

The Use of a Vaginal Pessary to Decide Whether a Mid Urethral Sling should be Added to Prolapse Surgery



Emilie Goessens,* Hanne Deriemaeker and Hendrik Cammu

From the Departments of Urology (EG) and Urogynaecology (HC), Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Brussels and Department of Urology, Algemeen Ziekenhuis West (HD), Veurne, Belgium

Abbreviations and Acronyms

MUS = mid urethral sling
NNT = number needed to treat
PFMT = pelvic floor muscle training
POP = pelvic organ prolapse
PVR = post-void residual urine volume
SUI = stress urinary incontinence

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* Correspondence: Department of Urology, Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Jette, Brussels, 1090, Belgium (e-mail: Emilie.Goessens@uzbrussel.be).

Purpose: Women with pelvic organ prolapse are at risk for stress urinary incontinence after prolapse surgery. Combining pelvic organ prolapse repair with anti-incontinence surgery reduces the incontinence rate but leads to over-treatment. Performing only pelvic organ prolapse repair leads to under treatment. Is a vaginal ring pessary a useful tool when deciding whether a mid urethral sling should be added to prolapse surgery?

Materials and Methods: We performed a retrospective cohort study in women with symptomatic pelvic organ prolapse but without bothersome stress urinary incontinence who underwent vaginal prolapse repair between January 1, 2008 and December 31, 2017. Preoperatively a pessary was inserted in all women to detect occult stress urinary incontinence. If the pessary revealed bothersome stress urinary incontinence, a concomitant mid urethral sling was proposed. The primary outcome at followup was de novo stress urinary incontinence.

Results: Included in study were 220 women. After pessary insertion 132 women (60%) remained continent, 20 (9%) reported nonbothersome stress urinary incontinence and 68 (31%) had bothersome stress urinary incontinence. The latter group was offered combined surgery. At followup bothersome stress urinary incontinence was present in 12 of the 132 women (9%) who had been continent preoperatively and in 7 of the 20 (35%) who had had nonbothersome stress urinary incontinence. In 132 women who were continent with the pessary a total of 11 mid urethral sling procedures would have been needed to prevent post-operative stress urinary incontinence in 1 (number needed to treat was 11). In the 20 women who had nonbothersome stress urinary incontinence only 3 mid urethral sling procedures would have been necessary (number needed to treat was 3).

Conclusions: In women with symptomatic pelvic organ prolapse a pessary is a useful tool when deciding whether to add a mid urethral sling.

Key Words: urethra; pelvic organ prolapse; pessaries; urinary incontinence, stress; suburethral slings

PELVIC organ prolapse refers to the descent of 1 or more of the anterior wall, posterior wall, uterus (cervix) or vaginal apex.¹ Pelvic floor damage due to muscular weakness, fascial defects or denervation injury is believed to result in POP.²

POP is common but its true prevalence is difficult to ascertain because prolapse above the hymenal ring is usually asymptomatic.³ The prevalence of symptomatic POP (a vaginal bulge, abnormal vaginal bleeding or discharge, etc) ranges from 3% to 6%.⁴

Risk factors for POP include patient age, parity, vaginal delivery, obesity and connective tissue disorders.⁵ POP can be treated surgically or conservatively by pelvic floor muscle training and/or a vaginal pessary. Pessary therapy of POP significantly improves most symptoms but side effects may develop, such as discomfort or pain, constipation and vaginal discharge, bleeding or infection.⁶

In a substantial number of women POP coexists with SUI.⁷ However, SUI is often mild or even asymptomatic. After repositioning the prolapsed structures SUI may become symptomatic, which is called occult SUI.¹ Women with occult SUI remain continent despite underlying urethral sphincter incompetence because of kinking or external compression of the urethra by prolapse.^{8–10} Occult SUI is diagnosed in 33% to 80% of clinically continent women with symptomatic and/or advanced POP.^{8–12} Therefore, women who undergo prolapse surgery are at risk for SUI being unmasked. Women with POP and symptomatic or occult SUI are considered to be at highest risk.^{9,13–15} Postoperative SUI develops in an average of 54% of women with occult SUI and in 26% without occult SUI.¹⁶ Thus, there is no guarantee that clinically continent women will avoid SUI postoperatively.²

There are 3 approaches to address the potential complication of postoperative SUI.^{16,17} 1) In the delayed approach prolapse is repaired without an anti-incontinence procedure regardless of preoperative prolapse reduction stress testing. This approach leads to under treatment. A subsequent anti-incontinence procedure is performed if bothersome SUI symptoms develop postoperatively. 2) In the universal approach an anti-incontinence procedure is performed in all women at POP surgery regardless of preoperative prolapse reduction stress testing. Overtreatment and increased complications can be expected. 3) In the selective approach an anti-incontinence procedure is performed at prolapse surgery only if SUI was detected.

In this study the selective approach was used. A MUS was added only in women with bothersome SUI after a vaginal ring pessary was inserted. The aim of this study was to determine whether a vaginal pessary is a useful tool to help decide whether a MUS should be added to prolapse surgery.

MATERIALS AND METHODS

A total of 382 women with symptomatic POP were seen at the urology outpatient department between January 1, 2008 and December 31, 2017. Included in study were continent women and women with occasional and non-bothersome SUI who said that they would not have presented to the outpatient department if not for POP. Women with a main complaint of SUI were excluded.

Women who were satisfied with the pessary at the second visit and refused intervention were also excluded.

Preoperative evaluation at the first visit comprised medical history, physical examination and vaginal ring pessary insertion. The pessary was inserted to detect occult SUI and provide the patient with more comfort while awaiting surgery since mean waiting time was approximately 2 months. For the physical examination the patient was positioned in the supine lithotomy position after emptying the bladder. During a Valsalva maneuver POP was assessed using a split vaginal speculum and staged by the 1972 Baden-Walker vaginal profile system.¹⁸ Ultrasound was performed to determine post-void residual urine volume before insertion of a suitably sized polyvinyl chloride ring pessary.

At the second preoperative visit women were asked about continence status and the pessary experience. They could report no incontinence, no bothersome incontinence or bothersome incontinence. In the latter case the women underwent a cough stress test. Physical examination was similar to that at the first visit except PVR was determined by inserting a 12 Charrière single use female urethral catheter. With the catheter in place the bladder was instilled with saline until comfortably full. The cough stress test was then performed before and after reducing prolapse with a pessary. Women who said that they were continent or did not have bothersome SUI underwent only ultrasound measurement of PVR.

Prolapse surgery consisted of 1 or a combination of procedures, including vaginal hysterectomy with uterosacral ligament suspension and anterior or posterior colporrhaphy. Women with underlying bothersome occult SUI were treated with Gynecare TVT™ tension-free vaginal tape. Procedures were performed in accord with previously described techniques.^{19–22} Prophylactic antibiotics were given in case of vaginal hysterectomy. All operations were performed by trainees in gynecology or urology under the supervision and assistance of a single urogynecologist (HC). Throughout the entire study period the practice patterns did not change in respect to prolapse surgery or MUS placement.

At the end of the operation a transurethral catheter and a vaginal pack were inserted. They were removed on postoperative day 1. Postoperative voiding dysfunction and urinary retention were managed by an indwelling or a suprapubic catheter, or clean intermittent self-catheterization.

Patients underwent a followup consultation 2 months after the operation. The postoperative examination was done in the same way as the second preoperative examination except for pessary insertion. The primary outcome at followup was SUI. The latter could be absent, present but nonbothersome and warranting no further therapy or present and bothersome, and warranting therapy. In the latter case PFMT or a MUS was proposed. Secondary outcomes included urgency and/or urge incontinence and postoperative complications. Successful therapy was defined as a satisfied woman for whom POP and SUI were no longer a problem and further treatment was not warranted. Patients were assessed by one of us (HC) with the aid of a continence nurse. All data were collected by chart review by 2 of us (EG and HD).

Descriptive statistics were used to describe demographics and perioperative data using Excel® with Microsoft® Office 2010. The Fisher exact test was applied to analyze categorical variables. Statistical significance was considered at $p \leq 0.05$. The study was approved by the hospital medical ethics committee.

RESULTS

Of the initial 382 women 162 were excluded from study, including 18 not fitted with a vaginal pessary, 10 who presented with bothersome SUI at the first visit, 123 who were satisfied with the pessary and did not want surgery and 11 who had incomplete medical records or were lost to followup. Therefore, 220 women (58%) with a mean age of 67 years (range 29 to 94) formed the final study group (fig. 1).

Table 1 shows preoperative prolapse grades. The anterior vaginal wall was the most commonly prolapsed compartment. Pessary insertion revealed bothersome occult SUI in 68 women (31%). A total of 20 women mentioned occasional urine loss upon effort but did not experience this symptom as a bother (fig. 2). In 61 of the 68 women the cough stress test confirmed the SUI complaint. In 7 women SUI was not objectified, 6 were not tested and 1 had a negative test. Nevertheless, these 7 women were also offered a MUS procedure.

Three women with objective bothersome SUI but PVR greater than 100 ml did not undergo anti-incontinence surgery due to the possibility of postoperative voiding dysfunction. The remaining 152 continent patients underwent only prolapse surgery. The surgical procedure consisted of anterior colporrhaphy in 207 women (94%), posterior colporrhaphy in 202 (92%), vaginal hysterectomy in 141 of 177 (80%) and MUS in 65 (30%). Of the 152 women who underwent only prolapse repair bothersome postoperative

Table 1. Preoperative grades of prolapse in 220 patients

Prolapse Compartment	No. Grade (%)			Absent
	3 or Greater	2	1	
Anterior	74 (34)	119 (54)	18 (8)	9 (4)
Posterior	25 (11)	53 (24)	107 (49)	35 (16)
Apical	34 (15)	76 (35)	48 (22)	62 (28)

SUI developed 19 (12.5%), including 7 of 20 (35%) who had not been bothered by SUI preoperatively and 12 of 132 (9%) who had been continent preoperatively (fig. 2). This difference was significant ($p=0.004$).

If all 152 women with symptomatic POP but no bothersome incontinence would have received a concomitant MUS, 8 procedures would have been needed to prevent postoperative SUI in 1 (NNT was $152/19=8$). Considering only women who were preoperatively continent after pessary insertion 11 MUS procedures would have been needed to prevent postoperative SUI in 1 (NNT was $132/12=11$). If all 20 women with nonbothersome SUI had received a MUS, the NNT would have been 3 ($20/7=2.9$).

Three of the 65 women who underwent a concomitant MUS procedure still experienced urine leakage upon effort postoperatively but they did not find it inconvenient and required no further treatment. One of the 3 incontinent women who did not receive an additional MUS no longer had SUI symptoms. The 2 other women still had unacceptable SUI, including 1 treated with PFMT and 1 who underwent a delayed MUS procedure.

Preoperative urgency/urgency incontinence was present in 42 women (19%), including 22 of the 152 (14%) who were considered continent before POP surgery and 20 of the 68 (29%) with bothersome SUI preoperatively. This was a significant difference (14%

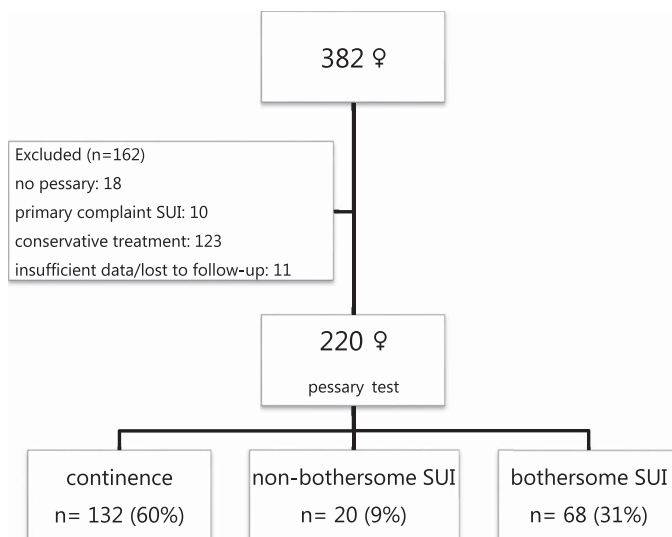


Figure 1. Flow chart

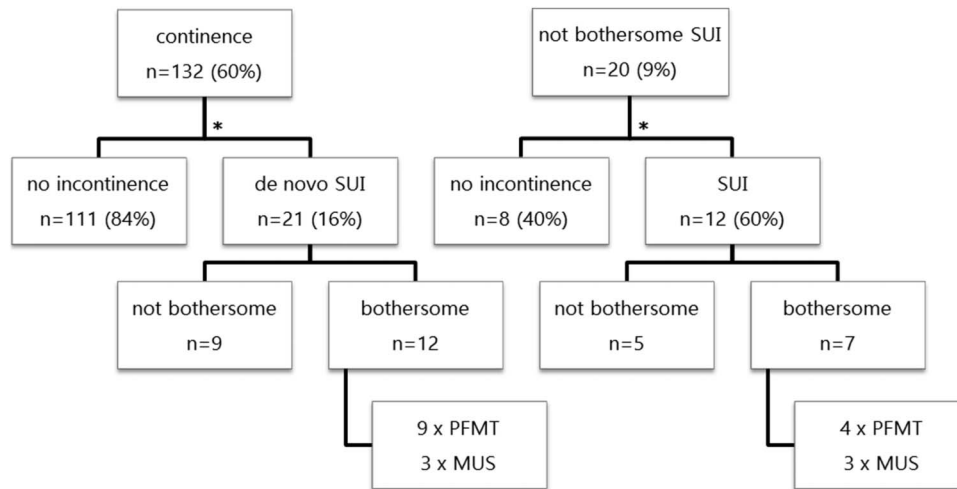


Figure 2. Postoperative outcome of prolapse surgery (asterisk) in 152 women who did not require MUS

vs 29%, $p=0.015$). Postoperatively urgency or urgency incontinence resolved in 29 of the 42 patients (69%) and developed de novo in 19 of 178 (11%). The difference in the rate of postoperative de novo urgency or urgency incontinence between women who did vs did not have bothersome SUI preoperatively was not significant ($p=0.681$). Postoperative urgency or urgency incontinence was treated with bladder retraining and/or sympatholytic drugs.

Table 2 lists postoperative complications. Nine women (4%) were in urinary retention or had voiding dysfunction. One case of urinary retention with a febrile urinary tract infection was treated with a suprapubic catheter and antibiotics. The other cases of urinary retention and voiding dysfunction were treated once with an indwelling catheter, 3 times with a suprapubic catheter and 4 times with clean intermittent self-catheterization. One woman was rehospitalized to cut the sling transvaginally despite clean intermittent self-catheterization. The cases of vaginal stenosis and sling erosion were resolved surgically. The vaginal vault abscess and the 3 cases of vaginal vault and Retzius space hematoma were drained.

Table 2. Postoperative complications

Complications	No. Surgery	
	Prolapse	Prolapse + MUS
Overall	155	65
Urinary retention or voiding dysfunction	3	6
Bladder perforation	1	1
Hematoma:		
Retzius space	—	1
Vaginal vault	1	1
Vaginal vault abscess	1	—
Vaginal stenosis	1	—
Sling erosion	—	1
Dyspareunia or perineal pain	5	1

Dyspareunia and perineal pain were documented when spontaneously reported by patients. They were not the result of systematic questioning. Nonfebrile urinary tract infection was not considered an important complication. Complications were more frequently seen in women with combined prolapse and MUS surgery than in those with prolapse surgery only (11 of 65 or 17% vs 12 of 155 or 8%) but only a trend toward statistical significance was found ($p=0.0536$).

DISCUSSION

Occult SUI is found in clinically continent women with symptomatic and/or advanced POP at an incidence of 33% to 80%.^{8–12} In our study 88 women (40%) had occult SUI, of whom 68 regarded incontinence as bothersome with 65 undergoing a concomitant MUS procedure. To our knowledge this is the first study in which a distinction was made between bothersome and nonbothersome (occult) SUI.

The 20 women with nonbothersome incontinence received no additional MUS. Bothersome postoperative SUI developed in 7 of these women (35%). If we had treated all women with nonbothersome incontinence with an additional MUS, 3 would have had to undergo surgery to prevent 1 from having bothersome SUI postoperatively. We think that a NNT of 3 is acceptable and we argue that an additional MUS procedure should also be performed in women in whom a pessary caused nonbothersome incontinence. After prolapse repair the rate of postoperative SUI in women who are clinically continent but found to have occult SUI upon testing is between 13% and 72% (mean 51%).²³

Bothersome postoperative SUI developed in only 12 of the 132 women (9%) who were continent preoperatively with a pessary and who underwent

prolapse repair. This 9% is lower than the average incidence of 26% (range 0% to 42%) in the literature.²³ If these 132 women had had a concomitant MUS procedure, 11 procedures would have been needed to prevent postoperative SUI in 1 woman (NNT of 11). We consider this overtreatment and advise against it. If we considered all 152 women who were preoperatively continent or not bothered by incontinence, the NNT would be 8. Our NNTs are corroborated by those in the literature since using the universal approach the NNT to prevent postoperative SUI in 1 woman ranges from 6.3 to 9,^{11,24} while the NNT is 3 when a selective procedure is done in women with occult SUI.²⁴

We combined prolapse surgery with a MUS in nearly all women in whom preoperative bothersome SUI was induced by a pessary. This approach led to the absence of bothersome postoperative SUI. When considering only nonbothersome postoperative SUI, we found only a 5% incidence of postoperative SUI (3 of 65 cases). The postoperative SUI rate in women with preoperative SUI who underwent prolapse plus anti-incontinence surgery has varied between 0% and 40% (mean 11%).²³ We do not know how many women with preoperative SUI would have become continent with only prolapse surgery. Some patients might have been overtreated.

Combination surgery seems especially beneficial in women with coexisting or occult SUI because they are at highest risk for postoperative SUI.²⁴ Therefore, the current literature favors the selective approach. According to a Cochrane Review, adding a MUS during vaginal POP repair might decrease postoperative SUI in women with POP and symptomatic or occult SUI.²⁵

A Dutch study showed that combination surgery did not increase the risk of overactive bladder

symptoms, urgency incontinence or surgery for voiding dysfunction.²⁶ These findings confirm our results. However, combination surgery exposes women to an increased risk of complications.^{3,23} In our study women who underwent combined surgery had more adverse events but not to a significant degree. This might have been the result of a β statistical error due to the limited number of patients and complications.

The strengths of this study include 1) a single center uniform patient treatment, 2) the collection of all research data and data processing by a neutral third party, 3) the performance or supervision of all interventions by the same physician and 4) the fairly large number of patients compared to similar studies.

The limitations of this study include 1) the retrospective design using a database with the possibility of missing or incomplete data, although missing data were kept to a minimum by previously excluding women with an incomplete chart, 2) the short followup of 2 months and 3) use of the Baden-Walker vaginal profile instead of the more elaborate POP-Q (Pelvic Organ Prolapse Quantification) system.

CONCLUSIONS

Women with symptomatic POP underwent prolapse surgery and received a MUS or were treated with only prolapse repair depending on whether the vaginal pessary revealed underlying troublesome SUI. Importantly, by doing so overtreatment was reduced and under treatment was kept within acceptable limits. We advocate that after the pessary test women with bothersome and nonbothersome SUI should undergo a concomitant MUS procedure.

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EDITORIAL COMMENT



To sling or not to sling, that is the question. SUI and POP share several common epidemiological risk factors but do not always coexist.^{1,2} POP can mask SUI due to urethral kinking and/or the bulge effect obstructing the urethra. With reduction of the prolapse occult SUI can be unmasked, although no unmasking technique to date has been foolproof.³

These authors propose an ambulatory pessary trial (as opposed to a brief pessary test in office) as a primary tool to decide whether an anti-incontinence procedure is needed at the time of prolapse repair. This tool attempts to minimize overtreatment and the potential complications of mesh sling placement such as mesh erosion, urinary retention and the need for subsequent surgery. It also attempts to minimize under treatment, patient dissatisfaction with postoperative SUI and the need for subsequent sling surgery. I suspect that this approach would be

more sensitive than the brief pessary test in office since it allows women to engage in regular activities during various stages of bladder fullness. However, this was not tested. This approach did miss some cases of occult SUI as postoperative SUI developed in 9% (19 of 152 patients) who were continent during the pessary trial and an additional 35% (7 of 20) who had nonbothersome SUI with the pessary trial had bothersome SUI postoperatively.

The ambulatory pessary trial adds another tool to our toolbox and another option to offer women during the complicated counseling process for the surgical treatment of POP.

Ariana L. Smith

*Department of Urology
University of Pennsylvania
Philadelphia, Pennsylvania*

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