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EDITORIAL

Dear Reader,

We are pleased to present to you the final issue of Pelviperineology Journal of 2025. Once again, we have prepared a high-quality issue featuring extremely important scientific studies—one that you won't be able to put down once you start reading. Our steadily increasing readership and the growing number of our readers from all four corners of the world are our sole source of motivation. We have always felt your support in carrying our journal to international standards, and we kindly ask for—and look forward to—this support continuing and growing.

On the other hand, as we have done before, we have also included studies that were presented at the 12th International Congress of Pelviperineology and Regenerative Medicine and accepted as oral presentations.

With my best wishes that 2026 brings health, happiness, success, prosperity, and peace.

Enjoy reading.

Prof. Dr. Ahmet Akın SİVASLIOĞLU

Editor-in-chief

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Awareness and perception of urogynecologists/urologists on the role of physiotherapy in the management of pelvic floor dysfunction: Cross-sectional study

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ABSTRACT

Objective: Urogynecology is a medical specialty where physiotherapists play a well-established and essential role. However, there is a common misconception among physicians and other healthcare professionals who often equate physiotherapy with physiotherapeutic tools or modalities. This study aimed to assess the level of awareness and perception among urogynecologists and urologists regarding the role of physiotherapy in managing pelvic floor dysfunction.

Materials and Methods: A cross-sectional, descriptive, census-based approach was used to recruit practicing urogynecologists and urologists in Nigeria. A total of 241 participants took part in the study. Data was collected using an electronic questionnaire comprising 29 semi-structured questions divided into three domains: Personal information, awareness, and perception. Data analysis was conducted using a pragmatist paradigm.

Results: Of the 241 respondents, 50.2% (n=121) were registrars, 40.7% (n=98) were senior registrars, and 9.1% (n=22) were consultants. The findings revealed that 57.7% (n=139) demonstrated "insufficient awareness," and 53.9% (n=130) had "insufficient perception" regarding the role of physiotherapy in managing pelvic floor dysfunction. Notably, among all participants, consultants showed higher levels of awareness and understanding of the physiotherapist''s role in treatment.

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Conclusion: Physiotherapy is a vital component in the multidisciplinary management of pelvic floor dysfunction, and it is important for urogynecologists and urologists to recognize its significance. The study concluded that the majority of Nigerian urogynecologists and urologists lack adequate awareness and understanding of physiotherapy's role in the management of pelvic floor dysfunction.

Keywords: Awareness; perception; urogynecologists; urologists; physiotherapy; rehabilitation

INTRODUCTION

Pelvic floor disorders are common in both men and women[1] and encompass a broad range of clinical conditions. These include urinary and anal incontinence, pelvic organ prolapse, lower urinary tract sensory and emptying disorders, defecatory dysfunction, sexual dysfunction, and various chronic pelvic pain syndromes.[2] These conditions significantly impact quality of life and have social, psychological, and functional consequences across all age groups.[3] The prevalence of urinary incontinence is estimated to be between 25% and 45% in women, while up to 80% of men may experience it following prostate surgery.[4,5] Pelvic organ prolapse affects 40% to 60% of parous women, and sexual dysfunction is reported by 30% to 49% of women in the general population.[6,7] Erectile dysfunction affects approximately 50% of men aged 50, and this figure rises to 70% in those aged 70 and above.[8] Ferreira et al.[9] noted that although pelvic floor dysfunction is more prevalent in women, men are also significantly affected. Most individuals suffering from these disorders report detrimental effects on daily activities, personal relationships, social interactions, and mental health. Pelvic floor dysfunction is closely linked with depression, anxiety, social isolation, and an overall decline in quality of life.

Several studies have emphasized the importance of interprofessional collaborative practice in urogynecology and urology, with many professional societies publishing guidelines that recommend patient care involving multiple healthcare professionals.[10,11] Furthermore, Bedretdinova et al.[12] highlighted that effective communication among healthcare providers and mutual understanding of each other's roles and responsibilities are crucial for building successful teams and achieving optimal patient outcomes.

Physiotherapists play a vital role in both urogynecology and urology. However, the term "physiotherapy" is often incorrectly equated with general conservative treatments or therapeutic modalities by healthcare providers.[13] In reality, physiotherapy refers to the specialized care provided by trained professionals aimed at optimizing movement and functional ability throughout the lifespan.[14] Specifically, pelvic floor physiotherapy addresses dysfunctions of the pelvic floor in men, women, and children.[15]

Chronic urological and urogynecological conditions are more prevalent than previously assumed, often presenting with complex comorbidities that severely affect patients' well-being. Increasingly, evidence suggests that a single-specialty approach is inadequate for managing such multifaceted issues. This outdated model has been linked to higher surgical failure rates, persistent symptoms, and suboptimal outcomes, highlighting the necessity for integrative care strategies, including physiotherapy.[15]

Previous studies underscore the importance of collaboration between urologists, urogynecologists, and physiotherapists in managing pelvic floor dysfunction.[16,17] However, little is known about the awareness and perceptions of these specialists regarding physiotherapy's role, particularly in low- and middle-income countries. In such regions, healthcare systems are often constrained by limited infrastructure, workforce shortages, and insufficient access to comprehensive medical and surgical care for pelvic floor disorders.

Given this context, there is a critical need for data on the awareness and perceptions of urogynecologists and urologists about physiotherapy's role in pelvic floor dysfunction—especially in Sub-Saharan Africa. Therefore, this study aimed to assess the level of awareness and perception among urogynecologists and urologists in Nigeria regarding physiotherapy interventions in the management of pelvic floor dysfunction.

MATERIALS AND METHODS

Study Design and Settings

A cross-sectional online survey was conducted to assess the awareness and perception of urogynecologists and urologists regarding the role of physiotherapy interventions in the treatment of patients with pelvic floor dysfunction. The study targeted Nigerian urogynecologists and urologists working in various governmental and non-governmental hospitals and clinics across the country. Ethical approval was obtained from the Research Ethics Committee of the College of Health Sciences, Bayero University, Kano (reference number: NHREC/06/13/19/79, date: 29.08.2024).

Participants were eligible for inclusion if they met the following criteria: (1) male or female medical doctors, (2) currently specializing or already specialized in urogynecology or urology, (3) residing and practicing in Nigeria, and (4) holding a valid practicing license issued by the Medical and Dental Council of Nigeria. Urogynecologists or urologists who were not practicing

or residing in Nigeria, or those without a current practicing license, were excluded from the study.

Sampling Size and Sampling Technique

A census-based sampling method was employed in this study. This approach involves collecting data from every member of the target population, allowing for comprehensive and in-depth information across multiple dimensions of the issue under investigation.[18] A total of 241 subjects gave their consent and participated in the study.

Ethical Considerations

Ethical approval was obtained from the Research Ethics Committee of the College of Health Sciences, Bayero University, Kano (reference number: NHREC/06/13/19/79, date: 29.08.2024). Participants were informed that by clicking the link and accessing the questionnaire, they were providing consent to participate, as the informed consent form was included with the questionnaire. All participants were assured of their anonymity and informed of their right to withdraw from the study at any time. The survey was conducted between November 2024 and March 2025.

Formation and Validation of the Questionnaire

The survey was conducted using a structured electronic questionnaire developed through Google forms. An expert panel comprising specialists in pelvic floor physiotherapy designed the questionnaire, which was organized into three domains: Personal information, awareness, and perception. To ensure the questionnaire was contextually appropriate, content validity was assessed by pretesting it with six urogynecologists/urologists. Their feedback was reviewed in a peer debriefing session, which resulted in minor recommendations. Based on these, the researcher revised and finalized the questionnaire to maintain the original intent while aligning it with the study's objectives. Divergent validity was evaluated by asking ten urogynecologists/urologists to complete both the developed questionnaire and another validated instrument by Kenny and Adamson[19] which measures physicians' knowledge and understanding of the physiotherapist's role in managing pelvic floor dysfunction. Pearson's Product Moment Correlation was used to analyze the results, revealing an insignificant correlation ($r=0.011$, $n=10$, $p=0.893$). This confirmed that the two questionnaires assess distinct constructs, ensuring that responses to one did not influence the other. Test-retest reliability was determined by having the same group of ten urogynecologists/urologists complete the questionnaire twice, with a two-week interval between administrations. The intraclass correlation coefficient was 0.786, indicating acceptable reliability. The two-week gap was deliberately chosen to minimize recall bias and ensure response independence. The final version of the questionnaire was distributed via email and WhatsApp to the target group. To enhance participation, follow-up reminders were sent every other day throughout the data collection period.

Statistical Analysis

Data analysis for this study was conducted using the Statistical Package for the Social Sciences (SPSS) version 24.0. A pragmatist paradigm guided the analysis, incorporating both qualitative (constructivist) and quantitative (positivist) approaches. This mixed-methods strategy was employed to provide a more comprehensive and in-depth understanding of the research topic. The significance level was set at 5%, with a 95% confidence interval (CI).[20]

Qualitative Analysis

Participants' responses were analyzed qualitatively using content analysis.[21] the researchers reviewed the responses multiple times to interpret their meanings within the local context.

In the second phase—systematic coding—responses were grouped into coherent categories: Positive, negative, and undecided, which were then labeled as codes (clusters of words with similar meanings). The initial coding of the result was conducted by three researchers and their results were compared and discussed with the wider research team until a consensus was reached. In the third phase, the codes were further synthesized and organized into subcategories, specifically focusing on awareness and perception. In the final stage, through collaborative discussions, these subcategories were merged into broader categories and then consolidated into major themes. These themes represented overarching patterns in the data, such as sufficient awareness, insufficient awareness, lack of awareness, sufficient perception, insufficient perception, and lack of perception.

Quantitative Analysis

Quantitative data analysis was carried out to examine differences in awareness and perception of the role of physiotherapy in managing pelvic floor dysfunction among urogynecologists and urologists with varying levels of professional experience (novice, experienced, expert). Normality of the data was confirmed using the Shapiro-Wilk test, and homogeneity of variances was verified using Levene's test.

A One-Way Analysis of Variance (ANOVA) was employed to assess differences, with awareness and current perception serving as the dependent variables and level of professional experience as the independent variable. Separate ANOVAs were conducted

for each dependent variable. When significant differences were detected, Bonferroni post-hoc tests were performed to identify specific group differences.

RESULTS

Socio-demographic Characteristics

Participants were categorized into three predefined age groups: 114 (47.3%) young adults, 124 (51.5%) middle-aged adults, and 3 (1.2%) older adults. A total of 241 individuals took part in the study, comprising urogynecologists and urologists. The majority of participants were employed in government hospitals, while the remaining worked in private healthcare facilities.

Regarding professional rank, 50.2% were registrars, 40.7% were senior registrars, and 9.1% were consultants (Table 1).

Findings on the Urogynecologists/Urologists' Awareness

Findings on urogynecologists and urologists' awareness, along with the emerging themes, are summarized in Table 2. Three major themes were identified: Sufficient awareness, insufficient awareness, and lack of awareness. The theme of insufficient awareness contained the highest number of codes. After coding, 26.5% of participants demonstrated sufficient awareness, 57.7% exhibited insufficient awareness, and 15.8% showed a lack of awareness. Participants in the sufficient awareness group had a clear understanding of physiotherapy's role in managing pelvic floor dysfunction. Those classified under insufficient awareness had some knowledge but lacked comprehensive understanding. Participants in the lack of awareness group were unaware of physiotherapy's role in this context.

Table 1. Demographic characteristics of the participants (n=241)

Variables	Number of doctors
Q1-age:	
Young adults (19-35 years)	114
Middle-aged adults (36-55 years)	124
Older adults (above 55 years)	3
Q2-gender:	
Males	218
Females	23
Q3-work setting:	
Government hospital	184
Non-government hospital	57
Q5-rank:	
Registrar	121
Senior registrar	98
Consultant	22
Q6-specialty:	
Urogynaecology	153
Urology	88

Findings on the Urogynecologists/Urologists' Perception

Findings on the urogynecologists' and urologists' perceptions, along with the emerging themes, are presented in Table 3. Three major themes emerged: Sufficient perception, insufficient perception, and lack of perception, with insufficient perception containing the highest number of codes. After coding, 28.6% of participants demonstrated sufficient perception, 53.9% exhibited insufficient perception, and 17.4% showed a lack of perception. Participants in the sufficient perception group held a strong understanding of physiotherapy's role in managing pelvic floor dysfunction. Those in the insufficient perception group had some awareness but lacked a full understanding. Participants classified as lacking perception had a poor understanding of physiotherapy's role in this area.

Findings on the Difference in Awareness and Perception Based on Professional Experience

Results from the One-Way ANOVA assessing differences in awareness and perception are presented in Tables 4 and 5, respectively. The analysis revealed significant differences in both awareness and perception among participants. Additionally, there was a significant linear trend showing that both awareness (p=0.004) and perception (p=0.013) increased with greater professional experience. Post-hoc comparisons indicated that significant differences were observed only between consultants and registrars. Consultants demonstrated higher levels of awareness [mean difference =4.68 (95% CI: 3.78 to 8.49), η^2=0.641, p=0.001] and perception [mean difference =3.85 (95% CI: 3.02 to 6.07), η^2=0.578, p=0.001]. The effect sizes (η^2) suggest that professional experience accounted for approximately 64.1% of the variance in awareness and 57.8% of the variance in perception.

DISCUSSION

Although urogynecology and urology have made significant advances in treating pelvic floor dysfunction, emerging

Table 2. Themes and number of codes for doctors' awareness

Themes	Number of codes	Number of doctors
Sufficient awareness	**1178**	**64**
Insufficient awareness	2567	139
Lack of awareness	691	38

Table 3. Themes and number of codes for doctors' perception

Themes	Number of codes	Number of doctors
Sufficient perception	1123	69
Insufficient perception	2123	130
Lack of perception	676	42

Table 4. One-Way ANOVA for the difference in awareness					
Professional experience	**N**	**Mean (SD)**	**F(df)**	***P*-value**	***P*-value trend**
Registrar	121	4.41 (0.39)	8.67 (2.238)	0.001	0.004
Senior registrar	98	6.23 (0.49)			
Consultant	22	9.09 (0.37)			
N: number of doctors; SD: standard deviation; F: ANOVA; df: degree of freedom					

Table 5. One-Way ANOVA for the difference in perception					
Professional experience	**N**	**Mean (SD)**	**F(df)**	***P*-value**	***P*-value trend**
Registrar	121	3.99 (0.21)	10.32 (2.238)	0.001	0.013
Senior registrar	98	5.91 (0.72)			
Consultant	22	7.84 (0.63)			
N: number of doctors; SD: standard deviation					

evidence suggests that a single-specialty approach may no longer be optimal for managing patients with complex pelvic floor conditions. This approach has been linked to higher rates of surgical failure, persistent symptoms, and suboptimal outcomes, highlighting the need to incorporate complementary treatments such as physiotherapy interventions.[15] Pelvic floor physiotherapy is a specialized branch of physiotherapy focused on alleviating symptoms related to pelvic floor dysfunction by improving muscle function. However, it remains unclear how well urogynecologists and urologists understand and perceive the role of physiotherapy in managing these conditions.

This study aimed to evaluate the awareness and perception of urogynecologists and urologists regarding physiotherapy's role in pelvic floor dysfunction management. The findings revealed that most participants demonstrated insufficient awareness and perception of physiotherapy's contributions. Limited knowledge among referring specialists could be as a result of the level of their education, their working place, and availability of collaboration with other professional which could hinder appropriate patient referrals, regardless of the effectiveness of physiotherapy. A brief review by Lough[22] emphasized that better understanding among referring specialists—including urogynecologists, urologists, or colorectal surgeons—of the specific treatments and skills physiotherapists provide can enhance referral rates and patient adherence to therapy.

The low levels of awareness and perception observed in this study align with prior research[23] that identified a significant gap between the potential and actual referral rates from pelvic floor specialists to physiotherapy for urinary incontinence. Those authors recommended raising awareness among key stakeholders about physiotherapy's role and advocated for developing tailored clinical care pathways to improve physiotherapy services and overall healthcare quality. In contrast, a study by Ansari et al.[24] found that 80% of doctors (including urogynecologists, urologists, and nephrologists) were aware of physiotherapy's role in managing stress incontinence, with urogynecologists showing higher awareness and perception compared to other specialties.

While this study also found that some urogynecologists and urologists possessed partial but insufficient awareness of physiotherapy's role in pelvic floor rehabilitation, a subset lacked awareness entirely. This may be related to the fact that the majority of participants were registrars, many of whom had not yet completed fellowship training. These results are consistent with findings by Abichandani and Radia[25], who reported inadequate awareness among resident doctors about physiotherapists' roles in antenatal and post-hysterectomy care—including relaxation techniques, breathing exercises, positioning, infant handling, and pelvic floor muscle training for incontinence—while noting limited perception of physiotherapy's broader contributions to women's special care.

The present study also demonstrated significant differences in awareness and perception between consultants and registrars, with consultants showing greater understanding of physiotherapy's role in pelvic floor rehabilitation. Furthermore, awareness and perception improved in a linear fashion with increasing professional experience, indicating that clinical exposure enhances understanding. This finding is consistent with earlier research[26], which showed that senior doctors tend to have deeper insight, utilize more reflective clinical decision-making, and are more likely to refer patients for pelvic floor physiotherapy compared to less experienced residents.

CONCLUSION

This study revealed that urogynecologists and urologists generally have limited awareness and perception of physiotherapy's role in managing pelvic floor dysfunction. Fostering mutual respect and understanding among healthcare professionals is crucial for developing an effective multidisciplinary team. Such collaboration not only enhances awareness of each professional's contributions but is also essential for effectively addressing the complex range of pelvic floor symptoms through combined expertise.

ETHICS

Ethics Committee Approval: Ethical approval was obtained from the Research Ethics Committee of Bayero University, the College of Health Sciences, Kano (reference number: NHREC/06/13/19/79, date: 29.08.2024).

Informed Consent: Informed consent was obtained.

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FOOTNOTES

Contributions

Concept: I.A.A., A.M.Y., J.M.N., M.S.D., Design: I.A.A., H.N., Data Collection or Processing: A.T.O., M.S.D., A.M.Y., J.M.N., Analysis or Interpretation: H.N., A.T.O., Literature Search: A.M.Y., I.A.A., M.S.D., Writing: A.M.Y., J.M.N., H.N., A.T.O.

DISCLOSURES

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Impact of obesity on surgical outcomes after v-NOTES hysterectomy: A single-center retrospective cohort study

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ABSTRACT

Objective: To evaluate the impact of body mass index (BMI) on surgical outcomes in patients undergoing vaginal-natural orifice transluminal endoscopic surgery (v-NOTES) hysterectomy.

Materials and Methods: This single-center retrospective cohort study included 104 women who underwent v-NOTES hysterectomy for gynecologic indications between May 2023 and March 2025. Patients were divided into two groups according to BMI: Group 1 (<30 kg/m², n=62) and Group 2 (≥30 kg/m², n=42). Demographic characteristics, operative time, uterine weight, conversion rates, hemoglobin change, hospital stay, and intra- and postoperative complications were compared. All procedures were performed by two surgeons experienced in both endoscopic and vaginal surgery, following a standardized ten-step v-NOTES technique.

Results: The median age was 54 years and the median BMI was 28 kg/m². Uterine weight was significantly higher in the obese group compared to the non-obese group (255 g vs. 172 g; p=0.020). However, there were no significant differences in operative time (44 vs. 47 minutes; p=0.169), conversion rates (1.6% vs. 4.8%; p=0.346), complication rates (3.2% vs. 4.8%; p=0.462), or hospital stay (48 hours in both groups; p=0.904). All complications were minor and successfully managed conservatively without reoperation.

Conclusion: Despite higher uterine weights in obese patients, surgical outcomes of v-NOTES hysterectomy were comparable between obese and non-obese women. These findings highlight the safety and feasibility of v-NOTES as a minimally invasive option across different BMI groups, supporting its broader application in gynecologic surgery.

Keywords: v-NOTES hysterectomy; body mass index; obesity; minimally invasive surgery; surgical outcomes

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INTRODUCTION

Vaginal-natural orifice transluminal endoscopic surgery (v-NOTES) is an innovative minimally invasive surgical technique that combines the advantages of both laparoscopic and vaginal approaches and has gained widespread acceptance among surgeons over the past decade.[1,2] By avoiding an abdominal incision, v-NOTES offers distinct advantages, including reduced postoperative pain, shorter recovery time, improved cosmetic outcomes, and lower complication rates.[3,4]

Obesity is strongly associated with increased technical difficulties and higher complication risks in gynecologic surgery.[5] In abdominal procedures, obese patients are frequently associated with greater blood loss, prolonged operative times, and delayed postoperative recovery.[6,7] Consequently, minimally invasive approaches have gained particular importance in this population, and v-NOTES has emerged as a promising alternative, especially for patients with risk factors such as obesity.[8]

While the safety and efficacy of laparoscopic and vaginal hysterectomy in obese women have been extensively studied, evidence regarding v-NOTES, particularly across different body mass index (BMI) categories, remains scarce.[9,10] Obesity-related pelvic anatomical changes, limited instrument manoeuvrability, and visualization difficulties represent potential barriers to the use of v-NOTES. However, with increasing surgical expertise and advances in technology, emerging evidence indicates that v-NOTES can also be performed safely in obese patients.[11,12]

In this context, evaluating the impact of BMI on surgical outcomes in patients undergoing v-NOTES hysterectomy is crucial to determine the safety and feasibility of this approach across different patient groups. This study aimed to compare operative time, complication rates, conversion to conventional laparoscopy, and length of hospital stay between patients with BMI <30 and those with BMI ≥30, thereby assessing the applicability of v-NOTES in obese women.

MATERIALS AND METHODS

This study was designed as a single-centre, retrospective cohort analysis. The medical records of patients who underwent v-NOTES hysterectomy for gynecologic indications between May 2023 and March 2025 were retrospectively reviewed. The study protocol was approved by the Institutional Review Board of University of Health Sciences Türkiye, Ankara Etlik City Hospital (approval no: AEŞH-BADEK2-2025-413, date: 19.08.2025). A total of 104 women, aged ≥18 years, who underwent elective condition v-NOTES hysterectomy with complete perioperative clinical data were included. Patients who required emergency surgery, underwent procedures other than v-NOTES, or had incomplete data were excluded from the study.

Participants were categorized into two groups based on BMI: Group 1 included 62 patients with BMI <30 kg/m², whereas Group 2 comprised 42 patients with BMI ≥30 kg/m².

The following variables were systematically extracted from the medical records: age, BMI (kg/m²), parity, history of previous surgery, and surgical indication. Operative parameters included operative time (minutes), uterine weight (grams), need for conversion to laparoscopy, preoperative and postoperative hemoglobin levels (g/dL), length of hospital stay (hours), and intraoperative or postoperative complications.

All procedures were performed by two gynecologic surgeons experienced in both endoscopic and vaginal surgery. When indicated, bilateral salpingectomy and/or oophorectomy were performed in conjunction with v-NOTES hysterectomy. Uterine weights were obtained from postoperative pathology reports. Laparoscopic conversion was carried out when deemed necessary, and intraoperative decisions regarding conversion and complication management were made based on real-time surgical findings.

Surgical Procedure

All v-NOTES hysterectomy procedures were performed according to the standardized ten-step approach defined in certified v-NOTES training courses.[13] The procedure comprised three phases: (1) An initial vaginal phase, including circumcision of the cervix and anterior/posterior colpotomy with dissection of the uterosacral ligaments; (2) a laparoscopic phase, during which the GelPOINT vPath transvaginal access platform (Applied Medical, Rancho Santa Margarita, CA, USA) was inserted, pneumoperitoneum was established at 10-12 mmHg, and adnexal pedicles were transected under endoscopic guidance; and (3) a final vaginal phase, in which the specimen was removed and the vaginal cuff was closed using absorbable sutures. When indicated, bilateral salpingectomy and/or oophorectomy were performed concomitantly. For transvaginal access, the GelPOINT® V-Path platform was used in all cases.

Statistical Analysis

All data were analyzed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was assessed by the Shapiro-Wilk test. Variables that did not conform to normal distribution were presented as median (minimum-maximum) and compared between groups using the Mann-Whitney U test. Categorical variables were expressed as frequencies and percentages, and comparisons between groups were performed with the chi-

square test or Fisher's exact test when appropriate. A *p*-value <0.05 was considered statistically significant.

RESULTS

A total of 104 patients were included in the study. Their general demographic and clinical characteristics are summarized in Table 1. The median age was 54 years (33-78), the median BMI was 28 kg/m² (21-57), and the median parity was 2 (0-6). Previous abdominal surgery was reported in 55.8%, and prior cesarean section in 25% of patients. The median operative time was 45 minutes (24-90), median uterine weight 186 g (48-1036), and median hospital stay 48 hours (24-120). The intraoperative and postoperative complication rates were 1.0% and 3.9%, respectively.

Patients were stratified into two groups according to BMI: Group 1 (n=62; BMI <30 kg/m²) and Group 2 (n=42; BMI ≥30 kg/m²). Intergroup comparisons are presented in Table 2.

There were no statistically significant differences in age (*p*=0.059) or parity (*p*=0.051) between the groups. Previous abdominal surgery was reported in 51.6% of Group 1 and 61.9% of Group 2 (*p*=0.622). The rates of prior cesarean section were 29% and 19%, respectively (*p*=0.465).

The median operative time was 44 minutes in Group 1 and 47 minutes in Group 2, with no significant difference (*p*=0.169). However, uterine weight was significantly higher in Group 2 compared to Group 1 (255 g vs. 172 g; *p*=0.020). Conversion rates were 1.6% (1 case) in Group 1 and 4.8% (2 cases) in Group 2, with no significant difference (*p*=0.346).

Preoperative hemoglobin levels were 13.3 g/dL in Group 1 and 12.9 g/dL in Group 2 (*p*=0.304), while postoperative hemoglobin levels were 11.5 g/dL and 11.8 g/dL, respectively (*p*=0.621). No significant difference was observed regarding hemoglobin decline. Median hospital stay was 48 hours in both groups (*p*=0.904).

Regarding complications, no intraoperative complications occurred in Group 1, whereas one patient (2.4%) in Group 2 required intraoperative blood transfusion due to bleeding (*p*=0.222). Postoperative complications were observed in 3.2% of Group 1 (1 hematoma, one transfusion) and 4.8% of Group 2 (1 hematoma) (*p*=0.462). All complications were successfully managed with conservative medical treatment, and no patient required reoperation. The bleeding originated from the vaginal cuff dissection site and was successfully controlled intraoperatively. In addition, one patient (1.6%) in the non-obese group required postoperative blood transfusion due to anemia secondary to vaginal cuff hematoma, which was managed conservatively without reoperation.

DISCUSSION

In this study, surgical outcomes of v-NOTES hysterectomy were compared according to body mass index. Patients with BMI ≥30 kg/m² showed comparable perioperative and postoperative results to those with BMI <30 kg/m². The only significant difference was a higher uterine weight in the obese group, whereas operative time, complication rates, hospital stay, and conversion rates were similar. These findings support the feasibility and safety of v-NOTES in obese women.

Obesity is known to increase technical difficulties during gynecologic surgery, raise anesthetic risk, and contribute to higher postoperative morbidity.[6,7,14] In conventional abdominal and laparoscopic hysterectomies, obese patients have been reported

Table 1. General characteristics of the cohort undergoing v-NOTES hysterectomy

Variables	
Number of patients	104
Age (years), median (min-max)	54 (33-78)
BMI (kg/m²), median (min-max)	28 (21-57)
Parity, median (min-max)	2 (0-6)
Prior surgery, n (%)	58 (55.8)
Prior caesarean section, n (%)	26 (25)
Operation time (min), median (min-max)	45 (24-90)
Uterine weight (g), median (min-max)	186 (48-1036)
Length of hospital stay (hour), median (min-max)	48 (24-120)
Hemoglobin before surgery (g/dL), median (min-max)	13.2 (8.6-15.9)
Hemoglobin after surgery (g/dL), median (min-max)	11.6 (8.2-14.8)
Indication for surgery, n (%)	
Myomatous uterus	23 (22.1)
Adenomyosis	3 (2.9)
Prolapse	20 (19.2)
Adnexal mass	21 (20.2)
Treatment-resistant DUB	7 (6.8)
Atypical endometrial hyperplasia	14 (13.5)
Endometrial intraepitelial neoplasia	7 (6.7)
Endometrial adenocarsinoma	9 (8.7)
Conversions, n (%)	3 (2.9)
Complications	
Intra-operative, n (%)	1 (1)
Post-operative, n (%)	4 (3.9)

Data are expressed as median, minimum, maximum or number (%)
BMI: body mass index; DUB: dysfunctional uterine bleeding; v-NOTES: vaginal-natural orifice transluminal endoscopic surgery

Table 2. Intergroup comparison according to BMI

Variables	Group 1 (n=62)	Group 2 (n=42)	*p*
Age (years), median (min-max)	54 (33-74)	53 (45-78)	0.059
Parity, median (min-max)	2 (0-6)	3 (0-6)	0.051
Prior surgery, n (%)	32 (51.6)	26 (61.9)	0.622
Prior caesarean section, n (%)	18 (29)	8 (19)	0.465
Operation time (min), median (min-max)	44 (24-90)	47 (27-85)	0.169
Uterine weight (g), median (min-max)	172 (58-1036)	255 (48-761)	0.020
Length of hospital stay (hour), median (min-max)	48 (24-120)	48 (24-96)	0.904
Hemoglobin before surgery (g/dL), median (min-max)	13.3 (8.9-15.8)	12.9 (8.6-15.9)	0.304
Hemoglobin after surgery (g/dL), median (min-max)	11.5 (8.2-14.7)	11.8 (8.9-14.8)	0.621
Conversions, n (%)	1 (1.6)	2 (4.8)	0.346
Complications			
Intra-operative, n (%)	0	1 (2.4)*	0.222
Post-operative, n (%)	2 (3.2)**	2 (4.8)***	0.462

Data are expressed as median, minimum, maximum or number (%)
p≤0.05 significant difference, comparison of groups
BMI: body mass index, Group 1: BMI <30 kg/m^2, Group 2: BMI ≥30 kg/m^2
*: Bleeding requiring intraoperative blood transfusion; **: One patient received postoperative blood transfusion; 1 patient had a postoperative hematoma; ***: Postoperative hematoma

to experience greater blood loss, longer operative times, and higher infection rates.[7,11,15] Minimally invasive approaches are therefore considered particularly valuable for this population, owing to their potential to mitigate these adverse outcomes.

In this regard, v-NOTES offers distinct advantages. The absence of an abdominal incision, direct endoscopic visualization of pelvic anatomy, and improved uterine mobilization are particularly valuable in obese patients.[1-3,16] Previous studies have suggested that uterine weights exceeding 280 g may increase technical difficulty and complication rates in laparoscopic hysterectomy.[16-20] In our study, although uterine weight was significantly higher in the obese group, operative time and complication rates did not appear to be adversely influenced. This finding suggests that the direct visualization provided by v-NOTES may overcome certain anatomic limitations associated with obesity.

The current evidence on the use of v-NOTES in obese women remains limited, though the available data are steadily expanding. In a comparative study, Kaya et al.[12] demonstrated that v-NOTES was associated with shorter operative times and lower postoperative pain scores than TLH in obese patients. Likewise, Nulens et al.,[9] in a retrospective cohort of 114 patients, reported low complication rates despite elevated BMI. Furthermore, Baekelandt et al.,[3] in a randomized controlled trial, showed that v-NOTES was associated with lower complication rates and shorter hospital stays compared with laparoscopy, while achieving non-inferior overall clinical outcomes.

An important contribution of our study is the demonstration that complication, blood loss, and conversion rates were not increased in obese patients. Although conversion was more frequent in the obese group (4.8% vs. 1.6%), this difference was not statistically significant. This finding underscores that, with careful patient selection and adequate surgical expertise, v-NOTES can be safely applied in obese women.

Our results are consistent with previous large series showing low complication rates and high feasibility of v-NOTES.[8-10,17,18] In our cohort, the low overall complication rate (3.9%) and absence of reoperation further support its safety profile. Moreover, previous studies have confirmed that v-NOTES is effective and safe in benign and complex gynecologic cases, comparable to conventional vaginal surgery.[18] Nevertheless, the decline in vaginal surgery rates globally has been attributed, at least in part, to limited training opportunities, thereby driving interest toward minimally invasive alternatives such as v-NOTES.[19]

Stuart et al.[21] recently conducted a large multicenter retrospective study including 4,565 patients who underwent hysterectomy with the v-NOTES technique. They reported an intraoperative complication rate of 3.2% (n=144) and a postoperative complication rate of 2.5% (n=115). The overall conversion rate was 1.6% (n=72), of which only 10 cases (0.2%) required conversion to laparotomy. The most common intraoperative complication was cystotomy, observed in 1.3% of cases, and notably, 50% of these events were performed by inexperienced surgeons. Only one ureteral injury was reported. Postoperative complications

most frequently included bleeding (n=28), vault complications such as infected vault hematoma (n=26), and cystitis (n=18). In our study, no major organ injury (such as cystotomy, ureteral or bowel injury) occurred. Minor complications were observed in 4% of cases intraoperatively (n=2) and in 4% postoperatively (n=2). The overall complication rate was 8% (n=4), and the 30-day readmission rate was 2% (n=2). Notably, the complete absence of major complications in our cohort represents an even more favorable outcome compared to the rates reported in the literature.[19] These findings further emphasize the safety and feasibility of v-NOTES, particularly when performed by experienced surgeons following standardized techniques.

Study Limitations

The strengths of our study include the uniformity of surgical technique, clear stratification of patients according to BMI, and the utilization of prospectively collected perioperative data for retrospective analysis. Nonetheless, the retrospective design and relatively limited sample size may limit the generalizability of our results.

CONCLUSION

This study contributes to the growing body of evidence regarding the impact of BMI on v-NOTES hysterectomy outcomes. Despite significantly higher uterine weights in obese patients, operative time, hospital stay, complication rates, and conversion requirements were comparable to those of non-obese patients. These findings support the safety and feasibility of v-NOTES in obese women, highlighting its potential as a minimally invasive option across diverse patient populations

ETHICS

Ethics Committee Approval: The study protocol was approved by the Institutional Review Board of University of Health Sciences Türkiye, Ankara Etlik City Hospital (approval no: AEŞH-BADEK2-2025-413, date: 19.08.2025).

Informed Consent: Retrospective study.

FOOTNOTES

Authorship Contributions

Surgical and Medical Practices: C.H., Concept: C.H., H.N.Ö., O.K.K., Design: H.N.Ö., V.K., Data Collection or Processing: H.N.Ö., N.Ö., V.K., Analysis or Interpretation: H.N.Ö., V.K., Literature Search: V.K., Writing: C.H., N.Ö.

DISCLOSURES

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

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Urethral ligament plication with a midline approach for stress urinary incontinence: Preliminary experience and outcomes

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ABSTRACT

Objective: To evaluate the short-term outcomes of urethral ligament plication (ULP) with a midline approach as a minimally invasive surgical option for the treatment of stress urinary incontinence (SUI).

Materials and Methods: This retrospective study included 23 women diagnosed with SUI who underwent ULP using a midline vaginal approach. A single non-absorbable polyester suture was placed through the lateral arms of the pubourethral ligament and tied beneath the urethra. The primary outcome measure was the cough stress test performed postoperatively on day 7 and day 30. Operative time, hospital stay, and development of complications were also recorded.

Results: At postoperative day 7, 16 patients (69.6%) had a negative cough stress test, while 7 (30.4%) remained positive. At day 30, continence was achieved in 17 patients (73.9%), with 6 patients (26.1%) testing positive. The mean operative time was 37.4±5.7 minutes, and the mean length of hospital stay was 1.26±0.45 days. No major intraoperative complications occurred.

Conclusion: The midline approach to ULP demonstrated promising short-term outcomes in the treatment of SUI, with continence rates comparable to previously reported paraurethral techniques. The procedure is simple, mesh-free, and appears safe; however, these findings are based on a pilot series and further studies with larger cohorts and long-term follow-up are required to confirm its efficacy and durability.

Keywords: Urethral ligament plication; stress urinary incontinence; polyester repair of pubourethral ligament; midline approach for SUI

INTRODUCTION

Stress urinary incontinence (SUI) is defined as the involuntary leakage of urine that occurs when intravesical pressure exceeds urethral closure pressure during activities such as coughing, sneezing, physical exertion, or exercise.[1] According to the Integral Theory, functional defects of the pubococcygeus muscle (PCM) and the pubourethral ligament (PUL), which are responsible for urethral closure at rest, may disrupt the continence mechanism and lead to urine leakage.[2]

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To date, more than 200 surgical techniques have been described for the treatment of urinary incontinence. Nevertheless, the primary therapeutic goal in SUI remains to prevent the elongation of a lax PUL and to ensure adequate periurethral collagen support.[3,4] In this context, mid-urethral sling (MUS) procedures have been widely adopted as the standard treatment for many years.[5] However, mesh-related complications have led to extensive debate, litigation, and even regulatory restrictions in several countries, thereby increasing interest in non-mesh alternatives. Moreover, in the evolving landscape of global healthcare, there has been a growing demand for shorter, minimally invasive procedures associated with faster recovery.[4]

Among these alternatives, the urethral ligament plication (ULP) technique described by Petros and Palma[4], which utilizes non-absorbable polyester sutures, has emerged as a promising approach. In the original ULP technique, bilateral dissection into both paraurethral spaces is performed, and four critical attachment points of the PUL that contribute to urethral closure—the mid-urethra, the retropubic portion, the external urethral ligament (EUL), and the PCM—are engaged bilaterally, mechanisms that were previously defined within the framework of the Integral Theory.[2] In contrast, in our study presenting the midline approach to ULP, the procedure is performed through a single midline incision, with a single knot placed only through the retropubic branches of the PUL.

The concept of PUL repair has been pioneered and elegantly described by Petros and Ulmsten[2] within the framework of the Integral Theory. Their work has established a new perspective on the pathophysiology and surgical treatment of SUI. Inspired by this foundation, we aimed to present our initial clinical experience with a midline approach to ULP. This modification does not intend to replace or challenge the original description, but rather to explore whether a simplified, less invasive route could provide practical advantages while maintaining clinical effectiveness in selected patients.

MATERIALS AND METHODS

This retrospective observational study was conducted at the Department of Obstetrics and Gynecology, Kırşehir Ahi Evran University Training and Research Hospital, between 2023 and 2025, by reviewing the medical records of patients who underwent surgery for SUI. Ethical approval was obtained from the Kırşehir Ahi Evran University Faculty of Medicine Health Sciences Scientific Research Ethics Committee (decision no: 2025-08/92, date: 29 April 2025).

The diagnosis of SUI was established in patients with a history of SUI symptoms and a positive cough stress test performed when the bladder was filled with approximately 300 mL of urine. Patients with urethral hypermobility demonstrated by the Q-tip test and those who achieved continence with retropubic support during the Marshall-Bonney test were selected for surgery. Preoperatively, all patients underwent assessment of pelvic organ prolapse according to the POP-Q system. Age, menopausal status, body mass index (BMI), parity, and operative time were recorded. Patients who underwent midline PUL plication performed exclusively by the principal surgeon and who had at least one month of follow-up were included. Exclusion criteria were surgery for indications other than SUI, concomitant procedures such as transobturator tape (TOT) or pelvic organ prolapse repair, operations performed by different surgeons, and incomplete follow-up data.

All patients were scheduled for postoperative follow-up at the 7th and 30th days. During these visits, patients were questioned about stress incontinence symptoms, and a cough stress test was performed with a bladder volume of at least 300 mL in the lithotomy position while separating the labia and asking the patient to cough 2-3 times. The presence of SUI symptoms on day 7 and at day 30, preoperative and postoperative hemoglobin (Hb) levels, cough stress test results, development of complications, and length of hospital stay were considered outcome variables.

Surgical Technique

All procedures were performed under spinal anesthesia in the low lithotomy position. For prophylaxis, 1 g of intravenous cefazolin was administered approximately 30 minutes before surgery. A Foley catheter was placed under sterile conditions. A vertical midline incision was made approximately 2 cm below the urethra. Through this single incision, paraurethral dissection was performed bilaterally until the retropubic portions of the PUL,[6] located laterally, were palpated. Non-absorbable polyester sutures (No. 2) were passed through each branch of the retropubic PUL, providing adequate tension, and tied at the midline at the level of the urethra (Figures 1, 2). The vaginal mucosa was then closed using 2-0 polyglactin sutures. The simplified technique had previously been introduced in a letter to the editor.[7] The Foley catheter was removed at 24 hours postoperatively. Hb levels were obtained 24 hours before and after surgery. All surgeries and subsequent follow-ups were performed by the same senior obstetrician-gynecologist.

Data were obtained from the hospital information management system, operative notes, laboratory results, and outpatient clinic follow-up forms.

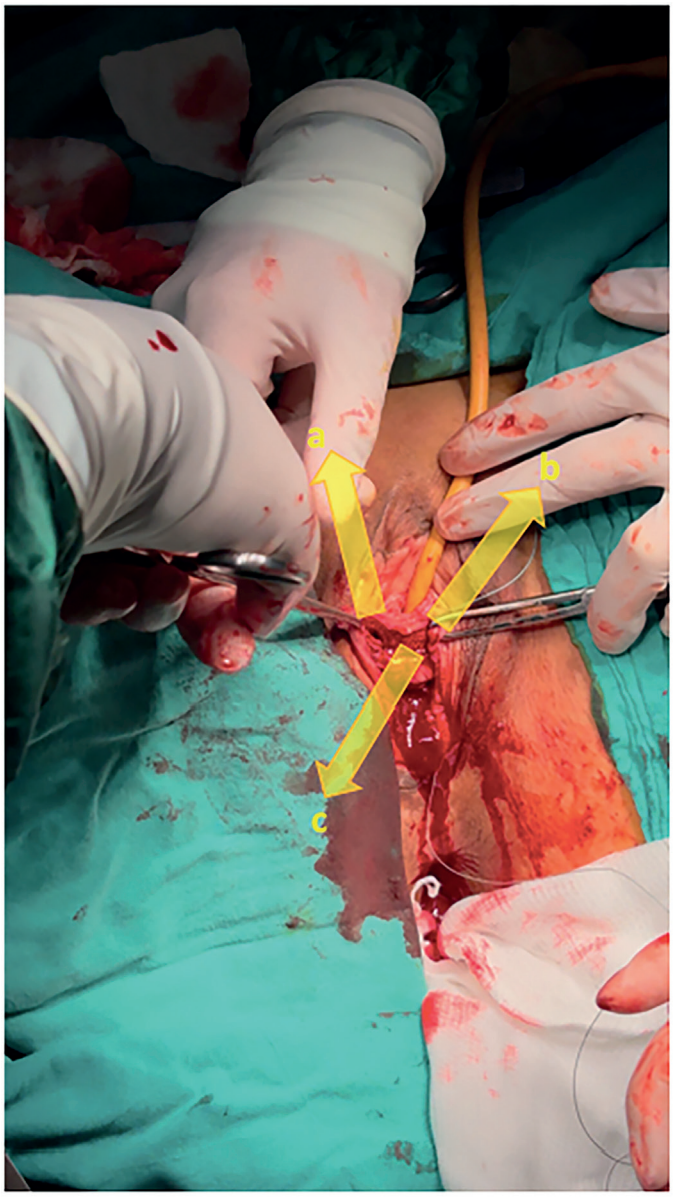

Figure 1. a: The sulcus created in the paraurethral area for the plication of the right PUL; b: The suture passed through the left lateralbranch of the PUL; c: A midline vertical incision made approximately 2 cm below the urethra
PUL: pubourethral ligament

Statistical Analysis

Statistical analyses were performed using SPSS version 29.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation and minimum-maximum values, whereas categorical variables were reported as numbers (n) and percentages (%). The distribution of continuous variables was assessed using the Shapiro-Wilk test. Differences between preoperative and postoperative Hb levels were analyzed with the Wilcoxon signed-rank test. Cough stress test results at days 7 and 30 were evaluated together with patients' subjective symptoms;

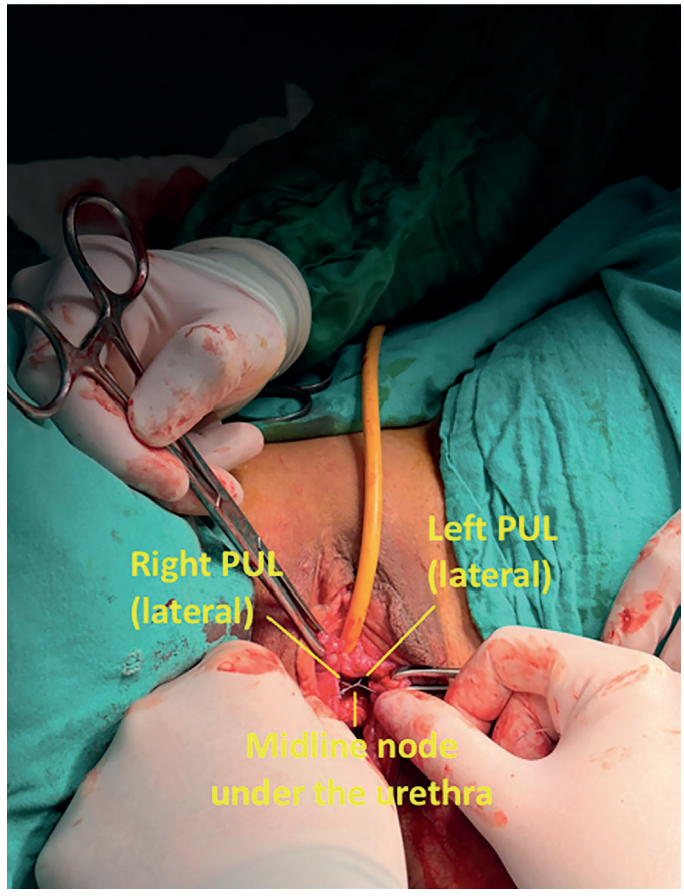

Figure 2. The suture passed through the right and left lateral branches of the PUL and was tied at the midline beneath the urethra
PUL: pubourethral ligament

the cough test was used only as a supportive observational tool. Associations between surgical success and categorical factors were analyzed using the chi-square test or Fisher's exact test where appropriate. A p-value <0.05 was considered statistically significant.

RESULTS

The mean age of the 23 patients included in the study was 57.4±5.8 years (range: 47-68), and the mean BMI was 29.5±3.1 kg/m² (range: 25-36). Sixteen patients (69.6%) were postmenopausal, while seven (30.4%) were premenopausal. Since patients with primary surgical indication of genital prolapse were excluded from the study, only stage 0 or stage I prolapse was observed in the POP-Q evaluation. Six patients (26.1%) were classified as stage 0, and 17 patients (73.9%) as stage I prolapse. The mean POP-Q values were as follows: Aa: -1.5±0.3, Ba: -2.0±0.4, C: -6.0±1.0, Ap: -1.3±0.3, Bp: -1.8±0.4, TVL: 9.0±0.5.

The mean preoperative Hb level was 12.8±0.35 g/dL, whereas the postoperative Hb level was 12.1±0.38 g/dL. The mean operative time was 37.4±5.7 minutes (range: 30-48), and the mean length

of hospital stay was 1.26±0.45 days. Table 1 demonstrates the demographic and perioperative characteristics of the patients.

At postoperative day 7 follow-up, SUI symptoms assessed by anamnesis had resolved in 16 patients (69.6%), while persisting in 7 patients (30.4%). At postoperative day 30, symptoms had regressed in 18 patients (78.3%), whereas 5 patients (21.7%) continued to report incontinence. According to the postoperative cough stress test, 16 patients (69.6%) were negative and 7 (30.4%) were positive on day 7, while at day 30, 17 patients (73.9%) were negative and 6 (26.1%) were positive. Detailed results are shown in Table 2.

At postoperative day 30, patients with a positive cough stress test had a significantly higher mean age (63.5±3.8 years vs. 55.3±4.8 years, p=0.001), BMI (33.0±2.4 vs. 28.2±2.3 kg/m², p=0.002), and operative time (45.7±1.8 min vs. 34.5±3.1 min, p<0.001) compared with those who tested negative. Detailed comparative results are shown in Table 3. Although all cases with treatment failure at day 30 were in the postmenopausal period, the association between menopausal status and surgical outcomes was not statistically significant (p=0.124).

All patients were advised to avoid sexual intercourse for 6 weeks postoperatively; therefore, early dyspareunia was not assessed. During the study period, no major complications such as acute urinary retention, hematoma, or intraoperative organ injury were observed. However, according to the Clavien-Dindo classification,[7] two complications (8.7%, n=2) occurred: One patient developed infected granulation tissue on postoperative day 27 requiring surgical excision under local anesthesia (Grade IIIa), and another patient reported severe vulvar pain at the one-month follow-up visit. Laboratory investigations including urinalysis, complete blood count, and C-reactive protein were within normal limits, and the pain resolved spontaneously without further intervention (Grade I).

Table 1. Demographic and perioperative characteristics of the patients

Variable	Mean ± SD	Minimum-maximum	Median
Age (years)	57.4±5.8	47-68	
BMI (kg/m²)	29.5±3.1	25-36	
Operation time (minute)	37.4±5.7	30-48	
Hb preop (g/dL)	12.8±0.35	11.9-13.3	
Hb postop (g/dL)	12.1±0.38	11.0-12.6	
Parity		1-5	3
Hospital stay (stay)		1-2	1

SD: standard deviation; BMI: body mass index; Hb: hemoglobin

Table 2. Postoperative outcomes of SUI symptoms and cough stress test

	Postoperative 7th day n (%)	Postoperative 30th day n (%)
SUI symptom present	7 (30.4%)	5 (21.7%)
SUI symptom absent	16 (69.6%)	18 (78.3%)
Cough test positive	7 (30.4%)	6 (26.1%)
Cough test negative	16 (69.6%)	17 (73.9%)

SUI: stress urinary incontinence

Table 3. Comparison of demographic and operative variables according to 30th-day cough stress test results

Variable	Negative (n=17)	Positive (n=6)	p-value
Age (years)	55.3±4.8	63.5±3.8	0.001
BMI (kg/m²)	28.2±2.3	33.0±2.4	0.002
Operation time (minute)	34.5±3.1	45.7±1.8	<0.001

Values are presented as mean ± standard deviation. Statistical analysis was performed using the Independent Samples t-test; BMI: body mass index

DISCUSSION

In the present study, the midline approach for PUL plication was assessed. This technique, characterized by being less invasive and technically simpler, achieved a 73.9% success rate at 30 days based on the cough stress test. These findings provide preliminary evidence that the midline approach may be a promising short-term alternative and could be considered among mesh-free surgical options for the management of SUI. Short-term outcomes demonstrated that ULP with the midline approach increased continence rates from 69.6% on postoperative day 7 to 73.9% on day 30. This improvement may be explained, as described in the Autogenic Ligament Procedure, by the progressive collagen deposition in response to the foreign material that typically intensifies during the postoperative weeks.[9] In contrast, Petros and Palma[4] reported that 30 of 31 patients undergoing the original bilateral paraurethral approach achieved a negative cough stress test before hospital discharge, indicating a higher early success rate even prior to the onset of collagen formation. Although our final success rate appears lower, the improvement observed between the two postoperative assessments suggests that approximation of the lateral arms of the PUL with non-absorbable polyester sutures may stimulate collagen deposition around the ligamentous structures and immediately beneath the urethra, thereby progressively reducing urethral hypermobility. However, it is

important to emphasize that in Petros's original ULP technique, all four critical sites contributing to urethral function (the mid-urethra, the retropubic portion, the EUL, and the PCM) are repaired, whereas in our study only a single site—the retropubic portion—was addressed, which may have limited the overall effectiveness of the procedure.

Sivaslıoğlu et al.[10] reported a 12-month cure rate of 83% in their ULP series, whereas Brasoveanu et al.,[11] in their evaluation of long-term outcomes of TOT and ULP, reported a 70% improvement rate in 40 patients undergoing ULP. In our series, a continence rate of 73.9% was achieved in the early follow-up period. The higher long-term success rates reported by Sivaslıoğlu et al.[10] may be attributable to the experience level of the urogynecology teams involved or directly to the surgical technique, namely bilateral repair of the lateral, medial, and external arms of the PUL. In addition, the lower surgical response rates reported by Brasoveanu et al.[11] may be explained by the limited sample size and the short, one-month follow-up period in our study.

Brasoveanu et al.[11] performed the ULP procedure on an outpatient basis and reported a mean hospital stay of 1.02±0.15 days even in the TOT group. These findings suggest that ULP could potentially be performed rapidly and simply under local anesthesia, even in office-based settings, in the future. Although we propose that the midline approach to ULP is a simpler and less invasive technique, it should be noted that all operations in our series were performed by a single surgeon. This surgeon had commenced residency training in obstetrics and gynecology nine years earlier and had been practicing as a specialist for the past five years, yet had only recently begun performing this specific technique. Therefore, it is likely that the surgical learning curve influenced our results. Indeed, while Brasoveanu et al.[11] reported a mean operative time of 9.9 minutes in the ULP group, the mean operative time in our series was 37.4±5.7 minutes, and the mean hospital stay was 1.26±0.45 days, findings that can most probably be attributed to the same reason.

As is well known, the MUS provides a scaffold along its entire length, thereby creating a well-defined U-shaped neocollagenous PUL,[10] the midline ULP transmits tensile forces through a single suture knot passed from the lateral arms and tied beneath the urethra (Figure 2). In this setting, the central transmission of tension may initiate a localized, albeit limited, collagen response around the knot. Although this reaction would not reproduce the broad U-shaped structure obtained with a mesh tape, it may still result in a U-like collagen accumulation radiating from the knot and thereby prevent further elongation of the lax PUL. Nevertheless, this explanation has not been demonstrated histologically or radiologically in our study; however, the mechanism underlying SUI cure in the patients may plausibly have developed through this process. In our study, patients with treatment failure at day 30 had significantly higher age, BMI, and operative times, suggesting that elderly, obese patients and those with longer procedures may be at greater risk of short-term surgical failure. However, although all patients with failure were postmenopausal, menopausal status was not statistically associated with surgical outcomes (p=0.124), most likely due to the limited sample size. In our study, the choice of a midline approach may evoke the impression of a modification of the Kelly plication. In Kelly and Dumm's[12] procedure, sutures are placed in the periurethral tissues at the bladder neck, whereas in our technique the sutures are passed through the retropubic arms of the PUL and tied at the midline. This strategy aims not merely to narrow the bladder neck, but to restore the ligamentous support of the urethra.[12] Nevertheless, it is true that the concept of approaching ULP through the midline has its roots in the historical familiarity of the Kelly plication.

Study Limitations

This study has several limitations. First, the relatively small sample size and the evaluation of outcomes limited to a one-month follow-up restrict the generalizability of our findings. Moreover, all operations were performed by a single surgeon who had only recently begun performing this technique, and therefore the potential influence of the learning curve should be considered. Complication assessment was confined to the early postoperative period; thus, long-term complications such as dyspareunia or chronic pelvic pain could not be evaluated. Finally, no direct control group with MUS or other surgical techniques was included, and our results can therefore only be compared indirectly with those reported in the literature. Despite these limitations, the present study provides encouraging short-term results in a limited series; however, it should be regarded as a pilot investigation that requires confirmation with 12-month outcomes.

CONCLUSION

Although the initial results from this pilot series are encouraging, the small sample size and short follow-up remain important limitations. If long-term durability is confirmed in larger cohorts, ULP with the midline approach may represent a safe and simple alternative for the treatment of SUI.

ETHICS

Ethics Committee Approval: Ethical approval was obtained from the Kırşehir Ahi Evran University Faculty of Medicine

Health Sciences Scientific Research Ethics Committee (decision no: 2025-08/92, date: 29 April 2025).

Informed Consent: Written consent was obtained from the patient for the sharing of the photographs included in the original document.

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FOOTNOTES

Contributions

Surgical and Medical Practices: A.T., Concept: A.T., F.D., Design: A.T., Data Collection or Processing: A.T., Analysis or Interpretation: A.T., Literature Search: A.T., F.D., Writing: A.T., F.D.

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Adnexal masses in adolescents: Clinical predictors of torsion and outcomes of fertility-sparing surgery

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ABSTRACT

Objective: Adnexal masses in adolescents present unique clinical challenges, particularly regarding fertility preservation. This study aimed to characterize the clinical profile, management, and outcomes of adolescents with surgically treated adnexal masses, with a specific focus on identifying risk factors for torsion and evaluating rates of ovarian conservation.

Materials and Methods: This retrospective cohort study included 92 adolescents (10-21 years) who underwent surgery for adnexal masses at a tertiary University Hospital between 2008 and 2018. Data on demographics, clinical presentation, imaging (IOTA classification), surgical details, and pathology were analyzed. A comparative analysis between torsion (n=29) and non-torsion (n=63) groups was performed, followed by multivariate logistic regression to identify independent predictors of torsion.

Results: The mean age was 17.3 years, and abdominal pain was the most common symptom (43.5%). Torsion occurred in 31.5% of cases. Younger age was the only independent risk factor for torsion (aOR =0.85 per year, p=0.018). Laparoscopy was the primary surgical approach (68.5%), and cystectomy was the most frequently performed procedure (68.5%). Final pathology was benign in 89.1% of cases, with cystadenofibroma (20.7%), hemorrhagic cyst (19.6%), and dermoid cyst (14.1%) being the most common. Malignancy was identified in 10.9% of cases.

Conclusion: Adnexal torsion is common in adolescents, and due to low cancer risk and advances in minimally invasive techniques, laparoscopy has become the gold standard, aligning with patient and parent preferences for less aggressive surgeries. Adnexal torsion is common in adolescents, and due to low cancer risk and advances in minimally invasive techniques, laparoscopy has become the gold standard, aligning with patient and parent preferences for less aggressive surgeries.

Keywords: Adolescents; adnexal torsion; laparoscopy; fertility-sparing

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INTRODUCTION

Ovarian masses in adolescents represent a significant clinical challenge, distinct from adult presentations in both pathology and management goals. While rare, with an estimated incidence of 2.6 cases per 100,000 girls, these lesions can profoundly impact future reproductive health and quality of life.[1,2] The predominant symptom, abdominal pain, is a common emergency department complaint, often leading to diagnostic difficulty in differentiating benign conditions from rare malignancies or surgical emergencies like ovarian torsion.[3,4]

The majority of adnexal masses in children and adolescents are benign, with malignancy present in only 4-11% of surgically excised neoplasms. Non-neoplastic lesions include functional cysts, torsion, and abscesses, while neoplasms consist of germ cell, epithelial, and other tumor types. Germ cell tumors are most common in this population, with mature teratoma being the prevalent type. Clinical symptoms often include abdominal pain, palpable masses, nausea, and hormonal changes such as menstrual irregularities. Management varies, with small benign masses treated conservatively and larger or complex ones requiring surgical intervention for diagnosis and symptom relief.[5,6]

Adnexal torsion is a serious surgical emergency that constitutes a considerable portion of surgical cases. The ovarian blood supply comes from both the ovarian and uterine arteries, and when the ovary twists, it can cause venous congestion, swelling, and a disruption in blood flow. This condition can affect females of any age but is most prevalent among women in their reproductive years. According to a 10-year review of surgical cases, ovarian torsion ranked as the fifth most frequent emergency, accounting for 2.7% of all cases. In children and adolescents, the incidence of adnexal torsion is 4.9 per 100,000 girls.[7,8]

Prompt diagnosis and intervention are crucial for preserving ovarian function, but this can be difficult since preoperative assessments often suggest a problem more than surgical findings confirm it. Pelvic ultrasound serves as the primary imaging method; however, clinical signs—especially the sudden onset of severe pain accompanied by nausea and vomiting—are critical and should take precedence over ambiguous imaging results. Given the importance of maintaining fertility and hormonal balance in younger patients, there has been a significant shift towards using minimally invasive techniques in ovarian-conserving surgical approaches.[9]

This study aimed to identify risk factors for adnexal torsion and evaluate ovarian preservation outcomes in adolescents undergoing surgery for ovarian masses, comparing torsion and non-torsion cases.

MATERIALS AND METHODS

This investigation was designed as a retrospective cohort study conducted at a King Saud University Hospital. The research covered an 11-year period from January 2008 through December 2018 and focused on female adolescents aged 10 to 21 years who underwent surgical treatment for adnexal masses. Data were gathered from patients admitted via the emergency department or through the gynecology ambulatory service, including pregnant individuals who presented with adnexal masses not related to ectopic pregnancy. Ethical approval for the study was obtained from the Institutional Review Board of King Saud University Hospital (number: 19/0068/IRB, date: 30.01.2019). All methods were carried out in accordance with relevant guidelines and regulations (Declaration of Helsinki). Informed general consent was obtained from each patient upon admission, which includes the right to use any information from the patient's file while maintaining the patient's confidentiality.

Eligibility Criteria

Eligibility criteria were strictly applied. Exclusion criteria included cases of ectopic pregnancy, Müllerian duct anomalies, autoamputated adnexa, masses not arising from gynecologic structures, biopsy-confirmed malignancies, recurrent or metastatic cancers, and disseminated cancer. The cohort consisted specifically of patients undergoing surgical management for adnexal masses, with case identification based on admission records from the obstetrics and gynecology department. Data collection drew from both electronic medical records (Cerner system) and archived paper records, popularly known as "yellow files," to ensure a comprehensive capture of relevant information.

Outcomes

Demographic data and clinical characteristics encompassed age, body mass index (BMI), presenting symptoms, imaging results (primarily ultrasound and alternative imaging modalities), and tumor marker levels. Surgical outcomes included the chosen operative approach, the origin of the mass (as determined intraoperatively versus pathology-confirmed), intraoperative complications, estimated blood loss, and procedures performed. Postoperative metrics comprised hospital stay duration, final histopathological diagnosis, and recurrence rates. Additional data points recorded to enrich the clinical portrait included the operating surgeon's subspecialty, the laterality of adnexal involvement, and any documentation of adnexal torsion, all contributing to a thorough appraisal of management and outcomes.

For imaging-based assessment, the study adhered to the International Ovarian Tumor Analysis (IOTA) classification system. This standardized sonographic framework evaluates adnexal lesions using predefined ultrasound criteria, considering features such as cyst wall characteristics, septations, presence of solid components, papillary projections, and vascular patterns as assessed by Doppler imaging. Benign versus malignant categorization relied on IOTA diagnostic rules, which integrate tumor size, echogenicity, and flow characteristics. In this adolescent cohort, ultrasound findings were consistently interpreted in line with IOTA guidelines to enable uniform risk stratification and to inform clinical decision-making regarding adnexal masses.

Statistical Analysis

Statistical methods All analyses were conducted in SPSS, version 25 (IBM Corp., Armonk, NY). Descriptive statistics are presented as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. To identify factors associated with adnexal torsion (TO vs. non-TO), univariate logistic regression analyses were first performed for candidate predictors (age, BMI, presenting symptoms, IOTA category, imaging, tumor markers, mass laterality, mass origin, and initial surgical plan). Variables with $p<0.10$ in univariate analyses were entered into a multivariate logistic regression model to obtain adjusted odds ratios (aOR) and 95% confidence intervals (CIs). For sparse cells, Fisher's exact test was used as appropriate. Model fit was assessed with the Hosmer-Lemeshow test. A two-sided p-value <0.05 was considered statistically significant. The study complied with ethical standards, with data collection commencing after formal departmental approval and consent where applicable.

RESULTS

Clinical characteristics of all girls presenting with abdominal pain and a pelvic mass are presented in Table 1. The study cohort

Table 1. Comparison of clinical characteristics between patients with and without torsion

Characteristic	TO (n=29)	Non-TO (n=63)	*P*-value
Demographics			
Mean age (years ± SD)	16.1±2.8	17.7±3.1	0.021
Mean BMI (kg/m² ± SD)	23.4±5.1	25.4±7.2	0.151
Presenting symptoms, n (%)			
Abdominal pain (isolated)	14 (48.3%)	26 (41.3%)	0.520
Abdominal pain + nausea/vomiting	8 (27.6%)	15 (23.8%)	0.694
Incidental finding	2 (6.9%)	9 (14.3%)	0.288[1]
Preoperative assessment, n (%)			
IOTA: Benign	17 (58.6%)	35 (55.6%)	0.782
IOTA: Malignant	3 (10.3%)	6 (9.5%)	0.900[1]
Other imaging (CT/MRI) performed	20 (69.0%)	43 (68.3%)	0.943
Tumor markers elevated	2 (6.9%)	5 (7.9%)	0.847[1]
Surgical & pathological factors			
Mass laterality, n (%)			
- Right	15 (51.7%)	30 (47.6%)	0.705
- Left	12 (41.4%)	27 (42.9%)	0.892
- Bilateral	2 (6.9%)	6 (9.5%)	0.643[1]
Mass origin: Ovarian, n (%)	25 (86.2%)	53 (84.1%)	0.794
Procedure performed, n (%)			
- Cystectomy	20 (69.0%)	43 (68.3%)	0.943
- Salpingo-oophorectomy	2 (6.9%)	5 (7.9%)	0.847[1]
- Salpingectomy	1 (3.4%)	3 (4.8%)	0.738[1]
Final pathology: Benign, n (%)	26 (89.7%)	55 (87.3%)	0.744

[1]: *P*-value calculated using Fisher's exact test due to expected cell counts <5. Statistically significant ($p<0.05$); SD: standard deviation; BMI: body mass index; TO: torsion; CT: computed tomography; MRI: magnetic resonance imaging; IOTA: International ovarian tumor analysis

comprised 92 adolescent females with a mean age of 17.25 years (±3.04) and a mean BMI of 24.92 kg/m² (±6.86). Abdominal pain was the most common presenting symptom (43.5%, n=40), frequently accompanied by nausea/vomiting (n=23). Other presentations included combined symptoms such as pressure symptoms with nausea/vomiting (n=3) and amenorrhea with vomiting (n=1), alongside incidental findings (n=11), isolated pressure symptoms (n=5), and abnormal uterine bleeding (n=4). Preoperative ultrasound (IOTA classification) indicated benign masses in 56.5% of cases (n=52) and malignant in 9.8% (n=9). Additional imaging computed tomography/magnetic resonance imaging was utilized in 68.5% of patients (n=63), with 40.2% (n=37) exhibiting normal imaging findings. Tumor markers were elevated in a minority, specifically HCG and CA125 in 2.2% (n=2), LDH and CA125 in 1.1% (n=1), and AFP and CA125 in 4.3% (n=4).

Surgical procedure for patients and pathology review is presented in Table 2. Surgical management was primarily laparoscopic (68.5%, n=63). Intraoperatively, masses were of ovarian origin in 84.8% (n=78), with paratubal (12.0%, n=11) and paraovarian (3.3%, n=3) sources less common. Fertility-sparing cystectomy was the most frequent procedure (68.5%, n=63). Other interventions included conservative surgery (10.9%, n=10), salpingo-oophorectomy (7.6%, n=7), salpingectomy (4.3%, n=4), cyst aspiration (3.3%, n=3), partial oophorectomy (3.3%, n=3), and oophorectomy (2.2%, n=2). Final pathology was predominantly benign (89.1%), with common diagnoses being cystadenofibroma (20.7%, n=19), hemorrhagic cyst (19.6%, n=18), and dermoid cyst (14.1%, n=13). Malignant pathology (10.9%, n=10) included dysgerminoma (n=2), mixed germ cell tumor (n=2), and single cases of immature teratoma, mucinous adenocarcinoma, granulosa cell tumor, Sertoli cell tumor, pure yolk sac tumor, and a sex cord tumor. For confirmed malignancies, management involved comprehensive surgical staging (including lymph node sampling and peritoneal cytology), multidisciplinary tumor board review, and adjuvant chemotherapy for advanced-stage disease. Recurrence was rare (4.35%, n=4).

Table 2. Surgical method for patients with and without adnexal torsion

Procedure and pathology	TO (n=29)	non-TO (n=63)
Adnexectomy	3	11
· Cystadenofibroma	1	3
· Hemorrhagic cyst	1	2
· Malignant (dysgerminoma, mixed GCT, granulosa)	1	4
· Other (e.g., complex benign)	0	2
Cystectomy	20	43
· Cystadenofibroma	6	13
· Hemorrhagic cyst	6	12
· Dermoid cyst	4	9
Mucinous cystadenoma	2	5
· Paratubal cyst	2	4
Salpingectomy	1	4
· Paratubal cyst	1	4
Conservative surgery	3	10
· Hemorrhagic cyst	2	5
· Endometrioma	1	3
· Other benign	0	2
Cyst aspiration	1	3
· Simple cyst	1	3
Partial oophorectomy	1	2
· Cystadenofibroma	1	2
Oophorectomy	0	2
· Benign pathology	0	2

GCT: giant cell tumor; TO: torsion

Clinical Characteristics Comparing Patients with Torsion and Those with An Alternate Diagnosis

The cohort was divided into two groups: Those with surgically confirmed torsion (TO, n=29) and those without (non-TO, n=63). Comparative analysis revealed that patients in the TO group were significantly younger (16.1±2.8 vs. 17.7±3.1 years, p=0.021). The prevalence of symptoms, including abdominal pain with nausea/vomiting (27.6% vs. 23.8%), and the use of additional imaging (69.0% vs. 68.3%) were similar between groups. Incidental discovery was less common in the TO group (6.9% vs. 14.3%), though not statistically significant. Surgical management emphasized cystectomy in both groups (69.0% vs. 68.3%), with no significant differences in the rates of more radical procedures or final benign pathology (89.7% vs. 87.3%) (Table 1).

The multivariate logistic regression analysis revealed that younger age significantly increases the risk of adnexal torsion. Specifically, for each additional year in age, the odds of torsion decrease by about 15% (aOR =0.85, 95% CI: 0.74-0.97, p=0.018), indicating higher risk in younger adolescents. Other factors, such as BMI and incidental mass discovery, did not significantly predict torsion after adjusting for age. Additionally, there was no significant association found between nausea and vomiting, pain, or malignant IOTA classification in the univariate analysis Table 3.

Table 3. Univariate and multivariate logistic regression analysis of factors associated with adnexal torsion

Factor	Univariate analysis		Multivariate analysis	
	OR	*P*-value	aOR	*P*-value
Age (per year)	0.86 (0.75-0.98)	0.021	0.85 (0.74-0.97)	0.018
BMI (per kg/m²)	0.95 (0.88-1.02)	0.155	0.95 (0.88-1.02)	0.173
Incidental finding	0.45 (0.09-2.17)	0.317	0.42 (0.08-2.12)	0.293
Abdominal pain + N/V	1.22 (0.46-3.21)	0.694	-	-
IOTA: Malignant	1.10 (0.26-4.68)	0.900	-	-

OR: odds ratio; CI: confidence interval; N/V: nausea/vomiting; aOR: adjusted odds ratio; BMI: body mass index; IOTA: International ovarian tumor analysis

DISCUSSION

Our Results and Their Interpretation

Our examination of 92 teenagers with adnexal masses reveals a clinical profile highlighting the significance of abdominal pain as a key symptom for surgical assessment, with an average age of 17.3 years. Laparoscopic surgery was frequently employed (68.5%), with a strong preference for fertility-sparing cystectomy, demonstrating effective conservative surgical techniques. Pathological findings are promising, showing 89.1% benign conditions and a low recurrence rate of 4.35%, which supports this organ-preserving strategy. Furthermore, the organized management of malignant cases, including tumor board assessments and personalized adjuvant treatment, reflects a thorough and standardized care approach at our facility.

The comparative study of the torsion (TO, n=29) and non-torsion (non-TO, n=63) groups reveals a significant finding: individuals with torsion are notably younger, with an average age difference of 1.6 years, which is clinically relevant in adolescents. Other factors, such as symptoms, preoperative imaging, and tumor marker levels, were remarkably similar between the groups, making it challenging to differentiate torsed from non-torsed masses before surgery. Additionally, high rates of cystectomy in both groups suggest that torsion did not increase the likelihood of radical surgery, highlighting a notable achievement in clinical practice.

The multivariate logistic regression analysis revealed that younger age significantly increases the risk of adnexal torsion. Specifically, for each additional year in age, the odds of torsion decrease by about 15% (aOR =0.85, 95% CI: 0.74-0.97, p=0.018), indicating higher risk in younger adolescents. Other factors, such as BMI and incidental mass discovery, did not significantly predict torsion after adjusting for age. Additionally, there was no significant association found between nausea and vomiting, pain, or malignant IOTA classification in the univariate analysis.

Comparison of Our Results to Similar Studies

Our study and Liu et al.'s[10] study share fundamental methodological similarities as retrospective cohort analyses of adolescent adnexal masses using multivariate logistic regression, yet reveal distinctly different torsion risk profiles. While we identified younger age as the sole significant predictor of torsion (mean 16.1 vs. 17.7 years in non-torsion, p=0.021), Liu et al.[10] demonstrated that clinical presentation characteristics—specifically acute onset pain (OR: 15.9), persistent/recurrent pain (OR: 24.2), and mass size >5 cm (OR: 4.1)—were the predominant risk factors. This contrast suggests potential population-specific differences or varying clinical assessment protocols. Methodologically, Liu et al.'s[10] larger sample (212 vs. our 92 patients) enabled more detailed pain characterization and identified a higher torsion prevalence (36.9% vs. 31.5%), while both studies maintained rigorous statistical approaches. Notably, Liu et al.'s[10] reported significantly lower ovarian conservation rates in torsion cases (66.7% vs. our 89.7%), which they attributed to necrotic changes requiring adnexectomy in 29.5% of torsion cases—a factor not specifically analyzed in our study. Both investigations confirmed the predominance of benign pathology and right-sided laterality in torsion cases, but diverged on mass size significance; Liu et al.'s[10] found categorical size >5 cm predictive, while we found no continuous size difference. These comparative findings suggest that torsion risk assessment should incorporate both demographic factors (age) and clinical presentation patterns, providing complementary rather than contradictory evidence for clinical decision-making.

Bergeron et al.'s[11] study did not specifically analyze adnexal torsion as a primary outcome, focusing instead on surgical specialty differences and general mass management. Our study provided dedicated torsion analysis, revealing that younger age was the sole significant predictor of torsion (16.1 vs. 17.7 years, p=0.021), while Bergeron's data showed gynecologists managed more torsion cases (24 vs. 35 by surgeons) without analyzing torsion-specific risk factors. Both studies found similar

high rates of benign pathology in torsion cases (89.7% in our study), but only our research conducted multivariate regression specifically for torsion prediction. Bergeron's work highlighted that emergent procedures—often including torsion cases—were associated with higher ovarian conservation rates, which aligns with our finding that cystectomy was equally common in both torsion and non-torsion groups (69%).

Luthra and Kumar's[12] study and our research both analyzed adolescent adnexal masses but differed significantly in methodology and demographics. Their 20-year series featured younger patients (median age 11 years) and included cases involving neonates, while our focus was solely on adolescents with a mean age of 17.25 years. Both studies reported high torsion rates (66.7% in Luthra vs. 31.5% in ours), but Luthra and Kumar's[12] had lower ovarian conservation (66.7% vs. our 89.7%), attributed to gangrenous cases requiring adnexectomy. Our larger sample (92 vs. 28) and multivariate regression provided stronger evidence for age as a torsion predictor. While both studies confirmed right-sided predominance and benign pathology, Luthra and Kumar's[12] reported higher malignancy rates (3.7% vs. 10.9%) and unique complications, highlighting the importance of fertility preservation.

Clinical Implications of Our Study

Our study highlights younger age as a key risk factor for adnexal mass torsion, emphasizing the need for early suspicion and intervention in patients under 16. With a 68.5% success rate for laparoscopic, fertility-sparing approaches, conservative surgical management is often warranted, even in torsion cases. The findings of consistent benign pathology (89.1%) and low recurrence (4.35%) advocate for age-aware triage and ovarian conservation through timely intervention in younger adolescents.

The strengths of our study include the use of robust multivariate regression analysis that identifies age as the key predictor of torsion, the application of standardized IOTA classification for imaging evaluations, thorough tracking of surgical and pathological outcomes, and careful statistical analysis. This was done within a clearly defined group of adolescents with specific exclusion criteria, ensuring our findings are focused and clinically relevant for this particular demographic.

Study Limitations

However, the limitations of our study include its retrospective, single-center design, which may impact the generalizability of our findings. The relatively small sample size (n=92) affects the statistical power regarding rare outcomes. There is also a possibility of selection bias due to hospital-based sampling, along with unmeasured confounding factors that might affect our results. Additionally, the absence of long-term follow-up data hinders our ability to evaluate fertility outcomes and patterns of late recurrence.

Recommendation for Future Research

In the future, research should focus on larger, multicenter studies to better understand how age can predict ovarian torsion in various populations. Long-term follow-ups will be crucial to evaluating fertility outcomes and recurrence rates after conservative surgery. Additionally, using advanced imaging techniques and molecular profiling could greatly improve our ability to assess risks before surgery. Conducting comparative studies on different surgical methods and their effects on ovarian function would be valuable for creating evidence-based approaches to preserving fertility in adolescents dealing with adnexal masses.

CONCLUSION

Adnexal torsion is common in adolescents, and due to low cancer risk and advances in minimally invasive techniques, laparoscopy has become the gold standard, aligning with patient and parent preferences for less aggressive surgeries. Adnexal torsion is common in adolescents, and due to low cancer risk and advances in minimally invasive techniques, laparoscopy has become the gold standard, aligning with patient and parent preferences for less aggressive surgeries.

ETHICS

Ethics Committee Approval: Ethical approval for the study was obtained from the Institutional Review Board of King Saud University Medical City (number: 19/0068/IRB, date: 30.01.2019).

Informed Consent: After explaining the procedure, all participants gave informed consent. We confirm that all methods were performed according to the relevant guidelines and regulations, per the Declaration of Helsinki.

FOOTNOTES

Contributions

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

DISCLOSURES

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

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Effects of vaginal spheres combined with pelvic floor muscle training on sexual function, urinary incontinence, and quality of life: A pilot randomized controlled trial

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ABSTRACT

Objective: To evaluate the effects of pelvic floor muscle training (PFMT), with or without vaginal spheres (VS), on urinary incontinence severity, pelvic floor (PF) muscle strength, sexual function, and pelvic organ support in women.

Materials and Methods: This single-center, two-arm, parallel-group pilot randomized controlled trial was conducted at a tertiary hospital between October 2024 and April 2025. Women aged 18-75 years with ≥6-weeks of urinary incontinence and/or sexual dysfunction and PF muscle weakness (modified Oxford scale ≤3) were recruited. Of 40 eligible candidates, 26 (65%) were randomized via sealed opaque envelopes to receive either PFMT-only (n=14) or PFMT with VS (VS+PFMT; n=12). Both groups completed a 6-week home-based PFMT protocol; the VS+PFMT group additionally used VS daily during light physical activity. Blinded assessors evaluated PF muscle strength (modified Oxford scale), urinary symptoms (ICIQ-SF and SSI), female sexual function index (FSFI), and pelvic organ support (POP-Q). Feasibility metrics included recruitment, retention, adherence, and safety.

Results: Of 26 participants, 14 (54%) completed the intervention (7 per group). Attrition was primarily due to time constraints and exercise fatigue. Two participants in the VS+PFMT group reported mild vaginal burning. Assessment and exercise log compliance were high. Within-group analysis showed statistically significant improvements in FSFI scores (Δ=+2.53; p=0.002), ICIQ-SF scores (p=0.043), PF muscle strength (p=0.001), and POP-Q measurements (p=0.008). No significant between-group differences were observed in clinical outcomes.

Conclusion: Adjunctive use of VS with PFMT appears to be a safe, feasible, and well-tolerated intervention. Within-group improvements suggest potential therapeutic benefit in PF function and sexual health.

Keywords: Feasibility trial; Kegel balls; pelvic rehabilitation; sexual health outcomes; urinary incontinence

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INTRODUCTION

Pelvic floor dysfunction (PFD) is a multifactorial condition most often associated with pelvic floor muscle (PFM) weakness. It presents with a wide spectrum of symptoms, including urinary incontinence, vaginal laxity, and sexual dysfunction, each of which has been shown to substantially impair women's physical, psychological, and sexual well-being, ultimately leading to a marked reduction in quality of life.[1] Although pelvic floor muscle training (PFMT) is widely recognized as the first-line conservative management for PFD, its effectiveness in routine practice is frequently limited. Barriers such as poor long-term adherence, difficulties in performing correct contractions without professional supervision, and low patient engagement contribute to suboptimal outcomes, despite the strong evidence supporting PFMT in controlled research settings.[2]

To overcome these limitations, several adjunctive intravaginal devices have been introduced. Among them, vaginal cones and vaginal spheres (VS) are most commonly discussed. Their mechanisms differ: Cones rely on active muscular retention against gravity, whereas VS provide passive internal stimulation through weighted movement, theoretically enhancing proprioceptive awareness during daily activity.[3] Despite increasing availability in clinical and commercial settings, there is still a lack of high-quality randomized trials evaluating their safety, acceptability, and clinical efficacy.[4]

In light of this gap, the present pilot randomized controlled trial (RCT) was designed to assess the feasibility, tolerability, and preliminary effects of combining VS with PFMT in women with PFD. We hypothesized that adjunctive use of VS would augment PFM strength and yield additional improvements in urinary symptoms, vaginal laxity, and sexual function compared with PFMT alone.

MATERIALS AND METHODS

Trial Design

This was a single-center, parallel-group feasibility and pilot RCT with a planned 1:1 allocation ratio, conducted at a tertiary hospital between October 2024 and April 2025. The study protocol was approved by the Institutional Review Board of University of Health Sciences Türkiye, Koşuyolu High Specialization Training and Research Hospital (approval no: 2024/14/889, date: 30/07/2024). The study assessed the acceptability, safety, and preliminary effects of PFMT with or without the addition of VS in women with PFD. No major protocol modifications occurred after commencement. ClinicalTrials.gov Identifier: (NCT07048145), registered July 01, 2025.

Participants

Women aged 18-75 years with urinary incontinence and/or sexual dysfunction for ≥6-weeks and PF weakness [modified Oxford scale (MOS) ≤3] were eligible. Exclusion criteria included prior pelvic surgery, severe prolapse (POP-Q stage IV), active infection, fecal incontinence, neurological disorders, pregnancy, recent childbirth (<6-weeks), or dyspareunia due to hyperactive PF. All participants were sexually active and fluent in Turkish. Eligible patients were identified during gynecology consultations and recruited by the principal investigator (obstetrician-gynecologist). Written informed consent was obtained before randomization.

Intervention Protocol

Both groups received a structured 6-week, home-based PFMT program targeting fast- and slow-twitch fibers. Daily sessions consisted of sets of rapid and sustained contractions, progressing from 5 sets (weeks 1-3) to 10 sets (weeks 4-6). Instruction and demonstration were provided by the investigator, with visual analogies used to aid comprehension. Participants were instructed to begin PFMT in the supine position during the first week to ensure correct activation of the PFMs. As strength and coordination improved, they were encouraged to progress to sitting and, subsequently, standing positions over the 6-week period. This structured progression was applied in both groups to avoid early plateau and to accommodate participants with weak PFMs. Adherence was tracked through self-reported exercise logs. Correct performance of the contractions could not be objectively verified in the home setting, which represents a key limitation of this feasibility study.

The intervention group additionally used a medical-grade silicone vaginal sphere (90 g, 3.5 cm diameter, with internal jiggle weights). It was inserted daily for 30 minutes during weeks 1-3 and 60 minutes during weeks 4-6, worn during light physical activity such as walking or household chores. The control group completed PFMT only.

Outcomes

The primary outcomes of this study were clinical changes in sexual function, urinary incontinence severity, PFM strength, and pelvic organ support, measured using validated assessment tools. All assessments were conducted at baseline and repeated at the 6-week follow-up by the same blinded investigator. Secondary outcomes related to the feasibility of the intervention included recruitment and retention rates, adherence to the protocol, and completeness of outcome data.

Primary Outcome Measures

PFM strength was assessed using the MOS, a 6-point grading system based on digital vaginal palpation.[5] The scale ranges from 0 (no contraction) to 5 (strong contraction with firm lift and compression against resistance). Assessments were performed by the same investigator, an obstetrician-gynecologist with formal training and clinical experience in PFM assessment, in the lithotomy position.

Female sexual function was assessed using the female sexual function index (FSFI), a validated self-administered questionnaire widely used in clinical research.[6,7] The FSFI comprises 19 items grouped into six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. Each domain is scored individually and contributes to a total score ranging from 2 to 36, with higher scores indicating better sexual function.

Urinary incontinence severity and its impact on quality of life were assessed using the international consultation on incontinence questionnaire-short form (ICIQ-SF),[8] a validated self-administered questionnaire.[9] The total score ranges from 0 to 21, with higher scores indicating greater severity. Scores are commonly categorized as mild (1-5), moderate (6-12), severe (13-18), and very severe (19-21).

The severity of urinary incontinence was further assessed using the Sandvik severity index (SSI),[10] a validated self-administered instrument.[11] The total score is calculated by multiplying the responses to these two items, resulting in a categorical classification of severity: Slight (1-2), moderate (3-6), and severe (8-9).

Pelvic organ support was assessed using the simplified pelvic organ prolapse quantification (POP-Q) system, a standardized tool that classifies prolapse based on the most distal point of vaginal descent relative to the hymen.[12] The staging ranges from 0 (no prolapse) to 4 (complete vaginal or uterine eversion.

No changes were made to the planned assessments or outcome measures after the commencement of the pilot trial.

Secondary Outcomes

Secondary outcomes included adherence (defined as completion of ≥80% of prescribed sessions via self-reported exercise logs) and qualitative feedback on tolerability and usability, obtained through brief semi-structured interviews at follow-up. Additionally, this pilot study aimed to explore key feasibility domains, including recruitment, adherence, and retention, to inform the design of a future full-scale randomized trial.

Sample Size

An initial target of 40 participants (20 per group) was pragmatically set, based on sample sizes used in similar feasibility studies on PFMT, to assess recruitment, adherence, and follow-up procedures.[13,14] Due to limited participant engagement and high dropout rates, only 14 participants (7 per group) completed the final assessments and were included in the analysis.

No interim analyses or stopping guidelines were planned or implemented, as this was a small-scale pilot trial without predefined thresholds for early termination.

Randomization

Participants were randomized in a 1:1 ratio using sealed opaque envelopes containing either "0" (PFMT) or "1" (VS+PFMT). The envelopes were prepared and shuffled by the principal investigator and numbered in advance. During enrollment, a clinic secretary uninvolved in the study implementation invited each participant to select one envelope.

Blinding of participants and providers was not possible due to the nature of the intervention. However, the principal investigator, who conducted outcome assessments at follow-up, remained blinded to group allocation to minimize bias.

The study adhered to the CONSORT 2010 guidelines and its extension for pilot and feasibility trials.[15]

Statistical Analysis

Quantitative methods were used to evaluate changes in primary clinical outcomes, including paired and independent t-tests for normally distributed data (e.g., FSFI), and non-parametric tests (Wilcoxon signed-rank, Mann-Whitney U) for skewed variables (e.g., ICIQ-SF, MOS, POP-Q). Categorical changes were analyzed using chi-square or McNemar tests where appropriate.

Secondary feasibility objectives, such as adherence and recruitment rates, were assessed using descriptive statistics. Informal qualitative feedback on intervention acceptability was obtained from participants during follow-up interviews and summarized narratively.

Analyses were conducted using SPSS version 27. All statistical tests were two-tailed, and p-values <0.05 were considered statistically significant.

RESULTS

Participant Flow

Twenty-six women were randomized to VS+PFMT (n=12) or PFMT-only (n=14). Follow-up assessments at 6-weeks were completed by 14 participants (7 from each group), resulting in a follow-up rate of 53.8% (Figure 1).

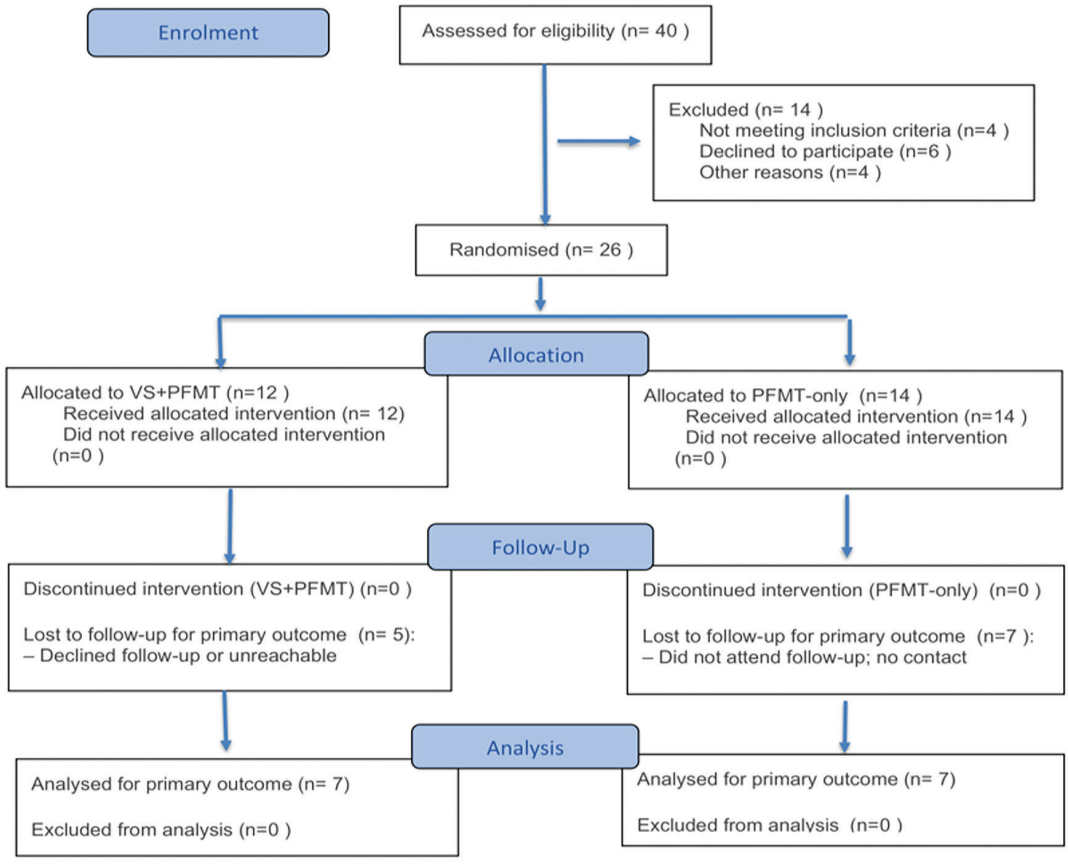

Figure 1. Flow diagram of participant progression through the feasibility and pilot randomized trial (VS+PFMT vs. PFMT-only)
Flow diagram illustrating participant progression through the feasibility and pilot randomized controlled trial comparing vaginal spheres combined with pelvic floor muscle training (VS+PFMT) versus PFMT-only. Of 40 eligible women, 26 (65%) were enrolled and randomized to either group. Fourteen participants (7 per group) completed follow-up assessments. Reasons for drop-out and discontinuation are detailed. No participants discontinued due to adverse events.
VS: vaginal spheres; PFMT: pelvic floor muscle training

Baseline Demographic and Clinical Characteristics

Baseline sociodemographic and clinical characteristics were comparable between groups. Menopausal status (16.7% vs. 7.1%, p=0.586), education level (p=0.823), income status (p=0.586), birth type (p=0.257), episiotomy history (p=0.716), and smoking status (p=0.232) showed no significant differences (Table 1).

Mean age was 41.8±8.6 years in the VS+PFMT group and 37.5±8.5 years in the PFMT-only group (p=0.214). The mean body mass index was similar across groups (27.1±4.6 vs. 27.7±4.3 kg/m², respectively). The mean number of births was 2.08±1.08 in the VS+PFMT group and 2.50±1.60 in the PFMT-only group. The mean duration of urinary incontinence prior to intervention was longer in the VS+PFMT group (72.8±105.9 months) compared to the PFMT-only group (15.4±31.6 months), although this difference did not reach statistical significance. The baseline SSI, MOS, ICIQ-SF total score, and FSFI total score were comparable between the two groups (Table 2).

Feasibility Outcomes

Recruitment

Although 40 participants were initially planned, a total of 26 women were ultimately enrolled in the study over a 6-week period. The most frequently cited reasons for declining participation included time constraints, social challenges, and the perception that the exercises were too frequent or difficult to perform. Four individuals could not be reached by phone, and eight participants who initially agreed to participate failed to attend despite two reminder calls and scheduled appointments.

Retention

Fourteen of the 26 enrolled participants (7 in the VS+PFMT group and 7 in the PFMT-only group) completed the follow-up evaluation, yielding a retention rate of 53.8%. Although this is below the commonly accepted 80% threshold for full trials, it was considered acceptable for a pilot feasibility study, especially given the nature of the intervention and the short study duration.

Table 1. Baseline characteristics of participants stratified by intervention group (VS+PFMT vs. PFMT-only)			
Variable	**VS+PFMT group (n=12)**	**PFMT-only group (n=14)**	***p*-value**
Menopause (yes)	2 (16.7)	1 (7.1)	0.586‡
Education			0.823†
- Primary school	5 (41.7)	3 (21.4)	
- Secondary school	1 (8.3)	1 (7.1)	
- High school	2 (16.7)	4 (28.6)	
- University	3 (25.0)	5 (35.7)	
- Postgraduate	1 (8.3)	1 (7.1)	
Income < expenses	2 (16.7)	1 (7.1)	0.586‡
Birth type			0.257‡
- Vaginal	7 (58.3)	8 (57.1)	
- Cesarean	3 (25.0)	1 (7.1)	
- Both	1 (8.3)	4 (28.6)	
Episiotomy (yes)	6 (50.0)	8 (57.1)	0.716†
Smoking status			0.232‡
- Non-smoker	7 (58.3)	8 (57.1)	
- <1 pack/day	3 (25.0)	6 (42.9)	
- >1 pack/day	2 (16.7)	0 (0.0)	

†: chi-square test; ‡: Fisher's exact test (used when expected cell counts were <5); data are presented as number and percentage (n, %); VS: vaginal spheres; PFMT: pelvic floor muscle training

Table 2. Baseline continuous characteristics by intervention group		
Variable	**VS+PFMT (n=12)**	**PFMT-only (n=14)**
Age (years), mean ± SD	41.8±8.6	37.5±8.5
BMI (kg/m²), mean ± SD	27.1±4.6	27.7±4.3
Number of births, mean ± SD	2.1±1.1	2.5±1.6
Duration of incontinence (months), mean ± SD	72.8±105.9	15.4±31.6
Sandvik score (pre), mean ± SD	5.5±2.9	3.2±3.3
Modified Oxford score (pre), mean ± SD	2.7±0.9	2.3±0.6
ICIQ-SF score (pre), mean ± SD	8.3±4.4	5.4±6.6
FSFI total score (pre), mean ± SD	20.4±9.4	23.1±5.3

Values are presented as mean ± standard deviation.
VS+PFMT: vaginal spheres plus pelvic floor muscle training; PFMT-only: pelvic floor muscle training alone; BMI: body mass index; FSFI: female sexual function index; ICIQ-SF: international consultation on incontinence questionnaire-short form

Acceptability

No participants discontinued the study due to dissatisfaction or discomfort with the interventions. The intervention using the VS+PFMT, which consists of two internal metal jiggle balls encased in medical-grade silicone and generates mechanical vibration through movement, was generally well tolerated (Figure 2). Only two participants reported mild transient vaginal burning, which did not require medical intervention. Overall, both the VS+PFMT and PFMT-only interventions were perceived as acceptable by the participants who completed the study.

Adherence

Self-reported adherence, tracked via exercise logs, indicated that most participants followed their assigned protocols as instructed. Although exact compliance rates varied, both groups demonstrated acceptable levels of engagement. In the VS+PFMT group, the combination of passive mechanical stimulation and scheduled PFMT may have supported motivation and adherence, despite the dual-task nature of the intervention.

Safety

No serious adverse events were reported in either group. Minor side effects were limited to two participants in the VS+PFMT group, who reported mild vaginal burning that resolved spontaneously. No participants in the PFMT-only group reported adverse effects.

Data Completeness

There were no missing data for any outcome variable, including validated instruments such as the FSFI, ICIQ-SF, SSI, and MOS grading. All data were entered manually and verified for completeness and accuracy.

Figure 2. Medical-grade silicone vaginal sphere used in the intervention
The device weighs 90 g, measures 3.5 cm in diameter, and contains internal jiggle weights to provide proprioceptive feedback and enhance pelvic floor muscle engagement

Preliminary Clinical Outcomes

Preliminary analyses were conducted to explore the potential clinical effects of the interventions. Changes in validated pelvic floor-related outcome measures, including the FSFI, the ICIQ-SF, the SSI, MOS and simplified POP-Q scores, were examined in participants who completed the follow-up assessment. Paired comparisons were used to evaluate within-group changes from baseline to post-intervention. Additionally, between-group comparisons of change scores were analyzed to assess preliminary group-level effects.

FSFI Outcomes

The mean FSFI total score (n=14, 7 for each group) significantly improved from baseline (M=24.61, SD=4.79) to post-intervention (M=27.14, SD=4.43), t(13)=-3.82, p=0.002, with a large effect size (Cohen's d=1.02). Scores showed normal distribution according to the Shapiro-Wilk test. Therefore, pre- and post-intervention values were compared using paired samples t-tests.

Among participants who completed the follow-up (n=14), significant improvements were observed in several FSFI subscales. Scores for desire (p=0.001), arousal (p=0.012), lubrication (p=0.013), and orgasm (p=0.035) increased significantly from baseline to post-intervention. No statistically significant change was observed in the satisfaction (p=0.146) and pain (p=0.620) subscales, as shown in Table 3.

Between-group comparisons showed no significant differences in total FSFI score changes (VS+PFMT: 2.40±2.66 vs. PFMT-only: 2.66±2.49; p=0.855) or in individual domains, except for pain. The PFMT-only group showed a greater improvement in pain scores (0.46±0.54 vs. -0.29±0.50; p=0.020) (Table 4).

ICIQ-SF Outcomes

A statistically significant improvement was observed in urinary incontinence symptoms following the intervention. The median ICIQ-SF score significantly decreased from baseline to post-intervention (Z=-2.02, p=0.043), based on the Wilcoxon signed-rank test.

At baseline, a significant difference was found between groups in the distribution of ICIQ-SF severity categories (p=0.018), with the PFMT-only group presenting more frequently with mild incontinence and the VS+PFMT group showing predominantly moderate symptoms. By the end of the intervention, this disparity was no longer evident (p=1.000), as both groups showed similar distributions, with the majority of participants falling into the mild incontinence category (Figure 3).

MOS Outcomes

The median score increased from baseline to post-intervention, and the change was statistically significant (Z=3.26, p=0.001) according to the Wilcoxon signed-rank test. This suggests that PFMT, with or without adjunctive intravaginal devices, was effective in enhancing pelvic floor contractility over the 6-week period.

Post-intervention comparisons of Oxford strength categories showed no statistically significant difference between the two groups. In the VS+PFMT group, 85.7% (6 out of 7) of participants were classified as having "Strong" pelvic floor strength, compared to 71.4% (5 out of 7) in the PFMT-only group (p=1.000). These findings suggest that both interventions were similarly effective in achieving high levels of PFM contractility.

POPQ Scores Outcomes

A significant reduction was observed in POP-Q scores from baseline to post-intervention (Z=-2.65, p=0.008).

Although both groups showed significant anatomical improvement in pelvic organ support based on POP-Q scores (p=0.008), the degree of change did not significantly differ between the VS+PFMT and PFMT-only groups (p=0.710).

Table 3. Pre- to post-intervention changes in FSFI domain scores among all participants (n=14)

FSFI domain	Mean difference (pre-post)	Std. deviation	Std. error mean	95% confidence interval	t	df	*p*-value
Desire	-0.64	0.60	0.16	-0.99 to -0.30	-4.02	13	0.001
Arousal	-0.64	0.82	0.22	-1.12 to -0.17	-2.92	13	0.012
Lubrication	-0.56	0.72	0.19	-0.98 to -0.14	-2.88	13	0.013
Orgasm	-0.31	0.50	0.13	-0.60 to -0.03	-2.35	13	0.035
Satisfaction	-0.29	0.69	0.18	-0.69 to 0.11	-1.55	13	0.146
Pain	-0.09	0.63	0.17	-0.45 to 0.28	-0.51	13	0.620

FSFI: female sexual function index; t: t statistic; df: degrees of freedom

Table 4. FSFI score pre-post change by intervention group

FSFI domain	VS+PFMT (mean ± SD)	PFMT-only (mean ± SD)	*p*-value
Total	2.40±2.66	2.66±2.49	0.855
Desire	0.69±0.54	0.60±0.69	0.801
Arousal	0.51±0.88	0.77±0.81	0.580
Lubrication	0.86±0.84	0.26±0.47	0.132
Orgasm	0.40±0.65	0.23±0.31	0.548
Satisfaction	0.23±0.69	0.34±0.75	0.771
Pain	-0.29±0.50	0.46±0.54	**0.020**

FSFI: female sexual function index; VS+PFMT: vaginal spheres plus pelvic floor muscle training; PFMT-only: pelvic floor muscle training alone

Harms

Two participants in the VS+PFMT group reported mild vaginal discomfort or burning sensation during the initial weeks of intervention. These symptoms resolved spontaneously and did not require medical treatment. No adverse events were reported in the PFMT-only group. In addition to minor physical complaints, some participants in the VS group expressed hesitancy related to the use of the device, indicating possible cultural or personal barriers to adherence.

DISCUSSION

This pilot randomized trial evaluated the short-term effects of PFMT, with or without adjunctive VS, in women with PFD. Significant improvements were observed in sexual function, urinary incontinence symptoms, and PFM strength across both groups, confirming the overall therapeutic value of structured PFMT. While the VS+PFMT group demonstrated greater improvements in FSFI subdomains such as lubrication and orgasm, the PFMT-only group showed comparatively greater gains in pain reduction and satisfaction. These patterns indicate that both approaches may provide domain-specific benefits, although the between-group differences did not reach statistical significance. The absence of group-level differences is likely attributable to the small sample size and limited power, rather than true clinical equivalence.

A structured PubMed search using keywords such as "PFMT," "vaginal cones," and "VS" identified more than ten RCTs on vaginal cones, but only two evaluating VS or Kegel balls. This discrepancy highlights a clear gap in the literature and underscores the novelty of our investigation, which provides feasibility data and short-term clinical outcomes for vaginal sphere use in a trial setting.

In addition to clinical outcomes, this study generated important feasibility insights. Recruitment was slower than anticipated, and retention at 6-weeks was modest, with approximately half of randomized participants completing follow-up. Despite these challenges, adherence among completers was high, and no serious adverse events occurred, suggesting that both interventions were generally acceptable and well tolerated. Collectively, these findings highlight the potential of adjunctive VS, but also emphasize the need for larger, adequately powered RCTs that can clarify clinical efficacy while addressing feasibility barriers such as recruitment and retention.

Our findings align with prior studies demonstrating that PFMT improves sexual function and urinary incontinence symptoms. A meta-analysis by Chen et al.[4] confirmed that PFMT leads to significant improvements in postpartum urinary symptoms and sexual health outcomes. Similarly, Villani et al. [3] compared PFMT alone to vaginal cone therapy and reported superior outcomes in dyspareunia and vaginal laxity among women using intravaginal devices. However, unlike Villani et al.'s[3] findings, our study did not observe statistically significant added benefit from VS use. This discrepancy may be due to differences in device type, intervention duration, or sample characteristics. While VSs may enhance muscle engagement through proprioceptive feedback,[16] their effect might require longer exposure or larger samples to become clinically evident. Our short follow-up and small sample size likely limited the ability to detect such differences.

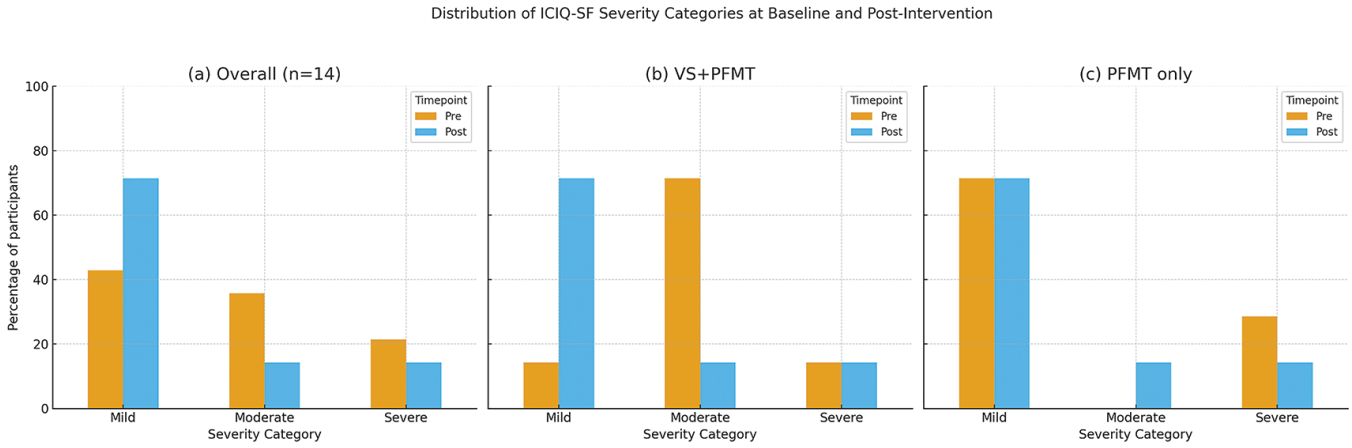

Figure 3. Distribution of ICIQ-SF severity categories at baseline and post-intervention: overall and groupwise comparison
Percentages of mild, moderate, and severe urinary incontinence are shown for (a) the overall sample (n=14), (b) the VS+PFMT group, and (c) the PFMT-only group. Bars represent the proportion of participants in each severity category at baseline (pre) and at 6-weeks (post)
ICIQ-SF: international consultation on incontinence questionnaire-short form; VS: vaginal spheres; PFMT: pelvic floor muscle training

While vaginal cones have been shown to enhance proprioceptive feedback by requiring active muscle engagement to prevent device displacement, VS lack this active resistance component. Instead, they rely on passive internal movement, which may stimulate awareness during daily activity, but their role in motor learning remains unexamined.[16] This mechanistic difference highlights the need for future studies comparing neuromuscular activation patterns and proprioceptive engagement across different device types.

In a RCT with a similar design to ours, VS were added to PFMT to improve adherence in women with urinary incontinence. However, the study found no significant improvement in adherence or treatment efficacy compared to PFMT alone.[17] The authors attributed poor adherence primarily to forgetfulness rather than a lack of perceived benefit. These findings, aligned with our own feasibility outcomes, emphasize the importance of behavioral support mechanisms, such as digital reminders and structured coaching, in future trials to enhance long-term compliance and optimize intervention effectiveness.

Similar to our findings, a recent pilot RCT by Brækken et al.[18] comparing intravaginal electrical stimulation and PFMT in women with weak PFMs found no significant difference between groups, despite observable improvements in both arms. The study concluded that a sample size of 95 participants per group would be needed to detect clinically meaningful differences.[18] This further underscores the need for adequately powered trials to evaluate the additive benefits of adjunctive therapies in pelvic floor rehabilitation.

Beyond clinical outcomes, this study provides critical feasibility insights to guide future definitive trials. Recruitment was slower than projected, and retention at 6-weeks remained suboptimal (53.8%), largely due to low motivation, time constraints, and sociocultural barriers toward pelvic floor interventions. Despite these challenges, adherence among completers was high, no serious adverse events occurred, and data completeness reached 100%, indicating good acceptability of the protocol and outcome measures.

Barriers to sustained engagement, such as competing responsibilities, travel, or lack of symptom awareness, have been previously reported as key factors limiting PFMT adherence in the general population.[19] Participants in our study expressed similar obstacles, including difficulty integrating exercises into their daily routines and underestimating the long-term benefits of PFMT. To address these issues, future trials should consider integrating mobile health applications, which offer portable, visual, and interactive platforms for structured PFMT delivery.[20] Apps may increase motivation, reduce boredom, provide real-time reminders, and offer feedback on progress, all of which can improve both adherence and retention. Additionally, culturally tailored education, remote support (e.g., WhatsApp or video follow-ups), and flexible scheduling may enhance inclusivity and engagement, particularly in populations with limited familiarity with exercise-based therapies.

Study Limitations

This study has several limitations inherent to pilot feasibility trials. First, the small sample size limited statistical power and precluded definitive conclusions regarding between-group differences. Although outcome assessors were blinded, participant blinding was not possible due to the nature of

the intervention, which may have introduced performance bias. Furthermore, the 6-week follow-up period may not fully capture long-term adherence or sustained clinical benefits. Most outcome measures were based on self-reported questionnaires, which are subject to recall and reporting bias. Additionally, we were unable to maintain consistent contact with participants who discontinued the study, which limited our ability to explore their reasons for dropout or reinforce motivation. Finally, as participants were recruited from a single tertiary care center, generalizability to broader populations may be limited.

These feasibility findings support the progression to a fully powered RCT, incorporating behavioral and digital adherence strategies to optimize implementation.

CONCLUSION

Adjunctive use of VS with PFMT appears to be a safe, feasible, and well-tolerated approach for women with PFD. Significant within-group improvements in muscle strength, urinary symptoms, sexual function, and pelvic support underscore its potential therapeutic value. These findings warrant further investigation in larger, adequately powered RCTs.

ETHICS

Ethics Committee Approval: The study protocol was approved by the Institutional Review Board of University of Health Sciences Türkiye, Koşuyolu High Specialization Training and Research Hospital (approval no: 2024/14/889, date: 30/07/2024).

Informed Consent: Written informed consent was obtained before randomization.

FOOTNOTES

Contributions

Surgical and Medical Practices: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K., Concept: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K., Design: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K., Data Collection or Processing: S.S.K., İ.B., Y.Ç.D., F.Ş., Analysis or Interpretation: S.S.K., E.K., F.Ş., Literature Search: S.S.K., İ.B., Y.Ç.D., B.K., Writing: S.S.K., E.K., İ.B., Y.Ç.D., F.Ş., B.K.

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Rare complications after sacrospinous fixation surgery: Two cases of gluteal-cutaneous sinus formation

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ABSTRACT

Sacrospinous fixation (SSF) is a commonly used surgical procedure to treat advanced forms of prolapse. While generally considered low-risk, SSF can lead to complications, including rare sinus and or fistula formation. This report highlights two rare presentations of gluteal sinus formation and associated osteomyelitis years post-SSF, using ethibond (Ethicon Inc., Somerville, NJ, USA) sutures in both cases. The first patient is a 72-year-old woman who developed a right-sided gluteal-cutaneous sinus six years post-surgery, which resolved after suture removal and surgical treatment. The second, a 63-year-old woman, developed a chronic discharging sinus and osteomyelitis, which required a multidisciplinary approach. These cases highlight rare but serious SSF complications, particularly when using non-absorbable braided sutures like ethibond (Ethicon Inc., Somerville, NJ, USA). Similar cases reported in the literature suggest that these sutures may contribute to chronic inflammation, suture erosion, and sinus formation. Monofilament sutures may be a safer alternative, as they are less likely to act as a nidus for infection. Therefore, we recommend using monofilament sutures for SSF. Early recognition through imaging and prompt surgical management are crucial to achieving good outcomes. Research into suture material to achieve the best outcome is warranted.

Keywords: Pelvic organ prolapse; sacrospinous fixation; complications; fistula formation; osteomyelitis; ethibond suture; braided sutures

INTRODUCTION

Pelvic organs prolapse describes the descent of one or more vaginal compartments, leading to considerable physical and psychological symptoms.[1] This condition results from weakness in one or more vaginal compartments—specifically, the anterior, apical, or posterior sections of the vagina.[2] Sacrospinous fixation (SSF) is a recognised surgical intervention for the treatment of advanced pelvic organ prolapse, especially in instances of uterine or vaginal vault prolapse. The procedure aims to restore pelvic anatomy by securing the vaginal vault or cervix to the sacrospinous ligament, thereby effectively preventing further descent.[3]

SSF is a low-risk procedure with reasonable success rates.[4] However, like any operation, it is associated with a range of postoperative complications. The most common one is temporary buttock pain, which typically resolves conservatively, but occasionally become chronic. However, more serious complications, can include bleeding or haematoma formation

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at the site of fixation, sciatic nerve damage causing radiating leg pain, and neurological impairments that may require exploration and removal of the sutures.[5]

Among the rarest and most severe complications are fistula and sinus formation, which may include gluteal-sacrospinous-vaginal fistulas and rectovaginal fistulas and gluteal sinus formation. Despite its extreme rarity, a limited number of cases have been reported in the literature.[6-14] This report highlights the importance of identifying these complications early and providing appropriate treatment. This report presents a rare gluteal-sacrospinous-vaginal formation and osteomyelitis that occurred years following sacrospinous ligament fixation.

CASE REPORTS

Case 1

The patient was a 72-year-old postmenopausal woman who presented with stage 3 uterine prolapse and stage 3 anterior wall prolapse, with pelvic organ prolapse-quantification (POP-Q) measurements as follows: Aa +2, Ba +2, Ap 0; Bp 0, C +3, D -2, GH 4; PB 3, TVL 10. She experienced significant vaginal bulge, soreness, and dryness but denied bladder, bowel, or sexual complaints. Different pessaries were tried but failed.

The patient underwent unilateral SSF with concurrent anterior colporrhaphy. Ethibond Excel sutures (Ethicon Inc., Somerville, NJ, USA) were placed using a Capio® SLIM device (Boston Scientific, Marlborough, MA, USA) between the right sacrospinous ligament and posterior surface of the cervix.

The posterior vaginal wall was closed with Vicryl® sutures (Ethicon Inc., Somerville, NJ, USA). The surgery achieved satisfactory cervical elevation without intraoperative complications. Her early recovery was uneventful, with significant symptom improvement. Follow-up visits at 3 months and 1 year revealed no complications.

Six years postoperatively, the patient presented with right buttock pain, intermittent swelling in the right buttock, and foul-smelling discharge. Examination revealed a discharging sinus (5 cm in depth) in the right buttock, while vaginal examination showed no signs of cellulitis.

Computed tomography (CT) imaging identified a right-sided pelvic tract extending from the posterior cervix to the right gluteal region (42×21 mm) with no bony destruction or significant muscle involvement. Bacterial cultures from swabs were negative.

Therefore, the patient underwent examination under anaesthesia, excision of the sinus tract, and removal of two ethibond Excel sutures (Ethicon Inc., Somerville, NJ, USA). The superficial part of the sinus tract was excised and the deep pat was curetted. The posterior vaginal wall was opened to access the ligament and to make sure there were no residual permanent suture. Postoperatively, she received 7 days of oral antibiotics and regular Aquacel dressing changes every 48 hours for 7 days.

Regular follow-ups observed progressive wound healing, leading to complete resolution of the sinus tract after 2 months. Long-term follow-up confirmed healing and the absence of recurrence of the sinus and the prolapse.

Case 2

The patient was a 63-year-old postmenopausal woman who patient presented with stage 4 uterine prolapse, stage 4 cystocele, and stage 1 rectocele, with POP-Q measurements as follows: Aa +3, Ba +5, C +5, GH 3, PB 3, TVL 8 cm, Ap -2, Bp -2, D -2. Her symptoms included urinary urgency, difficulty voiding, slow urinary stream, incomplete bladder evacuation, and a vaginal bulge associated with a sensation of prolapse.

The patient underwent unilateral SSF with concurrent anterior and posterior repair. Two permanent ethibond Excel sutures (Ethicon Inc., Somerville, NJ, USA) were placed using a Capio® SLIM device (Boston Scientific, Marlborough, MA, USA) between the right sacrospinous ligament and posterior surface of the cervix. The posterior vaginal wall was closed using PDS II sutures (Ethicon) and Vicryl® sutures (Ethicon Inc., Somerville, NJ, USA). She had an intraoperative anaphylactic reaction to anaesthesia during the surgery, but no surgical complications were recorded. The initial postoperative recovery was uneventful, and the patient was discharged after a two-day hospital stay. Her early recovery was uneventful, with significant symptom improvement. Follow-up visits at 3 months and 6 months revealed no complications.

Approximately four years following surgery, the patient began experiencing right hip pain and restricted mobility, necessitating the use of a walking stick. Later that year, she developed an abscess in the right buttock, which required surgical drainage. However, the incision site on the right buttock failed to heal, resulting in a chronic discharging sinus. Clinical examination revealed a discharging sinus in the lower right buttock along with vaginal stenosis. Swabs obtained from the sinus did not yield bacterial growth. Imaging (CT and magnetic resonance imaging scans) showed that there was fluid in the uterus and that there was a sinus tract that went from the right sacrospinous ligament to the ischio-anal fossa, down the back of the thigh, and into the popliteal fossa. Osteomyelitis of the ischial tuberosity was also identified. The patient subsequently underwent an examination under anaesthesia, vaginal exploration, and removal of the ethibond sutures. Concurrently, she had hysteroscopy and endometrial biopsy, which did not reveal any abnormality.

During follow-up visits, postoperatively, the patient reported that the vaginal discharge and the discharge from the sinus tract markedly reduced in volume. Despite these improvements, the sinus tract did not fully heal, and the patient continued to experience persistent pain, reduced hip abduction, and restricted mobility. The orthopaedic team reviewed the patient, ruled out direct involvement of the right hip, and prioritized treating the sinus tract. The patient was then referred to our centre for further management. Examination under anaesthesia a year later confirmed that the sinus tract had healed and exploration of the right sacrospinous ligament showed no evidence of retained sutures. The gynaecology team discharged her and referred her back to the orthopaedic team to manage her ongoing restricted mobility and limited hip abduction.

During follow-up with the orthopaedic team and physiotherapy, the patient demonstrated partial improvement in mobility. The orthopaedic team advised her to consider Botox injections, but she chose to continue with physiotherapy and exercise-based interventions instead. She reported no further concerns regarding the sinus tract or discharge at subsequent follow-up visits. She regained full independent mobility, and the physiotherapy team were pleased with the outcome as well as the patient.

DISCUSSION

SSF is a commonly performed surgical treatment for vaginal or uterine prolapse. The technique, initially described by Richter in 1968, is a modification of the Amreich procedure introduced in 1951.

The cases presented highlight rare and delayed complications associated with SSF using ethibond Excel sutures (Ethicon Inc., Somerville, NJ, USA). The first case involved the development of a pelvic sinus tract extending to the gluteal region. The second case demonstrated a more complex scenario, characterised by chronic sinus formation extending to the buttock, thigh, and femur and osteomyelitis. This necessitated a multidisciplinary approach to manage the patient's condition effectively.

We learned that early detection through imaging and timely surgical intervention is critical to successful outcomes. These cases emphasise the importance of long-term vigilance and patient education for delayed complications.

A comprehensive literature review (PubMed, Medline, Scopus) was performed to identify and compile case reports and studies on rare complications such as sinus and fistula formation following SSF. Gluteal abscesses seem to be the most common presentation in the reported cases in the literature. Some previous case reports used braided/multifilament sutures, while others used monofilament as shown in Table 1.

Table 1. Case reports in the literature regarding sinus and/or fistula formation following sacrospinous hysteropexy

Author	Suture type	Presentation	Time between operation and presentation	Outcome
Kadam and Chuan[6]	Non-absorbable – specific suture unknown	Right gluteal abscess	10 years	Surgical removal of the suture
Kim et al.[7]	Non-absorbable –specific type unknown- appeared to be similar to Mersilene (Ethicon, Somerville, NJ, USA)	Purulent discharge from right buttock-gluteal abscess	20 years	Removal of the sutures and deep drainage of the abscess using a multidisciplinary approach
Faber et al.[8]	Non-resorbable monofilament Prolene sutures	Right gluteal abscess and myositis	1 year	Conservative management with antibiotics
Ayesha et al.[9]	Non-absorbable monofilament Prolene suture	Right gluteal abscess	3 years	Surgical management – suture could not be visualised.
Hibner et al.[10]	Polyester – non-absorbable braided suture	Left rectal abscess	4 months	Surgical management and removal of sutures
Salimans et al.[11]	Non-absorbable braided polyester suture (Mersilene; Ethicon, Somerville, NJ, USA)	Gluteal abscess	19 months	Surgical removal of the sutures
Gafni-Kane et al.[12]	Polytetrafluoroethylene sutures – non-absorbable monofilament	Right ischio-anal abscess	7 years	Surgical removal of suture + fistulectomy
Huberts et al.[13]	Non-absorbable monofilament prolene sutures	Osteitis of the sacrum	7 years	Surgical removal of sutures
Gephart et al.[14]	Ethibond (Ethicon, Somerville, NJ) non-absorbable braided suture	Iatrogenic bladder diverticulum	11 years	Robotic-assisted laparoscopic excision of the diverticulum

Contributing factors may include infection and suture erosion into the vagina. The suture's non-absorbable and multifilament nature gives it the potential to act as a foreign body, as suggested in previous reports.[11,12] Hibner et al.[10] suggested that braided sutures possess capillary properties that enable the absorption of water and potential pathogens. These pathogens can readily adhere to the extensive surface area of multifilament sutures which may play a rule in abscess formation following SSF. Due to these properties, monofilament sutures are considered a more appropriate choice for areas where the risk of infection is significant. The downside of using monofilament sutures is that they are potentially more likely to cut through tissue leading to the recurrence of prolapse compared to multi-filamentous sutures.

We also want to reiterate the importance of adhering to fundamental principles when using non-absorbable sutures. These include selecting monofilament sutures over multifilament options, positioning the knots and suture line away from the incision line, avoiding breach of the cervical canal during suture placement on the cervix, and ensuring that the cervical canal is not kinked in a way that could compromise drainage of the uterine cavity.

CONCLUSION

We advocate for the use of monofilament sutures rather than multifilament/braided sutures in SSF. However, more research and data are needed to reach that conclusion.

ETHICS

Informed Consent: Written consent was obtained from the patients to publish in medical journals while keeping patients' data anonymous.

FOOTNOTES

Contributions

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

DISCLOSURES

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2025 Referee Index

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Fatima Chaudhry
Gülin Feykan Yeğin
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Karim Abdel Salam
Melike Demir Çaltekin
Melike Nur Akın
Meral Urhan Küçük
Murat Yassa
Nida Bayık
Ömer Tolga Güler
Öner Aynıoğlu
Paşa Uluğ
Pooja Balachandra
Rachel Nicholson
Rajesh Kumar Jha
Roberta Bugeja
Ronen Samuel Gold
Saratu Umar Aliyu
Sefa Arlıer
Talia Friedman
Tolga Güler
Traian Enache
Virginia De Carli Roncatti