Original Article

Feeding obturator as an airway adjunct during complete unilateral cleft palate repair

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ABSTRACT

Background and Aims: The palatal defect and abnormal dentition in cleft palate make mask ventilation and laryngoscopy difficult. This study aimed to assess the effect of feeding obturator on laryngeal view in unilateral complete cleft palate. **Methods:** Ninety non-syndromic infants scheduled for the first stage correction of complete unilateral cleft palate were randomised to Group A (no feeding obturator) or Group B (obturator used for induction and intubation). The primary objective was to assess effect of the feeding obturator on the Cormack–Lehane grade on laryngoscopy. Effects on face mask ventilation, easiness of laryngoscopy and intubation and the side effects were also measured. **Results:** Ninety patients completed the study. There was no statistically significant difference between the two groups regarding the CL grade ($P < 0.1$). However duration for intubation was significantly longer in Group A than Group B (31.4 ± 12.8 vs. 23.4 ± 40.7 sec, $P < 0.001$). The degree of difficulty of face mask ventilation was significantly greater in Group A than Group B ($P < 0.008$). Attempts for successful intubation and manoeuvres for successful intubation were significantly more in Group A than B ($P < 0.05$). Trauma occurred in ten patients in Group A relative to no patients in Group B. **Conclusion:** Use of a pre-sized obturator in infants with complete unilateral cleft palate does not improve the laryngoscopic view. However, it results in better face mask ventilation and easier and faster laryngoscopy and intubation.

Key words: Airway, cleft palate, feeding obturator

INTRODUCTION

Cleft lip with or without cleft palate is a common congenital malformation.[1] The majority of anaesthetic morbidity during the corrective procedures in these patients relates to the airway.[2] The defect in the palate together with the presence of abnormal dentition renders face mask ventilation and laryngoscopy difficult. Improper or lengthy management of the airway in such group of patients may lead to inadvertent consequences. A feeding obturator is a device that creates a seal between the oral and nasal cavities and helps the infant during feeding.[3] It may be made of different materials and designed based on the age of the infant as well as the size of the defect. The primary aim of the present study was to assess the effect of the application of the feeding obturator on the Cormack–Lehane (CL) classification of the laryngeal view in infants with the unilateral complete cleft palate. The effect of the feeding obturator on face mask ventilation, ease of laryngoscopy and intubation and the incidence of side effects during the process of airway management in this group of patients were also measured.

METHODS

This randomised prospective controlled study was reviewed and approved by the Ethics Committee of the Alexandria Main University Hospitals. A written

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informed consent was obtained from the parents for the participation of their infants in this study. The study has been registered in the Pan African Clinical Trial Registry under number PACTR201610001832267.

Ninety-eight American Society of Anesthesiologists' (ASA) grade I or II infants scheduled for first stage correction of complete unilateral cleft palate were enrolled in the study. Patients were excluded if they had any difficult airway associated with cleft palate like Pierre Robin, Treacher Collins, Van der Wounde, Velocardiofacial and Median facial dysplasia Syndrome.

Complete history was obtained from the parents, and all patients were subjected to thorough clinical examination and routine laboratory investigations. Patients were randomly allocated into two equal groups using a random number generating software (Research Randomizer Version 4.0) at the time of pre-operative assessment as follows: Group A – No feeding obturator was used during induction of anaesthesia and Group B – Infants were referred to the pedodontics department 7 days preoperatively to design a special sized feeding obturator. In case of any difficulty in obtaining the obturator, the procedure was postponed till the obturator was ready preoperatively. Induction of anaesthesia was done with the obturator in place.

The feeding obturator [Figure 1] was designed according to sizing previously done by a conventional compound impression material of the maxillary arch. The tray was seated until the impression material was adequately covering the anatomy of the upper gum pads. Once the impression material was set, the tray was removed, and the mouth was examined for residual impression material. The impression was then poured with dental stone to obtain an accurate cast. The feeding plate was fabricated on the dental stone model. All the undercuts and the cleft space were blocked with wax. The plate was made up of hard self-cured acrylic lined by soft denture material metal handle.

Figure 1: Structure of the feeding obturator

No premedication was done. All patients were fasting according to the American Society of Anesthesiology fasting rules. In the operation theatre, all patients were attached to a multichannel monitor in the form of continuous electrocardiogram, heart rate, pulse oximeter and non-invasive arterial blood pressure End-tidal capnography was attached after insertion of the endotracheal tube (ETT). Then, anaesthesia was induced with 8% sevoflurane in 100% oxygen with a silicone face mask size 0–1 connected to a Jackson-Rees circuit. Infants were in the supine position with a small pillow in-between their shoulders. An intravenous line was secured in place. Rocuronium 0.6 mg/kg IV was given to facilitate tracheal intubation. Sevoflurane was reduced to 3%. Tracheal intubation was attempted with a Macintosh blade size 0–1 after 3 min to ensure complete muscle relaxation. Induction of anaesthesia and tracheal intubation in all patients were done by a single investigator who has 7 years' experience in paediatric anaesthesia. A second investigator recorded the images of the technique of intubation and the best laryngeal view obtained at the time of intubation by a digital camera and documented the grade of laryngoscopy. Duration of intubation was measured from the insertion of the laryngoscope blade into the patient's mouth until confirmation of tracheal intubation by five consecutive waves of capnography. Failed attempt was defined as decrease in arterial oxygen saturation below 85%. In case of failure of intubation, face mask ventilation was resumed with 3% sevoflurane in 100% oxygen for 60 s and intubation was tried again after changing the laryngoscope blade type or size or use of an appropriate stylet. Intubation procedure was considered as a failure in case of three successive failed attempts, and muscle relaxation was reversed with sugammadex 2 mg/kg IV and the patient was scheduled for fiberscope-guided intubation.

The degree of difficulty of face mask ventilation was assessed by the following score.[4] Grade 1 – Ventilated by mask, Grade2 – Ventilated by mask with oral airway/adjuvant with or without muscle relaxant,

Grade 3 – Difficult ventilation (inadequate, unstable, or requiring two providers) with or without muscle relaxant and Grade 4 – Unable to mask ventilate with or without muscle relaxant.

The laryngoscopic view was assessed using the CL grade.[5] Difficulty in the process of intubation was assessed by the duration of intubation, number of intubation attempts and type and number of manoeuvres and/or adjuvants needed for intubation. Traumatic side effects if any were recorded only after tracheal intubation.

Based on a previous study,[6] a sample size of 90 was calculated to detect a difference of 30% in the CL grade of laryngoscopic view between the two groups with a two-sided Chi-square test, Type II error of 0.2% and Type I error of 0.05% using the MedCalc Statistical Software version 16.4.3 (MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org; 2016). Data were analysed using IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp. Qualitative data were described using number and per cent. Quantitative data were described using the mean and standard deviation. The significance of the obtained results was judged at the 5% level. The Chi-square test was used for categorical variables while the Student's *t*-test was used for normally distributed quantitative variables to compare between the two studied groups.

RESULTS

A total of 98 patients were screened for eligibility; 92 patients met inclusion criteria and were approached to participate, and two parents refused to engage their children in the study [Flowchart 1]. Data were normally distributed within the two groups. There was no statistically significant difference between the two groups regarding age, gender, weight and ASA physical status [Table 1]. The degree of difficulty of face mask ventilation was significantly greater in Group A than Group B ($P < 0.008$) [Table 2]. There was no statistically significant difference between the two groups regarding the CL laryngoscopic view ($P < 0.1$) and no patients in the two groups were categorised as Grade 4 [Table 2]. The duration of the intubation process was significantly longer in Group A than Group B ($P < 0.001$) [Table 2]. Less patients in Group A were intubated in 1st attempt compared to Group B ($P < 0.05$), and while no patients in Group B required the 3rd attempt for intubation, five patients in Group A were intubated in 3rd attempt [Table 2]. There was a statistically significant difference between the two groups regarding the manoeuvres needed for successful intubation ($P < 0.001$). While only five patients in Group B required one manoeuvre in the form of backward movement of the glottis, 18 patients in group A required the same manoeuvre, two patients in addition required repositioning of the head and neck and five more patients required change of blade type or size [Table 2]. Trauma to the gum was evident in ten patients in Group A while no patients suffered from trauma in Group B [Table 2].

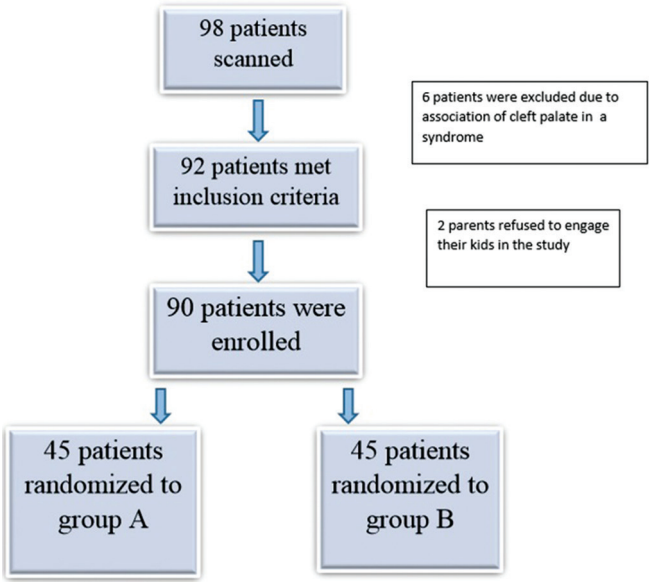
Table 1: Demographic data of the two groups

Patients' characteristics	Group A (*n*=45)	Group B (*n*=45)
Age (months)	7.1±2.5	6.2±2.6
Weight (kg)	6±0.5	5.8±0.6
Gender		
Male	18 (40.0)	25 (55.6)
Female	27 (60.0)	20 (44.4)
ASA		
I	21 (46.7)	22 (48.9)
II	24 (53.3)	23 (51.1)

Data are presented as mean±SD or *n* (%). SD – Standard deviation; ASA – American Society of Anaesthesiologists

DISCUSSION

The prevalence of cleft lip with or without cleft palate is variable throughout the world. Such congenital anomaly occurs in 2/1000 live births in North America, 1/600 live births in Central Europe and in 1.02/1000 live births in the Middle East. Surgical correction is the treatment modality of oropharyngeal clefts. Anaesthetic morbidity in such surgical procedures



Flowchart 1: Flow diagram

Table 2: Comparison of mask ventilation, laryngoscopic view, duration of intubation, number of attempts, manoeuvres to intubation and complications in the two groups

Mask ventilation/ laryngoscopic parameters	Group A (*n*=45)	Group B (*n*=45)	*P*
Mask ventilation			
Grade 1	27 (60.0)	39 (86.7)	<0.008
Grade 2	13 (28.9)	6 (13.3)	
Grade 3	5 (11.1)	0	
Laryngoscopic view			
Grade 1	19 (42.2)	28 (62.2)	0.1
Grade 2a	14 (31.1)	12 (26.7)	
Grade 2b	10 (22.3)	5 (11.1)	
Grade 3	2 (4.4)	0	
Duration of intubation (s)	31.4±12.8	23.4±40.7	<0.001
Number of intubation attempts			
1	35 (77.8)	42 (93.3)	<0.05
2	5 (11.1)	3 (6.7)	
3	5 (11.1)	0	
Number of manoeuvres for intubation			
0	20 (44.4)	40 (88.9)	<0.001
1	18 (40.0)	5 (11.1)	
2	2 (4.4)	0	
3	5 (11.1)	0	
Complications	10 (22.0)	0	0.001

Data are presented as mean±SD or *n* (%) and analysed using Student's *t*-test or Chi-square test. SD – Standard deviation

is mostly related to difficult airway management and post-operative airway obstruction.[7] The present study revealed that application of a feeding obturator in infants with unilateral cleft palate significantly enhanced face mask ventilation, facilitated the tracheal intubation procedure pictured as a shorter duration of intubation and less attempts for successful intubation as well as less intubation-related traumatic complications. However, the CL laryngoscopic view was not significantly modified by the presence of the feeding obturator during intubation. In most cases, a good laryngoscopic view was easy to obtain in the two groups. However, the view could not be maintained due to the tendency of the laryngoscope blade to slip into the defect, which leads to narrowing of the space needed for directing the ETT towards the larynx. This was reflected as longer duration of intubation as well as more attempts needed for tracheal intubation in Group A relative to Group B in spite of similar CL grading. Furthermore, a near normal contour of the mouth with the use of feeding obturator achieved better fit and alignment of the mask with the patient's face and resulted in better face mask ventilation.

Dealing with the airway in paediatric patients with palatal cleft has been discussed in the medical literature in a few studies. Most of these have focused on syndromic facial clefts without shedding light on patients with sole cleft lip or palate. Surgical interventions usually start in the first 6 months of the patient, during which difficulty in airway management is expected.[8] Dealing with such airway should be smooth and duration and manipulations for intubation should be minimised to prevent the development of post-operative airway oedema, that together with surgical repair may affect the airway patency.[9] The paraglossal approach for intubation has been evaluated aiming to move the resting point of the laryngoscope laterally. However, the narrow laryngoscopic view may add difficulty to intubation and increasing the risk of traumatic complications.[10] The technique was evaluated in a previous study using a gum elastic shield in patients with bilateral cleft palate to make a bridge over the defect.[6] However, the material of the shield was not clear enough in the study neither was it obvious whether the shield was uniform in size for all patients nor patient-customised. Furthermore, maintenance of face mask ventilation was not discussed in that study. The application of a piece of gauze to prevent falling of the blade into the palatal defect has been mentioned several times in the medical literature and claimed to help in the process of intubation after filling in the defect.[11] Surprisingly, no organised study has been performed to evaluate its efficacy and the technique of its application whether during face mask ventilation or tracheal intubation. Palatal obturator was used for facilitation of face mask ventilation in an adult patient with a bony palatal defect due to the previous excision of buccal squamous cell carcinoma. The obturator was effective in reducing air leak with minimal changes in end-tidal CO_2 until intubation.[12]

In the present study, we used the feeding obturator as a tool for filling the defect, by re-establishing and restoring the separation between the oral and nasal cavities, facilitating face mask seal during induction of anaesthesia and preventing falling of the blade into the defect thus improving the process of orotracheal intubation [Figure 2]. The feeding obturator is fabricated using an acrylic resin which acts originally as a temporary prosthesis for feeding until surgical correction is planned.[6] The main problem during intubation without the aid of feeding obturator was difficulty to stabilise the laryngoscope blade without falling into the defect leading to more attempts and more time to achieve successful intubation, and hence, more trauma. One limitation in the present study is performing all tracheal intubations by a single investigator, so that the results can not be generalised.

Figure 2: Left: Feeding obturator in place. Right: Direct laryngoscopy with the feeding obturator in place

CONCLUSION

From the present study, we conclude that the use of a pre-sized obturator has a little effect on the laryngoscopic view however, results in better face mask ventilation during induction of anaesthesia as well as easier process of laryngoscopy in infants with the complete unilateral cleft palate . The same technique is recommended to be studied in patients with the bilateral cleft palate and those with syndromic cleft facial anomalies where difficult airway is anticipated.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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