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Original Article

Low vs Standard Pneumoperitoneum Pressure During Laparoscopic Hysterectomy: Prospective Randomized Trial

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ABSTRACT **Study Objective:** To compare the use of low pneumoperitoneum pressure (LPP; 8 mm Hg) vs standard pneumoperitoneum pressure (SPP; 12 mm Hg) during mini-laparoscopic hysterectomy (MLH).
Design: Randomized controlled trial (Canadian Task Force classification I).
Setting: Tertiary care center.
Patients: Forty-two consecutive women scheduled to undergo MLH to treat benign uterine disease.
Interventions: Women were randomly selected to undergo MLH using LPP (n = 20) or SPP (n = 22). MLH was performed via 3-mm ancillary ports.
Measurements and Main Results: The primary outcome was to evaluate changes in abdominal and shoulder-tip pain via a 100-mm visual analog scale at 1, 3, and 24 hours postoperatively. All procedures were completed via mini-laparoscopy without the need to increase intra-abdominal pressure or convert to conventional laparoscopy or open surgery. Intraoperatively, 1 episode of severe bradycardia occurred in the LPP group, whereas no intraoperative complications were recorded in the SPP group ($p = .47$). No postoperative complications were recorded ($p > .99$). Abdominal pain was similar between groups at each time point. Incidence and intensity of shoulder-tip pain at 1 and 3 hours postoperatively was lower in the LPP group than in the SPP group ($p < .05$), whereas no between-group differences were observed at 24 hours ($p > .05$). Rescue analgesic requirement did not differ statistically between the LPP and SPP groups (20% vs 41%, respectively; $p = .19$; odds ratio, 2.7; 95% confidence interval, 0.69–11.08).
Conclusion: In experienced hands, use of LPP is safe and feasible. During performance of MLH, compared with SPP, LPP is a simple method that offers advantages of less shoulder-tip pain. Journal of Minimally Invasive Gynecology (2014) 21, 466–471 © 2014 AAGL. All rights reserved.

Keywords: Hysterectomy; Laparoscopy; Mini-laparoscopy; Pain; Pneumoperitoneum pressure

The role of minimally invasive surgery has dramatically increased over the past decades and continues to advance. Technical and technologic attempts have been made to improve patient care to minimize invasiveness and postoperative pain, to reduce the time to return to normal activity, and to increase patient satisfaction [1,2]. Although increasing evidence suggests advantages related to even less invasive techniques such as single-site, mini-laparoscopy, and micro-laparoscopy, less attention has been focused on the effect of pneumoperitoneum [3–9]. In non-isobaric procedures, pneumoperitoneum creates the necessary space in which to perform the operation laparoscopically. However, insufflation of gas into the abdomen is potentially dangerous because of increased intra-abdominal pressure [10]. Increase in intra-abdominal pressure is related to changes in cardiovascular and hemodynamic parameters, with an increase in mean arterial pressure and central venous pressure [11], and increased vascular resistance, with consequent reduction

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of visceral perfusion [12]. In addition, increased airway pressure and reduced pulmonary compliance are 2 obvious consequences of high intra-abdominal pressure during minimally invasive surgery [11]. Growing evidence in the field of general surgery has shown that reduction of intra-abdominal pressure during laparoscopy is related to improved postoperative outcomes. Several investigations have reported a decrease in pain perception, length of hospital stay, and analgesic rescue dosage in patients undergoing minimally invasive procedures using low pneumoperitoneum pressure (LPP) compared with standard pneumoperitoneum pressure (SPP). Despite the increased number of publications on this issue in various surgical specialties [13–17], no studies have evaluated the feasibility and advantages of LPP in patients undergoing gynecologic surgery. In theory, use of high intra-abdominal pressure is considered necessary to ensure good exposition of the pelvic area during gynecologic procedures. However, no evidence supports the belief that, compared with LPP, higher intra-abdominal pressure ensures better visualization. Hence, we designed a randomized trial with the objective to demonstrate the safety and feasibility of LPP during performance of minilaparoscopic hysterectomy (MLH) for treatment of benign uterine disease. In addition, we sought to evaluate whether, compared with SPP, use of LPP might potentially provide clinical advantages in patients undergoing MLH.

Materials and Methods

The study was performed at the Department of Obstetrics and Gynaecology of the University of Insubria (Varese, Italy) between June 4 and August 23, 2013. Approval of the Azienda Ospedaliero, Universitaria Ospedale di Circolo, Macchi Foundation, Ethics Committee was obtained, and all patients gave consent for the procedure and for use of their personal information for health research. Patients scheduled to undergo MLH were invited to participate in the study. Inclusion criteria were age $\geq$18 years; preoperative diagnosis of benign uterine disease, excluding pelvic floor dysfunction; and clinical follow-up of at least 30 days. Patients who did not meet these criteria were excluded from the final analysis.

As our policy, no patient scheduled to undergo minimally invasive hysterectomy was refused MLH for reasons of age, uterus size, obesity, previous surgical history, or anticipated difficulty of resection. Patients entered in the study were randomized via computer-generated list to undergo MLH with use of either LPP (8 mm Hg) or SPP (12 mm Hg) CO_2. Once patients were allocated to the LPP or SPP group, the treatment was revealed via telephone before the start of the procedure, and group allocation was concealed from patients and bedside clinicians.

The intraoperative anesthesiology protocol was standardized and followed in all cases. All patients received general endotracheal anesthesia, and after induction, patients received preemptive analgesia (30 mg ketorolac) and prophylaxis for postoperative nausea and vomiting (4 mg dexamethasone). Postoperative pain was treated with 1 g paracetamol intravenously every 6 hours for 3 times, beginning approximately 30 minutes before the end of surgery. Rescue analgesia (10 mg morphine subcutaneously or 30 mg ketorolac intravenously) was provided according to patient request. No preemptive infiltration of trocar sites with a local anesthetic was performed.

Women received a single dose of prophylactic antibiotic 1 hour before the intervention; antithrombotic prophylaxis was administered using low-molecular-weight heparin for 7 days, and compression stockings were used until the patient was fully mobile. All procedures were performed by the same experienced team of surgeons under direct supervision of the senior author (F.G.). During the study there were no significant differences in patient care or surgical techniques.

All patients underwent surgery in the morning to reduce the circadian difference in pain perception [18]. To perform laparoscopy, patients were placed in the lithotomy or Trendelenburg ($\leq$25 degrees) position to facilitate intraoperative exposure of pelvic organs. The bladder was drained via Foley catheterization. A Veress needle, introduced through the umbilicus, was used to create pneumoperitoneum, with CO_2 infused to distend the peritoneal cavity. Intra-abdominal pressure was maintained at 12 mm Hg during pneumoperitoneum creation and insertion of trocars, and then was maintained at 8 mm Hg (LPP group) or 12 mmHg (SPP group) according the randomization. Details of the surgical procedure have been reported elsewhere [19,20]. In brief, total laparoscopic hysterectomy was performed according to AAGL type IV-E classification [21]; an intrauterine manipulator (RUMI System; CooperSurgical, Inc., Trumbull, CT) in conjunction with a KOH cup (KOH Colpotomizer System; CooperSurgical) was inserted. After pneumoperitoneum was created, a 0-degree 5-mm laparoscope was introduced through the umbilicus. Under direct visualization, three 3-mm ancillary trocars were inserted, 1 suprapubically and 2 lateral to the epigastric arteries, in the left and right lower abdominal quadrants, respectively. Pneumoperitoneum was maintained using a dual tubing insufflation system that delivered CO_2 through both the umbilical port and an ancillary port. The insufflator was set at 20 L/min. CO_2 was introduced at standard room temperature (19°–21°C) with 0% relative humidity.

Hysterectomy was begun with coagulation and sectioning of the round ligaments and the infundibulopelvic ligaments. The broad ligament was opened up to the uterovescical fold, which was then incised via caudal reflection of the bladder. The uterine vessels, cardinal ligaments, and uterosacral ligaments were then coagulated and transected. Hysterectomy was completed via a circular colpotomy. The uterus was then extracted from the vagina with the intrauterine manipulator still in place. If the