

# Use of Cost-Effective Prophylactic 'Rocket' in Infants Undergoing Primary Cleft Lip Surgery: A Retrospective Cohort Analysis

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## Abstract

**Background and Objectives:** Adverse postoperative airway events are a significant problem in infants following primary cheiloplasty. This study aims to describe a simple inexpensive tool which, used prophylactically, can minimize postoperative airway obstruction (POAO). A retrospective cohort analysis was conducted among 314 infants who underwent primary cheiloplasty under general anesthesia at a hospital in Kanyakumari District in Tamil Nadu, India. **Materials and Methods:** The infants were divided into two cohorts, the first prior to introduction of the modified nasal airway (termed locally as "Rocket" due to its appearance once fixed in position), and the second after its use began in July 2007. The Rocket, consisting of an uncuffed endotracheal tube, 0.5 mm smaller in diameter than that used for intubation, was placed prophylactically prior to extubation in the nasal space of infants considered at risk. The incidence of POAO was compared between the two cohorts. **Results:** The incidence of POAO in cohort I ( $N = 86$ ) was 8.1%, which reduced significantly to 0.44% in cohort II ( $N = 228$ ) where the Rocket was used prophylactically prior to extubation. **Interpretations and Conclusions:** The prophylactic use of the Rocket minimized the occurrence of POAO following primary cheiloplasty in infants with cleft lip  $\pm$  cleft palate  $\pm$  cleft alveolus. The Rocket may be a cost-effective solution to prevent POAO in infants undergoing these procedures, particularly in challenging and rural circumstances, where access to short-acting agents and customized airways may be limited.

**Key words:** Cleft lip, complication, general anesthesia, postoperative airway obstruction

## INTRODUCTION

The incidence of cleft lip with or without cleft alveolus (CL  $\pm$  CA) and cleft lip and cleft palate with or without cleft alveolus (CL + CP  $\pm$  CA) is 1 in 600 births.<sup>[1,2]</sup> This deformity is distressing for the family and interferes with feeding. Left uncorrected, these babies suffer from repeated respiratory infections, abnormal speech, and social isolation.<sup>[2]</sup> Cleft lip surgery is usually performed at 3 months of age,<sup>[1,3,4]</sup> although it can be performed during the neonatal period.<sup>[5]</sup> Surgical correction during infancy has a higher risk of airway complications, however, gives better cosmetic results, improves feeding, and relieves parental anxiety.

Anesthetic morbidity and mortality in these infants is often related to airway issues.<sup>[6,7]</sup> The airway may be jeopardized during induction, intraoperatively, and due to postoperative airway obstruction (POAO).<sup>[1,8]</sup> POAO is frequently encountered following primary cheiloplasty,<sup>[9-11]</sup> especially in infants with

bilateral cleft lip and palate. This is particularly true in the developing world, where large volumes of these surgeries are performed, often under challenging and resource-scarce conditions. Because POAO is a life-threatening but preventable complication, a simple, effective solution can be lifesaving.

Commercially available preformed nasal airways and nasal stents<sup>[12,13]</sup> have been in use to obviate POAO, however, these are expensive and not readily available. This retrospective study proposes a simple method for reducing the risk of POAO following primary cheiloplasty using a modified nasal airway named Rocket, in view of its morphological appearance,

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fashioned inexpensively from components that are readily available in operating theatres around the world.

## MATERIALS AND METHODS

This retrospective cohort study was conducted at a multispecialty 200 bed hospital in Nagercoil, Tamil Nadu, India after obtaining Institutional Ethical Committee approval. All the 314 infants who underwent primary cheiloplasty in this centre between January 2005 and April 2012 were included in the study. The first cohort was for the period January 2005 to June 2007 and included 86 infants. The second cohort was for the period July 2007 to April 2012 and included 228 infants [Table 1]. All operations were performed by a single surgeon. All anesthetics were administered by two anesthesiologists from the Department of Anaesthesia at the Institution after ensuring absence of active upper respiratory infections. Induction was achieved with inhalational halothane or sevoflurane or with intravenous (IV) thiopentone sodium. Intubation techniques varied, however, a balanced anesthetic comprising analgesics, narcotics/inhalational agents, and muscle relaxants (atracurium or vecuronium) were administered to all babies.

Early postoperative upper airway obstruction was recorded to be present if a breathing baby had one or more of the following: (1) Noisy respiration (which settled with airway maneuvers), (2) retraction of chin and/or lower lip (which settled with airway maneuvers), (3) intercostal and subcostal retraction (which subsided with airway maneuvers), (4) wheezing which disappeared with airway manipulations, (5) desaturation, and (6) cyanosis. The incidence of these upper airway obstructive events was retrieved from patient records.

Rocket is a modified uncuffed polyvinyl chloride endotracheal tube (ETT), 0.5 mm smaller than the size used for intubation. The connector of the selected ETT was removed. At the end of surgery for all infants at risk, the patency of the nasal passage was first checked by passing a small soft lubricated feeding tube. The Rocket was then lubricated and inserted into the nostril. It was positioned at the lower end of the nasal passage, and its position was confirmed on laryngoscopy with its tip being visible in the oropharynx.

All babies who had wide CL  $\pm$  CA and CL + CP  $\pm$  CA and those in whom the surgeon and/or anesthesiologist thought had a compromised nasal passage at the end of surgery had a Rocket placed prophylactically prior to extubation. This amounted to a total of 103 infants between July 2007 and April 2012.

Tincture iodine was applied on the dorsum of the nose and mid forehead, and the Rocket was fixed using strips of stretchable adhesive tape (elastoplast). A long strip was fixed on the forehead, then onto the nose, circled around the Rocket, and finally pasted on the forehead adjacent to the proximal tape. Another small strip was placed across the nose for reinforcement [Figure 1].

The patency of the Rocket was checked by using a wisp of cotton at the proximal end of the modified airway

**Table 1: Demographic details of infants of both cohorts**

	Cohort I (Jan 2005- June 2007)	Cohort II (July 2007 -April 2012)
Total number of infants	86	228
CL $\pm$ CA	34	107
CL + CP $\pm$ CA	52	121
Sex	Males: 54 (62.8%) Females: 32 (37.2%)	Males: 129 (56.6%) Females: 99 (43.4%)
Mean age (range in months)	6.66 (2-12)	5.23 (1-12)
Weight (in kg)	6.30 (3.55-10.90)	5.83 (3.8-9.4)



**Figure 1:** Picture showing fixing of the rocket in an infant.

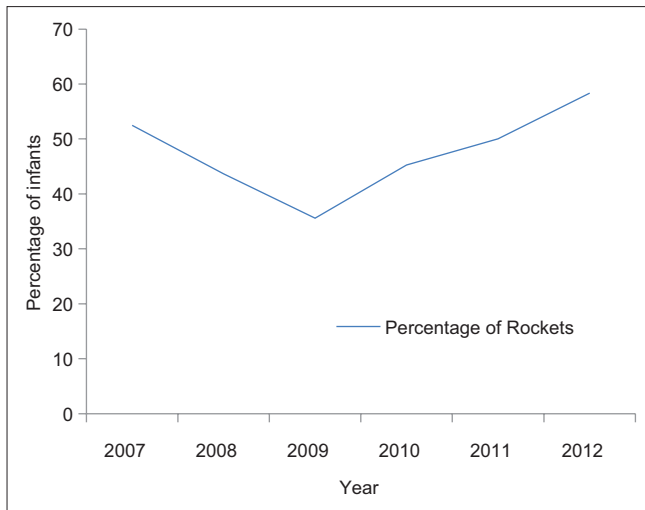
after extubation. The tube was then cut to size to allow approximately 2.5 cm to protrude out of the nostril. The patency of the Rocket was maintained during the postoperative period by the passage of a smaller size suction catheter every hour and applying suction when indicated. The babies were intensely monitored throughout the first 2 postoperative days for airway obstruction, which was recorded and retrieved.

The anesthesiologist evaluated the patient and the airway prior to removing the Rocket. When in doubt, the Rocket was temporarily obstructed to see whether respiration was being compromised. Intensive monitoring was continued for approximately 1 hour after removal of the Rocket.

The data was analyzed using the Statistical Package for the Social Sciences software (version 16.0, Chicago, SPSS Inc.) and Graph Pad online calculator (GraphPad software, SanDiego, CA, USA). Because it was a retrospective study, the sample size was not estimated beforehand.

## RESULTS

This study was a retrospective cohort analysis performed to test the significance of avoidance of POAO following primary cheiloplasty in infants belonging to Cohort II (i.e., had a modified nasal airway; Rocket used prophylactically).



**Figure 2:** Annual percentage of infants in whom the rocket was used in cohort 2.

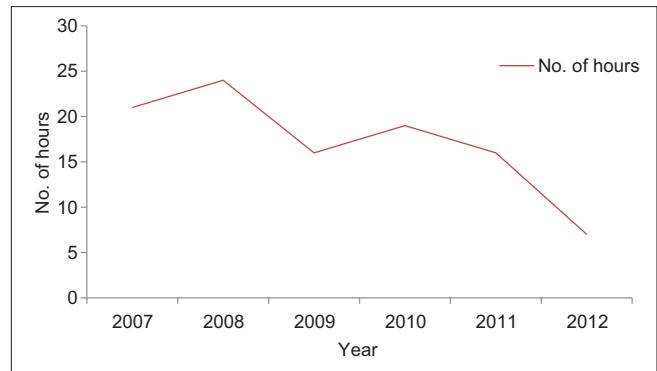
Table 2 shows an incidence of 8.14% infants having POAO in Cohort I. In order to reduce the incidence of POAO, a Rocket was used in infants who were considered at risk in cohort II. It was found that the Rocket was used in 56.20% of the infants with CL + CP ± CA and in 32.71% of the infants with CL ± CA. Prophylactic use of the Rocket in a total of 103 out of 228 infants (45.18%) reduced the incidence of POAO from 8.14% to 0.44% (one in 228 infants) [Table 2]. The analysis showed that, without use of the Rocket, the relative risk of POAO was 18.41. Fisher's exact test was performed using the Graph Pad online calculator and it showed that the Rocket had a significant effect in the avoidance of POAO following primary cheiloplasty in infants ( $P = 0.0006$  at confidence interval of 95%).

The absolute risk reduction (ARR) was noted to be 0.076 at 95% confidence interval. The number needed to treat by this calculation is 13.33. Further analysis also showed that anesthesiologists tended to use the rocket more frequently and that the average period of keeping the rocket in position reduced as the years went by [Figures 2 and 3].

## DISCUSSION

Cleft lip and/or palate is the most common birth defect (1:600 live births).<sup>[2]</sup> Primary cheiloplasty is usually performed at 3 months of age<sup>[1]</sup> when all the anesthetic issues related to the infant are present. In addition, the risks are magnified by the fact that the airway is shared by the surgeon and the anesthesiologist.

There are many obvious differences between the infant and the adult airway. The small infant nares, which offer resistance to airflow and obligate nasal breathing in the first 6 months of life,<sup>[13]</sup> become important management issues. Anesthesia for cleft surgeries needs to be administered keeping in mind the characteristics of the infant airway, secretions, blood, edema due to surgical manipulations, residual effect of



**Figure 3:** Average number of hours of Rocket usage per year.

**Table 2: Comparison of POAO in cohorts I and II**

	No POAO	POAO	Total
Cohort I	79	7 (8.14%)	86
Cohort II	227	1 (0.44%)	228
	306	8	314

POAO: Post Operative Airway Obstruction

muscle relaxants, opioids, and inhalational agents used for the anesthesia, all of which contribute to jeopardizing the airway postoperatively.<sup>[13]</sup>

In cleft infants, there is a sudden narrowing of the nasal area following cheiloplasty because of the reasons mentioned above, and because these small infants are obligate nasal breathers, the incidence of airway obstruction in the postoperative period becomes higher. In addition, the surgeon also alters the infant airway by the repair of the cleft. Hence, at the end of the surgery, the already small natural nasal airway of the infant is further narrowed.

A review of literature shows that various strategies have been used to overcome this lifethreatening complication. These include extubation after full recovery, changes in posture, tongue stitch, dexamethasone IV, use of preformed nasopharyngeal airways, and reintubation.<sup>[12,13]</sup> It is challenging for the anesthesiologist to ensure a quiet baby with adequate pain relief and a patent airway with respiratory adequacy after extubation. Preformed nasal airways are one of the solutions, however, infant sizes are not readily available. Hence, an alternative tool, which was freely available, was used as a modified nasal airway (Rocket). In cohort II, no other airway maneuvers, such as tongue sutures and changes in posture, were needed. In a single patient who developed respiratory obstruction, it was found to be due to secretions blocking the nasal airway. The obstruction was removed by aspirating the secretions from the nasal airway.

Indeed, the ease of use of our tool is noticeable from Cohort II, wherein anesthesiologists were found to have used the Rocket prophylactically, without complications, in 45.18% of the infants. Over a period of time, the frequency of usage of the Rocket increased except for the year 2009

when there was an unexplained fall in the usage of the rocket [Figure 2].

In regard to complications, one baby developed mild ulceration of the alar nasi, which healed well. There were no other significant complication. Moreover, the total number of hours for which the rocket was kept *in situ* reduced steadily over the study period.

Even though this study is retrospective in nature, it involves a large cohort of patients. Given the striking reduction in the incidence of POAO in infants following primary cleft lip repair, a prospective controlled study may be considered unethical. Having experienced the benefit of the Rocket during the postoperative period in highrisk cleft infants.

## CONCLUSION

In conclusion, we suggest that a “rocket” be considered prophylactically to minimize postoperative upper airway events in infants undergoing primary cheiloplasty. This may be particularly relevant to surgeries performed in challenging and rural circumstances, where access to short-acting agents and customized airways may be limited.

## 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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