



Preoperative ultrasound findings as risk factors of recurrence of pelvic organ prolapse after laparoscopic sacrocolpopexy

Fernanda Santis-Moya¹ · Rodrigo Pineda¹ · Victor Miranda¹

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Abstract

Introduction and hypothesis The objective of this study is to evaluate levator ani muscle avulsion (LAMA) and ballooning as risk factors for recurrence of pelvic organ prolapse (POP) after laparoscopic sacrocolpopexy (SCP). We hypothesize that these ultrasound findings are associated with a higher risk of POP recurrence.

Methods Retrospective cohort study of patients who underwent laparoscopic SCP between January 2015 and December 2018. Baseline translabial 3D ultrasound of the pelvic floor was performed. Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Impact Questionnaire (PFIQ-7) were applied. Both univariate and multivariate analyses were carried out.

Results One hundred thirty-four patients were included. On ultrasound, 32% of patients had levator ani muscle avulsion, and 36.5% had ballooning. Mean follow-up time was 16 months. There was a 13.4% anatomic recurrence; five of them (3.7%) also had symptomatic recurrence. After multivariate analysis we found that LAMA and ballooning were not significant: OR 0.99 (95% CI 0.098–10.1; $p = 0.99$) and OR 1.1 (95% CI 0.99–1.2; $p = 0.06$), respectively.

Conclusions LAMA and ballooning on pelvic floor US are not significant risk factors for anatomic POP recurrence after laparoscopic SCP. Laparoscopic SCP has a 13.4% and 3.4% anatomic and symptomatic recurrence rate, respectively, and the majority of patients reported significant improvement in quality of life.

Keywords Pelvic organ prolapse · Recurrence · Risk factors · Laparoscopy · Sacrocolpopexy

Introduction

Pelvic organ prolapse (POP) is a highly prevalent problem, affecting around 30 to 50% of women, and is expected to increase by 46% by the year 2050 because of rising life expectancy [1]. Women have a lifetime risk of POP surgery by age 85 years of 19% [2]. Surgical treatment includes pelvic reconstructive procedures with vaginal and abdominal approaches and obliterative procedures. Abdominal sacrocolpopexy (SCP) is associated with better anatomic and subjective outcomes and a lower recurrence rate compared to vaginal procedures [3–5].

Recurrence of POP after reconstructive surgery is difficult to estimate because of a lack of agreed definition [6]. Cure rates vary dramatically depending on the definition of treatment success used, and for abdominal SCP, it can range from 19% for an anatomic support definition to 97% for no retreatment for POP definition [7]. The LAS study by Freeman et al. has shown anatomical equivalence between the laparoscopic and open abdominal approach for SCP [8], and laparoscopic seems to be the preferred approach for SCP [9].

There are several risk factors identified with POP recurrence, and they are unlikely to be independent [10]. These include preoperative POP staging 3–4, familial history, wide genital hiatus, prior hysterectomy and younger age at the time of index surgery [10–12].

Ultrasound (US) has been shown to be effective in the assessment of pelvic floor disorders [13] and has been used as a tool to evaluate other risk factors for POP recurrence. The most studied are levator ani muscle avulsion (LAMA) and enlarged hiatal area or “ballooning.” These factors, which are mainly caused during childbirth, have been shown to be an important risk factor for primary and recurrent POP

✉ Fernanda Santis-Moya
fsantism@gmail.com

¹ Obstetrics and Gynecology Department, Pontificia Universidad Católica de Chile, Pedro de Valdivia 150 Dept. 1321 Providencia, Santiago, Chile

[14–16]. In patients with vaginal repair, levator avulsion has an odds ratio (OR) of 3 for POP recurrence, while the hiatal area on Valsalva adds an additional 7% per cm² for the odds of POP recurrence [17].

There are no studies that assess the impact of US evaluation on the recurrence of POP after laparoscopic SCP. The identification of ultrasound-associated factors with recurrence would help in patient counseling and surgery expectations.

The aim of this study is to evaluate levator ani muscle avulsion and ballooning as risk factors for anatomic recurrence of POP after laparoscopic SCP. We hypothesize that these ultrasound findings are associated with a higher risk of POP recurrence.

Materials and methods

This is a retrospective cohort study of patients who underwent laparoscopic SCP performed by two attending urogynecologists at the Pontificia Universidad Católica Clinical Hospital in Chile between January 2015 and December 2018.

Clinical and surgical data of women who underwent laparoscopic SCP for prolapse repair were extracted from an electronic database. Patients without formal postoperative POP-Q examination documentation, information regarding questionnaires or ultrasound, or 12-month follow-up were excluded.

All selected subjects underwent a clinical examination for prolapse grading using the Pelvic Organ Prolapse Quantification system (POP-Q), urine analysis and urodynamic study.

Translabial 3D ultrasound of the pelvic floor was carried out at baseline as part of the patient's assessment. It was performed after voiding, in supine position with hips flexed and slightly abducted. A GE Voluson s10 system (GE Kretz Ultrasound, Zipf, Austria) was used with a 4.8-MHz curved abdominal transducer covered with gel and a plastic sheath. The transducer was placed against the perineum, and the image was captured at rest, on maximum pelvic floor muscle contraction and during Valsalva maneuver. Dimensions of the levator hiatus were determined in the axial plane. The hiatal area was measured as the area delimited by the levator ani muscle, symphysis pubis and inferior ramus pubis. The level of minimum hiatal dimensions, identified as the minimum distance between the posterior margin of the symphysis pubis to the anterior margin of the levator ani muscle, was determined during contraction. At rest, the levator hiatal area was measured in the neutral position of the levator ani muscle before a levator ani muscle contraction. During Valsalva, the maximum anteroposterior diameter in the midsagittal plane was used for analysis. Volumes were recorded three times during contraction and Valsalva, and the best images were chosen for analysis. For the assessment of levator ani defects, the slices 2.5 and 5 mm cranial to the plane of minimum hiatal

dimensions were also used. Levator ani defects were scored as described by Dietz et al. [18]. The recorded data were analyzed offline using Voluson GE Kretz 4D-view 5.1 software (GE Kretz Ultrasound).

The Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Impact Questionnaire (PFIQ-7) (both in the Spanish-validated version) were applied. The same complete evaluation was repeated for all patients after 12-month follow-up, except the pelvic floor US.

Our primary outcome was to determine if levator ani muscle avulsion and/or ballooning was associated with a higher risk of anatomic POP recurrence after laparoscopic SCP. Levator ani muscle avulsion was diagnosed if three central slices showed an abnormal muscle insertion, either unilateral or bilateral. Ballooning was defined as a hiatal area on Valsalva ≥ 25 cm². Our secondary outcome was to measure anatomic and symptomatic recurrence. Anatomic recurrence was defined as prolapse \geq stage 2 according to POP-Q examination and/or retreatment for POP. Symptomatic recurrence was defined as a complaint of vaginal bulge measured as an affirmative answer to question #3 in the PFDI-20 questionnaire and any answer that was not “not at all” to the question: how much does it bother you?

Statistical analysis was performed with SAS statistical software package (SAS Institute, Cary, NC). Calculation of study size was not performed as there are limited data in the literature for power calculation. All data were analyzed using the Pearson chi-square test for categorical data, Student's *t* test for parametric continuous data or Wilcoxon rank-sum test for ordinal or nonparametric continuous data. Change in the patient-reported outcome questionnaire (PFDI-20 and PFIQ-7) was reported using repeated measure analysis of covariance. $P < 0.05$ was considered statistically significant for all the analysis. Upon completion of the univariate analyses, we selected variables for the multivariable analysis. Any variable whose univariable test had a *p* value < 0.25 could be a candidate for the multivariate logistic regression model along with all variables of known clinical importance. The idea of using a *p* value of 0.25 as a screening criterion for variable selection is based on the work by Bendel and Afifi (1977) [19] on linear regression and on the work by Mickey and Greenland (1989) [20] on logistic regression. These authors show that the use of a more traditional level (such as 0.05) often fail to identify variables known to be important.

This analysis was approved by the Institutional Review Board at the Pontificia Universidad Católica de Chile.

SCP surgery procedure

After establishing the pneumoperitoneum, four laparoscopic trocars were inserted (10 mm at the umbilicus, 10 mm above from the umbilicus, 5 mm in right iliac fossae and a 5 mm in

the left fossae). The posterior peritoneal layer was opened from the promontory down and medial to the right uterosacral ligament, to the cervix or vault, down to the vesicovaginal space until the level of the trigone, rectovaginal septum and levator ani muscle. The dissection at the sacrum consists of opening the posterior peritoneum until the anterior longitudinal ligament is reached. A tunnel underneath the right parietal peritoneum is then laterally dissected using diathermy and scissors and extended caudally up to the rectum so that the pelvic floor muscles of both sides become visible. In this zone, the dissection is around 1 cm proximal to the right iliac artery. Two pieces of a polypropylene plus polyglactin mesh (Vypro II; Ethicon, Somerville, NJ, USA), the latter of which had a self-styled Y shape, were bilaterally sutured to the anterior and posterior vagina or anterior and posterior cervix (when supracervical hysterectomy was also performed) and promontory with several polypropylene sutures (Prolene; Ethicon). The number of sutures depended on the length of the vagina. In general, four sutures were used to attach the anterior mesh arm and four sutures to attach the posterior mesh arm. Finally, the meshes were covered by closing the peritoneum with a 2–0 absorbable running suture (Vicryl; Ethicon).

Results

From January 2015 to December 2018, a total of 185 laparoscopic SCP surgeries were performed. One hundred thirty-four patients completed at least 12 months of follow-up and had their data complete for analysis. Mean age (range) was 60 (36–75) years, mean parity (\pm SD) was 3.4 ± 1.7 , and mean BMI (\pm SD) was 30 ± 4.1 . Of these, 24% had a previous cesarean section and 20% had instrumental delivery with forceps; 74.6% were sexually active, 14% were premenopausal, and 11% used hormone replacement therapy. Thirty-six percent reported previous hysterectomy, 18% previous prolapse surgery and 15% previous incontinence surgery, with transobturator tape being the most common. The initial POP-Q stage distribution was stage 3a: 62%, stage 3c: 24%, stage 3p: 4% and stage 4: 10%. Thirty percent of patients had occult stress urinary incontinence and 26% had urge incontinence.

On ultrasound, 43 patients (32%) had levator ani muscle avulsion, of which 11 had bilateral avulsion. The average hiatal area (range) was 28.8 (16 – 55) cm^2 , and 49 patients (36.5%) had ballooning according to our definition.

When evaluating surgical outcomes, mean operative time (range) was 148 (90–300) min. Concomitant surgeries were performed as follows: subtotal hysterectomy in 67% and anterior and posterior colporrhaphy in 4% and 10%, respectively; 34% had incontinence procedures (of which 89% were retropubic midurethral slings). There was a 2.2% conversion

to open laparotomy (3 patients), mean intraoperative bleeding was 100 ml, and mean length of hospital stay was 2.3 days.

Mean follow-up time was 16 months. After 12-month follow-up, PFDI-20 and PFIQ-7 were significantly reduced, as shown in Table 1. There were 13.4% of patients with anatomic recurrence, and five (3.7%) patients had symptomatic recurrence. All of the patients with symptomatic recurrence also had anatomic recurrence; 6.7% of patients developed de novo stress urinary incontinence, 3 patients (2.2%) had mesh erosion, and 10 patients (7.5%) developed de novo dyspareunia. Two of the patients with symptomatic recurrence were re-operated for POP, one underwent laparoscopic paravaginal repair for a recurrent cystocele, and the other patient underwent a repeated laparoscopic SCP for recurrent apical prolapse.

Table 2 displays recurrence rates in patients with levator ani muscle avulsion and ballooning, showing that both of these US findings are associated with increased anatomic recurrence, but not symptomatic recurrence. Preoperative POP stage 4 was also increased in patients with LAMA and ballooning.

When evaluating other factors related to anatomic and symptomatic recurrence, we found that preoperative POP stage 4 was strongly associated with anatomic (OR 13.6 IC 95% 1.9–97.7; $p = 0.009$) and symptomatic recurrence (OR 4.4 IC 95% 0.96–20.4; $p = 0.05$) (Table 3).

We performed multivariate logistic regression, and the variables included in our model were: levator any muscle avulsion, ballooning, POP stage 4, instrumental delivery, BMI > 30 according to p values and age due to its clinical importance in previous studies. After the analysis we found that LAMA and ballooning were not significant: OR 0.99 (95% CI 0.098–10.1; $p = 0.99$) and OR 1.1 (95% CI 0.99–1.2; $p = 0.06$), respectively (Table 4).

Discussion

In this study of 134 patients, we found that LAMA and ballooning on pelvic floor US were associated with a higher risk of anatomic recurrence. However, after multivariate analysis, this was not found significant. We also found a 13.4% and 3.7% risk of anatomic and symptomatic recurrence, respectively, with a higher risk in patients with preoperative stage 4 POP.

Table 1 Quality of life questionnaire results before and after SCP

	Before SCP	After SCP	p value
PFDI 20 ^a	102 (61–134)	16 (10–30)	0.007
PFIQ 12 ^a	80 (33–180)	4 (0–5)	0.03

^a Median (range)

Table 2 Recurrence rates in patients with and without levator ani muscle avulsion and ballooning

Outcome	Levator ani muscle avulsion		<i>p</i> value	Ballooning		<i>p</i> value
	Yes	No		Yes	No	
Anatomic recurrence	13	3	<i>p</i> = 0.003 OR: 3.1 (1.1–8.9)	15	1	<i>p</i> = 0.001 OR: 8 (1.2–25)
Symptomatic recurrence	3	1	<i>p</i> = 0.3 OR: 2.04 (0.3–11.3)	4	0	<i>p</i> = 0.08 OR: 1.09 (1–1.2)

Levator ani muscles are important in the support of pelvic organs, as they maintain the closure of the levator hiatus and prevent pelvic floor descent [21]. The levator hiatus defines the largest potential hernial portal within the envelope of the abdominal cavity [22]. Injury in these muscles is one of the main theories in the etiology of prolapse [23, 24]. Childbirth can cause levator ani muscle avulsion in up to 36% of patients, specifically after forceps delivery [25], but it can also cause enlargement of the levator hiatus even in the absence of levator trauma [26]. Both of these injuries are associated with POP [27].

Ultrasound imaging is currently playing a growing role in the investigation of pelvic floor disorders and in the evaluation of levator ani morphology. Levator avulsion and ballooning can be evaluated in translabial pelvic floor US. LAMA is the detachment of the levator muscle from its origin at the pubis, and ballooning is the increased distensibility of the levator hiatus, which according to Dietz is a hiatus ≥ 25 cm² [22, 28].

It has been found that women with LAMA have an increased hiatal area and decreased muscle strength, implying that the association between LAMA and prolapse is due to this secondary mechanism [29]. However, it is found that even in the absence of levator avulsion, excess distensibility of the levator hiatus (ballooning) may contribute to POP. This could be because increased levator hiatal dimensions describe components of the biomechanical properties of this muscle [22].

LAMA and ballooning are not only important in the mechanism of primary POP but have also been linked to increased risk of recurrence after vaginal repair procedures [15, 17]. This is the first study to evaluate these ultrasound findings as risk factors for anatomic recurrence after laparoscopic SCP. Although in the univariate analysis there was a significant higher risk of anatomic recurrence in patients with LAMA and ballooning, this was not significant after multivariate analysis, which could be explained by the small sample and recurrence rates. We should highlight the fact that ballooning had a near statistical significance (*p* = 0.06), suggesting that while SCP is the preferred procedure for these patients, apical repair is limited, and other mechanisms of reconstruction are needed. This could be a relevant investigation area. Although SCP has been shown to have better anatomic and symptomatic outcomes than vaginal surgery after apical repair [3–5], it has reported recurrence rates as high as 48–57% [4, 30]. However, this is highly dependent of the definition used [7]. In our study we found an anatomic recurrence of 13.4% and symptomatic recurrence of 3.7%, with a significant improvement in quality of life. More studies are needed to fully understand the biomechanics of POP, so that an individualized reconstruction surgery can be performed.

It is important to acknowledge that POP recurrence implies a series of factors and that these are not independent, which in part could explain why the multivariate analysis was non-

Table 3 Risk factors for symptomatic and anatomic recurrence

Outcome	Asymptomatic <i>n</i> = 129)	Symptomatic recurrence (<i>n</i> = 5)	<i>p</i> value	No anatomic recurrence (<i>n</i> = 116)	Anatomic recurrence (<i>n</i> = 18)	<i>p</i> value
Age ^a	59 (± 9.6)	61 (± 4.6)	0.4	59 (± 9.3)	62 (± 8.5)	0.76
Parity ^a	3.2 (± 1.2)	3.2 (± 2.5)	0.2	3,1 (± 1.2)	3.5 (± 1.8)	0.36
BMI ^a	30 (± 4)	27 (± 1.9)	0.15	28 (± 3.1)	30 (± 4.1)	0.17
Age > 60 years ^b	73 (56.6)	3 (60)	0.66	62 (53.4)	12 (66.7)	0.28
BMI > 30 ^b	4 (3.1)	1 (20)	0.14	58 (50)	13 (72.2)	0.3
Previous prolapse surgery ^b	24 (18.6)	0 (0)	0.4	22 (18.9)	2 (11.1)	0.41
Menopause ^b	115 (89.1)	5 (100)	0.75	96 (82.7)	15 (83.3)	0.8
Previous hysterectomy ^b	47 (36.4)	2 (40)	0.96	40 (34.5)	9 (50)	0.8
POP stage 4 ^b	6 (4.7)	2 (40)	0.03	5 (4.3)	3 (16.7)	0.04
Instrumental delivery ^b	24 (18.6)	0 (0)	0.2	22 (18.9)	2 (11.1)	0.14

^a Mean (standard deviation), ^b *n* (percentage)

Table 4 Logistic regression model estimating odds ratio of anatomic recurrence after laparoscopic SCP

Variable	OR	95% CI	<i>p</i> value
LAMA	0.99	0.098–10.1	0.99
Ballooning	1.1	0.99–1.2	0.06
Age > 60 years	1.05	0.95–1.17	0.3
POP stage 4	2.7	0.21–33.2	0.4
IMC > 30	1.2	0.8–2.1	0.29
Instrumental delivery	1.1	0.3–1.5	0.3

significant. Other studies have found that preoperative POP staging 3–4, familial history, wide genital hiatus, prior hysterectomy and younger age at the time of index surgery are also associated with an increased risk of recurrence [10–12]. In our study, only preoperative stage 4 POP was significant in the bivariate analysis. Not only was advanced prolapse stage associated with increased POP recurrence, but it was also associated with LAMA and ballooning in pelvic floor US. This confirms that damage in pelvic floor muscles is an important mechanism in severe POP.

Limitations to our study are primarily related to the retrospective study design, which allowed possible information bias. Also, our sample showed a low symptomatic recurrence making it difficult to reach statistical significance. Finally, these data are collected from a single institution, and they may not reflect the general population. Despite these limitations, this is the first study to evaluate ultrasound risk factors after laparoscopic SCP. Determining risk factors for recurrence of POP is important for preoperative counseling as it could help with the patient and surgeons' surgical expectations. Although we did not find statistical significance, this is an area that should be further analyzed in prospective studies, since ultrasound is an effective, reproducible and low-cost instrument and could be considered part of preoperative evaluation.

In conclusion, LAMA and ballooning on pelvic floor US are not significant risk factors for POP recurrence after laparoscopic SCP. SCP has a 13.4% and 3.4% anatomic and symptomatic recurrence rate, respectively, and the majority of patients reported significant improvement in quality of life.

Compliance with ethical standards

Conflict of interest None.

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