

ORIGINAL ARTICLE

A novel intubation technique in bilateral cleft palate pediatric patients: hard gum shield-aided intubation

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Summary

Background: Cleft palate anesthesia is challenging due to difficult airway. Left paraglossal intubation moves resting point of laryngoscope laterally but associated with narrower laryngoscopic view and possible trauma, and we invented the use of hard gum shield as a bridge over defective palate to facilitate intubation with possible wider window and defective tissue protection.

Methods: Eighty bilateral cleft palate children, ASA physical status I–II aged 9 months to 6 years scheduled for plastic surgery had general anesthesia, were involved in prospective, controlled, randomized study, and were randomly divided by closed envelope method into two groups: group I (40 patients): intubated by hard gum shield-aided intubation and group II (40 patients): intubated by left paraglossal intubation. Both techniques compared as regards (i) intubation time; (ii) Cormack and Lehane score; (iii) need for external laryngeal manipulation; (iv) easiness of intubation: easy, modest, or difficult intubation; and (v) complications: desaturation and failed intubation.

Results: Intubation time was shorter in group I (28.47 ± 3.78 vs. 37.63 ± 6.64 s, $P = 0.001$). Cormack and Lehane score was better in group I ($P = 0.003$). Need for external laryngeal manipulation was less in group I ($P = 0.015$). Easiness of intubation was better in group I ($P = 0.022$). No difference was found in complications between groups.

Conclusion: Hard gum shield-aided intubation facilitated intubation more than left paraglossal in bilateral cleft palate children with shorter intubation time, better glottic view, easier intubation, less need for laryngeal manipulation than left paraglossal intubation with no difference in complications.

Introduction

Cleft palate is a common congenital deformity associated with facial disfigurement causing feeding, speech, and dental and psychosocial problems. Plastic surgery aims to restore anatomy and function. The overall worldwide incidence is 1 in 700–800 live births. Approximately 85% of infants with a bilateral cleft lip and 70% with a unilateral cleft lip will have an associated cleft palate (1). Anesthetic challenges include difficult airway management and dealing with associated abnormalities and pediatric patients.

Incidence of difficult or failed laryngoscopy in patients with cleft lip and/or palate ranges from 4.0% to 7.4% (2–4). However, in patients with bilateral cleft lip and palate, the incidence of difficult laryngoscopy has been reported to be 16.5–45.8% (2,4). In infants with bilateral clefts of the lip and alveolus with protruding premaxilla, laryngoscopy is difficult because the blade has a tendency to sink in the cleft (5) and may lead to iatrogenic tissue trauma.

Difficult airway management in uncorrected cleft palate patients has been studied by many authors (1–16). Xue *et al.* (2) evaluated the incidence of difficult

laryngoscopy in infants with cleft lip and palate and observed its relationships with age, sites, and degrees of deformities and concluded that the important risk factors for difficult laryngoscopy include infants with cleft lip and palate, left cleft lip and alveolus, combined bilateral cleft lip and palate, micrognathia, and age <6 months. Difficult intubation occurred mainly in infants with laryngoscopic views of grades III and IV. The difficulty in intubation in cleft palate patients is due to the absence of the normal resting point for the lifting action of the laryngoscope in the midline. Many studies tested the efficiency of left paraglossal technique to overcome the difficult intubation (6,7) by moving the resting point of the laryngoscope from the midline laterally to the left.

However, clinically left paraglossal technique is associated with narrow glottic view due to protruding tongue. We examined the ability of a new technique for intubation (gum shield-aided intubation) in uncorrected bilateral cleft palate to facilitate the intubation in comparison with left paraglossal intubation that commonly used. Our technique depends on abolishing the defect in the palate through the application of hard gum shield over the deformed upper jaw, thus simulating a normal jaw and providing a steady resting point for midline laryngoscopy.

Patients and methods

A prospective, controlled, randomized study was carried out at Cairo University Specialized Pediatric Hospital in the period from January 1, 2010, to November 28, 2011, after obtaining permission from the local committee of ethics and research and an informed consent from the parent in charge and a consent from the father of the child whom picture is posted in the research. Eighty children, ASA physical status I–II, aged 9 months to 6 years with uncorrected bilateral cleft palate scheduled for corrective plastic surgery. Patients with suspected difficult airway due to causes other than cleft palate as receding mandible were excluded. Patients were exposed to routine preoperative evaluation including history, examination and investigations, premedication with I.M. midazolam 0.05 mg kg^{-1} and atropine 0.01 mg kg^{-1} 30 min before induction of anesthesia by inhalation of sevoflurane at inspired fraction of 2–6% through a face mask, and IV cannula was placed. Patients were randomly assigned to either group I ($n = 40$): scheduled for intubation by insertion of hard gum shield with its concave side over the deformed upper jaw and midline laryngoscopy or group II ($n = 40$): scheduled for intubation by left paraglossal approach (6). Randomization was carried out as follows: prior to induction, the experienced pediatric anesthesiologist blindly chose a slip of paper from a dark envelope

that contained two slips, with each slip marked with one of the two patient groups. Whichever group was written on the paper determined the technique of intubation that was to be used in that patient.

After the application of routine monitoring of the patient and an adequate depth of anesthesia by inhalation of sevoflurane at an inspired fraction of 2–6% was ensured, the face mask was removed and patients in group I got the hard gum shield applied over the deformed upper jaw (Figure 1) followed by midline laryngoscopy, and intubation with the laryngoscopic blade was selected according to the anesthesiologist preference. The size of gum shield was determined by selecting the size that approximates the size of lower jaw. For patients in group II, after the removal of face mask, a left paraglossal intubation (6) was applied by moving the resting point of the laryngoscope laterally to the left of the patient. For both patient groups, after intubation and removal of the laryngoscope from the mouth, the endotracheal tube is connected to an Ayres T piece with capnogram and manual ventilation was performed to ensure endotracheal intubation by obtaining three capnographic waves.

We assessed (i) the intubation time in seconds: time from removing the face mask till obtaining three capnographic waves by manual ventilation immediately after intubation; (ii) Cormack and Lehane grade of glottic view (17): Grade 1, visualization of the entire glottic aperture; Grade 2, visualization of only the posterior aspects of the glottic aperture; Grade 3, visualization of the tip of the epiglottis; Grade 4, visualization of no more than the soft palate. (iii) The need for external laryngeal manipulation by the anesthetist or the assistant was reported. (iv) Intubation easiness was graded by anesthetist as easy, modest, or difficult grade of intubation.



Figure 1 A child with bilateral cleft palate before induction of anesthesia (on the left) and during insertion of the hard gum shield over the upper jaw (on the right).

(v) Complications such as desaturation ($\text{SpO}_2 < 94\%$) and failed intubation (intubation time ≥ 60 s, the need for other technique or second) were assessed.

Sample size report (power analysis)

Group sample sizes of 40 in group I and 40 in group II achieve 80% power to detect a difference between the group proportions of 0.31 (odds ratio of 4.4) regarding the easiness of intubation. The proportion in group I is assumed to be 0.5 under the null hypothesis and 0.81 under the alternative hypothesis. The proportion in group II is 0.5. The test statistic used is the two-sided Fisher's exact test. The significance level of the test was targeted at 0.05. The significance level actually achieved by this design is 0.03.

Results

The study included 80 bilateral cleft palate pediatric patients with 40 patients in each group. The two groups showed no statistically significant differences in demographic data (Table 1).

Group I showed statistically significant shorter time of intubation than group II (Table 2). Group I was associated with significant better Cormack scoring of glottic view than group II with P value of 0.003 (by chi-square for trend; Table 3).

The use of hard gum shield intubation was moderately associated with better Cormack score (Somers' D correlation 0.344, P value 0.001; Figure 2).

The need for external laryngeal manipulation was less in group I than in group II (Group I: 7 patients [17.5%] and 33 patients [82.5%] did not need. Group II: 17 patients [42.5%] needed manipulation and 23 patients [57.5%] did not need).

Group I was associated with more easiness of intubation than group II with P value 0.007 (by chi-square for trend; Table 4). Figures 3 and 4 show intubation technique and Cormack score 1 respectively when using gum

Table 1 Comparison between both groups as regards age, sex, and weight

	Group I (Hard gum shield)	Group II (Left paraglossal)	P value
Age (years)	2.31 \pm 1.75	2.16 \pm 1.22	<0.65
Sex (%)	6 F (15), 34 M (85)	5 F (12.5), 35 M (87.5)	<0.745
Weight (kg)	13.14 \pm 4.15	13.79 \pm 4.04	<0.480

Data are presented as mean \pm sd for age and weight and as percentage for sex.

F, Female; M, Male.

P value < 0.005 is considered as statistically significant.

Table 2 Comparison between both groups regarding the time of intubation

	Group I (hard gum shield intubation)	Group II (left paraglossal intubation)
Time of intubation (s)	28.47 \pm 3.78*	37.63 \pm 6.64

Data are presented as mean \pm sd.

P value < 0.005 is considered as statistically significant difference (Mann–Whitney U -test).

* P value < 0.001.

Table 3 Cormack score (I–IV) in both groups

Cormack score	Group I (hard gum intubation, %)	Group II (left paraglossal intubation, %)
I	29 (72.5)	16 (40)
II	10 (25)	19 (47.5)
III	1 (2.5)	5 (12.5)

Data are presented as number and percentage of cases within each group.

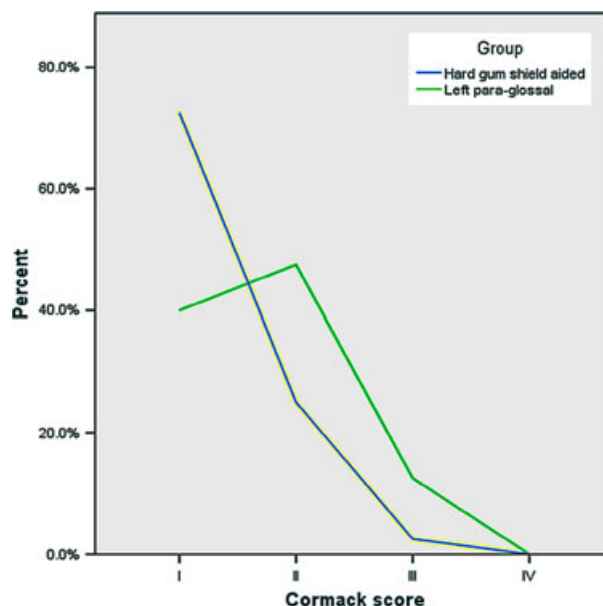


Figure 2 Linear correlation between the intubation technique used and the Cormack score.

shield-aided intubation in a 4-year-old child with bilateral cleft palate.

The use of hard gum shield intubation was moderately associated with better easiness of intubation (Somers' D correlation 0.283, P value 0.003). Both groups did not show statistically significant difference in rate of

Table 4 Easiness of intubation in both groups

Ease of intubation	Group I (hard gum shield intubation, %)	Group II (left paraglossal intubation, %)
Easy	34 (85)	23 (57.5)
Modest	5 (12.5)	12 (30)
Difficult	1 (2.5)	5 (12.5)

Data are presented as number and percentage of cases within each group.



Figure 3 A 4-year-old child with hard gum shield applied over bilateral cleft palate and a midline conventional laryngoscopy is used for intubation.

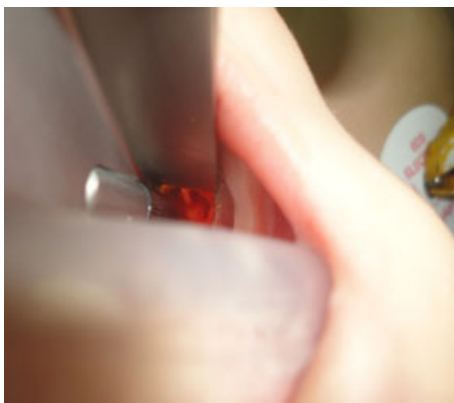


Figure 4 A glottic view (Cormack score 1) obtained with hard gum shield applied in a 4-year-old child.

complications reported. Group I had one case (2.5%) of desaturation during intubation, while group II had five cases (12.5%) of desaturation (P value 0.09). No cases of failed intubation were found in either group.

Discussion

The vital finding of our study is providing the ability of hard gum shield-aided intubation to facilitate intubation more than the widely used left paraglossal intubation in bilateral cleft patients. Hard gum intubation recorded

shorter intubation time, better Cormack and Lehane scoring of glottic view, easier intubation with less need for external laryngeal manipulation than left paraglossal technique. No difference between both techniques as regards complications: desaturation and failed intubation.

Our novel technique depends on applying the hard gum shield over the defective upper jaw to form a bridge, thus simulating normal jaw to enable the use of the midline as a resting point for the conventional laryngoscopy during intubation. Thus, our technique abolishes the cause of difficult intubation instead of moving the resting point of laryngoscopy laterally as in left paraglossal intubation that is currently used in bilateral cleft palate patients (6).

Intubation time was shorter in group I than in group II (28.47 ± 3.78 vs 37.63 ± 6.64 s), thus providing a privilege in a special type of patients characterized by rapid desaturation. Intubation time was 52.4 ± 12.4 s. in Sen *et al.*'s (6) study on left paraglossal intubation in 21 children with bilateral cleft lip and palate; this augments our results by recording longer time of intubation in left paraglossal technique than hard gum technique in our study; however, intubation time in Sen *et al.* is longer than the time recorded for same technique in our study, and this may be due to smaller sample size and age group in Sen *et al.* (6). Also, Sen *et al.* (6) did not clarify the accurate limits of recording the intubation time in contrast to our study that defined that time from face mask removal till three capnogram waves on manual ventilation.

Cormack and Lehane scoring of glottic view was better in hard gum than left paraglossal with 72.5% of cases in group I had score 1 vs 40% in group II. And score 2 was recorded in 25% of group I and 47.5% of group II. These results are in contrary to the results provided by Sen *et al.* (6) who reported that all the 21 cases in his study received Cormack scores 1 and 2 with reversed proportion to our study (66.6% of cases with score 1 and 33.3% of cases with score 2 in Sen *et al.* study). Disagreement of Sen *et al.*'s results with ours is augmented by the smaller age group in his search, which is theoretically associated with less better glottic view, but this may be explained by smaller sample size in his study. Xue *et al.* (7) criticized the results of Sen *et al.* (6) as he reported Cormack and Lehane score 1 and of glottic view in most patients, which is clinically difficult to obtain except in few patients with cleft palate even when using left paraglossal approach. Xue *et al.* (7) also mentioned that the left paraglossal laryngoscopy provides narrower glottic view than conventional midline laryngoscopy due to narrow distance between maxillary and mandibular grooves and also due to bulging of the tongue to the right side of the blade obscuring the view (10). These disadvantages of left paraglossal approach support the superiority of our novel technique.

The need for external laryngeal manipulation was less in group I than in group II. Sen *et al.* (6) revealed in his study on left paraglossal intubation that two-third of cases needed external laryngeal manipulation; this makes a conflict over the results of Sen *et al.* as in same search he reported that 66.6% of patients had Cormack and Lehane score 1 and 33.3% of cases had score 2. So our study shows the expected correlation between the ability of hard gum intubation to provide better Cormack and Lehane score and decreasing the need for external laryngeal manipulation, thus facilitating intubation more than left paraglossal technique.

Intubation was easier in group I than in group II with 85% of group I was easy and 12.5% with modest difficulty in comparison with 57.5% of group II was easy and 30% with modest difficulty. Sen *et al.* (6) reported one-third of cases as easy and two-third with slight difficulty. However, Xue *et al.* (7) criticized Sen *et al.*'s (6) results as according to Xue *et al.*'s experience, the left paraglossal intubation is associated with difficult intubation even with Cormack scores 1 and 2 due to narrower distance between maxillary and mandibular grooves or teeth compared with that via an oblique supero-inferior direction during the conventional midline laryngoscopy. This augments the ability of hard gum intubation to provide both better glottic view and easier intubation.

No difference between both groups for complications with group I got one case (2.5%) of desaturation during intubation, while group II reported five cases (12.5%) of desaturation with *P* value 0.090 with no cases of failed intubation in both groups.

Many authors (1–16) tried several solutions to overcome the difficulties in airway management in bilateral cleft palate patients; Kumar *et al.* (8) described the use of winged laryngoscopy in intubation of 35 pediatric patients with left, right unilateral or bilateral cleft palate. He described all cases as having easy intubation, but he defined easy intubation as successful intubation from first or second attempt, which is a wide definition with possibility of different grades of difficulty under the class easy. Xue *et al.* (9) criticized Kumar *et al.*'s (8) mentioning that the winged laryngoscope can be traumatic to upper jaw, it is only superior to conventional laryngoscopy in left cleft palate, it provides narrow glottic view, and also it does not allow the application of left paraglossal approach. In contrary to the use winged laryngoscope, the use of gum shield-aided intubation is protective to upper jaw, is suitable for most defects in upper jaw, and provides wide glottic view, and left paraglossal approach can be used if needed.

Henderson (11) recommended only right paraglossal when using Miller blade in unilateral cleft palate to avoid obscuring light bulb by the tongue. In bilateral Cleft palate and lip children, protruding premaxilla may obstruct the laryngeal view (2); thus, it is often difficult to induce the tube's tip into the glottis with risk of airway edema with repeated intubation trials (12). Again, it is another disadvantage for left paraglossal approach.

Other solutions for intubation in cleft palate patients included fiberoptic intubation through the laryngeal mask (13) or insertion of ETT into the trachea along the light wand (14) and also the gum-elastic bougie-guided intubation described by Semjen *et al.* (15). Khan *et al.* (16) tested the use of Truview PCD videolaryngoscope in the intubation of a child with cleft lip and palate and protruding premaxilla. However, these techniques require expensive equipment, expert use, and special training in opposite to our novel technique (gum shield intubation) that is cheap, available, and easily used by any anesthetist with no need for special training.

Limitations

Further studies can be carried out on cases with bilateral cleft palate associated with other anomalies of airway to clarify how the hard gum intubation will be helpful in such cases. Some cases were excluded from the study due to the absence of appropriate size of the hard gum, so we recommend manufacturing different sizes of the hard gum to be suitable for use in different ages.

Conclusion

The novel hard gum shield-aided intubation is simple, available, cheap, and effective technique that can be easily used to facilitate intubation more than the currently used left paraglossal intubation in cleft palate pediatric patients.

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Declaration

Written informed consent has been obtained from the father of the baby to use his photograph for publication purposes.

Conflict of interest

No conflicts of interest declared.

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