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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.

OATS and Visiting Surgeon

Two specialists in laparoscopic surgery, both working in the University Medical Center, the visiting surgeons, coached and evaluated the skills of the participants while performing a LH and gave feedback. A participating gynecologist could be coached by 1 visiting surgeon on 1 occasion, and by the other visiting surgeon during the next procedure. The visiting surgeon acted as a mentor during the procedures, and the participating gynecologist was the primary surgeon. At the beginning of the learning curve, the visiting surgeon assisted in the operation, and later in the learning curve observed only. The competence of the participating gynecologist was recorded after each LH by the visiting surgeon using the OSATS form (Fig. 1). The OSATS included 7 items (respect for tissue, time and motion, instrument handling, knowledge of instruments, use of assistance, flow of operation, and knowledge of the specific procedure) scored on a scale of 0 to a maximum of 5 points per item [15]. If a participating gynecologist reached a minimum score of 4 on each item ($7 \times 4 = 28$), evaluated at 2 independent procedures, this was considered a passing grade. Thereafter, the participant was considered ''competent,'' and further procedures were performed without the visiting surgeon.

Respect for tissue 1 Frequently used unnecessary force on tissue or caused damage by inappropriate instrument use	2	3 Careful handling of tissue but occasionally caused inadvertent damage	4	5 Consistently handled appropriately with minimal damage to tissue
Time and motion 1 Many unnecessary moves	2	3 Efficient time and motion, but some unnecessary moves	4	5 Clear economy of movement and maximum efficiency
Instrument handling 1 Repeatedly makes awkward or tentative moves with instruments through inappropriate use	2	3 Competent use of instruments, but occasionally appeared stiff or awkward	4	5 Fluid movements with instruments and no stiffness or awkwardness
Knowledge of instruments 1 Frequently asked for the wrong instrument or used an inappropriate instrument	2	3 Knew the names of most instruments, and used appropriate instrument for the task	4	5 Obviously familiar with the instruments required and their names
Use of assistance 1 Consistently placed assistants poorly or failed to use assistants	2	3 Good use of assistants most of the time	4	5 Strategically used assistant to the best advantage at all times
Flow of operation 1 Frequently stopped operating and seemed unsure of next move	2	3 Demonstrated some forward planning and reasonable progression of procedure	4	5 Obviously planned operation with efficiency from one move to another
Knowledge of procedure 1 Insufficient knowledge; looked unsure and hesitant	2	3 Knew all important steps of operation	4	5 Demonstrated familiarity with all steps of operation

Fig. 1. Objectively Structured Assessment of Technical Skills form.

Complications

During the study, all procedures during and after the learning curve were monitored on a case record form on which the following items were recorded: complications during the operation or detected within 6 weeks postoperatively, time of the procedure, amount of blood loss in milliliters as was measured in the collection canister by the operation team, conversion and reason for conversion, use of pain medication postoperatively, and length of hospital stay. Complications were classified as major or minor. Major complications registered included injury to bowel, bladder, ureters, vessels, or nerves; thromboembolic events such as deep venous thrombosis or pulmonary embolism; hematoma or hemorrhage requiring transfusion or surgical intervention; wound dehiscence requiring surgical intervention or readmission; wound infections including vaginal vault abscess requiring surgical intervention, prolonged hospital stay, readmission, or additional treatment; and other major complications. The severity of a complication was assessed according to the Common Terminology Criteria for Adverse Events (CTCAE), version 3.0 (http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf). An independent panel of 3 experienced clinicians familiar with laparoscopic surgery (1 surgeon, 1 anesthesiologist, and 1 gynecologic oncologist) differentiated between major and minor complications based on consensus. They also assessed whether and to what extent the complication was related to the operative procedure (Table 2). Conversions were not scored as major complications. All minor complications were separately presented to the 2 visiting surgeons, who graded the severity of the complication according to CTCEA and whether it was treatment- or procedure-related.

Statistical Analysis

Statistics were calculated using commercially available software (SPSS for Windows XP, version 16.0; SPSS, Inc., Chicago, IL). Frequency and descriptive values were calculated, as well as 95% confidence intervals (95% CIs) for proportions. Differences between groups were tested using the χ^2 test or the Mann-Whitney test. Significance was considered at $p < .05$ (2-tailed).

Results

Gynecologists and Procedures

During the study, 194 LH procedures were performed in the 8 participating hospitals. Twenty-eight procedures (14.4%) could not be included in the study. In 19 procedures, the participating gynecologist performed a procedure without the presence of the visiting surgeon before reaching the competence score; these cases were excluded from the analysis because of protocol violations. In 3 cases, data were incomplete, 3 patients withdrew after enrollment, 2 patients had a contraindication for laparoscopy, and 1 patient had unsuspected ovarian cancer. All these patients were excluded after they had given written informed consent. A total of 166 procedures were analyzed in this study. Eighty-three patients were operated on by the participating gynecologists during the learning curve and 83 patients were operated on by the participating gynecologists after the learning curve.

Table 2
Major complications according to assessment by an independent panel

Complication	Age, yr	Conversion	Grade[a]	Treatment-related	Procedure-related
During learning curve (n = 3)					
Perforation of ileum at trocar insertion, which was sutured at laparoscopy; 4 days postoperatively, laparotomy performed to treat another (unrecognized) bowel perforation on the contralateral side	44	No	3	Definitely	Yes
Bladder retention 900 mL 19 days postoperatively; readmission 1 day; urinary tract infection	47	No	3	Probably	No
Death 16 days postoperatively from massive pulmonary emboli 2 days postoperatively	76	No	5	Definitely	No
After learning curve					
Bladder lesion, laparotomy	37	Yes	3	Definitely	No
Hemorrhage 3500 mL as consequence	71	Yes	4	Definitely	No
Multiple-organ failure					
Urinary tract infection					
Ureter lesion					
Wound dehiscence requiring intervention					
Wound abscess					
Myocardial infarction 1 day postoperatively	77	Yes	4	Probably	No
Bladder lesion sutured at laparoscopy	34	No	3	Definitely	Yes
Transient ischemic attacks 14 days postoperatively; treated using anticoagulant agents	49	Yes	3	Probably not	No

[a] Common terminology criteria for adverse events (CTCEA) classification: http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/newadverse_2006.pdf.

Patients

Patient characteristics are given in Table 3. No significant differences were found between patients treated during the learning curve and those treated after the learning curve. Patient median (range) age was 52 (34–83) years. Most patients (>60%) were overweight, with a body mass index of 27 (16–47).

OSATS *and Visiting Surgeons*

Learning curves for the 11 gynecologists according to OSATS score are shown in Fig. 2. Nine gynecologists had a passing grade (28 points on 2 separate occasions) during the study, and were considered competent. Thereafter, they operated without the visiting surgeon. One gynecologist was withdrawn from the study because of multiple protocol violations. The gynecologist who started later in the study did not reach the competence score during the study. Within 1 year and within 3 to 13 procedures, 9 participating gynecologists achieved a passing grade and were able to perform LH independently.

Complications

The major complications are given in Table 2, and reasons for conversions in Table 4. Three major complications occurred during the learning curve (3 of 83 [3.6%]; 95% CI, .004–.08). Two major complications, perforation of the ileum and death due to massive pulmonary emboli, were scored by the independent panel as definitely related to the treatment. Perforation of the ileum was also scored as related to the procedure. The other major complication was scored as probably related to the treatment but not to the procedure. After the learning curve, 5 major complications occurred (5 of 83 [6.0%]; 95% CI, .009–11). Two bladder lesions and 1 massive hemorrhage were definitely treatment related; a myocardial infarction was scored as probably related to treatment, and transient ischemic attacks were scored as probably not related to treatment. All major complications after the learning curve were scored as not related to the procedure, except the bladder lesion.

The major and minor complication rates were comparable during and after the learning curve ($p = .72$ and $p = .81$, respectively). The amount of blood loss did not differ during and after the learning curve (125 vs 150 mL; $p = .14$). Operating time before and after the learning curve was not significantly different (2:00 vs 1:52 hours; $p = .21$). There were 6 conversions during the learning curve, and 14 thereafter ($p = .09$). The median (range) hospital stay was 3 (2–37) days (Table 5).

Table 3
Characteristics of 166 study patients

Variable	During learning curve (n = 83)	After learning curve (n = 83)	p Value
Age, median (range), yr	54.0 (34–83)	52.0 (34–81)	.67[a]
Missing data (n = 0)			
Weight, median (range), kg	79.5 (39.6–130)	75 (55-120)	.78[a]
Missing data (n = 10)			
Body mass index, %			.90[a]
<25	26.5	28.9	
25–30	36.1	33.7	
>30	32.5	30.1	
Missing data (n = 10)			
Previous abdominal surgery, No. (%)			.51[b]
Yes	30 (36.1)	26 (31.1)	
Missing data (n = 4)			
Comorbidity, No. (%)			.70[b]
Yes	29 (34.9)	29 (34.9)	
Missing data (n = 14)			
Yes	29 (34.9)	29 (34.9)	
Missing data (n = 14)			
Indication, No. (%)			.35[b]
Benign	47 (56.6)	40 (48.2)	
Malignant	36 (43.4)	41 (49.4)	
Missing data (n = 2)			

[a] Mann-Whitney test.
[b] $\chi 2$ test.

Discussion

The present study shows that implementing an advanced laparoscopic technique using on-site coaching and monitoring of established gynecologists by a visiting surgeon and OSATS is feasible. The objective of the study was to determine whether it was feasible to implement an advanced laparoscopic procedure in established gynecologists' practices, with a major complication rate during the learning curve that was comparable to that of a prospective multicenter study in the literature (7%) [17]. The major complication rate in the present study was 4.8% (95% CI, .002–.09) in 166 patients, 3.6% during the learning curve, and 6.0% thereafter. An independent panel scored 2 of the 3 major complications before the learning curve as related to the procedure, and only 1 of the 6 major complications after the learning curve as related to the procedure. No significant differences were found in major complications, conversion rate, or blood loss during or after the learning curve.

Major complication rates ranging from 1.2% to 11.1% have been reported in studies of LH [7,8,10,17,18]. Wattiez et al [10] noted that major complications occurred in 39 of 695 LH procedures (5.6%) performed by a surgeon in the first 6 years compared with 12 in 953 LH procedures (1.3%) in the 3 years thereafter. Altgassen et al [7] reported that most complications occur in the first 30 procedures, with a decrease in intraoperative major complications thereafter, from 4.2% (10 of 240 procedures) to 0.5% (2 of 428 procedures); postoperative complications decreased from 1.3% (3 of 240 procedures) to 0.5% (2 of 428 procedures). A study by Mäkinen et al [8] also described a significant drop in intraoperative major complications (ureter, bladder, and bowel lesions), from 4.6% to 1.6% (in a total of 2434 patients) when the surgeon had performed more than 30 LH procedures compared with those who had performed fewer than 30 procedures. Our

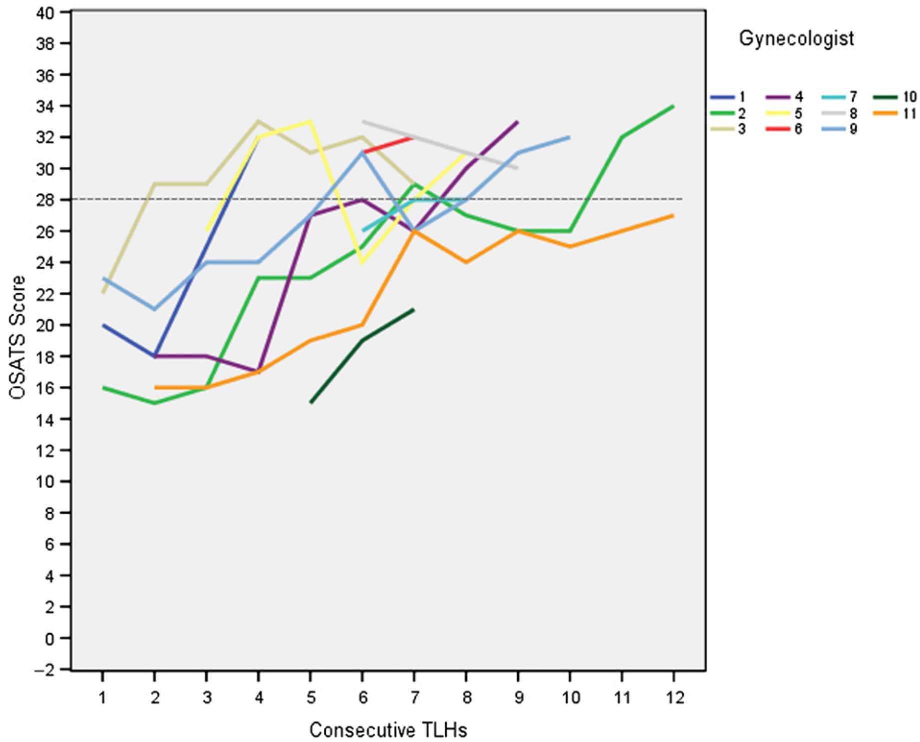

Fig. 2. Objectively Structured Assessment of Technical Skills (OSATS) learning curves for 11 participating gynecologists. TLHs = total laparoscopic hysterectomies.

intraoperative complication rate during the learning curve was 2.4% (2 of 83 procedures), and after the learning curve was 3.6% (3 of 83 procedures); postoperative major complications during the learning curve were 1.2%, and after the learning curve were 2.4%. Garry et al [17] demonstrated a similar complication rate in the eVALuate trial (7.2% and 7.1% after exclusion of conversion to laparotomy). However, in contrast to the present trial, in which surgical competence was measured qualitatively, Garry et al [17] defined surgical competence by the number of previously completed procedures, with a cutoff of 25 procedures. Compared with these numbers, the major complication rate in the present study was relatively low during the learning curve (3.6%), indicating that the presence of a visiting surgeon prevents complications during the learning curve. After the learning curve, our complication rate (6.0%) was favorable compared with that of Garry et al [17], the only other prospective multicenter trial, but higher compared with the other 3 studies. This might be explained in that these 3 studies were retrospective single-center trials and spanned a longer time and larger number of patients. In addition, retrospective studies may underestimate the rate of complications. It is reasonable to assume that in the next years, with increasing experience, the complication rate will decrease for the gynecologists who participated in our study. This has also been reported by others [19].

Table 4
Conversions to laparotomy during study

No. of conversions	Reason
During learning curve (n = 6)	Uterus too large (n = 3)
	Insufficient exposure (n = 2)
	Probable higher stage cancer (n = 1)
After learning curve (n = 14)	Uterus too large (n = 4)
	Insufficient exposure (n = 6)
	Major complication (n = 2)
	Probable higher stage cancer (n = 1)
	Instrumental problem (n = 1)

In several studies, conversions were also scored as major complications [7,18]. We decided not to score conversion as a major complication because the decision to convert and not to proceed laparoscopically can also be made for safety reasons for the patient or to prevent a complication. The most frequently observed indication for conversion was inability to perform the laparoscopic procedure because of inadequate exposure owing to adhesions or a too large uterus. After the learning curve, 14 conversions (16.9%) occurred. This was not significantly higher or lower than during the learning curve. It can be assumed that the participating gynecologists had less confidence without the mentor, and, therefore, converted more readily. Moreover, during the learning curve, the gynecologists were taught that in case of difficulty, it was preferable to convert to laparotomy to prevent complications rather than risk a complication.

Guided learning curves have been described previously, and it has been suggested that they result in fewer complications during the learning curve [15,20]. However, when implementing a new technique in this manner in an

Table 5
Clinical outcome of 166 procedures

Variable	During learning curve (n = 83)	After learning curve (n = 83)	p Value
Hospital stay, median (range), d	3.0 (2–11)	3.0 (2–37)	.18[a]
Missing data (n = 4)			
Complications, No. (%)			
Major	3 (3.6)	5 (6.0)	.72[b]
Missing data (n = 0)			
Minor	11 (13.3)	9 (10.8)	.81[b]
Missing data (n = 0)			
Conversions to laparotomy, No. (%)	6 (7.2)	14 (16.9)	.09[b]
Missing data (n = 0)			
Operating time, median (range), hr	2.00 (0.26–4.18)	1.52 (0.45–5.55)	.21[a]
Missing data (n = 6)			
Blood loss, median (range), mL	125 (10–1500)	150 (10–3500)	.14[a]
Missing data (n = 2)			

[a] Mann-Whitney test.
[b] χ^2 test.

established practice, a few previous conditions should be met. The centers participating must be within a reasonable distance for the visiting surgeon; the operating room must be equipped for advanced laparoscopic procedures, and the participating gynecologists must be familiar with the procedure, equipment, and techniques involved. After the surgeon is considered competent, ideally the visiting surgeon should still be available for consultation. The advantage of implementing a new technique in this manner is that the new procedure is implemented in the regional hospitals in their own operating rooms with their own staff and equipment. In summary, we had a uniform surgical protocol; training and assessment of all participants and monitoring of their learning curves; universally accepted criteria for complications; and an independent panel that evaluated all major complications. The disadvantages of monitoring a learning curve in this manner is that it is time consuming and costly. In the present study, the visiting surgeon was supported by UMCG in an educational setting, and the study was a preparation for a larger trial [16]. We would suggest that with this study we demonstrated that a guided learning curve by an experienced colleague, using OSATS as the feedback instrument and for assessment, is a safe way to implement an advanced laparoscopic technique. However, because the study was supported by UMCG, costs were not counted. Although this implementation study was not designed to calculate costs, it is interesting to debate how high costs may be to minimize complications; however, this was beyond the scope of this study.

Alternative options to monitoring learning curves have been described including workshops, bench or animal models, and virtual-reality programs [21–27]. Most of these methods are developed for training in basic skills of laparoscopy or as an introduction to a more advanced procedure, but most often not suitable to learn level 3 procedures. Live telesurgery was not available at the time of this feasibility and implementation study, but might be of use for experienced trainees [28]. An effective option to learn advanced laparoscopic skills is a fellowship ensuing residency; however, this is not feasible for most established surgeons [29]. A mini-fellowship [30] including an intensive course for 6 weeks might be easier for established surgeons to attend; however, such a fellowship can only be offered by clinics that specialize in a single technique (large numbers of procedures are a prerequisite for such a course). Such institutions are not available in many countries, including the Netherlands.

The OSATS has been used in trials monitoring learning curves of gynecology residents, but has not been used previously to determine competence in established surgeons and in an implementation strategy [11,22,31]. We choose this instrument to use a quality (competence score) rather than a quantity (certain number) control because the level of experience among the gynecologists differed, although all surgeons had experience in at least level 2 laparoscopy. A correlation between OSATS-score and complications during the surgical procedure was not found in this study and has not been described in the literature. There is, however, a correlation between the learning curve of a surgical procedure and the complication rate, i.e., in earlier studies [7–10] more complications are reported during than after the learning curve. Especially during training, objective assessment and structured feedback is essential to correct deficiencies [32]. Other scoring forms have been described [33]. We choose OSATS because it is a standardized form with which a lot of experience has been gained. The OSATS is not validated to determine a competence score during a learning curve in the manner we used it in this study. To achieve validation of OSATS for this use, a much larger number of established surgeons must be monitored. This is not feasible for the visiting surgeon, considering time investment and costs in a setting as described here.

In 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 OSATS is feasible. Because the advantages of laparoscopy over laparotomy in terms of quality of life and cost-effectiveness can be proved only in a randomized study, we currently are conducting a multicenter, prospective, randomized controlled trial in the Netherlands [16]. All gynecologists who participated in the present study are participating in this randomized controlled trial, which reflects effective implementation of LH in these hospitals.

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