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The introduction of laparoscopic sacral colpopexy to a fellowship training program

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Abstract

Introduction and Hypothesis—Minimally invasive sacral colpopexy has increased over the past decade with many senior physicians adopting this new skillset. However, skill acquisition at an academic institution in the presence of post-graduate learners is not well described. This manuscript outlines the introduction of laparoscopic sacral colpopexy to an academic urogynecology service that was not performing minimally invasive sacral colpopexies while also defining a surgical learning curve.

Methods—The first 180 laparoscopic sacral colpopexies done by 4 attending urogynecologists from January 2009 to December 2011 were retrospectively analyzed. The primary outcome was operative time. Secondary outcomes included conversion to laparotomy, estimated blood loss, and intra- and postoperative complications. Linear regression was used to analyze trends in operative times. Fisher's exact test compared surgical complications and counts of categorical variables.

Results—Mean total operative time was 250 ± 52 minutes (range 146–452) with hysterectomy and 222 ± 45 (range 146–353) for sacral colpopexy alone. When compared to the first 10 cases performed by each surgeon, operative times in subsequent groups decreased significantly with a 6 to 16.3% reduction in overall times. There was no significant difference in the rate of overall complications regardless of the number of prior procedures performed ($p=0.262$).

Conclusions—The introduction of laparoscopic sacral colpopexy in a training program is safe and efficient. The reduction in operative time is similar to published learning curves in teaching

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Author participation

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and non-teaching settings. Introducing this technique does not add additional surgical risk as these skills are acquired.

Keywords

Laparoscopy; Learning curve; Prolapse; Sacral colpopexy

Introduction

As the population ages and more focus is placed on improved quality of life, the number of women seeking and receiving treatment for pelvic organ prolapse is expected to rise. An estimated 245,970 women will seek treatment for prolapse in the year 2050 [1]. Sacral colpopexy, although potentially longer and more invasive than vaginal surgery, has been shown to provide more durable apical support with a reported success rate of 78–100%. [2,3] Surgeons have traditionally performed this operation through an abdominal incision, but with advances in surgical technology and skills, have transitioned to a minimally-invasive approach.

Laparoscopic sacral colpopexy has been shown to have similar complication rates compared to those done via an abdominal approach [4]. Operative times have been shown to be longer, but vary widely between 181 and 510 minutes [5–7]. Despite the longer operative times, patients often have less estimated blood loss, decreased hospital stays, less postoperative pain, and an overall improved convalescence when compared to open surgery [4,7,8]. Importantly, overall success rates have been similar to the abdominal approach at between 77–100%, with a meta-analysis of over 1000 patients noting an objective success rate of 92% [9,10].

The learning curves reported for laparoscopic sacral colpopexy have varied greatly, likely representing differences in surgeons' baseline skills, patient population, and the participation of trainees. Improved surgical time has been reported to occur at 18 to 30 cases, while improved complication and anatomic failure rates occur at 60 cases [5,11]. However, one study of over 1,500 total laparoscopic hysterectomies found that significant improvement in surgical outcomes continues to increase until approximately 125 cases [12]. The majority of learning curve literature was developed from non-teaching services.

Our aim was to describe the introduction of laparoscopic sacral colpopexy to an academic urogynecology service that was not performing minimally invasive sacral colpopexies. We also sought to define the surgical learning curve as defined by operative times and patient complications.

Methods

This retrospective cohort includes all women who underwent a laparoscopic sacral colpopexy by one of four attending urogynecologists at a tertiary health care center between January 2009 and December 2011. Prior to January 2009, none of the physicians had performed a laparoscopic sacral colpopexy though all had experience with basic laparoscopic techniques and had performed multiple open sacral colpopexies. To learn this

new skill, two attendings operated with departmental surgeons who possessed advanced laparoscopic skills: one a non-urogynecologist who performed laparoscopic sacral colpopexies and the other a gynecologic oncologist who did not perform laparoscopic sacral colpopexies. These two attendings then proctored the two other divisional surgeons, and then all four attendings subsequently operated with each other to refine their minimally-invasive skills. All surgeries were performed with the presence, and ultimately the assistance of a urogynecology fellow, an obstetrics and gynecology resident, or both.

After obtaining institutional review board approval, patient demographics including age, body mass index, parity, prior abdominal and gynecologic surgeries, past medical history, and pelvic organ prolapse quantification (POP-Q) exams were extracted from the medical record [13]. Operative times, estimated blood loss, and intraoperative complications were also recorded. Both the inpatient and outpatient medical records were analyzed to identify postoperative complications, mesh exposures, and postoperative prolapse stage.

The primary outcome was operative time, obtained from operating room records, and measured from skin incision to closure. Operative times included any concomitant procedures that were performed including ureteral stent placement and removal, as we were unable to assess the contributions of each individual component to overall time. Secondary outcomes included conversion to laparotomy, estimated blood loss, and intra- and postoperative complications. Given prior reports demonstrating significant decreases in operative times at 18–30 cases, we estimated that at least 30 cases needed to be performed by each surgeon in order to potentially identify significant changes in operative times and complication rates [5,11]. With the exception of one attending surgeon who completed his fellowship at this institution during the study interval, surgeons had between 1 and 9 cases proctored by non-urogynecology faculty during the study period that were excluded from this analysis because large parts of these cases were performed by the proctoring physician affecting learning curve data.

To decrease individual case variations, subjects were grouped chronologically in blocks of ten per surgeon for analysis. Trends in operative times were analyzed by linear regression. To obtain a normal distribution, the data were transformed using the natural logarithm conversion of the operative times. Covariates included fellow involvement and year of fellowship training. Results are presented as means with standard deviations for continuous normally distributed variables and medians with interquartile range for continuous non-normally distributed variables. Frequencies with percentages were used to describe categorical variables. Data were analyzed using SPSS version 19. A p-value <0.05 was considered significant.

Operative procedure

After pre-operative antibiotics and general anesthesia were administered, the patient was positioned in the lithotomy position with arms tucked at her side. In the majority of cases, ureteral stents were placed and removed at the conclusion of the surgery. A reusable uterine manipulator was then placed if hysterectomy was to be performed. Laparoscopic port placement included a 10mm umbilical trocar, one 5mm trocar in each lower quadrant, and

either a suprapubic or left periumbilical 10mm trocar. Hysterectomy was performed if the uterus was still present via transection of the round ligament, development of the bladder flap, and transection of either the utero-ovarian or infundibulopelvic ligaments depending on whether or not oophorectomy was performed. The posterior leaf of the broad ligament was dissected to isolate then transect the uterine vessels. A vessel-sealing device ensured hemostasis throughout (Covidien LigaSure, Mansfield, MA or Ethicon EnSeal, Somerville, NJ). Given the majority of hysterectomies were performed supracervically, cervical transection was done with monopolar scissors with subsequent suture imbrication of the cervical stump. Uterine morcellation was performed with a disposable morcellator (Gynecare Morcellex, Somerville, NJ or Karl Storz Rotocut G1 Morcellator, El Segundo, CA).

After retraction of the large bowel with sutures placed through the sigmoid epiploica, the sacral dissection was performed using a combination of monopolar scissors and a vessel-sealing device to expose the sacral promontory and the anterior longitudinal ligament. The middle sacral vessels were then identified and sealed. The vesicovaginal dissection was performed using a combination of scissors, monopolar energy, and a vessel-sealing device, revealing approximately 4–5 cm of anterior vagina from the level of the cervix. The rectovaginal dissection was completed in a similar manner to the level of the levator ani complex. Strips of polypropylene mesh (Gynecare Gynemesh PS, Somerville NJ) were then attached to the anterior and posterior vagina using a total of 10–14 interrupted delayed-absorbable monofilament sutures tied extracorporally. Both pieces of mesh were then simultaneously attached to the sacral promontory with a spiral tacking device (Covidien ProTack, Mansfield, MA), and the peritoneum overlying the mesh was closed with interrupted sutures. Cystoscopy with indigo carmine confirmed ureteral patency and absence of bladder injury.

Results

A total of 180 cases were completed during the study period. Subjects had a mean age of 57.8 ± 9.1 years and a BMI of 26.6 ± 4.1 kg/m² (table 1). At baseline, 72% had a POP-Q stage of III or IV, 57.8% had at least 1 prior major pelvic surgery, 41.1% had prior hysterectomy, and 25% had prior prolapse repair. Concomitant procedures included supracervical hysterectomy (56.7%), total hysterectomy (0.6%), salpingo-oophorectomy (21.1%), perineorrhaphy (6.1%), and lysis of adhesions (45%). Of the 20.1% of women with objective preoperative stress urinary incontinence, 4.4% had a midurethral sling placed, while the remaining desired a staged approach.

Mean total operative time was 250 ± 52 minutes (range 146–452) with hysterectomy and 222 ± 45 minutes (range 146–353) for sacral colpopexy alone. When compared to the first 10 cases performed by each surgeon, operative times in subsequent blocks decreased significantly with a 6 to 16.3% reduction in overall times (Figure 1 and Table 2). Median estimated blood loss (50cc, range 5–600cc) and mean operative set-up time, defined from intubation to skin incision, (19.4 ± 6.8 minutes) did not significantly change over the study period. Similarly, mean length of stay remained relatively constant (1.4 ± 0.6 days).

Fellow involvement was defined as the fellow being either the primary surgeon or first assistant. After the brief and excluded proctored interval, attending urogynecologists frequently assisted each other until they were comfortable enough to operate with a fellow as assistant. In the study period, two attendings were involved in 20 out of 180 cases. In cases with no fellow involvement (n=25), there was a significant decrease in operative time throughout the study period ($p<0.001$). Conversely, for cases with fellow involvement, year of fellowship training was not associated with a significant improvement in operative times (p 0.130, 0.92, 0.896 for years 1,2,3 respectively).

There was no significant difference in the rate of overall complications regardless of the number of prior procedures performed ($p=0.262$, complications listed in Table 3). Three cases were converted to laparotomy for extensive lysis of adhesions. Six cystotomies were all repaired laparoscopically. One patient underwent a laparoscopic appendectomy after concern for possible thermal injury during lysis of adhesions. Two patients had bowel serosal defects repaired with interrupted sutures; one injury occurred during lysis of adhesions and the other after a needle injury to the sigmoid colon.

Seven patients were readmitted to the hospital. Three patients had partial small bowel obstructions; two resolved with conservative management and one underwent repair of a small bowel herniation that occurred at a 5mm trocar site. One patient was admitted with a mesh infection which was originally managed with intravenous antibiotics. She ultimately underwent mesh removal for persistent pain 6 months post-operatively. An additional patient was admitted for each of the following: *Clostridium difficile* colitis, pleuritic chest pain with a negative work-up, and prolonged ileus that was managed conservatively.

In 91 patients (50.6%) with documented postoperative POP-Q exams, 36.3% had stage 0, 42.9% stage I, and 20.9% stage II prolapse. Of the 19 patients with stage II prolapse, the majority (74%) occurred in the posterior vagina, where 7 patients had a Bp = -1, while only 1 had a Bp = +1. Mean overall follow-up was 6.6 ± 5.7 months. Of the 58 patients (32%) who had at least 6 months of follow-up (range 6–24 months), there were no mesh exposures

Discussion

At this single academic institution, laparoscopic sacral colpopexy was efficiently introduced into a group of surgeons with extensive open, but minimal laparoscopic experience. The surgeons were able to achieve surgical times similar to those reported by both teaching and non-teaching hospitals [11,14]. A plateau in operative times was never reached, as the surgeons' times continued to improve, and thus these surgeons are likely still on their individual learning curves. Similarly, in his study of 185 women undergoing laparoscopic sacral colpopexy done by one senior surgeon, Claerhout et al noted a significant decline in operative time during the first 30 cases, but a plateau was not reached until after 90 cases [5]. Conversely, shorter learning curves have been demonstrated for laparoscopic sacral colpopexy at non-teaching institutions, with significantly decreased operative times noted at 15 to 24 cases [11,15]. Thus, trainee participation likely impacts the learning curve, but the magnitude of impact has not yet been elucidated.

Interestingly, mean operative time decreased significantly with each group of ten cases until cases 31–40 when there was a non-significant increase in overall times. Possible reasons for this rise include increased trainee participation or the selection of more surgically complicated patients as the attendings became more comfortable in the technique. Further review of these cases revealed no outliers or complications that could explain the longer times. In a training institution, adoption of a new surgical technique is likely to have oscillating operative times given the constant involvement and turnover of residents and fellows at different levels of training with diverse surgical experience and abilities. Indeed, mean operative times have been reported to vary greatly at academic institutions from 199 to 510 minutes [6,7,14,15].

Importantly, the overall complication rate remained low and did not change throughout the study period.. Multiple studies at non-teaching institutions previously have demonstrated that the rate of complications during adoption of the laparoscopic approach remained low [11,15]. Similarly, our study confirms that at academic institutions with varied trainee participation there was no increase in complications during the adoption of a new technique.

One major limitation of this study is its retrospective nature and therefore the inability to determine the contribution of various aspects of the sacral colpopexy or concomitant procedures on overall operative time. Paraisio et al, in a randomized controlled trial comparing laparoscopic versus robotic sacral colpopexy, found that extracorporeal suturing time contributed to approximately 40% of total surgical time [14]. Laparoscopic suturing, which is often described as one of the most difficult skills to master during sacral colpopexy, also has a known learning curve [17]. It is likely surgeons improved this skill throughout the study period which may be reflected in the decreasing operative times. However, given our retrospective study design, it is impossible to determine the magnitude of the impact of learning and mastering this surgical skill.

Another major limitation is the inability to determine the extent of fellow or resident participation in each case or the baseline skills of the trainees. The amount of fellow involvement likely varied based on attending surgeon preference, year of fellowship, and surgical skillset of the trainee.. Although trainee education impacts operative times, we believe that training the future generations in new surgical techniques is a necessity We have demonstrated that operative times can continuously improve despite trainee involvement reinforcing the idea that teaching facilities can efficiently introduce new surgical techniques..

In summary, the laparoscopic approach to sacral colpopexy can be safely and efficiently introduced into a fellowship training program with continued improved surgical times and a low rate of complications. Further research, ideally in a prospective trial at an institution naïve to the laparoscopic technique, will help decipher which portions of the case have the greatest impact on operative times and which portions improve with increased case number. Similarly, the impact fellow and resident involvement has on overall operative times and surgical learning is yet to be elucidated.

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Brief Summary

Laparoscopic sacral colpopexy can be efficiently and safely introduced in a urogynecology training program with decreasing operative times and no additional surgical risk.

Figure 1.
Operative times by number of cases performed

Table 1

Patient characteristics

Patient characteristics	Mean $\pm$ SD or Median (range)
Age (years)	57.8 $\pm$ 9.1
BMI (kg/m ²)	26.6 $\pm$ 4.1
Gravidity	3 (0–8)
Parity	2 (0–5)
Preoperative prolapse stage	3 (2–4)
Postoperative prolapse stage*	1 (0–2)

* Postoperative prolapse stage only available for 91 of 180 subjects

Table 2

Operative Times Compared to First 10 Cases

Cases per surgeon	Operative Time(minutes)	Percent reduction in operative time relative to first 10 cases	p-value
0–10	272.3	Reference	
11–20	245.9	9.7%	0.043
21–30	227.9	16.3%	<0.001
31–40	256.0	6 %	0.220
41–50	236.1	13.3%	0.003
51+	232.8	14.5%	0.003

Table 3

Surgical and Postoperative Complications

Complication	Number (%) of patients
Bladder injury	6 (3.3)
Bowel injury (two serosal injuries, one appendectomy)	3 (1.7)
Conversion to laparotomy	3 (1.7)
Blood transfusion	0 (0.0)
Corneal abrasion	3 (1.7)
Readmission	7 (3.9)
Small bowel obstruction	3 (1.7)
Surgical site infection	2 (1.2)
Mesh infection with removal of mesh	1 (0.6)