







Original Article

Use of the Limbs and Things Hysterectomy Model to Describe the **Process for Establishing Validity**

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ABSTRACT Study Objective: To demonstrate the process for establishing or refuting validity for the Limbs and Things hysterectomy

Design: Prospective study using Kane's framework for establishing validity (Canadian Task Force classification: II-2). Setting: Total laparoscopic hysterectomy (TLH) assessments completed in the operating room (OR) and simulation at 3 academic medical centers.

Participants: Obstetrics and gynecology residents (n = 26 postgraduate years 3-4), a gynecologic oncology fellow (postgraduate year 5), and a gynecology oncology attending.

Interventions: Participants were rated with the myTIPreport feedback application by nonblinded faculty in the OR after TLH. In-person, simulation-based assessments were provided by 2 faculty members blinded to experience level using myTIPreport and Global Operative Assessment of Laparoscopic Skills (GOALS). Videos of simulated TLHs were rated by 2 minimally invasive gynecology fellows.

Measurements and Main Results: OR scores for TLH steps were significantly higher than simulation assessments (p < .001) with "competent" marked more frequently in the OR. Number of robotic + conventional TLHs performed as primary surgeon was not significantly correlated with OR myTIPreport rating (Spearman r = .30, p = .14) but was significantly correlated with myTIPreport and GOALS in-person simulation ratings (Spearman r = .39 - .58, p = .001 - .04). Agreement between inperson simulation rater 1 and 2 myTIPreport assessments was 71.4% (weighted κ, .68; 95% confidence interval, .45–.90), and intraclass correlation for the GOALS overall assessment was .71 (95% confidence interval, .46-.85), indicating substantial agreement. Blinded video reviews showed similar agreement (73.1%) between raters but less correlation with experience (Spearman r = .32-.42, p = .11-.03) than in-person reviews. Using area under the receiver operating characteristic curve, mean score for the individual components of GOALS that best differentiated myTIPreport noncompetent and competent levels of performance was 4.3. Feedback acceptability and model realism were rated highly.

Conclusion: The scoring and generalization validity inferences for Limbs and Things and myTIPreport are supported when global assessments of performance are evaluated but not for individual components of the assessment instruments. Journal of Minimally Invasive Gynecology (2018) 25, 1051-1059 © 2018 AAGL. All rights reserved.

Keywords: Hysterectomy; Surgical simulation; Performance assessment

A survey of obstetrics and gynecology (OB/GYN) fellowship program directors showed that graduating OB/ GYN residents may be underprepared for advanced

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subspecialty training, implying the possible need to reevaluate the current structure of resident and fellow curriculum [1,2]. Of first-year fellows only 18% could independently perform a total laparoscopic hysterectomy (TLH), 20% could independently perform a total vaginal hysterectomy, and 46% could independently perform a total abdominal hysterectomy as rated by fellowship program directors. Simulation has shown promise in evaluating the performance of trainees and attending physicians. A previous meta-analysis of simulationbased educational assessments demonstrated that these assessments correlate positively with patient-related

outcomes [3]. The widely used Fundamentals of Laparoscopic Surgery program is used for credentialing of general surgeons; however, a systematic review suggested that more validity evidence is required to support its content (selection of tasks and scoring rubric) and consequences (favorable and unfavorable impact) assessment [4].

Simulation in gynecology has focused on teaching the steps of a procedure and providing formative feedback, but the literature is limited regarding implementation of summative, high-stakes evaluations of simulation performance before being given the opportunity to perform the procedure in the operating room (OR) [5–10]. This has limited the widespread incorporation of simulation in gynecologic education. In our experience as educators and trainees at different OB/GYN programs, many gynecologic surgery simulation programs do not include the conditions recommended for comprehensive simulation-enhanced curriculum proposed by Zevin et al [11]: "mandatory participation, proficiency-based training, distributed training schedule, and a component of overtraining (page 296)."

To address the lack of preparation of residents for independently performing surgical procedures and provide real-time feedback on surgical performance, some residencies and fellowships have begun using the myTIPreport application (https://www.mytipreport.org/) developed by the Foundation for Exxcellence in Women's Health Care, Inc. (Raleigh, NC) [12]. The application allows trainees and attending physicians to immediately evaluate resident performance after a procedure in the OR using a smartphone application. In addition, Limbs and Things LTD (Bristol, UK) developed the Surgical Female Pelvic Trainer Mk 2 to simulate laparoscopic gynecologic surgery. However, the evidence supporting the validity of the Limbs and Things trainer and myTIPreport is limited.

The objective of this study is to demonstrate the process for establishing or refuting validity using a contemporary validation methodology (Kane's validity framework) for the Limbs and Things Female Pelvic trainer and myTIPreport application [13,14]. Although the example used is for simulation and training validity, this framework has applicability to other realms in minimally invasive gynecology because it can be used for hospital privileging decisions, supporting or refuting the use of lab tests, and arguments for and against maintenance of certification components [15–17].

Methods

Design and Validity Framework Used

Messick and Kane offer detailed reviews of how validation has evolved [14,16,18]. In brief, contemporary validation is now viewed as a process and not an endpoint with different levels of evidence to support the overall construct. Kane's framework for validity was chosen because it can be used to integrate qualitative and quantitative data and multiple assessments can be integrated into the overall validity argument/

process [16]. As described in Cook et al [16], Kane's validity argument identifies 4 inferences needed to support construct validity: scoring, which is translating an observation into 1 or more scores; generalization, which is using the score[s] as a reflection of performance in a test setting; extrapolation, which is using the score[s] as a reflection of real-world performance; and implications, applying the score[s] to inform a decision or action.

Setting

The study collected evidence to support or refute these inferences using a convenience sample of OB/GYN residents, a gynecology oncology fellow, and a gynecology oncology attending and was completed at University of Florida in Jacksonville, Florida; Johns Hopkins in Baltimore, Maryland; and Mayo Clinic in Rochester, Minnesota. The study was exempt at each institution's institutional review board. The study was supported by the Mayo Clinic Graduate Medical Education Innovation Award, a \$30,000 grant that funded the simulation models and statistics.

Participants and Interventions

Residents (postgraduate years [PGYs] 3-4), a gynecology oncology fellow (postresidency), and a gynecology oncology attending (postresidency) were invited to participate in the hysterectomy simulations between August 2016 and December 2016. The 2 postresidency participants were chosen by the study coordinator because they recently completed training and their age was similar to the resident participants in an attempt to blind the in-person evaluators. They were instructed to not inform the in-person reviewers of their training level. Before participation in the simulations, de-identified demographic data, including the training level of the participant and number of each type of TLHs performed as a primary surgeon, were entered onto a paper form and placed in an anonymous envelope by participants. The participant transcribed his or her most recent (within a month of the simulation) myTIPreport evaluation from the OR for the type of hysterectomy that was going to be simulated to a de-identified printout of a blank myTIPreport evaluation. The myTIPreport assessments use the Dreyfus 5-stage model of adult skill acquisition: novice, advanced novice, apprentice, competent, expert, or not performed for each step of the procedure and an overall assessment of performance [19]. The myTIPreport application has written rater training instructions to explain when to use the performance ratings based on the level of guidance that is needed for each step of the procedure. This printout with the transcribed evaluation was entered into the anonymous envelope.

Simulated TLHs were then performed by the study participants between August 2016 and December 2016 using the Limbs and Things Surgical Female Pelvic Trainer Mk 2 (Fig. 1), a mobile laparoscope (TelePack; Karl Storz, Tuttlingen, Germany), and either an Ethicon Harmonic

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