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Minilaparoscopic Versus Conventional Laparoscopic Hysterectomy: Results of a Randomized Trial

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ABSTRACT **Study Objective:** To compare operative outcomes and postoperative pain of laparoscopic hysterectomy (LH) versus minilaparoscopic hysterectomy (MLH).
Design: Randomized controlled trial (Canadian Task Force Classification I).
Setting: Tertiary care center.
Patients: Seventy-six women scheduled to undergo a hysterectomy for a supposed benign gynecologic condition.
Interventions: Participants were randomly assigned to LH (n = 38) or MLH (n = 38). MLH was performed with use of 3-mm ports. Both patients and assessors of the postoperative outcomes were blinded to the size of port used, and patients' wounds were concealed by standard-size nontransparent dressings.
Measurements: Primary outcome was postoperative pain (both rest and incident on coughing and abdominal pain, as well as shoulder pain) by use of a 100-mm visual analogue scale.
Main Results: The two groups were similar in terms of operative outcomes. No intraoperative conversion from MLH to both LH and open surgery occurred. No significant difference in pain scores at 1, 3, 8, and 24 hours after surgery between groups was found. Rescue analgesic requirement was similar in the MLH and LH groups (21.1% vs 13.2%, p =.54).
Conclusions: Ports can safely be reduced in size without a negative impact on the surgeon's ability to perform LH. MLH appears to have no advantage over LH in terms of postoperative pain. Journal of Minimally Invasive Gynecology (2011) 18, 455–461 © 2011 AAGL. All rights reserved.

Keywords: Minilaparoscopy; Needlescopic hysterectomy; Laparoscopic hysterectomy; Pain; Port size

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Laparoscopy is increasingly replacing open surgery as the preferred treatment option in most patients across disciplines. During the 1990s it was widely recognized that the superior patient benefits of laparoscopic surgery could be attributed in large part to the reduction in operative trauma, mediated by smaller access incisions, gentle tissue handling, and decreased need of retraction and dissection.

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 number, and more commonly, the size of the operating ports and instruments, while maintaining the same high standard of surgical cure. Advances in instrumentation and progress in fiberoptic technology have armed the surgeons with smaller caliber instruments and better optics and light sources, thus triggering the emergence of needlescopic or minilaparoscopic surgery, defined as procedures wherein all ports are 3 mm or smaller. The concept behind minilaparoscopy is that smaller instruments cause less abdominal wall trauma and thus reduce incision-related morbidity and minimize pain and the stress response to surgery.

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Although gynecologic surgeons have been at the forefront of minimally invasive surgery and have embraced minilaparoscopy in its infancy for diagnostic purposes or minor therapeutic maneuvers [1], to date most of the literature on major needlescopic procedures has been published in general surgery and pediatrics journals. Some of the reluctance to adopt needlescopic techniques by the gynecologic surgical community seems to derive more from ideological preconceptions and personal beliefs than from "facts at hand." Many surgeons believe that the performance debt of miniaturized instruments severely limits the applicability of the technique, and many are unwilling to endure the difficulties of using finer instruments without high-quality unbiased data to satisfactorily prove cogent benefit for patients. However, in the setting of general surgery, a meta-analysis has recently shown that minilaparoscopy holds the advantage of eliciting a reduced level of wound pain compared with conventional laparoscopy, with better cosmetic results [2].

At our department, the process of implementation of needlescopic surgery began with the treatment of benign adnexal masses [3] and proceeded in stages to include, at first, hysterectomy in patients with small uteri [4] and later the surgical staging of endometrial cancer [5]. At each stage, actual surgical performance, including outcomes, has been critically revised, and research projects to address feasibility and safety have been completed. Therefore we determined that enough time had passed for designing a randomized clinical trial to compare minilaparoscopic hysterectomy versus conventional laparoscopic hysterectomy in unselected patients with benign gynecologic conditions.

Materials and Methods

Between October 2009 and May 2010, consenting patients scheduled to undergo hysterectomy at the Gynecology Department of the University of Insubria, Varese, Italy, were enrolled in this study, provided that indication for surgery was a supposed benign gynecologic condition. Patients who had a pelvic organ prolapse greater than grade I according to the pelvic organ prolapse classification were scheduled for a vaginal hysterectomy and were excluded from this study. No patient was refused minimal access surgery for reasons of uterus size, obesity, prior surgical history, or anticipated difficulty of resection. Patients with documented severe cardiopulmonary disease were refused a laparoscopic approach only after consultation with a senior member of the anesthesiology team. Cardiopulmonary disease was defined as a history of heart failure, myocardial infarction, unstable angina, or pulmonary obstructive disease poorly controlled or contraindicating prolonged Trendelenburg position.

Patients were randomly assigned to either an approach with all 5-mm ports (conventional laparoscopic hysterectomy [LH]) or a needlescopic approach in which 3-mm instruments were used (minilaparoscopic hysterectomy [MLH]). Randomization was performed on the basis of a block-randomization computer-generated list, with block size of 28. The surgeon was notified of the allocation in theater on the morning of the procedure. The study protocol was approved by the local ethics Committee and Institutional Review Board (IRB 1327-09).

Patients underwent a standardized anesthesia protocol, including induction with propofol (2 mg/kg) and fentanyl (1–2 μg/kg), neuromuscular blockade with rocuronium (0.6 mg/kg), preemptive analgesia with ketorolac 30 mg, and maintenance with sevoflurane (MAC 1.2) and fentanyl. Increases in blood pressure or heart rate were treated by additional doses of fentanyl (50 μg). Patients were ventilated with 50% air in oxygen in volume mode with tidal volume 8 to 10 mL/kg; respiratory rate was set at 12 to 14 breaths/min to keep end-tidal CO_2 at 35 mm Hg. Desametasone 4 mg was given for prophylaxis of postoperative nausea and vomiting.

Operative Technique

The same surgical team skilled in advanced laparoscopy performed all of the procedures. The same surgical technique was used for both conventional LH and MLH. Instrumentation included 5- or 3-mm graspers, scissors, monopolar electrocautery, and a suction-washing system. Tissue dissection and coagulation was performed with a bipolar PK System MoLly Forceps (Gyrus Medical Inc., Minneapolis, MN) that is available in both 3-mm and 5-mm sizes.

An intrauterine manipulator (RUMI System; CooperSurgical, Trumbull, CT) in conjunction with a Koh cup (Koh Colpotomizer System; CooperSurgical) was inserted. After pneumoperitoneum was created, a 0-degree operative laparoscope was introduced at the umbilical site. Under direct visualization, 3 ancillary trocars were inserted, 1 suprapubically and 2 laterally to the epigastric arteries, in the left and right lower abdominal quadrants, respectively.

During minilaparoscopic procedures, pneumoperitoneum was maintained with a dual tubing insufflation system delivering carbon dioxide through both the umbilical port and an ancillary port. Hysterectomy was started with coagulation and section of the round ligaments and the infundibulopelvic ligaments (in case of concomitant salpingoophorectomy) or of the uteroovarian ligament and the mesosalpinx (in case of ovarian preservation). The broad ligament was opened up to the uterovesical fold that was then incised with caudal reflection of the bladder. Afterward the uterine arteries, the cardinal ligaments, and the uterosacral ligaments were coagulated and transected. Hysterectomy was completed by performance of a circular colpotomy with a monopolar hook. The uterus was then extracted from the vagina with the intrauterine manipulator still in place. Vaginal cuff closure was performed transvaginally, with a running 0 polyglycolic acid suture on a half-circle HR26 needle. Large uteri were morcellated transvaginally after their complete detachment and motorized laparoscopic uterine morcellators have never been used. All port sites were approximated with surgical strips.

Postoperative pain was relieved with acetaminophen 1 g administered intravenously every 6 hours (starting