The present research report highlights the nonstandardised manufacturing of NPAs between different manufacturers, between different products of the same manufacturer and the potential airway mishaps, which may occur due to them. Most of the manufacturers of NPA do not specify the length in their product catalogues (Marshall, Radstock, UK; Nasosafe, Flexicare, UK; Nasoflo, Medis Medical, Tianjin, China) predisposing the patient to inadvertent airway disasters. We recommend standard length of NPAs to be available in different internal diameters for better patient acceptability due to wider variation in nasopharygeal anatomy in different racial groups. We also suggest introducing graduations on the external surface of the NPA so as to decide length of insertion in each patient, which can be adjusted with a flange and introducing uniformity in length specification of standard sized NPA devices.

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High-fidelity hybrid simulation for emergency cricothyroidotomy using a three-dimensional printed larynx and a simulated patient

Sophie Hugger, Robert Greif, Nils Corson and Sabine Nabecker

From the Department of Anaesthesiology and Pain Medicine, Bern University Hospital, University of Bern, Bern, Switzerland (SH, RG, NC, SN), the School of Medicine, Sigmund Freud University Vienna, Vienna, Austria (RG) and the Department of Anaesthesia and Pain Management, Sinai Health System, University of Toronto, Toronto, Canada (SN)

Correspondence to Sabine Nabecker, Department of Anaesthesiology and Pain Medicine, Bern University Hospital, University of Bern, Freiburgstrasse 18, 3010 Bern, Switzerland
E-mail: sabine.nabecker@insel.ch

Editor,

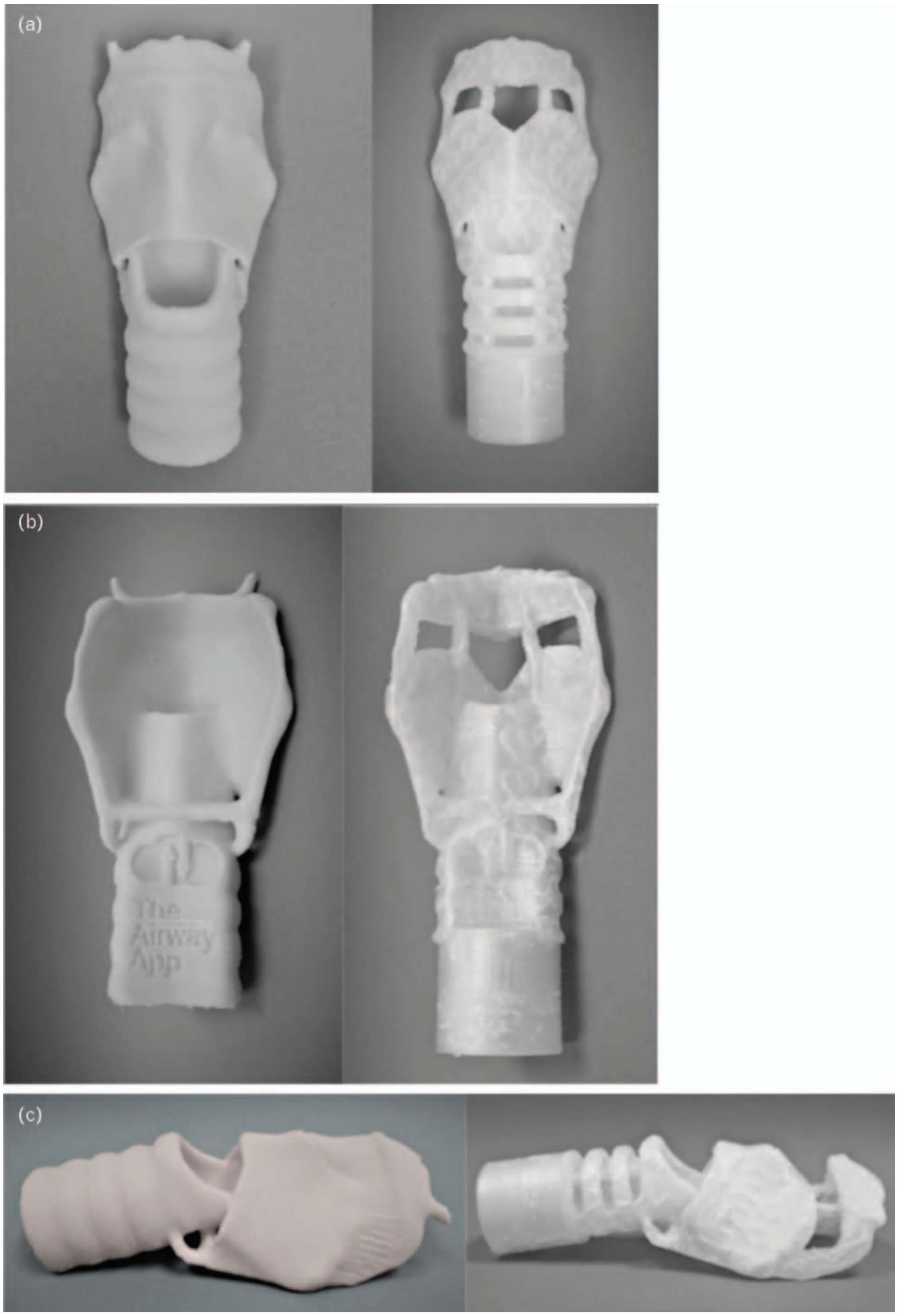
Emergency front-of-neck access is the life-saving rescue procedure in 'cannot intubate cannot oxygenate' situations.[1] Unfortunately, emergency front-of-neck access is associated with high first-attempt failure rates of 30 to 50%;[1] therefore, regular training is crucial and needed.[2] The scalpel-bougie-tube cricothyroidotomy is recommended.[3] Human/animal cadavers, anaesthetised animals and manikins have been used to train cricothyroidotomy. However, as well as the technical procedures, full-scale simulation trains the equally important human factors (communication, leadership, situational awareness and team/task management).[4] Hybrid simulation, using a cricothyroidotomy trainer and a trained simulated patient, trains the technical skills and human factors as realistically as possible.

We developed and pilot-tested a hybrid full-scale simulation using a novel cricothyroidotomy trainer: an inexpensive, three-dimensional (3D) printed model of the larynx was placed on the anterior neck of a simulated patient to enhance realism.[5] The authors are pleased to share the data file to print the 3D-airway model free of charge. The file is accessible at the website of the European Airway Management Society (EAMS) www.eamshq.net. This project was exempt from ethics committee approval as it did not fall under the Swiss Human Research Act and was undertaken from May to September 2019.

Various components were added to the original Duggan's open-access 3D cricothyroidotomy model[6] (Fig. 1) so that punctures between the hyoid bone and the thyroid cartilage and between the cartilage rings of the trachea are possible. At the tracheal end, we added a standard tube connector. Adhesive tape simulated the laryngeal membranes/ligaments.

To demonstrate the feasibility of the set-up, the cricothyroidotomy trainer was initially fitted on a manikin. Later, we placed it on the anterior neck of a simulated patient. First, a flexible neck protector (CRL-Nacken-Schnittschutz-Laurence, Ilsfeld, Germany) was placed around the neck as cut protection and then stab protection was added using commercially available aluminium sheeting (0.5 mm thick) cut to size. Over that, the 3D cricothyroidotomy trainer was fixed in place with adhesive tape and finally, a strip of fresh pig skin was placed to cover everything (Supplementary Video, http://links.lww.com/EJA/A526). Different thicknesses of pig skin increase the challenge for participants by representing various anatomical conditions (e.g. obesity). An intravenous cannula connected to flexible tubing was hidden under the pig skin and, when an incision into the pig skin took place; artificial blood was injected to mimic bleeding (Fig. 2). The tracheal end of the cricothyroidotomy trainer was connected to an artificial lung (SilkoBag-Rüsch, Athlone, Ireland) and placed under the volunteer's shirt. Successful cricothyroidotomy allowed confirmation of ventilation by visible 'thoracic' movements. For the pilot-test we used commercially available cricothyroidotomy sets (scalpel,

Fig. 1 Comparison of the cricothyroidotomy models: The Duggan (2017) three-dimensional cricothyroidotomy model (left) versus the new cricothyroidotomy trainer (right)



(a) View from the front. (b) View from the back. (c) View from the side.

bougie, cuffed tube – ScalpelCricset-VBM, Sulz, Germany).

The simulated patient was positioned supine with the neck extended without a pillow on an operating table. Standard noninvasive monitoring was simulated (ALSi-iSumuate, Fyshwick, Australia) allowing realistic deterioration of vital signs and monitor alarms. The simulated patient acted out a scenario as if experiencing a severe allergic reaction that had led to swelling of the

Fig. 2 Simulated bleeding after cutting the skin

upper airways and life-threatening respiratory distress (Supplemental material, scenario, http://links.lww.com/EJA/A525); additional instructions for the simulation were relayed to the simulated patient via an intra-aural earphone.

Three airway teams (a consultant, resident and nurse) pilot-tested this hybrid-simulation. Before the simulation, the teams were informed that a patient with a life-threatening respiratory condition was expected via ambulance and that airway manoeuvres had been unsuccessful due to swelling of the upper airway.

Paramedics handed over the tachypnoeic but stable simulated patient with the suspected allergic reaction and severe respiratory distress. Vital signs deteriorated rapidly (low oxygen saturation, tachypnoea, tachycardia and hypertension). The simulated patient acted agitated at being unable to breathe adequately.

The aim was to force the airway team to perform a cricothyroidotomy. If the team was reluctant, then the simulated patient collapsed (no movement, extremely low oxygen saturation, superficial respiration attempts, extreme tachycardia and hypotension). If there was further delay, then a simulation instructor entered the room acting as supervising physician and instructed the team to perform an immediate cricothyroidotomy. After successful tube placement and ventilation of the simulated lung, the simulated patient slowly recovered, which ended the simulation scenario. Simulation instructors then performed video-assisted debriefing and participants were asked for open feedback on the hybrid simulation and the cricothyroidotomy trainer.

Our 3D printed model is an inexpensive, stable, resistant and easily reproducible cricothyroidotomy trainer with a haptic and texture very close to reality. The possibility of challenging trainees by adding additional layers to modify the thickness of the pig skin (to simulate the neck of an obese patient) renders it particularly attractive.

After gathering the equipment together, the set-up of the cricothyroidotomy trainer and pig skin on the simulated patient was easy and fast, achievable within less than 8 min. However, procurement of the necessary materials was time-consuming and not-for-food refrigerated space for the pig skin is required.

All participants confirmed the realistic haptic of this hybrid simulation set-up and its suitability for cricothyroidotomy training. The technical skill performance of cricothyroidotomy in that setting was rated as relatively easy. The artificial blood added realism and enhanced the sense of urgency, but did not add difficulty. Some participants were initially confused by the slightly unnatural thickness of the simulated patient's neck, but this did not lead to any performance problems. The possibility of verifying the correct tube position by achieving realistic 'thoracic movement' with ventilation was a stress-relieving moment for all participants. Compared with the usual cricothyroidotomy training manikins, all participants confirmed that this hybrid simulation setup adds fidelity and is far more realistic. Thus, the participants confirmed the face validity of the hybrid simulation set-up with our 3D printed cricothyroidotomy trainer.

Participants valued the integration of a simulated patient into the training scenario, and the realistic training of communication, leadership and decision-making was seen as a major benefit over conventional manikin simulation set-ups. The simulated patient was able to provide feedback on how it felt to experience an airway emergency, and this was welcomed and well received by all participants. The cut and stab protection layers were comfortable and protective for the simulated patient and, in addition, it minimised skin contact with the pig skin. The simulated patient felt completely safe and comfortable.

A major limitation is that with our set-up it is only possible to practice the cricothyroidotomy: other airway management manoeuvres are not feasible. We cannot provide data on the educational and patient outcomes of the hybrid simulation.

In conclusion, this highly realistic, low-cost hybrid simulation offers the possibility of practising the life-saving skill of emergency cricothyroidotomy in a close-to-reality simulation. This helps the airway team to recognise the need to act and to perform a cricothyroidotomy early and with greater confidence, thereby potentially preventing devastating complications.[7]

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Conflicts of interest: RG is the current immediate past president of the European Airway Management Society. SN is committee member of the TEAMS committee (trainees of the European Airway Management Society). All other authors declare that they have no competing interests.

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Comments on ‘U-shaped relationship between preoperative plasma fibrinogen levels and severe peri-operative bleeding in cardiac surgery: A report from the Perioperative Events aSSesment in Adult Cardiac surgery (PESSAC) registry’ by Mion *et al.*

Nicolas Mayeur, Nicolas Savy and Hélène Charbonneau

From the cardiac and thoracic surgery and intensive care (NM, HC), Toulouse Mathematics Institute (NS), UMR5219-University of Toulouse; CNRS-UPS IMT F-31062 Toulouse Cedex 9, France

Correspondence to Nicolas Mayeur, MD, PhD, SCP Anesthésie CCVT, Clinique Pasteur, 45 avenue de Lombez, BP 27617 31076, Toulouse, Cedex 3, France
Tel: +33 562211683; fax: +33 562213193;
e-mail: n.mayeur@clinique-pasteur.com

Editor,

We read with great interest the article entitled ‘U-shaped relationship between preoperative plasma fibrinogen levels and severe peri-operative bleeding in cardiac surgery: A report from the Perioperative Events aSSesment in Adult Cardiac surgery (PESSAC) registry’.[1] Mion *et al.* conducted a large, retrospective, single-centre study in patients who underwent cardiac surgery with cardiopulmonary bypass to evaluate the relationship between plasma fibrinogen levels (PFL) and the risk of severe peri-operative bleeding. Surprisingly, their results showed that although a low level of fibrinogen appeared to be associated with a high risk of bleeding, a high level of fibrinogen did not necessarily protect the patient against the risk and could even be associated with severe peri-operative bleeding. In the study by Mion *et al.*, severe bleeding was defined as class 3 or 4 according to the Universal Definition of Perioperative Bleeding (UDPB).[2] This definition is more clinically relevant as it is based not only on peri-operative blood loss but also on peri-operative administration of both blood products and pharmacological haemostatic agents.

To analyse the relationship between PFLs and the risk of severe bleeding, Mion *et al.* performed a logistic regression with the PFL as a covariate. This covariate was continuous, and to capture the nonlinearity in the relationship with the risk of severe peri-operative bleeding, cubic B-spline modelling was involved.

Although the authors should be congratulated for their original study, we would like to address several methodological aspects that may question the reliability of the results presented.

Mion *et al.* adjusted the relationship between severe haemorrhage and the PFL according to the type of cardiac surgery. We suggest that in the absence of a more precise description of the multivariate analysis (other covariates and their odds ratios), the clinical pertinence of their main observation is questionable.

First, preoperative anaemia could be the largest potential confounder in the relationship between a high PFL and class 3 to 4 UDPB. Indeed, anaemia (related to inflammation or iron deficiency) is known to be an independent factor for red blood cell (RBC) transfusion and haemorrhage during cardiac surgery.[3] Mion *et al.* found preoperative anaemia was more frequent in the severe postoperative haemorrhage group. As a consequence, it would be interesting to establish the relationship between preoperative haemoglobinaemia and the PFL to reduce this potential confounding bias.

Second, it is noteworthy that patients with class 3 to 4 UDPB were more severe, with more baseline comorbidities (higher Euroscore 2), more complex procedures (aortic roots and combined), and more emergency procedures (29.5%). These factors are frequently associated with more complications, including haemorrhage, and should have been clearly identified as covariates in multivariate analysis.[4]