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New evidence to inform decisions and guidelines in difficult airway management

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In the event of failed tracheal intubation and difficult face mask ventilation after the induction of general anaesthesia, guidelines for 'difficult airway management'[1–4] recommend the insertion of a supraglottic airway. However, if this does not achieve effective oxygenation, they recommend progression to performance of an emergency front-of-neck airway (eFONA). Despite this unanimity, recommendations for eFONA are derived from low-level evidence,[2] and thus it is inevitable that many column inches have been devoted to debating which method of eFONA or which ventilation mode should be chosen in the 'cannot intubate, cannot oxygenate' situation.[5,6] In this issue of the *British Journal of Anaesthesia*, Laviola and colleagues[7] provide a new type of evidence to inform decision making around ventilatory strategies for eFONA.

Laviola and colleagues[7] carried out a study *in silico*. The phrase *in silico* is pseudo-Latin for 'in silicon', referring to modelling and simulating medical process on computers (with silicon chips), to differentiate it from *in situ*, *in vivo*, *ex vivo*, or *in vitro*. They used the Interdisciplinary Collaboration in Systems Medicine simulation suite, which generates computational models of how the human body will perform, to create 50 virtual patients (with various organ functions) who had become severely hypoxaemic (arterial haemoglobin oxygen saturation of 40%) because of upper airway obstruction after induction of anaesthesia. In these virtual patients, they assessed oxygenation and cardiopulmonary effects of five different eFONA devices with varying internal diameter of 1.8–6.0 mm. With more than 7000 simulations, they found that re-oxygenation was achieved in all ventilation strategies within 1 min. A smaller airway (ID, <3 mm), but not a larger

airway, quickly caused hyperinflation of the lungs resulting in pronounced cardiocirculatory depression (cardiac output <3 L min^{-1} and MAP <60 mm Hg) and impeding oxygen delivery if tidal volume was >200 ml and ventilation frequency was >8 breaths min^{-1}.[7]

There is clearly a need for an increased level of evidence around eFONA, so we are therefore obliged to ask what type of studies should we carry out, and what is the role of *in silico* studies (such as reported by Laviola and colleagues[7])? Firstly, we must assess the efficacy of each procedure (e.g. cannula cricothyroidotomy or scalpel–bougie cricothyroidotomy) and of each ventilation mode. Even if one procedure has been found faster than others, it does not necessarily mean that it should become the procedure of choice. The standard against which these interventions must be judged is that of effective (re-)oxygenation, and then on minimising complications. Therefore, we must consider these interventions as a whole to confirm both the effectiveness of the procedure and of the ventilation mode.

High-level evidence should be obtained from randomized controlled trials (RCTs) and meta-analysis thereof, but it would be virtually impossible to recruit sufficient numbers of patients who require rarely performed life-saving procedures, impractical to obtain written informed consent from possible participants, and unethical to allocate patients to possibly less effective life-saving emergency procedures. Therefore, decision making around eFONA is made based on surrogate end-points or on cohort studies.[8,9] However, these studies may not be able to provide absolute answers. One such study by Fennessy and colleagues[10] using ultrasonography indicated that the optimal incision length for emergency cricothyroidotomy would be an 80 mm incision commencing 30 mm above the suprasternal notch. This finding is in keeping with the Difficult Airway Society (DAS) Guidelines[1] but is not *prima facie*

evidence for them. In addition, there is growing evidence that use of jet ventilation through a small-bore needle is frequently ineffective and is associated with a higher incidence of life-threatening complications, but this is not in itself evidence for the scalpel technique. Given these issues among others, cohort studies alongside systematic reviews thereof are usually unable to draw firm conclusions.[11,12]

Appropriately preserved cadavers can provide life-like conditions, which may then be suitable for assessing the effectiveness of each procedure.[13] However, they do not facilitate study of the efficacy of each procedure in terms of effective oxygenation or adverse effects on cardiopulmonary function. Recently, simulation studies in manikins, in anaesthetised animals, or in an animal wet laboratory environment[14–16] have provided evidence as to which procedure might be more effective, easier to perform with less complications, and easier to master. Nevertheless, manikins and animal models may not be good surrogates for real patients, so contradictory results may be obtained.[14,16]

In silico simulation studies have a potential role, particularly in this area where clinical studies are difficult or insufficient. The coronavirus disease 2019 (COVID-19) pandemic triggered extensive use of computer simulations, calculations, and predictive modelling to provide insight into the spread of the virus and to guide government policies, despite their recognised inadequacies and the numerous unknown variables.[17,18] That experience underlines the pros and cons of *in silico* studies: they allow for the provision of evidence where none has previously existed, for the generation of evidence in scenarios where it may be impossible to gather data, and for the assimilation of information in a variety of situations that would take a long time to gather in a laboratory even if it were possible. The *in silico* study reported by Laviola and colleagues[7] has added a new type of evidence to the area of difficult airway management. However, for this new evidence to be considered valid, the underlying assumptions of the simulations must be considered. Use of *in silico* simulation is not new and the validity of the physiological model used has been established *in vivo*.[19] The authors have previously provided useful information about the efficiency of airway management and oxygenation in areas where clinical studies are not practical.[20,21]

Simulation is of course not new to anaesthesia. The role of simulators and simulation in anaesthesia training has been recognised for more than 50 yr,[22] initially as a tool for training, not just in technical skills but also in comprehension of facts, grasp of concepts, and a quick response.[23] The report of the Fourth National Audit Project (NAP4) of the Royal College of Anaesthetists (RCoA) and the DAS in 2011[24] identified that, although infrequent, anaesthetic airway complications remained commonly associated with poor standards of care. Human factors issues have been identified,[24,25] (and their role repeatedly reported[1,5]) as contributing to serious consequences associated with airway management. These are at least in part the comprehension of facts, grasp of concepts, and respect for co-workers that Spence noted in his 1997 editorial.[23]

The role of simulation and simulators is not only the teaching of technical skills, but also improving understanding as to how stress can affect decision making and behaviour, and how training in non-technical skills can improve performance. Successful management of a difficult airway, and in particular eFONA, is a high-stakes procedure. The need for a

training system has been repeatedly emphasised,[24,26] with some colleges mandating it.[27] This will require the use of a simulated environment.

The challenge is to integrate simulation training in a manner similar to that of safety-critical industries such as airlines or nuclear power; however, this raises the question of how much the environment should be informed by simulation. When considering COVID-19 modelling, Chin and colleagues[18] suggested that 'models need to be subjected to prespecified real time performance tests'. We should consider what their equivalent should be in the sphere of rarely performed techniques.

No simulated environment can perfectly reflect the attributes of every human being. However, virtual reality (*in silico*) simulators have already been developed for training in the technical and non-technical aspects of flexible bronchoscopy.[28] Recognising their shortcomings, it is now time to appreciate that *in silico* simulation can provide useful physiological information that can inform which techniques are best to perform in eFONA, not just how best to perform the chosen technique.

Although we believe that future guidelines must continue to consider human factors, transition triggers,[3] cohort studies, case reports, and manikin or *ex vivo* studies, we believe that they should also now consider the answers provided by complex simulation modelling. It is time for us as a profession to recognise and investigate the potential influence of complex physiological modelling on the conduct and the successful of rarely performed clinical skills.

Authors' contributions

Both authors contributed equally to the drafting of the article, revisions, and final approval of the submitted article.

Declarations of interest

AFMcN is the Royal College of Anaesthetists—Difficult Airway Society (RCoA—DAS) Airway Leads Advisor. TA is an editor of the *British Journal of Anaesthesia*.

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