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REGULAR ARTICLE

Pilot manikin study showed that a supraglottic airway device improved simulated neonatal ventilation in a low-resource setting

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ABSTRACT

Aim: We compared the performance of personnel in a low-resource setting when they used the I-gel cuffless neonatal laryngeal mask or a face mask on a neonatal airway management manikin.

Methods: At Mulago Hospital, Uganda, 25 doctors, nurses and midwives involved in neonatal resuscitation were given brief training with the I-gel and face mask. Then, every participant was observed positioning both devices on three consecutive occasions. The success rate and insertion times leading to effective positive pressure ventilation (PPV) were recorded. Participants rated the perceived efficiency of the devices using a five-point Likert scale.

Results: The I-gel achieved a 100% success rate on all three occasions, but the face mask was significantly less effective in achieving effective PPV and the failure rates at the first, second and third attempts were 28%, 8% and 20%, respectively. The perceived efficiency of the devices was significantly superior for the I-gel (4.7 ± 0.4) than the face mask (3.3 ± 0.8).

Conclusion: The I-gel was more effective than the face mask in establishing PPV in the manikin, and user satisfaction was higher. These encouraging manikin data could be a stepping stone for clinical research on the use of the I-gel for neonatal resuscitation in low-resource settings.

INTRODUCTION

Annually, 136 million babies are born worldwide. Approximately one million die each year due to intrapartum-related events, 96% of them in low- and middle-income countries (1–3). Successful resuscitation could prevent a large proportion of these deaths and improve the outcomes of neonates surviving asphyxia (3,4). Therefore, all birth attendants, including physicians, midwives and nurses, should have the knowledge and skills required to perform neonatal resuscitation (5). Providing effective positive pressure ventilation (PPV) is the single most important component of successful neonatal resuscitation (5). Ventilation is routinely initiated with face mask ventilation (FMV) followed by endotracheal intubation (ETT) in cases of FMV failure or the need for prolonged ventilatory support. Both these techniques may be difficult to perform, resulting in failure of effective resuscitation. Important air leakages and airway blockage have been reported during FMV. Skilled staff are required when ETT is performed (5). The laryngeal mask airway (LMA) may be considered during resuscitation as an alternative to FMV or ETT for PPV in newborns weighing more than 2000 g or delivered around, or after, 34 weeks of gestation (5). Several publications including a Cochrane review have shown that LMA achieved effective PPV in most of the treated patients, with

Abbreviations
ETT, Endotracheal tube; FMV, Face mask ventilation; LMA, Laryngeal mask airway; PPV, Positive pressure ventilation.

Key notes

- This study compared the use of the I-gel cuffless neonatal laryngeal mask or a face mask on a neonatal airway management manikin in a low-resource setting.
- The I-gel was more effective in establishing positive pressure ventilation, and user satisfaction was higher among the 25 doctors, nurses and midwives who took part.
- These positive findings could encourage further clinical research on the use of this device in low-resource settings.

a range of 95–99% (6–9) and reduced the need for ETT (1,10). In all of the previous studies, a classic inflatable size 1 LMA was used. The I-gel (Intersurgical Ltd, Wokingham, Berkshire, UK) is a new model of supraglottic airway device that has been made available and is designed to provide an efficient seal to the larynx without an inflatable cuff. The risk for trauma is minimised (2), and insertion is easy with a low risk of tissue compression or dislodgement (11). All these characteristics make the I-gel a potentially very useful alternative to FMV and ETT, especially in settings where the staff's skills in performing PPV are low. No randomised trials had been performed to evaluate the I-gel uncuffed supraglottic airway device and compare it with the FMV for neonatal resuscitation. A first step before conducting a clinical study on the neonates was to evaluate a high-fidelity training programme that could be implemented in health-care facilities with limited resources in a low-resource setting.

The aim of this study was to compare the performance, namely the ease of insertion and time to establish effective PPV, of personnel involved in neonatal resuscitation with limited experience in airway management when using the I-gel and face mask in a neonatal airway management manikin. The effectiveness of the two devices, as perceived by the participants, was also evaluated.

METHODS

A Helping Babies Breathe refresher course was held at the Labour Ward Theatre, Department of Obstetrics and Gynaecology, at the Mulago National Referral and Teaching Hospital Kampala in December 2012. Two certified neonatologists, who were also Neonatal Resuscitation Program instructors (NP, DT), held the course, which consisted of a didactic review of the Helping Babies Breathe neonatal resuscitation flowchart and practical hands-on skill stations. The lessons and practical skill stations included topics on the first steps of neonatal resuscitation, including thermal losses prevention, airway management and stimulation, and the use of the face mask. An additional module for training on the use of the I-gel was added.

The I-gel is a relatively new single-use supraglottic airway device, and the size 1 device is designed for neonates weighting 2–5 kg (Fig. 1). It comprises a soft, gel-like, noninflatable cuff made of thermoplastic elastomer that fits anatomically against the perilaryngeal structures and a rigid bite-block that acts as a buccal stabiliser to reduce axial rotation and malpositioning (11,12).

To teach the use of both devices, the face mask and the I-gel, to health staff, we used a high-fidelity manikin model, the SimNewB Laerdal (Laerdal, Stavanger, Norway). It provides realistic airways and good feedback with chest rise when effective PPV is provided. The face mask used was the Laerdal neonatal resuscitator (Laerdal Medical, Stavanger, Norway). We included all 25 of the staff available on daytime duty on a particular week.

All participants had previously used the face mask on a manikin model as well as in clinical practice for neonatal resuscitation. However, all of them said it was the first time they had placed a supraglottic airway device, in particular an I-gel. After the course, participants were asked to ventilate the manikin with the I-gel and face mask, respectively. Each participant was then observed positioning and inserting each of the two devices on three consecutive occasions. The order, starting with the I-gel or face mask, was randomly assigned using closed envelopes. The success rate and time to establish full chest rise, namely the insertion time, was recorded by a single unblinded observer. If more than 30 seconds elapsed before the chest rise was noticed, a new attempt was carried out. A five-point Likert scale was used to evaluate the ease of application and insertion and ventilation perceived by the participants. The perceived effectiveness of respective devices was scored by each participant immediately after the performance: one for insufficient, two for sufficient, three for fair, four for good and five for excellent. To avoid a desirability bias, participants were only informed afterwards of their involvement in this comparative study.

Figure 1 The I-gel and the face mask used in the study.

A convenience sample of healthcare volunteers was studied, and no sample size calculation was performed. The individual staff members consented to participate.

Data were collated and statistically analysed using the statistical package STATISTICA, StatSoft version 6 (www.statsoft.com). Differences between the two devices were determined using the paired t-test and the unpaired t-test, respectively. A p value of <0.05 was considered statistically significant.

RESULTS

A total of 25 healthcare providers, 12 doctors and 13 midwives and nurses, participated in the study. All 25 participants completed the study and obtained effective PPV with the manikin model (Table 1). The I-gel enabled them to reach effective PPV at the first attempt on all three consecutive occasions. These performances were

Table 1 Insertion success rate, mean time to successful ventilation, perceived ease of insertion and perceived effectiveness of ventilation with I-gel™ and FM

	I-gel™ (*N* = 25)	FM (*N* = 25)	p value
Success rate	n (%)	n (%)	
1st attempt	25 (100)	18 (72)	<0.001
2nd attempt	25 (100)	23 (92)	<0.001
3rd attempt	25 (100)	20 (80)	<0.001
Mean time to successful ventilation	Mean ± SD	Mean ± SD	
1st attempt (seconds)	6.2 ± 2.3	8.3 ± 4.7	0.18
2nd attempt (seconds)	5.2 ± 1.1	9.9 ± 14.1	0.68
3rd attempt (seconds)	4.5 ± 1.0	6.6 ± 5.9	0.38
Ease of application/ ventilation	Median ± SD (range)	Median ± SD (range)	
Score (one lowest, five highest)	4.7 ± 0.4 (1–5)	3.3 ± 0.8 (1–5)	<0.001

significantly better ($p < 0.001$) than those obtained with the face mask. In fact, the face mask only allowed an effective PPV on the first attempt in 18/25 (72%), 23/25 (92%) and 20/25 (80%) of the first, second and third occasions, respectively. The mean and standard deviation insertion times for the I-gel were not significantly different to the face mask on the first (6.2 ± 2.3 versus 8.3 ± 4.7 seconds, $p = 0.18$), second (5.2 ± 1.1 versus 9.9 ± 14.1 seconds, $p = 0.68$) and third (4.5 ± 1.0 versus 6.6 ± 5.9 seconds, $p = 0.38$) occasions. The effectiveness score expressed by the participants for the I-gel on a five-point Likert scale was 4.7 ± 0.4, compared with 3.3 ± 0.8 for the face mask ($p < 0.001$).

DISCUSSION

This manikin study was performed among birth attendants in Uganda immediately after a training course of both face mask and supraglottic airway device ventilation skills. The 25 participants obtained better PPV with the I-gel than the face mask and found the I-gel much easier to use.

Our results demonstrate that both skilled and unskilled participants could rapidly learn to ventilate the manikin with the uncuffed supraglottic airway device. All participants achieved effective PPV on the manikin on all attempts. Furthermore, PPV could be established more rapidly, even if this difference was not statistically significant. Several participants failed to establish PPV within 30 seconds with the face mask. These data confirm that it is indeed a challenge to establish an effective seal with a face mask and sustain good ventilation. It is important to note that all participants had prior clinical experience with the face mask, whereas it was the first time they inserted the I-gel device.

Furthermore, the participants found it easier to establish PPV with the I-gel compared to the face mask. The acceptability and satisfaction expressed by healthcare providers, especially in low-resource settings, is another important issue to consider. Our data are in agreement with a previous manikin study conducted in Kinshasa, Democratic Republic of Congo, where participants manifested a high degree of approval of neonatal resuscitation using a classic supraglottic airways device (13).

Both stillbirths and neonatal mortality are high in low-income countries (2,3). As intrapartum-related complications, previously labelled as birth asphyxia, are responsible for a large number of these deaths, programmes that aim to improve neonatal management at birth are crucial (3).

Antenatal care improvements and an increase in the proportion of births attended by skilled personnel are mandatory to decrease intrapartum-related complications (4,14). Bhutta and Black (3) have suggested that a strategy based on low-cost training materials and standardised training manuals and equipment such as manikins and resuscitation bags may help to reach this goal. However, the quality of educational interventions needs to be assessed in simulated as well as clinical settings.

As effective PPV is the most important intervention during neonatal resuscitation, educational efforts should mainly concentrate on this task and it is essential that all those involved in the care of newborn infants at birth are able to perform this procedure (5).

The 2015 International Guidelines for Neonatal Resuscitation state that a laryngeal mask may be considered during resuscitation as an alternative to a face mask for PPV among newborn infants weighing less than 2000 g or delivered around or after 34 weeks of gestation (5). In the setting of neonatal resuscitation, previous observational studies have showed that LMA allowed effective PPV in most of the patients that were treated, with a range of 95–99% (6–8). One quasi-randomised study showed that the LMA was more effective than face mask ventilation for neonates with an Apgar score of 2–5 at one minute after birth. The authors concluded that the LMA was safe, effective and easy to implement for the resuscitation of neonates with a gestational age of 34 or more weeks (10). A further study, conducted in a middle-income country, confirmed that the neonatal LMA Supreme (Teleflex Inc, Wayne, PA, USA) was more effective than a face mask in preventing endotracheal intubation in newborns with a gestational age of 34 weeks or more and, or, an expected birthweight of at least 1500 g needing PPV at birth (15). All these studies were conducted using a cuffed supraglottic airways device (6–10). The innovative design of the I-gel could simplify insertion and should be well suited for this task. A meta-analysis demonstrated that the LMA Supreme and the I-gel supraglottic airways device models were similarly successful and rapidly inserted during anaesthesia in adult patients (16).

While our study demonstrated that the use of the I-gel could be easily taught to local healthcare workers in low-income countries, it does have some limitations. It was a manikin study with only a small number of healthcare workers involved. The training was carried out *in situ* at the labour ward with limited time available. The knowledge retention over time was not assessed, nor was the ability to sustain PPV over a longer period of time. The skills acquired

using the I-gel on the manikin have not yet been applied in the delivery room. The insertion of the I-gel supraglottic airways device may be more difficult in a neonate than in a manikin. The comparison of the I-gel and face mask needs to be reproduced in a clinical setting. If it turns out that I-gel is superior to a face mask, the price issue must be addressed for it to become a real alternative in low-resource settings. It is a single-use device currently sold in the European Union for the equivalent of 12 U.S. dollars.

CONCLUSION

The use of the I-gel can easily be taught to healthcare workers in facilities in low-income countries within the framework of the Helping Babies Breathe curriculum. The neonatal I-gel was superior to the face mask in establishing effective PPV, and the healthcare workers felt it was easier to use than the face mask. These manikin data provide a useful stepping stone for future clinical research on neonatal resuscitation with a supraglottic airways device in low-resource settings.

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CONFLICT OF INTERESTS

None declared.

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