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Original Article

Minilaparoscopic Versus Single-Port Total Hysterectomy: A Randomized Trial

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ABSTRACT **Study Objective:** To compare perioperative outcomes and postoperative pain of minilaparoscopic (M-LPS) and laparoendoscopic single-site total hysterectomy (LESS).

Design: Prospectively randomized study (Canadian Task Force classification II-2).

Setting: Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Catholic University of the Sacred Heart, Rome.

Patients: A total of 86 patients underwent total hysterectomy. Seventy-one met the inclusion criteria and were included in this study. Three of them refused randomization, 34 were randomly assigned to undergo to single-port hysterectomy and 34 to undergo to minilaparoscopy.

Interventions: The operative technique is the same in the 2 groups with the exception of videolaparoscopy, port type, and some specific instruments. All surgical procedures were performed with an intrauterine manipulator. Single-port hysterectomy was performed through a multichannel single trocar inserted in the umbilicus. Minilaparoscopic hysterectomy was performed through one optical transumbilical 5-mm trocar and three 3-mm suprapubic ancillary ports.

Measurements and Main Results: Sixty-eight patients met the inclusion criteria and were enrolled in the study. The baseline characteristics of the 2 groups were comparable. Median operative time was longer in LESS with respect to M-LPS (120 minutes vs 90 minutes; $p = .038$). There were no differences between the 2 groups for median estimated blood loss, ileus, and postoperative stay. Additional 5-mm port insertion was needed in 1 case (2.9%) in the M-LPS group and in 2 cases (5.9%) in the LESS group, respectively ($p = .311$). No patient had development of intraoperative or early postoperative complications. Patients in the M-LPS group experienced a minor pain at each evaluation, compared with patients who underwent LESS. The rescue analgesic requirement was similar in the 2 groups.

Conclusions: Laparoscopic hysterectomy can be safely performed by M-LPS and LESS. M-LPS is associated with significantly lower operative time and less postoperative pain than LESS. Advantages of M-LPS hysterectomy than LESS have no noteworthy impact on the patients' early postoperative management. The decision on the best access to the hysterectomy might take into account the surgeon's skill and feeling with the different possible approaches. Journal of Minimally Invasive Gynecology (2013) 20, 192–197 © 2013 AAGL. All rights reserved.

Keywords: Hysterectomy; Minilaparoscopy; Single-port

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The authors declare that they have no conflict of interest.

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Many authors have demonstrated the feasibility and superiority of laparoscopy with respect to laparotomy in terms of patient's discomfort, hospital stay and postoperative delay [1]. Moreover, better early postoperative quality of life in laparoscopy than laparotomy has been found [2,3].

It was therefore predictable that the next step in the evolution of minimally invasive surgery would be to further reduce surgical trauma and minimize invasiveness of the procedures by decreasing the ports' number or the size maintaining the same high standard of surgical cure. One way to achieve this goal is performing laparoendoscopic single-site surgery (LESS) and the other reducing the port's dimension from 5 to 3 mm with the so-called "mini-laparoscopy" (M-LPS). These approaches, even more minimally invasive than standard laparoscopy (LPS), could offer the opportunity to significantly reduce intraoperative complications such as risk of bleeding and internal organ damage [4,5].

As far as M-LPS hysterectomy is concerned, Ghezzi et al [6] showed that ports could safely be reduced in size without a negative impact on the surgeon's ability to perform hysterectomy in patients with early-stage endometrial cancer. We have recently found that LESS hysterectomy could represent a valid option for total hysterectomy in patients with early endometrial cancer [7], and comparative trials suggest some advantage with respect to standard laparoscopy in terms of early postoperative pain [8–11]. The goal of this prospective randomized trial was to compare M-LPS and LESS hysterectomy in terms of perioperative outcomes.

Materials and Methods

Patients

Between May 2011 and February 2012, a prospectively randomized study was carried out at the Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Catholic University of the Sacred Heart, Rome-Italy. Consenting patients scheduled to be submitted to a total laparoscopic hysterectomy for benign, pre-malignant and malignant disease were evaluated for this study. Inclusion criteria for total laparoscopic hysterectomy were as follow: appropriate medical status for laparoscopic surgery; uterine size $<$12 weeks of pregnancy; no previous longitudinal major abdominal surgery. Patients who had a pelvic organ prolapse greater than grade I, were excluded from this study and were subjected to a vaginal hysterectomy. Preoperative workup included gynecologic examination and transvaginal ultrasonography. In cases of early endometrial and cervical cancer, staging MRI or CT was performed.

Our institutional review board approved the study (Protocol number P/473/CE/2011), and all women gave informed consent to use their data. All patients were adequately informed concerning the possible risks and benefits of the described technique and signed a written consent agreeing to undergo the procedure and to eventual conversion to LPS or laparotomy, if necessary.

Patients were randomly assigned to either a hysterectomy with LESS or with M-LPS. The surgeon was notified of the allocation in theater on the morning of the procedure. The same surgical team performed both techniques. Assignment to 1 of the 2 surgical approaches was on 1:1, using a 2-variable block randomized computer-generated list. Primary endpoints of the study were perioperative outcomes of the 2 surgical approaches, whereas early postoperative pain evaluation was the secondary endpoint.

The operative time (OT) was defined as the interval between the start of incisions to closure. The intraoperative complications were defined as bowel, bladder, ureteral, or vascular injuries, and the estimated blood loss $\geq$500 mL. Anemia was considered when the hemoglobin level was $\leq$8 g/dL and fever when body temperature was at least 38°C in 2 consecutive measurements at least 6 hours apart, excluding the first day after surgery.

Postoperative pain assessment (in the immediate postoperative period) was performed in all patients by use of a validated Visual Analog Pain Scale (VAS) and scored from 0 to 10 (0 = no pain and 10 = agonizing pain). Postoperative pain was subjectively reported considering the patient at rest at 20 minutes and 2, 4, and 8 hours after surgery. All patients were managed with the same intraoperative anesthetic protocol and postoperative analgesic drug (acetaminophen 1000 mg intravenously) was administered only on patient's demand.

LPS conversion was defined as single- or multiple 5-mm port insertion. The perioperative complications were defined as those occurring within the first month after the procedure. All surgeons were skilled in standard laparoscopy, and there were no significant differences in terms of previous single-port or minilaparoscopy experience [4,7,11,13].

Surgical Technique

The operative technique is the same in the 2 groups with the exception of videolaparoscopy, port type, and some specific instruments. Once achieved pneumoperitoneum (12 mm Hg), a careful inspection of the entire abdominal cavity was performed as first surgical step. All surgical procedures were performed with an intrauterine manipulator. After coagulation and section of the round ligament to enter into the retroperitoneal space, the ureter was visualized and a hemostatic clip was positioned at the origin of the uterine artery. To safely cauterize and dissect the ovarian vessels, a window was opened between the left ovarian pedicle above and the ureter below. The vesicouterine and vesicovaginal peritoneum was dissected starting from the lateral to the medial. These surgical steps allow an excellent skeletonization of the uterine vessels, medially to the ureter along the uterus, which can be easily cauterizated and sectioned. The vagina was incised circumferentially following the porcelain-valve of the uterine manipulator as a guide. The uterus and the adnexa were extracted through the vagina. The vaginal vault was closed with a running suture. A hydropneumatic

Fig. 1

Single-port.

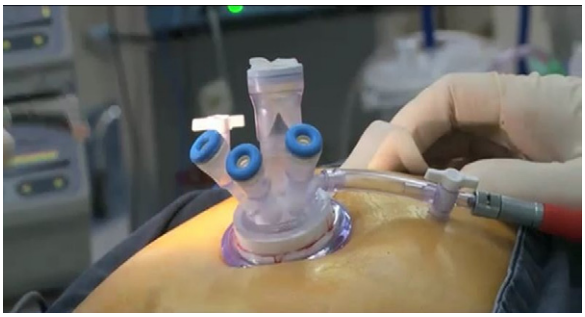
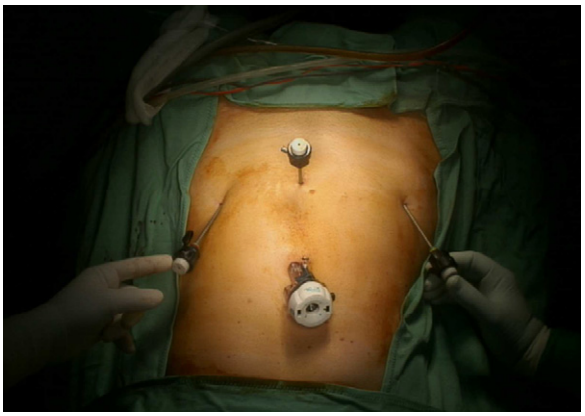


Fig. 2

Mini-laparoscopy.



test for bladder integrity at the end of surgery was always performed.

LESS hysterectomy (Fig. 1) was performed through a multi-channel single trocar (TriPort; Olympus Winter & Ibe GmbH, Hamburg, Germany) inserted in the umbilicus by use of an open technique (1.5–2 cm cutaneous incision), as previously reported [7]. Intraabdominal visualization was obtained with a 0-degree 5-mm telescope with a flexible tip (EndoEYE; Olympus Winter & Ibe GmbH). Working straight 5-mm instruments were inserted into the remaining 2 ports, choosing among graspers, cold scissors, suction/irrigation bipolar coagulator, and a multifunctional versatile laparoscopic device, which grasps, coagulates, and transects simultaneously (PKS cutting forceps, 43 cm; Gyrus ACMI, Hamburg, Germany). To prevent clashing between instruments and surgeon's hands and to facilitate surgical maneuver, the combination of one 33-cm–long instrument with a 43-cm–long instrument was adopted. The umbilical fascia was closed with a figure-of-eight 0-Vicryl.

M-LPS hysterectomy (Fig. 2) was performed through one optical transumbilical 5-mm trocar (Endopath Xcel 5 mm optiview; Ethicon Endo-Surgery, Cincinnati, OH) and three 3-mm suprapubic ancillary ports (Karl Storz Endoskope - 3 mm trocar set; Karl Storz, Tuttlingen, Germany). A 5-mm 0-degree endoscope (EndoEYE; Olympus Winter & Ibe GmbH) and 3-mm laparoscopic instruments (Karl Storz Endoskope - 3 mm Instrument Set; Karl Storz) were used, choosing among graspers, cold scissors, suction/irrigation, and bipolar coagulator (PK 3 mm; Gyrus ACMI, Hamburg, Germany). The umbilical incision was closed with a simple knot 3/0 Vicryl Rapide, whereas for 3-mm incisions, we used Steri-Strips.

Statistical Analysis

The primary hypothesis of this study was the noninferiority of pain evaluation (scaled with VAS) after hysterectomy performed with S-LPS (3-mm trocar) compared with the same procedure performed with LESS. The sample size calculation was based on the mean VAS score after LESS-hysterectomy in our previous clinical experience that was measured at 4 hours after intervention. The noninferiority margin was set on the mean difference of pain equal to 1.5 because this threshold was considered to indicate important differences on the basis of clinical judgment from standard day-to-day practice in our center. On the basis of this threshold, 56 total patients would be necessary for 80% power with a 2-sided type I error of 0.05. To face possible missing data or dropout in the follow-up, we aimed to recruit 34 patients per group, 68 in total. For statistical analysis, noninferiority of VAS-LPS was accepted if the estimated difference of the lower bound of the 2-sided 95% confidence interval (CI) was less 1.5. Then, univariate analysis was conducted to verify any differences between the 2 groups (LPS vs LESS). The Student *t* test, Mann-Whitney U test, Fisher's exact test, and χ^2 analyses were performed where occurred. Probability (p) values were considered to be statistically significant at the $<.05$ level. The SPSS statistical software program (SPSS Inc., Chicago, IL) and STATA Data Analysis and Statistical Software, version 10 (StataCorp LP, College Station, TX) were used.

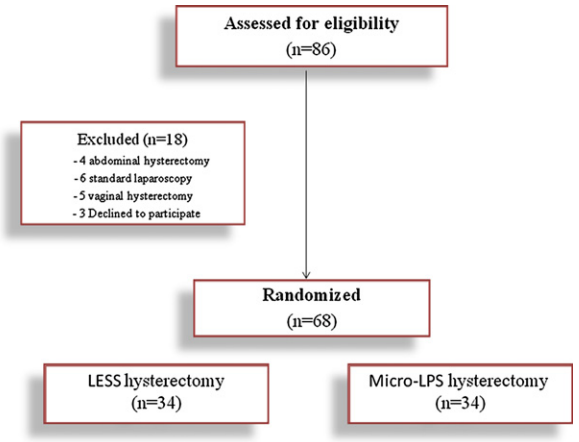
Results

During the study period a total of 86 patients underwent total hysterectomy at the Gynecologic Oncology Division of the Catholic University of the Sacred Heart of Rome. Seventy-one (82.6%) met the inclusion criteria and were included in this study. Three patients refused randomization, 34 were randomly assigned to undergo LESS, and 34 to undergo M-LPS. Flow-chart of the study population is displayed in Figure 3. Demographic and baseline characteristics are shown in Table 1. The 2 groups were comparable for median age, body mass index, menopausal status, parity, and indication for surgery.

The analysis of perioperative outcomes is summarized in Table 2. Concomitant monolateral/bilateral salpingo-oophorectomy was performed in 32 (94.1%) and

Fig. 3

Flow chart of the study population.



30 (88.2%) patients in the M-LPS and LESS groups, respectively (p = .4). The median OT was longer in LESS with respect to M-LPS (120 minutes [range 55–165] vs 90 minutes [range 42–195]; p = .038). There were no significant differences between the 2 groups in terms of estimated blood loss (30 mL [range 10–200] vs 30 mL [range 10–300]; p = .57), ileus (18 hours [range 16–26] vs. 20 hours [range 16–26]; p = .181) and postoperative hospital stay (2 days [range 2–4] vs. 2 days [range 1–5] p = .313). Additional 5-mm port insertion was needed in 1 case (2.9%) in the M-LPS and in 2 cases (5.9%) in the LESS group, respectively (p = .311). In all these cases, the additional 5-mm port insertion was required for bleeding control during or after colpotomy. No laparotomic conversion was necessary in the 2 groups. There was no postoperative fever or anemia in either group. We did not registered intraoperative or early postoperative complications in both groups.

Pain score was resumed in Table 3. Patients in the M-LPS group experienced a minor pain at each evaluation, compared with patients who underwent LESS. In particular, we observed minimal but statistically significant differences

Table 1

Demographics and baseline characteristics of the study population

Clinicopathologic characteristic	M-LPS (n = 34)	LESS (n = 34)	p value[a]
Age (y) (median [range])	50.5 (39–72)	55 (37–68)	.823
BMI (median [range])	24 (20–33)	23 (17–30)	.423
Menopause	18 (52.9%)	21 (61.8%)	.469
Nulliparous	6 (17.6%)	9 (26.5%)	.388
Previous cesarian section	1 (2.9%)	2 (5.9%)	.562
Previous abdominal surgery	8 (23.5%)	17 (50.0%)	.023
Indication for surgery	34 (50%)	34 (50%)	.33
Uterine myoma	6 (17.6%)	3 (8.8%)	
Endometrial hyperplasia	5 (14.7%)	9 (26.5%)	
In situ cervical cancer	10 (29.5%)	4 (11.7%)	
Early-stage endometrial cancer	13 (38.2%)	13 (38.2%)	
Adnexal masses	0 (0.0%)	5 (14.8%)	

BMI = body mass index.
[a] Student *t* test, Mann-Whitney test, Fisher exact test, or χ^2 analysis.

Table 2

Perioperative outcomes of the study population

Perioperative variables	M-LPS (n = 34)	LESS (n = 34)	p value[a]
Operative time (min) (Median [range])	90 (42–195)	120 (55–165)	.038
Estimated blood loss (mL) (Median [range])	30 (10–200)	30 (10–300)	.570
Intraoperative complications	0 (0.0%)	0 (0.0%)	NA
Fever	0 (0.0%)	0 (0.0%)	NA
Postoperative anemia	0 (0.0%)	0 (0.0%)	NA
LPS conversion	1 (2.9%)	2 (5.9%)	.311
Laparotomic conversion	0 (0.0%)	0 (0.0%)	NA
Concomitant mono/ bilateral oophorectomy	32 (94.1%)	30 (88.2%)	.4
Ileus (hours) (Median [range])	18 (16–26)	20 (16–26)	.181
Postoperative hospital stay (d) (Median [range])	2 (2–4)	2 (1–5)	.313
Early post-operative complication	0 (0.0%)	0 (0.0%)	NA

[a] Student *t* test, Mann-Whitney test, Fisher exact test, or χ^2 analysis.

Table 3

Postoperative pain outcomes

Abdominal pain at rest	M-LPS (n = 34)	LESS (n = 34)	p value[a]
VAS score at 20 minutes (Median [range])	2 (0–6)	3 (3–7)	.001
VAS score at 2 hours (Median [range])	2 (0–6)	3.5 (2–8)	.001
VAS score at 4 hours (Median [range])	2 (0–7)	3.5 (2–6)	.001
VAS score at 8 hours (Median [range])	2 (0–6)	3 (2–6)	.001
Analgesic rescue dose request	5 (14.7%)	7 (20.6%)	.295

[a] Student *t* test.

at first (median VAS score at 20 minutes was 2 in M-LPS and 3 in LESS: p = .001) and in the subsequent evaluations (median VAS score at 2 hours was 2 in M-LPS and 3.5 in LESS; p = .001. Median VAS score at 4 hours was 2 in M-LPS and 3.5 in LESS; p = .001. Median VAS score at 8 hours was 2 in M-LPS and 3 in LESS; p = .001). The rescue analgesic requirement was similar in M-LPS with respect to LESS (5 [14.7%] vs 7 [20.6%]; p = .295).

Discussion

In recent years, one of the challenges of gynecologists is to reduce further the surgical trauma for benign and malignant disease. M-LPS with smaller port diameter and LESS with the single access, showed encouraging results in terms of feasibility and reproducibility [4–11]. Many authors have demonstrated the feasibility of total LESS and M-LPS hysterectomy for the management of benign, preneoplastic, and malignant disease [6–14]. Trials comparing LPS with M-LPS or LESS procedures have yielded conflicting results about their relative advantages. Some authors reported that M-LPS and LESS results in less postoperative pain and longer OT than LPS [8,9,15,16], whereas others did not reach the same results showing any significant perioperative advantages of the 2 techniques with respect to LPS [6,10,11,17].

This study is the first randomized one that directly compared M-LPS and LESS for total hysterectomy. We can argue that comparing 2 minimally invasive surgeries, variations are minimal, and only a careful analysis can identify them. In our trial, we showed that there were no significant differences between the 2 techniques in terms of perioperative outcomes except for OT that was longer in LESS with respect to M-LPS. This result could be justified by the fact that M-LPS does not differ from standard laparoscopy for number of ports and ergonomics of the surgical field. In particular, we believe that the presence of an "active" second surgeon can reduce loss of time in some specific surgical steps as retroperitoneal space development and anterior and posterior peritoneal dissection. On the contrary, LESS with 2 operative instruments could be a waste of time in some particular procedures requiring a specific learning curve [7,18]. In the baseline characteristics we observed an higher rate of previous abdominal surgery in the LESS group, but in this study we only remove adhesions involving the pelvis and genital organs, whereas suprapubic adhesions were not treated. Despite this result, we believe that, after an adequate number of interventions, the operative time difference between the 2 approaches could be reduced.

In this study, the LPS conversion rate was similar between M-LPS and LESS and with those reported in another study [10]. As reported by other authors, all the hysterectomies were completed by minimally invasive approach without laparotomic conversion [6–12].

As far as early postoperative pain is concerned, we found that patients undergoing M-LPS experienced significantly less pain compared with those managed by LESS. Two previous randomized clinical trials on total hysterectomy showed no significant difference in terms of early postoperative pain for M-LPS and LESS compared with LPS [6,10]. A possible explanation to justify our data could be the presence of "multiple small" with respect to a "single large" incision. Furthermore, similarly to those reported for the robotic-assisted laparoscopy [14,19], a higher abdominal wall stress in the LESS group because of the single access of camera and instruments could be assumed. Despite the postoperative pain difference, we have not observed any significant difference in terms of rescue analgesic drug request between the 2 groups. Moreover, the postoperative pain data did not impact the length of postoperative stay.

We have previously demonstrated significant cosmetic advantages for LESS with respect to standard laparoscopy [4]. The nearly "scar-free" procedure allowed by minimally invasive surgery also has a significant impact on the patient's body image, which not only has a cosmetic impact, but also is an aid to cope with a past cancer diagnosis when the surgery is done in cases of malignant disease. Although this study was not intended to assess cosmetic results, one consistent positive outcome with a 3-mm port or in alternative single skin incision, in the general surgery literature, is better cosmetic outcome [20,21]. Thus all the efforts aimed to improve the patient's well-being after an intervention should be investigated and validated.

In conclusion, we demonstrated that laparoscopic hysterectomy could be safely performed by M-LPS and LESS and provide additional information with regard to the debate on the best approach to minimally invasive hysterectomy. Our study demonstrated that M-LPS is associated with significantly lower operative time and less postoperative pain compared with LESS and that both approaches fulfill the minimally invasive surgery philosophy. These results encourage every effort to further minimize surgical invasiveness and to introduce validated tools to service the potential advantages of new surgical techniques, whose incremental benefits are not likely to match those seen with the jump from open to conventional laparoscopic surgery.

As far as total hysterectomy is concerned, perioperative advantages of M-LPS toward LESS has no noteworthy impact on the patients' early postoperative management. Thus the decision on the best access to the hysterectomy might take into account the surgeon's skill and feeling with the different possible approaches.

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