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Pilot Study

Implementing an Advanced Laparoscopic Procedure by Monitoring with a Visiting Surgeon

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ABSTRACT **Study Objective:** To investigate the feasibility of safely implementing a total laparoscopic hysterectomy (LH) in established gynecologists' practices with on-site coaching and monitoring of the learning curve by an experienced visiting surgeon.
Design: Multicenter prospective feasibility and implementation study (Canadian Task Force classification II-2).
Setting: Eleven general gynecologists in 8 hospitals (1 university hospital and 7 regional hospitals) participated.
Patients: Laparoscopic hysterectomy was performed in 83 patients during the learning curve, and in 83 patients after the learning curve.
Interventions: During the learning curve, an experienced visiting laparoscopist was available for coaching during each LH. A competence score was marked on an Objective Structured Assessment of Technical Skills (OSATS) form. Complications were recorded intraoperatively and postoperatively for 6 weeks after surgery in all patients.
Measurements and Main Results: Nine of 11 gynecologists reached the competence score of at least 28 points during the study, from January 2005 to January 2007. A major complication occurred in 3 of 83 LH procedures (4%) performed during the learning curve, and in 5 of 83 LH procedures (6%) performed after the learning curve ($p = .72$).
Conclusion: The concept of a visiting surgeon for on-site coaching and monitoring of established gynecologists during the learning curve of an advanced laparoscopic procedure using Objectively Structured Assessment of Technical Skills is feasible. According to the observed complication rate during and after the learning curve, on-site coaching is a useful tool when implementing a new laparoscopic technique in established gynecologists' practices. Journal of Minimally Invasive Gynecology (2010) 17, 771–778 © 2010 AAGL. All rights reserved.

Keywords: Advanced laparoscopy; Complications; Continuous medical education; Implementation; Laparoscopic skills; Learning curve; Total laparoscopic hysterectomy

In gynecology, laparoscopy was first introduced as a diagnostic tool [1]; however, with the development of advanced equipment and improved anesthetic agents, an increasing number of operative procedures are performed at laparoscopy. The first laparoscopic hysterectomy (LH) was performed in 1990 [2]. Currently, total LH is being introduced as an alternative to abdominal hysterectomy in an increasing number of hospitals.

Compared with laparotomy, laparoscopy results in improved quality of life, embodied by smaller incisions, less postoperative pain, less immobility, shorter hospital stay, and faster return to normal functioning [3]. It seems that, in particular, obese patients benefit from a laparoscopic procedure, primarily because of fewer wound complications and shorter hospital stay compared with laparotomy [4–6].

There are several challenges when implementing an advanced laparoscopic technique. First, the learning curve for LH is long, varying from 3 to 10 years or 20 to 30 procedures, according to several studies [7–10], and most major complications occur during this learning curve [7–10]. Second, LH is a level 3 laparoscopic procedure that demands a high level of surgeon laparoscopic skills; however, most gynecologists are taught level 1 and 2

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laparoscopic procedures during their training [11]. Third, the higher costs associated with the use of disposable equipment and the longer operating time initially raise budgetary problems in many hospitals.

When implementing a new surgical technique by established surgeons, differences can be expected in level of experience. To assess and monitor technical skills during training, an Objective Structured Assessment of Technical Skills (OSATS) was developed [12,13]. This form is validated for assessment of laparoscopic and open abdominal skills in surgical procedures. It is an instrument to measure quality of surgical skills rather than counting the number of performed procedures (quantity). In addition to monitoring skills, it has been suggested that mentorship during the learning curve of an advanced laparoscopic procedure facilitates its implementation and warrants the safety of the patient [14,15]. Laparoscopic hysterectomy is not the standard treatment in patients with an indication for abdominal hysterectomy in many countries, although benefits have been described.

In a multicenter prospective study, implementation of LH was studied. The OSATS form was introduced to monitor the competence of established gynecologists while learning LH from an experienced laparoscopist, the visiting surgeon. The objective of this study was to investigate whether implementation of an advanced laparoscopic technique can be performed in a safe and feasible manner using the concept of a visiting surgeon for coaching and monitoring, and OSATS to define level of competence.

Materials and Methods

Gynecologists and Procedures

A multicenter prospective study was conducted in the north of the Netherlands at University Medical Center Groningen (UMCG) and 7 regional hospitals (3 teaching and 4 nonteaching hospitals) from January 2005 to January 2007. Because this was a feasibility and implementation study in preparation for a large randomized trial [16], there was no hypothesis testing, and a power calculation was not performed before the study. The regional hospitals were within 80 km of UMCG. The study protocol was approved by the medical ethical committee of UMCG. The 11 participating gynecologists had a specific interest in laparoscopic surgery and experience in at least level 2 laparoscopic surgery. These surgeons completed a postgraduate course including live animal experience and tutored experience in performing laparoscopic procedures. To maintain their competence, they were expected to perform at least 10 level 3 laparoscopic procedures each year. A maximum of 2 gynecologists per center were allowed to participate in the trial.

All participating gynecologists received an instruction digital video disk that demonstrated how to perform LH, together with a written standardized operation protocol (Table 1). All attended a laparoscopy workshop in the Skills Centre of UMCG. During this workshop, they trained on a bench model and practiced laparoscopic suturing while feedback was given by the visiting surgeons. Each procedure was performed according to the standardized operation protocol, using standard laparoscopic equipment; the McCartney tube (Tyco Healthcare/Kendall, Mansfield, MA), and a sealing instrument. During the learning curve, 1 of the visiting surgeons was present at each procedure. A protocol violation such as operating without a visiting surgeon during the learning curve resulted in exclusion. One of the participating gynecologists who attended the laparoscopy workshop entered the study later owing to logistical reasons at her hospital.

Patients

Consecutive patients with a clinical stage I, grade 1 or 2 endometrioid adenocarcinoma of the uterus without cervical involvement or patients with a benign indication for abdominal hysterectomy with or without bilateral salpingo-oophorectomy, aged 18 years or older, were included. All patients signed written informed consent before participating. Exclusion criteria included histologic type other than grade 1 or 2 endometrioid adenocarcinoma, clinically advanced disease (International Federation of Gynecology and Obstetrics stage 2 to 4), uterus size larger than 10 to 12 weeks of gestation, and cardiopulmonary contraindications to laparoscopy.

Table 1
Surgical treatment protocol for total laparoscopic hysterecomy with bilateral salpingo-oophorectomy

Preoperative thrombosis prophylaxis administered.
Preoperative antibiotic agents given at least 15 minutes before making the skin incision.
Patient positioned in the lithotomy position.
Insufflation of carbon dioxide and placing of 4 trocars.
Abdominal washing for cytologic analysis.
Bipolar coagulation or sealing of the round ligament before cutting with monopolar scissors; opening the peritoneum of the bladder and the pelvic sidewall.
Bipolar coagulation or sealing of the infundibulo pelvic ligament before cutting with monopolar scissors.
Placing the vaginal tube (McCartney tube); preparation of the bladder off the vagina.
Exposure of the uterine vessels, coagulation or sealing of the vessels after identification of the ureter.
Coagulation or sealing and cutting of the sacrouterine ligaments.
Cutting the vaginal wall on the rim of the vaginal tube; keeping the ureter in sight.
Removing the uterus; closing of the vaginal cuff with abdominal or vaginal stitching.