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Design and Evaluation of a Low-Cost Bronchoscopy-Guided Percutaneous Dilatational Tracheostomy Simulator

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Introduction: Bronchoscopy-guided percutaneous dilatational tracheostomy (BG-PDT) is an invasive procedure regularly performed in the intensive care unit. Risk of serious complications have been estimated in up to 5%, focused during the learning phase. We have not found any published formal training protocols, and commercial simulators are costly and not widely available in some countries. The objective of this study was to present the design and simulator performance of a low-cost BG-PDT simulator.

Methods: A simulator was designed with materials available in a hardware store, synthetic skin pads, ex vivo bovine tracheas, and a pipe inspection camera. The simulator was tested in 8 experts and 9 novices. Sessions were video recorded, and participants were equipped with the Imperial College Surgical Device, a hand motion–tracking device. Performance was evaluated with a multimodal approach, including first attempt success rate, global success rate, total procedural time, Imperial College Surgical Device–derived proficiency parameters, and global rating scale applied blindly by 2 expert observers. A satisfaction survey was applied after the procedure.

Results: A simulator was successfully constructed, allowing multiple iterations per assembly, with a fixed cost of US $30 and $4 per use. Experts had greater global and first attempt success rate, performed the procedure faster, and with greater proficiency. It presented high user satisfaction and fidelity.

Conclusions: A low-cost BG-PDT simulator was successfully constructed, with the ability to discriminate between experts and novices, and with high fidelity. Considering its ease of construction and cost, it can be replicated in almost any intensive care unit.
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Key Words: Tracheostomy, simulation, low cost, percutaneous dilatational tracheostomy, intensive care medicine, critical care.

Since its original description by Ciaglia et al,[1] percutaneous dilatational tracheostomy (PDT) has become the standard of care in many intensive care units (ICUs) worldwide.[2] Multiple studies have demonstrated benefits over surgical tracheostomy, including less bleeding, lower rates of infections, lower operative time, and lower costs.[3–5] Despite these advantages, serious complications occur in up to 5% of cases of PDT[6] and are proportionally higher during the learning phase.[7] The introduction of bronchoscopy-guided PDT (BG-PDT), has enhanced safety issues of the original PDT technique and has become the preferred technique in many centers.[5,8]

Although there has been widespread implementation of PDT in clinical practice, to the best of our knowledge, there are no PDT training protocols or individual learning curves described, in contrast with other ICU-related procedures, such as orotracheal intubation[9] or central venous catheterization (CVC).[10]

Simulation of technical skills has emerged as a key resource for healthcare training, enabling competency acquisition in a safe environment, without harming patients and using error as an input for the learning experience.[11] In CVC insertion, simulation-based training protocols have demonstrated fewer complications,[12,13] greater success rate,[14] better adherence to protocols,[15] and greater proficiency,[16] among other benefits.

Available commercial simulators for PDT have a high cost (>US $1000) and are not readily available in all countries. In the literature, multiple low-cost simulators have been published.[17–20] Despite this, some of them do not allow bronchoscopic guidance and have been assessed only with satisfaction surveys, with no objective or subjective measurements of operator performance. Moreover, both commercial and low-cost simulators are designed for single use, having to replace disposables after each training session.

The objectives of this study are as follows: (*a*) to describe the design of a low-cost simulator for BG-PDT, which allows multiple uses per assembly; (*b*) to perform a multimodal novice-expert comparison of BG-PDT performance in the simulator, including measurements derived from a hand motion–tracking device and blind assessment of the

video-recorded sessions; and (c) to assess user satisfaction with the simulator.

MATERIALS AND METHODS

Ethics

The institutional review board approved this report (Comité de Ética en Investigación, Facultad de Medicina, Pontificia Universidad Católica de Chile, Approval Number 180704005) and waived the need of an informed consent.

Bronchoscopy-Guided PDT

In brief, the technique of BG-PDT is usually performed by 2 physicians, one handling the bronchoscope and one performing the tracheostomy. Insertion site is identified by palpation of the tracheal rings and bronchoscopic confirmation of the site. The trachea is punctured with a needle and a Seldinger guidewire is advanced. Progressive dilatation over the guidewire is performed with the dilators until the adequate size of the stoma is reached. Finally, the tracheostomy cannula is inserted and fixed and the guidewire is removed.[19]

During the process, real-time bronchoscopic guidance allows the operator to choose an adequate insertion site, maintain visual control of the progressive dilatation steps, avoid critical anatomical structures (like the posterior tracheal wall), promptly diagnose potential complications, and confirm the final cannula position.[5] Procedural aspects of bronchoscopic guidance of PDT are detailed in a companion table (see Table, Supplemental Digital Content 1, detailing bronchoscopic guidance of PDT, http://links.lww.com/SIH/A458).

Simulator Design

A simulator was constructed with materials easily obtained from a hardware store, including a 20 × 30-cm plastic cutting board, polyvinyl chloride (PVC) pipes, screws, and zip ties. Other items needed included a 15 × 30-cm, 6-mm-thick, 3-layered synthetic skin pads (Piel sintética de tres capas, Training & Competence,[21] Santiago, Chile), a 7-mm diameter, flexible pipe inspection camera with a USB connector (Cámara Endoscópica 7-mm 5-m USB Android; DFast,[22] Santiago, Chile) and ex vivo bovine tracheas (although other large mammalian tracheas could be used). Three iterations were constructed and tested by experts until the final version was obtained, in which different methods to fasten the skin and PVC tubes (adhesive tape and paper clamps) were tested.

A 4-cm-diameter × 10-cm length × 2-mm-thick half PVC tube was fixed to a 20 × 30-cm cutting board. Four 5-mm holes were drilled 1 cm away from the edges of this PVC tube, so zip ties could be inserted (Fig. 1A). Twenty-centimeter bovine tracheas (from below the larynx until to the carina) were attached to the tube with zip ties, with enough tension, so no horizontal traction movements could happen during the PDT, but without collapsing the trachea (Fig. 1B). An 8 × 8-cm window was clipped from a 10-cm-diameter × 24-cm × 4-mm-thick length half PVC tube, which was placed over the smaller halfpipe. Five 2.5-cm screws were screwed completely to the cutting board, and three screws to the big halfpipe, to fasten the skin (Fig. 1C). Construction time of the simulator was 1 hour.

The synthetic skin was placed in direct contact with the trachea and fixed to the screws around the cutting board and PVC tube. The skin was stretched with enough tension to allow the assembly of the simulator, as it maintained the PVC tubes, skin, and trachea fixed in position (Fig. 1D). If the trachea and skin did not make contact, a piece of foam was installed in between the small PVC tube and the trachea, to elevate the trachea and allow correct assembly. A flexible pipe inspection camera was connected to a laptop computer to emulate the live bronchoscopic view (Fig. 1E), which was manipulated by a second operator (who facilitated the bronchoscopic view but was not part of the assessment).

For the next use of the model, the zip ties were loosened, the trachea was repositioned inferiorly 2.5 cm, and the skin reinstalled 2.5 cm away, making sure that the previously punctured areas remained out of working space, allowing for a new iteration of BG-PDT to be performed. Assembly for a new use took 5 minutes. Each trachea allowed for 6 iterations, and each skin pad for 9 iterations.

Participants

Nine novices and 8 experts were invited to participate in this study. The novices were defined as senior-year anesthesiology or internal medicine residents with no prior experience in BG-PDT. Because there are no learning curves published, we arbitrarily defined "expert" as someone who had performed 20 or more BG-PDT. This cutoff value was obtained by triplicating the number in which training of emergency cricothyroidotomy success rates plateaus,[23] a similar procedure, but with fewer steps than BG-PDT.

Before the evaluation, novices were shown relevant BG-PDT literature and a step-by-step video of the complete procedure performed in the simulator. Before the procedure, the simulator and PDT kit were presented to both groups and relevant questions resolved.

Bronchoscopy-guided PDT was performed with the Ciaglia Blue Rhino kit. Performance in the simulator was video recorded in such a way that no identification of the user was possible, to allow blind evaluation. Figures 2A to E show the critical steps of BG-PDT.

Performance Measurements

Novice-expert comparisons were performed using the following criteria: global success rate; first attempt success rate; total time of procedure (from asepsis to ventilator connection); hand motion–tracking device derived parameters; and Global Rating Scale (GRS) scores.

The Imperial College Surgical Assist Device (ICSAD) is an electromagnetic-based hand motion–tracking device(Isotrak Il; Polhemus Inc., Colchester, VT). It includes a field generator, 2 sensors, (which are installed at the dorsum of the hands of the operator), a transducer, and a data processor.[24] The system collects x, y, and z coordinates of each sensor in a 3-dimensional plane. Two dexterity parameters are derived from the ICSAD.[24] First, the total path length (TPL) corresponds to the summation of all the distance traveled by the sensor in the 3 dimensions. With a programmed frequency of 20 Hz (the standard programming), it has an estimated accuracy of 1 mm.[25]

The second parameter is the number of movements (NM) performed. Its capacity of discriminating each movement
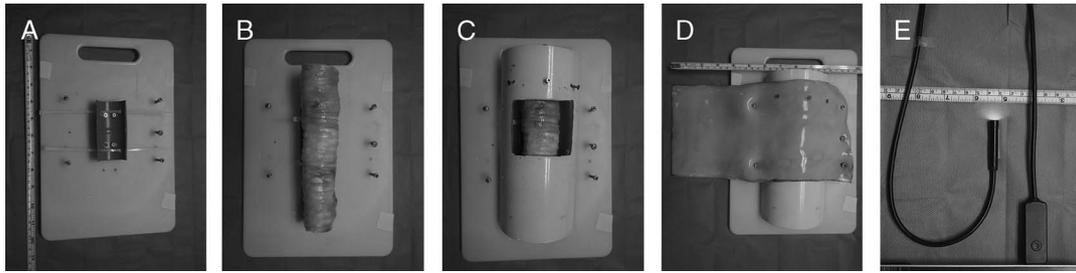
FIGURE 1. Step-by-step construction of the simulator. A, PVC tube attached to cutting board. B, Bovine trachea fastened to cutting board with zip ties. C, PVC tube with 8 × 8-cm window. D, Synthetic skin pad fixed to screws. E, USB pipe inspection camera used as bronchoscopy.

depends on the translational and rotational velocity threshold programmed beforehand.[24] Previous studies have successfully used thresholds between 7.5 and 50 mm/sec.[25–27] Motion tracking devices have been used effectively to assess technical proficiency in laparoscopic[28] and CVC training protocols,[29] correlating both TPL and NM with expertise and movement economy.[24,25,27] Figure 2A shows installation of ICSAD sensors during BG-PDT performance.

The objective structured assessment of technical skills (OSATS) scale is a GRS used in simulation-based training protocols.[10,28] Global Rating Scale has been regarded as a superior instrument over checklists in assessing technical proficiency and expertise.[30] It includes the following 5 areas in a 5-point Likert scale: respect for tissues, time and movements, use of instruments, procedural flow, and procedural knowledge. Two independent and blind experts (ICU physicians), with prior experience in the use of GRS in CVC training, scored each video-recorded session with OSATS scale (see Document, Supplemental Digital Content 2, describing OSATS scale, http://links.lww.com/SIH/A459).

After the simulation, an anonymous, e-mail-based survey was sent to experts. The following areas were evaluated in a 5-point Likert scale (1, completely disagree; 2, disagree; 3, indifferent; 4, agree; 5, completely agree): need for simulation training in BG-PDT training; trachea palpation; bronchoscopic assistance; progressive dilation; cannulation; and overall fidelity of the simulator. The survey ended with 2 open-ended questions that explored positive and negative aspects of the simulation (see Document, Supplemental Digital Content 3, describing the satisfaction survey used, http://links.lww.com/SIH/A460).

Statistical Analysis

As there are no previous data available for BG-PDT training, the number of participants recruited was similar to other published experiences,[31] and no sample size was calculated. Results are shown as median (interquartile range) or percentage accordingly. Nonparametric tests were used, as Mann-Whitney or Fisher exact test. Interrater agreement was assessed with Spearman r^2. Data were analyzed with Minitab v17 (Minitab Inc, State College, PA) and Graphpad Prism (Graphpad Softwares, La Joya, CA) softwares. Two-tailed P value of less than 0.05 was considered statistically significant.

RESULTS

Figure 1 shows the final iteration of the simulator and the step-by-step construction phases. The fixed cost was of US $30, and the costs of consumables were US $4 per use. Cost breakdown is presented in Table 1. The ICSAD's cost was not included in the project, because it was an asset previously acquired by the simulation center and was used to enhance the objective measurements, thus not required for the assembly of the simulator.

The expert group consisted of 3 intensive care specialists and 5 senior-year intensive care residents. The median number of real patient BG-PDT performed were 28 (21–293). None of them had performed BG-PDT in simulators, but all had participated in simulation-based CVC training. The novice group consisted of 5 internal medicine residents and 4 anesthesiology residents. When analyzing previous exposure to simulation training programs, only anesthesiology residents had performed CVC training. All novices were naive to BG-PDT with patients or simulators.

The measurements obtained in simulator performance showed statistically significant differences and thereby could be used to discriminate between novices and experts. Results of the multimodal analysis are shown in Table 2. Experts had higher global success rate (100% vs. 44%, $P = 0.03$), first attempt success rate (100% vs. 33%, $P = 0.01$), performed the procedure in less time [273 (262–302) seconds vs. 508 (382–630) seconds, $P = 0.006$] and with a higher movement
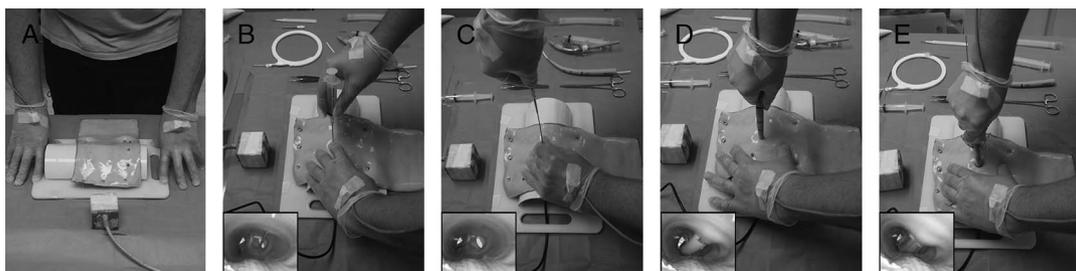
FIGURE 2. Bronchoscopy-guided PDT performance in the simulator and ICSAD installation. A, ICSAD sensors (installed in the dorsum of the operator's hand) and field generator. B, Tracheal palpation and puncture. C, Guidewire insertion. D, Progressive dilatation. E, Cannulation.

TABLE 1. Cost Breakdown of the Simulator

	Price (US $)	Price (US $) and No. Uses	Price per Use (US $)
Plastic cutting board (1)	$5		
Small PVC tube (1)	$1		
Big PVC tube (1)	$3		
Inspection camera (1)	$20		
Screws (8)	$1		
Zip ties (2 per procedure)		$2.5/50	$0.1
Synthetic skin (1)		$20/9	$2.2
Bovine trachea (1)		$10/6	$1.7
Fixed cost	$30		
Cost of consumables per use			$4

economy [TPL: 73.2 (62.8–80.6) m vs. 113 (88.7–117) m, $P = 0.005$; NM: 403 (361–479) vs. 569 (447–636), $P = 0.01$]. Spearman r^2 was of 0.91, meaning that both evaluators showed a high interrater agreement.

All experts answered the satisfaction surveys. Results are shown in Table 3. All agreed or strongly agreed with the statement "BG-PDT simulation-based training should be implemented in the ICU residency curricula," and the fidelity of both the overall process and subprocesses of the simulator was high. In the open-ended questions, participants stated that "the simulator could not replicate bleeding, which is an important complication of the procedure," and that "bovine trachea is a little bit more rigid than human trachea." Experts also stated that "its simplicity and ease of use makes it an interesting model for training" and "global consistency and palpation is really similar to patients."

DISCUSSION

The main findings of this study can be summarized as the following: we present a novel, easy-to-construct, low-cost BG-PDT simulator, which allows multiple uses. A multimodal performance evaluation was implemented, which included objective measurements derived from hand motion tracking device and blind video assessment of proficiency in the simulator. The simulator effectively discriminated between novices and experts. Application of OSATS scale had high interrater concordance in expert observers. Finally, fidelity assessment by experts through all the stages of the procedure was satisfactory.

Hand motion tracking devices, such as ICSAD, are useful tools for skills assessment. They have been used efficiently in different scenarios and training programs, providing an objective measurement of movement economy and procedural flow.[25–27,29] Because this is the first use of motion tracking devices in BG-PDT training, there are no benchmark values

TABLE 2. Novice-Expert Performance Comparison in the Simulator

Variable	Experts (8)	Novices (9)	P
Global success rate. %	100	44	0.03
First attempt success rate, %	100	33	0.01
Total time, s	273 (262–302)	508 (382–630)	0.006
Total path length, m	73.2 (62.8–80.6)	113 (88.7–117)	0.005
No. movements	403 (361–479)	569 (447–636)	0.01
OSATS score (5–25)	23.5 (23–25)	8.5 (8–16)	0.01

Values are expressed as median (interquartile range) or percentage.

TABLE 3. Expert Satisfaction Survey Results

Area	Median	Interquartile Range
Need of simulation in BG-PDT training	5	(5–5)
Palpation of the trachea	5	(5–5)
Bronchoscopic assistance	5	(5–5)
Percutaneous dilatation	5	(4–5)
Final cannulation	5	(5–5)
Overall fidelity of the simulator	5	(5–5)

of operatory proficiency. When compared with experiences published in CVC training, in both procedures the experts present higher movement economy and perform the procedure in less time than novices. Though not directly comparable, in BG-PDT, the experts had higher NM and TPL than CVC training, which may indicate that BG-PDT is a more complex procedure.

Despite being a low-cost model, our simulator exhibited many characteristics of the real procedure. Experts were satisfied with the overall process and subprocesses, including palpation, bronchoscopic guidance, dilation, and cannulation. Common complications of the procedure can be assessed in this model like nonmidline puncture, puncture through the cartilage, posterior wall trauma, and guidewire misplacement.

In the landmark report *To Err Is Human*, in 2000, 98,000 deaths in the United States were related to medical errors.[32] Other reports show that up to 50% hospital adverse events as procedure-related events and 13% of these were caused by direct technical errors.[33] Simulation training protocols help all healthcare professionals advance in their learning curve without potential harms to patients. Efforts to implement skills training protocols, interprofessional team training, and crisis simulation should be made in the ICU setting. Despite these suggestions, in low- and middle-income countries, one of the potential barriers for the implementation of simulation training includes the high cost and lack of availability of commercial simulators.[34]

Some limitations must be addressed in our study. First, no sample size calculation was performed. Despite this, the number of volunteers was similar to other published reports,[31] and our results showed statistically significant differences, diminishing the possibility of type 2 error. Some negative aspects of the simulator were mentioned by the participants, including the lack of bleeding. Anatomically correct bleeding modules could be added (ie, jugular or thyroid vasculature) between the trachea and the skin to improve fidelity but also could increase the building complexity and cost.

Low-cost and easy-to-construct simulators allow the implementation of simulation training for health care professionals in a wide range of settings. Studies have shown that low-cost simulators perform equally to commercial ones[35] and can effectively transfer skills to clinical practice.[36,37] The educational emphasis of training should be focused in effective feedback, deliberate practice,[38] and continuous training of professionals.

The development of an BG-PDT simulator is relevant because this is the first step for the introduction of a comprehensive training protocol for BG-PDT in our residency program. The multimodal evaluation will be useful for the evaluation of competency acquisition through the training program and

development of learning curves in the simulator, as we have already determined the basal level of novices and the benchmark level from experts. In addition, in the future, we intend to analyze competency transfer from the simulator to real patients.

CONCLUSIONS

We have presented a low-cost BG-PDT simulator, which effectively differentiates novices from experts, can be used multiple times, and presents high fidelity and user satisfaction. This low-cost simulator is the building block for the design of a future simulation-based training program in BG-PDT for residents. The simulator can be easily replicated in any ICU worldwide.

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