Complications of Primary Palatoplasty: A Twenty-One-Year Review

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The complications of 196 patients who underwent primary palatoplasties at North Carolina Memorial Hospital between 1963 and 1983 were reviewed. The von Langenbeck technique was utilized in 50 percent of the patients, the Wardill-Kilner technique in 45 percent, and the Dorrance technique in 5 percent. Intravelar veloplasties were performed in 34 percent of the patients. The incidence of postoperative complications was: deaths, 0 percent; malignant hyperthermia, 0 percent; aborted procedures, 0.5 percent; feeding difficulties, 0.5 percent; aspiration, 0.5 percent; reexploration for bleeding, 0.5 percent; pneumonia, 1 percent; upper respiratory tract infections, 2 percent; postoperative airway difficulties, 3 percent; oropharyngeal infections, 4 percent; and otitis media, 10 percent. Later evaluations demonstrated problems with otitis media in 17 percent of the patients and fistulas in 6 percent. An additional palatal operation of some type was later required in 22 percent of the patients, with 18 percent of the patients requiring a pharyngeal flap. Intravelar veloplasties were associated with a decreased incidence of secondary pharyngeal flaps but also an increased transfusion requirement. The Wardill-Kilner technique was associated with a higher incidence of postoperative fistulas, and the use of perioperative antibiotics was associated with fewer postoperative fistulas.

KEY WORDS: *cleft palate, palatoplasty, complications*

Cleft palate repair is a commonly performed surgical procedure with a low incidence of surgical complications. Several authors including Musgrave and Bremner (1960) and Wray et al (1979) have analyzed the complications associated with cleft palate repairs. The purpose of this study was to review a more recent series of primary palatoplasties and to assess the complications incurred by these patients. Multiple factors were evaluated to determine whether or not they contributed to a higher or lower incidence of complications. These factors were age, sex, an associated cleft lip or syndrome, a preoperative history of otitis media, preoperative weight, preoperative hematocrit, tympanostomy tube placement, perioperative antibiotics, intrapalatal injection of epinephrine, the type of palatoplasty, intraoperative blood, and intravelar veloplasty. The year of surgery was evaluated as a separate variable to examine trends in treatment methods and complications that developed over the 21 years. It was hoped that this analysis would suggest methods for improving future results.

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METHODS

The medical records of patients coded as having undergone palatoplasty at North Carolina Memorial Hospital between 1963 and 1983 were evaluated retrospectively. The charts of 11 patients whose palates were repaired at this hospital during this period could not be retrieved by

the medical record department, and these patients were excluded from the study. Patients who had only secondary palatal procedures at this hospital were excluded from this analysis, as were patients treated with primary pharyngeal flaps. The data in this study were derived from the analysis of the charts of the remaining 196 patients who had a primary palatoplasty during this 21-year period. Each of the complications as well as the need for pharyngeal flaps or transfusions were evaluated in regard to all of the factors mentioned in the introduction. Comparisons involving the year of operation considered the 21-year period in terms of three 7-year segments. The 7-year breakpoint was chosen arbitrarily although different surgeons were involved for the most part in the three different periods. Ninety-eight percent of the procedures during the last 7-year period were performed by the senior author (W.C.T.). For this analysis, hematocrits less than 30 percent and weights less than 10 kilograms were considered low. Blood loss data were acquired from the anesthesia record and were broken down into less than or greater than 30 ml for statistical analysis. The critical points utilized for designating hematocrits, weights, and blood loss as low were arbitrarily designated. However, it was felt that these points were appropriate for this primarily 1-year-old patient population. Most data were available in all charts. Missing data points were left out of the analysis. Comparisons were performed utilizing a Chi square test with $p < 0.05$ being considered significant.

RESULTS

The breakdown of the patients studied according to sex, race, and the type of cleft is shown in Table 1. Four of the patients with isolated cleft palates had only submucous palatal clefts. Sixty-one (64 percent) of the 96 patients with cleft lips and cleft palates were male, and 35 (36 percent) were female. Of the patients with isolated cleft palates, 42 (42 percent) were male, and 58 (58 percent) were female. All of the patients with cleft lips underwent repair of the cleft lip at some point prior to undergoing palatoplasty. Ten patients (5 percent) had a cleft palate as a part of a syndrome.

TABLE 1 Patient Population

Variables	*Patients (N)*	*Percentage of Total No. of Patients (%)*
Sex		
Male	103	53
Female	93	47
Race		
White	153	78
Black	40	20
American Indian	3	2
Type of Cleft*		
CP alone	100	51
CP with unilateral CL	54	28
CP with bilateral CL	42	21

* CP = Cleft Palate
CL = Cleft Lip

TABLE 2 Preoperative Characteristics of the Patients

Median age	18 mos. (Range: 7 mo–36 yr)
Median weight	10.1 kg (Range: 5.5–85.9 kg)
Mean hematocrit	36% (Range: 28–53%)
Mean WBC count	10,000 (Range: 2,300–19,800)
Preoperative history of otitis media	106 (54%)
Preoperative tympanostomy tube placement	16 (8%)

The characteristics of the patients at the time of palatoplasty are shown in Table 2. One hundred sixty-two (82 percent) of the patients were operated on during their second year of life, and only two patients were less than 1 year of age at the time of operation. The patient operated upon at the age of 36 presented with an unrepaired cleft at that age. Ninety-eight percent of the patients had hematocrits greater than 30 at the time of operation. None of the patients was acutely ill when operated upon.

The operations were performed by six different surgeons with four surgeons performing 95 percent of the procedures. During any given year, one surgeon generally performed the majority of the palatoplasties at this institution. The number of surgeons involved reflects changes in personnel that occurred during this 21-year period. The senior author performed more of the procedures (75) than any of the other surgeons and as mentioned, performed 98 percent of the palatoplasties during the last 7 years of the evaluation. The average number of palatoplasties performed during any given year was nine with a low of three in both 1963 and 1979 and a high of 17 in 1983. Seventy-one (36

TABLE 3 Characteristics of the Operations

Surgery Variables	*Patients (N)*	*Percentage of Total No. Patients Evaluated (%)*
Anesthesia		
General endotracheal	194	99.0
General via tracheostomy	1	0.5
Ether drip	1	0.5
Surgical technique		
von Langenbeck	98	50.0
Wardill-Kilner	87	45.0
Dorrance	11	5.0
Intravelar veloplasty	67	35.0
Tympanostomy tubes placed	30	15.0
Use of local epinephrine	123	63.0
Perioperative antibiotics	144	74.0

TABLE 4 Postoperative Complications of Palatoplasty at North Carolina Compared to Other Studies

	Incidence		
Complication	*North Carolina (%)*	*Musgrave and Bremner (1960) (%)*	*Wray et al (1979) (%)*
Death	0.0	0.26	0.0
Malignant hyperthermia	0.0	0.0	0.0
Aborted procedures	0.5	0.26	0.0
Reexploration for bleeding	0.5	0.0	2.1
Aspiration	0.5	0.0	0.0
Feeding difficulties	0.5	0.13	19.0
Pneumonia	1.0	0.26	0.0
URI	2.0	2.5	15.0
Airway difficulties	3.0	0.0	8.5
Oropharyngeal infections	4.0	0.52	0.0
Otitis media	10.0	0.77	8.0

percent) of the procedures were performed during the first 7 years of the study, 64 (33 percent) during the second 7 years, and 61 (31 percent) during the most recent 7 years. The characteristics of the surgical procedures are outlined in Table 3. One patient underwent a lip revision concurrently with the palatoplasty. The complications of the palatoplasty procedures are summarized in Table 4. Similar data from a review of 780 palatoplasty patients by Musgrave and Bremner (1960) and a smaller series of 47 patients by Wray et al are provided for comparison. One-third of the patients in the series of Wray et al (1960) were treated with a primary pharyngeal flap, which may explain why certain complications like bleeding, feeding difficulties, and respiratory tract problems occurred more frequently in that series of patients. Problems noted after the immediate postoperative period as well as later surgical procedures are enumerated in Table 5. Five of the 11 patients with fistulas subsequently underwent a secondary surgical procedure of some kind.

As mentioned, a wide variety of variables was considered as to whether they were associated with a higher incidence of any of the complications. None of the variables considered impacted upon the incidence of postoperative airway difficulties, respiratory tract complications or oropharyngeal infections. A low preoperative weight and a preoperative history of otitis media were associated with an increased incidence of early postoperative otitis media, but the use of epinephrine and the performance of an intravelar veloplasty (Table 6) were associated with a decreased incidence of this problem.

The median intraoperative blood loss was 30 ml. The only patient with a blood loss greater than 200 ml was the 36-year old patient. Eleven (6 percent) of the patients required transfusions in the postoperative period, but only one patient required surgical exploration for postoperative bleeding. There were no standard guidelines for determining the need for transfusion, however. The patient requiring reexploration was a 16-month old patient who lost 105 ml of blood at operation and then rebled postoperatively. Epinephrine was utilized in many cases in the hope of diminishing the likelihood of bleeding complications, but its use was not significantly

TABLE 5 Problems Noted After the Immediate Postoperative Period and Later Surgical Procedures

Problems and Later Surgical Procedures	*Patients (N)*	*Percentage of Total Patients Evaluated (%)*
Fistulas	11	6.0
Otitis media	33	17.0
Secondary operations		
Pharyngeal flaps	36	18.0
Palatal revisions	5	3.0
Fistula closure	2	1.0
Alveolar grafting	4	2.0
Vestibuloplasty	1	0.5

TABLE 6 Factors Significantly Associated with Intravelar Veloplasty

		Transfusions		
		No	Yes	Totals
Intravelar veloplasty	No	126	3	129
	Yes	59	8	67 $p<0.01$
	Totals	185	11	196
		Postoperative Otitis Media		
		No	Yes	Totals
Intravelar veloplasty	No	111	18	129
	Yes	65	2	67 $p<0.05$
	Totals	176	20	196
		Pharyngeal Flap		
		No	Yes	Totals
Intravelar veloplasty	No	99	30	129
	Yes	61	6	67 $p<0.05$
	Totals	160	36	196

associated with a decreased incidence of transfusions. The one patient that required reexploration was injected preoperatively with epinephrine. Intravelar veloplasty seemed to contribute to a higher rate of transfusions as shown in Table 6. The one patient who was reexplored for bleeding had an intravelar veloplasty. None of the other factors were significantly associated with an increased need for transfusions.

Fistulas developed more frequently after Wardill-Kilner palatoplasties and less frequently in patients who received perioperative antibiotics as shown in Table 7. None of the other factors considered was associated with changes in the incidence of fistulas. Thirty-three (17 percent) of the patients were noted to have continuing problems with otitis media. Of the variables considered, late difficulties with otitis media were only significantly associated with a preoperative history of otitis media. Late problems with otitis media were not incriminated in relationship to postoperative fistulas or the need for secondary surgical procedures.

At this institution, alveolar bone grafting is generally performed when patients requiring it reach 9 years of age. The small number of secondary bone grafting procedures and vestibuloplasties reflect the limited number of patients with residual alveolar defects who were followed until the age of 9 years. Every effort is made to maintain follow-up of cleft palate patients, but some of the patients either move to other parts of the country or simply stop returning to the medical center of their own volition.

The presence of a cleft lip was associated with a greater need for some type of secondary procedure other than a pharyngeal flap. Intravelar veloplasty seemed to contribute to a decreased requirement for secondary pharyngeal flaps as shown in Table 6. None of the other factors influenced the probability of pharyngeal flaps or secondary procedures being performed.

Several trends developed over the 21-year period of the study. The majority (95 percent) of the Wardill-Kilner procedures and all of the Dorrance procedures were performed in the first 14 years of the study period. The von Langenbeck repair was used almost exclusively during the last 7 years studied. The choice of procedure was made by the operating surgeon in each case. The trends noted in the type of repair utilized reflect differences of opinion among the various surgeons involved regarding the optimal technique for cleft palate repair. Fifty-three (79 percent) of the procedures incorporating intravelar veloplasty were performed after 1976 by one surgeon (W.C.T.). Epinephrine was utilized infrequently during the earlier time periods but was universally used during the last 7 years of the study. The vast majority (97 percent) of the patients operated upon during the most recent 7 years studied were treated with antibiotics perioperatively, whereas they were used irregularly in the previous time periods. The determinations of whether or not to perform an intravelar veloplasty and whether or not to use antibiotics or epinephrine were also made by the individual surgeons, and the noted trends, which were all statistically significant, reflect differences of opinion among the different surgeons involved. No transfusions were given during the first 7 years of the period studied. Intraoperative blood loss tended to be greater, and a significantly greater number of transfusions were required in the more recent time periods studied. As mentioned, there were no standard criteria for giving transfusions, and the trend toward more transfusions is at least partially due to an increased willingness and ability to give transfusions. Though only 4 percent of patients had tympanostomy tubes placed at some time prior to surgery in the first 7 years of the study, 55 percent of patients undergoing surgery during the most recent 7 years had tympanostomy tubes placed prior to or at the time of palatoplasty. This statistically significant trend toward using more

TABLE 7 Factors Significantly Associated with a Difference in the Incidence of Fistula Formation

		Perioperative antibiotics		
		No	Yes	Totals
Postoperative fistula	No	44	141	185
	Yes	8	3	11 $p<0.001$
	Totals	52	144	196

		Type of palatoplasty			
		von Langenbeck	Wardill-Kilner	Dorrance	Totals
Postoperative fistula	No	96	78	11	185
	Yes	2	9	0	11
	Totals	98	87	11	196
			$p<0.05$		

tympanostomy tubes reflects better surveillance of the ears because of an increasing concern on the part of the physicians involved regarding the problems that can result from repeated bouts of otitis media. The majority (65 percent) of the patients that developed postoperative otitis media were operated upon in the first 7 years of the study, and only one case of postoperative otitis media was reported during the last 7 years of the study. This trend, which was also significant, probably related to the increased utilization of tympanostomy tubes and closer attention preoperatively to the possibility of middle ear pathology.

Fistulas were not seen in the last 7 years studied. This significantly decreased incidence of fistulas could be a result of changes in surgical technique or any of the other factors noted to be changing. There was a trend toward a diminished need for secondary surgical procedures, including pharyngeal flaps, in more recent years. Only 13 percent of the patients operated upon in the last 7 years of the study required secondary pharyngeal flaps. This observation may be a result of changes in surgical technique or any of the other variables noted to be changing over the period studied.

Discussion

Cleft palates are repaired in order to provide a more competent mechanism for speech. All other indications for palate repair are secondary. An ideal method of repair would provide velopharyngeal adequacy with minimal operative morbidity and mortality and without interfering with maxillary growth. Several questions regarding the optimal operative management of cleft palates persist at this time. Some of the differences of opinion regarding optimal cleft palate management are reflected in the variety of methods utilized in this series.

The lack of mortality or malignant hyperthermia with any of the techniques utilized is gratifying and is somewhat similar to the findings of other studies (Musgrave and Bremner, 1960; Wray et al., 1979). Only 3 percent of the patients had a temporary airway problem. Median blood loss was acceptable, and transfusions were only needed in 6 percent of the patients. Postoperative airway problems and respiratory and oropharyngeal infections were rarely noted. This finding is consistent with the previous results of Musgrave and Bremner (1960). Wray et al (1979) noted more upper respiratory infections though some of his patients had pharyngeal flaps. Otitis media was noted in the immediate postoperative period in a higher percentage (10 percent) of cases than other authors have noted although it wasn't commonly noted in the last 7 years of the study. The 6 percent incidence of fistulas is relatively low and is similar to Musgrave and Bremner's (1960) 5 percent incidence. The lack of fistulas in the last 7 years studied is excellent. Twenty-one percent of the patients required either a pharyngeal flap or palatal revision because of velopharyngeal incompetence. This incidence is similar to that noted in other series of palatoplasties (Holtman et al, 1984; Witzel et al, 1979).

The variables that exist in this series of patients include some controllable and some uncontrollable factors. Uncontrollable factors include such things as sex, race, coexistent cleft lip or syndrome, and a history of otitis media. Sex and race were not significantly associated with any of the variables evaluated. A coexistent cleft lip was associated with a more frequent need for secondary procedures. This observation was expected in that procedures such as vestibuloplasties and alveolar bone grafts would only be performed on patients with coexistent cleft lips. Patients with a preoperative history of otitis media developed otitis media more frequently both in the immediate postoperative period and during later evaluation. Patients with an anatomical situation that predisposed to otitis media would be likely to develop the problem both preoperatively and postoperatively.

There are myriad factors that can be willfully manipulated in the management of patients with cleft palates. The optimal age for cleft palate repair is controversial. In this study, the age of the patient at the time of repair did not relate to the incidence of any postoperative complications, although very few patients were operated upon at an early age. Weight and to a lesser extent hematocrit are related to the age of the patient. A low preoperative weight was associated with an increased incidence of postoperative otitis media although the reason for this association is not clear. Age and weight were not otherwise associated with changes in the incidence of any of the other complications.

Three methods of palatoplasty were utilized in this study. The Wardill-Kilner method was associated with a higher incidence of fistulas. The increased incidence of fistulas may be a result of the Wardill-Kilner technique which results in three suture lines coming together at a single point. This point is inherently weak, possibly predisposing to breakdown and fistula formation in a higher proportion of patients. It is also possible that the patients selected to undergo Wardill-Kilner palatoplasties had larger anatomical defects. They might therefore have been more predisposed to the development of a fistula postoperatively. Confounding factors such as

the surgeon involved may also be critical. This study does not confirm the finding of Wray et al (1979) that a Wardill-Kilner type of palatoplasty is associated with a higher incidence of bleeding complications.

Epinephrine is felt by some to decrease the likelihood of bleeding complications (Dingman et al, 1949); others have suggested it may increase the incidence of infections (Tran et al, 1985). Neither bleeding nor infectious complications were common in this series, although the use of epinephrine was not significantly associated with changes in the incidence of either complication. The performance of an intravelar veloplasty was associated with an increased need for transfusions, but it resulted in a significantly diminished need for secondary pharyngeal flaps. Intravelar veloplasties are performed with the goal of improving palatal function and decreasing the incidence of postoperative velopharyngeal incompetence. The fact that intravelar veloplasties seem to contribute to a decreased need for secondary pharyngeal flaps bespeaks their utility. The cost of the added dissection may be increased blood loss. Both the use of epinephrine and intravelar veloplasties were associated with a diminished incidence of postoperative otitis media. Most of the episodes of postoperative otitis media were noted in the first 7 years of the study, and epinephrine and intravelar veloplasties were most frequently used during the last 7 years. Other factors associated with these two time periods may have contributed to this finding in that no other explanation is immediately available.

Perioperative antibiotics are frequently utilized in the hope of diminishing the incidence of postoperative infectious complications. The use of perioperative antibiotics with cleft palate repairs is controversial and the idea has both supporters (Jolleys and Savage, 1963; Duffy, 1966) and detractors (Marzoni and Kelly, 1983). Though the incidences of oropharyngeal infections and otitis media were not significantly modified in this study by the use of perioperative antibiotics, the decreased incidence of subsequent fistulas associated with their use may be a result of decreased bacterial contamination. No preoperative throat culture data were available to substantiate the need for antibiotics or to correlate with postoperative complications.

The results of this study would therefore suggest that Wardill-Kilner type repairs may be associated with a higher rate of postoperative fistula formation. Intravelar veloplasties appear to be desirable because of the decreased need for secondary pharyngeal flaps and a possibly diminished incidence of postoperative otitis media, even though the cost of the added procedure may be an increased need for postoperative transfusions. Perioperative antibiotics may be beneficial because of their association with a decreased incidence of postoperative fistula formation. Epinephrine appears to produce no obvious advantage or disadvantage other than a possible association with a diminished incidence of postoperative otitis media. Its use can be left to the surgeon's discretion. The data in this study do not allow conclusions as to the optimal timing of cleft palate repair, although the results from repairs performed for the most part in the second year of life appear reasonable.

The conclusions suggested by this study can only be made tentatively. Retrospective studies such as this one are limited by the possibility of inaccuracies in the hospital record. Problems treated by outside physicians may not be reported in the hospital chart. In addition, the variables were not controlled in a random fashion, and confounding variables may have influenced the findings of this study. The uncontrolled use of tympanostomy tubes, epinephrine, and perioperative antibiotics and the markedly increased utilization of all three during the most recently evaluated 7-year period makes conclusions regarding the benefits of their use less certain. Conclusions regarding Wardill-Kilner palatoplasties could be distorted since the majority of these procedures were performed in the earlier part of the period studied. As mentioned, patient selection factors may have also contributed to the less satisfactory results obtained with this method of palatoplasty.

Although the inclusion of an intravelar veloplasty seemed to decrease the need for secondary pharyngeal flaps, no speech data were available to accurately assess differences in velopharyngeal incompetence between the patients who received intravelar veloplasties and those who did not. A previous study from the University of North Carolina of a more limited sampling of patients has suggested that levator reconstruction is associated with better speech results, however (Dreyer and Trier, 1984). Alternatively, factors that did not appear to be statistically associated with better results may have appeared more valuable if their use had been randomized.

It can be concluded that palatoplasties are continuing to be performed with low morbidity and mortality rates. The vast majority of patients in this study was healthy and in the second year of life at the time of surgery, and these factors may contribute to a low rate of complications. The analysis of complications associated with palatoplasties encourages the use of intravelar veloplasties and perioperative antibiotics and suggests that the use of the Wardill-Kilner

method of repair may lead to more postoperative fistulas. Intrapalatal epinephrine may also be beneficial.

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