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Editorial

Laryngoscopy: time to change our view

Laryngoscopy and tracheal intubation are core skills for all anaesthetists. Experience suggests that difficulty with laryngoscopy occurs in as many as one in 75 patients [1]. This is the case when the anaesthetist is using a Macintosh laryngoscope but we should be aware that, when using other tools, the incidence is likely to be different. The Macintosh laryngoscope has inherited our 'gold standard' title by intrinsically being effective enough, and historically benefiting from millions of larygoscopies world-wide. It has become the control device which newer laryngoscopes are obliged to better, and by default remains the blade of choice for most anaesthetists.

In recently published guidance, there is a drive to move to disposable laryngoscopes and it is stressed that those purchasing them have the responsibility to ensure that the performance of these devices is at least as good as the reusable item [2]. As our gold standard reusable version fails as often as one in 75 cases, a failure rate we would not accept in other areas of life, seeking an equivalent disposable version may not be appropriate and we should be looking for devices that perform better. While we are not short of potential candidates trying to compete with the Macintosh [3–8], the anaesthetic community has so far failed to evaluate these alternative devices adequately. For this reason, we still do not have a reliable evidence base on which to choose one of the most basic tools of our trade.

When evaluating a treatment, we demand systematic reviews with bias-reducing research methods and clinically relevant outcome measures. To date, the literature on new laryngoscopes generally demonstrates level II evidence at best with very few randomised studies. Evidence based 'laryngoscopic practice' will only be available to us if we create a robust system of ongoing research and evaluation. If the laryngoscope were a drug, licensing and ethical prescribing would demand a rigorous development process. The standard includes pre-clinical or phase 0 trials in animal models, phase I and II studies in select populations, phase III large scale clinical or randomised controlled trials, and phase IV surveillance and monitoring [9]. In airway device research, the closest equivalent phase 0 models are cadaver or manikin studies and, while this may seem an attractive approach, it has not been validated. The clinical performance of laryngoscopes depends crucially on how they perform with all the variations of human anatomy. As a worst-case scenario, we could end up discarding a really good tool for human tracheal intubation because it failed to work in phase 0 models. Our phase I–II trials vary greatly in methods and populations studied. Phase III trials are few and far between and most are limited in patient numbers recruited. Phase IV (monitoring) is limited to major reported device failures while we rarely collect quality of performance or success rates. Mihai et al. recently published a large meta-analysis evaluating non-standard laryngoscopes [3]. Mihai's work was unable to draw clear or useful conclusions as to which performed best. The authors found small and variable population samples and heterogeneous data with differing endpoints; notably they had to exclude many papers. This lack of high level evidence in the literature demonstrates the complexities involved when conducting laryngoscope trials and, if nothing else, demonstrates that it is time to change the way we evaluate new devices.

Previous studies have focused on a variety of elements in the intubation process, including Cormack and Lehane grades, intubation times, subjective scoring systems (e.g. 1–5) and composite scoring systems such as Adnet's Intubating Difficulty Score (IDS). As a result they differ in what they proposed as significant findings; while one trial aimed to demonstrate a 20% improvement in intubation times, another aimed to show a 30% reduction in the number of patients with IDS scores > 1 and a further study looked at improving laryngoscopy views without exceeding what the authors deemed as a clinically acceptable increase in time taken (30 s longer than a Macintosh blade intubation). Recorded start and end times for intubation are not consistent between studies so absolute comparisons are difficult. Definitions of 'failed intubation' have also varied and have included failure to see the larynx, breaching a maximum time and unintentional oesophageal intubation [4–6, 8, 10–20]. These varying methodologies yield staggeringly different numbers of patients required in their power analyses, depending upon the measured outcomes and the differences considered to be significant. In many studies, sample sizes have been too small to have adequate power to determine whether the new devices provide a better view than the Macintosh and in some trials we have been guilty of studying the wrong group of patients (limiting to patients known or predicted to be easy to intubate and extrapolating the answers to be 'possibly useful for difficult laryngoscopy'). These alternative research methods have been developed to assess laryngoscopes with fewer patients by assessing multiple factors and, while these may be useful tools for initial evaluation, they do not answer the crucial question of how the device performs in clinical practice – 'how often can I intubate the trachea under vision in a reasonable period of time?'.

For future clinical studies, we must be clear about what sort of evidence we need to provide. A trial designed to show better performance in routine practice must be differently designed

to one that aims to show better performance for difficult (Macintosh) intubations. Clearly the literature does not provide agreement on the best methods to test our equipment and this will continue to be the case unless we clarify what assessment criteria we should use and how we quantify clinical significance. This is especially relevant with the current trends in the development of indirect or video laryngoscopy. Cormack and Lehane grading is less useful as indirect views of the larynx may be projected as a grade 1 or 2 view while the passage of a tracheal tube may still be difficult, with increased emphasis placed on the manual dexterity required to manipulate the tube relative to the projected image. We must appreciate details such as these when designing clinical trials for these newer devices.

In 2007, an 'airway device evaluation group' was formed with representation from industry, the Medicines and Healthcare products Regulatory Agency, and clinical and academic anaesthesia (A. Norris, personal communication). The aim was to develop a workable plan for the evaluation of new airway devices. Currently new devices are CE marked and are then usually released to market without clinical evaluation. It was accepted as inevitable by the group that prelaunch clinical evaluation was impractical so there was a need to develop a robust system of ongoing research or evaluation to assess devices once in clinical use. The Airtraq™ has sold in excess of 100 000 units to date (P. Dryden, personal communication), and it is therefore clearly popular with clinicians, but there have been only 23 publications covering 500 patients and five manikins in total; thus only 0.5% of total usage has helped contribute to our knowledge base. Similarly the Glidescope™, a reusable device, has sold more than 5000 units (P. Collinson, personal communication) and has 120 papers to date detailing only a small proportion of uses. One avenue explored therefore was that each use of a device should contribute to the greater knowledge of device performance. The possibility of including a 'report form' with each device sold for the first 10 000 units was discussed, but it is likely that return rates and return quality would be too unpredictable to gather valuable information.

Current practice allows for an 'evidence-based judgment' of sorts, where clinicians use equipment which they feel is effective and hospital Trust purchasing groups perform a cost evaluation according to their clinicians' needs. Most companies will support short-term evaluation trials for their products but these individual 'departmental trials' of new devices do not have sufficient power to demonstrate reliable performance. Without strong supporting clinical evidence, it is likely that the balance swings toward cost. Whilst it is clearly important for clinicians and industry to cooperate in product development, the potential hazards of involving industry and contract research organisations in product evaluation have recently been highlighted [21].

It is vital that each intubation tool is evaluated in a large enough number of patients to determine whether it is as good as, or ideally better than, the Macintosh blade in routine practice (that is to say, does it facilitate intubation under vision in more than 98% of patients?). Each new device should also be evaluated in patients who are difficult to intubate with the Macintosh blade to see if it would be useful in this important but much smaller group of patients. The ideal tool would be superior to the Macintosh in both scenarios. The challenges for clinical research are to define the best outcomes to show improvement and to achieve adequate patient recruitment. Pandit's recent editorial gives a hint as to the huge numbers of subjects that are likely to need to be recruited for this sort of work [22].

Probably the only way to answer the pertinent questions is to collect data from many centres on large cohorts of patients for every intubation device. In time this would give the profession reliable information on which to base our choice of equipment for the future and should bring precise study outcomes from the large numbers of subjects recruited. As a secondary benefit, it would help ensure that individual patient exposure to risk is no longer wasted by enrolment into underpowered studies.

Wilkes et al. have proposed an evaluation scheme for cost effective and evidence-based purchasing [23]. Their 'A way forward' proposes to establish a central device evaluation centre with a panel of experts to decide on gold standards and to encourage clinical trials and development of structured purchasing groups within each Trust. The fact remains, however, that we have very little supporting evidence for alternative laryngoscopes. A panel of 'like-minded' experts may demonstrate bias in a climate of low level evidence. If we require valid comparisons with our current standard – the Macintosh laryngoscope blade – then there would be little evidence supporting change and we would have to accept the status quo. The most beneficial remit for a device evaluation group would be to progress and co-ordinate the available evidence. Key and specific outcome measures that summarise 'real world performance' should be described, allowing research groups to collect more 'homogenous' sets of results and thus add to the same data set.

The confluence of three events may mean that now is the right time for our profession to re-examine the subject of laryngoscopy and tracheal intubation. The Fourth National Audit (jointly run by the Royal College of Anaesthetists and the Difficult Airway Society) is collecting details of serious complications related to airway management from every hospital in UK over a 1-year period from September 2008 to August 2009. This should give us an idea of the scale of the problem (if any) associated with tracheal intubation and other forms of airway management [24]. The recent launch of the National Institute for Academic Anaesthesia encourages us all to become involved in translational research with value at the clinical coal face [25]. Thirdly, advances in technology are permitting a new range of intubation aids to come to market that are capturing our imagination. These factors, coupled with a desire for evidence-based practice, may mean that now is the time to

change our view. We must nonetheless accept that, even if we can develop this evidence base, adoption of best laryngoscopic practice into routine clinical care is not a given, and may take some time [26]. Difficult intubation guidelines recommend the use of alternative laryngoscopes for subsequent attempts in difficult cases, so it is important that all anaesthetists are skilled in more than one intubation technique [27]. Limited training and practice opportunities mean that the majority of anaesthetists will only be able to attain competence with two or three devices. It may be that one of the new videoscopes outperforms the others: it may be that the Macintosh outperforms them all. It is incumbent upon us all to contribute to research and data collection programmes to ensure that we get the information we need to allow our specialty to make informed decisions regarding which skills we should concentrate on acquiring, and to enable us to choose the most effective devices in the future [28].

Wide-scale purchasing decisions are already being made on the basis of cost alone for laryngeal mask airways (A group of 56 hospitals plan to move to a single supplier of disposable laryngeal mask airway). It is time to change our view of laryngoscopy or else, with no reliable evidence, purchasing decisions will continue to be made on our behalf and we may find our Macintosh laryngoscope replaced by another intubation tool that we have not chosen for ourselves.

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Editorial

Airway incidents in critical care, the NPSA, medical training and capnography

'Every breath you take...I'll be watching you'
written by Sting, The Police, Synchronicity 1983

In this issue of *Anaesthesia* Thomas and McGrath review incidents reported to the National Patient Safety Agency (NPSA) involving airway devices in critical care [1]. Using a necessarily laborious process they identified 1085 airway incidents from 44 675 patient safety incidents associated with critical care, submitted in the 2 years from October 2005. They are to be congratulated for identifying important issues and themes given the limitations of the data provided. Airway incidents are not uncommon and have the potential to cause serious adverse outcomes [2].

The paper not only raises issues about the quality and usefulness of information within the National Reporting and Learning System (NRLS) but also identifies potentially remediable problems associated with the management and monitoring of the airway in intensive care. This in turn raises further questions regarding skills, training and equipment available within intensive care units (ICUs) in the UK.

Critical incidents and the NPSA

The NPSA is tasked with improving patient care in the National Health Service (NHS) with rapid analysis and responses to incidents that are logged into the NRLS. As of March 2008 the NRLS had received 2 536 940 incident reports, making it the largest single collection of patient safety incident reports in the world. In its review published in 2007 [3] the NPSA recognised limitations in its reporting system. Specifically 60% or more of data was missing in over half the fields of the national dataset and many reports were incomplete, often with limited data on causal and contributory factors. Local risk management systems also vary widely making data mapping complex and slow. Even where problems are identified it can take a long time, typically 12 months, for the NPSA to develop and disseminate solutions, and we do not know how often these reports remain with managers rather than reaching front line clinicians.

Thomas and McGrath acknowledge that the data collected was incomplete and there is no way of knowing how representative or accurate it is. While it is unsurprising that airway problems can be associated with serious harm, it is salutary to learn that partial dislodgement of a tracheal or tracheostomy tube causes more incidents of harm than complete removal. We are also informed that tube displacements were associated with turning and moving patients, and may have been commoner during periods when nursing staff may have been distracted or there were staff shortages. Partial displacement may be more common if the end of the tracheostomy is not well positioned in the trachea at initial tracheostomy, as may occur with standard sized tubes in large patients [4]. Daily sedation holds have become routine in many ICUs [5] and the increased likelihood of patient movement and agitation may also risk tube displacement.

Following an earlier survey of critical incident reporting in UK ICUs, Dr Thomas made suggestions for improving data collection and feedback [6]. NPSA incidents involving medication [7] and equipment [8] in critical care have previously been reported by Dr Thomas' group, illustrating the difficulties and limitations of making sense of this database. The intensive care society (ICS) has published standards for critical incident reporting in critical care [9]. The NPSA is actively working towards improving the system [10] and is collaborating with the Royal College of Anaesthetists (RCoA), the Association of Anaesthetists of Great Britain and Ireland, the ICS and others in focussing on critical incidents in anaesthetic and critical care [11].

Many of the initiatives prompted by incident reports (available from the NPSA website http://www.npsa.nhs.uk/nrls/alerts-and-directives/) are relevant to intensive care and anaesthetic practice. They include advice on misplaced nasogastric feeding tubes, hand hygiene, safer practice with epidural injections and infusions, correct site surgery, problems with infusions and sampling from arterial lines, and the risks of chest drain insertion.

Despite this it is likely that doctors are not reporting as many incidents as some other health care professionals, but there is little published evidence on the factors that influence reporting. A study from the United States asked