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Robot-assisted Surgery for the management of Apical Prolapse: A Bicentre Prospective Cohort Study

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Short version of title: Robot-assisted surgery for the management of apical prolapse.

Abstract

Objective: Robot-assisted surgery is a recognized treatment for pelvic-organ prolapse. Many of the surgical subgroup outcomes for apical prolapse are reported together leading to a paucity of homogenous data.

Design: Prospective observational cohort study (https://clinicaltrials.gov; identifier NCT01598467) assessing outcomes for homogeneous subgroups of robot-assisted apical prolapse surgery.

Setting: Two European tertiary referral hospitals.

Population: Consecutive patients undergoing robot-assisted sacrocolpopexy (RASC) and supracervical hysterectomy with sacrocervicopexy (RSHS).

Methods: Anatomical cure (simplified Pelvic Organ Prolapse Quantification (sPOPQ) stage 1,), subjective cure (symptoms of bulge) and quality of life (Pelvic Floor Impact Questionnaire [PFIQ-7]).

Main Outcome measures: Primary outcome: anatomical and subjective cure. Secondary outcomes: surgical safety and intraoperative variables.

Results: Total 305 patients included (RASC N=188, RSHS N=117). Twelve months follow-up available for 144 (RASC 76.6%) and 109 (RSHS 93.2%). Anatomical success of the

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apical compartment occurred in 91% (RASC)and in 99% (RSHS). In all compartments, success percentages were 67% and 65% respectively. Most recurrences were anterior compartment (15.7% RASC [symptomatic 12.1%]; 22.9% RSHS [symptomatic 4.8%]). Symptoms of bulge improved from 97.4% to 17.4% ($p<0.0005$). PFIQ-7 scores improved from 76.7 ± 62.3 to 13.5 ± 31.1 ($p<0.0005$). Duration of surgery increased significantly in RSHS (183.1 ± 38.2 versus 145.3 ± 29.8 [$p<0.0005$]). Intraoperative complications and conversion rates were low (RASC: 5.3% and 4.3%; RSHS: 0.0% and 0.0%). Four severe postoperative complications occurred after RASC (2.1%) and one after RSHS (1.6%)

Conclusion: This is the largest reported prospective cohort study on robot-assisted apical prolapse surgery. Both procedures are safe, with durable results.

Funding: none.

Keywords: pelvic organ prolapse, robot-assisted, sacral colpopexy, sacrocervicopexy, sacrocolpopexy

Tweetable abstract:

European bi-centre trial concludes that robot- assisted surgery is a viable approach to managing apical prolapse.

Introduction

Over the last fifteen years the number of robot-assisted procedures performed for the treatment of female pelvic organ prolapse (POP) has increased. This is, in part due to the perceived simplification of complex laparoscopic manoeuvres and improved surgeon ergonomics.[1, 2] Despite this increase, there is a paucity of scientific papers reporting on anatomical outcomes and surgical safety for large groups post robot-assisted sacrocolpopexy.

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Furthermore, there should be a concern regarding the heterogeneity of surgical subgroups and techniques used within the published literature[3]. In particular, most studies examining robot-assisted surgery for apical prolapse tend to combine surgery to support the vault (sacrocolpopexy) with surgery to support the cervix in patients with prior subtotal hysterectomy (sacrocervicopexy) and surgery to support the uterus (sacrohysteropexy) together. This makes it impossible to define outcomes relevant to each surgical subgroup, which has implications for how women are counselled regarding the selection of surgical approach. A recent paper by Anglim et al[4] reported on the factors influencing patient and surgeon decision-making regarding uterine preservation or hysterectomy in the management of apical prolapse. A factor was literature bias, the Cochrane review in 2016 stated that the level of published evidence was poor [5]. Furthermore, randomised controlled studies comparing robotic and laparoscopic apical repair include a low number of patients and acknowledge a diversity of surgeon experience, which makes true assessment of outcomes very challenging[6, 7]. The difficulty in performing a randomised control trial (RCT) in robotic surgery was described in an editorial by Collins et al. They describe the negative effect of patient, surgeon and healthcare system bias on RCT and highlight the role of prospective cohort studies in robot-assisted surgery[8]. The strength of this prospective European bicentre cohort study was to address these issues, in particular, to provide results from homogeneous groups of procedures performed by robotically experienced surgeons. The main outcome measurements were long-term prolapse outcomes, intra-operative variables and safety.

Methods

Study design

The Prospective Assessment of Robotic Sacrocolpopexy: a European Bicentre Cohort (PARSEC; https://clinicaltrials.gov; identifier NCT01598467) was set up to collect data from

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European hospitals performing robot-assisted apical repair for symptomatic POP. Patients were not involved in the development of this research. All consecutive patients undergoing RASC or robot-assisted laparoscopic supracervical hysterectomy with sacrocervicopexy (RSHS) between 2008-2016 in Cork University Maternity Hospital (Ireland), and Meander Medical Centre (The Netherlands) were included. Both hospitals provide tertiary level care for patients with POP. Preoperative counselling on alternative treatments and the risks and benefits of the procedure were discussed. Patients were consented accordingly. Vaginal prolapse was defined using the simplified Pelvic Organ Prolapse Quantification (sPOPQ)[9]. sPOPQ describes four vaginal landmarks (A: anterior vaginal wall; B: posterior vaginal wall; C: vaginal cuff/cervix; D: fornix posterior)[9, 10]. sPOPQ stage 1 describes either no prolapse or a minimal prolapse (>1 cm above the hymnal remnants). In stage 2, the given point descends 1 cm above to 1cm below the hymnal remnants. Stage 3 describes a prolapse which descends more than 1 cm beyond the hymenal remnants, but does not represent stage 4, which includes complete vaginal vault eversion or complete procidentia uteri. Stage 0 does not exist by definition of the sPOPQ system. Inclusion criteria were: symptomatic vaginal or uterine prolapse with sPOPQ stage $\geq$ 2. Exclusion criteria were: age < 18 year, poor health status with inability to undergo general anaesthesia, $\geq$ 3 previous laparotomies, planned pregnancy and patients with a known pelvic malignancy. In patients with their uterus still present, preoperative work-up for endometrial cancer or sarcoma was performed. An ultrasound and preoperative cervical cytology was performed in all patients.

The primary outcome measurement was anatomical cure, described as any sPOPQ point <2. Patients were followed-up routinely with vaginal examination at six weeks and twelve months postoperatively, or at the onset of new symptoms. Failure was defined as any postoperative sPOPQ point stage $\geq$ 2 or retreatment. Recurrences were divided in symptomatic and asymptomatic recurrences and scored per compartment. Recurrences were

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considered symptomatic when there were symptoms of bulge (sensation of, and/or seeing vaginal bulge) and/or retreatment (any POP reoperation (planned) or insertion of a vaginal pessary). Patients received a questionnaire preoperatively and at follow-up (at one and at five years). The questionnaires included questions regarding sensation of prolapse, quality of life (QoL) based on the Pelvic Floor Impact Questionnaire (PFIQ-7)[11] urinary and defecation symptoms, presence of dyspareunia, and use of medication. The PFIQ-7 combines three QoL scales: Urinary Impact Questionnaire, Colorectal-Anal Impact questionnaire and Pelvic Organ Prolapse Impact Questionnaire. Higher scores indicate a higher impact of symptoms on daily life (range 0-300). The questionnaire was discussed during the one-year postoperative visit or returned by post if clinical consultation was not possible. If no vaginal examination (sPOPQ) was available *and* no questionnaire at the 12-month time point, patients were considered lost to follow-up.

The secondary outcomes measured were safety of the procedure and intraoperative variables. 'Total surgery time' was defined as the time from first incision until the final suture was tied. Postoperative pain scores were measured on the first morning after surgery using the Visual Analogue Scale (VAS; range 0-10). Intra-operative complications were scored using the following definition: 'Any deviation from the ideal intraoperative course occurring between skin incision and skin closure, including both surgery or anaesthesia-related complications'[12]. A deviation from the planned intervention to manage unexpected intraoperative findings was not regarded as complication (e.g. severe intra-abdominal adhesions). In case of a conversion, an open abdominal sacrocolpopexy was performed, unless otherwise specified. Postoperative complications occurring within six weeks were defined as 'early complications' and scored following the Clavien-Dindo Classification[13]. Complications occurring after six weeks postoperatively were defined 'late'. To date there

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are no agreed standardised core outcome sets available for urogynaecology therefore specific recognised outcome measures were utilised in this study.

The surgical technique used for the RASC group is similar to that described by Clifton et al[14]. Surgeries were performed by five gynaecologists. All surgeries were performed with the assistance of the da Vinci robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA) and suspension was performed with type 1 polypropylene mesh (Prolene® [Ethicon Inc.] or Restorelle® [Coloplast]). Either a preformed Y shaped mesh was used, or two separate meshes, which were configured into a 'Y' shape intracorporeally. The mesh was distally attached using non-absorbable sutures (Ethibond® or Gore-Tex®). Proximal anchoring of the mesh to the sacral promontory was performed with titanium tacks (Autosuture Protack 5mm, Covidien, USA) or non-absorbable sutures (Gore-tex®). The peritoneum was approximated to cover the mesh completely using a 23 cm V-Loc suture (Covidien, Mansfield, MA, USA). The RSHS group had a supracervical hysterectomy performed prior to attaching the mesh to the anterior and posterior aspect of the cervix using mesh and sutures as for the RASC group. Additional procedures were performed when clinically indicated. Due to recent scientific data on the pathophysiology of ovarian malignancy and spill in case of sarcoma, concomitant salpingectomy and "in bag" morcellation was performed starting from the year 2015[15, 16].

This study was in accordance to the ethical regulations of the Clinical Research Ethics Committee (CREC, University College Cork, Ireland) and the National Central Committee on Research Involving Human Subjects (CCMO, The Netherlands). No funding was received to conduct this study. Statistical analysis was performed using SPSS v. 22.0 (IBM Corp., Armonk, NY, USA). Data were presented as mean ± standard deviation (SD) and median and interquartile range (IQR) for normally and non-normally distributed continues values respectively. In case of sPOPQ values with only 4 stages, data were presented as mean ± SD. Number and percentages were used for nominal and categorical values. Independent-Samples

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T-test, Mann-Whitney U test and Chi-Square Test or Fisher's Exact Test were used to compare data for mean, median and nominal values respectively.

Results

In total 305 patients were included. One hundred and eighty-eight patients underwent RASC and 117 patients RSHS (Figure 1). One hysteropexy was performed instead of supracervical hysterectomy due to severe adhesions (0.9%). The baseline characteristics of patients are depicted in Table 1. When no hysterectomy was performed previously, patients were significantly younger (59.9 versus 63.1 [p= 0.009]) and had on average a more severe pre-operative prolapse of the anterior compartment than patients undergoing RASC (mean S-POP point A stage 2.9 versus 2.5 [p<0.0005]). The median follow-up time was 12.6 and 14.8 months for RASC and RSHS, respectively. Ninety-five percentage of all patients were seen six weeks postoperatively and 83% 12 months postoperatively. Number of follow-up per subtype of surgery and reasons for loss to follow-up are listed in Figure 1.

Anatomical results

For both types of surgery, the mean values for all the sPOPQ anatomical landmarks improved significantly (RASC p<0.0005; RSHS p<0.0005). The apical compartment success rate was 91.4% for RASC and 99.0% for RSHS. All compartments were associated with a success rate of 67.1% for RASC and 64.8% for RSHS. However, when solely looking at symptomatic recurrences, the success rates increased to 73.6% and 88.6% respectively. Complaints of symptoms of bulge diminished significantly after surgery: preoperatively 297 of 305 patients (97.4%) complained of symptoms of bulge, postoperatively 44 of 253 patients (17.4%

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[p<0.0005]). QoL improved significantly: mean preoperative PFIQ-7 scores were 76.7 ± 62.3 and diminished postoperatively to 13.5 ± 31.1 [p<0.0005]. Further details of anatomical results are listed below in table 2.

Robot-assisted sacrocolpopexy (n=188)

Six weeks postoperative 88.1% of patients showed no prolapse (sPOPQ=1 for all anatomical landmarks). There were two apical recurrences, both stage 2 (1.1%). After 12 months, 94 of 140 examined patients (67.1%) showed no objective recurrence and 103 patients (73.6%) had no symptomatic recurrence [Table 2]. One hundred and twenty-eight patients had no recurrence in the apical compartment (91.4%). Of the 12 patients with apical recurrence, more than half were stage 2 (Stage 2: N=7 (5.0%); stage 3: N=4 (2.9%); stage 4: N=1 (0.7%). When assessing all three compartments an isolated anterior wall prolapse occurred most frequently in 22 patients (15.7%) (sPOPQ stage 2: N=10 (7.1%); stage 3: N=9 (6.4%); stage 4: N=1 (0.7%)); unreported stage at repeat surgery N=2 (1.4%)). Assessing recurrences, isolated cystoceles accounted for 47.8% of these; nine recurrences were asymptomatic (19.6%). Approximately a quarter (22.9%) of the postoperative patients required a prolapse-related reoperation, mostly consisting of vaginal repair (Table 3). Eight out of 140 patients (5.7%) reported symptoms of bulge, but had no objective prolapse during physical examination. Compared to RSHS, there was no difference in the objective success percentage. However, a significant difference was found in the number of patients with a symptomatic recurrence (73.6% versus 88.6%; p=0.006). In RASC, 184/188 patients (97.9%) reported preoperative symptoms of bulge versus 26/144 (18.1%) postoperatively (p<0.0005). PFIQ-7 scores improved significantly: preoperative 89.7 ± 64.1 versus postoperative 14.6 ± 32.3 (p<0.0005).

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Robot-assisted supracervical hysterectomy with sacrocervicopexy (n=117)

After six weeks, no recurrences were found in the apical compartment. After one year, one patient had a recurrent prolapse of the apical compartment (Stage 4; 1.0% [Table 2]). A redo-cervicopexy was performed, which revealed a laxity in the mesh, it was shortened, with no recurrence afterwards. Across all compartments, there were 37 recurrences (35.2%) of which 12 were symptomatic (11.4%). Twenty-four recurrences were anterior compartment prolapses, mostly being stage 2 (N=18) and asymptomatic. In 3.7% of patients prolapse related retreatment was necessary, including the redo-cervicopexy mentioned above. One hundred and thirteen of 117 patients (96.6%) reported symptoms of bulge prior to surgery versus 18 of 109 patients (16.5%) after surgery ($p<0.0005$). A significant improvement in QoL scores was found: 53.7 ± 52.0 versus 12.5 ± 30.0 ($p=0.002$). In one of the postoperative pathology examinations, one patient with endometrial cancer was identified. Further diagnostics showed an endometrial cancer FIGO stage IVB.

Secondary outcomes

Intra operative complications

In total, ten intraoperative complications (3.3%) were identified in both groups. All of these complications occurred in the RASC group, which was significantly higher in comparison to RSHS [Table 3; 5.3 % versus 0.0%; $p=0.008$]. The most common complication was cystotomy (6/10), of which two resulted in conversion. There was one haemorrhage from the presacral venous plexus due to the use of a metal retractor for holding small bowel out of the operative field. There were eight conversions, 4 due to intraoperative complications, of which one was due to excessive adhesions. Three were the result of atypical anatomy of the sacral promontory (prominent vasculature and therefore high risk of haemorrhage; unidentifiable

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sacral promontory due to significant presacral fat). Furthermore, in two cases, ventilation problems in steep Trendelenburg position prior to incision occurred: one surgery was abandoned and in the other an open sacrocolpopexy was performed instead.

Intraoperative data

The intraoperative variables are listed in Table 3. Concomitant procedures such as TVT-O, salpingo-ophorectomy and anterior colporrhaphy were significantly more frequently performed in RSHS than RASC (9.4% versus 2.1% [p=0.004], 8.5% versus 0.5% [p<0.0005], 11.1% versus 3.2% [0=0.005]). Duration of surgery was the lowest in the RASC group (145.3 minutes ± 29.8). Performance of supracervical hysterectomy, made the surgery significantly longer [mean difference 38 minutes]. Median blood loss was low for both surgeries: 25-50 millilitres [IQR 10-100]).

Early postoperative complications

There were 22 (7.2%) early postoperative complications, 16 (8.5%) after RASC and 6 (5.1%) after RSHS. The majority were minor stage 1-2 complications requiring small interventions. Five complications were severe (Clavien Dindo Classification ≥3; Table 3). One ischemic CVA occurred after RSHS (0.9%), with full recovery after therapy with anticoagulants. The remaining severe postoperative complications were after RASC (2.1%): one incisional hernia needing surgical correction, one haemorrhagic CVA resulting in subdural hematomas requiring surgery, one bowel perforation requiring colostomy and ICU admission.

Late complications

There were four mesh-related complications after RASC (2.1%): three vaginal mesh exposures and one patient with a vaginal mesh exposure and sacral discitis. Two of these four

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patients needed complete surgical mesh removal of the mesh (1.1%). Four late complications occurred after RSHS (3.4%): one vaginal mesh exposure, one exposure of a concomitant inserted TVT-O and two incisional port herniations, one needing surgical correction. In total, with early postoperative complications included, 1.0% of patients (3/305) were identified with an incisional hernia at trocar incision site.

Discussion

Main findings

The results from this large bicentre prospective cohort study demonstrates that the robotic approach is an effective and reproducible technique with excellent results associated with the apical compartment (91-99%). Recurrences were mostly located in the anterior compartment: 15.7% after RASC (symptomatic 12.1%) and 22.9% after RSHS (symptomatic 4.8%). Quality of life and subjective symptoms of bulge improved significantly. Intra- and postoperative complications were low. Mean duration of surgery was 145 minutes for RASC and 183 for RSHS.

Strengths and limitations

Strengths of this study include the size of study group, the prospective design and high recall and duration of follow up. Further strengths were the avoidance of heterogeneity across both the surgery subgroups and the surgical technique used as well as the experience of surgeons involved. The main goal of this study was to provide accurate numbers for each procedure, as differentiation between these two subtypes of surgery in other studies is often not clear. Choice for RASC/RSHS was dependent on the presence of the uterus. As there were differences in baseline characteristics between RASC and RSHS, interpretation of

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comparisons between results should therefore be done with caution. This was a limitation of this study.

Interpretation

The results regarding the apical compartment compare favourably with results from a previously reported systematic review[3]. The systematic review reported success rates for all compartments from 84% to 100%, which are higher than the success rates of 65%-67% in this study. The systematic review, included papers with low numbers of patients, heterogeneous surgeries, different definitions and variable follow-up periods, most were retrospective by design. Only one study by Culligan et al. prospectively presented one-year anatomical data on more than 100 robotic cases (N=150; sPOPQ exam N=143)[16]. While their definition of success, was comparable to ours, they reported on a heterogenous group of sacrocolpopexy and sacrocervicopexy. Approximately 80% of their group required a concomitant supracervical hysterectomy, which affects the surgical variables. They also had a much higher rate of concomitant anti-incontinence surgery (81%) than our two groups combined (5%). Of note, most of their recurrences were seen in the anterior compartment, similar to our findings. When solely looking at symptomatic recurrences occurring for all compartments, we found a 74% and 89% success rate for RASC and RSHS respectively. Nygaard et al.[17] performed a large systematic review assessing abdominal sacrocolpopexy, follow-up ranged from 6 months to 3 years and showed an apical success rate of 78-100%. Success rates in all compartments varied from 58-100%, showing that women are at risk for postoperative prolapse in other compartments.

Historically the treatment of anterior wall prolapse is problematic [18], and as our study illustrates it is similar post both RASC and RSHS. Placing the mesh as distal as possible on the anterior vaginal wall, could possibly improve anterior compartment results. There is a

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huge difference in the technique used to anchor the mesh to the anterior vaginal wall between surgeons, which has been described previously, leading possibly to different results[19]. Wong et al[20] described 79 women undergoing LSC, who considered themselves postoperatively cured or improved with no reoperation. After three years, 62% showed recurrence in the anterior compartment. Furthermore it highlighted that for every millimetre that the mesh was located further from the bladder neck (on Valsalva), the probability of a recurrent cystocele increases by 6-7%. Placing the mesh as close as possible to the bladder neck may improve the recurrence rate and the robotic system should facilitate this difficult and challenging dissection due to the improved freedom of movement and better suturing skills. However, as it might also increase complications rates, further research is necessary to confirm these theories.

Postoperatively a higher percentage of recurrent cystocele was seen after RSHS, which could possibly be explained by the higher sPOPQ stage A preoperatively, this is associated with higher risk of recurrence[21]. However, comparisons between the two types of surgeries must be analysed carefully, since this study was not set up as a randomised controlled trial. Prendergast et al.[22] conducted a study where just RSHS was included. The cure rate after one year (stage 1, using the standard POPQ assessment) was 72%. We found a success rate of 65%, again, mostly affected by recurrent anterior wall prolapses, many being stage 2 and not symptomatic. When scoring solely symptomatic recurrences, success percentage raised to 89% for RSHS. The clinical relevance of asymptomatic prolapse is unclear. Many definitions to describe success after POP repair have been used[23]. The hymen appears to be an important cut-off point in the occurrence of symptoms, which would be in line with our cut-off point sPOPQ stage 2 or higher. Repeat surgery, in case of recurrence, were higher after RASC than after RSHS.

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Significantly more intraoperative complications appeared in the RASC group. A history of previous hysterectomy, scar tissue and adhesions can complicate the RASC procedure, resulting possibly in more complications. Intraoperative blood loss, hospital stay and postoperative pain scores were low overall. Duration of surgery time was prolonged when adding a supracervical hysterectomy. Two RCT's on RASC, reported procedure and total surgery time: respectively 227 ± 47 and 265 ± 50 minutes (N=35, all post hysterectomy patients), 202.8 ± 46.1 and 246.5 ± 51.3 minutes (N=40, concomitant hysterectomy N=25)[6]. Surgeons were required to have performed at least 10 procedures of RASC before study participation. Mean surgery time in our study is shorter, probably due to the larger number of patients included and surgeon expertise. Increasing surgical expertise is associated with reduced operative times[24].

Based on the low percentage of severe early and late postoperative complications, both procedures can be classified as safe. In RSHS, one patient with endometrial cancer was identified postoperatively. Proper preoperative work-up should be performed for those patients with a uterus. Since the FDA suggested in-bag morcellation in their statement in 2014[25], we started in bag morcellation to avoid the risk of morcellating a possible malignancy intra-abdominally. Postoperative pain scores were low for both procedures. Hospital stay was significantly shorter in RASC than RSHS, which could possibly be explained by different postoperative hospital regimes.

Strengths of this study include the size of study group, the prospective design and high recall and duration of follow up. Further strengths were the avoidance of heterogeneity across both the surgery subgroups and the surgical technique used as well as the experience of surgeons involved.

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This study provides answers to the questions- 1) When I am a competent robotic surgeon how long on average should it take to perform either a sacrcolpopexy or sacrocervicopexy. 2) When counselling patients regarding success rates for robot-assisted apical prolapse surgery what are the figures for each subgroup? 3) Are each of the robot-assisted surgical procedures for apical prolapse safe for my patients?

Conclusion

This large prospective cohort study shows that robot-assisted apical repair surgery gives durable anatomical results. Apical success rates were 91% and 99% for RASC and RSHS respectively. Postoperative anterior wall recurrences can occur and patients should be counselled accordingly. Both procedures are safe and, when performed regularly, performed within accessible time ranges.

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Ethical Approval:

This study was in accordance to the ethical regulations of the Clinical Research Ethics Committee (CREC, University College Cork, Ireland) and the National Central Committee on Research Involving Human Subjects (CCMO, The Netherlands. Date of approval 13-12-2011).

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Conflicts of interest:

S.E.S.K. proctor for Intuitive Surgical.

I.A.M.J.B. proctor for Intuitive Surgical.

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The remaining authors report no conflicts of interest. Completed disclosure of interest forms are available to view online as supporting information.

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Authorship:

F van Zanten: data collection and manuscript preparation

S.E. Schraffordt Koops: study concept, data collection and manuscript editing

O.E. O'Sullivan: data collection and manuscript preparation and editing

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A.M.J. Broeders: data collection and manuscript editing

B.A. O'Reilly: study concept, data collection and manuscript editing

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References

1. Akl, M.N., Long, J. B., Giles, D. L., Cornella, J. L., Pettit, P. D., Chen, A. H. et al., *Robotic-assisted sacrocolpopexy: technique and learning curve.* Surg Endosc, 2009. **23**(10): p. 2390-4.
2. Tarr, M.E., Brancato SJ, Cunkelman JA, Polcari A, Nutter B, and Kenton K. *Comparison of postural ergonomics between laparoscopic and robotic sacrocolpopexy: a pilot study.* J Minim Invasive Gynecol, 2015. **22**(2): p. 234-8.
3. Serati, M., Bogani G, Sorice P, Braga A, Torella M, Salvatore S et al., *Robot-assisted sacrocolpopexy for pelvic organ prolapse: a systematic review and meta-analysis of comparative studies.* Eur Urol, 2014. **66**(2): p. 303-18.
4. Anglim, B., O.Sullivan. OE., and O'Reilly, BA., *How do patients and surgeons decide on uterine preservation or hysterectomy in apical prolapse?* International urogynecology journal, 2018.
5. Maher, C., Feiner B, Baessler K, Christmann-Schmid C, Haya N, and Brown J. *Surgery for women with apical vaginal prolapse.* Cochrane Database Syst Rev, 2016. **10**: p. CD012376.
6. Paraiso, M.F., Jelovsek JE, Frick A, Chen CC, and Barber MD *Laparoscopic compared with robotic sacrocolpopexy for vaginal prolapse: a randomized controlled trial.* Obstet Gynecol, 2011. **118**(5): p. 1005-13.
7. Anger, J.T., Mueller ER, Tarnay C, Smith B, Stroupe K, Rosenman A, et al., *Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial.* Obstet Gynecol, 2014. **123**(1): p. 5-12.
8. Collins, S. and P. Tulikangas, *Randomized trials in robotic surgery: a practical impossibility?* Int Urogynecol J, 2010. **21**(9): p. 1045-7.
9. Swift, S., Morris S, McKinnie V, Freeman R, Petri E, Scotti RJ et al., *Validation of a simplified technique for using the POPQ pelvic organ prolapse classification system.* Int Urogynecol J Pelvic Floor Dysfunct, 2006. **17**(6): p. 615-20.
10. Parekh, M., Swift S, Lemos N, Iskander M, Freeman B, Arunkalaivanan AS et al., *Multicenter inter-examiner agreement trial for the validation of simplified POPQ system.* Int Urogynecol J, 2011. **22**(6): p. 645-50.
11. Utomo, E., Blok BF, Steensma AB,and Korfage IJ, *Validation of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) in a Dutch population.* Int Urogynecol J, 2014. **25**(4): p. 531-44.
12. Rosenthal, R., Hoffmann H, Clavien PA, Bucher HC, and Dell-Kuster S, *Definition and Classification of Intraoperative Complications (CLASSIC): Delphi Study and Pilot Evaluation.* World J Surg, 2015. **39**(7): p. 1663-71.
13. Dindo, D., N. Demartines, and P.A. Clavien, *Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey.* Ann Surg, 2004. **240**(2): p. 205-13.
14. Clifton, M.M., J. Pizarro-Berdichevsky, and H.B. Goldman, *Robotic Female Pelvic Floor Reconstruction: A Review.* Urology, 2016. **91**: p. 33-40.
15. Rimbach, S. and M. Schempershofe, *In-Bag Morcellation as a Routine for Laparoscopic Hysterectomy.* Biomed Res Int, 2017. **2017**: p. 6701916.
16. Culligan, P.J., Gurshumov E, Lewis C, Priestley JL, Komar J, Shah N, et al., *Subjective and objective results 1 year after robotic sacrocolpopexy using a lightweight Y-mesh.* Int Urogynecol J, 2014. **25**(6): p. 731-5.
17. Nygaard, I.E., McCreery R, Brubaker L, Connolly A, Cundiff G, Weber AM,

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et al., *Abdominal sacrocolpopexy: a comprehensive review*. Obstet Gynecol, 2004. **104**(4): p. 805-23.
18. Lensen, E.J., Withagen MI, Kluivers KB, Milani AL, and Vierhout ME. *Surgical treatment of pelvic organ prolapse: a historical review with emphasis on the anterior compartment.* Int Urogynecol J, 2013. **24**(10): p. 1593-602.
19. O'Sullivan, O.E., C.A. Matthews, and B.A. O'Reilly, *Sacrocolpopexy: is there a consistent surgical technique?* Int Urogynecol J, 2016. **27**(5): p. 747-50.
20. Wong, V., Guzman Rojas R, Shek KL, Chou D, Moore KH, and Dietz HP, *Laparoscopic sacrocolpopexy: how low does the mesh go?* Ultrasound Obstet Gynecol, 2017. **49**(3): p. 404-408.
21. Aslam, M.F., Osmundsen B, Edwards SR, Matthews C, and Gregory WT., *Preoperative Prolapse Stage as Predictor of Failure of Sacrocolpopexy.* Female Pelvic Med Reconstr Surg, 2016. **22**(3): p. 156-60.
22. Prendergast, E., Silver H, Johnson LL, Simon M, Feinglass J, Kielb S, et al., *Anatomic Outcomes of Robotic Assisted Supracervical Hysterectomy and Concurrent Sacrocolpopexy at a Tertiary Care Institution at Initial Adaptation of the Procedure.* Female Pelvic Med Reconstr Surg, 2016. **22**(1): p. 29-32.
23. Barber, M.D., Brubaker L, Nygaard I, Wheeler TL 2nd, Schaffer J, Chen Z, et al., *Defining success after surgery for pelvic organ prolapse.* Obstet Gynecol, 2009. **114**(3): p. 600-9.
24. Lenihan, J.P., Jr., C. Kovanda, and U. Seshadri-Kreaden, *What is the learning curve for robotic assisted gynecologic surgery?* J Minim Invasive Gynecol, 2008. **15**(5): p. 589-94.

Figures and Table legends

Figure 1. Flow chart for included patients follow-up

Time to follow-up is presented as median [IQR].

Abbreviations: FU: follow up. IQR: interquartile range. Mo: months. N: number. RASC: robot-assisted sacrocolpopexy. RSHS: robot-assisted supracervical hysterectomy with sacrocervicopexy. sPOPQ: number of patients with a sPOPQ examination. QNR: questionnaire.

[1]. One patient with a history of laparoscopic sacrocolpopexy. [2]. Two patients with a history of ventral mesh rectopexy. [3]. One hysteropexy due to adhesions. [4]. Patients had no complaints and therefore refused consultation. [5]. Due to natural causes.

Table 1. Baseline characteristics and follow-up data.

Abbreviations: BMI: Body-Mass Index. Inc: incontinence. N/A: not applicable. POP: pelvic organ prolapse. Prev: previous. RASC: robot-assisted sacrocolpopexy. RSCR: robot-assisted sacrocolporectopexy. RSHS: robot-assisted supracervical hysterectomy with sacrocervicopexy. RSSCR: robot-assisted supracervical hysterectomy with sacrocervicorectopexy. S-POP: simplified pelvic organ prolapse quantification.
[a]Comparing RASC with RSHS [b]Excluding POP surgery. [c]Includes laparotomy, laparoscopic and supracervical hysterectomy. [d]Due to missing data, percentages cannot be calculated from the table. [d]Fishers' exact test.

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Table 2. Recurrences and retreatments.

Data presented as number (%) or mean values. Chi Squared Test was used to compare RASC with RSHS unless otherwise specified.

Abbreviations: AC: anterior colporrhaphy. ACNES: anterior cutaneous nerve entrapment syndrome. compart.: compartment(s) N: number. PC: posterior colporrhaphy. RASC: robot-assisted sacrocolpopexy. RSCR: robot-assisted sacrocolporectopexy. RSHS: robot-assisted supracervical hysterectomy with sacrocervicopexy. SC: sacrocolpopexy. Sympt.: symptomatic. TVT-O: transvaginal tape.

[a]All pessary [b]Fishers' Exact Test instead of Chi Square Test (expected count <5) [c]Compared to pre-operative mean values in Table 1 using Paired Sample T-Test. [d]Of these 33 procedures 22 used transvaginal mesh [e]One procedure was combined with perineorrhaphy [f]One cervical amputation [g]Before surgery, patient used a pessary. Peroperative the mesh was too loose and shortened [h]Includes one colpocleisis [i]Includes one discitis in which the mesh was removed at laparotomy. [j]Removal of mesh exposure in outpatient clinic.

Table 3. Intra-operative variables, hospital stay, pain scores and postoperative complications.

Data presented as number (%), unless otherwise specified.

Abbreviations: IQR: interquartile range. N/A: not applicable. RASC: robot-assisted sacrocolpopexy. RSHS: robot-assisted supracervical hysterectomy with sacrocervicopexy. TVT: Tension-free vaginal tape.

[a]Fishers' Exact Test instead of Chi Squared Test (expected count <5) [b]Conversion to laparotomy as first step to stop the bleeding; secondly an anterior colporrhaphy was performed [c]Includes one conversion to sacrospinal fixation with anterior/posterior colporrhaphy [d]More than one concomitant surgery in one patient was possible: scores do not add up.

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Characteristics	All patients	RASC	RSHS	p-value[a]
Age (y), mean ± SD	61.8 ± 9.8	63.1 ± 8.7	59.9 ± 11.2	0.009
BMI (kg/m^2), median [IQR]	25.8	26.6	25.2	0.009
	[23.8-29.0]	[24.4-29.7]	[23.2-27.7]	
Parity, median [IQR]	3.0	3.0	3.0	0.007
	[2.0-4.0]	[2.0-4.0]	[2.0-3.0]	
Postmenopausal, N (%)	274 (89.5)	186 (98.9)	88 (75.2)	<0.0005
Prev. intra-abd. surgery[b], N (%)	99 (32.5)	56 (29.8)	43 (36.8)	0.207
Prev. POP/incontinence. surgery, N (%)	167 (54.8)	147 (78.2)	20 (17.1)	<0.0005
Previous hysterectomy, N, (%)	188 (61.6)	188 (100.0)	0 (0.0)	<0.0005
Vaginal	121 (64.4)	121 (64.4)	0 (0.0)	-
Abdominal[c]	67 (35.6)	67 (35.6)	0 (0.0)	-
Diabetes mellitus, N (%)	21 (6.9)	10 (5.3)	11 (9.4)	0.171
Smoking[d], N (%)	42 (15.0)	25 (15.3)	17 (14.5)	0.337
sPOPQ, mean ± SD				
Stage A	2.6 ± 1.0	2.5 ± 1.0	2.9 ± 1.0	<0.0005
Stage B	2.1 ± 1.1	2.1 ± 1.1	2.0 ± 1.2	0.718
Stage C	3.1 ± 0.9	3.1 ± 0.8	3.0 ± 0.9	0.410
Stage D	2.6 ± 1.2	No uterus	2.2 ± 1.4	N/A
Symptoms of bulge, N (%)	297 (97.4)	184 (97.9)	113 (96.6)	0.488[d]

Abbreviations: BMI: Body-Mass Index. N/A: not applicable. POP: pelvic organ prolapse. Prev: previous. RASC: robot-assisted sacrocolpopexy. RSCR: robot-assisted sacrocolporectopexy. RSHS: robot-assisted supracervical hysterectomy with sacrocervicopexy. RSSCR: robot-assisted supracervical hysterectomy with sacrocervicorectopexy. sPOPQ: simplified pelvic organ prolapse quantification.

[a]Comparing RASC with RSHS [b]Excluding POP surgery. [c]Includes open, laparoscopic and supracervical hysterectomy. [d]Due to missing data, percentages cannot be calculated from the table. [d]Fishers' exact test.

Table 1. Baseline characteristics and follow-up data.

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	RASC	RSHS	p-value
	N=188	N=117	
6 weeks S-POP exam	**N=177**	**N=114**	
Success	156 (88.1)	97 (85.1)	0.463
Apical recurrence	2 (1.1)	0 (0.0)	0.521[b]
Retreatment[a]	3 (1.7)	0 (0.0)	0.282[b]
12 months S-POP exam	**N=140**	**N=105**	
sPOPQ A	1.4	1.4	<0.0005[c]
sPOPQ B	1.2	1.2	<0.0005[c]
sPOPQ C	1.1	1.0	<0.0005[c]
sPOPQ D	N/A	1.1	<0.0005[c]
Success	94 (67.1)	68 (64.8)	0.680
Success + asymptomatic recurrence.	103 (73.6)	93 (88.6)	0.006
Recurrence anterior compartment.	22 (15.7)	24 (22.9)	0.099
Symptomatic recurrence anterior compartment	[17 (12.1)]	[5 (4.8)]	
Recurrence posterior compartment.	6 (4.3)	8 (7.6)	0.285
Symptomatic recurrence posterior compartment	[2 (1.4)]	[4 (3.8)]	
Recurrence apical compartment	1 (0.7)	0 (0.0)	1.000[b]
Symptomatic recurrence apical compartment	[1 (0.7)]	[0 (0.0)]	
Recurrence multiple compartments including the apical compartment	11 (7.9)	1 (1.0)	0.012
Symptomatic recurrence multiple compartments including the apical compartment	[11 (7.9)]	[1 (1.0)]	
Recurrence multiple compartments excluding the apical compartment	6 (4.3)	4 (3.8)	1.000[b]
Symptomatic recurrence multiple compartments excluding the apical compartment	[6 (4.3)]	[2 (1.9)]	

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Retreatments	**N=144**	**N=109**	
Prolapse related	33 (22.9)[d]	4 (3.7)	<0.0005
- Anterior vaginal repair	12 (8.3)[e]	2 (1.8)	
- Posterior vaginal repair	6 (4.2)	-	
- Anterior and posterior vaginal repair	12 (8.3)[e,f]	-	
- Vaginal Pessary	-	1 (0.9)	
- Redo sacrocolpopexy	-	1 (0.9)[g]	
- Other	3[h] (2.1)	-	
Complication related	3 (2.1)	3 (2.8)	1.000[b]
- Remove (part) mesh	3[i] (2.1)	1 (0.9)[j]	
- ACNES	-	1 (0.9)	
- Incisional hernia	-	1 (0.9)	

Data presented as number (%) or mean values. Chi Squared Test was used to compare RASC with RSHS unless otherwise specified.

Abbreviations: AC: anterior colporrhaphy. ACNES: anterior cutaneous nerve entrapment syndrome. N: number. PC: posterior colporrhaphy. RASC: robot-assisted sacrocolpopexy. RSCR: robot-assisted sacrocolporectopexy. RSHS: robot-assisted supracervical hysterectomy with sacrocervicopexy. SC: sacrocolpopexy. TVT-O: transvaginal tape.

[a]All pessary [b]Fishers' Exact Test instead of Chi Square Test (expected count <5) [c]Compared to pre-operative mean values in Table 1 using Paired Sample T-Test. [d]Of these 33 procedures 22 used transvaginal mesh [e]One procedure was combined with perineorrhaphy [f]One cervical amputation [g]Before surgery, patient used a pessary. Intraoperatively the mesh was too loose and shortened [h]Includes one colpocleisis [i]Includes one discitis in which the mesh was removed at laparotomy. [j]Removal of mesh exposure in outpatient clinic.

Table 2. Recurrences and retreatments.

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Characteristics	RASC N=188	RSHS N=117	p-value
Intraoperative complications	10 (5.3)	0 (0.0)	0.008[a]
- Bladder injury	4 (2.1)	-	
- Bladder injury resulting in conversion	2 (1.1)	-	
- Conversion due to bleeding	2 (1.1)[b]	-	
- Vaginal injury	1 (0.5)	-	
- Ureteric injury	1 (0.5)	-	
Intraoperative conversions	8 (4.3)	0 (0.0)	0.026[a]
- Intraoperative complication	4 (2.1)	-	
- Adhesions	1 (0.5)	-	
- Promontory inaccessible	3 (1.6)[c]	-	
Concomitant surgery[d]	15 (8.0)	38 (32.5)	<0.0005
- TVT	4 (2.1)	11 (9.4)	0.004
- Adnexal (single/bilateral)	1 (0.5)	10 (8.5s)	<0.0005[a]
- Anterior colporrhaphy	6 (3.2)	13 (11.1)	0.005
- Posterior colporrhaphy	3 (1.6)	5 (4.3)	0.268[a]
- Other	2 (1.1)	2 (1.7)	0.640[a]
Salpingectomy	18 (9.6)	38 (32.5)	<0.0005
Blood loss in millimeters, median (IQR)	25 (10-50)	50 (10-100)	0.007
Total surgery time, mean ± SD	145.3 ± 29.8	183.1 ± 38.2	<0.0005
Hospital stay nights, median (IQR)	1.0 (1-2)	2.0 (1-3)	<0.0005
VAS, median (IQR)	2.0 (1-3)	2.5 (2-4)	0.305
Early postoperative complications	16 (8.5)	6 (5.1)	0.341
Grade 1	4 (2.1)	1 (0.9)	

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Grade 2	8 (4.3)	4 (3.4)	
Grade 3	1 (0.5)		
Grade 4	3 (1.6)	1 (0.9)	
Grade 5	-	-	
Late complications	4/144 (2.8)	4/109 (3.7)	0.472

Data presented as number (%), unless otherwise specified.

Abbreviations: IQR: interquartile range. N/A: not applicable. RASC: robot-assisted sacrocolpopexy. RSHS: robot-assisted supracervical hysterectomy with sacrocervicopexy. TVT: Tension-free vaginal tape.

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Table 3. Intra-operative variables, hospital stay, pain scores and postoperative complications.

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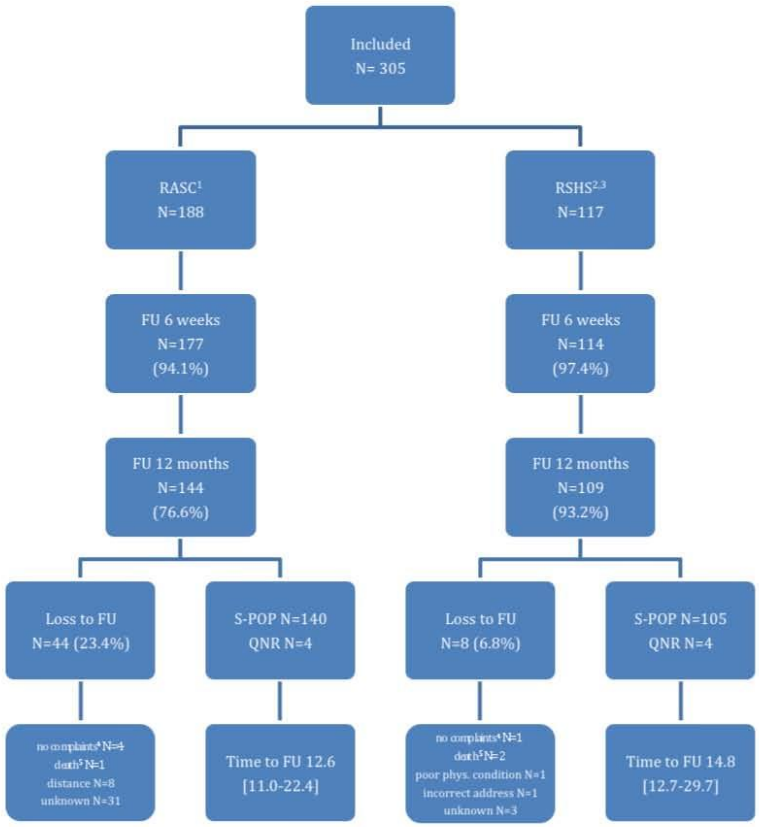


Figure 1. Flow chart for included patients' follow-up

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