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Original Article

A Randomized Trial Comparing Vaginal and Laparoscopic Hysterectomy vs Robot-Assisted Hysterectomy

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ABSTRACT **Study Objective:** To investigate the hospital cost and short-term clinical outcome of traditional minimally invasive hysterectomy vs robot-assisted hysterectomy in women primarily not considered candidates for vaginal surgery.
Design: Randomized controlled trial (Canadian Task Force classification I).
Setting: University Hospital in Sweden.
Patients: One hundred twenty-two women with uterine size ≤16 gestational weeks scheduled to undergo minimally invasive hysterectomy because of benign disease.
Interventions: Robot-assisted hysterectomy or traditional vaginal or laparoscopic minimally invasive hysterectomy.
Measurements and Main Results: All women underwent surgery as randomized. There were no demographic differences between the 2 groups. Vaginal hysterectomy was possible in 41% in the traditional minimally invasive group, at a mean hospital cost of $4579 compared with $7059 for traditional laparoscopic hysterectomy. This was reflected in a mean hospital cost of $993 more per robotic-assisted hysterectomy than for traditional minimally invasive hysterectomy when the robot was a preexisting investment. This hospital cost increased by $1607 when including investments and cost of maintenance. A per-protocol subanalysis comparing laparoscopy and robotics demonstrated similar hospital cost when the robot was a preexisting investment ($7059 vs $7016). Robotic-assisted hysterectomy was associated with less blood loss and fewer postoperative complications.
Conclusion: A similar hospital cost can be attained for laparoscopy and robotics when the robot is a preexisting investment. From the perspective of hospital costs, robotic-assisted hysterectomy is not advantageous for treating benign conditions when a vaginal approach is feasible in a high proportion of patients. Journal of Minimally Invasive Gynecology (2015) 22, 78–86

Keywords: Hysterectomy; Laparoscopic hysterectomy; Minimally invasive surgery; Robot-assisted laparoscopy; Vaginal hysterectomy

DISCUSS You can discuss this article with its authors and with other AAGL members at http://www.AAGL.org/jmig-22-1-JMIG-D-14-00303

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The potential benefit of robot-assisted laparoscopic surgery is enabling a higher proportion of minimally invasive surgical procedures. Despite guidelines supporting minimally invasive procedures, hysterectomy to treat benign gynecologic disease is still most commonly performed via laparotomy [1–9]. Vaginal hysterectomy is primarily performed in conjunction with surgery to treat prolapse, and the rate in the United States decreased from 22% in 2003 to 19% in 2009–2010, which coincides with the introduction of robotic-assisted surgery [1–4].

Robot-assisted laparoscopy has been widely adopted to treat benign gynecologic conditions, although no data have demonstrated a clinical or economic benefit over other operative approaches [3,10–17]. Recently, 2 large cohort studies found similar morbidity profiles as for laparoscopic hysterectomy, but a substantially increase in cost for robotic-assisted surgical procedures. However, factors that might influence the route of hysterectomy chosen, such as body mass index, uterine weight, and previous abdominal surgery, were not available [3,15]. A 2012 Cochrane review identified 2 randomized controlled trials of benign

Disclosures: Dr. Persson is a proctor in robotic surgery.

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gynecologic robotic-assisted hysterectomy and concluded that robotic surgery was not associated with improved effectiveness or safety [9]. However, both studies were potentially biased by inclusion of early robot adopters [9,18,19].

The Department of Obstetrics and Gynecology at Skåne University Hospital is a tertiary referral unit for both gynecologic oncology and complex benign gynecologic surgery. Robotic surgery was introduced in October 2005, and to date >1600 women have undergone robotic-assisted surgery, with approximately 300 procedures performed each year [20–22].

Before the implementation of robotic-assisted surgery, traditional laparoscopy was routinely used for hysterectomy, and minimally invasive surgery was used to perform 78% of all hysterectomies to treat benign disease in 2012.

The primary objective of the present study was to investigate the hospital cost of robotic-assisted hysterectomy compared with traditional minimally invasive hysterectomy (vaginal and laparoscopic) performed to treat benign gynecologic disorders in women with uterine size ≤16 gestational weeks after excluding women referred for vaginal hysterectomy. The secondary objective was to assess short-term clinical outcome.

Material and Methods

Between January 2010 and June 2013, 125 women meeting the inclusion criteria were offered participation in the study (Fig. 1; Table 1). Preoperative evaluation in all women included medical and surgical history, and clinical examination including a gynecologic examination and vaginal ultrasonography. Each woman was assigned an individual clinical research file containing all study protocols. One hundred twenty-two opaque envelopes containing the assigned surgical method in the proportion of 1:1 were closed, shuffled, and then numbered. After inclusion, randomization occurred via telephone during which the envelopes were opened in consecutive order at the central randomization office. The date, clinical research file number, patient name and social security number, and the assigned surgical method were recorded in the central study log. Before randomization, surgical procedures were scheduled to be performed on a day when it was possible to include all 3 approaches, and after randomization the patient was assigned a specific surgeon.

All patients were informed of their assignment. The route of traditional minimally invasive surgery was chosen by the designated surgeon, with vaginal hysterectomy as the first choice, followed by laparoscopic hysterectomy. The necessity of concomitant procedures, vaginal access, body mass index, and the presence of adhesions or endometriosis influenced the choice of surgical approach. Robot-assisted laparoscopic hysterectomy was performed using the da Vinci Si Surgical System (Intuitive Surgical, Inc., Sunnyvale CA). All 6 surgeons were consultants experienced in both vaginal and laparoscopic surgery, and 4 were gynecologic oncologists experienced in robotic-assisted surgery. The case load of hysterectomy to treat benign disease before commencing the study was approximately 110 annually, with 31% performed vaginally, 27% laparoscopically, and 15% robotically. However, most hysterectomies performed at our institution are to treat malignant disease, with the greatest proportion performed by the 4 gynecologic oncologists. The least experienced robotic surgeon had performed 49 robotic hysterectomies before the study, and a total of 231 robotic-assisted procedures by the end of the study, primarily in gynecologic oncology.

All women received oral prophylactic antibiotic therapy including 200 mg doxycycline (Doxyferm; Nordic Group BV, Hoofddorp, Holland) and 800 mg metronidazole (Flagyl; Sanofi-Aventis, Paris, France). All procedures were performed with the patient under general anesthesia. For robotic-assisted hysterectomy, two or three 8-mm robot trocars and one assistant 5- or 12-mm trocar were used. Laparoscopic hysterectomy was performed with the use of 4 ports: a reusable umbilical port or a 12-mm port (Xcel; Ethicon Endo-Surgery, Inc., Somerville, NJ) for the optics and 3 assistant ports, either three 5-mm or two 5-mm plus one 10-mm ports, in the lower quadrants. Vaginal hysterectomy was performed in the standard manner. For robot-assisted and total laparoscopic hysterectomy the peritoneum of the lateral sidewalls was opened, the ureters were visualized and lateralized, and the propria pelvic ligament or infundibulopelvic ligament and the round ligaments were divided, followed by electrocoagulation of the uterine arteries and cardinal ligaments. Then the vagina was incised, and the vaginal cuff was sutured using polyglactin 910 absorbable sutures (Vicryl; Ethicon) or V-Loc 180 sutures (Covidien; Mansfield, MA), at surgeon discretion either robotically, laparoscopically, or vaginally, with the latter in patients after vaginal coring of the uterus. During laparoscopic vaginal hysterectomy the procedure was similar except that the uterine arteries and cardinal ligaments were divided vaginally. Postoperative cystoscopy was not performed.

Total operating room time (from patient entry to departure from the operating room, including administration of anesthesia), total operative time (skin to skin including placement of a catheter, application of a fornix presenter, docking, and dedocking), intraoperative blood loss, and complications were recorded. Hemoglobin and C-reactive protein concentrations and body temperature were noted on the first postoperative day. All women received similar pain medication and were given a daily dose of 4500 IE tinzaparin (Innohep; LEO Pharma AB, Copenhagen, Denmark) for 10 days postoperatively. Length of stay and immediate postoperative complications were recorded. All patients were advised to contact the department if necessary. A postoperative visit was planned for 4 months after surgery. To assess short-term clinical outcome, all adverse events within this period were included with the exception of uncomplicated lower urinary tract infections because this was thought to be unrelated to the surgical method.