046[a]
Total hospital stay/day	15.6±3.9 (10.0-25.0)	19.7±5.9 (10.0-31.0)	-2.904	0.013[a]
History of bladder problems/month	11.4±10.6 (1.0-36.5)	9.3±8.7 (2.0-36.5)	-0.628	0.530[a]
Intensive care monitoring period/day	0.7±1.7 (0.0-7.0)	0.7±1.1 (0.0-4.0)	-0.793	0.428[a]
Narcotic analgesic administration/day	4.3±3.8 (1.0-18.0)	5.6±2.5 (1.0-11.0)	-2.221	0.026[a]
Parenteral nutrition/hour	72.8±25.6 (28.0-120.0)	90.5±41.0 (48.0-168.0)	-1.040	0.298[a]
Oral food intake/day	3.2±1.1 (1.0-6.0)	4.3±1.7 (2.0-7.0)	-2.292	0.026[a]
First flatus time/day	3.4±1.4 (2.0-6.0)	4.4±1.2 (2.0-7.0)	-2.495	0.013[a]
First defecation time/day	4.4±1.5 (3.0-8.0)	5.7±2.1 (2.0-8.0)	-2.276	0.023[a]
Nasogastric tube termination/day	2.7±1.3 (1.0-5.0)	4.2±2.0 (2.0-8.0)	-2.496	0.013[a]
Drain removal/day	9.6±2.8 (7.0-19.0)	9.8±3.7 (6.0-23.0)	-0.056	0.956[a]
First mobilization time/hour	13.1±3.2 (6.0-16.0)	26.4±6.3 (18.0-40.0)	-5.431	0.000[a]
Mobilization in the first 24 hours after surgery/times	5.9±2.3 (4.0-8.0)	1.0±1.4 (0.0-5.0)	-5.294	0.000[a]
Mobilization time in the first 24 hours after surgery/minutes	70.5±20.1 (40.0-105.0)	11.8±20.9 (0.0-90.0)	-5.039	0.000[a]

[a]: Mann-Whitney U test, SD: Standard deviation, Min: Minimum, Max: maximum

A study that examined the mobilization efficiency in the intensive care unit after organ transplantation revealed that the pulse rate was reduced to the normal limits after mobilization (22). Our study revealed that the pulse rate and blood glucose levels after mobilization were lower in the intervention group. Blood glucose levels may be higher in patients who remained inactive for a long time due to metabolic stress that may occur after the surgery. Our study revealed that the glucose levels of all patients were stable before the surgery. Blood glucose value is decreased in the intervention group due to the increased energy requirement of muscle tissue during mobilization, increased use of glucose, and increased insulin sensitivity along with mobilization. We believe that early mobilization can be effective in terms of early hyperglycemia control that is induced by metabolic stress and hepatic glucose metabolism regulation.

Mobilization is of great importance in terms of increasing muscle strength and function, decreasing the level of dependence, and providing cardiorespiratory healing and gravitational stimulation after major surgery without complication (2,3). Postoperative early mobilization was reported to increase oxygen transport and reduce the incidence of pulmonary complications (23). Our study revealed that the values of SPO_2 with and without oxygen support measured after mobilization were significantly higher in the intervention group in parallel with the literature and no early-stage pulmonary complications were observed in both groups.

Semerjian et al. (20) revealed that patients were mobilized at night after surgery and Persson et al. (11) and Arumainayagam et al. (24) revealed that patients were mobilized within the first 24 h (11,20,24). Guan et al. (16) revealed that patients were encouraged to get out of bed at least four times a day, 24 h after surgery (16). Dutton et al. (17) revealed that patients were sitting up on the bed in the first 48 h after surgery and the walking exercises were started after 48 h. Mukhtar et al. (18) revealed that patients were mobilized at least 6 h a day after the first mobilization. Retrospective (17,18,21,24) and prospective studies (7,8,15,20) on ERAS protocols in RC treatment were analyzed; early mobilization procedure was reported to be

Table 3. Vital signs and peripheral blood glucose values before and after mobilization

Parameter	Before/after mobilization	Intervention (n=20)	Control (n=20)	Test statistics	
		Mean ± SD (min-max)	Mean ± SD (min-max)	z/t	p
Systolic blood pressure/mmHg	Before	128.7±16.9 (90.0-152.0)	126.7±17.8 (95.0-160.0)	-0.298	0.766[a]
	After	117.7±15.12 (90.0-140.0)	120.6±22.6 (90.0-170.0)	-0.477	0.636[b]
Diastolic blood pressure/mmHg	Before	77.7±14.2 (40.0-94.0)	72.7±9.2 (60.0-91.0)	1.334	0.190[b]
	After	69.5±6.4 (58.0-80.0)	71.1±10.6 (50.0-97.0)	-0.577	0.568[b]
Pulse/min.	Before	85.9±12.6 (68.0-109.0)	83.5±16.0 (60.0-116.0)	0.515	0.609[b]
	After	92.0±11.5 (72.0-118.0)	101.3±15.3 (76.0-137.0)	-2.174	**0.036[b]**
Fever/°C	Before	36.6±0.3 (36.0-37.6)	36.6±0.4 (36.0-37.7)	-0.399	0.690[a]
	After	36.5±0.2 (36.2-36.8)	36.6±0.4 (36.2-37.6)	-0.302	0.763[a]
SPO_2/with O_2 support (%)	Before	97.1±1.8 (94.0-100.0)	96.8±1.6 (94.0-99.0)	-0.422	0.673[a]
	After	98.9±1.8 (92.0-100.0)	96.8±1.6 (94.0-99.0)	-4.005	**0.000[a]**
SPO_2/without O_2 support (%)	Before	92.6±2.9 (88.0-100.0)	92.6±2.7 (88.0-97.0)	-0.096	0.923[a]
	After	96.1±2.3 (92.0-100.0)	93.3±2.5 (89.0-98.0)	3.733	**0.001[b]**
Blood glucose (mg/dL)	Before	131.4±27.0 (107.0-212.0)	148.5±42.7 (98.0-248.0)	-1.382	0.167[a]
	After	109.8±24.3 (90.0-176.0)	139.3±41.7 (92.0-234.0)	-2.441	**0.015[a]**

[a]: Mann-Whitney U test [b]: Student t-test, SD: Standard deviation, Min: Minimum, Max: Maximum

applied; however, no information was given concerning the mobilization process in terms of its time, duration, and method. Our study revealed that patients in the intervention group were mobilized within the first 16 h following a standard mobilization procedure differently from the literature. Factors, such as the length of surgery and the presence of adequate medical staff for safe mobilization after surgery, were considered.

The literature reported that regaining regular intestinal functions took a shorter time in patients who underwent ERAS protocol (4,20). NG tube was reported to be removed in 2.0±0.3 days by Mukhtar et al. (18); on the first day after the surgery by Arumainayagam et al. (24); and immediately after the surgery by Saar et al. (15,18,24). The first defecation time in the literature was reported as 6.1±0.3/days by Mukhtar et al. (18) and 2.6±0.9/days by Saar et al. (15), Persson et al. (11) revealed that the time of the first bowel movement was 2 days earlier in the ERAS group (11). Moreover, Frees et al. (7) pointed out that the first defecation time was shorter in enterally fed patients. Our study revealed that the first defecation time was 4.4±1.5 days (intervention group), similar to the results of Frees et al. (7) and Mukhtar et al. (18) and it was 1.5 days shorter in the intervention group (5.7±2.1 days/control group) as in Persson et al. (11). Our findings suggest that early mobilization contributes to the early motility of bowel and NG tube removal.

Karl et al. (8) revealed that QoL was better on the third and seventh days after surgery in patients who underwent ERAS protocols. Porserud et al. (10) revealed that patients who were included in the exercise program had higher scores at functional capacity and physical area dimensions of QoL. Our study revealed that QoL was significantly better in the intervention group in terms of physical function, physical role difficulty, and general perception of health in the first month. In the third month after surgery, the scores of physical and emotional role difficulty, vitality, mental health, and general perception of health subdimensions were significantly better in the intervention group. RC treatment has a significant effect on QoL in patients who underwent RC in the early postoperative period. The disappearance of the difference that was observed in the physical function subdimension of QoL in the first month could be explained by the healing effect of the ERAS components jointly applied in both groups. Standardized ERAS protocols improve patient satisfaction and QoL in addition to improved clinical patient outcomes (6). Additionally, the inclusion of patients' relatives in the care planning will have positive effects on the healing process (25).

Rivas et al. (21) revealed that ERAS may have a positive effect on patients who underwent RC and only with multidisciplinary teamwork. Our multicenter study revealed that great importance

Table 4. Preoperative SF-36 quality of life and HADS scale score distributions

Score distributions	Intervention (n=20)	Control (n=20)	Test statistics	
	Mean ± SD (min-max)	Mean ± SD (min-max)	t/z	p
SF-36 physical function	74.3±21.8 (25.0-100.0)	61.5±32.9 (0.0-100.0)	-0.992	0.321[b]
SF-36 physical role difficulty	35.0±38.4 (0.0-100.0)	22.5±38.0 (0.0-100.0)	-1.190	0.234[b]
SF-36 emotional role difficulty	31.7±43.9 (0.0-100.0)	40.0±42.7 (0.0-100.0)	-0.710	0.478[b]
SF-36 vitality	47.8±22.7 (5.0-80.0)	44.3±22.5 (10.0-80.0)	0.489	0.627[a]
SF-36 mental health	55.0±19.6 (20.0-92.0)	52.0±18.2 (20.0-88.0)	0.502	0.618[a]
SF-36 social functioning	60.0±25.8 (12.5-100.0)	42.5±26.8 (0.0-100.0)	1.502	0.141[a]
SF-36 pain	48.5±25.4 (10.0-100.0)	56.5±38.2 (0.0-100.0)	-0.746	0.445[b]
SF-36 general perception of health	57.8±15.9 (35.0-90.0)	46.8±21.9 (10.0-80.0)	1.816	0.777[a]
HADS-anxiety	19.9±2.9 (11.0-23.0)	20.3±2.4 (15.0-24.0)	-0.270	0.978[b]
HADS-depression	18.2±2.4 (15.0-24.0)	18.4±2.1 (14.0-22.0)	-0.285	0.777[a]
HADS-total	38.0±4.2 (27.0-46.0)	38.6±3.0 (33.0-45.0)	-0.552	0.605[a]

[a]: Student t-test, [b]: Mann-Whitney U test, SD: Standard deviation, Min: Minimum, Max: Maximum, HADS: Hospital anxiety and depression scale

Table 5. Postoperative SF-36 quality of life and HADS scale score distributions

Score distribution		Intervention	Control	Test statistics	
		Mean ± SD (min-max)	Mean ± SD (min-max)	z	p
First Month	SF-36 physical functioning	41.0±19.4 (15.0-70.0)	26.8±16.2 (0.0-55.0)	-2.409	**0.016**[a]
	SF-36 physical role difficulty	11.3±12.8 (0.0-25.0)	3.8±9.2 (0.0-25.0)	-2.044	**0.041**[a]
	SF-36 emotional role difficulty	31.7±39.7 (0.0-100.0)	13.3±22.7 (0.0-66.7)	-1.406	0.160[a]
	SF-36 vitality	32.5±21.2 (10.0-85.00)	23.8±22.4 (0.0-60.0)	-1.813	0.070[a]
	SF-36 mental health	53.4±20.4 (28.0-96.0)	41.6±17.8 (20.-68.0)	-1.820	0.069[a]
	SF-36 social functioning	21.3±12.2 (0.0-50.0)	15.0±12.6 (0.0-37.5)	-1.501	0.133[a]
	SF-36 pain	53.0±13.7 (32.5-62.5)	54.6±13.1 (32.5-77.5)	-0.260	0.795[a]
	SF-36 general perception of health	38.8±11.7 (20.8-60.6)	21.9±16.1 (1.0-46.0)	-3.243	**0.001**[a]
	HADS-anxiety	21.4±2.1 (16.0-23.0)	20.4±3.1 (14.0-24.0)	-0.575	0.565[a]
	HADS-depression	20.1±2.1 (17.0-24.0)	20.3±2.3 (18.0-24.0)	-0.151	0.880[a]
	HADS-total	41.4±2.9 (35.0-45.0)	40.7±2.6 (35.0-45.0)	-0.589	0.556[a]
Third Month	SF-36 physical functioning	74.3±15.9 (40.0-90.0)	66.0±16.0 (40.0-100.0)	-1.922	0.055[a]
	SF-36 physical role difficulty	70.1±31.0 (0.0-100.0)	42.5±28.2 (0.0-100.0)	-2.838	**0.005**[a]
	SF-36 emotional role difficulty	73.9±40.8 (0.0-100.0)	45.0±39.4 (0.0-100.0)	-2.765	**0.006**[a]
	SF-36 vitality	66.3±16.1 (20.0-85.0)	41.0±21.1 (5.0-70.0)	-3.931	**0.000**[a]
	SF-36 mental health	83.4±11.8 (40.0-100.0)	60.8±20.5 (36.0-92.0)	-3.699	**0.000**[a]
	SF-36 social functioning	65.0±20.5 (12.5-87.5)	48.8±18.1 (25.0-87.5)	-2.486	**0.013**[a]
	SF-36 pain	49.3±2.4 (40.0-50.0)	53.6±9.7 (45.0-77.5)	-1.633	0.112[a]
	SF-36 general perception of health	64.3±15.5 (20.0-80.0)	38.0±15.9 (20.0-80.0)	-4.073	**0.000**[a]
	HADS-anxiety	22.3±1.7 (17.0-25.0)	20.6±2.9 (15.0-25.0)	-1.588	0.112[a]
	HADS-depression	18.0±1.8 (14.0-23.0)	18.0±1.4 (16.0-23.0)	-0.086	0.932[a]
	HADS-total	40.3±2.4 (34.0-46.0)	38.6±3.4 (33.0-45.0)	-1.282	0.200[a]

[a]: Mann-Whitney U test, SD: Standard deviation, Min: Minimum, Max: Maximum, HADS: Hospital anxiety and depression scale

was attached to the multidisciplinary teamwork for the surgeons who perform the surgery and the nurses responsible for clinical care to cooperate with the dieticians, physiotherapists, and all other health professionals.

Study Limitations

The limited number of patients for 3 years due to patients who had to be excluded from the study can be considered as the limitation of the current study. Additionally, the intervention

group was encouraged for early mobilization by the research team, which created a sense of exclusiveness and worthiness in the patients and their relatives, thus they were more actively involved in the process. More frequent communication with the researcher upon the request of the patients in the intervention group might have positively affected the responses to the surveys in the long run.

Conclusion

Early mobilization could be safely performed in patients who underwent RC and ileal diversion following the standard procedure, which has positively contributed to the healing process and improved their QoL.

Standardized ERAS protocols are needed to provide optimal supportive care in patients who underwent RC. More multicenter prospective randomized controlled studies with larger samplings are needed to evaluate different components of ERAS protocol in different countries.

Ethics

Ethics Committee Approval: The local ethics committee approval was obtained (İzmir Tepecik Training and Research Hospital, approval number: 14/2, date: 30.10.2014).

Informed Consent: Those who signed the informed consent form were included in the study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Ö.Ç., T.M., G.A., Concept: S.V., Ö.Ç., T.M., G.A., H.B., Design: S.V., Ö.Ç., T.M., G.A., H.B., Data Collection or Processing: S.V., Ö.Ç., T.M., G.A., Analysis or Interpretation: S.V., Ö.Ç., H.B., Literature Search: S.V., Ö.Ç., T.M., G.A., H.B., Writing: S.V., Ö.Ç., T.M., G.A., H.B.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Siracusano S, D'Elia C, Cerruto MA, Saleh O, Serni S, Gacci M, Ciciliato S, Simonato A, Porcaro A, DE Marco V, Talamini R, Toffoli L, Visalli F, Niero M, Lonardi C, Imbimbo C, Verze P, Mirone V, Racioppi M, Iafrate M, Cacciamani G, DE Marchi D, Bassi P, Artibani W. Quality of Life in Patients with Bladder Cancer Undergoing Ileal Conduit: A Comparison of Women Versus Men. In Vivo 2018;32:139-143.
2. Moschini M, Stabile A, Mattei A, Montorsi F, Cathelineau X, Sanchez-Salas R. Enhanced recovery after surgery (ERAS) in radical cystectomy patients: from consensus to evidences. Int Braz J Urol 2019;45:655-657.
3. Visioni A, Shah R, Gabriel E, Attwood K, Kukar M, Nurkin S. Enhanced Recovery After Surgery for Noncolorectal Surgery?: A Systematic Review and Meta-analysis of Major Abdominal Surgery. Ann Surg 2018;267:57-65.
4. Tyson MD, Chang SS. Enhanced Recovery Pathways Versus Standard Care After Cystectomy: A Meta-analysis of the Effect on Perioperative Outcomes. Eur Urol 2016;70:995-1003.
5. Djaladat H, Katebian B, Bazargani ST, Miranda G, Cai J, Schuckman AK, Daneshmand S. 90-Day complication rate in patients undergoing radical cystectomy with enhanced recovery protocol: a prospective cohort study. World J Urol 2017;35:907-911.
6. Aarts MA, Rotstein OD, Pearsall EA, Victor JC, Okrainec A, McKenzie M, McCluskey SA, Conn LG, McLeod RS; iERAS group. Postoperative ERAS Interventions Have the Greatest Impact on Optimal Recovery: Experience With Implementation of ERAS Across Multiple Hospitals. Ann Surg 2018;267:992-997.
7. Frees SK, Aning J, Black P, Struss W, Bell R, Chavez-Munoz C, Gleave M, So AI. A prospective randomized pilot study evaluating an ERAS protocol versus a standard protocol for patients treated with radical cystectomy and urinary diversion for bladder cancer. World J Urol 2018;36:215-220.
8. Karl A, Buchner A, Becker A, Staehler M, Seitz M, Khoder W, Schneevoigt B, Weninger E, Rittler P, Grimm T, Gratzke C, Stief C. A new concept for early recovery after surgery for patients undergoing radical cystectomy for bladder cancer: Results of a prospective randomized study. J Urol 2014;191:335-340.
9. Cerantola Y, Valerio M, Persson B, Jichlinski P, Ljungqvist O, Hubner M, Kassouf W, Muller S, Baldini G, Carli F, Naesheimh T, Ytrebo L, Revhaug A, Lassen K, Knutsen T, Aarsether E, Wiklund P, Patel HRH. Guidelines for perioperative care after radical cystectomy for bladder cancer: Enhanced recovery after surgery (ERAS®) society recommendations. Clin Nutr 2013;32:879-887.
10. Porserud A, Sherif A, Tollbäck A. The effects of a physical exercise programme after radical cystectomy for urinary bladder cancer. A pilot randomized controlled trial. Clin Rehabil 2014;28:451-459.
11. Persson B, Carringer M, Andrén O, Andersson SO, Carlsson J, Ljungqvist O. Initial experiences with the enhanced recovery after surgery (ERAS) protocol in open radical cystectomy. Scand J Urol 2015;49:302-307.
12. Aydemir O, Guvenir T, Kuey L, Kultur S. Validity and reliability of Turkish version of hospital anxiety and depression scale. Türk Psikiyatri Dergisi 1997;84:280-287.
13. Kocyigit H, Aydemir O, Olmez N, Memis A. Reliability and Validity of the Turkish Version of Short Form-36 (SF-36). İlaç ve Tedavi Dergisi 1999.
14. Lau CS, Chamberlain RS. Enhanced Recovery After Surgery Programs Improve Patient Outcomes and Recovery: A Meta-analysis. World J Surg 2017;41:899-913.
15. Saar M, Ohlmann CH, Siemer S, Lehmann J, Becker F, Stöckle M, Kamradt J. Fast-track rehabilitation after robot-assisted laparoscopic cystectomy accelerates postoperative recovery. BJU Int 2013;112:E99-106.
16. Guan X, Liu L, Lei X, Zu X, Li Y, Chen M, Wang L, Qi L. CORRIGENDUM: A Comparative Study of Fast-Track Versus Conventional Surgery in Patients Undergoing Laparoscopic Radical Cystectomy and Ileal Conduit Diversion: Chinese Experience. Sci Rep 2015;5:8177.
17. Dutton TJ, Daugherty MO, Mason RG, McGrath JS. Implementation of the Exeter enhanced recovery programme for patients undergoing radical cystectomy. BJU Int 2014;113:719-725.
18. Mukhtar S, Ayres BE, Issa R, Swinn MJ, Perry MJ. Challenging boundaries: an enhanced recovery programme for radical cystectomy. Ann R Coll Surg Engl 2013;95:200-206.
19. Singh V, Yadav R, Sinha RJ, Gupta DK. Prospective comparison of quality-of-life outcomes between ileal conduit urinary diversion and orthotopic

neobladder reconstruction after radical cystectomy: a statistical model. BJU Int 2014;113:726-732.

20. Semerjian A, Milbar N, Kates M, Gorin MA, Patel HD, Chalfin HJ, Frank SM, Wu CL, Yang WW, Hobson D, Robertson L, Wick E, Schoenberg MP, Pierorazio PM, Johnson MH, Stimson CJ, Bivalacqua TJ. Hospital Charges and Length of Stay Following Radical Cystectomy in the Enhanced Recovery After Surgery Era. Urology 2018;111:86-91.
21. Rivas JG, Alonso y Gregorio S, Ledo JC, Orejón RU, Doslada PU, Sebastián JD, Gomez AT, de la Pena Barthel JJ. Early recovery protocol in patients undergoing laparoscopic radical cystectomy Urol Sci 2017;28:2-5.
22. Senduran M, Yurdalan SU, Karadibak D, Gunerli A. Haemodynamic effects of physiotherapy programme in intensive care unit after liver transplantation. Disabil Rehabil 2010;32:1461-1466.
23. Kirkeby-Garstad I, Sellevold OF, Stenseth R SE. Mixed venous oxygen desaturation during early mobilization after coronary artery bypass surgery. Acta Anaesthesiol Scand 2005;49:827-834.
24. Arumainayagam N, McGrath J, Jefferson KP, Gillatt DA. Introduction of an enhanced recovery protocol for radical cystectomy. BJU Int 2008;101:698-701.
25. Baris N, Karabacak U. The inpatients' relatives' perception of the nursing role. J Marmara Univ Inst Heal Sci 2013;3:131.

ORIGINAL RESEARCH
Endourology

Doi: 10.4274/jus.galenos.2021.2021.0024
J Urol Surg, 2022;9(1):20-24

Comparison of Surgical and Functional Outcome of Laparoscopic Pyeloplasty and Robot-assisted Pyeloplasty for Congenital Uretero Pelvic Junction Obstruction

Aditya Abhishek Jha[1], Arjun Singh Sandhu[2], Sharat Chandra Dash[3], Raghav Talwar[4], Madhu Govindaiah[4], Gagandeep Singh[5], Anoop Handa[3], Nimit Solanki[2]

[1]Department of Urology, Military Hospital, Secunderabad, Telangana, India
[2]Department of Urology, Base Hospital Delhi Cantt, New Delhi, India
[3]Department of Urology, Army Hospital Research and Referral, New Delhi, India
[4]Department of Urology, Command Hospital Air Force, Bengaluru, Karnataka, India
[5]Department of Urology, Command Hospital, Udhampur, Jammu and Kashmir, India

What's known on the subject? and What does the study add?

Most of the studies done in the past show that with all other intraoperative and postoperative parameters being comparable between robotic and laparoscopic pyeloplasty, only total operative time and total blood loss happen to be both clinically and statistically significantly lesser in robotic pyeloplasty. Our study shows that in the experienced hand, only total operative time happens to be clinically and statistically significantly lesser in robotic pyeloplasty whereas, total blood loss is not clinically significantly lesser.

Abstract

Objective: A surge in the easy availability of robotic platforms has resulted in numerous surgical procedures, which were previously done using an open or conventional laparoscopic approach, are now being done using robots worldwide. A prospective randomized study was conducted to compare surgical and functional outcomes of conventional laparoscopic pyeloplasty with robotic-assisted pyeloplasty.

Materials and Methods: Patients who require pyeloplasty who presented to our institute between June 2015 and March 2018 were randomized into a robot-assisted or conventional laparoscopic pyeloplasty group. Common steps included a lateral trans-peritoneal approach, intraoperative antegrade double-J stent placement, stent removal at 4 weeks postoperative, and Diethylene Triamine Penta Acetate renogram at 4 weeks post stent removal. Records of intraoperative and postoperative variables were maintained for all patients. The comparison of continuous numerical data was done using the Independent t-test and categorical non-numerical data using the chi-square (χ^2) test. P-values of <0.05 were considered significant.

Results: This study includes 58 patients who were randomized into two groups with 29 patients each. No significant difference was noted for postoperative variables, such as the visual analog score for pain, drain placement duration, hospitalization duration, and time to return to daily activity. Intraoperative variables, such as total operative time (148.56 minute vs. 114.28 minute, p-value=0.001) and intraoperative blood loss (68.4 mL vs. 59.2 mL, p-value=0.001) were significantly lesser and favored robot-assisted pyeloplasty over conventional laparoscopic pyeloplasty.

Conclusion: In favor of robot-assisted pyeloplasty, both statistically and clinically intraoperative time was lesser, but intraoperative blood loss was lesser only statically and not clinically.

Keywords: Laparascopic pyeloplasty, robotic pyeloplasty, congenital ureteropelvic junction obstruction

Correspondence: Anoop Handa MD, Department of Urology, Army Hospital Research and Referral, New Delhi, India
E-mail: dr.anoop10@gmail.com **ORCID-ID:** orcid.org/0000-0003-2364-7854
Received: 09.12.2020 **Accepted:** 02.12.2021

Cite this article as: Jha AA, Sandhu AS, Dash SC, Talwar R, Govindaiah M, Singh G, Handa A, Solanki N. Comparison of Surgical and Functional Outcome of Laparoscopic Pyeloplasty and Robot-assisted Pyeloplasty for Congenital Uretero Pelvic Junction Obstruction. J Urol Surg, 2022;9(1):20-24.

Introduction

The management of ureteric pelvic junction obstruction (UPJO) has dramatically evolved over the past two decades. Laparoscopy has largely replaced open pyeloplasty and has become the standard of care for primary UPJO (1,2). However, conventional laparoscopic pyeloplasty (CLP) remains a technically demanding procedure that requires advanced intracorporeal suturing skills (3).

The availability of robotic platforms has altered the way urologists approach various complex reconstructive procedures. The need for precise intracorporeal suturing makes pyeloplasty a likely procedure, which would benefit from robotic assistance. Therefore, this randomized study aimed to compare functional and surgical outcomes following CLP and robot-assisted laparoscopic pyeloplasty (RALP) to explore this issue.

Materials and Methods

The study was conducted between June 2015 and Mar 2018 in a tertiary care center in Northern India. All patients of congenital UPJO presenting with pain, recurrent urinary tract infection, secondary renal calculus, or deteriorating renal function were randomized and recruited. Patients with secondary/recurrent UPJO were excluded from the study. The primary objective was to compare the success rate of the procedures between the two groups by demonstrating non-obstructed drainage and postoperative symptom resolution, with secondary objectives to compare surgical parameters like total operative time, total blood loss, intraoperative complications, postoperative pain, and durations of drain placement, hospitalization, and return to daily activity.

Statistical Analysis

Descriptive statistics were used to characterize the demographic data, laterality of obstruction (right/left), indication of surgery (pain, incidental detected), intraoperative finding, complications and success of surgery. Mean and standard deviation was used for quantitative continuous variables. Categorical non numerical data analysis was done with chi square test. The p value of <0.05 was considered statistically significant.

Catering to an alpha error of 5% and power of study as 80%, a sample size of 50 cases (25 cases in each group) was calculated. The feasibility of 10% lost to follow-up was factored in, thus we enrolled 58 cases in total (29 cases each group).

This single-center prospective randomized controlled trial randomized patients (1:1) using computer-generated random numbers into the two groups. Random numbers were generated using the RAND function of MS Excel. They were divided into two equal groups. The results were kept in serially numbered, sealed, opaque envelopes. These envelopes were kept with a third person. Once the patient was enrolled, a call was given to the third person to ascertain the group. Both surgeon and patient were informed about the technique only on the morning of the surgery, thus making it a double-blinded study.

The approval of the institutional ethical committee was obtained (Army Hospital (R & R), Delhi Cannt, approval number: 75/2015, date: 30.08.2015). Written informed consent was taken from all patients. Preoperative data recorded included age, sex, obstruction laterality, surgery indication, clinical abdominal findings, hemoglobin, blood urea, and serum creatinine levels. Anatomical radiological evaluation in ultrasonography and functional radiological evaluation in intravenous urography and Diethylene Triamine Penta Acetate (DTPA) renogram were also performed.

All surgical procedures were performed by consultants with equivalent experience. All surgeries were performed under general anesthesia in full lateral position after antibiotic prophylaxis administration (third-generation cephalosporin). Retro-grade pyelography was done before each surgery. Pneumo-peritoneum was created using the veress needle technique. For RALP, one camera and two robotic arms of the four-arm da Vinci Si surgical system were used with one additional 10-mm port for the assistant for suctioning or passage of suture materials and another 5-mm port for liver retraction (if required on the right side) (Figure 1). For CLP, one 10-mm camera port and two working ports were used (one 10 mm and another 5 mm) (Figure 2). All patients underwent Anderson Hynes dismembered pyeloplasty using 4-0 vicryl sutures and intra-operatively antegrade Double-J stent (DJS) placement. Intra-operatively recorded parameters included the nature of the obstruction, surgery duration, blood loss, intraoperative complication, and instances involving conversion to an open approach. At the end of the procedure, a 20 French Foley catheter and 26 French

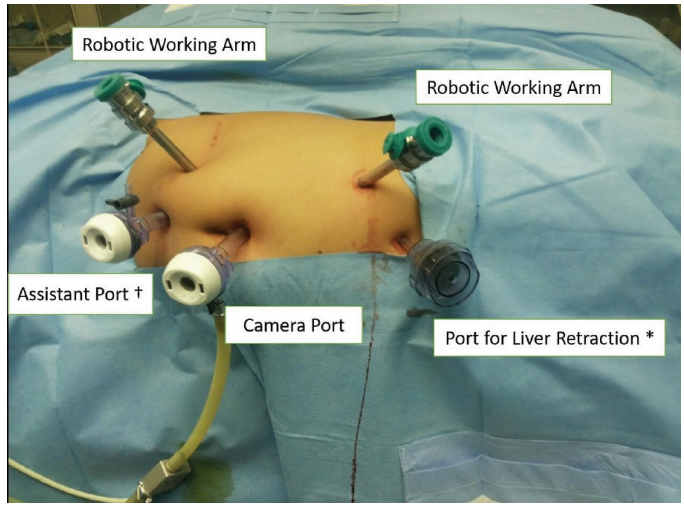


Figure 1. Port placement for right-sided robot-assisted pyeloplasty. *5-mm port used for right-sided pyeloplasty to retract the lobe of the liver (If required). †10-mm assistant port used for suction and passage of suture material

abdominal drains were placed in each case. Foley catheter was removed on a postoperative day (POD) 3 or 4. The abdominal drain was subsequently removed, once the drain output was less than 30 milliliters per day for two consecutive days.

In the immediate postoperative period, patients were monitored for any surgical complication, pain severity, which was assessed using the visual analog score (VAS) for three consecutive days, analgesia requirement (injection of tramadol at 50 mg intravenous was administered if patients had VAS of 2 or more on that day), hospital stay duration, drain placement duration, and time to return to daily activity.

Patients were followed up at 2 (for DJS removal) and 4 months (for DTPA scan) post-operatively. Additionally, a note was made of any postoperative complications.

Our study revealed a 100% success rate in both groups, which was defined by resolution of patient's symptoms and demonstration of non-obstructed drainage on postoperative DTPA scan.

Results

This study included 58 patients with congenital UPJO (29 patients in each group) who underwent surgical management during the study period at our center. Complete data were available for all patients at the end of the study period. Basic demographic data are shown in Table 1. No statistically significant difference was found between the two groups concerning age, sex distribution, and obstruction laterality. Our study revealed a marginally higher percentage of patients who presented with symptoms in the CLP group compared to the RALP group; however, this difference also was statistically insignificant.

Among the intraoperative variables (Table 1), crossing vessel was relatively more frequently seen in the RALP group, but generally, aperistaltic/stenotic segment was noted as the most common etiology of obstruction in both groups. This variable was statistically insignificant in our study. The mean total operative time in the CLP group, which included time for pneumo-peritoneum creation, port placement, and surgical procedure, was noted as 34.28 min more than the RALP group, which includes time for pneumo-peritoneum creation, port placement, docking time, console time, and undocking time. Similarly, the total blood loss in the CLP group was noted as 9.2 mL more than the RALP group. Reduction in both intraoperative time and blood loss was statistically significant and in favor of the RALP group. No intraoperative complications or conversion to an open approach was noted in either of the groups.

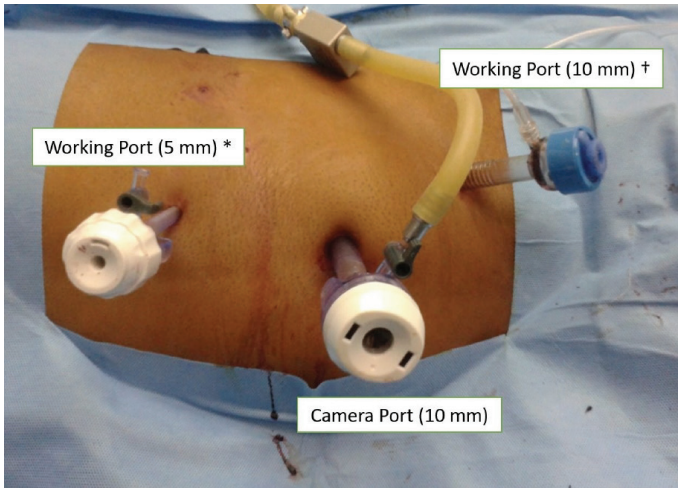


Figure 2. Port placement for left-sided laparoscopic pyeloplasty. *5-mm port used by the surgeon for holding tissue. †10-mm port used for passage of needle with suture material, suction, etc.

Among the postoperative variables (Table 2), the VAS score on POD 1/2/3, number of days of analgesia requirement, days of abdominal drain placement, hospitalization duration, and days required to return to daily activity were comparable and statistically insignificant between both groups. In both groups, no postoperative complications were noted, and all 29 cases in both groups demonstrated a non-obstructed flow pattern on follow-up with DTPA scan after 4 months.

Discussion

One of the most significant advances in the surgical field of the twenty-first century has been the introduction of laparoscopic surgery. Compared to open surgery, the major advantages of laparoscopic surgery include better cosmetics, lower

Table 1. Preoperative and intraoperative characteristics

Characteristics	CLP	RALP	p-value
Number of patients	29	29	-
Age in years	35.44+10.25	33.96+8.85	0.58
Sex (female/male)	13/16	10/19	0.38
Side (left/right)	13/16	17/12	0.25
Presentation			
Incidentally detected	7	8	0.73
Symptomatic (Pain)	22	21	0.73
Intraoperative finding			
Crossing vessel	8	10	0.52
Aperistaltic/stenotic segment	21	19	0.52
Total operative time (minutes)	148.56+15.15	114.28+12.98	0.001
Total blood loss (milliliter)	68.4+7.86	59.2+9.8	0.001
Intra-op complications	Nil	Nil	-

CLP: Conventional laparoscopic pyeloplasty, RALP: Robot-assisted laparoscopic pyeloplasty

Table 2. Postoperative comparison

Characteristics	CLP	RALP	p-value
VAS on post op day 1	4.86+0.33	4.66+0.51	0.11
VAS on post op day 2	2.84+0.40	2.78+0.32	0.56
VAS on post op day 3	1.26+0.41	1.14+0.36	0.28
Days analgesia Given	2.08+0.27	2.04+0.20	0.56
Days drain kept	4.16+0.62	3.96+0.67	0.28
Total hospitalization (Days)	5.16+0.85	4.96+0.88	0.42
Return to daily activity (Days)	20.4+2.6	20.2+2.4	0.8
Post op complication	Nil	Nil	-
Success of surgery	100%	100%	-

CLP: Conventional laparoscopic pyeloplasty, RALP: Robot-assisted laparoscopic pyeloplasty

postoperative pain, reduced intraoperative blood loss, reduced hospital stay duration, and early return to daily activities despite having similar functional and oncological outcomes. A few of the major limitations of laparoscopic surgery are counter-intuitive and scaled-up movements, ergonomically tiring for surgeons, and lack of three-dimensional vision. All these ultimately lead to a steep learning curve.

With the introduction of robotic platforms in urology since the early 2000s, many of these limitations have been overcome. The major advantages of robotic surgery compared to laparoscopy include three-dimensional vision, elimination of tremors, and a better range of movements. With the wider availability of robotic devices, an increasing number of procedures, which were initially done using laparoscopy, are now done using robotic platforms worldwide with excellent outcomes. However, the limitations with robotic surgery include the associated higher costs and requirement of larger space in the operating room.

A recent systematic review and meta-analysis by Autorino et al. (4) confirmed that laparoscopy represents an effective and less invasive technique of pyeloplasty, but RALP is likely to emerge as the new minimally invasive standard of care wherever robotic technology is available due to its precise suturing and shorter learning curve. Previous studies compared RALP with CLP and revealed advantages in RALP in respect of total operative time, intraoperative blood loss, and length of hospitalization but revealed comparable results for postoperative complication and success rate (5-7).

A statistically significant difference was found in the mean total operative time of 34.28 min favoring the RALP group in our study. This finding was found consistent with other studies in the literature. Hemal et al. (6) (98 min in RALP vs. 145 min in CLP), Kumar and Nayak (8) (129 min in RALP vs. 150 min in CLP), and Pahwa et al. (9) (141.73 min in RALP vs. 191.56 min in CLP) also demonstrated statistically significant reduction favoring the RALP group in their respective studies. The reduced operative time in the RALP group is probably due to the better three-dimensional vision, tremor elimination, and better range of movements compared to the CLP group.

Our study revealed a statistically significant reduction in the total blood loss favoring the RALP group. Similarly, other studies in the literature have demonstrated similar findings. Hemal et al. (6) (40 mL in the RALP vs. 101 mL in the CLP group) and Pahwa et al. (9) (46.37 mL in the RALP vs. 55.24 mL in the CLP group) demonstrated a statistically significant reduction in the total blood loss favoring the RALP group (6,9). We feel that the reduced blood loss in the RALP group is associated with better vision, which results in more accurate dissection and precise hemostasis.

Additionally, in our study, we did not find any statistically significant difference between VAS scores between the two groups on POD 1/2/3. Pahwa et al. (9) demonstrated comparative postoperative pain scores between both the groups (4.77 in the CLP group and 4.16 in the RALP group). Likewise, Riachy et al. (10) involved the pediatric population and revealed comparable pain scores between the two groups.

Our study revealed a comparable mean number of days of keeping the abdominal drain following the surgery between the two groups. Consistent with our findings, Kumar and Nayak (8) (1.36 days for CLP vs. 1.58 days for RALP) and Pahwa et al. (9) (2.68 days for CLP vs. 2.03 days for RALP) also demonstrated comparable results. The requirement of longer duration of drain placement in our study (4.16 days in RALP versus 3.96 days in CLP) compared to the above-mentioned studies was due to the removal of drain only when the output was <30 mL per day for 2 consecutive days (as per our institutional protocol), whereas the drains were removed once the output was <50 mL over 24 h in both other studies.

Our study revealed a comparable number of hospitalization days between both groups. Similarly, Kumar and Nayak (8) (2.90 days for CLP vs. 2.89 days for RALP) and Pahwa et al. (9) (3 days for CLP vs. 2.45 days for RALP) found comparable results. Contrary to these findings, Braga et al. (11) revealed that the hospital stays in the RALP was significantly lesser than the CLP group, (weighted mean difference: -0.5 days; 95% confidence interval: -0.6-0.4; $p<0.01$). The longer average duration of hospital stays in our study compared to the above-mentioned studies was attributable to the longer duration of abdominal drain placement in our patients.

The number of days required for the patient to return to daily activity was similarly comparable between the two groups in our study. We could not find any other study in literature which compared CLP and RALP concerning return to daily activity; however, Lasmar et al. (12) revealed that the time to return to normal activities following CLP ranged from 10 to 28 days (median 15 days).

In both, groups in our study, no intraoperative or postoperative complication and requirement for conversion to open approach were found. Similarly, Gettman et al. (5) and Kumar and Nayak (8) demonstrated no intraoperative complications or requirement for conversion to an open approach. Pahwa et al. (9) revealed a complication rate of 11.4% in the CLP group and 8% in the RALP group, all of which were Clavien grade one or two, mainly prolonged drain output, UTI, and gut injury.

Our study had a 100% success rate for both groups. Similarly, Kumar and Nayak (8) revealed a 100% success rate for both groups in their study. Other studies revealed comparable outcomes between the two groups, with Gettman et al. (5), demonstrating no recurrence following the RALP group versus one recurrence following the CLP out of 30 cases in each group at 18 months postoperative follow-up and Pahwa et al. (9) demonstrated recurrence in one case each out of 30 in both groups. All these studies, like ours, confirm the comparable functional outcome for both modalities of treatment if meticulously performed.

Study Limitatons

The limitation of our study include the small sample size and the fact that the operating surgeons already had vast experience and were well versed in laparoscopic pyeloplasty at the start of the study, but due to the recent installation of Da Vinci Si Robotic surgical platform at our institute, the experience of the whole team in robotic procedures were limited, which could lead to a bias and inadvertently increased operative time in the RALP group at least during the first half of our study.

Conclusion

Finally, our study revealed a statistically significant reduction in both; however, the total operative time and intraoperative blood loss favoring RALP, of these only a reduction of intraoperative time by 34.28 min favoring RALP were clinically significant, whereas marginally lesser intraoperative blood loss by 9.2 mL favoring RALP was not clinically significant. All other postoperative surgical and functional parameters were comparable in both groups. Our study results were consistent with previously published studies as expected since, ultimately, robotic assistance refines laparoscopy in terms of precision of suture placement and tissue dissection and unchanged basic surgical approach.

Ethics

Ethics Committee Approval: The approval of the institutional ethical committee was obtained [Army Hospital (R & R), Delhi Cannt, approval number: 75/2015, date: 30.08.2015].

Informed Consent: Written informed consent was taken from all patients.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: A.A.J., A.S.S., S.C.D., M.G., A.H., Concept: A.A.J., R.T., G.S., A.H., Design: A.A.J., S.C.D., R.T., G.S., A.H., Data Collection or Processing: A.A.J., R.T., M.G., G.S., N.S., Analysis or Interpretation A.A.J., A.S.S., S.C.D., R.T., M.G., G.S., N.S., Literature Search: A.A.J., S.C.D., M.G., A.H., Writing: A.A.J., A.S.S., S.C.D., R.T., M.G., G.S., A.H., N.S.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Baldwin DD, Dunbar JA, Wells N, McDougall EM. Single-center comparison of laparoscopic pyeloplasty, Acucise endopyelotomy, and open pyeloplasty. J Endourol 2003;17:155-160.
2. Winfield HN. Management of adult ureteropelvic junction obstruction--is it time for a new gold standard? J Urol 2006;176:866-867.
3. Warren J, da Silva V, Caumartin Y, Luke PP. Robotic renal surgery: The future or a passing curiosity? Can Urol Assoc J 2009;3:231-240.
4. Autorino R, Eden C, El-Ghoneimi A, Guazzoni G, Buffi N, Peters CA, Stein RJ, Gettman M. Robot-assisted and laparoscopic repair of ureteropelvic junction obstruction: a systematic review and meta-analysis. Eur Urol 2014;65:430-452.
5. Gettman MT, Peschel R, Neururer R, Bartsch G. A comparison of laparoscopic pyeloplasty performed with the daVinci robotic system versus standard laparoscopic techniques: initial clinical results. Eur Urol 2002;42:453-458.
6. Hemal AK, Mukherjee S, Singh K. Laparoscopic pyeloplasty versus robotic pyeloplasty for ureteropelvic junction obstruction: a series of 60 cases performed by a single surgeon. Can J Urol 2010;17:5012-5016.
7. Wang F, Xu Y, Zhong H. Robot-assisted versus laparoscopic pyeloplasty for patients with ureteropelvic junction obstruction: an updated systematic review and meta-analysis. Scand J Urol 2013;47:251-264.
8. Kumar R, Nayak B. Robotic versus conventional laparoscopic pyeloplasty: A single surgeon concurrent cohort review. Indian J Urol 2013;29:19-21.
9. Pahwa M, Pahwa AR, Girotra M, Abrahm RR, Kathuria S, Sharma A. Defining the pros and cons of open, conventional laparoscopy, and robot-assisted pyeloplasty in a developing nation. Adv Urol 2014;2014:850156.
10. Riachy E, Cost NG, Defoor WR, Reddy PP, Minevich EA, Noh PH. Pediatric standard and robot-assisted laparoscopic pyeloplasty: a comparative single institution study. J Urol 2013;189:283-287.
11. Braga LH, Pace K, DeMaria J, Lorenzo AJ. Systematic review and meta-analysis of robotic-assisted versus conventional laparoscopic pyeloplasty for patients with ureteropelvic junction obstruction: effect on operative time, length of hospital stay, postoperative complications, and success rate. Eur Urol 2009;56:848-857.
12. Lasmar MT, Castro HA Jr, Vengjer A, Guerra FA, Souza EA, Rocha LM. Transperitoneal laparoscopic pyeloplasty: Brazilian initial experience with 55 cases. Int Braz J Urol 2010;36:678-684.

ORIGINAL RESEARCH
Reconstructive

Doi: 10.4274/jus.galenos.2021.2021.0068
J Urol Surg, 2022;9(1):25-32

Trends and Outcomes of Sacral Neuromodulation: A Saudi Tertiary Care Center Experience

Mohammad Alghafees[1], Yahya Ghazwani[2], Meshari Alqahtani[1], Rakan Aldarrab[2]

[1]King Saud bin Abdulaziz University for Health Sciences College of Medicine, Riyadh, Saudi Arabia
[2]King Abdulaziz Medical City, Department of Urology, Riyadh, Saudi Arabia

What's known on the subject? and What does the study add?

The literature presents a gap when it comes to the trends and outcomes of sacral neuromodulation (SNM) globally, especially in the Middle East. This study evaluated the trends and outcomes of SNM in our patient population. The study could be an incentive for larger multicenter studies. Exploring the outcomes of SNM on a larger scale will improve the procedure.

Abstract

Objective: Sacral neuromodulation (SNM) is a validated treatment for overactive bladder syndrome and chronic non-obstructive retention. In Saudi Arabia, SNM is gaining popularity. It improves patient outcomes and eliminates the associated stigma with refractory urine retention. This study aimed to assess the trends and outcomes in patients with SNM in King Abdulaziz Medical City.

Materials and Methods: This retrospective cohort study targeted adult patients who underwent an SNM device implantation between January 1, 2016, and January 1, 2021. Frequency and percentage were used to display the categorical variables and minimum, maximum, mean, and standard deviation for the continuous variables.

Results: Of the 28 patients, 13 (46.4%) were males and 15 (53.6%) females. The mean age was 37.14+14.62 years. The most frequent indication was idiopathic bladder dysfunction (28.6%, n=8). The first stage success rate was 53.6%, of which 42.9% had the device permanently implanted in the second stage. The overall complication rates were 66.6% and 42.84% for device change and electrode change, respectively, with the most frequent complications as device protrusion and dislocation after device change (n=1, 33.3%) and urinary tract infections after electrode change (n=3, 21.42%).

Conclusion: The complication rate was similar to the literature. However, the first stage success rate was lower than the reported local and international rates. Regular documentation before and after implantation is important to gather data for future studies. Exploring the outcomes of SNM on a larger scale will improve preoperative, perioperative, and postoperative care, thereby supporting more patient satisfaction.

Keywords: Sacral neuromodulation, neurourology, bladder dysfunction

Introduction

Since its introduction in the 1990s, sacral neuromodulation (SNM) has been a beneficial treatment for chronic dysfunction of the urinary system, the bowels, and the pelvic floor. The first sacral SNM implantable systems were approved in 1997 by the Food and Drug Administration for urgency incontinence. According to the provided data by the American Board of Urology, SNM procedures constituted 76% of surgeries to rectify overactive bladder (OAB) dysfunction in 2012 (1). SNM has become a popular option for refractory OAB over the last 20 years and is an effective treatment for OAB and urge incontinence, resulting in a decreased number of voids, increased bladder holding capacity, normal bladder residual volume, and fewer leakage episodes. It has led to a higher quality of life, lower depression rate, and better quality of sleep (2). Globally, >150,000 procedures have been performed (2).

Correspondence: Mohammad Alghafees MD, King Saud bin Abdulaziz University for Health Sciences College of Medicine, Riyadh, Saudi Arabia
E-mail: Alghafees687@gmail.com **ORCID-ID:** orcid.org/0000-0003-1136-9578
Received: 29.05.2021 **Accepted:** 07.10.2021

Cite this article as: Alghafees M, Ghazwani Y, Alqahtani M, Aldarrab R. Trends and Outcomes of Sacral Neuromodulation: A Saudi Tertiary Care Center Experience. J Urol Surg, 2022;9(1):25-32.

SNM is an approved and validated treatment for OAB syndrome, chronic non-obstructive retention, and chronic pelvic pain. A literature review that assessed the current evidence available about SNM reported it as a safe and effective third-line treatment. The overall success rate ranges from 43% to 85%. Due to the invasive surgical technique and the presence of a permanent implant, SNM has a relatively high surgical revision rate, ranging from 9% to 33% (3). The most prevalent reported complications to include pain at the implant site (15-42%), followed by lead migration (4-21%), pain at the lead site (5.4-19%), leg pain (18%), and infection (5.7-6.1%) (3). The quality of studies related to SNM is generally low due to insufficient randomized controlled trials, and are mostly prospective observational studies with mid-term follow-up.

In Saudi Arabia, SNM is gaining popularity because it improves patient outcomes and eliminates the associated stigma with refractory urine retention (non-obstructive), OAB, chronic pelvic pain, chronic constipation, and fecal incontinence. This study aimed to assess the trends and outcomes of patients who received SNM at King Abdulaziz Medical City (KAMC).

Materials and Methods

This retrospective cohort study was conducted at KAMC, Riyadh, Saudi Arabia. All patients who underwent SNM implantation from January 1, 2016, to January 1, 2021, were included. Patients younger than 14 years and those with SNM implantation in a different hospital and followed-up at KAMC were excluded.

The variables, including demographic information, comorbidities, diagnosis, SNM indication, failure or success at the first and second stage of implantation, number of changes done in the time interval, and complications post-change, were extracted from the BESTCare system (ezCareTech, South Korea).

The Institutional Review Board of King Abdullah International Medical Research Center, the Ministry of National Guard-Health Affairs, Riyadh, Kingdom of Saudi Arabia, approved the study with the approval number NRC21R/095/03. The patients' confidentiality and anonymity were ensured, as serial numbers replaced the medical record numbers. The data was accessed and used by only the research team.

Statistical Analysis

The data were entered in Microsoft Excel 2019 (Microsoft Corporation, WA, USA), and the statistical analysis was done with the Statistical Package for the Social Sciences version 23.0 (IBM Corporation, NY, USA). Frequency and percentage are used to display the categorical variables and the minimum, maximum, mean, and standard deviation to display the continuous variables.

Results

The sample size was realized as 28 patients (n=28). Table 1 displays the sociodemographic profile of the sample. Almost half (n=13, 46.4%) were males and 15 (53.6%) females. The minimum age was 17 years and the maximum was 73 years, with a mean of 37.14±14.62 years.

Figure 1 displays the comorbidities occurring in the sample. More than half (n=16, 57.1%) of the patients were medically

Table 1. Sociodemographic profile of patients (n=28)

Demographical characteristics	n	%
Gender		
Male	13	46.4
Female	15	53.6
Age		
Mean	37.14	
Standard deviation	14.62	
Minimum	17	
Maximum	73	

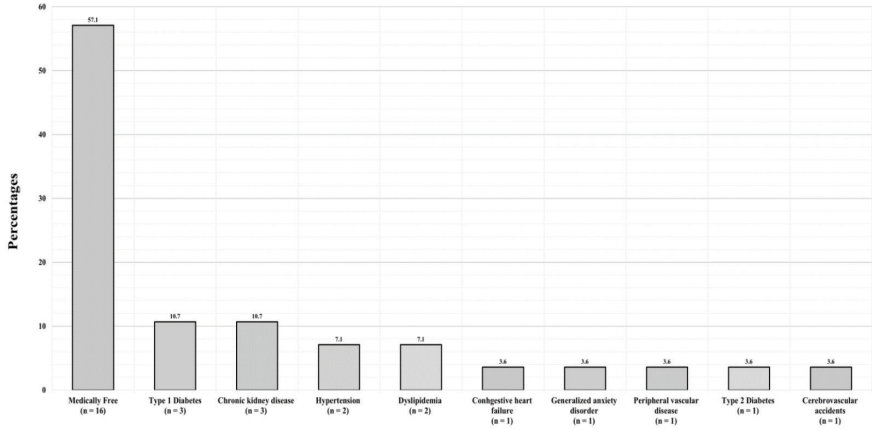


Figure 1. Presence of Co-morbidities among the participants

free, 3 (10.7%) had type 1 diabetes, 3 (10.7%) had chronic kidney disease, 2 (7.1%) had hypertension, 2 (7.1%) had dyslipidemia, 1 (3.6%) had congestive heart failure, 1 (3.6%) had generalized anxiety disorder, 2 (3.6%) had peripheral vascular disease, 1 (3.6%) had type 2 diabetes, and 1 (3.6%) had cerebrovascular accident.

Figure 2 presents the patients' diagnoses. The highest proportion (n=8, 28.6%) was idiopathic bladder dysfunction, followed by 6 (21.4%) with neurogenic bladders due to a spinal cord injury, 4 (14.3%) with OAB, 2 (7.1%) with urinary incontinence, 2 (7.1%) with chronic urinary retention, 2 (7.1%) with spina bifida, 2 (7.1%) with dysfunctional voiding, 1 (3.6%) with Fowler syndrome, and 1 (3.6%) with chronic interstitial cystitis.

Table 2 demonstrates the trials done with the patients and the outcome. More than half (n=15, 53.6%) had a successful first trial. The second stage trial was not performed in 16 (57.1%) and was successful in 12 (42.9%) patients.

Table 3 illustrates the device change history. A small proportion (n=3, 10.7%) of the sample had one device change, with the majority (n=25, 89.3%) never requiring a device change. The device change for the first patient was performed after 28 months and was complicated by the device protruding from the incision site, with minimal discharge. The second patient was after 42 months, complicated by the bulging of the device with pain around the device are and mild tenderness. The third patient interval was not recorded; however, no complication was associated with this device change.

Table 4 displays the battery change history. The majority (n=26, 92.8%) did not require a battery change, 1 (3.6%) patient had a battery change once and another 1 (3.6%) twice. The single battery change of the first patient occurred at 60 months and was not associated with complications. The first of the two battery changes in another patient was done at 24 months, without complications, and the second was done after 24 months, without complications.

Table 5 shows the electrode change/readjustment history. The majority of the sample (n=25, 89.2%) never had an electrode change/readjustment; however, 1 (3.6%) had it twice, 1 (3.6%) three times, and another 1 (3.6%) 9 times.

Table 2. Trials and their outcome (n=28)

Question	n	%
Trial at first stage		
Succeeded	15	53.6
Failed	13	46.4
Trial at second stage		
Not done	16	57.1
Succeeded	12	42.9

Table 3. Device changes history (n=28)

Question	n	%
How many device changes were done?		
None	25	89.3
1	3	10.7
Patient 1 with device changes		
Time Interval	28 months	
Complication incidence	Device protrusion from incision site with minimal discharge	
Patient 2 with device changes		
Time Interval	42 months	
Complication incidence	Bulging of the device, with pain around the device and mild tenderness	
Patient 3 with device changes		
Time Interval	Not documented	
Complication incidence	None	

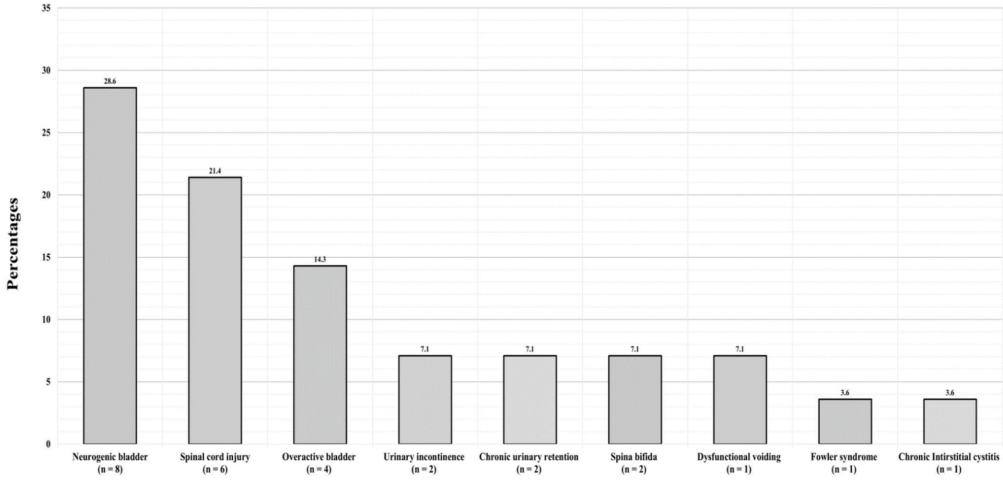


Figure 2. Diagnosis of the patients

The patient who required two electrode changes/readjustments had the first due to a history of trauma at the site of the device, which after the patient complained of an interrupted stream, at 3 months, without complications. The second was due to device erosion and malfunction at 9 months, without complications.

The second patient who required three electrode changes/readjustments had the first due to device displacement at 1.5 months, the second due to electrode displacement, causing a feeling of hesitancy and not feeling the vibrations at 21 months, and the third due to electrode displacement at 25 months, all without complications.

The third patient who required nine electrode changes/readjustments had the first due to pain at the site of the device at 12 months, with urinary incontinence; the second due to urinary incontinence at 4 months, with urinary tract infection; the third due to device erosion after 2 months, with urinary tract infection; the fourth due to a superficially palpable device after 4 months, with pain; the fifth due to electrode displacement at 7 months, with exposed wire from the incision site and minimal discharge; the sixth due to an exposed wire after 1.5 months, without complications; the seventh due to lower leg numbness triggered by turning the device on after 12 months, without complications; the eighth due to the protrusion of the device after 11 months, without complication; and the ninth due to the protrusion of the device at 1.5 months, with urinary tract infection.

Table 4. Battery change history (n=28)

Question	n	%
How many battery changes were done?		
None	0	92.9
1	1	3.6
2	1	3.6
Patient 1 with battery change once		
Time interval	60 months	
Complication incidence	None	
Patient 2 with device changes twice		
Time interval in first battery change	24 months	
Complication incidence in first battery change	None	
Time interval in second battery change	24 months	
Complication incidence in second battery change	None	

Figure 3 displays the rate of postoperative revisits. The revisits were due to a device change in 3 (10.7%) patients, battery change in 3 (10.7%), and electrode change/readjustment in 14 (50%).

Figure 4 demonstrates the complication rate in patients who had a device change. The overall rate of complications was 2 (66.6%). Device protrusion from the incision site, with minimal discharge, occurred in 1(33.3%) patient and the second (33.3%) due to devise bulging, with pain around the device and mild tenderness.

Figure 5 illustrates the complication rate in the group with an electrode change/readjustment. The overall rate of complications was 6 (42.84%), of which 3 (21.42%) had urinary tract infection, 1 (7.14%) urinary incontinence, 1 (7.14%) pain, and 1 (7.14%) exposed wire from the incision site, with minimal discharge.

Discussion

The current study presents an overview of the experience and follow-up in patients with SNM in Saudi attending KAMC. The mechanism of action of SNM and the clinical outcome of the therapy remained controversial in the literature; however, the results support the persistent clinical advantage of SNM, as reported in many studies (4-7). Many reports vary in terms of an association between the demographic characteristics, such as age and gender, and SNM outcome (4-7). In terms of gender, studies in the United States of America (USA) and China reported similar outcomes in patients of both genders (5,6). However, a study done in Iraq reported a difference in the SNM outcome, with females having better outcomes than males. This finding

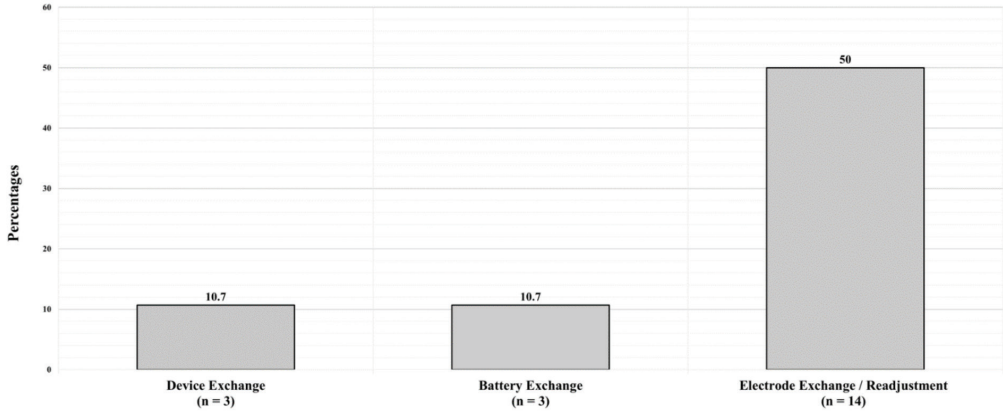


Figure 3. Overall rate of post-op revisits for device exchange, battery exchange and electrode exchange/readjustment

could be attributed to the different indications for the SNM in the two gender groups (8). The current study revealed that gender distribution was equally proportioned, with 13 (46.4%) males and 15 (53.6%) females, contrary to what is reported in the literature. In Kuwait, the experience of the only center performing SNM reported a major female predominance (81%) (9). Similarly, a study in the Netherlands reported a female predominance of 83% in the sample (7). These differences could influence the success rate in both genders. In terms of age, the study's sample had a mean age of 37.14±14.62 years, consistent with the samples reported in the literature (7,9,10).

The current study revealed that the most prevalent pathologies that indicated SNM include idiopathic bladder dysfunction, spinal cord injury, and OAB, which was diagnosed in 8 (28.6%), 6 (21.4%), and 4 (14.3%) patients, respectively. A tertiary center experience in Riyadh, Saudi Arabia, reported the only indication for SNM as idiopathic urinary retention (10). Another study in Iraq reported slightly similar figures, with the idiopathic etiology as the most prevalent pathology, followed by neurological disease and spinal cord pathology (excluding complete spinal cord injuries) in 54.2%, 45.8%, and 29.2%, respectively (8). Similar figures were reported in an Italian study, with idiopathic bladder dysfunction as the most frequent (11).

Regarding the success rate of SNM, the first stage success rate was 53.6%, of which 42.9% had the device permanently implanted in the second stage. The rate is lower than the rates reported in the literature. Locally, a study done in Riyadh reported a higher success rate of 88% after the first stage implantation. Internationally, a Brazilian study reported similar findings with a success rate of 83.3% for the first stage implantation, and the pulse generator was implanted in the whole group (12). This high rate of success, compared to the present study, could be explained by several possibilities, such as insufficient pre-implantation sensitivity, disease severity and type, patient mentality, and socio-medical history. This is reflected in the Netherland study with a significant association between the late loss of therapeutic outcome and a history of former psychiatric complaints (13). None of the participants in both studies had lower urinary tract symptoms (LUTS) secondary to spinal cord injury, as an indication for SNM. However, studies done in Switzerland and Iraq included patients with spinal cord injuries and reported a first stage success rate of 67% and 70%,

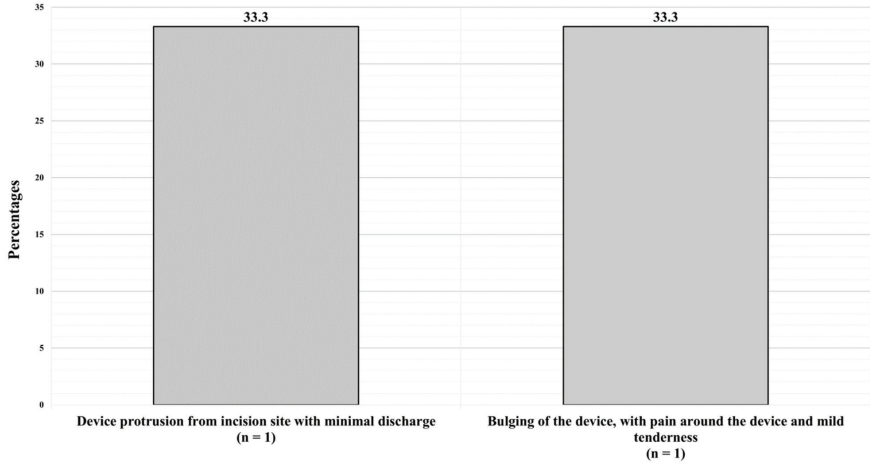


Figure 4. Complication rate among participants with device exchange

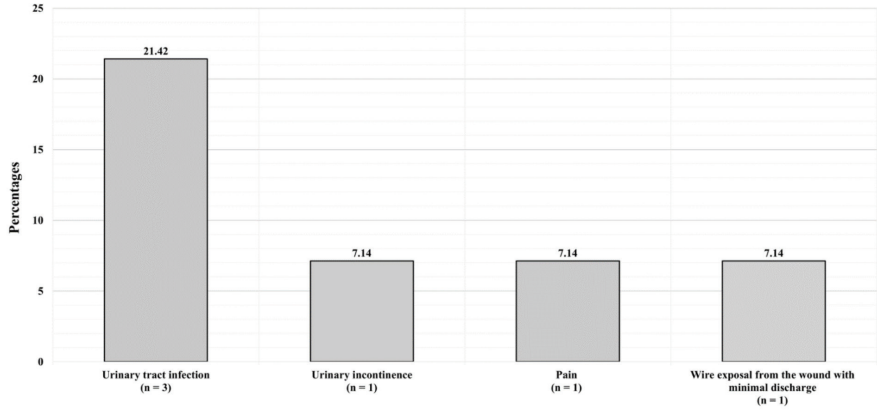


Figure 5. Complication rate among participants with electrode exchange/readjustment

Table 5. Electrode change/readjustment history (n=28)		
Question	**n**	**%**
Number of replacement/readjustments of electrodes done		
None	0	89.2
2	1	3.6
3	1	3.6
9	1	3.6
Patient 1 with electrode change for two times		
Indication for electrode change/readjustment in the first time	Trauma at the site of the device followed by an interrupted stream	
Time interval in the first time	3 months	
Complication incidence in the first time	None	
Indication for electrode change/readjustment in the second time	The device erosion and malfunction	
Time interval in the second time	9 months	
Complication incidence in the second time	No	
Patient 2 with electrode change for three times		
Indication for electrode change/readjustment in the first time	Displacement of the device	
Time interval in the first time	1.5 month	
Complication incidence in the first time	No	
Indication for electrode change/readjustment in the second time	Displacement of the electrodes followed by hesitancy and not feeling the vibrations.	
Time interval in the second time	21 months	
Complication incidence in the second time	No	
Indication for electrode change/readjustment in the third time	Displaced electrodes	
Time interval in the third time	25 months	
Complication incidence in the third time	No	
Patient 3 with electrode change for nine times		
Indication for electrode change/readjustment in the first time	Pain at the site of the device	
Time interval in the first time	12 months	
Complication incidence in the first time	Urinary incontinence	
Indication for electrode change/readjustment in the second time	Urinary incontinence	
Time interval in the second time	4 months	
Complication incidence in the second time	Urinary tract infection	
Indication for electrode change/readjustment in the third time	Erosion of the device	
Time interval in the third time	2 months	
Complication incidence in the third time	Urinary tract infection	
Indication for electrode change/readjustment in the fourth time	Superficially palpable device	
Time interval in the fourth time	4 months	
Complication incidence in the fourth time	Pain	
Indication for electrode change/readjustment in the fifth time	Displacement of electrodes	
Time interval in the fifth time	7 months	
Complication incidence in the fifth time	The wire exposed from the wound with minimal discharge	
Indication for electrode change/readjustment in the sixth time	Exposed wire	
Time interval in the sixth time	1.5 month	
Complication incidence in the sixth time	No	
Indication for electrode change/readjustment in the seventh time	Lower leg numbness triggered by turning the device on	
Time interval in the seventh time	12 months	
Complication incidence in the seventh time	No	

Table 5. Continued	
Indication for electrode change/readjustment in the eighth time	Protruding device
Time interval in the eighth time	11 months
Complication incidence in the eighth time	No
Indication for electrode change/readjustment in the ninth time	Protruding device
Time interval in the ninth time	1.5 month
Complication incidence in the ninth time	Urinary tract infection

respectively, which is still higher than the current study (8,14). Lastly, the differences could be due to the sample size and SNM indications.

In terms of complications, the overall post-device implantation complication rate equated to 66.6% with device protrusion and dislocation as the most frequent complication. Similarly, a study in Riyadh reported a 70% rate of complications post-implantation, with box site infection and an undesirable sensation as the only complications (10). The Iraqi study also reported a similar rate (62%) with infection and surgical site pain as the most frequent complications (8). Contrarily, a study done in Germany reported a lower post-device implantation complication rate (31%), with lead migration as the most frequent (15). These discrepancies in the complication rates could be multifactorial, ranging from the nature of the practice in each center to patient factors (e.g., lifestyle, wound care, and pregnancy).

Study Limitations

A study limitation is that it did not include the progression of therapy that occurred during or after the study period, which may affect the overall patient outcome. Additionally, due to the retrospective nature of the current study, irregular attendance of scheduled visits could cause incomplete or lost data. Thus, the clinical implications of the current study should be interpreted with caution.

Conclusion

The observed complication rate was similar to literature reports, although the first stage success rate was lower than the reported rates both locally and internationally. This could be attributed to several reasons, such as the placebo effect of the first stage stimulation test, insufficient pre-implantation sensitivity, disease severity and type, patient mentality, and socio-medical history. In summary, based on the current study, SNM remains a safe and effective treatment option in carefully selected patients with LUTS, without any severe debilitating complications. With the increased use of SNM, regular patient evaluation and follow-up before SNM and after implantation are vital for future research. The current study could be a baseline and an incentive for larger multicenter studies. Exploring the outcomes of SNM on a larger scale will result in improved preoperative, perioperative, and postoperative patient care, thereby supporting a higher patient satisfaction rate and the alleviation of burdens both on the patients and the healthcare facility.

Ethics

Ethics Committee Approval: The Institutional Review Board of King Abdullah International Medical Research Center, the Ministry of National Guard-Health Affairs, Riyadh, Kingdom of Saudi Arabia, approved the study with the approval number NRC21R/095/03.

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: Mo.A., Y.G., M.A., R.A., Design: Mo.A., M.A., R.A., Data Collection or Processing: Y.G., Analysis or Interpretation: Mo.A., Literature Search: Y.G., Writing: M.A.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Wenzler DL, Burks FN, Cooney M, Peters KM. Proof of concept trial on changes in current perception threshold after sacral neuromodulation. Neuromodulation 2015;18:228-232.
2. Su X, Cutinella M, Agran JE, Dinsmoor DA. Comparison of Active Stimulating Electrodes of Sacral Neuromodulation. Neuromodulation 2017;20:799-806.
3. Ammirati E, Giammò A, Manassero A, Carone R. Neuromodulation in urology, state of the art. Urologia 2019;86:177-182.
4. Ghazwani YQ, Elkelini MS, Hassouna MM. Efficacy of sacral neuromodulation in treatment of bladder pain syndrome: long-term follow-up. Neurourol Urodyn 2011;30:1271-1275.
5. Anger JT, Cameron AP, Madison R, Saigal C, Clemens JQ; Urologic Diseases in America Project. Predictors of implantable pulse generator placement after sacral neuromodulation: who does better? Neuromodulation 2014;17:381-384.
6. Meng L, Tian Z, Zhang W, Zhang Y, Wang J, Liao L, Ling Q, Zhang P, Wei Z, Zhong T, Xu Z, Wen W, Li J, Luo D. Influence of patient sex on the effectiveness of sacral neuromodulation: A cohort study from China. Int J Surg 2020;84:13-17.

7. van Wunnik BP, Govaert B, Leong R, Nieman FH, Baeten CG. Patient experience and satisfaction with sacral neuromodulation: results of a single-center sample survey. Dis Colon Rectum 2011;54:95-100.

8. Al-Azzawi IS, Al-Tamimi MAJ. The first Iraqi experience in sacral neuromodulation for patients with lower urinary tract dysfunction. Arab J Urol 2018;16:391-396.

9. Shehab Z, Yaiesh S, Al-Terki A, Al-Shaiji T. Sacral neuromodulation: Report of initial experience in Kuwait. AJU 2018;16:16-17.

10. Mehmood S, Altaweel WM. Long-term outcome of sacral neuromodulation in patients with idiopathic nonobstructive urinary retention: Single-center experience. Urol Ann 2017;9:244-248.

11. Cardarelli S, D'Elia C, Cerruto MA, Curti P, Ostardo E, Signorello D, Pastorello M, Caleffi G, Molon A, Artibani W. Efficacy of sacral neuromodulation on urological diseases: a multicentric research project. Urologia 2012;79:90-96.

12. Rios LA, Averbeck MA, Franca W, Sacomani CA, Almeida FG, Gomes CM. Initial experience with sacral neuromodulation for the treatment of lower urinary tract dysfunction in Brazil. Int Braz J Urol 2016;42:312-320.

13. Weil EH, Ruiz-Cerdá JL, Eerdmans PH, Janknegt RA, Van Kerrebroeck PE. Clinical results of sacral neuromodulation for chronic voiding dysfunction using unilateral sacral foramen electrodes. World J Urol1998;16:313-321.

14. Wöllner J, Krebs J, Pannek J. Sacral neuromodulation in patients with neurogenic lower urinary tract dysfunction. Spinal Cord 2016;54:137-140.

15. Kavvadias T, Huebner M, Brucker SY, Reisenauer C. Management of device-related complications after sacral neuromodulation for lower urinary tract disorders in women: a single center experience. Arch Gynecol Obstet 2017;295:951-957.

ORIGINAL RESEARCH
Functional

Doi: 10.4274/jus.galenos.2021.2021.0072
J Urol Surg, 2022;9(1):33-39

A Novel Survey of the Treatment Trends and Technical Details for Extracorporeal Shockwave Lithotripsy From Experienced European Endourologists

Serkan Yenigürbüz, Caner Ediz, Cumhur Yeşildal, Mehmet Pehlivanoğlu, Yunus Emre Kızılkan, Hasan Hüseyin Tavukçu, Ömer Yılmaz

University of Health Sciences Turkiye, Hamidiye Faculty of Medicine; İstanbul Sultan 2. Abdülhamid Han Training and Research Hospital, Clinic of Urology, İstanbul, Turkiye

What's known on the subject? and What does the study add?

Guideline recommendations on shockwave lithotripsy (SWL) are well known. In terms of the practical application of SWL, no such study has been published in Europe before. We share our results with this survey study.

Abstract

Objective: This study aimed to evaluate the practice of extracorporeal shockwave lithotripsy (ESWL) treatment from different aspects (indications, technical, and equipment-related characteristics) through a questionnaire response by the experienced endourologist in the European centers.

Materials and Methods: A survey of 72 questions on four main topics was prepared by our team to evaluate the demographics of technical equipment, treatment applications, and pretreatment preparations. The survey was mailed to 200 endourologists, of whom 97 academic endourologists enrolled, 75% of them were from university or training hospitals and 69% have experience of >10 years in urology.

Results: Of the urologist, 74% had direct access to ESWL-device, and the endourologist was mainly responsible for the ESWL unit with the 61% rate and was secondly the technician, which was trained on ESWL (25%). The factors that affect the decision for ESWL include the stone's size, location, density, composition, and kidney anatomy. Stone density was the most preferred for the ESWL decision and the cut-off value was <1000 hounsfield unit for the 71% of endourologists. Increased oral hydration and medical expulsive treatments were commonly used and recommended after the ESWL session. Routine antibiotic prophylaxis was not used by most of the endourologists (45%), and ureteroscopy (39%) was the most responded approach after steinstrasse formation.

Conclusion: Survey answers revealed that most of the experienced European endourologists decide to treatment alternatives following the suggested guidelines and ESWL is still a valuable option for urinary stone treatment.

Keywords: Extracorporeal shockwave lithotripsy, europe, survey

Introduction

Urolithiasis is a common problem in Europe, with an estimated prevalence of 5-9% (1). Extracorporeal shockwave lithotripsy (ESWL) has been introduced as the only non-invasive treatment modality for urolithiasis at the beginning of the 1980s and continued as the most popular option until lasers and flexible ureteroscopic instruments were available as minimal invasive stone management (2). The treatment concepts of upper urinary tract stones have rapidly changed in the last two decades, and as stated in a well-conducted study, flexible ureterorenoscopic stone management has become popular with an increase in the application (103%) in a 5-year study period (2009-2015), while the use of ESWL remained stable or decreased to a certain extent.

Correspondence: Serkan Yenigürbüz MD, University of Health Sciences Turkiye, Hamidiye Faculty of Medicine; İstanbul Sultan 2. Abdülhamid Han Training and Research Hospital, Clinic of Urology, İstanbul, Turkiye
Phone: +90 505 571 74 80 **E-mail:** serkanyenigurbuz@gmail.com **ORCID-ID:** orcid.org/0000-0002-4862-2103
Received: 05.06.2021 **Accepted:** 19.09.2021

Cite this article as: Yenigürbüz S, Ediz C, Yeşildal C, Pehlivanoğlu M, Kızılkan YE, Tavukçu HH, Yılmaz Ö. A Novel Survey of the Treatment Trends and Technical Details for Extracorporeal Shockwave Lithotripsy From Experienced European Endourologists. J Urol Surg, 2022;9(1):33-39.

(3). The possible reason is the more unfavorable conditions for ESWL including shock wave resistant stones, steep infundibular pelvic angles, long lower pole calyx, narrow infundibulum, and long skin-to-skin distance. The literature review revealed that complication rates between ESWL and retrograde intrarenal surgery were not effective in treatment modality selection (4,5).

The European Association of Urology (EAU) Guidelines still recommends SWL as the preferred modality in the treatment of medium-sized (<20 mm) upper urinary tract stones (6,7). The literature revealed no study on experienced endourologists with this guideline recommendation despite the decreasing trend of ESWL application, especially in the last 2-3 decades.

The study aimed to evaluate the practice of ESWL treatment from different aspects (indications, technical, and equipment-related characteristics) using a questionnaire for the experienced endourologists in the European centers.

Materials and Methods

Since it is a survey study, it does not require ethics committee approval. This prospective descriptive study was conducted according to the principles of the World Medical Association Declaration of Helsinki's "Ethical Principles for Medical Research Involving Human Subjects." No question was asked regarding the personal data of patients in the survey, thus obtaining informed consent from the centers was not considered.

A survey that was consisting of certain questions about the current trends with ESWL treatment was conducted using the web-based Survey-Monkey system. Survey questions were prepared by our team and mailed to 200 endourologists (addresses were derived from the EAU Section of Urolithiasis database system) in an electronic environment. A recall mail message was sent to all participant endourologists after 1 month following the first mail message from January to March 2016. The survey questionnaire preparation was aimed to evaluate some technical details that could not be given in the guides. The survey was prepared based on the EAU Guidelines. A total of 72 questions on four main topics were constructed to evaluate the demographics of technical equipment, treatment applications, pretreatment preparations, and anesthesia.

Statistical Analysis

All data from the Survey-Monkey system presented as frequencies of the responses. Only the response rates given to the questions from the Survey-Monkey system were given to us. Therefore, performing advanced statistical analysis was impossible as there was no data suitable for making separate statistics and grouping. This can be considered as the major study limitation.

Results

The examination of answers to the questionnaire revealed that European endourologists showed an approach following the guidelines.

The most remarkable and significant questions in our survey were presented with tables, including the response rate of each. Table 1 shows the ESWL approaches according to the demographics and history of patients, Table 2 the ESWL approaches for pretreatment preparations and anesthesia, and Table 3 the important questions and answers about ESWL options and approaches.

A total of 97 endourologists (48.5%) participated in the survey, of whom 75% were from university or training hospitals and 69% did have an experience period of >10 years in urology (Figure 1). Of them, 74% have direct access to ESWL-device at their department unit, of which the electromagnetic source-based units were the most common ones. Regarding the treatment responsibility, endourologists were conducting the management in the SWL unit in 61% of cases and technicians trained on SWL

Table 1. ESWL approaches according to the demographics and history of patients, including the response rate of each question

Question	Yes (%)	No (%)	Response rate (%)
Do you apply ESWL in appropriately-sized stones as the first option in anomalous kidneys?	50	50	43
Do you apply ESWL for appropriately-sized stones as the first option in obese cases?	38	62	43
Does the age of the case affect your decision-making for ESWL?	42	58	43
Does the gender of the case affect your decision for ESWL?	9	91	43
Does the socio-cultural status of the case affect your decision for ESWL?	25	75	42
Does the previous procedure for stone removal affect your decision for ESWL?	76	24	42.5
Do previous ESWL treatments in the same case affect your decision for this ESWL session?	87	13	42.5
Do the comorbidities present (hypertension, diabetes mellitus, etc.) affect your decision for ESWL?	58	42	42.5
Does the use of anticoagulants affect your decision for ESWL?	90	10	43
Does the presence of a solitary functioning kidney affect your decision for ESWL?	88	12	43

ESWL: Extracorporeal shockwave lithotripsy

conducted the treatment in 25% of cases. Both fluoroscopy and ultrasonography were used to capture an image and focus the stone in 66% of the participating centers; however, fluoroscopy alone was used in 33% and ultrasonography alone in 1%. A regular control for radiation exposure was performed in 78% of the centers and 86% had special radiation isolation using radiation protective equipment. Only 26% of the centers reported the use of a specially designed gel without air bubbles, which were causing problems for effective contact, whereas 71% used conventional gel. The majority of the responding urologists (85%) did not use any special maneuver or approach for coupling.

Most of the participants (78%) confirmed that ESWL is a minimally invasive treatment modality and 61% made their decisions according to the EAU guidelines (Figure 2). Informed consent for ESWL was used in a very common manner (88%); however, 6% never used a consent form before the treatment and 6% did not answer this question. Of the endourologists

Table 2. ESWL approaches for pretreatment preparations and anesthesia

Question	Yes (%)	No (%)	If necessary (%)	Response rate (%)
Do you perform pre-medication for patients' anxiety?	36	25	39	38
Do you monitor your patients during and immediately after ESWL for hemodynamic changes?	48	26	26	36,5
Do you apply prophylactic antibiotics before ESWL?	20	45	35	37,5
Do you accept ESWL as a "cost-effective modality" when you consider all available minimally invasive alternatives for stone management?	**74**	26	--	36,5
Regarding the social insurance concept of your country, do you accept ESWL as a reasonable and logical alternative?	**88**	12	--	36,5

ESWL: Extracorporeal shockwave lithotripsy

Table 3. Important questions and answers about ESWL options and approaches; a total response rate of each question

Question		%	Response rate (%)
What policy for ESWL has impacted the upper ureteral calculi?	The first option, if unsuccessful then URS	23	37.5
	URS as the first option	76	
Which position do you use in ESWL in lower ureteral stones?	Prone	48	33
	Supine	33	
How do you adjust the level of energy during treatment?	I begin with a lower level of energy and increase gradually	87	34.5
	I change the level of energy depending on the disintegration level of the stone(s)	9	
When do you evaluate the patient after ESWL?	>1 week later	45	35.5
	5-7 days later	23	
Which radiologic method do you use to evaluate your patient after ESWL?	Kidney ureter bladder radiography	63	36.5
	Ultrasonography	22	
What is your definition of "SUCCESS" after ESWL?	Clinically insignificant residual fragments	58	37
	Completely stone-free status without any fragment	42	
What is the meaning of clinically insignificant residual fragments?	≤3 mm	41	36.5
	≤2 mm	27	
What is the period for you to define the status of success after ESWL?	3 months	41	38
	1 month	38	
Which radiologic method do you prefer to perform in children before ESWL?	Ultrasonography	47	33
	Low dose CT	25	

ESWL: Extracorporeal shockwave lithotripsy, CT: Computer tomography

without ESWL unit in their hospital, 72% reported sending the patients for ESWL to another hospital, whereas 28% of them tended to treat the stone(s) with another minimally invasive modality, wherein flexible ureteroscopy (81%) was the most commonly performed procedure (Table 1). In addition to the renal collecting system anatomy, stone-related factors (size, location, density, and chemical composition) were the main parameters considered for the decision-making of ESWL. More than half of the endourologists (54%) assessed the stone burden by measuring the longitudinal axis of the stone and stone volume as the second approach (27%). Most of the endourologists reported using ureteral stenting before ESWL for solitary functioning kidneys (always 33%, if the stone is >1.5 cm; 29%), 27% of them were found not to routinely place any stent, and 13% did not respond to this question. Stone density has been used for ESWL indication and 71% of endourologists accepted <1000 hounsfield unit as a cut-off value for stone hardness to perform ESWL (Figure 3).

Most of the endourologist (83%) evaluated urinary tract infection status and 62% were in favor of completely stopping the anticoagulant medication before ESWL. No special bowel preparation was done by 62% of participants, whereas 38% recommended feeding with aqueous food or laxative agent. Nonsteroidal anti-inflammatory drugs (NSAIDs) (58%) were the most commonly used analgesics before ESWL. Pediatric ESWL was performed under either general anesthesia or Sedo-analgesia (depending on the age of the child) by the majority of the endourologists (58%); however, 42% did not perform ESWL for children. A maximum number of sessions was reported as 2 and 3 sessions and rates were 43% and 45%, respectively (Figure 4). The delivery rate of SW number/min was reported as 90 and 60 SW/min by 50% and 47% of the responders, respectively. The maximum number of SW in one session for adults were 3000 (33%), 3500 (21%), 4000 (18.5%), 2000 (13%), and 1000 (10%), respectively, and 2000 (38%), 1500 (25%), 1000 (10%), and 500 (10%), respectively, in children. The most preferred period between the two sessions was >10 days, with rates of 46% in kidney stones and 30% in ureteral stones. Increased oral hydration and medical expulsive treatment (MET) were commonly recommended after SWL sessions. Routine antibiotic prophylaxis was not used by most endourologist (45%), and ureteroscopy (39%) was the most commonly applied approach after steinstrasse formation (Tables 2 and 3).

Unfortunately, the Survey-Monkey system did not let us know who or what country the respondents were from. This is another limitation of this study. However, we know that the vast majority of people whose e-mail addresses were given were from central, southern, and eastern Europe.

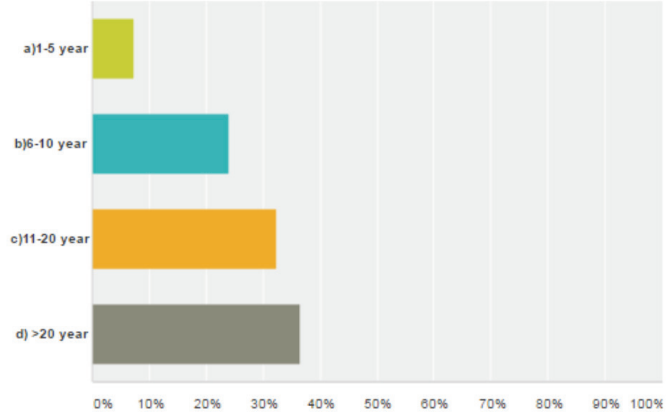


Figure 1. Experience period of European endourologists

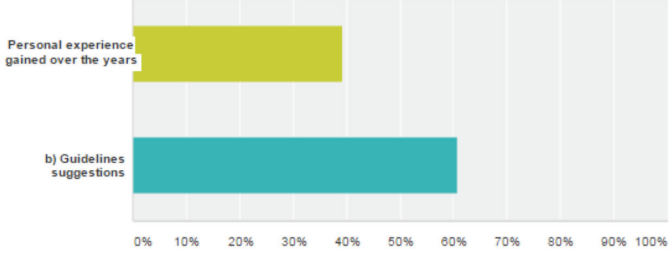


Figure 2. Guidance in treatment modality decision

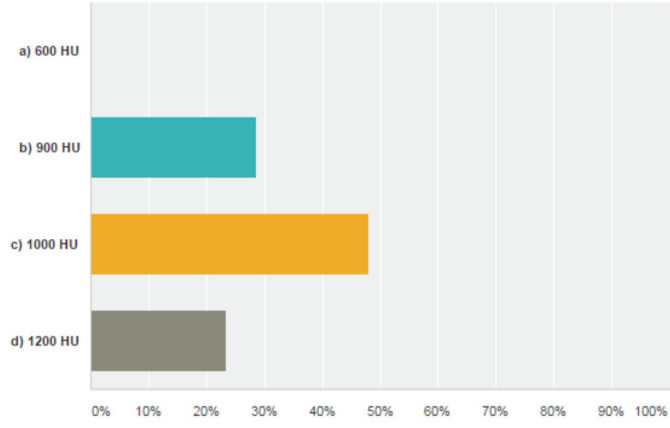


Figure 3. Cut-off value for stone density before ESWL

ESWL: Extracorporeal shockwave lithotripsy

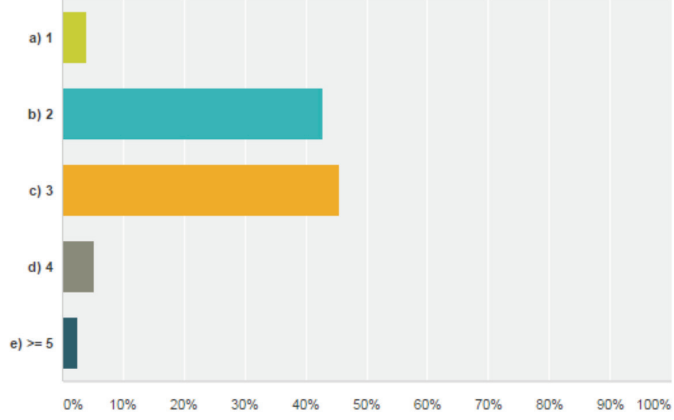


Figure 4. Maximum number of sessions for the same stone

Discussion

The response rate of this survey was 33-48.5%, which seems similar or higher than such studies reported thus far (2,8-10). All survey-based studies were mainly performed on a national platform and evaluated urinary tract stone management in general. Our study is the first that aimed to investigate ESWL trends and treatments for upper urinary tract stones in an international-based manner by including different European countries. Similar to our study, Lantz et al. (11) reported the comparative evaluation of ESWL practice in American and Canadian endourologists in 2016 and Sharma et al. (12) reported data of phone call-based survey from 21 different centers in the United Kingdom.

Regarding the ESWL practice in a special group of cases, most of the respondents (62%) do not use ESWL in patients with obesity with appropriate size stones, and 50% have applied ESWL as the first option in anomalous kidneys (Table 1). The EAU guidelines state that ureteroscopy is a better and safe procedure for the management of renal stones in patients with obesity (6). Passage of fragments after ESWL might be poor in horseshoe kidneys; therefore, ureteroscopy was prioritized in patients with obesity and skeletal malformations or anomalies.

Solitary functioning kidney is an important factor for ESWL treatment decision, which was emphasized in our survey with an 88% rate (Table 1). Our survey results revealed that 33% of participants placed a JJ stent in all cases, whereas 27% used stenting in patients with large-sized stones in solitary kidneys. Lantz et al. (11) demonstrated that 51% of Canadian urologists reported stenting the patients with solitary kidneys in a routine manner, whereas 66% of American urologists did routinely place a stent, suggesting that Canadian and American urologists are more cautious than European urologists. Medico-legal problems may be another reason for this approach in North America.

Our survey revealed that 62% of participants completely discontinued the anticoagulant treatment before ESWL. Low dose acetylsalicylic acid was not specifically stated in our question, thus it could be assumed that anticoagulant treatment meant covering low dose acetylsalicylic acid. Related to this issue, this rate was significantly higher for American urologists, where they tended to stop acetylsalicylic acid both for renal and ureteral stones (96% and 90%, respectively) when compared with Canadian urologists (88% and 62%, respectively) (10). The 2018 EAU Guidelines and American Urology Association (AUA) Guidelines on the temporary discontinuation or bridging of antithrombotic therapy in high-risk patients should be discussed with the internist (6,13). A published study evaluating the perinephric hematoma formation in patients with ESWL for renal and proximal ureteric stones reported the anticoagulant/antiplatelet medications as well as intraoperative hypertension to be significant risk factors (14). The rate of perirenal hematoma was lower (0.34%) in Razvi et al.'s (14) study compared to other series. However, our study results revealed that only low dose acetylsalicylic acid (81 mg) and nonsteroidal anti-inflammatory drugs were continued before ESWL while warfarin, heparin, dipyridamole, clopidogrel, and ticlopidine were discontinued. Anticoagulant/antiplatelet medications were found as a significant risk factor for perinephric hematoma (hazard ratio: 4.198). Another study reported that perirenal hematoma occurred in 0.53% of patients, of which 0.23% were only clinically symptomatic. All patients who had perirenal hematoma were reported using medication for cardiovascular diseases, but in this study low dose (100 mg) acetylsalicylic acid intake did not influence the perirenal hematoma (15). Another recent study reported similar rates for perirenal hematoma after ESWL (16). Razvi et al. (14) revealed the model of the ESWL machine. However, our study did not evaluate the different ESWL models, thus we could not comment on this issue.

Antibiotic prophylaxis is not used by most of the endourologists (45%) in our survey. The American urologists reported high rates of prophylactic antibiotic usage (78%); however, this rate was significantly low among the Canadian urologists, which was reported in 2% of the cases. Interestingly, both groups of urologists reported similar rates for the performance of routine urine culture examination (11). However, both EAU and AUA guidelines do not recommend routine use of antibiotics before ESWL (6,17). Our study revealed that 20% performed routine, antibiotic usage, which reflects the European approach as Sharma et al. (12) with 25% from the United Kingdom. Both guidelines recommend using prophylactic antibiotics in case of any suspicion of urinary tract infection. Our survey did not evaluate the ESWL application to patients with nephrostomy tubes but recommended to use of intravenous prophylactic antibiotics before ESWL in patients with the increased bacterial burden (6,7).

Our study revealed that NSAIDs (58%) is the most commonly used analgesics before ESWL, which is similar to Sharma et al. (12), and diclofenac was the most frequently used agent. The EAU guidelines recommend controlling pain during the ESWL procedure to limit pain-related movements for precise and successful targeting (6). Of the American urologists, 8% routinely used general anesthesia during ESWL, whereas only 5% among the Canadian urologists (11). Higher ESWL treatment success rates were reported with general anesthesia than intravenous sedation application; however, our institute does not routinely use general anesthesia for ESWL except for children (18). A recent review reported that simple analgesics, NSAIDs, and opioids could all reduce the pain that is associated with ESWL to a tolerated level. No compelling differences were revealed in the safety or efficacy of simple analgesics and NSAIDs; however,

analgesia was more often described as adequate for opioids than NSAIDs (19). Our study reported opioid usage in 21.6% of respondents.

MET was routinely used in 38% of cases and 39% of cases with larger fragments in our survey. Sharma et al. (12) reported using MET in 20% of the renal stone cases and 15% of ureteric stones after ESWL. The EAU Guidelines recommend using MET after ESWL for renal and ureteric stones to increase stone-free rates and reduce analgesic requirements (6). Our results demonstrated the highest application rates of MET than the previous reports in the literature.

The delivery rate of shock waves using 90 and 60 SW/min was reported in 50% and 47% of respondents, respectively. Other meta-analyses confirmed that ESWL efficacy could be improved with slower SW application rates, with approximately 50% significantly reduced costs (20-22). Of the Canadian urologists, 76% reported using a high SW delivery rate (120/min), and the American urologists reported similar SW rates with our results as 45% for 60 SW/min and 41% for 90 SW/min (11). Compatible with the EAU guidelines, our study revealed that3% of participants use 120 SW/min. The EAU guidelines pointed out that tissue damage increased with an increased SW rate (6). The maximum number of SW in one session for adults was 3000 in our survey, which was similar to both the Canadian and American urologists (11).

Proper acoustic coupling is recommended by the EAU guidelines since the air bubbles were not eliminated effectively during the acoustic coupling, which significantly decreases the delivery of SW energy and deflects 99% of SW as previously reported (6,23,24). Our study revealed that 26% of the participants reported using special gels whereas the others (71%) used normal ultrasonography gel (6,24).

Our study revealed that 48% preferred the prone position as the most preferred position for distal ureteral stones. However, Kamel et al. (25) revealed a higher stone-free rate for the supine transgluteal position compared with the prone position. Other studies supported and revealed successful results in supine transgluteal position for the distal ureteral stones with ESWL (26,27).

Study Limitations

Our study is the first one that reflected the European treatment trends and technical equipment of ESWL; however, it has some certain limitations. First, our survey had so many questions and this relatively time-consuming format could lower the response rates of the questionnaire. Additionally, a recall mail message was sent to all participants after 1 month following the first one. The participation rate could have been higher with more than one recall mail. However, our study is valuable because it is the first study on ESWL to reflect the approaches of experienced endourologists in Europe.

Conclusion

Data obtained from our study revealed that most experienced European endourologist make their treatment decisions according to the EAU guideline. ESWL is still preferred in the treatment of symptomatic urinary stones by the majority of our respondents. The literature review revealed no publication similar to this study from Europe.

Ethics

Ethics Committee Approval: Since it is a survey study, it does not require ethics committee approval.

Informed Consent: No question was asked regarding the personal data of patients in the survey, thus obtaining informed consent from the centers was not considered.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: S.Y., C.E., Y.E.K., H.H.T., Concept: S.Y., C.E., Y.E.K., Ö.Y., Design: S.Y., C.E., Y.E.K., Ö.Y., Data Collection or Processing: S.Y., C.Y., Y.E.K., H.H.T., Analysis or Interpretation: S.Y., C.Y., Y.E.K., H.H.T., Literature Search: S.Y., C.Y., Y.E.K., H.H.T., Writing: S.Y., C.E., M.P., Y.E.K., H.H.T., Ö.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Sorokin I, Mamoulakis C, Miyazawa K, Rodgers A, Talati J, Lotan Y. Epidemiology of stone disease across the world. World J Urol 2017;35:1301-1320.
2. Yildirim K, Olcucu MT, Colak ME. Trends in the treatment of urinary stone disease in Turkey. PeerJ 2018;6:e5390.
3. Heers H, Turney BW. Trends in urological stone disease: a 5-year update of hospital episode statistics. BJU Int 2016;118:785-789.
4. Srisubat A, Potisat S, Lojanapiwat B, Setthawong V, Laopaiboon M. Extracorporeal shock wave lithotripsy (ESWL) versus percutaneous nephrolithotomy (PCNL) or retrograde intrarenal surgery (RIRS) for kidney stones. Cochrane Database Syst Rev 2014:CD007044.
5. Junbo L, Yugen L, Guo J, Jing H, Ruichao Y, Tao W. Retrograde Intrarenal Surgery vs. Percutaneous Nephrolithotomy vs. Extracorporeal Shock Wave Lithotripsy for Lower Pole Renal Stones 10-20 mm : A Meta-analysis and Systematic Review. Urol J 2019;16:97-106.
6. Türk C, Neisius AA, Petrik A, Seitz C, Skolarikos KTA, Guidelines Associates: J.F. Donaldson TD, N. Grivas YR; EAU Guidelines on Urolithiasis. 2018.
7. Chaussy CG, Tiselius HG. How can and should we optimize extracorporeal shockwave lithotripsy? Urolithiasis 2018;46:3-17.

8. Ates F, Zor M, Yılmaz O, Tuncer M, Ozturk M, Gurbuz C, Atis G, Koca O, Yildirim A, Eryildirim B, Kucuk EV, Narter F, Senkul T, Sarica K. Management behaviors of the urology practitioners to the small lower calyceal stones: the results of a web-based survey. Urolithiasis 2016;44:277-281.
9. Schnabel MJ, Brummeisl W, Burger M, Rassweiler JJ, Knoll T, Neisius A, Chaussy CG, Fritsche HM. Stoßwellenlithotripsie in Deutschland: Ergebnisse einer deutschlandweiten Umfrage [Shock wave lithotripsy in Germany: Results of a nationwide survey]. Urologe A 2015;54:1277-1282.
10. Proietti S, Somani BK, Pietropaolo A, Saitta G, Rodríguez-Socarrás ME, Rosso M, Bellinzoni P, Gaboardi F, Giusti G. Italian endourological panorama: results from a national survey. Cent European J Urol 2018;71:190-195.
11. Lantz AG, McKay J, Ordon M, Pace KT, Monga M, Honey RJ. Shockwave Lithotripsy Practice Pattern Variations Among and Between American and Canadian Urologists: In Support of Guidelines. J Endourol 2016;30:918-922.
12. Sharma NL, Alexander CE, Grout E, Turney BW. Shock-wave lithotripsy: variance within UK practice. Urolithiasis 2017;45:193-201.
13. Culkin DJ, Exaire EJ, Green D, Soloway MS, Gross AJ, Desai MR, White JR, Lightner DJ. Anticoagulation and antiplatelet therapy in urological practice: ICUD/AUA review paper. J Urol 2014;192:1026-1034.
14. Razvi H, Fuller A, Nott L, Méndez-Probst CE, Leistner R, Foell K, Davé S, Denstedt JD. Risk factors for perinephric hematoma formation after shockwave lithotripsy: a matched case-control analysis. J Endourol 2012;26:1478-1482.
15. Schnabel MJ, Gierth M, Chaussy CG, Dötzer K, Burger M, Fritsche HM. Incidence and risk factors of renal hematoma: a prospective study of 1,300 SWL treatments. Urolithiasis 2014;42:247-253.
16. El-Nahas AR, Taha DE, Elsaadany MM, Zahran MH, Hassan M, Sheir KZ. Hospital admission for treatment of complications after extracorporeal shock wave lithotripsy for renal stones: a study of risk factors. Urolithiasis 2018;46:291-296.
17. Assimos D, Krambeck A, Miller NL, Monga M, Hassan M, Nelson CP, Pace KT, Pais VM, Pearle MS, Preminger GM, Razvi H, Shah O, Matlaga BR. Surgical Management of Stones: AUA/Endourology Society Guideline (2016). AUA/Endourological Society Guideline: Published 2016.
18. Sorensen C, Chandhoke P, Moore M, Wolf C, Sarram A. Comparison of intravenous sedation versus general anesthesia on the efficacy of the Doli 50 lithotriptor. J Urol 2002;168:35-37.
19. Aboumarzouk OM, Hasan R, Tasleem A, Mariappan M, Hutton R, Fitzpatrick J, Beatty L, Jones GE, Amer T. Analgesia for patients undergoing shockwave lithotripsy for urinary stones - a systematic review and meta-analysis. Int Braz J Urol 2017;43:394-406.
20. Li K, Lin T, Zhang C, Fan X, Xu K, Bi L, Han J, Huang H, Liu H, Dong W, Duan Y, Yu M, Huang J. Optimal frequency of shock wave lithotripsy in urolithiasis treatment: a systematic review and meta-analysis of randomized controlled trials. J Urol 2013;190:1260-1267.
21. Semins MJ, Trock BJ, Matlaga BR. The effect of shock wave rate on the outcome of shock wave lithotripsy: a meta-analysis. J Urol 2008;179:194-197.
22. Koo V, Beattie I, Young M. Improved cost-effectiveness and efficiency with a slower shockwave delivery rate. BJU Int 2010;105:692-696.
23. Pishchalnikov YA, Neucks JS, VonDerHaar RJ, Pishchalnikova IV, Williams JC Jr, McAteer JA. Air pockets trapped during routine coupling in dry head lithotripsy can significantly decrease the delivery of shock wave energy. J Urol 2006;176:2706-10.
24. Jain A, Shah TK. Effect of air bubbles in the coupling medium on efficacy of extracorporeal shock wave lithotripsy. Eur Urol 2007;51:1680-1687.
25. Kamel M, Salem EA, Maarouf A, Abdalla M, Ragab A, Shahin AM. Supine transgluteal vs prone position in extracorporeal shock wave lithotripsy of distal ureteric stones. Urology 2015;85:51-54.
26. Galli R, Sighinolfi MC, Micali S, Martorana E, Rosa M, Mofferdin A, Bianchi G. Advantages of the supine transgluteal approach for distal ureteral stone extracorporeal shock wave lithotripsy: outcomes based on CT characteristics. Minerva Urol Nefrol 2017;69:189-194.
27. Choo MS, Han JH, Kim JK, Shin TY, Lee WK, Lee SK, Lee SH. The transgluteal approach to shockwave lithotripsy to treat distal ureter stones: a prospective, randomized, and multicenter study. World J Urol 2018;36:1299-1306.

ORIGINAL RESEARCH
Endourology

Doi: 10.4274/jus.galenos.2021.2021.0092
J Urol Surg, 2022;9(1):40-46

Effectiveness of Second-look Flexible Ureteroscopy to Achieve A True Stone-Free Status in Retrograde Intrarenal Surgery

Oğuz Özden Cebeci[1], Tayyar Alp Özkan[2], Mustafa Savaş Yalçın[3], Özdal Dillioğlugil[4], İbrahim Çevik[3]

[1]University of Health Sciences Turkiye, Kocaeli Derince Training and Research Hospital, Clinic of Urology, Kocaeli, Turkiye
[2]Acıbadem Kocaeli Hospital, Clinic of Urology, Kocaeli, Turkiye
[3]Private Dr. Nazif Bağrıaçık Kadıköy Hospital, Clinic of Urology, İstanbul, Turkiye
[4]Kocaeli University Faculty of Medicine, Department of Urology, Kocaeli, Turkiye

What's known on the subject? and What does the study add?

The most desirable conditions following a successful retrograde intrarenal surgery (RIRS) procedure are a complete flush-out of all stone fragments and no stone-related events yet the residual stone fragments remain a challenging topic for urologists after RIRS. This study is demonstrating the benefits of a second-look flexible ureterorenoscopy (URS) following RIRS. Though in the present study we intervene to single or multiple calyceal stones with a stone basket to achieve a complete stone-free status. Our results confirm that a second-look URS decreases stone-related events for clinically insignificant stones

Abstract

Objective: Residual stone fragments remain a challenging topic for urologists following retrograde intrarenal surgery (RIRS). This study aimed to investigate the effectiveness of second-look flexible ureteroscopy (URS) to achieve a true stone-free status and decrease stone-related events.

Materials and Methods: The study included 176 consecutive patients treated with RIRS for kidney stones between October 2013 and December 2017. Patients were divided into two groups. Group 1 included patients who underwent only one session of RIRS (n=51) and group 2 included patients who undergo a second-look flexible URS after RIRS (n=125). Both groups were compared for stone-free rates and potential risk factors associated with stone-related events. Stone-related events were defined as urinary infection, renal colic, stone enlargement, and any additional intervention with shock wave lithotripsy or reoperation.

Results: Stone-free rate after RIRS for groups 1 and 2 were 37.25% (n=19/51) and 40.8% (n=51/125), respectively. The stone-free rates improved to 93.6% (n=117/125) in group 2 after the second-look flexible URS. The multivariable analysis revealed that type of intervention, stone size, and body mass index were independent prognostic factors for stone-related events. When group 2 was taken as a reference, the odds ratio for stone-related events was 8.48 (95% confidence interval: 2.95-24.42) in group 1.

Conclusion: Second-look flexible ureterorenoscopy increased the stone-free rates and diminished the number of stone-related events. We argue that performing second-look flexible ureterorenoscopy in the early period following RIRS in the presence or suspicion of residual stone fragments provides better treatment results.

Keywords: Retrograde intrarenal surgery, second-look flexible ureteroscopy, stone-free rate, residual stone fragments, stone-related event

Introduction

The most desirable conditions following a successful retrograde intrarenal surgery (RIRS) procedure are a complete flush-out of stone fragments and diminishing stone-related events (1,2). One of the primary metrics used to measure the RIRS outcome is the stone-free rate. Residual stone fragments of 4 mm or less after RIRS are accepted as clinically insignificant (3). RIRS studies revealed that in almost 20% of cases, clinically insignificant residual stone fragments are postoperatively observed (4);

Correspondence: Oğuz Özden Cebeci MD, University of Health Sciences Turkiye, Kocaeli Derince Training and Research Hospital, Clinic of Urology, Kocaeli, Turkiye
Phone: +90 262 317 80 00 **E-mail:** oguzozdencebeci@gmail.com **ORCID-ID:** orcid.org/0000-0003-2444-4661
Received: 05.08.2021 **Accepted:** 01.09.2021

Cite this article as: Cebeci OÖ, Özkan TA, Yalçın MS, Dillioğlugil Ö, Çevik İ. Effectiveness of Second-look Flexible Ureteroscopy to Achieve A True Stone-Free Status in Retrograde Intrarenal Surgery. J Urol Surg, 2022;9(1):40-46.

however, these residual stone fragments may grow and cause stone-related events, such as pain and infection (5,6).

Residual stone fragments were detected by ultrasonography (USG), kidneys, ureters, and bladder (KUB) radiography, or computed tomography (CT) (7). The most accurate imaging technique is the CT scan, which may show stones as small as 1 mm, although concerns about radiation exposure limit its use (8). Additionally, CT is underutilized for imaging due to economic reasons; residual stone fragments; therefore, a wide range of stone-free rates are reported following RIRS (9-12).

Various techniques and methods have been reported in the literature to achieve an utterly stone-free status and reduce radiation exposure, including artificial intelligence algorithms (13,14). This study aimed to investigate the effectiveness of second-look flexible ureteroscopy (URS) to achieve a true stone-free status and decrease stone-related events. To our knowledge, the use of routine second-look flexible URS for this purpose has not been previously studied.

Materials and Methods

This study retrospectively analyzed 282 consecutive patients who were treated with RIRS and laser lithotripsy for kidney stones between October 2013 and December 2017. This study was conducted following the Ethics Committee of Kocaeli Derince Traning and Research Hospital guidelines (approval number: 2018/24). All patients were informed about the procedures and alternative treatment modalities. The surgical choice was made by the patient with counseling from the surgeon. Written informed consent was collected.

A total of 106 patients were excluded as follows: cases in the learning curve (n=50); patients whose RIRS was performed by a different surgeon (n=29); cases with incomplete data on the stone type, CT scan, or follow-up (n=18); patients with poor visibility secondary to bleeding during RIRS (n=6); and cases of intraoperative complications necessitating secondary procedures (n=3). The remaining 176 patients comprised the study sample.

In this study, the second-look flexible URS procedure refers to the endoscopic control of the renal pelvis and major calyces with a flexible ureteroscope while removing the Double-J stent in the same session.

Patients are divided into two groups based on the type of management. Group 1 included patients undergoing only one session of RIRS (n=51) and group 2 included patients who underwent a second-look flexible URS after RIRS (n=125).

All RIRS operations were performed by a single surgeon (IC) under general anesthesia. A single dose second-generation cephalosporin was used for antibiotic prophylaxis. Before the ureteral access sheet placement, the ureter was examined with a semi-rigid ureteroscope for the presence of ureteral stones and any other unexpected pathology. A ureteral access sheath (9.5 Fr, Flexor Cook) was used. RIRS was performed using a 7.5 Fr Flex X2s (Karl Storz, Germany) URS. A Quantasystem-Litho Holmium: YAG laser (Milan, Italy) with 200-micron fiber was used for stone fragmentation. As possible, all stone fragments were extracted with a 1.7 F stone basket (NGage® Nitinol stone extractor, Cook, Bloomington, IN, USA). At the end of the RIRS, a 4.7 F Double-J stent was placed in case of ureteral balloon dilatation, first ureteral attempt, prolonged operation time due to stone size, ureteral mucosa edema, suspicious residual stone fragment, or hematuria. Extracted stone fragments were sent for X-ray diffraction stone analysis.

An immediate intraoperative stone-free rate was defined as the absence of stone fragments and reported by the surgeon at the end of the procedure. After RIRS in group 1 and after second-look flexible URS in group 2, X-ray KUB and ultrasound were performed on all patients to determine the presence of residual stone fragments. A detectable stone of any size (>1 mm) was considered as a residual stone. Unless a complication was observed, patients were discharged on a postoperative day following RIRS.

In cases where a Double-J stent is placed during RIRS, the stent was removed within 2 weeks, and a second-look flexible URS is performed. Residual stone fragments with sizes ranging from 1 mm to 4 mm were extracted with a basket catheter during the second-look flexible URS. Laser lithotripsy was applied in two patients with stones larger than 4 mm. A ureteral access sheath was not used while performing a second-look flexible URS, and patients were discharged on the same day of the procedure.

Preoperatively, all patients had routine laboratory work and a CT scan. Unless earlier intervention was indicated, patients received follow-up for stone-related events every 6 months thereafter.

The potential risk factors associated with stone-related events were analyzed, including age, gender, body mass index (BMI), stone size, operative difficulty, CT stone density and size (centralized to the mean and scaled to 5 mm), residual stone fragments, stone type, and stone management groups. Stone-related events were defined as urinary infection, renal colic, stone growth, and any additional shockwave lithotripsy or reoperation. The operative difficulty was categorized, based on the stone location, as accessible (isolated mid or upper calyx or renal pelvis stones), moderate (middle or upper calyx stones, with pelvis stones), or complex (lower calyx stone, with or without pelvis stones).

Statistical Analysis

Histograms and the Shapiro-Wilk test were used to test for normally distributed variables. Descriptive analyses were presented using the mean ± standard deviation. The chi-square test was used to compare categories, and the t-test was used for continuous variables. Univariable and multivariable analyses with logistic regression were used to assess the association between covariates. All analyses were performed using STATA 14.2 (StataCorp, TX). Statistical significance was set at 0.05, and all tests were two-tailed.

Results

This study included 176 patients who had initial RIRS for kidney stones. Age, gender, follow-up period, stone side, BMI, and operative difficulty were not significantly different between groups, except for size and density (detailed demographic and clinical data of patients are summarized in Table 1).

Immediate intraoperative stone-free rates for groups 1 and 2 were 43.14% (n=22/51) and 57.6% (n=72/125), respectively. Postoperative radiologically controlled residual stone fragments after the initial RIRS for groups 1 and 2 were 37.25% (n=19/51)

Table 1. Demographic and clinical data of the study groups.

	Group 1 RIRS only (n=51)	Group 2 Second-look flexible URS (n=125)	p-value
Age (year); mean ± SD	48.8±15.1	47.9±11.1	0.68
Follow-up (month); mean ± SD	21.2±10.9	20.5±11.7	0.69
Female; n (%)	18 (35.3)	31 (24.8)	
Male; n (%)	33 (64.7)	94 (75.2)	0.159
Left side; n (%)	25 (49)	74 (59.2)	
Right side; n (%)	26 (51)	51 (40.8)	0.217
BMI (kg/m²); mean ± SE	27.5±3.7	28.6±4.2	0.106
Size (mm); mean ± SE	20.1±9.3	16.5±9.1	0.006
Difficulty; n (%)			
Easy	31 (60.8)	21 (16.8)	N/A
Moderate	7 (13.7)	29 (23.2)	N/A
Hard	13 (25.5)	75 (60)	N/A
Stone density (HU); mean ± SD	910.8±320.8	1116.7±369.8	<0.001
Stone composition (Predominant component), n (%)			
Calcium oxalate	42 (82.35)	90 (72)	N/A
Calcium phosphate	6 (11.76)	19 (15.2)	N/A
Cystine	1 (1.96)	5 (4)	N/A
Uric acid	1 (1.96)	8 (6.4)	N/A
Struvite	1 (1.96)	3 (2.4)	N/A
First procedure Stone-free rate; n (%)	19 (37.25)	51 (40.8)	**0.663**
Second-look URS Stone-free-rate; n (%)	-	117 (93.6)	N/A
Postoperative stone-related events; n (%)			
No event	22 (43.14)	99 (79.2)	<0.001
Asymptomatic stone growth	2 (3.92)	10 (8)	N/A
Urinary infection	8 (15.69)	10 (8)	N/A
Renal colic	3 (5.88)	1 (0.8)	N/A
Emergency room admission	1 (1.96)	-	N/A
Shock wave lithotripsy	8 (15.69)	1 (0.8)	N/A
Reoperation	7 (13.73)	4 (3.2)	N/A

BMI: Body mass index, SD: Standard deviation, SE: Standard error, HU: Hounsfield unit, URS: Ureterorenoscopy

and 40.8% (n=51/125), respectively. After the second-look flexible URS, stone-free rates improved from 40.8% to 93.6% (n=117/125); for eight patients who were not considered stone-free, the residual stone fragments that are visibly smaller than 1 mm were not retrievable with a basket. Four patients (3.2%) with an initial stone size greater than 2 cm were reoperated (Table 1).

The univariable analysis indicated that BMI, size, operative difficulty, and type of intervention (group 1 vs. group 2) were significantly associated with SREs (Table 2). The stone-related events rate increased by 19.6% for each 5 mm increment in stone sizes. Age, stone density, stone type, side, gender, and radiologic residual stone fragments were not significantly associated with stone-related events (data not shown).

Accordingly, the final model variables included the type of intervention, operative difficulty, stone size, BMI, residual stone, and stone density (p<0.001). The type of intervention, stone size, and BMI were independent prognostic factors for stone-related events. When group 2 was taken as a reference, the odds ratio was 8.48 [95% confidence interval (CI): 2.95–24.42] for stone-related events in group 1. The odds ratio was 1.62 (95% CI: 1.21-2.18) for increasing stone size (Table 2).

No postoperative stone-related events were recorded in 69% (n=121) of the whole cohort. Urinary infection, asymptomatic stone growth, and reoperation were recorded in 10.2% (n=18), 6.8% (n=12), and 6.2% (n=11) of the patients, respectively. Postoperative shock wave lithotripsy (SWL) was determined in 9 patients; renal colic in 4, and 1 was admitted to the emergency room due to unrelieved colic symptoms.

Renal colic (5.9% vs. 1%), urinary tract infection (16% vs. 8%), emergency room admission (2% vs. 0), SWL (15.69% vs. 0.8%), and reoperation (13.8% vs. 3%) rates were significantly higher in group 1, whereas asymptomatic stone growth (4% vs. 8%) was higher in group 2 (Table 1). Initial stone sizes were larger than 20 mm in patients who had reoperations in group 2.

Discussion

Surgical management of kidney stones mainly relies on the stone sizes and locations. Percutaneous nephrolithotomy (PCNL) is the standard procedure for kidney stones larger than 2 cm, and SWL or RIRS is recommended for those smaller than 2 cm (1,2). However, RIRS obtains a much more common use than is approved in current urology practice (15,16) because "flexible URS is less invasive than PCNL but often with higher stone-free rates than SWL" (17).

The current study performs a second-look flexible URS following the RIRS in patients with a Double-J stent in place, thereby increasing stone-free rates and reducing the probability of stone-related events.

The most desirable conditions following a successful RIRS procedure are a complete flush-out of all stone fragments and

Table 2. Univariable and multivariable regression analyses of stone-related events

	Univariable		Multivariable	
	Odds ratio (95% CI)	**p-value**	**Odds ratio (95% CI)**	**p-value**
Type of intervention				
Second-look URS	1 Reference	-	1 Reference	-
RIRS only	10.78 (4.71-24.65)	<0.001	8.48 (2.95-24.42)	<0.001
Operative difficulty				
Easy	1 Reference		1 Reference	-
Moderate	0.26 (0.09-0.77)	0.016	0.67 (0.16-2.77)	0.582
Hard	0.25 (0.11-0.58)	0.001	0.78 (0.24-2.52)	0.68
Stone size, mm	1.44 (1.19-1.75)	<0.001	1.62 (1.21-2.18)	0.001
Body mass index, (kg/m²)	0.88 (0.79-0.98)	0.021	0.82 (0.72-0.95)	0.006
Residual stone in radiologic control				
Stone free	1 Reference	-	1 Reference	-
Residual stone ≥3 mm	1.74 (0.80-3.81)	0.163	1.35 (0.43-4.2)	0.604
Stone density categories, (HU)				
<500	1 Reference	-	1 Reference	-
500-999	0.48 (0.15-1.57)	0.223	0.46 (0.09-2.31)	0.349
1000-1500	0.35 (0.11-1.15)	0.083	0.64 (0.13-3.09)	0.576
>1500	0.13 (0.02-0.77)	0.025	0.35 (0.04-2.95)	0.332

CI: Confidence interval, HU: Hounsfield unit, URS: Ureterorenoscopy

the absence of stone-related events (18). Great treatment results have been reported following RIRS. The CROES study revealed high stone-free rates (85.6%) and low complication rates (3.5%) (9). Giusti et al. (10) revealed that stone-free rate values were highest (90.5%) in small stones at 1 cm but declined when the stone size increased (1-2 cm, 2-3 cm, and >3 cm in diameter with 78.8%, 70.5%, and 55% respectively).

Additionally, studies revealed different stone-free rates when focusing on subgroups. A review of seven RIRS revealed that stone-free rates ranged from 34.8% to 59.7%, with non-contrast CT performed postoperatively in the first 3 months. Of these patients, 3.7% to 35% had to undergo stone surgery again (11). Similarly, Rippel et al. (12) reported a 38% stone-free rate in patients who underwent CT control in the postoperative period following RIRS.

The natural history of asymptomatic kidney stones is another controversial issue in the literature. Clinically insignificant kidney stones may not be "insignificant," and residual stone fragments remain a "thorny" issue for both patients and urologists (13). Small and non-occlusive calyceal stones have the potential to both grow and cause pain (19). Stone-related events are observed in more than half of the patients with insignificant stones, the 5-year average SRE observation rate is 51.2%, of whom 14.3% had to go to the emergency department (20).

Hein et al. (21) have studied influential factors on stone-related events in patients who followed for 5 years after RIRS. They revealed that even smaller than 1-mm residual stone fragments potentially risk the stone-related events following RIRS. They concluded that RIRS should aim for complete stone clearance and that all residual stone fragments should be considered significant regardless of size. The current study improved the stone-free rates and achieved lower stone-related events with a second-look flexible URS. Our stone-related event rate for the whole cohort was 31.25% (n=55/176) at a mean follow-up of 21 months; it was higher in group 1 (56.9%) than group 2 (20.8%), a finding that supports the result of Hein et al. (21).

Stone-free status following RIRS is an independent predictor for hospital re-admission and re-hospitalization (3). A study reported that residual stone fragments size of <4 mm is prone to grow (28%), thus almost 20% of these patients underwent re-intervention. Registered re-intervention rate doubles (38%) if the size of the fragment is >4 mm. This study recommended a complete stone-free status to reduce re-intervention following URS (22). Complications associated with flexible URS increased from 7.7% in the perioperative period to 25.4% in the first 30 days postoperatively (23).

Our radiologically confirmed residual stone fragments (≥1 mm) after RIRS in group 2 was 59.2%. Remarkably, this decreased to 6.4% after the second-look flexible URS procedure ($p<0.001$) (Table 2). Patients without stone-related events significantly increased from 43.14% in group 1 to 79.2% in group 2 (Table 1). We failed to show a significant association with residual stone fragments in the stone-related events in the multivariable analysis; however, we revealed a significant difference between groups 2 and 1 (odds ratio: 8.48) (Table 2). Therefore, second-look flexible URS is beneficial because it decreases residual stone fragments and stone-related events.

In our clinical practice, stent removal is performed at 2 weeks postoperative. Simultaneous intervention for single or multiple stones that are retractable with a basket during stent removal provides economic and work-related advantages to improve patient satisfaction.

Like previous studies, the current study defines stone-related events to include stone growth, urinary infection, emergency room visit, or additional intervention (6,24). This study revealed that 31.25% (n=55/176) of the whole cohort were observed to have stone-related events at a mean follow-up of 21 months although 6.8% (n=12/176) were asymptomatic.

The radiologically evaluated postoperative stone-free rate after RIRS was 37.25% and 40.8% in groups 1 and 2. This difference was not statistically significant. We report an immediate intraoperative stone-free rate of 57.6% (n=72/125) for group 2; however, this proved to be 40.8% (n=51/125). The difference may be due to unfavorable intraoperative conditions, such as bleeding or dusting caused by low visibility. Finally, the stone-free rate increased to 93.6% after the second-look flexible URS. These residual stone fragments are easy to identify with the absence of dust or bleeding.

Non-contrast CT is recommended for detecting residual stones following RIRS (2), but patients are often at risk of exposure to excessive radiation. The International Commission on Radiological Protection reported thresholds for safe exposure as 50 mSv for a single year or 20 mSv per year for 5 years (25). The 5-year retrospective radiation exposure of patients referred to a tertiary clinic for stone treatment was analyzed. Even based on CT examinations alone, 26% of these patients were exposed to >20 mSV per year and 6% to >50 mSV per year (26). Patients who applied to the emergency department due to acute stone-related events were exposed to an average of 29.7 mSv (interquartile range: 24.2-45.1) radiation in their 1-year follow-up. However, 20% of them were exposed to >50 mSv annually (27). All patients were radiologically examined with X-ray KUB and USG during the follow-up; CT imaging was not performed of any patient.

Various techniques and methods have been reported in the literature to achieve a completely stone-free status and reduce radiation exposure, including artificial intelligence algorithms. (14). A study aimed to detect residual stone fragments with

the "Endoluminal Control" method. All calyceal spaces are re-controlled after lithotripsy during RIRS and a 97% success rate has been reported compared to CT results after 4-8 weeks. They revealed that a 2 mm residual stone fragment was missed in only one patient. The authors claimed that CT was not required to reduce radiation exposure when residual stone fragments were not seen after endoscopic control (28).

Danilovic et al. (29) revealed that the stone-free rate following RIRS was 93.0% accurate compared to CT when endoscopically controlled. They revealed no cases of a residual stone fragment of >2 mm in CT for patients who were evaluated as stone-free on the endoscopic evaluation.

The term "Second-look Flexible URS" was first used by Breda et al. (30). They used second-look flexible URS as a final diagnostic inspection after a single or repeated RIRS to confirm the stone-free status and revealed that 37% (n=19/51) of the patients had two or more RIRS procedures. Their overall stone-free rates after the first and second RIRS were 64.7% and 92.2%, respectively. Their stone-free rates for stones of ≤2 cm at first and second RIRS were 79% and 100%, the stone-free rates for stones of >2 cm were 52% and 85.1%, respectively. They argued that the need for a second-look flexible URS would decrease with experience; however, our results refute this viewpoint because our group 2 had a significant decrease in stone-related event rates (odds ratio: 8.48%-95%; CI: 2.95-24.42). Therefore, we believe that a routine second-look flexible URS at the time of stent removal may help reduce stone-related events.

Non-randomized, retrospective design is the most important limitation of this study. We excluded data from the first 50 patients in the study to eliminate patients treated during the learning curve; however, we found that patients in group 1 were operated on relatively earlier than patients in group 2, which may be a source of bias in favor of patients in group 2 in terms of surgical expertise.

Evaluation of postoperative stone-free rates without CT suggests that we may have missed small stone fragments. Still, the primary goal of the study was to determine the rate of stone-related events after the second-look flexible URS.

Unfortunately, we were unable to conduct a cost analysis, thus further studies may help quantify the economic implications of using second-look flexible URS.

Conclusion

Residual stone fragments remain a challenging topic for urologists in stone treatment. We revealed that second-look flexible URS increased the stone-free rates and diminished the number of stone-related events. Additionally, we argue that performing second-look flexible URS in the early period following RIRS in the presence or suspicion of residual stone fragments provides better treatment results.

Ethics

Ethics Committee Approval: This study was conducted following the Ethics Committee of Kocaeli Derince Traning and Research Hospital guidelines (approval number: 2018/24).

Informed Consent: All patients were informed about the procedures and alternative treatment modalities.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: O.Ö.C., Concept: O.Ö.C., T.A.Ö., Ö.D., İ.Ç., Design: O.Ö.C., T.A.Ö., M.S.Y., Ö.D., İ.Ç., Data Collection or Processing: O.Ö.C., T.A.Ö., M.S.Y., Ö.D., İ.Ç., Analysis or Interpretation: O.Ö.C., T.A.Ö., M.S.Y., Ö.D., İ.Ç., Literature Search: O.Ö.C., T.A.Ö., İ.Ç., Writing: O.Ö.C., T.A.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Assimos D, Krambeck A, Miller NL, Monga M, Murad MH, Nelson CP, Pace KT, Pais VM Jr, Pearle MS, Preminger GM, Razvi H, Shah O, Matlaga BR. Surgical Management of Stones: American Urological Association/Endourological Society Guideline, PART I. J Urol 2016;196:1153-1160.
2. Türk C, Petřík A, Sarica K, Seitz C, Skolarikos A, Straub M, Knoll T. EAU Guidelines on Interventional Treatment for Urolithiasis. Eur Urol 2016;69:475-482.
3. Buldu I, Tepeler A, Karatag T, Ozyuvali E, Elbir F, Yordam M, Unsal A. Which factors affect the hospital re-admission and re-hospitalization after flexible ureterorenoscopy for kidney stone? World J Urol 2016;34:1291-1295.
4. Kang M, Son H, Jeong H, Cho MC, Cho SY. Clearance rates of residual stone fragments and dusts after endoscopic lithotripsy procedures using a holmium laser: 2-year follow-up results. World J Urol 2016;34:1591-1597.
5. Candau C, Saussine C, Lang H, Roy C, Faure F, Jacqmin D. Natural history of residual renal stone fragments after ESWL. Eur Urol 2000;37:18-22.
6. Rebuck DA, Macejko A, Bhalani V, Ramos P, Nadler RB. The natural history of renal stone fragments following ureteroscopy. Urology 2011;77:564-568.
7. Acar C, Cal C. Impact of Residual Fragments following Endourological Treatments in Renal Stones. Adv Urol 2012;2012:813523.
8. Xiang H, Chan M, Brown V, Huo YR, Chan L, Ridley L. Systematic review and meta-analysis of the diagnostic accuracy of low-dose computed tomography of the kidneys, ureters and bladder for urolithiasis. J Med Imaging Radiat Oncol 2017;61:582-590.
9. de la Rosette J, Denstedt J, Geavlete P, Keeley F, Matsuda T, Pearle M, Preminger G, Traxer O; CROES URS Study Group. The clinical research office of the endourological society ureteroscopy global study: indications, complications, and outcomes in 11,885 patients. J Endourol 2014;28:131-139.
10. Giusti G, Proietti S, Villa L, Cloutier J, Rosso M, Gadda GM, Doizi S, Suardi N, Montorsi F, Gaboardi F, Traxer O. Current Standard Technique for Modern F lexible Ureteroscopy: Tips and Tricks. Eur Urol 2016;70:188-194.

11. Tokas T, Habicher M, Junker D, Herrmann T, Jessen JP, Knoll T, Nagele U; Training Research in Urological Surgery Technology (T.R.U.S.T.)-Group. Uncovering the real outcomes of active renal stone treatment by utilizing non-contrast computer tomography: a systematic review of the current literature. World J Urol 2017;35:897-905.
12. Rippel CA, Nikkel L, Lin YK, Danawala Z, Olorunnisomo V, Youssef RF, Pearle MS, Lotan Y, Raman JD. Residual fragments following ureteroscopic lithotripsy: incidence and predictors on postoperative computerized tomography. J Urol 2012;188:2246-2251.
13. Prezioso D, Barone B, Di Domenico D, Vitale R. Stone residual fragments: A thorny problem. Urologia 2019;86:169-176.
14. Suarez-Ibarrola R, Hein S, Miernik A. Residual stone fragments: clinical implications and technological innovations. Curr Opin Urol 2019;29:129-134.
15. Chung DY, Kang DH, Cho KS, Jeong WS, Jung HD, Kwon JK, Lee SH, Lee JY. Comparison of stone-free rates following shock wave lithotripsy, percutaneous nephrolithotomy, and retrograde intrarenal surgery for treatment of renal stones: A systematic review and network meta-analysis. PLoS One 2019;14:e0211316.
16. Scotland KB, Rudnick B, Healy KA, Hubosky SG, Bagley DH. Retrograde Ureteroscopic Management of Large Renal Calculi: A Single Institutional Experience and Concise Literature Review. J Endourol 2018;32:603-607.
17. Pearle MS. Is Ureteroscopy as Good as We Think? J Urol 2016;195:823-824.
18. Van Cleynenbreugel B, Kılıç Ö, Akand M. Retrograde intrarenal surgery for renal stones - Part 1. Turk J Urol 2017;43:112-121.
19. Hepsen E, Ozok HU, Cakici MC, Sari S, Karakoyunlu AN, Ersoy H. The effect of renal localization on the fate of clinically insignificant residual fragments after retrograde intrarenal surgery: A prospective 1-year follow-up study. Arch Esp Urol 2021;74:511-518.
20. Li X, Zhu W, Lam W, Yue Y, Duan H, Zeng G. Outcomes of long-term follow-up of asymptomatic renal stones and prediction of stone-related events. BJU Int 2019;123:485-492.
21. Hein S, Miernik A, Wilhelm K, Schlager D, Schoeb DS, Adams F, Vach W, Schoenthaler M. Endoscopically Determined Stone Clearance Predicts Disease Recurrence Within 5 Years After Retrograde Intrarenal Surgery. J Endourol 2016;30:644-649.
22. Chew BH, Brotherhood HL, Sur RL, Wang AQ, Knudsen BE, Yong C, Marien T, Miller NL, Krambeck AE, Charchenko C, Humphreys MR. Natural History, Complications and Re-Intervention Rates of Asymptomatic Residual Stone Fragments after Ureteroscopy: a Report from the EDGE Research Consortium. J Urol 2016;195:982-986.
23. Wolff I, May M, Hoschke B, Gilfrich C, Peter J, Ecke T, Schostak M, Lebentrau S. [Differences between the inpatient complication rate after ureterorenoscopy and the 30-day outcome reported by the patient - results of the German prospective BUSTER study]. Aktuelle Urol 2019;50:63-70.
24. Burgher A, Beman M, Holtzman JL, Monga M. Progression of nephrolithiasis: long-term outcomes with observation of asymptomatic calculi. J Endourol 2004;18:534-539.
25. 1990 Recommendations of the International Commission on Radiological Protection. Ann ICRP 1991;21:1-201.
26. Tzou DT, Zetumer S, Usawachintachit M, Taguchi K, Bechis SK, Duty BD, Harper JD, Hsi RS, Sorensen M, Sur RL, Reliford-Titus S, Chang HC, Isaacson D, Bayne DB, Wang ZJ, Stoller ML, Chi T. Computed Tomography Radiation Exposure Among Referred Kidney Stone Patients: Results from the Registry for Stones of the Kidney and Ureter. J Endourol 2019;33:619-624.
27. Ferrandino MN, Bagrodia A, Pierre SA, Scales CD Jr, Rampersaud E, Pearle MS, Preminger GM. Radiation exposure in the acute and short-term management of urolithiasis at 2 academic centers. J Urol 2009;181:668-672.
28. Wilhelm K, Hahn O, Schoenthaler M, Hein S, Neubauer J, Schnabel M, Neisius A. Stone-Free Rate after Treating Kidney Stones Exceeding 10 mm via Flexible Ureteroscopy: Can Endoscopic Assessment Replace Low-Dose Computed Tomography Control? Urol Int 2019;103:326-330.
29. Danilovic A, Cavalanti A, Rocha BA, Traxer O, Torricelli FCM, Marchini GS, Mazzucchi E, Srougi M. Assessment of Residual Stone Fragments After Retrograde Intrarenal Surgery. J Endourol 2018;32:1108-1113.
30. Breda A, Ogunyemi O, Leppert JT, Schulam PG. Flexible ureteroscopy and laser lithotripsy for multiple unilateral intrarenal stones. Eur Urol 2009;55:1190-1196.

ORIGINAL RESEARCH
General Urology

Doi: 10.4274/jus.galenos.2021.2021.0055
J Urol Surg, 2022;9(1):47-51

The Comparison of the Image Quality of Portable Miniature and Conventional Light Sources Used in Flexible Cystoscopy: An *In Vitro* Evaluation

Uygar Miçooğulları, Volkan Ülker

University of Health Sciences Turkiye, İzmir Tepecik Training and Research Hospital, Clinic of Urology, İzmir, Turkiye

What's known on the subject? and What does the study add?

In endourology, miniaturization and portability of endoscopic instruments are important for performing cystoscopy at bedside and office conditions. This study aimed to perform image quality and cost analysis of a portable light source in cystoscopy and compare its features with the conventional endoscopic light source. Our study revealed that portable halogen light sources provided comparable image quality to conventional xenon light sources during flexible cystoscopy. This study used the halogen portable light source that is cheaper than light-emitting diode portable ones, which is an additional advantage.

Abstract

Objective: Portability and miniaturization of endoscopic instruments are important in urological practice for flexible cystoscopy in bedside and office conditions. However, the adequacy of portable light sources is doubtful. Thus, this study aimed to compare the portable halogen and conventional light sources in terms of image quality and cost.

Materials and Methods: An *in vitro* model was designed using portable halogen and a conventional endoscopy light source. Two videos of simulated cystoscopy were recorded using the portable and another two using the conventional light source. These videos were rated in the following 5 areas: overall video quality, brightness, sharpness, contrast, and color. The imaging quality of the two light sources was compared. Additionally, the cost analysis was compared in both light sources.

Results: The image quality rating was performed by 83 evaluators. The overall video quality, brightness, sharpness, and contrast evaluation revealed a significant difference between the light sources in terms of brightness, and the score was higher in the conventional light source ($p<0.05$). Color reproduction results were as follows: 68.67% great similarity, 27.71% little similarity, and 3.61% no similarity between the images produced using the two light sources. A portable light source was considered to be cost-effective.

Conclusion: The portable light source resulted in minimal degradation in image quality for flexible cystoscopy compared with the conventional endoscopy light source. This system can capture high-quality images with minimal equipment and is easy to set up. We believe that a portable halogen light source is sufficient to perform cystoscopic procedures in bedside and office conditions with limited cost. Further studies are needed to evaluate the efficacy of new cystoscopy systems that integrate mobile technology and new portable light sources.

Keywords: Image quality, flexible cystoscopy, portable light source

Introduction

Cystoscopy is one of the most frequently used procedures in daily clinical practice in urology. Indications of cystoscopy include facilitating the urethral catheter insertion, hematuria and intravesical pathology diagnosis, biopsy, foreign body removal, ureteral stent placement or removal, and infravesical obstruction or ureteral orifice evaluation (1,2). Flexible scopes, compared to rigid ones, allow more comfortable endoscopy with minimal morbidity and have less postprocedural hematuria and analgesic need (3).

Correspondence: Uygar Miçooğulları MD, University of Health Sciences Turkiye, İzmir Tepecik Training and Research Hospital, Clinic of Urology, İzmir, Turkiye
Phone: +90 543 588 89 89 **E-mail:** uygarmico@hotmail.com **ORCID-ID:** orcid.org/0000-0003-4729-6104
Received: 20.04.2021 **Accepted:** 17.05.2021

Cite this article as: Miçooğulları U, Ülker V. The Comparison of the Image Quality of Portable Miniature and Conventional Light Sources Used in Flexible Cystoscopy: An *In Vitro* Evaluation. J Urol Surg, 2022;9(1):47-51.

Sometimes, performing bedside flexible cystoscopy, such as for critical patients in the intensive care unit (ICU) or in the emergency department (ED), might be necessary. A standard cystoscopy needs an endoscopy tower, which includes a light source and video unit. This transportation is generally time-consuming and impractical. Additionally, having an extra endoscopy tower in the ICU and ED is not financially feasible. In such cases, performing cystoscopy with a portable light source would be very practical. Small portable endoscope light sources have gained popularity, especially in otolaryngology, and we believe that they can also be used as alternative light sources in urology (4). Miniaturized endoscope systems are ideally sized for portability, and when integrated with smartphone devices, these systems can become widely accessible and can reach a bigger population regardless of geographic and socioeconomic constraints (5). However, there might be a concern of whether the quality of the image generated with the smartphone-endoscope system with a portable light source is sufficient for cystoscopy since an insufficient light source may lead to suboptimal endoscopy, where small bladder tumors may be missed or urethral access cannot be gained. This *in vitro* study compared the image qualities of flexible cystoscopy videos using portable halogen and conventional xenon light sources and analyzed the cost-efficiency of using a portable light source.

Materials and Methods

This 2-part study was designed using a flexible fiberoptic cystoscope (CYF-5, Olympus Tokyo, Japan), portable halogen light source (MAJ-524, Olympus, Tokyo, Japan), and conventional xenon light source (CLV190, Olympus, Tokyo, Japan). The same high definition (HD) video system and camera head were used with both light sources (Evis Exera III CV-190 and CV-S190-XZ-E/Q, Olympus, Tokyo, Japan).

In the first part of the study, the color reproduction was evaluated using Gretag-Macbeth color checker (Color Checker Mini, 5.7×8.25 cm, X-Rite Inc. Grand Rapids, MI, USA). The test environment was prepared by a doctor and a technician. The flexible cystoscope visualized a Color Checker at an angle of 90 degrees and a distance of 2 cm (Figure 1). Gretag-Macbeth is a test pattern that is scientifically designed to help determine the true color balance or optical density of any color rendition system. It is an industry-standard that provides a non-subjective comparison with a test pattern of 24 scientifically prepared colored squares. Each color square represents a natural object that provides a qualitative-maintaining color reference to countable values (Figure 2a). Video-1 and video-2 were recorded with portable and conventional light sources, respectively. Observers graded the color representation from 0 to 2 (0 as no similarity; 1 as little similarity; and 2 as great similarities) between the images taken using two light sources (Figure 2b, 2c).

In the second part of the study, the video image quality was compared in terms of the overall video quality, brightness, sharpness, and contrast. After obtaining written informed consent, video-3 and video-4 were recorded with the portable and conventional light sources, respectively, during urethrocystoscopy of the same patient. Both 15-sec-long videos included the view of verumontanum, ureteral orifices, and bladder wall. Then, two videos were rated by observers using a 5-point Likert scale, with 1 as unusable, 2 as very annoying, 3 as annoying, 4 as perceptible, but not annoying, and 5 as imperceptible images. The snap-shots of videos are shown in Figure 3. Eighty-three urologists and last-year residents of urology from 3 cities blindly evaluated 4 videos and rated them.

Cost analysis was made according to the retail prices provided by the authorized representative of Olympus in our country. For the analysis of the conventional system, the light source and the light cable were considered, excluding the endoscopy tray.

Statistical Analysis

The Statistical Package for the Social Sciences 22.0 (IBM, Chicago, IL, USA) version for Windows was used for statistical analysis. The Likert scale results from our crowd-sourced expert evaluators were summarized using descriptive statistics. First of all, the normality of the distribution of variables was evaluated

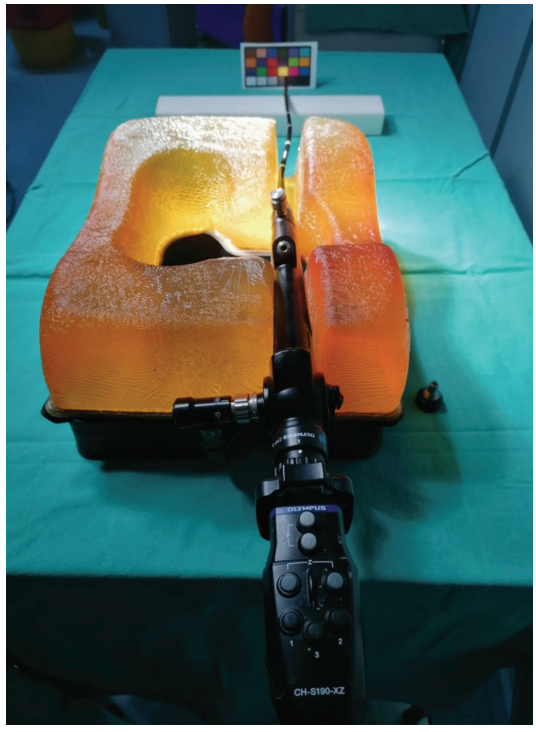


Figure 1. *In vitro* model for comparing different light sources with a Gretag-Macbeth Color Checker 7×8.25 cm and an Olympus fiberoptic flexible cystoscope

with three tests. The coefficient of variation (standard deviation /mean) was below 30% in all groups. The evaluation of the Skewness-Kurtosis values revealed that the current values were between -2 and +2 in all groups. The variables fitting the normal distribution were evaluated with the Student t-test. A p-value of <0.05 was considered significant.

Results

Eighty-three expert evaluators completed the image quality ratings. The overall video quality, brightness, sharpness, and contrast evaluation revealed that the only statistical difference between light sources was seen in terms of brightness ($p<0.05$) (Table 1). The brightness score was significantly higher in the conventional light source group (Table 1). The experts' ratings of image quality from both light sources are schematized in Figure 4a. Based on the Color Checker results, 57 of the expert evaluators rated images generated using two light sources as having great similarity, 23 as little similarities, and 3 as no similarity (Figure 4b). The costs of portable halogen and conventional xenon light sources used in tests were $1,150 and $15,000, respectively. The cost analysis indicated that the price difference between portable halogen and conventional xenon light sources including light cable was $15,050.

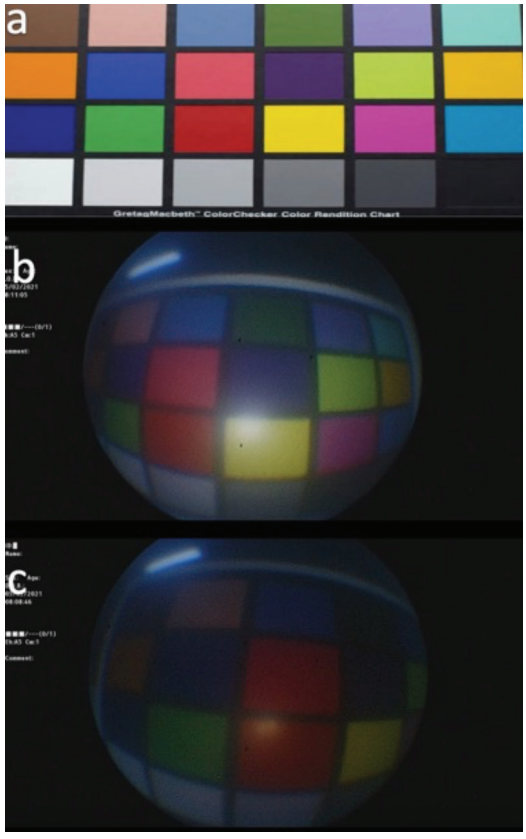


Figure 2A. Gretag-Macbeth X-rite Color Checker, 5.7×8.25 cm **B.** Screenshot of the video taken with the conventional xenon light source. **C.** Screenshot of the video taken with the portable halogen light source

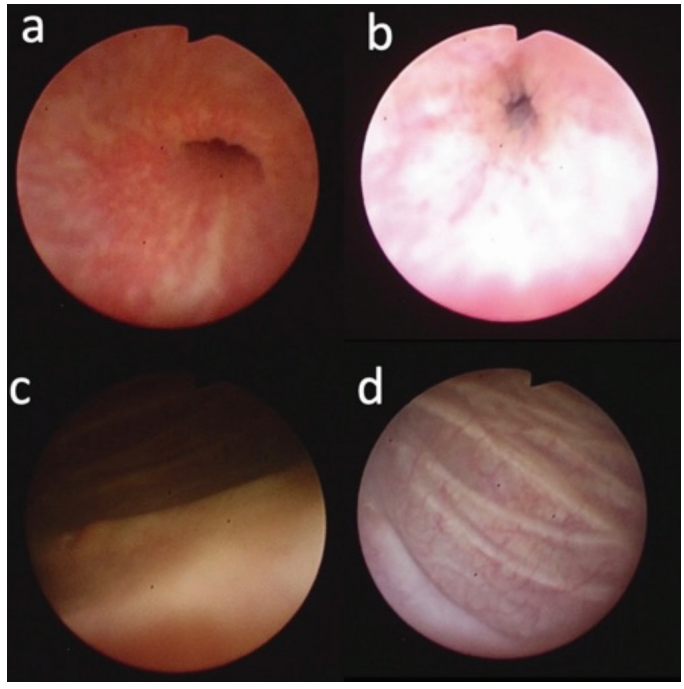


Figure 3A. Screenshot of the video of the urethra taken with the portable halogen light source, **B.** Screenshot of the video of the urethra taken with the conventional xenon light source, **C.** Screenshot of the video of the bladder and right ureter orifice taken with the portable halogen light source, **D.** Screenshot of the video of the bladder and right ureter orifice taken with the conventional xenon light source

Table 1. Image quality values for both light sources

Parameters	Group	n	Mean	Standard deviation	p
Overall video quality	Conventional light source	83	4.50	0.68	0.06
	Portable light source	83	4.31	0.62	
Brightness	Conventional light source	83	4.43	0.71	0.00
	Portable light source	83	2.89	0.92	
Sharpness	Conventional light source	83	4.40	0.62	0.059
	Portable light source	83	4.21	0.68	
Contrast	Conventional light source	83	4.20	0.83	0.078
	Portable light source	83	3.97	0.82	

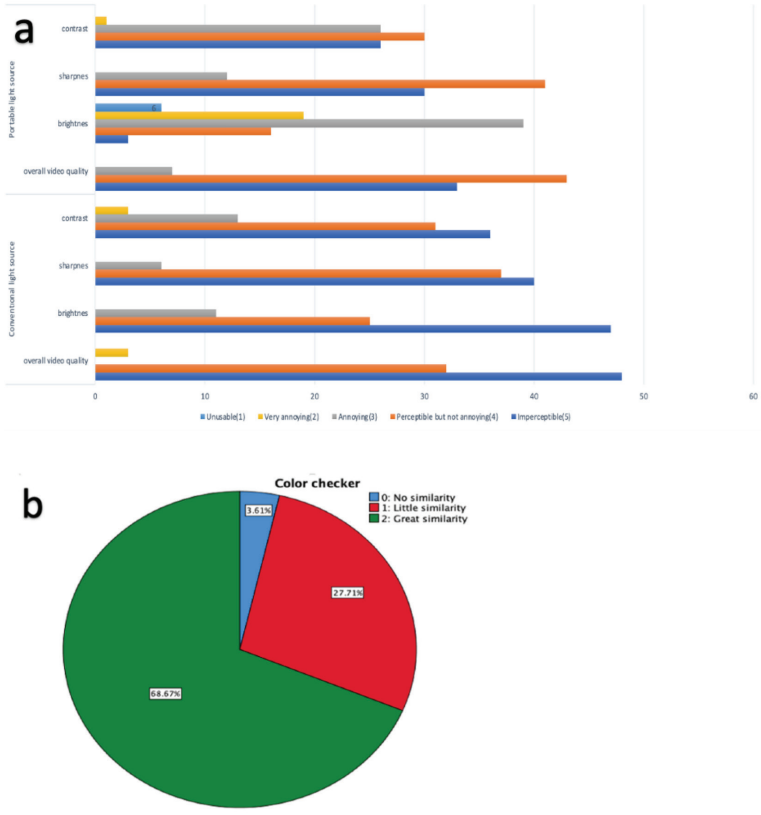


Figure 4A. Expert evaluators' ratings of image quality of both light sources, **B.** Ratings of color similarity with the color checker

Discussion

Cystoscopy has become an indispensable tool for urologists since it was first developed by Nitze in 1879 (6). Bedside cystoscopy provides great advantages and convenience when treating patients with limited mobility and those who stay in the ICUs (1,7). Additionally, conventional cystoscopy can provide high-quality images; however, bringing an endoscopy tower to the patient's room can be challenging (7). Since Nitze first developed the cystoscope, constant innovation and development have been done that led to the instruments urologists use today. A flexible cystoscope is the product of these developments (8,9). Digital flexible scopes require their integrated video and light source systems, while fiberoptic scopes can use a portable light source. Newer digital flexible cystoscopes are increasingly used in developed countries; however, fiberoptic flexible cystoscopes are still extensively used worldwide because of their significantly lower cost (10).

One of the most common indications for bedside flexible cystoscopy is the placement of a difficult urethral catheter (11). Flexible cystoscopy with a portable light source allows the urologist to perform fast and practical procedures at the bedside, ED, or the office. The main concern in cystoscopy with a portable light source is image quality, while the second concern is cost-effectiveness. This study assessed the quality of images made with a high-fidelity cystourethroscopy simulator using a portable light source and compared them to the ones made using a conventional light source.

Studies have evaluated the feasibility of integrating mobile technology into cystoscopy systems and clinical results have been presented (4,5,7,12,13). Chatzipapas et al. (12) compared a portable light-emitting diode (LED) light source with a conventional light source in rigid cystoscopy and revealed no difference in the image quality and diagnostic adequacy between the two setups. However, they did not conduct any statistical analysis in their study. Tse et al. (5) used a three-dimensional printed attachment that connected a smartphone with a portable LED light source. They concluded that portable LED light source was comparable to the conventional light source. Another study by Dutta et al. (13) revealed similar results with a portable LED light source and smartphone screen. Butler et al. (4) compared smartphone-generated light with portable light sources used in bedside laryngoscopy and reported similar results with both. Our study also revealed that a portable light source is comparable to a conventional xenon light source in terms of overall video quality, sharpness, and contrast. Only the brightness score of the conventional light source was significantly higher. Additionally,

any significant difference was not found between the two light sources in the color reproduction component. Our results support the previous studies. The halogen portable light source we used in this study is cheaper than LED portable ones, which is an additional advantage.

Another issue that needed to be evaluated was the cost of the light source. Previous studies reported significant cost differences. One study reported that the total cost of the endoscope system with a portable LED light source coupled with a smartphone was $750, while a conventional video cystoscope with a standard HD camera and xenon source costs $45,000 (5). Similarly, Chatzipapas et al. (12) revealed a $46,401 cost difference between the video system they tested. Our study revealed a $15,050 cost difference, which was significant between the two systems in the test platform. Considering the cheapest conventional light source of the same brand that can be used in ED or office, the cost together with the light cable is $4285. This is still $3,135 more expensive than a portable halogen light source. Additionally, the halogen portable light source was $200 cheaper than the portable LED light source. Its low cost may allow different departments to have their flexible cystoscope with portable light sources instead of sharing one conventional video endoscopy tower.

Study Limitations

Our study has some limitations. Mainly, only the light source component of the cystoscopy system was evaluated and a conventional HD camera system and monitor were used for recording index videos. Secondly, portable LED light source might have produced better results than the halogen light source, but we chose to evaluate halogen light source because it's cheaper than LED and has comparable results to conventional xenon light source. Our study results will help further develop a portable light source and smartphone combination that is flexible cystoscopy for ED or office use.

Conclusion

Our study showed that portable halogen light sources provided comparable image quality to conventional xenon light sources during flexible cystoscopy. The brightness parameter was better with a conventional light source; however, the difference was not statistically significant. The portable halogen light source is a reasonable alternative to a conventional xenon light source for bedside and office use. Portable light source's open-source design, low cost, and adaptability to smartphones may encourage its widespread and rapid adoption in clinical practice, especially in low-resource centers.

Ethics

Ethics Committee Approval: It is not necessary.

Informed Consent: Informed consent was obtained.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

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

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Clayman RV, Kramolowsky EV. Bedside flexible cystoscopy: an approach to the critically ill patient. J Urol 1986;135:1179-1180.
2. Beaghler M, Grasso M 3rd, Loisides P. Inability to pass a urethral catheter: the bedside role of the flexible cystoscope. Urology 1994;44:268-270.
3. Erdem MR, Topaloğlu K, Yücebaş ÖE, Şengör F, Aslan AR, Tosun Ç, Ramazanoğlu MA, Duvar S. Better Comfort for Both Patient and Doctor: Prospective Randomized Study about Flexible and Rigid Cystoscopy. J Urol Surg 2015;2:65-68.
4. Butler JJ, White SF, Myint CWM, Groves MW. The Feasibility of Utilizing Smartphone Flashlights as an Alternative Endoscopic Light Source in Emergency Situations. Ear Nose Throat J 2021;100:NP1-NP6.
5. Tse C, Patel RM, Yoon R, Okhunov Z, Landman J, Clayman RV. The Endockscope Using Next Generation Smartphones: "A Global Opportunity". J Endourol 2018;32:765-770.
6. Nitze M. Eineneue Beleuchtungs und Untersuchungs method fur Harnrohre, Harnblase, und Rektum. Wiener Med Wochen 1879;24:649.
7. Guo Y, Kshatri K, Matsumoto ED, Kapoor A. Expert and Crowdsourced Evaluation of Image Quality From a Novel Endoscopy Phone Light Adapter. Urology 2020;146:54-58.
8. Engelsgjerd JS, Deibert CM. Cystoscopy. 2020 Apr 24. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan–. PMID: 29630232.
9. Samplaski MK, Jones JS. Two centuries of cystoscopy: the development of imaging, instrumentation and synergistic technologies. BJU Int 2009;103:154-158.
10. Quayle SS, Ames CD, Lieber D, Yan Y, Landman J. Comparison of optical resolution with digital and standard fiberoptic cystoscopes in an in vitro model. Urology 2005;66:489-493.
11. Kadi N, Menezes P. ABC of flexible cystoscopy for junior trainee and general practitioner. Int J Gen Med 2011;4:593-596.
12. Chatzipapas I, Kathopoulis N, Protopapas A, Kyritsis N, Vlachos D E, Loutradis D. Mobile Cystoscope. HJOG 2017;16:23-28.
13. Dutta R, Yoon R, Patel RM, Spradling K, Okhunov Z, Sohn W, Lee HJ, Landman J, Clayman RV. Clinical Comparison of Conventional and Mobile Endockscope Videocystoscopy Using an Air or Fluid Medium. J Endourol 2017;31:593-597.

ORIGINAL RESEARCH
General Urology

Doi: 10.4274/jus.galenos.2021.2021.0054
J Urol Surg, 2022;9(1):52-56

Urologists Are No Longer the Primary Surgeons for Several Urologic Operations: A National Survey Among the Turkish Urologists

Serdar Madendere[1], Müslim Doğan Değer[2], Engin Denizhan Demirkıran[3], Hüseyin Alperen Yıldız[4]

[1]Gümüşhane State Hospital, Clinic of Urology, Gümüşhane, Turkiye
[2]Edirne Sultan 1st Murat State Hospital, Clinic of Urology, Edirne, Turkiye
[3]Şırnak State Hospital, Clinic of Urology, Şırnak, Turkiye
[4]Malazgirt State Hospital, Clinic of Urology, Muş, Turkiye

What's known on the subject? and What does the study add?

To best of our knowledge, this is the first study which investigates the performance percentages of the surgeries that could be performed both by the urologists and other surgeons. This study shows that the urologists are no longer the main surgeons for some urological surgeries, and many urologists avoid performing the major urologic surgeries. However, urologists mostly agree that they should perform these surgeries. The study was conducted to increase the awareness among urologists.

Abstract

Objective: To investigate the role, interest, and competence of the Turkish urologists for urologic surgeries which are also performed by the other surgeons.

Materials and Methods: We conducted a 22-item online survey and invited urologists by e-mail. Questions were asked to evaluate the attitudes, performances, and capabilities of the urologists in surgeries which could be performed by the other surgeons.

Results: A total of 305 responses were evaluated. The female incontinence surgery, pediatric urologic surgery, and adrenal surgery are mostly performed by the urologists in their hospitals. Turkish urologists mostly do not perform the following surgeries and interventions themselves and refer patients to the other surgeons for a percutaneous nephrostomy (47.2%), urinary diversions using the intestinal segments (44.9%), kidney transplantation (11.8%), and the transgender surgeries (7.2%). Almost half of the urologists do not perform adrenal surgeries (50.2%). Most urologists agree that they should be the main surgeons for all these surgeries.

Conclusion: Urologists are no longer the main surgeons for some surgeries which are included on the urologic curriculum. Many urologists avoid performing the major urologic surgeries. Urology educators should familiarize the new urologists with all the urologic surgeries.

Keywords: Urologic surgical procedures, transgender surgery, kidney transplantation, urinary diversion, adrenal surgery, female urology

Introduction

Many urologists have focused on the robotic and laparoscopic procedures, as a result of recent advances in minimally invasive surgery (1). These fields are promising for the development of urology in the future (2). However, urologists may no longer be the main surgeons for the certain operations, because of the involvement of the other departments. For example, in kidney transplantation, urologists were the main surgeons in the United States in the past; however, many kidney transplants are performed by the general surgeons nowadays (3).

Percutaneous nephrostomy and renal access before a percutaneous nephrolithotomy (PCNL) are performed by the interventional radiologists in some countries (4). While the transgender surgery requires urology involvement in many of the aspects, this field is mainly dominated by the plastic surgeons (5). Adrenal surgeries, pediatric urologic surgeries, and

Correspondence: Serdar Madendere MD, Gümüşhane State Hospital, Clinic of Urology, Gümüşhane, Turkiye
Phone: +90 541 626 28 12 **E-mail:** serdarmadendere@gmail.com **ORCID-ID:** orcid.org/0000-0001-7020-0276
Received: 20.04.2021 **Accepted:** 08.08.2021

Cite this article as: Madendere S, Değer MD, Demirkıran ED, Yıldız HA. Urologists Are No Longer the Primary Surgeons for Several Urologic Operations: A National Survey Among the Turkish Urologists. J Urol Surg, 2022;9(1):52-56.

female incontinence surgeries are also being performed both by the urologists and other surgeons. As a result, there is a risk that the surgical diversity of the urologists may decrease, and the residents may have less surgical exposure in these fields during the training. This could be defined as a loss for urology specialization economically and scientifically.

While involvement of the other departments in urology surgeries are observed, we hypothesized that the Turkish urologists are no longer the primary surgeons in some surgeries that they used to perform, and this may cause to a loss of interest and competence for the urology residents in the future. We conducted a survey to show the current situation, and to reveal the possible reasons for it. With this study, we would like to emphasize the importance of maintaining the surgical range in the urology department.

Materials and Methods

The study is based on the online survey that consisted of 22 questions with a multiple choice or yes/no options. The survey was created based on the checklist for reporting the results of internet E-surveys (CHERRIES) (6). Firstly, these questions inquired about the baseline characteristics of the responders. In the second part, there are questions about whether the urologists perform the listed surgeries in their hospitals. Common surgeries that could be performed by both the urologists and other surgeons like gynecologists, plastic surgeons, pediatric surgeons, general surgeons, and interventional radiologists were investigated with the questionnaire. The third part involves the perspectives of the urologists about whether the urologists or other surgeons should perform these surgeries. In the last part, self-confidence of the respondents in relation to the listed surgeries was evaluated.

After testing for feasibility with the ten responders, a total of 2305 actively working certified urologists and urology residents in the last year of the training were invited to the study by E-mail. After four weeks, reminder mails were also sent. Informed consent was not required because the study is not based on the patient groups. The survey was accessible between June and October 2020 through the web program Google Forms (Alphabet Co., Mountain View, CA). The Local Ethics Committee approved this study (Zonguldak Bülent Ecevit University - 2020/10-5, date: 13.05.2020).

Statistical Analysis

Descriptive statistics were used to analyze the practice patterns and demographics. The respondents were classified according to the academic title, hospital type, and experience in urology stream. For each surgery, we separately determined whether it was performed in the hospital of responders. The numbers and percentages of the urologists who perform these surgeries in their hospitals were assessed. The proportions of all the urologists who think that urologists should perform these surgeries were calculated. Frequencies were compared by using the chi-square test. A p-value <0.05 was considered statistically significant. Statistical analyses were performed by using IBM Statistical Package for Social Sciences, version 21.0, software (IBM SPSS Corp., Armonk, NY, USA).

Results

A total of 351 out of 2305 urologists participated in this study. The response rate was 15.2%. Among the questionnaires, a total of 46 incomplete questionnaires were excluded from the study, and 305 responses were evaluated. The median age of the responders was 36 years (27-66). The responders were employed in the urology practices for a median of ten (4-39) years. The demographics and other practice patterns are shown in Table 1. Urologists had high interest in the renal transplantation (97.4%), but mostly general surgeons perform renal transplantation (88.2%).

Most urologists stated that the female incontinence surgery, pediatric urologic surgery, and adrenal surgery are mostly performed by the urologists in their hospitals. Urologists remain in the minority for performing the other listed surgeries. The urologists, employed in the hospitals where these surgeries are performed by the urologists, mostly think that the urologists should perform these surgeries. In total, most urologists agree that all these surgeries should be performed by the urologists (Table 2, Figure 1).

Table 1. Baseline characteristics of 305 responders

Experience in practice in years, n (%)	0-5	63 (20.7)
	5-10	110 (36.1)
	10-15	48 (15.7)
	15-20	32 (10.5)
	20 and more	52 (17)
Age range in years, n (%)	25-34	144 (47.2%)
	35-44	96 (31.5)
	45-54	42 (13.7%)
	55-64	20 (6.6%)
	65 and more	3 (1%)
Title, n (%)	Residents	76 (24.9%)
	Specialists	184 (60.3%)
	Academicians	45 (14.8%)
Hospital type, n (%)	University hospital	78 (25.6%)
	Government based research hospital	70 (22.9%)
	State hospital	106 (34.8%)
	Private hospital	51 (16.7%)

Table 3, presents the percentages of the urologists who feel competent performing different surgery types and think urologists should perform these surgeries according to an academic title.

Except the percutaneous nephrostomy and pediatric urologic surgery, all the surgeries are mostly performed in the tertiary care hospitals.

Discussion

To the best of our knowledge, this is the first national research which illustrates the role and attitude of the urologists about surgical procedures that are also performed by the other surgeons. Our results demonstrate that the urologists are no longer the primary surgeons for some surgeries related to their field. On the other hand, most of them think that they should perform these surgeries.

Morrison et al. (5) showed that the urology residents had less theoretical and practical exposure to a transgender surgery than the plastic surgery residents. Urologists are surgeons for the genitourinary tract and urologic care which is essential for transgender patients having issues with a voiding dysfunction, fistulas, and penile prosthesis revision (7). Therefore, they should be at the center of transgender multidisciplinary teams. Training during the residency is essential to reach this awareness. On this point, the attitude of the training program director is significant. Comprehensive transgender practice during the residency may ensure the dominance of the urologists in this field in the future.

There is a similar issue between the urologists and general surgeons. This study shows that the kidney transplantation and even donor nephrectomy are performed mostly by the general surgeons despite the high interest of urologists. Similarly, in the United States, urologists are no longer the primary surgeons in this field (3). Adrenalectomy is another operation which could be performed by both the general surgeons and urologists. Fuletra et al. (8) highlighted that only 10% of the 3358 adrenalectomies were performed by the urologists in the United States. Only half of Turkish urologists perform adrenalectomy in

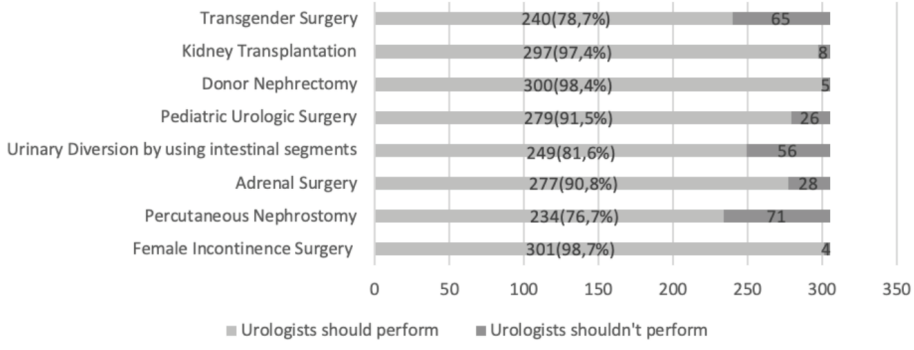


Figure 1. Total numbers of urologists who believe that urologists should perform these surgeries

Table 2. Percentages of urologists performing these surgeries in their hospital, and who think that urologists should perform these surgeries

Surgery type	Performing urologists[a]		Percentages of performing urologists who think urologists should perform the operation[b]		p-value[c]
	n	%	n	%	
Female incontinence surgery	256	83.9%	253	98.8%	0.624
Percutaneous nephrostomy	144	47.2%	125	86.8%	<0.01
Adrenal surgery	153	50.2%	146	95.4%	<0.01
Urinary diversion[d]	137	44.9%	129	94.2%	<0.01
Pediatric urologic surgery	242	79.3%	229	94.6%	<0.01
Donor nephrectomy	43	14.1%	42	97.7%	0.700
Kidney transplantation	36	11.8%	36	100%	0.290
Transgender surgery	22	7.2%	20	90.9%	0.146

[a]: The total number and percentages of urologists who answered that their urology department performs these procedures in their hospital, [b]: Percentages of responders performing these surgeries who agree that urologists should perform these surgeries in their hospita's urology department, [c]: In terms of the surgeries that are performed in their hospital, the p-value compares urologists who believe or do not believe urologists should perform the surgeries, [d]: Urinary diversions using intestinal segments

Table 3. Comparison of urologists who feel competent about the surgeries, and those who think urologists should perform these surgeries

Surgery type	Title	Capability for surgeries[a]		Urologists should perform these surgeries[b]	
		n	%	n	%
Female incontinence surgery	Residents	50	65.8%	74	97.4%
	Specialists	121	65.8%	183	99.5%
	Academics	40	88.9%	44	97.8%
	Overall	**211**	**69.2%**	**301**	**98.7%**
Percutaneous nephrostomy	Residents	55	72.4%	60	78.9%
	Specialists	130	70.7%	139	75.5%
	Academics	37	82.2%	35	77.8%
	Overall	**222**	**72.8%**	**234**	**76.7%**
Adrenal surgery	Residents	29	38.2%	66	86.8%
	Specialists	49	26.6%	167	90.8%
	Academics	32	71.1%	44	97.8%
	Overall	**110**	**36.1%**	**277**	**90.8%**
Urinary diversion[c]	Residents	42	55.3%	56	73.7%
	Specialists	74	40.2%	153	83.2%
	Academics	39	86.7%	40	88.9%
	Overall	**155**	**50.8%**	**249**	**81.6%**
Pediatric urologic surgery	Residents	34	44.7%	67	88.2%
	Specialists	115	62.5%	170	92.4%
	Academics	37	82.2%	42	93.3%
	Overall	**186**	**61.0%**	**279**	**91.5%**

[a]: Total numbers and percentages of urologists who feel capable of performing these surgeries, [b]: Total numbers and percentages of urologists who believe that urologists should perform these surgeries, [c]: Urinary diversions by using intestinal segments

their hospitals. Urologists should be well trained for a surgery of the retroperitoneum and should maintain adrenalectomy and donor nephrectomy in their repertoire. The urologist's experience will always be inextricably linked to the past, nature, and complexities of the kidney transplantation (9).

According to the Accreditation Council for Graduate Medical Education data, urology residents have limited exposure to the urinary diversions (10). Another study showing the practice patterns of certifying the American urologists found, only 37% of them performed any urinary diversions (11). There is a similar percentage among the responders of this study. The possible explanation for this situation is again insufficient exposure to the urinary diversions during their residency. Another possible reason may be the necessity of using the intestinal segments for some urinary diversions. Urologists should be competent to prepare the intestinal segments for urinary diversions by themselves instead of referring to the general surgeons. Urologists should be competent enough to perform the urinary diversions that may be required for emergency cases.

In the United States, gynecologists perform most sling procedures, and in Canada urologists perform 43% of these surgeries. The same study showed that the urologists diagnose fewer patients with a pelvic organ prolapse (POP) (12). On the other hand, there are similar outcomes for POP surgery performed by the urologists or gynecologists (13). Among our responders, there is higher performance and interest in a female incontinence surgery and pediatric urologic surgery compared to the other surgeries. Possible reasons are that these surgeries have shorter learning curves and urologists have more exposure during the residency.

Most urologists feel competent about a percutaneous nephrostomy, but performance rates are lower. Urologists tend to leave this field to interventional radiologists. In some countries, there is a trend that the most access for PCNL is performed by an interventional radiologist (14). But it is a fact that an interventional radiology department is not always available in the small cities and hospitals. Percutaneous nephrostomy replacement could be lifesaving in some cases. Therefore, urologists should be able to perform percutaneous renal access on their own. Urologists may successfully perform

the renal access with low complication rates (15). Residents should practice percutaneous nephrostomy during their training instead of referring the patients to the interventional radiologists continuously (16).

Study Limitations

This study should be evaluated with its limitations. There could be recall and response bias due to the nature of the survey. The responders may be only those interested or not interested in these surgeries. The results cannot be expanded due to its' demographic bias. Surgery types were assessed under general headings and not investigated in detail. Another limitation is that the surgeon preferences are given as percentages rather than the actual number of the surgeries.

Conclusion

In Turkey, urologists are no longer the primary surgeons for some surgeries they used to perform. Many urologists avoid performing the major urologic surgeries. As vital as it is for urologists to be involved in emerging technology and surgery procedures, it is also critical that they continue to conduct surgeries that are part of the urology curriculum. Urology educators should familiarize the new urologists with these surgeries and how to manage their complications. We hope that the urology will continue to be the focus of newly graduated doctors due to a vast range of surgical procedures available.

Ethics

Ethics Committee Approval: The Local Ethics Committee approved this study (Zonguldak Bülent Ecevit University - 2020/10-5, date: 13.05.2020).

Informed Consent: Informed consent was not required because the study is not based on the patient groups.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: S.M., M.D.D., E.D.D., H.A.Y., Concept: S.M., M.D.D., E.D.D., H.A.Y., Design: S.M., M.D.D., E.D.D., H.A.Y., Data Collection or Processing: S.M., M.D.D., E.D.D., H.A.Y., Analysis or Interpretation: S.M., M.D.D., E.D.D., H.A.Y., Literature Search: S.M., M.D.D., E.D.D., H.A.Y., Writing: S.M., M.D.D., E.D.D., H.A.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Eswara JR. Minimally Invasive Tecniques in Urology. 2018.
2. Özdener F, Sursal A, Narter F. Current Status of Urological Surgery Clinical Trials in the Middle East and Its Analysis in Comparison to Global. J Urol Surg 2019;6:266-272.
3. Sackett DD, Singh P, Lallas CD. Urological involvement in renal transplantation. Int J Urol 2011;18:185-193.
4. El-Assmy AM, Shokeir AA, Mohsen T, El-Tabey N, El-Nahas AR, Shoma AM, Eraky I, El-Kenawy MR, El-Kappany HA. Renal access by urologist or radiologist for percutaneous nephrolithotomy--is it still an issue? J Urol 2007;178:916-920.
5. Morrison SD, Dy GW, Chong HJ, Holt SK, Vedder NB, Sorensen MD, Joyner BD, Friedrich JB. Transgender-Related Education in Plastic Surgery and Urology Residency Programs. J Grad Med Educ 2017;9:178-183.
6. Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004;6:e34.
7. Dy GW, Osbun NC, Morrison SD, Grant DW, Merguerian PA; Transgender Education Study Group. Exposure to and Attitudes Regarding Transgender Education Among Urology Residents. J Sex Med 2016;13:1466-1472.
8. Fuletra JG, Schilling AL, Canter D, Hollenbeak CS, Raman JD. Adrenalectomy: should urologists not be doing more? Int Urol Nephrol 2020;52:197-204.
9. Branchereau J. Rede ning the urologist's role in kidney transplantation. 2020;(0123456789):3-4. doi: 10.1007/s00345-020-03520-5
10. Chang SS, Smith JA Jr, Herrell SD, Cookson MS. Assessing urinary diversion experience in urologic residency programs-are we adequately training the next generation? J Urol 2006;176:691-693.
11. Silberstein JL, Poon SA, Maschino AC, Lowrance WT, Garg T, Herr HW, Donat SM, Dalbagni G, Bochner BH, Sandhu JS. Urinary diversion practice patterns among certifying American urologists. J Urol 2013;189:1042-1047.
12. James MB, Theofanides MC, Sui W, Onyeji I, Badalato GM, Chung DE. Sling Procedures for the Treatment of Stress Urinary Incontinence: Comparison of National Practice Patterns between Urologists and Gynecologists. J Urol 2017;198:1386-1391.
13. Citgez S, Oncul M, Demirdag C, Ercili B, Cetinel B. Does being performed by urologist or gynecologist affect the outcomes of women who have had sacrocolpopexy? Eur J Obstet Gynecol Reprod Biol 2019;237:64-67.
14. Armitage JN, Withington J, Fowler S, Finch WJG, Burgess NA, Irving SO, Glass J, Wiseman OJ; BAUS section of Endourology. Percutaneous nephrolithotomy access by urologist or interventional radiologist: practice and outcomes in the UK. BJU Int 2017;119:913-918.
15. İşoğlu CS, İlbey YÖ. Our Multiple Single-step Access Results in Percutaneous Nephrolithotomy. J Urol Surg 2019;6:7-10.
16. Değer MD, Yıldız HA, Demirkıran ED, Madendere S. Current status of urological training and differences between institutions, Actas Urológicas Españolas 2022. https://doi.org/10.1016/j.acuroe.2022.01.003

ORIGINAL RESEARCH
Andrology

Doi: 10.4274/jus.galenos.2021.2021.0050
J Urol Surg, 2022;9(1):57-62

Changing the Demographic Characteristics of Males with Erectile Dysfunction During the Coronavirus Disease-2019 Pandemic: A Multi-institutional Comparative Analysis with the Non-pandemic Period

Volkan Şen[1], Bora İrer[2], Mustafa Ozan Horsanalı[3], Mehmet Oğuz Şahin[1], Sedat Eğriboyun[4], Onur Kizer[5], Bilgin Öztürk[6], Ege Sarıkaya[7], Şakir Ongun[8], Oktay Üçer[9], Ozan Bozkurt[7], Ömer Demir[7]

[1]*Manisa City Hospital, Clinic of Urology, Manisa, Turkiye*
[2]*İzmir Metropolitan Municipality Eşrefpaşa Hospital, Clinic of Urology, İzmir, Turkiye*
[3]*Çiğli Regional Training Hospital, Clinic of Urology, İzmir, Turkiye*
[4]*Ödemiş State Hospital, Clinic of Urology, İzmir, Turkiye*
[5]*Medifema Hospital, Clinic of Urology, İzmir, Turkiye*
[6]*İzmir Can Hospital, Clinic of Urology, İzmir, Turkiye*
[7]*Dokuz Eylül University Faculty of Medicine, Department of Urology, İzmir, Turkiye*
[8]*Balıkesir University Faculty of Medicine, Department of Urology, Balıkesir, Turkiye*
[9]*Celal Bayar University Faculty of Medicine, Department of Urology, Manisa, Turkiye*

What's known on the subject? and What does the study add?

Coronavirus disease-2019 has negatively affected sexual life, as well as all life aspects. Most of the studies were commentary or review articles, and only a few studies were designed as research articles that were based on online questionnaires. To the best of our knowledge, this study is one of the few clinical studies that compared the data of the pandemic period and normal period in literature. We revealed that patients who presented with erectile dysfunction (ED) during the pandemic period were younger, with milder ED symptoms.

Abstract

Objective: This study aimed to present the impact of coronavirus disease-2019 pandemic on seeking treatment in patients with erectile dysfunction (ED) and compare the clinical characteristics, demographics, and laboratory analysis of patients with ED during and before the pandemic period.

Materials and Methods: The clinical and demographic characteristics and laboratory analysis of patients with ED were compared between the time interval of March 9, 2020, to June 1, 2020, and the previous 3 months from the pandemics. The International Index of Erectile Function-5 questionnaire was used to assess ED and the results from two groups were compared.

Results: A 76.4% decreased total number of outpatient clinics and a 70.9% decreased number of patients with ED was observed; however a significant increase was detected in the ratio of patients with ED to the total number of patients during the pandemic period (1.7% vs. 2.1%, p=0.008). The median age of patients was smaller in the pandemic period. Mild ED was significantly higher in the pandemic period and moderate ED was detected higher in the period before the pandemic.

Conclusion: The admission rate of patients with ED has increased in the pandemic period. The patients presenting with ED during the pandemic period were younger, with milder ED symptoms.

Keywords: Erectile dysfunction, testosterone, COVID-19, coronavirus, SARS-CoV2

Correspondence: Volkan Şen MD, Manisa City Hospital, Clinic of Urology, Manisa, Turkiye
Phone: +90 553 389 68 59 **E-mail:** sen_volkan@yahoo.com **ORCID-ID:** orcid.org/0000-0003-2832-0682
Received: 13.04.2021 **Accepted:** 29.05.2021

Cite this article as: Şen V, İrer B, Horsanalı MO, Şahin MO, Eğriboyun S, Kizer O, Öztürk B, Sarıkaya E, Ongun Ş, Üçer O, Bozkurt O, Demir Ö. Changing the Demographic Characteristics of Males with Erectile Dysfunction During the Coronavirus Disease-2019 Pandemic: A Multi-institutional Comparative Analysis with the Non-pandemic Period. J Urol Surg, 2022;9(1):57-62.

Introduction

Erectile dysfunction (ED) is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance (1). ED is a worldwide health problem that is increasing with aging, with negative impacts on the quality of life among males (2). The prevalence of ED in the age group of 40-70 years old was reported between 25%–52% in literature (3-6). The pathophysiology of ED may be classified as anatomical, neurogenic, vasculogenic, drug-induced, hormonal, and/or psychogenic. Disasters like the coronavirus disease-2019 (COVID-19) pandemics lead to an increased psychological burden, a result of both fear from the disease and problems caused by social isolation. This psychological burden can negatively affect the erectile functions in males.

COVID-19 was firstly reported in Wuhan, Hubei province of China, and the World Health Organization declared COVID-19 as a pandemic on March 11, 2020 (7,8). The worldwide total cases reached 110,974,862 and the total deaths reached 2,460,792 (9). The first case was reported on March 11, 2020, and the actual number of cases and deaths from COVID-19 are 353,426 and 9,513, respectively, in Turkey (9). During the COVID-19 pandemic, the workload of hospitals has increased and several healthcare measures were taken by hospital systems and governments. Many of the hospitals have turned to quarantine or pandemic hospitals and had to serve solely patients with COVID-19. The number of outpatient clinics of urology has been decreased and elective surgeries have been canceled (9,10). Hence, the practice of sexual medicine has been dramatically impacted, as most procedures and consultations are essentially elective. Some articles evaluated the challenges in the practice of sexual medicine in the COVID-19 era in literature (11-15). Most of the studies were commentary or review articles, only a few studies were designed as research articles that were based on online questionnaires (11-16). This study aimed to present the impact of the COVID-19 pandemic on seeking treatment in patients with ED and compare the clinical characteristics, demographics, and laboratory analysis of patients with ED between the pandemic period and before the pandemic period. To the best of our knowledge, this study is one of the few clinical studies that compared the data of pandemic and normal period in the literature.

Materials and Methods

This study was approved by the local ethics committee and included a total of nine centers (Dokuz Eylül University - approval number: 2020/19-22, date: 17.08.2020). The total outpatient clinics and the number of patients with ED were retrospectively recorded. The clinical and demographic characteristics (age, body mass index, smoking, comorbidities, etc.) and laboratory analysis [total testosterone, glucose, prolactin, low-density lipoprotein (LDL), high-density lipoprotein, and total cholesterol] of patients with ED were compared between the time interval of March 9, 2020, (the first patient with COVID-19 was reported in Turkey) to June 1, 2020, and the previous 3 months from the pandemics, December 16, 2019, to March 9, 2020. The International Index of Erectile Function-5 (IIEF-5) questionnaire was used to assess ED and the results from the two groups were compared. According to total IIEF-5 scores, the score of 26-30 means no ED, 22-25 as mild ED, 17-21 as mild-moderate ED, 11-16 as moderate ED, and 0-10 as severe ED. The severity of ED was also compared between the groups.

Statistical Analysis

The Statistical Package for the Social Sciences software version 25.5 (IBM, NY, USA) was used for analyses. The Kolmogorov-Smirnov and Shapiro-Wilk normality tests were used to state the continuous normally distributed data. The chi-square test was used for the comparison of categorical data and the Mann-Whitney U test to compare parameters that were not normally distributed. Results were given as median [(minimum (min)-maximum (max)], number, and percentage (%). P-values of <0.05 were considered statistically significant.

Results

The total number of outpatient clinics was 40,631 in the period before the pandemics and 9,604 in the pandemic period. The number of patients with ED was 694 in the period before the pandemics and 202 in the pandemic period. A 76.4% decreased total number of outpatient clinics and a 70.9% decreased number of patients with ED was observed; however, a significant increase was detected in the ratio of patients with ED to the total number of patients during the pandemic period (1.7% vs. 2.1%, p=0.008). The median age of patients who were admitted during the pandemic period were smaller than the period before the pandemic, and their body mass index was found to be significantly higher [45 (min=20-max=74) years vs. 46 (min=18-max=79) years, p=0.043; 27.2 (min=20.7-max=38.5) kg/m^2 vs. 26.4 (min=18.7-max=36.2) kg/m^2, p<0.001; respectively]. Smoking rates were significantly detected higher in the pandemic period (55.4% vs. 43.5%). When the severity of ED was compared between the groups; mild ED was significantly higher in the pandemic period (4.5% vs. 0.9%) and moderate ED was higher before the pandemic (Figure 1). The comparison of the two groups in terms of demographics and clinical characteristics was presented in Table 1. According to laboratory analysis, the median values of LDL, total cholesterol, and total testosterone were significantly lower in the pandemic period (Table 2).

Discussion

COVID-19 has negatively affected sexual life, as well as all life aspects. Some reports were published about the challenges in the practice of sexual medicine in the COVID-19 era from several countries (11-15). Li et al. (11) evaluated the changes in people's sexual behavior during the COVID-19 pandemic with an online survey, that was applied to 189 females and 270 males in China and revealed a significant decline in frequency and overall sexual activity. Jacob et al. (12) investigated the level of sexual activity during the COVID-19 social distancing and self-isolation measures in the UK with an online survey. A total of 868 individuals responded to an online survey, 63.1% of them were females and the prevalence of sexual activity was <40%. They detected a significant correlation between the lower sexual activity and older adults, female gender, and unmarried status (12). Schiavi et al. (17) assessed the effects of the social distancing measures during the COVID-19 pandemic on the quality of life and sexual function of reproductive-age females. The individuals previously answered the Female Sexual Distress Scale (FSDS), the 36-Item Short Form Survey (SF-36), and the Female Sexual Function Index (FSFI) questionnaires. After 4 weeks from the restrictive measures, the same questionnaires were filled out by individuals via e-mail. A total of 89 females were included in their study and they revealed significant decreases in the mean sexual intercourses/month (6.3±1.9 vs. 2.3±1.8), the mean FSFI scores (29.2±4.2 vs. 19.2±3.3), and SF-36 scores (82.2±10.2 vs. 64.2±11.8). Additionally, a significant increase was found in the FSDS scores (9.3±5.5 vs. 20.1±5.2) and concluded that the COVID-19 pandemic and the restrictive social distancing measures have negatively influenced the quality of life and sexual function in females. Most of the published research studies were online survey based studies

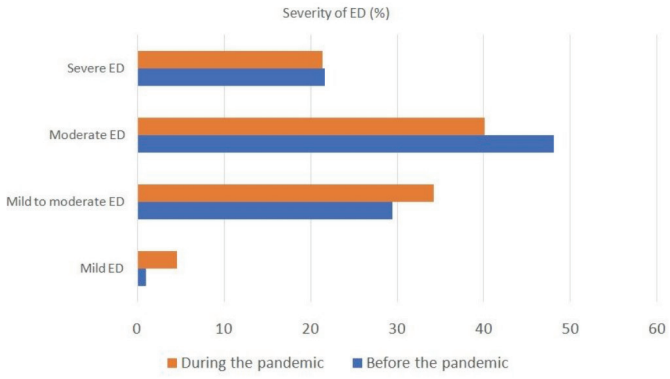


Figure 1. Comparison of ED severity between the pandemic period and the period before the pandemic
ED: Erectile dysfunction

Table 1. The comparison of the demographics and clinical characteristics of patients with erectile dysfunction between the pandemic period and the period before the pandemic

	Period before the pandemic (December 16, 2019-March 9, 2020) n=694	Pandemic period (March 9, 2020-June 1, 2020) n=202	p
Age, median (years) (min-max)	46 (18-79)	45 (20-74)	0.043
BMI, median (kg/m²) (min-max)	26.4 (18.7-36.2)	27.2 (20.7-38.5)	<0.001
Smoking (n,%)	302 (43.5%)	112 (55.4%)	0.003
Smoking, (package year), median (min-max)	0 (0-50)	20.0 (0-55)	0.279
Alcohol (n,%)	50 (7.2%)	11 (5.4%)	0.382
Hypertension (n,%)	222 (32.0%)	45 (22.3%)	0.008
Diabetes mellitus (n,%)	172 (24.8%)	39 (19.3%)	0.106
Coronary heart disease (n,%)	117 (16.9%)	17 (8.4%)	0.003
Hypertension (n,%)	106 (15.3%)	31 (15.3%)	0.980
Hyperthyroidism (n,%)	6 (0.9%)	0 (0.0%)	0.185
Hypothyroidism (n,%)	4 (0.6%)	2 (1.0%)	0.526
Psychiatric (n,%)	24 (3.5%)	9 (4.5%)	0.508
IIEF, median (min-max)	14 (7-25)	15 (7-25)	0.005
Severity of ED (n,%)			
Mild ED	6 (0.9%)	9 (4.5%)	<0.001
Mild to moderate ED	204 (29.4%)	69 (34.2%)	0.195
Moderate ED	334 (48.1%)	81 (40.1%)	0.044
Severe ED	150 (21.6%)	43 (21.3%)	0.921

BMI: Body mass index, ED: Erectile dysfunction, IIEF: International Index of Erectile Function, Min: Minimum, Max: Maximum

that evaluated the impacts of the COVID-19 pandemic on the sexual health of individuals (11,12,17), and several commentaries were published on COVID-19 and sexual health (13-15). However, the literature reported insufficient data on the changes in the management of patients with ED in the COVID-19 era. Thus, this study aimed to present the impact of the COVID-19 pandemic on seeking treatment in patients with ED and compare the clinical characteristics, demographics, and laboratory analysis of patients with ED between the pandemic period and before the pandemic period. Our study revealed that the rate of patients with ED who seek treatment has increased during the pandemic period, consistent with the studies which presented the negative effects of the COVID-19 pandemic on sexual life.

The prevalence of obesity is increasing worldwide and is reported as >20% in almost all countries (18,19). Several measures started to be taken in all countries due to the COVID-19 pandemic like restriction in movement, social distancing, self-isolation, and impeding economic activities across a broad spectrum of nonessential occupations (20). Most of the individuals who had an opportunity for remote working worked from their homes without physical activity. These measures also led to some changes in food consumption and a decrease in physical activity, which may have a role in weight gain (20). As expected, the body mass index values of patients with ED in the COVID-19 period were higher than the non-pandemic period in our study.

The COVID-19 outbreak negatively affects the mental health of the population and increases the likelihood of illnesses, such as anxiety and depression, getting worse (21). Worsening mental health and stress were reported as predisposing factors for increased smoking, frequency, and quantity, as well as relapse (21,22). Likewise, the literature revealed that the smoking rates were also higher in patients with ED during the COVID-19 pandemic in our study.

Many studies showed that the prevalence and ED severity increased with aging (23,24). Martins and Abdo (25) reported that younger patients with ED (<40 years) are more likely to have mild ED with a rate of 73.7%. Yang et al. (26) pointed out that young patients with ED had higher incidences of anxiety and depression. The median age of patients with ED was lower and the rate of mild ED was higher in the pandemic period compared with before the pandemic period in our study. Therefore, the studies revealed that the physiological factors likely more affect the younger patients and seem to be related with more mild ED severity.

ED is closely related to diabetes mellitus (DM), hypertension (HT), dyslipidemia, and metabolic syndrome, and with aging, the rates of all these comorbidities increases (1-4). Additionally, some studies reported the association between ED severity and coronary arterial disease (27,28). Al-Daydamony et al. (27) detected that patients with moderate and severe ED (IIEF-5 score of <17) had a significantly higher risk of coronary artery diseases than mild ED. García-Cruz et al. (28) reported that the presence and severity of ED correlated with the presence of HT, DM, dyslipidemia, and the number of cardiovascular risk factors. Patients with ED before the pandemic period were older and had more moderate ED in our study. Consistent with the literature, higher LDL and total cholesterol values and higher HT and coronary arterial disease rates were detected in these patients.

Ma et al. (29) compared the sex-related hormones of 119 reproductive-aged male patients with COVID-19 with 273 age-matched un-infected males and revealed that the serum total testosterone levels were significantly lower in patients with COVID-19. Studies do not support a consistent association between testosterone level and mood. There may be some males in whom hypogonadism contributes to depression; and chronic depressive illness may cause hypogonadism in some (30). The serum testosterone levels were lower in a patient with ED during the pandemic period in our study. The possible causes may be related to COVID-19 or psychological disorders, which can affect testosterone levels. However, further studies are needed to clarify this relationship.

Table 2. The comparison of the laboratory analysis of patients with erectile dysfunction between the pandemic period and before the pandemic period

	Period before the pandemic (December 16, 2019-March 9, 2020) n=694	Pandemic period (March 9, 2020-June 1, 2020) n=202	p
LDL, median (min-max)	127 (38-229)	110 (28-241)	<0.001
HDL, median (min-max)	44 (21-144)	40 (14-95)	0.440
Total cholesterol, median (min-max)	206 (85-586)	190 (108-400)	<0.001
Total testosterone, median (min-max)	434 (41-1098)	370 (11-835)	<0.001
Glucose median (min-max)	98 (61-497)	104 (59-516)	0.177
Prolactin, median (min-max)	10.0 (0.1-95.0)	9.3 (1.4-95.0)	0.913

Min: Minimum, Max: Maximum, LDL: Low-density lipoprotein, HDL: High-density lipoprotein

Study Limitations

The main limitations are its retrospective design and the lack of standardized psychological evaluation with questionnaires. However, the strongest part of the study was being one of the few clinical studies that compared the data of pandemic period and normal period of patients with ED in the literature.

Conclusion

COVID-19 negatively affected the sexual life of individuals. While a serious decrease was observed in the rates of application to outpatient clinics for many urological diseases, the application rate of ED patients has increased in the pandemic period. Patients presenting with ED during the pandemic period were younger, with milder ED symptoms.

Ethics

Ethics Committee Approval: This study was approved by the local ethics committee and included a total of nine centers (Dokuz Eylül University - approval number: 2020/19-22, date: 17.08.2020).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: V.Ş., Concept: V.Ş., Design: V.Ş., Data Collection or Processing: V.Ş., B.İ., M.O.H., M.O.Ş., S.E., O.K., B.Ö., E.S., Ş.O., O.Ü., O.B., Ö.D., Analysis or Interpretation: V.Ş., B.İ., M.O.H., M.O.Ş., S.E., O.K., B.Ö., E.S., Ş.O., O.Ü., O.B., Ö.D., Literature Search: V.Ş., Writing: V.Ş.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Hatzimouratidis K, Giuliano F, Moncada I, A. Muneer, A. Salonia, P. Verze Guideline Associates: A. Parnham, E.C. Serefoglu. EAU Guidelines on Erectile Dysfunction, Premature Ejaculation, Penile Curvature and Priapism. Edn. presented at the EAU Annual Congress London 2017. Publisher: EAU Guidelines Office. Place published: Arnhem, The Netherlands.
2. Fisher WA, Eardley I, McCabe M, Sand M. Erectile dysfunction (ED) is a shared sexual concern of couples I: couple conceptions of ED. J Sex Med 2009;6:2746-2760.
3. Zhang X, Yang B, Li N, Li H. Prevalence and Risk Factors for Erectile Dysfunction in Chinese Adult Males. J Sex Med 2017;14:1201-1208.
4. Braun M, Wassmer G, Klotz T, Reifenrath B, Mathers M, Engelmann U. Epidemiology of erectile dysfunction: results of the 'Cologne Male Survey'. Int J Impot Res 2000;12:305-311.
5. Quilter M, Hodges L, von Hurst P, Borman B, Coad J. Male Sexual Function in New Zealand: A Population-Based Cross-Sectional Survey of the Prevalence of Erectile Dysfunction in Men Aged 40-70 Years. J Sex Med 2017;14:928-936.
6. Nguyen HMT, Gabrielson AT, Hellstrom WJG. Erectile Dysfunction in Young Men-A Review of the Prevalence and Risk Factors. Sex Med Rev 2017;5:508-520.
7. Bogoch II, Watts A, Thomas-Bachli A, Huber C, Kraemer MUG, Khan K. Pneumonia of unknown aetiology in Wuhan, China: potential for international spread via commercial air travel. J Travel Med 2020;27:taaa008.
8. World Health Organization. Coronavirus disease 2019 (COVID-19) Situation Report –51 [Internet]. 11 March. 2020 [cited 2020 May 25]. Available from: https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200311-sitrep-51-covid-19.pdf?sfvrsn=1ba62e57_10.
9. WHO Coronavirus Disease (COVID-19) Dashboard. [Internet]. 22 Feb. 2021 [cited 2021 FEB 22]. Available from: https://covid19.who.int/.
10. Bozkurt O, Sen V, Irer B, Sagnak L, Onal B, Tanidir Y, Karabay E, Kaya C, Ceyhan E, Baser A, Duran MB, Suer E, Celen I, Selvi I, Ucer O, Karakoc S, Sarikaya E, Ozden E, Deger D, Egriboyun S, Ongun S, Gurboga O, Asutay MK, Kazaz IO, Yilmaz IO, Kisa E, Demirkiran ED, Horsanali O, Akarken I, Kizer O, Eren H, Ucar M, Cebeci OO, Kizilay F, Comez K, Mercimek MN, Ozkent MS, Izol V, Gudeloglu A, Ozturk B, Akbaba KT, Polat S, Gucuk A, Ziyan A, Selcuk B, Akdeniz F, Turgut H, Sabuncu K, Kaygisiz O, Ersahin V, Kahraman HI, Guzelsoy M, Demir O; Study Group of the Society of Urological Surgery. Nation-wide analysis of the impact of Covid-19 pandemic on daily urology practice in Turkey. Int J Clin Pract 2021;75:e13735.
11. Li W, Li G, Xin C, Wang Y, Yang S. Challenges in the Practice of Sexual Medicine in the Time of COVID-19 in China. J Sex Med 2020;17:1225-1228.
12. Jacob L, Smith L, Butler L, Barnett Y, Grabovac I, McDermott D, Armstrong N, Yakkundi A, Tully MA. Challenges in the Practice of Sexual Medicine in the Time of COVID-19 in the United Kingdom. J Sex Med 2020;17:1229-1236.
13. Miranda EP, Nascimento B, Torres LO, Glina S. Challenges in the Practice of Sexual Medicine in the Time of COVID-19 in Brazil. J Sex Med 2020;17:1222-1224.
14. Shindel AW, Rowen TS. Challenges in the Practice of Sexual Medicine in the Time of COVID-19 in the United States. J Sex Med 2020;17:1216-1219.
15. Torremade J, Martínez-Salamanca JI. Challenges in the Practice of Sexual Medicine in the Time of COVID-19 in Spain. J Sex Med 2020;17:1220-1221.
16. Cocci A, Giunti D, Tonioni C, Cacciamani G, Tellini R, Polloni G, Cito G, Presicce F, Di Mauro M, Minervini A, Cimino S, Russo GI. Love at the time of the Covid-19 pandemic: preliminary results of an online survey conducted during the quarantine in Italy. Int J Impot Res 2020;32:556-557.
17. Schiavi MC, Spina V, Zullo MA, Colagiovanni V, Luffarelli P, Rago R, Palazzetti P. Love in the Time of COVID-19: Sexual Function and Quality of Life Analysis During the Social Distancing Measures in a Group of Italian Reproductive-Age Women. J Sex Med 2020;17:1407-1413.
18. NCD Risk Factor Collaboration (NCD-RisC). Rising rural body-mass index is the main driver of the global obesity epidemic in adults. Nature 2019;569:260-264.
19. NCD Risk Factor Collaboration (NCD-RisC). Trends in adult body-mass index in 200 countries from 1975 to 2014: a pooled analysis of 1698 population-based measurement studies with 19·2 million participants. Lancet 2016;387:1377-1396.
20. Popkin BM, Du S, Green WD, Beck MA, Algaith T, Herbst CH, Alsukait RF, Alluhidan M, Alazemi N, Shekar M. Individuals with obesity and COVID-19: A global perspective on the epidemiology and biological relationships. Obes Rev 2020;21:e13128.
21. Patwardhan P. COVID-19: Risk of increase in smoking rates among England's 6 million smokers and relapse among England's 11 million ex-smokers. BJGP Open 2020;4:bjgpopen20X101067.

22. Stubbs B, Veronese N, Vancampfort D, Prina AM, Lin PY, Tseng PT, Evangelou E, Solmi M, Kohler C, Carvalho AF, Koyanagi A. Perceived stress and smoking across 41 countries: A global perspective across Europe, Africa, Asia and the Americas. Sci Rep 2017;7:7597.

23. Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and psychosocial correlates: results of the Massachusetts Male Aging Study. J Urol 1994;151:54-61.

24. Laumann EO, Paik A, Rosen RC. Sexual dysfunction in the United States: prevalence and predictors. JAMA 1999;281:537-544.

25. Martins FG, Abdo CHN. Erectile dysfunction and correlated factors in Brazilian men aged 18-40 years. J Sex Med 2010;7:2166-2173.

26. Yang Y, Song Y, Lu Y, Xu Y, Liu L, Liu X. Associations between erectile dysfunction and psychological disorders (depression and anxiety): A cross-sectional study in a Chinese population. Andrologia 2019;51:e13395.

27. Al-Daydamony MM, Shawky A, Tharwat A. Erectile dysfunction severity as a predictor of left main and/or three-vessel disease in acute coronary syndrome patients. Indian Heart J 2018;70 Suppl 3:S56-S59.

28. García-Cruz E, Piqueras M, Gosálbez D, Pérez-Márquez M, Peri L, Izquierdo L, Franco A, Luque P, Corral JM, Alvarez-Vijande R, Alcaraz A. La disfunción eréctil y su severidad están en relación con el número de factores de riesgo cardiovascular [Erectile dysfunction and its severity are related to the number of cardiovascular risk factors]. Actas Urol Esp 2012;36:291-295.

29. Ma L, Xie W, Li D, Shi L, Ye G, Mao Y, Xiong Y, Sun H, Zheng F, Chen Z, Qin J, Lyu J, Zhang Y, Zhang M. Evaluation of sex-related hormones and semen characteristics in reproductive-aged male COVID-19 patients. J Med Virol 2021;93:456-462.

30. Amiaz R, Seidman SN. Testosterone and depression in men. Curr Opin Endocrinol Diabetes Obes 2008;15:278-283.

ORIGINAL RESEARCH
Pediatric Urology

Doi: 10.4274/jus.galenos.2021.2021.0047
J Urol Surg, 2022;9(1):63-67

Urachal Remnants and Anomalies in Children: Rationales of Surgery

Beytullah Yağız

Ondokuz Mayıs University Faculty of Medicine, Department of Pediatric Surgery, Division of Pediatric Urology, Samsun, Turkiye

What's known on the subject? and What does the study add?

The prevelence of urachal anomalies are inconsistent in the literature due to employed imaging modality and inconsistent definitions. Major indications for surgery are presence of symptoms, infections and fear of future malignant transformation. After retrospectively evaluating our experience, we concluded that fistulography should not be performed routinely as it is hard to perform in children and does not add much to the management process. Voiding cystogram is recommended only in patients with suspected vesicoureteral reflux or if the results of the study may potentially alter the management process. Although potential future malignant transformation is still undetermined, malignancy should be considered as we found a neuroblastoma in the periurachal area.

Abstract

Objective: Urachal remnants are rare conditions in children with controversial management. Many of them present with complaints; however, the causality between the symptom and the condition is unclear, and a significant proportion of patients are incidentally identified. Meanwhile, indications of the surgical correction are controversial and the best way of surgical approach depends on the attending physician's experience. This study aimed to evaluate the results of surgically corrected urachal conditions in children.

Materials and Methods: This study included patients (n=21) who underwent surgery for urachal conditions between 2010 and 2020. Age, presenting symptoms, radiological evaluation, surgical approach, and results, and histological results are retrospectively evaluated.

Results: Of the patients, 12 (57%) were boys, and abdominal pain was the most common presenting symptom (43%). The exact anomaly could not be classified in 8 patients, but classified as urachal sinus (n=5), urachal cyst (n=4), patent urachus (n=2), urachal diverticulum (n=1), and neuroblastoma (n=1) in the rest. Patients with umbilical discharge presented significantly younger than patients with abdominal pain or incidentally recognized patients (2.4±1.2, 7.2±1.17, and 10.9±3.1 years, respectively; $p<0.05$). No operative complication is encountered. Histological examination revealed only 1 malignancy (neuroblastoma, 5%).

Conclusion: Urachal anomalies in children are confusing conditions as they are rare, with unclear significance. Major indications of surgery are complications (infection, persisting drainage, or pain) and potential risk of malignant transformation. Surgery can be offered if complicated and the risk of malignancy appears to be low although not zero.

Keywords: Urachus, surgery, children

Introduction

Urachus is the fibrous remnant of the allantois, which is expected to become obliterated around birth. This process widely varies among individuals and may remain as a bulge at the apex of the bladder or may exhibit as a completely open tract between the bladder and umbilicus. Urachal anomalies are significantly rare and commonly classified as urachal cyst, patent urachus, urachal sinus, and urachal diverticulum (1). However, as it is hard to define and classify a finding related to urachus in daily practice (radiological or clinical), Naiditch et al. (2) did not use the term "anomaly" and used "remnant" instead and mentioned the 5th entity as "urachal remnant/chords". Urachal conditions usually present with complications or maybe incidentally identified during the investigation of relevant or irrelevant conditions. The exact incidence is hard to estimate as the definition of the physiological and pathological conditions differ among the studies, and most series lack surgical and

Correspondence: Beytullah Yağız MD, Ondokuz Mayıs University Faculty of Medicine, Department of Pediatric Surgery, Division of Pediatric Urology, Samsun, Turkiye
Phone: +90 533 658 75 02 **E-mail:** beytullahyagiz@gmail.com **ORCID-ID:** orcid.org/0000-0003-0882-1789
Received: 03.04.2021 **Accepted:** 31.07.2021

Cite this article as: Yağız B. Urachal Remnants and Anomalies In Children: Rationales of Surgery. J Urol Surg, 2022;9(1):63-67.

histological confirmation. Thus, management is controversial as some recommend surgical removal, while others advocate a more conservative approach even in complicated cases, due to insufficient definitions and significant rarity (1,3-5). This study aimed to retrospectively evaluate the clinical features and surgical and histological results of children with urachal conditions.

Materials and Methods

This study includes patients who underwent surgery for a urachal condition between January 2010 and April 2020. Institutional board approval is obtained from the Ethical Board on Clinical Studies of Ondokuz Mayıs University (IRB registry number: 2020/502). The patient's age, presenting symptoms, surgical approach, diagnostic tools, and histological results are retrospectively evaluated. Patients who are admitted with abdominal pain, umbilical discharge, and urinary tract infection were all regarded as symptomatic and only the cases encountered during surgery of an irrelevant condition are regarded as "incidental," because relating a symptom with the urachal pathology is highly subjective and causes significant bias.

Statistical Analysis

Numerical variables were expressed as mean ± standard deviation depending on the distribution of variables. Categorical variables were expressed as numbers and percentages. The normality test of numerical variables was calculated with the Shapiro-Wilk test. One-Way analysis of variance with the post hoc Tukey test was used for statistical analysis of patients' age among admitting symptoms. Data were analyzed using the Statistical Package for the Social Sciences® Statistics 20 software (IBM® Corp, Armonk, NY, USA).

Results

During the study period, 21 children underwent surgery for urachal anomalies. Of the patients, 12 (57%) were boys and 9 (43%) were girls. The presenting symptoms include abdominal pain (n=9, 43%), umbilical discharge (n=7, 33%), incidental diagnosis during surgery (n=3, 14%), prenatal diagnosis (n=1, 5%) and recurrent urinary tract infection (n=1, 5%).

The mean age at presentation was 2.4±1.2, 7.2±1.17, and 10.9±3.1 years (mean ± standard error) for the patients admitted for umbilical discharge, abdominal pain, and incidental cases, respectively. The patients admitted with umbilical discharge were significantly younger than those admitted with pain and incidentally diagnosed ($p<0.05$) (Table 1).

Ultrasonographic (US) imaging yielded positive findings, which suggest a urachal condition in 14 patients (67%), whereas 3 patients underwent additional magnetic resonance imaging (MRI) and 2 patients underwent surgery as clinical findings suggested an anomaly despite the negative US. Three patients were incidentally diagnosed during surgery for irrelevant conditions (Meckel's diverticulum, acute appendicitis, and ureteroneocystostomy, respectively). Avoiding cystourethrography (VCUG) was obtained in 8 patients before surgery but did not provide any additional information regarding the urachal anomaly. Unilateral vesicoureteral reflux was identified in 2 patients (1 resolved with conservative follow-up and the other was the one who had incidental diagnosis during ureteroneocystostomy). Of the 7 patients who presented with umbilical discharge, 3 underwent an attempt of fistulography, but all failed to demonstrate a patent urachus or urachal sinus.

Nine patients (43%) underwent laparoscopic exploration while 12 (57%) underwent open surgery by a median (n=6), periumbilical smiling face (n=2), Rockey-Davis (n=2), Pfannenstiel (n=1), and right upper quadrant transverse (n=1) incisions (Figure 1). Simultaneous diagnostic cystoscopy was performed in 3 patients but did not yield any additional information or relief during surgery. Of the patients, 5 (24%) received a cycle of antibiotics before surgical correction for a relevant infection or abscess.

The predominant histological features were fibromuscular tissue (n=12; with 9 demonstrating uroepithelium), chronic inflammation (n=4), fibroadipose tissue (n=2), neuroblastoma (n=1), connective tissue with mucinous glands (n=1), and with uroepithelium (n=1). The only malignancy in our series was the 2-month-old girl with neuroblastoma who presented with a prenatal diagnosis of urachal anomaly (5%). The extraperitoneal location of the tumor above the bladder was confirmed by MRI and on surgical exploration (Figure 2). As radiological and laboratory findings were suggestive of a malignancy, the procedure was converted to open after diagnostic laparoscopy

Table 1. Presenting symptoms of the patients. The conditions recognized during an irrelevant surgery are considered as "incidental"

	n	Mean (years)	Std. Error	Minimum (years)	Maximum (years)
Umbilical discharge[a]	7	2.39214	1.191299	0.288	9.333
Abdominal pain[b]	9	7.20144	1.171635	0.481	11.750
Incidental[b]	3	10.86067	3.076675	5.083	15.583
Total	19	6.00737	1.068178	0.288	15.583

*Significant at 5% significance level, [a, b]: For all variables with the same letter, the difference between the means is not statistically significant

confirmed the preperitoneal location of the mass. The mass was located above the bladder between the medial umbilical ligaments and a small portion of the bladder wall was included in the excision. Histological examination revealed poorly differentiated neuroblastoma that demonstrated expansile protrusion into the detrusor muscle of the bladder (Figure 2). The major concerns about malignancy in these patients were the solid appearance on MRI and absence of infection signs.

Including the flap of full-thickness bladder wall into the excised specimen was necessary for 4 patients to ensure a clear margin that necessitated prolonged bladder drainage by urethral catheterization. No other morbidity or complication is encountered in these patients related to bladder wall violation.

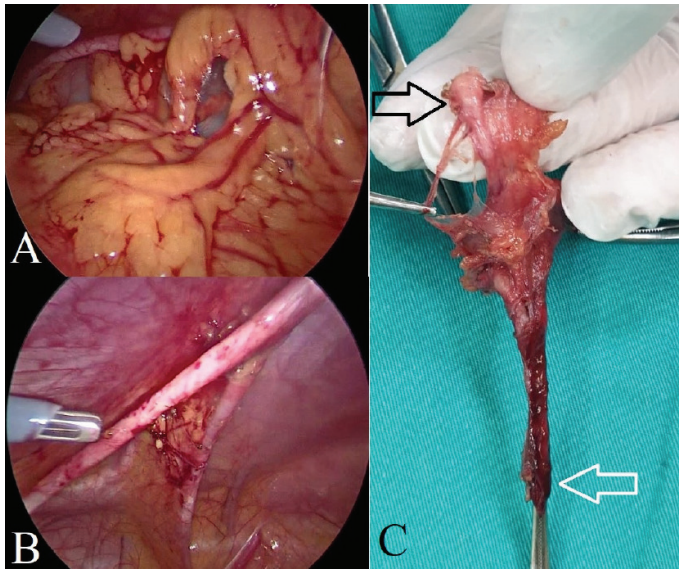


Figure 1. Laparoscopic view of a patent urachus with omental adhesions due to a previous infection (A). Major site of adhesion after omentum was released (B) and gross image of the specimen after excision (C). Black arrow indicates the caudal pole (bladder) and white arrow indicates the cranial pole (umbilical) of the tract (the tract is excised en bloc together with the median ligaments to ensure a clear margin)

Satisfactory classification of the condition was not possible in 8 patients (38%) due to the retrospective design of the study and insufficient clear definitions of urachal anomalies. Five (38%) patients were regarded as urachal sinus, 4 (31%) as urachal cyst, 2 (15%) as patent urachus, 1 (8%) as urachal diverticulum, and 1 (8%) as neuroblastoma (Figure 1).

No intraoperative or postoperative complication related to surgery was identified in any of the patients.

Discussion

Embryologically, urachus is a remnant tissue that is derived from allantois and usually obliterates after 18th gestational weeks and remains as a fibrous cord or peritoneal fold (6). Urachal anomalies are rare conditions and their exact incidence is quite impossible to determine due to conflicting reports, unclear definitions, and poor understanding of the anomaly, but generally estimated as 1% (7,8). However, Ozbek et al. (9) found a space-occupying urachal lesion by US examination in 180 of 182 patients (99%) who are admitted for irrelevant symptoms. Their prospective study revealed the mean diameter of the lesions as 13±5 mm (87% were ovoid; n=156) and sonographic protrusion into the bladder was demonstrated in 74% of the patients (n=133). Similarly, Cacciarelli et al. (10) identified an elliptical structure in 62 of 100 children by the US, but the significance of these images remains unidentified as only 1 patient underwent surgical excision and histological examination revealed a normal urachal remnant. Contrarily, Gleason et al. (7) revealed a 1.03% incidence of urachal anomalies using various imaging modalities in their retrospective study, in which most of the conditions were incidentally diagnosed and only 8.3% underwent surgical excision.

The most specific symptom for a urachal anomaly is an umbilical lesion or discharge but a significant number of patients are recognized during evaluation for abdominal pain or urinary tract infection, and it is quite subjective to relate the presenting

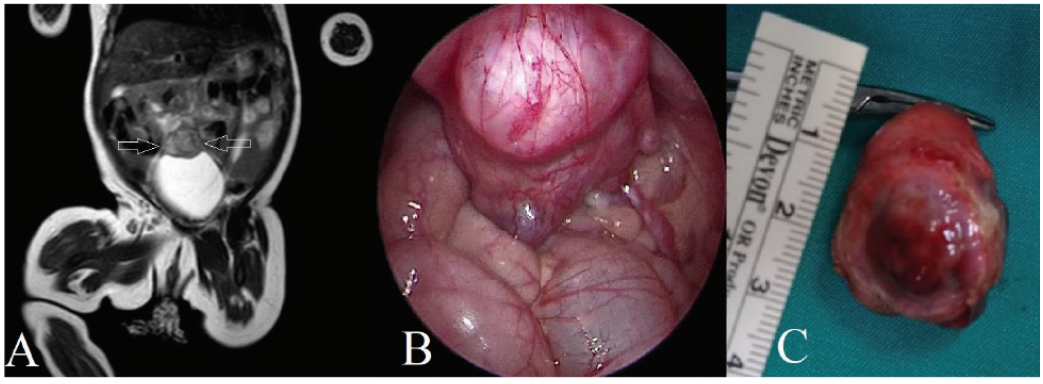


Figure 2. Coronal MRI section of the 2 months old patient with neuroblastoma. The heterogenous solid mass is indicated between the arrows in the apex of the bladder (A). Diagnostic laparoscopy revealed the preperitoneal mass between the median ligaments (B). Gross appearance of the excised specimen (C)

MRI: Magnetic resonance imaging

symptoms with the urachal condition and coin the term "incidental" (7,11). In our series, the most common presenting symptoms include abdominal pain, umbilical discharge, and incidental diagnosis, but we restricted the incidental term to only the patients who were recognized during surgery for other conditions. Relating the presenting symptom with the condition is quite difficult but significant as it may alter the decision on the management modality.

Most of the patients with urachal anomalies are incidentally recognized, and the US is the leading diagnostic tool. Urachal remnants, cysts, and diverticula can be seen as lesions that are ovoid or elliptical on US imaging (10). A sinus tract with or without air/fluid in it can also be demonstrated by the US but it's a subjective finding and reliability are unclear (12). Fistulography with a contrast medium may be performed when a patent urachus is suspected (i.e., in patients with umbilical discharge) but appears to be unreliable and demanding in our and others experience as canulation and visualization of a narrow lumen is challenging, and the cause of the umbilical discharge may be secondary to much more common lesions (i.e., umbilical granuloma) (12-14).

VCUG was also a commonly used imaging modality, especially for visualization of a urachal diverticulum or patent urachus (1,7,15). However, VCUG did not provide additional information about the urachal condition or change the clinical management process in our 8 patients who underwent preoperative imaging. Therefore, we have abandoned VCUG for urachal anomaly diagnosis and recommend only for evaluation of other coexisting conditions, such as vesicoureteral reflux, like many others (11,16).

Cross-sectional imaging modalities can be performed in selected patients when differential diagnosis, the extent, or nature of the anomaly are sought. We have performed MRI in 3 cases as all had solid mass images on the US, and histological examination of the surgical specimens revealed neuroblastoma that is located in the preperitoneal space above the bladder in one of our patients. A computerized tomography is a viable option; however, MRI appears as a superior imaging modality with improved soft-tissue resolution and the absence of radiation (1,7).

Another controversial issue about the urachal anomalies is the management option (surgical or non-surgical). The decision of surgery is mainly driven by two concerns, complications and risk of malignancy. Complications of urachal anomalies, such as infection or discharge, are the least controversial issues as many recommend surgical excision when present (1,7). However, some authors favor a more conservative approach to recommend surgery after multiple episodes of infection and advocate that complicated urachal anomalies can also be managed without surgery (4,5,11). Opponents of nonsurgical management propose that urachal malignancy is rare in children and conservative management is safe (2,7). Few cases of urachal malignancy are reported in children, with significantly diverse histological types from adults (as in our one case of neuroblastoma), which deepens the confusion on the origin of urachal tumors, and the risk of malignancy after childhood has insufficient data (15,17,18). Identifying the origin of the malign tumors in children is quite impossible; however, the disparity in reported types suggests that they may arise from ectopic tissues located in the urachus, and ectopic neural crest cells would be responsible for the neuroblastoma in our 2-month-old patient.

As the prevalence of urachal malignancy is highest in the 6th and 7th decade, studies with long-term follow-up are lacking, which are necessary to identify the number of rare anomalies that transform into this rare urachal malignancy (19,20). The length of follow-up is significantly short in most of the reports (<5 years) to safely conclude that risk of malignant transformation is low (4,11). As significant surgical complications are rare, both in our series and in the literature, elective surgical excision appears reasonable in children to avoid a future aggressive malignancy, in which 5-year survival is <50% (7,8,11,19). Conservative follow-up is a long road that requires patience, and most patients do not comply even with the annual follow-up controls (3).

The mode of surgical approach depends on the availability of instruments and familiarity with the techniques and can be performed by robotic, laparoscopic, or open approach. Laparoscopy became the technique of choice in recent years in our institution, but a paraumbilical smiling face incision provides sufficient exposure in selected patients (<2 years) as the bladder is still an abdominal organ and its apex can easily reach the umbilicus when distended (Figure 3).

Therefore, we recommend elective surgery for symptomatic or complicated cases (infection, persisting umbilical discharge, and unexplained lower abdominal pain). However, in the absence of complications and symptoms, we inform the parents of the theoretically low but unclear possibility of malignancy and leave the final decision to them for patients without clinical or radiological findings suggesting malignancy.

Conclusion

Urachal anomalies remain an enigma for the surgeon, radiologist, and pathologist. Management is less controversial in symptomatic patients who present with umbilical discharge, infection signs, or mass lesions that are suspicious for malignancy. Major controversy persists for asymptomatic patients concerning the risk of malignancy as no long-term data is available regarding the actual risk of malignant transformation.

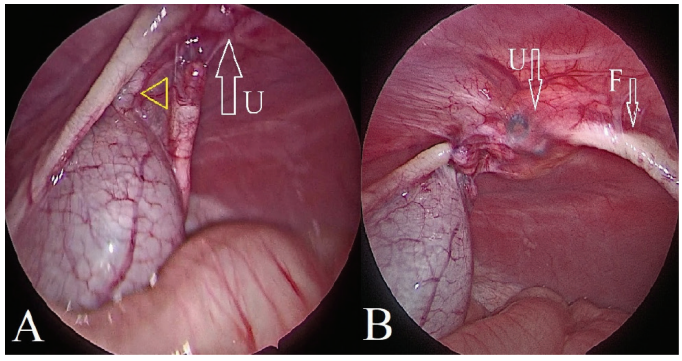


Figure 3. A patent urachus of a 5 months old infant was excised through a umbilical smiling face incision under laparoscopic vision. Note that dome of the bladder (yellow arrow head) reaches to the umbilicus (U) when the bladder is distended. (U; indicates umbilicus, F; indicates falciforme ligament and yellow arrow head indicates the urachus and the bladder dome)

Ethics

Ethics Committee Approval: Institutional board approval is obtained from the Ethical Board on Clinical Studies of Ondokuz Mayıs University (IRB registry number: 2020/502).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Conflict of Interest: No conflict of interest was declared by the author.

Financial Disclosure: The author declare that they have no relevant financial.

References

1. Buddha S, Menias CO, Katabathina VS. Imaging of urachal anomalies. Abdom Radiol (NY) 2019;44:3978-3989.
2. Naiditch JA, Radhakrishnan J, Chin AC. Current diagnosis and management of urachal remnants. J Pediatr Surg 2013;48:2148-2152.
3. Ashley RA, Inman BA, Routh JC, Rohlinger AL, Husmann DA, Kramer SA. Urachal anomalies: a longitudinal study of urachal remnants in children and adults. J Urol 2007;178:1615-1618.
4. Lipskar AM, Glick RD, Rosen NG, Layliev J, Hong AR, Dolgin SE, Soffer SZ. Nonoperative management of symptomatic urachal anomalies. J Pediatr Surg 2010;45:1016-1019.
5. Ueno T, Hashimoto H, Yokoyama H, Ito M, Kouda K, Kanamaru H. Urachal anomalies: ultrasonography and management. J Pediatr Surg 2003;38:1203-1207.
6. Pazos HM, Costa WS, Sampaio FJ, Favorito LA. Structural and ontogenetic study of the urachus in human fetuses. Cells Tissues Organs 2010;191:422-430.
7. Gleason JM, Bowlin PR, Bagli DJ, Lorenzo AJ, Hassouna T, Koyle MA, Farhat WA. A comprehensive review of pediatric urachal anomalies and predictive analysis for adult urachal adenocarcinoma. J Urol 2015;193:632-636.
8. Parada Villavicencio C, Adam SZ, Nikolaidis P, Yaghmai V, Miller FH. Imaging of the Urachus: Anomalies, Complications, and Mimics. Radiographics 2016;36:2049-2063.
9. Ozbek SS, Pourbagher MA, Pourbagher A. Urachal remnants in asymptomatic children: gray-scale and color Doppler sonographic findings. J Clin Ultrasound 2001;29:218-222.
10. Cacciarelli AA, Kass EJ, Yang SS. Urachal remnants: sonographic demonstration in children. Radiology 1990;174:473-475.
11. Dethlefs CR, Abdessalam SF, Raynor SC, Perry DA, Allbery SM, Lyden ER, Azarow KS, Cusick RA. Conservative management of urachal anomalies. J Pediatr Surg 2019;54:1054-1058.
12. Boothroyd AE, Cudmore RE. Ultrasound of the discharging umbilicus. Pediatr Radiol 1996;26:362-364.
13. Nagasaki A, Handa N, Kawanami T. Diagnosis of urachal anomalies in infancy and childhood by contrast fistulography, ultrasound and CT. Pediatr Radiol 1991;21:321-323.
14. Zieger B, Sokol B, Rohrschneider WK, Darge K, Tröger J. Sonomorphology and involution of the normal urachus in asymptomatic newborns. Pediatr Radiol 1998;28:156-161.
15. D'Alessio A, Verdelli G, Bernardi M, DePascale S, Chiarenza SF, Giardina C, Cheli M, Rota G, Locatelli G. Endodermal sinus (yolk sac) tumor of the urachus. Eur J Pediatr Surg 1994;4:180-181.
16. Rich RH, Hardy BE, Filler RM. Surgery for anomalies of the urachus. J Pediatr Surg 1983;18:370-372.
17. Clapuyt P, Saint-Martin C, De Batselier P, Brichard B, Wese FX, Gosseye S. Urachal neuroblastoma: first case report. Pediatr Radiol 1999;29:320-321.
18. Gupta S, Bhaijee F, Harmon EP. Mucinous neoplasm arising in a urachal cyst: a first in the pediatric population. Urology 2014;83:455-456.
19. Bruins HM, Visser O, Ploeg M, Hulsbergen-van de Kaa CA, Kiemeney LA, Witjes JA. The clinical epidemiology of urachal carcinoma: results of a large, population based study. J Urol 2012;188:1102-1107.
20. Mylonas KS, O Malley P, Ziogas IA, El-Kabab L, Nasioudis D. Malignant urachal neoplasms: A population-based study and systematic review of literature. Urol Oncol 2017;35:33.e11-33.e19.

ORIGINAL RESEARCH
Pediatric Urology

Doi: 10.4274/jus.galenos.2021.2021.0060
J Urol Surg, 2022;9(1):68-73

The Reliability of Bladder Volume Determination in Children Using Portable Ultrasonographic Scanner in Standing Position

Taner Ceylan, Hasan Serkan Doğan, Burak Çıtamak, Kamranbay Gasimov, Ali Cansu Bozacı, Vasileios Tatanis, Serdar Tekgül

Hacettepe University Faculty of Medicine, Department of Urology, Division of Pediatric Urology, Ankara, Turkiye

What's known on the subject? and What does the study add?

Post-void residual (PVR) volume measurement using ultrasonograpy is an important non-invasive tool used for diagnosis and monitoring the response to treatment in children with lower urinary tract dysfunction. Various portable ultrasonic scanner (PUS) devices are used for this purpose. We hypothesized measuring urinary volume in bladder in standing position first would probably be time-saving in PVR volume measuring process. In our study, measurements by PUS in both standing and supine positions were highly correlated. We concluded that PUS in standing position can be used to detect pre-voiding and post-voiding (PVR) volumes in UF procedure to prevent time-wasting and avoid possible anxiety of the children.

Objective: This study aimed to compare the pre-voiding bladder and post-voiding residual [BV, post-void residual (PVR)] volumes measured by the portable ultrasonic scanner (PUS) in standing and supine positions.

Materials and Methods: This study included 436 children. Two groups were composed (group-1: PUS vs. volume by catheter and group-2: PUS vs. infused volume during the urodynamic study) to evaluate the agreement of PUS measurements with true bladder volume. Additionally, the third group (group-3) was created to analyze the correlation between PUS measurements in different positions. In groups 1 and 2, PUS measurement agreements were evaluated using the paired sample T or Wilcoxon signed-rank tests. Following the agreement, correlations were analyzed using Pearson's or Spearman's coefficients depending on whether variables were distributed normally or not, respectively. Coefficients were interpreted as 0.90-1.00 (very high correlation) and 0.70-0.90 (high correlation).

Results: The catheter and PUS measurements were similar in group-1 (Wilcoxon signed-rank test, p=0.976) and were highly correlated (r=0.873). The measurements of volumes infused by urodynamic device and PUS were similar in group-2 that revealed the agreement of PUS measurements on different volumes and highly correlated at the 25th and very highly correlated at the 50th, 75th, and 100th percentiles of the estimated bladder capacity related to age. The BV and PVR measurements by PUS in standing and supine positions in group-3 were highly correlated, revealing that PUS can be used in both positions.

Conclusion: Measurements of BV before uroflowmetry or PVR volume by PUS in standing position gave similar results with those in the supine position.

Keywords: Portable ultrasonic scanner, uroflowmetry, post-void residual urine

Introduction

Lower urinary tract dysfunction (LUTD) has a varying prevalence of approximately 17-22% in the pediatric population (1). In the majority of cases, treatment response evaluation, diagnosis, and monitoring can be done by non-invasive methods, such as voiding diary, symptom scoring questionnaires, urinalysis, ultrasonography (USG), and uroflowmetry (UF) with post-void residual (PVR) volume measurement. Invasive tools, such as urodynamics, cystography, and cystoscopy, are indicated in a small selected group of cases (2,3).

Bladder catheterization is the "gold standard" method for accurate bladder or PVR volume measurement (4). However,

Correspondence: Taner Ceylan MD, Hacettepe University Faculty of Medicine, Department of Urology, Division of Pediatric Urology, Ankara, Turkiye
E-mail: drceylan73@gmail.com **ORCID-ID:** orcid.org/0000-0003-4044-1778
Received: 07.05.2021 **Accepted:** 31.07.2021

Cite this article as: Ceylan T, Doğan HS, Çıtamak B, Gasimov K, Bozacı AC, Tatanis V, Tekgül S. The Reliability of Bladder Volume Determination in Children Using Portable Ultrasonographic Scanner in Standing Position. J Urol Surg, 2022;9(1):68-73.

because of its invasive nature, it is not practical especially in those undergoing several repeating evaluations (5,6). The only non-invasive tool for measuring urine volume in the bladder is USG. Currently, a standard suprapubic USG or portable ultrasonic scanner (PUS) is used for this purpose. The use of USG to assess the bladder volume was first described in 1967 (7). It is quick, non-invasive, and well-tolerated, which may be performed in-office setting, requires less patient cooperation, and necessitates no extra instruments. USG reliability and compatibility with PUS have been investigated in several studies (8-10).

However, some problems may occur even during a simple procedure, such as UF with PVR measurement using USG, in children. Performing UF without sufficient bladder fullness can be time-wasting and the child's occasional resistance for not being in a supine position for PVR measurement with the fear of having a possibly painful procedure may limit the reliability and the feasibility of the tool. Understanding sufficient urine in the bladder in a standing position before UF and then measuring the PVR volume would probably reduce children's anxiety.

We hypothesized that measurements using PUS in both standing and supine positions are highly correlated and measurement in a standing position using PUS can be used for this purpose in children.

Materials and Methods

Our study was approved by the local ethical committee (ID: KA180089/10.01.2019). This study included 436 patients under the age of 18 years between March 2019 and February 2020. Exclusion criteria were the presence of neurogenic bladder, bladder surgery history, ovarian, and/or uterine cystic pathology in girls, vesicoureteral reflux (VUR) detected by previous voiding cystourethrography or video-urodynamic study (VUD), abdominal ascites, and any surgical incision in the suprapubic region. The parents of all children included in our study were signed a detailed consent form informing about USG measurement.

This study used a portable ultrasonic bladder scanner (SignosRT Bladder Scanner, Thermo Fisher Scientific Inc., USA) for all measurements. The scanner's probe was placed 1-1.5 cm above the pubic symphysis on the midline with a slight angle toward the bladder to obtain a good image (Figure 1). The digital output has been obtained from the automated volume measurements at a single 2-dimensional transverse scan. All measurements were performed two times by one pediatric urology fellow (T.C.) and the mean of these two consecutive mesurements were recorded as "bladder volume" in mililiters (mL).

Group 1 (n=185) was composed of patients who were planned to undergo an endourological intervention, such as pyeloplasty, ureteroscopy, percutaneous nephrolithotomy, and cystoscopy. After the anesthesia induction, the bladder volume was measured in the supine position using the PUS. Then, the child's bladder was catheterized to measure the actual bladder volume using 6 or 8 F Nelaton (according to the age) and the amount was recorded. Measurements in this group were used to investigate the agreement of the obtained volumes using a catheter and PUS by excluding the possible movement-related artifacts.

The second group (n=35) was used to assess the correlation of PUS with infused fluid during VUD at different fullness degrees and was composed of patients with non-neurogenic LUTD. Estimated bladder capacity by age in mililiters (EBC, mL) was calculated using the formula (age+2) x 30 (11). Then, a routine VUD study was performed with the urodynamic device (MMS, Medical Measurement Systems, B.V., Enschede, The Netherlands) and the measurements were performed using PUS at the 25%, 50%, 75%, and 100% of the EBC, simultaneously, and then recorded in mL. The measurements in this group were used to investigate the agreement of the volumes that were infused using an urodynamic device and PUS-detected volumes under normal outpatient conditions. The third group (n=216) was composed of patients with LUTD who underwent UF and PVR measurement in the same session. Bladder volumes were measured at the suprapubic area before and after voiding in both standing and supine positions in patients who underwent UF using PUS and were recorded in mL. The data of this group was used to evaluate the correlations of measurements in different positions.

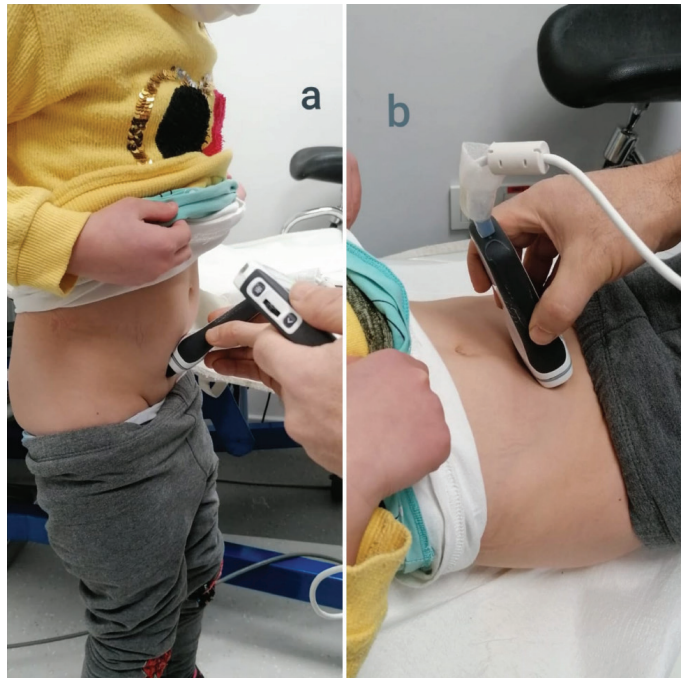


Figure 1. Measuring bladder volume by portable ultrasonic scanner in standing (a) and supine (b) positions

Statistical Analysis

Statistical analyzes were performed using the Statistical Package for the Social Sciences package program version 22 (IBM Statistical Package for the Social Sciences, Version 22, Illinois, USA), and a p-value of <0.05 was considered statistically significant. In groups 1 and 2, the agreement of PUS measurements with the reference values that were obtained by a catheter or infused volume was evaluated by the paired sample T or Wilcoxon signed-rank tests. Following the agreement confirmation, correlations have been analyzed using the Pearson coefficients for normally distributed variables and the Spearman coefficients not normally distributed variables. There was no reference value in group-3, thus the correlation of volume measurements in two different positions has been performed. The interpretation of coefficients was interpreted as 0.90-1.00 (very high correlation) and 0.70-0.90 (high correlation) (12).

Results

Of 185 patients in endoscopic intervention group (group 1), 126 (68.1%) were males and 59 (31.9%) were females. The mean age was 59±52 (1-204) months. Volumes obtained by PUS and catheter were in agreement (Wilcoxon signed-rank test, p=0.976) with a high correlation (r=0.873) between the measurements (Table 1). The correlation coefficients (Spearman's rho) for age groups of 0-59, 60-119, and 120–204 months were 0.742, 0.848, and 0.901 (p<0.001 for each), respectively.

The VUD group (group 2) included 35 patients, wherein 19 (54.3%) were males and 16 (45.7%) were females. The mean age was 108±40 (30-198) months. During the VUD study, the measurements of the bladder volumes by the urodynamic device and by PUS were in agreement and highly correlated at the 25th and very highly correlated at the 50th, 75th, and 100th percentiles of the EBC (Table 2).

A total of 211 patients, 97 (44.9%) females and 114 (55.1%) females were included in the UF group (group 3). The mean age was 116±42 (48-204) months. Before UF, the measured bladder volumes using PUS in both standing and supine positions were very highly correlated to each other. Similarly, PVR volumes of the same patients that were measured by PUS in both standing and supine positions were very highly correlated with each other (Table 3). The correlation coefficients (Spearman's rho) of standing and supine positions for patients younger than 120 months at pre-voiding and post-voiding measurements were 0.986 and 0.953 (p<0.001 for each), respectively. The same coefficients for children aged ≥120 months were 0.933 and 0.982 (p<0.001 for both), respectively.

Discussion

UF and PVR measurement are crucial for LUTD evaluation in children in addition to complete medical history and physical/neurological examination, bladder diaries, and symptom scoring questionnaires (13). Contrarily, invasive VUD studies are used to

Table 1. The comparison of the measurements using PUS and catheter under anesthesia

Measurement method	n	Mean (mL)	SD (mL)	Median (mL)	Min-max (mL)	Wilcoxon signed-rank test	Spearman's correlation coefficient	p
PUS	185	41	52	30	0-350	**0.976**	**0.873**	<0.001
Catheter	185	43	64	23	0-640			

SD: Standard, Min: Minimum, Max: Maximum, PUS: Portable ultrasonic scanner

Table 2. The comparison of the measurements by PUS and infused fluid by VUD device at different EBC percentiles

Bladder fullness	25 of EBC		50% of EBC		75% of EBC		100% of EBC	
Number of patients*	35		34		26		16	
	Infused volume	**Volume by PUS**	**Infused volume**	**Volume by PUS**	**Infused volume**	**Volume by PUS**	**Infused volume**	**Volume by PUS**
Mean ± SD (mL)	72±21	77±28	143±42	147±47	203±66	197±68	259±103	270±124
Median (min-max) (mL)	75 (22-100)	75 (27-146)	143 (45-200)	145 (43-245)	202 (67-300)	203 (60-310)	270 (90-400)	263 (85-570)
P values of related sample comparison tests	0.566[a]		0.197[b]		0.438[b]		0.366[b]	
Correlation coefficients	0.839[c]		0.934[d]		0.935[d]		0.938[d]	
p	<0.001		<0.001		<0.001		<0.001	

*: Number of patients who reached the aimed bladder fullness, EBC: Estimated bladder capacity, [a]: Wilcoxon signed-rank test, [b]: Paired sample t-test, [c]: Spearman correlation coefficient, [d]: Pearson correlation coefficient, SD: Standard deviation, Min: Minimum, Max: Maximum, PUS: Portable ultrasonic scanner

Table 3. Correlations of pre-voiding and post-voiding volume measurements by PUS in supine and standing positions

Measurement position	n	Mean (mL)	SD (mL)	Median (mL)	Min-max (mL)	Spearman's correlation coefficient	p
Pre-voiding (standing)	211	243	149	205	45-775	**0.968**	<0.001
Pre-voiding (supine)	211	249	150	212	50-780		
Post-voiding (standing)	211	29	42	16	0-278	**0.967**	<0.001
Post-voiding (supine)	211	29	41	18	0-272		

PUS: Portable ultrasonic scanner, SD: Standard deviation, Min: Minimum, Max: Maximum

investigate the bladder capacity, detrusor pressure, compliance, and the presence of VUR.

USG is a non-invasive, easily accessible, and repeatable tool and plays a major role during bladder evaluation in terms of residual urine volume assessment, detection of bladder wall pathologies and thickness, visualization of reno-ureteral unit regarding the accompanying abnormalities, and presence of rectal distension in children with LUTD (14,15). No significant differences were reported in the literature between the suprapubic standard USG and bladder catheterization in terms of bladder volume measurement (16). The urine volume in the bladder can also be measured using PUS. Recent studies revealed that standard USG and PUS were compatible in terms of bladder and PVR volumes (17-19). Additionally, PUS was reported as a reliable tool in bladder volume assessment compared to catheterization (20,21). Contrarily, PUS does not provide information about the rectal diameter, bladder neck, and urethra. The possible deviations from true bladder volumes because of the automated volume calculations at a single 2-dimensional transverse scan should be considered.

The patient's position during the measurement can impact the results. Possible anatomical interposition of peritoneal and intestinal structures between the bladder and the abdominal wall, especially in infants may cause deviations in measurements. The effect of position on USG measurements has been previously studied in a single study (22). They compared PUS and standard USG in 59 children and concluded that standing scanning could be used. However, they emphasized that the accuracy and correlation are lower in post-void measurements in children younger than 10 years. We detected that the correlation was quite high in both age groups; however, our study differs from this mentioned study as we used catheter measurements for comparison in a larger number of patients. The present study analyzed the correlation between detected volumes using catheterization and PUS in two ways. First, in the first group under anesthesia, we evaluated the correlation of these volumes in a child without physical activity and the impact of body movements on PUS. The correlation was high for all age groups, especially for children above 5 years, who can perform UF. Second, the correlation between volumes of the real-time infused fluid in the group under VUD was evaluated and volumes were detected using PUS in physically active children. The correlation was also very high. These results encouraged us to use PUS in bladder volume detection in supine and standing positions.

UF with PVR measurement is one of the mainstays of evaluating children with LUTD. However, voluntary voiding control, child cooperation, test room environment status, and bladder fullness degree are very important. Inadequate voided volume is one of the main obstacles in obtaining an informative result. Solid data on the amount of required voided volume is unavailable. A recent study revealed that the interpretation of the UF curve could even be done in small volumes (23); however, the consensus is to void during UF at least >50% of the EBC (24). A study from Taiwan proposed the age-specific lowest acceptable bladder capacity for UF interpretation as "(age in years×5)+50 mL" (25).

We can remove the disturbing factors during UF; however, inadequate bladder volume is the main problem during the test. Waiting for adequate bladder fullness and then repeating UF may be time-wasting for both parents and healthcare professionals. Therefore, PUS may provide great convenience and comfort. PUS can be used before UF to detect whether the bladder is adequately full or not. Additionally, asking the child for a supine position to perform a scan with PUS to evaluate bladder fullness may lead to resistance and may raise the child's concern about the procedure. Thus, a measurement process that can be done in a standing position can be advantageous in terms of saving time and decreasing anxiety. This study aimed to investigate the efficacy of PUS in measuring bladder and PVR urine volumes in standing positions. Following the presence of agreement and very high correlations in the above-mentioned groups, we evaluated the correlation of pre-voiding and post-voiding bladder volumes measured by PUS in supine and standing positions. Very high correlations were detected that confirm our hypothesis that PUS in a standing position can be used for detecting bladder volume before and after UF to prevent time-wasting and possible anxiety in children. The correlations were also very high for both age groups (<10 and

≥10 years), which was previously mentioned by Zillioux et al. (22) as an important factor.

Study Limitations

Our study is not without limitations. Since our urodynamics unit (VUD, UF, and PUS instruments) and abdominal USG device are settled in different buildings, it was impossible to make a simultaneous comparison between standard USG and PUS. However, this shortcoming has been overcome by obtaining the exact volume by catheterization or knowing the infused volume in VUD. The absence of blinding during PUS measurements in all study groups can be criticized as a methodological shortcoming. Another limitation can be the relatively small number of patients in the second group. The invasive nature of VUD, excluding the cases with VUR and neurogenic bladder, and our daily practice that is reserving VUD only for patients who did not respond to medical treatment are the possible causes of a small number in this group within the study period. The absence of infant age group patients in group-3 can be considered as a limitation. All patients in this group were old enough with voluntary voiding control to perform UF. However, the evaluation in infants using PUS is rarely indicated in daily practice regarding the need for uroflowmetric studies. The comparison of measurements in the younger age group, evaluation of the time loss, and patient anxiety in older children will be the objectives of our future studies.

Conclusion

Our study revealed that bladder volume measurements before and after UF in standing and supine positions are very highly correlated. These results showed that PUS in a standing position can be used to detect pre-voiding and post-voiding volumes during the UF procedure to prevent time-wasting and avoid possible anxiety in children.

Ethics

Ethics Committee Approval: Our study was approved by the local ethical committee (ID: KA180089/10.01.2019).

Informed Consent: The parents of all children included in our study were signed a detailed consent form informing about USG measurement.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: T.C., H.S.D., S.T., Concept: T.C., H.S.D., B.Ç., Design: T.C., H.S.D., S.T., Data Collection or Processing: T.C., K.G., A.C.B., Analysis or Interpretation: T.C., H.S.D., K.G., A.C.B., Literature Search: T.C., B.Ç., V.T., Writing: T.C., H.S.D.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declare that they have no relevant financial.

References

1. Vaz GT, Vasconcelos MM, Oliveira EA, Ferreira AL, Magalhães PG, Silva FM, Lima EM. Prevalence of lower urinary tract symptoms in school-age children. Pediatr Nephrol 2012;27:597-603.
2. Al-Shaikh G, Larochelle A, Campbell CE, Schachter J, Baker K, Pascali D. Accuracy of bladder scanning in the assessment of postvoid residual volume. J Obstet Gynaecol Can 2009;31:526-532.
3. Elsamra SE, Gordon Z, Ellsworth PI. The pitfalls of BladderScan™ PVR in evaluating bladder volume in adolescent females. J Pediatr Urol 2011;7:95-97.
4. Mainprize TC, Drutz HP. Accuracy of total bladder volume and residual urine measurements: comparison between real-time ultrasonography and catheterization. Am J Obstet Gynecol 1989;160:1013-1016.
5. De Gennaro M, Capitanucci ML, Di Ciommo V, Adorisio O, Mosiello G, Orazi C, Tubaro A. Reliability of bladder volume measurement with BladderScan in paediatric patients. Scand J Urol Nephrol 2006;40:370-375.
6. Padmore DE, Anderson PA, Tooth DS, Waye MA. Evaluation of a non-invasive method to determine bladder volume in children. Can J Urol 1997;4:305-308.
7. Holmes JH. Ultrasonic studies of the bladder. J Urol 1967;97:654-663.
8. Park YH, Ku JH, Oh SJ. Accuracy of post-void residual urine volume measurement using a portable ultrasound bladder scanner with real-time pre-scan imaging. Neurourol Urodyn 2011;30:335-338.
9. Nusee Z, Ibrahim N, Rus RM, Ismail H. Is portable three-dimensional ultrasound a valid technique for measurement of postpartum urinary bladder volume? Taiwan J Obstet Gynecol 2014;53:12-16.
10. Goode PS, Locher JL, Bryant RL, Roth DL, Burgio KL. Measurement of postvoid residual urine with portable transabdominal bladder ultrasound scanner and urethral catheterization. Int Urogynecol J Pelvic Floor Dysfunct 2000;11:296-300.
11. Koff SA. Estimating bladder capacity in children. Urology 1983;21:248.
12. Mukaka MM. Statistics corner: A guide to appropriate use of correlation coefficient in medical research. Malawi Med J 2012;24:69-71.
13. Austin PF, Bauer SB, Bower W, Chase J, Franco I, Hoebeke P, Rittig S, Walle JV, von Gontard A, Wright A, Yang SS, Nevéus T. The standardization of terminology of lower urinary tract function in children and adolescents: Update report from the standardization committee of the International Children's Continence Society. Neurourol Urodyn 2016;35:471-481.
14. Park YH, Ku JH, Oh SJ. Accuracy of post-void residual urine volume measurement using a portable ultrasound bladder scanner with real-time pre-scan imaging. Neurourol Urodyn 2011;30:335-338.
15. Cho MK, Noh EJ, Kim CH. Accuracy and precision of a new portable ultrasound scanner, the Biocon-700, in residual urine volume measurement. Int Urogynecol J 2017;28:1057-1061.
16. Williot P, McLorie GA, Gilmour RF, Churchill BM. Accuracy of bladder volume determinations in children using a suprapubic ultrasonic bi-planar technique. J Urol 1989;141:900-902.
17. Ghani KR, Pilcher J, Rowland D, Patel U, Nassiri D, Anson K. Portable ultrasonography and bladder volume accuracy--a comparative study using three-dimensional ultrasonography. Urology 2008;72:24-28.
18. Abdel-Fattah M, Barrington JW. The accuracy of Bardscan: a new tool for the measurement of the bladder volume. J Obstet Gynaecol 2005;25:186-188.

19. Park YH, Ku JH, Oh SJ. Accuracy of post-void residual urine volume measurement using a portable ultrasound bladder scanner with real-time pre-scan imaging. Neurourol Urodyn 2011;30:335-338.

20. Fuse H, Yokoyama T, Muraishi Y, Katayama T. Measurement of residual urine volume using a portable ultrasound instrument. Int Urol Nephrol 1996;28:633-637.

21. Ireton RC, Krieger JN, Cardenas DD, Williams-Burden B, Kelly E, Souci T, Chapman WH. Bladder volume determination using a dedicated, portable ultrasound scanner. J Urol 1990;143:909-911.

22. Zillioux JM, Corbett ST, Hunter E, Kern NG. Bladder scan accuracy in pediatric patients: Does patient position matter? J Pediatr Urol 2018;14:438.e1-438.e6.

23. Hyuga T, Nakamura S, Kawai S, Tanabe K, Naka Mieno M, Nakai H. Does small voided volume influence uroflowmetry curve patterns in Japanese children with daytime urinary incontinence? J Pediatr Urol 2019;15:663.e1-663.e5.

24. Austin PF, Bauer SB, Bower W, Chase J, Franco I, Hoebeke P, Rittig S, Walle JV, von Gontard A, Wright A, Yang SS, Nevéus T. The standardization of terminology of lower urinary tract function in children and adolescents: Update report from the standardization committee of the International Children's Continence Society. Neurourol Urodyn 2016;35:471-481.

25. Chang SJ, Chen JY, Chiang IN, Yang SS. Lowest Acceptable Bladder Capacity for Interpretation of Uroflowmetry Tests in Children. Low Urin Tract Symptoms 2017;9:161-165.

CASE REPORT
General Urology

Doi: 10.4274/jus.galenos.2021.2021.0064
J Urol Surg, 2022;9(1):74-75

Portal Hypertension Secondary to Benign Prostatic Hyperplasia

Mustafa Küçükyangöz[1], Emrullah Söğütdelen[1], Sebahat Gücük[2], Adnan Gücük[1]

[1]Bolu Abant İzzet Baysal University Faculty of Medicine, Department of Urology, Bolu, Turkiye
[2]Bolu Abant İzzet Baysal University Faculty of Medicine, Department of Family Medicine, Bolu, Turkiye

Abstract

Benign prostatic hyperplasia (BPH) obstructs the bladder outlet. Patients with BPH frequently present with lower urinary tract symptoms. However, patients with BPH can present with serious fatal complications unless diagnosed and treated sufficiently. In this case report, we present the case of a 63-year-old male patient with renal insufficiency, generalized edema, and portal hypertension due to chronic obstructive uropathy secondary to BPH. To the best of our knowledge, this is the first report to present portal hypertension secondary to BPH as a rare complication.

Keywords: Prostate, BPH complications, generalized edema, portal hypertension

Introduction

Benign prostatic hyperplasia (BPH) is defined as the enlargement of the prostate gland that obstructs the bladder outlet. BPH is an important cause of lower urinary tract symptoms (1,2). Patients with BPH usually present with voiding and storage symptoms (1,3,4). Complications such as recurrent or persistent urinary tract infections, macroscopic or microscopic hematuria, bladder stones, acute or chronic renal failure, incontinence, erectile dysfunction, and electrolyte imbalance are observed. Moreover, patients with chronic obstruction could present with hypertension secondary to hypervolemia (5,6).

Portal hypertension (PH) is defined as an increase in blood pressure between the inferior vena cava and portal veins mainly due to cirrhosis. Furthermore, diseases such as portal vein occlusion, primary biliary cholangitis, alcoholic hepatitis, hepatic vein thrombosis, and chronic right heart failure are possible causes of PH (7).

Renal insufficiency frequently occurs in chronic obstructive uropathies (8). Chronic kidney insufficiency further triggers right heart insufficiency (9). These diseases can cause PH depending on the volume load (10). In this report, we present the case of a patient with generalized edema, renal insufficiency, and PH secondary to BPH.

Case Report

A 63-year-old male patient admitted to the department of urology outpatient clinic of our institution for the swelling of the legs, lower abdomen, and genital area (Figure 1a). The patient had no history of PH or heart failure previously. After taken an informed consent, n the physical examination, a diffuse bilateral pedal, scrotal, penile, and lower abdominal edema was observed. In the deep abdominal palpation, we observed a mass effect of the overfilled bladder in the suprapubic region due to urinary retention.

Furthermore, the patient had the following laboratory results: white blood cell, 12,200/uL; hemoglobin, 6.39 g/dL; blood urea nitrogen, 225 mg/dL; creatinine, 12.45 mg/dL; aspartate aminotransferase, 9 u/L; alanine aminotransferase, 11 u/L; total prostate-specific antigen, 6.66 ng/mL; and free prostate-specific antigen, 1.63 ng/mL. The patient was consulted with the department of nephrology and was decided not to dialyze since all electrolytes were in the normal range and had no uremic complications.

To further explore renal insufficiency, abdominal ultrasound (US) (GE Healthcare, Chicago, IL, USA) was performed, revealing bilateral grade 3 hydroureteronephrosis with a 74 mL prostate volume, 37 mm ureteral stone, and 1.250 mL residual urine in the bladder. Furthermore, a color Doppler US of the portal system was performed, revealing dilatation of the hepatic veins as well as of the splenic vein and hilum.

Correspondence: Mustafa Küçükyangöz MD, Bolu Abant İzzet Baysal University Faculty of Medicine, Department of Urology, Bolu, Turkiye
E-mail: kucukyangoz42@hotmail.com **ORCID-ID:** orcid.org/0000-0003-4766-7454
Received: 22.05.2021 **Accepted:** 23.09.2021

Cite this article as: Küçükyangöz M, Söğütdelen E, Gücük S, Gücük A. Portal Hypertension Secondary to Benign Prostatic Hyperplasia. J Urol Surg, 2022;9(1):74-75.

A 16-French two-way urethral catheter was inserted into the patient to drain residual urine when significant residual urine was observed. The urine output of the patient was 1.500 mL in 10 min after catheterization. The patient was hospitalized to correct the hemoglobin deficit and monitor renal function. In the control kidney function tests, creatinine level decreased to 5.7 mg/dL and blood urea nitrogen to 167 mg/dL by day 5 of admission.

After histopathological confirmation of the prostate by transrectal US-guided biopsy with BPH, an open suprapubic transvesical prostatectomy and cystolithotomy was performed. The patient was discharged on postoperative day 3 with a urethral catheter, which was taken on postoperative day 7.

Physical examination on postoperative day 7 revealed the complete regression of a generalized edema (Figure 1b). In the control laboratory tests, creatinine was at 4.24 mg/dL and blood urea nitrogen at 111 mg/dL. Postvoiding residual urine was not observed on US. A control doppler US revealed that PH findings like a dilatation in the splenic and portal veins were completely regressed. The patient was followed up for one year and had normal renal function.

Discussion

Chronic urinary retention is characterized by the accumulation of urine in the bladder slowly and paimless with volumes ranging between 450 and 4.500 mL. In chronic retention, high pressure in the bladder causes an increase in the pressure of the pelvicalyceal system, leading to bilateral hydronephrosis. Subsequently, this may result in different degrees of renal failure (6).

PH is asymptomatic until severe complications, such as gastrointestinal bleeding from varices, ascites, and hepatic encephalopathy develop (11). In this study, bilateral grade 3 hydronephrosis, renal insufficiency, generalized edema, and PH secondary to BPH were observed. To the best of our knowledge, there was no PH presentation secondary to BPH. Thus, although a patient may be hospitalized for chronic urinary retention, PH and its complications should be considered.

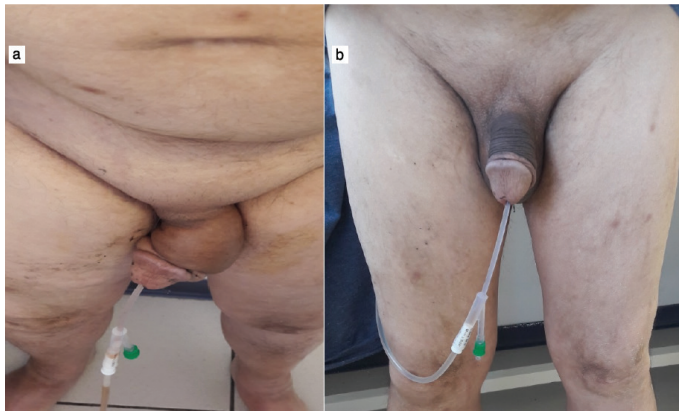


Figure 1. Bilateral lower extremity, penile, and abdominal edema a) at initial admission and b) on postoperative day 7

Conclusion

BPH is the most common cause of obstructive uropathy with rare fatal complications. Its presentation ranges from no symptoms to much more morbid situations like end-stage renal disease, right heart failure, and PH. Thus, if a patient presents with chronic urinary retention and generalized edema, PH should be checked although it is rare.

Ethics

Informed Consent: Informed consent was obtained.

Peer-review: Externally peer-reviewed.

Authorship Contributions

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

Conflict of Interest: No conflict of interest was declared by the authors.

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

References

1. Egan KB. The Epidemiology of Benign Prostatic Hyperplasia Associated with Lower Urinary Tract Symptoms: Prevalence and Incident Rates. Urol Clin North Am 2016;43:289-297.
2. Vasanwala FF, Wong MYC, Ho HSS, Foo KT. Benign prostatic hyperplasia and male lower urinary symptoms: A guide for family physicians. Asian J Urol 2017;4:181-184.
3. Mobley D, Feibus A, Baum N. Benign prostatic hyperplasia and urinary symptoms: Evaluation and treatment. Postgrad Med 2015;127:301-307.
4. Pearson R, Williams PM. Common questions about the diagnosis and management of benign prostatic hyperplasia. Am Fam Physician 2014;90:769-774.
5. Tseng TY, Stoller ML. Obstructive uropathy. Clin Geriatr Med 2009;25:437-443.
6. Speakman MJ, Cheng X. Management of the complications of BPH/BOO. Indian J Urol 2014;30:208-213.
7. Turco L, Garcia-Tsao G. Portal Hypertension: Pathogenesis and Diagnosis. Clin Liver Dis 2019;23:573-587.
8. McLean RH, Gearhart JP, Jeffs R. Neonatal obstructive uropathy. Pediatr Nephrol 1988;2:48-55.
9. Rangaswami J, McCullough PA. Heart Failure in End-Stage Kidney Disease: Pathophysiology, Diagnosis, and Therapeutic Strategies. Semin Nephrol 2018;38:600-617.
10. Bloom S, Kemp W, Lubel J. Portal hypertension: pathophysiology, diagnosis and management. Intern Med J 2015;45:16-26.
11. Tetangco EP, Silva RG, Lerma EV. Portal hypertension: Etiology, evaluation, and management. Dis Mon 2016;62:411-426.