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What should we expect in anaesthesia, critical care and pre-hospital care from extra glottic airways? Proven clinical performance for a variety of indications and patients

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A R T I C L E I N F O

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Extraglottic airway devices (EGA) – also commonly known as supraglottic airway – traditionally filled the gap between bag-mask ventilation and tracheal intubation. The laryngeal mask is among the best-studied airway device since its introduction in clinical routine and more than 6000 trials about EGA have been published over the last 33 years. A literature search of clinical trials publications on PubMed shows over 900 clinical trials involving the LMA Classic™ (Teleflex®, Wayne, USA), followed by LMA Supreme™ (Teleflex®, Wayne, USA), with 170 results in PubMed [1–10]. The first laryngeal mask was designed in 1981 by Dr. A.I.J. Brain, who described it in his first publication as part of a search for an alternative airway management device in daily anaesthesia practice, that is more practical as the facemask and less invasive as the tracheal intubation [11]. Since 1985, there has been an increased dynamic and advanced development in the use of this minimally invasive, extraglottic airway device to safely and easily manage the airway.

Although the initial clinical application from a "hands free" airway device for use in spontaneous breathing patients [12], EGA are now increasingly being used for airway management in cases that were previously managed exclusively by tracheal tube, (e.g., laparoscopic surgical procedures [10,13], caesarean section [1,14], bariatric surgery [15] or surgery in prone position [9]). With the further development of EGA, a prolonged use up to 7–9 hours is now possible [16–18]. The authors emphasize the improved seal technology (high volume-low pressure cuff) and indicate the importance to control the intra-cuff pressure [16–18]. Furthermore, the use of an EGA is a widespread recommended technique for managing unexpected difficult airway management situations. Many EGA can be used as a conduit for fiberoptic-guided tracheal intubation [19–21], rescue airway device by difficult tracheal intubation or failed intubation [22–24] and extubation aid [25].

In critical care medicine, the EGA could avoid some of difficulties with the use of the tracheal tube and may improve the visualization of the glottic and trachea during fiberoptic-guided percutaneous dilatational tracheostomy [26–28]. They also have a distinct value for managing a difficult airway and illustrating an alternative method for weaning from the respirator on the intensive care unit [29–31]. Also, the importance and wide distribution of EGA in airway management in the pre-hospital setting have increased considerably in the last decade. There are four main reasons for this: less practical experience with direct laryngoscopy technique [32,33]; a higher incidence of potential unanticipated difficult intubations [34]; airway equipment and alternatives are often limited in pre-hospital settings; and finally, application of EGA in pre-hospital medicine was associated with a higher success rate, compared to direct laryngoscopy [35]. Use of EGA for airway management during cardiopulmonary resuscitation has been associated with limited the hands-off time [36].

Several classifications of EGA have been proposed. On the one hand in regard to the presence or absence of an inflatable cuff, non-inflatable cuff devices (e.g., i-gel™ Intersurgical®, Wokingham, Berkshire, UK or SLIPA™ Curveair®, London, UK) may provide reduced risk of cuff-related morbidity (e.g., sore throat or compression injuries to pharyngeal nerves) [37–39] and less malposition [40], but may be associated with an increased incidence of leakage [41]. A more commonly employed classification divided in 1st and 2nd-generation EGA, is that it allows a positive pressure ventilation at a higher level and possess a mechanism for separation the respiratory and gastrointestinal tract. Another logical functional classification relates:

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(i) Number of cuffs (e.g. LTS-D™ with two inflatable balloons (VBM®, Sulz a.N, Germany)).
(ii) Location of the distal end in relation of the glottis (e.g., the tip (so called oesophageal seal) of the LMA Supreme™ (Teleflex®, Wayne, USA) and PLMA™ (Teleflex®, Wayne, USA) protrudes deeper into the upper oesophageal sphincter compared to the tapered tip of the i-gel that is potentially not inserted far enough into the post cricoid region [42,43]).
(iii) Perilaryngeal versus base-of-the tongue sealing mechanism. Perilaryngeal with directional sealing (PLMA™) forms a seal at the laryngeal inlet and the posterior cuff improves seal pressure by means of directional sealing forces. Perilaryngeal without directional sealing (ILMA™ Teleflex®, Wayne, USA; AuraOnce™ Ambu® GmbH, Bad Nauheim, Germany; Soft Seal™, Portex® Ltd, Hythe Kent, UK) have a cuff framing the laryngeal inlet. This limits the seal pressure due to the direction of forces by the cuff. Perilaryngeal sealers were derived from the classic laryngeal mask [44]. Base-of-the tongue sealing with an oesophageal cuff (LTS-D™) or without oesophageal cuff (CobraPLA™ Engineered Medical Systems®, Indianapolis, IN, USA) have a pharyngeal cuff seal at the base of the tongue [45]. Cuffless pre-shaped sealers (Streamlined liner of the pharynx airway - SLIPA™ or Baska Mask™ PROACT Medical Systems®, Frenchs Forest NSW, Australia) have a seal at the outlet from pharynx at the base of the tongue right up to the oesophageal inlet because of the sealing walls [44].
(iv) Protection against aspiration. Ideally, the distal tip of the device lays dorsocaudal to the arytenoid cartilage at the hypopharynx in the postcricoid region – the upper oesophageal sphincter. [5–7,46], whereby the tip of the epiglottis is aligned with the proximal part of the (adequately inflated cuffed) mask. There is no downfolding of the epiglottis and it does not obstruct the entrance to the larynx. The larynx is not compressed and is freely accessible. The laryngeal mask built up a leakage pressure at two different locations, labelled as oropharyngeal leak pressure and hypopharyngeal leak pressure (generated through the tip of the seal at the upper oesophageal sphincter). A higher oropharyngeal leak pressure reduces leak fraction during positive pressure ventilation. Oropharyngeal leak pressure is a key marker of the efficacy and safety of EGA [47,48]. A higher oropharyngeal leak pressure suggests a better seal between the EGA and the supraglottic mucosa and is thought to allow for greater levels of positive pressure ventilation and improved gastric aspiration protection. A critical factor contributing to airway protection is the efficacy of the seal with the hypopharynx. Oesophageal leak pressures or hypopharyngeal seal pressures ascertain the risk of aspiration but lack a clinical test and may only be determined post mortem.

However, for airway pressures above 20cmH_2O, the pressure towards the postcricoid region can be increased and, particularly with undetected incorrect positioning, this can result in gastric insufflation of air. The seal of the EGA on the upper oesophageal sphincter (hypopharyngeal seal pressure or ‘second seal’) therefore becomes quite critical. The second seal is defined as the caudal sealing of the EGA towards the upper oesophageal sphincter. This seal must be effective in both directions, meaning protect from gastric insufflation by positive pressure ventilation on a higher level and before regurgitation of gastric contents. The hypopharyngeal leak pressure is thus dependent on the EGA design as well its correct positioning [49]. A controversial and no consensus term constitute the third generation EGA with the presence of self-energizing or self-sealing cuff [50]. The construction material of EGA cuff has an important impact of the seal and airway protection. It varies from medical-grade silicone (LMA Classic™, LMA Flexible™, ILMA™, PLMA™, PLMA Protector™), styrene ethylene butadiene styrene (SEBS; i-gel™), ethylene–vinyl acetate copolymer (SLIPA™) to polyvinylchloride (PVC; LMA Unique™, LMA Supreme™, LTS-D™, CobraPLA™, AuraOnce™). Phthalate-free PVC devices like the Aura Gain™ or LMA Protector™ impart a more robust cuff and could lead to a decreased fold-over malposition [51]. Phthalates are used primarily as plasticizers in flexible PVC products to impart flexibility to plastics. PVC-based cuffs tend to create folding's in the proximal part of the EGA, with a potential leak as a result, even if the cuff is adequately inflated (maximal intracuff pressure of 60 cm H_2O [47]). Medical-grade silicone-based cuffs seem not to have this disadvantage when adequately inflated. Furthermore, the configuration of the gastric access in second-generation EGA is relevant to facilitate tracheal intubation. EGA with coaxial gastric access (e.g., LMA Supreme™) allows a faster insertion (18 vs. 30 s.) and higher first-pass success (80 vs. 71%) compared to the AuraGain™ [2,7] due to the less bulky tube and cuff. However, in contrast to conventional LMAs, the LMA Supreme™ does not allow the passage of a tracheal tube. Tracheal intubation is only possible by using a fiberoptic-guided insertion of a stylet (e.g. Aintree™ or Arndt™ catheter [52–54]).

In the opinion of the authors, the safety and effectiveness are not only dependent from the current EGA, rather participants (user experience) and field of application (e.g., surgery patient versus critical ill patient) must be considered. Many anaesthesiologists consider an EGA to be a “beginner” device. Compared to other techniques of airway management, EGA have a steeper learning curve to achieve successful ventilation. However, it must be remembered, that after placing the EGA, the surgical procedure has not even begun. An insufficient level of anaesthesia can result in significant problems in ventilating the patient. Precise knowledge of the surgery, as well as limitations of the specific EGA, is crucial to the successful use of an EGA throughout the whole procedure. The key to successfully using an EGA is not just dependent on the device itself, but also the clinical expertise and experience of the user. Brain described in his first publication both a “short” and “long” term learning curve for successful LMA usage [55]. Brimacombe seconded this observation that the optimal use of this device, resulting in a significant reduction of adverse events being achieved after two years and more than 750 applications [56]. We previously emphasized this critical point that a sufficient learning curve is needed to improve success rates and reduce adverse events.

In clinical anaesthesia, also of importance is the surgeon's acceptance for this type of airway management, especially in surgery of the upper airway and head [57]. Familiarity with the technique suggests that surgeons may differ in their ability or tolerance with the device to work around the EGA for surgical procedures of the upper airway or interventions with a variable positioning of the head and this can modify the failure rate of EGA significantly [58]. The type of the surgery must also be considered to estimate the risk of ventilation problems during the intervention [59]. The increase of patients presenting with bariatric surgery (presence of gastro oesophageal reflux disease and reduced pulmonary vital capacity), and more possible application of laparoscopic and minimally invasive surgery, have all some impact on choice of airway management procedure for clinical anaesthesia: in some cases representing opportunities for and in some barriers to EGA use.

The authors find that many anaesthesiologists are not even aware of potential implications of differences between the multiple available EGA. Individuals may be swayed considerably by limited personal experience and new devices may be introduced without adequate evaluation of efficacy or safety, or conversely, rejected without due cause. We feel that the approach to include an inhomogeneous group of performers is more clinically relevant than the study results that reflect the experience of a small team of anaesthesiologists who are highly skilled in airway management. Success rate, time for insertion and oropharyngeal leak pressure are influenced by reduced muscle tonus of the pharyngeal space and may be attributed to the individual shape and material between the different EGA [2–6,51].

Because of the wide range of indications for an EGA, one should expect the following features from an EGA [1–6,59]]:

- use in unexpected difficult airway
- use in a range of specific patient properties (e.g. pediatric vs. adult, obesity)
- easy and fast insertion
- positive pressure ventilation with an oropharyngeal leak pressure >25 cm H_2O
- low pharyngeal mucosal pressure to avoid soft tissue injury
- effective airway protection with reducing the risk of pulmonary aspiration
- separation of respiratory and gastric tract (vent air insufflation/regurgitated contents)
- the possibility of secondary intubation through the device
- single-use device with low cost

However, many clinically relevant questions have still to be answered. Large-scale randomized, international and multiple centre trials examining potential advantages or disadvantages of specific EGA are still lacking. Which studies can help us to choose the right EGA? Studies in the area of airway management cannot be transferred one-to-one to clinical practice as many factors might affect the performance of the specific device. The selection of participants with different levels of clinical experience should be evenly distributed between groups, and the patients must be comparable [1–8]. In pharmaceutical research, the evaluation of a new drug requires a very standardized way, and patient-related factors have to be considered. Additionally, the pharmaceutical industry has to prove in well-designed studies, and a predefined manner, that the pharmacologic agent is accomplishing its therapeutic goal. Indication, side effects, and safety have to be evaluated and described. This approach is more difficult in trials that focus on airway management. In the field of airway management evaluation of devices and tools are primarily driven by investigator-initiated studies. This often results in smaller studies that are performed by airway enthusiasts who have a high level of clinical expertise [1,5–8]. Study results are not directly transferable to every hospital, institution and individual anaesthesiologists. Cook et al. pointed out this problem and recommended a structured analysis of novel airway devices, similar to the developmental process of drugs [60]. The quality of each evaluation will vary with the individual's practice and experience, and also random chance.

In conclusion, extensive, randomized, controlled multicenter trials, including performers with different levels of expertise, are needed to characterize specific EGA and to identify potential advantages, limitations and disadvantages before the device is used in an extensive clinical setting. The Airway Device Evaluation Project Team from the Difficult Airway Society [61] recommended an infrastructure in which the required evidence can be obtained. Study results from smaller, well-designed, clinical relevant investigator-driven clinical trials can be beneficial to design these much-needed large-scale trials.

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