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Correction of pelvic organ prolapse by laparoscopic lateral suspension with mesh: A clinical series

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ABSTRACT

Objective: Illustrating the outcomes of laparoscopic lateral suspension by mesh for pelvic organ prolapse repair.
Study design: A retrospective observational study was conducted collecting medical records of 48 patients treated between May 2016 and April 2018 in two different centers in Italy. Pre- and post-operative clinical evaluations as well as patients' satisfaction scores were considered. Patients were followed for two years. Statistical analysis was determined using the chi-square test in intention-to-treat and per-protocol analyses, while Kaplan-Meier curves were built for assessing the prolapse recurrence and the symptoms recurrence. The Steel-Dwass test for pairwise comparisons was used to compare median scores from the King's General Health Perception Questionnaire answers.
Results: Regarding the anatomical result, the outcome was either optimal or satisfactory (PoP-Q $\leq$1) at 12 months in 92% of patients for anterior compartment, in 100% for apical compartment, and in 75% for posterior compartment (intention-to-treat). Kaplan-Meier curves depicted a repair of prolapse in 70% of cases, with better outcomes for the anterior and the apical compartment. Patient self-perception of health was over 80% at each follow-up evaluation.
Conclusion: Laparoscopic lateral suspension is a reasonable technique for treatment of pelvic organ prolapse. Further studies are needed to prove such a technique versus alternative surgeries.

Introduction

Pelvic organ prolapse is a common benign condition. Accurate data regarding the epidemiology and severity of pelvic organ prolapse is challenging. As a matter of fact, there is no consensus in relation to the degree of prolapse which can be considered a normal variation of female pelvic support, and what instead represent a true disorder [1,2].

Pelvic organ prolapse therapy is usually indicated for symptomatic women only and laparoscopic sacrocolpopexy and sacrohysteropexy with meshes are currently considered safe and effective surgical treatments [3,4]. Nevertheless, these procedures require dissection and fixation of the prosthesis to the sacral promontory, which can be very demanding and may lead to neurovascular injuries.

Since 1997, Dubuisson et al [5] depicted a prosthetic laparoscopic suspension of the uterus (or alternatively of the vaginal vault) which strength lies in the avoidance of sacral dissection.

The aim of this study is to illustrate the outcomes of the laparoscopic lateral suspension with mesh (LLS) technique in treating pelvic organ prolapse in a sample of women coming from two different centers.

Material and methods

Between May 2016 and April 2018, a retrospective collection of patients records was conducted. All of them were affected by pelvic organ prolapse and underwent laparoscopic lateral suspension with mesh. Patients were treated at the Azienda Ospedaliero-Universitaria S. Anna of Ferrara and at the Proctological Surgical Unit of the Policlinico of Abano Terme. Patients eligible for LLS surgery were those who presented a PoP-Q stage equal to or higher than 2, an absent or mild rectocele, and who complained pelvic

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organ prolapse-related symptoms. The choice of LLS rather than other techniques for treating pelvic organ prolapse were left to the patients, after careful information on each technique.

The surgical procedure was as the same LLS with mesh technique described by Dubuisson et al [5]. Briefly, laparoscopic dissection of the vesicovaginal space is firstly accomplished. Then, a V-shaped mesh is introduced into the abdomen and placed over the dissected anterior wall of the vagina. Thirdly, a 3-mm skin incision is made on both sides, approximately 2 cm above the iliac crest and 4 cm posterior to the anterior superior iliac spine to allow the introduction of laparoscopic grasping forceps. These are retroperitoneally pushed towards the round ligament, thus entering in the peritoneal cavity to grasp the mesh arms, which can be so retracted backwards. The skin incisions is consecutively sutured. A symmetrical lateral tension-free suspension to the anterior vaginal wall is provided, due to retroperitoneal fibrosis over the arms of the mesh which later occurs and encloses the prosthesis [6]. The V-prosthesis is obtained cutting a square shape mesh, leaving two arms of about 2 cm in width. The length of the arms is adapted to the patient' abdomen. The apex of the V is smoothed.

Medical records, gynecological examinations and questionnaires were used in order to collect information regarding risk factors, prolapse extent, patients symptoms before surgery and during follow-up. The extent of prolapse was quantified using the Pelvic Organ Prolapse Quantification grading system (PoP-Q) [7] and the Baden-Walker Halfway system [8] (for allowing comparisons with first reports of Dubuisson et al [5]). Quality of life was evaluated in a proportion of patients by the King's Health Questionnaire, conveniently clustered in 7-items [9]. Moreover, short term and long term complications were also assessed. The follow-ups were scheduled at 1 month, 3, 6, 12 and 24 months post-surgery.

In order to define anatomic cure, NIH Workshop guidelines to assess pelvic organ prolapse surgery anatomical outcome were adopted [10]. Complications were evaluated applying Clavien-Dindo grade [11], and mesh-related complications classified using the joint International Urogynecological Association/International Continence Society (IUGA/ICS) scale [12].

Descriptive data are reported per-protocol and intention-to-treat. Outcomes results are also reported as Kaplan-Maier curves. The rates of outcomes were compared with pre-operative assessments, both overall (in case of no-censored data - per-protocol comparisons) and in an intention-to-treat analysis (in case of missing or censored data), by using the chi-square test. The median score of the King's Health Questionnaire before surgery and at each follow-up was assessed using the Steel-Dwass test for pairwise comparisons. A p value <0.05 was set for significance. Kyplot 2.0 software was used for calculations.

Results

Forty-height women with pelvic organ prolapse were recruited. 23 of them underwent surgery in Ferrara, while 25 patients were treated in Abano Terme. All of them completed at least 1-month follow-up while 44 had a 3-months follow-up, 42 had a 6-months follow-up, 24 had a 12-months follow-up, 5 had a 24-months follow-up.

Demographic data and preoperative conditions of patients are shown in Table 1.

According to the PoP-Q staging system, the preoperative evaluation showed that 38% of patients had a stage 2, 56% had a stage 3 and 6% had a stage 4. Median PoP-Q value of the total population was 3.

LLS was performed alone in 65% of the cases, while 35% of women underwent a concurrent surgeries either gynecological (bilateral ovariosalpingectomy, salpingectomy) or urogynecologic (transobturator tape placement, Stapler trans-anal rectal resection, colpoperineoplasty, rectocele fascial repair) (Data in Brief). No severe intraoperative complications occurred. Early postoperative complications included one case of urinary tract infection, which was treated with intravenous antibiotics, and one case of

Table 1
Descriptive statistics: patients characteristics.

	All patients
	(n = 48)
Age (years), median (limits)	63 (37-86)
BMI (kg/m2), median (limits)	23.39 (19.5-33.1)
Parity, median (limits)	2 (0-5)
Number of vaginal deliveries, median (limits)	2 (0-5)
Multiparity, n (%)	31 (93.9) (missing 15 cases)
Menopausal, n (%)	43 (89.6)
Age from menopause, n (median, limits)	12 (1-35) (missing 10 cases)
Lower urinary tract symptoms and other symptoms, n (%)	
Urinary urgency	16 (33.3)
Urinary frequency	17 (35.4)
Stress urinary incontinence	21 (43.8)
Urge incontinence	21 (43.8)
Nocturia	12 (25)
Dysuria	10 (20.8)
Incomplete voiding	7 (14.6)
Bulging	24 (50)
Constipation	14 (29.2)
Sexual activity, n (%)	44 (91.7)
Dyspareunia	8 (16.7)
Pelvic pain, n (%)	10 (20.8)
Prior hysterectomy, n (%)	7 (14.5)
Prior POP surgery, n (%)	5 (10.4)
None	42 (87.5)
Laparoscopic sacrocolpopexy	0
Vaginal POP surgery	5 (10.4)
Other	0 (0)
Prior stress urinary incontinence surgery, n (%)	0 (0)

bradycardia. Four cases of long-term complications were observed: 3 patients needed a mesh re-fixation to the vagina after 6 months, and 1 patient underwent a surgical removal of an abdominal wall stitch granuloma. According to Clavien-Dindo classification of surgical complications, one 2nd grade and three 3rd grade complications were observed and treated (Data in Brief). No mesh exposures or extrusions were observed.

One month after surgery, 37.5% of women were found to have a PoP-Q equal to or greater than 1. The same PoP-Q score was observed in 70.1% of patients 12 months after surgery, and 80% after 24 months (per-protocol descriptive results) (Data in brief). The per-protocol rates were calculated by excluding missing data, thereby providing an estimate of the anatomical outcome. The Table reported in the Data in Brief file also provides descriptive data on symptoms associated to pelvic organ prolapse.

Table 2 reports anatomical outcomes rates and comparisons between pre-surgical and post-surgical assessment, while Table 3 reports symptoms outcomes between pre- and post-surgical evaluation.

Regarding the anatomical result, the outcome was either optimal or satisfactory (PoP-Q ≤ 1) at 12 months in 92% of patients for the anterior compartment, in 100% for the apical compartment, and in 75% for the posterior compartment (intention-to-treat analysis). The intention-to-treat rates were calculated on the whole database at the enrolling time, thereby providing another kind of estimate of the anatomical outcome.

As an additional way to illustrate the outcomes, the Kaplan-Meier curves were also built. Kaplan-Meier curves for the recurrence of any kind of prolapse, both using the Baden and Walker Halfway system and the PoP-Q staging system, showed that at least 70% of patients did not experience any pelvic organ prolapse recurrence. Fig. 1 reports the Kaplan-Meier curves, while additional information is reported in Data in Brief file. In the Kaplan-Meier curves, anatomical repair of cystocele or rectocele along with the improvement of some symptoms linked to the pelvic organ prolapse is reached in more than 70% of patients (Data in Brief), with higher rates for the anterior compartment. After 12 and 24 months from surgery, the cumulative recurrence prolapse rate was 8.3%, the persistence rate was 4.2%.

The 7-items King's Health Questionnaire was administered to 23 women before the surgical treatment and at each follow-up evaluation. Results are depicted in Fig. 1 (General Health perception trend) and in Data in Brief, which highlight how General Health perception was good in more than 80% of patients. The Steel-Dwass test for pairwise comparisons of King's Health Questionnaire median scores was the following: pre-surgery median 2 (limits 0–3); 1 month follow-up median 0 (limits 0–2), $p < 0.001$; first trimester median 0 (limits 0–2), $p < 0.001$; second trimester median 0 (limits 0–1), $p < 0.001$; one year median 0 (limits 0–1), $p < 0.001$; two year median 0 (limits 0–1), $p < 0.05$.

Comment

Pelvic organ prolapse treatment is on constant development, in fact only recently it has been understood the importance of patient's symptoms relief, alongside the anatomical success of the performed technique [13].

This study follows the one of Dubuisson et al [5], producing more evidence available for meta-analysis on the feasibility of the technique. Outcomes comparison with literature is limited due to the few amount of studies that exist on LLS. With regard to the operating time, in our study the mean duration of LLS surgery was 104 min, relevantly lower than the time reported for laparoscopic sacral colpopexy (LSC), 199 ± 46 min [14]. This discrepancy could be valued as a reason to prefer LLS over LSC. In Veit-Rubin 2017 report [6] the mean operating time was 201 min, being comparable

Table 2
Outcomes data: anatomical pattern.

	Pre-surgery	1 month post-surgery (no censored data)	Rates calculated on the whole database (intention-to-treat)	p value	
				Pre-surgery vs 1-month follow-up	Pre-surgery vs whole database rates (intention-to-treat)
Cystocele, n (%)					
0	4 (8.3%)	34 (70.8%)	26 (54.2%)	<0.001	<0.001
1	4 (8.3%)	12 (25.0%)	16 (33.3%)		
2	11 (22.9%)	2 (4.2%)	5 (10.4%)		
3	26 (54.2%)	0	1 (2.1%)		
4	3 (6.3%)	0	0		
Hysterocele, n (%)					
0	6 (12.5%)	44 (91.7%)	40 (83.3%)	<0.001	<0.001
1	11 (22.9%)	4 (8.3%)	8 (16.7%)		
2	17 (35.4%)	0	0		
3	12 (25.0%)	0	0		
4	2 (4.2%)	0	0		
Rectocele, n (%)					
0	21 (43.8%)	41 (85.4%)	32 (66.7%)	<0.001	0.113
1	17 (35.4%)	6 (12.5%)	8 (16.7%)		
2	9 (18.8%)	1 (2.1%)	8 (16.7%)		
3	1 (2.1%)	0	0		
4	0	0	0		
PoP-Q, n (%)					
0	0	30 (62.5%)	15 (31.3%)	<0.001	<0.001
1	0	16 (33.3%)	21 (43.8%)		
2	18 (37.5%)	2 (4.2%)	11 (22.9%)		
3	27 (56.3%)	0	1 (2.1%)		
4	3 (6.3%)	0	0		

Table 3
Outcomes data: symptoms.

	Pre-surgery	1 month post-surgery (no censored data)	Overall cases (intention-to-treat)	p value	
				Pre-surgery vs 1-month follow-up	Pre-surgery vs overall cases (intention-to-treat)
Urinary stress incontinence, n (%)					
Nothing	27 (56.3%)	42 (87.5%)	39 (81.3%)	0.003	0.031
Mild	12 (25.0%)	6 (12.5%)	8 (16.7%)		
Moderate	8 (16.7%)	0	1 (2.1%)		
Severe	1 (2.1%)	0	0		
Urinary urge incontinence, n (%)					
Nothing	27 (56.3%)	45 (93.8%)	41 (85.4%)	<0.001	0.008
Mild	10 (20.1%)	3 (6,3%)	6 (12.5%)		
Moderate	10 (20.1%)	0	1 (2.1%)		
Severe	1 (2.1%)	0	0		
Bulging, n (%)					
Nothing	25 (52.1%)	45 (93.8%)	38 (79.2%)	<0.001	0.008
Mild	9 (18.9%)	2 (4.2%)	9 (18.8%)		
Moderate	13 (27.1%)	1 (2.1%)	1 (2.1%)		
Severe	1 (2.1%)	0	0		
Constipation, n (%)					
Nothing	34 (70.8%)	43 (89.5%)	38 (79.2%)	0.048	0.646
Mild	8 (16.7%)	1 (2.1%)	6 (12.5%)		
Moderate	6 (12.5%)	3 (6.3%)	3 (6.3%)		
Severe	0	1 (2.1%)	1 (2.1%)		

to the one reported in the current study, in spite of additional concomitant surgeries. Moreover, the operating times reported in other works are not comparable to the one of this study due to dissimilarities in the surgical approach [15–17].

Concerning the anatomical outcome, the analysis of PoP-Q stage outcome shows a statistically significant improvement. Equal results were observed for the anterior and apical compartment. The anatomical success rate was between the 80% and 90% in the intention-to-treat analysis. These success rates are comparable with those reported for LLS [6], sacral colpopexy and sacral hysteropexy [3,18].

All the cases of de novo pelvic organ prolapse (i.e. appearance of a new prolapse that was absent before the treatment) were low to mild degree rectoceles, which did not significantly interfere in patients' quality of life. No mesh exposure or extrusion was noticed, while in literature exposure rate is as high as 5.5% [19]. Reoperation rate for pelvic organ prolapse was 6.3%, lower than 7.3% reported in literature for LLS [6]. Generally, a lower reoperation rate and a lower number of complications was found of both the other LLS [6] and sacral fixation studies [20,21].

At 1-year follow-up after surgery for pelvic organ prolapse, the rate of stress incontinence (de novo or persistent) is 6.6% [22]. In the current series, as reported in Data in Brief file, an incidence of 12.5% was observed at 1-month follow-up, and of 16.7% after 12 months from the surgery. De novo urinary incontinence was reported by just one woman after 1 month (2.1%) and by two women after one year (8.3%). The higher rate than what expected could be explained by the low numerosity of the series or by the retrospectivity of the data collection. Incidence of urge incontinence was 8.3% at both 1-month and 1-year evaluations. As no data are available in literature regarding urge incontinence after LLS, the finding is not comparable. It should be reported that some urinary symptoms can be not related to the surgery [23].

Vaginal bulging was the most frequent and bothersome preoperative symptom complained by the patients, since it affected a half of the sample. As reported in Data in Brief file, after 1 month it decreased to 6.3%, and at 1-year the rate was 12.5%. An equal outcome was measured evaluating bulge symptoms of all hysteropexies approaches [20].

Pelvic pain was observed in 6.3% of patients after 1 month, and 8.3% after 1 year (Data in Brief). No patient complained this symptom after 24 months after surgery. No other data regarding post-LLS pelvic pain are available in literature. However, this rate is lower if compared with sacral fixation techniques [24].

None of the sexually active patients complained dyspareunia at any postoperative evaluation. The outcome is therefore better than the one reported by Veit-Rubin (4.2%) [6], but should be cautiously interpreted due to the low sample size.

As regards patients' quality of life, this study shows a statistically significant improvement of King's Health Questionnaire General Health section at each follow-up evaluation.

Some limitations of the present study should be disclosed. The small sample size of the study was collected retrospectively, with patients coming from two hospitals, with three laparoscopic surgeons performing LLS. The small sample size does not allow best estimates of outcomes and complications. The concern is increased by the need to address missing and censored data of follow-ups. The aim of the study was to assess on our population a well defined advantageous technique [5] in terms of patients safety

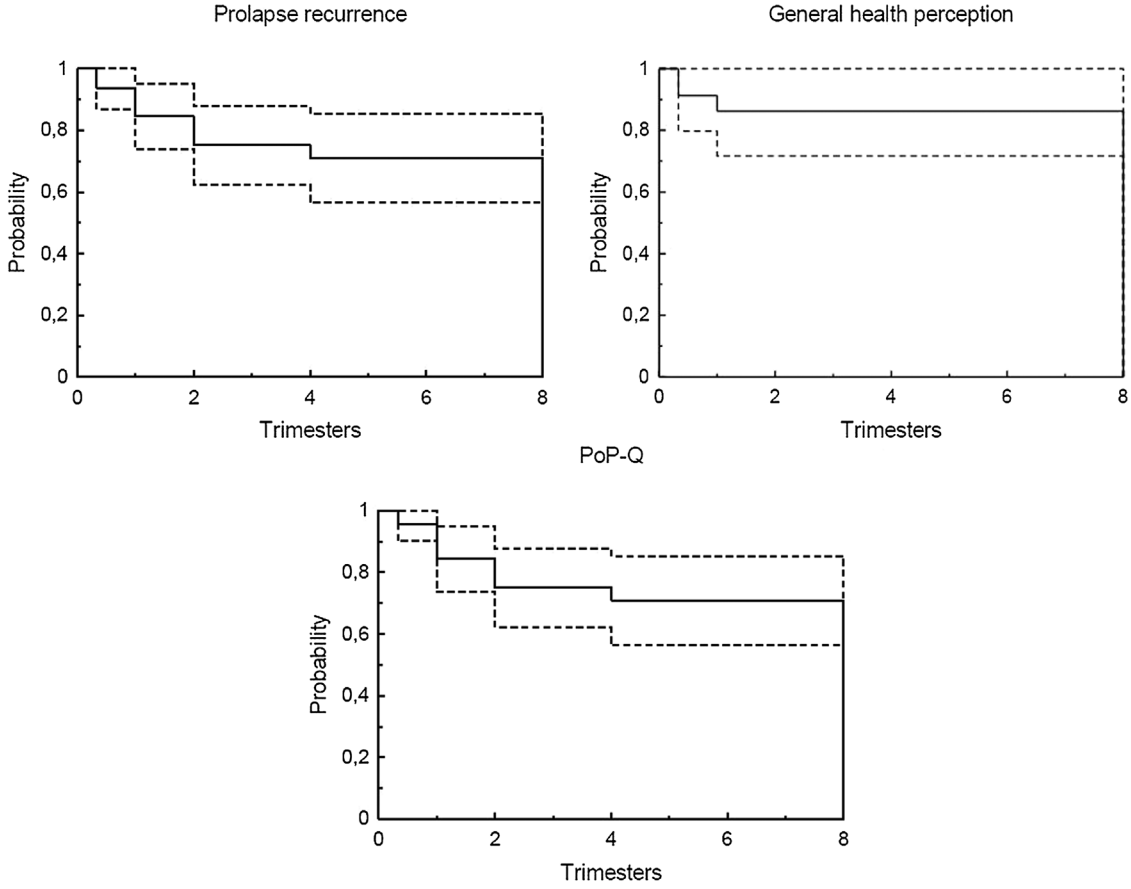

Fig. 1. On the left: Kaplan-Meier curve for recurrence of every kind of prolapse (+2 or over - Baden and Walker). On the right: Kaplan-Meier curve for the general health perception (King's 7-item score). Bottom: Kaplan-Meier curve for prolapse recurrence (+2 or over - PoP-Q).

and effectiveness. Therefore our data collection is retrospective in nature aiming to a prospective data collection of LLS prolapse repair versus traditional surgeries.

Conclusion

The outcomes of the LLS reported in this multicentric Italian sample are similar to those reported by Dubuisson's team. The findings suggest a certain degree of reproducibility of the technique, which achieves the goal of a good surgical treatment of the pelvic organ prolapse along with an improvement in quality of life. Additionally, LLS is also technically easier to perform.

Prospective observational studies or randomized controlled trials, which may compare LLS to traditional pelvic organ prolapse surgical treatments, should be encouraged.

Declaration of Competing Interest

All the authors disclose no conflicts of interest.

References

[1] Wilkins MF, Wu JM. Epidemiology of pelvic organ prolapse. Curr Obstet Gynecol Rep 2016;5:119–23.
[2] Barber MD, Maher C. Epidemiology and outcome assessment of pelvic organ prolapse. Int Urogynecol J 2013;24:1783–90.
[3] Barber MD, Maher C. Apical prolapse. Int Urogynecol J 2013;24:1815–33.
[4] Barber MD. Pelvic organ prolapse. BMJ 2016;354:i3853.
[5] Dubuisson JB, Jacob S, Chapron C, Fauconnier A, Decuypere F, Dubernard G. [Laparoscopic treatment of genital prolapse: lateral utero-vaginal suspension with 2 meshes. Results of a series of 47 patients]. Gynecol Obstet Fertil 2002;30:114–20.
[6] Veit-Rubin N, Dubuisson JB, Gayet-Ageron A, Lange S, Eperon I, Dubuisson J. Patient satisfaction after laparoscopic lateral suspension with mesh for pelvic organ prolapse: outcome report of a continuous series of 417 patients. Int Urogynecol J 2017;28:1685–93.
[7] Bump RC, Mattiasson A, Bø K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10–7.
[8] Baden WF, Walker TA. Genesis of the vaginal profile: a correlated classification of vaginal relaxation. Clin Obstet Gynecol 1972;15:1048–54.
[9] Kelleher CJ, Cardozo LD, Khullar V, Salvatore S. A new questionnaire to assess the quality of life of urinary incontinent women. Br J Obstet Gynaecol 1997;104:1374–9.
[10] Barber MD, Brubaker L, Nygaard I, et al. Defining success after surgery for pelvic organ prolapse. Obstet Gynecol 2009;114:600–9.
[11] Dindo D, Demartines N, Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205–13.
[12] Haylen BT, De Ridder D, Freeman RM, et al. An International Urogynecological Association / International Continence Society Joint Report on the Terminology for Female Pelvic Floor Dysfunction. Neurourol Urodyn 2010;29:4–20.
[13] Zimmerman CW. Pelvic organ prolapse: basic principles. In: Jones HW, Rock JA, editors. Te linde's operative gynecology. 11th ed. Wolters Kluwer; 2015. p. 843.
[14] Paraiso MF, Jelovsek JE, Frick A, Chen CC, Barber MD. Laparoscopic compared with robotic sacrocolpopexy for vaginal prolapse: a randomized controlled trial. Obstet Gynecol 2011;118:1005–13.
[15] Giannini A, Russo E, Mannella P, Simoncini T. Single site robotic-assisted apical lateral suspension (SS R-ALS) for advanced pelvic organ prolapse: first case reported. J Robot Surg 2017;11:259–62.

[16] Simoncini T, Russo E, Mannella P, Giannini A. Robotic-assisted apical lateral suspension for advanced pelvic organ prolapse: surgical technique and perioperative outcomes. Surg Endosc 2016;30:5647–55.
[17] De Los Ríos JF, González PA. A report of three cases of using Dubuisson's laparoscopic lateral ventrosuspension for correcting apical prolapse when there is contraindication for sacral suspension. Rev Colomb Obstet Ginecol 2008;59.
[18] Gutman R, Maher C. Uterine-preserving POP surgery. Int Urogynecol J 2013;24:1803–13.
[19] Dällenbach P, De Oliveira SS, Marras S, Boulvain M. Incidence and risk factors for mesh erosion after laparoscopic repair of pelvic organ prolapse by lateral suspension with mesh. Int Urogynecol J 2016;27:1347–55.
[20] Bradley S, Gutman RE, Richter LA. Hysteropexy: an option for the repair of pelvic organ prolapse. Curr Urol Rep 2018;19:15.
[21] Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2013CD004014.
[22] Veit-Rubin N, Dubuisson JB, Lange S, Eperon I, Dubuisson J. Uterus-preserving laparoscopic lateral suspension with mesh for pelvic organ prolapse: a patient-centred outcome report and video of a continuous series of 245 patients. Int Urogynecol J 2016;27:491–3.
[23] Sorrentino F, Cartwright R, Digesu A, et al. Associations between individual lower urinary tract symptoms and bacteriuria in random urine samples in women. Neurourol Urodyn 2015;34:429–33.
[24] Vieillefosse S, Thubert T, Dache A, Hermieu JF, Deffieux X. Satisfaction, quality of life and lumbar pain following laparoscopic sacrocolpopexy: suture vs. Tackers. Eur J Obstet Gynecol Reprod Biol 2015;187:51–6.