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Research Article

Comparison of Sacrocolpopexy Versus Lateral Colposuspension in Pelvic Organ Prolapse Surgery

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Introduction

Pelvic Organ Prolapse (POP) is a major issue concerning women's health, especially for those who have had at least one vaginal delivery. It is estimated that 1-3 per 1000 women may experience this condition. As average age and associated metabolic disorders like obesity increase, it is expected that POP rates will rise progressively [1,2]. Health care systems will therefore face an increased demand for treatment, and surgeons will need to respond with the most appropriate treatments, tailoring them according to patient characteristics, prolapse type and health care costs [3]. POP surgery increasingly uses the mini-invasive transabdominal approach [4]. Although Sacrocolpopexy (SC) is considered the gold standard for the correction of multicompartmental and single apical/uterine POP due to its successful long-term outcomes, it can involve major complications than trans vaginal mesh approach. However, to date there is no single technique for transabdominal mesh correction of POP, and there is an open debate about whether to preserve the uterus, whether to always perform a contextual posterior correction of the pelvic floor, and whether or not to use synthetic material [5].

Progressing from the anterior and posterior suspension techniques, Dubuisson et al presented the technique of Laparoscopic Lateral Colposuspension (LCS) for the first time in 1998, and over time it has demonstrated good anatomical and functional outcomes with a high degree of patient satisfaction [6-8]. In fact, this technique reduced the risks associated with morbidity related to retroperitoneal vascular and nerve injury by avoiding dissection of the sacral promontory and is indicated in all cases when vaginal dissection is not easy. The aim of this study was to compare the anatomical and functional results of apical

compartment POP correction using the two surgical techniques of SC and lateral LCS.

Materials and Methods

Data were prospectively collected from the maintenance database of two Italian hospitals in order to compare anatomical and functional outcomes of women with symptomatic apical POP who underwent LCS at the Obstetrics and Gynaecology Section (group A) with those of women who underwent SC at the Urology Section (group B). Some patients had concomitant surgical treatment of anterior/posterior vaginal wall defect. In case of Stress Urinary Incontinence (SUI) patients were treated by mid-urethral synthetic sling in group A, while in group B autologous rectus fascia pubo-vaginal sling was placed [9]. Those patients were excluded from the study. Informed consent was obtained by all patients, and the study received the approval of the local Ethical Committee. Patients were evaluated by a single specialty consultant for each centre, who performed medical interviews and clinical evaluations, using the Pelvic Organ Prolapse Quantification (POP-Q) to assess the POP. To all women was performed a concomitant stress urinary incontinence a stress-test evaluation at physiological volume of 300 ml confirmed by ultrasound. Overactive Bladder (OAB) symptoms were evaluated as the presence of urgency, with or without incontinence, with frequency and nocturia in the absence of underlying metabolic or pathologic syndromes [10-12]; constipation was defined according to Rome diagnostic criteria [13]. All patients also underwent invasive urodynamic examination. Urodynamic data included uroflowmetry, cystometry, pressure/flow; Valsalva Leak Point Pressure (VLPP) was performed by filling the bladder to 200 ml with the patient in a semi-recumbent position and with/without POP repositioning by a vaginal pack (according to International Continence Society -ICS- 2002 guidelines available online - https://pubmed.ncbi.nlm.nih.gov/11948720/) [14]. SUI, LUTS, POP have been defined in accordance with ICS/IUGA terminology [15]. All patients received preoperative ultrasound of the uterus and genitalia and a PAP-test to exclude comorbidity.

Surgery was conducted under general anaesthesia for both techniques. Patients who underwent LCS (group A) had lateral suspension as described by Martinello et al [16], while in group B women had laparoscopic robot assisted SC as described by Cormio et al [9]. In all cases the used mesh was in polypropylene, and concomitant hysterectomy was never performed. Postoperatively, patients were evaluated at 1, 3, 6 months and then annually. Objective results included clinical evaluation of POP and SUI *de novo* by POP-Q and Valsalva stress test, respectively. Data on constipation, OAB were recorded. Recurrent Urinary Tract Infections (UTIs) defined as symptomatic infections with positive urine cultures occurring 2 or more times in 6 months or 3 or more times per year were recorded. Objective outcomes included clinical assessment of persistent or *de novo* POP by POP-Q stage classification and *de novo* SUI. Recurrent (specifically persistent and/or de novo) POP was defined as significant if the POP-Q stage was greater than stage I. Persistent or *de novo* bowel and bladder symptoms were defined as symptoms that had not disappeared 6 months after surgery. Surgical complications were classified by Clavien-Dindo score [17]. Postoperative pain was postoperatively assessed by Visual Analogue Scale (VAS) ranging from 0 to 10 at 24 and 48 hours after surgery.

Statistical Analysis

Outcomes of this study were POP persistence-free survival. First descriptive statistics were performed to assess differences in the preoperative, intraoperative and postoperative characteristics of the two study groups. Continuous variables were reported as median and interquartile range and compared using the Mann-Whitney U-test, whereas categorical variables were reported as rates and tested by Fisher's exact test or the chi-square test, as appropriate. The rate of POP persistence was estimated non-parametrically using the Kaplan–Maier method. Uni-and Multi-variable cox-regression analysis was used to evaluate predictors of POP persistence. Statistical analyses were performed using Stata-SE 15 (StataCorp LP, College Station, TX, USA). All tests were 2-sided with a significance level set at $p<0.05$.

Results

A total amount of 138 women have been studied: 42 patients underwent LCS and were allocated in group A, and 96 underwent SC and were allocated in group B.

Preoperative and postoperative characteristics are reported in Table 1 and Table 2. There were no differences between the groups in terms of age, preoperative OAB and constipation symptoms, previous POP surgery or anterior vaginal wall prolapse ($p=0.4$, $p=0.8$, $p=0.81$, $p=0.2$, $p=0.14$). In both groups there was one patient who had pre-operative symptomatic apical POP stage 1 both after previous POP surgery who asked for surgical resolution. Between group A and B we found preoperative differences in terms of BMI, anterior vaginal wall defect POP-Q stage, previous hysterectomy, apical and posterior vaginal wall prolapse ($p=0.0001$, $p=0001$, $p=0.032$, $p=0.001$, $p<0.0001$, respectively). The mean duration of LCS was 104 minutes, while the mean duration of SC was 155 minutes. The mean follow-up of 10.47±4.52 months (1-24) for group A versus 33.6±28 months (range 3-113) for group B were significantly different in terms of overall POP recurrence, as shown by Kaplan-Meier curves ($p>0.0001$) (Figure 1).

	Group A Lateral Colposuspension (N=42)	Group B Mesh Sacrocolpopexy (N=96)	p-value
Age (year)	62.5 (54.0, 68.0)	63.5 (55.0, 69.0)	0.4
Body Mass Index (kg/m²)	23.1 (21.4, 25.1)	27.0 (24.0, 28.0)	<0.0001
Apical POP-Q stage, n (%)			
Average	33 (78.6%)	46 (47.9%)	0.0008
1	12 (36.3%)	7 (15.2%)	0.03
2	10 (30.3%)	10 (21%)	0.38
3	10 (30.3%)	19 (41.3%)	0.31
4	1 (3%)	10 (21.7%)	0.02
Anterior POP-Q stage, n			
Average	39 (92.9%)	94 (97.9%)	0.88
1	5 (12.8%)	2 (2.1%)	0.11
2	10 (25.6%)	3 (3.2%)	0.00002
3	21 (53.8%)	55 (58.5%)	0.62
4	3 (7.6%)	34 (36.2%)	0.0008
Preoperative OAB, n (%)	14 (33.3%)	34 (35.4%)	0.8
Preoperative constipation, n (%)	13 (31.0%)	45 (46.9%)	0.081
Previous POP Surgery, n (%)	3 (7.1%)	15 (15.6%)	0.2
Previous hysterectomy, n (%)	2 (4.8%)	18 (18.8%)	0.032
POP posterior, n (%)	25 (59.5%)	20 (20.8%)	<0.0001

Table 1: Preoperative characteristics of the study population (POP = Pelvic Organ Prolapse; OAB = Overactive Bladder).

	Lateral Colposuspension (N=42)	Mesh Sacrocolpopexy (N=96)	p-value
POP recurrence at last follow up, n (%)	30 (71.4%)	15 (15.6%)	<0.0001
POP persistence, n (%)	24 (57.1%)	13 (13.5%)	<0.0001
Anterior, n (%)	20 (47.6%)	12 (12.5%)	<0.0001
Apical, n (%)	7 (16.7%)	1 (1.0%)	0.0003
Posterior, n (%)	5 (11.9%)	2 (2.1%)	0.043
POP persistence, (POP-q>1)	6 (14.3%)	5 (5.2%)	0.07
Anterior, n (%)	5 (11.9%)	5 (5.2%)	0.16
Apical, n (%)	-	-	
Posterior, n (%)	1 (2%)	0	
POP de novo, n (%)	8 (19.0%)	6 (6.2%)	0.022

Anterior, n (%)	0 (0.0%)	2 (2.1%)	0.3
Posterior, n (%)	8 (19.0%)	5 (5.2%)	0.01
POP de novo, (POP-q>1)	3 (7.1%)	4 (4.1%)	0.46
Apical, n (%)	-	-	
Posterior, n (%)	3 (7.1%)	4 (4.1%)	0.46
Surgical Retreatment	4 (9.5%)	2 (2%)	0.04
- Mesh arm revision	3	-	
- Symptomatic posterior defect	1	1	
- Symptomatic anterior defect	-	2	
Postoperative constipation, n (%)	6 (14.3%)	43 (44.8%)	0.001
Postoperative OAB symptoms, n (%)	9 (21.4%)	16 (16.6%)	0.5
Postoperative SUI symptoms, n (%)	4 (9.5%)	9 (9.3%)	0.9

Table 2: Postoperative outcomes of the study (POP = Pelvic Organ Prolapse; OAB = Overactive Bladder; SUI = Stress Urinary Incontinence).

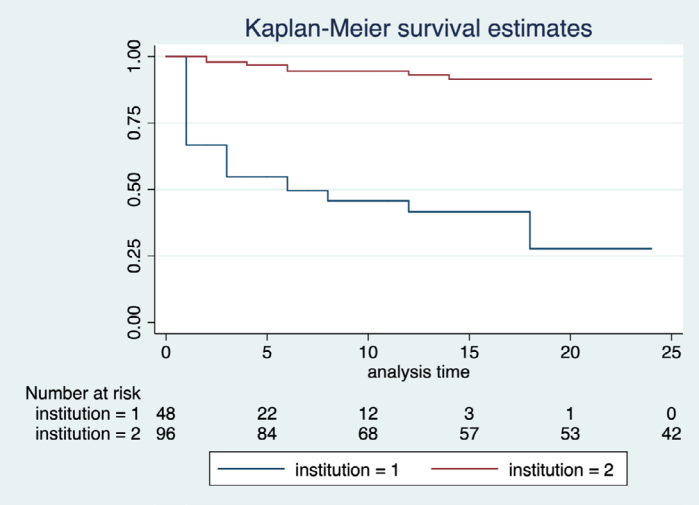

Figure 1: Overall post-operative POP recurrence.

No post-operative differences were observed in terms of *de novo* or persistent OAB/SUI (p=0.5, p=0.9). Group B compared with group A showed better anatomical outcomes on apical compartment (p>0.003). Comparing A and B in *de novo* anterior and posterior defect we did not find statistical difference. Anterior defect recurrence was found higher in group A with statistical difference (<0.0001). Patients treated with SC showed more postoperative constipation symptoms, while women treated with LCS had statistically significant better results (p=0.001). Uni- and multivariable Cox-regression analysis (Table 3) and Kaplan-Meier curves (Figure 1), showed that SC had a more durable outcome over time than lateral mesh, regardless of age, BMI, POP-Q, previous pelvic surgery, previous hysterectomy, and different follow-up numbers. Postoperative complications in group A were one wound infection resolved with antibiotic therapy (Clavien-Dindo grade 2), and three mesh dislocations that required surgical revision and reattachment to the vagina (Clavien-Dindo grade 3). Postoperative complications in group B were one wound dehiscence conservatively treated with local therapy (Clavien-Dindo grade 1), one respiratory acidosis treated in the intensive care unit for 2 days (Clavien-Dindo grade 3), three cases of mesh extrusion conservatively treated (Clavien-Dindo grade 2), and one bowel intraoperative lesion requiring surgical reintervention (Clavien-Dindo grade 3).

	Univariable Cox Regression Analysis			Multivariable Cox Regression Analysis		
Covariate	**H.R.**	**95% C.I.**	**P>|z|**	**H.R.**	**95% C.I.**	**P>|z|**
Age	0.99	0.95,1.02	0.528	0.99	0.96,1.03	0.601
Body Mass Index	0.90	0.81,1.00	0.045	1.01	0.91,1.12	0.864
POP-Q apical stage						
1-2-3*	Ref.			Ref.		
4	0.46	0.19,1.09	0.078	0.83	0.32,2.17	0.710
Previous pelvic surgery						
No	Ref.			Ref.		
Yes	0.89	0.32,2.52	0.827	1.35	0.44,4.15	0.597
Previous hysterectomy						
No	Ref.			Ref.		
Yes	0.28	0.07,1.18	0.084	0.48	0.11,2.05	0.322
Type of surgery						
LCS *	Ref.			Ref.		
SC	0.08	0.03,0.19	<0.001	0.09	0.04,0.23	<0.001

Table 3: Uni-and Multi-variable cox-regression analysis predicting recurrence (POP = Pelvic Organ Prolapse; LCS = Lateral Colposuspension; SC = Sacrocolpopexy).

Discussion

The aim of this study was to compare two techniques of apical vaginal compartment suspension in females with symptomatic uterus prolapse in terms of anatomical and functional outcomes. In literature data clearly demonstrate that SC is an intervention with excellent results in long-term follow-up [18]. The SC technique may differ in the extension of the dissection in the pelvis, in the use of pre-shaped or shaped meshes by the surgeon, for the positioning of the mesh on the anterior/posterior wall or on both walls of the vagina, and for the type of sutures used to secure the mesh [19]. Equally, the concept of vaginal suspension in a posterior direction with attachment to the anterior longitudinal ligament at the level of the sacrum proved success. The limitations of SC are mainly related to the potential complications that can happen in the dissection of the sacral promontory, which can lead to severe bleeding, and to ureteral lesions that can accidentally occur in the incision of the parietal peritoneum. Moreover, in some cases SC may not be performed due to technical limitations consequent to the type of patient. Dubuisson et al [7] introduced LCS as a new technique that provides for a symmetrical tension-free suspension of the vaginal vault laterally going to recreate a suspension like the broad ligament. This type of suspension involves a vaginal axis more like the physiological one with acceptable patient satisfaction (Ganatra AM, et al. (2009)). Furthermore, the LCS has the advantage of not having to dissect the retroperitoneum and is a simpler technique. In 2002 Dubuisson et al published a 1-year follow-up study on 35 women with genital prolapse treated by LCS, in which 9 out of 10 women were completely satisfied [20].

In our study SC gave a better outcome in terms of *de novo* occurrence and persistence of any POP ($p=0.022$, $p<0.0001$), and a more durable outcome over time than lateral mesh, regardless of age, BMI, POP-q grade, previous pelvic surgery, and previous hysterectomy (Figure 1) [21-23]. The type of approach in LCS, as minimally invasive would reduce these features and represents an exit strategy when the sacral support is not feasible [24-26]. Comparing data on anatomical support to upper vaginal compartment, we documented that SC had better results. SC was effective in 78.6% of the cases, while only 47.9% of women undergone LCS had the cure of apical POP with a higher recurrence rate. Indeed, although patients were different at the baseline,

the uni- and multivariable Cox-regression analysis and Kaplan-Meier curves indicated that SC had a longer POP recurrence-free time than LCS for any type of POP stage. Other studies found anatomical better results in LCS [21,27]. However, these authors reported the use of a polypropylene titanized mesh that may have improved the outcomes.

Regarding concomitant anterior vaginal wall defect both the procedures, LCS and SC were effective with cure rates greater than 90%. Our data on LCS seems to be better compared with those reported by Malanowska et al which documented an anterior defect repair rate of 76.2% [8]. *De novo* urinary dysfunction remains a major morbidity after POP surgical repair, with an incidence of 9–42% [28]. We did not found differences in postoperative OAB between the two surgical procedures, with rates like those found in the literature [23,29-31]. As reported recently by Mereu et al [22] 120 women were treated by LCS and within 6 months follow-up showed 19% of asymptomatic postoperative posterior POP-Q=2, probably due to pre-existing and not *de novo* POP. In our study a higher persistence of asymptomatic posterior defect (POP-Q<1) was recorded in the LCS patients (11.9% versus 2.1% of SC, p=0.0042); *de novo* symptomatic posterior defect rates were not statistically different between groups (7.1% versus 4.1%, p=0.46).

We found a significant advantage of LCS compared to SC in reducing postoperative constipation symptoms. Few paper report data about the effect of apical suspension on bowel functions. SC has been described as cause of constipation in a range between 0 and 25% of cases [24], while patients underwent LCS has shown a valuable negative change to constipation of 4% [8]. Furthermore, Malanowska et al documented how LCS has a valuable positive change to improve constipation in 46.1% of cases. Thus, lateral suspension may in some way have a minor influence on bowel function making LCS a good choice in cases where constipation is a severe problem for the patient. Soligo et al. reported a strong relationship between POP recurrence and constipation [32]. Our findings could suggest not only that the presence of posterior POP is sufficient to influence the recovery of bowel function, but also that the dissection of recto-vaginal space (to attach the mesh to the vaginal wall with subsequent soldering and secondary fibrosis) may have a key role in post-operative bowel activity [33]. However, alternative strategies have been proposed to avoid management of the sacral region and important local anatomical structures when SC is performed [34,35]. Yassa and Tug recently presented a two-year follow-up study on 17 patients who underwent uterus-preserving LCS, which recorded 100% healing of apical prolapse (p<0.01) and 88.2% healing of anterior prolapse (p<0.01) with no change in the posterior compartment nor constipation (p=0.5; p=0.1). Urinary symptoms were also significant improved (p<0.05) [36].

Operating time was shorter in LCS, this data is related to the minor dissection needed in lateral suspension. Similar operating time on LCS have been reported by Papadopulos et al in 2012 [37] and most recently from Malanowska et al [8]. Considering shorter operating time there are few procedures for apical POP that guarantee sexual function. LCS leads to a natural and therefore preferable vaginal axis in a short operating time making this procedure preferable in the event that a short-term anaesthesia is more appropriate for the patient. Although the impact of the two surgical techniques on sexual function was not among our goals it may be considered a limitation of our study related to its retrospectivity. As expected, complications rate was higher in SC group. Mesh-extrusions were evidenced in SC group, and it can be overcome using a single vaginal mesh rather than a double anterior/posterior vaginal mesh, regardless of the surgical approach and in the absence of clinically significant posterior POP, with positive impact on subjective outcomes and improved quality of life [19]. While mesh dislocation in the three women undergone LCS may also be considered as an error related to the learning curve which no longer occurred over time. Furthermore, the SC group presented more conservatively treated erosions/extrusions than the LCS group, which conversely recorded more surgical revisions of lateral arms of the mesh, maybe due to the use of permanent sutures on the vaginal walls to reduce the risk of recurrence [38,39]. Additionally, preserving uterus may decrease mesh exposure, operative time, and blood loss without any impact on anatomical outcome [40]. The reoperation rate for POP recurrence was significantly better in SC group. LCS group had reoperation rates similar to those reported in literature [8,23,28,29]. This shows how if the main goal was exclusively the correction of apical prolapse without other variables to be considered in counseling the intervention of choice should be SC.

Our investigation did not compare the effect of either open or mini-invasive surgical approach on overall results, but only anatomical and functional outcomes of two different methods to treat POP using either lateral (CS) or anterior/posterior (SC) attachment to the vaginal walls. These are different in thickness: lateral walls are more rigid and thick than anterior/posterior walls and it can explain our results, suggesting the diverse tissue response to intrabdominal pressure variations and supporting the dynamic theory of Papa Petros; additionally, the tension-free surgery can help avoid recurrence, decreasing post-operative pain, and mesh-related complications [41]. The main limitations of this study concern its retrospective nature, the lack of randomization and quality of life questionnaire, the different sizes of samples/follow-up numbers (resolved by the statistician using statistical tests), and data derived from two different hospitals by different surgeons using different techniques. However, there are very few studies in the literature in which both two valid techniques for POP correction have been compared with complete functional and anatomical implications. All continence surgery and vaginal surgery was excluded from the study. Furthermore, women underwent only pre-operative invasive urodynamic examinations, so it was not possible to make a compared urodynamic evaluation after surgery.

The strength of this study lies in the comparison of two

different techniques with unequal groups and follow-up numbers, with reliable outcomes: the surgical procedure represents the main factor predicting recurrence. We found that SC was superior to LCS in terms of correction of any stage of POP, while our data evidenced no difference in terms of recurrence of symptomatic POP-Q>1.

Conclusion

SC gives better long-term anatomical results compared to lateral CS, with better results in terms of POP recurrence. CS represents a valid alternative exit strategy in cases of difficult access to the retroperitoneum and exposure of the sacrum. CS is confirmed as a rapid and safe technique with low risk of retroperitoneal organ injury and bowel symptoms. Certainly, the type of surgical approach used in POP correction depends on the compartment involved, the degree of prolapse, patient symptoms and the surgeon's preference/experience.

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