Efficacy and patient satisfaction of pelvic organ prolapse reduction using transvaginal mesh: A Canadian perspective

Mélanie Aubé[1]; Marilyne Guérin[2]; Caroline Rheaume[2]; Le Mai Tu[1,3]

[1]Department of Urology, Centre Hospitalier Universitaire de Sherbrooke (CHUS), Université de Sherbrooke, Sherbrooke, QC; [2]Department of Obstetrics and Gynecology, Centre Hospitalier de l'Université Laval (CHUL), Université Laval, Quebec City, QC; [3]Department of Urology, Institut Universitaire de Gériatrie de Sherbrooke (IUGS), Université de Sherbrooke, Sherbrooke, QC; Canada

Cite as: *Can Urol Assoc J* 2018 May 28; Epub ahead of print.
http://dx.doi.org/10.5489/cuaj.5095

Published online May 28, 2018

***

Abstract

Introduction: Due to U.S Food and Drud Administration warnings and class-action lawsuits, the use of transvaginal mesh for pelvic organ prolapse surgery is controversial. We report data from two Canadian centres, focusing on recurrence and reoperation rates, complication rates, and patient satisfaction.
Methods: A retrospective medical chart review was performed. Patients were also invited to a long-term followup clinic for a complete questionnaire and gynecological exam. Patients unable to present to clinic for followup had the option to answer the questionnaire via telephone.
Results: A total of 334 patients were operated between 2000 and 2013. Median followup was 38 months for questionnaire and 36 months for physical exam. Thirty-seven patients (11.1%) required repeat operation, including 17 for recurrent prolapse and 10 for mesh exposure; 98.8% of patients reported feeling subjectively improved by their prolapse surgery.
Conclusions: Midterm results are satisfactory and patient subjective satisfaction is high following transvaginal mesh repair of pelvic organ prolapse.

Introduction

Pelvic organ prolapse (POP) is a common condition affecting aging women, with 11% of women requiring surgical intervention by age 80.[1] Prolapse may have significant negative effects on patient self-esteem and sexual function.[2] Recurrence rates are high, up to 30% with native tissue repair,[1] which prompted the development of new materials and mesh kits to further support the pelvic floor and prevent relapse. Since the development of these devices, the United States Food and Drug Administration (FDA) as well as Health Canada, have emitted various warnings about the use of transvaginal mesh (TVM), cautioning about increased risk of adverse events, without increased efficacy compared to traditional native tissue repair methods.[3,4,5] This gave rise to a multi-million dollar class-action lawsuit in the United States,[3] forcing a number of products off the market.

However, no class-action lawsuit ensued in Canada, and a number of Canadian urologists and gynecologists are still using TVM for prolapse repair.

Our aim was to share our centers' experience regarding synthetic TVM, focusing on POP recurrence and reoperation rates, complication rates as well as patient post-operative subjective satisfaction.

Methods

Outcomes from two clinical centres, focusing on POP surgery using TVM, were studied. The participating institutions, the Centre Hospitalier Universitaire de Sherbrooke (CHUS, Sherbrooke, QC, Canada) and the Centre Hospitalier de l'Université Laval (CHUL, Quebec City, QC, Canada), are both academic hospitals. The participating surgeons, a urologist and a gynecologist, are both fellowship trained in female pelvic reconstructive surgery.

All patients who underwent TVM POP repair in both centres were included in our study, including patients who underwent concomitant incontinence surgery and hysterectomy. Patients who had previously undergone mesh prolapse repair were excluded. Patients were offered all types of pelvic organ prolapse repair, and the type of surgery chosen was left to the discretion of the surgeon and the patient.

Post-operative follow-up was performed at 2 months, 6 months, 12 months and yearly thereafter, for a total of 3 to 5 years. A full questionnaire and gynecologic exam were performed routinely during follow-up appointments. The gynecologic exam consisted of a full assessment of the vaginal mucosa (atrophy, pain, mesh exposure, etc.) as well as an anatomic assessment of the pelvic compartments using the Simplified Pelvic Organ Prolapse Quantification (SPOP-Q) system.[6,7] The patients were also asked to fill out a validated subjective satisfaction questionnaire, the Patient Global Impression of Improvement (PGI-I).[8]

All patients whose routine follow-up was concluded were contacted in the aim of inviting them to a long-term follow-up appointment. As per ethics committee protocol,

the patients had to be contacted via a letter sent by postal mail, asking for their permission to participate before contacting them via telephone.
The long-term clinic visit consisted of a full history and gynecologic exam, as well as the PGI-I questionnaire. The history and exam were conducted by the treating surgeon, and the questionnaire was administered by a urology resident. Patients were allowed to answer the questionnaire and PGI-I via telephone if they were unable to present to the clinic. The telephone interview was conducted by a urology resident. Informed consent was obtained for each participant.

Continuous variables were reported as medians (interquartile range [IQR]) and categorical variables were described with proportions. The baseline characteristics and post-operative outcomes of the patients who presented for long-term follow-up versus those who did not were compared using the Mann-Whitney U test for continuous variables and the chi-square or Fisher exact test for proportions. The statistical analyses were performed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corporation, Armonk, NY, USA). p values of <0.05 were considered statistically significant.

This study was evaluated and approved by the ethics committee of all three participating institutions (CHUS 13-110 ; CHUQ B14-03-1915 ; IUGS 2014-425).

Results

334 patients underwent POP repair surgery using TVM, between 2000 and 2013.
Out of the 334 operated patients that we contacted, 157 responded, and 149 agreed to participate in long-term follow-up clinic. These patients are referred to as the long-term (LT) group. 116 of these patients presented to clinic for the full evaluation and physical exam, and 33 answered the questionnaire and PGI-I over the telephone. 185 patients either did not respond (n = 177) or declined to participate in the long-term follow-up clinic (n = 8), and are referred to as the short-term (ST) group. The patient distribution is illustrated in Figure 1.

Overall median follow-up for clinic visit and physical exam were 36 months (IQR 13 – 55), and follow-up for questionnaire and PGI-I were 38 months (IQR 16.5 – 61). Follow up for the LT group was 52 months (IQR 36 – 72) for the clinic visit and physical exam, and 61 months (IQR 42 – 79) for the questionnaire and physical exam. Median FU for the ST group was 22 months (IQR 8 – 38).

Both groups of patients bore similar baseline characteristics. The LT group was significantly younger (70 years [IQR 64 – 75] vs 71.5 years [IQR 66 – 78], p = 0.011) and more sexually active (39.6% [n = 59] vs 28.6% [n = 53], p = 0.009) then the ST group. A summary of patient baseline characteristics and baseline POP grading may be found in Table 1.

A total of 264 anterior compartment repairs were done with mesh, as well as 280 apical compartment repairs and 211 posterior compartment repairs. The Gynecare Prolift® system (Ethicon Division, Johnson & Johnson, New Brunswick, NJ, USA) was

the most popular system, used in 53% (n = 177) of patients. The Exair® mesh (Coloplast, Humlebæk, Denmark) was second in standing, used in 17.7% (n = 59). The Avaulta® (Bard, Murray Hill, NJ, USA) and the Elevate™ (American Medical Systems Inc, Minnetonka, MN, USA) systems were third and fourth most utilized, implanted in 7.2% (n = 24) and 5.7% (n = 19) of patients, respectively. The repartition of types of mesh used may be found in Table 2.

Repeat surgery and recurrent prolapse

8% of patients (n = 28) required a secondary procedure for either prolapse or urinary incontinence. In 11 cases (3.3%), repeat surgery was for recurrent prolapse only. In another 11 cases, surgery was for unmasked urinary incontinence (UI), and in 6 cases (1.8%) it was for both recurrent POP and unmasked UI. In total, 17 patients (5.1%) required a secondary procedure for recurrent POP, including 10 patients (6.7%) in the LT group. Of these 17 patients, 7 cases (2.1%) suffered from recurrence of a previously mesh treated compartment. The other 10 patients (3%) had developed *de novo* prolapse of a compartment that had never been treated with TVM. Median time to reoperation for POP was 18.5 months (IQR 9.5 – 33.75). The LT group had a significantly higher rate of *de novo* prolapse compared to the ST group (8 [5.4%] vs 2 [1.1%], $p = 0.027$), however overall reoperation rates for prolapse were similar in both groups. Reoperations during the follow-up period are presented in Table 3.

Complications

Mesh exposure

20 patients (6%) presented with vaginal mesh exposure on gynecologic exam during follow-up. Median time to identification of exposure was 17 months (2 – 121 months). The LT group presented with a significantly higher rate of mesh exposure when compared to the ST group (14 [9.4%] vs 6 [3.2%], $p = 0.021$), however time to exposure and number of symptomatic mesh exposures were not significantly different. Patients who were asymptomatic of their mesh exposure were treated with topical estrogen. Symptomatic patients were treated surgically with mesh excision (removal of the visible portion of mesh and primary closure of the vaginal mucosa).

Dyspareunia

8% (n = 9) of the 113 sexually active patients reported pain during sexual intercourse. The rate of dyspareunia did not differ between both groups. Despite this, 5 of these patients reported satisfaction with sexual intercourse.

Perineal pain

Only 2 patients (0.6%) reported *de novo* perineal pain after their mesh surgery.
Rates of complications during the follow-up period are detailed in Table 4.

Patient subjective satisfaction

A post-operative PGI-I score was available for 253 patients (75.7%), including all 149 patients in the LT group, obtained at the long-term follow-up visit, and 106 patients in the ST group, using the most recent PGI-I score found during the retrospective chart review. Overall, 81% of all patients (n = 206) and 78% of LT patients (n = 78) reported a PGI-I of 1, meaning they were very much improved with the surgery. 13% (n = 32) of all patients and 15% (n = 23) of LT patients scored a 2 (much better). 5% (n = 12) of all patients and 8% (n = 5) of LT patients scored a 3 (a little better). 2 patients (1%), including 1 in the LT group, reported being unchanged by the surgery (PGI-I score 4), and 1 patient (1%) in the LT group reported being a little worse (PGI-I score 5). No values of 6 and 7 were reported (much worse and very much worse, respectively). Overall, 99% of patients reported a subjective improvement with their TVM, including 98% in the LT group. There was no significant difference in the rates of post-operative subjective satisfaction between both groups. The PGI-I values may be found in Table 5.

Discussion

In 2008, the United States Food and Drug Association (FDA) issued a public health warning on the use of TVM for both POP and SUI. The FDA warned about potential serious complications that were not encountered with traditional non-mesh repair, including but not limited to: increased reoperation rate, pelvic pain and dyspareunia, and vaginal mesh exposure. An update of this warning was emitted in 2011, after a review of the medical literature on the subject by the FDA. In this update, it was reiterated that TVM surgery entailed higher risks than its native-tissue counterpart, without increased efficacy with regard to anatomical repair and patient symptomatology. Adverse events occurring secondary to mesh placement could induce life-altering sequelae, some persisting even after mesh removal. Vaginal mesh exposure was cited as the most frequent complication associated with TVM, occurring in 10% of cases, half of which required surgical treatment. Mesh contracture, causing chronic pelvic pain and dyspareunia, was also cited as an increasingly prevalent adverse event.[3]

Health Canada echoed the FDA by publishing a notice in 2010, along with an update in 2014, warning about potential complications associated with TVM. The Canadian warning, however, was somewhat less dichotomic than its American counterpart, stating that although most patients operated with TVM had good outcomes, an increased risk of complications was present when compared to non-mesh repair, and that some cases of POP could be treated without mesh. Patients were encouraged to seek information about type of device used, their surgeon's qualifications, and presence of other treatment options.[4,5]

The aforementioned notices prompted the Cochrane Library to produce a meta-analysis on the subject. Contrary to what the FDA had stated, the meta-analysis revealed that non-absorbable mesh repair reduces the risk of anatomical recurrence, repeat surgery

for prolapse recurrence, as well as patient awareness of prolapse after surgery, when compared to non-mesh repair.[9] A recent retrospective review by Ow, *et al.* also demonstrated superior efficacy of TVM repair versus native tissue repair at 3 years' follow-up, in both anterior and posterior compartments (anterior 23.9 % vs 7.4 %, $p < 0.01$, posterior 19.5 % vs 7.5 %, $p = 0.08$), in a group of 237 women undergoing repeat surgery after initial failure of native tissue repair.[10] In our population, comprised essentially of high-grade, multi-compartmental POP patients, reoperation rate for recurrence was low, only 6.7% in the LT group. And although native tissue repair remains a mainstay of prolapse therapy for uncomplicated POP, we consider that in populations similar to ours, use of mesh should be considered to reduce risk of anatomical recurrence and repeat prolapse surgery.

Mesh exposure is undeniably an issue when discussing TVM, as native-tissue repairs are inherently free of this complication. Exposure rates vary within the literature, ranging from 1.4 to 36%,[11,12,13,14,15] with the Cochrane review stating a 12% exposure rate, with 8% of patients requiring surgical excision of exposed mesh.[9] The exposure rate in our population was low (9% in the LT group), and although there is currently no literature demonstrating a protective effect of the use of vaginal estrogen pre and post-operatively for one year,[16] it remains a common practice regime that we apply in our centers. Also, median time to exposure was 17 months in our study; therefore, vaginal estrogen may be especially beneficial on a long-term basis, to be further evaluated. Furthermore, although half of our patients with mesh exposure required surgical treatment, the others' exposure improved or resolved by either augmenting frequency of estrogen applications, or restarting treatment in patients who had stopped. We therefore believe in the protective effect of vaginal estrogen against mesh exposure.

Dyspareunia is a multifactorial symptom, and in postmenopausal women can be caused by vaginal atrophy leading to decreased vaginal size, decreased lubrication, increased venous congestion, as well as loss of libido and declining sensation of clitoral and vulvovaginal tissues during intercourse.[17] Additionally, any form of vaginal surgery, be it mesh-augmented or not, causes vaginal scarring with subsequent loss of elasticity and vaginal deformity, which in turn may cause dyspareunia. A significant number of patients suffer from dyspareunia pre-operatively, and post-operative *de novo* dyspareunia is present in 4% of patients who underwent native tissue repair.[18] Furthermore, the Cochrane review did not show any difference in rates of *de novo* dyspareunia in both patient groups after surgery.[9] In our population, baseline dyspareunia was not assessed, and was present in 8% of sexually active patients post-operatively. Despite this, more that half of these patients deemed themselves to be satisfied with sexual intercourse. A comparison between baseline and post-operative rates of dyspareunia in our population would have been fruitful.

Patient self-reported satisfaction with their procedure was very high, with 81.4% of patients stating they were *very much improved* by their surgery (PGI-I of 1), and 98.8% of patients overall improved (PGI-I 1 through 3). Only 2 patients stated that they felt *no change* when compared to baseline (PGI-I of 4), and one patient stated that she felt *a little worse* (PGI-I of 5), however this last patient reported a subjective impression of POP recurrence despite having a negative physical exam.

Finally, surgeon experience, technique and volume are undeniable prognostic factors for operative success. As demonstrated by Kelly *et al.*, very high-volume surgeons (> 14 cases per year) are associated with the lowest reoperation rates. These high-volume surgeons represent the > 90th percentile, meaning that the vast majority of prolapse surgeons only perform a few cases per year.[19] Both our fellowship-trained, academic hospital-based surgeons perform on average 40 – 50 TVM cases per year, placing them in the very high-volume group.

Limitations of our study include its retrospective, non-controlled nature. Some patients may have done equally as well without mesh repair. The largest barrier to obtaining long-term data was our inability to contact patients directly, as per ethics committee protocol. A significant number of patients who participated in the long-term follow-up could not present to clinic for a physical exam. Post-operative PGI-I values were not available for all of the ST group patients. One could argue that the patients who did not respond to our request for long-term follow-up did so because they were not satisfied and sought treatment elsewhere. However, complications and reoperation rates were similar in both ST and LT groups, so this hypothesis would seem unlikely. It must also be mentioned that the majority of mesh products used in this study were pulled off the market due to the above-mentioned advisories and lawsuits. However, both participating surgeons are currently using new, yet similar, mesh products Restorelle® (Coloplast, Fredensborg, Denmark) and Uphold™LITE (Boston Scientific Corporation, Marlborough, MA) which likely have similar results to the products used in the study.

Conclusion

Although its use entails certain risks, in the hands of an experienced surgeon, and in appropriately selected patients, transvaginal mesh for prolapse repair still has its role. Despite FDA and Health Canada warnings, patient reported satisfaction is very high for these procedures. Patients must be adequately informed pre-operatively about potential risks associated with TVM.

References

1. Olsen AL, Smith VJ, Bergstrom JO, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* Apr;89:501-6
2. Handa VL, Cundiff G, Chang HH, et al. Female sexual function and pelvic floor disorders. *Obstet Gynecol* 2008 May;111:1045-52
3. UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication. U.S. Food and Drug Association [serial on the Internet]. 2011 Jul [cited 2017 Dec 5]. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm
4. Notice to Hospitals - Health Canada Issued Important Safety Information on Surgical Mesh for Stress Urinary Incontinence and Pelvic Organ Prolapse. Health Canada [serial on the Internet]. 2010 Feb [cited 2017 Dec 5]. http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2010/14626a-eng.php
5. Notice to Hospitals - Health Canada Issued Important Safety Information on Surgical Mesh for Stress Urinary Incontinence and Pelvic Organ Prolapse. Health Canada [serial on the Internet]. 2014 May [cited 2017 Dec 5]. http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/39475a-eng.php
6. Parekh M, Swift S, Lemos N, et al. Multicenter inter-examiner agreement trial for the validation of simplified POPQ system. *Int Urogynecol J* 2011 Jun;22:645-50
7. Swift S, Morris S, McKinnie V, et al. Validation of a simplified technique for using the POPQ pelvic organ prolapse classification system. *Int Urogynecol J Pelvic Floor Dysfunct* 2006 Nov;17:615-20.
8. Srikrishna S, Robinson D, Cardozo L. Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. *Int Urogynecol J* 2010 May;21:523-8
9. Maher C, Feiner B, Baessler K, et al. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse (Review). *Cochrane Database Syst Rev* 2016 Feb 9;2:CD012079
10. Ow LL, Lim YN, Dwyer PL, et al. Native tissue repair or transvaginal mesh for recurrent vaginal prolapse: what are the long-term outcomes? *Int Urogynecol J* 2016 Sep;27:1313-20
11. Schimpf MO, Abed H, Sanses T, et al. Graft and Mesh Use in Transvaginal Prolapse Repair: A Systematic Review. *Obstet Gynecol* 2016 Jul;128:81-91
12. Balchandra P, Marsh F, Landon C. Perioperative outcomes and prospective patient reported outcome measures for transvaginal mesh surgery. *Arch Gynecol Obstet* Oct 2015;292:875-82

13. Bjelic-Radisic V, Aigmueller T, Preyer O, et al. Vaginal prolapse surgery with transvaginal mesh: results of the Austrian registry. *Int Urogynecol J* Aug 2014;25:1047-52
14. de Tayrac R, Brouziyne M, Priou G, et al. Transvaginal repair of stage III-IV cystocele using a lightweight mesh: safety and 36-month outcome. *Int Urogynecol J* Aug 2015;26:1147-54
15. Heinonen P, Aaltonen R, Joronen K, et al. Long-term outcome after transvaginal mesh repair of pelvic organ prolapse. *Int Urogynecol J* July 2016;27:1069-74
16. Sun Z, Zhu L, Xu T, et al. Effects of preoperative vaginal estrogen therapy for the incidence of mesh complication after pelvic organ prolapse surgery in postmenopausal women: is it helpful or a myth? A 1-year randomized controlled trial. *Menopause* July 2016;23:740-8
17. Santoro N, Epperson CN, Mathews SB. Menopausal Symptoms and Their Management. *Endocrinol Metab Clin North Am* 2015 Sep;44:497-515
18. Gupta P, Payne J, Killinger KA, et al. Analysis of changes in sexual function in women undergoing pelvic organ prolapse repair with abdominal or vaginal approaches. *Int Urogynecol J* 2016 Dec;27:1919-24
19. Kelly EC, Winick-Ng J, Welk B. Surgeon Experience and Complications of Transvaginal Prolapse Mesh. *Obstet Gynecol* 2016 Jul;128:65-72

Figures and Tables

Fig. 1. Patient distribution flow chart.

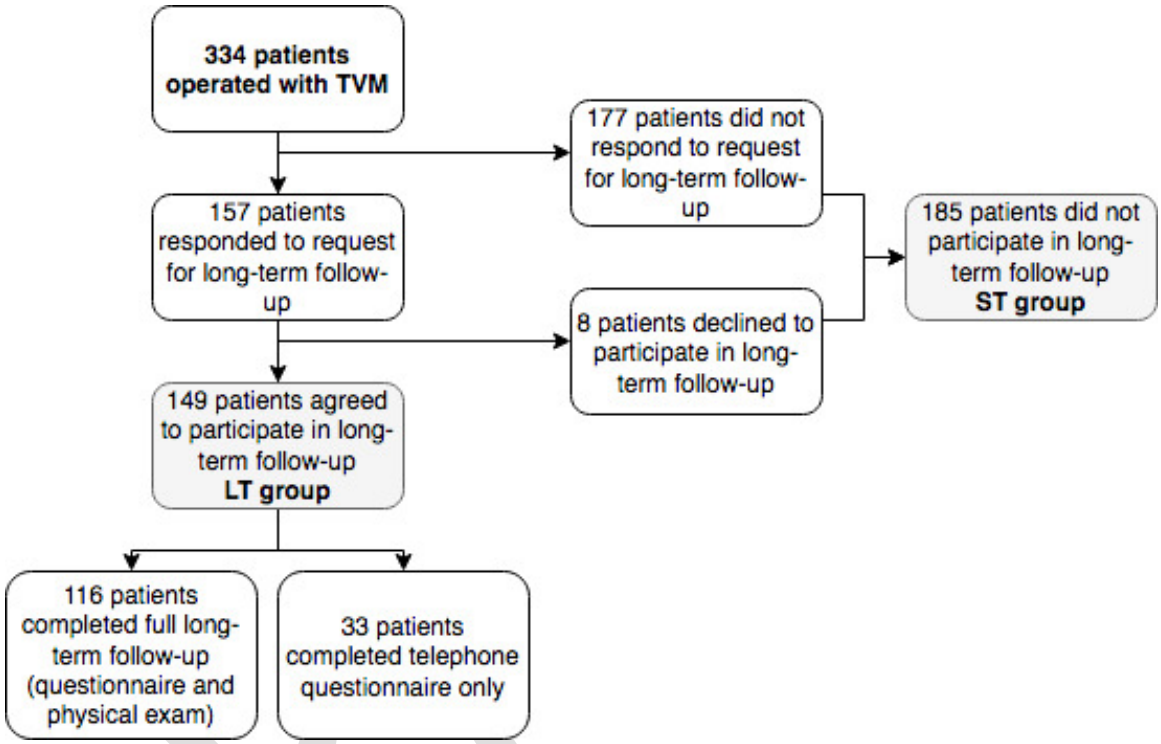

Table 1. Patient baseline characteristics				
Patient characteristics	**All patients (n=334)**	**LT group (n=149)**	**ST group (n=185)**	**p**
Age at surgery, median (IQR)	70.5 (65–76)	70 (64–75)	71.5 (66–78)	**0.011**
Parity, median (IQR)	3 (2–4.75)	3 (2–4)	3 (2–4)	0.105
BMI (kg/m^2), median (IQR)	27.3 (24.5–30.5)	27.1 (24.2–30.2)	27.5 (25.1–30.8)	0.320
Sexually active, n (%)	113 (34)	59 (40)	53 (29)	**0.009**
Concomitant hysterectomy, n (%)	33 (10)	14 (9)	19 (10)	0.855
Concomitant incontinence procedure, n (%)	197 (60)	88 (59)	109 (59)	0.999
Anterior prolapse, n (%)	268 (80)	119 (80)	148 (80)	0.999
Grade ≥3, n (%)	203 (61)	88 (59)	115 (62)	0.574
Apical prolapse, n (%)	298 (89)	135 (90)	162 (88)	0.064
Grade ≥3, n (%)	198 (59)	86 (58)	112 (61)	0.654
Posterior prolapse, n (%)	245 (73)	102 (69)	141 (76)	0.138
Grade ≥3, n (%)	119 (36)	52 (35)	66 (36)	0.909
Total grade ≥3 prolapse, n (%)	318 (95)	143 (96)	175 (95)	0.615
Total multiple compartment prolapse, n (%)	297 (89)	129 (87)	168 (90)	0.226

BMI: body mass index; IQR: interquartile range.

Table 2. Types of transvaginal mesh used				
Mesh name	**All patients (n=334)**	**LT group (n=149)**	**ST group (n=185)**	**p**
Prolift, n (%)	177 (53)	76 (51)	101 (54)	0.582
Anterior	18 (5)	6 (4)	12 (7)	0.466
Posterior	9 (3)	6 (4)	3 (2)	0.195
Anterior + posterior	150 (45)	64 (43)	86 (47)	0.58
Exair, n (%)	60 (18)	32 (22)	28 (15)	0.152
Anterior	18 (5)	11 (7)	7 (4)	0.222
Posterior	6 (2)	3 (2)	3 (2)	0.999
Anterior + posterior	36 (11)	18 (12)	18 (10)	0.595
Avaulta, n (%)	24 (7)	10 (7)	14 (8)	0.833
Anterior	0 (0)	0	0	
Posterior	15 (45)	7 (5)	8 (4)	0.999
Anterior + posterior	9 (3)	3 (2)	6 (3)	0.736
Elevate, n (%)	19 (6)	11 (7)	8 (4)	0.245
Anterior	10 (3)	6 (4)	4 (2)	0.351
Posterior	1 (0.2)	0	1 (1)	0.999
Anterior + posterior	8 (2)	5 (3)	3 (2)	0.704
Other	54 (16)	20 (13)	24 (13)	0.999

Table 3. Repeat procedures for urinary incontinence and prolapse				
Repeat procedure	**All patients (n=334)**	**LT group (n=149)**	**ST group (n=185)**	**p**
Total repeat procedures, n (%)	28 (8)	17 (11)	11 (7)	0.078
Incontinence only, n (%)	11 (3)	7 (5)	4 (3)	0.228
Prolapse only, n (%)	11 (3)	6 (4)	5 (3)	0.549
Incontinence and recurrent prolapse, n (%)	6 (2)	4 (3)	2 (1)	0.413
Total repeat procedures for recurrent prolapse, n (%)	17 (5)	10 (7)	7 (5)	0.317
De novo prolapse – new compartment, n (%)	10 (3)	8 (5)	2 (1)	**0.027**
Recurrent prolapse – same compartment, n (%)	7 (2)	2 (1)	5 (3)	0.467
Time to repeat surgery, median (IQR)	18.5 (9.5–33.75)	20.5 (11.25–34.5)	15.5 (8–29.75)	0.724

IQR: interquartile range.

Table 4. Postoperative complications of transvaginal mesh				
Complication	**All patients (n=334)**	**LT group (n=149)**	**ST group (n=185)**	**p**
Vaginal mesh exposure, n (%)	20 (6)	14 (9)	6 (3)	**0.021**
Time to mesh exposure, median (IQR)	17 (7.5–54)	24 (8–72)	12 (8.5–15.5)	0.259
Symptomatic exposure, n (%)	10 (3)	9 (6)	1	0.141
Surgery for mesh exposure, n (%)	10 (3)	9 (6)	1	0.141
Conservative treatment, n (%)	10 (3)	5 (3)	5	0.757
Dyspareunia, n (%) **Proportion of sexually active patients*	9 (8) **(n=113)*	7 (12) **(n=59)*	2 (4) **(n=53)*	0.168
Satisfaction with sexual intercourse, n (%) **Proportion of sexually active patients*	5 (4) **(n=113)*	5 (9) **(n=59)*	0 **(n=53)*	0.059
De novo perineal pain	2	2	0	0.198

IQR: interquartile range.

Table 5. Patient Global Impression of Improvement (PGI-I) scores				
PGI-I	**All patients (n=255)**	**LT group (n=149)**	**ST group (n=106)**	**p**
1 - Very much better, n (%)	206 (81)	116 (78)	92 (87)	0.074
2 - Much better, n (%)	32 (13)	23 (15)	9 (8)	0.125
3 - A little better, n (%)	12 (5)	8 (5)	4 (4)	0.766
4 - No change, n (%)	2 (1)	1 (1)	1 (1)	0.999
5 - A little worse, n (%)	1 (0.4)	1 (1)	0	0.999
6 - Much worse, n (%)	0	0	0	
7 - Very much worse, n (%)	0	0	0	
Subjectively improved by TVM surgery (PGI-I 1–3), n (%)	252 (99)	147 (99)	105 (99)	0.999

TVM: transvaginal mesh.