



Robotic Sacrocolpopexy: Results, Complications and Evaluation of Impact on Quality of Life

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Abstract

Introduction: Robotic surgery for pelvic organ prolapse provides the advantages of laparoscopic approach with a shorter learning curve and an improvement of the surgeon ergonomic. The main objective is to describe our series providing an analysis of intra/postoperative complications and as secondary objective to analyze the improvement in Quality of Life (QoL).

Materials and Methods: Prospective longitudinal study. Mean age, Body Mass Index (BMI), POP-Q stage, length hospital stay, operative time, surgical blood loss, intraoperative/postoperative complications according Clavien-Dindo classification, recurrence rate and EPIQ questionnaire score before and 6 months after surgery. Qualitative variables were analyzed by Chi-square test or Fisher Test and quantitative variables by T-Student test and ANOVA (SPSS 15.0).

Results: From 2006 to 2011 49 RASC were performed with a follow up of 25.5 months (SD 13.7), TOT was performed in 35 patients due to stress urinary incontinence. Five patients had intraoperative complications (10.1%). One presented a bleeding of the middle sacral artery, 3 bladder perforations and one vaginal perforation. Most frequent Clavien-Dindo postoperative complications were grade I and II (32.6% and 10.2%). Three grade IIIB complications (6.1%) were described. One mesh exposure, a relapsing vasovagal syncope due to an excessive tension of the mesh and a trocar hernia. The recurrence rate was 14.9% (7 patients) QoL scores improved in all categories except in functional defecation disorders and anal incontinence.

Conclusion: RASC has a low rate of complications with good anatomical results providing a significant improvement in QoL. High grade Clavien-Dindo complications and recurrence were factors that influenced in QoL.

Keywords: Robotic Sacrocolpopexy; EPIQ; QoL; RASC

Introduction

Pelvic organ prolapse (POP) surgery has evolved over the last decades remaining the abdominal approach the gold standard. Robotic surgery is a minimally invasive technique with the advantages of laparoscopic approach (less bleeding, shorter length hospital stay, good anatomical and functional results) with a shorter learning curve and an improvement of the surgeon ergonomic. The outcome of POP surgery is to provide a good anatomical correction of symptomatic prolapse, with a low rate of intra and postoperative complications, improving the quality of life (QoL) [2-6].

The use of validated QoL questionnaires allows an objective assessment of the clinical situation before and after surgery being a highly recommended practice. Several questionnaires have been performed to evaluate the clinical global in order to study, from a general point of view, the repercussion of symptoms in patients with POP [6]. Some questionnaires used are Medical Outcomes Study Short Form SF-36, King's Health Questionnaire, Incontinence Impact Questionnaire (IIQ), Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7) or the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) [6-10].

Robotic-assisted Laparoscopic Sacrocolpopexy (RASC) has been previously described by our group [4,6] and nowadays it is a consolidated technique [13]. To perform our study we decided to use EPIQ-questionnaire (Spanish validation) mainly because of its simplicity and applicability. The EPIQ questionnaire was developed by Lukacz et al. [10] in the United States and consists of 53 questions, some taken from other previously validated instruments and partly developed specifically for this questionnaire.

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Table 1: Clinical description of our series.

Variable	Mean/N	%
Age	66,1 (SD 8.7)	
Weight	65,9 (SD 9.9) Kg	
Height	159.5 (SD 5.7) cm	
BMI	25.9 (SD 3.3, range 17.3-36.4)	
High blood pressure	22/49 patients	44.9
Diabetes	7/49 patients	14.3
Multipara	22/45 patients	48.9
Previous hysterectomy	24/49 patients	49
Previous POP surgery	13/49 patients	26.4
POP Stage	N (patients)	%
I	0	0
II	4	8.1
III	35	71.4
IV	10	20.4

The main objective of this article is to describe our series of robotic sacrocolpopexy providing an analysis of intra and postoperative complications according to Clavien-Dindo classification. A secondary objective is to analyze the improvement in QoL through EPIQ questionnaire (Spanish validation).

Materials and Methods

A prospective cohort of patients undergoing robot assisted sacrocolpopexy between November 2006 and May 2011 was analyzed. The patients were diagnosed with anterior vaginal wall and/or cervical prolapse with/without stress incontinence. RASC were performed in all patients using Alyte® Y Mesh Graft, made by BARD®. Tension free suburethral sling was performed in patients when stress incontinence was associated. Two meshes were used when more than one pelvic floor compartment were repaired. All the interventions were performed by the same urologist.

The EPIQ-questionnaire was performed before surgery and at the 6th month in order to quantify the improvement in QoL.

Follow up was performed every 6 months in order to detect recurrence or other complications.

The variables analyzed were mean age, Body Mass Index (BMI), previous POP surgery, International Continence Society (ICS) staging system based on Pelvic Organ Prolapsed Quantification (POP-Q) stage, length hospital stay, operative time, surgical blood loss, intraoperative complications, postoperative complications according Clavien-Dindo classification [13] (Table 1) and recurrence rate. Recurrence was defined like a non complete correction of the prolapse (POP-Q stage ≥ 2). Qualitative variables were analyzed by Chi square test or Fisher test depending on the number of patients and quantitative variables by T-Student test and ANOVA using SPSS 15.0.

Results

We performed 49 RASCs from November 2006 to May 2011 in a single institution with a follow up of 25.5 months (SD 13.7); tension free sub urethral sling was performed in 35 patients due to urinary stress incontinence. One of the patients could not complete the EPIQ questionnaire because of reading and understanding difficulties.

Table 2: Grade I, II and IIIb complications.

	Description	N/Total	%	
Grade I	Pain	Shoulder	1/49	2%
		Inguinal	3/49	6.10%
		Sacral	1/49	2%
		Suprapubic	1/49	2%
		Hip	1/49	2%
		Abdominal Inespecific	1/49	2%
	Constipation	1/49	2%	
	Paralytic ileus	1/49	2%	
	Herpes episode	1/49	2%	
	Hyperglycaemia in diabetic patient	1/49	2%	
	UTI	1/49	2%	
	Nonspecific	3	6.10%	
	Grade II	Trocar infection	2/49	4%
CBA		1/49	2%	
Paralytic ileus		1/49	2%	
Heart failure in cardiac insufficiency		1/49	2%	
Mesh exposure		1/49	2%	
Excessive tension of the mesh		1/49	2%	
Trocar hernia		1/49	2%	
Grade III B	Mesh exposure	1/49	2%	
	Excessive tension of the mesh	1/49	2%	
	Trocar hernia	1/49	2%	

CBA (cerebrovascular accident).

In our series mean age was 66.1 (SD 8.7), the 57% of them were over 65 years old. Mean body mass index was 25.9 kg/m² (SD 3.3). 48.9 % were multipara, 49% were hysterectomized and 26.4% had a previous POP surgery. Thirty nine patients (79.6%) presented 2 or more pelvic compartment involved. 25 patients associated an apical prolapse, 9 patient's rectoceles and 5 enteroceles.

The length hospital stay was 3 days (interquartile range Q3-Q1:3) Two patients presented a longer stay, one for and acute urine retention owing to an excessive tension of the suburethral sling that had to be removed (14 days), and the other patients suffered an paralytic ileus that was resolve with conservative measures (10 days).

The mean operative time was 192.6 minutes (SD 16.8) with a mean estimated intraoperative blood loss of 50 ml (SD 30). One conversion to open surgical approach was performed due to intolerance to pneumoperitoneum (2.04%).

Five patients had intraoperative complications (10.1%). One presented a bleeding of the middle sacral artery controlled with cauterization, 3 patients suffered a bladder perforation during the vaginal dissection resolved with absorbable suture and one patient presented a vaginal perforation. Postoperative complications were analyzed according to Clavien-Dindo classification [13]. The most frequent complications were grade I and II (32.6% and 10.2%, respectively) (Table 2).

Grade IIIB complications were the most severe complications (3 patients, 6.1%) in our series. One patient had a mesh exposure that was surgically corrected. Other patient presented a relapsing vasovagal syncope due to an excessive tension of the mesh that

Table 3: Pre and post surgery scores correlation.

Categories	PreCx Mean (SD)	PostCx Mean (SD)	Diference (CI 95%)	p
QOL	68.1 (8.6)	30.9 (16.7)	37.2 (31.1- 43.1)	<0.001
OAB	49.6 (19.9)	37.5 (16.3)	12,1 (6- 18.1)	<0.001
AI	0	0	-	-
MD/P	45.2 (22.3)	28 (18.2)	17.2 (12.11- 22.3)	<0.001
FDD	31.9 (18.6)	32.5 (22.4)	-0.6 (-5.7- 4.5)	0.807
SUI	51.8 (26.5)	32.3 (17.9)	19.5 (10.7- 28.2)	<0.001
POP	85.4 (15.8)	30.6 (26.3)	54.8 (45.5- 64.1)	<0.001

QOL: Quality of Life; OAB: Over Active Bladder; AI: Anal Incontinence; MD/P: Micturition Difficulty/Pain; FDD: Functional Defecation Disorders; SUI: Stress Urinary Incontinence; POP: Pelvic Organ Prolapse

Table 4: Pre and post surgery score correlations: Intraoperative complications group.

Categories	PreCx Mean (SD)	PostCx Mean (SD)	Diference (IC 95%)	p
QOL	68.3 (9)	29.8 (16.7)	35.8 (32-45)	<0.001
OAB	48.4 (18)	35.1 (14.8)	13.3 (6.9-19.8)	<0.001
AI	0	0	-	-
MD/P	45.5 (21)	27.3 (16.2)	18.2 (12.7- 23.5)	<0.001
FDD	31.7 (19.5)	32.1 (21.7)	-0.4 (-4.7- 4)	0.872
SUI	53 (26.9)	31.3 (17.3)	21.7 (12.2- 31.3)	<0.001
POP	86.5 (14.3)	29.5 (25.3)	57 (48- 66)	<0.001

Table 5: Pre and post surgery scores correlations. Clavien-Dindo Grade IIIb group.

Categories	PreCx Mean (SD)	PostCx Mean (SD)	Diference (CI 95%)	p
QOL	59.6 (15)	34.8 (15.7)	24.8 (14.5- 35)	0.009
OAB	54.7 (6.1)	56 (19.7)	- 1.3 (-43.6- 40.9)	0.904
AI	0	0	-	-
MD/P	55 (13.2)	45 (8.6)	10 (-14.8- 34.8)	0.225
FDD	41.7 (18.9)	33.3 (29.3)	8.4 (-97.3- 114)	0.767
SUI	25 (5)	25 (5)	-	-
POP	73.3 (37.9)	33.3 (25.2)	40 (-111- 191)	0.373

Table 6: Pre and post surgery scores correlations. Recurrence Group.

Categories	PreCx Mean (SD)	PostCx Mean (SD)	Diference (CI 95%)	p
QOL	68.3 (7.5)	46.9 (20.1)	21.4 (-3.8-46.7)	0.081
OAB	48.7 (12)	48 (15.9)	0.7 (-19.8-21.2)	0.937
AI	0	0	-	-
MD/P	30.8 (21.5)	15.8 (9.2)	15 (-6-36)	0.126
FDD	30 (17.9)	26.7 (15.7)	3.3 (-9.5-7.6)	0.102
SUI	63.3 (22.5)	42.5 (22.3)	20.8 (-12.1-53.7)	0.165
POP	86.7 (10.3)	65 (28.1)	21.7 (-11.1-54.5)	0.15

required surgical correction. The third patient developed a trocar hernia that was corrected two months after the POP correction. Complications grade IV and V were not described.

We analyzed the followings variables: elderly patients (>65 years old), overweight (BMI>25), and previous hysterectomy/pelvic surgery with the risk of develop a postoperative complication and any association was found (p>0.05).

The recurrence rate was 14.9% (7 patients), the previous variables were analyzed in order to detect some association with the possibility of recurrence and we did not found any association in our series. To analyze the quality of life EPIQ questionnaire (Spanish validation)

was used. 48 of the 49 patients completed all the study. EPIQ questionnaire is divided in 7 categories (quality of life, overactive bladder, anal incontinence, micturition difficulty/pain, functional defecation disorders, stress urinary incontinence, pelvic organ prolapse) [11].

The results of pre and post surgery scores shows and improvement in all categories except in functional defecation disorders and anal incontinence. Anal incontinence questions were not properly answered. The greatest improvement was related to pelvic prolapse perception 84.7 vs. 22 CI 95% (48.5-76.8) (Table 3).

We performed an analysis on patients who developed

intraoperative/postoperative complications and recurrence. Patients with intraoperative complications (5 patients) showed an improvement in the same categories as when the whole complete series was studied (Table 4). Patients with significant postoperative complications classified as Clavien-Dindo IIIb (3 patients) shown improvement only in the overall quality of life category (Table 5). We did not find statistical significance in the improvement in the 7 patients who developed recurrence (Table 6).

Discussion

RASC is a minimally invasive surgery that combines the knowledge of the open and laparoscopic surgery [14]. Since Di Marco et al. [15] published his first paper in 2004; we found few references about complications and quality of life in this technique. We should take into account that pelvic floor correction could produce a pelvic dysfunction so routine use of questionnaire of quality of life must be used, especially when the final outcome of this kind of surgery is to provide an anatomical correction that associates an improvement in the QoL. Serati et al. [16] published a systematic review where 1488 patients were analyzed, being the study where more patients were studied.

Operative time in this review was 194 min (75-537). Others authors as Germain [17] or Bradley [18] described an operative time of 190 (75-340) and 301 min (205-440) respectively. In our institution the operative time was 192min. Operative time could be increased when other surgical intervention are associated such as a tension free suburethral sling or hysterectomy.

Main advantages of RASC regarding open approach are a decrease in the intraoperative blood loss and length hospital stay. In the Serrati 's review blood loss was 50 ml (10-1000), similar results are reported by Bradley et al. (66.2 ml) or our group (50 ml). When Geller et al. compared open and robotic approach a significant decrease was reported (103 +/- 96 mL compared with 255 +/- 155 mL, $P < 0.001$) and shorter length of stay (1.3 +/- 0.8 days compared with 2.7 +/- 1.4 days, $P < 0.001$). A length hospital stay of 2 days was reported by Serrati et al. [16].

In spite of in the published literature the incidence of intraoperative complications is low, it is mandatory to detect and resolve them during the intervention, since unnoticed lesions could develop important complications. Bradley and Serati [16] described similar intraoperative complications that in our series but we did not notice any intestinal or ureteral injury [18].

Clavien-Dindo classification is a useful tool that allows comparing and describing surgical complication. In our series grade I complications were the most frequent (16 patients, 32%). The incidence of grade II and IIIb were 10.2% and 6.1% respectively. Serrati et al. [16] describes an incidence of 3% (27 patients) for Grade I complications, 4% (39 patients) for grade II, <1% for grade IIIa (1 patient) and 2% (19 patients) for grade IIIb. Complications grade IV and V were not described.

The incidence of serious complications such as grade IIIb or higher is infrequent. Germain et al. [17] described one case of peritonitis due to a bowel perforation of a consecutive series of 52 patients. Bradley et al. [18] describes 2 patients (3.8%) who present intestinal obstruction that required surgical intervention.

Mesh erosion is described in several articles [16,20] with an estimated risk between 0% to 8%. Hudson et al. [20] published a

meta-analysis describing a risk of 4.1% (CI 95% 1.4-6.9) for mesh erosion/exposure. In our series one patient presented mesh erosion (2%) of the suburethral sling.

The recurrence rate is variable. In 2 published meta-analysis Hudson et al. reported in all 13 of the selected studies an overall apical anatomic cure rate of 98.6% (95% CI 97.0% to 100%) and Serati et al. [16] and objective and subjective cures ranged from 84% to 100% and from 92% to 95%, respectively. In our series we observed a recurrence rate of 14.3%; this result may be due to the POP stage of the patients (91.8% stage \geq III).

Multiple questionnaires have been used like the Pelvic Floor Distress Inventory- Short Form (PFDI-20), Pelvic Floor Impact Questionnaire Short Form 7 (PFDI-7) and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12). All these questionnaires have an important applicability problem, since they are long and hard to understand for patients, making it difficult to carry out. Due to this there is a great heterogeneity in the literature. We choose the EPIQ questionnaire (Spanish validated version), in our environment it was the most simple and useful questionnaire that we have nowadays, being useful for diagnosis and follow up.

In our series we observed an improvement in all categories except those related to anal incontinence and defecatory dysfunction with no modification of the EPIQ questionnaire score or a modification without statistical significance. These results may be due to a large number of patients presented anterior or middle compartment prolapse, and second, a great number of patients did not answer questions referred to anal incontinence. This point is another weakness of the study and their results must be regarded with caution. Other limitation in our series that should be corrected in the future is the analysis of sexual quality of life.

Geller et al. [19,21] reported mean scores for the Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ), and Pelvic Floor Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) preoperatively and at 12-month follow up with the following respective values: 117 vs. 38, 60 vs. 10, and 34 vs. 36.

Mourik et al. [22] used a Dutch variation of the Urinary Distress Inventory and Incontinence Impact Questionnaire. In their study, they reported an 88.1% satisfaction rate and 78.6% rate of sexual activity at 6 weeks to 8 weeks postoperatively.

Paraiso et al. [23] reported average PFDI, PFIQ, and PISQ scores preoperatively and at one year (128 vs. 44, 63 vs. 0, 20 vs. 16 respectively).

RASC is a safety and reproducible technique that has gained popularity in the pelvic floor surgery. But it remains uncertain if it provides any advantages comparing to laparoscopic approach. Geertje et al. [24] performed a systematic review of 2 randomized controlled trials comparing robotic and laparoscopic sacrocolpopexy reporting that there were no differences in anatomical outcomes, pelvic floor function, and quality of life. Costs for using the robot were significantly higher in both studies (US\$11,573 \pm 3191 vs. RASC US\$19,616 \pm 3135; $p < 0.001$ and LSC US\$ 14,342 \pm 2941 vs. RASC 16,278 \pm 3326; $p = 0.008$ respectively). Though RASC may have other benefits, such as reduction of the learning curve and increased ergonomics or dexterity, these remain to be demonstrated. In our opinion [25] and Jonk et al. [26] RASC provides an increased ergonomics and dexterity with a shorter learning curve that allows

the possibility of performing highly complex surgery, so that patients can benefit from this minimally invasive technique.

Conclusion

RASC is a safety technique with a low rate of complications and good anatomical results providing a significant improvement in QoL. High grade of Dindo-Clavien complications or recurrence were factors that influenced in QoL. Improvement in QoL must be a main objective and the use of validated questionnaires should be used as a routine in order of providing a good knowledge of our results. There is not a perfect validated questionnaire but in our centre, EPIQ questionnaire (Spanish validation) is a simple and easy to use questionnaire that provides useful information about the patients QoL situation.

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