Supraglottic airways in difficult airway management: successes, failures, use and misuse

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Summary

Supraglottic airway devices (SAD) play an important role in the management of patients with difficult airways. Unlike other alternatives to standard tracheal intubation, e.g. videolaryngoscopy or intubation stylets, they enable ventilation even in patients with difficult facemask ventilation and simultaneous use as a conduit for tracheal intubation. Insertion is usually atraumatic, their use is familiar from elective anaesthesia, and compared with tracheal intubation is easier to learn for users with limited experience in airway management. Use of SADs during difficult airway management is widely recommended in many guidelines for the operating room and in the prehospital setting. Despite numerous studies comparing different SADs in manikins, there are few randomised controlled trials comparing different SADs in patients with difficult airways. Therefore, most safety data come from extended use rather than high quality evidence and claims of efficacy and particularly safety must be interpreted cautiously.

Definitions and devices

Most supraglottic airway devices (SADs) are designed for use during routine anaesthesia, but there are other roles such as airway rescue after failed tracheal intubation, use as a conduit to facilitate tracheal intubation and use by primary responders at cardiac arrest or other out-of-hospital emergencies [1]. Supraglottic airway devices are intrinsically more invasive than use of a facemask for anaesthesia, but less invasive than tracheal intubation.

The term ‘extraglottic airway device’ may be more accurate than ‘supraglottic’, since it includes all devices that lie inside the oropharyngeal and oesophageal area, but outside the glottis. Figure 1 illustrates how depth of airway instrumentation correlates with anatomical position [2]. However, the term ‘extraglottic’ is not in common use in the English literature, so the term ‘SAD’ is used here to include all extraglottic devices.

Supraglottic airway devices can usefully be classified as first and second generation SADs and also according to whether they are specifically designed to facilitate tracheal intubation. First generation devices are simply ‘airway tubes’, whereas second generation devices incorporate specific design features to improve safety by protecting against regurgitation and aspiration [3]. The first generation SADs include the classic LMA™ (cLMA, Intavent Direct, Maidenhead, UK) and all other standard laryngeal mask airways (LMAs). This group also includes the CobraPLA™ perilaryngeal airway and CobraPLUS™ Airway (Pulmodyne, Indianapolis, IN, USA) although their design differs substantially from the cLMA.

The second generation SADs include the LMA ProSeal™ (PLMA), the LMA Supreme™ (SLMA) (both Intavent Direct) and the i-gel™ (Intersurgical, Wokingham, UK). These devices all incorporate a drain tube to separate the respiratory and gastrointestinal tracts and minimise the risk of aspiration. They also create a higher oropharyngeal leak pressure compared with the first generation SADs [4–8]. The SLIPA™ Airway (Streamlined Liner of the Pharynx Airway, 2011, 66 (Suppl. 2), pages 45–56 doi:10.1111/j.1365-2044.2011.06934.x

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SLIPA, CurveAir Limited, London, UK) has design features (a sump) that arguably makes it a second generation device but there is little evidence of performance benefit.

Some SADs are specifically designed to enable or assist in tracheal intubation, e.g. the LMA Fastrach\textsuperscript{TM} (Intubating LMA, ILMA, available in reusable and single use versions, Intavent Direct) and the Air-\textsuperscript{Q}TM Laryngeal Airway Device (also reusable and single use versions, Mercury Medical, Clearwater, FL, USA). Tracheal intubation may also be possible via other SADs not specifically designed for this role, while others are poorly suited to this role. In broad terms, standard LMAs, the i-gel and PLMA perform well while the Laryngeal Tubes and SLMA are less well suited to such use due to narrow calibre airway tubes (SLMA) or airway orifices (Laryngeal Tube family).

Finally, oesophageal blockers were initially designed for emergency airway management, e.g. in an out-of-hospital setting and for usage by medical personnel who do not perform tracheal intubation on a daily basis. They consist of two blocking cuffs, one in the laryngopharyngeal area (marked B in Fig. 1) and the other in the oesophageus (marked D in Fig. 1). Ventilation is provided through an outlet between the two cuffs. The Combitube\textsuperscript{TM} (Tyco Healthcare-Kendall, Pleasanton, California), Easytube\textsuperscript{TM} (Ruesch, Kernen, Germany) and different versions of the Laryngeal Tube (original Laryngeal Tube), disposable version (LT-D) Laryngeal Tube suction mark II (LTS II) and disposable version (LTS D), all VBM, Sulz, Germany) all belong to this group. Amongst the Laryngeal Tubes those without a drain (LT and LT-D) can be considered first generation SADs and those with a drain tube as second generation devices (LTS II and LTS-D).

**General considerations**

According to Brimacombe [9] there are five major considerations that highlight the role of a LMA in the management of the difficult airway: first and foremost, the anatomical and/or technical factors making facemask ventilation and laryngoscope-guided tracheal intubation difficult do not usually influence LMA insertion and function. Thus, in situations where facemask ventilation and laryngoscope-guided tracheal intubation have failed, the LMA has a high likelihood of succeeding. Secondly, the LMA can be used both as a ventilatory device and for intubation of the airway. Thirdly, tracheal intubation via the LMA can take place in an unhurried fashion while the patient is being oxygenated and his/her lungs ventilated. Fourthly, insertion of the LMA is atraumatic and does not reduce the chances of other techniques subsequently succeeding. Finally, the widespread use of the LMA in routine anaesthesia practice means that it is readily available and most anaesthesiologists reasonably skilled in its use.

Therefore, the use of the LMA is now included in many difficult airway guidelines. The American Society of Anesthesiologists includes the LMA as a ventilatory device at two points in the algorithm: first in the anaesthetised patient whose trachea cannot be intubated (anaesthetised non-emergency limb); and second in the anaesthetised patient whose trachea...
cannot be intubated and whose lungs cannot be conventionally ventilated (anaesthetised emergency limb) [10]. A similar strategy is described in the algorithm of the Difficult Airway Society in the UK [11]. This algorithm recommends the use of a cLMA: (i) during an unanticipated difficult tracheal intubation as a conduit for fibreoptic-guided tracheal intubation (with the ILMA as an alternative); (ii) during failed intubation in the setting of rapid sequence induction as a method of airway rescue (with the PLMA as an alternative); and (iii) as a rescue device in the event of a ‘cannot intubate cannot ventilate’ situation. Comparable uses can also be found in many other national recommendations such as those from Germany or Italy [12, 13]. In addition, Weiss and Engelhard recently published a proposal for management of the difficult paediatric airway [14]. In the situation of failed facemask ventilation and failed tracheal intubation, they recommended the use of the LMA or ILMA first for ventilation and also as a conduit for tracheal intubation. The LMA is likely to be equally prominent in the paediatric difficult airway guidelines currently under development by the Association of Paediatric Anaesthetists of Great Britain and Ireland and the Difficult Airway Society, and is also included as the Plan B after failed tracheal intubation in the recommendations of the working group on Paediatric Anaesthesia of the German Society of Anaesthesia and Intensive Care Medicine [15]. Therefore, the LMA and in particular the ILMA has become an integral part of each algorithm, especially in management of the unanticipated difficult airway. Of note, since the development of these guidelines, many of which are more than a few years old, numerous newer SADs have been designed and several have been shown to have performance benefits over the cLMA in some circumstances (e.g. improved airway seal, more reliable ventilation, easier use as a conduit, access to the gastrointestinal tract, improved protection against aspiration). It is therefore arguable that several SADs other than the standard LMA and ILMA should be included in updated difficult airway algorithms.

**Manikin vs patient-based studies**

Rai and Popat recently commented on the large number of manikin studies in airway management research and the relative lack of similar studies in patients [16]. They posed the question as to what should be the minimum evidence to label an airway device as efficacious and fit for purpose. They refer to an editorial by Cook, who suggested that a new airway device should undergo a three-stage process [17]. In stage 1, devices are evaluated on the bench-top and in specifically designed manikins; in stage 2, a rigorous pilot study takes place to determine whether the device is effective and safe; and in stage 3, the device is compared in a randomised controlled trial (RCT) against the current gold standard for the procedure for which it is expected to be used (e.g. in the case of first generation SADs, the cLMA).

The problem nowadays is that most studies only focus on stage 1, the manikin-based study, but do not progress to stages 2 or 3, which will require study of patients. There are several reasons for this. Many ethics committees do not consider approval necessary for manikin studies and if approval is applied for, it is usually easily obtained and participant information, consent and recruitment involve staff and not patients [18]. Furthermore, there are no adverse effects that might potentially halt the trial. The study can be completed in days, for example in a training course, rather than months or years.

But the patients’ anatomy and physiology differ in many respects, which cannot be modelled by simple manikins or even sophisticated simulators [19]. Manikins do not represent easy or difficult human anatomy in its enormous variety (for example the lack of obese manikins is a notable omission). The manikin’s upper airway ‘tissues’ are stiff, non-compliant, static and generally patent rather than soft, fragile, dynamic and collapsible as in humans. Secretions, lubrication and bleeding are simulated poorly (if at all); there are no coughing reflexes, or modelling of regurgitation or aspiration, that may impair ventilation or the view to the larynx. Difficulties in standard procedures such as mask ventilation or tracheal intubation are mostly reflected unrealistically and the fidelity of SAD insertion is also very poor [20].

Even when there are reasons why a manikin-based study is appropriate (e.g. the study design requires conditions that cannot be recreated in patients), there is a trend to extrapolate data from stage 1 to clinical practice. While it is extremely frequent to read in researchers’ concluding statements that ‘further clinical studies are needed to evaluate the effectiveness of the device in patients’, these studies are rarely done. One of the exceptions is a trial from our own group, where the study design was first applied to manikins [21] and in a follow up a RCT (level Ib) performed on patients in the operating room [22]. There are other examples where both stages are performed in the same study [23, 24].
Therefore, in accordance with Rai and Popat’s conclusion that “in very much the same way as the trainee graduates from a manikin to a patient when using a new airway device, it is time for serious researchers to move on to study patients rather than manikins”, the following articles will - whenever possible and not otherwise noted - reflect data obtained in human rather than manikin studies.

**Level of evidence**

More recently, Pandit et al. described a very reasonable strategy for airway equipment evaluation, based on the recommendation of the ‘Airway Device Evaluation Project Team’ of the Difficult Airway Society [25]. They refer to evidence-based hierarchies from level 1a to 5 (Table 1) and while acknowledging that there are other useful ways to judge research evidence, they propose that local purchasers might demand a minimum level of published evidence on a new airway device before considering it for purchasing.

Level 3b is judged the minimum level of evidence that can be subjected to a systematic review, in turn helping create level 3a evidence that can be assimilated into a wider evidence base. The authors acknowledge that level 2 and higher levels are of course acceptable (even desirable) and that results of RCTs will be useful, but for pragmatic reasons they try to define a minimum level of evidence to balance between what is achievable and what is meaningful. They illustrated this balance as level 5 being easily achievable but barely meaningful, whereas level 1 RCTs are very meaningful but difficult to achieve. For these reasons, level 3b is judged to be an appropriate point of balance as an adequate minimum level of evidence, that should be required before a purchaser might consider a device, although this evidence is not itself a sufficient criterion for equipment selection. While this argument is largely applied by Pandit et al. to purchase of devices for elective use, logically it is equally if not more important to apply it to devices for difficult airway management and emergency use.

**Ventilation via different SADs in a difficult to manage airway**

Since the development of the cLMA more than 20 years ago, there is now a much increased choice of SADs. For many SADs, however, there is still a lack of high-quality data regarding efficacy [1]. To fulfil the requirements of Cook’s stage 3, and the best evidence, RCTs comparing each new device against an established alternative are needed. These studies need to be suitably powered to detect clinically relevant differences in outcomes. Given the lack of such studies in elective anaesthetic use, it is not surprising that there are even fewer such studies in the setting of difficult-to-manage airways. Not only are ‘true’ difficult airways rare but, as this situation is potentially dangerous for the patient, best clinical practice is needed to resolve the airway challenges.

There is a considerable body of data (level 3b and 4) about the successful use of the ‘gold standard’ cLMA in patients with difficult to manage airways: over 300 publications including more than 3000 such patients [9]. Also the ILMA, designed especially for the management of the difficult airway, has been described as being successfully used for ventilation in the anticipated [26–32] and unanticipated [33, 34] difficult airway in 97–100% of cases.

Case reports or series (level 4) of successful ventilation in patients with difficult airways have been described for many other SADs: the LMA PLMA [35–41], the SLMA [42–44], the i-gel [45–50], the Ambu-i™[51], the Air-Q [52–55], the CobraPLA [56] and the CobraPLUS [57]. The Laryngeal Tube, designed for emergency ventilation, is also successfully described in difficult airway management in elective adult [58] and paediatric [59] patients in the operation room. Up until now there are no publications published in a peer reviewed journal about the use of the SLIPA in patients with difficult airways.

<table>
<thead>
<tr>
<th>Level of evidence</th>
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<tr>
<td>1a</td>
<td>Systematic review of RCTs</td>
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<td>1b</td>
<td>Single RCT</td>
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<tr>
<td>1c</td>
<td>All-or-none study (i.e. when all patients died before the therapy became available, but some now survive on it; or when some patients died before the therapy became available, but none now die on it)</td>
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<tr>
<td>2a</td>
<td>Systematic review of Level 2b cohort studies</td>
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<tr>
<td>2b</td>
<td>Single cohort study or low-quality RCT</td>
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<tr>
<td>2c</td>
<td>Outcomes studies that investigate outcomes of healthcare practices using epidemiology to link outcomes (e.g. quality of care, quality of life) with independent variables such as geography, income or lifestyle, etc.</td>
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<tr>
<td>3a</td>
<td>Systematic review of Level 3b studies</td>
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<td>3b</td>
<td>Single case-control or historical-control study</td>
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<tr>
<td>3c</td>
<td>Case report or case series</td>
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<tr>
<td>4</td>
<td>Expert opinion or ideas based on theory, on bench studies or first principles alone</td>
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The so-called second generation SADs offer some important benefits over the first generation SADs: (i) they provide a higher leak pressure, which makes ventilation with higher airway pressure possible; (ii) they offer feedback of correct pharyngo-laryngeal positioning with the tip in the post-cricoid region (PLMA and SLMA), which potentially reduces the chance of gastric insufflation; and (iii) access via the drain tube facilitates the insertion of a gastric tube for drainage of the stomach and potentially reduces the risk of regurgitation and aspiration [8]. Although these benefits are important in elective surgery, there are no clinical trials demonstrating benefit or higher success rates in difficult airways.

There are only a few RCTs comparing other SADs against the cLMA in patients with a difficult airway. In 1998, Langenstein and Moeller reported the success rates for ventilation via the cLMA and the ILMA in patients whose tracheas were difficult to intubate: efficacy was similar with 92% vs 93% success, respectively [60]. Two recently published RCTs, examining intubation through different SADs in patients with predictors of difficult intubation, did not find any significant difference in rates of successful ventilation between the single-use ILMA and the i-gel (78/80 vs 79/80, respectively) [61, 62].

In conclusion, there are reports of successful ventilation in patients with difficult airways, for many of the newer SADs, but there are not enough data to judge any individual device as superior. While several of the newer devices have design features that might be expected to improve ease of insertion or efficacy of subsequent ventilation, the cLMA remains the device with the greatest body of published literature. For many single-use LMAs there are no such published data at all. To some extent, therefore, the decision on which SAD to use to establish ventilation when airway management proves difficult is likely to be based on extrapolation from data in trials of patients undergoing elective anaesthesia whose airways are known not to be difficult to manage.

**Intubation through a SAD**

Intubation through a SAD has been reported using a blind technique and assisted by lightwands, optical stylets or flexible fibreoptic guidance. Flexible fibreoptic guided intubation through a SAD is facilitated by use of an Aintree™ intubation catheter (AIC; Cook Ireland Ltd., Limerick, Ireland, Fig. 2) [63–65] or a guide wire [66]. In some SADs these techniques are compulsory as the airway lumen or outlet is too small to advance a tracheal tube of appropriate size: this is so for the SLMA, Laryngeal Tube and Combitube.

The ‘gold standard’ for blind intubation is the reusable ILMA, which is only available for patients over 30 kg. In a meta-analysis in 2005, Brimacombe reported a 90% overall blind success rate in 2221 patients with normal airways in 23 non-RCTs (level 3a and 4) and a 90% success rate in 618 patients with abnormal airways in 16 non-RCT studies [67]. The success rate in patients with abnormal airways may increase to 100%, if a flexible Lightwand™ (Vital signs, Totowa, NJ, USA) [33, 68], a Trachlight™ (Teleflex Medical Europe Ltd, Athlone, Ireland) [69], a Foley optical stylet tool™ (Clarus Medical, Minneapolis, MN, USA) [70] or a flexible fibrescope [26, 28] is used.

Blind intubation via many SADs fails either because of non-alignment of the device orifice and the glottis or, more frequently, because a tube or introducer passed down the SAD exits the ventilation orifice posteriorly and enters the oesophagus. Most SADs therefore, with the exception of those specifically designed for intubation, require fibreoptic guidance to increase the rate of successful intubation, even in patients with normal airways, above around 15%.

Successful fibreoptic guided intubation of a difficult airway via many other SADs has been reported: via the cLMA in adults [71, 72] and children [73, 74] and the PLMA in grossly and morbidly obese patients [35]. Case reports have been published with the SLMA [75], Aura-i™ (Ambu) [51] and i-gel [49]. There is a report of successful fibreoptic guided intubation via the i-gel...
in two patients in whom the technique failed via a cLMA [50].

Just recently, a few level 1b studies (RCTs) have been published comparing different SADs with the ILMA. Results for blind intubation are reported in Table 2. There is one study comparing fibreoptic guided intubation through the single use ILMA and the i-gel in patients with predictors of a difficult airway [62]. Only one attempt was allowed for intubation and reported success rate was not statistically significantly different: ILMA (90%); i-gel (96%). Of note for blind intubation, the single-use ILMA was considerably more successful than the i-gel: 69% vs 15%, respectively.

In summary, for blind intubation via a SAD the largest number of published studies and the greatest clinical experience is for the reusable ILMA. Again, there are reports of successful fibreoptic guided intubation via many newer SADs but there are not enough data to judge any of them to be superior over the ‘gold-standard’ ILMA.

### The use of SADs for difficult airway management in the pre-hospital setting

The importance and prevalence of SADs in airway management in the pre-hospital setting have increased considerably in recent years. There are three main reasons for this: (1) emergency tracheal intubation outside the hospital environment is notably more likely to fail than during elective anaesthesia in hospital; (2)

<table>
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<tr>
<th>Study</th>
<th>n</th>
<th>DAM ILMA</th>
<th>Air-Q</th>
<th>CPLA</th>
<th>i-gel</th>
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<tr>
<td>Theiler et al., 2011 [61]†</td>
<td>80</td>
<td>Yes</td>
<td>69%</td>
<td>15%</td>
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<tr>
<td>Karim and Swanson, 2011 [31]†</td>
<td>154</td>
<td>No</td>
<td>99%</td>
<td>77%</td>
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<tr>
<td>Erlacher et al., 2011 [115]</td>
<td>180</td>
<td>No</td>
<td>95%</td>
<td>57%</td>
<td>47%</td>
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<tr>
<td>Darlong et al., 2011 [116]‡</td>
<td>60</td>
<td>No</td>
<td>90%</td>
<td>87%</td>
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</table>

DAM, patients with predicted difficult airway management; ILMA, LMA Fastrach; CPLA, Cobra perilaryngeal airway.

*†p < 0.001; one ‘visualised’ blind attempt (no movement of the fibrescope allowed); patients with predicted, but not known, difficult intubation.

‡p < 0.0001; after two attempts.

p not reported; after three attempts; the tracheas of all patients except one with Air-Q were subsequently successfully intubated with fibreoptic guidance.

p not significant; CPLA led to longer intubation time, more trauma, airway morbidity and tachycardia.
unrecognised oesophageal or hypopharyngeal intubation was recorded in up to 25% [76, 77]. One study also reported an incidence of unrecognised oesophageal intubations of 6.7% when tracheal intubation was performed by emergency medical service physicians [78]. While the 24-h mortality rate of patients whose tracheas were intubated correctly was reported as 10%, this rate increased dramatically to 70–90% for those with misplaced tubes [77–79].

With these high rates of failure of airway management, it can therefore justifiably be argued that in the pre-hospital setting all airways are, at least potentially, difficult airways. Use of SADs in the pre-hospital setting should be judged in this context.

It is therefore understandable that despite the fact that tracheal intubation is perceived as the optimal method of providing and maintaining a clear and secure airway, the 2010 European Resuscitation Guidelines recommend that tracheal intubation is only attempted when trained personnel are available to carry out the procedure with a high level of skill and confidence [85]. Several SADs are now included in these recommendations and in guidelines for out-of-hospital airway management, not only for management of difficult intubation but as a primary approach for those who do not perform tracheal intubation regularly [85–87].

The particular benefits of use of an appropriate SAD over facemask ventilation in the pre-hospital setting include higher success rate and tidal volume, less hand fatigue [88] and less gastric insufflation, regurgitation or aspiration (during continuous chest compression) [89]. Ventilation with an automated ventilator is possible, which frees the rescuer for other tasks [90]. Compared with tracheal intubation, SADs have a higher success rate and are quicker to insert [22, 91] and unlike tracheal intubation, they can generally be inserted without interrupting chest compressions (at least in manikins) [92]. The unique problems of pre-hospital care (e.g. lack of starvation, necessity for assisted ventilation perhaps during chest compressions) mean that second generation SADs logically have more desirable performance features than first generation devices.

Several SADs have been considered for pre-hospital airway management. There are published studies in patients undergoing CPR or during trauma management with the cLMA [93–96], the SLMA [44, 97], the ILMA [98–103], the i-gel [104], the Combitube [95, 96, 105–107] and versions of the Laryngeal Tube [108, 109]. None of these studies have been adequately powered to enable survival to be studied as a primary endpoint; instead, most researchers have studied insertion and ventilation success rates. There are no RCTs comparing different SADs (even in terms of successful ventilation and insertion times) in the pre-hospital setting. Such studies are needed to inform this evolving area of practice.

Of note, data obtained in the controlled environment of the operating room or in simulated manikin scenarios cannot automatically be transferred to the pre-hospital setting. An example of this is a recent study by Trimmel [110] comparing out-of-hospital intubation success rates of a conventional laryngoscope with those of the Airtraq® videolaryngoscope (King Systems, Noblesville, IN, USA) in the pre-hospital setting. Although the Airtraq has been demonstrated to be effective in elective patients in the operating theatre [111–114], in the pre-hospital setting anaesthesia trained emergency physicians achieved only 49% successful tracheal intubation with the Airtraq, whereas conventional laryngoscopy was successful in 99%. Moreover, in 54 of 56 patients where Airtraq intubation failed, direct laryngoscopy was successful on the first attempt.

Hence, there is not enough evidence to support the routine use of any specific SAD in pre-hospital airway management. The best technique is dependent on the precise circumstances and the competence of the rescuer achieved by training in patients under supervision in a controlled environment [85].

Conclusions

Several factors support the use of a SAD in the management of the difficult airway. Many studies and case reports or series have been published that illustrate the efficiency of SADs in difficult ventilation and failed intubation situations. Supraglottic airway devices are included in many guidelines and recommendations for securing the airway in diverse medical environments. By far the most publications and clinical experience still exist for the cLMA and ILMA. Numerous studies compare different SADs in huge variety of ‘clinical settings’ in manikins, but there are very few comparable studies in appropriate patients. The results of manikin studies cannot be assumed to transfer to clinical practice due to the low fidelity of manikins’ upper airways both in terms of anatomy and physiology. At present there is inadequate robust evidence to support any of the new SADs as superior to the so called ‘gold standards’. To determine whether any of
the newer SADs (with design features that might be anticipated to offer performance benefits) offer genuine clinical advantages, properly powered RCTs in patients with difficult-to-manage airways are needed, both in hospital and in the pre-hospital setting.

**Competing interests**

No external funding or competing interests declared.

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