Comparison of functional outcomes after robot-assisted laparoscopic sacrocolpopexy in women with a BMI below and above 30

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Abstract
The aim of this study was to assess the impact of body-mass index on robot-assisted laparoscopic sacrocolpopexy (RALSCP). A retrospective study was conducted on women who underwent a RALSCP. Data were collected prospectively from 17 obese and 78 non-obese patients treated between January 2008 and January 2013. Obesity was defined as a body-mass index (BMI) of ≥30 kg/m². Relationships with outcomes were analysed using Mann–Whitney U-test and Fisher’s exact test. The operating time was the same in both groups: 220 vs 200 min in the obese and non-obese groups, respectively (P=0.232). The median follow-up was 12 months in both non-obese and obese patients. Overall anatomic repair rate was 94.1% and 97.4% for obese and non-obese patients, respectively (P=0.95). The overall reoperation rate (including surgery for de novo urinary-stress incontinence) was 5.9% for obese vs 11.5% for non-obese patients (P=0.8). These findings suggest that RALSCP is a viable option for obese women. The complication rates and outcomes for obese women were similar to those for non-obese women.

Introduction
Obesity and pelvic-floor disorders are both increasing medical situations.1 In 2008, the prevalence of obesity among US adults was >30%, while the age-adjusted combined prevalence among women who were overweight (BMI 25–30) and obese (BMI ≥30) was 64.1%.1 In 2010, an estimated 17% of adults were obese in the European Union.2 Obesity and, especially, morbid obesity (a BMI >40.0 kg/m²) is associated with a relative risk of death of 1.62 (1.40–1.85, IC 95%) as compared to those with a normal BMI.3 Although previous studies have reported a correlation between obesity and pelvic-organ prolapse (POP), there is still ongoing debate on this association.4,5 As the prevalence of obesity and discomfort from POP is increasing in the Western world, it is important for surgeons to know how to manage such patients. In obese women, surgery may be associated with an increased risk of both perioperative and postoperative complications.6 Open abdominal sacrocolpopexy has been established as gold-standard procedure to correct prolapse of the anterior and/or apical vaginal-wall compartments.7 However, a minimally invasive laparoscopic approach has been developed over recent years, and has been shown to be comparable to surgery in terms of functional outcome whilst also demonstrating all the advantages of laparoscopy.8 Since 2004, a robot-assisted laparoscopic approach for sacrocolpopexy (RALSCP) has been suggested to be a viable alternative to a purely laparoscopic technique.9–11 To date, however, there are no specific data available concerning the results of RALSCP in obese women. The aim of our study, therefore, was to compare the functional outcomes associated with RALSCP in women with a BMI either below or above 30.

Materials and Methods

Population
In this study, we retrospectively reviewed all the prospective data from female patients who had undergone RALSCP between January 2008 and January 2013 and who had attended two tertiary care centers in France. The following data were extracted from their charts: age at the time of surgery, BMI, menopause status, initial stage of genital prolapse (according to the Baden Walker classification);12 past medical history, obstetric and surgical histories, past prolapse treatment(s), date of the sacrocolpopexy procedure, operative and perioperative data, complications, anatomical results, and functional results.

Each surgeon performed a prolapse-reduction maneuver using sponge-holding forceps in order to reveal the possible presence of masked urinary-stress incontinence. Operative and perioperative data included the concomitant surgical procedure (subtotal hysterectomy or mid-urethral sling); conversion to a laparotomy or a vaginal procedure; length of the operation; blood loss; type of analgesia (according to the WHO classification); occurrence of complications; analgesic requirements; length of hospital stay. The Ethics Committee of the Assistance Publique-Hôpitaux de Paris (AP-HP) (i.e., IRB approval) approved the study. The Ethics board approval number: CEROG-GYN 2014-0202R01

Received for publication: 11 May 2016. Revision received: 13 December 2016. Accepted for publication: 27 January 2017.

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Licensee PAGEPress, Italy
Urogynaecologia 2017; 30:178
doi:10.4081/ujg.2017.178

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Key words: Genital prolapse; laparoscopy; morbidity; outcomes; robotics.

Conflicts of interest: The authors declare that they have no conflict of interest.

Ethical approval: all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The Ethics Committee of the Assistance Publique-Hôpitaux de Paris (AP-HP) (i.e., IRB approval) approved the study. Ethics board approval number: CEROG-GYN 2014-0202R01

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Surgical procedure
All procedures were achieved using a three-arm da Vinci® surgical system using a trans-peritoneal four-port technique, as described previously.12 Two surgeons performed a RALSCP on all women. After identifying the right ureter, the left iliac...
vein, and the iliac-vessel junction, the peritoneum over the sacral promontory was incised medial to the right ureter and lateral to sigmoid colon. For placement of the posterior mesh, dissection of the recto-vagina was performed down to the level of the levator ani muscles, and a mesh was placed and sutured with non-absorbable sutures along the full length of the posterior vaginal wall and into the levator ani muscles. The upper extremity of the anterior mesh was sutured to the anterior vertebral ligament at the level of the sacral promontory with a non-absorbable suture. Complete peritonealization of the meshes was achieved by opposing the edges of peritoneum using an absorbable suture.

Surgical time was classified as either “strict operating time” (time for port insertion plus the procedure, but excluding preparation and docking of the robot) or as “overall operating time” (total time in operating theatre).

Complications
Regarding surgical complications, we have respected the 10 criteria proposed by Martin et al. in 2002 and, especially, the International Urogynaecological Association/International continence society (IUGA/ICS), as stated in the European Guidelines.1,4

Follow-up
Follow-up visits were at 6 and 12 months postoperatively, and then every year. At these visits, POP was assessed using the Baden Walker classification. Surgery was considered successful if the patient was symptomatically satisfied and if the POP score was below stage 2.

Statistical analyses
Statistical analyses of the data were performed using R statistical software (Bell Laboratories, Lucent Technologies, Paris, France). Descriptive statistics are shown as medians and IQRs (interquartile range). The Mann–Whitney U-test was used to compare continuous variables, and Fisher’s exact test compared categorical variables. A P-value of <0.05 was considered statistically significant.

Results
Population
In all, 95 women underwent RALSCP during the study period: 17 women were in the obese group and 78 in the non-obese group. The median BMI in the obese group was 32 (IQR 30.4–34.1) versus 23.6 (IQR 22.2–25.4) in the non-obese group (P<0.0001). All other characteristics did not significantly vary different between the two groups (Table 1).

Surgery
The surgical data are shown in Table 2. No significant difference was observed between the groups concerning a concomitant procedure, such as subtotal hysterectomy or a mid-urethral sling. Two meshes (anterior and posterior) were placed in 17 (100%) of the obese women and in 76 (97.4%) of the non-obese women (P=0.79). An isolated anterior mesh was placed in two (2.56%) women from the non-obese group. Perioperative complication rates were similar for the two groups (Table 3). Bladder injury occurred in three women (3.8%) who were all in the non-obese group (P=0.95). Conversion to abdominal laparotomy was required for one patient (5.9%) in the obese group because of pneumoperitoneum intolerance.

Outcomes and complications
The median follow-up period was 12 months for both groups: IQR 6–19.75 for non-obese and IQR 7–15 in the obese group (P=0.86). The overall anatomic repair rate was 94.1% and 97.4% for obese and non-obese groups, respectively (P=0.95). During the follow-up, a gynecological examination revealed that prolapse of the posterior compartment had recurred in one patient from the obese group after 12 months, and one prolapse had recurred in the anterior compartment in the non-obese group. Both these women underwent a subsequent procedure via the vaginal route.

Table 1. Patient’s characteristics [values are given as median (IQR) [range], number (percentage), or median (IQR) unless otherwise stated].

| Characteristic                        | Obese group (n=17) | Non-obese group (n=78) | P-value |
|--------------------------------------|--------------------|-------------------------|---------|
| BMI                                  | 32 (30.4–34.1)     | 23.6 (22.2–25.4)        | <0.0001*|
| Age, y                                | 63 (56–69)         | 64 (56.2–69.7)          | 0.63*   |
| Parity, n                            | 3 (1–3)            | 2 (2–3)                 | 0.54†   |
| Postmenopausal status                | 15 (88.2%)         | 66 (84.0%)              | 0.99†   |
| Tobacco use                          | 0 (0%)             | 11 (14.1%)              | 0.22†   |
| Previous cesarean delivery           | 3 (17.6%)          | 7 (9%)                  | 0.20†   |
| Previous hysterectomy                | 4 (23.5%)          | 7 (9%)                  | 0.20†   |
| Previous POP surgery                 | 2 (11.8%)          | 6 (7.7%)                | 0.95†   |
| POP stage (Baden Walker)             |                    |                        |         |
| Stage 0-1                            | 0 (0%)             | 0 (0%)                  | NS*     |
| Stage 2                              | 2 (11.8%)          | 5 (6.4%)                | 0.95†   |
| Stage 3-4                            | 15 (88.2%)         | 73 (93.6%)              | 0.8‡    |
| SUI (11.8%)                          | 16 (20.5%)         | 0.62‡                   |         |
| Masked SUI*                          | 10 (58.9%)         | 35 (44.8%)              | 0.60‡   |

BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); ICS, International Continence Society; IQR, interquartile range; POP, pelvic organ prolapse; POP Q, pelvic organ prolapse quantification grading system; SUI, urinary stress incontinence. *Patients without obvious urinary stress incontinence; †Welch 2-sample t test (Student’s t test); ‡Pearson’s χ² test with Yates continuity correction (χ² test).
Discussion

The ultimate aim of our study was to determine the impact of BMI on the outcome of RALSCP. We have reported that the overall anatomic repair rate was 94.1% and 97.4% for obese and non-obese groups, respectively (P=0.95). Moreover, no significant difference was observed in complication rates between the groups.

The current opinion is that obese patients are at higher risk of morbidity. A few previous studies have found that abdominal surgery for a gynecologic benign condition (other than POP) is associated with a greater incidence of wound infection in obese women compared to non-obese women. In contrast, vaginal surgery for a hysterectomy or POP in obese women is associated with less morbidity than abdominal surgery in terms of blood transfusions or urinary retention.18

Table 2. Operative data for laparoscopic sacrocolpopexy [values are given as number (percentage) or median (interquartile range)].

| Characteristic | Obese group (n=17) | Non-obese group (n=78) | P-value* |
|---------------|--------------------|------------------------|----------|
| Concomitant subtotal hysterectomy | 2 (15.38%)* | 1 (1.41%)* | 0.126° |
| Concomitant midurethral sling | 11 (64.11%) | 43 (55.11%) | 0.651° |
| Mesh location | | | |
| Anterior mesh only | 0 (0%) | 2 (2.56%) | 0.791° |
| Posterior mesh only | 0(0%) | 0 (0%) | NS° |
| Both anterior and posterior meshes | 17 (100%) | 76 (97.44%) | 0.791° |
| Operative duration, min | 220 (170-320) [125-370] | 200 (150-247.5) [90-410] | 0.232° |
| Length of hospital stay, days | 4 (4-5) | 4 (3-5) | 0.541° |

*Patients without previous urinary hysterectomy; °Pearson’s χ² test with Yates’ continuity correction (χ² test). ICS, international continence society; n, number; POP, pelvic organ prolapse.

Table 3. Complications and outcome.

| No. | Obese | Non obese | P-value* |
|-----|-------|----------|----------|
| Bladder injury n (%) | 0(0%) | 3(3.8%) | 0.95 |
| Laparocconversion n (%) | 1(5.9%) | 0(0%) | 0.39 |
| Urinary infection n (%) | 0(0%) | 8(10.2%) | 0.37 |
| Eventration | 0(0%) | 1(1.3%) | 0.39 |
| Reoperation for immediate complications (C1) | 0(0%) | 1(1.3%) | 0.39 |
| Reoperation for urinary incontinence (C2) n (%) | 0(0%) | 5(6.4%) | 0.64 |
| Reoperation for mesh exposure (C3) n (%) | 0(0%) | 2(2.6%) | 0.79 |
| Reoperation for recurrent prolapse (C4) n (%) | 1(5.9%) | 1(1.3%) | 0.79 |
| Global reoperation rate (C1+C2+C3+C4) n (%) | 1(5.9%) | 9(11.5%) | 0.8 |

Post-operative POP stage (Baden Walker) n (%) |
Stage 0-1 | 16(94.1%) | 76(97.4%) | 0.95 |
Stage 2 | 0(0%) | 1(1.3%) | 0.39 |
Stage 3-4 | 1(5.9%) | 1(1.3%) | 0.79 |

Post operative de novo functional disorders |
Constipation | 0(0%) | 2(2.6%) | 0.79 |
Straining to defecate | 0(0%) | 1(1.3%) | 0.39 |
Straining to void | 1(5.9%) | 5(6.4%) | 0.64 |
Stress urinary incontinence | 3(17.6%) | 9(11.5%) | 0.78 |
Urgo incontinence | 0(0%) | 1(1.3%) | 0.39 |

*Pearson’s χ² test with Yates’ continuity correction (χ² test). ICS, international continence society; n, number; POP, pelvic organ prolapse.

Table 4. Operative complications using IUGA/ICS classification.

| Obese | Non obese | P-value* |
|-------|----------|----------|
| T1 complications | 1 (7B/T1/S5) | 3 (4A/T1/S5) | 0.77 |
| T2 complications | 8 (4B/T2/S5) | 1 (6B/T2/S3) | 0.36 |
| T4 complications | 1 (1B/T4/S2) | 1 (1B/T4/S2) | 0.95 |

*Pearson’s χ² test with Yates’ continuity correction (χ² test).
In the literature, there are some discrepancies concerning the impact of BMI on RALSCP outcomes. Ploumidis et al. did not find a correlation between laparo-conversion and a high BMI: 50% of their patients had a BMI ≥ 29, suggesting that moderate obesity does not represent a contraindication for the robotic approach. In contrast, Gadommeix et al. report a higher risk of conversion when RALSCP was performed in patients with high BMI.

Two retrospective studies have evaluated POP surgery outcomes using an abdominal approach (laparotomy or laparoscopy) according to the patient’s BMI. A low rate of complications among obese patients and good anatomic results after a short-term follow-up were found.

In the present study, the operating time was the same in both groups: 220 vs 200 min in the obese and non-obese groups, respectively (P = 0.232). Two retrospective studies have already evaluated the technical feasibility of sacrocolpopexy by laparotomy and also laparoscopy among obese patients. Both techniques are available for obese women: the only difference is length of surgery. Considering the laparotomy approach, Bradley et al. found that operating times were significantly longer for obese women than non-obese women (189 vs 169 min; P = 0.02). In contrast, operating times reported in the laparoscopic study were similar for obese vs non-obese women, respectively, at 190 vs 180 min; P = 0.12. In both studies, the number of concurrent procedures for urinary-stress incontinence or hysterectomy was similar in both groups.

The ideal surgical approach, and especially the functional results, must be as minimally invasive as possible. To fulfill this criterion, ideal POP repair should be by laparoscopy or robot-assisted laparoscopy. However, laparoscopic sacrocolpopexy has not been widely adopted as it demands skill and motivation, and is associated with a long learning curve. Consequently, robotic-assisted surgery was developed to simplify the laparoscopic approach. This technique added three-dimensional vision and 7 degrees of freedom, which simplified complex laparoscopic tasks, such as suturing and knot tying.

We have hypothesized that robotic-assisted laparoscopy is of potential benefit for obese women because of the loss of ergonomics using the laparoscopic approach, due to the thickness of the abdominal wall. In the literature, only one retrospective study has specifically evaluated the impact of BMI in robot-assisted laparoscopy. Perioperative outcomes of 442 patients, who underwent robot-assisted laparoscopic hysterectomy for a benign or malignant condition, were analyzed according to BMI. Overall, no significant difference was found regarding operative time, estimated blood loss, length of hospital stay, and complication rates.

To the best of acknowledge, ours is the first retrospective study to report the impact of obesity on the use of robotic laparoscopic-assisted sacrocolpopexy. To conclude, RALSCP can be an alternative to the laparoscopic approach for obese women for a non-experienced laparoscopic surgeon, even if the operating time for RALSCP is longer than for laparoscopy. Because the posterior approach in obese patients significantly contributes to the difficulty and length of this procedure, the longer operating time for RALSCP, compared to laparoscopic sacrocolpopexy, is because of the lower number of posterior prosthesis mesh placements among obese patients. Moreover, docking times were not included in our study: this procedure increases anesthesia time by ~15 min.

In the present study, two meshes (anterior and posterior) were placed in all of the obese women and in 97.4% of the non-obese women (P = 0.791). Even if the posterior approach in obese patients significantly contributes to the difficulty and length of this procedure, we preferred to systematically place a posterior mesh in cases of hypothetical de novo posterior compartment prolapse. Although the impact of obesity on pelvic-floor disorders is well established for urinary and anal incontinence, the association between POP and obesity is still widely debated. The association between obesity and symptoms of pelvic-floor discomfort varies within the literature, which most likely reflects the use of different methodologies. Some researchers have not found obesity to be an independent risk factor for prolapse progression.

Conclusions

The findings from our study suggest that RALSCP is a viable option for obese women with similar functional results than those for non-obese patients. Our results should be confirmed by a large randomized controlled trial.
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