

PELVIPERINEOLOGY

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2025

Volume: 44

Issue: 1

April



Societatea Română de Uroginecologie





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The editorial and publication processes of the journal are shaped in accordance with the guidelines of the ICMJE, WAME, CSE, COPE, EASE, and NISO. The journal conforms with the Principles of Transparency and Best Practice in Scholarly Publishing ([doi.org/bestpractice](https://doi.org/10.21956/doi.org/bestpractice)). Pelviperrineology is indexed in Scopus, Ebsco HOST, Gale, J-Gate, Embase and TUBITAK ULAKBIM TR Index.

The journal is published online.

Owner: The International Society for Pelviperrineology

Responsible Manager: Ahmet Akin Sivaslioglu

Editorial Office: International Society for Pelviperrineology

e-mail: editorinchief@pelviperrineology.org

Quarterly journal of scientific information registered at the Tribunale di Padova, Italy n. 741 dated 23-10-1982 and 26-05-2004

The journal is property of the International Society for Pelviperrineology



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Address: Molla Gürani Mah. Kaçamak Sk.
No: 21/1 34093 İstanbul, Türkiye
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

Printer: La Grafica Faggian, Via F. Severi 2/4

Campodarsego (Padova) IT

E-mail: comm@lagraficafaggian.it

Printing Date: April 2025

ISSN: 1973-4905 E-ISSN: 1973-4913

International scientific journal published quarterly.

Official Journal of the: International Society for Pelviperrineology
(www.pelviperrineology.com)

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EDITORIAL

Dear Colleagues;

Our first issue of the year 2025 has been released. As has been always, studies with exceptionally high quality were included in this issue.

I would like to thank not only to authors but also our reviewers who have been increasing the scientific quality in a steady manner.

The insight evaluation of our journal has revealed that “The Journal of Pelviperineology” has a high “readability” rate across the World. This is our most important source of motivation.

Article evaluation process, from submission to publication is totally free of charge. Since we are not running a business and not money-orientated, these peculiarities of the journal further increases the prestige of it.

We look forward to receiving studies such as randomised studies, researchs, case reports, in brief, of any kind of scientific writings within the scope of the journal.

Your support has utmost importance and this will definitely make us very happy.

I wish all of you very healthy days.

Prof. Dr. Ahmet Akın SIVASLIOĞLU

Editor-in-chief



Deciphering the interplay between NEAT1, miR-139-5p, miR-129-5p, TGF- β 1, and collagen type I in pelvic organ prolapse

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Citation: Demirtaş Bilgiç A, Kasap B, Sezgin B, et al. Deciphering the interplay between NEAT1, miR-139-5p, miR-129-5p, TGF- β 1, and collagen type I in pelvic organ prolaps. Pelviperineology. 2025;44(1):1-7

ABSTRACT

Objective: Pelvic organ prolapse (POP) is a benign gynecological disorder characterized by the descent of pelvic organs due to weakened support structures. While the molecular mechanisms behind POP are not fully understood, previous studies have indicated an association with altered levels of collagen type I and transforming growth factor-beta 1 (TGF- β 1). Long non-coding RNAs (lncRNAs) and microRNAs (miRNAs), which are essential regulators of gene expression, may provide valuable insights into the diagnosis, prognosis, and treatment of POP. This study aimed to investigate the protein levels of TGF- β 1 and collagen type I, as well as the expression levels of miR-129-5p, NEAT1, and miR-139-5p key regulators of TGF- β 1 and collagen type I among patients with POP.

Materials and Methods: Thirty-four POP patients and thirty healthy controls were included in the study. The expression levels of miR-129-5p, NEAT1, and miR-139-5p were measured using quantitative polymerase chain reaction on RNA extracted from fascia tissues. TGF- β 1 and collagen type I protein levels were assessed via ELISA.

Results: Compared to healthy controls, POP patients exhibited significantly higher levels of miR-129-5p ($p=0.011$) and TGF- β 1 ($p=0.000$).

Conclusion: The findings suggest that miR-129-5p may play a crucial role in the pathophysiology of POP. Future studies should explore the role of lncRNAs in regulating miR-129-5p and their potential relationship with POP.

Keywords: miRNA; lncRNA; TGF- β 1; pelvic organ prolapse; collagen

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Received: 27 November 2024 **Accepted:** 13 January 2025 **Publication Date:** 11 April 2025



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INTRODUCTION

Pelvic organ prolapse (POP) is a disorder of pelvic floor dysfunction characterized by loss of pelvic wall uterine herniation, support and vaginal prolapse. Although some conditions and molecules are considered to be effective in the etiology of POP, the disease is known to be multifactorial.¹ Anatomical, physiologic, genetic, lifestyle and reproductive factors such as chronic cough, constipation, hysterectomy, childbirth and heavy lifting influence the development of POP, with a constant increase in intra-abdominal pressure.²

POP disease has shown multiple risk factors contribute to the degradation of pelvic floor connective tissue and collagen, resulting in damage to muscles, connective tissue, blood vessels, and nerves.³ In 1996, Jackson established a link between POP and collagen content. Since then, several studies have shown varying results, with some reporting an increase and others a decrease in the total collagen content of the vaginal wall and pelvic floor support tissues in POP patients.⁴ Transforming growth factor-beta 1 (TGF- β 1), which remodels the extracellular matrix (ECM) by regulating numerous enzymes and ECM components, stimulates collagen expression. Studies have determined that TGF- β 1 expression level decreased in different tissues from women diagnosed with POP.⁵

The mammalian genome contains sequences for both protein-coding RNA and non-coding RNAs (ncRNAs). There are many different groupings of known ncRNAs. In particular, ncRNAs longer than 200 nucleotides are called lncRNA and are involved in different biological and molecular processes. Involved in many steps of gene regulation, lncRNAs, especially micro RNA (*miRNA/miR*), regulate gene expression before and after transcription. miRNAs, which are approximately 21-25 nucleotides long, bind to mRNAs and cause their degradation or suppression of translation. Studies have shown that ncRNAs have crucial roles in the emergence and development of different diseases.^{6,7}

The association of miR-129-5p, NEAT1 and miR-139-5p with POP disease has not been previously shown in the literature. The aim of our study was to elucidate the association of miR-129-5p, NEAT1 and miR-139-5p, which are known to be effective in TGF- β 1 and collagen type I regulation, with POP disease. The primary goal of our study is to present new biomarker targets that will contribute to the diagnosis and treatment of POP disease and fill the research deficiency in the literature.

MATERIALS AND METHODS

Collection of Sample Material

The study was approved by the Clinical Research Ethics Committee

of Muğla Sıtkı Koçman University (approval number: 19/II, date: 15.09.2021). A total of 64 participants were enrolled, including 34 patients diagnosed with POP who received surgical treatment, and 30 control individuals who underwent hysterectomy without a POP diagnosis. All participants were recruited from the outpatient Clinic of the Department of Obstetrics and Gynecology, Muğla Sıtkı Koçman University Faculty of Medicine. Informed consent was obtained from all participants prior to their inclusion in the study.

Two 0.5x0.5 cm pieces of tissue were removed from the patients' pubocervicovaginal fascia (PSVF) during the surgical procedure. Two pieces of 0.5x0.5 cm tissue were removed from the PSVF of patients who had benign hysterectomy procedures but did not have POP as a control group. The tissues were kept at -80 °C in RNA lysis solution.

Gene Expression Analysis

Total RNA was extracted from tissue samples using the total RNA extraction Kit (MG-RNA-01-250, Hibrigen), with 50 mg of tissue processed for each sample. The levels of miR-129-5p expression, NEAT1, and miR-139-5p were determined by using the SYBR green real time-quantitative polymerase chain reaction (RT-qPCR) technique. RNA extracted from the tissue samples was first transcribed into complementary DNA (cDNA) using the cDNA synthesis kit (A.B.T.™, C03-01-20). The resulting cDNA was then analyzed with the 2X SYBR Green qPCR Mix (Hibrigen, MG-SYBR-01-80) and specific primers (Table 1) to determine the expression levels of the target genes. In this study, miR-26a served as the reference gene for miR-139-5p and miR-129-5p, while GAPDH was used as the reference for NEAT1.^{8,9} The relative gene expression levels were assessed using the $2^{-\Delta\Delta CT}$ method, with data derived from no fewer than three independent experiments.

Enzyme-Linked Immunosorbent Assay (ELISA) Analysis

For each sample, 50 mg of tissue was homogenized in 80 μ L of cold PBS using a tissue homogenizer. Quantification of TGF- β 1 and collagen type I levels was performed using the Human TGF- β 1 ELISA Kit (SunRedBio, Cat. No: 201-12-0135) and the Human COL-1 ELISA Kit (SunRedBio, Cat. No: 201-12-2078), following the manufacturer's protocols. The results were expressed in ng/mL.

Statistical Analysis

Statistical analyses were performed using SPSS version 22 for Windows (SPSS Inc., Chicago, IL, USA). Normality of gene expression data was assessed using the Shapiro-Wilk test. Independent t-tests were applied to normally distributed data, while the Mann-Whitney U test was used for non-normally

Table 1. Primers sequences

Gene/ncRNA	Primers
<i>NEAT1</i>	F 5' ATGCCACAACGCAGATTGAT 3' R 5' CGAGAAACGCACAAGAAGG 3'
<i>miR-139-5p</i>	F 5'ACACTCCAGCTGGGTGTAGTGTTCCTACTT 3' R 5'CTCAACTGGTGTCTGGAGTCGGCAATTCAGTTGAGCTGGAGAC 3'
<i>miR-129-5p</i>	F 5' ACACTCCAGCTGGGCTTTTGCGGTCTGG 3' R 5'CTCAACTGGTGTCTGGAGTCGGCAATTCAGTTGAGGCAAGCCC 3'
<i>miR-26a</i>	F 5'ACACTCCAGCTGGGTCAAGTAATCCAGGA3' R 5'CTCAACTGGTGTCTGGAGTCGGCAATTCAGTTGAGAGCCTATC3'
<i>GAPDH</i>	F 5' GAAGGTGAAGGTCGGAGTC 3' R 5'GAAGATGGTGATGGGATTTC 3'

distributed data. Descriptive statistical data are presented as minimum, maximum, and mean \pm standard deviation. A *p*-value of <0.05 was considered statistically significant.

In silico Analysis

To confirm our experimental findings, we identified and analyzed the target genes of miR-129-5p whose expression was significantly changed. The target genes of miR-129-5p were identified using the miRDB (<https://mirdb.org/mirdb/index.html>) tool. Gene ontology (GO) analysis was obtained using target mRNA matches with target scores of 95% and above. Target genes of miR-129-5p were analyzed using GO and pathway analyses using GeneCodis4 (<https://genecodis.genyo.es/>).¹⁰

RESULTS

Evaluation of miR-129-5p, NEAT1 and miR-139-5p Expression Levels

In the study, miR-129-5p, NEAT1 and miR-139-5p expression distributions were analyzed by RT-qPCR and $2^{-\Delta\Delta CT}$ mean and *p*-values were examined in patients with POP and control groups without POP diagnosis (Table 2).

When miR-129-5p expression level was analyzed in POP patients compared to control groups, a significant increase was detected in the patient group ($p=0.011$) (Figure 1). However, no significant difference was observed in miR-139-5p and NEAT1 expression levels between the two groups ($p=0.492$ and $p=0.570$,

respectively).

Evaluation of Collagen Type I and TGF- β 1 Protein Levels

In our study, collagen type I and TGF- β 1 protein levels were analyzed using ELISA method and mean protein levels and *p*-values were examined in patients with POP and control groups without POP diagnosis (Table 3).

Comparison between POP and control groups revealed a significant difference in TGF- β 1 level ($p=0.000$) (Figure 2), while no significant change was observed in collagen type I level ($p=0.091$).

In silico Analysis

miR-129-5p, which we determined to be effective in the mechanism of POP, was analyzed with the miRDB tool and 70 genes with a target score of 95% and above were identified. As a result of the examination with the GeneCodis 4 web tool, the common molecular functions, cellular components, biological processes and pathway analysis (KEGG pathway) in which the 70 identified genes are involved are shown in Figure 3.

DISCUSSION

Investigating the pathophysiology of POP disease and aiming to contribute to the existing literature, our study delved into the influence of NEAT1 on miR-129-5p and miR-139-5p, along with exploring the relationship between miR-139-5p and TGF- β 1, and miR-129-5p and collagen type I in POP. Expression and protein

Table 2. miR-129-5p, NEAT1 and miR-139-5p expression levels in POP and control groups

ncRNAs	POP (mean \pm SD)	Controls (mean \pm SD)	<i>p</i> *
NEAT1	1.15 \pm 1.09	0.85 \pm 0.51	0.492
miR-139-5p	35.72 \pm 28.81	44.59 \pm 40.08	0.570
miR-129-5p	6.80 \pm 6.63	3.48 \pm 5.46	0.011

*: Mann-Whitney U test, SD: Standard deviation, POP: Pelvic organ prolapse, lncRNAs: Non-coding RNAs

level results were meticulously assessed through statistical analysis. Comparative analysis of miR-129-5p, NEAT1 and miR-139-5p expression levels unveiled a significant elevation in miR-129-5p expression among POP patients in contrast to controls ($p=0.011$). Conversely, no substantial discrepancies were observed in NEAT1 and miR-139-5p expression levels ($p=0.492$ and $p=0.570$, respectively). Notably, scrutiny of TGF- β 1 and collagen type I protein levels revealed a marked increase in TGF- β 1 protein levels in POP patients relative to controls ($p=0.000$), while collagen type I levels exhibited no significant difference ($p=0.091$). Utilizing the miRDB tool, we identified target mRNA matches of miR-129-5p, deemed pivotal in POP mechanisms, with target scores exceeding 95%. To further unravel the pathogenesis of POP disease, GO and pathway analyses were conducted on these target mRNAs, leading to the identification of novel targets priming future investigations.

POP is a gynecological condition defined by the descent of one or more pelvic organs such as the small intestine, uterus, bladder, vagina, or rectum from their normal anatomical positions due to weakened supporting structures.¹¹ The pathophysiology of POP encompasses a spectrum of molecular mechanisms, yet its complexity remains incompletely elucidated. Notably, connective tissue impairment and consequent weakening emerge as pivotal contributors to POP development.¹² Constituting a fundamental

human tissue, connective tissue comprises fibrous ECM components. Perturbations in ECM structure and composition are widely recognized as correlates of connective tissue pathologies. Among the ECM's protein constituents, collagen and elastin assume central roles in dictating its mechanical properties.¹³

In mammalian systems, the potential involvement of TGF- β 1 in physiological tissue repair and collagen deposition has been substantiated through empirical investigations. Specifically, research has established its role in fostering the synthesis of collagen and fibronectin via transcriptional activation mechanisms.¹⁴ Given its implication in numerous pathological conditions, TGF- β 1 has been extensively scrutinized in endeavors to decipher the molecular underpinnings of POP. Qi et al.,¹⁵ in their investigation, documented a diminished expression of TGF- β 1 protein within the POP cohort relative to the control group, shedding light on its potential relevance in the pathogenesis of POP.

In the exploration of uterine prolapse, Li et al.¹⁶ uncovered an inverse relationship between TGF- β 1 expression and the progressive severity of the condition. Conversely, investigations into POP conducted in Türkiye yielded contrasting findings, indicating no significant alterations in TGF- β 1 levels across studied groups in serum samples.¹⁷ Examining postmenopausal cohorts with and without POP, comparable TGF- β 1 expression

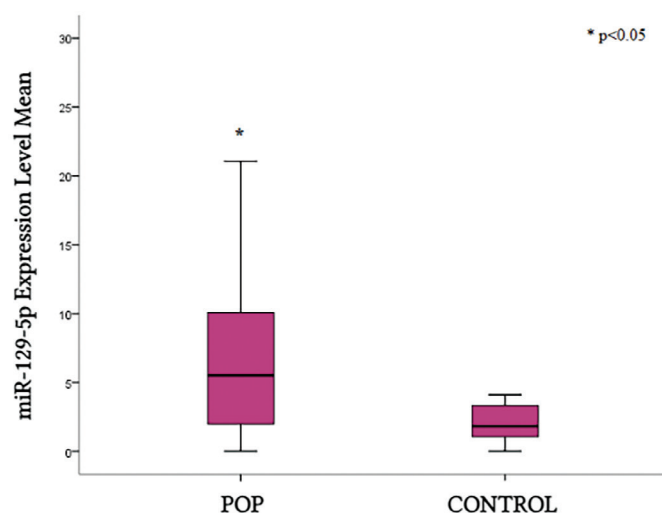


Figure 1. miR-129-5p expression level

POP: Pelvic organ prolapse

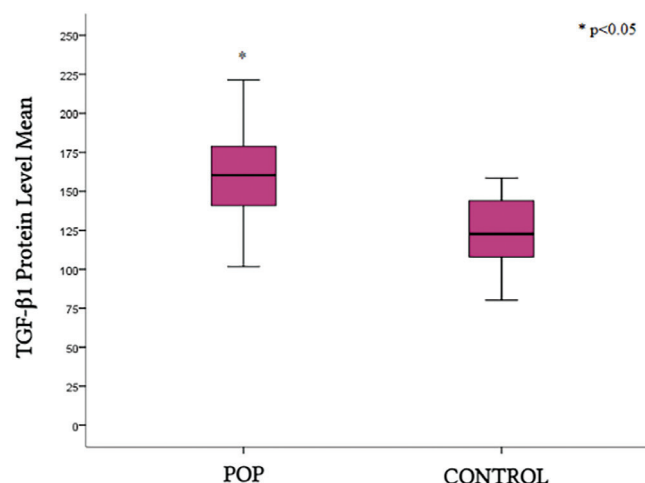


Figure 2. TGF- β 1 protein level

POP: Pelvic organ prolapse, TGF- β 1: Type I and transforming growth factor-beta 1

Table 3. Collagen type I and TGF- β 1 protein levels in POP and control groups

Proteins	POP (mean \pm SD)	Controls (mean \pm SD)	p^*
TGF- β 1	59.38 \pm 41.44	125.06 \pm 20.76	0.000
Collagen type I	76.48 \pm 15.27	72.02 \pm 11.92	0.091

*: Mann-Whitney U test, SD: Standard deviation, POP: Pelvic organ prolapse, TGF- β 1: Type I and transforming growth factor-beta 1

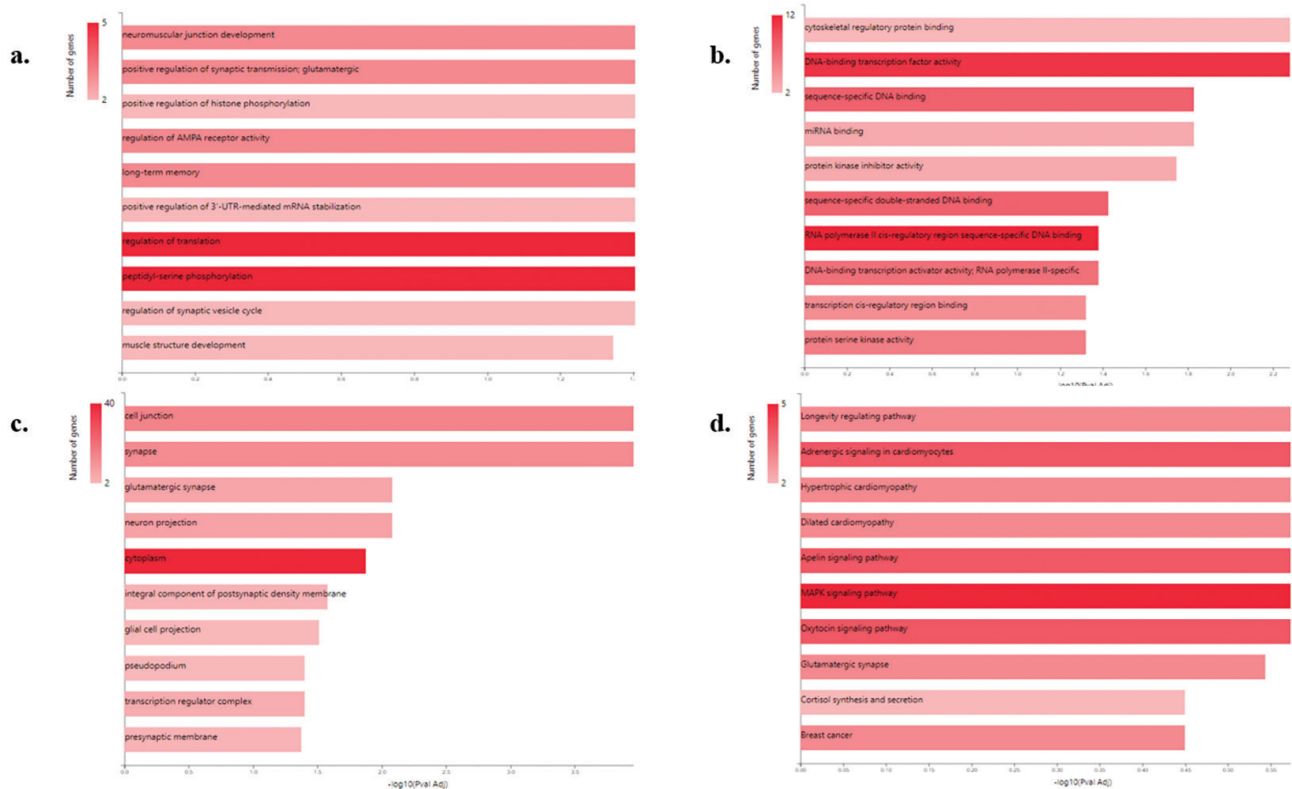


Figure 3. GO and pathway analysis of miR-129-5p target genes **a.** Biological process **b.** Molecular function **c.** Cellular component **d.** Pathway analysis (KEGG pathway)

GO: Gene ontology

levels were observed between the groups, with heightened levels noted in severe POP cases relative to mild or common presentations.¹⁸ In our thesis investigation, a notable elevation of TGF- β 1 protein levels by a factor of 1.2 was detected in POP patients in contrast to the control cohort ($p=0.000$). Moreover, findings by Carlin et al.¹⁸ corroborated our study, revealing escalated TGF- β 1 levels within the subset of high-severity POP patients. These collective observations underscore the nuanced role of TGF- β 1 in the pathogenesis and severity stratification of POP, delineating varying expressions across distinct clinical contexts.

In an in-depth investigation of the anterior vaginal wall and USL, it was demonstrated that individuals with POP exhibited a more fragmented and irregular collagen structure compared to their non-affected counterparts. Additionally, a decrease in the expression of collagen type I and collagen type III was noted within the patient group.¹⁹ In a POP study conducted by Vetuschi et al.,²⁰ a reduction in collagen type I expression level was observed in sagging tissues, while an increase in collagen type III expression level was noted. These variations in collagen levels are believed to disrupt the dynamic functionality of the pelvic floor.²⁰ However, findings by Kerkhof et al.²¹ contradicted

these observations, revealing no significant differences in collagen type I, III, and IV levels between the POP and control groups. In our study, although collagen type I protein levels were higher in POP patients than in the control group, the results were not statistically significant ($p=0.091$). However, our results are consistent with some studies in the literature and emphasize the complex and multifactorial nature of collagen dynamics in POP pathogenesis.

In endometriosis tissues, a gynecological disease that poses a serious health problem for women, NEAT1 was shown to be overexpressed while the expression of miR-124-3p was reduced. Consequently, NEAT1 was found to promote malignant behavior in endometriosis by targeting miR-124-3p.²² NEAT1, which is believed to be involved in the pathogenesis of gynecologic diseases, has rarely been studied in polycystic ovary syndrome (PCOS). Wu et al.²³ investigated the role of miR-324-3p, NEAT1 and bromodomain-containing 3 (BRD3) in PCOS tissues and PCOS mouse models. They found that the expression levels of NEAT1 and BRD3 were high, while the expression levels of miR-324-3p were low, particularly in the tissues of women with PCOS. Mechanistically, it was shown that NEAT1 targets miR-324-3p, miR-324-3p targets BRD3, and the high levels of NEAT1 and

BRD3, along with the low levels of miR-324-3p, increase PCOS severity.²³ In our thesis study, although the mean expression of NEAT1 in patients with POP was higher compared to the control group, the results were not statistically significant ($p=0.492$). While studies in the literature indicate an association between NEAT1 and gynecological diseases, our findings suggest that NEAT1 is not associated with POP.

A study has shown that miR-19-3p is upregulated in the tissues of individuals with POP, while IGF-1 and collagen type I expressions are downregulated. It has been suggested that miR-19-3p may affect collagen type I synthesis in POP by targeting IGF-1.²⁴ Uterine leiomyomas, or fibroids, are a gynecological disease affecting 30-50% of women of reproductive age, characterized by symptoms such as heavy menstrual bleeding, pelvic pain, and pressure. miR-139-5p, which exhibits tumor-suppressing properties, has been shown to be decreased in uterine leiomyomas, correlating with increased collagen type I expression.²⁵ Feng et al.²⁶ found that miR-139-5p expression is significantly upregulated in endometrial stromal cells in endometriosis.

Cervical intraepithelial neoplasia, caused by human papillomavirus, is known to be influenced by miRNAs. Zhang et al.²⁷ demonstrated that miR-129-5p levels decrease proportionally with the progression of cervical intraepithelial lesions. In intervertebral disc degeneration, miR-129-5p levels are lower compared to control groups. Additionally, miR-129-5p carried in extracellular vesicles from mesenchymal stem cells reduces apoptosis, ECM degradation, and M1 macrophage polarization in the nucleus pulposus tissues of patients with intervertebral disc degeneration.²⁸

Renal fibrosis has been shown to involve the determination of miR-129-5p by NEAT1, leading to the excessive accumulation of collagen type I which a main target of miR-129-5p.²⁹ In diabetic wound healing, miR-129-5p has been demonstrated to regulate specificity protein-1, a transcription factor involved in MMP-9 expression, significantly decreasing MMP-9 levels.³⁰ In our study, although the miR-139-5p expression level was higher in the control group, it was not statistically significant ($p=0.570$). Additionally, miR-129-5p levels were found to be 1.9-fold higher in POP tissues compared to controls, with the results being statistically significant ($p=0.011$). While miR-139-5p is associated with endometriosis, our findings indicate no significant relationship with POP. The results for miR-129-5p align with those reported in studies on cervical intraepithelial neoplasia.

CONCLUSION

Our study show that the expression levels of miR-129-5p and TGF- β 1 protein were higher in patients with POP compared to

control individuals. Previous studies have shown conflicting results regarding collagen levels in POP, with reports of both increases and decreases. It is known that an increase in miR-129-5p levels decreases collagen type I levels, while an increase in TGF- β 1 levels increases collagen type I levels. Our study suggests that the concurrent increase in miR-129-5p and TGF- β 1 levels may result in no net change in collagen type I levels. Additionally, the higher expression of TGF- β 1 in the patient group may be associated with the severity of POP, as TGF- β 1 is more highly expressed in severe cases compared to mild cases.

This study lays the groundwork for future research on POP. Future studies could investigate other lncRNAs that target miR-129-5p to further elucidate their relationship with POP. Additionally, identifying other target genes of miR-129-5p and exploring their roles in POP could provide deeper insights. Investigating other miRNAs that target TGF- β 1 and evaluating their relationships with POP would also be valuable. Future research should focus on identifying molecules that regulate these genes and conducting epigenetic regulation analyses, which could help identify potential biomarkers for POP.

ETHICS

Ethics Committee Approval: The study was approved by the Clinical Research Ethics Committee of Muğla Sıtkı Koçman University (approval number: 19/II, date: 15.09.2021).

Informed Consent: Informed consent was obtained from all participants prior to their inclusion in the study.

FOOTNOTES

Contributions

Concept: A.D.B., B.K., B.S., M.N.A., E.A., Ç.Ö., T.E., Design: A.D.B., B.K., B.S., M.N.A., E.A., Ç.Ö., T.E., Data Collection or Processing: B.K., B.S., M.N.A., E.A., Analysis or Interpretation: A.D.B., Ç.Ö., T.E., Literature Search: A.D.B., B.K., B.S., M.N.A., E.A., Ç.Ö., T.E., Writing: A.D.B., B.K., B.S., M.N.A., E.A., Ç.Ö., T.E.

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

Financial Disclosure: This paper was supported by Muğla Sıtkı Koçman University Research Support and Funding Office Grant No: 21/133/01/3/4.

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Vaginal reconstruction effectiveness and safety: Comparison of anterior versus posterior pelvic floor compartment reinforcement with partially absorbable mini mesh implant in 500 cases of apical pelvic organ prolapse

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Citation: Sumerova N, Neuman J, Fabian-Kovacs R, Shariat SF, Neuman N. Vaginal reconstruction effectiveness and safety: Comparison of anterior versus posterior pelvic floor compartment reinforcement with partially absorbable mini mesh implant in 500 cases of apical pelvic organ prolapse. *Pelviperineology*. 2025;44(1):8-16

ABSTRACT

Objective: To assess the vaginal reconstruction effectiveness and safety, comparing anterior versus posterior pelvic floor compartment reinforcement with partially absorbable mini mesh implant in 500 cases of apical pelvic organ prolapse (aPOP).

Materials and Methods: The seratom PA MR MN® (Serag Wiessner, Naila, Germany) lightweight partially absorbable mini mesh implants were used to treat stage II or greater apical and anterior or posterior pelvic floor compartment prolapse in women with aPOP. The patients were divided into two groups: Those with anterior prolapse predominance, for whom an anterior mini-mesh was implanted, and those with posterior prolapse predominance, for which a posterior mini-mesh was placed. The patients reported their functional outcomes on the first post-operative day (POD1) after surgery, one month, and four months afterwards. Anatomical outcomes were evaluated 1 month after surgery, using POP quantification (POP-Q) staging system. The reports of intra and post-operative (post-op) complications, post-op lower urinary tract symptoms, bowel symptoms and dyspareunia, anatomical and functional cure rates, were tabulated and assessed. The absence of bulging symptoms combined with no protrusion past the hymenal ring upon physical examination along with absence of surgery related adverse events or complications was considered success. Patient was considered satisfied if the operation was successful and subjective expectations were fulfilled at >80%.

Results: The study population (n=500) had a mean age of 62.7±9.4 years. Concomitant anterior and posterior colporrhaphy was performed in all cases. Four hundred fifty-two patients had completed medical files and follow-up (F/U) records, 48 patients (9.6%) had missing files or were lost to F/U. Three hundred ten individuals made up the anterior mini mesh group the first group. 12% of the patients of the first group had prior hysterectomies, 114 patients (36.7%) reported urgency-related stress incontinence (USI). The preoperative mean POP-Q C point was

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Received: 20 September 2024 **Accepted:** 22 January 2025 **Publication Date:** 11 April 2025



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1.1 [0-(+15], the Ba point was 4.01 [(-)2-(+)10], and the Bp was 0.8 [(-)3-(+)10]. 95.2% of the patients were satisfied at the 4-month F/U. Of the 142 patients in the second group, 28 (20%) had a prior hysterectomy, 48 (33.8%) reported USI. The preoperative POP-Q C point mean was 1.66 [0-(+)12], the Ba point was 1.27 [(-)2-(+)3], and the Bp was 1.9 [(-)2-(+)3]. At the 4-month F/U, the patient's satisfaction rating was 88.65%.

Conclusion: Excellent anatomical and quality of life outcomes were seen in patients treated with the seratom PA MR MN® mini-mesh system for POP, according to this current study. Within the 4-months after surgery, there was only one report of mesh exposure that was successfully treated surgically, and no other mesh related complications.

Keywords: Cystocele; mesh; pelvic floor; rectocele

INTRODUCTION

A complex network of muscles, ligaments, and connective tissues supports the reproductive organs of women and keeps them in their anatomical location in the pelvis. When one or more of these support structures are damaged due to aging, childbirth, or elevated intra-abdominal pressure, the condition known as pelvic organ prolapse (POP) occurs. Consequently, the vagina descends and there may be a varying degree of loss of normal pelvic function. About 50% of patients will have a vaginal bulge discovered during a routine gynecological checkup.¹ Urinary tract infections, obstructed defecation, pain, and, less frequently, urine retention can all be consequences of prolapse. Prolapse treatment is determined by the extent of the prolapse, its symptoms, the overall health of the woman, and the surgeon's skill and choice. Treatment options include conservative measures, mechanical treatments, and surgical procedures.^{2,3} The U.S Food and Drug Administration (FDA) revolutionized the surgical treatment of genital prolapse with its recommendation in January 2016 to reclassify surgical mesh for transvaginal repair of POP to the highest risk class of devices (class III). The FDA also directed the manufacturers of all surgical mesh products that remained recommended for POP transvaginal repair to cease marketing and distributing their products in the United States by April 2019.^{4,5} Similarly, guidelines for patient selection and informed consent for vaginal mesh placement have been issued by the International Urogynecological Association.^{6,7} This emphasizes the necessity of modifying implants, which might be accomplished via bettering the dissection process or surgical delivery.⁸ Our major goal was to create an implant that is more ligamentous than fascial, with the hope that it would better mimic the architecture of the connective tissues in the pelvic floor and drastically lower the overall bulk of the mesh implant. This may make it easier to reduce surgical risks related to mesh while maintaining the benefits of reinforcement in pelvic floor reconstruction. Examining the viability, safety, and surgical result of a novel skeletonized mesh fastened to the sacrospinous ligaments for advanced apical pelvic organ prolapse (aPOP) repair, comparing anterior versus posterior mini

mesh placement, was the aim of this study. Efficacy and safety of skeletonized mini mesh implants for advanced POP with 12-month follow-up were published earlier (2013).⁹

MATERIALS AND METHODS

A cohort of women who had significant aPOP and thus undergone POP reconstruction with seratom PA MR MN® mini-mesh reinforcement, was enrolled into this study. All patients gave their informed permission. The requirements of the ethics committee were all met.

The seratom PA MR MN® operations were conducted by an experienced urogynecology surgeon (MN), from October 2013 to December 2015. The study included 500 individuals with substantial POP symptoms who had been diagnosed with aPOP (based on POP-Q). An anterior mini-mesh was implanted for patients with anterior prolapse predominance, while a posterior mini-mesh was put for those with posterior prolapse predominance. The patients were divided into these two groups according with the mini-mesh compartment placement. On first post-operative (POD1), one month, and four months following surgery, the patients reported their functional results. Physical examination for prolapse evaluation was conducted at the 1st post-op month, including office pelvic examination included a maximum Valsalva maneuver and a preoperative, site-specific vaginal examination using a Sim's speculum in the lithotomy position. Using the conventional scoring system of the International Continence Society, we assessed POP-Q. The study's inclusion criteria were POP-Q stage II-IV and agreement to the POP reconstructive operation using the seratom PA MR MN® mini-mesh. This research did not include women with reproductive tract abnormalities, those who had previously pelvic radiation therapy, those who had a history of significant pelvic inflammatory disease or pelvic cancer, or those who were incapable of providing informed consent.

This skeletonized mini-mesh was designed to offer ligamentary qualities and a lower overall mesh mass. Seratom PA MR MN® mini mesh (Serag-Wiessner, Naila, Germany) was utilized. The partially absorbable materials used to make seratom PA MR

MN® mini implants generate a lightweight mesh that loses 50% of its bulk over the course of six months. The central section of the sacrosclastic ligament (SSL) was sutured to the mini-mesh using a specifically designed re-usable suturing device named SERAPRO® RSD-Ney (Serag-Wiessner, Germany). In order to correct both anterior compartment and apical prolapse, the mesh can be introduced through a longitudinal anterior vaginal wall incision and fastened to the SSL, or it can be put through a posterior vaginal wall incision to treat both apical and posterior compartment prolapse. The prolapsed compartment might be supported by the skeletonized mesh once the cystocele, rectocele, or enterocele was decreased by paravesical or pararectal dissection. Generally, the uterus was preserved throughout the study. When necessary, anti-incontinence surgery was added.⁹ As the data was retrieved out of the patient's medical records retrospectively with no active patient's participation. The operations were done in a routine manner, and as the patient's identity was kept discreet, this study was exempt of the need for the ethical committee approval. This study conduction was approved by the Assuta Medical Centers Ethical Committee (ASMC- 0117-23).

Statistical Analysis

Preoperative demographic and clinical characteristics:

General numerical data of the two groups (n=452) were provided with the use of mean, range, and standard deviation (SD). Continuous data such as age, and the discrete data of parity were given in this format. Other general, preoperative data included categorical, nominal information of symptoms and prior surgical procedures. These are displayed using frequency (n) and their respective proportions in percentages (%). The preoperative data belonging to group 1 (n=310) and group 2 (n=142) were displayed in the same way as previously described, with the addition of POP-Q points as numerical, continuous information being also presented with mean, range, and SD.

Post-op outcomes: The postoperative complication data for both group 1 (n=310) and group 2 (n=142) were represented with categorical, nominal data with frequency (n) and proportion in percentage form (%). Anatomical positions of POP-Q points were displayed on a chart using the mean values calculated from the numerical, continuous data collected at every follow-up.

All of the aforementioned data were summarized in a combination-bar chart, where categorical data of symptoms and numerical data of POP-Q points were shown as proportions (%) before and after the seratom procedure, with a trendline displaying the differences (D%) [POP-Q points Ba, C, and Bp were converted into categorical data, based on whether the numerical value would be considered a prolapse or not. e.g., if C >0, it

would be tallied as a data point in the “failure” category and presented on the chart after conversion to proportion (%)].

Statistical tests were used to show these data in a different way categorical data was analyzed with McNemar's test to see if the change in symptom frequency was significant, and the paired numerical data of POP-Q (prior to categorical conversion) was analyzed with a paired t-test to see if the before/after means of the points differed significantly. A two-tailed *p*-value of 0.05 was regarded as significant. In group 1, the outcomes yielded the difference in symptoms of urgency-related stress incontinence (USI), overactive bladder (OAB), and bowel symptoms to be “extremely significant”, dyspareunia as “very”, and pelvic pain as “not significant”. All POP-Q points had “extremely significant” outcomes. In group 2, the difference in symptoms of USI and OAB were “extremely significant”, bowel symptoms “very”, and dyspareunia and pelvic pain as “not significant”. The comparison of means of POP-Q points were “extremely significant” here too.

RESULTS

Five-hundred women were included in the study and had the seratom PA MR MN® lightweight partially absorbable mini-mesh procedure performed between October 2013 and December 2015. Forty-eight patients had missing data or were lost for follow-up. The pre-operative (pre-op) patient characteristics are listed in Table 1 [pre-op demographic and clinical characteristics of the study population with available data (452)]. The mean age

Table 1. Preoperative demographic and clinical characteristics of the study population with available data (452)

Demographic data (mean, range, SD)	Mean	Range	SD
Age	62.7	39.0-88.0	9.4
Parity	3.3	0-13	1.7
Procedures/symptoms (n,%)	n	%	
Previous hysterectomy	64	14%	
Prior TVT	30	6.7%	
Prior colporrhaphy	15	3.3%	
Prior POP reconstruction	19	4.2%	
USI	161	35.9%	
Dyspareunia	43	9.6%	
OAB	104	23.0%	
Bowel symptoms	32	7.1%	
Pelvic pain	14	3.1%	

SD: Standard deviation, TVT: Tension-free vaginal tape, POP: Pelvic organ prolapse, USI: Urgency-related stress incontinence OAB: Overactive bladder

of the study population at the time of the procedure was 62.7 SD ± 9.4 years (range 39-88). Sixty-four (14.3%) patients had a previous hysterectomy and 161 (35.9%) patients had stress urinary incontinence (SUI) symptoms. Three hundred ten individuals made up the anterior prolapse group in the first group. Patients' characteristics are listed in the Table 2 (pre-op demographic and clinical characteristics of the 1 group, total n=310). 11.6% of the patients had prior hysterectomies. Before surgery, 114 (36.8%) patients had SUI. The pre-op POP-Q C point mean was 1.1 (-5-15), the Ba point was 4.0 (-2-10), and the Bp was 0.8 (-3-10) (Table 2). All patients had concomitant colporrhaphy. In 117 (37.7%) of patient's concomitant sub midurethral sling was performed.

Regarding the occurrence of side effects and both subjective and objective success, the post-op, F/U records were good. Data on functional results and POP-Q points C, Ba, and Bp are shown in Table 3 (correlation of pre-op and post-op anatomical and functional results) both before and after surgery. The outcome measures, including urinary, sexual, bowel, and pain symptoms, and the subjective and objective success rates are shown in Figure 1. Significant reductions were observed in symptoms of bladder overactivity, including urgency, frequency, and nocturia, as well as urinary stress incontinence. Constipation, pelvic discomfort, and fecal incontinence were also decreased. Despite a general decline in bowel symptoms and overactive bladder, there were still 11 (3.6%) and 4 (1.3%) *de novo* occurrences, respectively. Of the patients, 18 (5.8%) experienced *de novo* SUI, 10 (3.2%) had *de novo* dyspareunia, and 11 (3.6%) had persistent pelvic discomfort. 95.2% of the patients were satisfied at the 4-month F/U. At the POD pelvic examination, 4 months after the treatment, there was a significant improvement in the anterior defect; the average POP-Q Ba point was -2.7 cm, Bp point was -2.8 cm, and C point was -5.4 cm (Figure 2). There was a significant

positive correlation between anatomical and functional success rate because the correlation coefficient is significantly different from zero ($p < 0.0001$). Higher scores are given to anatomical outcomes, which also lead to functional successes.

Table 2. Preoperative demographic and clinical characteristics of the 1st group, total n=310

Demographic data (mean, range, SD)	Mean	Range	SD
Age	63.6	39-88	8.7
Parity	3.4	0-13	1.8
Prolapse duration	2 years, 11 months	1.2 months-32 years	4.6
Procedures/symptoms (n, %)	n	%	
Previous hysterectomy	36	11.6%	
Prior TVT	16	5.2%	
Prior colporrhaphy	7	2.3%	
Prior POP reconstruction	11	3.5%	
USI	114	36.8%	
Dyspareunia	27	8.7%	
OAB	68	21.9%	
Bowel symptoms	21	6.8%	
Pelvic pain	9	2.9%	
POP-Q (mean range, SD)	Mean	Range	SD
Point C	1.1	0.0-(+)15.0	3.1
Point Ba	4.0	(-)2.0-(+)10.0	1.5
Point Bp	0.8	(-)3.0-(+)10.0	1.7

SD: Standard deviation, TVT: Tension-free vaginal tape, POP: Pelvic organ prolapse, USI: Urgency-related stress incontinence, OAB: Overactive bladder, POP-Q: Pelvic organ prolapse quantification

Table 3. Correlation of preoperative and postoperative anatomical and functional results

	Preoperative			Postoperative			Calculations			
	Before (n)	%	Total (n)	After (n)	%	Total (n)	D (%)	p-values	Test done	Significance
USI	114	36.8	310	18	5.8	309	31.0	<0.0001	McNemar's	Extremely
Dyspareunia	27	8.7	310	10	3.2	309	5.5	0.0021	McNemar's	Very
OAB	68	21.9	310	26	8.4	309	13.5	<0.0001	McNemar's	Extremely
Bowel symptoms	21	6.8	310	4	1.3	309	5.5	0.0005	McNemar's	Extremely
Pelvic pain	9	2.9	310	11	3.6	304	-0.7	0.8137	McNemar's	No
Ba	295	95.2	310	0	0.0	309	95.2	<0.0001	Paired T	Extremely
C	139	45.1	308	1	0.3	309	44.8	<0.0001	Paired T	Extremely
Bp	133	42.9	310	3	1.0	309	41.9	<0.0001	Paired T	Extremely

USI: Urgency-related stress incontinence, OAB: Overactive bladder

The complication rate was less than 2%, including urinary retention in 3 (1.0%) patients and mesh exposure in 1 (0.3%) woman, that was successfully treated surgically, and 6 cases (1.9%) of surgery failure in 4-month follow-up (Table 4).

One hundred forty-two patients were included in the second group, 28 (19.7%) had a prior hysterectomy, 48 (33.8%) reported USI. The preoperative POP-Q C point mean was 1.7 (-5-12), the Ba point was 1.3 (-10-3), and the Bp was 1.9 (-10-3). 100% of patients had concomitant colporrhaphy. In 48 (33.8%) of patient's concomitant sub midurethral sling was performed (Table 5).

Regarding the occurrence of side effects and both subjective and objective success, the post-op follow-up records showed high patients' satisfaction. Data on functional results and POP-Q points C, Ba, and Bp before and after surgery are shown in Table 6. Figure 3 shows the outcome measurements, including bowel, sexual, urine, and pain symptoms, as well as the subjective and objective success rates. Urinary stress incontinence and other symptoms associated with overactive bladder, such as urgency, frequency, and nocturia, were significantly reduced.

Fecal incontinence, pelvic pain, and constipation were also reduced. Despite a general decline in bowel symptoms and overactive bladder, there were still 2 (1.4%) and 14 (9.9%) *de novo* occurrences, respectively. Of the patients, 5 (3.5%) experienced *de novo* SUI, 9 (6.4%) had *de novo* dyspareunia, and 6 (4.2%) had *de novo* pelvic pain. At the 4-month F/U, the patient's satisfaction rating was 88.7%.

At the post-op pelvic examination, four months after the treatment, there was a significant improvement in the anterior defect; the average POP-Q Ba point was -2.1 cm, Bp point was -2.7 cm, and C point was -5.1 cm (Figure 4). There was a significant positive correlation between anatomical and functional success rate, because the correlation coefficient is significantly different from zero ($p < 0.0001$). Functional outcomes are also associated with higher ratings for anatomical results.

The complications rate included defecation difficulties in 1 (0.7%) patient, cystocele occurrence in 12 (8.5%) of patients and 10 cases (7.0%) of surgery failure in 4-month follow-up (Table 7).

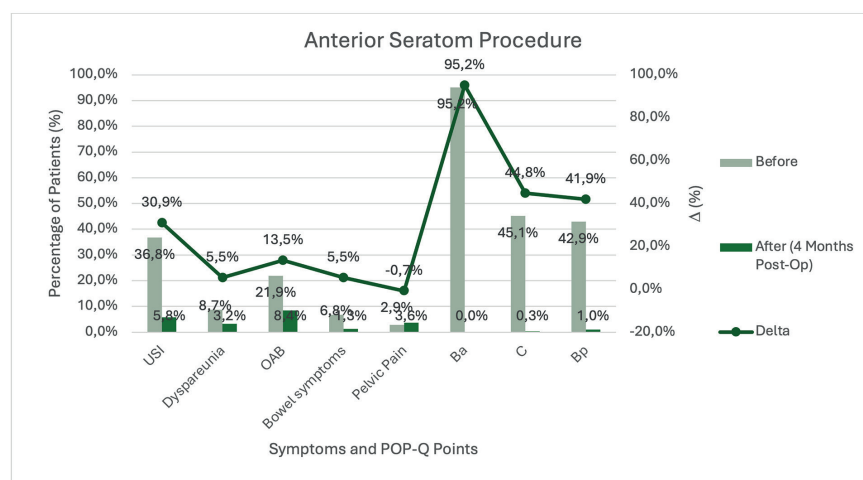


Figure 1. Postoperative outcomes in the 1st group

POP-Q: Pelvic organ prolapse quantification, USI: Urgency-related stress incontinence, OAB: Overactive bladder

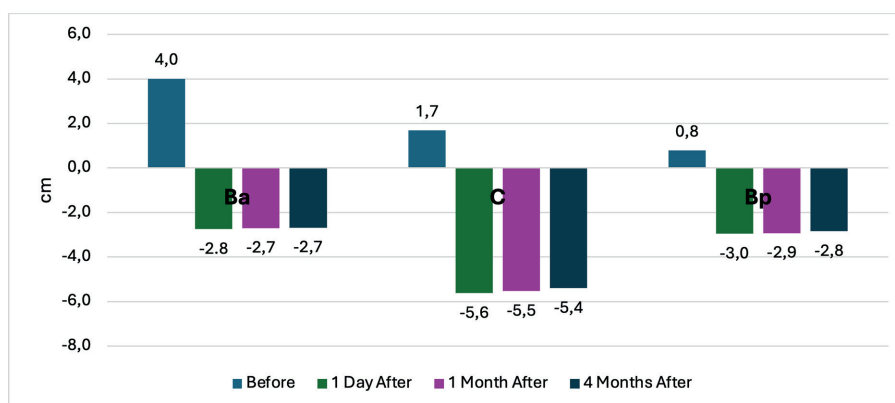


Figure 2. Anatomical results during follow-ups

Table 4. Complications rate, total n=310

Complications 1 day after surgery	n	%
Hemoglobin below 10 gr %	3	1.0
Fever above 38 °C	3	1.0
Hematoma	1	0.3
Urinary obstruction	1	0.3
Bleeding after emesis (treated by hemostatic sutures)	1	0.3
Complications 4 months after surgery	n	%
UTI	3	1.0
Urinary retention	3	1.0
Fever above 38 °C	3	1.0
Reoccurrence	8	2.6
Vaginal pain (>2 according to VAS)	2	0.7
USI	2	0.7
Rectocele	7	2.3
Cystocele	4	1.3
Mesh exposure	1	0.3
Cervical elongation	1	0.3
Constipation	2	0.7
UTI: Urinary tract infection, VAS: Visual analogue scale, USI: Urgency-related stress incontinence		

Table 5. Preoperative demographic and clinical characteristics of the 2nd group, total n=142

Demographic data (mean, range, SD)	Mean	Range	SD
Age	60.9	39-88	10.5
Parity	3.06	1-11	1.5
Prolapse duration	2 years, 3 months	1.2 months-17 years	2.8
Procedures/symptoms (n, %)	n	%	
Previous hysterectomy	28	19.7%	
Prior TVT	14	9.9%	
Prior colporrhaphy	8	5.6%	
Prior POP reconstruction	8	5.6%	
USI	48	33.8%	
Dyspareunia	16	11.3%	
OAB	36	25.4%	
Bowel symptoms	11	7.7%	
Pelvic pain	5	3.5%	
POP-Q (mean, range, SD)	Mean	Range	SD
Point C	1.7	0.0-(+)12.0	3.5
Point Ba	1.3	(-)3.0-(+)10.0	2.3
Point Bp	1.9	(-)3.0-(+)10.0	2.2
SD: Standard deviation, TVT: Tension-free vaginal tape, POP: Pelvic organ prolapse, USI: Urgency-related stress incontinence, OAB: Overactive bladder, POP-Q: Pelvic organ prolapse quantification			

Table 6. Correlation of the preoperative and postoperative anatomical and functional results

	Preoperative			Postoperative			Calculations			
	Before (n)	%	Total (n)	After (n)	%	Total (n)	D (%)	p-values	Test done	Significance
USI	48	33.8	142	5	3.6	141	30.3	<0.0001	McNemar's	Extremely
Dyspareunia	16	11.3	142	9	6.4	141	4.9	0.1904	McNemar's	No
OAB	36	25.4	142	14	9.9	141	15.4	0.0020	McNemar's	Very
Bowel symptoms	11	7.8	142	2	1.4	141	6.3	0.0077	McNemar's	Very
Pelvic pain	5	3.5	142	6	4.2	142	-0.7	1.0	McNemar's	No
Ba	73	51.4	142	11	7.8	141	43.6	<0.0001	Paired T	Extremely
C	76	53.5	142	1	0.7	141	52.8	<0.0001	Paired T	Extremely
Bp	82	57.8	142	1	0.7	141	57.0	<0.0001	Paired T	Extremely

USI: Urgency-related stress incontinence, OAB: Overactive bladder

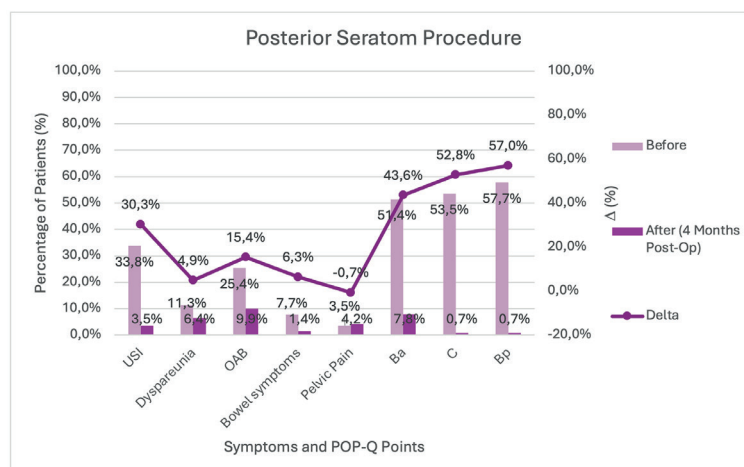


Figure 3. Postoperative outcomes in the 2nd group

POP-Q: Pelvic organ prolapse quantification, USI: Urgency-related stress incontinence, OAB: Overactive bladder

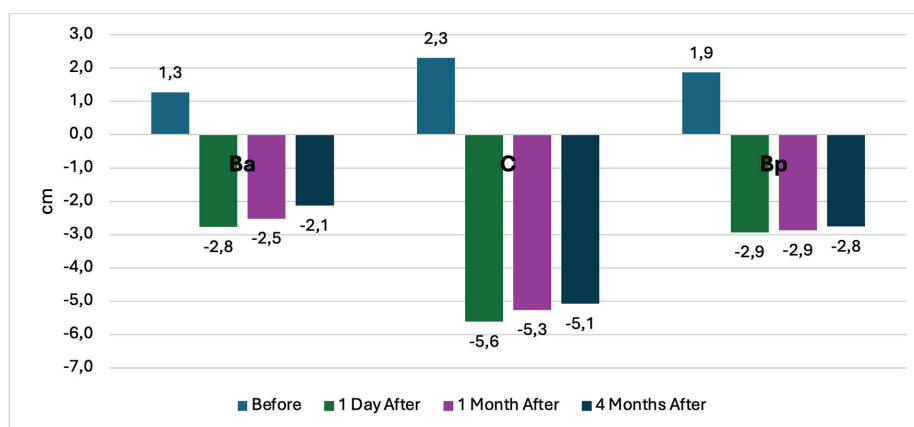


Figure 4. Anatomical results during follow-ups in the 2nd group

Table 7. Complications rate, total n=142

Complications 1 day after surgery	n	%
Low hemoglobin below 10	2	1.4
Vaginal bleeding-moderate	1	0.7
Fever above 38 °C	1	0.7
Complications 4 months after surgery	n	%
Cystocele	12	8.5
Thigh pain (> 2 according to VAS)	1	0.7
Cervical elongation	1	0.7
USI	2	1.4
Exposure of TVT	1	0.7
OAB	1	0.7
Digital assistance during defecation	1	0.7
Fever above 38 °C	2	1.4
Failure	10	7.0

VAS: Visual analog scale, USI: Urgency-related stress incontinence, TVT: Tension-free vaginal tape, OAB: Overactive bladder

DISCUSSION

The lifetime probability of women requiring surgery for pelvic floor disorders varies from 6% to 18%. Many women will not respond well to conservative treatments (such as pessaries or pelvic floor muscle training) or would want more conclusive treatment. Regrettably, following native tissue healing, recurrence rates are estimated to reach over 40%, with the anterior compartment accounting for around 13% of recurrences. While some research has demonstrated that mesh enhanced repairs in the anterior compartment yield superior subjective and objective results than native tissue repair, other studies have revealed that transvaginal mesh is associated with a greater risk of problems, including mesh exposure and dyspareunia. Compared to the more recent generation of transvaginal mesh, several of the meshes utilized in these studies were denser and bigger.¹⁰ Low mesh exposure rates have been found in randomized controlled studies, with even lower reoperation rates of 6% or below.^{11,12} Vaginal reconstruction using mesh is a very controversial procedure. The FDA publications express concern about possible

significant consequences and the lack of evidence supporting better subjective outcomes related to transvaginal mesh insertion for POP. Many surgeons have stopped using mesh in POP repair as a consequence. Nevertheless, rather than coming from specific long-term research, a large number of these issues are the result of voluntary reports made through the FDA's manufacturer and user facility device experience database.¹³ For patients and surgeons to make informed decisions, public objective and subjective data must be made available.⁹

In response to previous suggestions, we designed a mini lightweight implant that is more ligamentous than fascial made to resemble the natural structure of the connective tissues in the pelvic floor in order to reduce the mesh implant's overall size and foot print, yet to provide reinforcement in pelvic floor restoration while lowering the surgical risks associated with mesh. This study results show the feasibility, safety, and good surgical objective and subjective outcome of this new skeletonized mesh attached to the sacrospinous ligaments for advanced POP repair. No significant difference was noted when comparing mini-mesh placement with the anterior or posterior pelvic floor compartments. Hence, we conclude that vaginal implantation of the seratom PA MR MN® lightweight partially absorbable mini-mesh for the reinforcement of advanced POP reconstruction is a good treatment option, and that the surgeon might chose to implant it anteriorly or posteriorly. All surgical operations in our research were carried out by the highly experienced surgeon in accordance with the FDA's recommendations. However, the fact that the same physician (MN) conducted every surgical procedure is also a research limitation, together with the retrospective nature and shortF/U of the study. Nevertheless, the strengths of the study are the large group, extensive data collection, and the assessment of self-reported patient-centered outcomes. Furthermore, we aim to have provided some overview into how mesh-related problems can be decreased with skeletonized and reduced mesh surgery. When patients with different stages of POP were treated with a skeletonized and reduced mesh system, the current study demonstrated extremely low rates of mesh-related complications while guaranteeing good results for both anatomical findings and quality of life. Within the 4 months following surgery, there was only one report of mesh exposure.

CONCLUSION

This recent study reports excellent anatomical and quality of life short term results in women treated with the seratom PA MR MN® mini-mesh device for POP-both anterior and posterior compartments. There was just one case of mesh exposure in the four months follow-up after surgery, and it was successfully

treated surgically. No other mesh-related complications were reported.

ETHICS

Ethics Committee Approval: This study conduction was approved by the Assuta Medical Centers Ethical Committee (ASMC- 0117-23).

Informed Consent: All patients gave their informed permission.

FOOTNOTES

Contributions

Surgical and Medical Practices: M.N., Concept: N.S., S.F.S., Design: N.S., S.F.S., Data Collection or Processing: J.N., R.F.K., Analysis or Interpretation: N.S., Literature Search: N.S., Writing: N.S.

Conflict of Interest: Authors N.S., J.N., R.F. have nothing to declare. M.N. receives royalties from Serag-Wiessner.

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

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Evaluation of overactive-bladder syndrome's impact on woman sexual function

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Citation: Atlihan U, Öztürk B, Yazıcı Tekeli E, Uysal D. Evaluation of overactive-bladder syndrome's impact on woman sexual function. Pelviperrineology. 2025;44(1):17-23

ABSTRACT

Objective: To evaluate the effects of overactive-bladder (OAB) syndrome on sexual-function in women.

Materials and Methods: Evaluation of 101 healthy participants and 74 patients diagnosed with OAB syndrome were conducted retrospectively from January 2020 to January 2024. Age, body mass index, gravida, smoking-status, parity, alcohol status, education-level and delivery method of all patients were evaluated retrospectively. The pelvic organ prolapse/urinary incontinence sexual-questionnaire, the female-sexual function-index (FSFI), urogenital-distress inventory-short-form (UDI-6), and international-consultation-on-incontinence-questionnaire-overactive-bladder-module (ICIQ-OAB) measurements of all patients were evaluated retrospectively.

Results: The FSFI score was significantly lower (19.2 ± 1.8) in the OAB syndrome-group in comparison with the control-group (23.1 ± 2.1) ($p < 0.001$). The PISQ-score was significantly lower (33.6 ± 4.1) in the OAB syndrome-group in comparison with the control-group (35.8 ± 4.2) ($p = 0.042$). The UDI-6 score was significantly higher (13.4 ± 2.4) in the-OAB syndrome group in comparison with the control-group (8.8 ± 1.2) ($p < 0.001$). The ICIQ-OAB score was significantly greater (10.4 ± 2.9) in the OAB syndrome-group in comparison with the-control group (9.5 ± 2.4) ($p = 0.028$).

Conclusion: Because of the significant effects of OAB syndrome on females' sexual-health, we recommend medical professionals to focus more on sexual issues while treating people with OAB-syndrome. Prospective and large-scale cohort studies are needed to determine if sexual dysfunction contributes to or results from OAB syndrome.

Keywords: FSFI; PISQ; sexual function; overactive-bladder syndrome

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Received: 27 December 2024 **Accepted:** 24 March 2025 **Publication Date:** 11 April 2025



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INTRODUCTION

Overactive-bladder (OAB) syndrome is a condition that generally consists of a mix of symptom-including urine-frequency and nocturia, regardless of urge-incontinence.¹ Prior to the beginning of urge incontinence, OAB syndrome may produce frequent urination and a sense of urgency owing to detrusor overactivity. Because OAB syndrome impairs a person's capacity of working, travelling, sleeping, exercising, interacting with others, and forming personal connections, it dramatically lowers quality of life.^{2,3} It has been demonstrated that OAB syndrome significantly affects a patient's everyday functioning and health-related-quality-of-life (HRQL).^{4,5} OAB syndrome affects between 7.7% and 31.3% of adult women. Additionally, OAB syndrome is a prevalent, upsetting illness that has a detrimental effect on quality-of life (QoL). Due to underreporting, the illness is frequently undertreated.^{6,7} Due in part to variations in symptom evaluation, populations questioned, data collection techniques, and criteria used to identify OAB syndrome, estimates-of the incidence and effect of OAB syndrome on QoL fluctuate greatly.⁸ Up to 33 million Americans are thought to be afflicted with OAB syndrome.⁹ Up to 20% of people worldwide suffer from OAB syndrome.^{10,11} According to earlier reports, women seeking therapy for issues related to the lower urinary system frequently have sexual dysfunction.¹² Female-sexual dysfunction is a risk factor for women due to physiological, iatrogenic, and psychological-causes. Menopause, smoking, spinal cord injuries, abdominal surgery (e.g., hysterectomy), and some drugs (e.g., birth control-pills, antipsychotics, antihypertensives, antidepressants, etc.) are examples of physiological and iatrogenic variables. Anxiety, sadness, a poor body image, a record of emotional or physical abuse, and stress are examples of psychological components.¹³ There are less options for treatment for female sexual dysfunction (FSD), despite the fact that reported estimations of sexual dysfunction in females are greater than in males (43% vs. 31%).¹⁴ The World Health Organization and the diagnostic and statistical manual of mental-disorders^{15,16} classify FSD as a disease of arousal, orgasm, pain (dyspareunia and vaginismus), and desire (hypoactive sexual-desire, lack of sexual-desire). FSD may also occur as a result of OAB syndrome.³ OAB syndrome is categorized by the International Continence Society as a group of symptoms that may indicate lower-urinary tract dysfunction. Urinary-urgency, frequency, and urge incontinence are signs of OAB syndrome.¹⁷ Numerous research has assessed the effect of OAB syndrome symptoms on women's sexual function. The diagnosis of FSD is not universally accepted, and the findings of several investigations cannot be compared.¹⁸⁻²² Several researchers have found that OAB syndrome has a greater impact

on-sexual function than urodynamic stress-incontinence.^{22,23} The aim of our research was to make an evaluation regarding the-effects of OAB syndrome on sexual-function in females.

MATERIALS AND METHODS

Our research was constructed as a retrospective-cohort-study. The research was designed according to the Helsinki Declaration and informed consent forms were received from all patients. The study was initiated after obtaining Ethics Committee of Başkent University approval dated 12/12/2024 and numbered KA24/406. from the hospital ethics committee. In our study, 74 patients diagnosed with OAB syndrome, and 101 healthy patients were evaluated retrospectively between January 2020 and January 2024. Data from a total of 185 patients diagnosed with OAB syndrome and those in the healthy group were evaluated retrospectively. Age, body mass index (BMI), gravida, parity, smoking-status, alcohol status, education level and delivery method of all patients were analyzed retrospectively. Criteria for inclusions were determined as patients giving consent to take part in the research, presence of OAB syndrome, active sexual life. Exclusion-criteria were determined as having a record-of pelvic surgery, having a record of narcotic-drug or antidepressant use in the patient or partner, having a record of diabetes, hypertension and heart disease in the participant or partner, and having sexual-problems (premature ejaculation and impotence) in the partner. The pelvic-organ-prolapse/urinary-incontinence-sexual-questionnaire (PISQ-12), the female-sexual function-index (FSFI), urogenital-distress inventory-short form (UDI-6), and international-consultation-on incontinence-questionnaire-overactive-bladder-module (ICIQ-OAB) measurements of all patients were evaluated retrospectively. The abbreviated version of the pelvic organ prolapse/urinary-incontinence sexual-questionnaire serves as the basis for the PISQ-12 score. Clinicians and other medical professionals who are interested in evaluating the sexual function of females with pelvic organ prolapse or urine incontinence are the target audience. There are twelve items on the score, all of which are questions on facets of sexual life. The participant is asked to reflect on their sexual orientation throughout the last six months. There are several response options for each of these items, and they are weighed differently based on their significance.²⁴⁻²⁶ The 19-item FSFI questionnaire assesses six primary factors: Lubrication, orgasm, pleasure, pain/discomfort, sexual desire, and sexual arousal. This scale has a maximum raw value of 95, a minimum raw value of 4, a maximum value of 36, and a minimum value of 2 once the coefficients are multiplied. The complete scale was scored using the following effect coefficients: 0.4 for satisfaction, iorgasm, and pain/discomfort; 0.3 for sexual-arousal and

lubrication; and 0.6 for sexual desire. Sexual dysfunction was characterized as an FSFI score of less than 26.55.^{27,28} The effect of urogenital-symptoms brought on by female incontinence on life is the main emphasis of the UDI-6 questionnaire. The most commonly used questionnaire to measure QoL is the pelvic-floor impact-questionnaire (PFIQ). The UDI-6 has six questions referring to different symptoms of urogenital distress. The score ranges between 0 and 100. The score is interpreted as follows: The higher the score, the more disabled the person. All of the scores are added together to determine the final UDI-6 score, and the average value is then obtained by dividing the total by 6, and then multiplying by 25 to reach the scale score. In cases where items are left unanswered, only the average of the answered questions is calculated.^{29,30} The ICIQ-OAB-questionnaire is used in clinical practice and research worldwide to assess OAB syndrome and its associated effects on males' and females' QoL and treatment outcomes. Urinary-frequency, urgency, urge-incontinence, and nocturia-symptoms can all be measured with the ICIQ-OAB, which is based on the thoroughly validated ICS male and BFLUTS-questionnaires. total score between 0 and 16, where higher numbers denote more severe symptoms. Bother scales show the effect of certain symptoms on the patient but are not included in the final score.^{31,32}

Statistical Analysis

Statistical-analysis was conducted by-utilizing the SPSSx26.0 (IBM-Inc.-Chicago-IL-USA). Continuous variables were employed to calculate descriptive statistics including mean-standard deviation, and range values. The normality evaluation of the-distribution was conducted with the Kolmogorov-Smirnov test. The Independent t-test was employed to analyze by comparing the pair groups in the study data evaluation, and the qualitative data were compared using the chi-square test. The 95% confidence interval was employed to analyze the results. A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

The mean age of the women included in the research was 37.3 ± 7.9 , and the BMI score was 24.5 ± 4.5 kg/m². The mean parity of the women were 2.1 ± 1.2 , and the mean gravidity was 2.6 ± 1.2 . Among the participants included in the study, 74 (42.2%) patients were smokers, 41 (23.4%) patients were alcohol users, and 94 (53.7%) patients were university graduates. No significant difference was found between the groups with regard to demographic characteristics (Table 1).

The sexual desire score was significantly lower (3.3 ± 0.4) in the OAB syndrome-group in comparison with the control-group (4.1 ± 0.4) ($p < 0.001$). The sexual arouse score was significantly

lower (3.2 ± 0.3) in the OAB syndrome group compared with the control-group (3.9 ± 0.3) ($p < 0.001$). The vaginal moisturizing score was significantly lower (3.2 ± 0.3) in the OAB syndrome group compared with the control-group (3.9 ± 0.3) ($p < 0.001$). The pain score was significantly lower (3.3 ± 0.3) in the OAB syndrome-group compared with the control-group (4.1 ± 0.3) ($p < 0.001$). The sexual satisfaction-score was significantly lower (3.1 ± 0.3) in the OAB syndrome-group in comparison with the control-group (3.9 ± 0.4) ($p < 0.001$) (Table 2).

The physical factor score was significantly lower (14.8 ± 1.2) in the OAB syndrome-group in comparison with the control-group (16.3 ± 1.3) ($p = 0.038$) (Table 3).

The-FSFI value was significantly lower (19.2 ± 1.8) in the OAB syndrome-group compared with the control-group (23.1 ± 2.1)

Table 1. Comparison of demographic characteristics according to the presence of OAB syndrome

	Control group n=101	OAB syndrome group n=74	<i>p</i>
	Mean \pm SD		
Age (year)	37.2 ± 7.5	37.6 ± 8.1	0.28
BMI (kg/m ²)	24.4 ± 4.5	24.6 ± 4.6	0.34
Gravidity	2.6 ± 1.2	2.7 ± 1.2	0.24
Parity	2.1 ± 1.1	2.1 ± 1.2	0.66
Smoking (n-%)	41 (40.5%)	33 (44.5%)	0.16
Alcohol (n-%)	22 (21.7%)	19 (25.6%)	0.28
Education (n-%)			0.36
High school	45 (44.5%)	36 (48.6%)	
University	56 (55.5%)	38 (51.4%)	

OAB: Overactive bladder, BMI: Body mass index, SD: Standard deviation

Table 2. Comparison of FSFI measurements according to the presence of OAB syndrome

	Control group n=101	OAB syndrome group n=74	<i>p</i>
	Mean \pm SD		
Sexual desire	4.1 ± 0.4	3.3 ± 0.4	<0.001
Sexual arousa	3.9 ± 0.3	3.2 ± 0.3	<0.001
Vaginal moisturizing	3.9 ± 0.3	3.2 ± 0.3	<0.001
Orgasm	3.2 ± 0.4	3.1 ± 0.2	0.18
Pain	4.1 ± 0.3	3.3 ± 0.3	<0.001
Sexual satisfaction	3.9 ± 0.4	3.1 ± 0.3	<0.001
Total score of sexual function	23.1 ± 2.1	19.2 ± 1.8	<0.001

FSFI: Female sexual function index, OAB: Overactive bladder, SD: Standard deviation

Table 3. Comparison of PISQ measurements according to the presence of OAB syndrome

	Control group n=101	OAB syndrome group n=74	p
	Mean \pm SD		
Behavior and emotions	10.9 \pm 1.3	10.3 \pm 1.1	0.11
Physical factor	16.3 \pm 1.3	14.8 \pm 1.2	0.038
Factors related to sex partner	8.6 \pm 1.5	8.5 \pm 1.6	0.76
Total score	35.8 \pm 4.2	33.6 \pm 4.1	0.042

PISQ: Pelvic organ prolapse/urinary incontinence sexual questionnaire, OAB: Overactive bladder, SD: Standard deviation

Table 4. Comparison of sexual index measurements according to the presence of OAB

	Control group n=101	OAB syndrome group n=74	p
	Mean \pm SD		
FSFI	23.1 \pm 2.1	19.2 \pm 1.8	<0.001
PISQ	35.8 \pm 4.2	33.6 \pm 4.1	0.042
UDI-6	8.8 \pm 1.2	13.4 \pm 2.4	<0.001
ICIQ-OAB	9.5 \pm 2.4	10.4 \pm 2.9	0.028

OAB: Overactive bladder, FSFI: Female sexual function index, PISQ: Pelvic organ prolapse/urinary incontinence sexual questionnaire, UDI-6: Urogenital distress inventory short form, ICIQ-OAB: International consultation on incontinence questionnaire-overactive bladder module, SD: Standard deviation

($p<0.001$). The PISQ-score was significantly lower (33.6 \pm 4.1) in the OAB syndrome-group compared with the control-group (35.8 \pm 4.2) ($p=0.042$). The UDI-6 score was significantly higher (13.4 \pm 2.4) in the-OAB syndrome-group compared with the control-group (8.8 \pm 1.2) ($p<0.001$). The ICIQ-OAB score was significantly higher (10.4 \pm 2.9) in the OAB syndrome group in comparison with the control-group (9.5 \pm 2.4) ($p=0.028$) (Table 4).

DISCUSSION

This research analyzed the impact of OAB-syndrome on general and sexual QoL in sexually active females of reproductive age using validated questionnaires such as FSFI, PISQ, UDI-6 and ICIQ-OAB. Considering our results, general QoL and sexual health was found to be significantly influenced by OAB-syndrome. In this research, FSFI value was significantly lower in OAB syndrome group compared to control group. PISQ value was significantly lower in OAB syndrome group compared to control-group. UDI-6 value was significantly greater in OAB syndrome-group compared to control-group. ICIQ-OAB value was significantly greater in OAB syndrome-group compared to control-group. In

our study, no significant difference was found among the groups when evaluated with regard to age, BMI, number of births and education level. In addition to the severity of the condition, physiological, psychological, or socioeconomic variables may also have an impact on how much OAB syndrome symptoms impair sexual function. Certain bladder symptoms might make people feel embarrassed, which lowers their desire for sex. The research has contradictory information on the connection between OAB syndrome or urine incontinence and sexual dysfunction.^{20,33} Nonetheless, research indicates that symptoms of OAB syndrome negatively affect sexual function and other aspects of HRQL.^{34,35} Sexual dysfunction is an evolving multidisciplinary problem linked with a variety of biological, medical, and psychological elements. The urogynecological components of sexual dysfunction are gaining attention. According to reports, between 0.6% and 64% of females who report having lower urinary tract symptoms also have sexual dysfunction.^{12,36} A variety of factors other than OAB syndrome may contribute to sexual dysfunction, such as age, hormonal status, parity, pelvic organ prolapse, and previous-surgery for urinary-incontinence and genital-prolapse. Thyroid gland function and chronic diseases such as diabetes-mellitus, and sociocultural-determinants including relationship duration, education, and employment-status may play a role, as well.³⁷⁻³⁹ Few studies have examined the effect of OAB syndrome on patient desire in sexual-activity, despite prior research evaluating the association between pelvic health (e.g., urine-incontinence, pelvic-organ-prolapse) and sexual dysfunction.^{21,22} Because the cause of urinary incontinence during intercourse is not clear, the most widely accepted theory is that during sexual activity, detrusor activity increases due to mechanical pressure. Penetration has been found to be a contributing factor to urine incontinence during sexual activity in individuals with stress urinary incontinence, whereas orgasm has been found to be a contributing factor in individuals with OAB syndrome.^{40,41} Therefore, there are publications in the literature supporting the negative impact of sexual function in females with bladder-dysfunction.^{13,42} Due to OAB syndrome, urine leaks are erratic and inevitable, which may be upsetting and uncomfortable. Females having the syndrome often complain of having to urinate or use the restroom frequently during sexual activity.²¹ Urine leakage during orgasm, which is a frustrating situation for the patient, is common in females with urinary incontinence. It can also cause some women to feel dirty and therefore unpleasant. Laumann et al.¹⁴ reported that urinary tract symptoms contribute to arousal and pain disorders in women. Urinary incontinence may have a complex link with hypoactive sexual drive. Sexual desire can be eliminated, and dissatisfaction and melancholy can result from a progressive

loss of self-esteem and self-confidence due to a fear of leaking during sexual activity or orgasm and discomfort at the passage of urine.³⁸ It is challenging to evaluate sexual health, especially when it is linked to incontinence. Patients are not allowed to voice their ideas about how OAB syndrome or urine incontinence affects sexual health. Self-administered surveys offer a way to get data on sexual health without the possible embarrassment and response bias that come with questions given by interviewers. The multifaceted character of female sexual function is addressed by the FSFI, a helpful instrument created as a clinical trial evaluation tool.²⁷ In our study, FSFI score, and subgroups were significantly lower in OAB syndrome-group in comparison with control-group. On the other hand, Tannenbaum et al.⁴³ did not associate urinary frequency alone with any domain on the FSFI. Zahariou et al.⁴⁴ made a comparison between FSFI and OAB syndrome diagnosed by urodynamic and International Continence Society criteria. Shindel et al.⁴⁵ evaluated the FSFI together with an OAB-syndrome-questionnaire. Musco et al.⁴⁶ conducted pilot research in females undergoing percutaneous-tibial nerve-stimulation and found no linkage between OAB-syndrome severity and different FSFI-score grades. Because the PISQ has undergone extensive reliability and validity tests and is focused on evaluating sexual function in females with pelvic-floor diseases, it is a better questionnaire than general ones.²⁵ In females having pelvic-floor problems, the PISQ has been demonstrated to be a valid and consistent-instrument for evaluating sexual-function.⁴⁷ In the study by Ergenoglu et al.,⁴⁸ the PISQ-12 physical score and the first section of the-OABq-SF showed a modest connection, indicating the severity of the illness. In this current research, PISQ value was significantly lower in OAB syndrome group in comparison with control-group. In the study by Juliato et al.,⁴⁹ a significant correlation was found between the severity of symptoms in ICIQ-OAB and FSFI scores only in the postmenopausal-group, especially total score, orgasm, pain, lubrication, and arousal. In our study, no correlation analysis was performed between ICIQ-OAB and FSFI scores. However, FSFI score was seen to be significantly lower and ICIQ-OAB score was seen to be significantly higher in the OAB syndrome group.

Study Limitations

The factors affecting sexual function are quite diverse and study populations should take this diversity into account. Evaluations based on a single variable may not be comprehensive. The retrospective approach in this current research and the small-sample-size may be considered as limitations. The criteria for determining sexual dysfunction were assessed by self-reporting patients via a questionnaire and were not founded on objective

measures or physical examinations, which may be considered as another limitation.

CONCLUSION

Because of the significant impact of OAB syndrome on females' sexual health, we recommend medical professionals to focus more on sexual problems while treating individuals with OAB syndrome. The high prevalence of sexual dysfunction may be attributed to the fact that all cases with severe OAB syndrome are referred to our facility. Prospective and large-scale cohort studies are needed to evaluate if sexual dysfunction contributes to or results from OAB syndrome.

ETHICS

Ethics Committee Approval: Ethics committee approval was obtained from the Clinical Research Ethics Committee of Başkent University Faculty of Medicine before starting the study (date: 12/12/24, number: KA24/406).

Informed Consent: Signed consent was obtained from all participants.

FOOTNOTES

Contributions

Surgical and Medical Practices: U.A., Concept: B.Ö., Design: E.Y.T., Data Collection or Processing: D.U., Analysis or Interpretation: U.A., Literature Search: B.Ö., E.Y.T., Writing: U.A., D.U.

DISCLOSURES

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

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

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A prospective study on the effects of total abdominal intrafascial hysterectomy for benign indications on patients' pelvic floor functions

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Citation: Arslaner MO, Kasap B. A prospective study on the effects of total abdominal intrafascial hysterectomy for benign indications on patients' pelvic floor functions. Pelviperineology. 2025;44(1):24-30

ABSTRACT

Objective: The aim of this study was to evaluate the effects of total abdominal intrafascial hysterectomy operations performed for benign indications on patients' pelvic floor functions at the 3rd and 6th months postoperatively.

Materials and Methods: This study was conducted between May 2022 and November 2022 at the Obstetrics and Gynecology Clinic of Muğla Sıtkı Koçman University Training and Research Hospital. A total of 50 patients who underwent total abdominal intrafascial hysterectomy for benign indications were included in the study. The patients were administered the pelvic floor distress inventory-20 (PFDI-20) which includes pelvic organ prolapse distress inventory-6 (POPDI-6), urinary distress inventory-6 (UDI-6) and colorectal-anal distress inventory-8 (CRADI-8) questionnaires both before the operation and at the 3rd and 6th months postoperatively.

Results: In the study investigating the effects of the total abdominal intrafascial hysterectomy technique on the pelvic floor functions of the patients, there was a statistically significant decrease in the POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores at the 3rd month postoperatively compared to the preoperative period ($p < 0.001$ for all). At the 6th month postoperatively, there was also a statistically significant reduction in POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores compared to the preoperative period ($p < 0.001$, $p = 0.001$, $p < 0.001$, $p < 0.001$, respectively). A significant positive correlation was found between patients' body mass index and PFDI-20 scores.

Conclusion: After total abdominal hysterectomy operations performed using the intrafascial technique, a significant decrease in PFDI-20 scores was observed compared to preoperative scores. When hysterectomy operations are performed using the intrafascial technique, it preserves the pelvic floor functions due to the protective nature of the fascia, ligaments, muscles, and nerves.

Keywords: Cystocele; enterocele; pelvic floor; posterior syndrome; rectocele; urinary stress incontinence

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Received: 22 December 2024 **Accepted:** 07 April 2025 **Publication Date:** 11 April 2025



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INTRODUCTION

Common pelvic floor problems, while not life-threatening, affect psychological, social, and physical well-being, leading to limitations in a woman's work, family, and sexual life, thereby negatively impacting her quality of life. Therefore, treating pelvic floor dysfunction (PFD) will address not only the physical aspects of the problem but also its social and psychological dimensions. For this reason, understanding the pelvic floor correctly is crucial for grasping the problem accurately and applying the appropriate treatment method.¹

The pelvic organs -rectum, vagina, and bladder-lack a natural shape or resistance. Ligaments, muscles, and fascias form a musculo-elastic system that gives shape and function to the pelvic floor organs. These organs have functions such as urination, defecation, and coitus.² Peter E. Papa Petros proposed the "integral theory" which approaches the pelvic floor as a whole.³ According to the "integral theory", the normal functioning of pelvic floor structures requires the presence of normal anatomical components such as bones, muscles, ligaments, and fasciae, along with the healthy functioning of the central and peripheral nervous systems that innervate these structures. PFD is often associated with pelvic organ prolapse (POP), urinary incontinence, urination-defecation issues, sexual problems, and chronic pain. Studies have also shown that hysterectomy operations negatively impact pelvic floor functions.

Hysterectomy, one of the oldest surgical procedures dating back to the 1840s, is currently one of the most frequently performed gynecological operations. Since most hysterectomies are performed to improve the quality of life rather than to address life-threatening conditions, it is understandable that the associated morbidities should be emphasized. Hysterectomy is considered a safe procedure with a mortality rate of less than 0.1%.^{4,5}

Clinicians have long suspected a link between hysterectomy and PFD, but despite decades of research, this remains a highly debated topic.⁶⁻⁸ One reason for the debate is that the literature is filled with conflicting studies that complicate the determination of whether a connection truly exists. Post-hysterectomy PFD has been associated with nerve damage; however, this is often overlooked in the context of simple hysterectomy because the pelvic somatic nerves are located too laterally, and patients typically do not present classic symptoms of autonomic nerve damage. Traditional beliefs suggest that pelvic autonomic nerve damage manifests as bladder and bowel dysfunction, such as urinary urgency and fecal incontinence. However, recent literature indicates that smooth muscle also plays a role in the musculo-fascial support of the pelvic floor, supporting the likelihood that autonomic damage may present in more varied ways

than previously believed.^{9,10} Additionally, the risk of autonomic nerve injury is higher than its somatic counterparts, as they run medially along the surgical planes of hysterectomy around the cervix. Thus, there is a risk of autonomic nerve damage during hysterectomy procedures. While there are studies indicating that non-intrafascial (extrafascial hysterectomy, radical hysterectomy, etc.) hysterectomy operations do not lead to PFD, many studies exist that demonstrate they can cause PFD.^{11,12}

We planned this study to investigate the hypothesis that intrafascial hysterectomy operations, unlike extrafascial hysterectomy operations, do not lead to PFD due to the preservation of pelvic anatomical structures (fasciae, ligaments, muscles, etc.) and peripheral nerve fibers.

MATERIALS AND METHODS

All processes related to this thesis study were approved by the Clinical Research Ethics Committee of Muğla Sıtkı Koçman University Rectorate on May 11, 2022, with decision number 9/XI. All procedures conducted in the study adhered to the ethical standards of the Institutional and/or National Research Committee and complied with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Patients scheduled for total abdominal intrafascial hysterectomy for benign indications in our clinic were informed about the study's purpose and design. Those who volunteered to participate were included in the study after obtaining written informed consent. Preoperative cervical cytological screenings were performed on the patients. Patients planned for vaginal hysterectomy, total laparoscopic hysterectomy, those with malignant indications, those with urinary tract infections, those with known neurological diseases (such as multiple sclerosis), and those who had previously undergone pelvic floor surgery, such as surgery for POP or urinary system procedures, were excluded from the study. Patients who sustained urinary or gastrointestinal system injuries during the intrafascial hysterectomy were also excluded from the study. Information on volunteers' age, body mass index (BMI), obstetric history, medical history, previous surgeries, indication for hysterectomy, and preoperative complete blood count and biochemical values was recorded. Standard anesthesia was applied to all volunteers. All volunteers underwent standard laparotomic hysterectomy (total abdominal intrafascial hysterectomy). A Foley catheter was placed in the bladder before the operation and removed on the first postoperative day. Volunteers were evaluated using prepared survey forms [(pelvic floor distress inventory-20 (PFDI-20)] before the operation and at the 3rd and 6th months postoperatively.

The PFDI-20 consists of 20 questions and is a scale rated at level A for the assessment of PFD by the International Consultation on Incontinence group.¹²

Surgical Technique

Intrafascial hysterectomy is a procedure in which the cervix is removed while preserving the uterosacral ligaments. The hysterectomy begins with the cutting of the round ligament. The posterior peritoneum is then incised parallel to the infundibulopelvic ligament. If the adnexa are to be removed, the infundibulopelvic ligament is cut; if not, the utero-ovarian ligament is severed. Subsequently, the anterior peritoneum is dissected from lateral to medial to allow for bladder mobilization.

To confirm the uterine artery, the uterus is pulled upward using forceps for safe preparation, and the connective tissue around the cervix is cut with lateral traction of the peritoneum. While the original Aldridge procedure involves directly clamping the parametrial tissue beneath the internal cervical os, Noda's method places the parametrial clamps at the mid-position between the internal and external cervical os. Additionally, when the parametrial tissue, including the longitudinal muscle layer of the uterine cervix, is appropriately clamped, it facilitates the intrafascial approach.

Bilateral parametrial tissues are cut with scissors, including a part of the longitudinal muscle layer of the cervix, and then sutured with slowly absorbable suture material. After the bilateral parametrial tissues are secured, the bladder is checked to ensure that it is properly dissected beneath the position where the parametrial tissue was secured. With adequate traction on the uterus, the ends of the cut longitudinal muscle layer of the cervix are brought together using a scalpel or electrocautery. The uterus is gradually retracted by cutting the longitudinal muscle layer, especially as the uterosacral ligament is severed, with the uterus being clearly mobilized. When the intrafascial approach is performed properly, the vaginal canal opens spontaneously. It is important to confirm that the uterine cervix has been completely removed and to grasp the vaginal canal, including the vaginal mucosa, using long forceps. After sterilization and ensuring hemostasis at the vaginal stump, the vaginal cuff is closed with slowly absorbable sutures.

As can be seen, we conducted this study based on the hypothesis that the intrafascial hysterectomy technique, which preserves fasciae, ligaments, and nerves, will not lead to PFD.

Statistical Analysis

A power analysis performed using G*Power 3.1 software indicated a total sample size of 41, with a power of 0.99 and an effect size

of 0.63. Considering potential volunteer dropouts during the study duration, 50 volunteers were included in the study.

Statistical analysis of the data was performed using the SPSS (Statistical Package for the Social Sciences) version 25.0 software. Categorical measurements were summarized as counts and percentages, while continuous measurements were summarized as means and standard deviations (with median and minimum-maximum values reported where appropriate). The Kolmogorov-Smirnov test was used to determine whether the parameters in the study exhibited a normal distribution. For parameters that did not show a normal distribution, the Wilcoxon signed-rank test was used for binary group analyses. For parameters that exhibited a normal distribution, the Dependent Samples t-test was used for binary group analyses. A statistical significance level of $p < 0.05$ was accepted for all tests.

RESULTS

A total of 50 volunteers who underwent total abdominal intrafascial hysterectomy for benign gynecological indications were included in our study, which was planned as a prospective cohort study. The average age of the patients was 48.8 ± 7 (range: 36-76) years, while the mean preoperative BMI was recorded as 29.2 ± 5 (range: 20.4-48.8) kg/m². The median gravidity history of the patients was 2.5 (mean: 3.1), the median history of normal vaginal delivery was 1.5 (mean: 1.5), and the median history of cesarean delivery was 0 (mean: 0.9). The demographic characteristics of the patients are presented in Table 1.

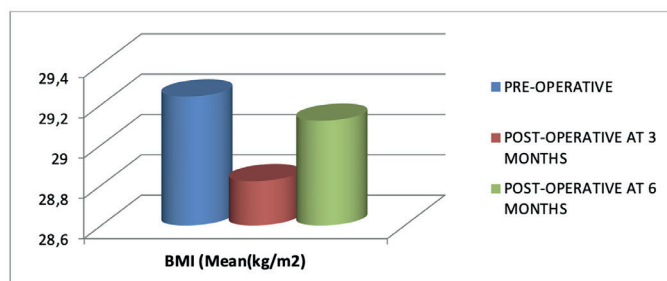
The indications for surgery in the patients were as follows: uterine fibroids (17.34%), uterine fibroids + atypical hyperplasia (17.34%), simple atypical endometrial hyperplasia (4.8%), myomatous uterus (2.4%), uterine fibroids + pelvic mass (2.4%), myomatous uterus + atypical hyperplasia (2.4%), uterine fibroids + adenomyosis (1.2%), uterine fibroids + adnexal mass (1.2%), uterine fibroids + pelvic inflammatory disease + pyosalpinx (1.2%), postmenopausal endometrial thickness increase + cancer phobia (1.2%), atypical hyperplasia + adnexal mass (1.2%), and postmenopausal adnexal mass (1.2%). The patients' BMI showed a decrease at the 3rd month postoperative compared to the preoperative period. The BMI change graph is presented in Figure 1.

The patients' preoperative pelvic organ prolapse distress inventory-6 (POPDI-6), colorectal-anal distress inventory-8 (CRADI-8), urinary distress inventory-6 (UDI-6) and PFDI-20 scores were compared with the postoperative 3-month scores, the preoperative scores with the postoperative 6-month scores, and the postoperative 3-month scores with the postoperative 6-month scores. The patients' preoperative POPDI-6 median

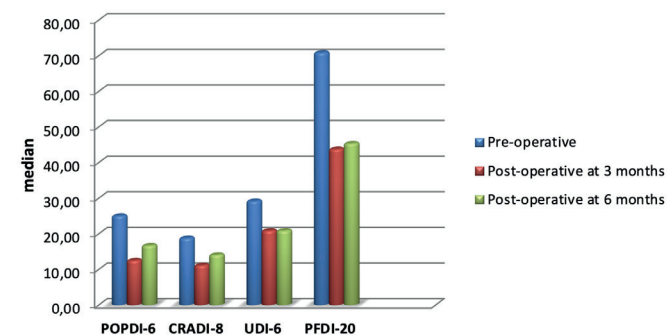
Table 1. Demographic characteristics of the patients

	Mean	Standard deviation	Median	Minimum	Maximum
Age (year)	48.8	7	47	36	76
Pre-operative BMI (kg/m ²)	29.2	5	29.1	20.4	48.8
Post-operative BMI at 3 months (kg/m ²)	28.8	5	28.6	20.8	46.8
Post-operative BMI at 3 months (kg/m ²)	29.1	5	29	21.1	47.6
Gravidity (n)	3.1	2.2	2.5	0	11
Vaginal delivery (n)	1.5	1.8	1.5	0	7
Cesarean section (n)	0.9	1.1	0	0	5

BMI: Body mass index

**Figure 1.** Change graph of BMI scores

BMI: Body mass index

**Figure 2.** Change graph of POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores (median values)

POPDI-6: Pelvic organ prolapse distress inventory-6, CRADI-8: Colorectal-anal distress inventory-8, UDI-6: Urinary distress inventory-6, PFDI-20: Pelvic floor distress inventory-20

was 25 (0-45.8), the preoperative CRADI-8 median was 18.7 (0-53.1), the preoperative UDI-6 median was 29.1 (0-75), and the preoperative PFDI-20 median was 70.8 (0-173.9) (Figure 2). At the 3rd month postoperative, the patients' POPDI-6 median was 12.5 (0-54.1), the CRADI-8 median was 11.1 (0-48.8), the UDI-6 median was 20.8 (0-62.5), and the PFDI-20 median was 43.7 (8.3-119.7) (Figure 2). At the 6th month postoperative, the patients' POPDI-6 median was 16.6 (0-54.1), the CRADI-8 median was 14 (0-50), the UDI-6 median was 20.8 (0-62.5), and the PFDI-20 median was

45.3 (2.9-133.3) (Figure 2). The patients' POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores are presented in Table 2.

The comparison of preoperative POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores with the postoperative 3rd month scores is presented in Table 3. The patients' preoperative POPDI-6 median was 25 (0-45.8), while the postoperative 3rd month median was 12.5 (0-54.1), and the difference was statistically significant ($p<0.001$). The preoperative CRADI-8 median was 18.7 (0-53.1), and the postoperative 3rd month median was 11.1 (0-48.8), with a statistically significant difference ($p<0.001$). The preoperative UDI-6 median was 29.1 (0-75), and the postoperative 3rd month median was 20.8 (0-62.5), showing a statistically significant difference ($p<0.001$). The preoperative PFDI-20 median was 70.8 (0-173.9), while the postoperative 3rd month median was 43.7 (0-119.7), and the difference was statistically significant ($p<0.001$).

The comparison of preoperative POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores with the postoperative 6th month scores is presented in Table 4. The patients' preoperative POPDI-6 median was 25 (0-45.8), while the postoperative 6th month median was 16.6 (0-54.1), and the difference was statistically significant ($p<0.001$). The preoperative CRADI-8 median was 18.7 (0-53.1), and the postoperative 6th month median was 14 (0-50), with a statistically significant difference ($p=0.001$). The preoperative UDI-6 median was 29.1 (0-75), and the postoperative 6th month median was 20.8 (0-62.5), showing a statistically significant difference ($p<0.001$). The preoperative PFDI-20 median was 70.8 (0-173.9), while the postoperative 6th month median was 45.3 (2.9-133.3), and the difference was statistically significant ($p<0.001$).

The comparison of postoperative 3rd month POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores with the postoperative 6th month scores is presented in Table 5. The patients' postoperative 3rd month POPDI-6 median was 12.5 (0-54.1), while the postoperative 6th month median was 16.6 (0-54.1), and the difference was not statistically significant ($p=0.109$). The postoperative 3rd month

Table 2. POPDI-6, CRADI-8, UDI-6, PFDI-20 scores

Survey	Mean (\pm SD)	Median	Minimum	Maximum
Pre-operative POPDI-6	24.3 (\pm 13.9)	25	0	45.8
Pre-operative CRADI-8	19 (\pm 13.3)	18.7	0	53.1
Pre-operative UDI-6	33.4 (\pm 21)	29.1	0	75
Pre-operative PFDI-20	77.2 (\pm 39.3)	70.8	0	173.9
Post-operative 3-month POPDI-6	15 (\pm 12)	12.5	0	54.1
Post-operative 3-month CRADI-8	14.1 (\pm 11.1)	11.1	0	48.8
Post-operative 3-month UDI-6	23.4 (\pm 16.8)	20.8	0	62.5
Post-operative 3-month PFDI-20	52.4 (\pm 33.1)	43.7	8.3	119.7
Post-operative 6-month POPDI-6	15.9 (\pm 12.4)	16.6	0	54.1
Post-operative 6-month CRADI-8	15.1 (\pm 11.5)	14	0	50
Post-operative 6-month UDI-6	24.5 (\pm 17.3)	20.8	0	62.5
Post-operative 6-month PFDI-20	54.9 (\pm 36.1)	45.3	2.9	133.3

The Kolmogorov-Smirnov test was used for normality testing. It was observed that the data did not conform to a normal distribution. The UDI-6 scores showed normal distribution. POPDI-6: Pelvic organ prolapse distress inventory-6, CRADI-8: Colorectal-anal distress inventory-8, UDI-6: Urinary distress inventory-6, PFDI-20: Pelvic floor distress inventory-20

CRADI-8 median was 11.1 (0-48.8), and the postoperative 6th month median was 14 (0-50), with no statistically significant difference ($p=0.058$). The postoperative 3rd month UDI-6 median was 20.8 (0-62.5) with a mean \pm standard deviation of 23.4 ± 16.8 , while the postoperative 6th month median was 20.8 (0-62.5) with a mean \pm standard deviation of 24.5 ± 17.3 , and the difference was not statistically significant ($p=0.054$). The postoperative 3rd month PFDI-20 median was 43.7 (8.3-119.7), and the postoperative 6th month median was 45.3 (2.9-133.3), with no statistically significant difference ($p=0.095$).

The results indicate a positive and statistically significant relationship between BMI and the preoperative PFDI-20 score ($r=0.323$, $p=0.011$). This finding suggests that patients with a higher BMI experience more severe symptoms related to PFD than patients with lower BMI. This result shows that BMI has a significant impact on pelvic floor health and obese patients may have weaker pelvic floor function.

The correlation analysis conducted three months after surgery shows that the relationship between BMI and PFDI-20 score has become slightly stronger compared to the preoperative period ($r=0.356$, $p=0.006$). This finding suggests that patients with higher BMI may show less improvement in pelvic floor symptoms after surgery. Although surgery generally reduces symptoms, overweight patients may experience a lower rate of recovery. This indicates that obesity may influence the treatment response process and that additional strategies may be required for pelvic floor rehabilitation in obese patients.

Sixth months after surgery, the positive correlation between BMI and PFDI-20 score persists, although the correlation coefficient has slightly decreased compared to the third month ($r=0.344$,

$p=0.007$). This result suggests that surgery continues to improve symptoms in the long-term, but patients with higher BMI still experience more significant symptoms. This finding points at the importance of weight management as a supportive factor in pelvic floor health.

Table 3. Comparison of preoperative and postoperative 3-month POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores

	Pre-operative ¹	Post-operative at 3 months ¹	<i>p</i> -value*
POPDI-6	25 (0-45.8)	12.5 (0-54.1)	<0.001
CRADI-8	18.7 (0-53.1)	11.1 (0-48.8)	<0.001
UDI-6	29.1 (0-75)	20.8 (0-62.5)	<0.001
PFDI-20	70.8 (0-173.9)	43.7 (8.3-119.7)	<0.001

¹: Median (minimum-maximum), *: Wilcoxon signed-ranks test, POPDI-6: Pelvic organ prolapse distress inventory-6, CRADI-8: Colorectal-anal distress inventory-8, UDI-6: Urinary distress inventory-6, PFDI-20: Pelvic floor distress inventory-20

Table 4. Comparison of pre-operative and post-operative 6-month POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores

	Pre-operative ¹	Post-operative at 6 months ¹	<i>p</i> -value*
POPDI-6	25 (0-45.8)	16.6 (0-54.1)	<0.001
CRADI-8	18.7 (0-53.1)	14 (0-50)	0.001
UDI-6	29.1 (0-75)	20.8 (0-62.5)	<0.001
PFDI-20	70.8 (0-173.9)	45.3 (2.9-133.3)	<0.001

¹: Median (minimum-maximum), *: Wilcoxon signed-ranks test, POPDI-6: Pelvic organ prolapse distress inventory-6, CRADI-8: Colorectal-anal distress inventory-8, UDI-6: Urinary distress inventory-6, PFDI-20: Pelvic floor distress inventory-20

Table 5. Comparison of post-operative 3-month and post-operative 6-month POPDI-6, CRADI-8, UDI-6, and PFDI-20 scores

	Postoperative 3 months ¹	Postoperative at 6 months ¹	<i>p</i> -value
POPDI-6	12.5 (0-54.1)	16.6 (0-54.1)	0.109*
CRADI-8	11.1 (0-48.8)	14 (0-50)	0.058*
UDI-6	20.8 (0-62.5)	20.8 (0-62.5)	0.054**
PFDI-20	43.7 (8.3-119.7)	45.3 (2.9-133.3)	0.095*

¹: Median (minimum-maksimum),*: Wilcoxon signed-ranks test, **: Paired samples test, POPDI-6: Pelvic organ prolapse distress inventory-6, CRADI-8: Colorectal-anal distress inventory-8, UDI-6: Urinary distress inventory-6, PFDI-20: Pelvic floor distress inventory-20

DISCUSSION

In our prospective cohort study, we investigated the effects of total abdominal intrafascial hysterectomy on pelvic floor functions to determine whether the intrafascial technique provides a protective effect on these functions. As observed, many studies in the literature suggest that extrafascial hysterectomies, particularly radical hysterectomies, impair pelvic floor functions. Some studies indicate no connection between pelvic floor functions and hysterectomy, while others suggest possible recovery of pelvic floor functions posthysterectomy. In our study, total abdominal hysterectomy performed using the intrafascial technique resulted in a significant reduction in PFDI-20 scores compared to preoperative scores.

Rortveit et al.¹³ demonstrated that hysterectomy is associated with POP. However, our study concluded that hysterectomy performed using the intrafascial technique does not pose a risk for POP.

Tan et al.¹⁴ conducted a study investigating the effects of total abdominal, total laparoscopic, total vaginal, total abdominal intrafascial, and total laparoscopic intrafascial hysterectomy on pelvic floor functions. In this study, which included a total of 260 patients, pelvic examinations, pelvic organ prolapse quantification (POP-Q), and pelvic muscle strength tests were performed at preoperative, postoperative 6 months, and postoperative 12 months. The PFDI-20 and female sexual function index questionnaires were administered. At postoperative 6 and 12 months, the incidence of POP and POP-Q scores in the total abdominal and total laparoscopic hysterectomy groups using the intrafascial technique were found to be significantly different from those in other groups, suggesting that the intrafascial technique is protective against POP. However, no significant difference was found between the intrafascial technique and other groups concerning stress urinary incontinence and colorectal anal dysfunction. In our

study, we also demonstrated that total abdominal hysterectomy performed using the intrafascial technique is protective regarding pelvic floor functions.

In a retrospective study by Vermeulen et al.¹⁵, 247 women who underwent laparoscopic and vaginal hysterectomy were evaluated using POP-Q examination and PFDI-20 questionnaire an average of 16 years later. It was found that 62% of the patients had a stage ≥ 2 prolapse according to the POP-Q, and 52% of these patients experienced moderate and/or severe symptoms according to the PFDI-20. Although our study indicates that performing hysterectomy using the intrafascial technique is protective of pelvic floor functions, the 6th month follow-up period may be insufficient to predict long-term outcomes.

Based on the hypothesis that hysterectomies performed using the intrafascial technique preserve fascia, ligaments, muscles, and nerves, thereby not impairing pelvic floor functions, our study found that the significant reduction in PFDI-20 scores at postoperative 3rd and 6th months compared to the preoperative period indicates that the intrafascial hysterectomy technique is protective of pelvic floor functions. We attribute this to 86% of patients having fibroids and their relief from symptoms caused by these fibroids (such as frequent urination, groin pain, a feeling of heaviness, and constipation) post-surgery. In a prospective study conducted by Dancz et al.¹⁶ with 145 volunteers, patients who underwent surgical treatment (hysterectomy, myomectomy) due to uterine fibroids were evaluated using the PFDI-20 questionnaire before and after surgery, and it was concluded that the surgical intervention improved pelvic floor symptoms. Additionally, the significant reduction in patients' BMI postoperatively, along with the significant positive correlation between BMI and PFDI-20 scores at preoperative, postoperative 3rd months, and postoperative 6th months, is also noteworthy in explaining the decrease in scores. In a study by Özgül et al.¹⁷, a significant correlation was found between BMI and PFDI-20 scores. Moreover, in a study by Leshem et al.¹⁸, significant improvement in pelvic floor symptoms was observed postoperatively in patients who underwent bariatric surgery due to obesity.

In our study, we concluded that total abdominal hysterectomy performed using the intrafascial technique is protective regarding pelvic floor functions. It would also be beneficial to investigate long-term outcomes.

Study Limitations

Our article is not a prospective randomized controlled trial comparing total abdominal extrafascial hysterectomy.

Additionally, the 6th month postoperative follow-up period may be insufficient for predicting outcomes in the later stages.

CONCLUSION

When planning a hysterectomy for benign indications, it is important to prefer the intrafascial hysterectomy technique, as it is expected to preserve pelvic floor functions. Furthermore, conducting prospective randomized controlled long-term studies that evaluate and compare hysterectomy techniques and types in this field would be beneficial.

ETHICS

Ethics Committee Approval: All processes related to this thesis study were approved by the Clinical Research Ethics Committee of Muğla Sıtkı Koçman University Rectorate on May 11, 2022, with decision number 9/XI. All procedures conducted in the study adhered to the ethical standards of the Institutional and/or National Research Committee and complied with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent: Those who volunteered to participate were included in the study after obtaining written informed consent.

FOOTNOTES

Contributions

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

DISCLOSURES

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

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

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Vulvar lipoma: A case report and brief literature review

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Citation: Mishina A, Petrovici V, Shor E, Mishin I. Vulvar lipoma: a case report and brief literature review. Pelviperrineology. 2025;44(1):31-34

ABSTRACT

The present study is a case report of vulvar lipoma and review of the available literature. Lipoma is the most common soft-tissue tumor of mesenchymal origin; nevertheless, it is rarely found in the vulva. To the best of the authors' knowledge, the medical literature has been limited to a few case reports and very small case series, in totally about 100 cases being published. A 36-year-old patient presented with a painless, slow-growing, mobile mass in the left labia majora. The ultrasound imaging revealed the presence of lipoma. Surgical excision was performed with the histopathological examination of the excised mass, that confirmed a lipoma.

Keywords: Benign tumor; lipoma; vulvar neoplasms

INTRODUCTION

Lipomas are the most common benign, slow-growing soft tissue tumors composed of mature adipocytes encapsulated in a thin, fibrous, well-circumscribed capsule.¹ Their prevalence is about 1% of the population.^{2,3} These mesenchymal neoplasms are observed anywhere in the human body, but are most frequently detected in the upper part of the back, neck, shoulder, abdomen and proximal portions of the extremities.^{1,4-6} We present a rare case of vulvar lipoma with review of the worldwide case literature.

CASE REPORT

The 36-year-old patient was admitted to the hospital due to the presence of a painless, soft, mobile mass on palpation in

the vulvar region on the left side. The gynecological history was unremarkable: Menarche occurred at the age of 12 years, subsequent menses were regular, with no family history, no history of vulvar trauma, and no changes in laboratory tests, that could serve as a reference point. The patient reported that the mass had steadily increased in size over the past year. Physical/gynecological examination revealed a 4.0×10.0 cm mass in the left labia majora (Figure 1), soft, painless, non-fluctuant to palpation, irreducible-cough impulse test being negative, no regional inguinal lymph nodes enlargement. The skin overlying this tumor without pathological changes. Ultrasound imaging showed a well-defined, hypodense, homogeneous mass 92.6×37.2 mm in the left labia majora (Figure 2). Surgical excision of the tumor was performed under epidural anesthesia

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Received: 10 October 2023 **Accepted:** 24 December 2024 **Publication Date:** 11 April 2025



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(Figure 3) and presented no technical difficulties. A histological examination revealed a circumscribed benign tumor composed of mature adipocytes, confirming the diagnosis of vulvar lipoma (Figure 4). The postoperative period was uneventful; the patient was satisfied with the cosmetic result. There have been no signs of recurrence 19 months later.

DISCUSSION

Vulvar lipomas are considered rare benign mesenchymal tumors, formed by mature adipose cells, with uncertain etiopathogenesis.³ The study of bibliographic sources from online databases Google Scholar and PubMed after the following keywords: “Vulvar lipoma”, “vulvar neoplasm” highlighted that, vulvar lipomas are very rare conditions; respectively, by now, the

specialized literature has been limited to a few case reports^{2,4,5,7-12} and very small case series¹³⁻¹⁵, in totally, about 100 cases have been published.⁸

The exact etiology of vulvar lipomas remains uncertain. Trauma (including chronic minor), obesity and genetic abnormalities are some of the reported risk factors, involved in the development of lipomas.²⁻⁵ According to data from the specialized literature, chronic intermittent irritation of the soft tissues in the vulva region is one of the possible causes, however, congenital lipomas undermine this speculation.⁴ According to cytogenetic research, breakpoints on chromosome 12q and other forms of involvement of the chromosomal region 12q13-q14, have been identified in benign lipogenic tumors.⁴ As a rule, lipomas are



Figure 1. Preoperative presentation of the left labia majora mass

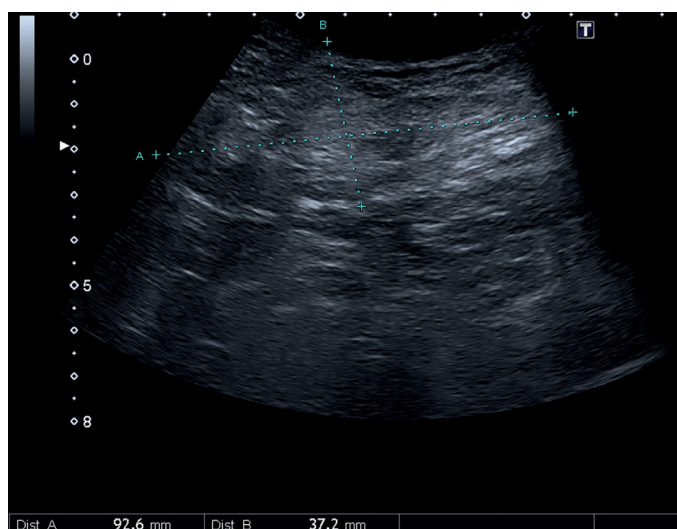


Figure 2. Ultrasound examination showing the well-defined, hypodense, homogeneous mass 92.6×37.2 mm in the left labia majora

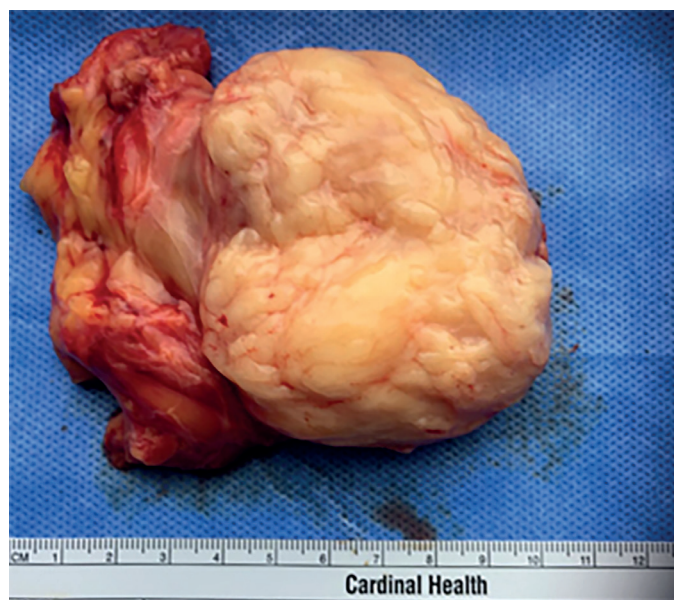


Figure 3. Excised specimen: Macroscopic appearance of lipoma

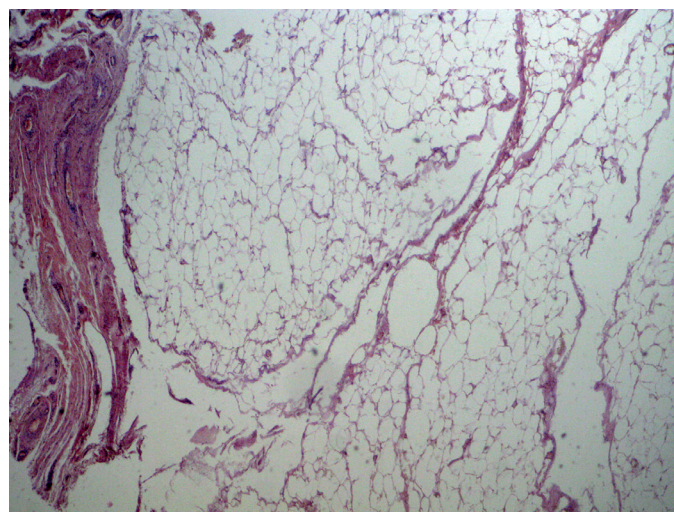


Figure 4. Histopathological specimen showing mature adipocytes with part of their capsule on coloration H&E ×25
H&E: Haematoxylin & eosin

observed between the fourth and sixth decades of life, but they are described in all age groups.^{1,3-5}

Vulvar lipomas are characterized by clinically benign evolution, marked by a single or multiple mass, painless, soft, slow growth, mobile, with uniform consistency on palpation.^{1,3,4,13,15} Most authors mention vulvar lipomas on the right side,^{1,3-5,7,8,13,14} nevertheless, they are also reported on the left side^{9,10,13} or bilaterally.¹¹ Although, primarily described as being a few centimeters in size, vulvar lipomas can be very large^{1,3,4,15}, thus, Ramírez-Macías et al.¹² described the vulvar lipoma of 51 cm. Therefore, they can be diagnosed in some cases only on the basis of clinical examination, without imaging methods.^{3,15} The most common pathologies involved in the clinical differential diagnosis of vulvar lipomas are: Bartholin gland cyst, Nuck duct cyst or liposarcomas^{3-5,10}.

Current imaging methods such as ultrasonography, computed tomography and magnetic resonance imaging can provide an accurate diagnosis, even for small mass.^{1,3,8,10,15} The use of these imaging techniques provides useful tools to detect the lipomatous consistency of vulvar mass, to appreciate the tumor extensions and the relationship with adjacent anatomical structures, as well as, to differentiate from other masses of the vulvar regions^{4,6,9,10,15}. The ultrasound examination is considered to be the first imaging method, which should be used for the diagnosis of tumor mass in the vulvar region, with the identification of lipomas as non-specific homogeneous echogenic structures with lobular features involving fat accumulation.^{3,15} Computed tomography and magnetic resonance imaging are useful in differentiating lipomas from liposarcomas or other pathologies.^{3-5,8,10} Computed tomography imaging reveals vulvar lipoma as a homogeneous, round or oval, hypodense, well-circumscribed mass with a density between -50 and -100 Hounsfield units, which is the pathognomonic sign for the diagnosis of these tumors.^{3,15} Magnetic resonance imaging visualizes lipomas as tumors containing adipose tissue, with high signal intensity on T1W and medium (intermediate) intensity on T2W images, and a decrease in signal with fat suppression.³ Thus, T2-weighted image signal intensity greater than that of fat is known to detect myxoid degeneration, neoplastic process or necrosis.¹

The definitive diagnosis is confirmed by histopathological analysis.³ Macroscopically, lipomas are detected as round or oval tumors with a smooth, lobulated surface with a yellow color on section.^{1,3} To exclude the possibility of malignancy, the histological examination is mandatory.^{3,4} Morphologically, lipomas stand out as tumors represented by mature fat cells (adipocytes) with thin fibrovascular connective tissue septa, surrounded by a fibrous capsule.⁴

Due to the rarity of vulvar lipomas, the optimal treatment is currently uncertain and controversial, including both: Minimally invasive approaches, such as liposuction, laser, ultrasound, or injection of pharmaceutical agents, as well as, open surgery used to remove these neoplasms.⁸ Reported treatment varies significantly, depending on clinical features, lipoma size and possible complications, which must be carefully considered. However, complete surgical excision with capsule removal, to prevent recurrence, remains the treatment of choice for vulvar lipomas, because it allows effective resolution of both: Symptoms and cosmetic concerns.^{1,3,5,8,9,15} According to the specialized literature data, the statistics of vulvar lipoma malignancy are not reported.^{4,5,9} The prognosis for the treatment of vulvar lipomas is favorable, according to research, no case of recurrence of this disease after surgical intervention has been published after the monitoring period of up to 24 months.^{1,9}

CONCLUSION

Vulvar lipomas are rare benign mesenchymal tumors, formed from mature fat cells. Ultrasound and magnetic resonance imaging are the essential diagnostic techniques. However, the definitive diagnosis is confirmed by histological examination, which can be crucial for achieving better results. Surgical excision is the treatment of choice in special for symptomatic patients.

ETHICS

Informed Consent: Written informed consent was obtained from the patient for publication of the present study.

FOOTNOTES

Contributions

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

DISCLOSURES

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

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

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Vesico-peritoneal fistulae after cesarean section: Insights from three case studies

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Citation: Saraç ÖD, Cömert EH, Çalışkan E. Vesico-peritoneal fistulae after cesarean section: Insights from three case studies. Pelviperrineology. 2025;44(1):35-38

ABSTRACT

Vesico-peritoneal fistula represents an abnormal path between the abdominal cavity and the bladder. In this study, we present three clinical cases of vesico-peritoneal fistula that developed after cesarean section, each exhibiting symptoms of pain and abdominal distension. The first case involved a bladder injury that was identified intraoperatively during the C-section and was promptly repaired. The remaining two cases were associated with thermal injuries inflicted by electrocautery during the surgical procedure. In all three patients, laboratory analyses revealed that urea and creatinine levels remained within normal limits. Diagnostic approaches varied: Two cases were diagnosed through transabdominal ultrasound-guided needle aspiration of ascitic fluid, while the third case was confirmed via cystogram. Therapeutic intervention for all cases involved cystoscopy, surgical excision of the fistula tract, excision of the bladder fistula, and subsequent multilayered bladder repair utilizing an omental flap. Postoperative management included a 10-day period of bladder drainage, after which all patients demonstrated uneventful recoveries. These findings underscore the importance of recognizing vesico-peritoneal fistula as a potential complication of C-section, particularly in the context of intraoperative bladder injury or electrocautery use.

Keywords: Cesarean section; vesico-peritoneal fistula; surgical complications; bladder injury; fistula diagnosis

INTRODUCTION

Cesarean section (CS) is a widely performed surgical intervention globally, aimed at mitigating risks to both mother and neonate when vaginal delivery is considered unsafe. Despite its frequent and routine nature, CS are not devoid of complications. One of the reported complications is urinary bladder injury occurring in 0.18% of all cesarean deliveries.¹ Bladder injury during primary

CS is 0.2% and during repeat CS is 0.6%.² The most common site of bladder injury was reported to involve the dome of the urinary bladder in that in 94% of cases.³

Among the rarer but clinically significant complications of CS is the development of vesico-peritoneal fistulae. A vesico-peritoneal fistula represents an abnormal communication between the urinary bladder and the peritoneal cavity, leading

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Received: 14 August 2024 **Accepted:** 10 February 2025 **Publication Date:** 11 April 2025



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to substantial morbidity if not accurately diagnosed and promptly managed. Bladder injuries during CS often result from surgical difficulties encountered while creation of a bladder flap over the lower uterine segment, usually due to scar tissue from previous surgeries. These injuries are most often attributable to ureteral transection or ligation associated with uterine incision extensions in the lower uterine segment or the vagina, and to attempts to achieve hemostasis.⁴

This article aims to elucidate the complexities of vesico-peritoneal fistulae subsequent to CS through a detailed examination of three distinct case studies. By analyzing the clinical presentations, diagnostic methodologies, therapeutic interventions, and outcomes associated with these cases, we seek to provide the medical community with a comprehensive understanding of this rare complication. Furthermore, we will underscore the necessity of a multidisciplinary approach in managing such intricate postoperative conditions. The insights gleaned from these cases will inform strategies for prevention, early detection, and effective management, ultimately enhancing clinical practice and patient care.

MATERIAL AND METHODS

Case 1

A 36-year-old women gravida 2, parity 2 admit to hospital with abdominal distention six weeks after her second cesarean delivery. Pelvic gynecological examination was normal except ascites seen on transvaginal and transabdominal ultrasound without any pelvic or abdominal mass or pyelectasia. Transabdominal ultrasound guided sampling of the clear peritoneal fluid was done and analysis revealed a creatinine level of 9.5 mg/dL indicating urinary ascites. Intravenous pyelography revealed contrast leakage from left posterior bladder wall. Her blood biochemical analysis was normal for urea, creatinine and hemogram was normal. She was operated immediately with Pfannenstiel incision and cystoscopy concomitantly. Cystoscopy guided double J guide insertion to the fistula showed a vesico-peritoneal fistula tract neighboring left side of the Kerr incision of the uterus. Her obstetrician was contacted and recalled that electrocoagulation of bleeding vessels between the bladder and vaginal wall was done on the left side of the Kerr incision. After fistulectomy and repair of the bladder with 2.0 polyglactin sutures, omental flap was placed between the bladder and the uterus. The bladder was than distended with methylene blue diluted in 400 mL of sterile saline and no leakage was seen. Folley catheter was kept in place for 10 days and the patient recovered uneventfully.

Case 2

A 28-year-old gravida three parity three women admit to emergency with abdominal distention, fever, and vaginal discharge. She had history of third cesarean section for placenta previa and placenta accreta spectrum four weeks ago. On pelvic examination she had clear fluid leake from the cervix. Transvaginal and transabdominal ultrasound showed no abdominal or pelvic mass but ascites. Also, there was a 2x4 cm fluid accumulation on right posterior side of the bladder not related to the adnexa. Transabdominal sampling of turbulent pale-yellow ascites revealed creatinine of 16 mg/dL. Her urine analysis revealed nitrite ++ positive urine with increased leucocyte and bacteria on microscopic examination of the urine. Her white blood cell (WBC) count was $1.5 \times 10^3/\mu\text{L}$ C-reactive protein (CRP) was 100 mg/L. Cystography was performed and two fistula tracts was observed one from bladder to cesarean Kerr incision to the uterus the other to the right side of the pelvic peritoneum near the round ligament. A Foley catheter was placed and extended spectrum antibiotic therapy with ceftriaxone 3 gr/day and cleocin 600 mg/day was commenced. After 48 hours of antibiotic therapy WBC drop to $9.5 \times 10^3/\mu\text{L}$ and CRP drop to 32 mg/L. She was operated with pfannnstiel incision. Methylene blue installation was done to guide the fistula planes and methylene blue was observed to leak from the cervix too. The urinary bladder was dissected away from the uterus. Kerr incision was excised and revised at the midline with fistulectomy at the dome of the bladder. The vesico-peritoneal fistula tract on the left side anterior to the Kerr incision was 1 cm away from the left ureter entrance to the bladder. A double J catheter was placed to the left ureter, fistulectomy and repair of the bladder with 2.0 polyglactin sutures was performed. Omental flap was placed between the uterus and the fistula tracts. Foley catheter was kept in place for 10 days with antibiotic therapy and the Double J catheter removed with cystoscopy one month after the operation. She recovered uneventfully.

Case 3

A 32-year-old gravity 2 parity 2 woman admitted to emergency room with abdominal pain and distension. One month ago, she had a cesarean section and had an intraoperative bladder injury with primary repair of the injured area. WBC count was within normal limits ($8.44 \times 10^3/\mu\text{L}$), CRP was 8.4 mg/L and creatinine level was 2.19 mg/dL.

Abdominal ultrasound showed diffuse fluid in the abdominal cavity. Vesico-peritoneal fistula due to previous surgery was suspected. Paracentesis was performed and after biochemical examination detected a creatinine level of 12 mg/dL, it was found to be compatible with urine. A cystogram was performed

afterwards and contrast fluid passage into the abdominal cavity was observed (Figure 1). After the diagnosis, cystoscopy was performed and simultaneous laparotomy was performed to visualize the defect in the bladder (Figure 2). Then the bladder defect at the dome of the bladder was repaired in a multilayer fashion with 2.0 vicryl via laparotomy and an omental flap was placed over it. After repair, the bladder was inflated with methylene blue diluted saline and no leakage was observed. After discharge, the patient's catheter was removed 14 days later and a control cystogram was performed and no pathology was observed on the cystogram.

DISCUSSION

Vesico-peritoneal fistula is a rare but important complication of obstetric surgery. Although emergency cesarean delivery, and cervical dilatation of 9-10 cm were proven risk factors for bladder injury, our cases were all elective cesarean deliveries without cervical dilatation.⁵ Risk of bladder injury increased in cesarean delivery cases with placenta previa 2.2 (1.9-2.4) as in one of our cases and repeat cesarean delivery 4.3 (4.1-4.6) as in all our cases.¹ Gungorduk et al.⁶ found that women with bladder injury were more likely to have had a previous cesarean section compared to the control group (72.4% vs. 34.2%; $p < 0.001$).



Figure 1. Passage of contrast medium into the peritoneal cavity on cystogram

In a meta-analysis by Jensen et al.⁷ it was reported that bladder injuries were recognized during the operation in 90 percent of the cases and post-repair complications were seen in 1 percent of the cases. Although recognition of bladder injury during cesarean section may decrease the morbidity of the patient, fistulas may occur late due to electrocoagulation as in one of our cases. Also, fistulas can occur despite primary repair of the bladder injury recognized during the operation as in one of our cases.

In the presence of vesico-peritoneal fistula, patients may present to the hospital repeatedly at different times with complaints of abdominal pain and abdominal distension, with or without fever.

In our cases, admission occurred between 28 to 42 days after the first operation, one of the three patients complained of fever but all patients had clinically evident abdominal distention easily diagnosed as ascites by ultrasonography. The biochemical analysis of transabdominal ultrasound guided ascite samples in our cases yielded a higher creatinine level than the upper cut-off value of 1.5 mg/dL for serum which indicates urine leakage to the peritoneal cavity. Although this comparison was also used to diagnose late urine leakage in other studies, early abdominal drain creatinine cut-off level for prediction of urine leakage after genitourinary surgery was set at ≥ 30 mg/dL.^{8,9} Unlike vesicouterine and vesico vaginal fistulas where vaginal urine leakage raises the suspicion of bladder injury, vesico-peritoneal fistulas admit with abdominal distention as the main symptom.^{10,11} Nevertheless, both vesico-peritoneal and vesicouterine fistulas can be observed rarely in the same case as reported in the literature and in one of our cases.¹⁰

In our cases, 10 to 14 days of Foley balloon drainage after appropriate repair was sufficient. Previous studies reported 1 to



Figure 2. Cystoscopic view of the instrument passed through the vesicoperitoneal fistula tract via laparotomy

42 days of transurethral catheterization where most reports had a median of 7 to 14 days as in our cases.⁷ Although no control graph was mentioned in the literature a control cystogram was performed after 14 days of catheterization in one of our cases to evaluate the bladder integrity and no extravasation was observed. As recurrent fistula was reported after fistula repair in 1.3% of the cases and unsuccessful repair was rare the use of control cystography should be case specific.⁷

We would like to conclude that vesico-peritoneal fistulas should be considered in the differential diagnosis of acute abdominal distention with ascites within several months after cesarean section in whom high creatinine level in ascites samples indicate urine leakage into the peritoneal cavity.

FOOTNOTES

Contributions

Surgical and Medical Practices: Ö.F.S., E.Ç., Concept: Ö.F.S., E.Ç., Design: Ö.F.S., E.H.C., Data Collection or Processing: Ö.F.S., E.H.C., Analysis or Interpretation: E.H.C., Literature Search: Ö.F.S., E.H.C., Writing: Ö.F.S., E.Ç.

DISCLOSURES

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

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

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