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Objective assessment of total laparoscopic hysterectomy: Development and validation of a feasible rating scale for formative and summative feedback

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ABSTRACT

Objectives: The aims of the study were to develop and gather validity evidence for a feasible rating scale for formative and summative assessment of total laparoscopic hysterectomy in the operating theatre.
Study design: The study was a prospective observer-blinded cohort study. The rating scale was developed according to the generic format of Objective Structured Assessment of Technical Skills. We applied the contemporary framework of validity to examine validity evidence of the content, response process, internal structure, relationship to other variables, and consequences. Two experienced gynecologists constructed a preliminary version of the rating scale, which was reviewed by a multicentre team of experienced gynecologists in a modified Delphi process. The surgeons (beginners and experienced surgeons) were video recorded during live performance of total laparoscopic hysterectomies. Two blinded raters evaluated the performances independently using the rating scale. Internal consistency reliability and interrater reliability were calculated as measures of internal structure. The performances of the two groups were compared and a pass/fail score was set to show the consequences of the rating scale.
Results: The content of the rating scale was defined during three Delphi rounds and upon agreement comprised of 12 items. Sixteen participants including 8 beginners and 8 experienced surgeons performed total laparoscopic hysterectomies. The internal consistency reliability of the items was 0.95 (Cronbach's alpha), and the interrater reliabilities (Intraclass Correlation Coefficient, absolute agreement) were 0.996 for one rater and 0.998 for two raters ($P < 0.001$ for all correlations). The beginners' mean performance score was 19.2 (SD 7.1) and the experienced surgeons' score was 36.4 (SD 3.9); the groups performed statistically significantly different ($P < 0.001$). The pass/fail score was 29.3 with no false positives and no false negatives.
Conclusion: With this study, a feasible rating scale for the objective assessment of total laparoscopic hysterectomy was developed with sound validity evidence. The rating scale is suitable for both formative and summative feedback in the commencement of surgical training in gynecology.

Introduction

Laparoscopic hysterectomy is a key surgical procedure indicated for an expanded spectrum of gynecologic pathologies including both treatment of benign conditions such as uterine leiomyoma, pelvic organ prolapse, endometriosis, and pelvic infection along with staging and treatment of gynecologic malignancies [1–3]. As a minimally invasive procedure, laparoscopic hysterectomy is upheld for being a more safe technique with reduced morbidity incidence, decreased blood loss, and less pain compared with abdominal hysterectomy [1]. Other benefits are shorter hospital stay and enhanced convalescence. Laparoscopic approach is favoured by gynecologists [4]. There is a tendency towards minimal access approach to hysterectomy; the national hysterectomy database in Denmark (population 5,7 million) registered a

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total of 3797 hysterectomies in 2017 of which 84% were minimally invasive and within this percentage 70% were performed laparoscopically [5].

Although the laparoscopic mode of access is advantageous, the duration of this procedure is longer and the risk of ureteral injury is higher compared with abdominal hysterectomy [1]. Technically proficient surgeons have a prominent role in reducing laparoconversions and operative complications [6]. The procedure in itself is challenging as suggested by a reported learning curve of 30 cases and a duration of up to 10 years [7,8]. Surgical volume is necessary to achieve proficiency, however, meticulous surgical training aimed at trainees and practising surgeons to upgrade their surgical skills is important to accelerate the learning curve [9].

Workplace-based assessment can be used to develop and ensure competence through both formative feedback (ongoing monitoring of performance to offer structured feedback) and summative assessment (final monitoring of performance for certification purposes) [10]. When using direct observation during a surgical procedure the educator can detect erroneous steps and via feedback instruct the trainee to advance. Observational assessment tools and structured rating scales targeting specific surgical skills abound in the clinical setting thus indicating an augmented awareness of their inherent educational potential [11].

A formative assessment tool applicable for total laparoscopic hysterectomy to evaluate technical surgical skills has been suggested by Tremblay et al. [12]. Yet, this tool is exceedingly comprehensive thus making the assessment time-consuming and diminishing the feasibility of the tool. In addition, validity evidence has not been provided for the existing assessment tool which is sine que non to draw equitable inferences from surgeons' performances [13].

The objectives of the current study were to develop and gather validity evidence for a feasible rating scale for formative and summative assessment of total laparoscopic hysterectomy in the operating theatre.

Materials and methods

The rating scale was developed as a procedure-specific checklist according to the generic model of the Objective Structured Assessment of Technical Skills (OSATS) [14]. Each item was assessed by a 5-point rating scale with explanatory anchors in the middle and at the ends.

We examined validity evidence by applying Messick's framework composed of the following five main sources: Content, Response process, Internal structure, Relationship to other variables, and Consequences [15].

Content

The two investigators and experienced gynecologists E.H. and C.R.L. constructed a preliminary content of the rating scale. The scale was based on the international accepted gold standard for the procedure of total laparoscopic hysterectomy with laparoscopic suturing of the vaginal vault [16].

A multicentre team of experienced gynecologists from university hospitals in Denmark and Sweden reviewed and edited the preliminary version of the scale in a modified Delphi process. These gynecologists were eligible due to their responsibilities for implementing and educating the procedure total laparoscopic hysterectomy at their respective workplaces. Besides evaluating the procedural steps and the relevance of the items, the gynecologists were instructed to suggest improvements and comment on the phrasing. Consensus in the team was expected to be reached after several iterations of opinion sampling. Following each iteration the items were revised by E.H. and C.R.L. and returned to the group until settling for a gold standard for procedural competence in total laparoscopic hysterectomy.

Response process

Video recordings of live total laparoscopic hysterectomies were collected prospectively. The eligible surgeons were divided into two groups: beginners (performed < 10 procedures) and experienced surgeons (performed > 200 procedures). One investigator (E.H.) collected video recordings from the Endobase®HDD recorders which were sent to the raters. Two independent raters (C.R.L. and C.O.), who were blinded to the operator, applied the developed rating scale to assess the operator performances.

Internal structure

Internal consistency reliability (Cronbach's alpha) was calculated to explore the extent of correlation between the different items of the assessment scale. To assess the agreement between the raters, interrater reliabilities (Intraclass Correlation Coefficient (ICC), absolute agreement definition) were calculated for one and two raters, respectively.

Relations to other variables

The performances of the beginners and the experienced surgeons were compared by their mean scores and the independent samples *t* test.

Consequences

A pass/fail score was set to demonstrate the consequences of performance assessment. The Contrasting Groups' Method was applied, that is, the intersection score between the score distributions of the beginners and the experienced surgeons [17]. We intended for as few false positives (passed beginners) and as few false negatives (failed experienced surgeons) as possible.

Statistical analysis

Analyses were conducted in SPSS Statistics version 24.0 (IBM, NY, USA). *P*-values less than 0.05 were considered statistically significant.

Ethics

No ethical approval was needed according to the Danish National Committee on Biomedical Research Ethics. Only procedures on patients already scheduled for total laparoscopic hysterectomies were included and all less experienced participants were supervised by a consultant to ensure the safety of the patient. Informed oral consent was obtained from the assessed surgeons, the video recordings were made anonymous, and patients cannot be identified.

Results

Content

From January 2016 to November 2016 the content of the rating scale was agreed upon after three Delphi rounds by nine

experienced gynecologists from eight different university hospitals, who contributed to all of the rounds (the response rate was 100%). The preliminary version of the scale contained 16 items which was then reduced to 14 items in the second round and finally reduced to 12 items in the third round (Table 1). The excluded items had emphasis on suture technique, which varied among the gynecologists in the Delphi team. No items were added. In every round the phrasing of the items was adjusted as advised by the team.

The 5-point rating scale was recoded into a score from 0 to 4 points for statistical analysis [18].

Response process

Sixteen procedures of total laparoscopic hysterectomy were performed by 16 participants counting eight beginners and eight experienced surgeons. These 16 video recordings were rated independently by the two blinded raters using the established rating scale.

Internal structure

The internal consistency reliability of the items measured as Cronbach's alpha was 0.95 ($P < 0.001$). The interrater reliabilities (Intraclass Correlation Coefficient (ICC), absolute agreement definition) were 0.996 for one rater and 0.998 for two raters (both $P < 0.001$).

Relations to other variables

The beginners' mean score was 19.2 (SD 7.1) and the experienced surgeons' mean score was 36.4 (SD 3.9) (Fig. 1). The group mean scores were statistically significantly different ($P < 0.001$).

Table 1
Rating scale for the objective assessment of total laparoscopic hysterectomy.

1. **If preservation of the ovary**: Division of fallopian tube and utero-ovarian ligament	1 Uses electro-surgery or cuts too close to ovarian artery. High risk of bleeding or thermal damage on the ovary	2	3 Mostly safe use of instruments. Low risk of arterial damage, minimal thermal damage on the ovary	4	5 Identifies clearly and divides skillfully with no bleeding, tissue trauma, or thermal damage on the ovary
2. **If oophorectomy:** Division of the infundibulopelvic ligament	1 Inadequate ligation of the ovarian artery e.g. with bleeding	2	3 Mostly safe ligation of the ovarian artery	4	5 Identifies clearly and divides skillfully with no bleeding or tissue trauma
3. Dividing the round ligament and opening the broad ligament	1 No division of the ligament in separate layers or inadequate surgery with tissue damage or bleeding	2	3 Mostly safe opening and division of the broad ligament into separate layers. Little bleeding or tissue trauma	4	5 Perfect opening and division of the broad ligament into separate layers with minimal bleeding
Care for the ureter and the pelvic wall	The ureter not visually identified, using electro-surgery or cutting in unfamiliar areas, causing risk of damage to the ureter		Mostly safe handling but required time, or performed suboptimal		Perfectly safe, skillfully identified ureter, no risk of thermal damage to the ureter
5. Opening the utero-vesical peritoneum and dissection of the bladder caudally to present the cervico-vaginal margin	1 Major difficulty to retract the tissue or grapping the bladder, causing risk of damage	2	3 Minor difficulty or inadequate dissection of the bladder peritoneum	4	5 Perfect presentation and dissection of the bladder peritoneum
6. Identification and skeletonizing (dissecting)	1 Vessels poorly identified and /or insufficiently skeletonized	2	3 Vessels identified and acceptably skeletonized	4	5 Perfect identification and perfectly skeletonized
7. Presentation and ligation of the uterine arteries	1 Using electro-surgery too close to the uterine arteries causing bleeding, inadequate identification, or ligation of uterine arteries	2	3 Mostly safe dissection and minimal risk of damage. Adequate identification and ligation of the uterine arteries	4	5 Perfectly safe use of electro-surgery, perfect presentation and ligation of the uterine arteries
Opening the vagina: Cephalic push of cup rim and visualizing the cervico-vaginal delineation. (Using the assistant to provide cephalic push)	Insufficient cephalic push (cup rim), poorly visualized cervico-vaginal delineation or difficulty or heavy bleeding in circumferential colpotomy		Sufficient cephalic push (cup rim), well visualized cervico-vaginal delineation but difficulty or unnecessary bleeding in circumferential colpotomy		Perfect cephalic push (cup rim), perfect visualized cervico-vaginal delineation, skillfully circumferential colpotomy, minimal bleeding
9. Suturing: Catching the needle	1 Major difficulty catching the needle	2	3 Minor difficulty cathcing the needle	4	5 Perfect catch of the needle
10. Driving (swinging) the needle through tissue	1 Imprecise driving of needle or excessive force or incorrect swing	2	3 Minor difficulty driving the needle, suboptimal swing of the needle	4	5 Perfect, accurate and fast swing of the needle through tissue, minimal force used
11. Placement and depth of sutures in the vaginal cuff	1 Suboptimal distance/uneven distance between sutures, bleeding	2	3 Acceptable distance and depth of sutures, few corrections	4	5 Perfect distance and depth, complete hemostasis
12. Suturing of the vagina and tying the knot (if no barbed wire sutures)	1 Imprecise handling of suture. Unfamiliar with correct technique, risk of insufficient knots	2	3 Reasonably handling of suture. Shows correct technique, acceptable knots	4	5 Perfect and correct knotting of suture. Perfect knots
Time consumption for the whole procedure (minutes) (from instrument insertion to instrument removal excluding closure of port sites):					
Uterus weight (grams):					
Sum of points:					

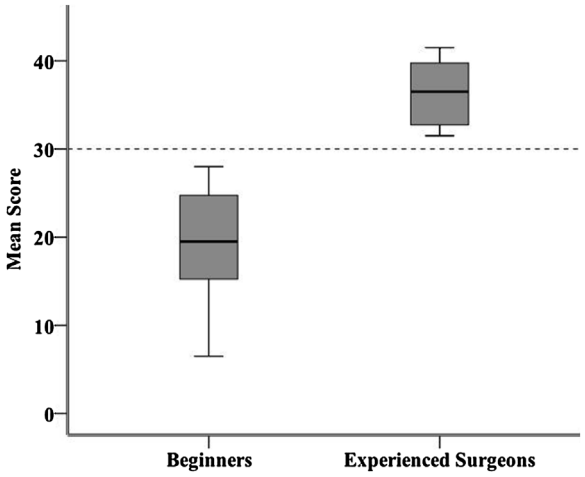

Fig. 1. The box plot shows the performances of the beginners and the experienced surgeons. The median values, maximum scores, and minimum scores are depicted. The dashed line demonstrates the pass/fail score.

Consequences

The pass/fail score was 29.3 set by the Contrasting Groups' Method (Fig. 2). Accordingly, no false positives and no false negatives were identified.

Discussion

With this study, we present a feasible rating scale in total laparoscopic hysterectomy for formative and summative assessment of surgical performance.

Content

Validity evidence of the content was established by the modified Delphi process. The premise of the 'Delphi' is that a distilling of the topic at aim can be attained when summing up expert opinions [19]. A risk of subjectivity coexists with this premise, however, we prioritized the fact that expert opinions are an acknowledged source of data [20]. With a generally accepted number of qualified physicians in the Delphi team from two countries and eight different hospitals we endeavored to gain representativeness [21]. Also, the anonymity in the team averted the likelihood of subject bias and peer group pressure. The team settled for 12 items in the final rating scale which is apt and feasible compared with other examples of the OSATS [22].

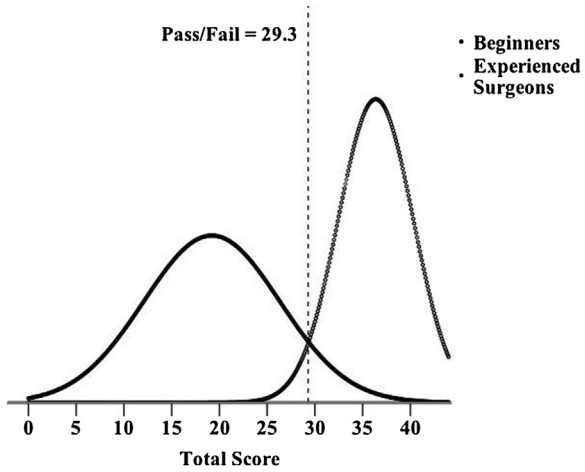

Fig. 2. The pass/fail score obtained by the Contrasting Groups' Method is illustrated by the dashed line.

Response process

We used blinded video recordings to rule out potential sources of bias as may be the case with direct observation [23]. Nevertheless, there is a slight risk that the raters recognised certain details of the surgical performance thereby identifying certain participants. This could potentially have biased the assessments. Another potential limitation is the so-called restriction-of-range effect, which may have influenced both raters' rating approaches, provided that their ratings were restricted to one part of the scale [24].

Internal structure

The internal consistency reliability of 0.95 showed optimal *internal structure* indicating that the scale items assessed the same overall feature, that is, performance of total laparoscopic hysterectomy. Statistically significant inter-rater reliability of 0.998 between the two raters demonstrated a high level of agreement. Equally, the significant ICC of 0.996 regarding one rater indicated that no particular leniency error existed, that is, a rater lenient towards either higher or lower ratings [24]. It is encouraging that only a single rater was ample to gain sufficient reliability thus providing feasibility to the rating scale. Performing total laparoscopic hysterectomy is by itself time-consuming and therefore a post-operative assessment of the operator will not be feasible if multiple raters are needed to gain reliability. The overall compelling findings of reliability make the tool suitable for providing formative feedback, that is, repetitive assessment of competence, since a reliability coefficient of 0.70 to 0.79 is deemed acceptable [25]. Furthermore, it can also be used for high stakes summative assessment such as board certification or licensure where a reliability of greater than 0.90 is recommended.

Relations to other variables

Significant outcomes showed that the experienced surgeons outperformed the beginners. Their performances were also more consistent compared with the beginners' (Fig. 1). This finding is in alignment with the 3-stage learning model on motor skills by Fitts and Posner [26]. The model presents three conceptual stages in the sequence of motor skills acquisition starting with the cognitive stage (first stage) followed by the associative stage (second stage) and ultimately reaching the autonomous stage, in which we denote the experienced surgeons of our study. In this final stage, superb performance is carried out in a fluent manner with limited variation and minimal cognitive effort in contrast to the cognitive stage where performance is typically inconsistent, conscious, and erroneous. Similar findings of performance consistency in the experienced group are demonstrated in other studies regarding surgical and technical skills acquisition in the field of gynecology [22].

Consequences

By virtue of credentialing, a pre-set pass/fail score is of particular importance. A major strength in our study was the pass/fail score that demonstrated sound contrast between the two experience groups with no false positives or false negatives. Thus, the calculated pass/fail score possesses great *consequence* leading the beginners towards experienced level. In the scope of mastery learning, where a specific level of proficiency is achieved without any restrictions on training extent, a pass/fail score will serve as the point of reference for the physician knowing when he/she *masters*

total laparoscopic hysterectomy [27]. A systematic review on standard setting as regards to surgical training and credentialing emphasizes that such cut-offs are evident in current literature and should be estimated to demonstrate standards of technical performance both in simulated and clinical settings [28].

Though we consider this rating scale as indispensable for standardised training and assessment, we also recognise the limitation of including not more than 16 participants. This could partly be explained by the complex nature of this surgical procedure making it challenging to recruit more participants. A limited sample size could potentially hamper general inferences. However, it is worth keeping in mind that the outcomes of our study are all statistically significant and therefore germane for use in live surgery.

Another novel attempt to provide an objective assessment tool for total laparoscopic hysterectomy has been published by Knight et al. [29]. They have made a great effort in their study to compile validity evidence by applying the contemporary validity framework for an assessment tool in simulation-based training with virtual reality. In the establishment of a comprehensive training program in total laparoscopic hysterectomy, we believe, that their study would be a considerable input representing the initial level of competence [30]. Although a pass/fail score is absent in their study, beginners can benefit substantially from training in a simulation-based setting before performance of live surgery provided that they train until mastering a predefined level of proficiency, that is, mastery learning. The next advancing level in a training program for total laparoscopic hysterectomy would be supervised and formal training during live surgery as suggested in our study. Provided this rating scale, beginners will receive standardised feedback and eventually obtain certification when passing the calculated pass/fail score.

In conclusion, we purpose an objective assessment rating scale for total laparoscopic hysterectomy applicable for formative and summative assessment. The scale has proven feasible and with solid validity evidence. We stress the importance of applying this assessment scale in the commencement of gynecologic surgical training.

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Disclosures

The authors Mona M. Savran, Elise Hoffmann, Lars Konge, Christian Ottosen, and Christian Rifbjerg Larsen have no conflicts of interest or financial ties to disclose.

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