REVIEW ARTICLE

Are new supraglottic airway devices, tracheal tubes and airway viewing devices cost-effective?

Simon J. Slinn, Stephen R. Froom, Mark R.W. Stacey & Christopher D. Gildersleve

Department of Anaesthetics and Intensive Care Medicine, University Hospital of Wales, Cardiff, UK

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Summary
Over the past two decades, a plethora of new airway devices has become available to the pediatric anesthetist. While all have the laudable intention of improving patient care and some have proven clinical benefits, these devices are often costly and at times claims of an advantage over current equipment and techniques are marginal. Supraglottic airway devices are used in the majority of pediatric anesthetics delivered in the UK, and airway-viewing devices provide an alternative for routine intubation as well as an option in the management of the difficult airway. Yet hidden beneath the convenience of the former and the technology of the latter, the impact on basic airway skills with a facemask and the lack of opportunities to fine-tune the core skill of intubation represent an unrecognised and unquantifiable cost. A judgement on this value must be factored into the absolute purchase cost and any potential benefits to the quality of patient care, thus blurring any judgement on cost-effectiveness that we might have. An overall value on cost-effectiveness though not in strict monetary terms can then be ascribed. In this review, we evaluate the role of these devices in the care of the pediatric patient and attempt to balance the advantages they offer against the cost they incur, both financial and environmental, and in any quality improvement they might offer in clinical care.

Introduction
In this review we examine the history, development and current usage of supraglottic airway devices, tracheal tubes and airway viewing devices in order to assess the impact and value of these tools in our practice of pediatric anesthesia. With each device there are pros and cons that may be explored and an understanding of these will help to give a value judgement on their cost and clinical effectiveness.

Supraglottic airway devices
From its inception, the laryngeal mask airway (1) has revolutionized the art of airway management. Where facemasks were previously used, Supraglottic Airway devices (SADs) are now in common use, freeing up the hands of the anesthetist to carry out other tasks. Since the design patent of the classic laryngeal mask airway expired in 2003 an ever-increasing number of SADs have become available, each competing with this classic design. SADs can be classified into first-generation devices, a simple airway tube that sits above the glottis, and second-generation devices, SADs that have an additional drainage tube (2).

While a plethora of different SADs is now available, the classic laryngeal mask airway has the greatest body of evidence to support its use in children (3–5). The flexible laryngeal mask airway, a flexible version of the classic laryngeal mask airway and available down to size 2, is used in upper airway surgery and in particular for tonsil and adenoid surgery. It may be more difficult to insert if poor or incorrect technique is used; however, it has been shown to perform as well as the classic laryngeal mask airway (6,7). The perceived advantages of improved esophageal and pharyngeal
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The simplicity of insertion and effectiveness at maintaining an airway has been the key to the success of SADs in children. But has their introduction diminished the skill set of trainee anesthetists in that basic art of maintaining a pediatric airway? This is not a new argument, in the early 1990s, when the laryngeal mask airway was in its infancy, senior anesthetists were concerned that the ability of future anesthetists to maintain a pediatric airway might suffer as a result of the arrival of the laryngeal mask airway (35,36). Whether this concern is now manifest in the modern anesthetist is most subjective and difficult to prove. So, rather than trying to prove the subjective assertion that the airway skill set has declined, it may be more productive to offer a stand-alone, coherent argument in favor of routine facemask anesthesia. Firstly, using a facemask to deliver anesthetic is undoubtedly less invasive than a SAD or tracheal tube. In addition, the evidence for a SAD providing a better airway compared to a facemask is equivocal (37,38). This would suggest that in the spontaneously breathing child, the only benefit of the SAD is that it frees up the hands of the anesthetist, hardly a ringing endorsement for a technique that is now used in the majority of pediatric anesthetics. Secondly, higher rates of complications are seen with the use of smaller sized SADs (4), this may be due to sizing issues or poor technique. Additionally, increased gas leakage is noted.
at lower airway pressures when using a SAD in infants compared to older children (12), thus raising doubts regarding the efficacy and safety of positive pressure ventilation via a SAD in infants and younger children. Thirdly, the natural tendency when a cuff leak is heard is to either change the SAD or overinflate the cuff increasing the chance of upper airway damage (39). It is imperative therefore that cuff pressures are measured in all cases. Finally, the art of holding and maintaining a pediatric airway is a skill that only comes with practice and requires muscle memory and endurance. The goal should be to become an expert in this skill and not see it as a brief stepping-stone to the attractions of SAD insertion. It is our view that you cannot put a price on the simple skill of holding a facemask.

**Cuffed tracheal tubes**

The uncuffed vs cuffed tracheal tube (TT) debate has raged in pediatric anesthesia since 1990s. Many institutions routinely use uncuffed TTs in children under the age of 8 years and arguments for this stance are commonly cited (40,41).

The hypothesis that uncuffed TTs provide a good seal at the cricoid cartilage is based on the erroneous assumption that the cartilage is circular, whereas it is in fact an elliptical structure (42). Therefore to prevent a large leak from an uncuffed TT, the tube needs to have a relatively large external diameter and paradoxically, this will cause pressure on the narrower lateral walls of the cricoid with the consequent risk of mucosal damage. No studies to date have demonstrated increased airway mucosal damage from cuffed TTs, provided the appropriate sized TT is selected and cuff pressure is measured (41).

There are several advantages of using a cuffed TT in all children, these include: the avoidance of repeated attempts at laryngoscopy and intubation, reduction in aspiration risk, and improved reliability of end-tidal gas analysis. In addition, lower gas flows may be used without the intentional leak in the system, reducing both anesthetic agent cost and contamination of the operating theater environment with anesthetic gases (40).

Modern high volume, low-pressure cuffed tracheal tubes such as the Microcuff® PET (Kimberly-Clark, Health Care, Atlanta, GA, USA) have been shown to demonstrate all these advantages with no increase in the risk of postextubation stridor (43).

Given the lack of evidence of harm caused by cuffed tracheal tubes and the added advantages that a cuffed tube may offer, it is unfortunate that it is unlikely to become the TT of choice of the pediatric anesthetist until the unit cost is closer to that of the uncuffed variety. Using a direct cost comparison is flawed however. There is a consistent finding in comparative studies that more uncuffed than cuffed TTs are used per case, as there is no need to change a cuffed tube due to excess leak. In addition, the cost saving of lower gas flows and reduced volatile agent cost should be judged against the initial outlay for a cuffed TT, thus balancing somewhat the cost comparison (41).

**Airway viewing devices**

The advent of videolaryngoscopy has seen a step change in the approach to intubation in the normal child and has provided a range of options for management of the difficult airway. Typically, these devices have a high-resolution digital camera located close to the tip of the blade, which, with its wide angle of view allows the user to see around corners. They are complimented by displays of varying optical quality. Four devices have established themselves for use in children <2 years of age (44), though in this rapidly developing market, new devices steadily appear and are pushed directly into clinical use without systematic evaluation, or at least comparative studies with either conventional laryngoscopy or the more established videolaryngoscopes. The established four are: the GlideScope® (GVL®, Verathon Medical, Aylesbury, UK), the Storz Miller 1 paediatric videolaryngoscope (Karl Storz, Tuttingen, Germany), the Airtraq® Disposable Optical Laryngoscope (Prodol Meditec, Vizcaya, Spain), and the TruView PCD® Infant (Truphatek, Netanya, Israel). Airtraq® claim more than one million intubations worldwide, though this is of course impossible to verify and GlideScope® has a large body of literature to support its credentials.

Early versions of the GlideScope® had just one pediatric blade whereas the current generation, the GlideScope® AVL has the advantage of four single-use Stats or blades, with a reusable video baton. The improved shape, which is both narrower and longer than the original, requires mouth opening of only 10 mm (44) and is thus of value in children with small mouths or with limited mouth opening and has an intrinsic advantage over videolaryngoscopes such as the Airtraq® with its thicker blade. Initial studies demonstrated that the GlideScope® provides a laryngoscopic view equal to or better than direct laryngoscopy (45,46), with a longer time for intubation with the GlideScope® (45) or no difference (46). These mixed findings have been subsequently confirmed using this videolaryngoscope in anatomically normal neonates and infants (47).

The Storz DCI videolaryngoscope incorporates a fibroptic camera lens into the light source of the blade with an 80-degree field of view. There are currently two pediatric Miller-like blades available, a size...
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0 and 1. The smaller blade has a height of only 5 mm making it useful in small infants with minimal mouth opening (44). Manikin studies of intubation with a simulated difficult pediatric airway have demonstrated that the videolaryngoscope improved glottic exposure when compared with direct laryngoscopy without increasing time to intubation (48). The Storz Miller 1 videolaryngoscope has since been evaluated in children with normal airway anatomy and demonstrated improved views of the glottis, but required a longer time for intubation (49). The Miller 0 and 1 and Macintosh 2 blades for the Storz device are reusable and cleaned between uses. Single-use versions of the adult D and Macintosh blades are now available, and it is expected that disposability will filter down to the smaller blades in time.

A 2014 revamp of the Airtraq® Disposable Optical Laryngoscope has seen the release of the fully disposable Airtraq SP and in parallel with other videolaryngoscopes the Airtraq Avant which features reusable optics within a disposable blade. This latter device has a service life of 50 uses, but the smaller of two versions will only accommodate a tracheal tube down to 6 mm and requires a minimum mouth opening of 17 mm. This will have limited application in the pediatric population. The Airtraq SP is available in two pediatric sizes: Infant (Size 0, tracheal tube 2.5–3.5) and Pediatric, (Size 1, tracheal tube 4.0–5.5). Both require a mouth opening &gt;12 mm (44), which limits its universal applicability. There is some evidence using the original fully disposable version of the device to suggest that Airtraq® decreases intubation time and number of intubation attempts in normal children compared with conventional laryngoscopy (50,51), though there are significant limitations with these small studies. The adult sizes of the Airtraq device can now be complimented with a Wi-Fi camera which allows real-time sharing of images and video recording of intubations with iPad®, iPhone® and PC.

The TruView PCD® Infant has a prism and lens system that provides a 46° angle of refraction. The device also has a port through which oxygen can be injected; this acts as an antifogging mechanism as well as increasing the oxygen fraction in the airway during intubation (44). Four pediatric sizes are available, facilitating intubation from the sub 1-kg neonate through to the teenage years. The height of the blade is 8 mm, placing it between the Storz and GlideScope blades for ease of access when mouth opening is small. Laryngeal views are equivalent to that of direct laryngoscopy, but a longer time to intubation is noted (52).

The videolaryngoscope, literally, provides a new view in the world of laryngoscopy. It is a powerful tool for teaching, allowing the teacher to see what the operator is viewing (53). It provides options for intubation of both normal and difficult airways and, for example, offers a new approach to tracheal tube exchange in the intensive care environment. As a product that started life as an aid for difficult intubation, there is now ingress into the world of routine direct laryngoscopy, and the videolaryngoscope might now be advocated as a first line device for routine intubation. A laryngoscopic view previously confined to the operator is now available to all on screen, tablet, phone, and computer both within the anesthetic room and beyond using Wi-Fi connectivity. Are we now obliged to record each and every intubation and include this evidence in the anesthetic record of every patient as irrefutable evidence of tracheal tube position to prevent subsequent litigation? What then the role of the conventional laryngoscope? It is important to remember that in the clamor for this new technology that the art of laryngoscope use is a fundamental anesthetic skill. It is reliable, reproducible and low-tech. Once the art is mastered, as with riding a bicycle, it is the same art across the wide range of conventional laryngoscopes that are used in pediatrics. What price the loss of this skill if we neither teach it correctly nor practice until we achieve mastery? Mastery of this core skill must be a prerequisite to moving on to more sophisticated airway tools.

The videolaryngoscope is a very different animal; each needs to be used in its own individual and very idiosyncratic way. For example, the Storz device looks and feels almost like a conventional laryngoscope and indeed is used in almost the same way, whereas the Airtraq device is far removed from this ‘norm’. Each device has an optimum technique of use that needs to be learnt and practised. An evaluation as to which is ‘best’ for all situations and intubations is actually counterproductive as all offer a unique option. While it is evident that videolaryngoscopes do have an important role in modern anesthetic practice, it is difficult to argue that they should replace the conventional laryngoscope. A meta-analysis comparing a range of pediatric videolaryngoscopes and direct laryngoscopes demonstrated improved glottic visualization with videolaryngoscopes in normal and difficult airways. However, this advantage is offset by a higher incidence of failure and a longer time to intubation (54). If we analyze difficult airway use in isolation, then the fraction of cases that actually need a videolaryngoscope to achieve successful intubation is tiny. Given that the unit cost of any of these devices is several thousand pounds that outlay may be difficult to justify. The natural endpoint is that we then become dependent on the reliability of complex technology to perform an easy psychomotor task. The conventional laryngoscope may rest easy for now.
Disposability and variant Creutzfeldt-Jakob disease

When concerns regarding the risk of the Transmissible Spongiform Encephalopathies (TSEs) became apparent the UK Department of Health (DoH) published guidance which specified that all equipment for tonsillectomy and adenoidectomy should be disposable (55). This guidance was rooted in concern that cross-contamination to healthy individuals may occur from surgical equipment used on patients with latent disease as the prion proteins were found to be highly concentrated within the tonsil lymphoid tissue. The Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland endorsed these guidelines and recommended using single-use airway devices, where such devices were as reliable and safe as reusable alternatives, to minimize the risk of transmission of prion disease (56). In particular, it highlighted that all airway devices, including SADs used for tonsillectomy and/or adenoidectomy should be discarded after use and not used again. In all other cases, where prion transmission is not a risk reusable SADs should be sterilised. This advice is based on evidence that microscopic traces of tissue can remain on surgical instruments after washing, autoclaving, and disinfection and that routine methods for cleaning SADs do not completely remove protein deposits (57–59). Protein cross-contamination occurs during batch cleaning and autoclaving (60) and furthermore, sterilisation methods do not denature prions (61).

Following release of this guidance, there was a proliferation of single-use surgical and anesthetic equipment accompanied by concerns regarding their quality and efficacy (56). After increased morbidity was shown when using disposable surgical instruments, the DoH reversed its decision with regard to surgical equipment, but kept the guideline in place for all anesthetic equipment (62), which remains to this day. While increased morbidity with respect to surgery is relatively easy to demonstrate with easy to audit outcomes: blood loss, rates of return to theater, and incidence of primary and secondary hemorrhage, no such easy outcome parameters exist in the clinical evaluation of airway equipment. So, despite one of several reviews demonstrating that single-use laryngoscope blades severely underperformed compared to their reusable counterparts (63), the lack of quantifiable harm to patients reduces the impact of such reviews. It is reasonable to argue that anesthetists should balance the risk of transmitting Variant Creutzfeldt-Jakob disease (vCJD) against the use of inferior airway equipment (64).

Thus far, there are no proven cases of vCJD transmission via airway equipment, and this is perhaps not surprising given that analysis of over 63 000 tonsil specimens found no presence of the pathogenic form of the prion protein (65). Data from The National CJD Research and Surveillance Unit, which report deaths attributable to vCJD, report only one case since January 2012 compared with a peak incidence of 28 in 2000 and from a projection of a year on year increase in reported cases the incidence has fallen (66). Some scepticism among anesthetists regarding the transmission of vCJD via reusable equipment is revealed in the results of a survey of UK practice looking at compliance with the DoH guideline on the use of disposable airway equipment for tonsillectomy. Fifty five percent of responders disagreed with the guideline, and full compliance was only seen in 16% of responders (67).

With a lack of evidence to suggest that reusable airway equipment that is suitably decontaminated poses a risk to patients, and in light of the absence of pathogenic prion protein in tonsil specimens where does this leave existing guidance with respect to the use of single-use airway devices in adenoid and tonsil surgery? And if the patient safety argument holds for this subset of patients, then the driver for single-use equipment across all other procedures is weakened, the argument distilling to one of cost.

It is difficult to directly compare the cost of reusable devices with single-use alternatives. With the increasing availability of a plethora of single-use versions, the unit cost is a fraction of that of the reusable classic laryngeal mask airway. While the manufacturer recommendations indicate that the classic laryngeal mask airway may be reused up to 40 times, tests indicate this lifespan could safely be increased to 60 uses before failing the recommended preuse tests (68). The total cost of the classic laryngeal mask airway then has to take into account cost of sterilisation per use. While the up-front cost of a plastic SAD is small, the hidden cost lies in the consequent disposal. An estimated 500 million SADs have been used worldwide up to 2006 (69), antedating a surge in single-use SAD manufacture that we have seen in recent years. Approximately 85 000 tons of PVC medical devices are used in Europe annually and given that recycling is not an option the default method of disposal is incineration.

A comparison of the environmental impact of life cycles of reusable and disposable SADs strongly favors the use of reusable devices (70). Indeed, it can be argued that the continued use of reusable products is integral to a practice of ‘Sustainable Anesthesia’ (71). Given the superiority in performance and smaller environmental cost of reusable SADs, these remain a more cost-effective option than single-use SADs.
Conclusions
The modern trend for disposable airway devices is as much driven by aesthetics and market demands for single patient, single-use equipment as evidence that reusable airway devices carry any more than a tiny risk of disease transfer. However, with demands for patient safety overly paramount, this trend will not be reversed despite the performance advantages and lower wider environmental cost of, in particular, reusable SADs. Here, the NHS has chosen arguably the lesser cost-effective option. The one disposable success story, that of the cuffed tracheal tube has had limited take-up, ironically due to cost despite it’s clinical effectiveness.

Airway viewing devices represent the future of laryngoscopy but at considerable up-front monetary cost and the potential longer-term cost to our core skill, use of the conventional laryngoscope. This threat to one part of our skill set is amplified by the overwhelming use of SADs in clinical practice and the loss of the art of face-mask anaesthesia. These twin threats represent the true costs of this advance in airway technology. Perhaps the final arbiter of cost-effectiveness will be the quality and safety of patient care. Time will be our judge.

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Conflict of interest
The authors declare no conflict of interest.

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