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Full length article

Transvaginal mesh surgery for pelvic organ prolapse does not affect sexual function at long term follow up★

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ABSTRACT

Objective: Pelvic Organ Prolapse (POP) may impair sexual health. Though sexual dysfunction in women with POP is associated with reduced sexual arousal and dyspareunia, sexual outcomes have not been fully investigated. Transvaginal mesh repair (TVMR) is a POP therapeutic option, but is debated as a possible cause of worsening in sexual function. Aim of this study is to evaluate pre- and post-operative sexual outcomes in women undergone to TVMR.

Study Design: Data coming from sexually active women submitted to TVMR for POP with commercial mesh kits (device whose production has been suspended) were prospectively collected from 2012 to 2016 in a tertiary referral center. POP was measured according to the POP-Q classification. Patients' characteristics, operative and post-operative data were collected. Follow-up was carried out at month 1, 6, 12 and then yearly. Sexual function was measured through FSFI (Female Sexual Function Index) questionnaire. Minimum follow up was 12 months. FSFI score was assessed in these women before and after TVMR. A sub-analysis according to mesh kit used was made.

Results: From 2012 to 2016, 155 women underwent TVMR active for stage III or higher POP and 56 (36.6%) were sexually active, while 52 (92.9%) had adequate follow-up. Median age was 62 years (IQR 56–66), median BMI was 24,7 kg/m2 (IQR 22,3–28,9) and median parity was 2 (IQR 1–2). All patients presented anterior compartment POP and 14 (269%) had previous POP surgery. Urodynamic SUI was present in 13 (250%) patients. Commercial mesh kits used were Prolift© in 19 patients (36.5%) and Elevate© in 33 (63.5%). Median follow up was 42 months (IQR 22–59). Globally, FSFI was unaltered from TVMR at 12 months and at last follow up ($p = 0.856$). In detail, even if dyspareunia was reported in 1 patient, pain sub score was stable at long term follow up after TVMR ($p = 0.124$). Globally, there were 8 (15.4%) perioperative complications, none exceeding Clavien 2. At late follow up here was 1 (1.9%) mesh vaginal erosion occurred and there were 4 (7.7%) de novo stress urinary incontinence. Preoperative characteristics, surgical complications and outcomes were similar between mesh kits ($p > 0.05$).

Conclusion: In our experience, global sexual function doesn't seem to be affected by TVMR when performed by expert surgeons. Despite being a confounding factor, lost at follow up rate was low, thus affecting only in a mild way surgical outcomes. Also ageing might be a confounding factor during follow up to establish real mesh impact on sexual function. Dyspareunia was a rare complication in patients during follow-up and pain was not a major complaint.

Introduction

Pelvic Organ Prolapse (POP) is an underestimated condition that may involve up to 50% of parous woman, but only 10–20% of them are checked by a medical doctor for this condition [1].

The overall prevalence of POP changes significantly according to the definition used ranging from 3 to 6% according to patients' reported symptoms to 41–50% according to medical epidemiology reports [2]. As ageing is associated with an increased POP risk, the

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increase in women life expectancy is accompanied with subsequent high expectation for Quality of Life (QoL) beyond menopause especially in active lifestyle and sexual activity [3–5].

POP may induce lower urinary tract, sexual and anorectal dysfunction. Symptoms of sexual dysfunction associated with POP can be classified in dyspareunia, both superficial (introital) or deep, obstructed intercourse, vaginal laxity, vaginal wind, abstinence and urethral, vulvar, vaginal, perineal and pelvic pain [6].

Data provided are conflicting. Age, education, menopause, vaginal dryness, depression and lack of 'passionate love' for their partner did not confound the association between pelvic floor symptoms and sexual function [7].

In the United States, more of 300,000 surgical POP procedures are performed each year (22.7 cases for 10,000 women) with a 13–25% reoperation rate. It is estimated that the lifetime risk of experiencing POP related surgery ranges from 6.3 to 19% [2].

Also POP's treatment has an important impact for costs and management of national service care, but also for individual women's health and QoL (1)

According to a joint report coming from the International Continence Society (ICS) and International Urogynecological Association (IUGA) the POP repair surgical outcomes to consider are objective outcomes, patient-reported outcomes, satisfaction outcomes, QoL and perioperative data [8]. Urinary, bowel, vaginal and sexual symptoms are important subjective outcome measures used to evaluate patient-reported outcomes after surgery for POP [9]. POP's surgical repair may be followed by improvement, worsening or no change in these symptoms while some patients may develop them de novo.

Establishing the patients' starting symptoms and the surgery effect can help the surgeon to better assist patients before, during and after operation, thus obtaining the best surgical target and respect patients' expectations. In fact, the most important factor to consider is not just the anatomical result, but also to restore the pelvic organs function thus maintaining a normal sexual function in sexually active women.

Functional outcomes are completely different between abdominal and vaginal wall reconstruction and sexual function must be mandatorily taken into consideration

Transvaginal mesh repair is now debated as a possible cause of worsening in sexual function as stated in the recent FDA warning update and future mesh need pre-market approval [10]. In fact, there is an increasing interest in mesh complication and biocompatibility, even if polypropylene is considered safe in animal model, while mesh kit weight and structure is important to determine mesh related complications [11]. At present time, such procedures have been limited until further evidences would be provided in some countries. Aim of our study is to evaluate the impact of prosthetic surgical POP repair on female sexual function.

Materials and Methods

We have retrospectively analyzed all the data of patients who underwent anterior compartment POP vaginal mesh repair in our tertiary referral center between January 2012 and December 2016 since the last available follow up. Concomitant apical or posterior compartment POP was not an exclusion criterion. Data were prospectively collected in our center database before, during and after surgery. All the follow up data were registered at month 1, 6, 12 and then yearly.

Minimum follow up for being eligible was 12 months.

Surgical techniques were the same as previously described by Nair et al for Prolift© and by Stanford et al for Elevate© [12,13].

Primary study endpoint was to assess if transvaginal mesh surgery for POP may impair sexual function in sexually active patients at late follow up. Secondary endpoints were to evaluate transvaginal mesh repair safety, subjective and objective outcomes.

Exclusion criteria were incomplete or inadequate follow-up and preoperative sexually inactive patients.

The preoperative assessment of patients included age, body mass index (BMI), comorbidity, parity and type of childbirth, aborts, menopausal age, previous gynecological or POP surgery, prolapse type and stage according to Pelvic Organ Prolapse Quantification System (POP-Q), LUTS, presence and type of concomitant urinary incontinence [14].

Intraoperative and postoperative assessment included type of mesh kit used, intraoperative complications, short- long- term postoperative complications. Complications were classified according to Clavien Dindo scale and divided between medical and surgical [15].

Follow up evaluation included late complications, reintervention, anatomical and subjective outcomes. Mesh related complications were classified according to IUGA/ICS classification [16]. Anatomical outcomes were defined through POP stage according to POP-Q and POP recurrence or de novo POP were defined as stage

Table 1
Preoperative Patients' Characteristics.

Preoperative Patients' Characteristics (n=52)					
Mesh Kit		Total (n = 52)	Prolift (n = 19, 36.5%)	Elevate (n = 33, 73.5%)	p-value
Age (years), median (IQR)		62 (56-66)	63 (57-66)	62 (56-66)	0.812
BMI (Kg/m^2), median (IQR)		24.7 (22.3-28.9)	25.7 (23.1-28.8)	24.7 (21.3-28.9)	0.855
Anterior Vaginal Wall Prolapse Stage (POP-Q), n (%)	3-4	52(100%)	19(100%)	33 (100%)	NA
Apical Vaginal Segment Prolapse Stage (POP-Q), n (%)	3-4	24 (46.2%)	9 (474%)	15 (45.5%)	0.894
Posterior Vaginal Wall Prolapse Stage (POP-Q), n (%)	3-4	11 (21.1%)	4 (21.0%)	7 (21.2%)	0.989
Parity, median (IQR)		2 (1-2)	1 (1-2)	2 (1-2)	0.383
Child weight at birth >4 Kg, n (%)		13 (25.0%)	4 (21.1%)	9 (27.3%)	0.618
Menopausal Age, median (IQR)		50 (48-54)	50 (47-54)	50 (49-53)	0.742
Previous Hysterectomy, n (%)		11 (21.1%)	5 (26.3%)	6 (18.2%)	0.489
Urodynamic Urinary Incontinence	Any Kind. n (%)	20 (42.6%)	8 (42.1%)	12 (36.4%)	0.489
	SUI, n (%)	13 (25.0%)	5 (26.3%)	8 (24.2%)	0.868
	DOI, n (%)	4 (7.7%)	2 (10.5%)	2 (6.1%)	0.561
	MUI, n (%)	3 (5.8%)	1 (5.3%)	2 (6.1%)	0.905
Previous POP Surgery, n (%)		14 (26.9%)	7 (36.8%)	7 (21.2%)	0.221
Concomitant MUS, n (%)		7 (13.5%)	2 (10.5%)	5 (15.2%)	0.638
Concomitant Posterior Vaginal Mesh, n (%)		2 (3.8%)	1 (5.3%)	1 (3.0%)	0.687

Continuous variables are compared through Mann-Whitney U test. Categorical variables with Chi-Square test.
Legend: IQR: Interquartile Range; POP-Q: Pelvic Organ Prolapse Quantification System; POP: Pelvic Organ Prolapse; SUI: Stress Urinary Incontinence; DOUI: Detrusor Overactivity Incontinence; MUI: Mixed Urinary Incontinence; MUS: Mid-Urethral Sling.

III POP in treated or untreated compartment. Subjective outcome was evaluated through the POP validated Patients Global Impression of improvement (PGI-I) questionnaire with these scores: 1= very much better ; 2=much better; 3= a little better; 4= no change; 5=a little worse; 6=much worse; 7=very much worse [17].

Sexual function was measured through Female Sexual Function Index (FSFI) questionnaire validated in our national language which evaluates 6 domains: desire, arousal, lubrication, orgasm, satisfaction and pain [18]. FSFI score was assessed in women who had an active sexual life before and after POP surgical repair at follow-up visit.

Patients with incomplete data sets were excluded from statistical analysis

A descriptive statistical analysis was performed for every pre-, intra- and post- operative variable according to its type. We compared patients' characteristics and outcomes according to mesh kit through Mann Whitney U test for continuous variables and Chi-Square or Fisher's Exact Test (according to sample dimension) for categorical variables. Differences between FSFI and its sub scores at baseline and FSFI and its sub scores at one year and at least follow-up were calculated through Paired t-test. Different mesh kit FSFI were than compared through independent sample t-test. All statistical analyses were done with SPSS® (SPSS Inc., Chicago, IL, USA). A P value of 0.05 or less was considered statistically significant.

Study was performed in accordance with applicable laws and regulations, good clinical practices and ethical principles as described in the Declaration of Helsinki. All patients had underwritten informed consent before surgical procedure to collect and store data for further clinical studies and to record follow up visits.

Results

A total of 155 women underwent anterior trans vaginal mesh repair for III or higher stage of POP in our department during data recording.

Overall, 56 (36.1%) patients were sexually active at surgery time, 4 patients (7.1%) had an inadequate follow-up and were excluded from statistical analysis. Thus, a total of 52 patients (33.5%) were included, and all of them had a complete data-set. Median age at surgery was 62 years. Preoperative patient's characteristics are summarized in Table 1. No patient reported dyspareunia before surgery. Commercial mesh kit used was Prolift© (Johnson & Johnson) in 19 patients (36.5%) and Elevate© (AMERICAN MEDICAL SYSTEMS) in the remaining 33 patients (63.5%). Choice was made according to mesh kit availability depending on the operation period. No differences were observed in preoperative patients' characteristic between mesh kits, as reported in Table 1.

Median operative time was 55 min (IQR 45–70) and concomitant Mid Urethral Sling (MUS) was placed in 7 patients with coexisting symptomatic Stress Urinary Incontinence, furtherly confirmed with urodynamic evaluation before surgery. In Prolift© patients, median operative time was 57 min (IQR 45–80), while in Elevate© was 50 min (IQR 45–60). No intraoperative complication was recorded. In the Prolift© group there were 6 perioperative complications (18.2%), 4 medical (fever and UTI) and 2 surgical (delayed wound healing) and none exceeded Clavien 2. In the Elevate© group there were 2 perioperative complications (6.1%), 1 surgical Clavien 1 (hematoma) and 1 medical Clavien 2 (fever). There was a statistically significant difference in global perioperative complications between groups at Fisher's Exact test ($p = 0.014$), significantly higher in Prolift©. However, when considering only surgical complications, Fisher's Exact test found no statistically significant difference ($p = 0.264$)

Median follow up was 42 months (IQR 22–59) with a median age at last check visit of 67 years. All patients involved remained sexually active at last follow up.

Regarding late complications, in particular, only 1 patient reported dyspareunia (1.9%) in our experience. Mesh vaginal extrusion was reported in 1 patient (1.9%) at late follow up graded 2Aa/T2/S1 (IUGA/ICS classification), but it was successfully managed conservatively. Both these complications were in the Proflift© group. De Novo Stress Urinary Incontinence occurred in 4 (7.7%) patients who had subsequent MUS placement. No women reported de novo urge urinary incontinence, while with just POP correction 1 (1.9%) patient resolved urge urinary incontinence and 1 (1.9%) a mixed urinary incontinence.

POP recurrence in treated compartment occurred in 2 patients (3.8%) that underwent repeated surgery and were both in Prolift© group: 1 patient had a stage III apical vaginal segment prolapse and stage II posterior vaginal wall prolapse and underwent a following

Table 2
Global Follow Up Patients' Characteristics.

Global Follow Up Patients' Characteristics (n = 52)		12 months Follow Up Characteristics (n = 52)	Last Follow Up Characteristics (n = 52)
Age (years), median (IQR)		63 (57-67)	67 (61-71)
BMI (Kg/m^2), median (IQR)		24.9 (22.4-28.9)	25.1 (22.5-29.3)
Anterior Vaginal Wall Prolapse Stage (POP-Q), n (%)	0	44 (84.7%)	41 (78.9%)
	1-2	6 (11.5%)	11 (21.1)
	3-4	2 (3.8%)	0 (0.0%)
Apical Vaginal Segment Prolapse Stage (POP-Q), n (%)	0	43 (82.8%)	43 (82.8%)
	1-2	8 (15.3%)	9 (17.3%)
	3-4	1 (1.9%)	0 (0.0%)
Posterior Vaginal Wall Prolapse Stage (POP-Q), n (%)	0	31 (59.5%)	29 (55.8%)
	1-2	17 (32.7%)	22 (42.3%)
	3-4	4 (7.8%)	1 (1.9%)
Repeated POP Surgery, n (%)		0 (0.0%)	5 (9.6%)
PGI-I, median (IQR)		2 (1-3)	2 (1-3)
Mesh vaginal extrusion, n (%)		1 (1.9%)	0 (0.0%)
Urinary Incontinence	Any Kind, n (%)	17 (42.6%)	13 (25.0%)
	SUI, n (%)	12 (23.1%)	8 (15.4%)
	UUI, n (%)	3 (5.8%)	3 (5.8%)
	MUI, n (%)	2 (3.8%)	2 (3.8%)
Subsequent MUS Surgery, n (%)		0 (0.0%)	4 (7.8%)

Legend: IQR: Interquartile Range; POP-Q: Pelvic Organ Prolapse Quantification System; POP: Pelvic Organ Prolapse; PGI-I: Patient Global Impression of Improvement; SUI: Stress Urinary Incontinence; UUI: Urge Urinary Incontinence; MUI: Mixed Urinary Incontinence; MUS: Mid-Urethral Sling.

transvaginal hysterectomy and posterior colporrhaphy and 1 patient had a recurrent stage III anterior vaginal wall prolapse with concomitant SUI and made a subsequent anterior colporrhaphy with mid-urethral sling placement. De novo stage III posterior vaginal wall prolapse reported were 4 (7.8%) and 3 of them underwent subsequent surgery with 2 posterior colporrhaphy and 1 posterior vaginal mesh (Prolift©). The patient who did not underwent surgery reported no symptoms and refused operation.

Subjective outcome was defined through PGI-I at last follow up, which was median 2 (IQR 1–3), much better. Global Follow up characteristics are reassumed in Table 2.

When comparing follow up between the two mesh kits, groups were found without statistically significant differences, as reported in Table 3. Mean follow up differed between groups ($p < 0.001$) as in Prolift© group was 79.2 months (SD 24), while in Elevate© group was 50 months (SD 32). However, no statistically significant difference was found in each follow up element, as reported in Table 3.

Regarding sexual function, at last follow-up there were no statistically significant difference in term of total FSFI score ($p > 0.05$). Even at sub-scores analysis desire, excitement, lubrication, orgasm, satisfaction and especially pain were unaffected by surgery ($p > 0.05$) as showed in Table 4. In Table 5 we reported comparison between groups, and outcomes was similar, independently from mesh kit used.

Discussion

In this study we reported our experience with transvaginal mesh repair for POP in sexually active women, that resulted to be safe and well tolerated with a good subjective and anatomic success rate, low complications rate, including mesh related complications even at a long term follow up. Regarding our primary endpoint, sexual function was not impaired from surgery, as reported from FSFI and results remained stable at last follow up.

Sexually active patients were generally young and with a low BMI, as emerged from our data, so they might appear to be suitable also for abdominal sacrocolpopexys. The decision to treat them with a vaginal approach, was due to isolated anterior compartment prolapse in most cases or to previous abdominal surgery. In fact, in our center we also perform laparoscopic robot-assisted sacrocolpopexys, that is performed from the same surgeons who perform transvaginal mesh surgery, so the surgical approach choice was made considering the patient globally.

Furthermore, when we reported the recurrence rate and reintervention for POP, the decision to treat the recurrent POP vaginally was due to surgeons' experience and patients' characteristics as previously stated, but abdominal approach was also considered during the choice.

Only 4 patients (7.1%), had incomplete follow up or data sets, a small proportion if compared to the total sexually active population, thus their exclusion, may affect only partially the global results reported. In fact, patients with incomplete follow up may be due to unsuccessful surgery results, including low FSFI values, or to other factors. However, if we consider the low lost at follow up rate, we may assume that the global study results might be considered reliable.

In addition, we might report that despite the prospective and precise follow up carried on and an invasive urodynamic assessment available for most patients, urinary symptoms were not always evaluated with validated questionnaire, thus they were not available for the whole cohort of patients reported. In fact, study design is retrospective. For this reason, all urinary symptoms, including stress or urge incontinence were evaluated on patients' reported symptoms to avoid biases related to the low availability, especially at long term follow up, of the validated questionnaires and because we wanted to focus more on sexual function.

However, currently the effect of vaginal mesh repair on sexual function is controversial and available data are mainly related to anterior compartment prolapse as some reports showed no significant effect of anterior compartment mesh repair, while other reports described high postoperative dyspareunia [19]. The studies on posterior compartment mesh repair are limited until more robust data are available [20]. Our cases refer mainly to anterior compartment defects.

In 2008 FDA's warning reported that there were insufficient data regarding dyspareunia, sexual function and mesh complications were rare, while the 2011 FDA update communication reported that serious complications associated with transvaginal

Table 3
Follow Up Patients' Characteristics according to Mesh Kit.

Follow Up Patients' Characteristics according to Mesh Kit (n = 52)		12 months Follow Up Characteristics		Comparison	Last Follow Up Characteristics		Comparison
Mesh Kit		Prolift (n = 19, 36.5%)	Elevate (n = 33, 73.5%)	p-value	Prolift (n = 19, 36.5%)	Elevate (n = 33, 73.5%)	p - value
Anterior Vaginal Wall Prolapse Stage (POP-Q), n (%)	0	15 (79.0%)	29 (87.8%)	0.443	15 (79.0%)	26 (78.8%)	1.000
	1-2	2 (10.5%)	4 (12.2%)	1.000	4 (21.0%)	7 (21.2%)	1.000
	3-4	2 (10.5%)	0 (0.0%)	0.129	0 (0.0%)	0 (0.0%)	NA
Apical Vaginal Segment Prolapse Stage (POP-Q), n (%)	0	15 (78.9%)	28 (84.8%)	0.708	15 (78.9%)	28 (84.8%)	0.708
	1-2	3 (15.8%)	5 (15.2%)	1.000	4 (21.0%)	5 (15.2%)	0.708
	3-4	1 (5.3%)	0 (0.0%)	0.365	0 (0.0%)	0 (0.0%)	NA
Posterior Vaginal Wall Prolapse Stage (POP-Q), n (%)	0	10 (52.6%)	21 (63.7%)	0.436	10 (52.6%)	19 (57.6%)	0.730
	1-2	6 (31.6%)	11 (33.3%)	0.897	8 (42.1%)	14 (42.4%)	0.982
	3-4	3 (15.8%)	1 (3.0%)	0.132	1 (5.3%)	0 (0.0%)	0.365
Repeated POP Surgery, n (%)		0 (0.0%)	0 (0.0%)	NA	4 (21.0%)	1 (3.0%)	0.054
PGI-I, median (IQR)		2 (1-2)	2 (1-3)	0.712	2 (1-2)	2 (1-3)	0.747
Mesh vaginal extrusion, n (%)		1 (5.3%)	0 (0.0%)	0.365	0 (0.0%)	0 (0.0%)	NA
Urinary Incontinence	Any Kind, n (%)	7 (36.9%)	10 (30.3%)	0.761	6 (31.6%)	7 (21.2%)	0.510
	SUI, n (%)	5 (26.3%)	7 (21.2%)	0.739	4 (21.0%)	4 (12.1%)	0.443
	UUI, n (%)	1 (5.3%)	2 (6.1%)	0.905	1 (5.3%)	2 (6.1%)	0.905
	MUI, n (%)	1 (5.3%)	1 (3.0%)	1.000	1 (5.3%)	1 (3.0%)	1.000
Subsequent MUS Surgery, n (%)		0 (0.0%)	0 (0.0%)	NA	1 (5.3%)	3 (9.1%)	0.618

Continuous variables are compared through Mann-Whitney U test. Categorical variables with Chi-Square test or Fisher's Exact Test according to sample dimension.
Legend: IQR: Interquartile Range; POP-Q: Pelvic Organ Prolapse Quantification System; POP: Pelvic Organ Prolapse; PGI-I: Patient Global Impression of Improvement; SUI: Stress Urinary Incontinence; UUI: Urge Urinary Incontinence; MUI: Mixed Urinary Incontinence; MUS: Mid-Urethral Sling.

Table 4
Sexual Quality of LIfe before and after Transvaginal Mesh Repair for Pelvic Organ Prolapse.

Sexual Quality of LIfe before and after Transvaginal Mesh Repair for Pelvic Organ Prolapse		Preoperative Characteristics(n = 52)	12 months Follow Up Characteristics (n = 52)	p value	Last Follow Up Characteristics (n = 52)	p value
FSFI, mean (SD)	Global Score	16.3 (5.1)	16.2(4.9)	0.886	16.4 (5.0)	0.856
	Desire	3.2 (0.8)	3.1 (0.8)	0.592	3.1 (0.8)	0.597
	Arousal	2.9 (1.1)	2.8 (0.9)	0.741	2.8 (0.9)	0.746
	Lubrication	2.7 (1.1)	2.6 (1.0)	0.421	2.5 (1.0)	0.322
	Orgasm	2.7 (1.0)	2.6 (1.1)	0.662	2.6 (1.1)	0.635
	Satisfaction	2.8 (0.9)	2.7 (0.9)	0.423	2.6 (0.9)	0.336
	Pain	3.0 (1.1)	3.6 (1.2)	0.187	3.8 (1.7)	0.124

Legend: FSFI: Female Sexual Function Index; SD: Standard Deviation. Variables are compared through Student's t-test.

Table 5
FSFI sub-analysis according to mesh kit.

FSFI sub-analysis according to mesh kit Prolift (n = 19, 36.5%) Elevate (n = 33, 73.5%)		Preoperative Characteristics		p-value	12 months Follow Up Characteristics		p-value	Last Follow Up Characteristics		p -value
		Prolift	Elevate		Prolift	Elevate		Prolift	Elevate	
FSFI, mean (SD)	Global Score	18.6 (11.6)	16.4 (10.3)	0.508	17.1 (11.7)	14.5 (9.8)	0.422	17.4 (11.5)	14.8 (9.9)	0.419
	Desire	3.4 (1.8)	3.4 (1.6)	0.928	2.9 (1.9)	2.9 (1.8)	0.939	2.9 (1.8)	2.9 (1.7)	0.942
	Arousal	3.1 (2.0)	2.9 (1.9)	0.676	2.8 (1.9)	2.6 (1.7)	0.721	2.8 (2.0)	2.6 (1.9)	0.739
	Lubrication	3.0 (2.3)	2.7 (2.0)	0.622	2.9 (2.4)	2.2 (2.0)	0.187	2.9 (2.3)	2.0 (1.9)	0.197
	Orgasm	3.1 (2.1)	2.7 (2.1)	0.549	2.8 (2.5)	2.4 (1.9)	0.566	2.8 (2.2)	2.4 (2.0)	0.566
	Satisfaction	3.2 (2.0)	2.9 (1.9)	0.668	2.9 (2.1)	2.6 (1.9)	0.531	2.9 (2.0)	2.5 (1.8)	0.487
	Pain	2.8 (2.8)	3.8 (2.2)	0.213	3.0 (2.7)	4.0 (2.1)	0.152	3.1 (2.6)	4.2 (2.2)	0.132

Legend: FSFI: Female Sexual Function Index; SD: Standard Deviation. Variables are compared through Student's t-test.

POP repair with mesh are not rare, identifying such as "vaginal shortening, tightening, and/or pain due to mesh contraction as a previously unidentified risk of transvaginal POP repair with mesh, and it provides recommendations for patients and health care providers."

The FDA statement in 2011 initially generated great confusion in patients, the public, physicians, and the media with a high increase of lawsuit [21]. According to lawsuits and media, there are numerous reports of chronic pelvic pain and dyspareunia after mesh vaginal repair [22]. In a study of 726 transvaginal mesh procedures for POP with ten different kits between 2006 and 2010, dyspareunia was reported by 10% of 181 sexually active patients, at 12 months from surgery [23]. In a systematic review the dyspareunia rate after a vaginal mesh procedure was reported in 8.9% cases (range; 0–67%; 95% CI 8.0–10.0) [24]. In a retrospective review of 398 procedures performed for the removal of vaginal mesh dyspareunia was the primary indication in 57% of cases [25].

In a systematic review, a significantly higher incidence of dyspareunia was observed after vaginal than abdominal (open or laparoscopic) repair of apical compartment prolapse but there was no significant difference between the incidence of dyspareunia for mesh repair versus fascial vaginal repair [26].

It is clear that surgery employing synthetic mesh may induce an important inflammatory reaction which can modify the healing and reconstruction of these tissues, creating an anomalous situation which sometimes weighs heavily on the women sexual health and her physical and mental wellbeing [27]. Although surgery improve anatomical outcomes, individual domains of FSFI may worsen especially pain and lubrication domain [28,29].

Randomized trials comparing vaginal mesh versus native tissue repair surgery did not demonstrate a difference in de novo dyspareunia, or in postoperative dyspareunia [30,31]. In fact, the most important risk factor for postoperative dyspareunia is preoperative dyspareunia and pain during sexual intercourse is frequently reported by women with POP [32].

Others risk factors included younger age, fibromyalgia, early postoperative pain, poorer physical health, and somatization. Understanding risk factors for pelvic pain after mesh implantation may improve patient selection [33]. Moreover it is very important to establish the baseline sexual function before POP surgery, preferably using validated condition specific questionnaires [34]. In fact, mesh vaginal repair for POP seems to improve parameters of sexual function measured by FSFI questionnaire. Pain affected patients only during the initial postoperative months [35].

Counselling with patients for knowing their problems, doubts, expectations must drive surgeon about the decision of a correct surgical approach [36].

Our study is included in this controversial topic. Our data were collected in high volume center for POP's surgery with a high surgical expertise and with a correct preoperative counseling which underline that surgery does not restore the native anatomy and function of patient. In our findings we did not found an increase in dyspareunia in patients submitted to the previously available commercial kit whose production has been now suspended. A further analysis according to patients' FSFI questionnaire demonstrated that surgery did not affect the sexual function domain. Moreover, as the sub score pain analysis demonstrated, pain was not significantly worse after mesh placement, although domain sub score increased from baseline at last follow up. These data should be carefully interpreted, as ageing and menopause may affect this domain [37] and we evaluated patients with a long term follow up. The other domain remained stable during all the follow up, demonstrating that desire, lubrication, orgasm and satisfaction remained substantially stable.

Mesh kit used was not related to perioperative surgical complications rate, or to subjective or objective outcomes, thus suggesting that the type and shape of these polypropylene mesh or the surgical technique were not associated with outcomes or complications. However, follow up differed between groups, this was related to the commercial mesh kit recall, that made one mesh kit (Prolift©) unavailable much time before the other one (Elevate©), thus affecting the results.

Limitations in the study are its retrospective nature, the small sample analyzed and the variability between patients and commercial mesh kit, that makes comparison difficult as these kits are no longer available. Moreover, we did not have the possibility to compare our patients with a control group.

Surgeons' experience could have affected the outcomes too, as proved by the low complications rate reported, low POP recurrence rate and substantially high patient subjective satisfaction after surgery. Surgical expertise, more than mesh kit implanted could be an important predictive factor for post-operative functional and anatomical outcome as this kind of surgery needs an adequate learning curve [38].

The onset of de novo dyspareunia is not statistically significant in patients who underwent trans vaginal mesh repair if correct informed and followed in the short and long period. We have not noticed a significant increase in the overall sexual function and the FSFI domains either, this is probably due to the long follow-up and the progressive ageing of the patients that worsen desire, lubrication, orgasm and satisfaction. Further studies are mandatory to clearly assess the mesh impact in POP repair on sexual function.

Comment

In our experience, global sexual function doesn't seem to be affected by transvaginal mesh repair of the anterior and/or apical POP when performed by expert surgeons, independently from mesh kit used. Ageing might be a confounding factor when reporting sexual function. Dyspareunia was a rare complication in patients during follow-up and pain was not a major complaint and the complication rate was low.

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