Original Paper

Urologia Internationalis

Urol Int
DOI: 10.1159/000323862

Received: September 27, 2010
Accepted after revision: December 14, 2010
Published online: February 24, 2011

Long-Term Outcomes after Robotic Sacrocolpopexy in Pelvic Organ Prolapse: Prospective Analysis

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Key Words
Robotic sacrocolpopexy · Robotic surgery · Vaginal vault prolapse · Pelvic organ prolapse

Abstract
Objective: To evaluate the feasibility and long-term outcomes of our initial series of robot-assisted laparoscopic sacrocolpopexy. ***Methods:*** We conducted a prospective analysis of our series of robotic sacrocolpopexy. Inclusion criteria: patients with grades III and IV cystocele and or other symptomatic pelvic organ prolapse. We performed a transperitoneal four-trocar technique with the Da Vinci robotic system using two polypropylene meshes for fixation to the sacral promontory. The primary outcome was recurrence; secondary outcomes included operating room time, blood loss, conversion to open surgery, complications and length of stay. ***Results:*** 31 consecutive procedures were included. Mean patient age was 65.2 (50–81) years. Mean operating room time was 186 (150–230) min. We converted 1 case to laparoscopy (3.2%). There were two major complications (1 acute myocardial infarction and 1 reoperation for excess tension with syncopes), two minor complications (1 wound infection and 1 ileus) and no recurrences at a mean follow-up of 24.5 (16–33) months. ***Conclusions:*** Robotic sacrocolpopexy could possibly improve with experience after overcoming the learning curve. There is no doubt it is a reproducible technique, but its safety and efficacy still need to be proven. Our initial series demonstrated good outcomes and no recurrences at 24.5 months of follow-up.

Introduction

The vaginal approach to pelvic organ prolapse is considered to be less invasive, but may be technically difficult, mainly in patients with previous surgery, and has a high risk of recurrence [1]. The abdominal approach may solve this problem (efficacy 93–100%) [1], but implies high morbidity and a long hospital stay when performed through open incisions. Laparoscopic sacrocolpopexy was introduced by Nezhat et al. [2] in 1994 and summed up the advantages of the abdominal approach and minimally invasive surgery. It is considered a reliable procedure that effectively and consistently resolves vaginal vault prolapse [3].

Robot-assisted laparoscopic sacrocolpopexy was introduced in 2004 as an additional step in the evolution of minimally invasive surgery [4]. Preliminary published data on the use of the Da Vinci system up to date are promising, although they need to be improved and repro-

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duced in more institutions, and larger series and prospective trials are needed [5, 6].

Our objective is to describe the technique and outcomes of robot-assisted laparoscopic sacrocolpopexy. Our primary aim was to assess long-term recurrence. Secondary aims were to evaluate operative time, conversion, blood loss, length of stay and incidence of complications.

Methods

We conducted a prospective study analyzing the outcomes of our initial series of robotic sacrocolpopexy. This study was approved by the Robotic Surgery Plan of the Hospital Clínico San Carlos, Madrid, Spain [7]. Patients were consecutively operated on from November 2006 to May 2008. Every symptomatic prolapse (cystocele, rectocele, uterus prolapse, vaginal vault prolapse) was included in the study. There were a number of relative contraindications related to anesthetic risk [8].

We used the prolapse classification by grades: grade 0 (no prolapse), grade I (prolapse within the introitus), grade II (descent of the pelvic organ to the introitus with Valsalva), grade III (prolapse external to the introitus with Valsalva), and grade IV (prolapse out of the introitus both in rest and Valsalva). We considered inclusion criteria the indication for surgery. Among them we considered the following symptomatic organ prolapses: vaginal vault prolapse (n = 18), grade III cystocele (n = 22), and grade IV cystocele (n = 9). Exclusion criteria were absolute contraindications for surgery (anesthetic, cardiopathies and severe lung disease) and relative contraindications (prior abdominal surgery, obesity). Recurrence is defined as the development of prolapse during follow-up.

Preoperative Protocol

Preoperative Evaluation/Informed Consent. Every patient underwent clinical assessment, physical exploration, ultrasound, cystogram and urodynamic study; MRI was performed in selected cases. Patients were given full information about the procedure and informed consent was obtained.

Thromboembolic Prophylaxis. Leg compression was applied transoperatively and low molecular weight heparin was given accordingly to patient's risk.

Antibiotic Prophylaxis. Cephazoline (quinolones in case of β-lactamic allergies): first dose intravenously 30 min before surgery and two more doses postoperatively [9].

Operating Room (OR) Preparation

Under general anesthesia, the patient is placed in the dorsal lithotomy position. Pressure areas are protected with pads. A Foley catheter is inserted. We routinely place a transobturator suburethral mesh (Uretex-TOT and Align TO®; Bard España) to treat urinary incontinence or to avoid it postoperatively.

Surgical Technique

We use a periumbilical open approach (Hasson trocar). Pneumoperitoneum is set at 12 mm Hg and the rest of the trocars are inserted under direct vision: one robotic trocar (right hand of the surgeon) and one auxiliary 12-mm trocar to be used by the assistant surgeon on the right side of the patient. Two robotic trocars on the left side of the patient: left hand of the surgeon and fourth robotic arm. This trocar is used to retract sigmoid colon and uterus if needed.

After positioning the patient 30–40° Trendelenburg, the Da Vinci robot is docked between the legs. The procedure starts with anatomic identification and adhesiolysis if needed. Sigmoid mesocolon is retracted to the left with atraumatic forceps at the fourth arm and the promontory is identified, both visually from the console and by touch from the table. The assistant surgeon is very important as he 'feels' the promontory better than console surgeon. The posterior peritoneum is then opened and the anterior surface of the promontory dissected to expose the anterior longitudinal ligament. The peritoneal incision is continued down to the anterior rectal region. With a blade valve in the posterior vaginal cul-de-sac, the uterosacral ligaments are stretched to incise the exposed peritoneum between them. Rectovaginal fascia is dissected from medial to lateral in both sides, gaining access to the posterior portion of levator ani muscles. The posterior portion of the non-absorbable mesh, 8 × 3 cm rectangle-shaped with a semicircular notch in one of the short sides (Pelvitex®, acellular collagen-covered polypropylene), was attached with non-absorbable 2-0 stitches to the right and left levator ani muscles, and then the midpoint of the mesh was anchored to the posterior vaginal wall.

For the vesicovaginal dissection the bladder is identified by the balloon of the Foley catheter, a vaginal valve is placed in the anterior cul-de-sac or at the fornix of the vagina (previous hysterectomy). The pearly white anterior surface of the vagina is used as a landmark. The posterior surface of the vagina is also dissected from the peritoneum. The anterior portion of the mesh is Y-shaped. Both short legs of the mesh are attached to the anterior and posterior surfaces of the vagina with 2-0 non-reabsorbable interrupted suture, fixing the mesh as down as possible trying to not transfix vagina. Then the mesh is passed through the avascular portion of the right broad ligament.

First the posterior mesh and then the long leg of the anterior are fixed to the promontory with one or two stitches of non-absorbable suture. These stitches are performed lateral to medial and very gently. At this moment, the correction of prolapse is checked. Finally, the peritoneum is sutured over the mesh with a 3-0 running absorbable braided suture to exclude it completely from the abdominal content.

Postoperative Management

Patients received oral intake 6 h after surgery and they were allowed to walk 12 h after. The Foley catheter was withdrawn within 24 h. We recommended avoiding hard physical activities and sexual intercourse for 2–4 weeks.

Data Collection

Preoperative Data. Patients' demographics, childbirth, previous abdominal surgery and results of specific tests performed (ultrasonography, cystography, urodynamic study and eventually MRI) were collected.

Intraoperative Data. OR time (including general anesthesia, patient positioning, TOT placement, robot setup time and complete procedure up to patient coming out the OR) and intraoperative complications were recorded. We compared OR time between the first 10 cases and the rest to evaluate the team learning curve.

Postoperative Data. Hospital stay and incidence of postoperative complications were also registered. Long-term postoperative

complications, mainly recurrence, were collected during outpatient follow-up visits (1 and 2 weeks, 1, 3 and 6 months, and 1 and 2 years after surgery).

Statistical Analysis

The Mann-Whitney U test or median test were used to compare continuous variables (expressed as mean ± SD or median and interquartile range. Categorical variables are expressed as percentages. The null hypothesis was rejected in each statistical test when $p < 0.05$. Analysis was performed using Windows SPSS version 15.0 software.

Results

From November 2006 to May 2008, 31 patients were consecutively operated on. Mean (range) patient age was 65.2 (50–81) years. All of them were multiparous women. 54.8% of them had previous abdominal surgery (41.9% hysterectomy). All cases in the series were symptomatic prolapses: vaginal heaviness sensation (n = 31), vaginal bulging (n = 26), dyspareunia (n = 26), stress urinary incontinence (n = 10) and urge incontinence (n = 12).

Indications for surgery: vaginal vault prolapse (18 patients, 58.1%), grade III cystocele (22 patients, 71%), and grade IV cystocele (9 patients, 29%). Ten patients (32.2%) showed stress urinary incontinence at the urodynamic study. We performed MRI in 5 cases: 2 of them showed cystocele and 3 vaginal vault prolapse.

Mean (range) OR time was 185.8 (150–230) min. For the first 10 cases it was 200 (180–230) min and for the rest 179 (150–220) min ($p < 0.001$). One case was converted to conventional laparoscopy due to adhesions (3.2%). There were two intraoperative complications: cases 2 and 19 had a bladder perforation and a vaginal tear, respectively. Both were immediately sutured. All but 1 patient underwent transobturator suburethral mesh (Uretex-TOT and Align TO®; Bard) placement.

Mean postoperative stay was 4.6 (2–16) days. Minor complications included 1 case of umbilical port mild infection treated with oral antibiotics and 1 patient with delayed bowel function (5 days). There were two major complications: case 27 had postoperative acute myocardial infarction, which was successfully treated and her postoperative stay was 16 days. Patient 21 had syncopal crisis when standing up since postoperative day 1. It was attributed to excessive tension in the posterior mesh. Robot-assisted laparoscopic reoperation was carried out freeing the posterior mesh and anchoring it without tension. The postoperative course was uneventful this time and she was discharged 14 days after the first surgical procedure. If we discard these 2 prolonged cases, mean postoperative stay goes down to 3.7 days (29 patients).

After a mean follow-up of 24.5 (16–33) months there were no recurrences. The whole group of patients has had a successful repair of their prolapse on physical examination and they are satisfied with their outcome.

Discussion

Robot-assisted laparoscopic sacrocolpopexy is a new procedure combining our knowledge in open and laparoscopic surgery and the benefits of robotic approach. Firstly, robotic surgery has a shorter learning curve (7–10 cases) than laparoscopic surgery. We have significantly reduced OR time from case number 10 (200 vs. 179 min, $p < 0.001$). Table 1 shows a comparison of our operative time with literature's. Akl et al. [10] have recently published a mean OR time of 197.9 (SD 66.8) min, decreasing by 25.4% after completion of the first 10 cases.

Other known advantages of robotic surgery are 3-D vision, dexterity, multiarticulated instruments improving dissection and suturing, and surgeon comfort and ergonomics. Pelvic floor laparoscopic surgery may take an important advantage of robot assistance due to several reasons: the surgical field is narrow and static, the procedure requires the placement of two meshes and intracorporeal suturing and knot tying and may imply a long operative time. Robotic surgery ergonomics translate into enhanced safety during the surgical procedure and more ability to solve possible incidents. We have found the lack of tactile sensation is a drawback that makes very important the assistance from the table, but it may be soon overcome thanks to enhanced 3-D vision.

In our series, as in others [11], previous abdominal surgery was not considered a contraindication (54.8% of our patients), although lysis of adhesions may prolong operative time.

We routinely used a supraumbilical open approach (Hasson) and we had no complications. The surgical procedure performed to place the anterior mesh in this series was similar to other authors' description [12]. We have chosen Y-shaped polypropylene meshes covered by acellular collagen, in order to make them more biocompatible trying to reduce the risk of mesh extrusion. Vaginal mesh extrusion and erosion have been described as postoperative complications by other authors [10, 12]. There were no mesh extrusions in this series.

Regarding anti-incontinence, we have routinely placed transobturator suburethral mesh (TOT) along the whole

Table 1. Robotic sacrocolpopexy: comparison of outcomes with published series

Reference	n	Mean operative time, min	Conversion	Mean hospital stay, days	Intraoperative complications	Complications	
						short-term	long-term
Ayav et al. [12]	18[1]	186	1 (O)	7 (4–13)	rectal tear (1)	urinary infection (2)	–
Elliott et al. [11]	30	200	1 (O)	1	–	vaginal bleeding (1) trocar infection (2)	rectocele (1) vault prolapse (1) mesh extrusion (2)
Daneshgari et al. [14]	15	317	3 (1 O, 1 LAP, 1 TV)	2.4 (1–7)	serosal injury (1)	no	–
Geller et al. [13]	73	328	1 (O)	1.3	bladder perforation (1)	pulmonary embolus (1) prolonged ileus (4) postoperative fever (3) pneumonia (2) wound infection (2)	–
Akl et al. [10]	80	198	4 (O)	2.6	bladder perforation (2) small bowel perforation (1) ureter injury (1)	prolonged ileus (1) pelvic abscess (1)	vaginal erosion (5) recurrence (3)
Moreno Sierra et al., this study	31	186	1 (LAP)	4.6 (2–16)	bladder perforation (1) vaginal perforation (1)	port infection (1) prolonged ileus (1) AMI (1) Redo robotic surgery (1)	–

Follow-up: Ayav et al., 12 months; Elliott et al., 24 months; Daneshgari et al., 3.1 months; Geller et al., 6 weeks; Akl et al., 4.8 months; Moreno-Sierra et al., 24.5 months.

O = Open; TV = transvaginal; LAP = laparoscopy.

[1] Colpohysteropexy (n = 12), mesh rectopexy (n = 2), sutured rectopexy + sigmoid resection (n = 4).

series (10 patients, 32.2%, showed stress urinary incontinence at the urodynamic test). TOT placement, performed under general anesthesia, before or after robotic sacrocolpopexy, may prolong mean OR time 15 min. No other anti-incontinence techniques have been performed in our series. Akl et al. [10] describe mid-urethral sling placement in 21% of patients and Burch procedure in 4%. Geller et al. [13] performed concurrent anti-incontinence surgery in 50.7% of cases. This is a matter of controversy nowadays. We decide to treat or prevent urinary incontinence and other groups prefer to treat when symptoms appear.

To the best of our knowledge, there are five groups reporting robot-assisted laparoscopic sacrocolpopexy outcomes in the English literature. The first description was by Di Marco et al. [4] at Mayo Clinic, Rochester, Mich., USA. This group published their 2-year outcomes in 2006 [11]. The team of Ayav [12] published in 2005 a series of 18 pelvic prolapses including 12 colpohysteropexies. Daneshgari et al. [14] published in 2007 the outcomes of 15 cases. More recently, Geller et al. [13] communicated the outcomes of a retrospective cohort study comparing robotic and abdominal sacrocolpopexy, showing less blood loss, longer operative time and shorter length of stay for the robotic group. Finally, Akl et al. [10] reported in 2009 their technique and outcomes in a series of 80 patients. Table 1 shows the comparison of outcomes of these groups and ours.

Conversion to the open or laparoscopic procedure may happen and it has been described by all the groups [10–14] (table 1). In the present series, we had to convert 1 case to the laparoscopic approach due to adhesions and obesity (3.2%).

Regarding intraoperative complications, both bladder and vaginal perforations were due to difficulties to identify the plane during vesico-vaginal dissection. In both cases the robot was a very useful tool to accomplish a safe and comfortable repair. On the other side, we believe none of the postoperative complications were related to the Da Vinci robot: the umbilical port infection was related to the laparoscopic approach. The prolonged ileus is less frequent after the laparoscopic approach, however it is a possible consequence of abdominal surgery. These two short-term complications that we considered minor and the case of acute myocardial infarction in a 70-year-old patient were successfully solved with medical treatment.

This was not the case in patient 21. This young patient (54 years old) had syncopal crisis when standing up since postoperative day 1. Since she had no previous related conditions we suspected possible excessive tension in the posterior mesh, so we decided to reoperate trying to identify and solve the problem. The robotic approach was utilized. The posterior mesh was freed from its promontory attachment and fixed freely to the anterior mesh. The postoperative course was uneventful this time and the patient was discharged 14 days after the first surgical procedure.

We do not intend to underestimate complications and we must consider this operation is usually performed in patients who have undergone multiple previous operations, with great prolapses, thus complications and recurrences are not infrequent.

Concerning our postoperative stay, we are aware that comparatively it is longer than data reported by American teams [10–13]. Differences in health policies may be partially responsible for this outcome. Mean reported hospital stay varies from 1 to 7 days (table 1). Our mean hospital stay was 4.6 days. Nevertheless, the majority of our patients, with the exception of 2 prolonged cases, were discharged 3–4 days after surgery.

We report the outcomes of a small cohort of patients representing our initial experience. Another limitation of this study is the lack of comparison with other techniques. We share this drawback with other reports [10, 12–14], except Geller et al. [13]. At this moment a systematic literature review is very difficult due to the small number of published outcomes and important technical differences between groups: the majority of series refer only to vaginal vault prolapse, while others include rectopexy and even sigma resection [14]. We believe every symptomatic or obstructive prolapse may benefit from the robotic approach. On the other side, the major strength of this prospective analysis is its long follow-up (mean 24.5 months), one of the longest reported to date (table 1).

Finally, we want to comment that we are aware of the high costs of robotic surgery. We have not yet done a cost analysis in our department, but Judd et al. [15] did a comparative analysis between open, laparoscopic and robotic sacrocolpopexy where the costs were USD 5,792, 7,353 and 8,508 respectively. It is obvious that intraoperative costs are higher for laparoscopic and robotic sacrocolpopexy, but the differences tend to diminish when shorter hospital stays are considered.

Conclusions

Robotic sacrocolpopexy could possibly improve with experience after overcoming the learning curve. There is no doubt it is a reproducible technique, but its safety and efficacy still need to be proven. Our initial series demonstrated good outcomes and no recurrences at 24.5 months of follow-up.

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