

ORIGINAL ARTICLE

Surgical Complications in 1408 Primary Cleft Palate Repairs Operated at a Single Center in Guwahati, Assam, India

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Objective: To analyze surgical complications after primary cleft palate repair in a setting with limited resources.

Patients and Design: A total of 1608 consecutive cleft palate repairs with 1408 follow-ups, operated upon between 2011 and 2013, were reviewed retrospectively through medical records. Patients were 10 months to 50 years old at the time of surgery, with a median age of 9 years.

Setting: Guwahati Comprehensive Cleft Care Center, Guwahati, India.

Intervention: Primary cleft palate repair.

Main Outcome Measures: Postoperative complications in terms of necrosis, dehiscence, fistula, infection, and “hanging palate” were assessed, as was perioperative bleeding. Logistic regression was used with complication (yes/no) as the binary dependent variable and with age, cleft type, and surgeon (visiting/long-term) as covariates.

Results: The overall incidence of postoperative complications was 16.9% with a fistula rate of 13.6%. The incidence of perioperative bleeding was 1.8%. Logistic regression analysis identified cleft severity ($P \leq .001$) and visiting surgeon ($P \leq .01$) as factors related to the incidence of postoperative complications. Age at surgery was related to both the incidence of postoperative complications ($P \leq .001$) and perioperative bleeding ($P < .05$).

Conclusion: Due to increased risks of surgical complications, older patients with complete clefts should only be operated upon after careful consideration. In addition, these patients should be assigned to surgeons experienced with this cleft type.

KEY WORDS: *bleeding, cleft palate, fistulas, late palate repair, outcomes*

The incidence of fistulas and surgical complications after primary cleft palate repair is well documented in the literature (Cohen et al., 1991; Phua and Chalain, 2008; Murthy et al., 2009; Sullivan et al., 2009; Landheer et al., 2010; Lu et al., 2010; Becker and Hansson, 2013; Jackson et al., 2013). However, even though most cleft patients are born in the developing part of the world (World Health Organization, 2000; Haub et al., 2013), most reports come from Western institutes. It is likely that these studies do not represent a setup where hygiene conditions are suboptimal, nasoalveolar molding is unavailable, and patients present at

all ages. Although some reports exist that are from resource-challenged settings covering this subject, the series are often small and follow-up rates are not always accounted for (Lambadusuriya et al., 1988; Morioka et al., 2007; Abdurrazaq et al., 2013). The lack of follow-ups is a particular challenge in most developing settings. This is especially apparent at surgical missions, but even in a center-based setup, follow-up rates can be disappointing (Maine et al., 2012; Rossell-Perry et al., 2013). Missed daily wages, traveling time, and costs may be hurdles too big to overcome if the incentive to return for follow-up is small or unclear to the patient (Schwarz and Bhai Khadka, 2004; Adeyemo et al., 2009).

At our center, around 2000 cleft patients are operated upon each year. Encouraging patients to return for checkup is highly emphasized. Patients' traveling expenses are reimbursed, and follow-up camps are conducted in areas where patients have less tendency to return for postoperative evaluation. The large volume of patients and the relatively high follow-up rate gives us a unique opportunity to investigate clinical outcomes in this type of setting. In this study we report on the surgical complications after 1608 consecutive primary palate repairs with a follow-up rate of 87.6%. To our knowledge, this is the largest series of its kind.

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TABLE 1 Background of 1608 Consecutive Primary Cleft Palate Repairs

Characteristic	Data
Age	Mean = 10.4 y Median = 9 y Range = 10 mo–50 y
Sex	Male: 841 (52.3%) Female: 767 (47.7%)
Diagnosis	Veau 1: 183 (11.4%) Veau 2: 474 (29.5%) Veau 3: 770 (47.9%) Veau 4: 181 (11.3%)
Surgeon	Permanent: 1292 (80.3%) Visiting: 316 (19.7%)
Follow-up	87.60%

PATIENTS AND METHODS

All patients undergoing primary palate repair between February 2011 and October 2013 at Guwahati Comprehensive Cleft Care Center in Guwahati, India, were retrospectively reviewed in the study. The background data of the patients and information regarding follow-up and complications were collected from medical records and are listed in Table 1.

Of 1608 consecutive primary palate repairs, 1258 (78.2%) patients returned for early follow-up (<4 weeks), 728 (45.3%) returned for intermediate follow-up (1 to 4 months), and 498 (31%) returned for late follow-up (>4 months). There were 200 (12.4%) patients who did not come back for any follow-up, leaving 1408 (87.6%) cases to be evaluated for postoperative complications. All 1608 patients were reviewed for perioperative bleeding that required blood-transfusion or a return to the operating room.

Clefts were classified according to the Veau classification (Table 2). Submucous clefts were regarded as Veau 1. Surgeons were labeled as either visitors or long-term staff (>6 months of service at the center). The visitors were either Operation Smile-credentialed surgeons or fellows under supervision according to Operation Smile guidelines (Abenavoli, 2005). Most of the credentialed surgeons operated on clefts regularly at home or had a long mission history. The majority of the patients were operated upon with the Bardach two-flap technique with intravelar veloplasty. The patients typically received a single intraoperative dose of cefuroxime 30 mg/kg and postoperative oral amoxicillin, 15 mg/kg three times a day for 5 days. At the time of discharge, patients received written instructions including pictographs regarding postoperative care.

TABLE 2 Veau Classification for Cleft Palates

Class	Extent of Cleft
1	Soft palate only
2	Hard and soft palate
3	Unilateral cleft lip and palate
4	Bilateral cleft lip and palate

TABLE 3 Incidence of Complications After 1608 Primary Palate Repairs With 1408 Follow-Ups

Type of Complication	Incidence, % (Rate)
Fistula	13.6 (191/1408)
Partial dehiscence	3.8 (54/1408)
Complete dehiscence	0.2 (3/1408)
Partial flap necrosis	1.3 (18/1408)
Complete flap necrosis	0.8 (11/1408)
Hanging palate	0.9 (12/1408)
Infection	0.2 (3/1408)
Perioperative bleeding*	1.8 (29/1608)

* Requiring transfusion (one patient) or return to the operating room for surgical ligation with cauterization (28 patients).

At the time of follow-up, complications in terms of dehiscence, necrosis, infection, fistula, and “hanging palate” were recorded in a standardized manner by a cleft surgeon. In keeping with previous fistula studies, postoperative fistulas were recorded when a breakdown occurred along the suture line posterior to the incisive foramen (Cohen et al., 1991; Emory et al., 1997; Phua and Chalain, 2008; Becker and Hansson, 2013). Thus, alveolar fistulas in Veau 3 and Veau 4 clefts were not regarded as complications.

Ethics

This study was reviewed and approved by Operation Smile India Institutional Ethics Committee.

Statistical Analyses

Statistical analyses were performed using IBM SPSS Version 21 for Windows (IBM Corp., Armonk, NY). Odds ratios with 95% confidence intervals were calculated using logistic regression models. For the 1408 patients who returned for follow-up, postoperative complication (yes/no) was used as the binary dependent variable. Cleft type (ordinal value, Veau 1 to 4), age (as continuous numeric variable), and surgeon (visiting or long-term) were used as covariates. A similar regression analysis was conducted with perioperative bleeding (yes/no) as the dependent variable. However, in this model all 1608 patients were included.

P values of <.05 were considered significant.

RESULTS

Of the 1408 patients who returned for follow-up, 237 (16.9%) patients suffered one or more postoperative surgical complications (Table 3). The overall fistula rate was 13.6%. When logistic regression was used, cleft type, age at surgery, and surgeon (visiting/permanent) contributed significantly to predict the incidence of postoperative complications (Table 4). According to this calculation, the odds of having one or more complications increased by an average of 3.1% per year. However, the risk of complications did not increase in a linear fashion, as can be seen

TABLE 4 Logistic Regression Analysis of Factors Related to Postoperative Complications After Primary Palate Repair

Covariate	OR (95% CI)*	P Value
Cleft type†	1.516 (1.269–1.811)	<.001
Age	1.028 (1.010–1.045)	<.01
Surgeon‡	1.599 (1.154–2.214)	<.01

* OR = odds ratio; CI = confidence interval.

† According to Veau classification.

‡ Visiting versus long-term (>6 months of service at the center).

when the patients were divided into different age groups (Fig. 1; Table 5). The complication rates according to cleft type and surgeon can be seen in Figures 2 and 3 and Table 5.

The overall incidence of perioperative bleeding was 1.8% in this series. The logistic regression analysis singled out age as the only covariate linked to this type of complication (odds ratio = 1.052, 95% confidence interval, 1.012 to 1.093, $P < .05$). Thus, the odds of perioperative bleeding increased by an average of 5.2% per year. The incidence of perioperative bleeding according to age group can be seen in Figure 4.

DISCUSSION

Recent articles from Western hospitals report of fistula rates ranging from 2.4% to 21% (Phua and Chalain, 2008; Murthy et al., 2009; Sullivan et al., 2009; Landheer et al., 2010; Lu et al., 2010; Becker and Hansson, 2013; Jackson et al., 2013). However, these series include either a limited number of patients or data from operations that occurred over several decades, which in turn might skew the results or lead to indefinite conclusions. Furthermore, these complication rates might not be generalizable in a wider perspective considering that most cleft patients are born in regions where resources and access to hygienic conditions are limited. On the other hand, studies from resource-challenged areas are less numerous, and series of patients are often markedly limited by low follow-up rates. As a consequence, results often vary and reported fistula rates range from 0% to 57% (Lambadusuriya et al., 1988; Morioka et al., 2007; Pham and Tollefson, 2007; Maine et al., 2012; Abdurrazaq et al., 2013; Rossell-Perry et al., 2013).

Our sample consisted of 1608 patients with an 87.6% follow-up rate. The incidence of postoperative complications was 16.9% with a fistula rate of 13.6%. Our logistic regression analysis identified cleft severity, age at surgery, and visiting surgeons as factors related to the incidence of postoperative complications. Several previous studies have also found a relationship between the extent of the cleft and the rate of postoperative complications (Cohen et al., 1991; Phua and Chalain, 2008; Landheer et al., 2010; Maine et al., 2012). This is not surprising, given that wide complete clefts require more extensive surgery or closure under greater tension compared with incomplete clefts.

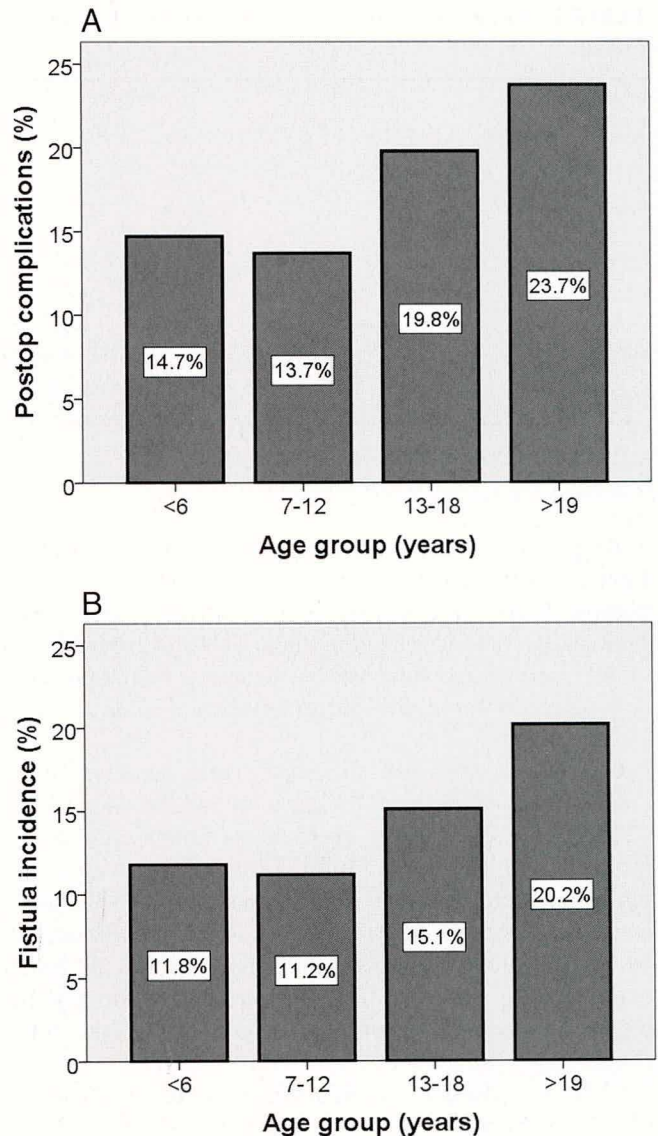


FIGURE 1 Incidence of surgical complications after 1408 late palate repairs depending on age at surgery. A: The overall complication rate. B: The rate of fistulas.

Some previous studies have not been able to correlate age with the incidence of fistulas (Cohen et al., 1991; Maine et al., 2012). However, in these studies patients have been operated upon at ages younger than 2 to 3 years. Our results show that the risk of postoperative complications and fistulas indeed is significantly higher in older patients, but our data indicate that complication rates are fairly consistent until the early adolescent years. We also found that the risk of perioperative bleeding increased significantly with age, but this increase followed more of a linear pattern. Taken together, the adult patients had an almost double risk of postoperative fistulas and a close to eightfold risk of perioperative hemorrhage compared with children 6 years or younger. It should be emphasized, therefore, that older cleft palate patients should be operated on only after careful consideration. Previous authors have linked high

TABLE 5 Complication Rates After 1408 Cleft Palate Repairs, Depending on Age, Cleft Type, and Operating Surgeon

Cleft Type	Surgeon	Age Groups			
		<6 y, Rate (%)	7–12 y, Rate (%)	13–18 y, Rate (%)	>19 y, Rate (%)
Veau 1–2	Long-term*	13/206 (6.3)	9/145 (6.2)	12/105 (11.4)	9/82 (11.0)
	Visiting	7/41 (17.1)	5/31 (16.1)	7/26 (26.9)	3/21 (14.3)
Veau 3–4	Long-term*	48/313 (15.3)	27/187 (14.4)	28/139 (20.1)	26/115 (22.6)
	Visiting	13/74 (17.6)	8/50 (16.0)	8/45 (17.8)	14/28 (50.0)

* >6 months of service at the center.

complication rates among older cleft palate patients with increased cleft width, vertically displaced palatal shelves, and tissue fibrosis (Lambadusuriya et al., 1988; Morioka et al., 2007). Where our center is located, the use of chewing tobacco and betel nut is a common habit that may further increase the risks among older patients due to oral inflammation and fibrosis (Prasad et al., 2014).

Previous research has also shown that speech outcomes in older patients are disappointing, especially in patients with complete clefts. In the Sri Lanka project, where 32 adolescents (10 to 19 years) and 24 adults (>19 years) were evaluated after primary palate repair, it was concluded that patients with complete clefts would not improve their speech if the repair was performed after the age of 13 years (Mars et al., 2008). It can be pointed out, therefore, that older patients with complete clefts have a high risk of complications after primary palate repair, and at the same time, the benefits may be very limited. Our results also indicate that if these operations are undertaken, the patients should be assigned to a surgeon with experience with this type of cleft panorama. Visiting surgeons had a higher complication rate in general, but this trend was especially apparent in the more complex cases. Of the adult patients with complete clefts (Veau 3 to 4) who were operated upon by a visiting surgeon, 50% suffered from one or more complications. This can be compared with a 22.6%

complication rate among the same type of patients who were operated upon by the center's long-term staff. At this point, it is unclear which exact factors contributed to this outcome. However, it is clear that the patients in a less developed environment can differ greatly from those in a Western setting, where they are treated with presurgical molding and operated upon at standard ages. As a consequence, the clefts may be wider and less aligned than one is used to seeing, which may require adjustments of standard surgical technique or wound closure under greater tension. It was previously found that both the experience of the surgeon and the familiarity with the working environment can have a great impact on the complication rate. It has been shown that less experienced surgeons can have higher complication rates but also that complication rates vary among surgeons in general (Cohen et al., 1991; Shaw et al., 1992; Emory et al., 1997). Two studies have also reported that an unfamiliar working environment can affect the outcomes. Rossell-Perry (Rossell-Perry et al., 2013) reviewed his complications after working both at a center and on outreach missions in Peru and found that fistula rates increased from 3.8% to 25% and hemorrhages increased from 2.3% to 17.1% in the mission setup. In line with this, Maine et al. (2012) found that both North American and local surgeons had fistula rates over 50%

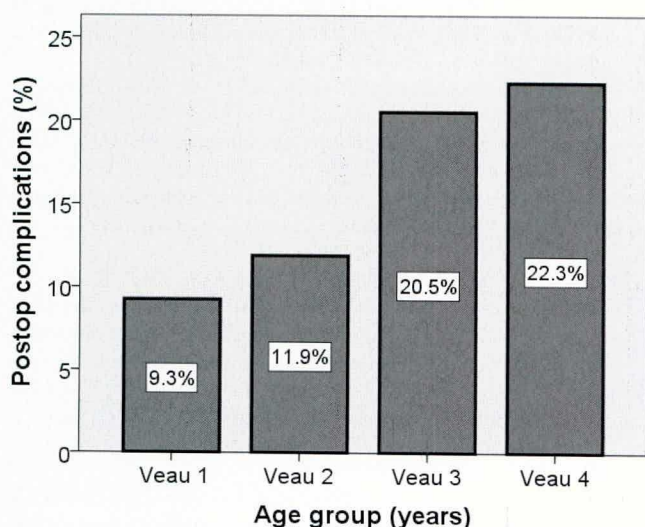


FIGURE 2 Incidence of surgical complications after 1408 late palate repairs, according to cleft type.

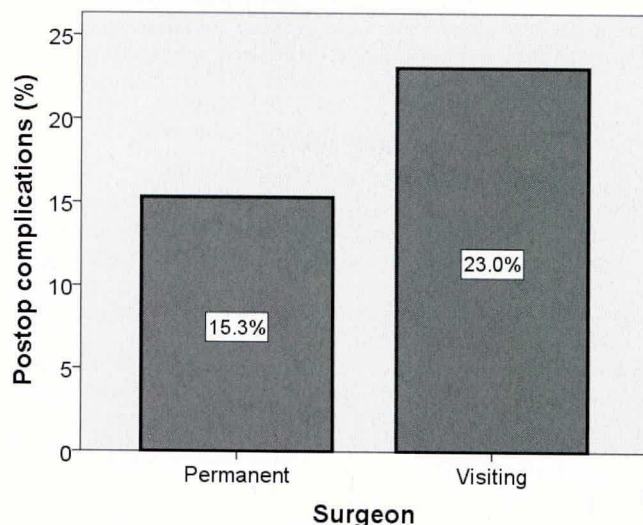


FIGURE 3 Incidence of surgical complications after 1408 late palate repairs depending on whether the surgeon was a visitor or part of the permanent staff for more than 6 months.

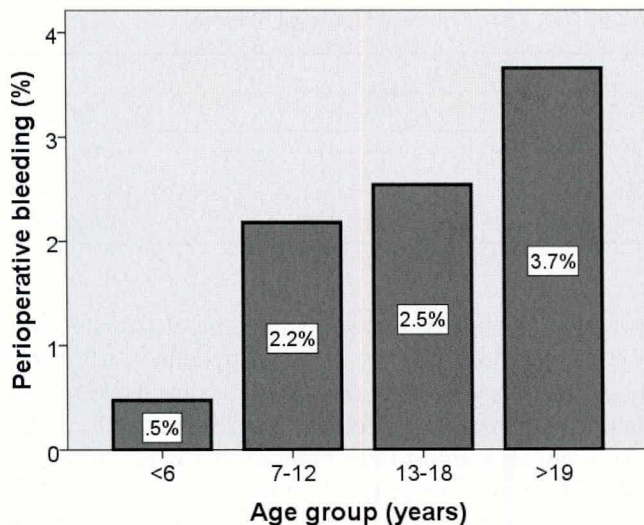


FIGURE 4 Incidence of perioperative bleeding that required transfusion or return to the operating room, according to age group.

during a mission in Ecuador. It was reported that this rate was 10 times higher than what some of the surgeons experienced in their private clinics.

In conclusion, our analysis found that cleft severity and visiting surgeons are factors related to the incidence of postoperative complications and that age at surgery is related to both the incidence of postoperative complications and perioperative bleeding. Therefore, older patients with complete clefts should only be operated on after careful consideration. In addition, these cases should be assigned to surgeons with experience with this cleft type.

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