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1 REVIEW ARTICLE

Q1 **A systematic review and meta-analysis of conventional laparoscopic**
 3 **sacrocolpopexy versus robot-assisted laparoscopic sacrocolpopexy**

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A B S T R A C T

Background: Robot-assisted laparoscopic sacrocolpopexy (RALSC) has spread rapidly without the availability of comprehensive and systematically recorded outcome data. *Objective:* To systematically review and compare the outcomes of laparoscopic sacrocolpopexy (LSC) and RALSC. *Search strategy:* PubMed and Scopus were searched for reports published from 2000 to 2014, using the search terms “robotic sacrocolpopexy,” “laparoscopic sacrocolpopexy,” and “sacral colpopexy.” *Selection criteria:* Studies were included if they directly compared the outcomes of RALSC and LSC, the sample size in each group was more than 15, the follow-up duration was longer than 3 months, and the report was in English. *Data collection and analysis:* The studies’ characteristics, quality, and outcomes were recorded. Random-/fixed-effects models were used to combine data. *Main results:* Data on 264 RALSC and 267 LSC procedures were collected from seven studies. The mean operative time was longer in the RALSC group (245.9 minutes vs 205.9 minutes; $P < 0.001$). The estimated blood loss in the two groups was similar (114.4 mL vs 160.1 mL; $P = 0.36$). The differences in incidence of intraoperative/postoperative complications were also similar ($P = 0.85$ vs $P = 0.92$). The costs of RALSC were significantly higher than were those of LSC series in each of three studies ($P < 0.01$ for all). *Conclusions:* The clinical outcomes of prolapse surgery are similar with RALSC and LSC, but RALSC is less efficient in terms of cost and time.

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41 1. Introduction

42 Pelvic organ prolapse (POP) is estimated to affect 30% of US women
 43 aged 50–89 years and the morbidity increases with age [1]. A study from
 44 the USA [2] predicted that the morbidity of prolapse will increase by 46%
 45 over the next 40 years. In both high- and low-income countries, there is
 46 a growing need for high-quality, cost-efficient POP treatment for an in-
 47 creasing population of women of advanced age whose awareness of
 48 health has improved [3].

49 The ideal procedure for POP repair should be effective and safe,
 50 have durable benefits, and improve sexual, urinary, and bowel func-
 51 tion. New procedures must meet these criteria. The gold-standard
 52 procedure for the surgical treatment of POP is open abdominal
 53 sacrocolpopexy (ASC) [4]. A minimally invasive laparoscopic
 54 approach—laparoscopic sacrocolpopexy (LSC)—has also become

55 available and provides similar outcomes to those of ASC [5]. However,
 56 LSC is technically more challenging because it requires the surgical skills
 57 to perform suturing with knot tying and the ability to accurately deter-
 58 mine the correct planes for safe dissection of the vesicovaginal and
 59 rectovaginal spaces.

60 Since 2004, robot-assisted laparoscopic sacrocolpopexy (RALSC) has
 61 emerged as a possible alternative to a conventional laparoscopic
 62 technique [6–8]. The robotic technology is associated with improved
 63 dexterity and precision, facilitating the suturing of mesh to the vagina.
 64 Moreover, the robotic camera provides closer visualization, enabling
 65 better preservation of the vessels overlying the sacral promontory and
 66 therefore potentially reducing blood loss. Finally, the robotic technology
 67 could affect learning curves—e.g. surgeons might need fewer cases to
 68 gain competence.

69 However, despite the fact that RALSC has been rapidly incorporated
 70 into clinical practice, comprehensive and systematic outcome data have
 71 not yet been published. When comparing LSC with RALSC, some ques-
 72 tions regarding the efficacy, cost, training, and adoption still need to
 73 be answered [9–12]. The aim of the present study was, therefore, to
 74 systematically review the currently published peer-reviewed litera-
 75 ture and compare the outcomes of RALSC and LSC.

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2. Materials and methods

2.1. Search strategy

A systematic review and meta-analysis was performed in line with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) [13] and Meta-analysis of Observational Studies in Epidemiology (MOOSE) [14] guidelines. The 23-item Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument for developing and reporting recommendations was applied [15]. PubMed (Medline) and Scopus were searched systematically for records published between January 1, 2000, and December 31, 2014, using the terms “robotic sacrocolpopexy,” “laparoscopic sacrocolpopexy,” and “sacral colpopexy.”

2.2. Selection criteria

Two investigators (K.P. and Y.Z.) reviewed the abstracts of identified reports independently. The predetermined inclusion criteria were published original research, direct comparison of the outcomes of RALSC and LSC, sample size in each group greater than 15, and duration of follow-up more than 3 months. Articles were excluded if the language was not English or if duplicate data on the same cohort were presented.

2.3. Data extraction

The two reviewers independently abstracted the relevant data from each eligible study, using a custom, piloted spreadsheet that listed the variables of interest. When discrepancies arose, a third investigator [Ya.W.], who was not involved in the original extraction, arbitrated. If relevant data were not clear, the corresponding author of the original study was contacted by e-mail.

The abstracted demographic data included age, body mass index, and previous surgery. Intraoperative data included the operative time (defined as procedure time and, in the RALSC group, docking time), estimated blood loss (blood loss associated with the entire operation), concomitant procedures, intraoperative complications, conversion rates, transfusion, and length of hospital stay. Postoperative outcomes included the duration of follow-up, recurrent prolapse (using the pelvic organ prolapse quantification [POP-Q] system [16] and defined as POP-Q stage 2 or more), postoperative complications, subjective satisfaction, and rates of mesh erosion and reoperation. The strengths and limitations, including potential bias and loss to follow-up, were documented for each included study. The primary outcomes were operative time, estimated blood loss, and intraoperative/postoperative complications. The secondary outcomes included the anatomic cure rate defined as apical prolapse less than or equal to POP-Q stage 1, erosion rate, conversion, transfusion, length of hospital stay, reoperation, prolapse recurrence, subjective satisfaction, and cost.

To make the outcomes from the various studies more comparable, intraoperative complications were graded using the Satava system [17] and postoperative complications were graded using the Clavien–Dindo severity system [18]. According to the Satava classification, intraoperative complications are categorized into grade 1 (no consequences for the patient), grade 2 (endoscopic retreatment required), and grade 3 (incidents requiring open or laparoscopic surgery) [17]. The Clavien–Dindo severity system includes five grades of severity for postoperative complications, ranging from a slight deviation from the normal postoperative course (grade 1) to death (grade 5) [18].

2.4. Assessment of methodological quality

The Jadad scale [19] was used to evaluate the methodological quality of eligible randomized controlled trials (RCTs). This scale is based on three items: randomization (0–2 points), blinding (0–2 points), and withdrawals and dropouts (0–1 points). A score of 1 is given when

randomization or blinding is mentioned, and a further point is given if the respective item is used appropriately. A description of the number of, and reasons for, withdrawals and dropouts is also accorded a score of 1. Studies are considered to be of low quality if they have a total score of 2 or less, and of high quality if they have a total score of 3 or more [20].

The Newcastle–Ottawa Scale [21] was used to assess the risk of bias of eligible cohort studies. This scale was used to assess the quality of cohort studies on the basis of participant selection, comparability of the study cohorts, and ascertainment of the outcome measures. The scale uses a star scoring method, through which studies can be awarded one star in each category other than comparability, for which two stars can be awarded. The maximum score with the modified Newcastle–Ottawa Scale is nine stars for comparative cohort studies; cohort studies with fewer than six stars cannot be used in comparisons.

2.5. Statistical analysis

Meta-analyses were performed including all studies. Additionally, the studies were grouped into subgroup 1 (RCTs) or subgroup 2 (cohort studies), and two separate meta-analyses were conducted to evaluate the consistency of the results. The Mantel–Haenszel fixed-effects method [22] and the DerSimonian–Laird (random-effects) method [23] were used as appropriate to calculate pooled relative risks (RRs). Both models provide similar results if there is no heterogeneity. Funnel plots and the Begg test were used to evaluate publication bias.

The statistical analysis was performed with SPSS version 22.0.0 (IBM, Armonk, NY, USA). Effect estimates and their 95% confidence intervals (CIs) were log-transformed and the standard error of each estimate was calculated. The statistical heterogeneity between the studies was assessed using the I^2 statistic and its 95% CI. A result of $I^2 = 0\%$ indicates no heterogeneity; the larger the value for I^2 , the larger the heterogeneity [24]. The pooled RR estimates derived from the two separate meta-analyses (meta-analysis of RCTs and meta-analysis of cohort studies) were compared with a test of interaction [25]. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Characteristics of the selected studies

A total of 92 papers were initially identified. Seven studies [10,26–31] including 531 patients were retrieved (Fig. 1). Overall, 262 patients underwent RALSC and 269 patients underwent LSC; the mean follow-up duration was 13.5 months after RALSC and 15.6 months after LSC. Two studies [10,26] were RCTs (subgroup 1) and five [27–31] were cohort studies (subgroup 2). All studies were considered to be of high quality (Supplementary Material S1). There was no evidence of substantial publication bias in the seven studies (Fig. 2).

3.2. Preoperative results

All seven studies [10,26–31] provided preoperative data. There were no significant differences in age, body mass index, previous surgery for POP, and prior hysterectomy between patients who underwent RALSC and those who underwent LSC ($P > 0.05$ for all comparisons) (Table 1, Supplementary Material S2).

3.3. Concomitant procedures

All seven studies [10,26–31] reported data for concomitant procedures. Hysterectomy (reported in five studies [10,26–28,31]) and pelvic floor repair (reported in six studies [10,26–31]) were the most common concomitant procedures. Concomitant hysterectomy was performed for 90 (40.4%) of 223 patients who underwent RALSC and 65 (33.3%) of 195 patients who underwent LSC ($I^2 = 0\%$; $P = 0.34$). Pelvic repair

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