Effect of Modified Furlow Vs Two-Flap Technique on Eustachian Tube Function

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ABSTRACT

Background: One of the most common congenital defects of the face is cleft palate (CP). A middle ear issue nearly always affects children who have cleft palates. The way that palatoplasty is performed has a significant impact on how well middle ear function is restored after CP correction.

Objective: This study aimed to assess the significance of modified Furlow vs two-flaps technique on Eustachian tube (ET) dysfunction.

Patients and methods: Seventy two cleft palate patients were divided into 2 groups: Group1 included 42 patients done by modified Furlow Z-plasty operation. Group 2 included 30 patients done by two flaps palatoplasty. Pre- and post-operative ear evaluation done at 1, 3,6,12 months.

Results: Repair of cleft palate leading to direct improvement of ET dysfunction improvement ear function. Modified Furlow showed early improvement at 3 months post-operative of middle ear function (p value 0.004), but had no superiority after one year over two flaps Palato-plasty.

Conclusion: The two procedures showed significant effect as regards decreasing severity of ET function and middle ear affection. Thus, supporting conservative management of middle ear effusion instead of prophylactic tube insertion.

Keywords: Furlow vs two-flap technique, CP, ET.

INTRODUCTION

At one every 650 live births, Cleft Palate (CP) is among the most common congenital abnormalities. Normal maxillary development, no fistula formation, normal speech, normal ET function, and satisfactory aesthetic outcomes are the goals of cleft closure. The patients' and their families' ultimate objective being their psychological and social well-being [(1-2)]. It has been shown that newborns with CP virtually always have otitis media with effusion. Increased incidence of hearing loss due to middle ear disease [(3–5)].

The soft palate is tensed by the tensor and levator veli palatine muscles, which insert in it. As a result, the soft palate slides upward and backward. This leads to dilation of the ET and velopharyngeal closure [(6, 7)]. Language development is thought to be impacted by the conductive hearing loss that middle ear effusion generates when CP is left untreated. This hearing loss seem to improve with palatoplasty or the insertion of ventilation tubes, and it seems to linger until early adulthood [(1, 6, 8)].

Although several methods for palatal closure have been reported, the best surgical method is still unknown [(6)]. The method used in palato-plasty is a significant aspect that may have an impact on how well middle ear function is restored after CP treatment. Regretfully, there is still a lot of disagreement on this[(9)]. This study aimed to assess the significance of Modified Furlow vs Two-Flap Technique on ET dysfunction**.**

PATIENTS AND METHODS

Two arm prospective clinical study included CP patients who presented to Maxillofacial Surgery Unit, General Surgery Department, Faculty of Medicine, Sohag University and Department of Plastic Surgery, Cairo University through the period from January 2020 to September 2023.

Inclusion criteria: Patients ranging in age from 1 to 7 years. Their weight was more than 9 kilograms, and their hemoglobin level was more than 10 gm/dl.

Exclusion criteria: Patients with syndromic conditions and those in critical health conflicting surgical results and recurring instances.

Preoperative assessment: All patients were subjected to full history taking, general examination and local examination to assess the type of CP. Preoperative ear examination was done using the otoscope and tympanometry. Routine laboratory investigations (CBC, bleeding profile) were performed for all cases. Echocardiography was done if indicated. Type of cleft classified according to Veau classification [(7)].

Methodology

The patients were divided into two groups: Group 1 where patient were repaired using modified Furlow palatoplasty (standard technique with buccinator myomucosal flap modification) [(10)]. Group 2 where patients were treated by tow flap technique (Standard procedure) [(11)].

Operative procedure: General anaesthesia was used for the treatment of every patient. Sevofluorane inhalational induction. Intravenous access was achieved via cannula

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insertion, administration of 0.02 mg/kg atropine, and infusion of 2 mg/kg propofol. Switching from sevofluorane to isofluorane after endotracheal intubation. After using povidone-iodine (Betadine, purdue products L.P.) to clean the surgical field, the patient was covered with sterile cloths so that only the surgical site was visible. Placing a Dingman mouth retractor in order to provide optimal operating field exposure. After which, a local anaesthetic containing Adrenalin (1:200000 Adrenalin with xylocaine) is infused for its hemostatic action.

Modified Furlow palatoplasty [10]: (standard technique with buccinator myomucosal flap modification):

1. A coloured suture 4\0 was used to identify the parotid duct. A local anaesthetic was infused into the donor site of the buccinator flap that would eventually be used.
2. Creating the double opposed z-plasty: The uvula's edges were first refreshed, and then they were sewn together using 5-0 PDS or Vicryl suture. The right side oral mucosa flap was then produced using the traditional Furlow-Z palatoplasty technique without suturing it to the border of the hard palate, creating an L-shaped gap to be filled in the following stage by the Buccinator flap.
3. Creating the buccinator myomucosal flap: An average of 3.5 to 5.0 cm in length and 1.2 cm in breadth, the left buccinator myomucosal flap was delineated inferior to the parotid duct. It is located on the buccal mucosa 2 mm in front of the retromolar trigone's base and extends anteriorly to the oral commissure, around 6 to 8 mm away. Initially, the mucosa was cut over the whole flap's markings, exposing the buccinator muscle beneath. This was followed by a dissection through the muscle at the flap's tip reaching the buccal fat level. The flap was then turned so that its mucosa was facing the oral cavity, and it was sutured as far forward as possible into the hard palate defect, creating an L-shaped defect. Lastly, 4-0 Vicryl sutures were used to loosely seal the buccinator flap cheek donor region.

Tow flap technique [11]: (Standard procedure)

Two posterior mucoperiosteal flaps that reach to the alveolar cleft were placed using this technique.

1. A lateral incision was made with a blade or Colorado needle just medial to the dentition, starting at the incisive foramen and continuing back to the hamulus, following the injection of 1 to 2 ml of a 2% lidocaine/epinephrine solution into each side of the palate.
2. Lifting the palate flaps: An elevator was used to lift the mucoperiosteal flaps, starting from the lateral and anterior edges of the hard palate. Based on the larger palatine vessels, these flaps were created. Both mild traction and blunt dissection can be used to mobilise the neurovascular bundle.
3. Muscle retropositioning: The tensor and levator veli palatini, the two largest velar muscles, were separated from their aberrant connection to the hard palate using scissors and a #15 blade. To establish a functioning muscle sling, the goal of the muscle dissection procedure was retropositioning of the muscle fibres in the soft palate.
4. Vomer flaps and closure of the nasal lining: Using a periosteal elevator, the palate's nasal myomucosal edge was released from the palatal shelves. In order to achieve midline closure in continuity with the nasal myomucosal border of the pared palate, the nasal mucoperiosteum of the vomer was pushed up and raised. Closing the fissure from its anterior border to the adenoid tissue was possible in the majority of instances. Using either 5-0 Vicryl, the nasal lining was sutured to the vomer flaps. The top, or nasal, portion of the uvula was closed with the same suture. Usually, the uvula is edematous due to manipulations.
5. Intravelar veloplasty and oral lining closure: Using 3-0 or 4-0 Vicryl, the previously transposed muscles were approximated and closed as a distinct layer. In order to incorporate all three layers (oral, muscular, and nasal) in the suturing, one or two (though this is more difficult) vertical mattress sutures are inserted close to the point where the soft and hard palates converge, which is where the majority of fistulas form. Next, the midline of the oral mucosa was sealed with interrupted 4-0 Vicryl. Lastly, the flaps' lateral edges were nailed to the palate's margins. One of the two methods to reduce bleeding at the flap margins is either bipolar electrocautery or monopolar suction.

Postoperatively: For almost a day, every patient who had no issues was monitored. Since airway integrity may be compromised in the early postoperative phase, special attention was paid to this care. All patients were advised to follow a soft, entirely liquid diet for four weeks following surgery. Foods that were solid had to be pureed. To stop the patient from using their fingers or thumb to interfere with the repair, arm restraints were utilised. **Postoperative medications:** Miconazole (Daktarin gel, Johnson & Johnson, Ireland) gel 2cc three times per day, Xylometazoline (Otrivin nasal drops, GlaxoSmithKline Ltd, United Kingdom), and intravenous (IV) Cefotaxime (Cefotax, E.I.P.I.C.O., Egypt) 25 mg/kg/12 hours per day were administered to all patients for the following five days. Three nasal drops each day and 2.5 cc of paracetamol (Calpol drops,

Johnson & Johnson, Ireland) as needed, up to four times per day.

Pressure Tympanogram: was done one-month post-operative routinely, if it was normal, it would not be repeated. If tympanometry was abnormal, medical treatment was prescribed for the patient and the test was repeated after 3 months.

After that, tympanometry was carried out on each kid using a portable tympanometer (Welch-Allyn Diagnostics Inc., USA). Type A (+99 to −99 mm H2O), type B (flat curve without a discernible peak), or type C (>100 mm H_2O) tympanograms were analysed (Figure 1). Children who had abnormal tympanograms (type B or C) and otoscopic evidence of OME were considered to have positive screenings, and they were scheduled for a follow-up session three months after the first screening.

Ventilation tubes (VT) were not routinely placed before palatoplasty, but only post-operative in indicated cases, which were persistent type B and type C, persistent otitis media more three months despite the medical treatment, and recurrent otitis media more than five times per year.**Follow up:** All cases were asked for regular visits for postoperative followed-up at one week, 3 weeks, 1 month, 3 months, 6 months, and 1 year.

Data collection: Demographics, types of palatal cleft, palatoplasty technique, preoperative and postoperative ear examination, and time and frequency of VT insertion were among the data gathered.

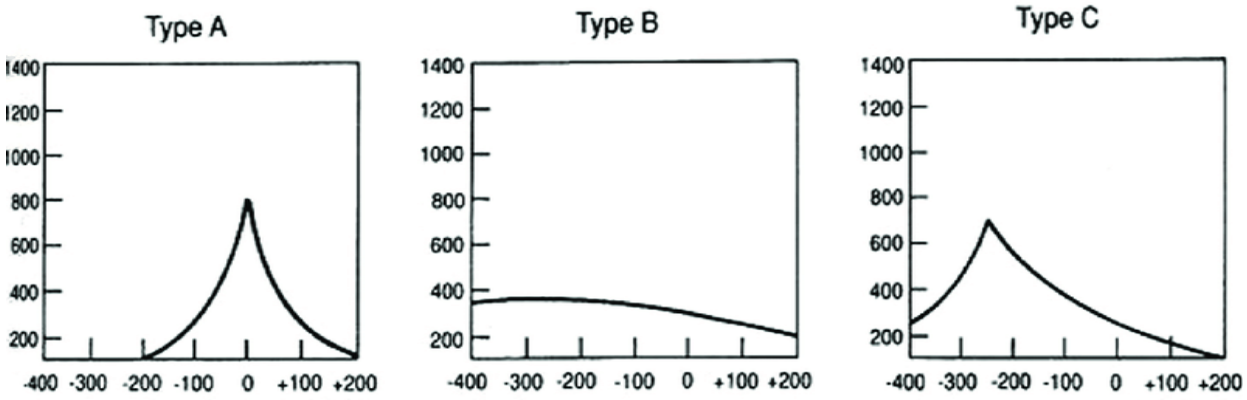

Figure (1): Different types of Tympanogram [(12)].

The presence of a B or C tympanogram and a verified middle ear effusion on an otoscopic examination performed by an ENT specialist were the research criteria for diagnosing OME. Throughout the research period, children with active otitis media received the necessary therapy. Our hospital's ENT staff received referrals for cases who needed surgery.

Tympanograms arranged based on plot form. Normal middle ear pressure and eardrum and conduction bone mobility are indicated by a normal Tympanogram, designated Type A. Tympanograms type B and C may show ET dysfunction or middle ear fluid.

Ethical approval: Sohag Medical Ethics Committee of Sohag Faculty of Medicine gave its approval to this study. The patients' legal guardians or parents signed informed consent forms. The Helsinki Declaration was followed throughout the study's conduct.

Statistical analysis: Each patient's data was entered into a file, processed using the SPSS V. 20.0, and then examined in a Microsoft Excel spreadsheet. The outcomes were compared using the X^2-test. P value ≤ 0.005 was seen as noteworthy.

RESULTS

This study included seventy-two patients with CP. Regarding the overall patient population, there was thirty-five (48.6%) males and thirty-seven (51.4%) females, their ages ranged from nine months to eighty-four months (7y), and with mean age of 39.49 ± 19.286 months. The patients were divided into two groups**:** group (1) and group (2). In group (1) there were 21 males (50%) and 21 females (50%) ranging between nine and eighty-four months with a mean age of 32.29 months, while in group (2), there were fourteen males (46.7%), sixteen females (53.3%). Their ages ranged from nine to eighty-four months with a mean age of 49.57 months.

Pre-operative diagnosis:

In group (1): Soft palate 8 (19%) cases, soft and hard 5 (11.9%) cases, complete unilateral 18 (42.9%) cases, complete bilateral 11 (26.2%) cases (Table 1).

In group (2): Soft palate 11 (36.7%) cases, soft and hard 6 (20%) cases, complete unilateral 8 (26.7%) cases, complete bilateral 5 (16.7%) cases (Table 1).

Table (1): Types of cleft pre-operative.

Variable	No.	Complete bilateral	Complete unilateral.	Soft and hard palate	Soft palate
Group (1)	42	11	18	5	8
Group (2)	30	5	8	6	11

As regards ear evaluation and ET dysfunction before surgery, In group (1): 37 (88.1%) had effusion, 2 (4.8%) had otitis media, normal ears were 3 (7.1%) (Table 2). **In group (2)**: 24 (80%) had effusion, 3 (10%) had otitis media and normal ears were 3 (10%) (Table 2).

Table (2): Descriptive data and compression pre and post-operative

Time of ear evaluation	Variable	Group 1 (42)	Group 2 (30)	P Value
Preoperative	Effusion	37(88.1%)	24(80%)	Non-Significant 0.18
	Otitis Media	2(4.8%)	3(10%)	
	Normal	3(7.1%)	3(10%)	
One-month post-operative	Effusion	36(85.7%)	20(66.6%)	Non-Significant 0.101
	Otitis Media	1(2.4%)	4(13.3%)	
	Normal	5(11.9%)	6(20%)	
3 months post-operative	Effusion	30(71.4%)	17(56.7%)	Significant 0.004
	Otitis Media	2(4.8%)	10(33.3%)	
	Normal	10(23.8%)	3(10%)	
6 months post-operative	Effusion	31(73.8%)	15(50%)	Not Significant 0.012
	Otitis Media	0	5(16.7%)	
	Normal	11(15.3%)	10(33.3%)	
One year post-operative	Effusion	25(59.5%)	20(66.7%)	Not Significant 0.142
	Otitis Media	0	2(6.7%)	
	Normal	17(40.5%)	8(26.7%)	

As regards ear evaluation and ET dysfunction after the operation by 1y: In group (1): Effusion in 25 cases (59.5%), no otitis media, and was normal in 17 cases (40.5%) (Table 2). **In group (2)**: Effusion in 20 cases (66.7%), otitis media in 2 cases (6.7%), and was normal in 8 cases (26.7%) (Table 2). There is no significant relation between type of operation and ear condition post-operative after 1 year follow up (P value 0.142 table 2). **As regards frequency and time of ear tube insertion,** 25 cases (34.7%) spared from ear ventilation tube insertion, 1 case (1.4%) at 3 months post-operative, 3 cases (4.2%) at 6 months post- operative, 43 cases (59.7%) at 12 months post- operative. **Group (1)**: 17 cases (40.5%) spared from insertion, 1 cases (2.4%) at 6 months post-operative, 24 cases (57.1%) 12 months post-operative (Table 3). **Group (2)**: 8 cases (26.7%) spared from insertion, 1 cases (3.3%) 3 months post-operative, 2 cases (6.7%) at 6 months post-operative, 19 cases (63.3%) at 12 months post-operative (Table 3).

Table (3): Descriptive statistics of post-operative Ear Tube Insertion after the operation by 12 m

Variable	Group 1	Group 2	P value
No tube insertion	17(40.5%)	8(26.7)	0.355
Insertion of tube at 3 m	0	1(3.3%)	
Insertion of tube at 6 m	1(2.4%)	2 (6.7%)	
Insertion of tube at 12 m	24(57.1%)	19(63.3%)	

DISCUSSION

The method of palato-plasty is a crucial component that may have an impact on how well CP restoration works in terms of speech and middle ear function [9, 13]. In modern practice, the favoured procedures are modified Furlow palatoplasties and two flap palatoplasties. In two flap palatoplasty, the soft palate muscles are reoriented side to side, whereas in Furlow palatoplasty, they are reoriented across the cleft [10]. The least amount of tympanostomy tubes required and the lowest frequency of otitis media with effusion were linked to Sommerlad and Furlow palatoplasties. The Sommerlad and Furlow palatoplasties were superior to the von Langenbeck palatoplasty, the Veau-Wardill-Kilner V-to-Y pushback method, and the 2-flap palatoplasty in terms of hearing results. To gather data that might bolster these conclusions, more studies are advised [11].

In this study, comparing age distribution with other series it appears to be with the similar distribution, and parameters with other series [14, 15]. In this study, there were female predominance 37 (51.4%), while males were 48.6%. This is very near to other researcher series about sex distribution. **Venkatesh *et al.*** [15] reported 50 %:50% M: F, but in **Biazon and Giani** [16] male gender was predominant 59.5%:39.5% M: F, which is different than the other study of **Abdel tawab *et al.*** [14] where female predominance was obvious 35%:65% M: F.

Our study showed no significant relation between the type of the CP and pre-operative ear condition and ET dysfunction. This consists with **Paliobei *et al.*** [17] where they observed no significant association between cleft type and preoperative ear condition. This concurred with other researches [4, 18, 19].

For post-operative ear evaluation: Five cohort studies [10, 20-23], which included studies of OME prevalence in children who had undergone various surgical procedures. Four investigations [10, 21, 22, 23] found no significant variation in prevalence across their research groups, suggesting that surgical approach (Furlow palatoplasty, von Langenbeck palatoplasty, VWK Palato-plasty, and Sommerlad IVVP) had no effect on the prevalence of OME postoperatively. However, in the research by **Hassan and Askar** [24], IVVP was related with a lower incidence of OME than VWK Palato-plasty.

In our work, we detailed data which have agreement with the previous studies. No significant effects at one month post-operative in normalization of ear condition between the 2 groups (p 0.008).

At 3 months follow up post-operative: A significant effect of modified Furlow over two flaps Palato-plasty appear with P value 0.004, increasing number of otitis media children at two flap group may make this significant result. **At 6 months follow up post-operative:** The significant relation between type of operation and ear condition was not noticed. **Reevaluation and follow up after one year:** This showed no significant difference between the effects of the two different operative procedure. This is in agreement with **Guneren *et al.* [10], Teblick *et al.* [20], Spauwen *et al.* [21]** and **Sischo *et al.* [22].**

Our work indicating that: There was no significant association between ET function and type of Palatoplasty technique. Many researches have focused on a single method of hearing management, ventilation tubes. However, because of the capacity of spontaneous resolution, a more conservative approach to OME management has begun to emerge [25-27]. Studies have revealed that a basic CP repair operation alone can help restore hearing in persons with CP, **Smith *et al.* [11]** and **Polzer *et al.* [25]** observed that the improvement in ET function resulting from Palatoplasty did not emerge immediately.

In this study, we found significant spontaneous improvement under conservative management, which was more at short follow up but not significant at one year post-operative in the 2 groups. This disagrees with **Lou *et al.* [26]** who mentioned that the improvement is progressive and hearing return to normal at age of 6 years. We can explain this discrepancy as our follow up is shorter than this age in most of cases, we focused only on ET function. So extended study may be needed.

This study showed no significant relation between type of operation and number or time of ear ventilation tube insertion. This agrees with **Sischo *et al.* [21], Lithovius *et al.* [27]** and **Antonelli *et al.* [28].** But, disagrees with **Smith *et al.* [11]** who investigate at 2 years post-operative but we investigated our result at 1 year post-operative this may explain the results.

CONCLUSION

Association between ET dysfunction and otitis media from one side and CP from other side, not affected by the severity of cleft type. Without intervention hearing affection is unavoidable. Repair of cleft led to direct improvement of ET dysfunction. Modified Furlow showed early improvement of middle ear function but had no superiority after one year over two flaps Palato-plasty. But the two procedures showed significant effect as regards decreasing of severity of ET dysfunction with allowing of conservative management of middle ear instead of prophylactic tube insertion.

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