

SHORT SCIENTIFIC REPORT

Comparing the Cric-Guide® emergency front of neck access device to a scalpel-bougie-tube technique in a porcine model that simulates bleeding

A randomised crossover study

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The Cric-Guide is a device in development that aims to increase the success of bougie insertion into the trachea during emergency front of neck access (eFONA), a step that can present difficulties with the Scalpel-Bougie-Tube (SBT) technique. The Cric-Guide features a 'U-shaped' scalpel with a depth guard that is used to make the initial incision through the skin and cricothyroid membrane (CTM, Fig. 1). The bougie then passes along a channel into the trachea, and a preformed endotracheal tube is railroaded over the top. The device is not currently commercially available but undergoing preclinical trials to test its effectiveness, with previous studies including a simulated obese porcine model² and a human cadaveric study.³

During eFONA, bleeding can occur from the incision site, obscuring the view and making it more difficult to pass the bougie into the trachea. Therefore, to test the Cric-Guide, we developed a pig larynx model that simulated bleeding. We then used a small randomised crossover study in the simulation laboratory, to compare the performance of the SBT (as described by the Difficult Airway Society)¹ and Cric-Guide techniques. The study protocol received ethics approval (REC reference: 2020.0320) from St George's Research Ethics Committee, St George's University of London, UK, on 8 February 2021.

The model consisted of a porcine larynx and trachea, over which lay infusion tubing and a 20 G cannula pointing towards the CTM. Gauze packing was used to stabilise the tissue and channel the artificial blood upwards when an incision was made in the skin. Porcine skin was placed

over the top and everything mounted in a Frova Crico Trainer (VBM Medical, Sulz, Germany).

The participants were anaesthetists, and they received training on both techniques, followed by an opportunity to practice on a plastic model. Block randomisation, using an online random number generator (Research Randomizer Version 4.0), allocated the participant to perform either the SBT or Cric-Guide technique first. The primary outcome was time taken to perform the procedure, and after the participant had finished, the tissue was dissected and inspected for damage to the posterior tracheal wall.

As the data were nonnormally distributed, a Wilcoxon matched pairs signed rank test was used for analysis. For the outcomes with categorical data, a McNemar's test was performed. A χ^2 test was used to analyse technique preference. The sample size of 25 was calculated from previous work, and a 0.05 significance level used throughout.

Twenty-five anaesthetists participated in the study, of whom the majority were trainees, Specialist Registrar grade (84%). Twenty-two (88%) had performed eFONA simulation training within the last 12 months.

There was no significant difference in insertion time between the SBT and Cric-Guide techniques: median [IQR, range] was 62 [48 to 85, 31 to 122] s vs. 51 [32 to 83, 24 to 155] s, $Z = -1.461$, $P = 0.072$. The bougie passed successfully on the first attempt with the Cric-Guide 22 times (88%) compared with 12 times (48%) with the SBT technique ($P = 0.018$), and overall required fewer

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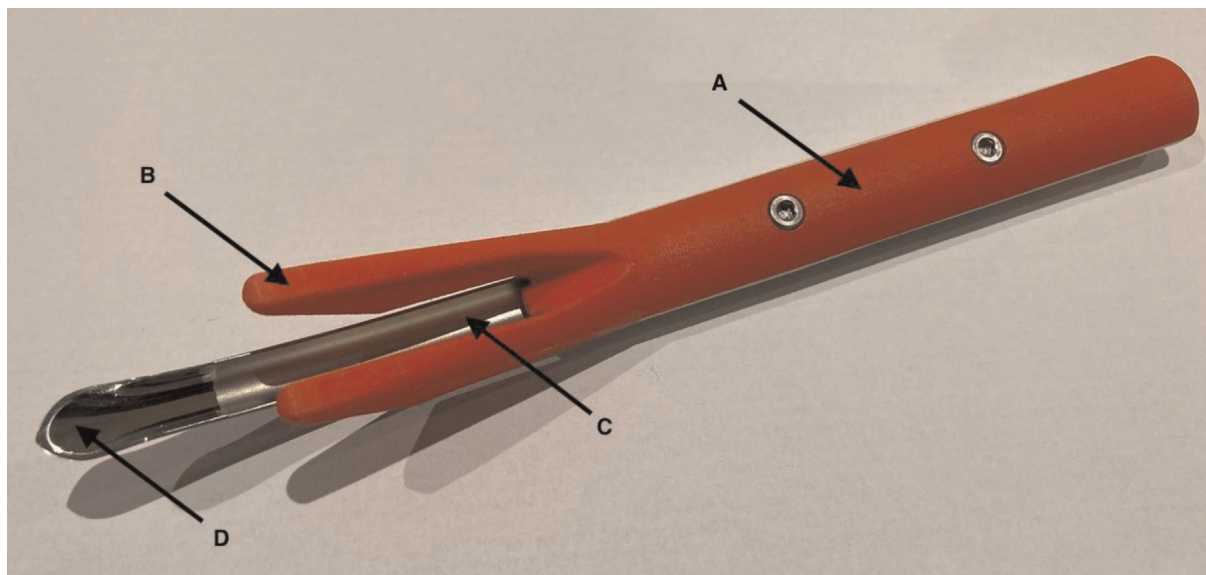
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Fig. 1 Cric-Guide: (a) Handle, (b) Depth guard, (c) Channel for bougie, (d) 'U-shaped' scalpel blade. (Image courtesy of Dr. R. Vanner).



attempts for insertion ($Z = 2.526$, $P = 0.0057$). One false lumen occurred with the Cric-Guide technique. There was more posterior tracheal wall damage with the Cric-Guide ($Z = -2.828$, $P = 0.023$), with two full thickness perforations occurring. There was no difference in how participants rated the ease of use ($Z = -1.025$, $P = 0.154$), or preference ($P = 0.317$), between the two techniques. Overall, participants felt that the Cric-guide would be suitable for clinical use ($Z = -3.299$, $P = 0.0005$).

A common feedback theme was that the Cric-Guide allowed easy bougie insertion. This step with the SBT technique requires fine motor control, which can be difficult in an emergency situation. The Cric-Guide acts as an introducer, simplifying the process, with the bougie passing along a channel into the airway.

Two factors may have contributed to the higher rates of posterior wall damage with the Cric-Guide. Firstly, the Cric-Guide comes in three sizes, and we selected the largest for our participants to use, assuming that our porcine model was compared with a larger patient. However, measurement of the specimens afterwards suggested we should have been using a smaller device, which would not have passed as deep into the airway. This emphasises the consequences of failing to select the correct size of device with this technique. Secondly, the blade on this prototype model was not as sharp as a standard scalpel, and so, greater force was required to make the incision. This gave less control, but if addressed in subsequent versions of the device would hopefully reduce the rates of posterior wall damage.

Previous attempts have been made to produce a front of neck trainer that bleeds in order to increase the fidelity of the simulation from a sensory and psychological

perspective.⁴ However, we felt that bleeding from the incision also impairs the view of the procedure site, increasing the difficulty of the task. In our model, a cannula was placed under the skin, over the CTM, and 50 ml syringes were used to infuse an artificial blood at a rate that caused it to flow out of the skin incision, obscuring the view of the tissues. However, as the Cric-Guide acts as an introducer, there is less requirement to visualise the hole in the CTM, and this may have been one of the factors why it took fewer attempts to insert the bougie.

The Cric-Guide performed well compared with the SBT technique, and it provides an innovative solution to a potentially challenging step in the currently recommended eFONA technique. However, blade sharpness in this prototype should be improved. Future studies can then re-assess the risk of posterior wall damage to decide if it is comparable to the SBT technique, or alternatively, that the increased risk is justified by improved bougie placement. Research should also evaluate whether choosing the appropriate size of Cric-Guide delays the start of the procedure, as any increase in time could result in adverse clinical outcomes in an eFONA situation.

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