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Neonatal resuscitation using a laryngeal mask airway: a randomised trial in Uganda

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ABSTRACT

Objective Mortality rates from birth asphyxia in low-income countries remain high. Face mask ventilation (FMV) performed by midwives is the usual method of resuscitating neonates in such settings but may not always be effective. The i-gel is a cuffless laryngeal mask airway (LMA) that could enhance neonatal resuscitation performance. We aimed to compare LMA and face mask (FM) during neonatal resuscitation in a low-resource setting.

Setting Mulago National Referral Hospital, Kampala, Uganda.

Design This prospective randomised clinical trial was conducted at the labour ward operating theatre. After a brief training on LMA and FM use, infants with a birth weight >2000 g and requiring positive pressure ventilation at birth were randomised to resuscitation by LMA or FM. Resuscitations were video recorded.

Main outcome measures Time to spontaneous breathing.

Results Forty-nine (24 in the LMA and 25 in the FM arm) out of 50 enrolled patients were analysed. Baseline characteristics were comparable between the two arms. Time to spontaneous breathing was shorter in LMA arm than in FM arm (mean 153 s (SD±59) vs 216 s (SD±92)). All resuscitations were effective in LMA arm, whereas 11 patients receiving FM were converted to LMA because response to FMV was unsatisfactory. There were no adverse effects.

Conclusion A cuffless LMA was more effective than FM in reducing time to spontaneous breathing. LMA seems to be safe and effective in clinical practice after a short training programme. Its potential benefits on long-term outcomes need to be assessed in a larger trial.

Clinical trial registry This trial was registered in https://clinicaltrials.gov, with registration number NCT02042118.

What is already known on this topic?

- Birth asphyxia contributes to almost 1 million neonatal deaths.
- Positive pressure ventilation is the most important component of successful neonatal resuscitation.
- Ventilation with face mask (FM) is a difficult skill to master, particularly in low-income settings.

What this study adds?

- A cuffless laryngeal mask airway (LMA) reduced time to spontaneous breathing compared with FM during newborn resuscitation in a low-resource setting.
- LMA is effective and easy to use after a short-term training programme even in the hands of inexperienced staff.

INTRODUCTION

Each year, intrapartum-related complications (birth asphyxia) result in 1.2 million stillbirths, 700 000 term newborn deaths and an estimated 1.2 million babies developing neonatal encephalopathy (previously called hypoxic ischaemic encephalopathy).[1 2] Of these, 96% occur in low-income and middle-income countries.[3 4] Successful resuscitation could prevent a large proportion of these deaths and improve the outcomes of neonates surviving asphyxia.[3 5 6] Therefore, all birth attendants, including physicians, midwives and nurses ought to have the knowledge and skills required to perform neonatal resuscitation.[7] Providing effective positive pressure ventilation (PPV) is the single most important component of successful neonatal resuscitation.[7] Ventilation is routinely initiated with face mask (FM) followed by endotracheal intubation in case of face mask ventilation (FMV) failure or need for prolonged ventilatory support. Endotracheal intubation is the most difficult skill to master in neonatal resuscitation and mostly properly performed only by experienced physicians.[8] Mask leakage, airway blockage and poor chest expansion have been reported during FMV.[9] The American Heart Association and the European Resuscitation Council Guidelines have proposed to use the laryngeal mask either as a primary device, replacing FM if ventilation is ineffective, or as an alternative to intubation during resuscitation of the late-preterm and term newborns (≥34 weeks gestation and/or birth weight >2000 g).[10] Several publications including a Cochrane review have shown that the laryngeal mask allowed effective PPV in most of the treated patients (range 95%–99%)[11–14] reducing the need for intubation.[15] In previous studies, a classic inflatable size 1 laryngeal mask was used.[11 12 15 16] The i-gel size 1 is a new model of cuffless laryngeal mask airway (LMA), also described as a supraglottic airway, that has recently been made available for newborns (2–5 kg). It is designed to provide an

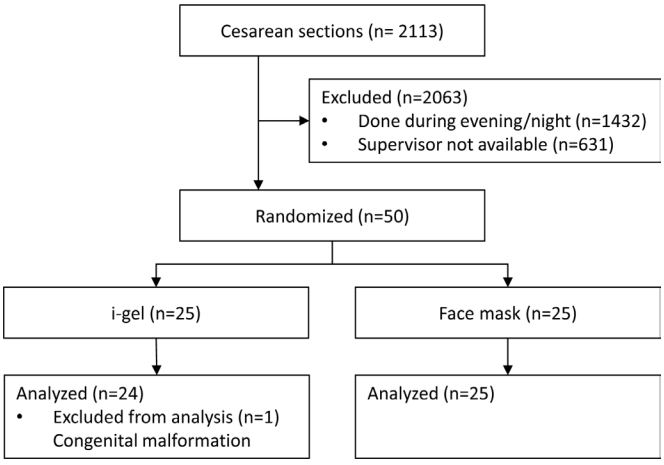

Figure 1 CONSORT flow diagram.

efficient seal to the larynx without an inflatable cuff. Positioning is easy with a low risk of tissue compression or dislodgement.[17] All these characteristics make the cuffless LMA a potentially useful alternative to FM and endotracheal intubation, especially in settings where the staff skills in performing PPV are insufficient.[15] In a previous manikin study conducted in a low-resource setting, we found that the LMA was more effective than FM in establishing PPV,[18] but there are no published randomised trials comparing the LMA with the FM during neonatal resuscitation.

The aim of the current trial was to determine if the LMA can reduce the time to spontaneous breathing of newborns needing PPV in a large delivery ward, where resuscitation is mainly performed by midwives. The safety of the intervention was determined by the assessment of clinical outcomes and side effects.

PATIENTS AND METHODS

Setting

This was a phase II, single-centre, prospective, open-label, randomised controlled trial (RCT) conducted at the Department of Obstetrics and Gynaecology, Mulago National Referral Hospital in Kampala, Uganda, where about 33 000 deliveries occur every year. Due to local organisational aspects, the trial was conducted at the operating theatre where 15–30 caesarean sections, most of them on emergency basis, are performed each day.

Inborn infants satisfying the following inclusion criteria were eligible to participate in the trial: gestational age >34 weeks by best obstetric estimate (last menstrual period or ultrasound scan), expected birth weight >2000 g, need for PPV at birth and written parental consent. Exclusion criteria included presence of major malformations.

Recruitment and implementation

Participants were recruited in the operating theatre among mothers awaiting caesarean section because of fetal distress. The bilingual consent form was given to mothers assessed by a doctor from the obstetric department, proficient in Luganda, the most common local language in the Kampala region. Recruitment took place only daytime on days when a supervisor available to oversee resuscitations (figure 1). This safety requirement delayed the completion of the study.

Training

Before the trial, all the staff involved in neonatal resuscitation participated in a Helping Babies Breathe (HBB) refresher course (version 1). All participants had previously attended at least one course on neonatal resuscitation. Two certified instructors in neonatal resuscitation held the course. It consisted in a review of the HBB action plan and practical hands-on skill stations. The training included simulation scenarios involving key procedures of the action plan (thermal loss prevention, stimulation, clinical assessment, airway management and so on) and the use of the FM (Laerdal silicon resuscitator, Laerdal Medical, Stavanger, Norway). The HBB course does not include chest compressions and medications. An additional module for training on the use of the i-gel (Intersurgical, Wokingham, Berkshire, UK) LMA was added. A high-fidelity model (SimNewB Laerdal manikin, Laerdal Medical) was used to train the staff in the use of both devices (LMA and FM). It provides realistic airways and good feedback with chest rise when effective PPV is provided. The staff learnt an insertion technique that is similar in the manikin compared with the newborn. A silicon lubricant facilitated the procedure (not needed in the newborn due to oral secretions). The LMA was placed with the outlet facing towards the chin of the baby with the head maintained in a neutral position. The chin was pressed down to open the mouth while the soft tip got inserted into the mouth towards the hard palate. The device was further inserted downward along the hard palate until the tip met a definite resistance. If the cuff was correctly located against the laryngeal inlet, PPV resulted in chest rise. FMV was taught according to the HBB curriculum. In case of failed FMV, the participants were instructed to apply following corrective measures before considering the alternative airway: reapplication of the mask, repositioning of the head and increase of the inspiratory pressure. The use of suction was de-emphasised. Twenty-eight participants (13 midwives or anaesthetist nurses and 15 physicians) were trained. A minimum of three successful LMA insertions and three FMV performances in the manikin were required of all participants before starting the trial. All staff participating in the study had received similar HBB neonatal resuscitation training prior to the course.

Intervention

All neonates were cared for in accordance with the updated Mulago Hospital neonatal resuscitation flow chart based on HBB (version 1). All resuscitations were performed by health staff under supervision of instructors who could provide corrective measures, if needed. The HBB principle of the Golden Minute was applied and included drying, stimulation and, if necessary, clearing the airways of the baby with a bulb suction device. Heart rate (HR) was assessed at 60, 90, 180 and 240 s. PPV with LMA or FM was initiated in case of apnoea and/or gasping and/or HR <100 bpm at 1 min of life. PPV was administered with a 240 mL silicon self-inflating bag with a pop-off valve limit at 35 cm H_2O (Laerdal Medical). Silicone, round-shaped FM (size 1, Laerdal Medical) and i-gel LMA (size 1) were available at each delivery (figure 2). Babies that failed on the assigned device (LMA or FM) were converted to the alternative device (LMA or FM). Failure was defined as poor HR response and/or lack of chest rise. Manual ventilation was initiated in room air at a frequency of 40–60 breaths per minute. Endotracheal intubation is not possible in this setting. All babies with 5 min Apgar score <5, respiratory distress, hypothermia (axillary temperature <36.0°C) or signs of encephalopathy were transferred to the neonatal special care unit.

Data collection

All resuscitations were recorded on audio-enabled video using a waterproof Lumix DMC-FT5 HD camera (Panasonic, Osaka,

Figure 2 The i-gel and face mask.

Japan) attached to a mount on the resuscitation table. Recording started manually at time of birth and stopped at the end of the resuscitation procedure. The baby, the health providers' hands and the tablet for data recording were continuously filmed with narrow field of view. This allowed precise assessment of time to spontaneous breathing, assistance by supervisor and conversion to alternative device by trial arm. The HR of the patient was collected using the NeoTap app (www.Tap4Life.org), a newly developed mHealth software for Android and IOS mobile devices. HR was obtained by advanced users (NJP and CL) auscultating the heart and simultaneously tapping the screen for three beats. HR data at 30 and 60 s after birth are not possible with current pulse oximetry technology.

Three research assistants recorded perinatal data postoperatively in an Excel database (Microsoft Corp, Redmond, Washington). The video data were reviewed separately by two investigators. Non-matching data were reviewed by a third investigator.

Outcomes

Primary outcome was the time to spontaneous breathing defined as the sum of time elapsed from birth to initiating PPV and the ventilation time. Secondary outcomes were admission to neonatal unit in the first 48 hours of life, hypoxic ischaemic encephalopathy, death and adverse effects secondary to the procedure (vomiting, bleeding or laryngospasm). HR was added as an outcome because a non-invasive method was made available.

Sample size

In accordance with a previous study on this topic,[15] we expected a longer time to spontaneous breathing with FM than with LMA. Moreover, we estimated time to spontaneous breathing to be longer in our sample because of delays in delivery and difficulties in assessing fetal distress at Mulago Hospital. Time to spontaneous breathing was modelled with gamma distribution as right-skewed data of duration.[19] In accordance with local clinical observations and available information in a similar setting, we hypothesised a mean time to spontaneous breathing of 210 s (with shape parameter k 5.3) with FM and of 150 s (with shape parameter k 6.8) with LMA.[15] With a power of 0.80 and a type I error of 0.05, the sample size was estimated in 23 subjects per arm, for a total of 46 subjects.[20] This number was increased by 10% to cater for post hoc exclusions, thus we planned to enrol 50 subjects. This sample size was also considered appropriate for a task-shifting trial emphasising safety aspects when involving midwives for the first time in advanced airway management.

Random assignment

Each newborn was randomised at birth using a small opaque plastic container concealing 25 white and 25 black toothpicks. The colour of the randomly plucked toothpick determined if LMA or FM would be used. If the baby needed resuscitation, the toothpick would be broken and removed from the container. If not, it was put back into the container. This randomisation method was found appropriate for a low-resource context with limited space and power availability.

Statistical analysis

Categorical data were expressed as number and percentage and were compared between the two arms using Fisher's exact test. Birth weight was expressed as median and IQR and compared between the two arms using Mann-Whitney test. Duration data (time to spontaneous breathing, start of PPV and ventilation time) were modelled with gamma distribution, which is often used to model the time required to perform some procedures. In fact, the gamma distribution is bounded on the left at zero, thus excluding negative values (and negative duration data are impossible). The gamma distribution is also positively skewed, meaning that it has an extended tail to the right of the distribution. This allows a non-zero probability of very long time required to perform the procedure, even though the typical time to perform the procedure may not be very long. Observed duration data were summarised as mean and SD. The effect of the device (LMA and FM) on duration data was assessed using a gamma model. HR was recorded at different time points during the trial and was expressed as mean and SD. A linear mixed effect models was used to assess the effect of the device on HR, accounting for the longitudinal structure of the data. A p value less than 0.05 was considered statistically significant. Statistical analysis was performed using R V.3.2.2 software (R Foundation for Statistical Computing, Vienna, Austria).[21]

Ethical considerations

The protocol was approved by the Institutional Review Board of Mulago National Referral Hospital, the Uganda National Council of Science and Technology, the National Drug Authority and by the Regional Committee for Medical Research Ethics of Southern Norway, Section D in Norway.

The i-gel LMAs were purchased for the study without corporate sponsorship.

Written and oral information was obtained from the parent(s) on maternal admission, and a senior investigator was available to discuss any questions regarding the trial. Informed written consent was signed by a parent or caregiver before admission to the operating room.

RESULTS

Fifty patients (25 LMA and 25 FM) were enrolled in 2014 from April 24 to August 5. The trial was ended on August 7 after the last completed follow-up. One patient in the LMA arm was excluded after resuscitation due to congenital cardiac malformation, thus the final sample included 49 patients (figure 1). All patients were delivered by emergency caesarean section. Maternal and neonatal characteristics were comparable in the

Table 1 Baseline maternal and neonatal characteristics by trial arm

	LMA (intervention) n=24 n (%)	Face mask (comparator) n=25 n (%)	p Value
Caesarean section	24 (100)	25 (100)	–
Primiparous	9 (38)	9 (36)	0.99
(Pre-) Eclampsia	0	3 (12)	0.23
Placenta abruption	0	2 (8)	0.49
Oligohydramnios	2 (8)	1 (4)	0.61
Foul smell	3 (13)	4 (16)	0.99
Meconium stained	10 (42)	13 (52)	0.57
Male gender	13 (54)	13 (52)	0.99
	Median (IQR)	Median (IQR)	
Gestational age (weeks)	Not available	Not available	–
Birth weight (gram)	3100 (2962–3478)	2700 (2520–3400)	0.13
Apgar score 1 min	4 (3–5)	4 (3–5)	0.73
Apgar score 5 min	8 (7–9)	7 (6–9)	0.26
Apgar score 10 min	10 (9-10)	9 (8–10)	0.17

two arms (table 1). Accurate gestational age was unavailable for most patients.

Forty-two resuscitations (86%) were performed by midwives (21 in FM group and 21 in LMA group), while the remaining 7 (14%) by physicians (three in FM group and four in LMA group). Information on the procedure is shown in table 2. Overall, PPV started after a mean of 64 s (60 s in LMA arm and 68 s in FM arm; p=0.26). Total ventilation time was shorter in LMA arm than in FM arm (mean 93 s vs 140 s, p=0.02). Assistance from the supervising physician was required in nine procedures (three in LMA arm and six in FM arm; p=0.46). Incorrect FM position (n=4) had an impact on PPV prior to repositioning. Misplaced LMA (n=1) that could lead to potential side effect was verbally corrected in one instance before insertion. All procedures were effective in the LMA arm, whereas 11 patients receiving FM were converted to LMA after 150 s because response to FMV was deemed unsatisfactory by the supervisor (p=0.0002) because of poor HR response and/or lack of chest rise.

Mean time to spontaneous breathing was 153 s (SD 59) with LMA and 216 s (SD 92) with FM (p=0.005; table 3). The model estimated a mean reduction of 31% (95% CI 11% to 44%) in time to spontaneous breathing with LMA. The outcome in the first 48 hours of life was similar in the two arms (table 3). Thirteen patients needed admission to the neonatal unit (five in LMA arm and eight in FM arm), two patients in FM arm suffered hypoxic ischaemic encephalopathy and one patient in FM arm died within the first 48 hours of life. There were no adverse effects of the LMA such as laryngospasm, bleeding or vomiting.

HR increased during the first 240 s of life (p<0.0001) and was higher in LMA arm than in FM arm (p=0.0006), but the rate of increase was similar in the two arms (p=0.48) (figure 3 and online supplementary table 1). The proportion of patients with HR <100 bpm decreased in both arms from about 80% at 30 s after birth to 4% at 240 s after birth.

DISCUSSION

The most relevant results of this small phase II trial include (A) time to spontaneous breathing and total ventilation time were significantly shorter in the LMA arm than in FM arm; (B) almost half (44%) of the neonates who did not respond to FMV were successfully rescued with the LMA; (C) use of neonatal LMA was safe, even in the hands of inexperienced health staff.

A few observational studies and RCTs have evaluated the use of cuffed laryngeal masks during neonatal resuscitation and have unanimously concluded that laryngeal mask allowed effective PPV in most of the treated patients (range 95%–99%).[11 13 14] One quasirandomised study showed that successful resuscitation with the laryngeal mask was significantly higher, and the total ventilation time with the laryngeal mask was significantly shorter than with FMV. The authors concluded: 'the laryngeal mask is safe, effective and easy to implement for the resuscitation of neonates with a gestational age of 34 or more weeks'.[15] Another recent study from Vietnam confirmed that a new neonatal laryngeal mask (Supreme-LMA) was more effective than FM in preventing endotracheal intubation in newborns needing PPV at birth.[22] All these studies were conducted by using a cuffed laryngeal mask.[23] Our findings add that a cuffless supraglottic airway is also more effective than an FM in achieving a rapid recovery of neonates in need of PPV at birth. The innovative design of the LMA simplifies positioning and should be well suited for clinical settings lacking staff experienced in airway management.

Training of staff involved in neonatal resuscitation has been identified as a crucial factor in reducing neonatal mortality. The

Table 2 Time to start of ventilation, ventilation time, assistance by supervisor and conversion to alternative device by trial arm

	LMA (intervention) n=24 Mean (SD)	Face mask (comparator) n=25 Mean (SD)	p Value	Effect of the intervention Mean ratio (95% CI)
Start of PPV (s)	60 (11)	68 (36)	0.26	0.88 (0.70 to 1.10)
Ventilation time (s)	93 (52)	140 (90)	0.02	0.67 (0.47 to 0.93)
	n (%)	n (%)		OR (95% CI)
Assistance from the supervising physician	3 (13)	6 (24)	0.46	0.46 (0.07 to 2.52)
Conversion to alternative device	0	11 (44)	0.0002	0.00 (0.00 to 0.29)

PPV, positive pressure ventilation.

Table 3 Primary and secondary outcomes by trial arm

	LMA (intervention) n=24 mean (SD) range	Face mask (comparator) n=25 mean (SD) range	p Value	Effect of the intervention Mean ratio (95% CI)
Primary outcome			0.005	0.70 (0.56 to 0.89)
Time to spontaneous breathing (s)	153 (59) 45–300	216 (92) 65–395		
	n (%)	n (%)		OR (95% CI)
Secondary outcomes				
Admission to neonatal unit (first 48 hours)	5 (21)	8 (32)	0.52	0.56 (0.12 to 2.42)
Neonatal encephalopathy	0	2 (8)	0.49	0.00 (0.00 to 5.51)
Death within 48 hours	0	1 (4)	0.99	0.00 (0.00 to 40.63)
Adverse effects (vomiting, bleeding or laryngospasm)	0	0	0.99	Not applicable

LMA, laryngeal mask airway.

meta-analysis of existing studies suggests that neonatal resuscitation training in facilities is associated with a 30% reduction in intrapartum-related neonatal mortality.[24] Low-intensity high-frequency training programme are essential for maintaining skills and proper clinical practice.[6 25 26] FMV is an essential part of this training, but reaching and maintaining adequate performance represent a continuous challenge for both experienced and inexperienced caregivers.[25]

Task-shifting the use of supraglottic airways to non-doctor or inexperienced health staff in rural areas could be one way to improve the current situation. In agreement with previous studies,[15 22] our data suggest that the learning curve to reach adequate proficiency in the use of supraglottic airways is steep. Ventilation with LMA can also be performed using one hand only. This may be crucial in remote setting where birth attendants typically work alone and may need to resuscitate the baby by the mother.

Video-recording allowed precise and objective assessment of the primary outcome. The camera was manually operated by the supervisor. This led to a minor disturbance around the resuscitation table. Once started, the camera did not seem to interfere with clinical activity. The overall impression was that video-recording was well accepted by local staff. The potential use of the video for feedback and training was beyond the scope of this trial but is appealing and as has been used mostly in high-income settings.[9 27]

There are some limitations in this RCT. First, it was a phase II trial, so only a limited number of patients were included. Second, it was open-label as no masking or blinding is possible in this type of trial. Third, health caregivers responsible for resuscitation were under supervision of a trained person potentially influencing the procedure, but this was similar for both arms.

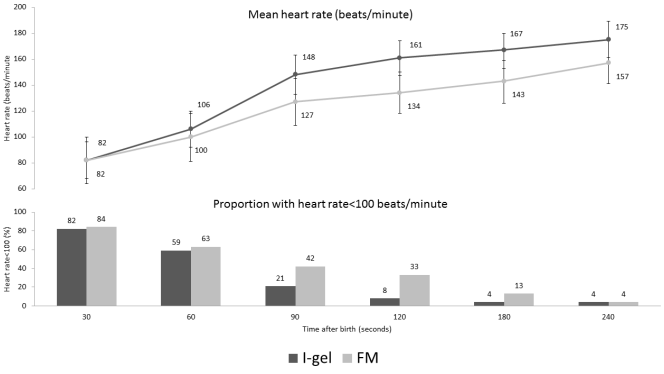

Figure 3 Mean heart rate (bpm).

Additional data such as accurate gestational age, signs of fetal distress, blood gases and oxygen saturation were not available in this low-income setting. HR was instead obtained with an mHealth tool (www.tap4life.org).

Earlier studies have assessed cuffed laryngeal masks during neonatal resuscitation in high-income and middle-income settings with experienced staff. This trial assesses the efficacy and safety of a cuffless supraglottic airway in the hands of staff inexperienced in administrating PPV at birth after a short training programme in a low resource setting.

CONCLUSION

Mastering PPV during newborn resuscitation is a difficult skill. A cuffless LMA reduced the time to spontaneous breathing during newborn resuscitation compared with FM. The LMA seems to be safe and effective in a low-income setting after a short training programme.

Contributors NJP had the idea and was responsible for conception and design, outcome assessment, acquisition of data, data analysis and interpretation, and drafted the manuscript. DT was responsible for trial design, outcome assessment, data analysis and manuscript writing. CL was responsible for on-site trial planning, data gathering, data analysis and critically revising the manuscript for important intellectual content. JN was responsible for on-site trial planning, data analysis, and critically revising the manuscript for important intellectual content. SMH was responsible for outcome assessment, acquisition of data, data analysis and interpretation, and critically revising the manuscript for important intellectual content. JB was responsible for on-site trial planning, data analysis and interpretation, and critically revising the manuscript for important intellectual content. FC was responsible for statistical analysis and interpretation, and critically revising the manuscript for important intellectual content. TT was responsible for conception and design, outcome assessment, data analysis and interpretation, and critically revising the manuscript for important intellectual content.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Institutional Review Board (IRB) of Mulago National Referral Hospital, the Uganda National Council of Science and Technology, the National Drug Authority and by the Regional Committee for Medical and Health Research Ethics (REK VEST) in Norway.

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