Glottic view using supraglottic devices in pediatric patients

NCT02532465

IRB Approval Date: 8/7/2015

Glottic view using supraglottic devices in pediatric patients

PI: Senthil G Krishna
Co-investigators: Georgio Veneziano, Mumin Hakim, Joseph D Tobias

Describe the background and rationale for this project. Reference to peer reviewed literature is desirable: Endotracheal intubation is the gold standard for securing the airway. However, while managing patients with difficult airways, various supraglottic devices have been used as rescue airway devices. Laryngeal mask airways (LMAs) are among the most commonly used supraglottic devices. After placement, subsequent intubation with an endotracheal tube via the LMA is achieved either blindly or with the use of a fiberoptic device. Several modifications of the LMA have been developed since its introduction in 1983 to improve their ease of initial use, multimodal function, and subsequent facilitation of ETT placement. Modifications of the classic LMA have included the intubating LMA (I-LMA) and variants (LMA Fastrach, Air-Q and LMA-Supreme).

Another supraglottice device and variant of the LMA is known as the i-gel. The i-gel does not have an inflatable cuff. In the i-gel, the traditional cuff of the LMA is replaced with a soft, gel-like, and transparent thermoplastic elastomer (styrene ethylene butadiene styrene) which is a mirror impression of the supraglottic/periglottic anatomy and creates a non-inflatable seal.[1] The unique features of i-gel also include a separate conduit for gastric suction, an epiglottic ridge, and a ridged flattened stem to aid insertion and reduce the risk of axial rotation, a rigid stem and a bite block.[2,3] The i-gel® has also been used in rescue airway management and as a conduit for tracheal intubation.[3-10]

Recently, there have been attempts to compare the various LMAs and the ease of subsequent intubation through the different types of LMAs in adult patients.[11-12] The aim of our current study is to compare the fiberoptic view through the internal aspect of the i-gel versus the Air-Q LMA in pediatric patients. By examining the fiberoptic view through these two devices, we will determine which device provides a clearer passage to the glottic opening and is therefore the preferred conduit to aid endotracheal intubation in difficult airways.

Describe the significance of the proposed research:
Although management of the difficult airway is generally rare in the pediatric population, it is one of the leading causes of perioperative morbidity and mortality. Simple and effective techniques to secure the difficult airway are needed. This study would help define the optimal supraglottic device for that purpose.

State the primary and secondary objectives of the study: We will compare the fiberoptic view of the glottic aperture by passing a fiberoptic

bronchoscope through two types of supraglottice airways (the Air-Q LMA or the i-gel LMA).

If this research is hypothesis driven, succinctly state the hypothesis: The i-gel LMA will provide a better bronchoscopic view of the glottic aperature than the Air-Q LMA.

Outline the major steps and methodologies in the clinical protocol(s). If necessary, include a description of any procedures being performed already for diagnostic or treatment purposes: General anesthesia with the use of an LMA or supraglottic device is routinely performed on more than half of the pediatric patients undergoing general anesthesia every day in our operating rooms. There will be no change in the anesthetic care during these procedures; however, 100 patients would be randomized to one of two types of supraglottic devices; i-gel or LMA (Air-Q). Following placement of the supraglottic device, a fiberoptic bronchoscope will be inserted through the LMA to its distal end and a picture of the glottis aperture will be obtained. The following scoring system will be used[13,14]:

1. vocal cords not seen, but ventilation adequate
2. vocal cords + anterior epiglottis
3. vocal cords + posterior epiglottis
4. only vocal cords seen

Placement of the fiberoptic bronchoscope will be performed after the administration of general anesthesia and 100% oxygen to avoid any risk of oxygen desaturation. The procedure will take less than 15 seconds and the bronchoscope will not exit the distal end of the supraglottic device. Therefore, it will not touch the airway. Given this, there is no additional risk although the use of the fiberoptic bronchoscope for the purpose of the study only.

Identify the variables to be measured and how they will be statistically evaluated: A Fishers' exact test and a contingency table will be used to compare the bronchoscopic view through the two different supraglottic devices. Most importantly, the percentage of acceptable/good view (grade 3 or 4) will be compared to poor view (grade 1).

References:

1. Levitan RM, Kinkle WC. Initial anatomic investigations of the i-gel airway: A novel supraglottic airway without inflatable cuff. Anaesthesia 2005;60:1022–6.
2. Uppal V, Gangaiah S, Fletcher G, Kinsella J. Randomized crossover comparison between the i-gel and the LMA-Unique in anaesthetized, paralysed adults. Br J Anaesth 2009;103:882–5.

3. Lee JR, Kim MS, Kim JT, Byon HJ, Park YH, Kim HS, et al. A randomised trial comparing the i-gel (TM) with the LMA Classic (TM) in children. Anaesthesia 2012;67:606–11.
4. Michalek P, Hodgkinson P, Donaldson W. Fiberoptic intubation through an i-gel supraglottic airway in two patients with predicted difficult airway and intellectual disability. Anesth Analg 2008;106:1501–4.
5. Campbell J, Michalek P, Deighan M. i-gel supraglottic airway for rescue airway management and as a conduit for tracheal intubation in a patient with acute respiratory failure. Resuscitation 2009;80:963.
6. Michalek P, Donaldson W, Graham C, Hinds JD. A comparison of the i-gel supraglottic airway as a conduit for tracheal intubation with the intubating laryngeal mask airway: A manikin study. Resuscitation 2010;81:74–7.
7. Theiler L, Kleine-Brueggeney M, Urwyler N, Graf T, Luyet C, Greif R. Randomized clinical trial of the i-gel™ and Magill tracheal tube or single-use ILMA™ and ILMA™ tracheal tube for blind intubation in anaesthetized patients with a predicted difficult airway. Br J Anaesth 2011;107:243–50.
8. Halwagi AE, Massicotte N, Lallo A, Gauthier A, Boudreault D, Ruel M, et al. Tracheal intubation through the i-gel™ supraglottic airway versus the LMA Fastrach™: A randomized controlled trial. Anesth Analg 2012;114:152–6.
9. Francksen H, Renner J, Hanss R, Scholz J, Doerges V, Bein B. A comparison of the i-gel with the LMA-Unique in non-paralysed anaesthetised adult patients. Anaesthesia 2009;64:1118–24.
10. Janakiraman C, Chethan DB, Wilkes AR, Stacey MR, Goodwin N. A randomised crossover trial comparing the i-gel supraglottic airway and classic laryngeal mask airway. Anaesthesia 2009;64:674–8.
11. Kapoor S, Jethava DD, Gupta P, Jethava D, Kumar A. Comparison of supraglottic devices i-gel® and LMA Fastrach® as conduit for endotracheal intubation. Indian J Anaesth 2014;58:397-402.
12. Theiler LG, Kleine-Brueggeney M, Kaiser D, Urwyler N, Luyet C, Vogt A, et al. Crossover comparison of the laryngeal mask supreme and the i-gel in simulated difficult airway scenario in anesthetized patients. Anesthesiology 2009;111:55–62.
13. Briamacombe J, Berry A. A proposed fiber-optic scoring system to standardize the assessment of laryngeal mask airway placement. Anesth Analg 1993;76:457-459.
14. Francksen H1, Renner J, Hanss R, Scholz J, Doerges V, Bein B. A comparison of the i-gel with the LMA-Unique in non-paralysed anaesthetised adult patients. Anaesthesia 2009;64:1118-24.