GENERAL GYNECOLOGY

Laparoendoscopic single-site versus conventional laparoscopic gynecologic surgery: a metaanalysis of randomized controlled trials

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OBJECTIVE: To assess the current evidence regarding the efficiency, safety, and potential advantages of laparoendoscopic single-site surgery (LESS) for treating gynecologic diseases.

STUDY DESIGN: We comprehensively searched PubMed, Embase, and the Cochrane Library from their inception to December 2012. Two authors screened out duplicates and independently reviewed eligibility of each study. We included randomized controlled trials comparing LESS with conventional laparoscopy (CL) for treating gynecologic diseases. The primary outcomes were perioperative complication rate, conversion rate, postoperative pain, and cosmetic satisfaction.

RESULTS: We included 6 randomized controlled trials with 439 participants in the final analysis. There were no significant differences between LESS and CL in terms of perioperative complication rate (15.5% and 14.3%; risk ratio, 1.11; 95% confidence interval [CI], 0.74–1.67; $P = .61$), conversion rate (3.8% and 1.1%; risk ratio, 2.75; 95% CI, 0.73–10.33; $P = .13$), postoperative pain (weighted mean difference [WMD], −0.22; 95% CI, −1.29 to 0.85; $P = .68$), analgesic requirement (WMD, 0.41; 95% CI, −1.69 to 2.51; $P = .70$), and cosmetic satisfaction (WMD, 0.19; 95% CI, −0.30 to 0.68; $P = .46$). There were also no differences in terms of operative time ($P = .65$), hemoglobin change ($P = .23$), time to first flatus ($P = .17$), and length of hospital stay ($P = .99$) between both techniques.

CONCLUSION: This metaanalysis provides evidence that LESS is comparable in the efficacy and safety, but does not offer potential advantage such as better cosmesis and lesser pain compared with CL for treating gynecologic diseases.

Key words: gynecologic, laparoendoscopic single-site, LESS, laparoscopy, metaanalysis

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Laparoscopic surgery is a well-established alternative of laparotomy in various fields of gynecology. It has many advantages such as less pain, quicker recovery, shorter hospital stay, and a better cosmesis.[1] In recent years, the laparoendoscopic single-site (LESS) technique was created to improve cosmesis by reducing the number of incisions. This technique has been applied to a number of surgical procedures including hysterectomy,[2-4] adnexal surgery,[5-8] cholecystectomy,[9] appendectomy,[10] nephrectomy,[11] and colectomy.[12]

Even though randomized controlled trials (RCTs) comparing LESS and conventional laparoscopy (CL) for gynecologic diseases have been reported, most used small sample sizes and have shown conflicting results.[2-7] A metaanalysis could solve this limitation by pooling all available data together instead of another large-sized RCT. The aim of this study was to search and systematically analyze available RCTs to evaluate the efficacy, the safety, and the potential advantages of LESS in comparison with CL for gynecologic diseases.

Materials and Methods

The review was planned and conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for systematic reviews and meta-analysis[13] and the recommendations of the Cochrane Collaboration.[14,15] This was a metaanalysis of published summary data and therefore did not require ethics approval.

The literature search comprised the following electronic databases from their inception through December 2012 without restriction to regions, publication types, or languages: Medline (via PubMed), Embase, and the Cochrane Library. The literature search was constructed using key words such as "uterus," "ovary," "adnexa," tube," or "salpinx" for organ; "myoma," "leimyoma," "fibroid," "cyst," or "tumor," for disease; "single site," "single incision," "single port," "laparoendoscopy," "laparoscopy," "pelviscopy," "hysterectomy," "cystectomy," or "enucleation" for intervention; and "complication," "conversion," "pain," "cosmetic," or "operative time" for outcome. The complete search strategy for PubMed was as follows: ("single port" OR "single incision" OR "single site") AND (laparoendoscop* [Title/Abstract] OR laparoscop* [Title/Abstract] OR pelviscop* [Title/Abstract]) AND (uter* [Title/Abstract] OR ovar* [Title/

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Abstract] OR adnexa* [Title/Abstract] OR tub* [Title/Abstract] OR salping* [Title/Abstract] OR hysterectomy [Title/Abstract] OR cystectomy [Title/Abstract] OR enucleation [Title/Abstract] OR myom* [Title/Abstract]) and adapted for each database as necessary. Studies and abstracts that were presented at recent congresses (American College of Obstetricians and Gynecologists [2007-2012], American Association of Gynecologic Laparoscopists [2007-2012], International Federation of Gynecology and Obstetrics [2007-2012]) were also searched. The Clinical Trials database (http://clinicaltrials.gov) was searched for articles in other archived registries. The bibliographies from the included trials were manually searched to identify additional trials. The "Related citations in PubMed" function of PubMed articles was also used to expand our search criteria. Two authors (TS and SJS) screened all abstracts that were identified by the literature search and reviewed the full articles of potentially eligible studies to determine whether they met inclusion criteria.

Study selection

A study should meet the following conditions to be eligible: (1) the type of a study should be a RCT; (2) the participants of a study should be women who received laparoscopy for gynecologic diseases; (3) as for the type of intervention, a study should compare LESS with CL. Studies were excluded if LESS was not the main intervention but a part of multimodal intervention; and (4) as for the type of outcome, a study should measure at least 1 of the outcomes of interest as mentioned below.

A study should be excluded from the metaanalysis in the following conditions: (1) if it was a retrospective comparative study (cohort or case-control study), an editorial, a letter to the editor, a review article, a case report, or a study of animal experiment; (2) if 2 or more studies were reported by the same surgical department and/or authors and showed an overlap between the results; (3) if multicenter studies contained data that were already included in other single-center study; (4) if the necessary data was extrapolated from the reported outcomes; and (5) if the outcomes of interest were not evidently described for LESS and CL.

Outcomes of interest

The following outcomes were used to compare LESS and CL. The primary outcomes were perioperative complication rate, conversion rate, postoperative pain, and cosmetic satisfaction. If sufficient data were available, perioperative complications were subdivided into intraoperative complications and postoperative complications within 30 days of operation. Postoperative complications were classified according to the Clavien-Dindo grading system.[16] Conversions were defined as follows: (1) addition of trocars, or (2) conversion to laparotomy. Postoperative pain was measured using a visual analog scale (VAS) and analgesic requirement. Cosmetic satisfaction was measured according to a scale that was administered to the patient 30 days postsurgery. The secondary outcomes were operative time, estimated blood loss (EBL), hemoglobin change, time to first flatus, and length of hospital stay.

Data extraction

Two of the authors (TS and SJS) independently extracted data from the included studies. They extracted the study identification (first author, year of publication), country where the trial was conducted, source of data, indication of surgery, number of patients, age, body mass index (BMI), duration of follow-up, period of each trial, and the outcomes of interest, which were mentioned previously, from all the studies finally selected. Data were entered into 2 separated databases for double-check. When the 2 entries did not match, it was resolved by the adjudicating senior author (YWJ and WDJ) with consensus achieved by discussion.

Risk of bias in individual studies

The risk of bias was independently assessed by 2 authors (WDJ and SSJ) using the 12 criteria (rating: yes, no, unclear) recommended by the Cochrane Back Review Group.[15] These criteria assessed the risk of bias on the following domains: selection bias, performance bias, attrition bias, reporting bias, and detection bias. If necessary, discrepancies were rechecked by the third reviewer (YWJ) and consensus was achieved by discussion. Studies that met at least 6 of the 12 criteria had no serious flaw and they were rated as having a low risk of bias.

Statistical analysis

All metaanalyses were performed using Review Manger 5.2 (Cochrane Collaboration, Oxford, UK). The weighted mean difference (WMD) and risk ratio (RR) were used to compare continuous and dichotomous variables, respectively. All results were reported with 95% confidence intervals (CIs). Heterogeneity between studies was assessed using the Higgins I^2. A value greater than 50% was considered to have substantial heterogeneity. The random-effects model was used if there was heterogeneity between studies; otherwise, the fixed-effects model was used.[14] Subgroup analyses were performed to compare LESS adnexal surgery and hysterectomy with CL procedures. Funnel plots were used to assess for potential publication bias. Sensitivity analyses were used to estimate the influence of studies with a high risk of bias on the overall effect.

RESULTS

Studies identified

A total of 6 RCTs were identified from 497 citations (Figure 1). One of 6 RCTs had insufficient data,[3] but the author responded to our request for the supplementary data. Therefore, 439 patients in 6 RCTs were included in our analysis. Although 1 study[6] was sponsored in part by Olympus Winter and IBE, Hamburg, Germany, the other 5 studies[2-5,7] were not in a relationship with industry. All included studies reported that the authors had nothing to disclose and did not report any potential conflicts of interest. Two hundred nineteen patients received LESS and 220 patients received CL. The characteristics of the included studies are summarized in Table 1.