Holmium Laser Enucleation of the Prostate Simulation: Analysis of Realism and Level of Difficulty by Holmium Laser Enucleation of the Prostate-naïve Urologists

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OBJECTIVE To evaluate the opinion of Holmium laser enucleation of the prostate (HoLEP)-naïve urologists about a surgical simulator and the level of difficulty at each step.

MATERIALS AND METHODS We evaluated 40 HoLEP-naïve urologists in a course involving 4 steps: lecture introducing Holmium laser basics and technique; live surgery; video explaining prostate enucleation using simulators; and simulator trial. A survey was applied to evaluate content validity and face validity of the simulator. Subjects also ranked the level of difficulty of each surgical step.

RESULTS All urologists agreed on the importance of a validated HoLEP simulator in training; 95% agreed that simulation-based training is essential for patient safety. The mean rate of face validity of all analyzed components was 8.4 (8.1-9.0). Instrumentation was considered the most realistic component, followed by laser-tissue interaction. Positioning the fiber and bladder neck incisions (BNIs) at 5 and 7-o'clock were the easiest steps. Detaching the median lobe from the bladder neck, BNI at 12, dividing the mucosal bridge distally, and joining the upper and lower incisions were the most difficult steps. Residents found more difficulty in joining the BNIs distally (3.6 vs 2.4, $P = .006$) and in dividing the mucosal bridge distally (4.0 vs 3.0, $P = .038$) when compared to specialists.

CONCLUSION HoLEP-naïve urologists found this simulator useful and important for patient safety. Most components were considered realistic. Simulation was able to reproduce the levels of difficulty usually found in real life cases. The level of expertise may influence the learning process of some steps. UROLOGY 125: 34−39, 2019. © 2019 Elsevier Inc.

Endoscopic enucleation has been recommended as a first line option for surgical treatment of benign prostatic obstruction (BPO), especially for prostates of great volume.[1,2] For this purpose, Holmium laser enucleation of the prostate (HoLEP) has been the most studied procedure. Randomized controlled trials have attested its efficacy and safety when compared to transurethral resection of the prostate (TURP) and open prostatectomy.[3,4]

However, the introduction of methods with demanding technical skills may represent a challenge. Its acceptance among professionals depends on variables such as personal skills and expertise with other techniques. One of the major concerns regarding the dissemination of HoLEP is its steep learning curve,[5] estimated between 20 and 60 cases.[6,7] A committed period of active training is essential to master the method.

Recently, the development of surgical simulators,[8,9] together with the creation of modular training approaches,[10] and the improvement of surgical techniques,[11,12] have led to an increase in the interest for the method all over the world. To date, there is no single standardized approach defined for learning HoLEP, or which tools should be used during the learning curve.

Information regarding physician's opinions about these tools and about their level of difficulty in each step of the procedure are important to define the best way of teaching the technique. In the present work, we analyzed the opinion of HoLEP-naïve urologists about the use of a surgical simulator using validated questionnaires. We also analyzed

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their opinion about the level of difficulty at each step of the HoLEP technique on the simulator.

METHODS

We performed a prospective study based on a modular teaching course including 40 urologists who had never performed a HoLEP procedure. All selected urologists had experience with traditional methods for surgical treatment of BPO such as TURP and open prostatectomy.

The course involved 4 steps: first, urologists watched a 20-minute lecture introducing Holmium laser physics basics, surgical instruments and the trilobar surgical technique as described by Gilling et al.[13] In the second step, they watched a live surgery of a 60-g prostate performed by a urologist who had performed more than 50 HoLEP cases. Next, they watched a 10-minute video explaining the prostate enucleation using the simulators they were about to test (https://www.youtube.com/watch?v=fT-Xbj_EDOc). Finally, they performed a trial in the simulator. At this moment, a mentor stayed beside them to help orient surgical steps.

For simulation of HoLEP we used a synthetic prostate model.[9] It contains an adenoma, a capsule, and a surgical plane between them. Enucleation is performed with a real Holmium laser generator and real endoscopic instruments and laser fiber.

At the end of the course, all participants filled a questionnaire including age, duration of urologic practice, previous experience with TURP, and laparoscopic surgery and their academic degree. A survey was applied to evaluate content validity and face validity of the simulator.[9] Content validity was based on 3 questions: (1) Is there a role for a validated HoLEP simulator in training? (2) Are simulation-based training and assessment essential for patient safety? and (3) Should simulation be implemented into training programs? To answer these questions, a Likert scale was used. Regarding face validity, urologists graded the realism of components of the simulator using a 10-point scale (1 = very poor and 10 = very realistic). Analyzed components were: Instrumentation, tactile feedback, prostate model, laser-tissue interaction, irrigation, bubbles, and overall experience.

After training, subjects ranked the level of difficulty of each surgical step described in the Gilling technique.[13] We analyzed 14 steps: (1) positioning fiber, (2) bladder neck incisions (BNIs) at 5 and 7-o'clock, (3) join BNIs distally, (4) ease beak of scope under median lobe, (5) detach median lobe from bladder neck, (6) hockey stick incisions at apices, (7) open tissue plane postero-laterally, (8) BNI at 12-o'clock, (9) drop lateral lobes down from above, (10) divide mucosal bridges distally, (11) join upper and lower incisions, (12) open tissue plane around lateral lobes working retrograde to bladder neck, (13) prolapse lateral lobe into bladder, and (14) detach lateral lobe from bladder neck. Information was correlated with age, level of expertise (residents vs specialists), and type of institution (teaching vs nonteaching). Level of difficulty was rated from 1 to 5.

The impression of surgeons who adopted HoLEP in clinical practice after having completed the training was reassessed with a follow-up questionnaire with content validity questions 1-3 and with a question regarding overall realism of the simulator.

For statistical analysis we used nonparametric Kruskal-Wallis and Mann-Whitney tests to measure results according to subjects' characteristics. We also divided surgical steps in 3 major parts and performed a Kruskal-Wallis test to compare difficulty scores between them. Statistical analyzes were performed in SPSS 19.0 software for Windows, and significance was considered at $P \leq .05$.

RESULTS

Mean age was 40 years (29-70). Six subjects were residents and 34 were specialists, of whom 6 had a PhD degree. Twenty (50%) worked in a teaching hospital and 20 did not. All participants—but residents—had expertise in performing conventional TURP procedures. Residents had performed a mean of 50 TURPs (20-80), and specialists had performed a mean of 314 TURPs (30-3000). Thirty-eight subjects declared they had developed good laparoscopic skills and 2 didn't. Mean time of professional activity was 10.4 years (1-42).

When asked if there was a role for a validated HoLEP simulator in training, 100% of subjects agreed or strongly agreed. When they were asked whether simulation-based training and assessment were essential for patient safety, 95% (38 out of 40) agreed or strongly agreed. Finally, 100% agreed that the simulation should be implemented into training programs. There was no difference according to age, time of practice, level of expertise, or type of institution of practice.

Regarding face validity, the mean rate of all 7 analyzed components was 8.4 (8.1-9.0). Instrumentation was considered to be the most realistic component (mean rate 9.0) followed by the laser-tissue interaction (mean rate 8.6). Irrigation and bubbles were also above the mean rate. Urologists thought that the prostate model was considered the least realistic component (Fig. 1). Face validity results did not vary according to surgeon age, expertise, or teaching hospital experience.

Finally, we analyzed the level of difficulty of each step of the procedure. Positioning the fiber and BNIs at 5 and 7-o'clock were the 2 easiest steps. Conversely, detaching the median lobe from the bladder neck, BNI at 12, dividing the mucosal bridge distally, and joining the upper and lower incisions were thought to be the most difficult steps (Table 1).

Table 1. Level of difficulty of HoLEP surgical steps based on the trilobar technique

HoLEP Surgical Steps	Mean Level of Difficulty (Min and Max)
(1) Positioning fibre	2.3 (1-5)
(2) BNIs at 5 and 7-o'clock	2.3 (1-5)
(3) Join BNIs distally	2.8 (1-4)
(4) Ease beak of scope under median lobe	3.0 (1-4)
(5) Detach median lobe from BN	3.2 (2-5)
(6) Hockey stick incisions at apices	2.9 (1-5)
(7) Open tissue plane posterolaterally	3.1 (2-5)
(8) BNI at 12-o'clock	3.3 (1-5)
(9) Drop lateral lobes down from above	3.0 (1-5)
(10) Divide mucosal bridges distally	3.2 (2-4)
(11) Join upper and lower incisions	3.4 (2-5)
(12) Open tissue plane around lateral lobes working retrograde to bladder neck	3.1 (2-5)
(13) Prolapse lateral lobe into bladder	3.0 (2-5)
(14) Detach lateral lobe from bladder neck	3.0 (2-4)

BN, bladder neck; BNI, bladder neck incisions; HoLEP, holmium laser enucleation of the prostate.

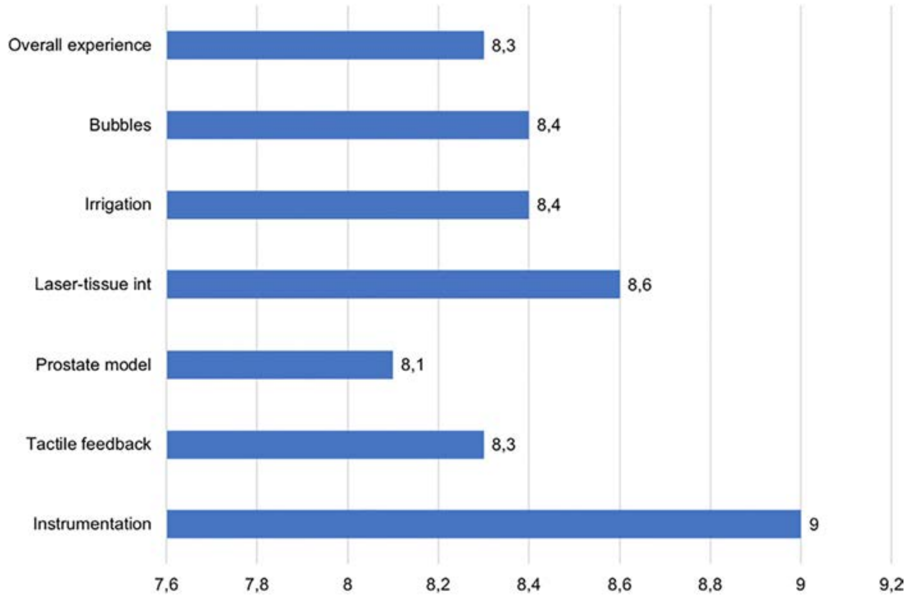

Figure 1. Face validity of the HoLEP simulator by HoLEP-naïve urologists. (Color version available online.)

We divided surgical steps in 3 major parts. The first stage comprised positioning the fiber until thoroughly detaching the median lobe from the bladder neck (steps 1 through 5). The second stage consisted of performing hockey stick incisions, opening tissue planes posterolaterally, performing a BNI at 12-o'clock, and dropping lateral lobes down from above (steps 6 through 9). The third stage consisted of dividing mucosal bridges distally, joining upper and lower incisions, opening tissue planes around lateral lobes, and releasing lateral lobes from the bladder neck (steps 10 through 14). We performed a nonparametric test comparing difficulty scores from these stages. A Kruskal-Wallis test revealed significant difference across groups ($P = .006$). Scores from stage 1 and stage 2 were significantly different (Mean 2.70 vs 3.09, $P = .014$) and also those from stage 1 and stage 3 (Mean 2.70 vs 3.18, $P = .005$). Scores from stages 2 and 3 were not significantly different (Mean 3.09 vs 3.18; $P = .595$).

When correlating the level of difficulty of the steps with the analyzed variables, we found that urologists who worked in a teaching-hospital found more difficulty in positioning the fiber when compared to those who did not work (1.6 vs 3.0, $P = .045$; Kruskal-Wallis test). Additionally, residents found more difficulty in joining the BNIs distally (3.6 vs 2.4, $P = .006$; Mann-Whitney test) and in dividing the mucosal bridge distally (4.0 vs 3.0, $P = .038$; Mann-Whitney test) when compared to specialists, respectively (Fig. 2). The level of difficulty of other steps was not different according to these

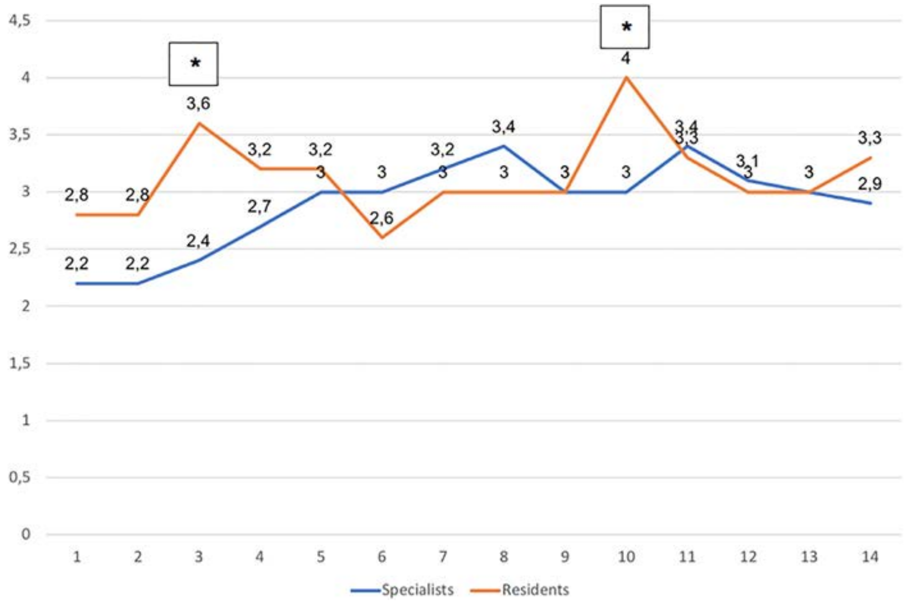

Figure 2. Difficulty rate of each step of HoLEP technique according to the level of expertise (*P <.05). (Color version available online.)

variables. Surgeon age was also not significant in defining the level of difficulty of these steps.

After 1 year, 8 urologists declared to have adopted HoLEP in clinical practice. Most subjects declared not to have adopted HoLEP due to lack of availability of equipment. Of 8 subjects, 7 completed a follow-up questionnaire. All 7 subjects agreed that a HoLEP simulator has an important role; similarly, 100% of them agreed that it should be implemented in residency/training programs. Of subjects who replied, 4 (57%) agreed that simulation-based learning is essential for patient safety. Overall realism of the simulator among these subjects after 1 year was rated at 6.1 (range 5-8).

DISCUSSION

In this study, we analyzed for the first time the opinion of HoLEP-naïve urologists about the use of a simulator for their training. We also analyzed their opinion about the level of difficulty of each surgical step based on the simulator experience. Participants found that simulators should be used for training and that they are important to assure patient safety. Additionally, the model was considered to be realistic in most aspects. Regarding surgical difficulty, the final two-thirds of the procedure were significantly more difficult than the beginning. Dividing the mucosal bridge distally and joining the upper and lower incisions were thought to be the most difficult steps.

During the last 25 years, many laser-based techniques have been developed for surgical treatment of BPO. Laser techniques can be particularly beneficial given the profile of patients with BPO, with advanced age and multiple comorbidities.[14] In most countries vaporization has been the most adopted technique due to ease of performance and reproducibility. In order to create an enucleation-like cavity, some have evolved into vapo-incision or vapo-resection techniques.[15] Such hybrid techniques however are still inferior to anatomical enucleation in terms of tissue removal.[16]

According to the European Association of Urology guidelines, HoLEP has been considered as a first option for surgical treatment of BPO.[1] One of the major concerns regarding the dissemination of HoLEP is the steep learning curve, and the definition of teaching strategies is essential to widespread the method. The use of training models could adopt a critical role, similarly to what happens in laparoscopic training.[17]

A validation analysis of this simulator was performed by the Holmium User Group at Cambridge University Hospitals.[9] In their work, 36 urologists, including 13 trainees and 23 senior urologists of varying levels of experience were evaluated. Similarly to our results, regarding content validity, 97% agreed that the simulation should be implemented into training programs, and almost all believed that simulation-based training and assessment are essential for patient safety. Regarding face validity, participants ranked all components of the simulator greater than in a 10-point scale. Instrumentation and tactile feedback were considered most realistic components.

In our analysis, participants agreed that instrumentation was the most realistic component. However, they found laser-tissue interaction, bubbles, and irrigation to be more realistic than tactile feedback. Finally, in both studies, participants agreed that the prostate model was the least realistic component. In both studies, all analyzed components were above acceptability threshold of 5 of 10. However, in Aydin's analysis, all components but instrumentation were rated below 8, and in the present study all were rated above. Such differences might be explained by participants' characteristics. In Aydin's study, trainees had already performed a mean of 3 HoLEP procedures (0-15), and the experienced group had performed a mean of 5 HoLEP procedures (0-50). In our study, despite having relevant experience with TURPs, all participants were completely HoLEP-naïve.

Another HoLEP simulator, the VirtaMed uses a virtual approach. It has the advantage of being portable and allows simulation of the enucleation and the morcellation phases. This simulator was validated with 53 participants, comprising 3 groups: HoLEP experts (n = 11), intermediates (n = 24), and novices (n = 18). Enucleation efficiency (grams per hour) was significantly superior for experts. Face validity was rated by experts as acceptable. Content validity questions showed that 85% of participants agreed that simulator-based assessment is essential for patient safety and 87% agreed that there was a role for a validated virtual reality simulator for use in HoLEP training.[8]

Regarding level of difficulty, participants found that detaching the median lobe from the bladder neck, BNI at 12, dividing the mucosal bridge distally, and mainly joining the upper and lower incisions were thought to be the most difficult steps in this model. These have been considered by experts the most difficult steps when performing real cases.[10] This fact underscores that this model may reproduce real surgery principles. Also of note, scores of difficulty from the two-thirds of the procedure were significantly higher than those from the beginning. Taken together, these data suggest that virtual training of HoLEP should be more extensive and repetitive for these steps, in particular the final two-thirds of surgery. Furthermore, during the initial cases of surgical training, trainees could be granted more autonomy in the beginning of surgery but should receive more meticulous intervention from experts in most difficult steps.

We believe limitations concerning the learning of HoLEP will be overcome with time. Initially, HoLEP was performed only through the trilobar technique, which involves all the steps described in this manuscript. Now, in most centers, enucleation has been performed through the bilobar and en-bloc techniques. A retrospective analysis of 304 cases has suggested that the 2-lobe technique provides shorter operative and enucleation times when compared to the trilobar technique.[18] Similarly, the en-bloc technique has the potential to ease some difficult intraoperative steps and to improve the learning curve of HoLEP. The latter eliminates the need to perform steps such as BNI at 12 or joining the upper and lower incisions.[11]

Interestingly, the level of difficulty of only a few steps (joining the BNIs distally and dividing the mucosal bridge distally) was influenced by the level of expertise of the participants. We believe that the relative small number of residents and the heterogeneity of the specialists regarding their experience with endoscopic surgery might explain this fact.

The current study should be interpreted in the context of limitations. This model does not simulate the morcellation phase; furthermore, a single simulator is not generalizable to all situations. However, the advantages of this prostatic model are that this model is anatomical, and actual HoLEP instruments and a real holmium laser are used in the simulation process. Another limitation is the fact that only few subjects re-evaluated their opinions and perceptions on the simulator after achieving expertise.

CONCLUSION

HoLEP-naïve urologists found that this simulator/ prostate model should be used for training and that they are important to assure patient safety. Most of the components of the model were found to be realistic, especially the instrumentation and laser tissue interaction. The model was able to reproduce levels of difficulty usually found in real life cases, with most difficult steps in the final two-thirds of surgery. Urologist expertise may influence the learning process of some steps.

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EDITORIAL COMMENT

Holmium laser enucleation of the prostate (HoLEP) has become an established surgical modality for the treatment of benign prostatic obstruction, particularly for larger glands or patients who require anticoagulation.[1] Despite the advantages of HoLEP, the steeper learning curve, and access to appropriate equipment has hindered widespread adoption.[2]

The study by Antunes et al evaluated implementation of a structured course consisting of video lectures, surgery observation, and simulator use. The simulator consisted of a prostate model as well as real endoscopic instruments. Forty HoLEP naïve urologists were enrolled to take the course and surveyed on their opinions of the usefulness, difficulty in a 14-step surgical technique, and future patient safety. Recruits included residents in training, urologists with significant but varying experience in endoscopic and open BPH surgery, including both academic and nonacademic urologists.

Overall, the urologists survey agreed that a HoLEP simulator is important and should be implemented in training. The respondents found the most realistic component of the simulator to be the instrumentation and the prostate model was considered the least realistic component. As acknowledged by the authors, only 8 urologists went on to adopt HoLEP and of the 7 that responded to follow-up surveys, the overall realism of the simulator was only 6.1 (1-10 scale). Thus, the validity of this model cannot be confirmed yet given the limited follow-up information. The study structure is strong, and the goals and implementation were clearly stated; however, it would be interesting to see if experienced HoLEP surgeons who participate in the simulation find it to be realistic and potentially beneficial to trainees.

This study is certainly timely in the fact that surgical simulation is becoming increasingly incorporated into training programs, given its ability to allow trainees to learn the technical and cognitive components of a particular procedure without placing a patient at risk.[3] HoLEP in particular is an important technology where surgical simulation could play an important role for helping it gain adoption by the broader urologic community. Other simulators have previously been evaluated and validated using virtual simulators rather than physical models, which were found to be acceptable.[4] Despite the implementation of different simulation strategies, it remains to be seen if simulation definitively improves patient outcomes or surgeon skill.

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AUTHOR REPLY

Holmium laser enucleation of the prostate (HoLEP) is the most complete and sophisticated surgical treatment for benign prostatic obstruction. No other technique is capable of removing so much tissue in such a minimally invasive manner. The great challenge of prostate surgeons is to develop methods to shorten and facilitate its learning curve. Simulators are attractive and safe tools that could serve this purpose.

The 2 main limitations of the simulator model used in our study are that it does not reproduce bleeding, and that it lacks a morcellation phase. Despite this fact, urologists' evaluation was positive. However, the validation of our modular teaching course was impaired by the unavailability of lasers in most of the facilities where trainees work. Acquisition of the HoLEP equipment will allow the evaluation of the course impact in a near future.

Simulators should also be tested in a prospective and controlled trial to allow the analysis of the real impact of this tool on the most common used outcome measure that is the enucleation rate. Whether the plateau will be achieved sooner among new users who took some time in the simulators or if they will help to increase the urologist's fidelity to the method, is not known. Until these questions are not resolved, it is the opinion of the authors that simulators are important tools that should be used during the HoLEP-naïve urologists learning curve.

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