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A systematic review and meta-analysis comparing single port laparoscopic myomectomy with conventional laparoscopic myomectomy

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ABSTRACT

Objective: We systematically evaluated if there are any clinical differences in the safety and feasibility of single port laparoscopic myomectomy when compared to conventional laparoscopic myomectomy.
Study Design: A meta-analysis and systematic review was conducted in accordance with the PRISMA statement. We searched different databases including Medline, Embase, Cochrane, and Google Scholar up to April 2018. Comparative studies as randomized controlled trials and prospective and retrospective cohort studies were included.
Results: A meta-analysis was performed on the safety, feasibility, and potential benefits. Two randomized controlled trials and six cohort studies (2 prospective and 4 retrospective) were meta-analyzed to compare the surgical outcomes of 907 patients. Rates of minor complications were not different between the two groups [OR 1.33 (0.67, 2.63), $I^2 = 0\%$]. Major complications requiring re-operation occurred in two cases in the single port group and in the conventional group respectively. There was no significant statistical difference between the groups. Conversion to laparotomy did not occur in either group, and the conversion rate from single port to the multi-port operation was 2.1% (6/288). The pain score one hour after operation was significantly lower in the single port group [MD -0.41 point (-0.63, -0.18), $I^2 = 3.7\%$]. However, this difference was not observed at six and 24 h postoperatively. There was no difference in the operation time, estimated blood loss, or hemoglobin decrease between the two groups.
Conclusion: A meta-analysis showed that single port laparoscopic myomectomy is comparable to conventional laparoscopic myomectomy in terms of safety and feasibility and more advantageous in terms of immediate postoperative pain. If performed based on the appropriate patient selection criteria including size and number of myoma, single port laparoscopic myomectomy can have similar surgical outcomes to those of conventional laparoscopic myomectomy. Further research and resources are required to identify whether single port laparoscopic myomectomy is more beneficial in terms of cosmetic results, patient satisfaction, and pregnancy outcomes.

Introduction

Uterine leiomyomas are the most common benign uterine tumor in women of childbearing age. Since the introduction of laparoscopic surgery the cases of laparoscopic myomectomy has steadily increased [1]. In order to maximize the advantages of laparoscopic surgery, single port laparoscopic surgery was introduced. However, single port laparoscopic surgery is generally considered to be more difficult than conventional laparoscopic surgery. The most important factor is the limited number of simultaneously available surgical instruments, and collisions between the instruments are also prone to occur. Therefore, single port laparoscopic surgery should be performed by a skilled surgeon. According to a previous study analyzing the learning curve for single port laparoscopic myomectomy (SPLM), the proficiency for SPLM was achieved after about 45 operations [2].

SPLM has been introduced relatively recently owing to the specific challenges related to myomectomy. Myomectomy requires more suturing and knot tying than do other benign operations, and it is difficult to suture thick layers of the uterus while maintaining

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adequate tension. It is also a laborious procedure to secure sufficient traction in the process of separating myomas from the uterine bed [3].

With advancements in surgical techniques and experiences, studies comparing SPLM with conventional laparoscopic myomectomy (CLM) are being published. However, most of the studies are limited to a small number of patients. In this situation, the present study intended to analyze the safety, feasibility, and potential benefits of SPLM. To this end, we compiled the latest findings related to SPLM from published studies that have compared SPLM and CLM and meta-analyzed these results.

Materials and methods

Literature search and study selection

This systemic review and meta-analysis was conducted under the PRISMA guidelines [4]. The authors searched Medline, Embase, Cochrane, and Google Scholar databases until April 2018 and did not limit the region, language, or publication type. We searched for articles containing "myomectomy" in the title, including a combination of "single site" and its synonyms "single port" and "single incision". The screening process of the results of the initial literature search and the evaluation of eligibility were conducted independently by the two authors (DL, JRL) and collated. Only comparative studies as randomized controlled trials (RCTs) and prospective and retrospective cohort studies comparing SPLM and CLM were included. We excluded studies comparing conventional laparoscopic studies with other surgical techniques (e.g., robot-assisted, hand-assisted). Abstracts for conferences without a full manuscript, technical reports, and editorial articles were also excluded.

Data extraction

In comparing the two surgical methods, we considered the safety of the operation as the most important factor and defined the incidence of complications as the primary outcome. Surgical complications were graded according to the Clavien-Dindo classification [5]. Grade I (without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions) and grade II (requiring pharmacological treatment with drugs other than such allowed for grade I) complications were defined as minor complications. Grade III (requiring surgical, endoscopic or radiological intervention), grade IV (life-threatening complication), and grade V (death) complications were classified as major complications. In addition, the success rates of the two modalities were compared to evaluate the effectiveness of both procedures. Procedure failure was defined as the need for an additional port in SPLM and the transition to open surgery in CLM.

Secondary outcomes were defined as postoperative pain, operation duration, estimated blood loss during surgery, hemoglobin reduction after surgery, and hospital stay after surgery. Postoperative pain was analyzed using a self-reporting visual analog scale (VAS) or numerical rating scale (NRS). The scores ranged from 0 to 10, with high scores indicating severe pain. Two RCTs compared the differences in analgesic use (dose or number of injection) for objective pain evaluation [9,10], but most studies did not include objective indicators for pain.

Data extraction was carried out independently by two researchers (DL, JRL), and the results were collected. Differences between the two researchers were resolved through discussion between the two researchers (DL, JRL) and the third researcher (CSS).

Quality assessment and Statistical analysis

The risk of bias in RCTs was evaluated using Cochrane Collaboration's tool [6]. For observational studies, the Newcastle-Ottawa scale (NOS) was adopted [7]. According to NOS, scores of 5–9 were defined as high quality and a score under 5 was defined as low quality. The process of evaluating the research quality was also conducted independently by two researchers (DL, JRL). When the findings of the two researchers did not match, the third researcher (CSS) reviewed the scores of the two researchers and adjudicated them.

The meta-analysis was conducted using R version 3.5.0 for windows developed by the R Foundation (https://www.r-project.org/foundation). We adopted the random effects model to determine appropriate weighting of studies. Study heterogeneity was assessed using Higgins I^2 values. When substantial heterogeneity was observed (I^2 >50%), sensitivity analysis were conducted. The odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for variables with dichotomous data. For these variables, the weighted summary OR was calculated using the Mantel-Haenszel method. For continuous data, the standard mean difference (SMD) was calculated and corrected according to the sample bias. The results of each study were presented, and the total SMD with the 95% CI was indicated. These results were then summarized and presented as a forest plot. Depending on the study the numerical data was not given as mean with standard deviation, but was gives as median with range or quartile values. In that case, we used a formula to estimate the mean and standard deviation using median with range or quartile values according to the previous statistical study [8]. We transformed the data using the automated conversion formula provided in the paper. A sensitivity analysis was performed for all variables, and funnel plots were used to estimate the potential publication bias.

Results

Study selection and characteristics of single port laparoscopic myomectomy

In the database search for the meta-analysis, 239 papers were screened. Fig. 1 shows the flowchart for the selection of the retrieved articles. Ultimately, two RCTs [9,10] and 6 cohort studies [11–16] met the inclusion criteria. The characteristics of the studies are summarized in Table 1. Combining all the studies included in the analysis, 408 patients were assigned to the SPLM group and 499 patients were assigned to the CLM group. The inclusion criteria for myomectomy were 5 or less myomas in most studies, and included only myomas with size of 14 cm or less.

Quality assessment

The results of the risk-of-bias analysis for the RCTs using Cochrane Collaboration's tool are presented in Supplementary Fig. 1. Random allocation was performed using computerized software; however, due to the nature of the studies, patients had to be informed as to how the procedure would be performed, which limited the blinding of the participants. The results of the observational studies using the NOS are presented in Table 1, with all studies showing scores of 6 or more.

Primary outcomes

All the studies included in the meta-analysis reported major complications. The frequency of major complications requiring re-operation was low in both groups. Major complications such as massive bleeding or trocar site herniation occurred in two case in the SPLM group (one case of massive bleeding; one case of trocar site herniation which occurred 6 months after operation) and two cases in the CLM group (one case of massive bleeding; one case of

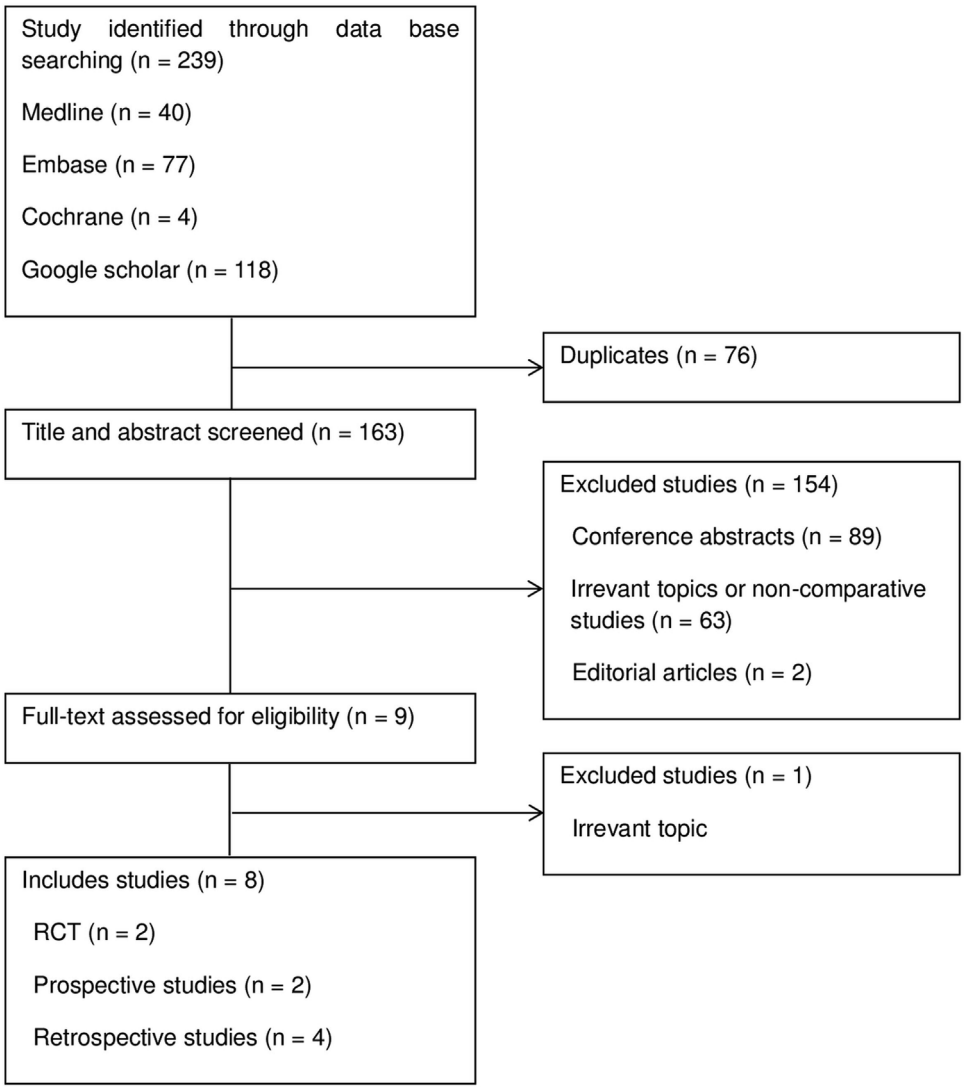

Fig. 1. Flow diagram of study selection.

RCT, randomized controlled trial.

Table 1
Studies included in meta-analysis and characteristics of single port laparoscopic myomectomy.

Author	Study type	No. of patients (SPLM vs. CLM)	NOS	Inclusion criteria on myoma (no. / size)	Single port system	Suture methods of myometrium repair / Suture layer	Myoma evacuation
Kim et al. (2014)	Retrospective cohort	59 vs. 59	7	≤5 / ≤14 cm	Glove port	Interrupted suture / Single or two layer	Electric morcellator
Choi et al. (2014)	Retrospective cohort	55 vs. 102	7	<3 / ≤10 cm	Glove port	Continuous suture with clip / Two layer	Scalpel with bag
Kim et al. (2015)	Retrospective cohort	61 vs. 93	6	NS / <12 cm	Commercial kit	Interrupted or continuous suture / Single or two layer	Scalpel with bag (SPLM) or Electric morcellator (CLM)
Lee et al (2017)	Retrospective cohort	100 vs. 69	7	≤5 / ≤13 cm	Commercial kit	8-shaped interrupted suture / Single or two layer	Scalpel with bag
Han et al. (2013)	Prospective matched cohort	10 vs. 10	7	<3 / ≤7 cm	Glove port	Continuous suture, non-running lock / Single layer	Scalpel
Kim et al. (2014)	Prospective matched case-control	45 vs. 90	8	≤4 / ≤8 cm	Commercial kit	Interrupted extracorporeal suture / Single layer	Scalpel
Song et al. (2015)	RCT	50 vs. 50	NA	≤4 / ≤12 cm	Commercial kit	Barbed suture / Single or two layer	Scalpel with bag
Lee et al (2018)	RCT	28 vs. 26	NA	≤4 / <10 cm	Glove port	Interrupted or continuous suture / Single or two layer	Electric morcellator

SPLM, single port laparoscopic myomectomy; CLM, conventional laparoscopic myomectomy; NOS, Newcastle-Ottawa scale.

5 mm trocar site herniation in connection with drain removal), and there was no statistically significant difference. Seven of the eight studies were able to be included in the meta-analysis on the minor complication. The rate of minor complications, including infection (wound, pelvis, or urinary track), blood loss requiring transfusion, ileus, and voiding difficulty was not different between the two groups [OR 1.33 (0.67, 2.63), $I^2 = 0\%$] (Fig. 2), and no heterogeneity was observed. Conversion to laparotomy did not occur in either group, and the conversion rate from SPLM to a multi-port operation was 2.1% (6/288).

Secondary outcomes

The results of the pain score according to the time interval after operation are shown in Fig. 3. The VAS or NRS score at postoperative one hour was significantly lower in the SPLM group [MD -0.41 point (-0.63, -0.18), $I^2 = 3.7\%$] with minor heterogeneity. However, these differences were not observed at six and 24 h postoperatively.

When analyzing the additional surgical outcomes, there were no differences in operation time [MD -0.1 min (-0.56, 0.37), $I^2 = 90.7\%$], estimated blood loss [MD -0.1 mL (-0.36, 0.15), $I^2 = 55.1\%$], or hemoglobin decrease after surgery [MD 0.12 g/dL (-0.15, 0.38), $I^2 = 67\%$] between the two groups (Fig. 4A, B, C). In addition, there was no difference in the duration of hospital stay after surgery [MD -0.3 day (-0.7, 0.1), $I^2 = 87.7\%$] (Fig. 4D).

While some studies have reported pregnancy outcomes, the number of studies is very low. In two studies that compared pregnancy outcomes (pregnancy rate, miscarriage rate, and live birth rate) and delivery methods, there was no significant difference [11,16]. In only one study that analyzed cosmetic outcomes and patient satisfaction, the SPLM group was found to have better results [9].

Publication bias

A funnel plot analysis was performed to analyze the publication bias, and the results of the primary outcome (minor complications) are presented in Supplementary Fig. 2. No publication bias was observed in either of the two groups. The number of cases was too small to analyze the publication bias for major complication.

Sensitivity analysis

The results of sensitivity analysis of the outcomes with substantial heterogeneity were not changed after exclusion of the study with the strongest effect.

Discussion

Meta-analysis results comparing SPLM with CLM

In this meta-analysis, two RCTs and six observational studies were analyzed to compare the surgical outcomes. When the safety was analyzed using the complication and conversion rates, there were comparable results between SPLM and CLM. In addition, SPLM was found to be more effective than CLM in reducing pain immediately after surgery. Operative time, estimated blood loss during surgery, and hospital stay after surgery did not differ between the groups. Therefore, SPLM is comparable to CLM as an option for clinicians to consider when making a surgical plan according to the location, number, and size of the myoma, and it may even be more favorable to patients in terms of pain reduction immediately after surgery.

Complications that may occur during or after surgery are the most important factor for the surgeon to consider in determining the appropriate surgical procedure. According to our meta-analysis, when a skilled physician performed the surgery, the major and minor complications of SPLM did not differ from the complications of CLM. Paul et al. analyzed 1,001 CLM cases performed by a single surgeon, and 0.2% of the patients experienced complications requiring re-operation [17] which is similar to this study. The rate of additional trocar use in the SPLM group was 2.1%, and none of the patients were converted to laparotomy. Considering these results, planning a surgery using single port laparoscopic myomectomy is a reasonable choice in terms of safety.

According to this meta-analysis, the subjective pain score expressed by the patients was significantly lower in the SPLM group than in the CLM group at one hour after surgery. One RCT that objectively compared the analgesics dose needed for postoperative pain control showed a significantly decreased use of analgesics in the SPLM group from one to six hours

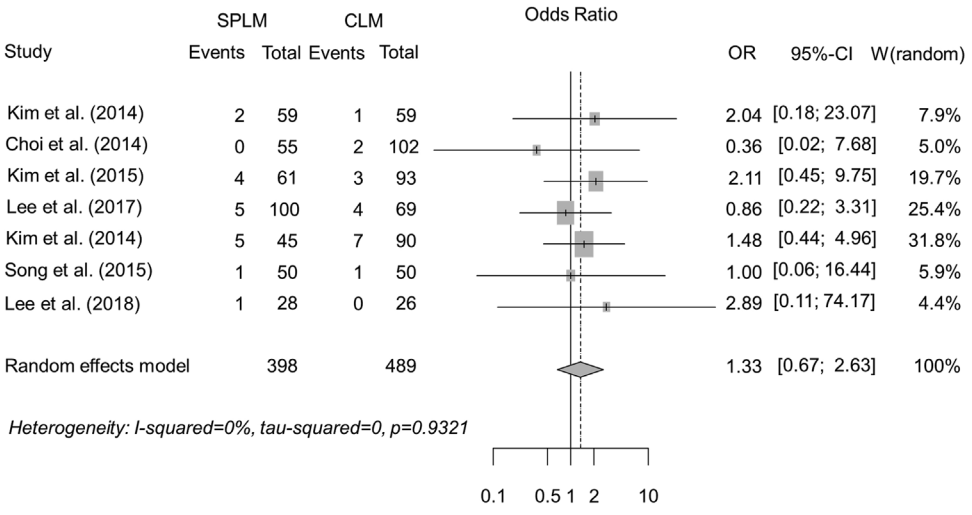

Fig. 2. Meta-analysis of minor complications (no.).
SPLM, single port laparoscopic myomectomy; CLM, conventional laparoscopic myomectomy.

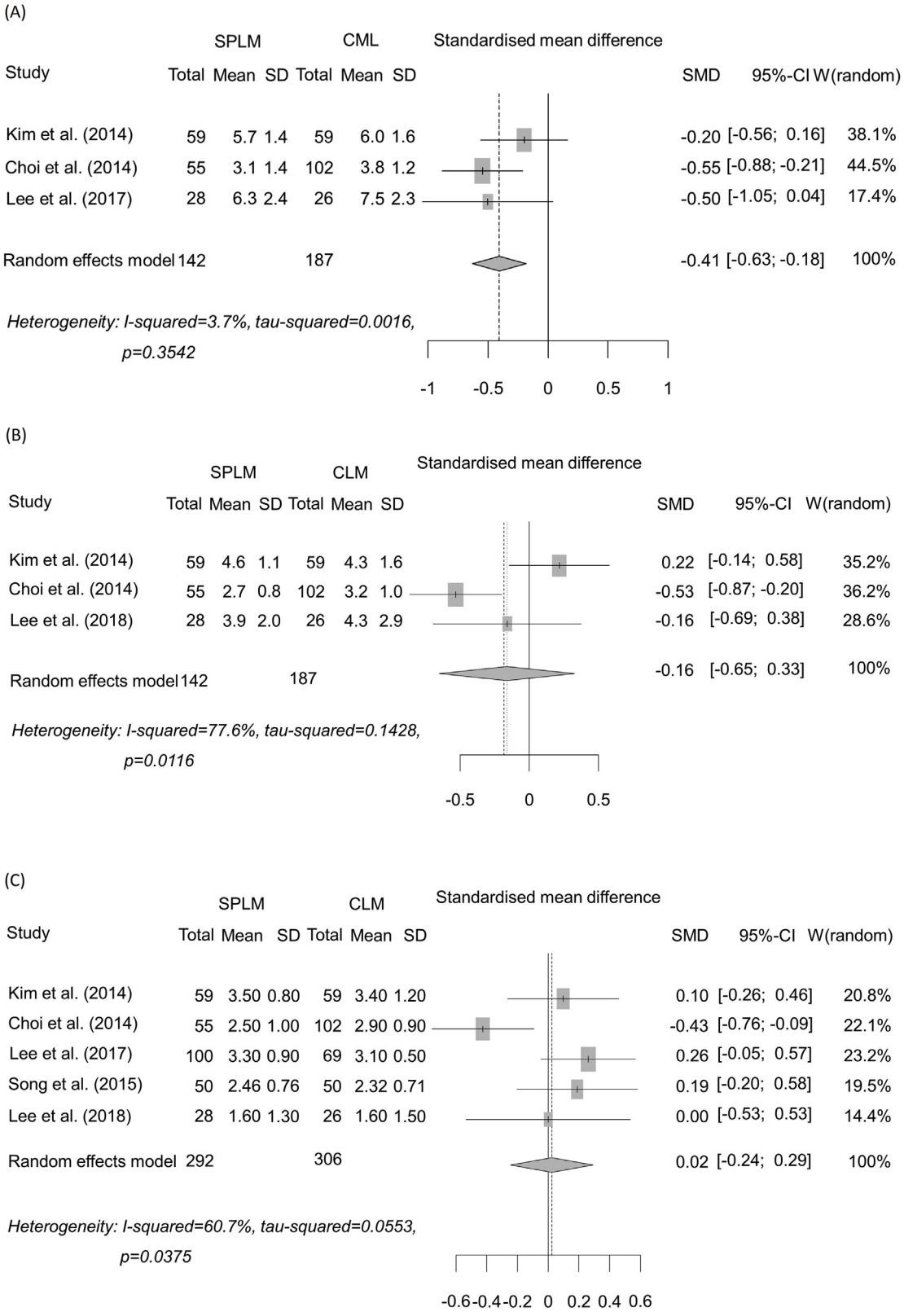

Fig. 3. Meta-analysis of VAS or NRS score after the operation; (A) 1 h, (B) 6 h, (C) 24 h.
SPLM, single port laparoscopic myomectomy; CLM, conventional laparoscopic myomectomy.

postoperatively but no difference thereafter [9]. These results suggest that SPLM is superior to CLM in terms of immediate postoperative pain. A key advantage of SPLM is the fact that only one incision is made on the umbilicus, which confers several advantages over incision in other areas of the abdomen. As there are few intrinsic blood vessels and nerves in the umbilicus and no muscular layer beneath it, less muscle tension-induced pain occurs at this site [18].

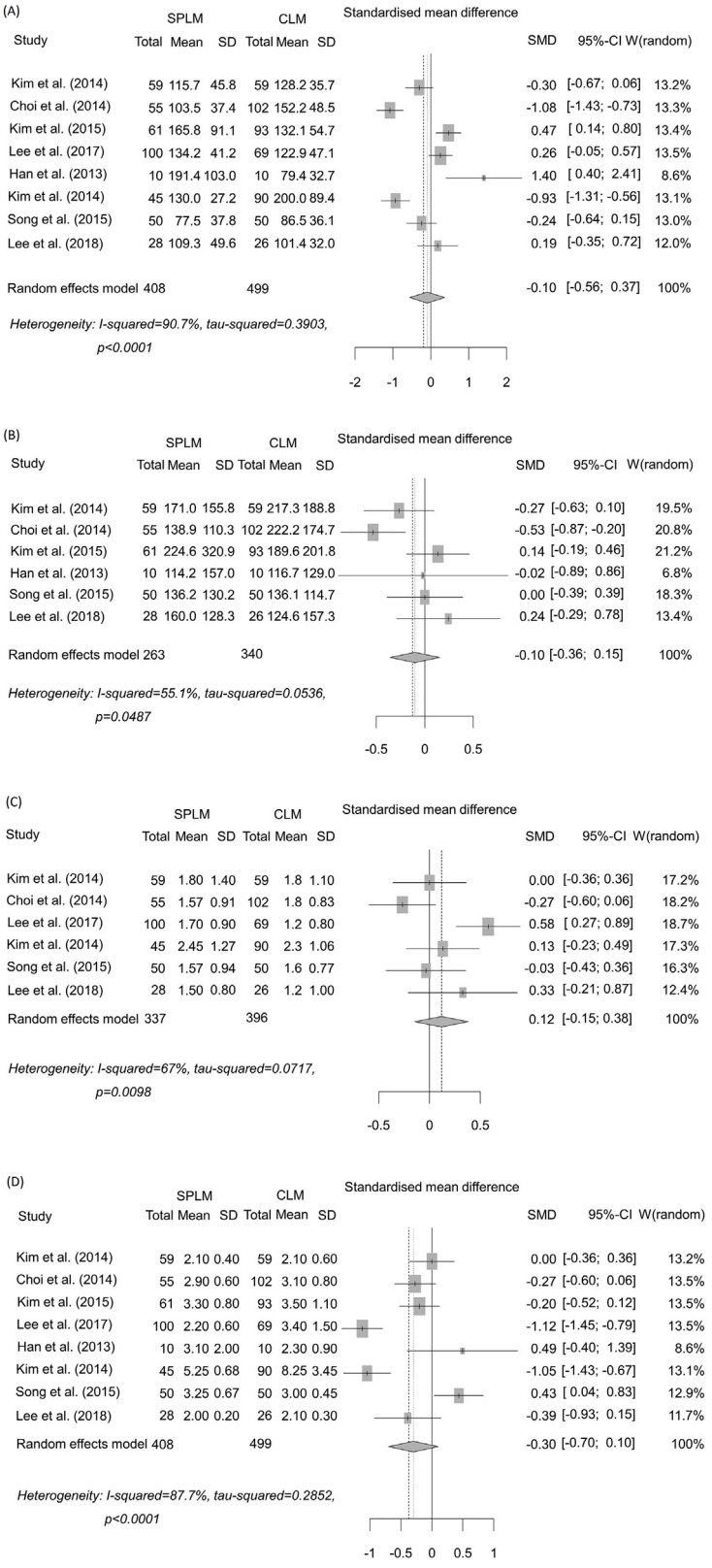

Fig. 4. Meta-analysis of operation outcomes; (A) operative time (min), (B) estimated blood loss (mL), (C) hemoglobin decrease (g/dL), (D) post-operative hospital stay duration (days).
SPLM, single port laparoscopic myomectomy; CLM, conventional laparoscopic myomectomy.

Systematic review regarding SPLM

Single port laparoscopic surgery is known to offer greater cosmetic satisfaction due to fewer trocar incisions. Recent studies have shown that 64% of women prefer single port incision among various incision approaches for gynecologic surgery [19]. There is only one study comparing SPLM and CLM using the validated surgical wound evaluation index [9]. SPLM resulted in more

favorable cosmetic outcomes and higher patient satisfaction than did CLM, but this data remains confined to one study.

The duration of surgery, bleeding during surgery, and duration of recovery after surgery are indicators that reflect the feasibility of surgery. In general, SPLM is known to be more difficult to perform than CLM, although the results of this meta-analysis showed no difference between the factors reflecting the feasibility. As noted above, approximately 45 operations are required to obtain propensity for SPLM [2]. Therefore, it is considerable that the necessity of such surgical training can be a blockage to the adoption of SPLM. However, once the propensity has been established, this meta-analysis proves that SPLM can be performed without concerning about the side effects or procedure failures compared to CLM.

When comparing the surgical procedures of SPLM and CLM, the three main processes of myoma enucleation, suturing, and morcellation represent key differences. Various surgical instruments and techniques have been developed to facilitate these procedures in SPLM. The most important factor affecting the difficulty of uterine myomectomy is that myomectomy requires a greater number of sutures than do other gynecologic procedures. Some studies have used continuous sutures to reduce the time required for sutures. In early studies, the continuous suture was performed without locking; however, it is difficult to maintain sufficient tension. In order to compensate for these drawbacks, one study used a clip to reinforce the continuous suture [12]. Recently, barbed suture material has been introduced. In this meta-analysis, barbed suture material was used in only one study. In studies comparing the results of using barbed sutures to those of conventional suture material in laparoscopic myomectomy, the surgical difficulty, total operation time, and blood loss during surgery were reported to be decreased with the use of a barbed suture [10,20].

The process of removing myomas in vitro is another time-consuming step. Since SPLM provides a larger opening for removing the specimen, it is convenient to use a bag that allows morcellation to be conducted more safely without the concern of malignant particle spreading [21]. In addition, it is possible to remove myomas rapidly with a scalpel without using an electrical morcellator, which enables a shorter operation time while preventing potential injuries caused by the morcellator [11,14,22]. Considering these advantages, six studies included in this analysis used a scalpel, and four studies used a bag to prevent the intra-abdominal spread of tissue fragments.

Since most women who undergo myomectomy are of reproductive age, the postoperative obstetric outcome is a crucial determining factor of the optimal surgical modality. There is concern that uterine rupture may occur due to insufficient suturing and knotting in laparoscopic myomectomy, which may lead to maternal and fetal mortality. In the initial study, the rupture rate was reported to be 1.0%, whereas it was reported to be 0.6% in a recent study [23,24]. Two studies included in this article reported no uterine rupture in both the SPLM and CLM groups [11,16].

The limitation of this study is that the number of previous studies on obstetrical or cosmetic outcomes, which is an important factor in determining myomectomy methods, is small. In the single study (RCT) that analyzed cosmetic outcomes and patient satisfaction, the SPLM group was found to have better results than the CLM group. There is also a lack of comparative studies on pregnancy outcomes after myomectomy. In two studies that compared obstetrical outcomes, there was no significant difference between the groups, but the number of subjects was too small for performing a meta-analysis. Therefore, further studies on this subject should be performed in the future.

Conclusions

SPLM was comparable to CLM in terms of safety and feasibility when patients were selected according to the inclusion criteria regarding the size and number of the myomas. SPLM was found to be more advantageous in terms of immediate postoperative pain. Moreover, myomas may be removed more quickly and safely from the abdominal cavity in SPLM than in CLM. SPLM can be expected to yield obstetric outcomes equivalent to those of CLM, including rupture rates during pregnancy, though more cases with long-term observation are necessary to confirm these results. The question of whether SPLM is more beneficial in terms of cosmetic results, patient satisfaction, and pregnancy outcomes also warrants additional well-designed prospective studies in the future.

Disclosure

The authors report no conflict of interest.

Acknowledgements

None.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ejogrb.2019.06.001.

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