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Modified Platelet Rich Plasma (PRP) Technique in Repair of Primary Cleft Palate

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Abstract

Objectives: Evaluation of the impact of Platelet Rich Plasma (PRP) added during primary repair of the full cleft palate and comparing the results with those obtained without PRP application.

Design: A prospective single randomized study.

Setting: All patients attending at pediatric surgery and otolaryngology departments, Al-Azhar University hospitals, Cairo, Egypt.

Patients: Forty patients divided into two equal groups. All patients underwent 2- flap technique palatoplasty. Group A; 20 patients had PRP injection (3-5ml injected in each layer) during palatoplasty, while group B; 20 patients without PRP application. All patients were followed up in the out-patient clinic for 13 (12-17) months.

Results: Forty patients presented with complete cleft palate, 25 men and 15 women aged 18 months on average (12-24 months). All patients undergone 2- flap palatoplasty without complications with intraoperative. In group A, no cases of postoperative fistula (0%) after palatal surgery, while fistula occurred in 4 cases (20%) of patients in group B. There was a lower incidence of fistula in group A than in group B (p=0.113).

Conclusions: PRP application is feasible and effective technique. Formation of the fistula following primary palatoplasty is decreased with PRP application.

Keywords: Cleft palate; Platelet Rich Plasma; Palatoplasty; Palatal fistula

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Introduction

The most prominent oral and maxillofacial congenital anomaly is the cleft palate. The prevalence of cleft palate is 3.4-22.9 per10, 000 births with or without cleft lip [1]. Cleft palate operation is aiming to cover the defect and to improve the velopharyngeal function [2]. The development of complications depends on several factors as: extent of cleft, timing of repair, type of surgical repair and surgeon's experience [3]. Fistulas were reported to happen in 0-77.8% of patients following primary palatoplasty [4]. The extensive usage of PRP in the healing process of various types of tissue is because platelets provide a readily available source of essential GFs and signaling that can control and regulate the tissue healing process, such as leukocyte-derived catabolic cytokines and fibrinogens [5]. PRP has been used in dental and maxillofacial surgery to repair dental extraction or tumor resection defects, as well as alveoloplasty [6]. Rapid healing, reduced risk for infection, less post-operative pain and quicker recovery have been documented in all these procedures. The objective of the current research would be to evaluate the impact of PRP application in primary cleft palate repair using a new modified technique of PRP application and comparing results with another patient group, utilizing the same surgical procedure without PRP use. The fistula has been selected because it is the most dangerous and most frequent complication following cleft palate repair.

Patients and Methods

This prospective research was performed on 40 full cleft palate children. They were between 12 and 24 months of age with an average age of 18 months. Patients attended the out-patient clinics of Al-Azhar university hospitals. From June 2014 to December 2017. The essence of the disease and different therapeutic options was explained with the agreement of our institutional ethical committee and written informed consent of the parents or guardians of all patients to be involved in this research. With sealed envelopes opened in the operating room, randomization was achieved.

All patients underwent full history, regular systemic examination,

full examination of the head and neck as well as preoperative laboratory investigations.

Exclusion criteria

Patients with previous palatoplasty, patients with cleft lip or soft palate only and syndromic patients. The same surgical technique and the same physician are applied to all patients (AY). Sufferers have been split into two equal groups at random: Group A; Twenty patients (50%) received autologous PRP prepared from the own blood of the patient where (3-5 ml) of PRP injected in the nasal mucosal layer and (3-5 ml) injected in the oral mucosal layer during palatoplasty. Group B: Twenty patients (50%) who did not receive PRP during palatoplasty.

Preparation of the platelet Rich Plasma (PRP)

The anesthetist drew 15 mL of peripheral venous blood from the patient with a 16 or 18-gauge butterfly needle or syringe during the operation and under sterile conditions to prevent inflammation and platelet damage. In a simple vacuum tube, the gathered blood was kept (without anticoagulant or calcium). Using a tabletop centrifuge (Low Speed Centrifuge [800]; Jiangsu Zhengji Instruments, Jiangsu, China) machine, the specimen was instantly centrifuged for 12 mins at 3,200 rpm at operation room temp without any external activation. The blood was therefore divided into three density-based layers: the lower layer comprising red blood cells; the middle layer comprising PRP consisting of easily obtainable white blood cells and platelets (WBCs; Buffy coat); and the top layer comprising platelet-poor plasma. This method obtained platelets concentration 4.63 folds above the baseline value. Also, it had 1.82 higher concentrations of WBCs and few RBCs (Figure 1).

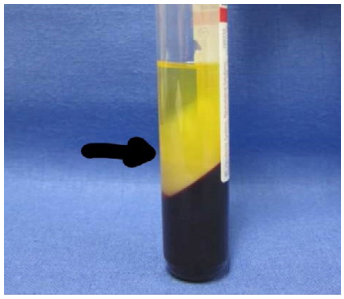

Figure 1: PRP layer (Middle layer) after centrifugation.

Hematological analysis

The WBC, red blood cell (RBC), and platelet counts in the whole-blood samples, PPP, and PRP were determined by using an automated cell count analyzer (Sysmex KX-21N, Sysmex Corp., Kobe, Japan).

Surgical Technique of Bardach 2-Flap Palatoplasty

Patients Position: The patient was put on the operating room bed in a supine position. The anesthesia treatment team conducted general anesthesia and endotracheal intubation was done with either a standard endotracheal tube or a RAE tube. The tube is placed in the middle of the lower lip on the chin and fastened by an adhesion tape, then, a shoulder rolls placed. Antibiotics have been given intravenously.

Then the surgical site is toweled off, draped, and to display the surgical site, the Dingmans mouth retractor is usually positioned. Using 1% lidocaine and 1: 100000 Epinephrine, the palate is injected. The 2-flap palatoplasty with optimal muscle dissection technique [7] was used in both groups. The technique is simple and enables the soft palate muscles to be revealed easily. Using a Cottles elevator, surgical scissors, and mono-polar electrocautery, the aspect of the hard palate and cleft margin was dissected. The nasal mucosa is raised and extended to the soft palate from the superior aspect of the hard palate. The extent of the soft palate musculature has been easily defined by doing this. Muscle fiber release would then be laterally extended till the haulms and the tensor veli palatine muscle were visualized. To permit medial progression, all soft tissues, musculature, and nasal mucosal lining were identified and released. To enable a tension-free closure, advance of the nasal layer, musculature, and oral layer was adequate. The vomer flaps were elevated to minimize the tension in case the nasal layer was hard to approximate. 4-0 Vicryl with a TF needle was utilized in an easy, interrupted manner to shut down the nasal layer of the uvula. The same suture would then be used in a through-and-through manner to approximate the mid-uvula with a mattress stitch. Interrupted sutures using 4-0 Vicryl with a PS-4c needle, the nasal mucosal layer was closed both anteriorly and posteriorly. The central part of the nasal layer is closed following muscle approximation, to avoid excessive tension in the nasal layer.

PRP application

After nasal layer closure was completed, a 16 gauge needle syringe was used to inject 3-5ml of PRP in the nasal layer of repair, the oral layer was then closed beginning at the base of the uvula and using a 4-0 Vicryl with a TF needle in a simple interrupted fashion, then, 3-5 ml of PRP had been injected into the oral repair layer. The same technique was done in group B, but without PRP application.

Postoperative care

Intravenous and oral antibiotics were administered to all patients in compliance with the hospital pediatric surgical procedure, i.e., two intravenous injection doses of cefotaxime 25 mg/kg body weight 12hrs a day for the first 24hrs postoperatively. Amoxicillin and clavulanic acid oral suspension 25 mg/kg of body weight 12 hours a day and metronidazole syrup 20 mg/kg body weight 8 hours per day are treated. These drugs should be taken for 10 days.

Follow up

Fistula occurrence was tested visually, parents were asked about nasal regurgitation if there was no visible evidence of a fistula, and a sharp periodontium probe has been utilized to verify a hard palate fistula if there was a history of nasal regurgitation. Postoperative results were recorded, tabulated, and compared with preoperative data as regard developed fistula.

Statistical method

MedCalc® version 'Ostend Belgium' program had been used for sample size calculations, statistical calculator centered on 95% confidence interval and study power 80% with 5% α error, sample size had been calculated depending on these values producing a minimal sample size of 20 instances in each group.

Statistical analysis

The data obtained has been tabulated and statistically analyzed utilizing SPSS (Statistical Package for Social Sciences) software version 20.0 (SPSS Inc., Chicago, Illinois, USA). For qualitative data, inferential analysis was conducted utilizing Chi square testing for independent groups. At $P < 0.05$, the significance level has been deemed to be significant.

Results

From June 2014 to December 2017, 40 patients presented with complete cleft palate class 2 according to Veau classification with an average age at the time of surgery became 18 (range, 12-24) months. They were 25 men (62.5%) and 15 women (37.5%) At a proportion of 1.6:1 to M:F In the demographic information and preoperative clinical presentation, both groups were comparable. 2-Flap palatoplasty (Bardach) was applied for all patients without complications such as intraoperative bleeding or recovery complications. No postoperative fistula or infection has existed in group A (with PRP application), while in group B (without PRP application), 4 patients (20%) had a postoperative fistula; three of them (15%) located at the hard palate and one fistula (5%) located at the intersection between a soft and hard palate. Although the occurrence of postoperative fistula has been higher in group B, There was no substantial difference among the two groups (p=0.113) (Table 1).

Table 1: postoperative fistula in both groups.

Postoperative		Group A	Group B	p-value
Fistula	Present	0(0%)	4(20%)	0.08
	Absent	20(100%)	16(80%)	
Site	Hard palate	0(0%)	1(5%)	
	At junction of hard and soft palate	0(0%)	3(15%)	

Discussion

Because of its important physical and biological characteristics, we used an autologous PRP in the current research which might help to reduce postoperative palatal fistula and achieve better outcomes in cleft palate repair. The aim of cleft palate repair is not only to close the palatal defect but also to push the palate back to ensure a normal speech. Palatal fistula, with reported rates of up to 58%, has been the most frequent postoperative complications of cleft palate operation, with preventive measures that can decrease the occurrence of fistula formation (4% -10%) [8,9]. Post-operative fistula usually occurs due to vascular necrosis of the flap [10]. For the primary repair of cleft in hard palates, many methods are used, such as Bardach two-flap, Von Langenbeck's, and single-layer muco-periosteal flaps [11]. Likewise, local muco-periosteal flaps, palate turnover flaps, tongue flaps, pharyngeal flaps, musculo-mucosal facial artery flaps, myo-mucosal buccal flaps, free bone grafts, cartilage or dermal fat, large or recalcitrant fistula free tissue transfer, and a cellular dermal matrix [12]. In the present study, the Bardach two-flap technique was applied to all patients in both groups. For further standardization, the same surgeon operated on all the patients. Authors have tried to isolate variables which trigger fistulas. Palatal soft tissue tension following palatal repair, upper respiratory tract infection, postoperative hemorrhage, multilayer closure failure, and cleft severity were the most popular factors [13]. No study has tried to link factors such as localized infection or mechanical trauma with the occurrence of postoperative palatal fistulas [14]. Palatal splints, bandages and other devices have been used in previous research to minimize the incidence of postoperative palatal fistulas. A cellular dermal graft was the most popular appendage utilized [15]. Acrylic splints and a celluloid acetone dressing have been used to secure the hard palate after closure [16].

Reddy RR, et al. (2018) found that if a pack soaked with antibiotic cream was put on the palate post-surgery for five days compared to a group with no pack used, the frequency of fistula occurrence following primary palatoplasty was substantially decreased [17]. PRP is an autologous concentration of human platelets in a small amount of plasma comprising bioactive factors taking responsibility hemostasis, hemostasis, new connective tissue synthesis and revascularization [18]. Autologous PRP was shown to be effective and safe in supporting the natural wound healing process, soft tissue regeneration, bone reconstruction and enlargement [19]. PRP technology is an innovative regenerative treatment for acute and chronic injuries. It has been commonly used for a recipient tissue to be repaired, reconstructed, or supplemented [20]. In neck and head surgery, otolaryngology, cardiovascular surgery, burns and wound care oral and maxillofacial surgery, plastic surgery, and periodontics, PRP has an exceptionally wide variety of clinical healing applications. Molecules such as platelet-derived growth factor, growth factor B transformation, epidermal growth factor, fibroblast growth factor, insulin-like growth factor I, vascular endothelial growth factor and others are found in Alpha granule platelets. These factors promote local inflammation, granulation tissue formation, the proliferation of cells, and the production of cells essential for the regeneration of tissues, rendering the use of PRP to be more attractive than the use of single recombinants [21,22]. The use of materials like acrylic splints, a cellular dermal matrix, and a cellular acetone dressing to protect the hard palate after closure has the disadvantages of being expensive, time consuming and might cause adverse reactions. So, we tried to use a natural material that is easily prepared, applicable and comfortable to the patients. The current research was conducted using PRP to test a potential decrease in fistula rates. After suturing, each of the Palatal Flap's nasal and oral mucosal layers was injected with 3-5 ml of PRP. Autologous PRP is a bactericidal due to its high WBCS contents, and this might decrease the incidence of postoperative infection which is considered as one of the main causes of fistula occurrence after palatal repair.

Early interference in current research (patients aged 12-24 months) with the use of PRP, had encouraging results regarding fistula occurrence and postoperative complications. The present study revealed that no postoperative fistula or infection has occurred in group A (with PRP application) while in group B (without PRP application), 4 patients (20%) had a postoperative fistula.

The results in our study were comparable to those reported by El- Anwar et al, during full cleft palate repair via the V-Y push back technique, autologous PRP was topically applied among repaired nasal and oral mucosal layers with no postoperative oronasal fistula encountered. The use of the same palatal repair surgical procedure without PRP in the control group revealed an oronasal fistula in 13.6% of the cases [23]. Gonzalez-Sanchez JG, et al. (2011) used bone grafts mixed with autologous PRP for repairing recurrent cleft palate fistulas with a healing rate of 90.9%. In current research, we addressed the role of autologous [24]. The two patient groups had well-balanced demographic information and preoperative clinical presentation in PRP in cleft palate repair, and only one surgeon performed all operations using the same surgical concept, the same material for suture. Eventually, the objective follow-up was for all patients. The limitations of present study were the median follow-up time was very limited, being a single center trial, the need to evaluate and affirm the value of this technique in a broad randomized study and compare it with other techniques to repair cases of palatal defects.

Conclusion

The findings of this research provided evidence that the formation of fistula following primary palatoplasty was decreased when autologous PRP was applied. Compared to other techniques, more research with greater samples are required to confirm the safety of PRP application in palate repair.

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