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Original Article

A Prospective, Comparative Study for the Evaluation of Postoperative Pain and Quality of Recovery in Patients Undergoing Robotic Versus Open Hysterectomy for Staging of Endometrial Cancer

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ABSTRACT **Study Objective:** To measure and compare postoperative pain and patient satisfaction in patients undergoing either robotic or open laparotomy for surgical staging of endometrial cancer.

Design: Prospective, comparative study (Canadian Task Force classification II).

Setting: University hospital.

Patients: A total of 142 patients undergoing either robotic or open laparotomy for surgical staging of endometrial cancer.

Interventions: Patients scheduled for surgical staging of endometrial cancer at a single institution were identified. The patients underwent either robotic or open hysterectomy for staging of endometrial cancer. The choice of operative approach (robotic vs laparotomy) was made by the faculty physician before enrollment. Patients participated in the study for up to 48 hours for pain assessments and up to 10 ± 3 days postoperatively for quality of recovery assessments.

Measurements and Main Results: The following measurements were performed: postoperative pain with the visual analog scale (VAS), 24-hour opioid consumption, and quality of recovery using the Quality of Recovery Questionnaire (QoR-40). The study was terminated owing to futility, given the lack of open procedures at our institution. Despite that lack of statistically significant difference between VAS scores at rest and with leg extension, there was a significant decrease in 24-hour opioid consumption in the robotic group. In addition, the QoR-40 showed an increased perception of recovery in patients within the robotic group compared with the laparotomy group.

Conclusion: Patients with endometrial cancer who underwent robotic surgery had decreased postoperative opioid consumption and improved quality of recovery compared with those who underwent surgery via laparotomy. Journal of Minimally Invasive Gynecology (2016) 23, 429–434 © 2016 AAGL. All rights reserved.

Keywords: Endometrial cancer; Laparotomy; Postoperative pain; Quality of recovery; Robotic surgery

Endometrial cancer is the fourth most common cause of cancer among women in the United States, trailing only breast, lung, and colorectal cancers and the most common gynecologic cancer in the country. It is estimated that more than 54,870 new cases of endometrial cancer were diagnosed and more than 10,170 deaths from endometrial cancer occurred in 2015 [1]. Surgical treatment is the primary treatment of choice for the majority of patients. The standard surgical approach includes total hysterectomy, bilateral salpingo-oophorectomy, with surgical staging to include selective pelvic and para-aortic lymphadenectomy [2].

Traditionally, surgical staging of endometrial cancer has been performed via laparotomy; however, multiple studies have shown a minimally invasive approach with laparoscopy to be safe, efficacious, and associated with decreased

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perioperative morbidities in these patients compared with laparotomy [3]. The Gynecologic Oncology Group conducted the largest randomized controlled trial to date (the LAP2 Study) comparing laparoscopy and laparotomy in patients with newly diagnosed endometrial cancer. The LAP2 Study showed decreased postoperative complications and decreased length of stay despite longer operating times and a 25% rate of conversion to laparotomy [4]. The first 802 patients participated in a quality of life (QoL) study; results showed that within the first 6 weeks after surgery, the patients in the laparoscopy group reported better QoL on all scales except fear of recurrence. A follow-up report published in 2012 documented similar recurrence-free survival and overall survival in the 2 groups [5].

Since being cleared by the Food and Drug Administration for use in performing hysterectomy, the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA) has become an increasingly common tool for hysterectomy in both benign and oncology settings. The da Vinci system reportedly provides numerous advantages to the surgeon and patient, including less blood loss, shorter operative time, and shorter length of stay compared with both laparoscopy and laparotomy [6–9]. Previous studies have suggested that a robotic-assisted approach may be preferred over laparoscopy and laparotomy in the surgical treatment of endometrial cancer patients.

Postoperative pain is another important endpoint for comparing different surgical techniques. Although expected, postoperative pain is associated with patient satisfaction and QoL. Limited studies have investigated postoperative pain and QoL in patients undergoing robotic hysterectomy for endometrial cancer. Retrospective studies comparing postoperative pain scores and narcotic use following laparoscopic and robotic endometrial cancer staging have shown conflicting results [10,11]. The primary objective of the present study was to prospectively compare associated postoperative pain, opioid consumption, and the quality of recovery in patients undergoing traditional laparotomy and those undergoing robotic-assisted surgical staging of endometrial cancer.

Patients and Methods

This single-center, prospective, double-arm comparative study was conducted at The Ohio State University Wexner Medical Center between March 2009 and March 2012. We included patients eligible for postoperative pain and quality of recovery assessment after either robotic or laparotomy surgical staging for endometrial cancer. The study was approved by the center's Institutional Review Board, and written informed consent was provided by all patients.

For each patient, the decision to pursue 1 of the 2 operative approaches (robotic or open) was made by the faculty physician before enrollment, based on uterine size, history of previous surgeries and adhesions, or ability to remove the uterus through the vagina. Six of the 7 physicians were performing robotic procedures at that time. Importantly, the existence of this trial did not influence the physician's clinical judgment regarding the choice of surgical approach.

The eligible patients were females age 18 to 85 years with a preoperative diagnosis of apparently uterine-confined endometrial carcinoma. All patients were scheduled for either robotic hysterectomy or open abdominal hysterectomy, with or without bilateral salpingo-oophorectomy, and with or without retroperitoneal lymphadenectomy. Patients remained in the study for up to 10 $\pm$ 3 days postoperatively for pain and quality of recovery assessments.

Patients were excluded from the study who had a known hypersensitivity to opioids, had received chemotherapy or radiation within the year preceding the study, had undergone concomitant procedures at the time of surgical staging, had a history of narcotic abuse within the past year, or had an American Society of Anesthesiologists (ASA) score of IV or V or an Eastern Cooperative Oncology Group status of 4 or 5. Also excluded were patients diagnosed with any chronic pain condition and/or psychiatric problems, or with any pain or illness that in the opinion of the principal investigator would interfere with study assessments.

The study's primary objective was to measure and compare the severity of postoperative pain as measured on a visual analog scale (VAS) score at rest at baseline and on postoperative day (POD) 1 and POD 2. As secondary objectives, we analyzed the difference in postoperative VAS scores reported by the patients after leg extension during the same time points, measured opioid consumption in the first 24 hours after surgery, and compared the quality of postoperative recovery between the 2 groups at POD 1 and POD 10 $\pm$ 3 days using the Quality of Recovery Questionnaire (QoR-40).

Once a patient agreed to be a part of the study and signed inform consent, she was asked to rate her baseline pain on a scale of 1 to 10 using the VAS at rest and after leg extension. After hysterectomy, the patient was approached on POD 1 and POD 2 to complete the same VAS score assessments that she completed at baseline. Of note, VAS scores for POD 2 were not available for all patients, because most patients undergoing robotic hysterectomy were discharged before 24 hours.

Postoperative pain management was standardized between the 2 groups. Patients received intravenous (IV) morphine or hydromorphone via patient-controlled analgesia (PCA) for the first 24 hours after surgery in accordance with our institution's standard of care. After discontinuation of the PCA, the patients received the same IV opioids on a scheduled basis, with additional IV doses as needed. When patients were transitioned to oral medications, they received scheduled Percocet (oxycodone/acetaminophen, 5–325 mg), 2 tablets every 6 hours, and additional oxycodone (5 mg tablets) as needed for breakthrough pain. Morphine equivalents were calculated to compare the 24-hour narcotic consumption. Patients were not allowed to receive IV or oral nonsteroidal anti-inflammatory drugs (NSAIDs) for pain for up to