Publication and innovation in airway management: quality not quantity!

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Airway management is probably the most important key competence in anaesthesiology with a direct bearing on the outcome of anaesthesia. Deaths directly attributable to anaesthesia have fortunately been decreasing over recent decades and are estimated to be approximately 1/100 000 cases.1-3 Problems arising from airway management were reportedly responsible for approximately 40% of deaths related to anaesthesia.4 The UK’s fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society5 found that there were 46 severe events related to airway management per million general anaesthetics, or 1: 22 000. This translates to a mortality rate of 5.6 per million general anaesthetics or 1: 180 000 patients anaesthetised.

Taking these numbers into account, it is not surprising that airway management is a topic of major research interest and that each year thousands of studies that probe all the specific problems of airway management are published. However, the research is rarely of high quality. Many studies do not report on technical innovation but instead seek to compare a variety of devices, arbitrarily chosen, in a variety of settings. Owing to the generally low number of study participants or outcomes with questionable relevance, such as the time required for insertion with differences in the range of seconds, these studies frequently fail to provide satisfying answers to the clinical questions of the day.

We would like to address problems with studies related to airway management in the European Journal of Anaesthesiology using as an example two two such studies in this issue of the Journal. This is not because the studies are poorly performed or lack good scientific conduct. They report on innovation in airway management as well as its feasibility and complications.6,7 L’Hermite et al.6 from Nimes University Hospital, France compared the incidence of sore throat following three different supraglottic airway devices (SAD) in a randomised single-blind controlled trial. Altogether a total of 546 patients scheduled to undergo short elective surgery under general anaesthesia were randomly allocated to receive the LMA-Unique, the LMA Supreme (Teleflex Medical Europe Ltd., Athlone, Ireland) or the I-gel (Intersurgical Ltd., Wokingham, UK). Their primary study endpoint was the incidence of sore throat 24h postoperatively following placement of the SADs. Also, their clinical performance, ease of use and associated adverse events were used as secondary endpoints. The authors analysed 177, 174 and 173 patients who received LMA-Unique, the LMA Supreme and the I-gel, respectively. In total, 104 patients (23.9%) reported a postoperative sore throat at 24h, with no difference between groups (P = 0.34). Overall, the I-gel laryngeal mask had the best performance in this study.

Theoretically, the best SAD should cause little postoperative sore throat, and then with low severity (mild complaints), and low morbidity; it should be easy to use,
rapidly introduced at the first attempt, and should provide high airway leak pressure. However, the present study failed to show any statistical difference between the different devices. At least the cuffs of the LMA masks (LMA Supreme and LMA Unique) and the I-gel have different technical specifications. The authors were not able to explain the similar level of postoperative sore throat except that the lack of statistical difference between groups could be the consequence of insufficient power. But, if we take into account recent studies into SADs, it is cuff pressure that seems to be a significant factor for sore throat and complications. Was the study based on a real clinical problem or was it trying to answer an open question related to our choice of supraglottic devices? Furthermore, what are the clinical implications of what we learn from such studies?

Spapen et al. from the University Hospital Brussels have investigated leakage around a newly developed two-cuff endotracheal tube in a comparative study using an in-vitro benchtop model of an artificial rigid trachea. The group developed a tracheal tube equipped with two polyvinylchloride cuffs [PVC and a supplementary port opening between the cuffs through which a continuous positive pressure of 5 cmH₂O is provided (polyvinylchloride double-cuffed PVC_{dc})]. They compared this PVC_{dc} with four different cuff types (cylindrical PVC; conical PVC; cylindrical polyurethane; conical polyurethane). Of all cuffs, the PVC_{dc} outperformed the other cuffs used.

Having tracheal tubes with this new feature would allow a reduction in bacteriological contamination the lungs by secretions. But there are limitations which should be addressed. This is a benchtop study using an artificial trachea that may vary significantly from human tracheae. Also, the authors demonstrated that secretions were absent from the lungs for only 60 min. From a clinical point of view, this new tracheal tube is quite interesting, especially for ICU patients with a high risk for pneumonia. Unfortunately, because of the design of the study this exciting question was not explicitly answered. The risk of pneumonia in ICU patients increases with hours or days, not merely during the first 60 min.

Although of great interest, this is just a first study with a new tracheal tube and only the future will show if it has real benefit for human ICU patients, and if it works for anaesthesiology and the operating room, too. This is a study based on a real clinical problem with morbidity and some mortality that needs a solution. The open question is: does the new intervention solve the problem? Do we know now how to address that and can we save more lives in our ICU?

The European Journal of Anaesthesiology is grateful to receive, review and publish airway management-related research. However, in the light of the large number of papers being submitted, to qualify for publication some prerequisites are becoming important:

(1) Does the research question address a real clinical problem? For example, a research group might compare how many seconds it takes first year students to insert four different SADs. They might even find a significant difference if the sample size was sufficiently large. They work hard and spend time on a well designed and conducted study, but what can the anaesthesia community learn from it? How can we improve clinical outcome or teach airway management more efficiently to our students and residents? We know that this was not the original research question but this brings us to the key points. The European Journal of Anaesthesiology welcomes airway management studies that address research questions based on ‘real’ clinical problems intended to increase our knowledge of the topic and the specific application of devices. There is less interest in comparisons of procedures or devices involving manikins that will not solve a clinical problem.

(2) That does not mean that the European Journal of Anaesthesiology will not publish any manikin studies. Again, it is the research question that counts. If it is a totally new strategy, a novel airway teaching approach, or a how a different airway rescue team algorithm should be applied, a manikin study might be the best way to show the effectiveness of the new approach. The way to operate a new device to establish a patent airway safely and quickly might be best shown on a variety of manikins; as we know they are not all the same. Beyond that we are interested in how new and also old airway devices in new indications are applicable, and might be safely used in different patient groups, because that would influence our practice. Placing a variety of airway devices under different conditions with different anaesthesia providers in manikins adds very little to that.

(3) Another problem of many manuscripts submitted to the European Journal of Anaesthesiology is the small sample size in studies with multiple comparisons. If a reasonable clinical outcome is considered relevant during the planning phase of an airway study and the subsequent sample size calculation is statistically not underpowered, the small number of patients in each group will be appropriate. But who is going to change their clinical practice because a device worked a bit better in 30 to 50 patients? We need properly powered studies with larger sample sizes that have genuine clinical impact. Well designed studies with high numbers are not that difficult to perform, given that there is no shortage of patients who qualify for airway management. The researchers should be prepared to go that ‘extra mile’ if their aim is to change clinical practice, and not merely to get out another paper.

(4) Airway management is often performed in clinical situations where previous informed consent is
Another important point to address is the study of the difficult airway and rapid sequence induction. For research in patients with known and real difficult airway the same conditions as above should count. What is even more important is to understand why that specific research project had to be done in that patient group, and what precautions were taken if airway management failed during the application of a new device or a new or different approach to the airway. The ethical question to be answered is why was this specific patient a research subject in a study with an imminent risk of further airway compromise? The same applies to rapid sequence intubation studies. Another very suitable and often used approach to the study of the difficult airway or rapid sequence intubation is the use of a ‘surrogate’ difficulty, achieved by immobilising the neck or placing an extraction collar that limits mouth opening. If a problem occurs, reverting to normal airway procedure for these studies should not endanger; otherwise, healthy patients simply because they consented to be part of a study. The discussion needs to include why the specific research question could not have been studied in another way and why these otherwise healthy patients underwent a potentially dangerous study procedure. Patients should never be subjected to even the best research idea if it places them at risk when the answer might be found with other means.

(6) Studies must also have a clinically relevant outcome using standardised criteria as outcomes or endpoints because we want to improve patient care, increase patient safety or address economic or procedural advances. Best practice is to compare new products to the ‘gold standard’ or best clinical practice. Equal performance often addressed in noninferiority studies should at least come up with a procedural or financial advantage to justify the implementation of the new devices. A minimum level of evidence, as described earlier by ‘Airway Device Evaluation Project Team’, should be sought before considering publication in the European Journal of Anaesthesiology. Any airway study intended to examine performance in a series of patients but without a solid research question should not be proceeded with. The same applies to nonrelevant comparisons between different devices or methods; comparing apples with oranges. Many recent studies have used different criteria which impede proper comparisons. How can we compare one study with the ‘time to visualise vocal cords’ with another where the endpoint is ‘successful ventilation’? It simply is not possible.

We all know that not every good idea will become a new device. Not all new devices on the market are suitable for all kind of patients, are clinically useful and are eventually accepted into routine practice.

For the testing of new devices for the first time an approach that includes both bench and patient studies is appropriate. Thereafter, we need problem orientated clinical assessments, with safeguards for the patients recruited, that have endpoints directly related to clinical practice; both approaches have their place. The outcomes need to be specified and described in adequate detail as a prerequisite, in the same way that adherence to formal reporting standards of clinical trials is becoming necessary.

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