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Construction and validation of a non–organic, homemade, low–cost cricothyrotomy simulator. A cross-sectional study

Construção e validação de um simulador de cricotireotomia não orgânico, caseiro e de baixo custo: um estudo transversal

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ABSTRACT

Introduction: Cricothyrotomy is a procedure that may save lives in emergency acute respiratory failure. Cricothyrotomy must be trained during undergraduate medical education, and low-cost simulators may offer a satisfying solution in economical and practical terms.

Objective: The aims of this study were to build and assess the face, content, and construct validity of a low-cost, homemade cricothyrotomy simulator developed by the authors.

Methods: Forty-seven students and nine surgeons performed three successive simulated cricothyrotomies and answered a face and content validity questionnaire. The construct validity was tested by comparing procedural duration and a global performance score intra- and between groups.

Results: Most face and content validity questionnaire items were highly and positively rated, with no difference between the groups. Accordingly, students and surgeons agreed that the simulator resembles a human neck anterior surface, is easy and safe to use, allows the performance of critical steps of the cricothyrotomy, and exhibits potential teaching feasibility. Procedural duration decreased between the first and third attempts among students (mean time decrease = 61.85 s; 95% CI – 41.86 – 81.85; $p < 0.001$), and a significant difference was found between surgeons' and students' performance duration (mean difference = 101.36 seconds [95% CI = 69.08 – 133.64] $p < 0.001$), suggesting construct validity. The students' performance scores improved between the first and second attempts (mean difference = 2.25 points; CI 95% = 1.31 – 3.20; $p < 0.001$).

Conclusions: The non-organic, homemade, low-cost cricothyrotomy simulator has acceptable face, content, and construct validity and is suitable for use as a training tool by undergraduate medical students.

Keywords: Airway management; Cricoid, surgery; Medical education, undergraduate; Simulation training; Validation study.

RESUMO

Introdução: *A cricotireotomia é um procedimento que pode salvar vidas em caso de insuficiência respiratória aguda de emergência. A cricotireotomia deve ser treinada durante a graduação médica, e simuladores de baixo custo podem oferecer uma solução satisfatória em termos econômicos e práticos.*

Objetivo: *Este estudo teve como objetivos construir e determinar as validades de face, conteúdo e construção de um simulador caseiro de cricotireotomia de baixo custo desenvolvido pelos autores.*

Método: *Quarenta e sete estudantes e nove cirurgiões realizaram três cricotireotomias simuladas sucessivas e responderam a um questionário de validade de face e de conteúdo. A validade de construto foi testada comparando tempos procedurais e um escore de desempenho global intragrupos e intergrupos.*

Resultado: *A maioria dos itens do questionário de validade face e de conteúdo foram avaliados de forma positiva, sem diferença entre os grupos. Assim, estudantes e cirurgiões concordaram que o simulador se assemelha a uma superfície anterior do pescoço humano, é fácil e seguro de usar, permite a realização de etapas críticas da cricotireotomia e apresenta potencial viabilidade de ensino. O tempo de procedimento diminuiu entre a primeira e a terceira tentativa entre os estudantes (diminuição média do tempo = 61,85 s; IC 95% – 41,86 – 81,85; $p < 0,001$), e foi encontrada diferença significativa entre os tempos de atuação dos cirurgiões e dos estudantes (diferença média = 101,36 segundos [IC 95% = 69,08 – 133,64] $p < 0,001$), sugerindo validade de construto. Os escores de desempenho dos alunos melhoraram entre a primeira e a segunda tentativa (diferença média = 2,25 pontos; IC 95% = 1,31 – 3,20; $p < 0,001$).*

Conclusão: *O simulador de cricotireotomia inorgânico, de fabricação caseira e de baixo custo possui validade de face, conteúdo e construção aceitáveis para ser usado como ferramenta de treinamento para estudantes de graduação em Medicina.*

Palavras-chave: *Gerenciamento das Vias Aéreas; Cartilagem Cricoide; Cirurgia; Educação Médica; Graduação; Treinamento de Simulação; Estudo de Validação.*

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INTRODUCTION

Cricothyrotomy is a life-saving procedure used in emergency airway management. Cricothyrotomy accounts for approximately 0.45% of emergency airway interventions as the last resource to establish a patent airway in "cannot intubate, cannot oxygenate" (CICO) scenarios. Thus, mastering cricothyrotomy is crucial for physicians, especially those involved in emergency, critical, or anesthesia care.[1] Nevertheless, proficiency achievement poses challenges, notably the limited availability of high–fidelity simulators and the financial investment regarding cost–efficiency[2–4].

Simulators serve as tools for the acquisition and improvement of procedural skills in airway management[5–7]. Simulators also facilitate hands-on practice in a stress–free and safe environment, fostering mastery of technical and non-technical procedural skills[5,6]. Skills acquired through simulation training can be effectively transferred to clinical practice[5,7–9], thus contributing to patient safety and minimizing costs associated with medical errors[10]. Implementing simulation-based learning in some medical education contexts may face obstacles primarily related to the institutional budget, physical space, or clerical support.

Commercially available high-fidelity simulators are expensive[5,7,11], and exceed the needs for basic skill training[5,12–17]. While high-fidelity simulators are essential for training non-technical skills and crisis resource management, low–fidelity simulators may be more effective for technical skills [13,14]. The abovementioned factors have contributed to fostering research on low-cost, low-fidelity simulators[2,3,5–8,10–12,18–22]. For example, Kei et al. introduced the REAL CRIC Trainer, a cost-efficient simulator that includes skin, tissue, and bleeding components[3]. Similarly, Varaday et al. developed a homemade cricothyrotomy model that showed potential as a training tool[21]. However, data on the psychometric validity of low-fidelity cricothyrotomy simulators are still scarce.

This study aimed to validate the psychometric performance – face, content, and construct validity – of a non-organic, homemade, low-cost cricothyrotomy simulator specifically developed for this study.

METHOD

The Institutional Research Ethics Committee approved this observational cross-sectional study (Certificate of Presentation of Ethical Review number 49469321.7.0000.0121). Written informed consent and authorization for the use of images were obtained from the study participants. This study complies with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement[23].

Forty-seven medical students and nine surgeons were recruited from December 2021 to July 2022. The inclusion criterion for students was having been approved in the surgical technique discipline of the medical course, and the exclusion criterion was having had previous training in cricothyroidotomy. The inclusion criterion for surgeons was an experience with at least two emergent cricothyrotomies in actual patients.

The simulator was designed to mimic the structures of the anterior human neck and the airway involved in the performance of the cricothyrotomy: skin, thyroid, and cricoid cartilages, cricothyroid ligament, trachea, main bronchi, and lungs. The cartilages were sculpted in epoxy resin over a corrugated plastic electrical conduit simulating the trachea. A replaceable kinesiology tape covered a 1 cm hole between the thyroid and cricoid components, simulating the cricothyroid ligament. Garden hose Y-shaped accessories adapted to the distal part of the trachea component simulated the main bronchi, and rubber balloons adapted to the bronchi component simulated the lungs. The assembled components were embedded into a high–density foam piece with rounded contours simulating the anterior face of a human neck. The simulator was covered with an artificial skin made of a tulle mesh embedded in skin-color silicone resin. The set was attached to a base made of two medium-density fiberboard (MDF) boards with hinges at one end, allowing the replacement of the cricothyroid ligament component and the skin incision site between attempts. The construction cost of the simulator was estimated by summing the acquisition prices of the simulator components.

A cricothyrotomy kit containing a scrubbing bowl, gauze pads, straight forceps for antisepsis, a fenestrated drape, a disposable scalpel with a number 15 blade, curved forceps, and simulated antiseptic solution (tap water) was available for performing the simulated procedures.

Before participating in the simulation session, each participant completed a demographic questionnaire that included age, self-declared gender identity, and dominant hand. The students were asked about the semester they were attending in the medical course, while the surgeons were inquired about their specialty, time in practice and the number of cricothyrotomies performed.

Thirty minutes before starting the simulation session, students watched a video demonstrating the steps of an emergent cricothyrotomy using the simulator.

The cricothyrotomy demonstration followed a pre-defined 13-step task sequence: (1) glove wearing, (2) skin antisepsis, (3) drape positioning, (4) assembly of the scalpel, (5) palpation of the cricothyroid ligament, (6) transversal skin incision over the cricothyroid ligament, (7) assuring the incision is approximately 1-cm wide, (8) 90° rotation of the scalpel to pass the bougie, (9) bougie advancement into the trachea, (10) tracheal tube lubrication, (11) positioning of the tracheal tube

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into the trachea, (12) tracheal cuff inflation, (13) lung inflation. After watching the video, the students were allowed to ask questions and clarify doubts with the instructor.

Afterward, each participant performed a sequence of three simulated cricothyrotomies at 3 to 5-minute intervals, during which the instructor replaced the cricothyroid ligament component, repositioned the artificial skin for the next attempt and replaced the cricothyrotomy kit.

The procedures were digitally recorded with cameras focused on the participants' hands to allow blind assessment and rating of the student's technical performance. Procedural duration was obtained from the video recordings.

The participating surgeons performed three consecutive simulated cricothyrotomies at 3 to 5-minute intervals between them, using their techniques of choice. The procedures were video recorded, and performance duration was obtained from the videos.

After completing the cricothyrotomy attempts, the participants answered a 22-item questionnaire addressing criteria for face and content validity, usability, students' self-perceived preparedness or surgeons' perceptions about the simulator's realism, and general opinions about the relevance of teaching cricothyrotomy to medical students.

The criteria for face validity included the simulator's resemblance to a human anterior aspect of the neck and the haptic sensations produced by the simulator components (items 1 and 2). The criteria for content validity included the participants' perceived capacity of the simulator to reproduce the steps of an emergent cricothyrotomy and its use as a teaching or training tool for undergraduate medical students (items 8 – 15). The criteria for usability included the easiness and intuitiveness of assembly, portability, safety, construction, and operational costs (items 3 – 7 and 19 – 22). Miscellaneous topics included one question directed at surgeons addressing the realism of the cricothyrotomy performed on the simulator (item 18); two questions directed at medical students addressing the perceived self-preparedness for performing an emergent cricothyroidotomy in an actual patient, and the role of the simulator experience in acquiring cricothyrotomy skills (items 16 and 17); and one question addressed the perceived relevance of developing cricothyrotomy skills during undergraduate medical education (item 20). The items were rated on 11-point (0 - 10) numerical rating scales, where zero represented the most negative and ten the most positive perceptions. To meet the construct validity criteria, performance on the simulator should differentiate students' and surgeons' procedural duration, identify distinct student performance levels, and capture the students' technical changes across sequential attempts.

The students' technical performance was independently assessed by the two authors based on the video recordings using a 13-item checklist containing the steps of cricothyrotomy as demonstrated to the students before data collection. The items were rated on binary (yes/no) scales indicating the performance or not of each step[24,25]. Discrepant ratings were reviewed, and the final performance scores comprised the average of the two raters' scores.

Statistical Analyses

Shapiro-Wilk and Kolmogorov-Smirnov tests were used to assess the adherence of data to the normal distribution. Scores assigned to items in the validation questionnaire were compared between students and experts using the Mann-Whitney U tests and summarized as median and 25^{th} – 75^{th} percentiles. Two–way, repeated measures ANOVA (groups x attempts) was used to compare performance duration between students and experts. Data are summarized as mean and 95% confidence limits. Square root transformation was applied to the students' performance scores, and one–way, repeated measures ANOVA (attempts) followed by the Student–Newman–Keuls *post hoc* test were used to compare the students' performance scores among the three attempts. For reporting, squared marginal means and 95% confidence intervals (95% CI) were estimated to return summary scores to the original scale. Statistical significance was set at an alpha probability lower than 5%. The internal consistency of the face and content validity questionnaire was assessed by estimating the Cronbach' alpha coefficient.

The sample size was estimated based on a minimal expected difference in performance duration between students and surgeons of at least 0.8 standard deviations, assuming an alpha = 5% and 1 – beta = 20%. Accordingly, a sample including 24 students and eight surgeons was adequate for two-tailed comparisons using the Mann–Whitney test, with an allocation rate of at least three students to one surgeon. Sample size calculations were performed using G*Power software, version 3.1 [26].

RESULTS

Study sample

Forty-seven students and nine surgeons completed the study without losses or missing data. The study flow diagram is shown in Figure 1.

The demographic data of the samples are shown in Table 1.

Simulator construction cost

The construction cost of the simulator was estimated

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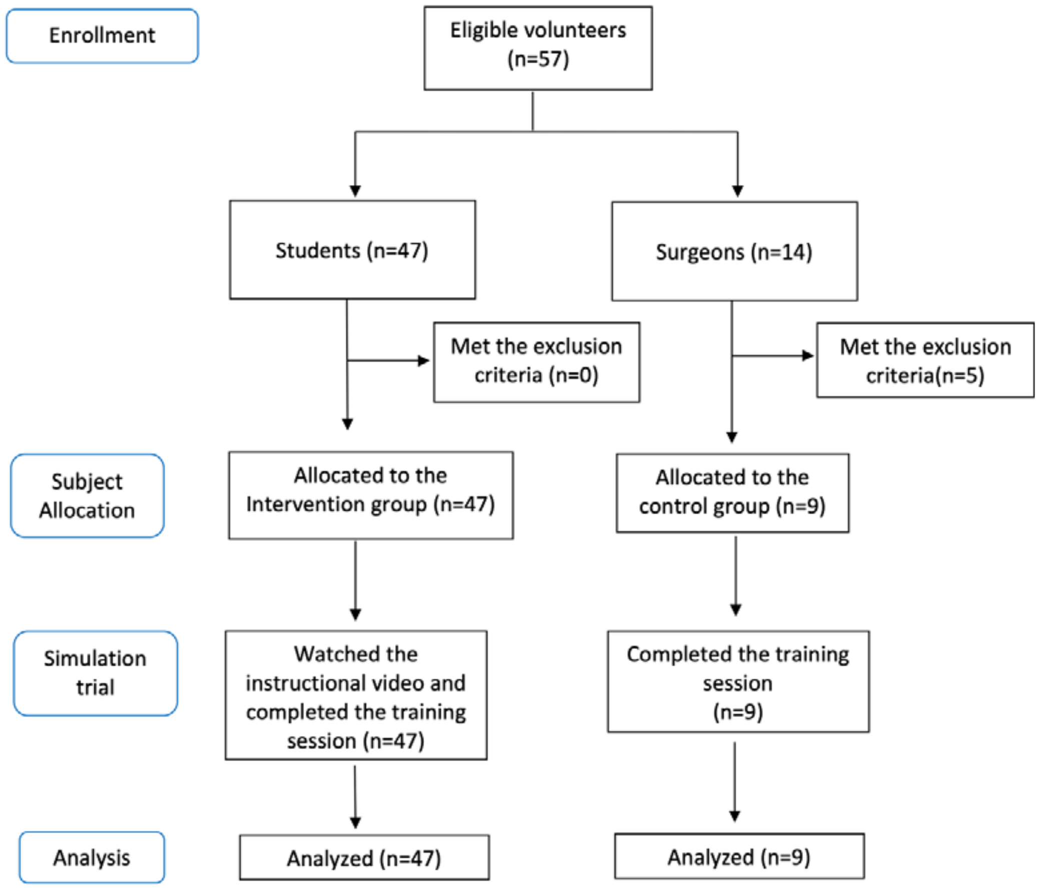
Figure 1. Study flow diagram.



Source: the authors.

Table 1. Participants' demographic data.

Groups	Students n = 47	Surgeons n = 9
Age (years)[a]	23 (19 – 40)	42 (31 – 56)
Self–declared gender identity (n)[b]		
Male	32	9
Female	15	0
Non–binary/other/prefer not to disclose	0	0
Dominant hand (n)[b]		
Right-handed	45	8
Left-handed	2	1
Students' semester in the medical course[a]	7 (5 – 12)	–
Specialty (n)[b]		
Head and neck surgery	–	6
General/digestive surgery	–	3
Years in the specialty [a]	–	13 (2 – 32)
Self-reported number of performed cricothyrotomies (n) [a]	–	4 (2 – 25)

Source: the authors. a: values are expressed as medians (Minimum–Maximum). b: values are expressed as frequencies.

at US$ 30 and the session cost was estimated at ¢40 for each attempt. The simulator is shown in Figure 2.

Face and content validity

The Cronbach's alpha coefficient of the face and content validity questionnaire was 0.88 (95% CI = 0.83 – 0.92). Responses to the validation questionnaire are shown in Table 2. Accordingly, students and surgeons assigned similarly high ratings to the visual and tactile resemblance of the simulator to the front surface of a human neck. The simulator was considered capable of reproducing the main cricothyrotomy steps, and its adequacy as a teaching device was rated highly by students and surgeons. Usability was suggested by the high ratings assigned to the simulator's easiness and intuitiveness of assembly, portability, safety, and low cost. Students and surgeons were also very positive regarding the relevance of acquiring cricothyrotomy skills in medical education. No differences were found between the students' and surgeons' ratings. The experience in the simulator contributed to the students' positive perceptions about their acquisition of cricothyrotomy skills and their self-preparedness to perform it in actual patients. Surgeons positively rated the realism of the simulator.

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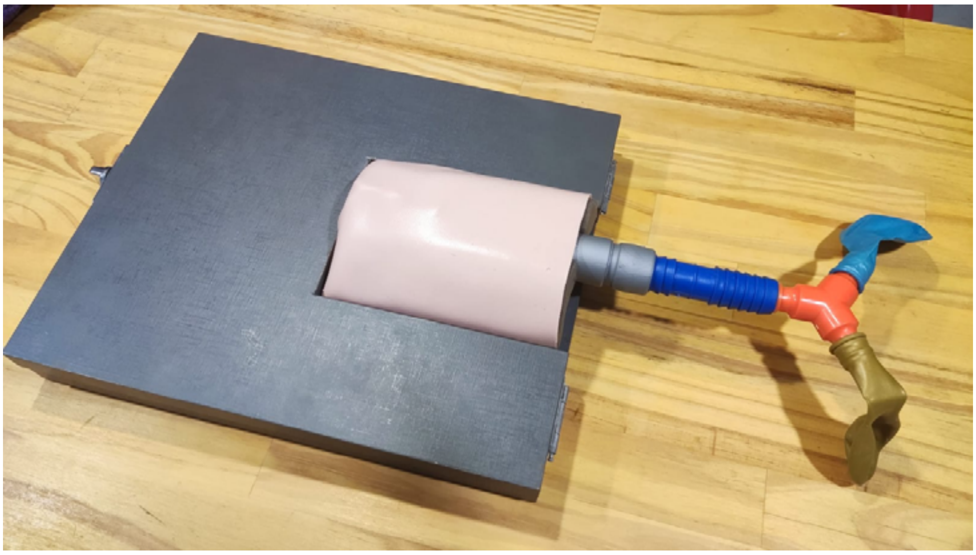
Figure 2. External view of the simulator.



Source: the authors.

Table 2. Comparison between students' and surgeons' responses to the face and content validity questionnaire.

Parameter	Students	Surgeons	p-value
Face validity			
The model looks like a neck.	9 (8 – 10) [7 – 10]	9 (7.5 – 9.25) [6 – 10]	0.255
The model feels like a neck to the touch.	9 (8 – 10) [5 – 10]	9 (7.75 – 9.25) [7 – 10]	0.247
Content validity: reproducibility of the steps of an emergent cricothyrotomy and use as a teaching tool			
Palpation of anatomical references.	10 (9 – 10) [7 – 10]	10 (8.75 – 10) [8 – 10]	0.552
Skin incision.	9 (8 – 10) [6 – 10]	9.5 (8.75 – 10) [8 – 10]	0.481
Bougie pass into the trachea.	9 (9 – 10) [7 – 10]	10 (8.75 – 10) [8 – 10]	0.582
Tube advancement over the bougie.	10 (9 – 10) [7 – 10]	10 (8.75 – 10) [8 – 10]	0.251
Tube positioning and cuff inflation	10 (9 – 10) [7 – 10]	10 (9.75 – 10) [9 – 10]	0.980
Stability of the tube during bag ventilation.	10 (9 – 10) [8 – 10]	10 (9.75 – 10) [9 – 10]	0.979
The simulator can be applied as teaching tool to undergraduate students.	10 (10 – 10) [9 – 10]	10 (10 – 10) [9 – 10]	0.187
The simulator allows learning the cricothyroidotomy techniques .	10 (10 – 10) [9 – 10]	10 (9.5 – 10) [8 – 10]	0.114
Usability			
The simulator assembly is intuitive.	10 (9 – 10) [7 – 10]	10 (9.57 – 10) [9 – 10]	0.464
The simulator assembly is simple.	10 (10 – 10) [8 – 10]	10 (9.75 – 10) [9 – 10]	0.594
The simulator can be assembled anywhere.	10 (10 – 10) [7 – 10]	10 (9.75 – 10) [9– 10]	0.625
The simulator can be used anywhere.	10 (9 – 10) [6 – 10]	10 (9.75 – 10) [9 – 10]	0.318
The simulator poses risks to users.	1 (1 – 2) [1 – 3]	1 (1 – 2) [1 – 2]	0.354
The simulator is user-friendly.	10 (10 – 10) [8 – 10]	10 (9.5 – 10) [8 – 10]	0.639
The construction cost of US$ 30.00 is reasonable.	10 (9 – 10) [6 – 10]	10 (10 – 10) [9 – 10]	0.318
The cost of US$ 0.40 per training session is reasonable.	10 (9 – 10) [1 – 10]	10 (10 – 10) [9 – 10]	0.298
Student self-perceived preparedness			
I feel capable of performing a cricothyroidotomy.	8 (8 – 9) [5 – 10]	–	–
The simulator was decisive for the acquisition of cricothyrotomy skills.	10 (10 – 10) [8 – 10]	–	–

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Table 2. Continuation.

Parameter	Students	Surgeons	p-value
Surgeons perceived the realism of the simulator			
The model allows the exact experience of cricothyroidotomy.	–	7.5 (7 – 9) [7 – 10]	–
Perceived relevance of acquiring cricothyrotomy skills during the undergraduate medical course			
Cricothyroidotomy training is essential in medical education	10 (10 – 10) [7 – 10]	10 (10 – 10) [10 – 10]	0.215

Source: the authors. Data summarized as median (25th – 75th percentiles) [minimum – maximum].

Table 3. Comparison of performance duration between students and surgeons.

	Attempt 1		Attempt 2		Attempt 3	
	Students	Surgeons	Students	Surgeons	Students	Surgeons
Procedural duration (s) [a]	268.57 ± 62.48 [248.57 – 288.58]	156.55 ± 95.57 [110.84 – 202.27]	222.11 ± 44.42 [c] [207.85– 236.36]	122.33 ± 68.49 [89.76 – 154.91]	206.72 ± 33.65 [d] [196.06 – 217.39]	114.44 ± 49.62 [90.08 – 138.81]
Mean difference (s) [b]	112.02 [62.12 – 161.92] p = < 0.001		99.77 [64.22 – 135.33] p = < 0.001		92.28 [65.68 – 118.88] p = < 0.001	

Source: the authors.
a. Data expressed as mean ± standard deviation [95% confidence interval].
b. Data expressed as mean difference between groups [95% confidence interval].
c. p = 0.001 compared to students' attempt 1.
d. p < 0.001 compared to students' attempt 1 and p = 0.02 compared to attempt 2.

Construct validity

The surgeons' procedural duration were shorter than the students' in all attempts (Table 3). Procedural duration did not change across the surgeons' attempts, but the students' times decreased significantly from the first to the third attempt.

The students' technical performance scores increased significantly from the first (mean ± SEM = 9.01 ± 0.01; 95% CI = 8.16 – 9.91) to the second attempt (mean ± SEM = 11.56 ± 0.0009; 95% CI = 11.14 – 11.99; p = < 0.001) but stabilized from the second to the third attempt (mean ± SEM = 11.32 ± 0.01; 95% CI = 10.25 – 12.43).

DISCUSSION

Cost-effective, objective-driven simulators are critical in medical education[5,9,15,15], especially for vital procedures such as cricothyrotomy[1], given the dramatic and life-saving nature of this procedure in CICO scenarios[20–22]. This study provides evidence for the reliability of a homemade, low-cost cricothyrotomy simulator for training undergraduate medical students in cricothyrotomy.

A simulator must demonstrate its face, content, and construct validity to be considered educationally beneficial and merit advanced psychometric testing[10,27,28]. Validation strategies can be distinguished into subjective and objective approaches. Subjective approaches evaluate novices' and experts' opinions, while objective approaches evaluate experimental prospective performances. Face and content validity are examples of subjective validity, while construct validity requires an objective parameter. Face validity refers to how realistic the simulator looks and feels to the user and its acceptance, implying that some resemblance must be perceived between the simulator and human anatomical structures. Also, haptic sensations returned to the operator during simulation must be similar to those returned during the performance on an actual patient. Content validity refers to the capability of the simulator to allow the performance of the main steps of the target procedure, as assessed by experts. The simulator developed for this study met the face and content validity criteria.

Construct validity requires demonstrating that performance on the simulator can discriminate distinct performance levels, for example, between experts and novices, or changes in performance in time, indicating gain of familiarity or skills during repeated attempts. Accordingly, the simulator consistently differentiated performance duration between surgeons and students, and students' performance scores improved from the first to the second attempt, suggesting that the simulator may have met the criteria for construct validity[27,28].

Our results suggest high face validity of the simulator, based on the participants' favorable judgment about the resemblance and haptic similarities between the simulator and the human anterior neck anatomy. Favorable experts' judgment about the capacity of reproducing the main steps

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of an emergent cricothyrotomy and the usefulness of the simulator as a teaching tool suggests the content validity of the simulator. Evidence for the construct validity of the simulator is provided by its capacity of discriminating between novice and expert performance and capturing student improvement across attempts[14].

This study must be interpreted considering its limitations. The study primarily focused on assessing the simulator's face, content, and construct validity and did not explore other forms of validity (e.g., concurrent and criterion validity), which would have demanded a randomized controlled design. Also, long-term educational skill retention was not addressed in this study. Cricothyrotomy is a time-sensitive procedure. We did not impose time limits on students to complete the procedures. Adding time limits and increasing the number of procedures would have provided additional metrics of skill acquisition. Furthermore, assessing the simulator performance in a simulated CICO situation was not done. Skill transfer to the practice on actual patients was not aimed in this study because of the rarity of the procedure in the clinical setting and because the most skilled operator will always be prioritized in a CICO life-threatening situation.

CONCLUSION

In conclusion, the non-organic, homemade, low-cost cricothyrotomy simulator described in this study has acceptable face, content, and construct validity to be used as a training tool by undergraduate medical students.

AUTHORS' CONTRIBUTION

Ian Novy Quadri: helped in Study concept, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data Curation, Writing - Original Draft, Writing - Review & Editing, Visualization, Project administration.

Getúlio Rodrigues de Oliveira Filho: Study concept, Methodology, Software, Validation, Formal analysis, Resources, Data Curation, Writing - Original Draft, Writing - Review & Editing, Visualization, Project administration.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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