

Laparoscopic Sacro(Hystero)colpopexy: Twenty Years after

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Abstract

Objective: Assessment of long term outcome following laparoscopic sacro(hystero)colpopexy (LSCP).

Design: Combine retrospective and prospective monocentric study using standardized quality of life questionnaires and pelvic organ prolapse quantification system (POP-Q).

Setting: A tertiary gynecology unit in the North West of France.

Population: One hundred and four consecutive women who had laparoscopic LSCP at the University Hospital of Caen between 1993 and 2002.

Methods: Women were examined in gynecology clinic and completed questionnaires or answered postal questionnaires if unable to attend the unit.

Main outcome measures: POP recurrence rate assessed by POP-Q score. Assessment of functional outcome using validated questionnaires (PDFI-20, PFIQ-7). Risk factors for recurrence.

Results: Eighty women were contacted after a median of 13 years. Fifty-one women were examined and a further 29 women completed questionnaires only. Twenty women (25%) had a repeat surgery for recurrence, mainly cystocele after 6 years average. Eleven women (21.5%) had recurrent prolapse at examination. Multivariate analysis identifies large cystocele as a significant risk factor for recurrence ($p=0.049$). Long term complication rate is 11.3% including 5 vaginal erosions occurring after 3 to 12 years (6.25%). Quality of life questionnaires showed improvement in bladder and pelvic symptoms but impairment in bowel symptoms, mainly constipation, without impact on QoL scores: 92.5% said their quality of life was improved after laparoscopic LSCP after 13 years.

Conclusions: LSCP is an effective treatment of pelvic organ prolapse. Recurrence and erosion happen later than described in literature. Quality of life is improved after 13 years with a 25% reoperation rate.

Keywords: Sacrocolpopexy, Laparoscopy, Pelvic organ prolapse

Introduction

Pelvic organ prolapse (POP) is a very frequent pathology [1] due to various defects in the pelvic ligaments and fascia, possibly associated to weak collagen. The intensity of the symptoms is not always correlated with the anatomical lesions. When symptoms are severe, quality of life may be deeply impaired [2]. Treatment of POP, when required, is mainly surgical [3]. Literature underlines the importance of the quality of the first surgical repair; at least 30% of patients experience a POP recurrence [1,3]. The aim of POP surgery is to restore the anatomy and to improve function on the long term. Sacrocolpopexy (SCP) is an old technique, first time described by Scali in 1958 [4] with and without associated hysterectomy, with good results reported in literature [5]. Sacrocolpopexy means that the vagina is reinforced by a synthetic mesh fixed to the promontory. Hysteropexy is a technique which sutures a mesh to the uterus at the level of the isthmus and secures it to the promontory. The Scali technique with uterus preservation must be considered as a SCP because the meshes are reinforcing anterior and posterior vagina the same way as when the uterus is absent. Laparoscopic sacrocolpopexy (LSCP) has been developed in the early 90ies in France [6-9], ten years before the use of vaginal mesh. SCP and LSCP have been considered in many publications as the "gold standart" in POP surgery and its results have been compared to vaginal techniques, mainly without mesh and mainly in "young" women that are still sexually active [3]. The required level of skills to perform LSCP is limiting its systematic

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use. In the unit of Gynaecology of the University Hospital of Caen, Normandy, France, first LSCP has been performed in 1993 by a surgeon performing routinely laparoscopic surgery since 1988. Before 1993, POP repair was performed mainly vaginally using conventional techniques as colporrhaphy, myorrhaphy, sacrospinous fixation, Manchester operation and Bologna procedure. In case of recurrence, abdominal SCP was performed. Laparoscopic Burch procedures started in 1991 [10], 18 months before first LSCP. The aim of the study was to evaluate the cure rate, recurrence rate and complications, years after the LSCP operation. We describe remarkable long-term follow up of series of patients from our unit, with outcome measures of examination according to the International Continence Society (ICS) [11], quality of life (QoL) questionnaires validated in French (PDFI-20, PFIQ-7) regarding urinary, pelvic, and bowel symptoms [12].

Subjects and Methods

This is a retrospective monocentric single operator study of all laparoscopic sacrocolpopexies performed for genital prolapse, according to the double mesh technique [6-9], at the unit of Gynecology of the University Hospital of Caen between January 1993 and December 2002. Our national ethical committee approved the study (CEROG 2015-GYN-1102).

Inclusion criteria were all POP with level 1 defect (stage 2 or more) and/or recurrence of POP after previous vaginal surgery.

We excluded patients who had laparoscopic mesh suspension for Masters and Allen Syndrome [12] as well as those who had a conversion to laparotomy for any reason because the aim of the study was to assess the outcome of successful LSCP in time. Patients were found through the French hospital discharge data base, the Programme of Medicalisation of Information System (PMSI) and all the hospital files as well as the operative and consultation reports were reviewed by two independent investigators.

The study has been conducted in 3 steps. First step was the analysis of the medical files in order to gather pre, per and post-operative data like BMI, previous history, staging of the POP according to the *International Continence Society (ICS): Pelvic Organ Prolapse Quantification POP-Q* [11], SUI, surgical report, associated procedures (hysterectomy, ovariectomy, etc.), complications.

In the second step, all women were directly contacted by phone first (to get their agreement to participate, confirmed later by signature) and by mail (questionnaire). Quality of life (QoL) has been evaluated with the French validated short version of Pelvic Floor Distress Inventory 20 (PDFI 20) with the three sub groups of questions: Urinary Distress Inventory (UDI 6), Colo-Rectal and Anal Distress Inventory (CRADI 8) and Pelvic Organ Prolaps Distress Inventory (POPDI 6). Pelvic Floor Impact Questionnaire (PFIQ 7) has also been completed. This questionnaire has also three sub groups : Urinary Impact Questionnaire (UIQ 7), Colo-Rectal and Anal Impact Questionnaire (CRAIQ 7) et Pelvic Organ Prolaps Impact Questionnaire (POPIQ 7) [2,12].

Last step was a clinical assessment of the anatomy. This examination, performed by an independent gynecologist (EM), was standardized to assess the anatomical defects according to ICS POP-Q.

Surgical technique

The procedures have all been performed by the senior author (PVT) using the same surgical technique previously described for first 44 women [6,9]. When supracervical hysterectomy was scheduled, manual morcellation was performed with in-bag retrieval. Monopolar and bipolar energy was used in the first patients, replaced by harmonic energy in 1995. The operation starts with the dissection of the promontory, of both pararectal spaces medial to the uterosacral ligament and the rectovaginal space down to the levators. Vesicovaginal dissection is performed on the upper half of vagina, above the trigone. Suspension is then performed with one posterior mesh of polypropylene (fixed to the levators and to the uterine isthmus if this organ was present, to the vaginal vault if not) and one anterior mesh fixed to the vagina and to the isthmus or the vault. Promontofixation without tension and peritonisation of the mesh is the last step of the LSCP. The mesh was stapled to the levators, to the vagina, to the uterine isthmus with Endohernia (AutoSuture) 4.8mm staples and to the promontorium with 4.0mm staples. Laparoscopic Burch colposuspension [10] was almost systematically performed between 1993 and 2000. Later, TVT was used but only in case of objective stress urinary incontinence (SUI).

For the purpose of statistical data analysis, qualitative variables were described as frequency and percentages and quantitative ones as mean (ranges). To risk factors for recurrence we used few statistical tests: chi-squares, Fisher exact test, or t-test, Mann-Whitney tests, as appropriate. The level of significance was set to 0.05 for these main analyses (bi sided tests). Analyses were carried out at the "Unité de Biostatistique et Recherche Clinique" (Caen University Hospital) using SPSS software vs 19.

Results

Of the 104 women who had a LSCP between 1993 and 2002, 6 have deceased (5.8%) and 18 (17.3%) were impossible to contact despite repeated attempts. Eighty women were contacted and all accepted to participate in the study and fill the questionnaires. Fifty-one patients agreed to come for clinical assessment (Figure 1). Average follow up was 13.6 years (range 11-20 years).

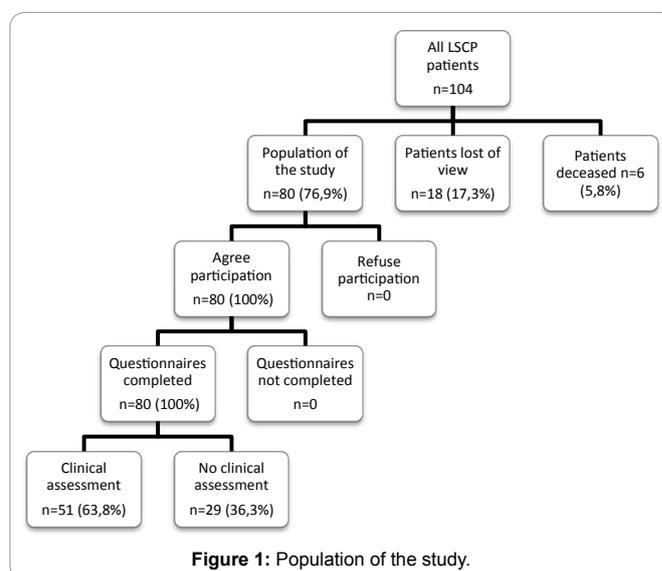


Figure 1: Population of the study.

Main characteristics of the population are described in Table 1. Preoperatively, 55% of patients presented with prolapse of the 3 compartments (n=44) and 45% presented with SUI (n=36) and 17.5% with occult SUI (n=14). Preoperative characteristics are shown in Figure 2. Average operation duration, including associated procedures, was 130min (60-220). Subtotal hysterectomy was performed in 3 patients (3.8%) and SUI repair in 50 patients (62,5%). Eight intra-operative complications (10%) occurred: 6 bladder injuries and 2 vaginal injuries. Short term results have been published in 2001 for the first 44 women of this series [13].

Long term anatomic results

After average follow up of 13.6 years, 20 women have been re operated for recurrence (25%). In 19 of these, only one compartment recurred. In 11 patients (55% of recurrences), it appeared to be the anterior compartment (cystocele), in 7 patients (35%) the posterior compartment (rectocele) and in 2

patients (10%) apical compartment (uterine or vault prolapse). Recurrence happened after 5.9 years average for cystocele, 7.4 years for rectocele and 7.3 years for vault or uterine descent. The POP-Q results for the 51 women that were examined clinically are shown in Figure 3. Eleven women (21.5%) had an anatomical recurrence (POP-Q stage 2 or more). In 7 women (63.6%), it was a cystocele. Recurrence was asymptomatic in 8 women (72.7%). Among the 11 with recurrence at the clinical evaluation, 6 already had a re-operation during the follow up period and 4 of them presented a recurrence on the same compartment that had been re-operated (always cystocele).

Risk factors for recurrence

We were looking for correlations between previous prolapse history, BMI, initial POP-Q stage and recurrence. The only significant correlation was with the presence of a cystocele stage 3 or 4 at the beginning (Table 2).

Long term functional results

Among the 80 women of our study, 15 (18.8%) had SUI recurrence and repair during the follow up period after 6.4 years average. The SUI repair was associated with POP repair in 5 women (33.3%). At the time of the evaluation, 5 patients complained of de novo SUI.

Functional results are described on Table 3 and evolution of symptoms and QoL on Table 4. Urinary symptoms were mainly urinary incontinence and/or bladder over activity and recurrence of symptoms happened after 8.9 years on average. After analyzing QoL questionnaires, 92.5% of women had no more urinary symptom (UDI-7 score of 20/100) and 93.8% had

Age at LSCP	54,4 [35-77]
Age at study	69,1 [46-91]
Body Mass Index (kg/m ²)	23,8 [18,4-36,3]
Parity	2,9 [1-7]
Ménopausal n (%)	52 (65%)
Previous hysterectomy n (%)	19 (23,8%)
Abdominal	11 (13,8%)
Vaginal	8 (10%)
Previous POP repair n (%)	16 (20%)
Abdominal	3 (3,8%)
Vaginal	13 (16,3%)
Previous SUI repair n (%)	9 (11,3%)
Pre-operative symptoms n (%)	
Pelvic heaviness	79 (98,8%)
Urinary symptoms	38 (47,5%)
Bowel symptoms	6 (7,5%)

Table 1: Clinical characteristics of the study population

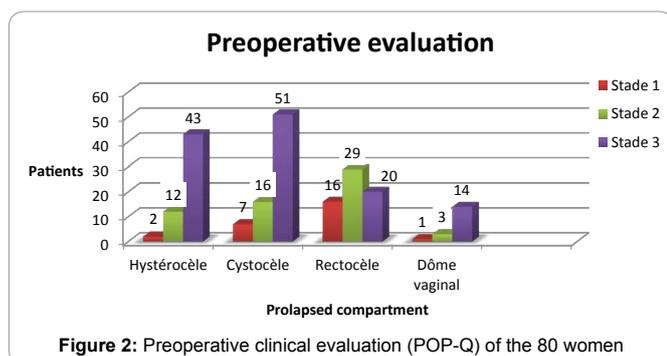


Figure 2: Preoperative clinical evaluation (POP-Q) of the 80 women

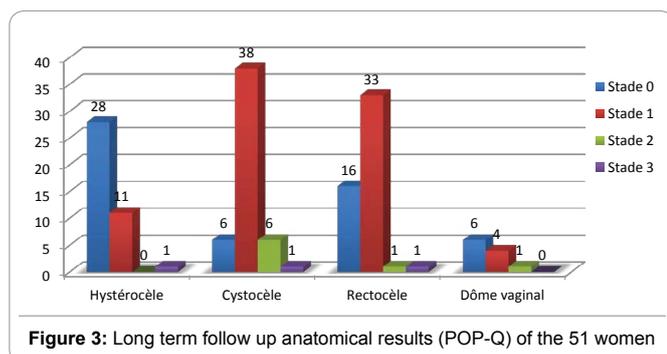


Figure 3: Long term follow up anatomical results (POP-Q) of the 51 women

	n/N	(%)	p
Multiparity			
Yes	20/76	26,3%	0,568
no	0/4	0%	
Menopausal			
Yes	14/52	26,9%	0,852
No	6/28	21,4%	
Previous hysterectomy			
Yes	4/19	21,1%	1,000
No	16/61	26,2%	
Previous POP repair			
Yes	1/15	6,7%	0,331
No	19/65	29,2%	
Uterine descent stage 3			
Yes	13/43	30,2%	0,517
No	3/16	18,8%	
Cystocele stage 3			
Yes	17/51	33,3%	0,049
No	3/29	10,3%	
Rectocele stage 3			
yes	16/60	26,7%	0,883
No	4/20	20%	
Vault prolapse stage 3			
Yes	4/14	28,6%	1,000
no	1/5	20%	
Hysterectomy during LSCP			
Yes	0/3	0%	0,563
No	20/77	25,9%	
BMI > 25			
Yes	N (average) 20 (34)	Standart deviation 3.2	P(Mann Whitney) 0.225
No	80 (23.4)	3.2	

Table 2: Risk factors for recurrence

	Urinary symptoms	Pelvic symptoms	Defecation < 3 per week
Patients symptomatic before surgery n (%)	38 (47,5%)	79 (98,8%)	6 (7,5%)
Patients symptomatic after follow up n (%)	15 (18,8%)	6 (7,5%)	10 (12,5%)
Unchanged	28 (35%)	6 (7,5%)	6 (7,5%)
Worse	10 (12,5%)	0	2 (2,5%)
De novo	5 (6,3%)	0	2 (2,5%)

Table 3: Long term functional results.

	Evaluation of POP symptoms n (%)	Evaluation of QoL n (%)
Improved	64 (80%)	74 (92,5%)
Unchanged	15 (18,8%)	5 (6,3%)
Worse	1 (1,3%)	1 (1,3%)

Table 4: Long term evaluation of QoL.

no impairment of QoL (UDI score 10.8/100). Pelvic symptoms were mainly heaviness and discomfort. Recurrence of symptoms happened after 8.9 years on average. At the time of our study, 96.3% of women presented no symptom (POPDI-6 score 14/100) and 95% had no impairment of QoL (POPQI-7 Score 7,5/100). Rectal symptoms were mainly constipation and/or obstructed defecation and recurrence happened after 6.8 years on average (1 to 11 years). In 80% of women, constipation was associated with POP recurrence. 86.3% of patients didn't complain of bowel symptoms (CRADI-8 score 20.2/100) and 93.1% had no impairment of QoL (CRAIQ-7 score 12/100).

Long term dyspareunia

The average age at the time of study was 69.1 years (range 46-91). Twenty-seven patients were still sexually active (33.7%) and 5 complained of de novo dyspareunia. Among the 42 patients that were not sexually active, none complained of de novo dyspareunia after the LSCP until the end of their sexual life.

Long term complication rate

Global rate of long term complications was 11.3% (9 patients) including: 5 vaginal mesh erosion occurring after 7.2 years (3 to 12) on average and 4 incisional hernias, after 4.8 years (1 to 10) on average. 3 of them had BMI > 25.

Discussion

There are few publications in the literature about long term results of LSCP [1] as presented in Table 5. Higgs et al. reported retrospective results after a median of 66 months in 103 women with vault prolapse [13]. Surgical technique was heterogeneous in this series; some women had a double approach (vaginal and laparoscopic) for mesh insertion with high vaginal erosion rate. Some had a single mesh sutured to the vault and the promontory with high anterior and posterior compartment recurrence. Some had laparoscopic insertion of a long posterior mesh and sometimes an additional anterior mesh. Granese, et al. [14] reported a series with 43 months of follow up in 138 women with vault prolapse. Technique was close to ours. No validated QoL questionnaires were used. Bowel symptoms like constipation and obstructed defecation increased during follow up from 7% to 13% and from 1.5% to 5.8% respectively. Sergent, et al. [15] published a prospective observational study of 116 women with POP, using the same QoL questionnaires as in our series, with a mean follow up of 34.2 months. Fifty-six subtotal hysterectomies (48.2%) and 29 SUI (25%) repairs were performed concurrently (vs 3.8% and 62.5% in our series). QoL questionnaires (PFDI, PFDIQ, and PPISQ-12) showed all significant improvement without impairment of bowel symptoms as in our series, maybe because of the younger age of the patients at the end of the follow up. The highest rate of anatomical failures was on anterior compartment. Sarlos, et al. [16] published a prospective study of 85 women with POP and 60 months of follow-up. Supracervical hysterectomy in

	Higgs et al. (23)	Granese et al. (18)	Sergent et al. (19)	Sarlos et al. (47)	Rivoire et al. (22)	Bui et al. (28)	Our series	
Study type	Retrospective	Prospective	Prospective	Prospective	Retrospective	Prospective	Retrospective	
Patients	103	138	116	85	131	84	80	
Prolapse	Vault	Vault	All	All	All	All	All	
Age at study	?	67 (58-76)	52,2 (30-70)	?	60,4 +/- 9,5	54 (30-75)	69,1 (46-91)	
Clinical examination	66	?	116	68	108	84	51	
Questionnaire	103	?	116	85	131	84	80	
Follow up (months)	66 (37-124)	43 (6-96)	34,2 (+/- 20,5)	60	33,7 +/- 17,4	30,7(7-102)	13,6 (11-20)	
Long term complications	Vaginal erosions (%)	9,0%	0,70%	3,40%	0%	5%	1,20%	6,2%
	Spondylodiscitis (n)	0	0	1	0	1	1	0
	Other	0	0	1 rectovaginal fistula	2 bladder erosions	1 vesicovaginal fistula	1 chronic pain	4 incision hernias
Anatomic recurrence	Anterior	22,70%	11,60%	12,2%	8,8%	17,5%	12,5%	21,5%
	Apical	4,0%	5%	2,6%	1,5%	13,7%	1,0%	3,9%
	Posterior	28,0%	12,30%	1,7%	5,9%	8,3%	9,5%	3,9%
Reoperation rate for POP	16,0%	20,20%	?	5,8%	5,0%	?	25,0%	
Subjective cure	Global	79,0%	83,30%	?	95,3%	98,0%	81%	93,8%
	De novo constipation/ obstructed defecation	?	18,80%	1,70%	4,7%	14,0%	13%	2,5%
	De novo SUI	?	5%	5%	37,6%	?	21,40%	6,3%
	De novo dyspareunia (among sexually active)	46,0%	3%	1%	24,0%	0,0%	15,70%	18,5%
	Sexually active	58,2%	?	73%	48,0%	61,0%	83,30%	33,7%
Reoperation rate for SUI		11,0%	?	?	18,8%	5,0%	?	18,8%

Table 5: Laparoscopic sacrocolpopexy long term results in literature.

case of uterine prolapse was systematic in this series. Most of recurrences occurred on the anterior compartment and within 12 months after initial surgery. Constipation rate increased from 1% one year after surgery to 4.7% after 5 years. Bui, et al. [17] presented a prospective series of 84 women with 30.7 months of follow up. Eighty-three women had hysterectomy. As in our series, anorectal scores (CRADI-8 and CRAIQ-7) showed impairment in time. The de novo dyspareunia rate is high contrasting with the improved PISQ-12 score. No explanation was provided. Rivoire, et al. [18] published a retrospective series of 131 women with 33.7 months of follow up. Technique was similar to our series but almost all had supracervical hysterectomy at the time of the LSCP. No QoL score was used to evaluate subjective results but 14% of patients had de novo constipation after LSCP. Urinary symptoms were not detailed but 51% of women were incontinent before and 47% after procedure despite 86% associated SUI repairs, mainly Burch colposuspension as in our series.

To date, our series has the longest follow-up described, with an average follow up of 156 months. Recurrence rate is high (25% reoperation, 21.5% at examination) happening after 5.9, 7.3 and 7.4 years for anterior, apical and posterior compartment respectively. SUI recurred after 8.9 years, pelvic symptoms after 8.9 years and rectal symptoms after 6.8 years on average. Vaginal mesh erosion happened after 7.2 years on average, later than after vaginal mesh insertion described in the literature: 41% after 24 months [19], but similar to the series of Higgs [13].

Rivoire, et al. stated that there is no recurrence happening after 40 months [18]. Our study suggests that recurrence and complication may occur much later. Later than the end of follow up of all published studies and thus, results and complication rates of LSCP appear to be very optimistic and should be revised.

If anatomic results are deteriorating in time, amazingly, QoL is not degraded; scores demonstrate no impairment of QoL in 92.8 to 95% of women which is consistent with the results of all other series having a shorter follow up except for Higgs [13], probably explained by the heterogeneity of his series. The difference between anatomic and functional outcomes underlines the usefulness of validated QoL questionnaires [2]. Improving function should be our first target.

Spondylodiscitis occurred 3 times in the literature review (0.4%) and 4 other severe complications as fistulas and mesh erosion into the bladder were reported. Amazingly, incisional hernias were not reported in any series but ours. A recent publication [20] found an incidence of 3.5% in laparoscopic surgery after a follow up of 32.2 months. Obesity was a risk factor as in our series. The rate ranges between 2 and 6% in a recent meta-analysis of publications about Robotic Assisted SCP (RASCP) [21].

In all series (except for Granese [14] and Higgs [13] who did not systematically reinforce the recto vaginal fascia with a posterior mesh), anatomic recurrence occurred mainly on anterior compartment. We found that a preexisting large cystocele was a risk factor for recurrence. Unfortunately we didn't quote precisely enough the anatomic defects of the vesico vaginal fascia at start. We think that defects like lateral detachment from the arcus tendineus or even low central defects cannot be repaired by an abdominal approach. LSCP can only reattach the fascia to the pericervical ring and reinforce it at the upper half of the anterior vagina, above the level of the trigone. For women with a

big cystocele (stage 3 and 4), with lateral defect, vaginal approach with mesh might theoretically be the best solution. Unfortunately, no long term results nor specific comparative trials have been published to date, only series with 3 years follow up [22,23]. A randomized French study is ongoing [24].

Anorectal function after LSCP seems to be impaired in most mid-term series [14,16-18] as on long terms in our series but impact on measured QoL is little. It may be due to pararectal or presacral dissection causing nerve lesions [18].

This series describes the result of our first 104 LSCP for POP, including our learning curve as in 4 of the 6 reviewed publications [13,14,17,18]. According to David [25], LSCP learning in an experimented surgical team induces high operative time, but remains safe for patient and doesn't modify outcome. As reported in our previous publication about short term results in 44 women of the same series [6], operation time was 240 minutes in the very first patients and decreased to 155 minutes after 30 operations, as in most series [1].

Performing supracervical hysterectomy at the time of LSCP is the rule in literature [15-18]. In our series, we systematically preserved the uterus unless there was a specific medical reason, like myoma or adenomyosis, to remove it (in 3 women only). This fact, added to the length of the follow up, might have influenced the outcomes. The risk of undiagnosed uterine malignancies at the time of supracervical hysterectomy during LSCP has been evaluated at 0.6% from 1488 operations in a meta-analysis of publications about Robotic Assisted SCP [26].

RA SCP was not available when our series started but a recent meta-analysis of 1488 women concluded that there was no difference in anatomic results or global complication rate between LSCP and RASCP [27]. Blood loss was less but operative time was longer and cost higher in RASCP. Associated hysterectomy was performed in 33% of women. Here again, average follow up was short (19 months) and longest was 34 months and it seems likely that most of recurrences, erosions are underdiagnosed.

We acknowledge that our series has some potential sources of bias. It's a retrospective study and 23% of patients were lost of view. The numbers are too small to evaluate some risk factors for recurrence like BMI or hysterectomy or rare complications like spondylodiscitis. Only 51 of the 80 women could be clinically assessed.

In summary, results of LSCP performed with the described technique are good at long term according to satisfaction index and QoL questionnaires. 25% of patients had to be re operated 5 to 8 years after first procedure, mainly for recurrence of cystocele. Anatomic results keep degrading in time; ageing might be a crucial factor. Preexisting large cystocele is a risk factor for anterior compartment recurrence.

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None

Disclosure of interest

None for any of the authors

Contribution to authorship

Elodie Massou: She was the fellow doing the research,

contacting and assessing the patients, collecting the data.

Angélique Chéret: She was the senior consultant, designing the research and supervising the fellow.

Naama Marcus-Braun: She did her fellowship in the university hospital of Caen and participated to the data collection. She reviewed the paper for correct English.

Peter von Theobald: He was the senior surgeon operating all the patients and he wrote up this paper.

Details of ethics approval

Institutional review board approval:

The Ethical Review Committee « *Comité d'éthique de la recherche en obstétrique et gynécologie* » has examined the research entitled: « Laparoscopic sacrocolpopexy: long term review after 13 years ». Submission number: CEROG 2015-GYN-1102.

This research was found to conform to generally accepted scientific principles and medical research ethical standards. This research was found to be in conformity with the laws and regulations of the country in which the research experiment was performed.

Founding

None

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