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ORIGINAL ARTICLE

Postoperative complications associated with extubation strategies following palatoplasty: a single-center retrospective analysis

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Abstract
Purpose Palatoplasty carries a high risk of airway obstruction as a postoperative complication. Since 2007, the protocol in our hospital has been to leave an endotracheal tube in place after surgery while the patient is moved to the pediatric intensive care unit. Extubation is then performed after achievement of hemostasis and recovery of consciousness. We compared the cases over the 5-year periods before and after the introduction of this revised post-surgical management plan to investigate its effect on post-operative complications.
Methods This was a retrospective cohort study involving a single pediatric hospital. The subjects were 199 children aged 1–3 years, who underwent palatoplasty between January 2002 and July 2012. Changes in the incidence rates of postoperative complications were statistically examined.
Results There were significantly more postoperative complications among the patients who were extubated in the operating room than among those extubated in the intensive care unit (operating room group, 22/94 cases; intensive care unit group, 10/105 cases; $P < 0.01$). Serious complications, such as hypoxemia and airway obstruction, also occurred more frequently in the operating room group.
Conclusion Extubation in an intensive care unit was possibly associated with a reduction in postoperative complications.

Keywords Cleft palate · Perioperative care · Postoperative complications · Airway obstruction · Pediatric intensive care unit

Introduction

Owing to its characteristic manipulations inside the oral cavity, palatoplasty carries a high risk of postoperative airway and respiratory complications. There is a danger of airway obstruction because of postoperative bleeding, or swelling of the tongue or oral cavity mucous membranes, in addition to the risk of atelectasis, pneumonia, and other life-threatening adverse events associated with aspiration [1–9].

Our hospital opened a pediatric intensive care unit (PICU) in June 2007 and adopted a new postoperative management plan, whereby instead of conducting extubation in the operating room (OR), patients are transferred to the PICU with an endotracheal tube in place. Extubation is performed in the PICU after complete hemostasis is achieved and consciousness is recovered. The patients are discharged from the PICU essentially after overnight observation of their respiratory status. In this study, we compared the effects of extubation in the OR and in the PICU on post-operative complications over the 5-year periods before and after implementing the change in the management plan.

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Table 1 Demographics of patients in the operating room extubation group (Group A) and the PICU extubation group (Group B)

	Group A ($n = 94$)	Group B ($n = 105$)	*P* value
Age (months)	16 [15–18]	17 [16–18]	NS
Gender (male/female)	42/52	57/48	NS
Height (cm)	77.2 ± 5.0	76.2 ± 3.4	NS
Body weight (kg)	9.6 ± 1.1	9.4 ± 1.1	NS
Diagnosis			
Isolated cleft palate	41	51	NS
Cleft lip and palate (unilateral)	37	37	
Cleft lip and palate (bilateral)	15	17	
Submucous cleft palate	1	0	
Type of surgical intervention			
Push-back palatoplasty	73	78	NS
Intravelar veloplasty	20	27	
Congenital deformity (*n*)	6	20	<0.01*
Difficult airway (*n*)	5	4	NS
Size of endotracheal tube (mm)	4.5 [4.0–5.0]	4.0 [3.5–5.0]	NS
Total dosage of fentanyl (μg/kg)	4.5 [0.0–6.1]	8.0 [5.4–10.7]	<0.01*

Age and total dosage of fentanyl are expressed as median [interquartile range]

Height and body weight are expressed as mean ± standard error

Size of endotracheal tube is expressed as median (minimum–maximum) of the internal diameter

* $P < 0.05$ is considered significant; *NS* not significant

Methods

The study was approved by the Shizuoka Children's Hospital Institutional Review Board, and requirement for written informed consent was waived by the Institutional Review Board because of the retrospective nature of the study. All patient records/information were anonymized and de-identified prior to analysis. The study used a retrospective cohort design at a single pediatric hospital, involving 199 children aged 1–3 years, who underwent palatoplasty in the Department of Plastic Surgery between January 2002 and July 2012. All of the surgical procedures were performed either by a single attending plastic surgeon or by plastic surgery fellows directly supervised by the attending plastic surgeon. The procedure comprised a push-back (PB) palatoplasty and intravelar veloplasty (IVV), during which the Dingman mouth gag was relaxed every 60 min (Table 1). The hospital's standard anesthetic records and nursing records were retrospectively reviewed.

Throughout the study period, there were no major changes in the anesthetic methods and recording rules. All patients received general anesthesia which was induced with sevoflurane in oxygen, except for a case where inhalation anesthesia was contraindicated. Propofol, fentanyl, and neuromuscular blockade, rocuronium or vecuronium were used to facilitate tracheal intubation as required. Maintenance of anesthesia was achieved with sevoflurane and propofol in an oxygen and air mixture. Intraoperative analgesia was provided by using fentanyl 1–2 μg/kg boluses, remifentanil infusion at the rate of 0.1–0.5 μg/kg/min, ketamine, and/or nitrous oxide. If necessary, neuromuscular blockade was antagonized with neostigmine and atropine at the end of anesthesia. Extubation in the OR was performed once patients recovered adequate spontaneous respiration and consciousness. After close observation in the recovery room, patients returned to the general ward. Patients who were extubated in the PICU were transferred to the PICU with an endotracheal tube in place after surgery. Extubation was performed in the PICU after complete hemostasis was achieved and consciousness was recovered; the patients were then returned to the general ward after overnight observation of their respiratory status in the PICU.

The items examined were (1) patient background, including age at the time of surgery, gender, height, weight, disease type, surgical method, presence of congenital deformities potentially causing airway/respiratory system complications, and the presence of a difficult airway (modified Cormack−Lehane grade IIb or higher [10]); (2) the time frames related to the surgery, including operation time, time under anesthesia, time from the end of surgery to discharge from the OR, time from the end of surgery to extubation, and days from the end of surgery to hospital discharge; and (3) the presence of postoperative complications. Comparisons were made between the two groups of patients according to the location where the extubation was performed (Group A, OR; Group B, PICU). Postoperative complications were defined as any airway/respiratory system-related adverse event that occurred up to 24 h after extubation and required intervention or special observation. Postoperative complications were classified as major or minor depending on the extent of intervention required. Minor complications included requiring observation only, suctioning the airway, increase of oxygen flow, use of a nebulizer/inhaler containing medication such as epinephrine, or temporal airway resuscitation by manual ventilator support. Major complications included requiring re-intubation and mechanical ventilator support.

Statistical analyses were performed using JMP (version 9.0; SAS Institute, Cary, NC, USA) and R (R Development Core Team [2010], R Foundation for Statistical Computing, Vienna, Austria; http://www.R-project.org). Statistical significance was set at $P < 0.05$. Height and weight were expressed as means ± standard errors and were analyzed with Welch's t test. Age, total fentanyl dose, operation time, time under anesthesia, time from the end of surgery to discharge from the OR, time from the end of surgery to extubation, and days in hospital are expressed as median (interquartile range), and the Wilcoxon rank-sum test was performed. Chi-squared test and Fisher's exact test were used for univariate analyses. Finally, logistic regression analysis was used to adjust the effects of potential confounding factors to calculate the adjusted odds ratio for the incidence of postoperative complications in Group B versus those in Group A.

Table 2 Breakdown of congenital deformities

	N
Group A ($n = 6$)	
Pierre Robin sequence	2
22q11.2 deletion syndrome	1
Ring × chromosome	1
Other chromosomal abnormalities	2
Total	6
Group B ($n = 20$)	
Pierre Robin sequence	9
Trisomy 21	3
22q11.2 deletion syndrome	2
Apert syndrome	1
Opitz syndrome	1
Holoprosencephaly	1
Kabuki syndrome	1
Other	2
Total	20

Results

Patient background

Significant differences were not observed between the two groups regarding age at the time of surgery, gender, height, weight, disease type, surgical method, presence of difficult airways, and size of endotracheal tube used. The largest proportion of patients had an isolated cleft palate, followed by unilateral cleft lip and palate, bilateral cleft lip and palate, and submucous cleft palate. Among the patients, PB palatoplasty was the most frequently chosen surgical method, with IVV used for the remainder (Table 1). Group B, in comparison with Group A, involved significantly more patients with congenital deformities that could have led to airway/respiratory system complications, as well as a significantly higher mean total fentanyl dose. The breakdown of the congenital deformities is shown in Table 2. The Pierre Robin sequence was most common, accounting for 42 % (11/26) of the deformities.

Operative time frames

The operation time (Table 3) was significantly longer for patients in Group B; however, no significant difference was found in the total time under anesthesia between the two groups. The time from the end of surgery to discharge from the OR was significantly longer in Group A. Moreover, after leaving the OR, the patients in Group A generally underwent observation in the post-anesthetic recovery room, after which they returned to the general ward. The median time from the end of surgery to extubation was 12 min in Group A and 164 min in Group B. No difference was found between the groups regarding the duration of their post-surgical hospitalization.

Postoperative complications

Regardless of the presence of congenital deformities, there were significantly more postoperative complications (Table 4) in Group A than in Group B. There were significantly fewer complications in the PICU extubation group than in the OR extubation group, even after adjusting for age, presence of congenital deformities, and operative time (odds ratio 0.28; 95 % confidence interval 0.12–0.67; $P < 0.01$). Moreover, many of the complications in Group A had the potential to be classified as major complications, such as hypoxemia ($SpO_2 < 90$ %), sustained minor bleeding, airway obstructions caused by a swollen tongue, labored breathing, and bradycardia. Indeed, the proportion of patients in Group A that required re-intubation ($n = 6$) was significantly higher than in Group B ($P < 0.01$). In Group B, however, nine patients manifested inspiratory stridor or hoarseness, probably associated with intubation, all of which improved after a single inhalation of adrenaline (Table 5). Atelectasis occurred in one patient in Group B, which did not hinder extubation, and this patient recovered under close observation.

Discussion

The widely used palatoplasty method, first reported by Ganzer [11], is characterized by a setback of the palate. Wardill [12] and Kilner [13] subsequently modified the

Table 3 Comparison of operative time frames in the operation room extubation group (Group A) and the PICU extubation group (Group B)

	Group A ($n = 94$)	Group B ($n = 105$)	P value
Operation time (min)	143 [114–174]	155 [125–196]	0.04*
Anesthesia time (min)	220 [181–244]	215 [183–243]	NS
Time from the end of surgery to discharge from the operating room (min)	17 [13–24]	12 [10–16]	<0.01*
Time from the end of surgery to extubation (min)	12 [6–15]	164 [86–346]	<0.01*
Hospital stay (days)	13 [12, 13]	13 [12, 13]	NS

Data are expressed as medians [interquartile range]

* $P < 0.05$ is considered significant; *NS* not significant

Table 4 Comparison of postoperative complications in the operation room extubation group (Group A) and the PICU extubation group (Group B)

Postoperative complications							
Total				Patients with any congenital deformity			
Group A ($n = 94$)	Group B ($n = 105$)	P Value	OR (95 % CI)	Group A ($n = 6$)	Group B ($n = 20$)	P Value	OR (95 % CI)
22	10	<0.01*	0.34 (0.15–0.77)	4	2	0.01*	0.06 (0.01–0.53)

OR odds ratio, *CI* confidence interval

* $P < 0.05$ is considered significant

Table 5 Breakdown of the postoperative complications in the operating room extubation group (Group A) and the PICU extubation group (Group B)

Complications	n
Group A	
Minor	
Hypoxemia	17
Stridor, hoarseness	11
Respiratory distress	4
Bradycardia	1
Symptoms recorded:	
Continuous minor bleeding	6
Obstructive airway due to copious oral secretion	5
Lingual swelling	3
Major, requiring re-intubation and mechanical ventilation	6
Group B	
Minor	
Stridor, hoarseness	9
Atelectasis	1

original palatoplasty method, which, along with the concept of palate muscle reconstruction, has evolved into PB palatoplasty [14]. Additionally, a variety of other methods have been devised, including the Furlow method [15] and IVV [16, 17], but no single method has been determined to be superior to the others, with different institutions employing different styles. Regardless of the method, each one carries a high risk of postoperative complications, such as airway obstruction and swelling of the tongue or oral cavity mucosa. These complications have several causes, including extended pressure from the mouth gag that causes swelling of the tongue or oral cavity, major/minor bleeding or secretions caused by surgical manipulations, and anesthesia-related laryngeal swelling. To avoid airway obstruction and other serious adverse events [3, 6, 7], perioperative management is extremely important [18–22]. Taking both language acquisition and jaw development into consideration, palatoplasty is usually performed 12–18 months after birth, as was the case for the patients in this report. However, these young patients have a significant risk of upper airway obstruction, resulting from the presence of a large tongue occupying the oral cavity and an unduly flexible neck.

To minimize the risk of postoperative complications, we adopted a new postoperative management plan whereby extubation is performed in the PICU, after achieving hemostasis and recovery of consciousness. Antony and Sloan [18] reported that patients with congenital deformities, especially the Pierre Robin sequence, were in danger of experiencing perioperative airway obstruction [22–24]. For this reason, many institutions give special consideration to patients at high risk for complications, such as their postoperative management in the PICU. In the present study, there were significantly more postoperative complications among the patients with congenital deformities in Group A than in Group B (Table 4). Moreover, there was also significantly more postoperative complications among those without congenital deformities in the OR extubation group. Accordingly, special postoperative attention should be given to those patients regardless of whether they have congenital deformities. Regarding the complications (Table 5), we consider that the good outcomes in the patient group in which extubation was delayed (Group B) may be explained by the ability to control postoperative bleeding and confirm complete hemostasis, and to achieve an adequate arousal reaction by securing the time after surgery. The accuracy of the evaluation of such hemostasis and arousal reaction was improved by establishing a reliable monitoring system. Therefore, the time from the end of surgery to extubation (Table 3) could be the most important outcome in terms of reducing postoperative complications, particularly airway obstruction. If a PICU bed is not available or if extubation is to occur in the OR, the patient should be carefully evaluated for hemostasis and recovery of consciousness, and all other extubation criteria must be strictly followed. Moreover, on examining the severity of the complications, many complications in Group A were serious, with six patients requiring re-intubation (Table 5). Fortunately, none of the patients in either group developed neurological sequelae, but practitioners should always be aware of the risk of these types of severe complications.

The operative time was statistically longer for the patients in Group B, but this increase was clinically insignificant (Table 3). Patients in Group A had longer stays in the OR and were closely observed in the recovery room; therefore, more time was spent observing these patients before they returned to the general ward. By contrast, the patients in Group B were quickly transferred to the PICU after surgery, where their airway and respiration could be closely monitored before and after extubation. This postoperative management plan is also considered to be advantageous from the standpoint of efficient use of the OR. The median time to extubation for the patients in Group B was 164 min, with extubation usually being performed on the same day as PICU admission. If patients could not be extubated on the same day because of inadequate control of continuous minor bleeding from their oral cavity, they were extubated on the following day. Ohara et al. [2] reported a mean post-surgical intubation time of 1.36 days, with a postoperative management plan similar to that used in our Group B patients. In their study, postoperative atelectasis was observed in three of 64 patients (4.7 %). The complications relating to prolonged mechanical ventilation were minimized by the immediate evaluation of extubation readiness after PICU admission. In this study, there was no difference in the length of hospital stay between the two groups of patients.

The present study has important limitations. First, this is a single-center retrospective study. Multicenter data, obtained under a well-structured prospective design, would provide more information with which to evaluate the advantage of this postoperative management plan. Second, the fact that all of the surgeries were performed, or supervised, by the same surgeon may have eliminated any possible confounding factors, but the involvement of multiple surgeons may result in different outcomes. Third, the anesthetic technique and extubation procedure were not protocolized. During the study period, there were no major changes in the practice of the anesthetic methods or recording rules. However, the possibility that any confounder other than extubation strategy may exist cannot be excluded. Fourth, the type of endotracheal tube and the presence or absence of a cuff was not examined. Fifth, cost-effectiveness was not investigated; however, because the daily cost of intensive care in Japan is not as high as in some countries, e.g., the United States, we believe that our postoperative strategy would provide economic benefit, considering the reduction in postoperative complications. In addition, there is no independent post-anesthesia care unit (PACU) that has medical attendants in our hospital. In medical facilities that have a PACU with resident medical attendants, the delayed extubation strategy described in this study is performed in the PACU, which may result in safer postoperative care. Moreover, at a facility with an independent PACU and where adequate staffing could be secured, the present study could have compared patients who were extubated in the OR and then observed in an attended PACU with patients extubated in the OR and then observed in the PICU. Finally, regardless of the presence or absence of congenital deformities, postoperative complications were significantly more common among patients extubated in the OR in our study. However, it is possible that there were unidentified factors that increased the risk of postoperative complications, even in patients without congenital deformities. If these risk factors could be elucidated in further studies, a selective delayed extubation strategy that maintains medical safety may become possible.

In conclusion, the patients transferred to the PICU after palatoplasty, with an endotracheal tube in place, exhibited a significantly lower incidence of postoperative complications, regardless of the presence of congenital deformities. Moreover, the severity of the complications was also lower in the PICU extubation group. This management plan may offer potential benefit from the standpoint of postoperative safety and should be further examined through randomized comparative trials.

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study and maintained the initiative in terms of the post-surgical safety management.

Compliance with ethical standards

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Conflict of interest The authors declare no conflicts of interest.

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