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ORIGINAL ARTICLE

Prospective comparison of short-term functional outcomes obtained after pure laparoscopic and robot-assisted laparoscopic sacrocolpopexy

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Abstract
Objective To prospectively compare short-term functional outcomes achieved by laparoscopic or robot-assisted sacrocolpopexy for pelvic organ prolapse.
Materials and methods We prospectively collected clinical and operative data over 24 months for female patients who underwent either pure laparoscopic sacrocolpopexy (LSCP) or robot-assisted laparoscopic sacrocolpopexy (RALSCP). Clinical data included age, BMI and assessment of PFDI-20 score. Perioperative data included operative time and complications. Post-operative outcomes included hospital stay, length of catheterisation, pain and functional outcomes as assessed by clinical examination and PFDI-20 score assessment.
Results Overall, 67 women with a median age of 65 were included: 47 in the LSCP arm and 20 in the RALSCP arm. RALSCP was superior in terms of blood loss (median 55mls vs. 280; $P = 0.03$) and strict operative time (median 125 min vs. 220; $P < 0.0001$), but this time advantage was nullified when comparing overall operating room time (215 min vs. 220). With a median follow-up of 16 months, the overall anatomic repair rate was 98.5%, and there was an improvement in overall PFDI-20 score before and after surgery ($P = 0.001$) but with no difference between the two surgical approaches.
Conclusions RALSCP allows for a safe and effective repair of pelvic organ prolapse in female patients. Whilst being equivalent to LSCP in terms of functional outcome, it is superior in terms of blood loss and strict operative time. These results are based on short-term assessment, and further studies of larger populations with longer follow-up and objective assessments of outcome are needed to make any definitive statement.

Keywords Pelvic organ prolapse · Stress urinary incontinence · Laparoscopic surgery · Robotics

Introduction

Female pelvic floor disorders rank amongst the most common disorders affecting women and include conditions such as urinary incontinence and pelvic organ prolapse (POP). POP is estimated to affect 30% of women aged 50–89 years, and the lifetime risk of requiring surgery is 11% [1, 2]. POP is a consequence of defective anatomical pelvic supports and can affect the anterior, middle (apical vaginal wall) and posterior compartments. Repair is possible abdominally, vaginally or minimally invasively, though the transvaginal approach is more familiar to non-urologists. Open abdominal sacrocolpopexy is the established gold standard procedure and is indicated when there is prolapse of the anterior and/or apical vaginal wall compartments [3]. The ideal POP repair must be effective, safe, durable, anatomical and preserve function (sexual, urinary and bowel), and it is these criteria that new procedures must fulfil. A minimally invasive laparoscopic approach has been developed over recent years, and it has been shown to be

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comparable in terms of functional outcome whilst demonstrating all the known advantages of laparoscopy [4, 5]. However, laparoscopic sacrocolpopexy (LSCP) has not been widely adopted as it demands skill and motivation and it is associated with a long learning curve. It is this background upon which the rise of Robotic surgery has taken place. Since 2004, authors have suggested that the robot-assisted laparoscopic approach for sacrocolpopexy (RALSCP) could be an alternative to a pure laparoscopic technique [6–8]. Hypothetically, the improved dissection and suturing capability afforded by the robotic platform will improve not only operative time but more importantly functional outcome and durability. Herein, we present the short-term results from a prospective comparison of LSCP or RALSCP for POP repair obtained in female patients at our institution.

Materials and methods

Patient population

After ethical approval from our local committee (AP-HP), we prospectively collected the clinical data from all female patients who underwent either a LSCP or a RALSCP in our department between January 2008 and November 2010. As a preoperative work-up, all women underwent symptom assessment using the PDFI-20 (Pelvic Floor Distress Inventory) validated self-questionnaire designed for French-speaking patients [9], a systematic urogynaecological physical examination to assess the type and the severity of the prolapse according to the Baden and Walker classification [10], urine analysis, Papanicolaou smear, pelvic ultrasonography and urodynamic studies. To detect occult stress urinary incontinence (SUI), prolapse was systematically repositioned into the correct anatomical site with a sponge-holding forceps. Concomitant or occult clinical SUI was then assessed using the Bonney manoeuvre and distal Marshall test. The following data were collected: age at the time of surgery, body mass index (BMI), menopause status, past medical, obstetrical and surgical histories, and the existence of urinary incontinence. We also recorded intraoperative parameters including operative time, blood loss, complications, concomitant procedure (such as TVT or TOT), length of hospital stay (LOS), length of catheterisation, analgesic requirements and type of analgesia according to the WHO classification (Level 1, 2 or 3) (http://www.who.int).

Operative technique

Two experienced surgeons [11, 12] were individually dedicated to each procedure, and the patients underwent either LSCP or RALSCP at the physician's discretion. LSCP was performed via a transperitoneal approach, and for the RALSCP, we used the 3-arm da Vinci® surgical system and a transperitoneal four-port technique. The surgical principles were identical in both groups, as described previously [5, 6]. Briefly, the procedure commenced with a Hasson style open insertion of the primary trocar to create a pneumoperitoneum. We then introduced two standard laparoscopic ports to perform enterolysis followed by the placement of retracting sutures through both the sigmoid tenia and the uterus to expose the sacral promontory and the posterior compartment. Subsequently, we made a peritoneal incision from the sacral promontory to the Pouch of Douglas. After careful dissection of the inter-rectovaginal space, a two-piece Y-shaped polypropylene mesh (Parietex®, Tyco Healthcare, Gosport, UK) was fixed posteriorly to the levator ani muscles using a non-absorbable suture (polypropylene 2–0). The midpoint of the mesh is anchored to the posterior wall of the vagina. The anterior portion of mesh was then introduced and fixed within the intervesicovaginal space to the anterior/apical vaginal wall with a running suture (polypropylene 2–0) and passed through the right broad ligament. The tails of both meshes were fixed to the sacral promontory with a strong non-absorbable polyester suture (Mersuture 0). The peritoneal incision was reapproximated with a running absorbable suture (polyglactin 2–0). Operative time was classified as 'strict operating time' (time for port insertion plus procedure and excluding the preparation and docking of the robot) or 'overall operating time' (total time in operating theatre). Post-operatively, all patients routinely had an indwelling urethral catheter for 2 days or longer if deemed appropriate (e.g. bladder injury).

Complications

The early post-operative complications were defined according to the Clavien grading system for surgical morbidity [13]. Events considered Clavien grade I-II were ranked minor complications. Major complications (Clavien III-IV-V) were defined as any event requiring reoperation or unexpected intensive care unit (ICU) management.

Follow-up

Patients were systematically reviewed at 1, 3, 6 months and yearly, or if there were intercurrent urinary symptoms. The follow-up consisted of a physical examination, uroflowmetry, symptom re-evaluation (PFDI-20) and urodynamic studies if there were urinary symptoms. The results were subjectively classified as success (no more symptoms), improvement or failure (persistence of symptoms). The anatomical recurrence of a prolapse was defined as a prolapse of at least grade 2 according to the Baden and Walker classification.

Statistical analysis

For statistical analysis, the Mann–Whitney *U* test was used to compare continuous variables and Fishers exact test to compare categorical variables. A *P* value of less than 0.05 was considered significant. All tests were carried out with 'Stata' software, v. 10.0.

Results

Population

Overall, 67 female patients with a median age of 64 years were included. Amongst them, 20 underwent RALSCP and 47 underwent LSCP. Both groups had similar characteristics except for age. The main characteristics of these women from both groups are presented in Table 1. The median BMI for the whole population was 24. Overall, 15 patients had a prior history of gynaecological surgery, including 5 patients with a previous colposuspensions and 6 patients who had undergone a hysterectomy. The vast majority of patients (76%) were post-menopausal. According to the Baden and Walker grading system, patients suffered from symptomatic prolapse of different degrees: 17 had grade II, 45 grade III and 5 grade IV, and less than one-third ($n = 18$) had associated urinary incontinence. We found high-grade cystocele and rectocele in half and a third of the patients, respectively. At least two pelvic compartments were involved in over 80% of the patients. The median overall summary score of PFDI-20 at baseline was 160.

Table 1 Patient characteristics

	RALSCP	LSCP	*P* value
Patients (%)	20	47	
Age (years)			
Mean (SD)	60 (11.5)	66.7 (12.8)	**0.05**
Median (range)	59.5 (34–78)	67 (41–90)	
Body mass index			
Mean (SD)	24.7 (3.5)	24.1 (3.9)	0.4
Median (range)	24 (21–34)	24 (19–37)	
Menopausal status (%)			
Pre	4 (20)	12 (25.5)	
Post	16 (80)	35 (74.5)	0.4
Obstetric history (%)			
Nulliparous	2 (10)	2 (4.2)	
Parous	18 (90)	45 (95.8)	0.3
Clinical complaint at presentation (%)			
Prolapse	16 (80)	29 (61.7)	0.1
Pain	0	1 (2.1)	0.7
Incontinence	2 (10)	10 (21.3)	0.2
Prolapse and incontinence	2 (10)	7 (14.9)	0.5
Urinary incontinence (%)			
No	13 (65)	36 (76.6)	
Yes	7 (35)	11 (23.4)	0.2
Occult	3 (15)	15 (31.9)	
Previous gynaecological surgery (%)	4 (20)	11 (23.4)	

Significant *P* values are in bold

Surgery

In the RALSCP group, intraoperative complications occurred in three patients due to the following reasons: one conversion to laparotomy due to adhesions and two bladder injuries. In addition, we encountered two delays secondary to a technological dysfunction, but both did not necessitate a change in surgical approach. In the LSCP group, intraoperative complications occurred in nine patients: three conversions into laparotomy for anaesthetic reasons (difficulty arising as a consequence of the Trendelenburg position), five bladder injuries and one bowel injury. Blood loss was significantly lower in the RALSCP group. Strict operative time, as defined earlier, was significantly shorter in the RALSCP group. However, there was no difference in the overall length of time the patient was in the operative theatre. Full data are provided in Table 2.

There was a statistically significant difference regarding the length of bladder catheterisation, which was removed earlier in the RALSCP group, with a median of 2 days versus a median of 3 days in the LSCP group. During the post-operative course, we encountered 20 minor complications (mostly slight deviation from the normal post-operative course without the need for pharmacologic treatment or surgical, endoscopic, interventions such as urinary retention at catheter removal ($n = 8$) or ileus ($n = 12$)) and 4 major complications (i.e. 4 abdominal wall abscesses), respectively. Besides, we found no difference between the two groups according to the grading from the Clavien-Dindo classification [14]. Detailed data are provided in Table 2. There was no difference regarding the use of analgesia or LOS between the two groups ($P = 0.4$ and $P = 0.5$, respectively).

Outcomes

The median follow-up was 16 months (range 10–36), and the overall anatomic repair rate was 98.5%. According to patient's clinical interview, the success rate for resolution of symptoms was 95.5%. During the follow-up, a gynaecological examination revealed a prolapse recurrence in one patient from the RALSCP group at 6 months. This woman refused to undergo a subsequent procedure. Overall, the

Table 2 Operative, post-operative data and complications

	RALSCP	LSCP	*P* value
Patients (%)	**20**	**47**	
Intraoperative complications (%)			
None	17 (85)	38 (81)	0.9
Conversion to open procedure	1 (5)	3 (6)	
Other	2 (10)	6 (13)	
Concomitant procedure (%)			
None	14 (70)	22 (47)	**0.006**
TVT	3 (15)	24 (51)	
TOT	3 (15)	1 (2)	
Operative blood loss (ml)			
Mean (SD)	55 (30)	280 (81)	**0.03**
Median (range)	50 (0–100)	300 (100–400)	
Strict operative time (mins)			
Mean (SD)	128 (48)	231 (68.5)	**<0.0001**
Median (range)	125 (90–270)	220 (80–420)	
Overall operating room time (mins)			
Mean (SD)	217 (40.9)	231 (68.5)	0.4
Median (range)	215 (160–280)	220 (80-420)	
Immediate post-operative period			
Duration of catheter			
Mean (SD)	2.5 (1.8)	3.1 (1.6)	0.03
Median (range)	2 (1–10)	3 (1–7)	
Class of Painkiller			
Level 1, e.g., Paracetamol	12	32	0.4
Level 2, e.g., Tramadol	7	15	
Level 3, e.g., Morphine	1	0	
Hospital stay (days)			
Mean (SD)	5.1 (1.1)	6.4 (3.3)	0.5
Median (range)	5 (2–8)	5 (3–20)	
Post-operative complications according to Clavien's classification			
Grade I	4	10	0.3
Grade II	1	5	0.3
Grade IIIA	–	–	–
Grade IIIB	1	3	0.7
Midterm outcomes			
Urinary infection	1	3	0.7
Vaginal erosion	–	1	0.7
Dysuria	–	3	0.3
Dyspareunia	–	1	0.7
Prolapse recurrence	1	–	0.3
de novo urinary stress incontinence	–	1	0.7
Constipation	1	3	0.7
Median length of follow-up (months)	15	18	0.05

Significant *P* values are in bold

following adverse outcomes were reported during follow-up: urinary infections ($n = 4$), dysuria ($n = 3$), constipation ($n = 4$), vaginal erosion from the anterior mesh ($n = 1$), dyspareunia ($n = 1$), and de novo urinary incontinence ($n = 1$). We found no significant overall difference between the two groups allowing for the short-term follow-up. The median overall summary score of PFDI-20 at last follow-up was 27. There was a significant improvement in overall PFDI-20 score before and after surgery ($P = 0.001$), but no significant difference between the two surgical approaches.

Discussion

The concept of 'promontofixation' was described many years ago and the first open sacrocolpopexy followed in the 1950s [14, 15]. With a 78–100% success rate and a median re-operation rate of only 4.4%, it has been proven superior to sacrospinous-based vaginal reconstruction for POP [16, 17]. However, despite these facts, there is evidence available to challenge the notion that open sacrocolpopexy is the gold standard approach for POP in the modern era. LSCP was first described in 1992 [18], and there is now long-term comparative evidence of its equivalence to open surgery in terms of functional outcome [19]. In a comparative cohort study, Paraiso et al. [20] demonstrated equivalent clinical outcomes whilst also reporting LSCP takes longer but leads to less blood loss and shorter hospital stay. This conclusion can now be extrapolated to RALSCP but with potential additional benefits above LSCP. First reported in 2004, there are several published series of RALSCP illustrating that it combines the ability to emulate the open surgical principles of repair with the benefits of minimally invasive surgery, including shorter recovery, earlier hospital discharge and less bleeding [21]. Its arguable superiority to LSCP as a minimally invasive technique lies in its shorter learning curve, relative ease of suturing, shorter operating times and further reduction in blood loss [6–8, 22]. Geller et al. [22] published a comparative retrospective study of 178 patients (73 RALSCP vs. 105 open sacrocolpopexy). They reported similar short-term (6 week) vaginal vault support with longer operating time, less blood loss and shorter length of stay. In the only study that has attempted to compare LSCP with RALSCP, White et al. [23] reported their experience of single-port LSCP. They collected data prospectively on ten patients who underwent single-port LSPC and compared them to historical cohorts of patients who had undergone either conventional LSCP ($n = 10$) or RALSCP ($n = 10$). This cannot, however, be considered a comparative study of LSCP versus RALSCP as it was not the primary aim, and the cohorts were historical.

To our knowledge, the current report is the first prospective study to directly compare the short-term outcomes of

RALSCP with LSCP. In respect of post-operative outcomes, we found no difference between the two groups at both early and short-term intervals. Post-operative results were equivalent for pain, hospital stay, functional outcome and overall complication rate. Within the LSCP group, there were 5 bladder injuries (10%), which compares to a published rate of 1.4–10.7% [19] and explains the difference in the median length of catheterisation post-operatively (3 vs. 2 days). We have also validated the findings of other series of RALSCP by showing the blood loss is significantly less compared to LSCP [7, 20]. A notable finding in our study was our ability to demonstrate that the 'strict operative time' (excluding time for preparation and docking of robot but including port placement) for RALSCP is significantly less than LSCP. Specifically, RALSCP was a median of 95-min quicker, but this advantage was not carried over into overall operative room time. Operative times for both RALSCP and LSCP have been reported in the literature. In the recent review by Ganatra et al. [19], operative time for LSCP ranged from 96 to 286 min, and such variation is seen in published RALSCP series, ranging from 172 to 317 min for Daneshgri et al. [6, 24]. More recently, Xylinas et al. [25] have reported a mean operative time for RALSCP of 144 min. This data is difficult to extrapolate as to a large extent, the time is significantly influenced by the experience of the surgeon (step in the learning curve) and on the definition of the operative time (strict operative time, time of anaesthesia or time in operative room). However, despite the unavoidable pre-console requirements, we have illustrated the pure operative time of RALSCP is significantly less than LSCP.

We would like to address some limitations of our study. Though prospective in design, patients were treated sequentially not simultaneously and were not randomised. The surgeons who performed both techniques had a long experience of robotic surgery and of pure laparoscopy and consequently short learning curves. A surgeon with no experience in robotic surgery may not produce the same outcomes, even if the learning curve appears to be shorter in robotic surgery compared to laparoscopy [26–29]. The incidence of post-operative complications is still the most frequently used surrogate marker of quality in surgery. The vast majority of reports do not investigate complication rates of sacrocolpopexy in relation to the surgical approach, and there is a lack of a standardised reporting system. Thus, we strongly advocate to report complications according to a validated system as we did herein, since it remains the best way to acknowledge that both RALSCP and LSCP are safe and lead only to minimal complications in the vast majority of cases. Furthermore, despite the distinct technical advances robotic surgery has introduced, the issues of prohibitive costs must be considered when comparing operative results with other techniques. It has been shown that the least expensive surgical approach from the hospital costs perspective is open abdominal sacrocolpopexy [30]. Arguably, based on results and the current climate, it may appear unjustified to propose RALSCP as the new gold standard treatment of POP, but it is imaginable in an economically unrestrained environment that all surgery for POP would be performed robotically, as we feel it is a superior technique to LSCP.

Conclusion

RALSCP allows for a safe, effective, short-term durable repair of pelvic organ prolapse in female patients. Whilst being equivalent to LSCP in short terms of functional outcome, it is superior in our hands in terms of blood loss and operative time. However, these results are still preliminary, and further studies of larger populations with longer follow-up are needed to make any definitive statement regarding surgical access.

Conflict of interest The authors declare that they have no conflict of interest.

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