



Original article

A trial to improve the outcome of cleft palate repair in pediatric age by using fibrin glue

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Abstract

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Cleft palate is among the commonest craniofacial abnormality with an incidence of about 1 in every 2000 to 2500 births. Cleft palate repair is a challenging procedure with multiple operations described for the same anomaly. The aim of this study is to improve the outcome of cleft palate repair by using fibrin glue as an adjuvant in the repair with its effect on lowering postoperative complications. A prospective study was carried on 30 patients for primary cleft palate repair operated upon by double flap palatoplasty with the use of human fibrin glue in the repair. Fibrin glue was injected between the oral and nasal layers of palate and at suture line. Six cases showed postoperative complications, with rate of complication 23.3 %, Three of them (10%) were complicated by oronasal palatal fistula. Two of them (6.6%) were small and closed spontaneously within 2 months postoperatively and the third case (3.3%) was presented primarily by local wound infection and later on had showed an oronasal fistula and needed

surgical repair, two cases(6.6%) were complicated by upper airway obstruction immediately postoperative and one case (3.3%) was complicated by reactionary hemorrhage. It was concluded that fibrin glue is an adjuvant that can be used with surgical repair of cleft palate for improving surgical outcome and lowering postoperative complications.

1. Introduction:

Cleft palate is a common craniofacial abnormality that result from failure of fusion of parts of primary and secondary palate during the second month of gestation. They have an incidence of about 1 in every 2000 to 2500 births. They are usually but not always associated with a cleft lip. In a small percentage of cases, the cleft palate is one of multiple congenital anomalies in the context of a major genetic syndrome. The extent of the cleft varies: Some involve only the soft palate, others extend through the hard palate but spare the alveolar ridge , while others are complete. The defect may be unilateral or bilateral (1).

The most frequent complication of palatoplasty is the occurrence of an oronasal fistula (ONF). Other complications described include complete wound dehiscence, oropharyngeal infection, airway obstruction, upper respiratory tract infection, pneumonia, bleeding, feeding difficulties, aspiration, hyperthermia, postoperative airway obstruction, otitis media, and even mortality (2)

Intraoperative hemostasis is usually achieved by the conventional methods of bipolar cautery or external pressure. However extensive cauterization can lead to tissue necrosis, presenting postoperatively as a palatal fistula, Though fibrin sealants were first introduced in 1970 (3)

Fibrin glue is a topical tissue adhesive, a two-component system; one component contains highly concentrated fibrinogen, factor VIII, fibronectin, and traces of other plasma proteins, the other component contains thrombin, calcium chloride, and antifibrinolytic agents such as aprotinin. Mixing the two components promotes clotting. Fibrinogen is activated by thrombin in the presence of calcium, and the resultant clot aids hemostasis and tissue sealing and is completely absorbed during wound healing without foreign body reaction or extensive fibrosis (4)

2. Patients and Methods:

The cases were operated upon in Beni-Suef university hospital, 30 patients with primary cleft palate were included in our study. They

had primary cleft palate repair with the use of human fibrin glue in the repair.

The age of the patients in our study ranged from 9 months to 3 years, they were males and females, they all had primary cleft palate repair after informed consent from parent(s) or guardian(s).

We excluded patients who had history of allergy to any component of fibrin glue, Patients who are not fit for surgery, Patients with major co-morbidities e.g. cardiac anomalies, Syndromic patients and recurrent cases.

For all patients, Detailed history taking, Pregnancy history, Ages of the parents, Medications taken during the pregnancy, Personal habits, such as alcohol or cigarette use during the pregnancy, The occupations of both parents may also suggest potential teratogens exposure and Pregnancy complications, such as maternal illnesses or premature delivery. Perinatal history: Any nursery complications, Feeding difficulties, Family history and Consanguinity.

Physical examination including: Weight, Length, Orthodontic consultation, Head circumference on the infant to determine if the infant is normal/small/large for gestational age, Size and the shape of the cranium, Overall appearance of the face to exclude facial clefts, Position, size, and formation of the tongue. The oral cavity for: Presence or absence of teeth, Degree of hard

and soft palate clefting, Presence or absence of the uvula or Presence of a bifid uvula, Evidence of pitting of the lips or palate, Examination for tongue tie or lip tie, Manual palpation of the palate, especially if a bifid uvula is noted, may suggest a submucous cleft palate and Examination of the ear for effusions, recurrent infections and conductive hearing deficits.

Routine labs and investigations: These included complete blood count, electrolytes, blood urea nitrogen, creatinine, total protein and albumin. Other investigations were done to exclude any other anomalies.

Informed consent for the study: Including cleft palate repair with use of fibrin glue in the repair and explaining its benefits and possible complications.

Two flap palatoplasty by extending the relaxing incisions along the alveolar margins to the edge of the cleft. This designs flaps entirely dependent on the circulation from the greater palatine vessels, but also much more versatile in terms of their placement. The flap is then anteriorly and laterally based as the gingival/palatal junction incisions are not made.

Closure of the cleft in this scenario relies upon: Excellent mobility of the lateral side of the palatal flap and Medial dissection of the medial side of the palatal flap to be able to mobilize the flaps and gain width by

losing height of the palatal arch. Closure of nasal layer, figure (1) and closure of oral layer, figure (2) after the dissection.

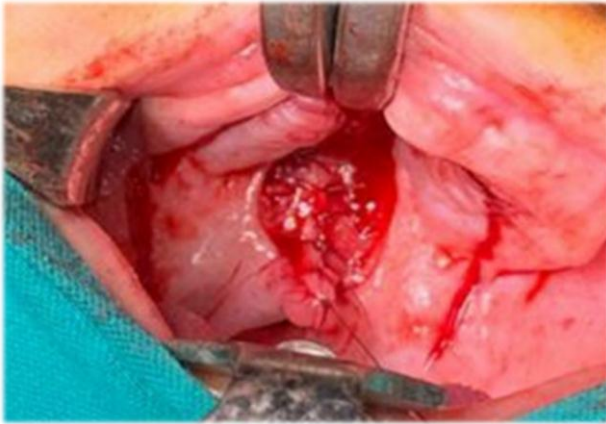


Fig. (1): Closure of nasal layer.



Fig. (2): Closure of oral layer.

Fibrin glue was prepared from fresh frozen plasma to obtain thrombin from it by adding calcium chloride to the plasma and using centrifuge at 3200 cycles per minute for 20 minutes at 4-6C in a cooling centrifuge, and from cryoprecipitate to obtain fibrinogen. Fibrin glue will be applied by a dual-syringe, figure (3), with one side containing one centimeter fibrinogen and the other side containing one centimeter thrombin, between the oral and nasal layers of palatal repair

after being closed and at suture line also, figure (4).



Fig. (3): Dual syringe with fibrin glue.

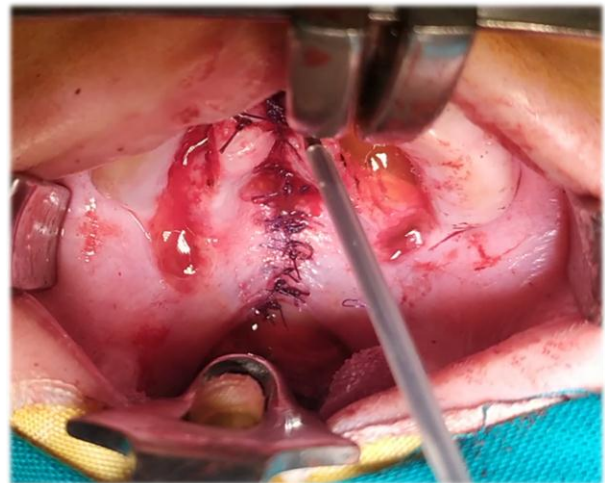


Fig. (4): Injection of fibrin glue between oral and nasal layers.

All patients were followed up from the moments of leaving operative room for a minimum of six months postoperatively for documentation of data. the patients were followed up 2 times per week in the first 2 weeks, weekly for two months and monthly for the later 4 months and postoperative pictures were taken for documentation, figures (5) and (6). All the patients were subjected to post-operative assessment to detect any complications.



Fig. (5): Three weeks postoperative.



Fig. (6): Three months postoperative.

Analysis of data was performed using SPSS 17 (Statistical Package for Scientific Studies) for Windows. Description of variables was presented as follows: Description of quantitative variables was in the form of mean, Standard Deviation (SD), minimum, maximum and rang, Description of qualitative variables was in the form of numbers (No.) and percents (%). All statistical tests were performed at a significance level of 5% (P 0.05).

The significance of the results was assessed in the form of P-value that was differentiated into: Non-significant when P-value > 0.05. Significant when P-value ≤ 0.05 and Highly significant when P-value ≤ 0.01.

3. Results:

Total number of patients included in the study was 30 patients: 24 males (80%), and 6 females (20 %). The mean age of patients in our study was 14.10 ± 3 months . a minimum of 9 months and a maximum of 18 months. According to presence of cleft palate and cleft lip, 6 patients(20%) had cleft palate and cleft lip and 24 patients(80%) had cleft palate only. According to palatal index in this study, no cases in mild group, 20 cases(66.6%) in moderate group of palatal index(palatal index 0.2-0.4) and 10 cases(33.3%) in sever group of palatal index(palatal index more than 0.4). Technique used for repair of cleft palate was double flap palatoplasty for all cases. And all cases were operated upon by one stage repair. There had no deaths or major life threatening complications in this study.

Table(1) Type of complication.

	Number	Percent
Fistula	3	10
Upper airway obstruction	2	6.6
Hemorrhage	1	3.3
Wound infection	1	3.3
Total	7	23.3

Table (2) Number of complicated cases.

	Number	Percent
Complicated	6	20
non complicated	24	80
Total	30	100

There is no significant difference between presence of fistula and palatal index, p.value = 0.209 and correlation coefficient was 0.281.

There is no significant difference between presence of fistula and timing of operation, p.value = 0.305 and correlation coefficient was 0.229.

There is no significant difference between presence of fistula and type of cleft, p.value = 0.608 and correlation coefficient was 0.263.

There is no significant difference between presence of fistula and duration of surgery, p.value = 0.209 and correlation coefficient was 0.281. 1.

4. Discussion:

The goals of palatal surgery are closure of the communication between the oral and nasal cavities, and construction of a functional velum that allows good speech production. Many techniques have evolved to achieve the primary goals of palate repair with single operation and primary healing (5)

Cleft palate repair is not free of complications. The most frequent complication of palatoplasty is the occurrence of a fistula. Other complications described include

complete wound dehiscence, oropharyngeal infection, airway obstruction, upper respiratory tract infection, pneumonia, bleeding, feeding difficulties, aspiration, hyperthermia, postoperative airway obstruction, otitis media, and death (6)

In **1991 Cohen et al** (7) reported with respect to type of palatoplasty, 43% fistula rate with VeauWardill Kilner Pushback Procedure, 10% with Furlow Double Opposing Z Plasty and 22% with the Von Langenbeck procedures.

Double flap palatoplasty show lower rate of postoperative oronasal fistula as the rate of fistula is (5%) and better velopharyngeal function (8)

As regard to The frequency of oronasal fistula after primary cleft palate repair without the use of fibrin glue varied in the included studies from 0% (9) to 60.9% (10)

The presence of an oronasal fistula is associated with functional problems such as hypernasality, audible nasal escape, regurgitation, and recurrent infections that can require reoperation (11).

For this variety of complications many surgeons and practitioners sought for solutions to gain better prognosis and less complications for the patients.

The idea of using the fibrin glue was to reduce the incidence of oro-nasal fistula by closing

the dead space, haemostasis, accelerating the process of healing and its antibacterial action. Fibrin adhesive is formed of thrombin and fibrinogen mixed thoroughly to form fibrin adhesive (12)

The complication rate was 23.3%, (7 cases) in our study. Two cases were complicated by Upper airway obstruction(6.6%) and we prevented that obstruction in the following cases by using Nelaton catheter of appropriate size introduced from the nostril till the pharynx during the application of fibrin glue and was removed after confirmation of fibrin glue complete coagulation and securing airway.

One case was complicated by reactionary hemorrhage(3.3%) and we closely observed the patient in the operating room and gave him Tranexamic acid (kapron) with a dose of 5mg per kg body weight and the bleeding stopped spontaneously without need for surgical intervention or blood transfusion, one case was complicated by wound infection (3.3%) and three cases were complicated by oronasal fistulae(10%) two of them(6.6%) were small at the junction between soft and hard palate without any nasal regurgitation that closed spontaneously within 2 months of postoperative follow up and the other one(3.3%) was the same case that had wound infection in early postoperative period and continued beyond our follow up period for further surgical intervention.

According to number of complicated cases we had 6 (20%) complicated cases. One case(3.3%)was complicated by wound infection in the first postoperative week and complicated by oronasal fistula later in the third postoperative week, Two cases(6.6%) was complicated by small oronasal fistula at the junction between hard and soft palate, Two cases(6.6%) were complicated by nasal obstruction and one case(3.3%) was complicated by reactionary haemorrhage.

The objective of this study was, as proof of principle, to demonstrate that fibrin glue can be used safely and may decrease the occurrence of adverse events following cleft palate repair. By injection of fibrin glue between the oral and nasal flaps in double flap palatoplasty, using a nasogastric tube (Nelaton catheter) to prevent infiltration of fibrin glue in the nasal cavity and that can cause nasal obstruction and close postoperative observation to detect and deal with any complication that may appear to us.

5. Conclusion and Recommendations:

Palatal surgery is complex surgery that needs a devoted surgeon oriented about various surgical techniques with their modifications.

One of the adjuvants that is evolved in various surgical procedures and in palatal surgery is the fibrin glue with its known effect in improving tissue healing and haemostatic effect in the sake of decreasing incidence of

early complications of bleeding and later on oronasal fistula.

Based on the findings of our study we recommend the use of fibrin glue. For better evaluation of the effect of adding fibrin glue as an adjuvant to cleft palate repair further studies of the same design but on larger scale and longer period of follow-up is recommended. Also further studies to detect the benefit of using fibrin glue in secondary cleft palate surgeries are to be considered.

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