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Original Article

Outcomes of Total Laparoscopic Hysterectomy Using a 5-mm Versus 10-mm Laparoscope: A Randomized Control Trial

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ABSTRACT **Study Objective:** To determine if the use of a 5-mm umbilical incision and laparoscope would result in a higher likelihood of earlier discharge from hospital after total laparoscopic hysterectomy (TLH) compared with a 10-mm umbilical incision and laparoscope. Secondary objectives of the study were to determine if the use of a 5-mm laparoscope would lead to a reduction in postoperative pain scores and a shorter operating time without an increase in complication rates.

Design: Prospective, randomized, double-blinded, clinical trial (Canadian Task Force classification I).

Setting: A tertiary care setting.

Patients: Seventy-eight patients scheduled for TLH were prospectively recruited.

Interventions: Women undergoing TLH were assigned to either a 5-mm umbilical port and laparoscope (5LH) or a 10-mm umbilical port and laparoscope (10LH). All patients underwent a standardized operative technique and anesthetic protocol. Patients and research assistants responsible for postoperative pain assessment were blinded to group. Analysis was by intention-to-treat.

Measurements and Main Results: The primary outcome measure was length of hospital stay. Secondary outcome measures were operating time, pain scores on postoperative days 1 and 7, and complication rates. There was no difference in length of hospital stay between the 2 arms. Compared with the 10LH group, the 5LH group had shorter operative times (32.6 vs 40 minutes; p = .01) and less postoperative pain on day 1 (2.5 vs 3.3; p = .03 for "pain with movement") and on day 7 (.92 vs 1.8; p = .002). Complication rates were similar between the 2 groups.

Conclusion: TLH with a 5-mm laparoscope resulted in shorter operative times and less pain on postoperative days 1 and 7, compared with a 10-mm laparoscope, with similar length of stay and complications. Journal of Minimally Invasive Gynecology (2016) 23, 101–106

Keywords: Laparoscopic hysterectomy; Laparoscopy/methods; Mini-laparoscopy; Pain; Port size

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Hysterectomy is the most common gynecologic surgical procedure performed in reproductive-aged women. Every year more than 500 000 hysterectomies are performed in the United States [1] and approximately 30 000 in Australia [2]. Compared with abdominal hysterectomy, the advantages of a laparoscopic approach include decreased postoperative intravenous analgesia requirements, shorter length of hospital stay, enhanced time to recovery, and faster return to work and daily activities [1]. Longer operating times have been shown to be offset by shorter hospital stays, with similar hospital costs overall [1].

As minimally invasive surgical techniques have evolved, there has been considerable interest in further minimizing the "invasiveness" of procedures. By decreasing the number and/or size of the operating ports and surgical instruments,

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it is hoped that patient outcomes will improve further. Advances in the manufacture of surgical equipment and fiberoptic technology have led to the development of smaller caliber instruments and improved optics and light sources and the emergence of the concept of "mini-laparoscopy" [3].

Although internationally there has been a trend toward smaller incisions and surgical instruments, research has tended to focus on a reduction in size of the ancillary ports but not the primary port. Several studies in the gynecologic and general surgical literature have shown that mini-laparoscopic instruments offer safe alternatives to conventional laparoscopy but have thus far failed to demonstrate a significant decrease in postoperative pain scores [3,4]. We hypothesize that this failure to show improvements in postoperative pain scores after mini-laparoscopy may be attributable to the larger diameter of the primary port used for the laparoscope.

The use of a 10-mm transumbilical laparoscope for minimally invasive hysterectomy has been standard practice among laparoscopic gynecologic surgeons in Western Australia. Despite their widespread availability, 5-mm laparoscopes are not routinely used because of a perception that the image quality and definition are inferior compared with 10-mm laparoscopes. We have previously demonstrated that the use of a 5-mm umbilical port resulted in a higher proportion of patients being discharged home after total laparoscopic hysterectomy (TLH) on the first postoperative day compared with patients whose procedure was performed using a 10-mm umbilical port [5]. This was, however, a retrospective analysis and hence subject to potential sources of bias.

Our hypothesis was that the use of a 5-mm umbilical incision and laparoscope would result in a higher likelihood of earlier discharge from hospital after TLH compared with a 10-mm umbilical incision and laparoscope. We also hypothesized that the use of a 5-mm laparoscope would lead to a reduction in postoperative pain scores and a shorter operating time without an increase in complication rates.

Methods

In this prospective randomized trial, patients were recruited between July 1, 2013 and February 28, 2014. There were no changes to the study methodology after trial commencement. Women who were scheduled to undergo a TLH were eligible to participate in the study and were enrolled by one of the authors (S.S. or J.T.). Indications for hysterectomy were early-stage endometrial cancer, microinvasive cervical cancer requiring simple extrafascial hysterectomy, prophylactic risk reduction surgery, complex adnexal masses not deemed to be high risk for malignancy, and dysfunctional uterine bleeding. Exclusion criteria were the need for comprehensive surgical staging of malignant disease, a previous midline laparotomy, and suspected or known severe endometriosis. The trial was conducted in the Department of Gynecologic Oncology at St. John of God Hospital, Subiaco, Western Australia.

Our primary outcome measure was length of hospital stay. Secondary outcome measures included pain scores on postoperative days 1 and day 7, operating time, and complication rates.

The study sample size was based on detecting a clinically significant reduction in length of hospital stay when the 5-mm umbilical port technique was used. Previously published institutional data showed a reduction in length of hospital stay for 5-mm umbilical incisions (38% discharged on day 1; mean length of stay, 1.9 days) when compared with 10-mm umbilical incisions (3% discharged day 1; mean length of stay, 3.05 days) [5]. A priori calculations showed a required sample size of 32 patients per trial arm to demonstrate a 30% increase in the discharge rate on day 1 at alpha = .05 for 80% power.

Patients were randomly assigned to undergo TLH using either a 1-0 mm umbilical incision and laparoscope (10-mm laparoscopic hysterectomy [10LH]) or a 5-mm umbilical incision and laparoscope (5-mm laparoscopic hysterectomy [5LH]). The ancillary ports in both treatment groups were 5 mm in diameter. Randomization was performed on the basis of a block-randomization computer-generated list, with a block size of 6.

The surgeon was notified of the allocation in the operating theatre on the morning of the procedure. Patients were blinded to their randomization. The study protocol was approved by the Human Research Ethics Committee at St. John of God Hospital, Subiaco (reference no. 607) and registered with the Australian and New Zealand Clinical Trial Registry (clinical trial no. ACTRN12613000696796).

Patients underwent a standardized anesthesia protocol, including induction with propofol (2–3 mg/kg) and fentanyl (1.5 μg/kg), neuromuscular blockade with rocuronium (.5 mg/kg), and maintenance with sevoflurane (.7–2.0% endotracheal concentration) and fentanyl. Increases in blood pressure or heart rate were treated by additional doses of fentanyl (50–100 μg) as required and at discretion of the anesthetist. Dexamethasone 4 mg was given for prophylaxis of postoperative nausea and vomiting. Postoperatively, patients were initially managed with a fentanyl protocol in recovery (20-μg boluses, every 5 minutes as required until discharge from recovery) and regular paracetamol and celocoxib with oxycodone and tramadol as required.

Surgery was performed by 1 of 2 gynecologic oncologists (S.S. or J.T.), who had both undertaken laparoscopic fellowships before gynecologic oncology subspecialty training. The same surgical technique was used for both 10LH and 5LH. Instrumentation included graspers, scissors, monopolar electrocautery, and a suction-washing system. Tissue dissection and coagulation was performed with a Ligasure 5-mm device (Covidien, Mansfield, MA). The surgical technique is described in Appendix A.

The rectus sheath in patients randomized to the 10LH arm was closed using an interrupted 1.0 synthetic absorbable