Review article

A critique of elective pediatric supraglottic airway devices

MICHELLE C. WHITE DCH FRCA*, TIM M. COOK FRCA† AND PETER A. STODDART MRCP FRCA*

*Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children, Bristol, UK and
†Consultant Anaesthetist, Royal United Hospital, Bath, UK

Summary

In 1988, when the Laryngeal Mask Airway-Classic™ (Intavent Orthofix, Maidenhead, UK), was introduced there were only two choices of airway management: tracheal tube or facemask. The supraglottic airway, as we now understand the term, did not exist. Yet, 20 years later, we are faced with an ever increasing choice of supraglottic airway devices (SAD). For many SADs, with the exception of the LMA-Classic™ and LMA-Proseal™ (Intavent Orthofix, Maidenhead, UK), there is a lack of high quality data of efficacy. The best evidence requires a randomized controlled trial comparing a new device against an established alternative, properly powered to detect clinically relevant differences in clinically important outcomes. Such studies in children are very rare. Safety data is even harder to establish particularly for rare events such as aspiration. Therefore, most safety data comes from extended use rather than high quality evidence which inevitably biases against newer devices. For reason of these factors, claims of efficacy and particularly safety must be interpreted cautiously. This narrative review aims to present the evidence surrounding the use of currently available pediatric SADs in routine anesthetic practice.

Keywords: Laryngeal mask; proseal; airway; children; pediatric

Introduction

In 1988, when Brain (1) introduced the Laryngeal Mask Airway-Classic™ (cLMA, Intavent Orthofix, Maidenhead, UK), there were only two choices of airway management: tracheal tube (TT) or facemask. The supraglottic airway, as we now understand the term, did not exist. Yet, 20 years later, we are faced with an ever increasing choice of supraglottic airway devices (SAD).

A SAD can be pragmatically defined as a device designed to maintain a clear airway, which sits outside of and creates a seal around the larynx. The term extraglottic may be more accurate but is not in common use. Most SADs are designed for use during routine anesthesia, but there are other roles such as airway rescue after failed intubation, use as a conduit to facilitate tracheal intubation and use by primary responders at cardiac arrest or other out-of-hospital emergencies. This review focuses on their primary role: elective anesthesia. SADs are intrinsically more invasive than use of a facemask for anesthesia, but less invasive than tracheal intubation. Accepting that
use of a facemask is impractical for many procedures, the choice of airway therefore often lies between TT and SAD. Given its lower invasiveness, reasons not to use a SAD for all cases relate to concerns over (i) stability of the airway, (ii) surgical access, (iii) ability to ventilate through the device, (iv) safety, particularly protection of the airway against regurgitation and pulmonary aspiration.

Aims and limitations
This narrative review aims to present the evidence surrounding the use of currently available pediatric SADs in routine anesthetic practice: the cLMA, flexible LMA (fLMA, Intavent Orthofix, Maidenhead, UK), LMA-Unique™ (ULMA, Intavent Orthofix, Maidenhead, UK), Cobra Perilaryngeal Airway (CobraPLA, Engineered Medical Systems, Indianapolis, IN) and LMA-Proseal™ (PLMA, Intavent Orthofix, Maidenhead, UK). As larger children and adolescents necessitate the use of adult sized devices, the i-gel™ (Intersurgical, Wokingham, UK) and LMA-Supreme™ (SLMA, Intavent Orthofix, Maidenhead, UK) are also discussed. Both the i-gel and SLMA are currently only available in adult sizes but pediatric sizes are in development and expected to be released in 2009.

In this review we divide SADs into first and second generation devices. First generation devices are simply ‘airway tubes’, whereas, second generation devices incorporate specific design features to improve safety by protecting against regurgitation and aspiration.

For many SADs, with the exception of the cLMA and PLMA, there is a lack of high quality data of efficacy. The best evidence requires a randomized controlled trial comparing a new device against an established alternative, properly powered to detect clinically relevant differences in clinically important outcomes. Such studies in children are very rare. Safety data is even harder to establish particularly for rare events such as aspiration. Therefore, most safety data comes from extended use rather than high quality evidence which inevitably biases against newer devices. For reason of these factors, claims of efficacy and particularly safety must be interpreted cautiously. Although children are not ‘small adults’ and we cannot extrapolate from adult data, where adult evidence is relevant (or the only data available), this is reported.

First generation supraglottic airway devices
The laryngeal mask airway (cLMA, fLMA, ULMA) and other laryngeal masks

Historical context. The cLMA was invented by Brain in 1983(2) and introduced into routine practice in 1998 (1). It is a re-usable device made of silicone and can be considered the benchmark against which all other SADs must be judged. The fLMA was introduced in 1990, specifically designed for use in ENT and dental anesthesia (3). In 1997, the first single-use LMA, the ULMA made from polyvinyl chloride (PVC) was introduced (4). In 2003, the design patent for the cLMA (but not its epiglottic bars) expired and since then many other single-use devices have been manufactured, the first of which was the Portex Soft Seal, released in 2003 (5). Single-use devices (termed laryngeal masks (LM), to distinguish them from the LMA) are generally made of PVC or plastic, although a number of silicone devices are also available. Some manufacturers have also produced reusable versions and economic and technical comparisons for some of the available devices are presented elsewhere (5).

However, as there is minimal pediatric clinical data to support their efficacy or safety compared with the cLMA, we are unable to make specific recommendations concerning different manufacturers. We present the evidence for cLMAs and fLMAs in pediatric practice.

Classic and flexible LMA. The cLMA (Figure 1a) is widely used in routine anesthesia for children and has also greatly aided the management of children with difficult airways (6). Although the evidence base in children is smaller than in adults, the efficacy and safety in pediatric practice has been reported in several large studies (7–9). The cLMA has first time insertion rates of 90%, overall insertion rates of 99–100% and a low rate of serious complications (<11%) (7,8). However, in small infants, increased complication rates up to 47% are reported (7–9). Complications commonly encountered are obstruction and laryngospasm. Epiglottic downfolding is commonly seen during fibreoptic inspection of the larynx via the cLMA but its relation to airway obstruction is less clear (7,10). The airway leak pressure in infants is also lower than in larger children (11,12), raising concerns over the ability to
provide both effective and safe, positive pressure ventilation via a cLMA. Safety concerns focus on gas leakage around the cuff potentially leading to gastric distension and increased risk of regurgitation and pulmonary aspiration. Neuropraxia and ulceration can also occur.

The efficacy of the fLMA (Figure 1b) has been evaluated in a number of large studies (13,14). Moylan evaluated the fLMA in 145 children undergoing 2500 radiotherapy procedures (14). Flynn evaluated single use and reusable fLMAs in 100 children undergoing dental procedures and found them to be equally efficacious (13). The fLMA is useful for head and neck surgery including ENT, dental and ophthalmic anesthesia. For adenotonsillectomy, the fLMA is reported as similar or better than the TT (15–17), yet airway management with a TT is still commonest practice (18). This may be because of concerns over transmission of infection with re-usable devices. Routine methods of cleaning laryngeal masks do not completely remove protein deposits (19–21), and commonly used methods of sterilization do not denature prions (22). The advent of quality single-use fLMAs (13) may change this practice.

Many anaesthetists choose the cLMA rather than a facemask for airway management for the practical reason of allowing their hands to be free for other tasks. However, the actual evidence for the cLMA providing a better airway than a facemask during routine anesthesia is equivocal (23,24) including a recent study of critical care nurses, which showed no difference in successful ventilation using a cLMA or facemask (25). Compared with the TT, the cLMA is less invasive and this has implications in children with upper respiratory tract infections in whom the cLMA is reported as having fewer airway complications than the TT (26).

Clinical end points are often used to guide cuff inflation and determine optimal positioning and seal, but when used in a study of 640 children, significant cuff hyperinflation (median cuff pressures of 90 to >120 cm H2O) resulted (27). A subsequent study in 200 children reported that lowering cuff pressures to the recommended range (<60 cmH2O), improved the airway seal (28). Therefore routine use of cuff manometers is recommended (27,28).

In summary, the cLMA and fLMA have revolutionized pediatric anesthetic practice. They are the most well established SADs in children, have the largest evidence base for efficacy and safety and are the benchmark by which other devices should be evaluated. In most cases they are a more practical choice than using a facemask, and in children with an upper respiratory tract infection they are associated with fewer complications than a TT (26).

Limitations include: higher complication rates in small infants (7–9); cuff hyperinflation and poor seal if a pressure manometer is not used (27,28); and concerns around cuff leakage and potential gastric inflation during positive pressure ventilation (11,12).

Cobra Perilaryngeal Airway

The Cobra Perilaryngeal Airway (CobraPLA) (Engineered Medical Systems, Indianapolis, IN)
(Figure 2a,b) is single use, first generation SAD, introduced in 2003. It comprises a widened distal end (head) with a somewhat flexible tip, and a proximal cuff which when inflated occupies the lower oropharynx. It is manufactured in eight sizes, four of which are designated for pediatric use: size 0.5 (2.5–7.5 kg); size 1.0 (7.5–15 kg); size 1.5 (16–30 kg); size 2.0 (31–60 kg).

The CobraPLA has been compared with the ULMA by Szmuk (200 children) (29) and Gaitini (80 children) (30) and no differences were reported for time or ease of insertion. Gaitini (30) reported higher overall oropharyngeal leak pressures with the CobraPLA, but Szmuk (29) reported no difference. Both studies reported no laryngeal obstruction on fibreoptic inspection in contrast to with Polaner who reported epiglottic folding causing partial or complete obstruction of the larynx in 77% of infants (31). Szmuk also reported less gastric insufflation with the CobraPLA compared with the ULMA (29). However, Passariello, observed gastric insufflation in 21% of children ventilated at pressures of 20 cmH2O or less (32). This gives cause for concern particularly as an adult study by Cook was stopped early after two cases of aspiration were seen in low-risk elective adult patients (33). Although, other adult studies have reported favorable results (34–36), the Cobra PLA, like the ULMA or cLMA has no specific design features to prevent regurgitation or aspiration.

In summary, the Cobra PLA seems similarly efficacious to the cLMA, without offering any obvious advantage. The evidence base, compared with the cLMA is very much smaller and concerns over safety have yet to be resolved. Therefore, currently the authors do not recommended the CobraPLA for routine use in children.

Second generation pediatric devices

Laryngeal Mask Airway – Proseal. The PLMA (Figure 3a) is second generation SAD designed for controlled ventilation and increased airway protection. Pediatric sizes have been available in the world market since 2005 but only in the UK since 2007. The PLMA differs from the cLMA (Figure 3b) having an oesophageal drain tube and integral bite block; the cuff section is larger and more bowl-shaped, and in adult sizes (3–5) there is an additional dorsal cuff but this is lacking in pediatric sizes (2.5, 2.0, 1.5) and the neonatal size 1.0 (Figure 3c).

The pediatric PLMA has been extensively studied and consistently performs well when evaluated for ease of insertion (first time insertion 84–94%), effective airway management (99–100%), mean oropharyngeal leak pressure (24–40 cm H2O) and fibreoptic view of the larynx (86–92%) (37–39). Several randomized controlled trials have compared the PLMA with the cLMA (11,12,40–43). These studies are summarized in Table 1 and show that the PLMA is easy to insert, has good anatomical position (except size 1.5) and significantly higher oropharyngeal leak pressures compared with the cLMA. To date, no randomized controlled trial has compared the PLMA with the CobraPLA.
Manufactures guidelines recommend the size 1.5 is used in children weighing 5–10 kg and Goldmann’s results (12) suggest that this size may be too large for very small infants. Fibreoptic examination of the airway during use showed narrowing caused by ‘bulging of supraglottic tissue’ thereby obstructing.
the view of the vocal cords. Despite this finding the airway was not compromised and was superior to the cLMA. This is similar to other studies of the cLMA, where epiglottic downfolding is reported without causing clinical airway obstruction (7,10). Although several studies (12,37,39) report high insertion success rates with the size 1.5, very much lower first time (58% vs 40%) and overall (75% vs 37%) insertion success rates are reported in one study (44). A size 1.0 is available and has been used in neonatal resuscitation and manikin studies (45,46) but its efficacy in routine elective anesthesia is unknown.

Insertion techniques. The PLMA is at least as easy to use as the LMA (11,12,40–43), but the optimal insertion technique is unclear. The manufacturers recommend using digital manipulation or the metal introducer tool (47) (Figure 3d). However, gum elastic bougie (GEB) guided insertion techniques (Figure 3e) are reported as comparable with the introducer tool (48), and better than a digital technique (49). Suction catheter guided techniques are also reported as more successful and associated with less mouth trauma than digital techniques (50). The use of jaw thrust and/or partial cuff inflation have also given high success rates (39). Clinical tests of malposition described for adults, such as depth of insertion, leak pressure and maximum minute ventilation to resting minute ventilation ratio (MMV/RMV) have also been verified in children (51). Gel displacement tests (47,52), bilateral chest movement and square wave capnography, all of which are very simple to perform, are also used to assess positioning in many studies (12,39,53) and by the authors of this article, in routine clinical practice.

New uses. The PLMA has been compared with the TT in sixty children, aged 6 months to 8 years, undergoing laparoscopy, and reported to have comparable ventilatory efficacy (53). In this study the mean oropharyngeal leak pressure for PLMA was 29 ± 3 cm H₂O and first time insertion success rate 88%. Despite this favorable result, more studies are needed before the PLMA can be recommended for routine use during pediatric laparoscopic surgery. Another use of the PLMA is for gastroscopy (54). When compared with nasal cannulae, the operation and anesthesia times were shorter in the

<table>
<thead>
<tr>
<th>Ease of insertion</th>
<th>Laryngeal view on fibreoptic bronchoscopy</th>
<th>PMLA vs cLMA</th>
<th>Mucosal trauma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goldmann (43)</td>
<td>No difference but initial airway quality better with PLMA</td>
<td>Better with PLMA</td>
<td>22 vs 18 neutral</td>
</tr>
<tr>
<td>Size 2.5</td>
<td></td>
<td></td>
<td>37 vs 26 flexion</td>
</tr>
<tr>
<td>n = 30</td>
<td></td>
<td></td>
<td>15 vs 13 extension</td>
</tr>
<tr>
<td>Lardner (42)</td>
<td>No difference</td>
<td>Better with PLMA (84% vs 40%)</td>
<td>23 vs 16</td>
</tr>
<tr>
<td>Size 2.0</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>n = 51</td>
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<td></td>
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<tr>
<td>Shimbori (41)</td>
<td>No difference</td>
<td>No difference</td>
<td>No difference (19 vs 18)</td>
</tr>
<tr>
<td>Size 2.0</td>
<td></td>
<td></td>
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<tr>
<td>n = 60</td>
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<td></td>
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<tr>
<td>Lopez-Gill (40)</td>
<td>No Difference</td>
<td>No difference</td>
<td>33 vs 26</td>
</tr>
<tr>
<td>Size 2.0</td>
<td></td>
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<tr>
<td>n = 240</td>
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<td></td>
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<tr>
<td>Goldmann (11)</td>
<td>No difference</td>
<td>No difference</td>
<td>18 vs 15 neutral</td>
</tr>
<tr>
<td>Size 2.0</td>
<td></td>
<td></td>
<td>33 vs 29 flexion</td>
</tr>
<tr>
<td>n = 30</td>
<td></td>
<td></td>
<td>13 vs 11 extension</td>
</tr>
<tr>
<td>Goldmann (12)</td>
<td>No difference but initial airway quality better with PLMA (P = 0.001)</td>
<td>Better with cLMA as obstruction seen in 5 vs 1 patient in PLMA vs cLMA groups respectively</td>
<td>27 vs 19 neutral</td>
</tr>
<tr>
<td>Size 1.5</td>
<td></td>
<td></td>
<td>36 vs 28 flexion</td>
</tr>
<tr>
<td>n = 30</td>
<td></td>
<td></td>
<td>18 vs 15 extension</td>
</tr>
</tbody>
</table>

Table 1
Summary of randomized controlled trials comparing the PLMA with cLMA
PLMA group and oxygen saturations were higher (100% vs 94%) (36). There was no difference in the ease of performing the endoscopy procedure.

Limitations. There is some evidence the PLMA may be too large in very small infants (12,44). The PLMA is a re-usable device and no single-use version exists. Single-use devices are encouraged to reduce the possibility of transmission of prions and other infectious material from one patient to another (55). However, many hospitals still use reusable SADs for economic reasons and user preferences (56).

In summary, the evidence base for the PLMA is smaller than the cLMA as it is a newer device. The PLMA is easy to insert whichever technique is chosen and has yet to be outperformed by any other SAD (11,12,40–43). This, combined with the added safety feature of the oesophageal drainage tube, makes the PLMA the optimum pediatric SAD available for use in routine anesthesia.

Other second generation devices currently only available in adult sizes

i-gel airway. The i-gel™ (Intersurgical, Wokingham, UK) (Figure 4a,b) is a relatively new single-use device. There are no pediatric size i-gels at the time of writing, but these are under development and anticipated to be released in 2009. The i-gel has a noninflatable cuff made from a gel-like thermoplastic elastomer. The manufacturers claim the cuff is ‘anatomically shaped’ and the airway seal improves as the device warms to body temperature. The stem is elliptical in cross-section to minimize axial rotation and provide greater stability. It contains both airway and drainage tubes, and an integral bite block.

Early adult reports show overall insertion rates of 97–100% but median seal pressures vary widely from 20 to 32 cm H2O (57–60), the limits of which are as low as the cLMA and as high as the PLMA. Few complications are noted and in particular the incidence of sore throat is very low; 1/71 (57) and 9/100 patients (58). There is one report of neuropaxia (61) associated with the i-gel and due to its bulky size this possibility should be kept under review. This aside, the i-gel’s offers the possibility of a genuine improvement on the PLMA. It retains the safety feature of the oesophageal drainage tube while it’s elliptoid shape offers greater stability. Whether such stability is retained in the pediatric sizes, especially in infants under 10 kg where both the cLMA (7,8,62) and PLMA have had reported problems (7,12,44,62) remains to be seen.
Laryngeal Mask Airway – Supreme. The LMA-Supreme™ (SLMA; Intavent Orthofix, Maidenhead, UK) (Figure 5) is another new single-use device currently unavailable in pediatric sizes although, like the i-gel, these are anticipated in 2009. The SLMA was designed to combine the desirable features of the PLMA and the intubating laryngeal mask airway (ILMA). Namely, the ability to achieve high seal pressures and separation of the gastrointestinal and respiratory tracts (PLMA), together with extreme ease of insertion without the need for introducer tools or inserting fingers in the mouth (ILMA). Therefore, the SLMA has both an airway and oesophageal drainage tube together with an integral bite block molded into a firm, ellipsoid anatomically shaped stem which facilitates easy insertion. The stem is much stiffer than the PLMA but is intended to accommodate movements of the head and neck unlike the rigid metal stem of the ILMA. The inflatable cuff design of the PLMA is retained but has been modified and enlarged to enhance the anatomical fit in the pharynx.

When compared with the PLMA, the SLMA performed equally well with respect to insertion success (97%), oropharyngeal leak pressure (28 cm H2O) and gastric access (63). The literature in adults is growing (4,63,64) but it is too early to determine the role of this SAD in adults or children.

Other devices

New SADs continue to be developed at such a rate that keeping up-to-date in this subject is difficult. Other currently available adult SADs include, the Laryngeal Tube and Laryngeal Tube Sonda II (VBM, Medizintechnik, Gmblt, Sulz, Germany) (Figure 6),
first and second generation reusable SADs respectively; and the Streamlined Liner of the Pharyngeal Airway (SLIPA, Hudson, RCI) (Figure 7a,b) which has a unique hollow boot-shaped chamber providing storage (50 ml) for regurgitated liquids and particulate matter. Their role and that of other SADs in routine anesthetic practice is not established. There is currently insufficient evidence (and in some cases negative evidence) (61,65–70) regarding these devices and the authors do not recommend any of them for use in children or adolescents, while other alternative SADs exist which have been more extensively evaluated.

**Conclusion**

Since the early 1990s, pediatric anesthetic practice has been revolutionized by increasing use of the cLMA and fLMA. The cLMA has the largest evidence base for safety and efficacy and is therefore the benchmark by which other devices are compared. The last 5 years has seen the development of numerous SADs, several of which are now available in pediatric sizes with more expected soon (see Table 2). Many new SADs, with the exception of the PLMA, appear to offer little or no benefit for clinician or patient, over existing ones; and evidence supporting efficacy and safety is often absent or inadequate. The PLMA has yet to be outperformed by any other SAD making it the premier SAD in children and the benchmark by which newer second generation devices should now be compared.

New devices will continue to reach the market place and while some offer the possibility of a genuine advance, considerable high quality research is required to sort the ‘wheat from the chaff’.

**Conflicts of interest**

T. Cook has received speaker fees from Intavent Orthofix and the LMA Company. M. White and P. Stoddart have declared no conflicts of interest.

**References**


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**Table 2**

**Summary of supraglottic airway devices**

<table>
<thead>
<tr>
<th>Pediatric sizes; recommended weight range</th>
<th>Pediatric OLP pressure (cm H₂O)</th>
<th>Overall insertion success rate</th>
<th>Areas of potential concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>cLMA</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1.0 : &lt;5 kg</td>
<td>11–30 depending on size of device</td>
<td>99–100%</td>
<td>Size 1.5 poor anatomical ‘fit’</td>
</tr>
<tr>
<td>1.5 : 5–10 kg</td>
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<td></td>
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</tr>
<tr>
<td>2.0 : 10–20 kg</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2.5 : 20–30 kg</td>
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<td></td>
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<tr>
<td>Cobra PLA</td>
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<tr>
<td>0.5 : 2.5–7.5 kg</td>
<td>15–18</td>
<td>100%</td>
<td>Gastric inflation and in adults cases of aspiration</td>
</tr>
<tr>
<td>1.0 : 7.5–15 kg</td>
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<tr>
<td>1.5 : 16–30 kg</td>
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<tr>
<td>2.0 : 31–60 kg</td>
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<tr>
<td>PLMA</td>
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<tr>
<td>1.0 : &lt;5 kg</td>
<td>13–37</td>
<td>99–100% (one report of 74% in size 1.5 subgroup)</td>
<td>Size 1.5 poor anatomical ‘fit’ and possible difficult insertion</td>
</tr>
<tr>
<td>1.5 : 5–10 kg</td>
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<tr>
<td>2.0 : 10–20 kg</td>
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<td>2.5 : 20–30 kg</td>
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<tr>
<td>i-gel</td>
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<tr>
<td>Expected 2009</td>
<td>99–100%</td>
<td></td>
<td>One episode of neuropraxia in an adult</td>
</tr>
<tr>
<td>SLMA</td>
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<tr>
<td>Expected 2009</td>
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2nd generation devices incorporate design features to reduce regurgitation risk.

OLP; Oropharyngeal leak pressure.

For references see text.

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