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Evolution of patients with and without pre-operative stress urinary incontinence after surgical cystocele repair by mesh implantation using a vaginal approach

Évolution des patientes avec ou sans incontinence urinaire à l'effort préopératoire après une cure chirurgicale de cystocèle par voie vaginale avec une implantation prothétique

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Introduction

Pelvic organ prolapse (POP) and urinary incontinence (UI) are two common complaints in women and up to 20% of females may undergo surgery for either condition by the age of 85-years (1,2). POP and UI may occur together in up to 80% of women with pelvic floor dysfunction (3,4). In 40-50% of women with POP, stress urinary incontinence (SUI) may occur preoperatively due to related pathophysiological mechanisms (5,6). However there is no direct link between POP and SUI and their frequent association is complex with many unknown factors. The two conditions are reported to share some risk factors including age, obesity and injury during labour (7). *De novo* SUI is defined as SUI that only occurs after the reduction of a coexisting prolapse (8). This type of SUI is hidden and does not become apparent until the prolapse is reduced either in the clinic or after surgical repair. It is considered to be one of the causes of distress after POP repair and in non-informed patients it can be perceived as a surgical complication.

The aetiology of *de novo* SUI is not fully understood and it has been suggested that it is caused by mechanical pressure created by the prolapse beneath the urethra (9,10). This effect may disappear when the prolapse is treated, hence *de novo* SUI. The reported incidence of *de novo* SUI varies between 2% and 43% and the risk increases in patients with previous occult SUI (11–14). Few data have focussed on *de novo* SUI in women without preoperative occult SUI and most studies only report the postoperative evolution of pre-existing SUI. It has been shown that preoperative SUI can be cured by POP surgery in 27% of cases (15).

Because there is no identifiable relationship between SUI and POP, the treatment strategies for the two conditions are distinct. The surgical approach can be transvaginal, laparoscopic, or open. Non-surgical management can initially be proposed as an option. However, many patients look for definitive treatment in order to resolve their POP symptoms.

The choice of procedure depends on the surgeon's training and experience, resulting in significant practice variations.

For two decades, the use of synthetic nonabsorbable mesh has reduced the risk of prolapse recurrence in comparison with native tissue repair (16). The second generation Uphold™ LITE system (Boston Scientific, MA, USA) is a prefabricated mesh kit that decreases biomaterial load in order to avoid mesh-related complications and to provide an enhanced facility for apical suspension (17). Following recent alerts regarding transvaginal mesh repair, this technique has currently been suspended in all centres.

The primary aim of this descriptive study was to evaluate SUI in the perioperative period of mesh repair surgery in patients with and without previous SUI, including the rate of later interventions for SUI. The role of physiotherapy in cases of persistent or *de novo* SUI was also evaluated. This report shares our experience and determines the short-term outcomes of POP repair using the Uphold™ LITE system.

Material and methods

Study design and patients

This retrospective, descriptive study included all women with symptomatic prolapse who underwent cystocele repair with the Uphold™ LITE system in our department between July 2016 and April 2019. All women were operated on by a single surgeon. A total of 36 patients were identified as a retrospective cohort representing actual clinical data.

All patients complaining of a symptomatic per vaginal mass were examined in the outpatient clinic to confirm the diagnosis of cystocele. Clinical assessment of the prolapse was done using the Baden–Walker half way scoring system which consists of four grades: grade 0 (no prolapse), grade 1 (halfway to hymen), grade 2 (reaching to hymen), grade 3 (halfway past hymen), grade 4 (maximum descent) (18). The study included all patients with

symptomatic anterior wall prolapse. Clinical evaluation of SUI was performed using the cough stress test (CST) before and after manual reduction of the prolapse to detect occult SUI.

The CST was performed in the clinic with the patient in various positions (standing, semi-supine or lithotomy) with the urinary bladder in semi-repletion (patients were asked to fill their bladder before the consultation). The patient was then asked to cough many times and the urethra was observed for synchronous urinary leakage. The urodynamic study was not performed systematically as a routine examination in either the pre- or post-operative period but was reserved for cases with complicated UI (mixed or severe UI, post-SUI surgery, etc.).

All selected patients gave their informed consent for only prolapse surgery without any concomitant intervention(s) (e.g. hysterectomy, rectocele repair, etc.) and without associated incontinence repair, even if present preoperatively. All patients were informed orally and were able to refuse participation in this study.

Surgical procedure

All surgical procedures were performed under general anaesthesia. Prophylactic intravenous antibiotics were administered prior to surgery (2 g amoxicillin/clavulanic acid). The vaginal approach prolapse repair was performed by insertion of an Uphold™ LITE vaginal support system with a Capio Device (Boston Scientific, MA, USA) as described by Letouzey et al. (19). Two to three simple interrupted sutures (Prolene® 3.0) were inserted at the distal portion of the mesh and vaginal mucosa below the neck of bladder to stabilize the mesh for better support. Four to six simple interrupted sutures (Monosyn® 3.0) were inserted at the right and left paravaginal fascia and urethrovesical junction. Vaginal packing was continued for 24 h post-surgery and patients received 1 day of urethral catheterization. Post-void residual (PVR) volume was checked routinely after removal of the catheter using a bladder scan (Verathon Inc., Bothell, WA, USA).

Data collection

Preoperative data including medical history and physical examination results were recorded. Demographic data including: age, number of births, history of previous prolapse, incontinence repairs and comorbidities (diabetes, obesity, cardiovascular disease or anticoagulants) were collected. Data were collected preoperatively, peri- and postoperatively before discharge and at outpatient visits 1 month, 3 months and 12 months post-surgery. All perioperative data were recorded: type of intervention and approach, coding system (French CCAM), associated surgery for SUI, type of anaesthesia given, type of mesh used, operative time, adverse events, complications, catheterization and hospital duration including all late discharges. The database was checked to eliminate duplicates or missing data.

Postoperative follow-up

Postoperative clinical follow-up was performed by the same surgeon for all patients except for those who were followed by their primary urologist in other centres (the follow-up reports for these patients were transmitted to our centre). Physical examination of the surgical site was done at each follow-up consultation. The evolution of preoperative SUI and persistence of SUI after prolapse repair were assessed, including an evaluation of the incidence of *de novo* SUI in patients without preoperative SUI. An interval of 3 months post-surgery was allowed before confirming *de novo* SUI. The presence of either persistent or *de novo* postoperative SUI was assessed objectively using the CST.

All patients with either persistent or *de novo* SUI following POP repair underwent physiotherapy sessions with a review of their efficacy and orientation to surgical SUI treatment using a mid-urethral sling (MUS), either with tension-free vaginal tape (TVT) or

transobturator tape (TOT) in cases of physiotherapy failure. The Marshall test, which consists of placing the index and second finger on either side of bladder neck to support the proximal urethra with a relatively full bladder, was used to determine whether the urine loss was caused by urethral hypermobility. The indication for MUS insertion was dependent on persistence of SUI after physiotherapy and a positive Marshall test associated with a positive CST.

Outcome criteria

The primary outcome measure was SUI pre-, peri- and post-POP surgery in patients with and without previous SUI, including the rate of later interventions for SUI. The secondary aim was to evaluate our experience and determine the short-term outcomes of POP repair using the Uphold™ LITE system.

Statistical analysis

The incidence of *de novo* SUI was calculated as the number of patients with *de novo* SUI over the total number of patients without preoperative occult SUI and the incidence of persistent SUI was calculated as the number of patients with persistent SUI over the number of patients with previously documented SUI.

Excel (Microsoft office 2019) and JMP software were used for the statistical analyses of descriptive and clinical data.

Results

Thirty-six patients were included. The demographic data for these patients are shown in Table 1. Mean operative time was 41 ± 12 min, intraoperative blood loss was negligible, mean duration of hospitalization was 1 day, duration of urinary catheterization was 1 day (surgeon's preference) and mean PVR was 76 ± 107 ml. Three bladder injuries occurred during surgery

(8.3%), all managed with 1 week of catheterization. There was no incidence of other organ injury. There were two cases of acute postoperative urinary retention (5.5%), which is defined as the inability to completely or partially empty the bladder. All patients were able to urinate successfully after reinsertion of the catheter and 2 days after removal of the catheter, as confirmed by a bladder scan (Table 2).

Out of the 36 patients, 12 (33.3%) women were diagnosed with preoperative SUI using the CST; SUI was either obvious or unmasked after manual cystocele reduction. After only POP repair, SUI resolved in six of these women (50%) and persisted in six (50%); these were confirmed with the CST. Physiotherapy sessions were proposed for all patients with persistent SUI with reported improvement in three patients (50%) without further relapse or subsequent incontinence surgery at time of this report. All patients confirmed their actual physiotherapy participation with a mean number of five physiotherapy sessions. Failure of physiotherapy was affirmed in the other three cases (50%) who were later treated by MUS surgery, either with TVT or TOT depending on the surgeon's preference.

Of the 24 women (66.6%) without previous SUI, six (25%) reported the presence of *de novo* postoperative SUI at the 3 month follow-up visit; these were all confirmed with a CST. One of these cases (16.6%) was treated successfully by physiotherapy without any later complaints and a MUS was inserted for the other five patients (83.3%) (Fig. 1). The risk of having persistent postoperative SUI in patients with preoperative SUI was 50%. Conversely, the risk of developing *de novo* postoperative SUI in patients without pre-existing SUI was 25%. Patients with preoperative SUI were therefore twice as likely to have persistent SUI postoperatively as patients without preoperative SUI (RR=2.0 [95% CI: 0.8175-4.8928]; p=0.128).

Eight of our 36 patients (22.2%) underwent MUS insertion post POP repair, either with TVT or TOT. Five (62.5%) of these slings were inserted in patients with *de novo* SUI

and three (37.5%) in patients with persistent preoperative SUI. No SUI recurrence was reported or found clinically after 1 year of follow-up post-MUS insertion.

Regarding physiotherapy, the risk of failure of physiotherapy was 50% in patients with persistent SUI and 83.3% in patients with *de novo* SUI. All patients presenting with post-operative SUI were followed for 1 year with no patient lost to follow-up. At the time of this report, there were no reported cases of mesh exposure or infection and no case of mesh removal or redo. Two patients underwent subsequent surgery for POP relapse (5.5%) by laparoscopic sacro-suspension (Table 3).

Discussion

The close relationship between POP and UI requires optimal preoperative assessment to predict the probability of developing *de novo* postoperative SUI or persistent SUI after prolapse repair. Discussion with the patient explaining all possible postoperative outcomes can be helpful and beneficial to select the most appropriate management strategy. This information will play an important role in assuring patients, in order to avoid miss perception of these symptoms as a surgical complication. Assessment should include a full clinical examination with a CST before and after bedside manual prolapse reduction, including an evaluation of the severity of incontinence if present and, preferably, done by the patient. The aim of a CST is to recreate the patient's UI to establish the diagnosis of SUI and to assess the results of SUI treatment. The International Continence Society's (ICS) definition of SUI does not include the CST and this test is generally associated with a lack of standardisation.

Therefore, the ICS uniform-CST recommendations indicate the main elements to meet with this test (bladder volume, number of coughs and leakage detection) and for its interpretation (20). The American Urological Association recommends a preoperative urodynamic assessment with reduced prolapse in women with stage \geq II cystocele to evaluate occult SUI

(21). Watchful waiting with possible postoperative physiotherapy can be offered to patients with preoperative SUI; the delay and number of physiotherapy sessions should be defined as should the delay required to confirm physiotherapy failure. Postoperative visits can also easily detect the occurrence of *de novo* SUI and these patients can be directly offered a MUS or, alternatively, a trial of physiotherapy depending on the severity of incontinence and the patient's wishes. The delay to the diagnosis of *de novo* SUI should also be defined and standardized. The choice of suitable post-POP SUI repair is individualized for each patient depending on the surgeon's experience and preference. In our centre, we offer MUS for all cases of post POP SUI after failure of physiotherapy in fit and willing patients either with TOT or TVT slings. The insertion of a MUS depends on a positive CST associated with a positive Marshall test. No incontinence relapse has been reported in any of our patients at the follow-up visits at the time of writing.

Controversy exists on the advantages of primary prevention using a combined repair approach with anti-incontinence procedures at the primary POP repair. This combined repair may reduce the risk of postoperative SUI in patients with preoperative occult SUI (22) and reduce *de novo* SUI by about 15% (23). However, combined repair is associated with an increased risk of complications whereas POP repair alone is sufficient to resolve about 27% of patients with SUI (24). Furthermore, this combined repair can increase short-term voiding difficulties and adverse events (25), although fewer cases report persistent SUI after this combination according to the 2013 Cochrane review. Some recent studies have offered combined treatment for patients with high-risk predictors of SUI with continence rates of 95% with no lower urinary tract symptoms or complication differences compared to prolapse repair only (26). However, the risks and benefits of this combination are unclear especially in patients who were previously continent. In particular, there are ethical concerns regarding increased morbidity compared to the morbidity associated with the problem requiring

correction. The management protocol for this group of patients with high-risk predictive factors for *de novo* SUI remains unclear at present and therefore a shared decision-making process between the clinician and patient must occur.

Surgical treatment of symptomatic prolapse is the gold standard and the abdominal approach is proposed for sexually and physically active patients. The vaginal approach is reserved for older patients with comorbidities and when the abdominal approach is not feasible (i.e. multi-operated abdomen). This technique using the vaginal approach allows easier access to prolapsed organs, a shorter operative time with faster recovery and better cosmetic results (i.e. no obvious scar). Our experiences with this technique found satisfactory results in terms of primary prolapse repair and in the early or delayed complication rate reflected by patients' satisfaction. All of our patients were operated on by a surgeon experienced in prolapse repair either via the abdominal or vaginal approach. Nonetheless, as widely known, these types of surgery require a long learning curve.

Application of a mesh is associated with a number of complications including a risk of exposure and infection. In 2011, the US Food and Drug Administration alerted patients and health professionals to the complications of transvaginal placement of these meshes. A review of the surgical treatment of POP by the Cochrane Library concluded that there was insufficient evidence for superior success rates with vaginal mesh surgery and alerted practitioners and patients to the complications associated with meshes, especially a deterioration in sexual function compared to laparoscopic sacro-suspension (LS) (27,28). However, according to a recent French study, both techniques have similar functional and success rates. LS is safer than transvaginal mesh (TVM) and should be considered as a valuable primary surgical option (29). On the other hand, LS has an extensive learning curve and long operative time compared to TVM (30) and this approach is not feasible for all cases due to interfering patient or technical factors. The need for a vaginal approach should be

proposed to these patients. As a result of these alerts and the following suspension of TVM POP repair, native tissue POP repair may be the solution when transvaginal repair is required.

Our study focussed on the evolution of SUI in patients with and without preoperative SUI and SUI evolution after POP repair, and how to manage these variables either by surgery or observation and physiotherapy. In our experience, the technique using synthetic mesh (Uphold™) and bilateral sacrospinous fixation via the vaginal approach seems reproducible and is associated with only mild complications with a high rate of satisfaction and acceptable objective and subjective cure rates 1 year post-surgery.

The main limitation to our study is the small cohort; this is reflected in the statistical significance of our results. Some pre- and postoperative data for the patients were missing particularly regarding functional information such as the severity of incontinence if present either pre- or post-POP repair, before and after physiotherapy, and after physiotherapy failure motivating MUS insertion. This information should be provided by the patients themselves using validated surveys or questionnaires to review their satisfaction rather than verbal subjective assessment. In addition, there was no pre- and postoperative urodynamic study, which is mandatory for patients presenting with POP associated with urinary symptoms (31). These types of assessment are beneficial to evaluate patient comfort after prolapse reduction, to compare POP associated symptoms before and after surgery and finally to evaluate the efficacy of the Uphold™ LITE system.

Conclusion

Prolapse repair surgery by sacrospinous fixation of Uphold™ LITE can resolve up to 50% of cases of pre-existing SUI and 50% of cases can be improved by physiotherapy. Postoperative *de novo* SUI was noted in 25% of patients requiring subsequent repair with a MUS in the majority of cases. The risk of having persistent SUI is more likely when there is preoperative

SUI compared to patients without preoperative SUI. Prospective, comparative and long-term data are required to confirm these results.

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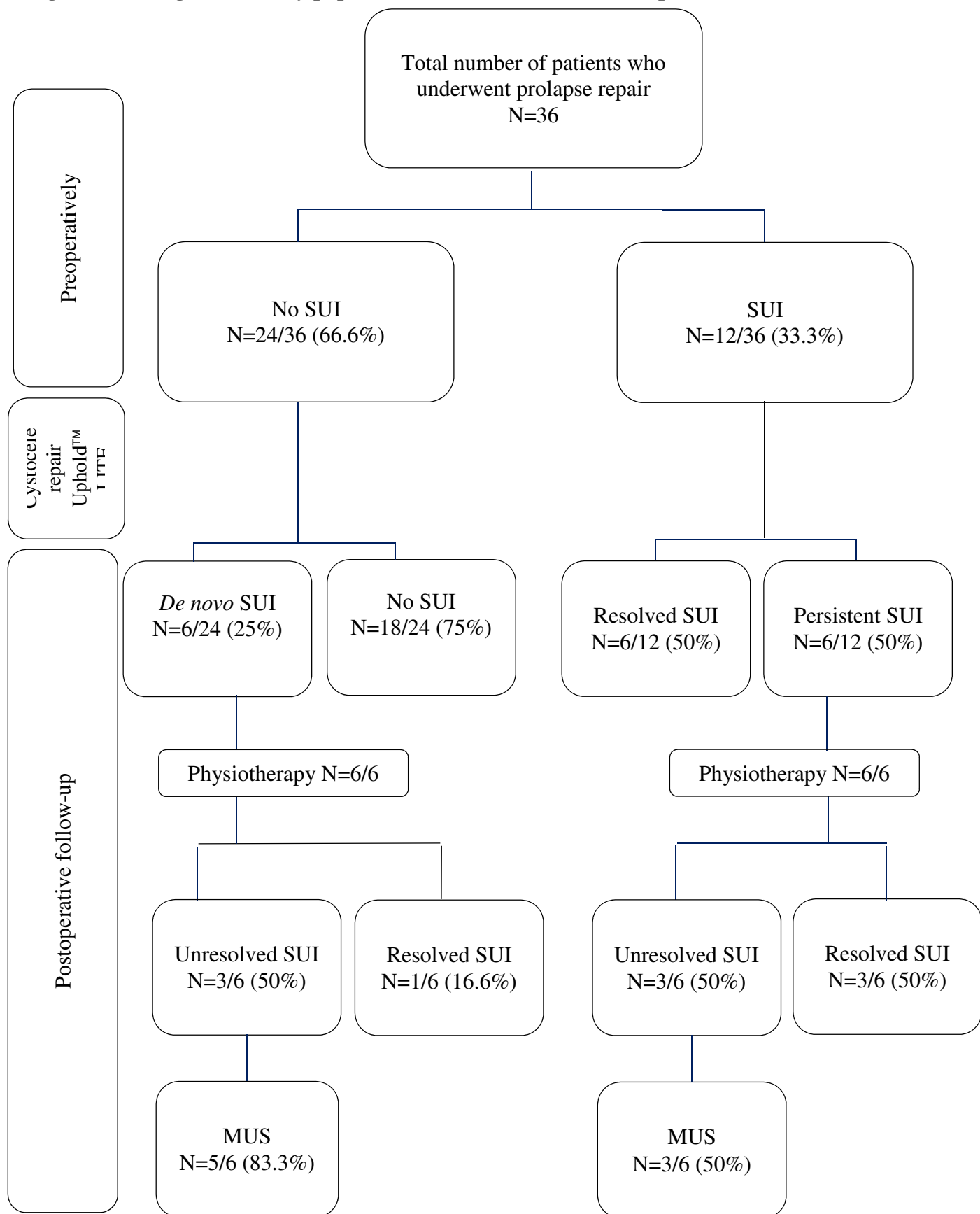
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Fig. 1. Flow diagram of study population at inclusion and follow-up.



SUI: stress urinary incontinence; MUS: mid-urethral sling;

Table 1. Demographic characteristics of the study population

Variable	
Age (years)	72 ± 7 (56-86)
Parity	3 ± 2
BMI (kg/m ²)	27 ± 5 (20-34)
Diabetes mellitus	9 (25)
History of hysterectomy	8 (22.2)
History of LS	2 (5.5)
History of MUS	4 (11.1)
Cystocele	
I	0
II	4 (11.1)
III	27 (75)
IV	5 (13.8)
History of UUI	5 (13.8)
History of SUI	12 (33.3)
No history of SUI	24 (66.6)
Trial of pessary	12 (33.3)
Follow-up time (months)	12

Data shown are the mean ± standard deviation (range: min-max), or n (%).

BMI: body mass index; LS: laparoscopic sacropexy; MUS: mid-urethral sling; UUI: urge urinary incontinence; SUI: stress urinary incontinence.

Table 2. Perioperative data and complications

Variable	
Hospital stay (days)	1 (1-3)
Operative time (min)	41 ± 12 (24-79)
Post void residual (ml)	76 ± 107 (0-500)
Duration of urinary catheter (days)	1.6 ± 1 (0-10)
Removal of vaginal gauze (days)	1
Bladder injury	3 (8.3)
Urinary retention	2 (5.5)
Bowel injury	0

Data shown are the mean ± standard deviation (range: min-max), or n (%).

Table 3. Postoperative complications and results

Variable	N (%)
Mesh failure/need for surgery	0
Mesh removal	0
Recurrent prolapse/need for surgery	2 (5.5)
Laparoscopic sacropexy	2
TVM	0
Infected haematoma	0
Buttock pain	0
No. of patients with <i>de novo</i> OAB	1 (2.7)
No. of patients with persistent SUI	6/12 (50)
No. of patients with resolved SUI	6/12 (50)
No. of patients with <i>de novo</i> SUI	6/24 (25)
MUS for persistent or <i>de novo</i> SUI	8/36 (22.2)
Persistent SUI	3/6 (50)
<i>De novo</i> SUI	5/6 (83.3)
Type of MUS	
TVT	6/8 (75)
TOT	2/8 (25)
Post-operative physiotherapy for persistent SUI	6/6 (100)
Success	3/6 (50)
Failure	3/6 (50)
Post-operative physiotherapy for <i>de novo</i> SUI	6/6 (100)
Success	1/6 (16.6)
Failure	5/6 (83.3)

SUI: stress urinary incontinence; OAB: overactive bladder; TVT: tension-free vaginal tape; TOT: transobturator tape; MUS: mid-urethral sling.