



Full length article

A comparison between the vaginal patch plastron associated with the anterior sacrospinous fixation and the Uphold™ LITE vaginal support system for the treatment of advanced anterior vaginal wall prolapse

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ABSTRACT

Objective: The aim of the present study was to compare efficacy and safety of the vaginal patch plastron (VPP) associated to the anterior sacrospinous fixation (SSLF-A) with a TVM procedure (Uphold™ LITE support-system) for the treatment of the advanced anterior vaginal wall prolapse.

Study design.

Single-center retrospective study. Women with symptomatic anterior prolapse $\geq$ III stage according to the POP-quantification (POP-Q) system and submitted to the VPP associated with the SSLF-A or to the Uphold™ procedure were included. Primary outcome was to compare objective and subjective cystocele relapse and reoperation rate at 6- and 12-month follow-up. Secondary outcome was to describe peri- and postoperative complications. Pearson chi-square test and exact Fisher test were adopted for categorical variables, while intergroup Mann-Whitney *U* test and intragroup Wilcoxon Rank Sum Test for continuous variables; the statistical analysis was conducted at 95 % confidence level.

Results: Fifty-five women in VPP-group and 118 women in Uphold-group were included. At 6-month follow-up, objective anterior relapse in VPP-group (3/55, 5.4 %) was like Uphold-group (5/118, 4.2 %; $p = 0.71$), as well as objective apical relapse (0/55, 0 % vs 3/118, 2.5 %; $p = 0.55$); no significant difference emerged in bulge symptoms (1/55, 1.8 % vs 5/118, 4.2 %; $p = 0.67$). At 12-month follow-up women were telephonically investigated; no significant difference emerged in bulge symptoms (1/55, 1.8 % vs 6/118, 5.1 %; $p = 0.43$). Reoperation rate for the composite outcome POP relapse, stress urinary incontinence (SUI) and removal of the TVM resulted lower in the VPP group (1/55, 1.8 % vs 13/118, 11 %; $p = 0.03$). Post-operative buttock pain (32/55, 58.2 % vs 24/118, 20.3 %; $p < 0.0001$) and post-operative urinary retention (16/55, 29.1 % vs 6/118, 5.1 %; $p < 0.0001$) were higher in VPP-group, with a complete resolution between 2 and 3 weeks after treatment.

Conclusion: VPP associated with SSLF-A was as effective as Uphold™ LITE support-system for both anterior and central compartment prolapse treatment at 6- and 12-month follow-up. VPP-group presented a lower reoperation rate for the composite outcome prolapse relapse repair, SUI, and removal of the mesh.

Introduction

Pelvic organ prolapse (POP) is a high prevalent condition, with a prevalence of the anterior compartment prolapse reported around the 30 % in post-menopausal women [1]. Population based studies reported a 11 to 19 lifetime risk of being submitted to a POP or incontinence

surgery [2], with a risk of reoperation that increases following every POP surgical repair [3].

During the last decades, synthetic transvaginal meshes (TVM) have been introduced in urogynecology with the aim to improve surgical outcomes in POP and stress urinary incontinence (SUI) surgery. When introduced, TVM were self-shaped by surgeons. Subsequently, second

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generation pre-cut TVMs have been produced by manufacturers [4]. Among second-generation TVMs, the Uphold™ LITE support system has been adopted both for apical and anterior prolapse repair [5–6] with optimal anatomical and functional results. However, in the last decade concerns about the safety related to synthetic non-absorbable TVMs emerged and, after numerous patient class actions in the United States (US), Australia and New Zealand, TVMs have been banned or paused for clinical practice worldwide [7]. In this climate of concerns about TVM implantation, native tissue repair (NTR) for POP has returned to the forefront. Indeed, we reconsidered a vaginal autologous technique for the treatment of the anterior vaginal wall prolapse, already described at the end of the 90 s: the vaginal patch plastron-VPP [8]. In the VPP, a rectangle of vaginal mucosa is left on the cystocele and is adopted to support the bladder [6]. Traditionally, this rectangle was anchored in a total of 6 points (3 points for each side of the VPP) at the arcus tendinous fascia pelvis (ATFP). We modified the classical VPP technique by the association of a bilateral anterior sacrospinous ligament fixation (SSLF-A), with the objective of better restoring level 1 support [9].

The aim of this study is to compare the VPP associated with bilateral SSLF-A with the Uphold™ LITE support system procedure for the treatment of the advanced cystocele.

Materials and methods

Study design

This is a single-center retrospective study carried-out at the Urogynecological Unit of Jeanne de Flandre Hospital in Lille, France. Women ≥ 18 years old affected by anterior vaginal wall prolapse $\geq$ III stage (Aa or Ba > 1 cm) according to the pelvic organ prolapse quantification (POP-Q) system and [10] scheduled for the Uphold™ procedure or for the VPP associated with the SSLF-A [11], from February 2016 to September 2017 and from March 2019 to March 2022 respectively, were included. In 2019 the FDA ordered mesh manufacturers to stop selling devices for transvaginal repair of pelvic organ prolapse in the United States, and the same happened in Europe [7]; therefore, during the two different study periods, the related surgical procedure was considered as the standard of treatment for the vaginal repair of the anterior vaginal wall prolapse. Women were excluded from the study analysis if affected by connective tissue diseases, immunodeficiency, auto-immunological diseases or if previously submitted to augmented mesh procedure for the anterior prolapse repair. Considering the cohort of women included in the VPP group, this is a secondary analysis of a previous published study [9]. Pre-operative evaluation included the record of medical history, pelvic floor dysfunction (PFD) symptoms (vaginal bulge, urgency urinary incontinence-UUI, stress urinary incontinence-SUI, voiding dysfunction symptoms) and a physical examination, performed by a trained urogynecologist. The terminology used to describe PFD symptoms was in accordance with the standardization document of the International Urogynecological Association and the International Continence Society-IUGA/ICS [12]. Physical examination was performed in the lithotomy position with maximal Valsalva maneuver, to assess POP presence according to the POP-Q system [10]. Six months after surgery, all women were submitted to a post-operative follow-up visit: PFD symptoms, anatomical outcomes, and post-operative complications, in accordance with the Clavien-Dindo classification system, were recorded. Anatomical anterior vaginal wall prolapse relapse was defined as the presence of a cystocele $\geq$ II stage (Aa or Ba ≥ -1 cm). Anatomical central or posterior compartment relapses were defined as an apical prolapse $\geq$ II stage (C or D ≥ -1 cm) or a posterior vaginal wall prolapse $\geq$ II stage (Ap or Bp ≥ -1 cm). Posterior vaginal wall decompensation was defined as the presence of a posterior vaginal wall prolapse $\geq$ I stage (Ap or Bp ≥ -3 cm), in women who did not present any rectocele or peritono/enterocele at baseline. Subjective relapse was defined as the presence of bulge symptoms when anatomical relapse was identified. At a 12-month follow-up after surgery, women were

telephonically questioned about PFD symptoms (according to the IUGA/ICS standardization document) [12] and reintervention.

Primary outcome of the study was to compare the objective and subjective anterior vaginal wall prolapse relapse rate and the POP reoperation rate between the two techniques. Secondary outcome was to identify differences in peri- and post-operative complications.

The Institutional Ethical Board approved our informed consent allowing us to anonymously use data for research purposes in conformity with the laws and regulations of the country in which the experiment was performed. The study was conducted according to the Declaration of Helsinki.

Surgical procedures

SSLF-A technique isolated [13] and associated with the VPP [10] have been already described. The procedure can be performed under regional or general anesthesia according to the anesthesiologist's choice and/or patient's preference. The VPP, a rectangular vaginal strip (about 6–8 cm $\times$ 4 cm) on the anterior colpocele with its upper edge placed 2 cm from the urethral orifice, is delimited. Sixty cc of lidocaine 1 % and normal saline mix are injected in the paravesical spaces and at the edges of the VPP. The VPP is then incised and the paravesical spaces are bilaterally dissected up to the ischial spine. The SSL running from the ischial spine to the sacral bone is palpated and identified. A suture-capturing device, that allows an easy placement of the suture without eye-control, is adopted. The suture used are non-absorbable, polypropylene monofilaments. The SSL suture is placed almost 2 cm far away from the ischial spine to avoid nerve and vascular injuries [14]. A second SSL passage using the same stitch is usually performed. Two sutures are placed to the ATFP: a lateral suture on the tendonal ATFP halfway between the pubis and the sciatic spine and an anterior suture on the lower edge of pubo-ischial branches. The same procedure is performed on the other side. The VPP will be tied to the SSL and to the ATFP by the 3 lateral stitches (upper site for the SSL suture, middle and inferior sites for the 2 arcus tendineus sutures for each side) placed on each edge of the VPP (Fig. 1). The SSL suture is also secured to the cervix or to the top of the vagina if previous total hysterectomy. Before the suspension of the VPP, the vaginal closure begins. The VPP is suspended (Fig. 2), and the vagina is completely sutured. The use of vaginal packing is not mandatory.

Standardization of the Uphold™ LITE support system has been already described [15].

Intraoperative data and perioperative complications were recorded.

Statistical analysis

The Statistical Package for Social Science (SPSS) version 21.0 was used for data analysis. Continuous variables were reported as mean $\pm$ standard deviation (SD) or as median $\pm$ interquartile range, as appropriate. The Kolmogorov-Smirnov test was used to analyze the normal distribution of variables (>0.05). Difference in distribution was tested with Pearson chi-square test and the exact Fisher test for categorical variables. For continuous variables, the Mann-Whitney *U* test for intergroup differences and the Wilcoxon Rank Sum Test for intragroup differences were adopted as appropriate. The statistical analysis was conducted at 95 % confidence level.

Results

One hundred-eighty-two women affected by anterior vaginal wall prolapse $\geq$ III stage (Aa or Ba > 1 cm) were submitted to VPP or Uphold procedure during the evaluated study periods: 62 patients in the VPP associated with the SSLF-A group and 120 patients in the Uphold group. However, 7 women in the VPP group (7/62; 11.3 %) and 2 woman in the Uphold group (2/120; 1.6 %) were non-considered eligible for the study analysis; in VPP group, 1 woman had a diagnosis of endometrial cancer

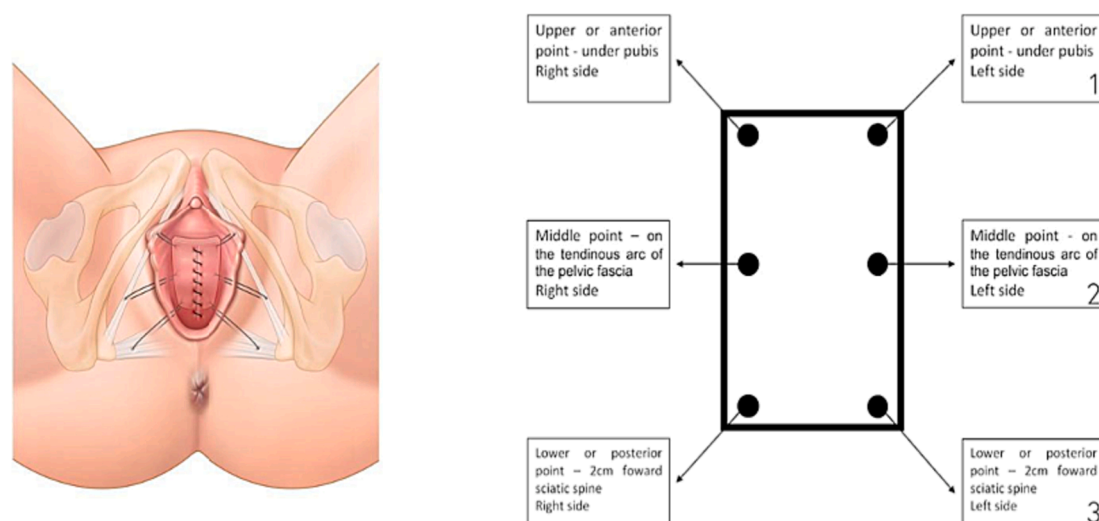


Fig. 1. A) The pelvic structures (sacrospinous ligament and arcus tendineus) where the sutures of the vaginal patch plastron have been placed are shown; B) Schematic visualization of the 6 fixation points of the vaginal patch plastron.

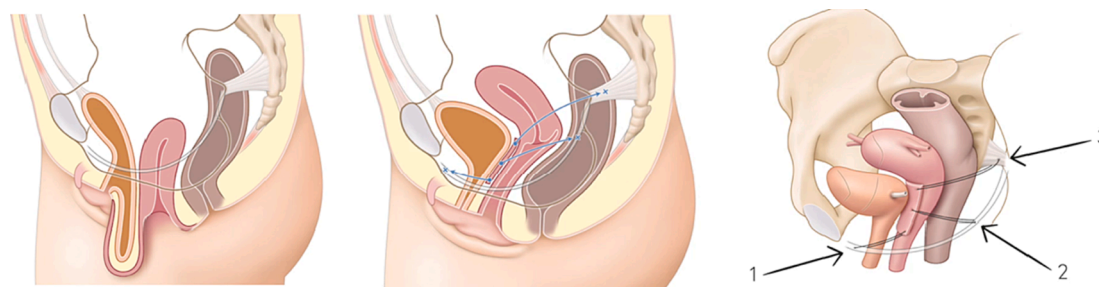


Fig. 2. A) Anterior and apical prolapse are highlighted concomitantly with the sacrospinous ligament and the arcus tendineus fascia pelvis; B and C) The rectangular vaginal patch plastron is anchored and suspended to the sacrospinous ligament (point 3) and the arcus tendineus fascia pelvis pre-pubically (point 1) and in its mid-portion (point 2).

4 months after surgical procedure, another one was lost at follow-up and 5 patients have been previously submitted to anterior augmented mesh repair, while in Uphold group 1 patient was lost at follow-up and 1 patient has been previously submitted to anterior TVM repair. Finally, 173 women, 55 women in VPP group and 118 women in Uphold group, were included in the study analysis. Baseline characteristics of the study population are reported in Table 1. Pre-operative POP-Q score is reported in Table 2. Additional surgeries at time of the study procedures are shown in Table 3. General anesthesia was adopted in the 89.1 % of VPP group (49/55) and in the 81.3 % of the Uphold group (96/118; $p = 0.28$), followed by regional anesthesia in the other cases. Operative time was evaluated only among patients submitted to the isolated procedure. Uphold operative time resulted in 26 (IQR 20–31.25) minutes, significantly inferior to VPP operative time of 40 (IQR 35–58) minutes ($p < 0.0001$). Women were discharged the same day of the procedure in the 28.8 % (34/118) of patients submitted to Uphold and in the 34.5 % (19/55) of patients submitted to the VPP ($p = 0.55$). Postoperative anatomical surgical outcomes are reported in Table 4. The incidence of post-operative surgical complications is reported in Table 5. Time of buttock pain resolution was between 2 and 3 weeks for both the procedures. When obstructive urinary symptoms were postoperatively evidenced, intermittent catheterization or indwelling bladder catheter were adopted, with a resolution reported between 2 and 3 weeks. Comparison of pre- and post-operative PFD symptoms at follow-up and the reoperation rate at 12-month follow-up are reported in Table 6.

Table 1

General and surgical characteristics of the study population at baseline.

	Uphold (n = 118)	VPP (n = 55)	p value
Age (mean $\pm$ SD), years	69.3 (8.4)	70.1 (7.5)	0.43
Vaginal delivery, n (%)	114 (96.6)	53 (96.4)	0.99
Parity, median (IQR)	2 (2–3)	2 (2–3)	0.74
Cesarean section, n (%)	5 (4.2)	2 (3.6)	0.99
Menopause, n (%)	118 (100)	53 (96.4)	0.09
Previous hysterectomy, n (%)	29 (24.5)	22 (40)	0.04
General previous POP surgery, n (%)	19 (16.1)	14 (25.4)	0.14
Anterior native tissue repair, n (%)	4 (3.4)	5 (9.1)	0.14
Posterior sacrospinous ligament fixation, n (%)	1 (0.8)	1 (1.8)	0.53
Posterior native tissue repair, n (%)	2 (1.7)	5 (9.1)	0.03
Posterior mesh, n (%)	5 (4.2)	3 (5.4)	0.71
Laparoscopic sacrocolpopexy, n (%)	8 (6.7)	7 (12.7)	0.25
Resection of previous vaginal mesh, n (%)	2 (1.7)	0 (0)	0.99
Incontinence surgery, n (%)	1 (0.8)	4 (7.3)	0.03
TVT	1 (0.8)	2 (3.6)	
TOT	0 (0)	2 (3.6)	
Burch	0 (0)	0 (0)	

VPP: Vaginal Patch Plastron; TVT: Tension Free Vaginal Tape; TOT: Trans-Obturator Tension Free Vaginal Tape; SD: Standard Deviation; IQR: Inter-quartile Range.

Table 2
Baseline POP staging according to the POP-Q system in the study population.

	Uphold (n = 118)	VPP (n = 55)	p value
Anterior vaginal wall prolapse, n (%)			0.62
Stage III	104 (88.1)	47 (85.4)	
Stage IV	14 (11.9)	8 (14.6)	
Apical compartment prolapse, n (%)			0.38
Stage I	18 (15.2)	6 (10)	
Stage II	60 (50.8)	22 (36.7)	
Stage III	20 (16.9)	12 (21.7)	
Stage IV	11 (9.3)	10 (16.7)	
Posterior vaginal wall prolapse, n (%)			0.61
Stage I	23 (19.4)	13 (23.6)	
Stage II	13 (11.0)	9 (16.3)	
Stage III	8 (6.7)	2 (3.6)	
Stage IV	4 (3.4)	3 (5.4)	

VPP: Vaginal Patch Plastron.

Table 3
Surgical procedures performed in the study population at time of pelvic surgery.

	Uphold (n = 118)	VPP (n = 55)	p value
Double passage to the ligament, n (%)	0 (0)	52 (94.5)	<0.0001
Vaginal hysterectomy, n (%)	2 (1.7)	0 (0)	0.99
Posterior sacrospinous ligament fixation, n (%)	0 (0)	13 (21.7)	<0.0001
Posterior mesh repair, n (%)	12 (10.2)	0 (0)	0.01
Posterior native tissue repair, n (%)	0 (0)	6 (9.8)	0.0008
Midurethral sling, n (%)	10 (8.5)	1 (1.8)	0.17

VPP: Vaginal Patch Plastron.

Table 4
Anatomical and subjective relapse of the population at 6-month follow-up.

	Uphold (n = 118)	VPP (n = 55)	p value
Anterior vaginal wall objective relapse, n (%)	5 (4.2)	3 (5.4)	0.71
stage II	2 (1.7)	3 (5.4)	
stage III	3 (2.5)	0 (0)	
stage IV	0 (0)	0 (0)	
Apical compartment objective relapse, n (%)	3 (2.5)	0 (0)	0.55
stage II	1 (0.8)	0 (0)	
stage III	2 (1.7)	0 (0)	
Posterior vaginal wall objective prolapse relapse*, n (%)	0/12 (0)	1/15 (6.7)	0.99
stage II	0 (0)	1 (6.7)	
Anatomical decompensation of posterior vaginal wall*, (%)	1/71 (1.4)	3/30 (10)	0.07
stage I	0 (0)	2 (6.7)	
stage II	1 (1.4)	1 (3.3)	
Subjective relapse, n (%)	5 (4.2)	1 (1.8)	0.67

° Calculated among women who had posterior vaginal wall prolapse surgery.

*Calculated among women who did not have posterior vaginal wall prolapse at baseline.

VPP: Vaginal Patch Plastron.

Discussion

The VPP associated with the SSLF-A demonstrated to be as effective as the Uphold™ LITE support system for both the advanced (Aa and/or

Table 5
Clavien-Dindo classification of perioperative complications.

	Uphold (n = 118)	VPP (n = 55)	Treatment	p value
Grade I				
Paravaginal hematoma	0 (0)	1 (1.8)	Observation	0.15
Postoperative buttocks pain	24 (20.3)	32 (58.2)	Analgesics	<0.0001
Grade II				
Infectious surgical site complication	1 (0.8)	1 (1.8)	Antibiotics	0.22
Postoperative urinary retention	6 (5.1)	16 (29.1)	Intermittent catheterization/ indwelling bladder catheter	<0.0001
Grade III B				
Ureteral kinking	0 (0)	1 (1.8)	Double J stent	0.11
Bladder injury	1 (0.8)	0 (0)	Double plane suture	0.99

SSLS-A: Anterior Sacrospinous Ligament Suspension; VPP: Vaginal Patch Plastron.

Table 6
Postoperative pelvic floor dysfunction symptoms and postoperative reintervention in the study population at 12-month follow-up.

	Uphold (n = 118)	VPP (n = 55)	p value
Subjective relapse, n (%)	6 (5.1)	1 (1.8)	0.43
Occult stress urinary incontinence, n (%)	41/86 (47.7)	11/37 (29.7)	0.06
Persisting stress urinary incontinence, n (%)	14/33 (42.4)	6/18 (33.3)	0.52
New onset urgency urinary incontinence, n (%)	4/72 (5.5)	6/44 (13.6)	0.18
Persisting urgency urinary incontinence, n (%)	10/47 (21.3)	2/11 (18.2)	0.99
Reoperation rate, n (%):	13 (11.0)	1 (1.8)	0.03
MUS	9 (7.7)	1 (1.8)	
Mesh resection	2 (1.7)	0 (0)	
Posterior SSLF	1 (0.8)	0 (0)	
Laparoscopic sacrocolposuspension	1 (0.8)	0 (0)	

SSLS-A: Anterior Sacrospinous Ligament Suspension; VPP: Vaginal Patch Plastron.

Ba > 1 cm) anterior vaginal wall prolapse repair (objective cure rate 94.6 % and 95.8 % respectively; $p = 0.71$) and the apical compartment repair (objective cure rate 100 % and 97.5 % respectively; $p = 0.55$) at 6-month follow-up. As well as the anatomical result, the subjective cure rate for the vaginal bulge symptom resulted extremely high and significantly similar at 12-month follow-up for both groups (98.2 % and 94.9 % for the VPP group and the Uphold group respectively; $p = 0.43$). Following the interdiction of non-absorbable synthetic TVM use in several countries, NTR for POP returned to be the main typology of surgery when a vaginal approach is indicated [7]. Previous research described a greater superiority of TVM techniques in comparison with NTR procedures, both for anatomical and for subjective outcomes. Indeed, the last 2016 Cochrane Systematic Review by Maher et al. evidenced that women submitted to TVM procedures for POP treatment presented a lower objective recurrence of POP and a lower awareness of POP after surgical repair in comparison with NTR procedures [16]. Our results show the autologous VPP to be as effective as a TVM procedure in improving both objective and subjective outcomes, in women affected by an advanced anterior vaginal wall prolapse, considered as the most difficult compartment to treat due to the higher relapse rate in comparison with the other vaginal compartments [17]. Considering the surgical history of the 2 study groups, our results are surprising. Indeed,

women submitted to the VPP presented a higher rate of previous hysterectomies. Indeed, the damages to the supportive structures of the pelvic floor resulting from hysterectomy can increase the risk of recurrence of POP and several studies have proposed a passive role of hysterectomy in increasing risk of POP [18–19]. These data confirm the strength of the VPP procedure; indeed, even if affected by a higher risk of POP relapse due to the previous pelvic surgeries, the VPP group presented a similar anatomical and subjective relapse rate when compared with the Uphold group.

Not secondary, in our study we observed a reoperation rate for the composite outcome POP relapse repair, SUI surgical treatment and removal of the TVM significantly higher in the Uphold group compared with the VPP group (11.0 % vs 1.8 %; $p = 0.03$). Maher et al. in their Systematic Review reported a higher risk of reoperation for the same composite outcome in women submitted to the TVM procedure [16]. The warning about safety of TVM such as the worldwide modification of the regulations and of the recommendations of the different scientific societies are deeply affecting the clinical practice for the management of the POP. Although TVM is related to lower relapse rate, lower reoperation rate for POP relapse and lower awareness of POP [16], NTR due to its lower rate of complications is the main option for the vaginal surgical management of POP. Indeed, we reintroduced the VPP associated with the SSLF-A with the aim of finding an autologous vaginal procedure presenting an efficacy profile like the TVM procedures, with a lower reoperation risk. Nowadays, it has been clearly established that the complication rate related to the meshes varies according to the material properties [20], the experience of the surgeon [21] and the route of implantation, with the vaginal approach significantly more related to adverse events [22]. Stricter evaluation of mesh materials, accreditation of physicians for implantation of TVM and a multidisciplinary approach for TVM indications and for management of complications are needed to enable the future of these surgical devices for POP management [7]. However, this significant difference in reoperation rate looks to be related mainly to *de novo* SUI, reported as higher (even if not significantly) in the cohort of women submitted to TVM procedure. *De novo* SUI is a well-known result of the resolution of urethral obstruction by anatomical reconstruction and even if postoperative SUI may appear only transiently, a small number of serious cases may require surgery. We can speculate that the anatomical hypercorrection and the higher rigidity related to the implant of TVM may determinate a longer and non-transient SUI, leading to a higher number of surgeries performed for this issue in comparison with native tissue repair.

Concerning the perioperative complications, the VPP resulted significantly more related to buttock pain and urinary retention. The higher rate of buttock pain in the VPP we retain may be related to the double passage of the suture at the sacrospinous ligament, with the possibility of a transitory damage of the nervous structures presented at this site [23]. However, this symptom was treated by analgesics and tended to self-resolve between 2 and 3 weeks after surgery. Post-operative bladder dysfunction is a common complication of gynecologic and urogynecologic surgery [24–25]. When postoperative bladder dysfunction was evaluated, the VPP procedure resulted significantly more associated. Even in this case it generally regressed between 2 and 3 weeks, after indwelling or intermittent bladder catheters.

This study presents several limitations such as the evaluation of objective results at short-term follow up, the evaluation of subjective outcomes and of PFD symptoms telephonically and without validated questionnaires, the retrospective design with all intrinsic limits of such design. Moreover, a prospective two arms parallel study was not feasible due to the banning of TVM from the French market. At the same time, we described a NTR technique highlighting optimal results in comparison with a TVM procedure, with strict inclusion and exclusion criteria, in a selected population affected by advanced cystocele (Aa and/or Ba > 1 cm).

Further studies are needed to evaluate long-term outcomes and to evaluate the procedure in a wider population. Prospective parallel

studies comparing the VPP with classical NTR procedures (such as the anterior colporrhaphy) are needed to confirm the promising data related to the VPP.

Conclusion

The VPP associated with the SSLF-A has been proved to be as effective as TVM procedure (Uphold™ LITE support system) at 12-month follow-up. Furthermore, the Uphold™ LITE support system group presented a higher reoperation rate for the composite outcome prolapse relapse repair, stress urinary incontinence and removal of the mesh. Further studies are needed to evaluate these outcomes at long-term follow-up and with a larger sample size.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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