RBEM Revista Brasileira de Educação Médica

ORIGINAL ARTICLE

DOI: https://doi.org/10.1590/1981-5271v48.4-2022-0270.ING

Development and validation of face and content of a realistic simulator for suprapubic cystostomy training

Criação e validação de face e conteúdo de simulador realístico para treinamento de cistostomia suprapúbica

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ABSTRACT

Introduction: Performing a suprapubic cystostomy should be a competence of the urologist and general surgeon. The training of this competence through simulation appears as a safe, risk-free alternative for patients and resident physicians.

Objective: to create a realistic simulator for suprapubic cystostomy training and obtain its face and content validation.

Method: the procedure was carried out in the simulator by experts who later responded to a semi-structured questionnaire to evaluate anatomical realism and the usefulness of the simulator as a teaching and training tool.

Results: Twenty-one urologists with a mean age of 41.2 years evaluated the simulator. Anatomical realism had an average score of 4.24 (maximum score 5) and usefulness as a teaching tool obtained an average of 4.76 (maximum score 5).

Conclusion: the developed simulator is, therefore, useful for the practical teaching of puncture cystostomy, it was validated in terms of face and content, and can be incorporated into the curricula for the training of resident physicians, especially in general surgery and urology.

Keywords: Cystostomy; Educational technology; Simulation Training; Validation Study; medical education.

RESUMO

Introdução: *A realização da cistostomia suprapúbica deve ser uma competência do médico urologista e cirurgião geral. O treinamento dessa competência por meio da simulação surge como alternativa segura, livre de riscos para pacientes e médicos residentes.*

Objetivo: *Este estudo teve como objetivos criar um simulador realístico para o treinamento de cistostomia suprapúbica e obter sua validação de face e conteúdo.*

Método: *O procedimento foi realizado no simulador por especialistas que posteriormente responderam a um questionário semiestruturado para a avaliação do realismo anatômico e a utilidade do simulador como ferramenta de ensino e treinamento.*

Resultado: *Avaliaram o simulador 21 urologistas com idade média de 41,2 anos. O realismo anatômico teve nota média de 4,24 (nota máxima: 5), e a utilidade como ferramenta de ensino obteve média de 4,76 (nota máxima: 5).*

Conclusão: *O simulador desenvolvido é, portanto, útil para o ensino prático de cistostomia por punção, pois foi validado em face e conteúdo, e, por isso, pode ser incorporado aos currículos da formação de médicos residentes, sobretudo em cirurgia geral e urologia.*

Palavras-chave: *Cistostomia; Tecnologia Educacional; Treinamento por Simulação; Estudo de Validação; Educação Médica.*

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Chief Editor: Rosiane Viana Zuza Diniz.
Associate Editor: Fernando Almeida.

Received on 01/18/23; Accepted on 04/10/24.

Avaluated by double blind review process.

DOI: https://doi.org/10.1590/1981-5271v48.4-2022-0270.ING

INTRODUCTION

Acute urinary retention (AUR), one of the most common urological emergencies, is defined as the inability to completely empty the bladder[1]. This condition can have several etiologies, with benign prostate hyperplasia being the most common cause[2]. Other causes of acute obstructive urinary retention are urethral strictures, urethral stones, prostate cancer, and abscesses, among others[2]. It is estimated that more than 10% of men in their 70s and around 33% of those in their 80s will be affected within 5 years[3]. Acute urinary retention requires immediate intervention, with urine drainage being indicated. This drainage is preferably performed by urethral catheterization; however, when urethral catheterization is impossible or contraindicated, suprapubic cystostomy is indicated[4]. There are exceptional situations in which the cystostomy is necessary in the absence of obstruction, such as in cases of necrotizing fasciitis and urinary fistulas, with the aim of urinary diversion.

Suprapubic cystostomy is a surgically performed connection carried out through the abdominal wall, between the urinary bladder and the external environment, to allow urine drainage when normal urinary flow is blocked[5] or needs to be diverted. According to literature data, inexperienced doctors tend to insist on several attempts at urethral catheterization, even after initial failure, which increases the risk of iatrogenic injury to the urethra[6] and it is known that trauma during urethral catheterization is the cause of 17-32% of urethral strictures[7,8,9], a pathology that causes great morbidity and discomfort to patients.

Suprapubic cystostomy is a procedure that is widely performed in clinical practice and should be a basic skill of every urologist and general surgeon[6]. This can be performed through an open procedure or by puncture, which is generally done with a trocar. The trocar can be used while utilizing several techniques: direct puncture with a trocar (using disposable kits or reusable devices), puncture with a modified trocar, with the aid of the Seldinger technique, cystoscopy-guided puncture, ultrasound-guided puncture, and fluoroscopy-guided puncture[10].

Direct puncture with the trocar without the use of additional technology can be performed safely at the bedside, as long as it is performed using the correct technique and in selected patients[10]. The procedure should be avoided without the aid of ultrasound in patients with previous lower abdominal surgery or with urinary retention due to trauma to the pelvis[10]. Similarly, using the puncture technique utilizing only palpation and anatomical references in patients who do not have a distended bladder should be avoided[10].

In Brazil, the competency matrix for Medical Residency in General Surgery, prepared by the Ministry of Education in 2018, includes performing puncture cystostomy as a competency that must be acquired in the first year of specialization by resident doctors in training[11], which reinforces the need to expand its teaching.

Although it is a basic procedure, puncture cystostomy is not free from complications. The incidence of intestinal perforation, one of the most feared complications, can reach 2.4%, with mortality reaching 1.8%[12]. Even rectal injury has already been described[13].

Given the importance of this procedure in clinical practice, it is necessary that doctors in training have access to adequate training to learn the surgical technique. In the case of suprapubic cystostomy, this training is hindered because this procedure is carried out, most of the time, in emergency units, under unfavorable circumstances for practical teaching to the doctor who will perform the cystostomy, often for the first time[14]. Moreover, this in-service surgical training, based on Halsted's model, "see one, do one, teach one", has its limitations in modern surgical practice[15]. Changes in society and medical practice in recent years, with an emphasis on patient safety, increased patient expectations and the judicialization of medicine, have limited the role of doctors in training in operating rooms and emergencies[16].

More recently, the pandemic caused by the COVID-19 virus has also brought new obstacles. There was a loss in the training of resident doctors, with a reduction in surgical volume, with future consequences that have not yet been established[17]. In addition to the reduction in surgical volume, limiting the number of students and people in closed environments, due to health recommendations, are aggravating factors that harm traditional medical education. Despite the difficulties imposed, COVID-19 allowed everyone involved in the training of surgeons to stop to reflect on their performance and to look for some areas of teaching for improvement, including technologies that assist training[18].

This entire problem reinforces the need for simulation, which emerges as a solution to these aforementioned challenges. Simulation is defined as a technique to replace or amplify real experiences, through guided experiences that evoke and replicate substantial aspects of the real world, in a fully interactive way[19]. Thus, the simulation proposes to allow the doctor in training to go through their learning curve outside the operating room, facilitating training in a safe and "consequence-free" environment. Errors can be made and evaluated without putting any patient at risk[16].

Several simulator models for suprapubic cystostomy training have been described in the literature since 2008 [4-6,14,20-23] and these described simulators vary in their realism. The main advantage of models with a low level of realism is their

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lower cost. The ideal surgical simulator is one that provides an experience as close to reality as possible. It must also be capable of promoting sensory feedback when carrying out the procedure, demonstrating the immediate correlation between the performed maneuver and the resulting effect[24].

Validity measures whether the simulator or training device is actually teaching or evaluating what it is intended to be taught or measured. The validation of a simulator can have both a subjective and objective approach. Subjective validity is simpler to achieve and consists of face and content validity. Face validity is assessed informally by experts or non-experts, being related to the realism of the simulator: does it actually represent what it is supposed to represent? Content validity would be the judgment of the adequacy of the simulator as a teaching modality and involves a formal evaluation by subject matter experts of the training device: does the simulator realistically teach what it is supposed to teach?[25]

Objective validity is more challenging and takes more time. We have concurrent validity, which would be the performance of a simulator when compared to a model that is considered the gold standard. Predictive validity would be the ability of the simulator to predict the user's performance in the real procedure, measured through tools such as the Objective Structured Assessment of Technical Skills (OSATS). With this validity, the simulator can be used to evaluate whether or not the doctor in training is able to perform the real procedure. We also have construct validity, which would be the simulator's ability to differentiate an experienced surgeon from a beginner or inexperienced one. This characteristic is crucial for the simulator to be accepted as a tool to assess skills. For this purpose, OSATS can also be used to compare the performance of users with different degrees of experience[25]. The types of validity are summarized in Chart 1.

While reviewing the literature, we found that most of the described suprapubic cystostomy simulators mainly assessed subjective validity, that is, face and content validity. Three studies assessed the compatibility of the simulator with the use of ultrasound to guide the puncture. Regarding realism, we believe that only two simulators described in the literature are realistic[21,22], as they attempt to mimic an anthropomorphic pelvis to perform the procedure. This review is detailed in Chart 2.

The aim of this work is to create a realistic simulator model for puncture suprapubic cystostomy training and validate this simulator in relation to face and content validity. We justify

Chart 1. Types of validity.

Validity type	Definition
Face Validity	Subjective evaluation of the realism of a simulator made by users. Usually using questions with a Likert scale.
Content validity	Evaluation of whether the content of the simulator reflects knowledge and skills required in the actual procedure. It usually uses expert opinions.
Construct validity	Ability of the simulator to differentiate the experience levels of users or groups. This is proven when experts outperform non-experts during simulated, standardized tasks
Concurrent validity	Comparison of a new simulator with another model considered the gold standard
Predictive Validity	Ability of the simulator to predict performance during the actual procedure. This is accomplished by comparing the task carried out in the simulator to the performance in the operating room.

Source: adapted from Kozan et al [16].

Chart 2. Simulator models for suprapubic cystostomy training.

Author	Year	Compatible with Ultrasound	Validity	Realistic
Shergill et al[20]	2008	No	Construct and Predictive	No
Hossack et al[6]	2013	No	Face	No
Singal et al[21]	2015	No	Face and Content	Yes
Olapade-Olaopa et al[23]	2015	No	N/A	No
Palvolgyi et al[22]	2017	Yes	Face and Content	Yes
Nonde et al[14]	2018	Yes	Face and Content	No
Gao et al[5]	2019	No	N/A	No
Randhawa et al[5]	2022	Yes	Face, content	No

Source: prepared by the authors. N/A – validity not assessed.

DOI: https://doi.org/10.1590/1981-5271v48.4-2022-0270.ING

this study by the need to improve the teaching of suprapubic cystostomy, as it is a basic skill for general surgeons and is often neglected in medical residency curricula. Furthermore, the current difficulties for practical surgical teaching are evident.

METHOD

Design, participants and ethics

This study consists of a cross-sectional validation study. Doctors specializing in urology, who work in the city of Natal, state of Rio Grande do Norte, Brazil, were invited to participate in the validation study of a realistic simulator for puncture cystostomy training. The volunteers were provided with a free and informed consent form. The intervention was carried out in the Skills Laboratory at Universidade Federal do Rio Grande do Norte, in July 2022, on a single day. The research protocol was reviewed and approved by the Research Ethics Committee of Hospital Universitário Onofre Lopes (Huol-UFRN) with Certificate of Presentation for Ethical Appreciation Number 36779520.5.0000.5292 and Opinion number 4.247.077.

Simulator creation

The simulator was created in partnership with the company MedSkills[26], from June 2020 to April 2022. This company specializes in creating realistic simulators for medical procedures. The simulator consists of an anthropomorphic structural body that represents the human lower abdomen and has a window where a pressurized reservoir is placed. The structural body is equipped with an external layer that mimics the skin, made of elastomer and an internal layer that mimics the other layers of the abdomen, made of polyurethane. The pressurized reservoir mimics the bladder chamber and is made of metal; It is filled with liquid that mimics urine, and its color is obtained from a yellow hydrophilic dye. The aforementioned pressurized reservoir is hermetically closed by a puncture disc made of elastomer (the same one that mimics the skin) and is adjusted to the window of the anthropomorphic structural body. A hard polymer device, which mimics the pubic bone, is placed beneath the skin.

To generate positive pressure in the pressurized reservoir, there are two connections (serum equipment), one connected to a source of pressurized liquid (by gravity) and another open to the ambient air. To allow multiple uses, reducing costs, the puncture disc is rotated in its plane, allowing it to be reused up to 30 times by always presenting a new area after each training session.

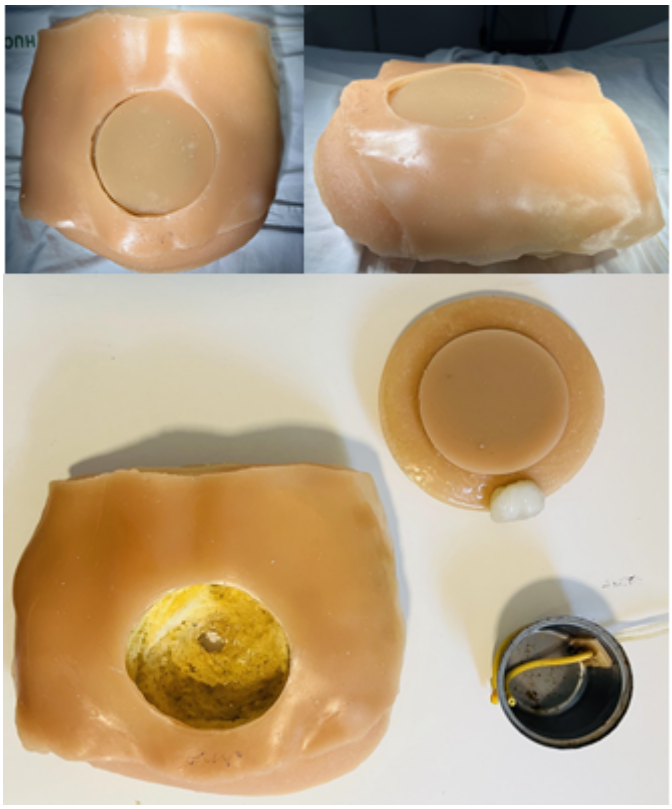
The device was developed and manufactured based on reprocessed materials, reducing the environmental impact and allowing reduced costs related to its use. The estimated cost is around R$ 900.00 *reais* (Figure 1).

Simulation and Validation Questionnaire

Each participant received instructions on the standardization of practice, in which a station for performing cystostomy by suprapubic puncture was simulated. The standardized technique was: physical examination and identification of the anatomical references in the patient's lower abdomen to perform the procedure; palpation of the bladder globe and pubic symphysis; antisepsis and asepsis; local anesthesia and bladder puncture with a needle 5 cm above the pubic symphysis; puncture with a trocar at this point vertically or slightly inclined; removal of the obturator to observe urine output; passage of cystostomy catheter; removal of the trocar; observe urine output through the catheter and its fixation to the skin. The device used in the validation to perform the procedure was a 12-French diameter cystostomy catheter manufactured by Cook Medical, which was obtained through donation.

After carrying out the procedure (performed as shown in Figure 2), the participants answered a feedback questionnaire, which contained questions on a 5-point Likert scale, which correspond to three domains: anatomical realism, with 1-not realistic and 5-very realistic (5 questions); usefulness of the simulator as a training tool, with 1-not useful and 5-very useful (4 questions); general impression about the simulator,

Figure 1. Realistic simulator developed for puncture cystostomy and its components.



Source: prepared by the authors.

DOI: https://doi.org/10.1590/1981-5271v48.4-2022-0270.ING

Figure 2. Use of the simulator with the puncture cystostomy technique.

Source: prepared by the authors.

with 1-totally disagree and 5-totally agree (4 questions). Additionally, demographic data were collected, such as age, sex, years of experience as a urologist, approximate number of cystostomies performed per year and whether or not ultrasound was used to guide punctures in clinical practice. At the end of the questionnaire, there was an open field for comments and suggestions.

Statistical analysis

The average responses were obtained for each domain, as well as the standard deviation. The internal consistency of the questionnaire was evaluated using Cronbach's alpha. A Cronbach's alpha between 0.6 and 0.7 was considered acceptable internal consistency; between 0.7 and 0.9, as good internal consistency; and above 0.9, as excellent internal consistency[27]. Reliability was assessed using item-total correlation (ITC). An ITC equal to 0.15 was considered acceptable[27].

RESULTS

A total of 21 urologists participated in the study, one of which was female and the others, male. The average age was 41.2 years, ranging from 28 to 55 years. The average number of years of experience as a urologist was 10.1 years, ranging from 1 to 30 years of experience. The average number of cystostomies performed per year was 11.2, ranging from 2 to 30 procedures per year. No participant reported using ultrasound to guide punctures in their clinical practice.

The results of the questions in each domain, as well as their statistical analysis, are summarized in Table 1. The questionnaire internal consistency was assessed by Cronbach's alpha coefficient, which overall was 0.807, considered good. Reliability measured by the item-total correlation of each question, also shown in table 3, was satisfactory.

In the first domain of the questionnaire, anatomical realism, we had an average of 4.24 in the responses. Question 3 was the one with the worst performance (average of 3.81). This question assessed whether the touch and texture of the tissues were realistic. According to comments from some participants, there was some resistance when removing the trocar from the skin, little more than the real experience. This aspect can be improved by changing the consistency of the elastomer, making it more malleable.

The domain that evaluated the usefulness of the simulator as a training and evaluation tool had a very satisfactory performance, with an average of 4.76. The domain that evaluated the impression of the simulator had an average of 4.74. Urologists who have used the simulator recognize its usefulness as a training tool for performing cystostomies. They also recommend that the simulator can be used in the medical residency program curriculum and agree that the skills developed with the simulator use can be transferred to the actual procedure.

In the comments field open for suggestions, we had nine comments suggesting that an improvement in the consistency of the tissue, mainly reducing its resistance to theremoval of the trocar sheath, could make the experience more realistic. Another point addressed was the suggestion to make the pubic symphysis more noticeable (two comments), an important anatomical repair for the puncture.

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Table 1. Questionnaire result by item.

Questions	Average	Standard deviation	Corrected Item-Total Correlation
1) Anatomical structures are realistic (pelvis, pubic symphysis)	4.14	1.01	0.44
2)Model size is realistic	4.57	0.60	0.30
3) The tissues are realistic (by touch and texture)	3.81	0.87	0.32
4) Tissue manipulation is realistic (by incision; anesthetic injection; catheter insertion)	3.90	0.94	0.47
5) Entry into the bladder with the trocar is realistic (urine output)	4.76	0.44	0.21
Global average of the anatomical realism domain	4.24		
1) Useful for teaching anatomy	4.62	0.50	0.25
2) Useful for Puncture Cystostomy Teaching	4.86	0.36	0.25
3) Useful for improving the technique of puncture cystostomy	4.71	0.46	0.33
4) Useful as a tool for practical evaluation of resident physicians regarding the competence to perform puncture cystostomy	4.86	0.36	0.67
Average of the usefulness domain as a teaching tool	4.76		
1) Would recommend this simulator as a form of suprapubic cystostomy training	4.76	0.44	0.75
2) Training with this model would help resident physicians feel more confident in performing the actual procedure	4.76	0.44	0.55
3) This model could be incorporated into the urology medical residency curriculum	4.76	0.44	0.43
4) The learnings acquired with this simulator can be transferred to the real procedure with the patient	4.67	0.48	0.58

Source: prepared by the authors.

DISCUSSION

We presented a realistic simulator for cystostomy training, made on a simple budget. Our simulator received face and content validation by a group of experts and can be used effectively to improve the training of resident doctors. The simulator might not be an ideal substitute for real-life doctor-patient interaction, but it is a safe and efficient way to impart proficiency in surgical skills.

The demographic data of the research participants demonstrate a population of professionals with extensive experience in the area, as well as in carrying out the proposed procedure, which provides reliability in the assessment of content validity. As a health technology, our research into a simulator creation and validation aligns with the Ministry of Health agenda of research priorities, in its axis of technology development and innovation in health[28].

None of the urologists participating in the research uses ultrasound to guide the puncture in their routine, which may reflect the unavailability of some technologies in the professional's daily life, especially in the Unified Health System environment. This information reinforces the value of our simulator for training and for real clinical practice in our environment, even though it is does not have compatibility with the use of ultrasound for training.

Our face and content validation had a considerable sample of urologists (experts), (n = 21), when compared to other simulator validation studies for the same purpose.

The first simulator presented in the literature, the UroEmerge[20], consisted of a 3-liter irrigation bag, secured with tourniquets in a plastic box. Several other models were described subsequently. Hossack et al.[6] described a model that consisted in a party balloon wrapped in ribbon, inside a "plastic lunch box." This model was tested with general surgery residents. In 2015, a model recommended for countries with few resources, the *UCH bladder manikin*, was described[6]. This is a non-realistic, low-cost model, made in a wooden box and no validation study was carried out. Another non-realistic, low-cost, ultrasound-compatible model was described in 2018[14]. It used gloves, a used glove box, and used IV bags; the system was attached to a cervical collar. The idea of this study was to use materials easily found in the emergency sector.

To the best of our knowledge, there are two realistic simulators described in the literature that attempt to mimic the lower abdomen. The first[21], described in 2015, used polyurethane foam with resin glue to simulate the bony pelvis and a silicone bag with a lock to maintain bladder distension. Like ours, this simulator was not compatible with the use of ultrasound. The validation of this simulator was carried out

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by 6 urologists and the rest of the evaluators were general surgeons, while our study included the participation of 21 specialists in urology.

Another realistic simulator, described in 2017, the VesEcho Training System[22], consists of a replica of the bony pelvis, a reservoir mimicking the bladder and an external gelatin that provides anatomical realism and it is compatible with ultrasound. The face and content validation of this simulator was carried out in a practical station with urology resident physicians. Thus, we are the third realistic simulator described in the literature.

One difficulty we encountered was the COVID-19 pandemic, which made it difficult to hold meetings to improve the model and, subsequently, to carry out the validation study, delaying the completion of the study.

We had suggestions for improvement regarding some aspects of anatomical realism, mainly related to the consistency of the elastomer used for layers of the skin and the abdominal wall. If we increase malleability, resistance to multiple punctures is lost and, consequently, the durability of the plate used in the model. New tests and research are necessary to find the material with the best cost-benefit and the best relationship between realism and durability.

As a perspective for the evaluation of our simulator, we intend to use tools in the future to assess its objective validity. The application of an Objective Structured Assessment of Technical Skills (OSATS) station between beginners and experienced doctors, comparing the performance of each one, would allow construct validity to be assessed. The use of the same tool (OSATS), during the procedure in the simulator and subsequently, on the actual patient, would allow the predictive validity to be evaluated.

In this study, the participating urologists reported believing that our simulator is very useful for teaching cystostomy. It is suggested that the simulator can be incorporated into the curricula of medical teaching institutions, especially in urology, leading to a greater number of performed procedures and the consequent increase in the confidence of professionals in training.

CONCLUSIONS

We developed a new realistic simulator for suprapubic cystostomy, ready to use, reusable, and which has an acceptable cost. The model was submitted to face and content validation. It has received good reviews from urologists in several areas, including regarding its anatomical realism, its use as a training tool, and its recommendation for inclusion in a medical residency curriculum. Additional studies are needed to assess its construct and predictive validity.

AUTHORS' CONTRIBUTION

Christophe Bezerra Anselmo: participated in the design and conception of the study, curation, creation of the simulator, application of the intervention, analysis and interpretation of data and preparation of the manuscript. José Luiz de Souza Neto: participated in the design of the study, the creation of the simulator and the final review of the manuscript, with critical and intellectual participation. José Ademar dos Santos Junior: participated in the creation of the simulator, the application of the intervention and the final review of the manuscript, with critical and intellectual participation. Rodolfo Alves da Silva: participated in the analysis and interpretation of data, methodology and final review of the manuscript, with critical and intellectual participation. Paulo José de Medeiros: participated in the design and conception of the study, analysis and interpretation of data, methodology, administration and supervision of the project, and the final review of the manuscript, with critical and intellectual participation.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

SOURCES OF FUNDING

The authors declare no sources of funding.

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