Laparoendoscopic single-site myomectomy compared with conventional laparoscopic myomectomy: a multicenter, randomized, controlled trial

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Objective: To compare surgical outcomes of laparoendoscopic single-site myomectomy (LESS-M) vs. conventional laparoscopic myomectomy (LM).
Design: Multicenter, noninferiority, randomized, controlled trial.
Setting: University hospitals.
Patient(s): A total of 100 subjects with symptomatic uterine myomas were randomly assigned to either LESS-M or conventional LM. Surgical outcomes were comparatively assessed between the groups on the basis of the intention-to-treat principle.
Intervention(s): Laparoscopic myomectomy.
Main Outcome Measure(s): The time required for uterine defect suturing.
Result(s): There were no differences in baseline demographics (age, body mass index, surgical indication, number of myomas, and size and location of the largest myoma) between the two groups. The suturing time (mean ± SD) was 21.9 ± 10.7 minutes (95% confidence interval 18.8–24.9 min) for the LESS-M group and 23.3 ± 12.4 minutes (95% confidence interval 19.8–26.9 min) for the conventional LM group, with no significant difference between the two groups. The other surgical outcomes, such as total operative time, operative blood loss, postoperative hemoglobin change, degree of surgical difficulty, postoperative pain scores, operative complication, and length of hospital stay, were similar between the two groups. Three subjects (6%) assigned to the LESS-M group underwent conventional LM because of difficulty in myoma enucleation and suturing, whereas no failure to intended procedure occurred in the conventional LM group (6% vs. 0).
Conclusion(s): Laparoendoscopic single-site surgery is a feasible and safe treatment option for myomectomy that offers surgical outcomes comparable to those with conventional LM.
Clinical Trial Registration Number: NCT01984632. (Fertil Steril® 2015;104:1325–31. ©2015 by American Society for Reproductive Medicine.)
Key Words: Laparoendoscopic single-site surgery, laparoscopic myomectomy, myoma, myomectomy

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Uterine myomas are found in as many as 70% of women and can cause symptoms such as pelvic pressure and abnormal uterine bleeding. Laparoscopic myomectomy is currently accepted as a safe and efficient alternative to open myomectomy for managing uterine myomas and provides significant advantages, including

better cosmetic results, less postoperative pain, and shorter recovery time over open myomectomy (1–6). Recent innovations in technology (such as a multichannel single-port, articulating instruments, and high-definition laparoscopes) have allowed laparoscopic surgeons to perform laparoendoscopic single-site surgery (LESS) with the aim of further reducing the invasiveness of conventional laparoscopy, ranging from two to five incisions.

Although LESS has been widely used for the last 8 years in various gynecologic procedures, including hysterectomy, ovarian cystectomy, salpingectomy, or cancer surgery (7–12), the widespread use of LESS for myomectomy (LESS-M) has been limited to gynecologists with advanced laparoscopic skills, owing to the difficulty in multiple suturing and tying. Until now there have been few reports in the literature about the application of LESS to myomectomy (7, 10,13–15). However, most of the previous studies on LESS-M were small case series or retrospective comparative studies with conventional laparoscopic myomectomy (LM) (7, 10,13–15). We therefore performed this randomized trial to compare surgical outcomes of LESS-M vs. conventional LM in patients who had an indication for laparoscopic myomectomy.

MATERIALS AND METHODS

Study Design and Subjects

This study was prospectively conducted between November 2013 and December 2014 at four institutions (Kangbuk Samsung Hospital; CHA Gangnam Medical Center; National Health Insurance Service Ilsan Hospital; Samsung Medical Center). Women with an indication for laparoscopic myomectomy for symptomatic uterine myoma(s) were asked to participate in this study. Inclusion criteria were as follows: women with symptomatic myomas, such as menorrhagia, pelvic pressure/pain, or infertility; women who were planning to undergo laparoscopic myomectomy; women who had four or fewer myomas, with the largest myoma $\leq$12 cm; women who were not pregnant at the time of presentation; and women between 18 and 55 years of age. Exclusion criteria were as follows: women with a dominant pedunculated subserosal or submucosal type myoma; women who underwent concomitant complex surgical procedures at the time of laparoscopic myomectomy, such as severe adhesiolysis or resection for severe endometriosis; women with any suggestion of malignant uterine or adnexal diseases; women with major medical comorbidities or psychiatric illnesses, which could affect follow-up and/or compliance; and women who refused to participate or give consent to the procedures.

Before the randomization, all eligible subjects received standardized information about the trial by the clinician, orally and in writing. Subjects were randomly assigned to the LESS-M group or the conventional LM group at a 1:1 ratio using a random permuted-block randomization algorithm with stratification according to participating institution via an interactive Web-based response system (www.randomization.com). A study nurse called the coordinating center just before general anesthesia on the day of surgery for the purpose of randomization. The protocol was approved by the institutional review board of each participating institution and was registered with ClinicalTrials.gov (Identifier: NCT01984632). The study was performed in accordance with the protocol, and all subjects provided written informed consent before participation.

Study Treatment

One surgeon from each participating institution performed all the surgeries at that institution. All participating surgeons had comparable surgical skills (16–18), a preference for laparoscopic surgery, and experiences of more than 20 cases of LESS-M before the study started. All subjects underwent the same standard preparation before surgery, including prophylactic antibiotics 30 minutes before the procedure. The use of various commercial ports (or trocars), laparoscope, and laparoscopic instruments was allowed during the procedures, according to each surgeon's preference. After the introduction of general anesthesia, subjects were placed in the Trendelenburg position. After uterine sounding and cervical dilation, a uterine manipulator was fixed onto the cervix to effectively make a surgical field: a RUMI uterine manipulator (Cooper Surgical) was used. For LESS-M, a multichannel single port was inserted through the umbilicus. Before initiating the uterine incision, a local vasoconstrictor such as dilute vasopressin was injected into the serosal and/or overlying myometrium, and just around the myoma, to reduce blood loss. Using the Harmonic Scalpel (Ethicon Endo-surgery), SonoSurge (Olympus Medical), or EnSeal G2 tissue sealer (Ethicon Endo-surgery), a longitudinal myometrial incision was made over the myoma. After identifying the cleavage plane, the myoma was enucleated by means of adequate traction with a laparoscopic myoma screw or forceps. Coagulation of significant bleeding was obtained with a bipolar electrosurgical device. Myometrial closure was performed in a single or double layer. Closure was performed using a 23-cm or 30-cm polyglyconate unidirectional barbed suture with a 37-mm half circle taper-point needle (V-Loc, Covidien). The first stitch was locked by a loop at one end of the uterine incision, and then a continuous suture was passed through to the opposite end of the uterine incision and cut without tying a knot. The myomas, which were placed into the specimen retrieval endopouch, were removed transumbilically with a knife morcellation protected with a wound retractor that was connected to a single-port system. The procedure was completed by establishing control of uterine hemostasis, washing the pelvic cavity, and absorbing any clots that had formed. The peritoneum, fascia, subcutaneous tissue were then approximated and closed layer by layer using the 2-0 Polysorb suture (Covidien), and skin adhesive (Dermabond, Ethicon) was used to close the incision.

The operative technique of conventional LM was comparable to that of LESS-M, except for the port placement and the method for myoma morcellation. A 12-mm trocar in the intraumbilical area and three ancillary 5-mm trocars placed in the suprapubic area and both lower lateral abdomens were placed for conventional LM. Under 5-mm laparoscopic vision through an ancillary trocar, the enucleated myomas were removed with a power morcellator (Wisap), which was introduced through the 12-mm trocar in the umbilicus.