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PhD THESIS

**UPDATES IN MINIMALLY INVASIVE SURGERY
FOR PELVIC FLOOR DISORDERS**

- S U M M A R Y -

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Pelvic floor disorders (PFD), such as stress urinary incontinence (SUI) and pelvic organ prolapse (POP), are conditions that can impact women of any age, significantly affecting their self-esteem and quality of life. Studies estimate that women face a 25% lifetime risk of encountering a PFD. These disorders, often multifactorial in origin, can lead to various complications including urinary and anal incontinence, POP, and sexual dysfunction. Factors such as age, weight, parity, and history of hysterectomy contribute to the risk, with approximately 17% of women experiencing PFD during their lifetime.

The prevalence of SUI increases with age, with rates ranging from 14.8% to 31.8% in women over 50, and surgical intervention becoming necessary for about 4% of affected women. Projections indicate a significant rise in the incidence of urinary incontinence, potentially affecting 28.4 million women in the United States by 2050 due to increased life expectancy and population growth.

POP, detected in up to 50% of women through vaginal examination, and in 3–6% based on reported symptoms, underscores the importance of apical vaginal support in maintaining pelvic organ integrity. With an aging population, it is estimated that there will be 4.9 million cases of pelvic POP by 2050.

Advancements in surgical treatments for SUI have evolved over the past decades, resulting in a wide array of procedures, with over 120 different surgical techniques explored for SUI in females. These procedures aim to provide adequate support to the urethrovesical junction, typically achieved through the placement of mesh, which witnessed a global increase in sales to approximately 3.7 million units between 2005 and 2013. However, in response to safety concerns, the Food and Drug Administration (FDA) has proposed elevating the risk categorization of urogynecological meshes, requiring stricter premarket notification and implementation of specific controls within the United States.

Following FDA warnings and the adoption of procedures like peri-urethral bulking agents, synthetic meshes have gained popularity. Specifically designed for urethral suspension in managing female SUI, transobturator tape (TOT) offers unique features such as a non-woven polypropylene composition overlaid with silicone on the urethral side, preventing polypropylene retraction and inhibiting periurethral fibrosis expansion.

Amidst concerns over transvaginal synthetic meshes, patients are seeking alternative urinary incontinence treatments. Despite the rise of mid-urethral slings in the mid-90s, the Burch colposuspension, renowned for its high success rates of 56–88%, is experiencing a resurgence. Laparoscopic retropubic surgery, first reported in 1991, has garnered increased interest, highlighting the growing preference for minimally invasive approaches.

Treatment options for POP vary based on severity and symptoms, encompassing observation, vaginal pessaries, and various surgical techniques including vaginal, open abdominal, laparoscopic, and robotic procedures, native tissue repair, or graft augmentation. Sacrospinous ligament fixation (SSLF) has emerged as a well-established surgical method for managing vaginal vault prolapse, with high success rates.

Following the FDA reclassification in 2016, native tissue repair and laparoscopic procedures gained significance, emphasizing the importance of minimally invasive approaches. Laparoscopic pectopexy, introduced in 2007 by Noe, stands as a novel technique for apical repair, reflecting ongoing advancements in POP treatment.

RESEARCH MOTIVATION

Although numerous retrospective studies have shown the rate of cure and complications in the treatment for POP and SUI, comparing different type of procedures with or without mesh, more data is needed to validate these results, as part of a management algorithm for patients with POP and SUI.

The motivation for research lies in addressing these clinical challenges through minimally invasive surgical approaches aimed at improving outcomes and reducing surgical complication.

In our studies we aimed to provide an in-depth analysis of patient preferences and clinical outcomes associated with surgical techniques for SUI and POP.

The primary aim of the first study was to compare the follow-up outcomes of two surgical techniques in the treatment of POP: SSLF and laparoscopic bilateral fixation of the vagina to the iliopectineal ligament using a polyvinylidene fluoride (PVDF)-mesh (pectopexy technique). The comparison focused on the cure rate and postoperative complication rate, including de novo cystocele, de novo rectocele, pelvic pain, de novo constipation, de novo SUI, dyspareunia, and de novo urgency.

For the second prospective study, our aim was to conduct a comprehensive analysis of patient preferences and clinical outcomes associated with two surgical approaches for addressing stress SUI: the TOT procedure and the pubourethral ligament (PUL) plication procedure. We analyzed clinical data pertaining to patient characteristics, treatment efficacy, and postsurgical outcomes to evaluate patient preferences and real-world clinical effectiveness.

For the third prospective cohort study, we aimed to conduct a comprehensive analysis of patient preferences and clinical outcomes associated with these two prominent surgical techniques for treating SUI: we examined 145 patients who underwent surgical treatment for SUI, with 71 patients undergoing the modified laparoscopic Burch procedure and 74 patients receiving the TOT procedure

For SUI treatment, we evaluated the rates of postoperative complications and the cure rate after TOT procedure, PUL plication procedure and modified laparoscopic Burch procedure in the era of mesh litigation.

This research intended to answer the following questions:

1.Which procedure provides a higher cure and less complications: SSLF technique or laparoscopic bilateral fixation of the vagina to the iliopectineal ligament via a PVDF-mesh (pectopexy technique)?

2.What are the patients preferences for either the TOT procedure or the PUL procedure based on thorough discussions with their doctor about potential risks, complications, and literature-reported cure rates for each procedure in the SUI treatment?

3. What are the patients preferences for either the TOT procedure or laparoscopic Burch procedure based on thorough discussions with their doctor about potential risks, complications, and literature-reported cure rates for each procedure in the SUI treatment?

4.Is there alternative of free mesh procedures in the treatment of SUI or POP with same effectiveness and less complications related to mesh?

RESULTS

I. PERSONAL CONTRIBUTION: LAPAROSCOPIC PECTOPEXY VERSUS VAGINAL SACROSPINOUS LIGAMENT FIXATION IN THE TREATMENT OF APICAL PROLAPSE

We performed a prospective cohort evaluation including all eligible patients (160 patients) who underwent surgery for POP stage II–IV in the Department of Obstetrics and Gynecology of Timisoara University City Hospital, between January 2015 and December 2020. The patients included in our study underwent either laparoscopic pectopexy or vaginal SSLF procedure.

The following parameters were evaluated for each patient: BMI, parity, post-menopausal and postoperative complications.

The follow-up period comprised evaluation at 1, 12 and 24 months after the procedure. The follow-up visits targeted the following parameters: de novo cystocele, de novo rectocele, pelvic pain, de novo constipation, de novo SUI, dyspareunia and de novo urgency.

Inclusion criteria: patients diagnosed with POP-Q II–IV according to the POP-Q were eligible for the study and the degree of the genital prolapse was assessed via a physical examination for prolapse quantification.

The indications for both procedures were the same. Patients, in general, complain about symptoms related to vaginal protrusion or associated symptoms of the urinary bladder.

The patient had also been examined when lying down. This preoperative assessment is important to prevent an over- or under-correction and can also sometimes give information about the quality of the tissue.

Both procedures were performed by the same surgical team.

The cure rate was assessed by vaginal examination. The success of surgical treatment was defined as the position of the cervix being above the level of the hymen.

The patients were divided into two groups based on the performed surgical intervention: 82 (51.25%) in the “SSLF” group and 78 (48.75%) in the “LP” group.

Significant differences were observed in age, BMI, and postmenopausal status between the two groups. The mean age of patients in the SSLF group was 64.56 years, higher than the mean age of 59.16 years in the LP group ($p = 0.002$). The mean BMI for the SSLF group was 28.59, slightly higher than the LP group’s mean BMI of 27.60 ($p = 0.003$). Regarding menopausal status, there was a significantly higher proportion of postmenopausal women in the SSLF group (93.90%) compared to the LP group (74.35%) ($p < 0.001$).

In summary, patients undergoing SSLF surgery were significantly older, had slightly higher BMI and were more likely to be postmenopausal compared to those undergoing LP surgery.

With regard to the frequency of concomitant posterior colporrhaphy procedures, in the SSLF group 29.27% (24 out of 82) had undergone a concomitant posterior colporrhaphy, while in the LP group this rate was slightly lower at 24.36% (19 out of 78).

Regarding the perioperative outcomes, the Delta Hb, which represents the change in the hemoglobin value between pre- and post-operation levels, was found to be 1.01 (SD: 0.41) in the entire study group of 160 patients. In the subgroup analyses, the SSLF group had a Delta Hb of 1.04 (SD: 0.42), whereas the LP group ($N = 78$, 48.75% of the study group)

recorded a Delta Hb of 0.98 (SD: 0.40), with no statistically significant difference between the two subgroups ($p = 0.516$).

Regarding the mean length of hospital stay, the entire study group averaged 2.34 days (SD: 0.47). The SSLF group had a slightly shorter mean hospital stay of 2.18 days (SD: 0.39) as compared to the LP group, which averaged 2.50 days (SD: 0.50), a difference found to be statistically significant ($p < 0.001$).

Lastly, the mean operating time was measured for both surgical techniques. The study group had a mean operating time of 47.00 min (SD: 18.35) overall. When divided by technique, the SSLF group had a significantly shorter operating time, averaging 32.20 min (SD: 6.28), compared to the LP group which took 62.56 min on average (SD: 13.23, $p < 0.001$).

In the evaluation of postoperative complications between the SSLF group and the LP group, differences were found to be statistically insignificant for most complications. DN urgency was experienced by 6.87% of the overall study group, with a similar occurrence between the SSLF ($N1 = 5$, 6.10%) and LP group ($N2 = 6$, 7.69%), $p = 0.93151$.

Comparable trends were found for de novo cystocele (8.75% overall, 8.54% in SSLF vs. 8.97% in LP, $p = 0.85561$) and de novo rectocele (5.62% overall, 4.88% in SSLF vs. 6.41% in LP, $p = 0.74162$).

Pelvic pain was present in 5.00% of all patients, but was notably more frequent in the SSLF (7, 8.54%) than in the LP group (1, 1.28%), although the difference was not statistically significant ($p = 0.06422$). Similarly, constipation was experienced by 6.87% of patients, with a greater occurrence in the SSLF (9, 10.87%) compared to the LP group (2, 2.56%), $p = 0.05732$.

Dyspareunia occurred in 4.37% of all patients, slightly more frequently in the SSLF (6, 7.32%) than the LP group (1, 1.28%), but without significant difference ($p = 0.11762$). Lastly, de novo stress urinary incontinence (DN SUI) was seen in 8.75% of all patients, evenly distributed between the SSLF (8, 9.76%) and LP groups (6, 7.69%), $p = 0.85561$.

These results indicate that both surgical procedures have comparable postoperative complication rates, with no significant difference in the occurrence of any specific complication.

The cure rate was high in both the SSLF group ($N1 = 82$, 51.25%) and the LP group ($N2 = 78$, 48.75%). Specifically, 95.12% of the patients (78 out of 82) in the SSLF group and 93.59% of the patients (73 out of 78) in the LP group were cured post-surgery, leading to an overall cure rate of 151 out of 160 patients. This difference in cure rates was not statistically significant ($p = 0.6741$, Chi-square test).

On the other hand, the failure rate was found to be low in both groups. Specifically, the failure rate was 4.88% (4 out of 82 patients) in the SSLF group and 6.41% (5 out of 78 patients) in the LP group, resulting in an overall failure rate of 9 out of 160 patients.

Limitations of the study include the fact that all procedures were performed by the same surgical team in a single center, which may be subject to bias. Other study limitations are represented by the small follow-up period and the small study population.

Given the logistical and financial constraints, particularly around the intricate organization and the costs of rigorous data management, using a prospective cohort study emerged as a more feasible and cost-effective approach than an RCT for this particular research.

In conclusion, in this prospective study with a mean of two years' follow-up, the SSLF procedure and LP procedure were effective with a high cure rate and safety in the treatment of POP with a low rate of complications after 2 years of follow-up.

LP is a promising prolapse correction technique, although more research is still needed to determine its long-term outcomes. The SSLF maintains its value in prolapse surgery with the increasing importance of native tissue repair. Both SSLF and LP are effective in the treatment of POP, with favorable anatomical and subjective results and low rates of serious postoperative complications.

II. PERSONAL CONTRIBUTION EVALUATING PATIENT PREFERENCES AND CLINICAL OUTCOMES IN STRESS URINARY INCONTINENCE: A SHORT-TERM FOLLOW-UP STUDY OF THE TRANSOBTURATOR TAPE PROCEDURE AND PUBOURETHRAL LIGAMENT PLICATION (A MINIMALLY INVASIVE TECHNIQUE)

We conducted a prospective cohort analysis encompassing all eligible participants (80 patients) who underwent surgery for SUI at the Department of Obstetrics and Gynecology of Timisoara University City Hospital, spanning from January 2019 to December 2020. The cohort consisted of 80 patients, with 40 undergoing the TOT procedure and 40 undergoing the PUL plication procedure.

Patients opted for either the TOT procedure or the PUL plication procedure based on thorough discussions with their doctor. These discussions thoroughly explored potential risks, complications, and literature-reported cure rates for each procedure, enabling a more informed and collaborative decision-making process.

In continuation, we conducted a comprehensive clinical evaluation of each patient. This evaluation included a standardized history, urogynecology examination, cough test, and urinalysis.

Women experiencing SUI may also encounter issues related to urination, such as overactive bladder, dysfunctional voiding, or detrusor underactivity. Additionally, some patients may exhibit an elevated post-void residual volume before surgery, potentially impacting the treatment results.

The study enrolled adult female patients, aged 18 years or older, who were clinically diagnosed with authentic SUI and exhibiting symptoms. These patients had normal urethral closing pressure and demonstrated a positive result on the cough test. As a requisite element of the study's protocol, all participants were required to fill out the UDI-6 questionnaire, which was administered both during their initial evaluation and at subsequent follow-up appointments.

Both procedures were performed by the same surgical team. A single dose of an antibiotic for prophylaxis was administered preoperatively. The Foley catheter was removed 12–24 h after surgery in the TOT group and no Foley catheter was placed in the PUL group.

The following parameters were evaluated for each patient: the duration of surgery, hospital stay, hemoglobin loss, and postoperative complications, including the results of the validated UDI-6 questionnaire completed both before surgery and at follow-up visits.

The follow-up period comprised evaluation at 6, 12, and 18 months after the procedure. The follow-up visits targeted the following parameters: the cure rate, the rate of significant improvement, and complications: acute urinary retention, de novo impetuosity, dyspareunia, chronic pelvic pain, and mesh erosion. The surgeon carried out a clinical examination that involved sling palpation in the TOT group, checking the vaginal mucosa for mesh erosion, and performing a cough stress test.

The cure rate was defined by the absence of leakage during the pad test and/or by a negative stress maneuver (cough test or Valsalva test). Other outcomes included the duration of surgery, hospital stay, hemoglobin loss, de novo impetuosity, acute urinary retention, dyspareunia, chronic pelvic pain, and vaginal erosion.

The patients were categorized into two groups based on the performed surgical intervention: 40 (50%) in the “TOT” group and 40 (50%) in the “PUL” group.

Significant disparities were noted in age, parity, and postmenopausal status between the two groups. The mean age of patients in the TOT group was 63.80 years, surpassing the mean age of 51.42 years in the PUL group ($p = 0.001$). The mean BMI for the TOT group was 28.73, marginally higher than the PUL group’s mean BMI of 27.99 ($p = 0.182$).

Concerning menopausal status, there was a markedly higher percentage of postmenopausal women in the TOT group (100%) in contrast to the PUL group (30%) ($p < 0.001$). Additionally, patients in the TOT group exhibited a higher mean parity of 2.20, compared to a mean parity of 0.98 in the PUL group ($p = 0.002$).

Hemoglobin loss, indicating the change in hemoglobin levels before and after surgery, was determined to be 0.96 for the entire study group. When examining the subgroups, the TOT group showed a hemoglobin loss of 0.99, while the PUL group showed a hemoglobin loss of 0.93. Importantly, there was no statistically significant difference between these two subgroups ($p = 0.381$).

In terms of average hospital stay, the TOT group had a mean hospital stay of 1.02 days (SD: 0.15). The PUL group was composed of patients who were not hospitalized, as they had just an ambulatory stay, as per the protocol of the procedure.

Finally, the average duration of the surgical procedures was evaluated for both operative techniques. For the entire study group, the mean operating time was 13.35 min (SD: 4.10). When the techniques were analyzed separately, the TOT group had a notably longer operating time, averaging 16.80 min (SD: 2.76), compared to the PUL group, which had an average operating time of 9.90 min (SD: 1.46). This difference was highly statistically significant ($p < 0.001$).

The analysis of postoperative complications within the study groups is presented in Table 9. Among the entire study cohort, 1.25% encountered DN imperiosity, with one case (2.5%) observed in the TOT group and none observed in the PUL group. Likewise, acute urinary retention occurred in 1.25% of the overall study group, with only one case (2.5%) identified in the TOT group.

Chronic pelvic pain was present in 3.75% of all patients and was notably only in the TOT group, with 3 cases (7.5%) being noted. Similarly, vaginal erosion was experienced by 5% of patients, with 10% in the TOT group and none in the PUL group.

Dyspareunia occurred in 2.5% of all patients, with only 2 cases (5%) being reported in the TOT group.

In both groups, the TOT group (33 cases, 82.5%) and the PUL group (28 cases, 70%), the cure rates were notably high. Specifically, after the procedures, 76.25% of the patients (61 out of 80) experienced a cure. However, it is worth noting that this disparity in cure rates did not yield statistical significance ($p = 0.293$). The postoperative improvement rate was significantly enhanced, with 12.5% (10 out of 80) of patients showing better outcomes, split into 10% in the TOT group (4 cases) and 15% in the PUL group (6 cases).

At the 6-month follow-up, both groups, the TOT group (30 cases, 75%) and the PUL group (26 cases, 65%) maintained high cure rates. Specifically, 70% of the patients (56 out of

80) were cured after the procedures. However, the difference in cure rates was not statistically significant ($p = 0.464$). The improvement rate at the 6-month follow-up was also comparable between the two groups, with this being 10% in the TOT group (4 cases) and 7.5% in the PUL group (3 cases).

At the 12-month follow-up, high cure rates persisted in both groups, with this being presented in the TOT group (29 cases, 72.5%) and the PUL group (24 cases, 60%). Specifically, 66.25% of the patients (53 out of 80) were cured after the procedures. However, once again, the difference in cure rates did not achieve statistical significance ($p = 0.344$). Likewise, the improvement rate at the 12-month follow-up remained similar in both groups, with this being 10% in the TOT group (four cases) and 5% in the PUL group (two cases). Notably, this difference in cure rates was also not statistically significant ($p = 0.675$).

Lastly, at the 18-month follow-up, high cure rates were observed in both groups, with this being presented in the TOT group (26 cases, 67.5%) and the PUL group (24 cases, 60%). Specifically, 63.75% of the patients (51 out of 80) were cured after the procedures. However, as in previous intervals, the difference in cure rates did not reach statistical significance ($p = 0.641$). The rate of significant improvement at the 18-month follow-up was comparable between the two groups, with this being 10% in the TOT group (four cases) and 5% in the PUL group (two cases). Again, this difference in cure rates was not statistically significant ($p = 0.675$).

The average UDI-6 score before the procedure for the entire study group stood at 41.30 (SD: 25.72). In the TOT group, the mean preoperative UDI-6 score was slightly higher at 42.07 (SD: 25.53), while the PUL group displayed a mean preoperative UDI-6 score of 40.54 (SD: 26.21), with no statistically significant distinction between the two groups ($p = 0.775$).

After the procedure, the average UDI-6 score for the entire study group was 12.40 (SD: 6.47). Within the TOT group, the mean postoperative UDI-6 score decreased to 10.31 (SD: 4.80), whereas the PUL group exhibited a slightly higher mean postoperative UDI-6 score of 14.23 (SD: 7.30), again with no statistically significant difference between the two groups ($p = 0.146$).

The study is limited by a small sample size (80 patients) and a single-center setting, potentially restricting its applicability to a wider population and different healthcare settings. It focuses on specific patient characteristics, has a short follow-up period (6–18 months post-procedure), and relies on self-reported data, which may introduce bias. The study also lacks a predefined sample size calculation, shaped by its patient-centered approach, practical clinical constraints, and its exploratory nature.

These limitations suggest caution when applying the study's findings to the treatment of SUI, although offering a non-mesh alternative (PUL plication procedure) for SUI treatment may be a valid choice. Nonetheless, it offers valuable preliminary insights into patient preferences and outcomes in SUI treatment, serving as a foundation for more comprehensive future research.

In summary, our study suggests that the PUL plication procedure yields cure rates comparable to those of the TOT procedure, offering a potential mesh-free alternative for treating SUI. This is particularly significant considering mesh restrictions in certain countries and the ongoing exploration of non-mesh options.

Nonetheless, it is crucial to recognize that our study featured a relatively short follow-up period, limiting our ability to thoroughly assess long-term comparative outcomes' further research is essential to validate and expand upon these initial findings.

III. PERSONAL CONTRIBUTION: EVALUATING PATIENT PREFERENCES AND CLINICAL OUTCOMES FOR MODIFIED LAPATOSCOPIC BURCH COLPOSUSPENSION AND TRANSOBTURATOR TAPE PROCEDURE IN STRESS URINARY INCONTINENCE TREATMENT

We performed a prospective cohort evaluation including all eligible patients who underwent surgery for SUI in the Department of Obstetrics and Gynecology of Timișoara University City Hospital, between January 2019 and December 2020. The patients included in our study underwent either modified laparoscopic Burch colposuspension or the TOT procedure.

The choice of patients for either the modified laparoscopic Burch group or the TOT group was based on comprehensive discussions between the patients and their doctors. During these discussions, the potential risks, complications and cure rate from the literature of each procedure were thoroughly discussed, allowing for a more informed and collaborative decision-making process.

The following parameters were evaluated for each patient: BMI, parity, post-menopausal status, duration of surgery, postoperative complications, blood loss, hospital stay.

Women with SUI can also experience voiding dysfunctions, such as overactive bladder, dysfunctional voiding, detrusor underactivity, or increased post-void residual volume. These conditions may affect treatment outcomes, resulting in the following inclusion criteria: female patients aged over 18, diagnosed with genuine, symptomatic SUI, normal urethral closing pressure, and positive cough test.

The primary outcomes of this study were centered around understanding patient preferences and evaluating the success rates of two surgical techniques for managing SUI. Additionally, an analysis of patient demographics and clinical characteristics was conducted to explore their potential influence on the selection of the surgical method. The success rate was defined by the absence of leakage during the pad test and/or by a negative stress maneuver (cough test or Valsalva test). We used the pad test if the cough test was negative but patient reported leakage during daily activities.

Secondary outcomes included the operation time and hospitalization duration, as well as assessment of intraoperative and short-term complications (bowel perforation, de novo urge incontinence, acute urinary retention) and long-term complications (post void residual volume, dyspareunia, chronic pelvic pain, and mesh erosion).

Both procedures were performed by the same surgical team. A single dose of antibiotic for prophylaxis was administrated.

The follow-up period comprised evaluation at 1, 12, and 24 months after the procedure. The follow-up visits targeted the following parameters: success rate, complications: post void residual volume, dyspareunia, mesh erosion, and chronic pelvic pain.

Significant differences were observed for age, BMI, and parity between the two groups. The mean age of patients in the modified laparoscopic Burch group was 48.02 years \pm 4.71 years, significantly lower than the mean age of 66.04 \pm 6.55 years in the TOT group.

Furthermore, patients in the TOT group had a higher mean parity of 2.27 \pm 0.89, compared to a mean parity of 1.67 \pm 0.65 in the modified laparoscopic Burch group ($p < 0.001$). Regarding menopausal status, there was a significantly higher proportion of postmenopausal women in the TOT group (91.89%) compared to the modified laparoscopic Burch group (28.17%) ($p < 0.001$).

In terms of cure rate, there was no significant difference between the two groups. A total of 99 patients (68.28%) were considered cured postoperatively, with 47 (66.20%) in the modified laparoscopic Burch group and 52 (70.27%) in the TOT group ($p = 0.598$). Significant clinical improvement was observed in 34 patients (23.45%), 18 (25.35%) in the modified laparoscopic Burch group and 16 (21.62%) in the TOT group ($p = 0.596$). Treatment failure was reported in 12 patients (8.28%), with an equal distribution in both groups ($p = 0.921$).

Follow-up visits at one month were completed by all patients (100%) in both groups.

At the one-year follow-up visit, 141 patients (97.24%) returned, including all 71 patients in the modified laparoscopic Burch group and 70 patients (98.59%) from the TOT group. At the two-year follow-up visit, 135 patients (93.10%) participated, including all in the modified laparoscopic Burch group and 64 (86.48%) in the TOT group, a statistically significant difference.

In the multivariate logistic regression model employed to identify potential risk factors for operative failure, which includes surgery type (Burch vs. TOT) as well as the other covariates: age, menopausal status, parity, and BMI, all of these factors failed to exhibit a statistically significant influence. The analysis suggests that, after controlling for the included covariates, there is no strong evidence to favor one surgical method over the other in terms of the likelihood of being cured.

Peri-operative outcomes showed no significant difference in hemoglobin loss between the modified laparoscopic Burch group and TOT group, with a median loss of 0.9 g/dL (IQR = 0.69–1.04) and 0.86 g/dl (IQR = 0.66–1.19), respectively, ($p = 0.868$).

Significant differences were observed regarding operation time and hospitalization duration. The median operation time was significantly shorter in the TOT group, with a 15 min median (IQR = 12.25–18.00) compared to the modified laparoscopic Burch group, with a 27 min median (IQR = 25.00–29.50) ($p < 0.001$). Furthermore, patients in the TOT group had a shorter median hospital duration of just 1 day (IQR = 1–1) compared to the 2 days median (IQR = 2–2) of the modified laparoscopic Burch group ($p < 0.001$).

In terms of intraoperative complications, bowel perforation was reported in one patient (1.40%) from the modified laparoscopic Burch group at the moment of direct entry. The patient had a history of previous surgery with extended adhesions. None from the TOT group ($p = 0.489$) had intraoperative complications.

Short post operative complications are the following: de novo urge incontinence and acute urinary retention.

In terms of short-term complications, de novo urge incontinence occurred in two (2.81%) and three (4.05%) patients from the modified laparoscopic Burch group and TOT group, respectively, with no significant difference ($p = 1.000$). Acute urinary retention was reported in one patient from the TOT group only ($p = 1.000$).

Reported long-term complications are post void residual volume, chronic pelvic pain, dyspareunia, and mesh erosion.

In terms of long-term complications, there were four cases (5.63%) of post void residual volume in the modified laparoscopic Burch group at 1 month follow-up and two cases (2.70%) in the TOT group at 1 month follow-up. However, a significant difference was found in the incidence of dyspareunia, with six cases (8.10%) reported in the TOT group, with four cases (5.71%) reported at 12 months follow-up, compared to none in the modified laparoscopic Burch group. Mesh erosion was recorded in four cases (5.40%) in the TOT group, with three cases (4.68%) reported at 24 months follow-up. Chronic pelvic pain was reported with three cases in

TOT group, two cases (2.85%) at 12 months follow-up and one case (1.56%) reported at 24 months follow-up. In the modified laparoscopic Burch group, chronic pelvic pain was reported in one case (1.40%) at 12 months follow-up.

The main limitations of the study are its small study population and the short follow-up period. Also, the inclusion of both pre and postmenopausal patients and inclusion of patients who will follow up. Those who follow up could present more complications that could bias the results.

Another limitation of our study that is worth mentioning is the fact that it was a single-center study, and the procedures were performed by one surgical team, thereby potentially limiting the generalizability of the findings.

The main strength of our study is that, to our knowledge, there are no previous studies that have provided a comprehensive overview of patient preferences and factual clinical outcomes for the two surgical techniques in SUI treatment.

In conclusion, the findings provide a comprehensive overview of patient preferences and factual clinical outcomes for the two surgical techniques in SUI treatment. This study contributes to understanding the factors influencing patient choice and offers valuable insights into the real-world application of these techniques, enhancing patient-centered care in SUI management. This represents a topic of interest, given mesh implants are restricted in certain countries and alternatives to mesh use are continuously investigated.

The complication rates for the modified laparoscopic Burch procedure in our study were lower than for the TOT procedure in the studied period. However, the relatively short follow-up period limits the evaluation of long-term comparative outcomes.

GENERAL CONCLUSIONS AND PERSONAL CONTRIBUTIONS

We believe our research makes a significant contribution to the field, particularly with the innovation of conducting the first prospective study that provides a detailed comparison of patient preferences and actual clinical outcomes for two surgical techniques in treating SUI (Modified laparoscopic Burch colposuspension and TOT procedure).

Looking ahead, one of the research directions includes delivering results on the cure rates and postoperative complications associated with alternative, mesh-free surgeries for SUI and POP. This focus is especially pertinent given the mesh usage restrictions in various countries and the continued investigation into non-mesh alternatives procedures.

However, it is important to acknowledge that our studies had a relatively brief follow-up period, which constrains our ability to fully evaluate long-term comparative outcomes. Thus, further research is critical to substantiate and build upon these preliminary results.

In our research, we have endeavored to make a significant and innovative contribution to the field of urogynecology by conducting the first prospective study that comprehensively compares patient preferences and actual clinical outcomes between two distinct surgical approaches for the treatment of SUI: the modified laparoscopic Burch colposuspension and the TOT procedure. This study stands out for its emphasis on directly capturing patient-reported outcomes and clinical efficacy, providing valuable insights into the practical application and patient satisfaction associated with these techniques.

Our investigation delves into various aspects of surgical treatment, highlighting the nuances of each procedure's impact on patient quality of life, symptom alleviation, and overall

satisfaction. This detailed examination sheds light on the complex decision-making process that patients and clinicians undergo when selecting an appropriate surgical intervention for SUI. The comparative analysis not only enhances our understanding of each technique's strengths and limitations but also contributes to the broader discourse on optimizing surgical care for POP.

Looking forward, our research trajectory is set to explore the cure rates and postoperative complications associated with alternative, mesh-free surgeries for SUI and POP. This line of inquiry is particularly relevant in light of the global scrutiny and regulatory limitations on mesh use in surgical practices. With various countries imposing restrictions on mesh-based procedures, there is a pressing need to validate and refine mesh-free surgical alternatives that ensure patient safety without compromising efficacy.

Our current research, while pioneering, is limited by its relatively short follow-up period. This limitation constrains our capacity to thoroughly assess the long-term sustainability of clinical outcomes, a critical factor in determining the overall success of surgical interventions for chronic conditions like SUI and POP.

Recognizing this gap, we advocate for extended longitudinal studies to better understand the durability of these surgical solutions over time.

In conclusion, further research is imperative to substantiate our initial findings and expand the body of evidence supporting mesh-free surgical options. By continuing to investigate these alternatives, we aim to contribute to safer, more effective treatment modalities for patients suffering from pelvic floor disorders, ultimately enhancing the standard of care and patient well-being in the field of urogynecology.