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Simulation and education

The Supreme Laryngeal Mask Airway™ (LMA): A new neonatal supraglottic device: Comparison with Classic and ProSeal LMA in a manikin☆

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ABSTRACT

Aim: The study aims to compare the performances (ease of insertion, time to establish effective ventilation and maximal inflation pressure) of classic™ (cLMA), ProSeal™ (PLMA) and Supreme™ (SLMA) Laryngeal Mask Airway when used in a neonatal airway management manikin by inexperienced delivery room trainees. The quality of the three devices, as perceived by participants, was also evaluated.
Methods: Health-care professional trainees were given a brief supervised training with the three devices. Every trainee was then observed positioning each of the three different LMAs in a single occasion. Success rate, time (IT) and maximal inflation pressure (PI_{max}) were recorded by a single unblinded observer. A 4-point scale was used to rate participants' perceived quality.
Results: A total of 40 health-care professional trainees participated in the study.

There were five, three and one failed insertions at the first attempt with the cLMA, PLMA and SLMA, respectively. No failures to establish an effective airway within three attempts were recorded. The success rate at first attempt was comparable among the three devices. The mean IT was significantly lower with the SLMA as compared with PLMA ($p < 0.01$), but not to cLMA. The mean PI_{max} was higher with SLMA than with cLMA and PLMA ($p < 0.01$). The ease of insertion as well as the effectiveness of ventilation were perceived by the participants as superior with SLMA as compared with cLMA and PLMA ($p < 0.01$).
Conclusions: Neonatal SLMA is superior to PLMA in terms of time to establish effective ventilation; furthermore, maximal inflation pressure and quality perceived by the operator are higher with neonatal SLMA than with cLMA and PLMA. These manikin data could provide a useful guide for planning potential future clinical research involving the newly developed supraglottic device in neonates.

Active resuscitation at birth is required in approximately 5–10% of cases.[1,2] Rapid establishment of a patent airway and effective ventilation is the cornerstone in neonatal resuscitation, and testing and training in the necessary skills would ideally take place in neonates: but, due to ethical and practical issues, this is unsuitable. Therefore, manikins are used for this purpose.

The laryngeal mask airway (LMA) has been shown to be effective for airway management during neonatal resuscitation and has been included in the international guidelines since 2000.[1,3,4]

Recent manikin and clinical studies have shown that the newer neonatal ProSeal LMA™ (PLMA, LMA™, Laryngeal Mask Airway Co. Ltd, Jersey, UK), with modified features that include an oesophageal drain tube, provides higher seal pressure as compared with the classic LMA™ (cLMA, LMA™, Laryngeal Mask Airway Co. Ltd, Jersey, UK), while having a similar ease of insertion.[5–7] In 2007, a new disposable LMA became available: the Supreme LMA™ (SLMA, LMA™, Laryngeal Mask Airway Co. Ltd, Jersey, UK). Among the main characteristics of this polyvinyl chloride (PVC)-made laryngeal mask airway are an oesophageal drain tube and a firm, curved and anatomically shaped airway tube that is designed to facilitate ease of insertion, without requiring the placement of fingers in patient's mouth or the use of an introducer tool.[8] Studies in adult patients showed that medical students and trainees as well as anaesthesiologists had a high insertion success rate and short positioning time with SLMA.[9–12]

The modified cuff of the SLMA allows airway seal pressures similar or close to those achievable with the PLMA and higher compared

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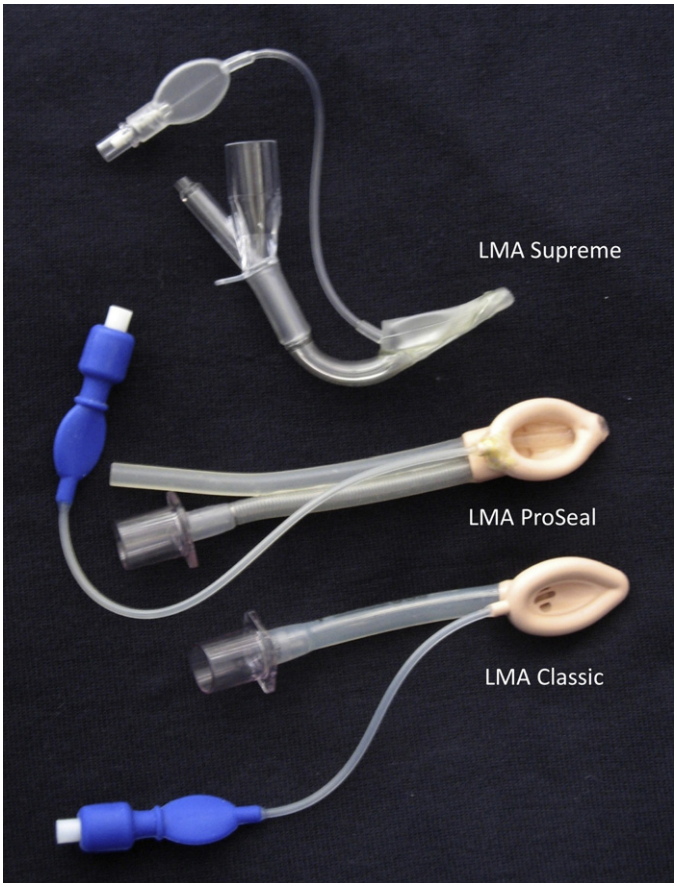

Fig. 1. The neonatal LMA Classic, LMA ProSeal and LMA Supreme.

with those recorded with the cLMA.[7,13] Recently, a neonatal SLMA (size 1) prototype has been produced (Fig. 1). This device has not yet been approved for clinical use in neonates but was made available to our institution for research purposes.

We aimed at comparing the performances in terms of ease of insertion, time to establish effective ventilation (IT) and maximal inflation pressure (PI_{max}) of cLMA, PLMA and SLMA when used in an airway management manikin by inexperienced delivery room trainees. Furthermore, we evaluated participants' perceived quality of the three devices.

1. Methods

1.1. Subjects

Institutional board review approval was obtained. Health-care professional trainees of our regional perinatal level III centre, with no previous experience in LMA usage, were recruited.

1.2. Study design

The procedure was conducted based on a previous manikin study protocol.[5] Participants received a standardised 15 min training on the cLMA, PLMA and SLMA for neonatal resuscitation. All LMAs were size 1, which are indicated for neonates weighting 2000–5000 g, according to the manufacturer's instructions.[14] Training was conducted by two experienced LMA users (MM and DT) and included the description of the devices and illustration of the insertion techniques on a manikin (Neonate Airway Trainer, Laerdal, Norway). Every trainee practiced the insertion of each device once under guidance and was then observed positioning each of the three different LMAs on a single occasion.

The instructions were to pick up the completely deflated mask, to insert it into the manikin, to inflate the cuff with a calibrated aneroid manometer (Hi-Lo Hand Pressure Gauge; Mallinckrodt Medical, Athlone, Ireland) to an intracuff pressure of 60 cmH_2O,[14] to connect the LMA to a self-inflating bag and to establish ventilation. The sequence in which any participant positioned the devices was randomised (sealed opaque envelopes). Because of the small size of the introducer strap in the neonatal PLMA, the fingertip technique (traditionally used with adult sizes) was unsuitable for positioning the size 1 PLMA: therefore, the specific introducer provided by the manufacturer was attached to the PLMA before use, and the device was inserted with the midline approach technique suggested by the manufacturer.[14] The cLMA was positioned using the standard digital technique recommended by Brimacombe et al.,[15] and the SLMA was inserted with the technique described in the instruction manual released for adult sizes' SLMAs.[8] The manikin palate was lubricated before the beginning of each test, to simulate the physiological secretions present in the neonate's mouth.

1.3. Measurements

A single unblinded observer recorded the time taken from picking up the cLMA, the PLMA or the SLMA to the first inflation of the lungs (IT). The number of insertion attempts (maximum three allowed) and any failure to establish an effective airway were also recorded. A failed insertion attempt was defined as removal of the device from the mouth. A failure to establish an effective airway was defined as a failure to achieve a successful insertion within the three attempts. When positioning of the device and ventilation were obtained, participants were asked to manually ventilate with a self-inflating bag at a respiratory rate of 40–60 breaths per min. When a constant respiratory rate was obtained after approximately 10–15 breaths, PI_{max} (obtained by fully squeezing a 240 ml self-inflating bag, Laerdal Medical AS, Norway) was recorded for five consecutive breaths, and the mean of these values was considered for analysis. Pressure was registered by a manometer (Mallinckrodt pressure manometer, Mallinckrodt, Athlone, Ireland) connected to the self-inflating bag. Participants were blinded to the measurements. After completion of the manikin tests, each participant was required to rate on a four-point scale the perceived ease of insertion (1 = very difficult, 4 = very easy) and the perceived effectiveness of ventilation (1 = inadequate, 4 = excellent) achieved with each device.

1.4. Statistics

Statistical analysis was conducted by using one-way analysis of variance (ANOVA) test and Bonferroni *post-hoc* analysis and Kruskal–Wallis with Dunn's *post hoc* analysis, where appropriate. A p value <0.05 was considered as significant.

2. Results

A total of 40 health-care professional trainees (12 paediatric residents, 15 anaesthesia residents, seven midwifery trainees and six nurse trainees) participated in the study.

There were five, three and one failed insertions at the first attempt with the cLMA, PLMA and SLMA, respectively. No failures to establish an effective airway within three attempts were recorded (Table 1). The success rate at first attempt was comparable among the three devices.

The IT was significantly lower with the SLMA as compared with PLMA ($p < 0.01$), but not with cLMA. The mean PI_{max} was higher with SLMA than with cLMA and PLMA ($p < 0.01$).