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Role of Autologous Platelet Rich Fibrin in Closure of Palatal Fistula

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1. Abstract

1.1. Background: Following palate repair, palatal fistula is a frequent side effect, Due to many factors, this issue is somewhat difficult to manage, The target of the treatment is to regain the proper nutrition, hearing and speech, which has a significant effect on the social and psycho-logical well-being of patients and their families. Ideally, treating cleft palate requires a collaborative effort toaccomplish this task.

1.2. Objective: Interpretation of the platelet-rich Fibrin (PRF) role on the healing of wounds past palatal fistula closure.

1.3. Methodology: This A prospective investigation was carried out at the Pediatrics' Department of Al-Azhar University in Cairo, Egypt. Eighty patients (of both genders) were randomly picked and operated using PRF which was placed using two flaps in closure of palatal fistula between the oral and the nasal mucosa. Through 6 months follow-up, effectiveness of wound healing was evaluated by observing the recurrence of the fistula.

1.4. Results: Except for the recurrence of oro-nasal fistula in two patients, all cases in the research group were successfully treated without fistula development or wound dehiscence during all of the follow-up time.

1.5. Conclusion: The PRF use showed that throughout the entire follow-up period, most of the cases under study experienced satisfactory healing.

2. Introduction

Anomalies of the cleft lip and palate (CLP) are part of the most common congenital abnormalities. No matter a person's race, cleft palate affects about 1 in every 2,000 live births globally [1].

For CLP, we don't know a definite aetiology. Radiation, malnutrition, maternal teratogenic medications, hypoxia, and chemical exposures are some of the potential contributing reasons for this multifactorial abnormality [1].

Malnutrition, frequent ear infections, hearing loss, poor speech, and facial deformities are some of the pathological effects of a cleft palate [2,3].

The recurrence or fistula development subsequent to repair surgery for cleft palate is a common and difficult issue in wound healing. This happens because the blood vessels of the flap are stretched or damaged causing wound breakage. Primary cleft palate fistula recurrence rates have been estimated to be as high as 76% [4].

A trained cleft team must plan a thorough long-term course of treatment for cleft lip patients. In order to give the child the advantages and confidence of clear speech, good teeth, and a beautiful face, Collaboration between lip care experts in core areas is crucial [5].

The purpose of this paper is to address how to meet the aforementioned issues using the most recent tissue engineering techniques and prevent fistula recurrence after surgical closure.

A new invention of platelet concentrate called platelet rich fibrin (PRF) is relatively simply created and processed without the need of biochemical ingredients. The buildup of platelets that produce cytokines and growth factors is what drives its creation.6Fibrin sealants are used to seal microvascular bleeding in cardiovascular surgery [6].

The aim of this study is to evaluate the consequence of platelet-rich Fibrin (PRF) on the healing of wound following surgical palatal fistula closure.

3. Methodology

Study design: it is a prospective study was carried on Eighty patients have palatal fistula following primary cleft palate repair.

Study settings: Eighty patients have palatal fistula following primary cleft palate repair were chosen from the pediatric surgery and plastic surgery departments, outpatient clinic, Al Hussein and Sayed Galal University Hospitals, and Al-Azhar University in Cairo, Egypt. After repair they followed for 12 months started 1 June 2019 till 30 may 2022.

Patient selection: we selected All patients with palatal fistula (soft or hard type) more than 8 months have passed since previous primary cleft palate treatment. They consist of 18 males and 12 females, the age range was between 20 and 30 months.

For allocation, the participants were split into a single group.

Mechanism for allocation concealment: we choose all patients randomly, then their family histories and drug use histories were evaluated. The anesthesiologist evaluates the general condition of each patient to ensure that there are no other diseases in the body.

Preliminary tests: whole blood count, Echocardiography and coagulation profile (PT, PTT, and INR). The anesthesiologist assessed the patient's chest condition.

Inclusion criteria: Patients with hard or soft palatal fistula and a history ofcleftpalate surgery for more than 8 months. Patients range in age from 20 to 30 months.

Patients with systemic illnesses or bleeding disorders were excluded.

The surgical process and any potential postoperative complications were explained to the parents.

To close palatal fistulas utilising PRF preparation, all patients received two flap palatoplasty surgery.

Only the surgeon who was involved in the surgical operation was biassed in the blind evaluation of the results.

Operative procedure technique: after assessment of medical and surgical history and estimation of body weight monitoring is started before induction in the form of direct observation, precordial stethoscope, ECG, Non-invasive ABP, Pulse oximetry, End tidal CO2 and temperature. IV line is secured and pre-medication with anticholinergics (atropine 0.01 mg/kg) and antibiotics, followed by inhalational induction with sevoflurane and non-depolarizing muscle relaxant (atracurium 0.3 - 0.4 mg/kg). Endotracheal intubation using miller laryngoscope and cuffed armord endotracheal tube was secured with tape in the midline to the chin. A mouth packs were used to secure the tube. Controlled ventilation and anesthesia should be maintained by sevoflurane and muscle relaxant. Thepatientput in asupinewith head ring to support the head andshoulderrollbelowtheshoulders. Over the closed eyes, sterile tapes were applied.

The anesthesiologist draws 10 mL of venous blood into a 10 cm sterile plastic syringe for PRF preparation, which is then immediately transferred into a plain tube without any anticoagulants, with a volume of 10 ml.

To prepare PRP, the centrifuge was set at 3000 rpm for 10 minutes. Then, 1 cm of distilled water was added to the fibrin and 1 cm to the thrombin to dissolve them. We then mixed the two solutions using a double-action mixing pump, and 2 cm of PRP was added to the previously mixed solution to create the PRF. The palatal repair surgery was initiated after the preparation of the surgical tools.

After infiltrating 3 ml of 2% lidocaine with 1:2000 GO epinephrine into the palate to induce hemostasis, the blood was centrifuged concurrently with the procedure, which had already begun.

An incision was made along the lateral edge of the soft and hard palate as well as one surrounding the fistula between the oral and nasal mucosa to begin the two flap palatoplasty procedure.

Both the palatal flaps in addition to the nasal mucosa were lifted and brought closer to the midline of the fistula. Using Vicryl stitches by burying the knots the nasal layer was sutured.

The PRF was produced, put over wet gauze to drain serum, and After fixing the membrane with two or three stitches into the mucosa, a stable membrane was created by laying over the nasal layer.

In the following step, We approximated and sutured the palatal mucosal flap. At the end of the operation, anesthesia was stopped, the mouth bag was removed, and muscle relaxation was reversed with anticholinesterase drugs (neostigmine 70 ug/kg) and anticholinergic drugs (atropine 0.02 mg/kg) and endotracheal extubation after fulfilling its criteria.

Post-operativecare: Arm restriction to inhibit wound trauma via the kid's fingers. feeding with a plastic syringe, as breastfeeding or bottle feeding were discouraged during the first week to prevent trauma from suction.

Post operative: antibiotics taken orally for seven days following surgery. Every 12 hours for five days, 125 mg of the antibiotic cephalosporin via PO. Every eight hours for five days, nystatin antifungal drops were used. For five days, use Otrivin baby nasal drops.

Every six hours, paracetamol drops 12 drops.

Follow up visits: 1st visit: at the 1st week after surgery, the appearance of a fissure or wound infection was evaluated and the patient's nutritional instructions and aftercare were confirmed. 2nd visit: at the 3 weeks after surgery weeks to check for recurrence of fistula. We subjectively assessed the occurrence of fistulas by checking each patient for food or drink passing to the nose. 3rd visit: 6 months after surgert to confirm whether there is a late postoperative fistula recurrence.

Evaluation of the variables: Age (20–30 months), palatal fistula type (soft or hard), gender (male/female) and fistula recurrence rate (Figure 1).

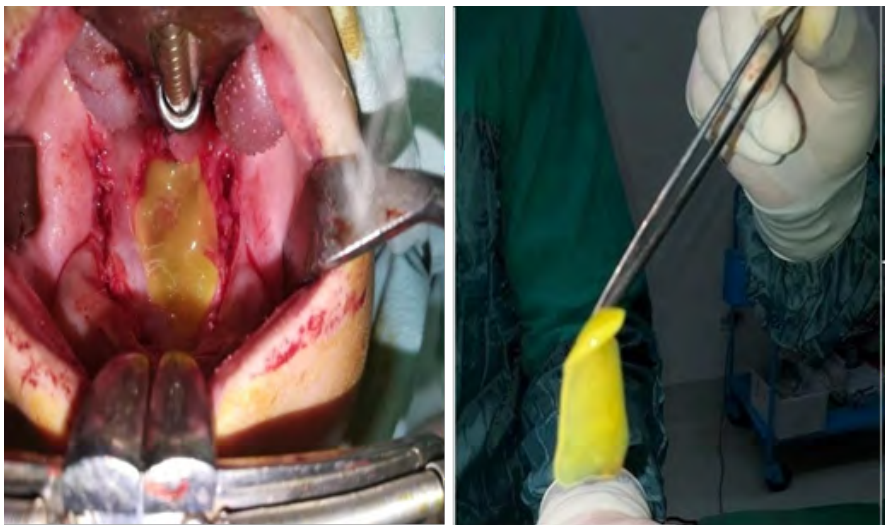

Figure 1: Demonstrate applying of platelet-rich fibrin to close palatal fistula

3.1. Statistic Data Analysis

Data that was collected was examined using SPSS Inc.'s statistical software for social sciences, version 20.0 (Chicago, IL, USA). Standard deviation (SD) was used to express quantitative data as mean. We used frequency and percentage to depict qualitative data.

The subsequent tests were run: The proportions between qualitative factors were compared using the Chi-square (x2) significance test. The margin of error was 5%, and the confidence interval was set at 95%. As a result, the following p-value was declared significant:P-value for probability P-value< 0.05 was considered significant.P-value 0.001 was considered statistically significant.P-values over 0.05 were deemed insignificant.

4. Results

Table 1 and 2

Table 1: Shows data on the patient's demographics

	Demographicdata	Total(n=80)
Gender	Females	24(30.0%)
	Males	56(70.0%)
Age (Month)	20-25 months	38(47.5%)
	>25-30 months	42(52.5%)
	Range[Mean±SD]	20-30(25.75±3.36)
Palatal fistula	Soft	12(15.0%)
	Hard	68(85.0%)
Cleft lip	Bilateral	12(15.0%)
	Rt	24(30.0%)
	Lt	24(30.0%)
	None	20(25.0%)

Table 2: Thistableshowsthe outcomes of complications.

Complications	Total(n=80)
Recurrence of oro-nasalfistula	2(2.5%)
Woundinfection	4 (5%)
Postoperativebleeding	2(2.5%)
Outcomecomplications	8 (10%)

5. Discussion

The ideal goal in closing the palatal fistula is to close the defect anatomically and functionallyhelp prevent hearing loss, stuttering, nasal food or liquid leaking, maxillary growth restriction, and proper speech [6,7].

After cleft palate surgery, the most frequent consequence is thought to be palatal fistula. Even with the best hands, fistulas can develop on the hard palate after surgical treatment. Any failure increases the risk of fistula. Therefore, every effort should be made to properly repair the palate during the first surgery. Treatment of palatal fistula is a difficult procedure for cleft palate surgeons. The techniques used today in the treatment of fistulas can be divided into two groups: In different cases, local mucoperiosteal flaps and surrounding tissues such as lingual flaps, palatal flaps, buccal mucosa or both are used to close the defect. Repair attempts with palatal tissue can be difficult due to inadequate tissue and scarring from previous closure attempts.In addition, the rate of return is up to 25% without using PRF.

Following analysing the literature, we discovered that PRF membranes had never been employed in the surgical closure of palatal fistulas created following cleft palate surgery, thus we started this investigation as a prospective study during the registration procedure.

In this work, we attempted to unify the surgical procedure as the two flaps in closure of palatal fistula in order to prevent fistula formation due to technical difference. In the literatures, the fistula

recurrence rate without PRF varies between 3% and 45 [8].

In the hands of skilled surgeons, a study by Kalzel et al. found no statistically significant difference in the rates of fistula between Bardach surgery and Furlow palatoplasty [9,10].

Another technique for mending palate clefts that are less than 20 mm in length is the application of the buccal fat pad. It is located in the palate's posterior two-thirds.10 Palatal scarring may be lessened by using the buccal fat pad [11].

Expanding the tissue with an osmotic expander implanted during the initial stage of treatment is another way to repair a cleft palate. A self-expanding device made by OSMED (Ilmenau, Germany) was implanted beneath the mucoperiosteal layer of the hard palate to help create additional tissue for the 24- to 48-hour cleft palate repair procedure. Although there are some technical issues with the ideal filling phase, tissue expansion makes palatal repair simpler and more comfortable, and bone peeling may not be required [12].

The greatest need for cleft surgeons has always been proper wound healing after the repair of cleft palate. Because scar tissue can make it challenging to close the oro-nasal communication due to lack of tissue laxity depending on the size of the defect, secondary repair of impaired wounds is more challenging. Because of the fibrosis and impaired vascularization that happen following surgeries, the likelihood of the fistula recurrence is higher once the defect is closed [4,13].

The extent of the initial defect is the most crucial factor, but other factors like the surgical approach, local tissue damage, the surgeon's experience, and the timing of the repair are also related to the prevalence of these complications.13 The mentioned problems have social and psychological impact on the patients [14].

Hyaluronic acid, hydroxyapatite, PRP, and PRF are just a few of the materials that have been used to build tissue engineering scaffolds. They encourage undifferentiated mesenchymal cells to regenerate bone [15].

Other artificial materials such as alloderm and collagen membranes are also used as metagrafts in the surgical closure of palatal fistulas [16].

They are included in a multilayer repair made up of the interpositional graft, nasal mucosa, and oral mucosa. These serve as a framework for the growth of tissues and the creation of mucosal epithelium [17].

Use of acellularized dermal matrix (AlloDerm) has also been documented in the literature to encourage closure. It has been used to treat palatal fistulas and cleft palate [18]. patients who were reviewed in the past by Clark et al. received decellularized dermal allograft for closure of palatal fistulas. It has been shown that large clefts of the hard and soft palate can be closed by this method safely and efficiently. However, it is not efficient at treating existing fistulas [19,20].

In 2012, Aldekhayel et al. conducted evidence-based review utilizing acellular dermal matrix (n = 92) in primary with an average width of 14.2 mm for four studies. In the control group, this rate was 10.6% while the overall fistula incidence was 5.4%. Palatal fistulas were treated with acellular dermal matrix in five studies (n = 74). Total fistula recurrence in patients was 8.1%, compared to 12.9% in controls [19,21].

11 recurrent cleft palate fistulas were treated by Glicerio et al. using local mucoperiosteal flaps plus PRGF gel combined with autologous bone grafts were placed on two pieces of solid collagen to fill the bone defect between the palate and the asal mucosa in an experimental, prospective, longitudinal study. Incomplete bone closure of the palatal fistula with a 90.9% healing rate (6-24 million months followed) reduced the recurrence rate using other techniques by other authors [4,23].

They came to the conclusion that using PRGF along with autologous bone graft is a safe, efficient method of treating recurrent cleft palate fistulas, but the recurrence rate can be reduced with PRF.

For this reason, we tried to evaluate the clinical value of the autologous blood product "PRF", which has recently started to be used in many tissue engineering protocols, in supporting wound healing after palatoplasty. Fibrin contributes to tissue regeneration by acting as a carrier in the migration of fibroblasts and endothelial cells [24].

For regulating the release of growth factors and hasten wound healing without setting off an inflammatory response, PRF has recently been used in plastic and maxillofacial surgery. Research shows that it has a lot of potential for osteoblast cell adhesion, development, and differentiation, and it has been included into bone grafts in vitro [5].

Choukroun et al. provided the initial description of the PRF preparation saying that it is a simple, fast and inexpensive way that provides products from autologous blood without requiring additional chemicals and decreases infections and immunosuppression. Additionally, it offers cytokines and growth elements that are helpful for the healing process [21,22].

For maxillary sinus lifts and reconstructive surgery for alveolar clefts, PRF has been utilized in conjunction with bone grafting. It had increased bone maturity and density, both radiographically and histologically. It operates as a biologic connection, attracting stem cells and osteoprogenitor cells while also promoting neovascularization [23].

In a study by Choukroun et al. the researchers sought to determine how well PRF and freeze-dried bone allograft (FDBA) worked together to improve bone repair following a maxillary sinus lift operation. Their findings revealed a 50% decrease in healing time prior to implant insertion [24].

Simonpieri et al.25, reported that dental implants placed right away using a mixture of PRF and a bone graft have shown good

clinical outcomes in terms of natural bone repair [25].

In the pig tibia bone defect model, Yilmaz et al. found that B-TCP and PRF have both individual and combined healing effects. The results showed that when B-TCP and PRF were combined, more new bone was formed than when they were used separately [26].

Regarding our study, we prepared the PRF immediately during the surgery, it was easy to maneuver, and was placed in the surgery field in a way that it would collide between the nose and mouth folds.

6. A Dispute of Interest

No conflicts of interest exist between the author(s) and the research, writing, or publication of this paper.

7. Conclusion

During the entire follow-up period, using PRF proved to be successful in healing the majority of the study cases.

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