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Face, Content, and Construct Validations of Endoscopic Needle Injection Simulator for Transurethral Bulking Agent in Treatment of Stress Urinary Incontinence

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INTRODUCTION AND OBJECTIVES: Endoscopic injection of urethral bulking agents is an office procedure that is used to treat stress urinary incontinence secondary to internal sphincteric deficiency. Validation studies important part of simulator evaluation and is considered important step to establish the effectiveness of simulation-based training. The endoscopic needle injection (ENI) simulator has not been formally validated, although it has been used widely at University of California, Irvine. We aimed to assess the face, content, and construct validity of the UC, Irvine ENI simulator.

METHODS: Dissected female porcine bladders were mounted in a modified Hysteroscopy Diagnostic Trainer. Using routine endoscopic equipment for this procedure with video monitoring, 6 urologists (experts group) and 6 urology trainee (novice group) completed urethral bulking agents injections on a total of 12 bladders using ENI simulator. Face and content validities were assessed by using structured quantitative survey which rating the realism. Construct validity was assessed by comparing the performance, time of the procedure, and the occlusive (anatomical and functional) evaluations between the experts and novices. Trainees also completed a postprocedure feedback survey. Effective injections were evaluated by measuring the retrograde urethral opening pressure, visual cystoscopic coaptation, and postprocedure gross anatomic examination.

RESULTS: All 12 participants felt the simulator was a good training tool and should be used as essential part of urology training (face validity). ENI simulator showed good face and content validity with average score varies between the experts and the novices was 3.9/5 and 3.8/5, respectively. Content validity evaluation showed that most aspects of the simulator were adequately realistic (mean Likert scores 3.9-3.8/5). However, the bladder does not bleed, and sometimes thin. Experts significantly outperformed novices ($p < 001$) across all measure of performance therefore establishing construct validity.

CONCLUSION: The ENI simulator shows face, content and construct validities, although few aspects of simulator were not very realistic (e.g., bleeding).This study provides a base for the future formal validation for this simulator and for continuing use of this simulator in endourology training. (J Surg Ed 75:1673−1678. © 2018 Association of Program Directors in Surgery. Published by Elsevier Inc. All rights reserved.)

KEY WORDS: surgical simulation, endoscopic skills, bladder neck injection, urinary incontinence, urethral bulking agent, simulator validity

COMPETENCIES: Patient Care, Practice-Based Learning and Improvement

INTRODUCTION

One approach to the treatment of mild stress urinary incontinence (UI) caused by intrinsic sphincter deficiency in female patients or by prostatectomy in male patients, is an endoscopic injection of urethral bulking agents (UBAs) such as polydimethylsiloxane (Macroplastique). UBAs are injected either into the bladder neck or periurethrally, to increase the resistance of the bladder neck and urethra and achieve continence.[1-4] The success of this procedure is dependent on the accuracy of needle placement, the injection method,

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and the experience of the surgeon performing the procedure. Endoscopic guidance is essential to ensure accurate placement of the UBA into the submucosal layer and to reveal adequate expansion under the bladder neck mucosa.[3] However, there are increasing constraints on surgical training due to several factors including reduced trainee work hours, higher operating room, and supply costs, a focus on further minimizing medical errors, and the ethical dilemmas surrounding the acquisition of surgical skills on patients. Thus, there is a need for validated simulators that can be used to acquire surgical skills and increase resident competency outside of the operating room.[5] In order to provide an opportunity for competency training in the endoscopic treatment of UI, the simulator must be realistic and teach the skills needed in the OR.[6]

Validation studies are an important part of simulator evaluation and are considered an important step to establish the effectiveness of simulation-based training. The endoscopic needle injection (ENI) simulator has not been formally validated, although it has been used widely at UC Irvine. The aim of this study was to assess the face, content, and construct validity of the UC Irvine ENI simulator.

MATERIALS AND METHODS

Study Participants

This is a single-institution study based on the data collected during a session of our curriculum, which has been used during residency training to both teach and improve the skills necessary for the endoscopic correction of UI. At the University of California, Irvine (Orange, CA), 6 urologists (experts group) and 6 urology trainees (novice group) completed urethral bulking agent (UBA) injections on a total of 12 porcine bladders using ENI simulator.

Simulator Setup

Dissected female porcine bladders were mounted in a modified Hysteroscopy Diagnostic Trainer (Fig. 1). Using routine endoscopic equipment from Karl Storz (cystoscopy tower with the cystoscopy lens 0 degree, 20 Fr sheath, light, and camera HD) for this procedure with video monitoring. Surgical lubricant was mixed with methylene blue to simulate the UBA and allow immediate visibility and visual feedback of the created mounds to the trainees. The syringe was filled with this simulated UBA. An endoscopic macroplastique needle and the reusable administration device (Cogentix Medical) used for performing transurethral injections with UBAs was primed before each trainee began injection to ensure the integrity of the needle. Trainees were introduced to the topic of endoscopic bladder neck injection for the treatment of UI, with instructions on where and how to inject before starting the procedure. Each trainee was instructed to put the needle through the cystoscope and inject 1 cc of the simulated UBA into the bladder neck at the 3, 6, and 9 o'clock positions. The transurethral tunneling technique was explained to the trainees, to ensure they understood the subtleties of injection and practiced proper technique.[5] The trainees photographed the bladder neck preinjection and postinjection to determine the reduction in the surface area after coaptation.

FIGURE 1. Dissected female porcine bladders were mounted in a modified Hysteroscopy Diagnostic Trainer.

Assessment

All participants performed ENI of UBA on the simulator. Following the simulation, all participants completed structured quantitative questions which assess the face, content, and construct validities (Tables 1 and 2). These questions were designed to determine the perception of the simulator on a 5-point Likert scale (1: poor, 5: excellent).

The face validity was assessed by how useful the simulator was as a training method for endoscopic UBA and how such simulator training will help in understanding the principle of the UBA. The means were compared between the experts and the novices. Content validity was assessed by analysis of the survey from the experts' rating of the realism of the simulator, while the construct validity was assessed through an objective and subjective evaluation of the technical skill (i.e., the bladder was taken out of the model, opened sagittally through the detrusor, and evaluated). The injection sites were evaluated with respect to the position of the mounds along the bladder neck and the bladder wall submusocal layer. If the mound had extravasated and could be seen from the outside was recorded as a measure of the trainee's performance (Fig. 2). A blinded expert graded the injection on a scale of 1 to 5 (1 = unacceptable, 5 = excellent) based on 3 separate parameters: performance, time of the procedure, and occlusiveness by anatomical and functional evaluations.

In order to assess the efficacy of UBA injection in treating UI, we objectively measured the retrograde leak pressure with a manometer before and after each injection.

Photographs of the coaptation of the urethra with the simulated UBA injections were obtained. The occluded

TABLE 1. Post-Procedure Trainee Feedback for Novices Group

	1: Strongly Disagree	2: Disagree	3: Neutral	4: Agree	5: Strongly Agree	Mean
1. I found this simulator training helped me to understand the principles of UBA injections.	0	0	0	2	4	4.6
2. I found the model provides a reasonable representation of the proximal urethra and bladder.	0	0	0	4	2	4.3
3. I would attend future training sessions with this simulator.	0	0	0	0	6	5
4. I believe that practicing with this simulator will improve my skills in injecting urethral bulking agents for the treatment of urinary incontinence.	0	0	0	1	5	4.8
5. I believe that an attending's real-time evaluation of my technique on the simulator is an appropriate assessment tool for my skills in performing urethral bulking agent injections.	0	0	0	4	2	4.3
6. I believe that the session increased my confidence in my UBA injection techniques.	0	0	0	1	5	4.8
7. How useful would the simulator be as a training tool for endoscopic UBA.	0	0	0	1	5	4.8
8. Training with this simulator should be required before entering the OR for the procedure of urethral bulking agent injection for the treatment of urinary incontinence	0	0	0	2	4	4.6
9. The urethra and the bladder tissue felt realistic	0	0	1	5	0	3.8
10. The injection of the bucking agent was realistic	0	0	1	4	1	4
11. The spatial orientation of the urethra and bladder was realistic	0	1	1	4	0	3.5
12. The instruments were realistic	0	0	0	5	1	4.1
13. The coaptations after the injection were realistic	0	0	0	5	1	4.1

TABLE 2. Postprocedure Trainee Feedback for Experts Group

	1: Strongly Disagree	2: Disagree	3: Neutral	4: Agree	5: Strongly Agree	Mean
1. I found this simulator training helped me to understand the principles of UBA injections.	0	0	1	4	1	4
2. I would attend future training sessions with this simulator.	0	0	0	1	5	4.8
3. I believe that practicing with this simulator will improve my skills in injecting urethral bulking agents for the treatment of urinary incontinence.	0	0	0	5	1	4.2
4. I believe that an attending's real-time evaluation of my technique on the simulator is an appropriate assessment tool for my skills in performing urethral bulking agent injections.	0	0	1	4	1	3.5
5. I believe that the session increased my confidence in my UBA injection techniques.	0	0	1	5	0	4.2
6. How useful would the simulator be as a training tool for endoscopic UBA.	0	0	0	5	1	4.2
7. Training with this simulator should be required before entering the OR for the procedure of urethral bulking agent injection for the treatment of urinary incontinence	0	0	0	6	0	4
8. The urethra and the bladder tissue felt realistic	0	0		6	0	4
9. The injection of the bucking agent was realistic	0	0	4	2	0	3.3
10. The spatial orientation of the urethra and bladder was realistic	0	0	5	1	0	3.1
11. The instruments were realistic	0	0	0	6	0	4
12. The coaptations after the injection were realistic	0	0	4	2	0	3.3

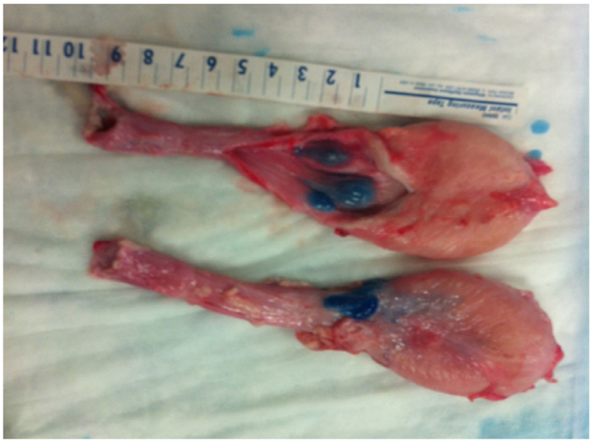

FIGURE 2. The bladders were cut through to visualize the mounds created. The top bladder shows mounds that are in the correct position along the bladder neck and the correct layer along the bladder wall. The bottom bladder shows mounds that have extravasated to the outside.

area was then measured by cytoscopic photographs of the urethra before and after injections (Fig. 3). The percentage of reduction of open space in the urethra was used as an objective marker for grading the failure or success of the UBA injection. In order to assess the efficacy of UBA injection in treating UI, we objectively measured the retrograde leak pressure with a manometer before and after each injection (Fig. 4).

Statistical Analysis

To compare the performance of the expert (fellows and the attending surgeon) and novice (residents and medical student) groups, nonparametric analyses using Wilcoxon rank-sum test (Statistical Package for the Social Sciences version 16); a 2-tailed significance level of $p < 0.05$ was considered significant.

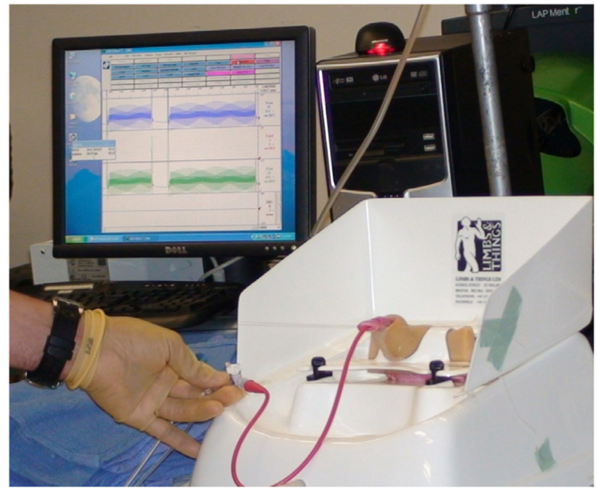

FIGURE 4. Retrograde leak pressure with a manometer was measure before and after injection.

RESULTS

Face Validity

Six experts group (1 experienced attending, 5 female pelvic medicine, and reconstruction surgery [FPMRS] fellows), and 6 novices group (5 urology residents and 1 medical student) completed the UBA injections using the ENI simulator. Experts and novices felt that the simulator would be useful as a training method for endoscopic UBA with a mean of 4.2 for experts and 3.5 for novices. They also found this simulator helped in the understanding of the principles of UBA injection with a mean of 4 for experts and 3.8 for novices (Table 3). A Likert score of 4/5 has been reported to be adequate to demonstrate face validity,[7] and consequently, our study demonstrated face validity of this model as a training tool.

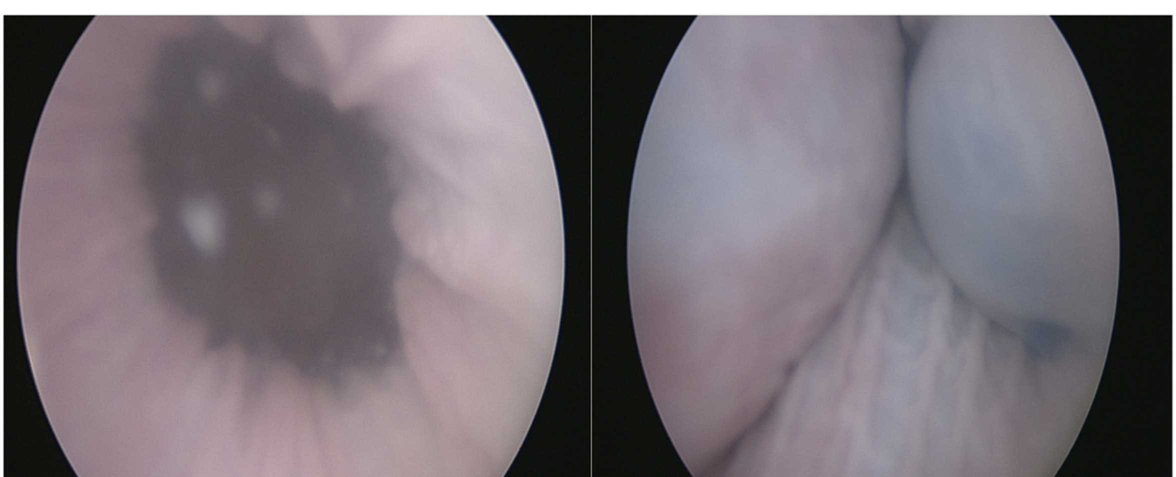

FIGURE 3. Cystoscopic views were taken of the bladder neck (A) before and (B) after the injection to determine the reduction in the open surface area after coaptation with the UBA.

TABLE 3. Face Validation Questionnaire

Question to Subjects (Based on 1-5 Likert Scale, 5 = Excellent	Experts (Mean)	Novices (Mean)
How useful would the simulator be as a training methods for endoscopic UBA	4.2	4.8
Training with this simulator should be required before entering the OR for the procedure of urethral bulking agent injection for the treatment of urinary incontinence	4	4.6
I believe that practicing with this simulator will improve my skills in injecting urethral bulking agents for the treatment of urinary incontinence.	4.2	4.8
I found this simulator training helped me to understand the principles of UBA injections.	4	4.6
I believe that an attending's real-time evaluation of my technique on the simulator is an appropriate assessment tool for my skills in performing urethral bulking agent injections.	3.5	4.3

Content Validity

Content validity was assessed by 6 experts using qualitative surveys. The experts rated in a mean 4/5 on Likert scores in most of the questions. Although some experts felt the aspects of the model were acceptable, there was considerable variability in experts rating on content validity with some aspects of the simulator not appearing realistic; furthermore, most of the comment showed that the model does not bleed. The spatial orientation of the urethra and the bladder and the injection of the bulking agent were rated in a mean of 3.1 and 3.3, respectively (Table 4).

Construct Validity

Data were available on a total of 12 bladders. Multiple assessment measures including technical skill assessment were used to evaluate the injection techniques and the integrity of the mounds created. Of the 12 bladders injected, 6 were performed by the experts group. Three of the 6 injections (50%) were observed to have mounds that extravasated outside of the bladder. The other 6 bladders were injected by novices group, 4 of the 6 bladders (66%) were observed to have mounds that extravasated outside of the bladder (Table 5).

The performance of the fellows and the residents were rated on their performance (the time required to perform the injection, the overall time, and occlusiveness of the resulting mound); on a scale of 1 to 5 by an expert in endoscopic UBA injection procedures (G.G.).

In general, the overall mean of performance was significantly higher for experts than novices (4.1/5 vs 2.6 /5, respectively, $p < 0.0036$). The experts rated better in all categories of the procedure, especially the occlusiveness score 4.1/5 vs 2.7/5 with $p < 0.0101$, while the retrograde pressure measurement unexpectedly decreased in 5 bladders from 12 (42%). This finding was secondary to urethral tear and leakage of the injected fluid. The mean of the urethral closing pressure was higher with the expert group than the novice ($p < 0.003$). The mean of the whole procedure time was 6.1 minutes for the expert and 12.1 minutes for the novice group ($p < 0.001$). The step for the injection to the completion of the mound was recorded. We found that the experts completed this step faster than the novices with a mean of 4.2 minutes and 6.0 minutes for the novice group ($p < 0.002$).

DISCUSSION

Surgical simulators have become an increasingly crucial component of surgical residency programs. The training and assessment of residents on simulators can shorten the length of time needed to acquire skills and ultimately improve surgical outcomes, as well as patient safety.[8] With the learning curve of endoscopic injections and the expense of the UBA, this simulator offers great value to urology residents, fellows, and practicing urologists for developing skills or fine-tuning the delicate motion required for maintaining the stability of the needle and puncturing the submucosa at the proper angle and depth. Face and content validity of this simulator showed and confirmed the statistical difference that it is realistic and

TABLE 4. Content Validation Questionnaire

Question to Subjects (Based on 1-5 Likert Scale, 5 = Excellent	Experts (Mean)	Novices (Mean)
The instruments were realistic	4	4.1
The urethra and the bladder tissue felt realistic	4	3.8
The spatial orientation of the urethra and bladder was realistic.	3.1	3.5
The injection of the bulking agent was realistic	3.3	4
The coaptations after the injection were realistic	4	4.1

TABLE 5. Technical Skill Assessment

Generic Skill (Based on 1-5 Likert Scale, 5 = Excellent	Experts (Mean)	Novices (Mean)	p Value
Time injection to the completion of the mound	4.2 min (2–6.9)	6.0 min (4.6–8)	<0.002
Total procedure time	6.1 min (4.5–7.9)	12.1 min (10–14.6)	<0.001
Occlusiveness score	4.5/5	3.6/5	<0.0101
Overall performance	4.1/5	2.6	<0.003
The quality of the final procedure (retrograde pressure measurement)	4.8	2.6	<0.001

suitable for teaching purposes. Construct validity was confirmed for most of the steps of the endoscopic injection procedure. Although our project is not without limitation. First, we are aware that we have a small sample size to confirm the validity of our model, but this qualitative research with its statistical analysis could consider as a base for future formal validation of this model.

Secondly, bladder compliance and wall thickness are not uniform and will most likely vary from the bladders injected for stress UI in a clinical setting. To minimize the effect of this limitation on our results, we kept low volumes of water in the bladder or performed a small posterior cystotomy, to allow for leakage of the injected fluid and to prevent overdistension.

Measuring urethral retro-resistance pressure (URP) allows occlusiveness after injection to be evaluated, as the pressure curve eventually plateaus (Fig. 4).[9,10] The methods for obtaining accurate URP may be improved in future studies by ensuring the integrity of the urethra. Urethral tears are often unavoidable during training. Furthermore, the change in URP and its correlation with postprocedure UI needs to be studied in a clinical population.

There is controversy in the surgical and educational literature regarding the level of realisticity of the model or simulator to be a useful training tool. It is likely that the level of simulator reality required is dependent on the task being taught and on the context of the training. This study showed that although some aspects of the model are not realistic, it is still useful for training in the early part of the learning curve.

The effectiveness of continued practice with the simulator as a means of improving the operative skills required for the effective and consistent treatment of UI with the use of UBA must be evaluated in future studies. We believe this pilot study paves the road for the future of training, assessment, and skill improvement by simulating the endoscopic correction of UI.

CONCLUSION

Our study provides evidence to support the continuing use of the UCI ENI simulator in urology training as it clearly showed face, content, and construct validities. Although few aspects of the simulator were not very realistic, it was considered a good training model. This study provides a basis for the future formal validation for this simulator with an expansion of the sample size and could be used to develop a performance-based training curriculum.

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