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A Multidisciplinary International Collaborative Implementing Low Cost, High Fidelity 3D Printed Airway Models To Enhance Ethiopian Anesthesia Resident Emergency Cricothyroidotomy Skills

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Abstract

Background: Similar to other sub-Saharan countries, Ethiopia suffers from a severe shortage of adequately trained health professionals. Academic partnerships can support sustainable training programs and build capacity for low-resource settings. 3D modeling and simulation-based training provide necessary tools, especially for rarely-encountered clinical situations, such as needle cricothyroidotomy.

Methods: Departments of Anesthesiology, Otolaryngology, and Learning Health Sciences collaborated to develop a low-cost, high-fidelity simulator and Cricothyroidotomy Skills

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Maintenance Program (CSMP). Twelve anesthesia residents at St. Paul's Hospital Medical Millennium College in Addis Ababa, Ethiopia participated in CSMP. The program consisted of a didactic session with presentation and demonstration and an immersive CICO scenario. Program evaluation was performed using pre/post-training knowledge and 2 procedural performance assessments-the CSMP Global Rating Scale and the Checklist. With consent, performances were videotaped and rated independently by 3 University of Michigan faculty.

Results: Improvements were identified in all areas, including residents' knowledge, measured by mean summed test scores, (Mpre=3.31,Mpost=4.46, $p=0.003$), time to perform cricothyroidotomy (Mpre=96.64,Mpost=72.82, $p=0.12$), residents' performance quality, measured by overall mean Global ratings, (Mpre=0.20;Mpost=0.70) with improvements identified at the item-level, $p=0.001$ with moderate to large effect sizes, and residents' ability to complete tasks, measured by mean Checklist ratings (Mpre=0.51,Mpost=0.90, with item-level improvements observed, $p=0.01$, with small-to-large effect sizes. Residents' self-reported confidence also improved, (Mpre=1.69, Mpost=3.08, $p=0.001$).

Conclusion: Our work shows that cricothyroidotomy skills taught to anesthesia residents at SPHMMC with a 3D printed laryngotracheal model improves knowledge, skills, and confidence. The creation of a low-cost, high-fidelity simulator and a CSMP has the potential to impact patient care and safety world-wide.

Keywords

global health; printing; three dimensional; anesthesiology; otolaryngology; emergencies; learning

BACKGROUND

A clear need for a vast increase in global medical training and education exists. This need presents opportunity for low-cost, effective educational innovation. In 2015, the Lancet Commission on Global Surgery report brought to light the fact that five billion people lack access to safe, affordable surgical and anesthesia care.¹ The Commission estimated that performance of a minimum of 143 million additional surgical procedures would be necessary each year to save lives and prevent disability. This highlights a severe shortage of surgeons, anesthesiologists, and obstetricians (SAO providers) with the Commission estimating the need to train an additional 1.27 million personnel to reach the 2030 goal of having 20 providers for every 100,000 population.²

These workforce deficits are especially critical in Sub-Saharan African countries. Ethiopia, for example, has one physician anesthesiologist for every 5,000,000 population in comparison to the United States with one physician anesthesiologist for every 8772 population, a 570-fold difference.³ Although the Ethiopian government has responded by increasing the number of medical schools and anesthesia residency training programs, the education of these residents remains a challenge. Academic partnerships to improve training the health workforce is one of the sustainable ways of capacity building for low-resource settings.

Simulation is a method used in health care education to replace or amplify real patient experiences with scenarios designed to replicate real health encounters, using lifelike mannequins, physical models, standardized patients, or computers.⁴ Although first applied to medical training in the 18th century⁵, increased use occurred in the 1960s with the development of Resusci-Anne and Harvey mannequins.⁶ Today, it is commonly asserted that every health professional training institution has either a simulation center, simulation equipment, or a simulation-based educational program.⁴ Amongst the many documented benefits, is the ability to learn, practice, and obtain competence in procedures rarely seen in clinical scenarios.

One such procedure is front-of-neck access (FONA), the final common pathway for the rare, but life-threatening, Cannot-Intubate-Cannot-Oxygenate (CICO) scenario. This can include needle cricothyroidotomy, scalpel-bougie technique, or emergency tracheostomy depending on the clinical situation, the personnel present, and the equipment available. Recently, the World Bank has published Disease Control Priorities, 3rd edition in which the emergency surgical airway is considered 1 of 44 essential surgical procedures.⁸ Given the lack of resources in low- and middle-income countries (LMICs) as well as the high incidence of trauma and advanced disease, needle cricothyroidotomy should be in the armamentarium of all emergency medical physicians, including surgeons, anesthesiologists, intensivists, and emergency room physicians.

To fill a perceived void in continuing medical education on pediatric airway management for anesthesia faculty and nurse anesthetists, the Departments of Pediatric Anesthesiology, Pediatric Otolaryngology, and Learning Health Sciences created a Cricothyroidotomy Skills Maintenance Program (CSMP). After development of the curriculum, it was felt our CSMP was an ideal way to assist with education and training of LMIC physicians and, therefore, it was trialed on anesthesia residents training at St. Paul's Hospital Medical Millennium College in Addis Ababa, Ethiopia. This study aimed to assess the impact of the novel CSMP on needle cricothyroidotomy knowledge and skills of resource-poor healthcare trainees using a high fidelity, low cost laryngotracheal model produced using Computer Aided Design (CAD) and 3D printing.⁹

METHODS

Following review and exemption determination by the University of Michigan and St Paul's Hospital Medical Millennium College Institutional Review Boards, twelve Ethiopian anesthesia residents (seven first year, five second year) participated in our CSMP. The multi-part program consisted of Pre-training (Pre) which included a knowledge test, confidence survey, and procedural performance assessment. The training session included a 20-slide PowerPoint (Microsoft; Redmond, WA) presentation to review the Pediatric Difficult Airway Algorithm, and a hands-on demonstration of correct needle cricothyroidotomy skills by one of the authors. A novel laryngotracheal model, produced with CAD and 3D printing from medical grade silicone, was incorporated into a mannequin to produce a low-cost, high-fidelity simulator for procedural performance assessment and training. Prior to performance of the cricothyroidotomy, each participant was described a real-life scenario that resulted in a CICO situation by one of the authors and then instructed to perform a

needle cricothyroidotomy with the provided equipment. Equipment consisted of a 14 gauge Ravussin needle and a Meditech Rapid-O2 Cricothyroidotomy Insufflation Device contained within a blue plastic bag. (Figure 1)

Post-training (Post) included the survey, knowledge test and procedure skills assessment conducted in the same fashion as pre-training. Residents' performances were videotaped at their consent and later rated independently by three University of Michigan faculty evaluators (two Anesthesia faculty, one Otolaryngology – Head and Neck Surgery resident).

Captured Measures and Scoring Processes:

Captured measures included pre- and post-training learner confidence, knowledge, and procedural performance quality. Self-reported learner confidence toward performing needle cricothyroidotomy was captured via 1 item scored on 5-point rating scale ranging from 1 (no confidence) to 5 (very confident). The knowledge test consisted of 7 multiple choice items measuring residents' understanding of the pediatric CICO algorithm and equipment necessary for successful performance of a needle cricothyroidotomy.

The procedural performance assessments included one objective measure– timing of the procedure (in seconds), and two observation-based performance measures captured using two tools–the CSMP Global Rating Scale, and the CSMP Checklist. The CSMP Global Rating Scale, a 6-item tool scored on 3-point scales and anchored as 0 (Not done) to 2 (Done correctly) was adapted from the OSATS, which has demonstrated its value at measuring technical skills in surgical settings⁹. The CSMP Checklist is a 9-item tool that represented nine step-wise tasks associated with proper cricothyroidotomy, also scored on the same 3-point scale. The pre-post assessments were administered in a conference room under the supervision of one of the authors without any preset time limit.

Analyses:

Differences in residents' pre- and post-training confidence, knowledge, and procedural time were identified using paired student t-test. For both the Global and the Checklist, pre-and post-training scores were compared for all items combined, and at the item-level, using a five-facet Rasch model (Resident x Time (Pre/Post) Training Year x Rater x Items), with effect sizes calculated as $\eta^2 = Z^2/N-1$. Statistical significance was established a priori as $p < 0.05$, with $\eta^2 < 0.20$, 0.50 , and 0.80 aligning with small, moderate, and large practical effect. Once analyses suggested there were no performance differences across training levels (both scales $X^2=0.0$, $df=1$, $p=1.00$), all data were combined for analyses. Inter-rater reliability for the 3 raters was estimated using Fleiss Kappa. Fleiss kappa was calculated separately for pre- and post-training for Global and the Checklist tools (all items combined), and also for both tools at the item-level.

FINDINGS

Confidence

Residents' mean post-training self-reported confidence was higher ($M_{\text{post}}=3.08$, $SD=0.86$) than self-reported pre-training confidence ($M_{\text{pre}}=1.69$, $SD=1.03$), $t(12)=4.45$, $p=0.001$, $d=1.14$.

Knowledge

Post-training knowledge, measured by mean summed scores, was higher ($M_{\text{post}}=4.46$, $SD=1.27$) than pre-training knowledge ($M_{\text{pre}}=3.31$, $SD=0.63$), $t(12)=3.64$, $p=0.003$.

Procedural Time

Mean post-training total time to perform cricothyroidotomy (measured in seconds) was lower ($M_{\text{post}}=72.82$, $SD=15.68$) than pre-training total time ($M_{\text{pre}}=96.64$, $SD=40.99$), but differences were not statistically significant, $t(10)=1.71$, $p=0.12$.

Procedural Performance

Global ratings. Overall, residents' mean Global performance ratings were higher following training ($M_{\text{post}}=0.70$) than prior to training ($M_{\text{pre}}=0.20$), $X^2=677.3$, $df=1$, $p=0.001$ (Table 1). At the item-level, there were statistical differences when comparing pre- and post-training mean ratings, with $p=0.0001$ for all six items. Effect sizes ranged from moderate (items 2 and 4) to large (items 1, 3, 5–6).

Checklist ratings

Overall, residents' mean Checklist ratings were higher following training ($M_{\text{post}}=0.90$) than prior to training ($M_{\text{pre}}=0.51$), $X^2=242.5$, $df=1$, $p=0.001$ (Table 2). At the item-level, there were statistical differences when comparing pre- and post-training mean ratings, with $p=0.01$ for 8 items. No statistical improvement following training was identified for one item (item 7; Reconfirms position by aspiration of air), $M_{\text{pre}}=0.14$, $M_{\text{post}}=0.28$, $p=0.06$. Effect sizes ranged from small (items 1 and 4) to large (items 3 and 5).

Inter-rater reliability

Inter-rater reliability for the Global items estimated via Fleiss Kappa ranged from fair (Item 2; time and motion) to substantial (Item 3; instrument handling, item 5; knowledge of procedure, and item 6; overall performance). Inter-rater reliability for all six items combined was moderate with pre- and post-test Fleiss Kappa values of 0.48 and 0.59 respectively.

Inter-rater reliability for the Checklist items estimated via Fleiss Kappa ranged from poor (Items 2, 4, and 5) to moderate, (items 3, and 7) to high (Items 1, 6, 8, and 9). Inter-rater reliability for all 9 items combined was high with pre- and post-test Fleiss Kappa values of 0.80 and 0.90 respectively.

INTERPRETATION

To our knowledge, this is the first formal emergency airway management training for anesthesia residents in a LMIC. The need for this training cannot be overstated. As clearly delineated in the DCP, 3rd edition, there are gross disparities in access to and safety of surgical procedures around the world “related to shortages of both human resources (eg, skills and staffing) and physical resources (eg, equipment and supplies).”⁷ While this has been a stimulus for national and international efforts, in the realm of “human resources”, there remains the challenge of education and training of physicians.

Our study shows that our CSMP curriculum significantly improved residents trainee skills of a LMIC with our zero risk, low-cost, high-fidelity 3D printed laryngotracheal simulator. This was confirmed using 2 assessment tools with at least reasonable interrater reliability. Although not statistically significant, trends suggested improved time measures. International anesthesia trainee knowledge and confidence were also improved.

The incidence of encountering a CICO scenario is difficult to ascertain. Within the anesthesia literature, there are several estimated incidences reported^{10,11,12}, the largest and most comprehensive being The Fourth National Audit Project of the Royal College of Anesthetists¹³. While they reported an incidence of 133/2,872,600 (1/22,000) general anesthetics, this number includes all airway problems. That being stated, difficult or delayed intubation, failed intubation, and ‘can’t intubate, can’t ventilate’ accounted for 39% of the events. An emergency surgical airway was attempted in 58 of the 133 anesthesia-related events (for an incidence of 1/50,000 general anesthetics) and a cricothyroidotomy was the first approach in 29 of these. Twelve of the 19 narrow-bore and 3 of the 7 wide-bore cannulae failed. Furthermore, of the 58 cases, only 25 were performed by anesthesiologists and only 9 of these were successful. Only 10 of the 133 reported cases were in children under the age of 10 years and 8 of these were during anesthesia. A detailed review of the 133 anesthesia-related cases found airway management to be suboptimal in 82% of the cases and education/training was found causal in 47% of these. The Pediatric Difficult Intubation (PeDI) registry is a multicenter web-based registry consisting of prospectively collected tracheal intubations supervised or performed by anesthesiologists in elective and non-elective tracheal intubation situations. Data collected between August 2012 to January 2015 found 1018 difficult tracheal intubations, 19 of which failed intubation and 6 of which were impossible to mask ventilate. Reported data do not describe any CICO scenarios or need for/use of emergency surgical airways.¹⁴

While the first difficult airway management algorithm was introduced by the American Society of Anesthesiologists (ASA) in 1993¹⁵, it wasn’t until 2012 that a pediatric-specific algorithm was released.¹⁶ The final common step in all algorithms is needle cricothyroidotomy, thus, anesthesiologists must know how to manage a difficult airway crisis and be confident in performing a front-of-neck access (FONA) when one is indicated.

Prior to the introduction of medical simulation, trainees acquired skills by observation and hands-on teaching. Inherent problems with this approach include a) risk to patients and b) inability to acquire the skills for procedures rarely encountered in clinical practice. While

detailed discussion on the development, implementation, and effectiveness of medical simulation for training is beyond the scope of this paper, a recently published systematic review lends tremendous support to this teaching methodology.¹⁷ This review, out of the UK, looked at 49 studies that investigated use of 3D printing for in surgical training, anatomic education, and preoperative planning. While they acknowledge many limitations, including few participants, cross-sectional studies, and heterogeneity of study design, they found clear enthusiasm about 3D printed models for surgical training. A similar literature review for anesthesia was performed in Australia.¹⁸ The paucity of studies, eight only, did not permit any analysis so the studies were summarized and the authors proposed future endeavors for their department and challenged the anesthesia community as a whole to collaborate and embrace this promising teaching modality.

This study has several limitations. First of all, the sample size is small. At the time of our visit, there were only 15 total anesthesia residents at St. Paul's Hospital Millennium Medical College. Secondly, all participants were from the same institution, therefore, results are not able to be generalized to other institutions within Ethiopia nor institutions within other LMICs. While all physicians caring for patients with potential for airway emergencies should be trained in needle cricothyroidotomy, all of our residents were from the department of Anesthesiology. Lastly, our study assessed the skills given a bag containing the necessary equipment. In low resource settings, the likelihood of practitioners having that equipment at their disposal is unlikely. However, during our training module, we did discuss use of alternatives to the Ravussin needle and Rapid O2 insufflation device. Indications and identification of landmarks as well as steps of the procedure would not be different.

Future directions will follow translation into clinical practice and retention of skills over time. Given the rarity of the CICO scenario, the ability to correlate simulation training to clinical practice for this particular procedure is exceptionally difficult and perhaps impossible. Our simulator and equipment were given to the SPHMMC Department of Anesthesiology and residents encouragement to review needle cricothyroidotomy skills. Twice yearly visits to Addis are planned for two of the authors at which time knowledge and skill retention will be evaluated.

The multidisciplinary nature of our group was essential in development and implementation of our CSMP. Expertise from each department contributed to a simulator and educational curriculum that was well received by pediatric airway experts in Departments of Pediatric Anesthesiology and Pediatric Otolaryngology. It is our hope that by increasing accessibility to training and education, we can facilitate the translation of knowledge and skills needed for performance of needle cricothyroidotomy to other Ethiopian trainees. Ultimately, we aim to develop and equip local physicians of LMICs with skills and capabilities to routinely teach additional LMIC colleagues, aspiring for exponential growth of vastly needed medical expertise.

CONCLUSION

Our multidisciplinary team has demonstrated a low cost, high fidelity 3D printed educational training simulation model within a Cricothyroidotomy Skills Maintenance Program can

significantly improve the life-saving, rarely performed, and previously difficult to rehearse skill of needle cricothyroidotomy.

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Figure 1:
(Left) 14 gauge Ravussin Needle Cannula, Meditech Rapid-O2 Cricothyroidotomy Insufflation Device, (Center) laryngotracheal simulator with external skin removed to show tracheal model, (Right) Ethiopian anesthesia resident performing needle cricothyroidotomy

Table 1.

Global Mean Ratings and Inter-rater reliability of 3 judges, estimated by Fleiss Kappa

No.	Item	Pre Mean (SD)	Post Mean (SD)	Effect size (η^2)	Fleiss Kappa Pre / Post
1	preparation for procedure	0.34 (0.48)	0.97 (0.80)	0.58	0.23 / 0.53
2	time and motion	0.37 (0.55)	0.80 (0.67)	0.39	0.46 / 0.43
3	instrument handling	0.09 (0.28)	0.66 (0.68)	0.78	* / 0.67
4	flow of procedure	0.34 (0.48)	0.74 (0.58)	0.43	0.64 / 0.81
5	knowledge of procedure	0.00 (0.00)	0.51 (0.58)	0.91	* / *
6	overall performance	0.03 (0.17)	0.51 (0.50)	0.92	* / *
Combined (6 items)		0.20 (-)	0.70 (-)	-	0.48 / 0.59

* Incalculable because variability was 0-0

Table 2.

Checklist Ratings and Inter-rater reliability of 3 judges, estimated by Fleiss Kappa

No.	Item	Pre Mean (SD)	Post Mean (SD)	Effect size (η^2)	Fleiss Kappa Pre / Post
1	Identifies landmarks	1.51 (0.66)	1.69 (0.58)	0.08	0.87 / 0.50
2	Attaches saline-filled syringe to Ravussin cannula	0.23 (0.60)	1.07 (0.98)	0.69	0.39 / 0.04
3	Stabilizes cricothyroid with nondominant hand	1.00 (0.84)	1.27 (0.83)	0.10	0.71 / 0.67
4	Inserts Ravussin thru CTM while aspirating	0.11 (0.40)	0.99 (0.97)	0.79	0.18 / 0.16
5	Slides cannula off needle into trachea	0.40 (0.60)	1.10 (0.89)	0.57	0.09 / 0.16
6	Removes needle	1.00 (1.00)	1.50 (0.86)	0.26	0.73 / *
7	Reconfirms position by aspiration of air	0.14 (0.36)	0.09 (0.28)	–	0.40 / *
8	Stabilizes/secures cannula	0.51 (0.85)	0.90 (0.97)	0.15	0.90 / 0.93
9	Connects rapid-O ² tubing to cannula	0.94 (0.84)	1.47 (0.79)	0.38	0.77 / *
Combined (9 items)		0.51 (-)	1.12 (-)		0.80 / 0.90

* Incalculable because variability was 0.0