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EDITORIAL

Dear Reader

In the last issue of 2024, we are here with high-quality scientific studies. We also had the opportunity to share with you the publications that were accepted as oral presentations at the 11th International Pelviperinology Congress. I wish you enjoyable reading.

I would like to express my gratitude to everyone who contributed and wish everyone a happy and healthy new year.

See you next year,

Prof. Dr. Ahmet Akın SİVASLIOĞLU

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Outcomes of transobturator tape surgery in the treatment of stress urinary incontinence: 24-month results

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ABSTRACT

Objective: Urinary incontinence is a symptom defined as objectively demonstrable involuntary urinary leakage causing a social or hygienic problem. The prevalence is twice as high in women as in men. It affects the individual's entire daily life, restricting social activities and also increasing healthcare costs. This study investigates the results and complication rates of the transobturator tape (TOT) procedures used for stress urinary incontinence (SUI) treatment in a tertiary center in central Türkiye.

Materials and Methods: Forty-four patients undergoing TOT procedures for SUI were prospectively evaluated. Their sociodemographic and clinical characteristics and operative outcome parameters were analyzed.

Results: The mean age of the patients was 51.22±8.63 years, their body mass index was 28.45±4.32 kg/m^2, 128 (63.7%) patients were menopausal, and the mean duration of menopausal period was 9.56±5.34 years. Surgery was successful in 40 (90.9%) cases, the mean operative time was 24.26±4.82 minutes, mean pre- and post-operative hemoglobin values were 11.80±1.06 g/L and 10.75±1.03 g/L, respectively, and the mean length of hospital stay was 1.06±0.22 days. Groin pain and dyspareunia were present in one (2.8%) patient, urinary tract infections and urine retention in one (2.8%), and mesh erosion two (4.6%). The successful and unsuccessful surgery groups were comparable in terms of age, numbers of pregnancies and parities, duration of symptoms, numbers of patients who delivered via the vaginal route, numbers who underwent episiotomies, numbers of menopausal patients, and the mean duration of the menopause.

Conclusion: This study shows that the TOT procedure, a minimally invasive and easily performed technique with a very low complication rate, has a very high success rate in appropriate and correct SUI indications.

Keywords: Stress urinary incontinence; surgery success; transobturator tape

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INTRODUCTION

Urinary continence refers to the ability to retain urine outside periods of voluntary voiding, its mechanism depending on the anatomical and functional urethral length, urethral closure pressure and anatomical support, and pelvic floor muscle activity during stress.[1] Urinary incontinence is defined by the International Continence Society as an objectively demonstrable involuntary leakage of urine that causes a social or hygiene problem.[2] Urinary incontinence is a symptom and a condition that affects the individual's entire daily life, restricts social activities, and also increases healthcare costs. Its frequency in women varies between 14% and 49%, and it is twice as common in women.[3-5]

Stress urinary incontinence (SUI) is defined as involuntary leakage of urine from the urethra without detrusor contraction, due to increased intra-abdominal pressure during activities such as exercise, sneezing, coughing, or laughing.[6] The two basic mechanisms involved in the etiopathogenesis of SUI are urethral hypermobility and intrinsic sphincter deficiency. Weakness of the pelvic floor muscles and connective tissue causes hypermobility in the urethra due to inadequate support for the bladder neck in anatomical terms, while neuromuscular damage to the urethral sphincter also causes intrinsic sphincter deficiency.[7] Advanced age, obesity, vaginal delivery, family history, smoking, diabetes, stroke, menopause, urogenital surgery, cognitive disorders, and dementia constitute known risk factors for SUI.[8]

Previous medical treatment and surgery should be investigated during the evaluation of SUI. Urodynamic evaluation should be performed in the presence of significant urge incontinence and SUI that does not improve despite surgical treatment.[2]

The aim of treatment in SUI is to improve the individual's quality of life by relieving the symptoms. It includes conservative and medical smoking cessation, Kegel exercises including pelvic floor training, pessary use, pharmacological treatment, and surgical procedures such as the Marshall-Marschetti, Burch, transvaginal tape, and transobturator tape (TOT) procedures.[9,10]

Suburethral sling procedures, which generally involve the placement of midurethral slings or bladder neck slings, form the basis of surgical treatment of SUI in modern medical practice. However, slings cannot always correct SUI and may rarely cause bladder hyperactivity, obstruction, or difficulty in emptying the bladder.[2,11] The TOT procedure was first introduced by Delorme in 2001 to avoid complications (bladder perforations, vascular, and bowel injuries) associated with other retropubic placement operations, and is today widely employed in the surgical treatment of SUI.[2,5]

This study aimed to compare the therapeutic success, intra- and postoperative results, and complication rates of the TOT procedure used in the surgical treatment of SUI in a tertiary center.

MATERIALS AND METHODS

This retrospective cohort study involved 44 TOT procedures at the Obstetrics and Gynecology Clinic of University of Health Sciences Türkiye, Antalya Training and Research Hospital, Türkiye, which serves as the largest reference center in Central Anatolia. The institution's Local Ethics Committee of University of Health Sciences Türkiye, Ankara Training and Research Hospital approved the study (reference date: 3/13) and written consent was obtained from the patients during hospitalization for all surgical procedures. The study was performed in compliance with the ethical principles for medical research involving human subjects as set out in the 18th World Medical Association Declaration of Helsinki.

Surgical procedures were performed by a gynecologist specializing in the field (BSI). Patients with symptomatic SUI and urge urinary incontinence, and urinary tract infection, and pregnant women were included in the study, while patients receiving chronic anticoagulant therapy were excluded.

Preparation Before Surgery

The day before surgery, the patient scheduled for TOT underwent blood tests, coagulation tests, and electrocardiography, and was evaluated by the anesthesiologist. The patient was administered prophylactic intravenous antibiotics (1 g cefazolin) approximately 30 minutes before surgery, and a bladder catheter was also inserted.

Operative Procedure

The patient was placed in the supine lithotomy position under spinal anesthesia, and the surgical site was covered to maintain a sterile field following disinfection. Local anesthetic containing epinephrine was injected into the paraurethral area and into the lower parts of the vaginal wall. The polypropylene mesh band (Safyre™, Autofixation Systems) covered with the plastic sheath used for the sling in the TOT procedure was installed from outside to inside with the help of helical trocars, as described by Delorme. The time elapsing from local anesthetic application to the closure of the incision site was measured and recorded as the operative time. The bladder catheter was removed after mobilization on the sixth to eighth hours postoperatively. Patients who were able to urinate spontaneously were discharged on the first postoperative day.

Statistical Analysis

Data were analyzed on SPSS version 15.0 for Windows software (SPSS, Chicago, IL, USA). The Kolmogorov-Smirnov test was used to determine the normality of distribution of all continuous variables. Normally distributed variables were compared between the groups using the paired t-test, while the Wilcoxon test was applied in case of non-normally distributed variables. Categorical data were analyzed using Pearson's chi-square or Fisher's exact test, as appropriate, and were expressed as numbers and percentages. A *p*-value lower than 0.05 was regarded as statistically significant.

RESULTS

Thirteen of the 57 patients initially accepted for the study were excluded due to unsuitability (urinary incontinence, urinary tract infection, and anticoagulant therapy). The remaining 44 patients were subjected to analysis. All cases were evaluated from hospital admission to discharge.

Table 1 shows the participants' demographic and clinical characteristics. The patients' mean age was 51.22±8.63 years, and their mean body mass index (BMI) was 28.45±4.32 kg/m^2. The mean number of pregnancies was 4.28±1.34, mean number of parities 3.82±1.61, and the mean duration of symptoms 6.20±2.72 years. Forty-three (97.2%) patients delivered via the vaginal route was and one (2.8%) by cesarean section. Twenty-seven (61.4%) underwent episiotomies, 128 (63.7%) were experiencing the menopause, and the mean length of menopause was 9.56±5.34 years.

Operative outcome parameters are given in Table 2. The success of surgery was 40 (90.9%), the mean operative time was 24.26±4.82 minutes, pre- and post-operative hemoglobin levels were 11.80±1.06 g/L and 10.75±1.03 g/L, respectively, and the mean length of hospital stay was 1.06±0.22 days. No bladder injuries, urethral injuries, vaginal lacerations, bowel injuries, vascular injuries, or pelvic hematomas occurred during the surgical procedures, although groin pain and

Table 1. The demographic and clinical characteristics of the study participants

Features (n=44)	**Mean ± SD**	**Median (min-max)**	**Number**	**%**
Mean age (years)	51.22±8.63	44.0 (24.0-71.0)		
BMI (kg/m^2)	28.45±4.32	26.32 (23.28-37.14)		
Gravity	4.28±1.34	4.0 (2.0-11.0)		
Parity	3.82±1.61	3.0 (1.0-9.0)		
Duration of symptoms (years)	6.20±2.72	6.00 (2.0-15.0)		
Number of patients delivered via vaginal			43	97.2%
Number of patients perform episiotomy			27	61.4%
Number of patients delivered via cesarean section			1	2.8%
Number of patients in menopausal period of life			28	63.7%
Menopausal period (year)	9.56±5.34	7.00 (2.0-18.0)		
Systemic diseases n (%)				
Hypertension			12	27.3%
Diabetes			10	22.7%
Goiter			9	20.5%
Chronic obstructive pumonary disease			8	18.2%
Hypertension + diabetes			5	11.4%
Hypertension + goiter			4	9.1%
Hypertension + chronic obstructive pumonary disease			3	6.8%
Diabetes + goiter			3	6.8%
Smoking status (%)			18	41.0%
Alcohol consumption (%)			4	9.1%
Caffein consumption (%)			9	20.5%
Cell phone usage (%)			40	90.1%
Drug abuse (%)			4	9.1%

SD: Standard deviation, BMI: Body mass index

dyspareunia were present in one (2.8%) patient, urinary tract infections and urine retention in one (2.8%) patient, and mesh erosion in two (4.6%), all of which were observed in the early stage. Medical treatments were administered to the patients for the groin pain, urinary tract infections, and dyspareunia, and the vaginal lacerations were primarily repaired. The mesh erosions were asymptomatic and were followed-up. Bladder catheterizations were applied for urine retention over an average of one week, after which the catheters were withdrawn. The surgical success rate was determined as 90.9% at six months. No complications occurred during long-term follow-up.

The data results for the patients with successful and unsuccessful operative outcomes are compared in Table 3. The two groups were comparable in terms of mean age (50.73±3.60 vs. 54.50±9.53, respectively, p=0.102), BMI (29.25±3.59 vs. 31.50±3.18, p=0176), numbers of pregnancies [3.5 (2.25-6.25) vs 4.0 (3.0-5.0), p=0.508], parities [2.0 (1.25-3.5) vs. 3 (2.0-4.0), p=0.119], duration of symptoms (6.85±2.96 vs. 8.75±3.30, p=0.233), numbers of patients who delivered via the vaginal route [39 (97.5%) vs. 4 (100.0%), p=0.660], numbers of patients who underwent episiotomies [26 (65.0%) vs. 2 (50.0%), p=0.552], numbers of menopausal patients [25 (62.5%) vs. 4 (100.0%), p=0.282], and length of menopause (8.52±4.18 vs. 10.75±2.98, p=0.214).

DISCUSSION

This study assessed the operative outcomes of the TOT procedures used for SUI treatment in our hospital. We compared the data results for successful and unsuccessful patients postoperatively. No significant differences were observed in terms of mean age, numbers of pregnancies, numbers of parities, or duration of symptoms, numbers of patients who delivered via the vaginal route, who underwent episiotomies, or who were experiencing the menopause, or mean length of the menopausal period.

SUI has become an important health problem as average life expectancy has increased, especially in middle-aged and older menopausal women. Since estrogen levels in the reproductive period decrease rapidly with the menopausal process, SUI is observed more frequently in this time of life. The average age of women undergoing the TOT procedure, the leading surgical treatment method for SUI, in studies varies between 45 and 60.[2,12] In the present study, and consistent with the previous literature, the mean age of the patients who underwent TOT was 51.22±8.63 years, and 63.7% were in the postmenopausal period. In addition, no significant difference was determined between the successful and unsuccessful treatment groups in terms of either age (50.73±3.60 vs. 54.50±9.53, respectively) or duration of menopause (8.52±4.18 vs. 10.75±2.98).

The operative time in TOT surgery, which entails a shorter surgical time and hospital stay compared to other sling procedures,

Table 2. Operative outcome parameters

	Mean ± SD	Median (min-max)	Number (%)
Success of surgery			40 (90.9%)
Duration of operation (minutes)	24.26±4.82	19.00 (15.0-29.0)	
Preoperative Hb (gr/L)	11.80±1.06	12.7 (10.4-13.4)	
Postoperative Hb (gr/L)	10.75±1.03	10.12 (9.6-13.2)	
Hospital stay (days)	1.06±0.22	1.00 (1.0-2.0)	
Complications			4 (9.1%)
Bladder injury			-
Uretral injury			-
Bowel injury			-
Vascular injury			-
Pelvic hematoma			-
Vaginal injury			-
Groin pain + dyspareunia			1 (2.8%)
Urinary tract infection + urine retention			1 (2.8%)
Mesh erosion			2 (4.6%)

SD: Standard deviation, Hb: Hemoglobin

Table 3. A comparison of data for successful and unsuccessful patients after surgery			
	Group 1 Successful treatment (n=40)	**Group 2 Unsuccessful treatment (n=4)**	***p*-value**
Mean age (years)	50.73±3.60	54.50±9.53	0.102
BMI (kg/m²)	29.25±3.59	31.50±3.18	0.176
Gravity	3.5 (2.25-6.25)	4.0 (3.0-5.0)	0.508
Parity	2.0 (1.25-3.5)	3 (2.0-4.0)	0.119
Duration of symptoms (years)	6.85±2.96	8.75±3.30	0.233
Number of patients delivered via vaginal	39 (97.5%)	4 (100.0%)	0.660
Number of patients perform episiotomy	26 (65.0%)	2 (50.0%)	0.552
Number of patients in menopausal period of life	25 (62.5%)	4 (100.0%)	0.282
Menopausal period (year)	8.52±4.18	10.75±2.98	0.214
BMI: Body mass index			

varies between 15 and 30 minutes.[13,14] In the present study, the operative time was 24.26±4.82 minutes and the length of hospital stay was 1.06±0.22 days. These results were also compatible with the current literature.

Previous research has determined that the factors affecting the success of TOT are urethral mobility, mixed type urinary incontinence, and the type of mesh used.[15] The presence of mixed type urinary incontinence and lack of mobility of the urethra reduce the success of treatment. Success also varies depending on the type of mesh used. Age is not a factor in success, although the failure rate increases in procedures performed on women over 70. Body weight is also not a factor related to success, although morbid obesity (over 35 years of age) has been described as a risk factor for failure.[2,16] Similar results emerged from the present study, consistent with the previous literature.

A study involving the type of mesh used compared the autologous pubovaginal sling with the synthetic TOT Safyre sling and concluded that the success rate of the autologous pubovaginal sling was much higher.[6]

A woman with normal bladder functions can empty at least 85% of her post-voiding bladder volume, and the post-voiding residual bladder volume should be less than 50 cc. It should be remembered that postoperative edema, infection, and dysuria may cause urinary retention in sling procedures. If this urinary retention persists longer than a week to 10 days, the sling band should be loosened immediately by reopening the same vaginal incision line.[2,17] In the present study, temporary urinary retention was observed in only one (2.8%) patient after TOT surgery, and this disappeared following temporary bladder catheterization performed for approximately one week.

The TOT procedure has a very low complication rate compared to other sling operations. While urination difficulty is the most prominent complication in the Burch procedure, those that may be seen in sling procedures include groin pain, urinary tract infections, vaginal injuries, dyspareunia, urinary retention, and mesh erosion.[18] Such erosion refers to the emergence of the mesh placed through the vagina by destroying the underlying vaginal tissue and mucosa, instead of the fibroblastic activity that the mesh placed in TOT should normally create.[19] While bladder perforation and inability to urinate or difficulty urinating are the most common and important complications of the midurethral region retropubic sling placement procedure, the reason why these complications are less common in TOT surgery is that the mesh does not form folds in the suburethral region and runs horizontally.[20] The fact that the surgical maneuvers applied in TOT surgery are far distant from the retropubic region is another reason why complications are observed less frequently compared to other sling surgeries.[21] No serious complications were involved in any case in the present study. The most common complication was mesh erosion (5.6%).

Study Limitations

The potential limitations of this study include the lack of comparison with other sling operations and the absence of long-term results. Particular strengths are that a single experienced urogynecologist performed the TOT surgery and evaluated the results, and that the findings can be adapted to the whole of Türkiye since the clinic where the study was conducted represents the center of the country.

CONLUSION

In conclusion, this study shows that the TOT procedure, a minimally invasive and easily applied technique with a very low complication rate, has a very high success rate in appropriate and correct SUI indications. However, further studies with larger

cohorts are needed to confirm the results of the current study and to determine long-term outcomes.

ETHICS

Ethics Committee Approval: Ethics committee approval was obtained from the University of Health Sciences Türkiye, Antalya Training and Research Hospital Clinical Research Ethics Committee before starting the study (decision no: 3/13, date: 2024.03.21).

Informed Consent: Consent was obtained from the patients during hospitalization for all surgical procedures.

FOOTNOTES

Contributions

Surginal and Medical Practies: B.S.İ., B.Ç.K., A.F.Y., O.H., Concept: B.S.İ., B.Ç.K., H.A.İ., Design: B.S.İ., A.F.Y., Data Collection or Processing: B.S.İ., B.Ç.K., O.H Analysis or Interpretation: B.S.İ, Literature Search: B.S.İ., B.Ç.K., O.H., H.A.İ., Writing: B.S.İ., O.H., H.A.İ.

DISCLOSURES

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

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Post-placental insertion of the intrauterine device after cesarean delivery versus delayed insertion: A randomized controlled trial

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ABSTRACT

Objectives: One particularly effective method of long-acting, reversible, and reasonably priced contraception for spacing out pregnancies is the intrauterine device (IUD), especially in areas with poor access to medical facilities. Alongside contraceptive implants, IUDs are known to offer high satisfaction rates among users. For postpartum contraception, IUD insertion immediately after placental delivery, following either vaginal or abdominal delivery, is considered feasible. Additionally, insertion within 48 hours of delivery is also a viable option. To compare the post-placental insertion (PPIUD) of an IUD among women who had a cesarean birth against those who planned for interval IUD installation 6 weeks postpartum in terms of expulsion rate and patient compliance.

Materials and Methods: This randomized controlled trial involved 97 patients who were recruited from an outpatient clinic and received the intervention of IUD insertion. It was carried out at the Tertiary Care Hospital's Obstetrics and Gynecology Department at Ain Shams University Maternity Hospital from July 2022 to March 2024.

Results: There were no statistically significant difference between the studied groups regarding age, body mass index, parity and history of previous IUD use. None of the cases in either group experienced failed insertion or perforation during insertion. Pelvic pain, dyspareunia and abnormal bleeding in month-6 follow-up were significantly less frequent in PPIUD group. None of the cases in either group experienced perforation, pelvic inflammatory disease or pregnancy in month-6 follow-up. IUD removal, expulsion and failure by month-6 were non-significantly more frequent in PPIUD group. Also, there were no statistically significant difference between the study groups regarding baseline and month-6 hemoglobin. Hemoglobin significantly less reduced in PPIUD. Patient satisfaction in month-6 was significantly higher in PPIUD group.

Conclusion: PPIUD of the IUD following cesarean delivery is a safe, simple, efficient, and practical method of contraception that can replace delayed IUD insertion because of its immediate and sustained contraceptive benefit, patient comfort, convenience, and lower incidence of side effects. As such, it qualifies for popularization as a first-line contraceptive agent in eligible patients.

Keywords: Cesarean delivery; intrauterine device; post-placental insertion

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INTRODUCTION

Egypt's population reached about 100 million people in the early 2020s. The population of Egypt has increased by about 30 million in the last 15 years.[1] If desired, contraceptive alternatives should be started as soon as possible after delivery.[2] This is because recurrent pregnancy rates during the first year of childbirth can range from 10-44%, with greater rates among high-risk adolescents.[3,4]

In non-lactating women, ovulation occurs at an average of 39 days postpartum, but it can occur as early as 25 days, putting postpartum women at risk of unwanted and short-interval pregnancy.[3] Women who have a cesarean section may be more likely to resume sexual activity sooner than women who had vaginal deliveries.[5] At least 70% of pregnancies occur unintentionally in the first year after giving birth. Between 40% and 57% of women report having unprotected intercourse before their normal 6-week postpartum visit.[3]

Preterm delivery, low birth weight, and small for gestational age are among the risks associated with infants born from short-interval pregnancies.[6] It has been discovered that using a very efficient form of contraception results in better interpregnancy intervals.[4,7] It is advised by the World Health Organization (WHO) to wait at least 24 months before trying to get pregnant again.[8]

Pregnancy during breastfeeding is common in Egypt and lactational amenorrhea method isn't enough to prevent unintended pregnancy.[9] Long-acting reversible contraception (LARC) started after delivery reduces the number of quick repeat pregnancies, and post-placental intrauterine device (PPIUD) implantation right away is both safe and economical.[8]

The American Academy of Pediatricians and the American College of Obstetricians & Gynecologists advise intrauterine devices (IUDs) as a first-line method of contraception. IUD usage immediately after giving birth is often advantageous over the dangers, according to the Centers for Disease Control and Prevention's U.S. Medical Eligibility Criteria for Contraceptive usage, which does not impose any limits on use.[6]

Because many women have low postpartum visit follow-up rates, especially those who are most at risk of short interpregnancy intervals, scheduling LARC in the early postpartum period is also appealing. 10-40% of women do not show up for the postpartum appointment.[10] Postpartum may be the best time for women to use IUDs, particularly if they would otherwise struggle with access, motivation, or adverse effects. Randomized studies included in a Cochrane Review suggested that post-placental IUD implantation was both safe and effective.[11]

Immediate PPIUD implantation is an interesting technique for extending access to postpartum IUDs because it requires no extra postpartum appointment.[6]

Aim of the Work

The purpose of this study was to compare the PPIUD of an IUD in women who had a cesarean birth versus those who planned for interval IUD installation 6 or more weeks postpartum in terms of expulsion rate and patient compliance.

MATERIALS AND METHODS

From July 2022 to March 2024, 97 patients were recruited from an outpatient clinic and received IUD insertion as the intervention in this randomized controlled trial, which was carried out at a Tertiary Care Hospital in the Gynecology and Obstetrics Department at Ain Shams University Maternity Hospital (ASUMH). The trial was approved by the ethical committee (approval number: MD 240/2022, date:16/9/2022) and the patients provided informed consent.

Women who recruited from outpatient clinic and received the intervention of IUD insertion, divided into two groups: Group (A) (PPIUD group): Fifty women who had immediate post-placental IUD insertion.

Group (B) (delayed insertion group): Fifty women who had delayed IUD insertion at the 6th week postpartum visit**.**

Pregnant women who planned to deliver by caesarean section in ASUMH with age between 18-40 years old were included in the study. While, women who refuse to use an IUD as a method of contraception and would rather use other methods, as well as those with conditions listed in Category 3 or 4 for Cu-IUD in the Medical Eligibility Criteria for Contraceptive Use WHO-2015, intrapartum complications and anemia patients were not allowed to participate in the study.

According to a classification based on a population supplemented with iron, the following levels are classified as anemic: hemoglobin (g/dL) and hematocrit (percentage) levels below 11 g/dL and 33%, respectively, in the first trimester; 10.5 g/dL and 32%, respectively, in the second trimester; and 11 g/dL and 33%, respectively, in the third trimester.[12]

All women underwent history taking, examination, and investigations to determine eligibility based on inclusion and exclusion criteria.

Following protocol approval by the ethics committee of the Department of Obstetrics and Gynaecology, Faculty of Medicine Ain Shams University, pregnant women who intended to have an elective caesarean section at ASUMH were recruited from the antenatal clinic. Counseling was provided on several postpartum

contraceptive techniques, including immediate PPIUD and delayed IUD placement. All participants provided informed written permission prior to enrollment in the trial, after which the goal, potential risks, and complications were discussed.

Alternatively, eligible patients were randomly assigned to one of two groups: Patients who underwent an immediate post-placental IUD implantation are in Group (A) (PPIUD group). Patients in Group (B) (delayed insertion group) had their IUDs inserted later than planned during their sixth week postpartum appointment.

• **Type of IUD:** Model TCu 380 A with safe load® Pregna.

• **Group A (PPIUD group):** cesarean section was performed by experts in post-placental IUD insertion as follows:

1) The uterus became hemostatic after the placenta was removed, and then the IUD was implanted. The uterine incision was started to close, and then the IUD was manually positioned near the top of the uterine fundus. The threads were manually inserted softly into the lower uterine region before the uterine incision was closed. Once this was done, the incision around the uterus could be closed. During the puerperal phase, the strings naturally passed through the cervix.

2) Ring forceps would be used to expand the cervix from above if it was closed. Ring forceps can be used to insert strings through the cervix. If this was carried out, the resident would double-check before sealing the uterine incision to ensure the IUD was still at the fundus. Strings can be trimmed at a follow-up visit.

3) To be sure the IUD was placed correctly, an ultrasound was performed following the cesarean section.

• **Group B (control group) (delayed insertion group):** Expert supervisors performed the cesarean section, and then contacts were made to arrange for delayed IUD insertion at the sixth week postpartum appointment, as follows: Procedure: Qualitative beta human chorionic gonadotropin done before doing procedure. Prepare the IUD before beginning the process, insert the vaginal speculum, and then prepare the vaginal wall with betadine. Apply the tenaculum to the anterior cervical location, then insert and withdraw the uterine sound. Insert the IUD according to the package directions, and then cut threads 2-3 cm from the cervical os. An ultrasound was conducted to ensure the IUD was properly implanted.

• **Follow-up:** Follow-up visits will be undertaken at 6 months after insertion (questionnaire, ultrasound).

Outcome Measures: The study primary outcomes were expulsion rate and patient Compliance; assessed by a questionnaire with scoring system, at 6 months. While the secondary outcomes were Bleeding pattern, pain/dyspareunia, pelvic inflammatory disease (PID) requiring hospitalization: By history taking. Perforation and failure rate: By history taking and ultrasound.

Statistical Analysis

The acquired data was coded, tabulated, and statistically analyzed with IBM SPSS version 22.0 and Microsoft Office Excel 2007. Descriptive statistics were calculated for quantitative data using minimum and maximum ranges, mean ± standard deviation for normally distributed data, and number and percentage for qualitative data. Then proper statistical analysis were performed. *P*-values <0.050 were considered significant, otherwise non-significant.

RESULTS

In the enrollment stage, it is needed to assess 121 cases for eligibility, from them 21 were excluded, 13 for non-meeting inclusion criteria and 8 declined to participate. The randomized 100 cases were allocated in the study groups (50 in each). In PPIUD group all the 50 allocated cases received the allocated intervention, then 4 cases were lost in month-4 follow-up, for that 50 cases were analyzed at intervention and only 46 cases in month-4. In Delayed group only 47 allocated cases received the allocated intervention, then 3 cases were lost in month-4 follow-up, for that 47 cases were analyzed at intervention and only 44 cases in month-4 (Figure 1). Table 1 reveals that there is no statistically significant difference between the study groups in terms of age, body mass index (BMI), parity, and previous IUD usage. Table 2 revealed that none of the patients in either group had failed insertion or perforation

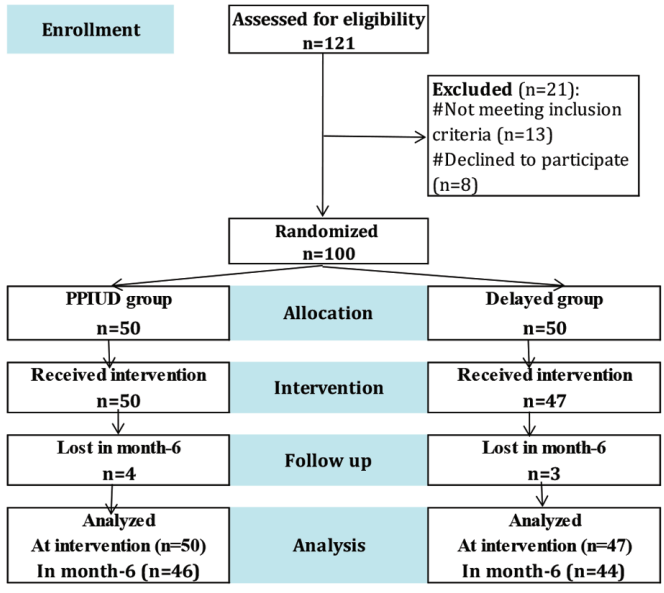

Figure 1. Flow chart of the studied cases
PPIUD: Post-placental insertion

during insertion. Table 3 showed that: Pelvic pain, dyspareunia and abnormal bleeding in month-6 follow-up were significantly less frequent in PPIUD group. None of the cases in either group experienced perforation, PID or pregnancy in month-6 follow-up. Table 4 showed that: IUD removal, expulsion and failure by month-6 were non-significantly more frequent in PPIUD group. Table 5 showed that: No statistically significant difference between the study groups regarding baseline and month-6 hemoglobin. Hemoglobin significantly less reduced in PPIUD. Hemoglobin significantly decreased in either group. Table 6 showed that: Patient satisfaction in month-6 was significantly higher in PPIUD group.

DISCUSSION

This study aimed to assess the expulsion rate and patient compliance with IUD implantation six weeks or more postpartum in women who had cesarean delivery against those who intended for interval IUD installation.

A total of 97 patients who were recruited from an outpatient clinic and received the intervention of IUD insertion participated in this randomized controlled trial from July 2022 to March 2024 at the tertiary care hospital's obstetrics and gynecology department at ASUMH.

In this study, 121 cases had their eligibility evaluated, and 100 patients were randomly assigned to the PPIUD group or the delayed insertion group. Out of all the eligible patients, 8 women declined to take part in the trial, and 13 patients were removed from the study due to inclusion requirements.

Out of the 100 randomized cases, 50 were assigned to the PPIUD group and 50 to the delayed group. All 50 cases in the PPIUD group received the allocated intervention initially. However, during the month-4 follow-up, 4 cases were lost, (resulting in the analysis of 50 cases at the intervention stage) and only 46 cases at month-4.

Table 1. Demographic characteristics between the studied groups

Vatiables		PPIUD group (total=50)	Delayed group (total=47)	*p*-value
Age (years)	Mean ± SD	28.8±4.4	29.6±3.5	^0.333
	Range	21.0-38.0	19.0-37.0	
BMI (kg/m²)	Mean ± SD	28.8±2.2	28.4±1.8	^0.230
	Range	23.1-34.3	23.8-31.9	
Parity (n, %)	Primi	13 (26.0%)	13 (27.7%)	#0.854
	Multi	37 (74.0%)	34 (72.3%)	
Previous IUD use		12 (24.0%)	10 (21.3%)	#0.749

BMI: Body mass index, ^: Independent t-test. #: Chi-square test, SD: Standard deviation, PPIUD: Post-placental insertion, IUD: Intrauterine device

Table 2. Insertion findings between the studied groups

Vatiables	PPIUD group (total=50)	Delayed group (total=47)	*p*-value
Failed insertion	0 (0.0%)	0 (0.0%)	NA
Perforation	0 (0.0%)	0 (0.0%)	NA

NA: Not applicable, PPIUD: Post-placental insertion

Table 3. Month-6 findings between the studied groups

Findings	PPIUD group (total=46)	Delayed group (total=44)	*p*-value	Relative effect Relative risk 95% CI
Pelvic pain	4 (8.7%)	11 (25.0%)	#**0.038***	0.35 (0.12-1.01)
Dyspareunia	6 (13.0%)	14 (31.8%)	#**0.032***	0.41 (0.17-0.97)
Abnormal bleeding	3 (6.5%)	10 (22.7%)	#**0.029***	0.29 (0.08-0.97)
Perforation	0 (0.0%)	0 (0.0%)	NA	NA
PID	0 (0.0%)	0 (0.0%)	NA	NA
Pregnancy	0 (0.0%)	0 (0.0%)	NA	NA

NA: Not applicable, PID: Pelvic inflammatory disease, #: Chi-square test. *: Significant. Relative effect: Effect in PPIUD group relative to that in delayed group, PPIUD: Post-placental insertion, CI: Confidence interval

Table 4. IUD removal, expulsion and failure between the studied groups				
Findings	**PPIUD group (total=46)**	**Delayed group (total=44)**	***p*-value**	**Relative effect Relative risk 95% CI**
Removal	1 (2.2%)	0 (0.0%)	§0.999	NA
Expulsion	4 (8.7%)	1 (2.3%)	§0.361	3.83 (0.44-32.91)
Failure	5 (10.9%)	1 (2.3%)	§0.203	4.78 (0.58-39.33)

NA: Not applicable, PID: Pelvic inflammatory disease, §: Fisher's Exact test, Relative effect: Effect in PPIUD group relative to that in delayed group, CI: Confidence interval, PPIUD: Post-placental insertion, IUD: Intrauterine device

Table 5. Baseline and month-6 hemoglobin (gm/dL) between the studied groups					
Time		**PPIUD group (total=46)**	**Delayed group (total=44)**	**^*p*-value (groups)**	**Relative effect Mean ± SE 95% CI**
Baseline	**Mean ± SD**	12.3±0.9	12.1±1.0	0.552	0.1±0.2
	Range	10.2-13.9	10.1-13.8		-0.3-0.5
Month-6	**Mean ± SD**	12.0±1.0	11.8±1.0	0.282	0.2±0.2
	Range	9.9-14.0	9.5-13.4		-0.2-0.6
¤Change	**Mean ± SD**	-0.2±0.3	-0.4±0.3	**0.005***	0.2±0.1
	Range	-0.8-0.5	-1.1-0.2		0.1-0.3
△*p*-value (times)		**<0.001***	**<0.001***		

¤Chage= Month-6 - baseline, negative values indicate reduction. ^: Independent t-test. △: Paired t-test, *:Significant. SE: Standard error, Relative effect: Effect in PPIUD group relative to that in delayed group, CI: Confidence interval, PPIUD: Post-placental insertion

Table 6. Patient satisfaction (Likert scale 0-10) in month-6 among the studied groups				
Masures	**PPIUD group (total=46)**	**Delayed group (total=44)**	**^*p*-value**	**Relative effect Mean ± SE 95% CI**
Mean ± SD	8.8±2.3	7.6±3.2	**0.035***	1.3±0.6
Range	0.0-12.0	3.0-12.0		0.1-2.4

^: Independent t-test, *: Significant, SE: Standard error. Relative effect: Effect in PPIUD group relative to that in delayed group, CI: Confidence interval, PPIUD: Post-placental insertion

In the delayed group, only 47 out of the allocated cases received the intervention initially. Subsequently, 3 cases were lost during the month-4 follow-up, leading to the analysis of 47 cases at the intervention stage and only 44 cases at month-4.

One of the biggest issues facing the health care system in third-world nations like Egypt is patient dropout. Patients with low socioeconomic position, low levels of education, and limited access to medical facilities sometimes place insufficient emphasis on health-related concerns. This issue also surfaced when patients were placed in the group with the delayed IUD.[13]

The results of the current study showed that there was no statistically significant difference in age, BMI, parity, or history of prior IUD usage between the groups under examination (*p*-values =0.333, 0.230, 0.854, 0.749).

The most worrying post-insertion complications of IUD are menorrhagia, dysmenorrhea and acute abdomen, which may have life-threatening consequences.[5]

At time of insertion, our study results reported no cases in either group, experienced failed insertion or perforation during insertion. However, after 6 months of insertion, our study results revealed that pelvic pain, dyspareunia and abnormal bleeding during follow-up, were significantly less frequent in PPIUD group (*p*-value= 0.038, 0.032, 0.029)

In agreement with our findings, Tawfik et al.[14] conducted a prospective study that enrolled 300 women to compare between PPIUD during cesarean section versus delayed IUD (DIUD) insertion and showed a significant difference in bleeding and back pain in 6 weeks follow-up. As bleeding and pain were more evident in DIUD group in comparison to PPIUD group (33.3%

vs. 21.3% respectively, p=0.03) for bleeding and (46.7% vs. 34% respectively, p=0.02) for pain.

These findings agreed with a study conducted by Khurshid et al.[13] which compared PPIUD versus DIUD; they also reported a higher incidence of pain at 6 weeks follow-up in DIUD in comparison to PPIUD (16.3% vs. 8.7% respectively, p=0.02) and bleeding was more evident in DIUD group in comparison to PPIUD (15.4% vs. 5.09% respectively, p=0.007), and no cases were reported with PID in either group.

Menorrhagia caused by intrauterine contraceptive devices (IUCD) has been explained by a number of mechanisms, including increased endometrial prostaglandins, which in turn cause increased capillary permeability and vascularity with decreased platelet activity, and the induction of an inflammatory response by IUCD, which increases the production of nitric oxide, a powerful vasodilator. It has been suggested that faulty angiogenesis might cause other vascular abnormalities as well. For example, abnormal vasculature can have poor contractility and hemostatic dysfunction as a result of abnormal angiogenesis, which can result in severe bleeding and reduced uterine artery vascular impedance.[15]

Regarding complications, our study results reported that none of the cases in either group experienced perforation, PID or pregnancy in month-6 follow-up. Moreover, by the month-6 follow-up, occurrences of IUD removal, expulsion, and failure were observed to be non-significantly more frequent in the PPIUD group.

In agreement with our results, Tawfik et al.[14] reported no significant difference between the 2 groups regarding infection occurrence (p>0.05). Moreover, expulsion rate was higher in PPIUD (4%) in comparison to DIUD group (1.3%), However, this difference was statistically insignificant. Also, there was insignificant difference between both groups regarding pregnancy rate on top of the IUD (p=0.7).

These findings were in concordance with another study of Elsokary et al.[16] that reported an expulsion rate of 1.96% in DIUD in comparison to 4.17% in PPIUD, with no significant difference between the 2 groups (p=0.5). Also, they reported insignificant difference between the 2 studied groups as regards pregnancy on top of the IUD.

In a prospective study conducted by Al Safty et al.[17], higher expulsion rates were reported. Specifically, in the PPIUD group, 85% of patients were retained, while 15% were expelled. In comparison, among patients in the DIUD group, 92% were retained, and 8% were expelled. But when it came to expulsion rates, there was no statistically significant difference between the studied groups.

Our findings are supported by Khurshid et al.[13] report that there were no incidences of pelvic infection or perforation in either group. This is also in line with previous authors' reports that there were no cases of perforation in postpartum intrauterine contraceptive device insertion.[18-20] When compared to the delayed IUD group, the PPIUD group's side-effect profile was generally better, particularly during the first six weeks and six months of use.[13]

The findings of Levi et al.[5] who evaluated the immediate post-placental IUD insertion at cesarean delivery, are consistent with our findings. They enrolled 90 patients undergoing cesarean delivery and followed up at 6 weeks and 12 months postpartum. They reported no unintended pregnancies or acute IUD-related complications, and they suggested that the immediate PPIUD of Copper IUD was a safe and effective procedure.

On the other hand, 1000 patients were included in a parallel-group randomized controlled study by Bayoumi et al.[21], which compared the IUD placement during puerperal and post-placental periods in women who were having cesarean sections. A larger sample size, long-term patient follow-up up to 12 months after insertion, low participant attendance at follow-up visits, and data suggesting that women from disadvantaged social and economic backgrounds are more likely to miss postpartum visits could all potentially account for the higher expulsion rates observed in the post-placental group.[16-22] It's unclear if variations in expulsion are caused by the kind of IUD, the insertion technique, the time of insertion, or the provider's training and experience. Furthermore, during the follow-up at 6 and 12 months following implantation, no significant pelvic discomfort was noted.[21]

Furthermore, Whitaker et al.[23] examined the expulsion following PPIUD in comparison to delayed insertion after 4-6 weeks and found a statistically significant difference.

Regarding Hemoglobin level, our study results revealed that there was no statistically significant difference between the study groups regarding baseline and month-6 hemoglobin levels. However, hemoglobin change was significantly less reduced in the PPIUD group compared to the Delayed group (p-value =0.005). Notably, hemoglobin levels significantly decreased in both groups over the study period (p-value <0.001).

Only limited data are available regarding assessment of patients' satisfaction in both groups of the study. Consequently, our results assessed the patients' satisfaction in month-6 using Likert scale (0-10) and revealed that pelvic pain was significantly more frequent in delayed insertion group. Consequently, patients' satisfaction was significantly higher among PPIUD group at 6 months after insertion (p-value =0.035).

de Albuquerque et al.[24] corroborated our findings, indicating a high level of satisfaction among women with the post-caesarean IUD at the 6-week visit (92.4%). Furthermore, all of these women expressed their willingness to recommend the method to others. Even after 6 months post-insertion, 86.9% of participants remained satisfied with the method.

These findings corroborate those of earlier research by Levi et al.[5], which showed that after six months, 80% of the women had reported being "happy" or "very happy" with their IUD, and 47% of them had not requested to have their IUD removed. Nobody who used an IUD said they were "unhappy" with it.

Furthermore, Tawfik et al.[14] noted that there was an insignificant difference between the two groups (p=0.09) in the overall satisfaction rates for DIUD and PPIUD, which were 88.9% and 83.1%, respectively. Similarly, Elsokary et al.[16] reported that the satisfaction rate of cases with IUD was high in both groups with 90.20% and 91.67% in immediate and delayed insertion groups respectively. However, those studies followed up the patients up to 12 months after insertion.

In contrast to our results, Bayoumi et al.[21] reported no statistically significantly difference between the studied groups after one year of continuous use regarding satisfaction with IUD insertion with (p-value =0.14) which is not in harmony with our results.

This suggests that inserting the IUD immediately after placental expulsion is more comfortable and largely symptom-free for patients. Any potential discomfort is likely masked by the postpartum uterine contractions, while any spotting is concealed by lochia. Notably, further cervical dilation was unnecessary for any patients in the PPIUD group, making the procedure quicker, easier, and more comfortable for the patient.[13]

Considering that most women will resume sexual activity by the sixth week postpartum, the immediate postpartum period presents an opportune time to initiate contraception. This period coincides with a high level of motivation among women to postpone subsequent pregnancies.[25] Providing effective long-acting contraception before discharge from the hospital is particularly relevant in countries with socioeconomic and demographic characteristics similar to Egypt. In Egypt, women commonly experience short interpregnancy intervals, with a significant proportion having had three previous cesarean sections, placing them at increased risk of complications.[26]

This study suggests that post-placental IUD insertion is a promising contraceptive method for long-acting, reversible, and cost-effective pregnancy spacing. The findings contribute to the growing evidence that providing LARC during delivery can enhance the uptake of effective contraception.[5]

The strength points of this study

Firstly, it is randomized controlled clinical trial. Secondly, a speculum examination and ultrasound were used to evaluate the IUD's location, allowing for descriptions of the many situations that may arise following post-placental IUD implantation. Thirdly, analysis of satisfaction was carried out using the standard Likert scale, which is the most reliable tool for assessment of satisfaction.

Study Limitations

A few noteworthy study limitations include that the sample size was less than in prior research, and the study was not multicentric since Bayoumi et al.[21] included a total of 1000 patients, which increases the possibility of publication bias. Another drawback is that the study's external validity was diminished because it was restricted to a single site and its target group was not well-represented.

CONCLUSION

PPIUD of the IUD following cesarean delivery is a safe, simple, efficient, and practical method of contraception that can replace delayed IUD insertion because of its immediate and sustained contraceptive benefit, patient comfort, convenience, and lower incidence of side effects. Therefore, among patients who meet the eligibility requirements, it can be used as a first-line contraceptive drug. It can be used in conjunction with maternal-child health services to ensure that, prior to hospital release, patients are satisfied and have access to the appropriate long-term reversible contraception.

ETHICS

Ethics Committee Approval: The study was conducted at the Department of Obstetrics and Gynaecology, Ain Shams University Gynaecology and Obstetrics Hospital (ASUMH) Tertiary Hospital and ethics committee approval was received (approval number: MD 240/2022, date: 16/9/2022)

Informed Consent: Retrospective study.

FOOTNOTES

Contributions

Surgical and Medical Practices; F.M.E.; R.M.A.; A.R.M.R.; M.O.S.; A.G.A.; A.G.E.; Concept: F.M.E.; R.M.A.; A.R.M.R.; M.O.S.; A.G.A.; A.G.E.; Design: F.M.E.; R.M.A.; A.R.M.R.; M.O.S.; A.G.A.; A.G.E.; Data Collection or Processing: F.M.E.; R.M.A.; A.R.M.R.; M.O.S.; A.G.A.; A.G.E.; Analysis or Interpretation: F.M.E.; R.M.A.; A.R.M.R.; M.O.S.; A.G.A.; A.G.E.; Literature Search: F.M.E.; R.M.A.; A.R.M.R.; M.O.S.; A.G.A.; A.G.E.; Writing: F.M.E.; R.M.A.; A.R.M.R.; M.O.S.; A.G.A.; A.G.E.

DISCLOSURES

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

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Effect of the interaction between physical and mental health treatments in women with chronic pelvic pain: A randomized controlled trial

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ABSTRACT

Objectives: To prospectively evaluate a mindfulness protocol and pelvic floor physical therapy (PFPT) for women with chronic pelvic pain (CPP) who were otherwise physically and mentally healthy, comparing the effectiveness of the treatments separately and together.

Materials and Methods: Women with CPP were randomized into two groups. Each group initially underwent a mindfulness protocol or PFPT (including electrotherapy, biofeedback, trigger point massage, and basic pelvic kinesiotherapy guidance), being switched to the other therapy after the first intervention, so all participants underwent both interventions. Participants were evaluated at 4 time points: Baseline, after each intervention and 8 months after the final therapy using the SF-36, the Mindful Attention Awareness Scale (MAAS), the visual analog scale (VAS), pelvic assessment, and electromyography questionnaires.

Results: Of 49 included women, 38 participated in both interventions and completed all 4 evaluations. In 7 physical examination and biofeedback scores, the group performing PFPT first achieved significant gains ($p<0.05$) immediately after the first intervention, while the group starting with mindfulness achieved significant gains only after the second intervention. In other 6 physical examination and biofeedback scores, both groups achieved significant gains immediately after the first intervention. In the MAAS, VAS, and in 4 domains of the SF-36, the sum of the interventions showed progressively significant improvement. At follow-up, gains were sustained in more than 85% of the 29 domains.

Conclusion: The results suggest that performing both therapies simultaneously could optimize gains in quality of life, pain management, and pelvic floor health in women with CPP.

Keywords: Chronic pain; mindfulness; pelvic pain; physical therapy

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INTRODUCTION

Chronic pelvic pain (CPP) in women is a complex multifactorial pain syndrome that is commonly seen in clinical practice. It is an important health problem and a source of disability. It is defined as non-cyclic pain from a physical and emotional experience that lasts for at least 6 months and is severe enough to cause functional disability and require treatment.[1-4]

The International Classification of Diseases-11 defines all pain lasting ≥3 months to be chronic, and although this new definition significantly increases the number of women suffering from CPP, outdating existing epidemiological data, it may prove beneficial for early diagnosis and treatment.

Very few studies have included women with symptoms <6 months, and given that women tend to wait a long time before seeking help, this represents a challenge: Women suffering from CPP describe their health journey as long and frustrating, involving countless specialists who often dismiss their pain. A common story heard from these women is their difficulty finding professionals who value their complaint and symptoms.[5,6]

CPP causes central nervous system changes that perpetuate the perception of pain even in the absence of the lesion that initiated the pain. Myofascial trigger points, which are observed in CPP, are characterized by abnormal contractions of focal muscle, which appear as tense bands that often do not correlate with the presence of injury and may be associated with varying degrees of sensitivity and motor dysfunction. These myofascial trigger points are classified as active or latent, depending on the presence or absence of spontaneous pain, respectively, when the muscle is at rest, and as referred pain when distant from the myofascial trigger points. Thus, pelvic floor dysfunction is often associated with CPP, since myofascial structures, viscera, and the central nervous system are interconnected.[2,3,6,7-11]

Mindfulness, self-awareness retraining similar to meditation, has been clinically applied in medicine as an alternative therapy for various health conditions, such as CPP.[12,13] It has been suggested that stress reduction influences the up- and downregulation of pain responsiveness inherent to central sensitization and neuroendocrine pathophysiology of the skin.[5,6]

In another treatment approach that differs from past decades, the prevalence of myofascial disorders in CPP, which was formerly estimated at around 8 percent, is now considered 85-90%, and physical therapists more commonly involved in the assessment and multidisciplinary treatment of CPP and pain management. Pelvic floor physical therapy (PFPT), an evidence-based and globally accepted therapy for treating of many pelvic floor disorders, has a low risk of adverse effects, is non-invasive, and has a moderate cost.

In this study, we propose an innovative approach: Evaluating the effectiveness of a multidisciplinary treatment for women with CPP that consists of PFPT and a mindfulness protocol.

Thus, rehabilitation has the tools to deal with these neuroplastic changes, including top-down cognitive interventions (mindfulness) and bottom-up physical interventions (PFPT) that induce neuroplastic changes in areas distributed throughout the nervous system and affect CPP outcomes.[14]

MATERIALS AND METHODS

Trial Design

This was a parallel-group controlled trial with equal randomization (1:1 for 2 groups) conducted in a single center in Brazil. The trial is registered at the Brazilian Registry of Clinical Trials (ID13375).

Patient Population

A total of 64 women were recruited from the pelvic dysfunction and CPP outpatient clinic of the hospital urology sector. Eligible participants included women >18 years of age with CPP. The exclusion criteria were pregnancy in the last 12 months, active infectious diseases, currently cancer treatment, cognitive impairment that impeded understanding of the treatment guidelines and/or inability to respond to the questionnaires.

Outcomes

The primary outcome was the improvement (gains) in quality of life, pain management, and pelvic floor health from baseline to 8 months after the final therapy as measured by SF-36, Mindfulness Attention Awareness Scale (MAAS), visual analog scale (VAS), physical examination, and biofeedback questionnaires.

Sample Size

To detect a difference between groups of one standard deviation (standardized effect size considered moderate to large) for any of the evaluated outcomes, a sample size of 22 patients per group was initially calculated. Considering α=0,05, a power of 90%, and 10% of losses, 25 patients were required for each group (50 patients in total). The sample size calculation was performed on WINPEPI version 11.65.

Randomization and Sequencing of Assessments During the Survey

A computer-generated list of random numbers prepared by an investigator with no involvement in the trial was used for allocation of the participants to 1 of 2 treatment groups, and the allocation sequence was concealed in sealed envelopes.

Study participants were initially randomized to a mindfulness protocol (n=25) or PFPT (n=24) for 8 weeks (Figure 1). Both groups received basic guidance about the pelvic floor and how to recognize and locate it in their own body. All patients and physicians were aware of the allocated arm.

PFPT involved individualized treatment and the mindfulness protocol involved group therapy, both of which were performed once a week for 60 minutes by a pelvic physical therapist specializing in women's health and a professional mindfulness specialist, respectively. Patients were reassessed a second time (T2) after undergoing one of the treatment interventions. Following the first treatment, the protocols were reversed: The group of patients who had undergone PFPT underwent the mindfulness protocol, and vice versa. The participants were reassessed at a third time point (T3) after having undergone both treatment interventions, and again 8 to 10 months after the final intervention (T4).

Anamnesis and Physical Assessment

A researcher assessed the participants at 4 points during the study using a modified structured anamnesis form from the International Association for the Study of Pain, while another performed physical and electromyographic assessment. The latter were based on physical therapy assessment sequences suggested by Berghmans et al.[15], a modified Glazer scale, and European Union Surface ElectroMyoGraphy for Non-Invasive Assessment of Muscles (SENIAM) recommendations.

In the anamnesis, the patients provided information about their sociodemographic profile and the possible underlying pathology or primary cause of CPP. Through structured questionnaires validated for the Portuguese language, the patients also reported on quality of life (SF-36) and pain (VAS regarding activities of daily living: Leisure, work, during and after intercourse, urination, defecation, and long periods of sitting), and they also answered the MAAS.

The physical examination began with abdominal and vulvar assessment (respiratory type, abdominal contractures, and surgical scars) in the lithotomic position with an empty bladder. The evaluation consisted of intravaginal, single-digit gloved palpation by the examiner, observing and respecting each patient's pain condition around the pelvic "clock", observing active and latent trigger points for referred suprapubic, abdominal and/or lumbar pain.[9,16,17]

Pain mapping data provided an individualized pain profile for each participant, following Jantos.[10] Trigger points were evaluated in superficial and deep perineal musculature around the clock. As recommended by SENIAM and following Bertotto et al.[17], an average of 3 maximum voluntary contractions was used.

Through physical palpation, the degree of perineal muscle

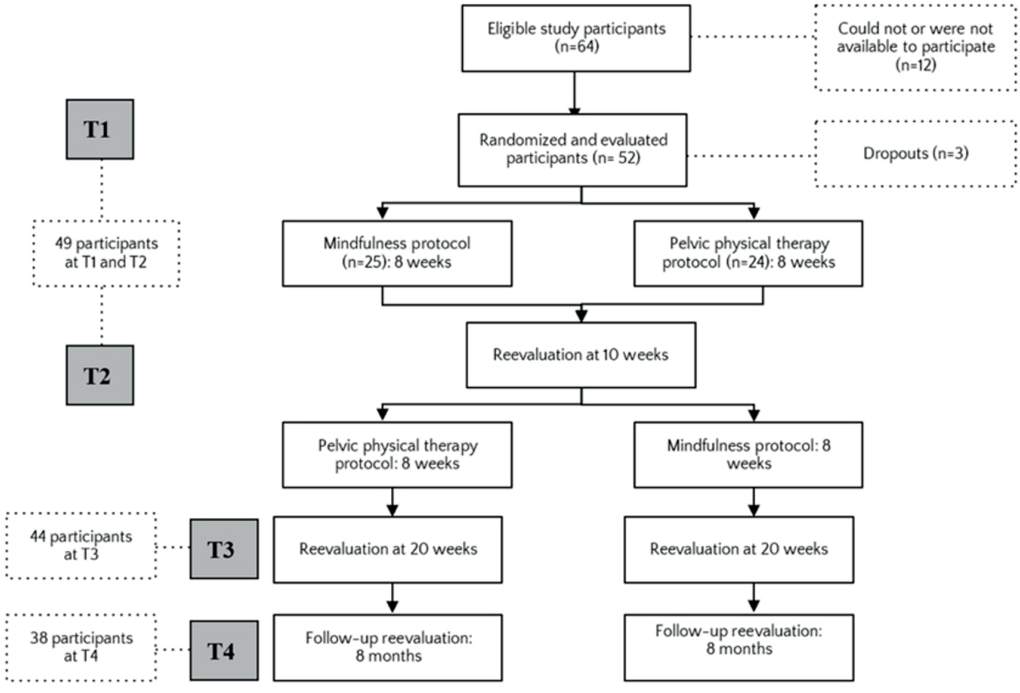

Figure 1. Patient inclusion and intervention flowchart
T1: Pretreatment; T2: First assessment; T3: Assessment after undergoing both treatment interventions; T4: Late comparison at follow-up

contraction (modified Oxford scale: 0-5s), sustained for "n" seconds, pre-contraction, fast contraction, and relaxation were evaluated.

In addition, the electrical activity of the pelvic floor muscles at rest and at maximum voluntary contraction was evaluated by electromyography, according to a modified Glazer protocol.[18]

Mindfulness

In the present study, the mindfulness protocol involved 2-hour weekly meetings for 8 weeks. The classes were led by a specialized mindfulness instructor from the Mente Aberta Institute of the Universidade Federal de São Paulo (Brazilian Center for Mindfulness and Health Promotion). This institute uses a mindfulness-based health promotion protocol based on the mindfulness-based stress reduction model. Mindfulness-based health promotion includes exercises from programs such as mindfulness-based cognitive therapy, mindfulness-based relapse prevention, and Breathworks' Mindfulness for Health. A main theme was presented in each of the 8 weekly sessions (Supplementary Table S1).

Pelvic Floor Physical Therapy

PFPT was based on assessment and treatment with electromyography biofeedback (Supplementary Table S2). It was performed using an intravaginal probe appropriate to the diameter of the vaginal canal of each patient so that pain or discomfort was not worsened.

To calibrate the contraction in biofeedback, an average of 3 maximum voluntary contractions was used, following Bertotto et al.[17] and SENIAM recommendations, a reference protocol for musculature in general. A modified Glazer protocol was also used to guide contraction and relaxation: With initial rest, fast contraction, sustained contraction of 30 seconds, and final rest.[18]

As shown in the Supplementary Table S2, electrotherapy was used with currents of 3 Hz/250 µs for 20 minutes and 50 Hz/250 µs according to the individualized contraction time of each patient.[10,19]

All patients had weekly individual orientation and homework: Intravaginal massage of trigger points, the use of heat, kinesiotherapy (relaxation and contraction of perineal muscles, breathing associated with contraction of the transversus abdominis), and pelvic tilt exercises.

The patients were included in a WhatsApp group in which they could interact with the other participants and the physical therapist, in addition to individual private contact with the therapist.

All participants were given the same anatomical guidance about the pelvic floor, such as recognizing, feeling, contracting in everyday situations.[9]

Statistical Analysis

The data were entered into Microsoft Excel and later exported to IBM SPSS Statistics 20.0 for statistical analysis. Categorical variables were described as frequencies and percentages. The normality of quantitative variables was assessed using the Kolmogorov-Smirnov test. Normally distributed quantitative variables were described as mean and standard deviation, while asymmetrically distributed variables were described as median, minimum, and maximum. Categorical variables were associated using the chi-square test or Fisher's Exact test according to the number of categories and expected frequencies at the initial time point. For baseline comparison, normally distributed quantitative variables were compared using Student's t-test for independent samples, while asymmetrically distributed variables were compared using the Mann-Whitney U test. Generalized estimating equation models were used to compare the evolution of the treatment groups over the different time periods, while a logarithmic transformation was used to compare asymmetrically distributed quantitative variables. The significance level was set at 5%.

RESULTS

Eligible participants were recruited from September 2018 to May 2020. A total of 49 patients were allocated as follows: 24 to the group that began with PFPT and 25 to the group that began with the mindfulness protocol. Participants were evaluated at baseline, after each intervention, and 8 months after the final therapy. The sample was homogeneous in terms of baseline sociodemographic and clinical characteristics (Table 1), with no significant differences between the groups. Of the 49 patients, 38 participated in both interventions and were evaluated at all 4 time points.

SF-36 Quality of Life Questionnaire

In the mental health domain, significant differences were observed between the groups over time (p=0.001) (Figure 2, Table 2); in the group that started with PFPT, there was a significant improvement (p<0.05) in mental health scores after both interventions were performed (Time 3). In the group that started with meditation, there was a trend toward improved mental health after undergoing the mindfulness protocol (Time 2). However, when this group underwent PFPT (Time 3), there was a significant drop in mental health scores, with a trend toward

improvement during follow-up (Time 4). In the remaining seven domains of the SF-36 questionnaire, the groups varied similarly over time; the scores of both groups improved significantly, except in the emotional performance domain, which remained stable (Table 2).

Mindfulness Attention Awareness Scale

In the MAAS questionnaire, there was a trend toward improvement in both groups during the therapeutic process, and the gains were significant in follow-up (Time 4) (Table 2).

Visual Analog Scale

The VAS results were the mean of pain scores at different times, i.e., at leisure, at work, during and after sexual intercourse, urination, evacuation, and remaining in a sitting position. Both groups showed significant and progressive improvement in all post-intervention stages (Times 2 and 3), maintaining the gains in follow-up (Time 4) (Supplementary Figure S1, Supplementary Table S2.

Physical Examination and Biofeedback

Regarding the physical examination and biofeedback, the groups evolved differently in most scores. The 7 evaluated scores were PEX_0002/0006/0009/011 (number of vaginal trigger points, contraction orientation, coordination, timing, respectively) and BFB_0001/0005/0007 (initial rest, mean of sustained contraction, and final rest, respectively). The group that started with PFPT obtained significant improvement soon after the first intervention (Time 2) and maintained these gains in the following evaluations. The group that started with meditation obtained significant improvement only at Time 3, after both interventions had been completed (Figure 3, Table 2).

In the other 6 physical examination and biofeedback scores (PEX_001/003/0005/0008 - abdominal pain and contracture,

Table 1. Comparison of clinical and demographic characteristics between the groups

Characteristics	Physical therapy + meditation (n=24)	Meditation + physical therapy (n=25)	*p*-value
Age (years), mean (SD)	52.4 (8.9)	52.3 (11.3)	0.974
BMI (kg/m2), mean (SD)	26.6 (4.9)	28.1 (4.1)	0.260
Marital status, n (%):			0.387
Married	16 (66.7)	13 (52.0)	
Separated/single/widow	8 (33.3)	12 (48.0)	
Education level, n (%):			0.950
Elementary school	7 (31.8)	9 (36.0)	
High school	11 (50.0)	12 (48.0)	
Higher/graduate	4 (18.2)	4 (16.0)	
Smoker or former smoker, n (%)	5 (20.8)	5 (20.0)	0.999
Clinical diagnosis associated with pelvic pain, n (%)	19 (79.2)	22 (88.0)	0.463
Medication use, n (%)	17 (70.8)	14 (56.0)	0.435
Physical/psychological abuse or trauma, n (%)	18 (75.0)	13 (52.0)	0.170
Some complication, n (%)	9 (37.5)	11 (44.0)	0.863
Any pelvic surgery, n (%)	17 (70.8)	17 (68.0)	0.999
Physical activity >3 x a week, n (%)	7 (29.2)	6 (24.0)	0.932
Daily consumption of >3 cups of coffee, n (%)	7 (29.2)	3 (12.0)	0.171
Associated urinary loss, n (%)	22 (91.7)	20 (80.0)	0.417
Bladder pain when urinating, n (%)	14 (58.3)	19 (76.0)	0.311
Bladder-emptying difficulties, n (%)	18 (75.0)	23 (92.0)	0.138
History of recurrent urinary tract infection, n (%)	10 (43.5)	7 (30.4)	0.541
Ingestion of more than 2 L, n (%)	3 (12.5)	5 (20.0)	0.702
Emptying the bladder >11 times a day, n (%)	7 (30.4)	9 (36.0)	0.919

Student's t-test for independent samples was used for quantitative variables and Fisher's exact test or chi-square test was used for categorical variable
BMI: Body mass index; SD: Standard deviation

Table 2. Comparison of scores over time between the physical therapy + meditation and meditation + physical therapy groups

	Physical therapy + meditation				Meditation + physical therapy				*p*-value*
Scores	**Times**				**Times**				
	T1 (n=24)	**T2 (n=24)**	**T3 (n=23)**	**T4 (n=21)**	**T1 (n=25)**	**T2 (n=25)**	**T3 (n=21)**	**T4 (n=17)**	
SF-36									
MH	44 (12-84)^{A}	54 (12-100)^{AB}	72 (20- 100)^{aB}	72 (24-96)^{B}	52 (16-84)^{AB}	64 (4-88)^{A}	44 (0-96)^{bB}	60 (8-92)^{AB}	0.001
RE	33.3 (0-100)	16.7 (0-100)	33.3 (0-100)	100 (0-100)	33.3 (0-100)	66.7 (0-100)	100 (0-100)	66.7 (0-100)	0.636
SF	25 (0-100)^{A}	62.5 (0-100)^{B}	62.5 (12.5- 100)^{B}	100 (12.5-100)^{B}	37.5 (0-100)^{A}	50 (0-100)^{B}	62.5 (12.5-100)^{B}	62.5 (12.5-100)^{B}	0.724
P	41 (20-62)^{A}	41 (10-90)^{AB}	51 (10-90)^{AB}	51 (20-90)^{B}	31 (0-80)^{A}	50 (0-90)^{AB}	50 (10-100)^{AB}	51 (10-90)^{B}	0,147
RF	55 (10-95)^{A}	67.5 (20-95)^{A}	85 (20- 100)^{AB}	80 (30-100)^{B}	50 (15-90) ^{A}	60 (5-95)^{A}	75 (0-100)^{AB}	75 (10-100)^{B}	0.604
RF	12.5 (0-100)^{A}	87.5 (0-100)^{B}	100 (0- 100)^{B}	75 (0-100)^{B}	25 (0-100)^{A}	50 (0-100)^{B}	75 (0-100)^{B}	75 (0-100)^{B}	0.112
V	42.5 (0-95)^{A}	60 (0-100)^{A,B}	55 (0-100)^{B}	65 (5-90) ^{A,B}	40 (5-85) ^{A}	60 (5-85) ^{A,B}	55 (10-100)^{B}	60 (5-85)^{A,B}	0.516
GH	37 (5-92) ^{A}	61 (10-95) ^{B}	62 (20-90) ^{B}	62 (15-95)^{B}	42 (0-82)^{A}	52 (20-72) ^{B}	52 (22-72)^{B}	55 (25-92)^{B}	0.344
MAAS	52.9±17.3^{A}	58.8±16.0 ^{A,B}	59.5±18.1 ^{A,B}	60.8±16.9^{B}	57.5±19.5^{A}	62.0±17.0^{A,B}	63.1±17.4^{A,B}	64.4±17.4^{B}	0.972
Pain-VAS	6.7 (0-10)^{A}	4 (0-9.3)^{B}	3.7 (0-9.3)^{C}	0 (0-8.3)^{C}	7 (0-10)^{A}	6 (0-9.3)^{B}	1.7 (0-8)^{C}	0 (0-5.3)^{C}	0.070
PEX+BFB									
PEX_0001	23 (95.8%)^{A}	11 (45.8%)^{B}	6 (27.3%)^{C}	4 (21.1%)^{C}	23 (95.8%)^{A}	19 (79.2%)^{B}	6 (28.6%)^{C}	3 (17.6%)^{C}	0.108
PEX_0002	7 (2-13)^{A}	2 (0-7)^{aB}	1 (0-10)^{BC}	1 (0-3)^{C}	6.5 (2-10)^{A}	5.5 (2-11)^{bA}	2 (0-4)^{B}	1 (0-4)^{C}	<0.001
PEX_0003	1.5 (0-3)^{A}	4 (0-5)^{aB}	4 (0-5)^{aBC}	5 (0-5)^{C}	1 (0-5)^{A}	2 (0-5)^{bB}	3 (0-5)^{bBC}	4 (1-5)^{C}	0.002
PEX_0004	1 (0-4)	2 (0-4)	1 (0-4)	0 (0-4)	0 (0-4)	1 (0-4)	0 (0-4)	0 (0-4)	0.742
PEX_0005	1.5 (0-6)^{A}	5 (0-8)^{aB}	5.5 (0- 10^{B}	8 (0-14)^{C}	1.5 (0-8)^{A}	2 (0-8)^{bB}	4 (0-10)^{C}	6 (0-10)^{C}	<0.001
PEX_0006***	13 (59.1%)^{A}	22 (95.7%)^{B}	19 (90.5%)^{B}	18 (97.7%)^{B}	10 (43.5%)^{A}	12 (52.2%)^{A}	18 (94.7%)^{B}	16 (94.1%)^{B}	0.009
PEX_0007	3 (2-5) ^{A}	5 (3-8)^{aB}	4 (3-6)^{aB}	4 (3-8)^{B}	3 (2-5)^{A}	3 (1-6)^{bAB}	4 (2-6)^{bAB}	4 (2-11)^{B}	0.011
PEX_0008	10 (41.7%)^{A}	21 (87.5%)^{B}	19 (86.4%)^{BC}	18 (94.7%)^{C}	4 (16.7%)^{A}	9 (37.5%)^{B}	14 (70%)^{BC}	13 (76.5%)^{C}	0.245
PEX_0009	3 (12.5%)^{A}	16 (66.7%)^{aB}	16 (72.7%)^{B}	17 (89.5%)^{B}	1 (4.2%)^{A}	2 (8.3%)^{bA}	15 (71.4%)^{B}	13 (76.5%)^{B}	0.004
PEX_0010	20 (87%)	10 (55.6%)	7 (50%)	4 (23.5%)	20 (100%)**	18 (81.8%)	11 (61.1%)	3 (20%)	**
PEX_0011	4 (16.7%)^{A}	17 (77.3%)^{aB}	15 (71.4%)^{B}	15 (79%)^{B}	7 (29.2%)^{A}	10 (41.7%)^{bA}	17 (81%)^{B}	15 (88.2%)^{B}	0.001
BFB_0001	2.4 (0-33.6)^{A}	6.0 (0-16.4)^{aB}	4.5 (0-19.9)^{AB}	5.3 (1.5-20)^{B}	0 (0-9.1)^{A}	2.2 (0-19.6)^{bA}	5.8 (0-19.7)^{B}	5.9 (1.6-24.4)^{B}	0.002
BFB_0002	0.7 (0-1.6)	0.8 (0.2-1.9)^{a}	0.7 (0.3-1.8)	0.8 (0-1.6)	0 (0-1.7)^{A}	0.5 (0-1.4)^{bA}	1.0 (0-1.8)^{B}	0.9 (0.3-1.6)^{B}	0.004
BFB_0003	0.8 (0-2.3)^{A}	1.3 (0-3)^{B}	1.3 (0-2.6)^{B}	1.4 (0-1.9)^{B}	0 (0-1.9)^{A}	0.8 (0-2.5)^{B}	1.2 (0-2.2)^{B}	1.2 (0.7-1.9)^{B}	0.163
BFB_0004	16.5 (0-123.9)^{A}	42.1 (0-171.6)^{aB}	46.4 (0-108.3)^{B}	44.9 (7.5-149.2)^{B}	0 (0-90.2)^{A}	18.1 (0-174.7)^{bB}	28.0 (0- 252.8)^{C}	31.4 (4.4-118.8)^{D}	0.035
BFB_0005	7.4 (0-57.6)^{A}	20.1 (0-67.7)^{aB}	26.3 (0-103.4)^{B}	23.2 (3.6-74.4)^{B}	0 (0-60.1)^{A}	11.1 (0-100.7)^{bA}	13.6 (0-135.7)^{B}	22.5 (2.8-62.6)^{B}	0.031
BFB_0006****	33.4 (17.7-87.1)^{A}	24.9 (13.3-43.8)^{aB}	26.2 (12.6-47.3)^{A}	26.9 (17-61.8)^{aA}	29.7 (19.3-56.6)^{A}	34.5 (20.5-67.5)^{bA}	31.3 (13.8-83.5)^{AB}	22.7 (12.1-38.8)^{bB}	0.001
BFB_0007	2.1 (0-13.2)^{A}	5.7 (0-15.6)^{aB}	5.8 (0-11.8)^{B}	5.7 (1.9-10.1)^{B}	0 (0-12.1)^{A}	1.8 (0-14.2)^{bA}	5.0 (0-20.6)^{B}	4 (1.5-29.5)^{B}	0.001

Different lowercase letters represent differences between groups within each time, different uppercase letters show differences between times within each group.
Times: T1: Pretreatment; T2: First assessment; T3: After the sequence of treatments; T4: Late comparison at follow-up; *: The *p*-value <0.05 of the interaction when indicates that the groups varied in different ways throughout the assessment moments; **: Assessment was impossible due to the lack of negative participants at baseline in the meditation + physical therapy group; ***: Head position; ****: Only patients who could perform a contraction with a head command were included; BFB: Biofeedback; GH: General health; MAAS: Mindfulness attention awareness scale; MH: Mental health; P: Pain; PEX: Physical examination; RE: Role-emotional; RP: Role-physical; SF: Social functioning; V: Vitality; VAS: Visual analog scale; PEX_0001: Number of women with abdominal pain and contracture; PEX_0002: Mean number of myofascial trigger points in the vagina; PEX_0003: Mean of muscle power according to the Oxford scale; PEX_004: Grades of pelvic organ prolapse; PEX_0005: Mean of sustained contraction in seconds; PEX_0006: Number of women with contraction orientation; PEX_0007: Number of repetitions of one-second fast contractions in 11 seconds (with a 2-second rest between them); PEX_0008: Number of women showing contraction with puborectal musculature elevation; PEX_0009: Number of women with coordination; PEX_0010: Number of women who used accessory muscles; PEX_0011: Number of women with timing (pre-contraction); BFB_0001: Mean of initial rest in seconds; BFB_0002: Mean of fast contraction ramp-up in seconds; BFB_0003: Mean of contraction ramp-down in seconds; BFB_0004: Mean of maximum voluntary contraction in seconds; BFB_0005: Mean of sustained contraction in seconds; BFB_0006: Mean variability of the amplitude of sustained contraction (%); BFB_007: Mean of final rest in seconds

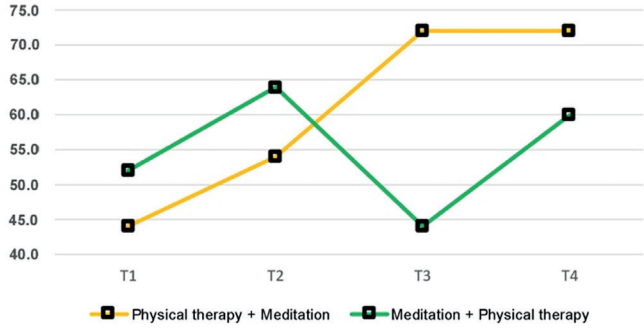

Figure 2. Mental health results (SF-36) over time in both treatment groups
*: p<0.05; T1: Pretreatment; T2: First assessment; T3: Assessment after undergoing both treatment interventions; T4: Late comparison at follow-up

power, endurance, and pubo-vaginal/rectal elevation, respectively; BFB_003/004 - fast contraction ramp-down and maximal voluntary contraction, respectively), there was a significant improvement (p<0.005) after the first intervention (Time 2) in both groups, followed by maintained gains or significant progressive improvement in the other evaluations (Figure 4, Table 2).

In the fast contraction score (PEX_0007), the group that started with PFPT had significant improvement after the first intervention (Time 2) and maintained it throughout follow-up. The group that started with meditation, despite a trend toward improvement, only showed significant improvement in follow-up (Time 4) (Table 2).

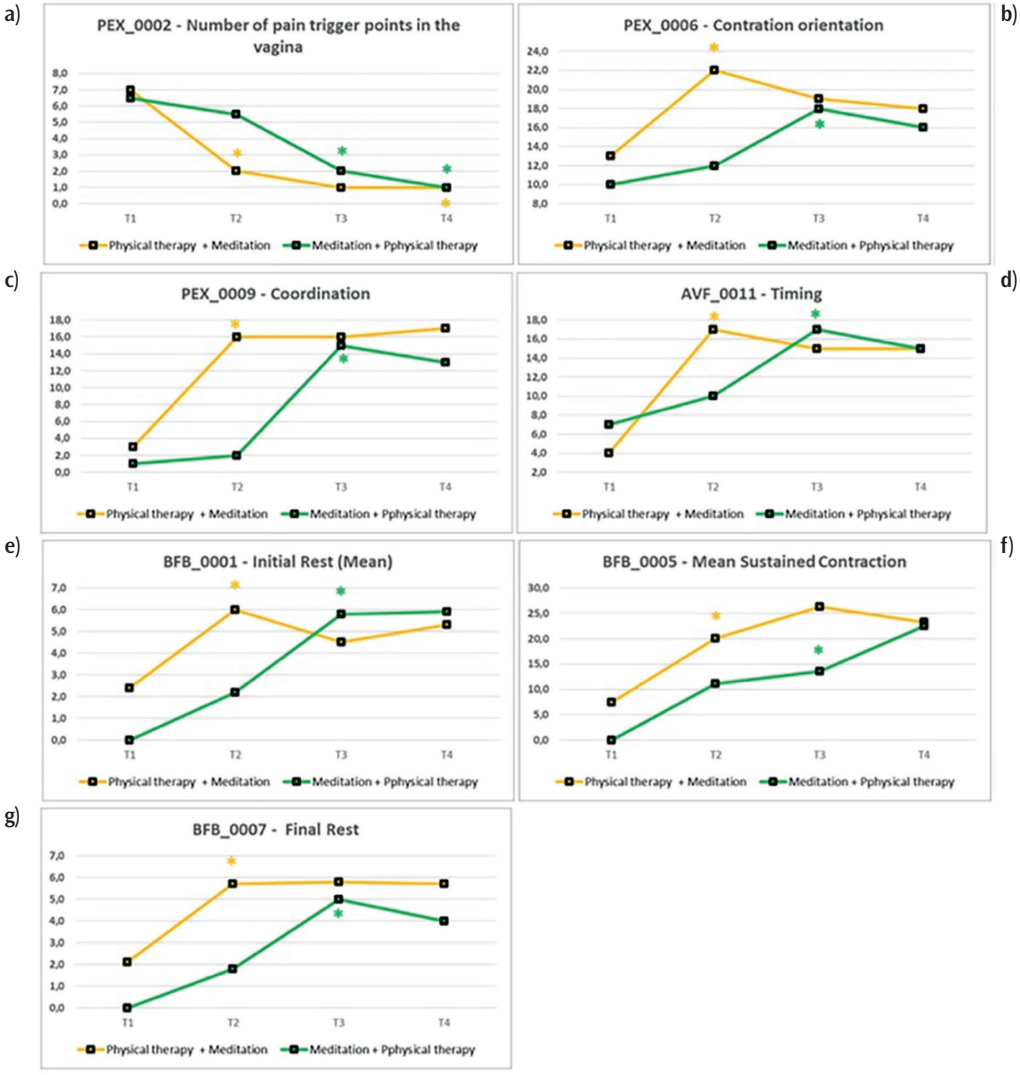

Figure 3. Physical examination and biofeedback scores PEX_0002/0006/0009/0011 and BFB_0001/0005/0007. a) PEX_0002 - Mean number of myofascial trigger points in the vagina; b) PEX_0006 - Number of women with contraction orientation; c) PEX_0009 -Number of women with coordination; d) PEX_0011 - Number of women with timing (pre-contraction); e) BFB_001 - Mean of initial rest in seconds; f) BFB_005 -Mean of sustained contraction in seconds; g) BFB_007 - Mean of final rest in seconds.
*: P<0.05, the group starting with pelvic floor physical therapy obtained significant gains earlier (T2) than the group starting with mindfulness, which obtained significant gains only at T3

In the fast contraction ramp-up score (BFB_0002), the group that started with PFPT did not change over time, while the group that started with the meditation protocol showed significant improvement after the second intervention (Table 2).

In mean variability of the amplitude of sustained contraction (BFB_0006), the group that started with pelvic physical therapy obtained a significant improvement after the first intervention (Time 2), although at the other time points it returned to its initial state. The group that started with the meditation protocol obtained significant improvement only during follow-up (Time 4) (Table 2).

DISCUSSION

The present randomized controlled trial evaluated the effectiveness of a multidisciplinary therapy comprising PFPT and a mindfulness protocol in women with CPP. The participants were evaluated at 4 time points, and the effectiveness of each therapy was observed separately and as the sum of both interventions. A limitation of this study is that it represents the experience of a single center, which limits the generalization of the results to populations with different characteristics.

Some results suggest that there is a difference between starting treatment with PFPT and meditation, while others suggest that there is no difference. One score indicating that it is ideal to start with PFPT was mental health (SF-36), which showed progressive improvement during the therapeutic process, while starting with the meditation protocol had a negative effect on mental health, since scores decreased during the second intervention. This could be related to the fact that patients received psycho-emotional support from the group meetings provided by the cognitive

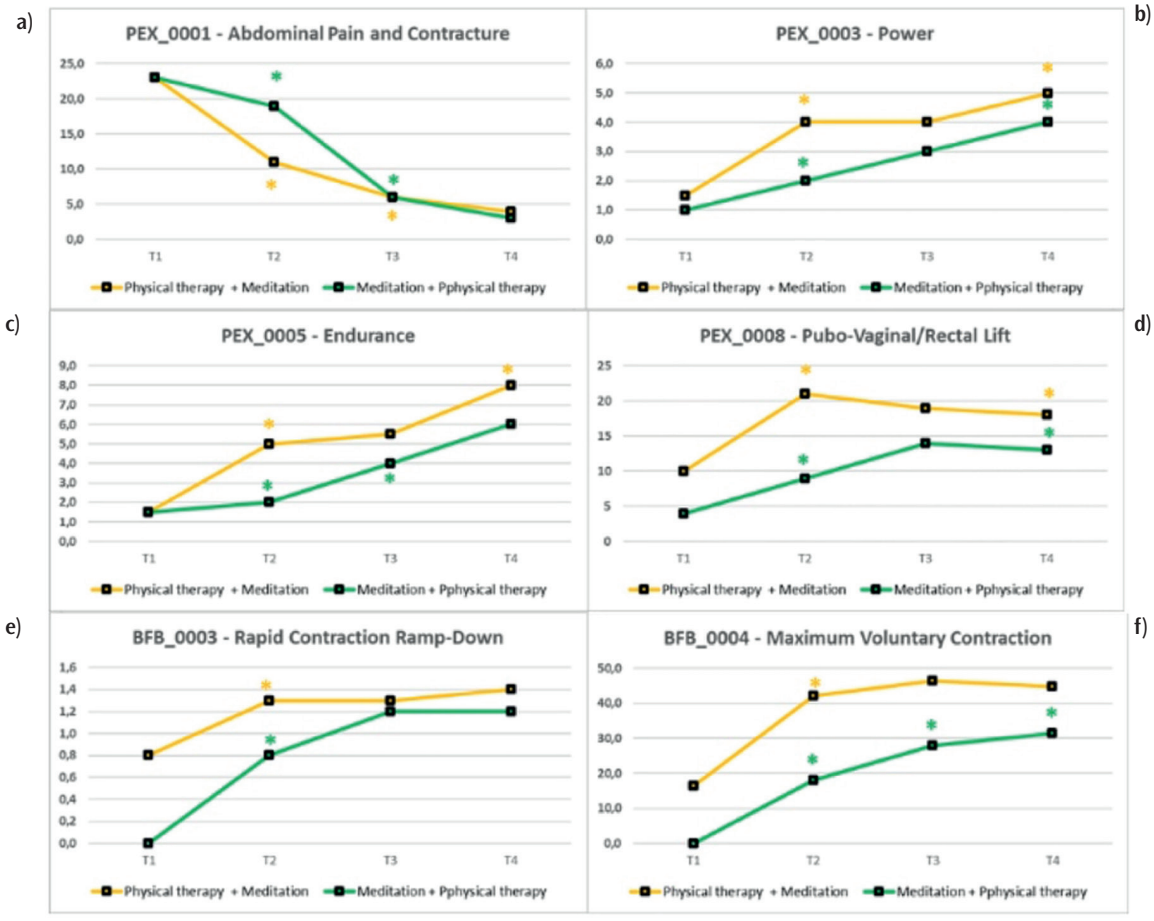

Figure 4. Physical examination and biofeedback scores PEX_0001/0003/0005/0008 and BFB_0003/0004. a) PEX_0001 - Number of women with abdominal pain and contracture; b) PEX_0003 - Mean of muscle power according to the Oxford scale; c) PEX_0005 – Mean of sustained contraction in seconds; d) PEX_0008 -Number of women showing contraction with puborectal musculature elevation; e) BFB_0003 -Mean of contraction ramp-down in seconds; f) BFB_0004 - Mean of maximum voluntary contraction.
*: $P<0.05$, both groups obtained significant gains immediately after the first intervention (T2)

intervention, which was followed with real contact with the pain site in PFPT, temporarily exacerbating the sensation of pain.

When PFPT was the first intervention, significantly faster improvement occurred in the physical examination domains number of trigger points (PEX_0002), contraction orientation (PEX_0006), fast contraction (PEX_ 0007), coordination (PEX_0009), and pre-contraction (PEX_0011), as well as in the biofeedback results initial rest (BFB_0001), mean sustained contraction (BFB_0005) and final rest (BFB_0007) (Figure 4, Table 2).

There is consensus in the literature that PFPT is an effective treatment for myofascial pain, which is a cause or consequence of CPP in most women with this condition. This is especially the case when it includes correct orientation of muscle contraction and relaxation, release of pain trigger points, electrical stimulation, negative electromyographic biofeedback, the use of heat, and kinesiotherapy.[6,9,11,19]

When the mindfulness protocol occurred first, the gains were significantly greater or more rapidly acquired for sustained contraction - endurance (PEX_005), fast contraction ramp-up (BFB_0002), and mean sustained contraction (BFB_0004), suggesting that mindfulness training can prepare patients for physical learning (Table 2).

Mindfulness focuses on teaching two skills: Self-regulation of attention, which leads to an awareness of the present moment, and an orientation towards one's own experiences, accepting them without judgment. These elements enable mindfulness practitioners to be less reactive and to free themselves from maladaptive patterns of thought and behavior triggered by the experience of pain.[5,12,13,20]

Mindfulness-related neural mechanisms of pain relief have been explained by neuroimaging studies. Zeidan et al.[21] observed that mindfulness induced greater activation of the bilateral orbitofrontal cortex and the rostral anterior cingulate cortex, in addition to greater thalamic deactivation. Orbitofrontal cortex activation is associated with increased positive mood and altered contextualization of sensory events, while rostral anterior cingulate cortex acts on affective pain modulation. Both reduce ascending nociceptive inputs (thalamic deactivation) to somatosensory cortical regions. Such cognitive control modulates the habitual patterns of catastrophizing, fear, anxiety, and avoidance associated with the subjective experience of pain.

However, other scores, including abdominal pain and contracture (PEX_0001), contraction with puborectal musculature elevation (PEX_0008), contraction ramp-down (BFB_0003), as well as the social functioning, physical performance, and general health domains of the SF-36 questionnaire and the VAS did not differ according to initial therapy type, since the groups had a similar evolution during the treatment process and significant improvement occurred soon after the first intervention (PFPT or mindfulness protocol).

Other scores showed that the sum of the interventions was effective: Abdominal pain and contracture (PEX_0001), the VAS scales for both groups, and the contraction support-endurance (PEX_005) and maximum voluntary contraction (BFB_004), for the group that started with the mindfulness protocol (Table 2).

These analyses suggest that simultaneous performance of both therapies would optimize gains in quality of life, pain management, and pelvic floor health of women with CPP. This may be due to the fact that these therapies focus on different dimensions of CPP. While PFPT acts on the myofascial component of the pain stimulus, mindfulness acts on minimizing the central amplification of pain.[22]

The literature corroborates our results, showing the need for 3 levels of CPP treatment due to its multifactorial and multidimensional nature: Organic (damage/disturbance), personal (disability level), and social (limited participation due to behavioral consequences), indicating that a broader approach involving interdisciplinary care is required. However, no previous study has described a PFPT protocol associated with a mindfulness protocol.[6,9,23,24]

In addition, of the 28 scores included in the SF-36, MAAS, VAS, physical examination and biofeedback questionnaires, gains were evidenced in 22 during follow up in the group that started with PFPT [all except: "Is there pelvic organ prolapse?" (AVF_004), "use of accessory muscles" (AVF_010), "contraction ascent ramp" (BFB_002), "contraction orientation" (BFB_006), "emotional performance" and "vitality" (SF-36)]. In the group that started with meditation, gains were evidenced in 23 [all except: "mental health", "emotional performance", "vitality", "is there pelvic organ prolapse?" (AVF_004), "use of accessory muscles" (AVF_010)] (Table 2).

These results differ from most patients who receive traditional, unimodal therapy for CPP and continue to seek a medical cure for their pain. It appears that the patients in the present study acquired self-control and learned to face their pain in a more rational and functional way.[23,25]

CONCLUSION

In conclusion, our results suggest that multidisciplinary treatment consisting of PFPT and mindfulness training is safe and effective for women with CPP. As a study limitation and a suggestion for future research, larger prospective multicenter studies should perform both interventions simultaneously to optimize the results.

ETHICS

Ethics Committee Approval: All processes in the present study were conducted in accordance with the ethical standards of our institution and the 1975 Declaration of Helsinki (2008 revision). The protocol of this study was approved by Hospital de Clínicas (ethics committee approval 58855116.6.0000.0096; DATA and the Brazilian Registry of Clinical Trials (ID13375).

Informed Consent: Written informed consent was obtained from all participants prior to enrollment.

FOOTNOTES

Contributions

Concept: C.C.B.; Data Collection or Processing: C.C.B., C.M., G.A., R.R., R.D.F.; Analysis or Interpretation: C.C.B., T.M.; Writing: C.C.B., C.M.

DISCLOSURES

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

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

Information: All relevant data are within the paper. This paper includes results of the doctoral dissertation submitted by the principal investigator to Universidade Federal do Paraná (UFPR) in 2022, which is available for download from the UFPR Institutional Digital Repository (https://hdl.handle.net/1884/81117).

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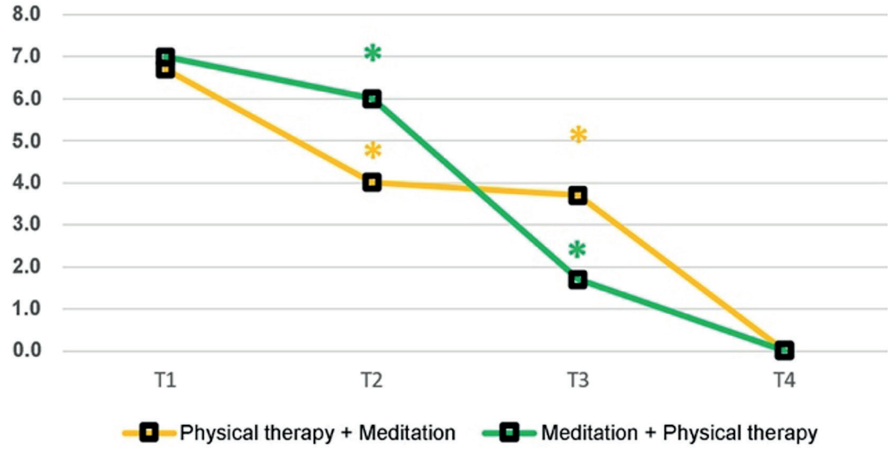
Supplementary Table S1. Content of the 8-session mindfulness program

1st session	What is mindfulness? Exiting autopilot
2nd session	Breath mindfulness
3rd session	Mindfulness in daily life
4th session	Extending mindfulness skills to challenging situations
5th session	Mindfulness of mind and thoughts
6th session	Day of silence
7th session	Mindfulness and compassion
8th session	Mindfulness for life

Supplementary Table S2. Pelvic floor physical therapy program

1st	2nd	3rd	4th	5th	6th	7th	8th
Reception and basic orientation	Electrotherapy 3 Hz 15 min	Electrotherapy 3 Hz/250 Ms 15 min					
Anatomical orientation	Electrotherapy <10 Hz	Electrotherapy -50 Hz/250 Ms watching voluntary contraction					
Orientation about finding the perineum	Reorientation		Awareness of contraction				
Orientation about feeling the perineum	Reorientation		Internal and external self-touch	Internal and external self-massage			
Orientation about contracting the perineum	Biofeedback	Biofeedback as a participant	Negative biofeedback				
Orientation about the use of heat*	Self-perception		Perineal massage		Perineal massage with contraction		
Forward	Orientation about contraction and relaxation	Orientation about daily exercises					



Supplementary Figure S1. Mean of pelvic pain scores according to the visual analog scale in both treatment groups

*: $P<0.05$, both groups obtained significant gains immediately after the first intervention (T2)

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Clinical parameters of uterine artery embolization in patients with postpartum hemorrhage

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ABSTRACT

Objectives: Postpartum hemorrhage (PPH) is a leading cause of maternal deaths in the world. To decrease maternal mortality rates, surgical and non-surgical methods are used in treatment of patients with PPH. Uterine artery embolization (UAE) is an important procedure to treat patients with PPH without surgery. The objective of this study was to determine critical patient parameters the success of UAE for the treatment of PPH.

Materials and Methods: From 2018 to 2022, a total of 22 women who have given birth (mean age was 29.4±6.0 years) who were diagnosed PPH was included in the study and their demographic and clinical characteristics were recorded. Patients were subjected to UAE using polyvinyl alcohol and the significant clinic parameters were determined on the success of the UAE.

Results: The UAE method was successful in 14 patients. The success rate for UAE was about 64%, and the age, body mass index, gravidity, parity, and type of delivery were deeply associated with the clinical efficiency of UAE method in patients with PPH. Moreover, no correlation was found between gestational age of the cases and the success of the UAE method.

Conclusion: Our findings suggest that UAE is an effective treatment method to stop uterine bleeding with low complication.

Keywords: Postpartum hemorrhage; uterine artery embolization; pregnancy; risk factors

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INTRODUCTION

Postpartum hemorrhage (PPH) is a life-threatening complication of childbirth. Generally, PPH is diagnosed in women who lost about 500 mL of blood after normal vaginal delivery or approximately 1000 mL of blood loss after cesarean delivery within 24 hours of birth. PPH is the leading cause of maternal mortality. Every year, an average of 14 million women is diagnosed with PPH in the world, and 70,000 of these cases result in death. Therefore, PPH is recognized as an important public health problem globally.[1-5]

PPH is a serious condition when occurs about 1 to 5 in 100 women giving birth. PPH is generally observed within a day after giving birth but can be happened up to the 12th week.[6,7] There are many factors that can induce an individual's chance of developing PPH. Uterine atony (or uterine tone) is considered to be the main cause of PPH.[8-10] Also, uterine inversion, uterine rupture, placental defects (placental abruption, placenta previa, retained placenta, placenta accrete), obesity, preeclampsia, infections, and intrahepatic cholestasis of pregnancy are other risk factors of the PPH.[3,11-13]

Uterine artery embolization (UAE) is an important radiologic procedure which was first described in 1995. UAE is defined as nonsurgical treatment method for women who want to preserve their uterus and avoid surgery. In this method, embolic agents [usually polyvinyl alcohol (PVA)] are injected into both uterine arteries to decrease perfusion to uterine fibroids and stimulate ischemic alterations without permanent damage to the uterus. Therefore, UAE is accepted as an alternative method instead of hysterectomy to prevent PPH in clinic.[14-16]

UAE is an alternative non-surgical method used in the treatment of PPH, but our knowledge of the clinical potentials of UAE is unfortunately insufficient. In this report, we aimed to investigate the clinical success of UAE methods in patients with PPH after delivery.

MATERIALS AND METHODS

A total of 22 cases of women were diagnosed with PPH and treated at the Clinic of Obstetrics and Gynecology, Private Erciyes Hospital, Kayseri, Türkiye, between 2018 and 2022. The study protocol was reviewed and approved by the Local Ethics Committee of Acıbadem University (2022-09/10).

PPH was detected in women who gave birth between the ages of 20-40. UAE was performed using PVA (embolic agent) by an experienced radiologist. To confirm the embolization in the vessels, angiograms were taken with an angiography device using contrast media with hydrophilic catheters placed in the uterine artery. It was observed that there was no bleeding in the angiograms and the procedure was terminated. The patients were kept under observation in the gynecology service after the UAE procedure, and surgical procedure was performed on the patients who were not clinically successful. The patients' demographic and clinical data, including maternal age, body mass index (BMI), gravida and parity, gestational age, type of delivery, obstetric history, indications, postpartum processing time, embolizing vessel, early and late complications after embolization, technical and clinical success of embolization, and hospitalization time were all recorded.

Statistical Analysis

The statistical package for the Social Sciences (SPSS) version 20.0 software was used for statistical analysis. The Mann-Whitney U test and Student's t-test were used for statistical analysis. Data are presented as mean ± standard deviation and p value <0.05 was considered significant.

RESULTS

A total of 22 women with PPH were treated with the UAE method using PVA and their clinical success was compared with the different characteristics of the cases. Clinical characteristics and the outcomes in patients are shown in Table 1. The average age of the patients was 29.4±6.0 years old (range: 20-40). The mean BMI was calculated as 22.3±3.6 kg/m^2 (range: 18-30). The average gestational age was 38.6±6.0, gravidity was 2.1±1.2 (range: 1-5), and parity was 1.6±0.8 (range: 1-4). More than half of the pregnant women included in the study had a normal vaginal spontaneous delivery (63.6%). It was determined that thirteen of these 22 women (59.1%) did not have pathological conditions in their pregnancy history. In this study, 77.3% of the 22 women with PPH were diagnosed as having uterine atony. An average of 2.9 hours after delivery, 86.4% of the women underwent bilateral UAE. Early and late complications did not observe in the majority of cases after the UAE. The average hospitalization time was 3.04±1.6 days.

As shown in Table 2, 14 women were treated successfully with UAE using PVA without any additional intervention. Of the eight women who failed the UAE method, four cases had to undergo a hysterectomy operation because of severe PPH. Furthermore, bilateral hypogastric artery ligation was performed in two patients. There is a statistically significant relationship between the success of the UAE method and the age, BMI, gravidity, parity, cesarean delivery, and length of hospital stay of the women who gave birth. Large for gestational age, high BMI, gravidity, and parity of the patients increase the clinical success of UAE. There were no significant differences with gestational age and normal vaginal spontaneous delivery between the successful UAE and unsuccessful UAE subgroups.

Table 1. Clinical characteristics and the outcomes in patients treated with UAE using PVA

Characteristic	Value
Age (years)	29.4±6.0 (range: 20-40)
BMI (kg/m²)	22.3±3.6 (range: 18-30)
Gravidity (n)	2.1±1.2 (range: 1-5)
Parity (n)	1.6±0.8 (range: 1-4)
Gestational age	38.6±1.4 (range: 35-40)
Type of delivery	
Normal spontaneous vaginal delivery	14 (63.6%)
Cesarean delivery	8 (36.4%)
Obstetric history	
Placental abruption	1 (4.5%)
Gestational hypertension	2 (9.1%)
Fetal distress	2 (9.1%)
Twin pregnancy	1 (4.5%)
Preeclampsia	2 (9.1%)
Placenta previa	1 (4.5%)
N/A	13 (59.1%)
Indications	
Uterine atony	17 (77.3%)
Placenta accrete	1 (4.5%)
Placenta previa	1 (4.5%)
Right uterine artery tear	1 (4.5%)
Uterine arteriovenous malformation	2 (9.1%)
Postpartum process time (hour)	2.9±1.75 (range: 1-6)
Embolizing vessel	
Bilateral uterine artery	19 (86.4%)
Right uterine artery	1 (4.5%)
Left uterine artery	2 (9.1%)
Early complications	
Atelectasis	1 (4.5%)
Urinary system infection	3 (13.6%)
Wound infection	1 (4.5%)
N/A	17 (77.3%)
Late complications	
Incisional hernia	2 (9.1%)
Oligomenorrhea	1 (4.5%)
Infertility	1 (4.5%)
N/A	18 (81.8%)
Hospital stay (days)	3.04±1.6

PVA: Polyvinyl alcohol; UAE: Uterine artery embolization; BMI: Body mass index

Table 2. Significant parameters affecting the success of the UEA method in patients diagnosed with PPH

	Uterine artery embolization		*p*
	Successful (n=14)	Unsuccessful (n=8)	
Age (years)	26.4±4.6	34.8±4.1	<0.001
BMI (kg/m²)	20.6±2.4	25.1±3.7	0.019
Gravidity (n)	1.5±0.8	3±1.3	0.025
Parity (n)	1.28±0.5	2.25±1.0	0.031
Type of delivery			
Normal spontaneous vaginal delivery	7 (50%)	6 (75%)	0.546*
Cesarean delivery	7 (50%)	2 (25%)	<0.001
Hospital stay (days)	2.0±0.0	4.9±1.2	<0.001

UAE: Uterine artery embolization; PPH: Postpartum hemorrhage; BMI: Body mass index; *: $p>0.05$

DISCUSSION

In the literature, the optimal conditions of UAE have not yet been sufficiently investigated in patients with PPH because there is not enough evidence from randomized controlled trials. In the present study, we reported that UAE was a non-surgical treatment method in women with serve PPH, and some clinical characteristics and outcomes decide the efficiency of UAE in patients. Obtained results demonstrated that the age, BMI, gravidity, parity, and type of delivery of the patients were determined as significant parameters affecting the success of UAE.

After vaginal and cesarean delivery, the contraction of the uterine muscles provides the compression of the blood vessels attached to the placenta, thus this mechanism stops the bleeding. Inability to contract or weak contraction of the uterine muscles (also called uterine atony) causes life-threatening blood loss. According to the World Health Organization (WHO), uterine atony has been reported as the most important cause of PPH.[17,18] Uterine atony was diagnosed in about 77% of the 22 PPH patients included in our study.

In our study, advanced maternal age adversely (34.8±4.1 years) affects the success of the UAE in patients with PPH and resulting in surgical intervention. Experimental and clinical studies reported that older maternal age (≥35 years) is an independent risk factor for PPH. Decreased vascular reactivity and vascular stiffness are important pathological conditions that increase with advanced maternal age. Aging leads to decrease in the elasticity of the soft birth canal and disruption of uterine contraction.[19,20] Moreover, the prevalence of placenta previa and placental abruption in advanced maternal age provoke PPH. All these complications that increase PPH negatively affect the efficiency of the UEA method in women who have given birth at an advanced age.

According to the WHO, a BMI over 25 kg/m^2 is considered overweight.[21] Tissue injury and surgical morbidity are pathological conditions observed more frequently in overweight women than in normal weight women. The prevalence of pregnant women with overweight is a significant parameter to explain the increase in PPH incidence.[22,23] It has been reported that overweight and obesity are limiting parameters for UEA method in the prevention of bleeding in gynecological cases, but there is no sufficient study on the relationship between overweight and the success of UEA in PPH.[24] Our findings demonstrated that the increase in BMI is a parameter that negatively affects the clinical success of UEA in treatment of PPH.

Clinical studies reported that uterine atony is the most common cause of PPH, and multiparity and high gravidity are significant risk factors for uterine atony. Therefore, multiparity and high gravidity are closely associated with PHH.[25,26] In this study, multiple pregnancy and multiparity were associated with an increased risk of UAE.

In order to evaluate clinical success of the UEA method, type of delivery and postpartum process time were examined on patients with PPH. Our results indicated that no statistically significant difference was observed in the clinical success of IEA by normal spontaneous vaginal delivery. Also, UAE method was successful in 7 out of 9 women with PPH after cesarean section ($p<0.05$). Compared to normal spontaneous vaginal delivery, cesarean delivery increases the risk of PPH and hemorrhage-related morbidity. Therefore, the application of the UEA method using PVA has a big potential for the treatment of PPH after cesarean delivery. In the literature, there is no study about relationship between type of delivery and the efficiency of the UAE method in patients with PPH.

It is well-known that UAE is an important alternative method to treat PPH without surgery. Similar to the literature, a 2.5-fold decrease was observed in the length of hospital stay of the patients treated with the UAE method.[27]

CONCLUSION

The authors' findings suggest that the age, BMI, gravidity, parity, and type of delivery of the patients have significant effect on success of UEA in patients with PPH. Furthermore, the absence of early and late complications in most of the women after the IEA procedure has emerged as another important advantage of the technique.

ETHICS

Ethics Committee Approval: The study protocol was approved by the Local Ethical Committee of Acıbadem University, Türkiye (2022-09/10).

Informed Consent: Informed consent was provided from all patients who wanted participated in the study.

FOOTNOTES

Contributions

Surgical and Medical Practices: Z.A., B.S.F.; Concept: Z.A., B.S.F., B.K.; Design: Z.A., B.S.F., B.K., D.U., C.M.G., E.D.Ç.; Data Collection or Processing: Z.A., B.S.F. B.K.; Analysis or Interpretation: Z.A., B.S.F., B.K., C.M.G., E.D.Ç.; Literature Search: Z.A., B.S.F., B.K., D.U., C.M.G., E.D.Ç.; Writing: Z.A., B.S.F.

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Assessment of the knowledge of urinary incontinence and pelvic organ prolapse in postpartum women - A cross sectional study

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ABSTRACT

Objectives: The objective of this study was to evaluate the knowledge of urinary incontinence (UI) and pelvic organ prolapse (POP) among women postpartum.

Materials and Methods: The author of the "prolapse and incontinence knowledge questionnaire (PIKQ)" was approached and permission was taken for use and translation of the questionnaire used in this study. An ethical clearance was obtained from ethical committee of Ramaiah Medical College. All participants were screened and those meeting the inclusion criteria were enrolled in the study. The participants were then administered the PIKQ questionnaire and demographic questionnaire that consisted of details of age, educational qualifications and socio-economic status.

Results: Sixty-six women were administered the PIKQ. Data analysis of the scores obtained suggested that 6% of the women postpartum had more than adequate knowledge on UI and 42% of women postpartum had more than adequate knowledge on POP. Further analysis demonstrated a good correlation between the PIKQ score and age of the women postpartum who were aged between 30 and 34 years.

Conclusion: In the current study, 6% of women postpartum had higher than usual knowledge on UI and 42% had higher than usual knowledge on POP. Women postpartum had limited knowledge about POP and UI. This study emphasizes that a greater understanding of pelvic floor disorders may prove to be beneficial.

Keywords: Pelvic floor dysfunction; pelvic organ prolapse; postpartum women; urinary incontinence

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INTRODUCTION

Pelvic floor dysfunction (PFD) is a term that refers to a broad range of conditions affecting the structure and function of pelvic organs, including the bladder, urethra, uterus, vagina, rectum, and supporting tissues.[1] Two of the most common types of PFD are urinary incontinence (UI) and pelvic organ prolapse (POP), which significantly affect a woman's physical, emotional, and social well-being. Pelvic floor disorders (PFDs) are prevalent worldwide, yet many women, particularly in developing countries, lack awareness of these conditions.[1]

UI, defined as the involuntary leakage of urine, is one of the most frequent PFDs, with urgency UI (UUI) and stress UI (SUI) being the most prevalent subtypes.[2] UUI occurs with a sudden and intense urge to urinate, often linked to frequent urination and nocturia. Risk factors for UI include childbirth, obesity, aging, and reduced physical activity. Studies suggest that postpartum women are at an increased risk of developing UI, with vaginal delivery identified as a significant contributing factor.[3] Despite the availability of effective conservative treatments, including pelvic floor exercises and lifestyle changes, many women remain unaware of these options, leading to a delay in seeking treatment.[4]

POP occurs when the pelvic organs descend from their normal anatomical position due to the weakening of the pelvic floor muscles and connective tissues. Symptoms may include a feeling of heaviness in the pelvic region, difficulty with urination or defecation, and discomfort during sexual activity.[5] POP is particularly common in women following vaginal delivery, with the risk increasing three-to five-fold after a single vaginal birth.[6] Similar to UI, many women are unaware of the causes, symptoms, and treatment options for POP, leading to significant underreporting and undertreatment of the condition.[7]

In India, the reported prevalence of UI and POP among postpartum women is 10.6% and 1.6%, respectively.[6] However, these figures may underestimate the true burden due to societal stigma, lack of awareness, and cultural barriers that prevent women from seeking help.[7] Literature reviewed suggests that women often consider PFDs to be an inevitable part of aging or childbirth, and many are reluctant to seek medical care due to feelings of embarrassment and fear of invasive treatments.[8] Moreover, studies highlight that a significant knowledge gap exists, particularly among women who do not frequently visit healthcare providers. This lack of understanding can delay diagnosis and treatment, further exacerbating the physical and psychological impact of these conditions.

The prolapse and incontinence knowledge questionnaire (PIKQ), developed by Shah et al.[9] in 2008, is a validated tool for assessing women's knowledge of UI and POP. It has been adapted and validated in multiple languages, including Turkish and Thai, demonstrating good reliability in assessing knowledge across different cultural contexts.[10] Studies using the PIKQ suggest that women with higher knowledge of PFDs are more likely to seek treatment and manage their symptoms effectively. However, most of these studies have focused on women attending specialized urogynecology clinics, leaving a gap in our understanding of knowledge levels among postpartum women in the general population.[2,6,11,12]

Given the limited research on UI and POP in postpartum women in India, this study aims to assess their knowledge of these conditions using the Kannada version of the PIKQ. This study seeks to bridge the knowledge gap by evaluating the extent of understanding about UI and POP among postpartum women and identifying factors that influence their awareness. Understanding these factors is critical for developing targeted interventions that improve awareness, promote early detection, and encourage appropriate treatment.

Objectives of the Study

1. To assess the knowledge of postpartum women regarding UI and POP using the validated Kannada version of the PIKQ.

2. To explore associations between knowledge levels and socio-demographic factors such as age, education, and socio-economic status.

Expected outcomes: This study anticipates revealing significant gaps in knowledge about UI and POP among postpartum women. It is expected that demographic factors like education and socio-economic status will play a role in knowledge levels. Furthermore, the study aims to highlight the need for enhanced patient education programs and public health initiatives to address these knowledge gaps, improve early diagnosis, and reduce the burden of PFDs on postpartum women in India.

MATERIALS AND METHODS

This cross-sectional, descriptive study aimed to evaluate the knowledge of postpartum women regarding UI and POP. The study was conducted among women within 3 to 12 months postpartum a vaginal delivery, a critical period during which the female body, particularly the pelvic floor, undergoes recovery after childbirth. The objective was to identify key factors influencing their knowledge of these conditions, considering variables such as age, educational background, and socio-economic status.

Based on Aparna D. Shah et al.'s[9] 2008 study titled "a reliable, valid instrument to assess patient knowledge about urinary

incontinence and pelvic organ prolapse", the sample size was calculated assuming an expected population standard deviation of 10. Using a t-distribution, a sample size of 65 was required to estimate the mean with 95% confidence and a precision of 2.5. Accounting for potential non-responses and withdrawals, the sample size was increased by 20%, bringing the final required number of participants to 78.

Participants were recruited from two sources:

1. Hospital medical records department: This was used to identify women who had recently delivered babies.

2. Pediatric department: Women attending postnatal visits for infant vaccinations were approached.

All eligible women were informed of the study's purpose and informed consent was obtained. The PIKQ, translated into Kannada by linguistic professionals and validated with an intra-class correlation coefficient of 0.8, was administered along with a demographic questionnaire.

Women aged 25-49 years who were 3 to 12 months postpartum and could understand, read, and speak English or Kannada were included in the study. Exclusion criteria consisted of women who had undergone a hysterectomy, had a history of UI or POP prior to pregnancy, or had a history of gynaecologic cancer.

Data on participants' knowledge of UI and POP were collected through the PIKQ and demographic forms. In addition to knowledge, factors like age, education, and socio-economic status were analyzed to understand their influence on knowledge acquisition. Educational attainment was categorized into primary, secondary, and tertiary levels, while socio-economic status was determined using the Modified Kuppuswamy scale.

The study received approval from the Institutional Ethics Committee of Ramaiah Medical College with ref. no: MSRMC/EC/PG-04/2022. Additionally, permission was obtained from the hospital administration, and all participants were assured confidentiality. The original authors of the PIKQ questionnaire were approached for permission to use and translate the tool for this study.

Outcome Measure

The primary outcome measure for this study was the PIKQ, a 24-item survey specifically designed to assess knowledge of UI and POP. The questionnaire consists of two scales: The UI scale and the POP scale, each containing 12 questions. These questions cover a range of topics, including epidemiology, pathophysiology, diagnosis, and management of UI and POP. The survey uses a simple response format of "Yes", "No", and "I don't know" for each question.

Each correct response was assigned one point, while incorrect responses, unfilled answers, or "I don't know" responses received zero points. The total scores for each scale (UI and POP) were calculated by summing up the correct answers, with a maximum possible score of 12 on each scale. Higher scores indicated greater knowledge about UI and POP, respectively.

In addition to the knowledge assessment, demographic information was collected, including participants' age, parity (number of childbirths), menstrual status, marital status, annual household income, and the highest level of education attained. The study also asked participants about their employment in the medical field, any personal history of UI and/or POP, whether they had consulted a urologist or urogynaecologist, and whether they had received any treatment for UI or POP.

To assess expertise levels, scores of 80% or higher on the UI scale and 50% or higher on the POP scale were interpreted as demonstrating significant awareness, based on the original scoring guidelines provided by the authors of the PIKQ. These thresholds were set using frequency data from previous studies, where participants scoring at or above these levels were considered to have higher-than-average knowledge about these conditions.

Statistical Analysis

A descriptive analysis framework was used to summarize the data. Continuous data such as age was summarized as mean and standard deviation (SD). The primary objective of knowledge about UI and POP in postpartum women was summarized as mean and SD in percentage. The normality distribution of age and PIKQ score was assessed. Spearman's correlation test was used to assess the correlation between the age and PIKQ score.

RESULTS

This study evaluated the knowledge of UI and POP among 66 postpartum women, with a mean age of 28 years (SD ±3), ranging from 25 to 36 years. The demographic characteristics of the study population are described in Table 1.

The participants demonstrated moderate knowledge in both areas, with a mean score of 52% (SD ±18) for UI and 44% (SD ±15) for POP as depicted in Table 2.

Table 1. Demographic variables of the study population

Variables	Valid percent
Primiparous women (n=41)	62%
Multiparous women (n=25)	38%
College graduates	68%
High school	32%

Notably, 6% of the women exhibited high knowledge of UI (≥80%), while 42% had a relatively higher-than-usual understanding of POP (≥50%).

The data was further analysed to assess the correlation of PIKQ scores based on the age groups. In the age group 25 to 29 there was no significant association between age and PIKQ scores (r=0.001, p=0.993).

In the age group 30 to 34 years a moderate positive correlation was observed between age and PIKQ scores (r=0.521, p=0.100) in this group, although this relationship did not reach statistical significance. This result may suggest a trend of increasing knowledge with age among these women, though more evidence is required to confirm this finding and is represented in Figure 1.

In the age group 35 to 39 years there was a weak and non-significant correlation (r=0.211, p=0.789) was observed in this group, indicating minimal association between age and PIKQ scores among older postpartum women.

The knowledge of UI and POP was further analysed to determine the correlation of PIKQ Scores and primiparous is represented in Table 3 and 4 and multiparous women is represented in Table 5 and 6.

There was a weak correlation between knowledge of UI and POP, age and education. A negative correlation was noted between age and knowledge of POP. It was also observed that education had a weak correlation with knowledge of POP.

The results of the correlation in Table 5 and 6 demonstrated a weak correlation with age, education in multiparous women and knowledge of both UI and POP.

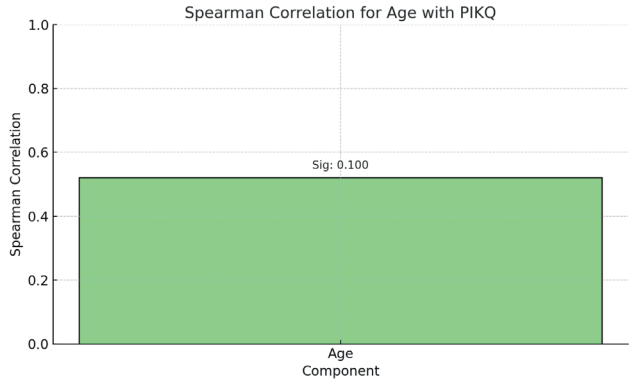

Figure 1. Association between age 30 to 34 years and PIKQ scores
PIKQ: Prolapse and incontinence knowledge questionnaire

Table 2. Descriptive data of mean and standard deviation of knowledge scores in postpartum women

Component of PIKQ	Mean score (in percentage)	Standard deviation (in percentage)
Knowledge of urinary incontinence	52%	18%
Knowledge of pelvic organ prolapse	44%	15%

PIKQ: Prolapse and incontinence knowledge questionnaire

Table 3. Correlation of UI and primiparous women

	Age	Education
Knowledge of UI in primiparous correlation	0.086	0.375
Coefficient sig. (2 tailed)	0.0592	0.016

UI: Urinary incontinence

Table 4. Correlation of POP and primiparous women

	Age	Education
Knowledge of POP in primiparous correlation	-0.197	0.270
Coefficient sig. (2 tailed)	0.216	0.87

POP: Pelvic organ prolapse

Table 5. Correlation of UI and multiparous women

	Age	Education
Knowledge of UI in multiparous correlation	0.233	0.142
Coefficient sig. (2 tailed)	0.262	0.498

UI: Urinary incontinence

Table 6. Correlation of POP and multiparous women		
	Age	**Education**
Knowledge of POP in multiparous correlation	0.246	0.091
Coefficient sig. (2 tailed)	0.236	0.664
POP: Pelvic organ prolapse		

DISCUSSION

The present study aimed to assess the knowledge of UI and POP among postpartum women. The results indicated that only 6% of participants demonstrated a high level of knowledge regarding urinary incontinence, while 42% showed a higher-than-usual understanding of POP. This finding aligns with Chen et al.[11], who reported a significant knowledge gap about PFDs among women. Additionally, a systematic review by Fante et al.[13] corroborated this notion, emphasizing the limited awareness of these conditions among women and highlighting the pressing need for increased education and outreach.

Further analysis was performed to determine the correlation between age and PIKQ scores among postpartum women. The study found no significant correlation between the awareness of UI and POP in the age group of 25-29 years (r=0.001, p=0.993). This result is consistent with Prudencio et al.[14], who concluded that young women possess minimal knowledge about pelvic floor anatomy and function. Interestingly, a moderate positive correlation was observed among women aged 30-34 years (r=0.521), although it did not reach statistical significance (p=0.100). Conversely, women aged 35-39 years displayed a weak, non-significant correlation with knowledge of UI and POP (r=0.211, p=0.789). This suggests that while age may not be a robust determinant of knowledge of PFDs in postpartum women, there is a potential trend indicating increasing knowledge levels as women mature through their 30s.

To explore the relationship between knowledge of UI and POP and educational status, the study compared average PIKQ scores among women with different educational backgrounds: Those who completed schooling up to the 8th standard, 12th standard, and college graduates. The results indicated that college graduates had higher PIKQ scores than those with lower educational qualifications, with all women scoring above 80% in knowledge being college graduates. This finding suggests that lower educational attainment is associated with a lack of knowledge regarding UI and POP. This aligns with Chen et al.[11], who also identified a link between lower educational qualifications and non-proficiency in knowledge about UI and POP.

Since most participants in the study belonged to lower socio-economic strata, a deeper analysis of socio-economic status was not conducted. However, the clear trend emerged that those women with higher knowledge levels were primarily college graduates, indicating that education plays a crucial role in enhancing awareness.

The analysis further revealed notable differences in knowledge levels between primiparous and multiparous women. Primiparous women showed a slightly better understanding of urinary incontinence, evidenced by a correlation of 0.086 with age and a coefficient significance of 0.0592 for education. However, the knowledge of POP among primiparous women was weaker, with a negative correlation of -0.197. In contrast, multiparous women demonstrated a weak correlation with both UI (0.233) and POP (0.246), indicating that their experiences of childbirth may not significantly enhance their knowledge about these conditions.

These findings suggest that while childbirth experience may contribute to some degree of knowledge about UI among primiparous women, multiparous women may not necessarily gain additional insights regarding either condition with subsequent pregnancies. This lack of awareness in both groups underscores the need for targeted educational interventions that address the unique challenges and knowledge gaps faced by postpartum women, regardless of their parity.

Both UI and POP are prevalent conditions that remain under-discussed and under-treated among postpartum women. Low awareness is likely a significant factor contributing to the reluctance to seek medical attention for these disorders. The World Health Organization's 2nd International Consultation on Incontinence underscores the necessity of raising awareness and education around these conditions. Implementing educational and motivational programs specifically targeting UI and POP could empower women with the knowledge they need, ultimately fostering increased healthcare-seeking behaviors.

In this study, few women reported experiencing UI or POP or sought therapy for these conditions. Literature indicates that individuals are more likely to pursue medical attention for health issues when symptoms become particularly bothersome. Hence, creating awareness about health issues is vital for encouraging behavioral changes, reducing illness indicators, and improving adherence to therapy, particularly in chronic conditions.

Recent research emphasizes the importance of increasing knowledge and education regarding PFDs among women,

especially during the postpartum period. Nur Farihan et al.[12] highlighted a significant gap in awareness of UI and POP among pregnant women, advocating for targeted educational programs to bridge this knowledge gap. Similarly, Haylen et al.[15] emphasized the critical role of patient education in effectively managing PFDs and reducing the stigma associated with these conditions.

Geoffrion et al.[16] demonstrated that a workshop-based learning program focused on UI and POP led to improvements in both knowledge and quality of life for participants, with sustained positive outcomes at a three-month follow-up. Moreover, a study by Mahishale and Parikh[17] in Belgaum, Karnataka, found a high prevalence of PFDs and a significant lack of knowledge about PFD rehabilitation, further emphasizing the need for education and rehabilitation services to empower women to seek timely care.

The consensus across these studies is clear: Healthcare professionals should prioritize awareness campaigns and education about UI, POP, and pelvic floor rehabilitation to improve health outcomes and encourage women to seek appropriate care. With only 5.6% of women demonstrating knowledge of pelvic floor rehabilitation in some studies, comprehensive awareness programs covering both prevention and management of PFDs are urgently needed.[17] Empowering women through knowledge can significantly enhance their health-seeking behaviors and overall well-being, leading to improved quality of life.

Study Limitations

The present study has several limitations. Firstly, reliance on "self-reported outcomes" poses a potential bias risk, necessitating the recommendation for more objective measures in future research. Additionally, the author's role in participant selection and assessment may introduce bias, warranting a more rigorous selection process in subsequent research. Moreover, the study's uneven distribution of participants' education levels, with a higher percentage of graduate degrees, compromises generalizability. Lack of control over confounding variables, including age, education, and socio-economic status, may have impacted the study's outcomes. Further studies with larger sample sizes could provide stronger evidence of these associations.

CONCLUSION

In conclusion, this study reveals varying levels of knowledge among postpartum women regarding UI and POP. Educational attainment, age groups, and limited awareness highlight the need for targeted interventions to improve understanding. Initiatives promoting awareness and education are vital for empowering women to seek appropriate healthcare and addressing the low prevalence of therapy utilization. Health professionals should prioritize educational programs to enhance women's knowledge and encourage proactive healthcare-seeking behaviours.

ETHICS

Ethics Committee Approval: The study received approval from the Institutional Ethics Committee of Ramaiah Medical College with ref. no: MSRMC/EC/PG-04/2022.

Informed Consent: Informed consent was obtained from all individual participants included in the study. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

FOOTNOTES

Contributions

Concept: R.S., D.R., B.T.; Design: R.S., D.R., B.T.; Data Collection or Processing: R.S., D.R., B.T.; Analysis or Interpretation: R.S., D.R., B.T.; Literature Search: R.S., D.R.; Writing: R.S., D.R.

DISCLOSURES

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The effect of vaginal cuff suspension to uterosacral ligaments in vaginal hysterectomy on improvement of lower urinary tract symptoms and pelvic organ prolapse

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ABSTRACT

Objectives: To evaluate the effects of suturing the cuff to the uterosacral ligaments (USL) during vaginal hysterectomy on healing with regards to anatomy and lower urinary tract symptoms (LUTS).

Materials and Methods: This study was carried out on patients, who applied to the Urogynecology Outpatient Clinics of Muğla Research and Training Hospital between the dates of March 2021 and March 2022 and were diagnosed as having uterine prolapse. All of the patients were operated on by the same experienced surgeon (Prof. AAS) and the newly created vaginal cuff was sutured to the USL. In the preoperative period, all patients underwent pelvic organ prolapse quantification (POP-Q) system measurement, and were questioned about LUTS, including stress urinary incontinence, urgency, urge incontinence, frequency, hesitancy, abnormal micturition, nocturia, dysuria, pelvic pain, fecal incontinence, incomplete evacuation of stool, constipation, and vaginal wind. The patients, who were operated on, were reevaluated with respect to POP-Q and LUTS in the follow-up period at the 3rd, 6th and 12th months.

Results: A total of 80 patients were included in this study. POP-Q points; Aa, Ba, C, Ap and Bp measurements were significantly deeper and genital hiatus measurements were significantly narrower after surgery than during the preoperative period. No statistically significant difference was observed in the perineal body and with respect to total vaginal length measurements. Moreover, statistically significant improvements were found in the symptoms of urgency, urge incontinence, stress urinary incontinence, frequency, abnormal micturition, nocturia, pelvic pain, fecal incontinence, incomplete evacuation of stool and constipation. In the POP-Q scoring performed in the postoperative follow-up of the cases, the C value was taken as a reference for *de novo* vaginal vault prolapse. There were 8 cases of recurrence. The mean C value was +3.6 in these cases. Recurrent cases were treated with LeFort colpocleisis, iliococcygeal fixation and posterior intravaginal sling (PIVS) operations. No recurrence was observed in the follow-ups.

Conclusion: The suturing of the newly created vaginal cuff during vaginal hysterectomy to the USLs is a very simple, easily applicable, highly effective surgical technique with low morbidity and low risk of vaginal vault prolapse. This technique should be included in the armamentarium of all surgeons dealing with urogynecology due to the positive effect it provides in LUTS as well as anatomical healing.

Keywords: Apical suspension; pelvic organ prolapse; uterosacral ligaments; vaginal hysterectomy

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INTRODUCTION

Hysterectomy is the surgical removal of the uterus. It is one of the most commonly performed gynecologic procedures in Turkiye, ranking second in the world after cesarean section.[1,2] The number of women who have hysterectomies each year is significant, and the majority of them are performed for benign reasons such as leiomyoma, adenomyosis, severe abnormal uterine bleeding that does not respond to medical treatment, and uterine prolapse.[3] Today, many urogynecologists prefer vaginal hysterectomy for apical compartment defect and uterine prolapse. The likelihood of a woman having prolapse surgery during her lifetime is 11-19%, and this rate rises as the elderly population grows. The vast majority (80-90%) of pelvic organ prolapse (POP) is treated vaginally, with abdominal surgery being less common. Vaginal hysterectomy plays an important role in the treatment of prolapse worldwide.[4,5] In recent years, surgical techniques have advanced rapidly to improve outcomes in female pelvic functional reconstructive surgery and to reduce prolapse recurrence rates.[6,7] Because of postoperative apical recurrences, it is now accepted that apical support for a permanent repair during vaginal hysterectomy is required. Uterosacral ligament (USL) plication is a popular procedure for this type of apical support.[5-8]

In this thesis study, we aim to look at anatomical and lower urinary tract symptoms (LUTS) and effects of suturing the vaginal cuff to the USLs, which we did to prevent recurrent prolapse in vaginal hysterectomies.

MATERIALS AND METHODS

This prospective cohort study was conducted in the Department of Obstetrics and Gynecology of the Faculty of Medicine of Muğla Sıtkı Koçman University, Muğla, Türkiye. Ethical approval was obtained from the Faculty's Ethics Committee (no. 4/III; 17 February 2021). The study was conducted according to the recommendations of the Helsinki Declaration. Written informed consent was obtained from all patients before undergoing surgery. This study was conducted with 80 patients at the Urogynecology Polyclinic of Muğla Sıtkı Koçman University Training and Research Hospital Gynecology and Obstetrics Clinic between March 2021-March 2022. Preoperative evaluation, surgery and postoperative follow-up of the patients were performed by the same surgical team. The necessary information was obtained from the hospital database and patient files.

1. Inclusion Criteria: Completed fertile period or "not pregnant/no risk of pregnancy" status, uterine prolapse (C point $\geq$0), the patient accepting to be treated with vaginal hysterectomy for uterine prolapse, patients able to communicate well and adapt to the diagnosis-treatment and follow-up process, and patients able to 3rd, 6th and 12th-month controls.

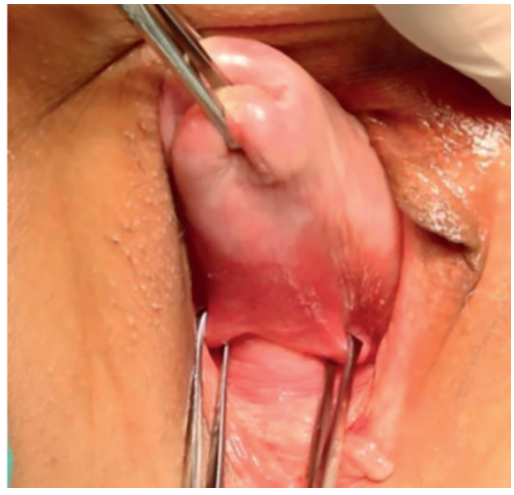
2. Exclusion Criteria: a history of previous pelvic floor surgery, known adverse reactions to non-absorbable suture material such as erosion, fistula, and abscess development, and the need for ovarian removal (adnexal mass, BRCA 1/2 positivity, family history of ovarian cancer)

3. Preoperative Patient Evaluation: Anamnesis, Physical Examination, and Pelvic Examination:

Patients were evaluated at the urogynecology outpatient clinic. A detailed anamnesis was taken, followed by a physical and pelvic examination. The urogynecologic patient evaluation form included information about the patient's age, parity, body mass index, menopausal status, POP-quantification (POP-Q) scoring, and upper urinary tract stone (UUTS). POP-Q scoring included Aa, Ba, C, D, D, Ap, and Bp points, as well as genital hiatus (Gh), perineal body (Pb), and total vaginal length (TVL). The patients were given a detailed explanation of vaginal hysterectomy and cuff suspension surgery for USL. A signed consent form was obtained from each patient at least 48 hours before surgery and kept in the files. Before surgery, bowel cleansing was not performed.

4. Surgical Procedure:

After regional anesthesia was applied to the patient, the patient was placed in a high dorsal lithotomy position. The uterosacral ligaments, exposed when the uterus was pulled forward and upward, were shown being held with Allis clamps (Picture 1a). The border of the bladder could be identified from the reflection in the vaginal epithelium covering it. The bladder was removed from the incision line with the help of an assistant. A circular incision was made in the upper part of the cervix, at the level where the bladder reflex is observed. At the same time, the level

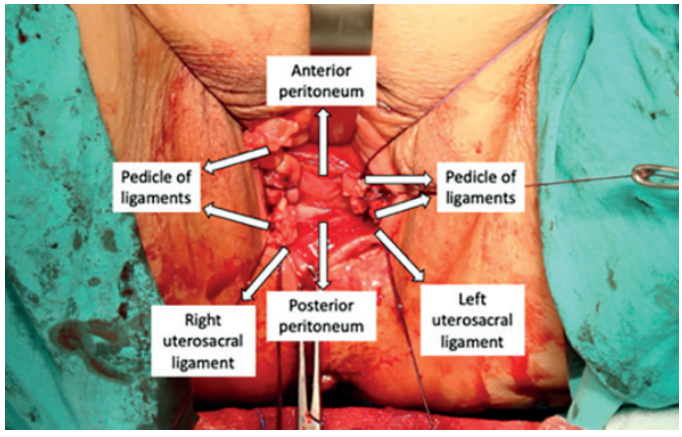


Picture 1a. Demonstration of uterosacral ligaments held with Allis clamps

of this incision also determined the postoperative total vaginal length. Thin laces called “plica uterovesicalis” were held with small pean clamps. Then it was cut and tied. The bladder was removed from the cervix via sharp and blunt dissection. The cardinal ligaments extending to the pelvic wall on the right and left sides of the cervix were held with a Haeney clamp, cut and tied with no. 0 late absorbable sutures. Bilateral uterine arteries were held with curved Heaney clamps, cut and tied. The USLs, which were exposed by traction of the uterus, first in a forward position and then upward, are held, cut and sutured. The sutures belonging to the USLs were left uncut and kept. The posterior peritoneum was cut and opened. The anterior peritoneum was curved from below with a finger and cut open with scissors. The ligament pedicles were held in place by opposing Heaney clamps. These pedicles included the round ligament, ligamentum ovary proprium, ligamentum latum and tuba uterina. Each pedicle was tied with two stabilizing sutures placed first medially and then distally. Picture 1b shows the appearance of the retained sutures after the uterus is removed and which structures these sutures belong to. Three sutures held on the right belong to two ligament pedicles and the right uterosacral ligament. The three sutures held on the left belong to the two ligament pedicles and the left USL.

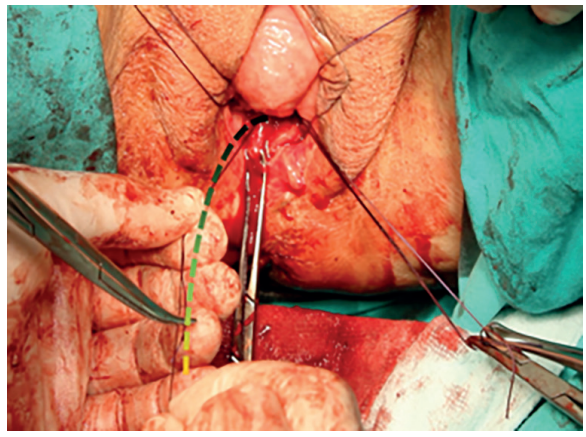
Hemostasis was evaluated at this stage with the retained pedicles. After peritonization, the tied suture was not cut but instead secured, serving as a reference point for the next steps (Picture 1c). The sutures of the right and left ligament pedicles were connected to each other in a reciprocal manner. Simultaneously, the right and left USLs were also mutually connected.

At the end of this stage, the sutures of the USLs and pedicles were cut (Picture 2). One end of the peritonised suture and fix were passed through the upper leaf of the cuff, and the other end passed through the lower leaf. If double needle suture material is not used, free needles can also be used.

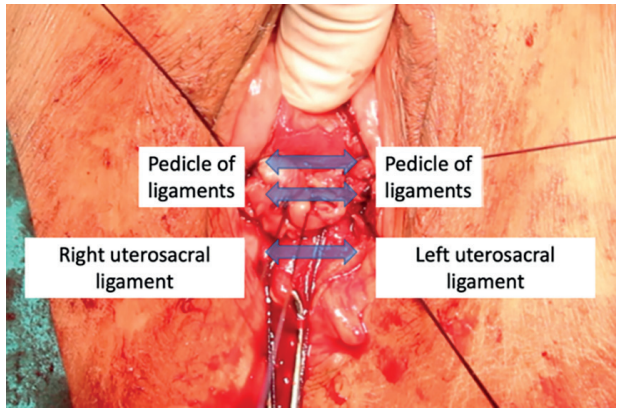


Picture 1b. The appearance of the retained sutures after the uterus was removed, showing the structures to which these sutures belong

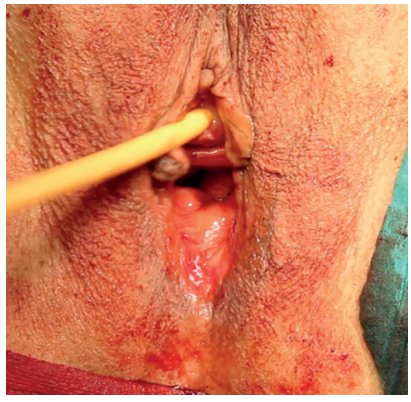
The cuff was closed by individually suturing it using size 0 late-absorbable suture material. After the vaginal cuff was pushed in with the help of an assistant, the sutures extending from the upper and lower leaves of the cuff-continuing from the suture used in peritonization-were placed in the deep plane. This ensured the connection between the cuff and the USL, providing apical support simultaneously with the vaginal hysterectomy. Picture 3 shows the post-operative view.



Picture 1c. After peritonization, the tied suture was not cut but fixed at key points for the next steps



Picture 2. The sutures of the USLs and pedicles were cut
USLs: Uterosacral ligaments



Picture 3. Post-operative appearance

5. Postoperative Patient Evaluation: UUTS and Pelvic Examination:

The bladder catheter was removed at the 8th postoperative hour and the patients were mobilized. In routine practice, the patient was discharged 48 hours postoperatively and scheduled for a follow-up visit on the 10th postoperative day. At the 3rd, 6th, and 12th postoperative months, symptoms were assessed and re-evaluated through pelvic examination. Current symptoms and POP-Q values were recorded on urogynecologic follow-up forms. A postoperative POP-Q C value of >0 was considered indicative of *de novo* vaginal cuff prolapse.

Statistical Analysis

Skewness/Kurtosis values were used to test normality in the obtained data. Values were expressed as mean ± standard deviation, median (minimum-maximum), or frequency (%). The Independent Samples t-test and Mann-Whitney U test were used to compare continuous variables between two groups. The non-parametric test was analyzed using One-Way ANOVA with the Kruskal-Wallis test when comparing variables between more than two groups. Relationships between continuous variables were analyzed using Spearman or Pearson correlation analysis. The chi-square test was employed to compare categorical data, including both counts and percentages, between groups. All analyses were conducted using the SPSS 20 software, with a significance level set at 0.05. Statistical results were assessed for their consistency with the literature and any observed differences.

RESULTS

As a result of the examination of demographic characteristics, it was seen that the mean age and body mass index (kg/m²) were 63.33±8.42 and 28.75±3.20, respectively. The number of patients who were not in menopause was 5 (6.2%), and the number of patients in menopause was 75 (93.8%). When the parity was evaluated, it was seen that 1 (1.2%) patient was nulliparous, 8 (10%) patients were primiparous, and 71 (88.8%) patients were multiparous (Table 1).

The women in the study had their preoperative and postoperative POP-Q measurements compared at the 3rd, 6th, and 12th months. As a result, there were statistically significant differences between the groups in terms of Aa, Ba, C, Ap, Bp, Gh.

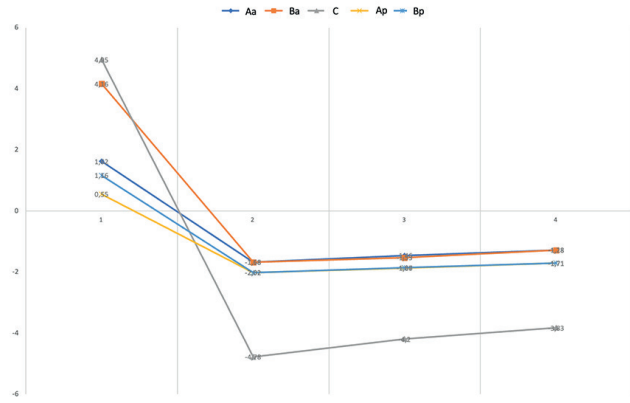


Figure 1. Variation of Aa, Ba, C, Ap, and Bp values over time

Table 1. Demographic data of the patients included in the study

Demographic data	**(n=80)**
Age (years)	63.33±8.42
BMI (kg/m²)	28.75±3.20
Menopausal status	
No Yes	5 (6.2%) 75 (93.8%)
Parity	
Nulliparous Primiparous Multiparous	1 (1.2%) 8 (10%) 71 (88.8%)

Mean ± SD, (%), BMI: Body mass index; SD: Standard deviation

Table 2. Vaginal measurements of patients according to POP-Q (cm)

	Preoperative (Mean ± SD)	**Postoperative 3rd month (Mean ± SD)**	**Postoperative 6th month (Mean ± SD)**	**Postoperative 12th month (Mean ± SD)**	**p**
Aa (cm)	1.62±2.42	-1.68±1.37	-1.46±1.57	-1.28±1.56	**0.00***
Ba (cm)	4.16±2.33	-1.68±1.94	-1.53±2.01	-1.28±2.03	**0.00***
C (cm)	4.95±2.91	-4.78±2.57	-4.20±2.87	-3.83±3.04	**0.00***
Ap (cm)	0.55±3.14	-2.02±1.04	-1.87±1.31	-1.71±1.33	**0.00***
Bp (cm)	1.16±3.58	-2.02±1.04	-1.86±1.33	-1.71±1.36	**0.00***
Gh (cm)	4.62±0.96	3.83±0.76	3.82±0.76	3.82±0.76	**0.00***
Pb (cm)	2.21±0.59	2.23±0.57	2.23±0.57	2.23±0.57	0.98*
Tvl (cm)	8.10±1.31	8.12±1.31	8.12±1.31	8.12±1.31	0.99*

Aa: Aa point; Ba: Ba point; C: C point, Ap: Ap point; Bp: Bp point; Gh: Genital hiatus; Pb: Perinal body; Tvl: Total vaginal length; *Kruskal-Wallis test; **One-Way ANOVA test

No statistically significant difference was observed in terms of Pb and TVL (Table 2, Figure 1).

During the 3rd, 6th, and 12th months after surgery, there was a significant decrease in symptoms such as a sudden urge to urinate, stress urinary incontinence, frequent urination, abnormal emptying, nocturia, pelvic pain, fecal incontinence, difficult defecation, and constipation ($p<0.05$). There was no statistically significant change in complaints about difficulty starting urination or dysuria ($p>0.05$). Table 3 shows the clinical findings of the women, who participated in the study (Table 3).

Table 3. Results of clinical findings of the patients included in the study

	Preoperative	Postoperative 3rd month	Postoperative 6th month	Postoperative 12th month	p
SUU					**0.000***
Yes No	43 (46.3%) 37 (53.7%)	3 (3.7%) 77 (96.3%)	3 (3.7%) 77 (96.3%)	4 (5%) 76 (95%)	
SUSI					**0.002***
Yes No	5 (6.3%) 75 (93.7%)	-	-	-	
SUI					**0.000***
Yes No	23 (28.8%) 57 (71.2%)	1 (1.3%) 79 (98.7%)	1 (1.3%) 79 (98.7%)	-	
Frequent urination					**0.000***
Yes No	36 (45%) 54 (55%)	1 (1.3%) 79 (98.7%)	3 (3.9%) 77 (96.1%)	8 (10%) 72 (90%)	
Difficulty in urination					0.11*
Yes No	2 (2.5%) 78 (97.5%)	-	-	-	
Abnormal excretion					**0.000***
Yes No	32 (40%) 48 (60%)	-	-	-	
Nocturia					**0.000***
Yes No	48 (60%) 32 (40%)	4 (5%) 76 (95%)	1 (1.3%) 79 (98.7%)	2 (2.5%) 78 (97.5%)	
Dysuria					0.39*
Yes No	1 (1.3%) 79 (98.7%)	-	-	-	
Pelvic pain					**0.000***
Yes No	37 (46.3%) 43 (53.7%)	-	2 (2.5%) 78 (97.5%)	4 (5%) 76 (95%)	
Fecal incontinence					**0.007***
Yes No	4 (5%) 76 (95%)	-	-	-	
Difficult defecation					**0.007***
Yes No	4 (5%) 76 (95%)	-	-	-	
Constipation					**0.000***
Yes No	13 (45%) 67 (55%)	2 (2.5%) 78 (97.5%)	-	1 (1.3%) 79 (98.7%)	
Sound from vagina					
Yes No	-	-	-	-	

* Pearson x^2 test. (%); *AHI: sudden urge to; AHI: sudden urinary sensory incontinence; SUI: Stress urinary incontinence

The C value was used as a reference for *de novo* vaginal cuff prolapse in the POP-Q evaluation during the cases' postoperative follow-up. Accordingly, *de novo* vaginal cuff prolapse was found in 8 cases (mean C value +3.6). The C value was greater than zero in two cases at three months, three cases at six months, and three cases at twelve months. Two of the three patients with a C value >0 at the sixth month were asymptomatic until the 12th month of postoperative follow-up. These patients underwent recurrence surgeries in the 12th month after becoming symptomatic. In the study cohort, the rate of *de novo* vaginal prolapse was 10%. LeFort colpocleisis, iliococcygeal fixation, and PIVS procedures were performed in four, three, and one of these cases, respectively. No recurrence was observed in the 1-year follow-up of these cases.

Based on the findings of our study, we observed statistically significant anatomical improvements in Aa, Ba, C, Ap, and Bp values, as well as a narrowing of Gh. There was no effect of surgery on Pb or TVL. When the results were analyzed for symptomatic improvement, it was found that symptoms such as sudden urge to urinate, urge incontinence, stress urinary incontinence, frequent urination, abnormal emptying, nocturia, pelvic pain, fecal incontinence, difficulty with defecation, and constipation showed statistically significant improvement.

DISCUSSION

One of the most important steps in vaginal hysterectomy for a patient with apical prolapse is to return the vaginal cuff to its anatomically normal position and provide apical support, i.e., the De-Lancey 1 support point. Several techniques have been developed to accomplish this. Although several different apical suspension procedures are available for women with pelvic organ prolapse, there is limited data on their long-term efficacy and safety profiles, and there is no universal definition of "success" for these techniques in prolapse surgery. Essentially, anatomical and symptomatic improvement is considered successful surgery.[8] In this surgical technique, the strongest ligaments of the pelvic floor are used to suspend the cuff. A cadaveric study demonstrated that the middle part of the USL can weigh up to 17 kg.[9] The use of a strong ligament, such as the USL, for apical prolapse prevention is beneficial. The recurrence rates reported in studies on high USL suspension in the literature were investigated. According to Pedersen et al.[10], 19% of women had cuff prolapse in the sixth postoperative month, and 35% underwent re-prolapse surgery after an average follow-up of 7.2 years. Another study of 302 women found a recurrence rate of 13%, and a systematic review published in 2010 discovered a recurrence rate of 9.4%.[11,12] A retrospective cohort analysis of 219 patients revealed a recurrence rate of 24.7%.[13] All of these rates show that cuff prolapse, which occurs in 43% of patients after hysterectomy, is reduced with apical USL support.[14] According to our findings, recurrence occurred in 8 (10%) of the 80 patients, who underwent vaginal hysterectomy and cuff application with USL. This recurrence rate outperforms the studies discussed above. We believe this is due to our surgical technique and the non-absorbable sutures we used. The same surgeon performed recurrence surgeries on 8 patients (mean C value +3.6), including four with colpocleisis, one with posterior intravaginal sling (PIVS), and three with bilateral iliococcygeal fixation. Patients experienced symptomatic and anatomical improvement during the postoperative period following recurrence surgery. In addition to reducing the rates of prolapse recurrence, the surgical technique we employed allows for repairs using natural tissue, thereby avoiding complications associated with mesh. Vaginal mesh and related kits for prolapse surgery were introduced in the United States in 2005 to improve natural tissue repair in vaginal prolapse. Many transvaginal mesh products have been developed to help prevent vaginal cuff prolapse. The Food and Drug Administration (FDA) issued public warnings about the safety of mesh products due to an increase in reports of mesh-related complications such as vaginal erosions, infections, granulomas, dyspareunia, vesicovaginal fistulas, and chronic pain, as well as a lack of superior functional outcomes.[15] As a result, these synthetic mesh products have not been shown to consistently improve problems associated with apical compartment defects. Although data is limited, recurrence rates and subjective measures of improvement do not outperform natural tissue repair, and different types of vaginal mesh kits have not been shown to be superior to one another. In terms of mesh-specific complications, it has been determined that it is more logical to use mesh surgery for specific cases or patient-specific risk factors such as recurrence after natural tissue repair than as a routine technique.[16] The PIVS is a popular surgical technique for apical prolapse. However, the FDA issued a public health statement in 2008 and provided an update in 2011 regarding the increased complication rates associated with the use of mesh in vaginal surgery.[17] Although the PIVS procedure has a similar success rate to many other apical prolapse surgical techniques, mesh-related complications are a disadvantage. The most commonly reported morbidities are mesh erosion, pelvic infection, dyspareunia, pelvic pain, and sexual dysfunction.[18,19]

Abdominal sacrocolpopexy, while superior in some objective outcomes, is comparable to vaginal ligament suspensions in terms of subjective outcomes in the short to medium term and, like PIVS, has a higher risk of mesh exposure in the long term. Although hysteropexy is a surgical option for the treatment of symptomatic vaginal apical prolapse, the available data are of low quality. More comparative research is required before

this procedure can be widely implemented in routine clinical practice.[20] When comparing sacrocolpopexy to sacrospinous fixation, surgeons prefer sacrospinous fixation in terms of surgical time and patient postoperative recovery, despite the fact that sacrocolpopexy is more successful in the long run.[13]

Sacrospinous ligament fixation is another surgical option for treating apical prolapse. In a retrospective study of 10,210 eligible patients, 7,127 underwent USL, while 3,083 underwent sacrospinous ligament fixation. When complications from the two surgical techniques were compared, USL was associated with a lower risk of complications with the exception of urinary tract infection.[21]

Ureteral injuries are a feared complication of USL suspension. According to one study, the incidence rate of this complication was 1.2%, while another found an average rate of 1.8%.[11,22] Furthermore, diagnostic cystoscopy with contrast media enables early diagnosis and intraoperative management, reducing long-term complications. Recently, intraoperative strong Doppler ultrasound has been proposed as a non-invasive method for determining ureteral patency during pelvic surgery.[23] Only 0.6% of ureteral injuries require ureteral implantation, as most ureteral obstructions can be resolved by removing the offending uterosacral sling sutures.[11] It is also recognized that the addition of an anterior compartment repair increases the risk of ureteral kinking.[24] In a cadaveric study, the distance between the middle of the USL and the ureter was found to be 2.3 cm.[9] Suturing the ligament without shifting laterally may help to avoid ureteral complications. There were no ureteral complications in the 80 patients in our study. Neurosensory injury and uterine artery injury are two additional rare complications of USL plication. To avoid complications, it is important to avoid using sutures that are too deep or deviated.

One of the significant findings from our study was the narrowing of Gh. In a study by Vaughan et al.[25], surgical success rates were compared retrospectively by categorizing patients into three groups. These three groups included women with persistently wide Gh after surgical repair, women with improved Gh after surgery, and women with stable Gh before and after surgery. In this study, women with persistently enlarged Gh had a higher risk of anatomic failure after surgery than that in the other two groups.[25] In another study, both posterior and non-posterior repair groups were present, and it was discovered that a lower preoperative Gh was associated with surgical success, regardless of posterior repair performance.[26] DeLancey and Hurd[27] also discovered that patients, who experienced two or more recurrent prolapses after surgery had a larger urogenital cavity.

Today, the choice of surgical approaches is largely determined by the surgeon's preferences and experience. When discussing surgical options with patients, data comparing efficacy and potential risks is critical.[28] The technique discussed in our study is feasible, simple, low-cost, and systematizable when compared to existing surgical methods. Additionally, it is a safe procedure performed with natural tissue, thereby avoiding some complications associated with other techniques.

Our findings revealed statistically significant improvements in Aa, Ba, C, Ap, and Bp values, as well as a significant narrowing of Gh. At the same time, there was a significant improvement in symptoms such as a sudden urge to urinate, urge incontinence with sudden urge to urinate, stress urinary incontinence, frequent urination, abnormal emptying, nocturia, pelvic pain, fecal incontinence, difficult defecation, and constipation at one year follow-up compared to preoperative symptoms. There were no intraoperative complications among our patients. The data from our study revealed that both symptomatic and anatomical success was achieved. The most important criterion for successful treatment of pelvic organ prolapse in patients is the absence of prolapse-related symptoms and anatomical improvement of the prolapse.[29] In order for the data to be generalized, large-scale studies involving more patients and conducted in different centers are needed.

Study Limitations

The mean age of the patients in our study was 63.33±8.42 and the follow-up period was 12 months. Conducting this study with a patient group with a lower mean age or utilizing a follow-up period of longer than 12 months might change the surgical recurrence rates and long-term results of the surgery. At the same time, the surgeries in the study were performed by a surgeon, who was specifically specialized and experienced in urogynecological surgery. This may reduce the generalizability of the study and could alter the surgical results when performed by different teams.

CONCLUSION

Suturing the vaginal cuff to the USLs simultaneously with vaginal hysterectomy is a simple and feasible surgical technique. According to the results of this study, this technique is seen as an effective surgical intervention that provides symptomatic relief as well as anatomical recovery.

ETHICS

Ethics Committee Approval: Ethical approval was obtained from the Faculty of Medicine of Muğla Sıtkı Koçman University's Ethics Committee (no. 4/III; 17 February 2021).

Informed Consent: Prospective study.

FOOTNOTES

Contributions

Surgical and Medical Practices: A.A.S.; Concept: A.A.S., D.A.G., İ.G.; Design: A.A.S., D.A.G., İ.G.; Data Collection and/or Processing: D.A.G.; Statistical Analysis: D.A.G., İ.G., R.E.P.; Project Development: A.A.S., D.A.G.; Writing: D.A.G.

DISCLOSURES

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