Supraglottic airway devices: recent advances

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Matrix reference 3A01, 2A01

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Key points

The majority of general anaesthetics are now delivered with a supraglottic airway device (SAD) maintaining the airway.

Efficacy and safety therefore matter. This is particularly so when SADs are used where a tracheal tube would traditionally have been used.

For the majority of SADs, there is limited published evidence of efficacy or safety.

Newer SADs have been designed to improve efficacy (airway seal) and safety (gastric access and protection from aspiration).

It is difficult to prove increased safety of these devices compared with the classic laryngeal mask airway, but available evidence supports this claim.

The classic laryngeal mask airway (cLMA, Intavent Direct, Maidenhead, UK) was introduced into clinical practice in 1988 and by 1989 had been purchased by almost every hospital in the UK. Over the next few years, anaesthetists widened the indications for its use dramatically.[1] Since that revolution, although there have been numerous attempts to compete with the cLMA, further progress has largely been by evolution.

According to the NHS Purchasing and Supply Agency 'Evidence Based Purchasing Guide' (July 2008), there are 27 standard LM devices available.[2] The cLMA has over 2500 studies supporting it, whereas all others had only 18 between them. There were published comparative data for only three of more than 20 single-use standard laryngeal masks, and that evidence is largely based on lack of harm: benefit or equivalence to the cLMA has largely not been demonstrated.

However, this article focuses on newer supraglottic airway devices (SADs), introduced in the last 10 yr, which offer potential benefits over the cLMA. It is based largely on published evidence but is also refined by personal experience.

Terminology

The following terms and abbreviations are used throughout this article. SAD=supraglottic airway (synonymous with extraglottic or periglottic airway). LMA=laryngeal mask airway: a protected term describing a laryngeal mask (of any type) manufactured by the original manufacturers of the device. LM=laryngeal mask: a laryngeal mask manufactured by anyone other than the original manufacturers.

Clinical evidence: efficacy *vs* safety

It is worth distinguishing between clinical evidence relating to the *efficacy* and *safety* of performance. This is an often misunderstood area. Small clinical evaluations of tens or hundreds of patients can be used to determine the efficacy of performance of particular devices in absolute and relative terms. As most devices perform adequately, most of the time many hundreds of uses are generally used to make meaningful comparisons: something that is done in only a minority of publications.

Conversely, safety evaluations (for example, ventilation failure rates or more pertinently the risk of aspiration or of neuropraxia) may need many thousands of cases before concerns are identified. In reality, this means that the risk profile of a new device (unless it is particularly unsafe) is unlikely to be established for several years after introduction.

These factors must be borne in mind when evaluating some of the published results and manufacturer's claims regarding the newer arrivals in the market.

Can we define a 'best SAD'?

It is likely impossible to define a 'best SAD' as the term may be used to mean 'safest', 'most reliably inserted', 'most reliable for controlled ventilation', 'cheapest', etc. Moreover, the context is variable, SADs may be used in hospitals for low-risk patients undergoing elective surgery (spontaneous or positive pressure ventilation), for more complex patients and operations (extended indications), for difficult airway management, for airway rescue, out of hospital by less experienced (or novice) users, and during cardiopulmonary resuscitation. Each use demands different performance characteristics. This short article cannot address all these areas of practice and concentrates on in-hospital anaesthesia use in elective patients. We focus on the following questions:

What are the limitations of the cLMA?
What prevents anaesthetists using a cLMA for all elective cases?
Do any of the newer SADs have benefits over the cLMA and if so what?

Challenges to the current 'benchmark': cLMA

Dr Brain's cLMA was introduced into clinical practice in 1988 and has an enormous body of evidence to support its use: both in terms of efficacy and safety. There are over 2500 papers and some 270 million uses. The literature describes only one death directly attributable to the device, although this is certainly an underestimate.[3] Before the cLMA, airway management options consisted of facemask or tracheal intubation. Twenty years on, the cLMA (and derivative LMs) is still the dominant choice of airway for anaesthesia in the UK, being used in an estimated 50% of cases.

More recently, changes in the surgical population, surgical techniques, and medical economics have altered the surgical 'environment'. The increase in obesity (and therefore gastro-oesophageal reflux), more use of laparoscopic and minimally invasive surgery, the drive to shorter length of hospital stay, and increased cost pressures have all had some impact on choice of airway management devices for anaesthesia: in some cases representing opportunities for and in some barriers to SAD use.

The limitations of the cLMA are largely that (i) controlled ventilation is not always possible due to the moderate pharyngeal seal and (ii) there is a risk of pulmonary aspiration of regurgitant matter.

Owing to the low-pressure seal afforded between the cLMA and the pharynx (median $\sim$20 cm H_2O, rarely $>$30 cm H_2O),[4] when the airway pressure increases above the pharyngeal seal (during controlled ventilation), ventilating gas is lost, leading to a risk of hypoventilation, environmental pollution, and drug wastage. Equally important, as airway pressure increases, a larger proportion of gas leaks and a larger proportion of this leaking gas enters the oesophagus and stomach, likely increasing the risk of regurgitation and aspiration.

Aspiration requires regurgitant fluid to reach the laryngeal inlet: logically, two features may impact on this, although neither has been studied extensively. First, the seal the SAD makes with the oesophagus (*oesophageal seal*) will act as a barrier to ingress into the pharynx and second the bulk of the SAD in the pharynx combined with the seal with the pharynx (*pharyngeal seal*) will determine the likelihood of spill into the larynx. Devices made of a soft compliant material may also be less likely to form channels that may predispose to aspiration than those made of more rigid material. Devices with a functioning drain tube may enable regurgitant fluid to bypass the pharynx and oral cavity completely. Thus, devices with the least likelihood of aspiration might logically be anticipated to be those with a high oesophageal seal, a high pharyngeal seal, soft material, good pharyngeal volume, and a good drain tube. Obesity, gastro-oesophageal reflux, laparoscopic surgery, and increased use of the lithotomy position are all challenges to use of the cLMA.

Aspiration and the cLMA

In 1993, the incidence of aspiration during anaesthesia using either a facemask or a tracheal tube in a study of over 214 000 patients was found to be of the order of 1 in 4000 for elective patients and 1 in 900 emergencies.[5] Two-thirds of aspirations occurred during intubation or during extubation. Several attempts to determine the incidence of aspiration during cLMA anaesthesia have found lower numbers ($<$1 in 10 000): although case mix inevitably interferes with this analysis.[1] Keller and colleagues[3] reported three cases of aspiration via a cLMA (one fatal) and reviewed the subject identifying that 19 of 20 cases in the literature had risk factors for regurgitation. Asai's accompanying editorial listed in excess of 20 risk factors for aspiration, making it difficult to imagine many patients without risk. In a study comparing the cLMA with the ProSeal LMA (PLMA), elective patients without risk for aspiration routinely had their stomachs drained via the PLMA drain tube.[6] A substantial number had gastric contents that were both acidic and well in excess of the 25 ml regarded as having the potential to lead to lung damage. The reality is of course that many elective patients have both risk factors for aspiration and a significant gastric volume when starved: but very, very few aspirate.

The cLMA protects from aspiration by having a moderately snug seal over the larynx having few folds in the material once inflated, occupying a moderate volume of the hypopharynx, and by having a quite high oesophageal seal 40–50 cm H_2O. Reasonable protection from aspiration of regurgitant fluid has been well demonstrated in cadavers. These same features have not generally been confirmed for any other 'standard' LMs.

How might the cLMA be improved?

(i) Improve protection against aspiration in the event of regurgitation.
(ii) Improve the ability to deliver positive pressure ventilation in a variety of patients and positions.
(iii) As a result, expand the safety profile and the case mix for which the device is suitable.

Alternatives to the cLMA: devices available.
SADs can be divided as follows.

First-generation SADs

These are SADs which fit the description 'simple airway device'. They include the cLMA, flexible LMA, and all LMs. In addition, they include the laryngeal tube (LT) and cobra perilaryngeal airway. They may or may not protect against aspiration in the event of regurgitation, but have no specific design features that lessen this risk. They are not considered here further.

Second-generation SADs

SADs that have been designed for safety and which have design features to reduce the risk of aspiration. In several cases, the efficacy of that design is unproven. Efficacy for ventilation is often a by-product of design for safety. These include:

- PLMA
- i-gel

- Supreme LMA (SLMA)
- Laryngeal tube suction II (LTS-II) (and disposable version LTS-D)
- Streamlined liner of the pharynx airway

Owing to limited space, the last device is not discussed here but further information is available at http://www.slipa.com/.

ProSeal LMA

The PLMA (Intavent Direct) shows several modifications from the cLMA:

(i) oesophageal drain tube
(ii) posterior inflatable cuff
(iii) reinforced airway tube
(iv) integral bite block
(v) introducer

The drain tube runs through the device from the tip to the proximal end. When the PLMA is correctly positioned, the tip of the device forms a high-pressure seal with the oesophageal inlet and the drain tube runs in continuity with the oesophageal lumen (Fig. 1).

The posterior cuff and the increased bulk of the PLMA mask together substantially increase the pharyngeal seal. In nine studies of 1470 patients, the seal pressure has been shown to be significantly higher than the cLMA (27–31 compared with 16–20 cm H_2O).[4] In one study, the pharyngeal seal exceeded 20 cm H_2O (above the median seal of the cLMA) in 87% of the patients. In about 20% of the patients, the pharyngeal seal exceeds 40 cm H_2O: a level few other SADs ever reach.[7]
The net effects of the modifications are as follows:

(i) Airway seal is improved, enabling positive pressure ventilation (PPV) at higher pressures and therefore for a wider spectrum of patients in a wider selection of positions.
(ii) The oesophagus is effectively isolated from the airway. This functional separation of the gastrointestinal and respiratory
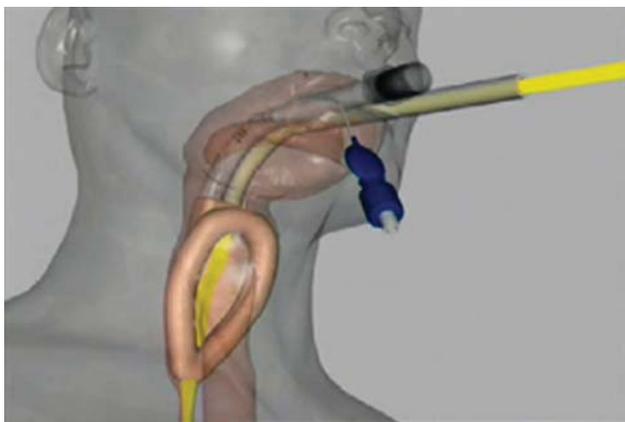
tracts mimics the function of a rudimentary larynx and is a feature of several second-generation SADs.
(iii) Simple tests enable correct positioning of the PLMA to be confirmed.
(iv) The stomach may be accessed with an orogastric tube.
(v) The insertion technique has differences.

PLMA insertion

Owing to the larger bulk of the PLMA tip and the absence of a back-plate on the device, poor insertion technique leads to posterior folding over of the device. In 2100 patients over 28 comparative studies, the PLMA was successfully inserted on first attempt in 87%, compared with 93% for the cLMA.[4] If three attempts were allowed, insertion success rose to close to 100% with no difference between devices. There are three insertion techniques for the PLMA insertion.

(i) Standard: identical to the cLMA, but demanding careful attention to detail.
(ii) Introducer: a metal introducer is attached to the concave side of the device. It is then introduced in the same manner as an intubating LMA.
(iii) Bougie-guided: a bougie is placed upside down into the oesophagus and the PLMA is railroaded into place via the drain tube (suction catheters or orogastric tubes are alternatives).

In a study comparing the three techniques in 240 patients, the bougie-guided technique had a significantly higher success rate (100% first-time success) without increasing time or airway trauma.[8]

PLMA positioning

The tip of the PLMA is formed by the distal end of the drain tube. This must sit in the oesophageal inlet to ensure best performance. The ease of passage of an orogastric tube into the stomach via the oesophageal tube (and hence correct positioning of the device tip) has been shown to correlate with optimal anatomical airway positioning over the larynx, that is, correct airway positioning is dependent on getting the mask tip to the top of the oesophagus.

Airway protection with the PLMA

Several design/performance features suggest that the PLMA will decrease aspiration risk.

(i) Increased pharyngeal leak pressure reduces leak fraction during PPV, reducing the risk of gastric inflation.
(ii) The drain tube vents any gas leaking into the oesophagus, reducing the risk of gastric inflation.
(iii) Should regurgitation occur, the drain tube vents fluid and small solids beyond the pharynx. This reduces the risk of aspiration and its appearance in the drain tube alerts the anaesthetist to the existence of regurgitation.

(iv) The large bulk of the PLMA occupies the pharynx and peri-laryngeal tissues lessening the space available for regurgitated fluid to 'pool'.

(v) Increased oesophageal and pharyngeal seal decreases the risk of any pooled fluid entering the laryngeal inlet.

Each of these theoretical benefits is supported by evidence: from bench-top studies, case reports, and formal clinical trials.[4] In fresh cadavers, the PLMA significantly improved the prevention of gastric regurgitation soiling the airway when compared with the cLMA.[9] Even when the drain tube was clamped, the PLMA withstood nearly twice the fluid pressure (80 cm H_2O) before aspiration occurred: with the drain tube, open aspiration was eliminated.

Is the PLMA safer than the cLMA?

Assuming an aspiration risk with the cLMA of 1:11 000, a properly powered clinical trial in elective patients (power 80%, $\alpha=5\%$) designed to detect a 50% reduction in aspiration would require 1.3 million patients per group. Thus, clinicians will require, for the PLMA and other devices, to use a combination of understanding of design and evidence from bench-top tests, case reports, and clinical trials in forming their own decisions. There have been a handful of reports of aspiration with the PLMA, in some but not all, positioning was unlikely to be optimal.

Paediatric sizes (1.5–2.5) have recently been introduced, but evaluations are more limited than for adults at present.

The clinical utility of the PLMA has enabled enthusiasts and experts to considerably extend the indications for use of a SAD into territories previously the preserve of the tracheal tube and into difficult airway management. The PLMA is supported by more clinical evidence of both efficacy and safety than any other second-generation SAD. Of note, there is no clinical study in which the PLMA is outperformed by any other SAD. As such it should be regarded as the benchmark for second-generation SADs. Indeed, it might be argued that given the evidence for the increased efficacy and safety of the PLMA over first-generation SADs, it has superseded them: the continuing dominance of the cLMA and LMs might justifiably be queried.

i-gel

The i-gel (Intersurgical, Wokingham, UK) is a novel SAD designed by UK anaesthetist, Muhammed Nasir (Fig. 2). It has the following features:

(i) Single use.
(ii) Cuffless: the mask is made of a soft polymer and is shaped similarly to an inflated LMA posteriorly with its anterior shape designed to 'fit the perilaryngeal structures'.
(iii) Narrow-bore oesophageal drain tube.
(iv) Short, wide-bore airway tube.
(v) Integral bite block.

The i-gel is notably easy to insert: due to a combination of a very, very low coefficient of friction when lubricated and the fact there

Fig 2 Adult i-gels size 3, 4, and 5.

is no cuff to inflate. Its use has been rapidly adopted in some centres. The manufacturers report more than 2 million uses.

There are increasing numbers of formal evaluations with most reporting positive findings. First-time insertion success rates are >85% and this approaches 100% with three attempts.[10] Most studies report a pharyngeal seal that is higher than the cLMA (reported means 26–30 cm H_2O). The drain tube has been reported to protect against aspiration and to provide an early indication of regurgitation.

On first examination, the i-gel would appear to be an excellent alternative to the PLMA: we would suggest that this is as yet unproven. Several studies report failed ventilation rates of around 5%, higher than for the PLMA, which one might speculate is contributed to by the cuffless nature of the device: it either works or it does not. The manufacturers suggest that this may be due to sizing problems and this needs further evaluation.

There are case reports of complications arising—tongue trauma and nerve damage, which need further research, but like the cLMA reports of complications often follow more widespread use.

In terms of airway protection, the design of the i-gel intentionally included a rather truncated tip, with the aim of reducing post-use dysphagia. As a result, when correctly positioned, the i-gel penetrates into the oesophagus rather less than LMAs and its oesophageal seal is low. It is unknown whether this has an impact on protection against aspiration: the manufacturers state the seal is 'enough'. There has been only one case of aspiration with the i-gel reported in the literature.

Paediatric i-gels were introduced in 2009: preliminary evaluations are positive.

In the authors' opinion, the i-gel is a highly promising second-generation SAD. There is good evidence that its performance profile is comparable with the cLMA for routine airway management [with several recent randomized clinical trials (RCTs) suggesting relative equivalence] and it has some features that add

Fig 3 Supreme LMA.

benefit. Its ease of insertion and wide lumen make it well worth considering as a SAD for both airway rescue and as a conduit for assisted intubation. However, before its uses are extended, more rigorous evaluation is recommended: there is, to date, only one rather low-quality and inadequately powered RCT comparing it with the PLMA. Adequately powered, high-quality RCTs comparing the i-gel with the other second-generation SADs are required.

Supreme LMA

The SLMA (Intavent Direct) is a single-use second-generation SAD from the LMA family. It is described by some as a 'single-use ProSeal LMA' but it has important differences in design and function. In fact, it has features of the PLMA (drain tube, large mask), ILMA (rigid stem, insertion technique), and the LMA-Unique (PVC material and single use) (Fig. 3). Its features are:

(i) Single use
(ii) Large inflatable plastic cuff, but no posterior cuff (cf. PLMA)
(iii) Oesophageal drain tube
(iv) Preformed semi-rigid tube
(v) Fins in the mask bowl to prevent epiglottic obstruction (cf. PLMA, cLMA)

The SLMA has been evaluated in several cohort studies and RCTs. Results, which remain limited in number, suggest that it is readily inserted (∼90% first attempt, 100% after three attempts) and provides a clear airway almost invariably.[11] [12] The reinforced tip reduces the risk of fold-over, compared with the PLMA. Like all LMAs, a degree of airway obstruction due to compression of the larynx from behind, with vocal cord shortening, occurs infrequently. This has been reported for both cLMA and PLMA: over time, it has become apparent that it is not a major clinical problem.

Pharyngeal seal is intermediate between cLMA and PLMA with most reporting a seal of 26–30 cm H_2O: its oesophageal seal is not reported.

The described features suggest that it is likely to provide good protection against aspiration: although this remains conjecture.

To date, there is little evidence of use of the SLMA in advanced settings or for difficult airway management: this will inevitably emerge.[12] However, there are design features that suggest that perhaps the PLMA may still out-perform it for advanced use and the cLMA, PLMA, or i-gel may have more beneficial features for difficult airway management.

As an example, the SLMA drain tube runs through the middle of the airway tube (rather than next to it in the PLMA) dividing it into two narrow lumens. This limits its use for airway inspection and for use as a conduit for intubation: while a fibrescope will fit through the channels relatively easily, an Aintree Catheter fits only with difficulty.

Being made of PVC, the SLMA may cause more trauma than silicone devices (such as the cLMA and PLMA) and the low-friction i-gel. Definitive evidence of this is awaited.

Laryngeal tube suction mark II

The LTS-II (VBM GmbH, Sulz, Germany) is a two-lumen SAD based on the LT. The oesophageal drain tube runs posterior to the airway tube and extends beyond it. It has negligible penetration of the UK market. Insertion is relatively easy but ventilation once inserted less reliable than the PLMA. It has a high pharyngeal and oesophageal seal. There is insufficient published literature to draw firm conclusions about performance and safety. Limitations include a relatively high airway obstruction rate (10%), occasional glottic placement, and limited functionality as a conduit due to small airway orifices. A single-use version (LTS-D) is available.

Summary

First-generation SADs. There is no robust evidence of any device outperforming the classic LMA. For many devices, there is no evidence of efficacy or safety, except individual unpublished experience.

Second-generation SADs. The PLMA stands alone, with solid evidence of efficacy and safety both in routine and advanced use. The i-gel, SLMA, and LTS-II have increasing positive evidence and are likely to compete effectively both with first- and second-generation devices. These developments offer the opportunity (though not the necessity) for SADs to take an ever larger role in modern airway management.

It has been advocated that the use of a SAD with a drain tube should become as the standard of care. We are some way off that yet, but the argument that 'safer SADs' should be in routine use is an interesting one.

Conflict of interest

T.C. has been paid for lecturing for the LMA Company and Intavent Orthofix. He has also received 'at cost' or free equipment from numerous airway equipment manufacturers for research. Neither author has any financial interest in any such company.

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Please see multiple choice questions 18–20.