G Chir Vol. 37 - n. 3 - pp. 113-117
May-June 2016

original article

Robotic versus laparoscopic sacrocolpopexy for apical prolapse: a case-control study

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SUMMARY: **Robotic versus laparoscopic sacrocolpopexy for apical prolapse: a case-control study.**

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The apical prolapse has always been considered the most complex of the defects of the pelvic floor, for both the difficulty of the surgical corrective technique and for the high post-surgical recurrence rate. Today, the laparoscopic sacrocolpopexy can be considered the standard treatment for apical prolapse. In the last years, several author performed robotic sacrocolpopexy, obtaining positive results. So, we developed a case-control study in order to compare the surgical outcome of robotic group with a control group of laparoscopic approach in patients with symptomatic apical pro-lapsed between January 2015 and December 2015 at University Hospital Policlinico "P. Giaccone" and Ospedali Riuniti "Villa Sofia-Cervello", Palermo. Our experience shows that robotic sacrocolpopexy can be considered in positive way for clinical results obtained: all procedures were executed with no complications, we noted a lower intraoperative blood loss and a shorter hospital stay than in laparoscopic group. Although the mean operative time and the economic costs are higher in robotic surgery, this study demonstrates that the use of robotic platform for repairing of symptomatic apical vaginal prolapse is feasible, safe and associated with short-term satisfactory results, representing therefore a valid alternative to laparoscopic approach.

KEY WORDS: Robotic surgery - Sacrocolpopexy - Robotic sacrocolpopexy - Laparoscopic surgery - Apical prolapse.

Introduction

The apical prolapse has always been considered the most complex of the defects of the pelvic floor, for both the difficulty of the surgical corrective technique and for the high post-surgical recurrence rate. This is a fairly frequent pathological condition. It is estimated that in her life 1/10 women undergoes a hysterectomy and up to 10% of these requiring surgical correction of apical prolapse (1). The standard treatment for surgical management of apical prolapse is abdominal sacrocolpopexy (ASC) (2). The progress made in the field of laparoscopic surgery in the past decades and the numerous literature reports that confirmed the considerable advantages respect to abdominal open surgery, allowed the spread of laparoscopic sacrocolpopexy (LSC). The technique was introduced in 1994 by Nezhat, integrating the experience of open conventional surgery with the advantages of minimally invasive approach, in order to minimize morbidity and accelerating the recovery of patients (3). Today, the LSC can be considered the standard treatment for apical prolapse. Several studies over the years have compared the laparoscopic approach with the open abdominal surgery. LSC is associated with less intra-operative blood loss, reduction in post-operative pain and a shorter hospital stay (4). Currently, with reference to minimally invasive surgery the most advanced and sophisticated tool available is the DaVinci Surgical System (Intuitive Surgical Inc., Sunnyvale, California, USA). The robotic surgical systems have been developed with the aim of facilitating the technically difficult procedures: the 3D-HD vision system, the use of a dedicated console and instruments with great flexibility and precision of the movements, also allow the execution of the most complex surgical maneuvers, acheiving excellent results. In the last years, several surgical operations were performed with robotic system, like robotic-assisted sacral colpopexy

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(RSC), obtaining positive results (5). With this background we developed a case-control study in order to compare the surgical outcome of RSC group with a control group of laparoscopic approach (LSC) in patients with symptomatic apical prolapse. Primary end-points were to evaluate the safety, feasibility and non-inferiority of robotic group compared to laparoscopic procedures.

Patients and methods

This case-control study is based on the analysis of data collected between January 2015 and December 2015 at University Hospital Policlinico "P. Giaccone" and "Ospedali Riuniti "Villa Sofia-Cervello", Palermo. We analyzed 20 patients undergone to sacrocolpopexy for symptomatic apical prolapse performed with robotic approach by one surgical team experienced in gynaecological (6-8) and laparoscopic surgery (9, 10) with appropriately training and mentoring in robotic surgery. Data on age, body mass index (BMI), medical history (11), surgery type and timing, blood loss, morbidity, hospital stay and readmission rate were collected and compared with a selected sample of 20 patients with equivalent characteristics treated with laparoscopic approach by the same team. All patients showed the following inclusion criteria: symptomatic apical prolapse (Stage III-IV according to POP-Q system), previous laparoscopic or vaginal hysterectomy performed only for benign disease. Exclusion criteria were extensive adhesions, severe obesity, severe morbidity with inability to maintain Trendelenburg position. All procedures were performed by an experienced gynecologist with more than 300 laparoscopic procedures for the correction of the pelvic floor defect. The patients were informed of both surgical techniques and risks related to them. Each patient underwent to a standard preoperative protocol with the collection of demographic data, ASA score, careful gynecological and uro-gynecological evaluation with determination of functional symptoms (presence or absence of urinary stress incontinence), classification of the degree of severity of the prolapse using the POP-Q system. We also made a perioperative evaluation according to the following parameters: surgical complications, recovery time to spontaneous urination, drugs administered. The primary outcomes of this study were the surgical success rate and resolution of symptoms. Secondary outcomes were mean operative time, intraoperative blood loss, surgical complications and length of hospital stay (12). We made a follow-up to 6 months after surgery to evaluate possibility of recurrence.

Surgical technique

After general anesthesia the patient was placed in dorsal lithotomy and steep Trendelenburg position. Ports were placed after creating pneumoperitoneum by Veress needle insertion (13-15) or by Hasson's technique via trans-umbilical open laparoscopy (16).

Robotic approach

All robotic procedures were performed using DaVinci Surgical System (Intuitive Surgical Inc., Sunnyvale, California, USA). We used three robotic arms, a 12-mm trocar at the umbilicus for the camera, two 8-mm lateral robotic trocars at each lower quadrant of the abdomen, and a fourth conventional laparoscopic trocar for the bedside assistant for suction, irrigation, retraction of tissues. The process began with the identification of the promontory of the sacrum. The posterior peritoneum was opened and the front surface of the promontory dissected to expose the anterior longitudinal ligament. The peritoneal incision continued to the front of the rectum region. We dissected the rectovaginal space from medial to lateral to both sides, to facilitate posterior access to the levator ani. Then we placed a non-absorbable polypropylene mesh, with prolene 2-0, on the right and on the left of the levator ani; the middle point of the mesh was thus anchored to the posterior vaginal wall. For bladder dissection we identified the balloon of the Foley catheter; a vaginal intruder was inserted into the cul-de-sac or vaginal fornix. The anterior pearly white surface of the vagina was used as a reference point and then we dissected posterior surface of the vagina. The anterior portion of the mesh was shaped to Y. Both branches of the mesh were attached to the anterior and posterior vagina surfaces with prolene 2-0. Then the prosthesis was passed through the avascular portion of the broad ligament. Then the long branch of the mesh was fixed to the sacral promontory with one or two non-absorbable sutures.

Laparoscopic approach

In these procedures, we placed a 10-mm trocar at the umbilicus for the camera and other three 5-mm trocars at each lower quadrant of the abdomen and in sovrapubic region (17). The surgeon was on the left side of the patient and the first assistant on the right side. The surgical technique was the same used in robotic approach.

Statistic analysis

The statistical analysis was performed with SPSS for Windows (version 17.0) taking into consideration mean and standard deviation (SD). We analysed series data with Mann-Whitney test and differences between categorical groups using the Fisher exact test with statistical significance (p) of < 0.05 and a 95% confidence interval.

Results

40 women were included in the study. In 20 cases we performed RSC (case group) and in 20 women LSC

(control group). The demographic and anamnestic characteristics of the two groups are described in Table 1. For the cases group (RSC) the mean age was 61.5 years (range 54-70), only one woman was nulliparous; 70% of them had previous vaginal hysterectomy and 30% laparoscopic hysterectomy. In the LSC group the mean age was 60.9 years (range 48-72); only two women were nulliparous; 60% of them had previous vaginal hysterectomy and 40% laparoscopic hysterectomy. All cases under study were symptomatic prolapse. The data of two groups are comparable in terms of mean age, BMI, number of pregnancies, urinary stress incontinence, previous hysterectomy (vaginal or laparoscopic). A comparison of surgical outcome is presented in Table 2. In the RSC group all procedures were performed correctly without conversion; in LSC group there was a case of conversion to laparotomy. The mean operative time was longer in robotic group: 140.7 ± 12.12 min compared to 85.3 ± 18.22 min (P < 0.001) in the laparoscopic group. Blood loss were significantly lower for the robotic group (56 ± 12.65 ml) compared to laparoscopic group (125,1 ± 15.89 mL) with P < 0.001. We did not registered intraoperative complications in either arm nor needs of re-intervention (18). The mean hospital stay was 2,8 ± 0,63 days in robotic group and 3 ± 0,67 days in laparoscopic group with no significative differences. The follow-up (19, 20) consisted of medical history on urinary symptoms, questionnaire on quality of life, visual pain scale, clinical monitoring including physical examination (with reference to the POP-Q system) and an assessment of the post-void residual. There was no recurrence after 6 months for both groups.

TABLE 1 - COMPARISON OF TWO GROUPS ROBOTIC AND LAPAROSCOPIC.

	Robotic (n = 20)	**Laparoscopic (n = 20)**
Age (mean), ys	61,5	60,9
BMI	27,5	27,3
Previous pregnancy (mean), n	2	1,7
Urinary stress incontinence	20%	40%
Previous hysterectomy		
- vaginal	70%	60%
- laparoscopic	30%	40%

TABLE 2 - COMPARISON OF SURGICAL OUTCOME.

	Robotic (n = 20)	**Laparoscopic (n = 20)**	**P-value**
Mean operative time, min	140,7±12	85,3±18,2	< 0.05
Blood loss, ml	56±12,65	125,1±15,89	< 0.05
Intraoperative complications	-	-	
Conversion rate	-	5%	
Mean hospital stay, days	2,8±0,63	3±0,67	NS
Readmission	-	-	
Recurrence after 6 month	-	-	

Discussion

Robotic surgery is born with the intent to overcome the limitations of laparoscopic surgery (two-dimensional vision, movements of the instruments, unnatural positions of the surgeon, dissociation between instrument control and vision, inability to make microsutures and intracorporeal knotting) maintaining the positive aspects (reduced blood loss, less post-operative pain, decrease in surgical infections, reduced hospital stay) of mini-invasive surgery (21).

The advantages of robotic surgery are:

- reduced tissutal trauma;
- reduced intraoperative bleeding
- shorter hospital stay and less postoperative pain
- reduction of functional recovery time
- ability to easily perform complex surgical maneuvers
- increased safety for the patient.

These advantages have greatly improved the precision of anatomical dissection, resulting in less bleeding. However, it has not yet been proven if the use of robotic surgery result in better clinical outcomes than conventional laparoscopy (22). Several recent studies support the use of robotic surgery in gynecologic oncology (23, 24) and in the correction of pelvic floor defects. The RSC was introduced in 2004 as the last step in the evolution of minimally invasive surgery (25). Preliminary literature data on the use of the robotic system are promising, although they need to be confirmed and expanded especially with studies that include more cases and analyze more aspects (26, 27). Paraiso et al. (28) published a randomized controlled trial that included 78 women with stage 2-4 POP-Q for vaginal prolapse after hysterectomy, in order to compare robotic sacral colpopexy with laparoscopic technique. The primary outcome was operative time, while secondary outcomes were postoperative pain, functional activities, bowel and bladder symptoms, quality of life and cost. This study showed that the mean time taken to perform surgery was longer in the robotic group and RSC had significant additional cost but the anatomical and functional results were the same of a laparoscopic approach. Sierra et al. (29) conducted a prospective analysis with 31 patients to evaluate the reproducibility and long-term results of their first actions of RSC. The primary end-point of this study was the evaluation of long-term recurrence. Se-

condary end-point were the evaluation of surgical time, rate of conversion to open surgery, intraoperative blood loss, hospital stay and incidence of complications. The authors concluded that in patients with symptomatic apical prolapse RSC is a reproducible technique, although safety and effectiveness have yet to be proven. In our study there were no statistically significant differences in demographics data and in medical history of the examined patients. Instead we have seen significant differences ($p< 0.001$) in operative time which was longer in robotic group. This is explained by the relative lack of experience of the surgical team. Literature data shows that, with adequate training, docking and operative time gradually decrease. The intraoperative blood loss in the robotic approach was lower than in laparoscopic group; this is explained with the use of three-dimensional vision (30) and precision movements of the robotic surgical procedure.

Conclusion

This retrospective analysis carried at our institution shows as the robotic treatment of sacrocolpopexy is a safe and feasible technique. Further clinical studies on larger samples and heterogeneous patients will be necessary in order to clarify the real advantages of robotic treatment. Our experience shows that RSC can be considered in positive way for clinical results obtained: all procedures were executed with no complications, we noted a lower intraoperative blood loss and a shorter hospital stay than in laparoscopic group. Although the mean operative time and the economic costs are higher in robotic surgery, this study demonstrates that the use of robotic platform for repairing of symptomatic apical vaginal prolapse is feasible, safe and associated with short-term satisfactory results, representing therefore a valid alternative to laparoscopic approach.

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