

Multidimensional Validation of a 3D-Printed Simulator for Transurethral Enucleation of the Prostate Incorporating Simulated Bleeding and Laser Hemostasis

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Abstract

Purpose

To evaluate the face and content validity, preliminary known-groups validity evidence, and task workload of a three-dimensional (3D)-printed simulator for transurethral enucleation of the prostate (TUEP) incorporating continuous simulated vascular flow and laser hemostasis.

Methods

In this prospective single-center validation study, six less-experienced and six expert urologists each completed one standardized simulated TUEP using a 60-g prostate model. Face validity was assessed using 7-point ratings, and content relevance using 4-point ratings and content validity indices (CVIs). Objective procedural performance was compared between experience groups, and task workload was explored using a modified NASA Task Load Index–based questionnaire.

Results

Overall realism was rated 5.50 (5.00–6.00). All eight educational-content items achieved an I-CVI of 1.00, with S-CVI/Ave and S-CVI/UA both 1.00. Experts had shorter enucleation times than less-experienced participants (34.50 ± 3.02 vs 45.67 ± 5.24 min; $p = 0.001$) and shorter vascular-management and laser-hemostasis times (3.83 ± 0.75 vs 7.67 ± 2.34 min; $p = 0.009$). Several workload dimensions also differed between groups.

Conclusion

The simulator demonstrated favorable face and content validity, while selected objective performance measures provided preliminary known-groups validity evidence. Its ability to reproduce simulated bleeding and laser hemostasis may support early-stage structured TUEP training, although longitudinal studies are required to establish learning effects and clinical transfer.

1. Introduction

Benign prostatic hyperplasia (BPH) is common in older men and may require surgical treatment when lower urinary tract symptoms are refractory to conservative management. TUEP is a guideline-recommended option that provides effective tissue removal and durable functional outcomes [1, 2]. However, TUEP is technically demanding and requires recognition of the verumontanum, external urethral sphincter, and surgical capsule, together with proficiency in enucleation, vascular management, and laser hemostasis. Learning-curve studies suggest that approximately 30–50 cases may be required before relatively stable performance is achieved [3, 4].

Simulation may facilitate early skill acquisition outside the operating room. Cadaveric, virtual-reality (VR), and physical models have all been used for TUEP training, but each has limitations [5–7]. Cadaveric models are resource intensive and lack true circulation, whereas VR systems may provide limited tissue haptics and require specialized hardware [5, 8–10]. Physical models permit use of clinical instruments and can reproduce key anatomy, but previous TUEP simulators have incompletely represented bleeding, hemostasis, and safety-related structures [11–13].

We therefore developed a 3D-printed TUEP simulator incorporating a capsule–adenoma plane, external urethral sphincter, simulated vessels with continuous flow, and laser hemostasis. This study evaluated its face and content validity, preliminary known-groups validity evidence based on objective performance, and task workload across surgeons with different TUEP experience.

2. Materials and Methods

2.1 Study design and participants

This prospective, single-center simulation validation study was conducted at the First Hospital of Tsinghua University from December 2023 to May 2024. The evaluation comprised face validity, content validity, preliminary known-groups validity evidence based on objective performance, and exploratory task-workload assessment.

Twelve urologists were enrolled and prespecified as less-experienced ($n = 6$) or expert ($n = 6$). Less-experienced participants had never independently completed a full TUEP procedure, although previous observation, assistance, or performance of selected steps under supervision was permitted. Experts had independently performed > 50 TUEP procedures, a threshold selected on the basis of previous learning-curve literature [3]. None had previously used the study simulator. We hypothesized a priori that experts would demonstrate greater procedural efficiency and better safety-related performance.

2.2 Simulator and standardized procedure

The simulator consisted of a reusable training apparatus and replaceable standardized 60-g prostate models. The model incorporated a hydrogel adenoma, surgical capsule with an identifiable capsule–adenoma plane, urethra, verumontanum, external urethral sphincter, simulated vasculature, bladder, and periprostatic tissue. A perfusion system generated continuous simulated vascular flow, permitting bleeding and laser hemostasis during enucleation. Bladder-wall and sphincter contraction–relaxation were mechanically simulated.

All procedures used a Youlu thulium fiber laser (60 W, 2.0 J, 25 Hz; 550- μ m fiber) and a 26-Fr HAWK laser resectoscope with a 30° lens. Participants received the same orientation and live demonstration and then completed one standardized simulated TUEP procedure using the en bloc enucleation technique. Briefly, an inverted U-shaped incision adjacent to the verumontanum was used to expose the surgical capsule; the adenoma was dissected toward the 12-o'clock position using blunt sheath dissection and

laser cutting, followed by incision of the anterior groove and continued dissection along the capsular plane until complete detachment. Each participant performed one procedure to minimize repeated-practice effects.

A TUEP surgeon with > 500 independent cases supervised procedural standardization and technical safety but did not assess study outcomes. This supervisor had participated in simulator development. The six experts who completed face- and content-validity assessments had not participated in simulator development.

2.3 Objective performance and preliminary known-groups validity evidence

The prespecified primary performance measures were enucleation time and time for vascular management and laser hemostasis. Enucleation efficiency was calculated as the fixed adenoma mass (60 g) divided by enucleation time and was treated as a derived measure rather than independent validity evidence. Safety-related outcomes included capsular perforation, verumontanum injury, external urethral sphincter injury, and simulated procedural success, defined as complete enucleation without any of these injuries. Detailed operational definitions are provided in the Supplementary Methods (Online Resource 1) .

All objective outcomes were recorded by an independent TUEP surgeon with > 260 procedures who was not involved in simulator development. The assessor was not blinded to participants' experience level. Given the two-group design and small sample, these comparisons were intended to provide preliminary known-groups validity evidence rather than establish a complete skill gradient.

2.4 Face and content validity

After simulation, the six experts independently completed a realism questionnaire adapted from the Simulation Realism Survey [14]. Visual, anatomical, mechanical, and overall realism were rated on 7-point Likert scales (1 = strongly disagree; 7 = strongly agree). Technical difficulty was rated separately from 1 (substantially easier than clinical TUEP) to 7 (substantially more difficult), with 4 indicating comparable difficulty.

Content validity was evaluated using eight educational domains adapted from the Global Assessment of Urological Endoscopic Skills [15]. Experts first rated the relevance of each domain on a 4-point scale; ratings of 3 or 4 were considered relevant. Item-level CVI (I-CVI), scale-level CVI by average agreement (S-CVI/Ave), and universal agreement (S-CVI/UA) were calculated [16, 17]. An I-CVI ≥ 0.83 and S-CVI/Ave ≥ 0.90 were prespecified as acceptable. Experts then rated how well the simulator delivered each educational function on a 7-point Likert scale. Complete questionnaires and detailed item-level validity results are provided in Online Resource 1 (Tables S2–S3 and Supplementary Appendices S1–S3).

2.5 Task workload

Task workload was explored using a modified questionnaire based on the NASA Task Load Index (NASA-TLX) [18]. The six original dimensions—mental demand, physical demand, temporal demand, performance, effort, and frustration—were retained, with two study-specific dimensions, technical difficulty and psychological interference, added. Three urologists not included in the final analysis piloted the questionnaire for clarity. Each dimension was rated independently from 1 to 20 immediately after simulation; no composite NASA-TLX score was calculated. These analyses were considered exploratory. Detailed task-workload results and the complete questionnaire are provided in Online Resource 1 (Table S4 and Supplementary Appendix S4).

2.6 Statistical analysis and ethics

No formal sample-size calculation was performed because this was an exploratory validation study. Analyses were conducted using SPSS 26.0. Continuous variables were compared using *independent-samples t-tests* (with *Welch* correction when required) or *Mann–Whitney U* tests according to distribution; categorical variables were compared using *Fisher’s exact test*. Ordinal ratings are reported as *median* (first and third quartiles [*Q1–Q3*]). Tests were two-sided, with $p < 0.05$ considered statistically significant. No adjustment for multiple comparisons was applied to exploratory workload analyses.

This noninterventive simulator-based educational study involved no patients, animals, or biological specimens. Under institutional requirements, formal ethics approval was not required. All participants volunteered and provided informed consent.

3. Results

3.1 Participant characteristics

Twelve urologists completed the study. None of the six less-experienced participants had independently completed a full TUEP; two had assisted in > 50 cases and performed selected steps under supervision, whereas four had mainly observed or occasionally assisted. All six experts had independently completed > 50 TUEP procedures. Median age was 32 years in the less-experienced group and 51 years in the expert group. No participant had previously used a TUEP-specific simulator. Key participant characteristics are presented in Table 1, with additional baseline information provided in Supplementary Table S1.

Table 1
Baseline characteristics of participating urologists.

Age, yr <i>Median(Q1-Q3)</i>	Less-experienced (n = 6)	Experts (n = 6)	Total (n = 12)
	32.00 (29.25–34.50)	51.00 (42.25–61.25)	38.00 (32.00–52.00)
Male, n (%)	6 (100%)	6 (100%)	12 (100%)
Professional rank, n (%)			
Chief physician	0 (0%)	2 (33.3%)	2 (16.7%)
Associate chief physician	0 (0%)	4 (66.7%)	4 (33.3%)
Attending physician	4 (66.7%)	0 (0%)	4 (33.3%)
Resident physician	2 (33.3%)	0 (0%)	2 (16.7%)
Previous simulator-based TURP training?			
Yes	4 (66.7%)	5 (83.3%)	9 (75%)
No	2 (33.3%)	1 (16.7%)	3 (25%)
Previous TUEP simulator training?			
Yes	0 (0%)	0 (0%)	0 (0%)
No	6 (100%)	6 (100%)	12 (100%)
Previous participation in > 50 TUEP cases, n (%)			
Primary surgeon	0 (0%)	6 (100%)	6 (50%)
Assistant	2 (33.3%)	0 (0%)	2 (16.7%)
Observed/occasionally assisted	4 (66.7%)	0 (0%)	4 (33.3%)

3.2 Objective performance

Experts had shorter enucleation times than less-experienced participants (34.50 ± 3.02 vs 45.67 ± 5.24 min; $p = 0.001$) and shorter times for vascular management and laser hemostasis (3.83 ± 0.75 vs 7.67 ± 2.34 min; $p = 0.009$). Derived enucleation efficiency was correspondingly higher (1.75 ± 0.16 vs 1.33 ± 0.15 g/min; $p = 0.001$).

Capsular perforation occurred in 0% versus 33.3%, verumontanum injury in 0% versus 16.7%, and external urethral sphincter injury in 16.7% versus 33.3% of experts and less-experienced participants, respectively; none of these differences was statistically significant. Simulated procedural success was achieved by 83.3% of experts and 50.0% of less-experienced participants ($p = 0.545$). These findings

provided preliminary known-groups validity evidence for selected objective performance measures (Table 2).

Table 2
Comparison of objective performance between the less-experienced and expert groups.

Performance measure	Less-experienced group (n = 6)	Expert group (n = 6)	P value
Enucleation time (min)	45.67 ± 5.24(95% CI 40.17–51.17)	34.50 ± 3.02(95% CI 31.33–37.67)	0.001
Enucleation efficiency (g/min; derived measure)	1.33 ± 0.15(95% CI 1.17–1.49)	1.75 ± 0.16(95% CI 1.58–1.92)	0.001
Time for vascular management and laser hemostasis (min)	7.67 ± 2.34(95% CI 5.21–10.12)	3.83 ± 0.75(95% CI 3.04–4.62)	0.009
Capsular perforation, n (%)	2 (33.3%)	0 (0%)	0.455
Verumontanum injury, n (%)	1 (16.7%)	0 (0%)	1.000
External urethral sphincter injury, n (%)	2 (33.3%)	1 (16.7%)	1.000
Simulated procedural success, n (%)	3 (50.0%)	5 (83.3%)	0.545

3.3 Face and content validity

Overall realism was rated 5.50 (5.00–6.00). Key anatomical features received favorable ratings, including the bilateral lobes [6.00 (5.75–7.00)], external urethral sphincter [6.00 (5.00–6.25)], and capsule–adenoma plane [5.50 (4.75–6.00)]. Median-lobe protrusion into the bladder received the lowest anatomical score [3.00 (2.75–4.00)]. Simulated blood flow, bladder-wall contraction, and sphincter contraction were each rated 6.00. Technical-difficulty realism was 3.00 (2.00–3.25), indicating that experts considered the simulation somewhat easier than clinical TUEP. Detailed face-validity ratings are provided in Online Resource 1 (Table S2).

All six experts rated every educational-content item as relevant (I-CVI = 1.00 for all items; S-CVI/Ave = 1.00; S-CVI/UA = 1.00). Educational-function ratings ranged from 5.00 to 6.50; blunt dissection/laser cutting and hemostasis received the lowest median ratings (5.00), whereas assessment of learning outcomes and procedural quality received the highest (6.50). Detailed item-level ratings and content-validity indices are provided in Online Resource 1 (Table S3).

3.4 Task workload

Less-experienced participants reported higher physical demand [6.00 (4.00–8.50) vs 4.00 (1.00–4.25); $p = 0.030$], temporal demand [8.00 (4.50–11.00) vs 2.00 (1.00–5.00); $p = 0.015$], performance score [11.00 (5.75–12.00) vs 3.00 (1.75–5.25); $p = 0.009$], effort [8.00 (3.75–10.50) vs 3.00 (2.00–3.75); $p = 0.018$], and technical difficulty [9.00 (4.75–12.00) vs 4.00 (1.00–5.00); $p = 0.022$]. Mental demand, frustration, and psychological interference did not differ significantly. Given the modified instrument and absence of

multiplicity adjustment, workload findings were interpreted as exploratory. Detailed workload results are provided in Online Resource 1 (Table S4).

4. Discussion

This study provides multidimensional preliminary validation of a 3D-printed TUEP simulator incorporating continuous simulated vascular flow and laser hemostasis. Experts rated its overall realism and educational relevance favorably, and selected objective measures discriminated between prespecified experience groups. Significant between-group differences were observed in several workload dimensions. Previous TUEP simulator studies have commonly emphasized expert-based realism and content assessment [11–13]; the present study extends this approach by integrating objective known-groups comparison and task-workload assessment within the same standardized simulator. These findings support the simulator as a potential early-stage structured training environment, but they should not be interpreted as evidence of training effectiveness or clinical skill transfer.

Anatomical realism is particularly important for TUEP because identification of the surgical capsule, external sphincter, and capsule–adenoma plane underpins safe enucleation [9, 19]. Ratings for these structures were favorable, consistent with previous physical TUEP simulator studies [11–13]. The current simulator additionally incorporated continuous simulated blood flow and laser hemostasis to address limitations of earlier physical models in reproducing bleeding-related tasks. Nevertheless, the model did not fully reproduce clinical complexity. Median-lobe protrusion into the bladder received the lowest anatomical realism rating, possibly because the model was characterized predominantly by bilateral-lobe enlargement with limited median-lobe protrusion. This highlights a limitation of a single anatomical configuration, which may not capture the morphological heterogeneity of BPH or adequately simulate different anatomical phenotypes and complex cases. Technical difficulty was also rated lower than that of real surgery, consistent with broader limitations of physical simulation models [20]. Limited adenoma–capsule adhesion reduced separation resistance and tissue-traction feedback, while manufacturing constraints limited the fineness and distribution of the vascular network. Transient laser–material flashes further reduced the realism of laser–tissue interaction. Future versions should therefore incorporate varied prostate morphologies and volumes, improved interface mechanics, finer vascular structures, and optimized laser-responsive materials.

The known-groups comparison showed shorter enucleation and hemostasis-related times among experts, consistent with the prespecified hypothesis. Similar experience-related discrimination has been reported for VR Holmium Laser Enucleation of the Prostate (HoLEP) and physical Transurethral Resection of the Prostate (TURP) simulators [8, 21]. The difference in vascular-management and hemostasis time is particularly relevant to the intended design of the present simulator because these tasks require recognition of simulated vessels, control of the endoscopic field, and appropriate laser use rather than enucleation speed alone. However, enucleation efficiency in our study was mathematically derived from a fixed 60-g adenoma and should not be interpreted as independent validity evidence.

Differences in injury events and simulated procedural success were not statistically significant and should be interpreted cautiously given the small sample and low event counts. Accordingly, the present findings support only preliminary known-groups validity evidence and do not establish a full proficiency continuum or training threshold.

The CVI findings should also be interpreted separately from simulator performance. Complete agreement that the eight educational domains were relevant confirms content coverage, but does not indicate that every function was reproduced equally well. This distinction is illustrated by lower ratings for enucleation and cutting and hemostasis despite uniformly high CVIs. Workload findings provided an additional, exploratory perspective: less-experienced participants reported greater physical and temporal demands, effort, perceived technical difficulty, and poorer self-rated performance. Previous surgical simulation studies have similarly associated greater experience or progression toward proficiency with lower workload [22, 23], and simulation-based anatomical endoscopic enucleation of the prostate (AEEP) training has been associated with reduced subsequent workload during clinical HoLEP[24]. Because our questionnaire added two study-specific dimensions and has not undergone formal psychometric validation, these findings should not be interpreted as establishing workload thresholds.

Several limitations warrant emphasis. The study was single center, included only 12 participants and two experience levels, and used one simulated procedure per participant; it therefore cannot evaluate learning curves, proficiency thresholds, retention, or transfer to clinical performance. Objective outcomes were assessed by a single evaluator who was aware of participant experience, introducing potential observer bias. The groups also differed in age and professional rank, so observed differences cannot be attributed solely to TUEP experience. Task-workload findings should also be regarded as exploratory given the modified assessment approach described above. Finally, the standardized model incompletely reproduced complex anatomy, tissue mechanics, dynamic bleeding patterns, and clinical technical difficulty. Its most defensible educational role is therefore early familiarization with instruments, anatomical landmarks, capsular-plane identification, basic enucleation steps, and hemostasis-related tasks rather than simulation of complex cases or replacement of supervised clinical training. Larger multicenter studies incorporating broader experience levels, blinded or multiple assessors, repeated training, and clinical-transfer outcomes are required.

5. Conclusions

The 3D-printed TUEP simulator demonstrated favorable face and content validity, while selected objective measures provided preliminary known-groups validity evidence. Experience-related differences in task workload were also observed. The simulator may support early-stage structured TUEP training, but longitudinal multicenter studies are needed to confirm learning effects and transfer to clinical practice.

Declarations

CRediT authorship contribution statement

Enlong Zhang: Methodology, Investigation, Data curation, Formal analysis, Writing – original draft; **Jiawei Zhang, Wenjia Wang:** Investigation, Data curation, Writing – original draft; **Zhiqiang Song, Yanhua Qin, Zhe Ma, Shihai Li:** Investigation, Data curation; **Jianchen Wu:** Conceptualization, Methodology, Supervision, Writing – review & editing.

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Declaration of competing interests

Authors **Enlong Zhang, Jiawei Zhang, Wenjia Wang, Zhiqiang Song, Yanhua Qin, Zhe Ma,** and **Jianchen Wu** are inventors on the Chinese utility model patent (ZL202421891170.9) and the pending Chinese utility model patent application (202620525301.4) related to the simulator evaluated in this study.

Ethics approval and consent to participate

This was a noninterventional educational validation study based on a surgical simulator and involved no patient intervention, animals, or human biological specimens. According to institutional requirements, formal ethics approval was not required for this type of simulation-based educational study. All participants volunteered to participate and provided informed consent before study initiation.

Data availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Declaration of generative AI and AI-assisted technologies in the manuscript preparation process

During the preparation of this work, the authors used ChatGPT (OpenAI) to assist with English translation and to improve the language, organization, and readability of the manuscript. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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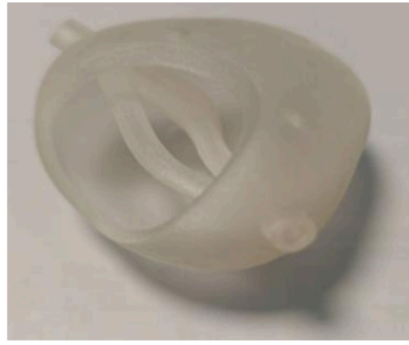
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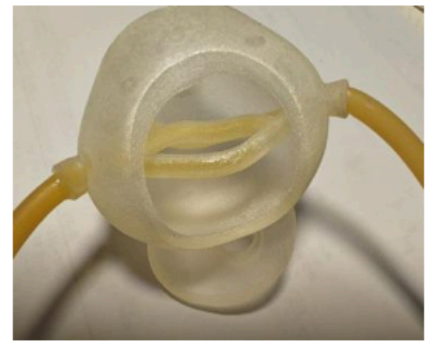
Figures



a



b



c

Figure 1

3D-printed prostatic surgical capsule and simulated internal vasculature.

a, b Representative views of the 3D-printed prostatic surgical capsule. c Simulated internal vasculature connected to the perfusion system for continuous simulated blood flow.

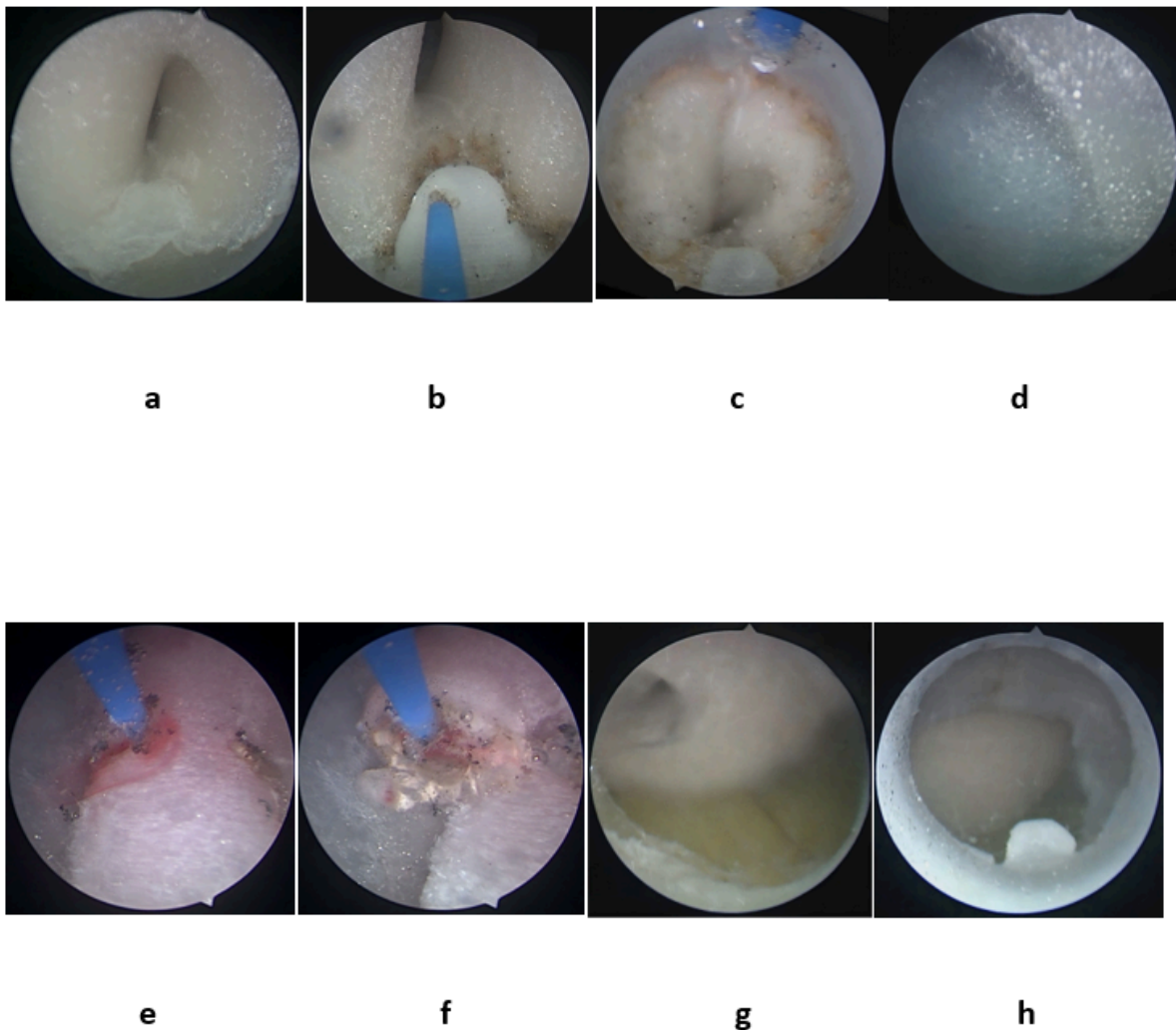


Figure 2

Representative endoscopic views during simulation training.

a Endoscopic identification of the bilateral prostatic lobes, verumontanum, and prostatic urethra. **b** Inverted U-shaped incision adjacent to the verumontanum to establish the surgical capsular plane. **c** Dissection of the bilateral adenomatous lobes toward the 12-o'clock position along the surgical capsular plane, followed by longitudinal incision of the anterior groove. **d** Blunt sheath dissection along the surgical capsular plane to separate the adenoma. **e, f** Exposure of simulated vessels and laser hemostasis. **g** Complete detachment of the adenoma and displacement into the bladder. **h** Prostatic fossa after complete enucleation.

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