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Effect of Platelet-Rich Fibrin on Postoperative Complications in Surgical Repair of Secondary Cleft Palate

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ABSTRACT

Background: Cleft palate is a congenital craniofacial anomaly characterized by the failure of proper fusion of the palatal shelves during embryogenesis. It might seriously affect speech, feeding, and the facial appearance. The latter may cause psychosocial problems. Despite improvement in techniques of surgery, the most serious postoperative complications include formation of oronasal fistula and tissue necrosis. Platelet-Rich Fibrin [PRF] is an autologous fibrin matrix rich in growth factors that lately has emerged as a promising supplementary approach in the management of cleft palate repair over conventional techniques for enhanced wound healing and lessened complications.

Aim: This study tried to find out the safety and efficacy of PRF when applied to cleft palate surgical repair with regard to post-operative morbidity, the development of fistula, tissue necrosis and functional improvement.

Materials and Methods: A randomized clinical trial was designed with 40 pediatric patients diagnosed with cleft of the secondary palate. They were then divided into two different groups: one with standard repair and one with PRF repair using platelet-rich fibrin. The postoperative complications [e.g., necrosis, fistula formation, and general healing] were duly noted and compared between the two groups.

Results: The incidence of fistula formation and tissue necrosis was significantly less in the PRF group compared to the control group [5.0%, 10.0% vs 30.0% and 35.0%, respectively]. In addition, wound dehiscence was a significantly higher in the control than the PRF group [25.0% vs 5.0]. No statistically significant difference could be found concerning the duration of hospitalization or the total of velopharyngeal function.

Conclusion: PRF application during cleft palate surgery showed great promise in the reduction of postoperative complications with improvement of the overall outcome.

Keywords: Platelet-Rich Fibrin; Cleft Palate; Oronasal Fistula; Reconstruction; Healing, Velopharyngeal Insufficiency.

INTRODUCTION

Cleft palate is a congenital anomaly and one of the most common anomalies. It is due to the incomplete fusion of palatal shelves during embryonic development between the sixth and 12th weeks of gestation. It very strongly contributes to speech development, feeding, hearing, and facial aesthetic defects. According to epidemiological studies, cleft palate occurs in approximately 33 out of 100,000 live births worldwide and thus is among the most common congenital craniofacial anomalies [1].

Generally, the etiology of cleft palate will be regarded as multifactorial, including both a genetic and an environmental component. While the genetic component is well underlined, mutations of genes responsible for the regulation of epithelial cell differentiation, such as interferon regulatory factor-6 [IRF6], strongly associated with the development of cleft palate. Cleft palate also forms part of the symptomatology in syndromic cases, such as ***Van der Woude*** syndrome. Identified other environmental risk factors for the development of cleft palate are maternal smoking, intake of alcohol, and drug administration during pregnancy [2,3].

Surgical repair of the cleft palate should be usually made within the first year of life for optimal speech and feeding. Thus, the major goals of this surgery are to close the cleft, recreate a normal velopharynx, and avoid long-term complications in speech and feeding. The techniques for repair of cleft palate were multiple and included von Langenbeck's palatoplasty, Furlow's double-opposing Z-plasty, and two-flap palatoplasty [4].

Despite refinement in these techniques, techniques still have complications [e.g., wound dehiscence, oronasal fistula, and tissue necrosis], especially in wide clefts due to tension across the closure site [5].

Over the last ten years, bioactive agents have emerged with application potential as an adjuvant treatment in cleft palate management and accelerating the healing process. Agents used for this purpose include Platelet-Rich Fibrin [PRF]. PRF constitutes high levels of platelets, cytokines, and growth factors that enhance the process of wound healing and stimulation of tissue regeneration [6].

Since PRF is devoid of anticoagulants, as opposed to platelet rich plasma [PRP], it can be assumed to be a better option for clinical applications. The application of PRF in cleft palate surgery is advantageous in view of the process of repair of tissues and reduces the incidences of complications of fistula and necrosis [7].

Since the use of PRF may enhance the healing process and the stimulation of the tissue regeneration process, and taking into consideration that the problem of the cleft palate repair is not yet resolved, the efficacy of PRF should be definitely defined on such types of surgery. Thus, the present study attempts to estimate the effects of PRF application in cleft palate repair, focusing on postoperative complications and functional results.

METHODS

This was a prospective, randomized clinical trial, which included 40 pediatric patients with cleft palate due to the secondary palate at a tertiary medical institution. The subjects were sorted into two random groups: one [the control group], who underwent conventional cleft palate repair, and the other [the PRF group], where PRF was added along with the conventional surgical procedure.

The inclusion criteria included unilateral and bilateral cleft of the secondary palate in children aged between 1 and 6 years old.

The exclusion criteria of the study were systemic diseases, previous cleft surgeries, and allergic reactions to the anesthesia.

Surgical procedure: All surgeries were performed under general anesthesia using endotracheal intubation to maintain airway patency and ensure procedural safety. The cleft palate repairs utilized the two-flap palatoplasty technique. For patients in the PRF group, 10 mL of blood was drawn preoperatively, and platelet-rich fibrin [PRF] was prepared through centrifugation. The resultant fibrin clot was applied over the surgical site before closure to enhance healing and reduce postoperative complications. The control group underwent the same surgical procedure without PRF application.

Outcome Measures: The co-primary outcomes of interest were postoperative complications, including oronasal fistula, tissue necrosis, and wound dehiscence. Secondary outcomes included duration of hospital stay and status regarding the velopharyngeal function in accordance with speech assessments.

Follow Up:

Early post-operative: Patients were evaluated clinically to exclude airway obstruction and bleeding. All data was documented for all the included patients.

Discharge criteria: Children were discharged once they were stable from a respiratory standpoint typically, on the first or second postoperative days.

Post discharge follow up: Patients were scheduled to regular follow up visits, two times per week in the first 2 weeks, weekly for two months and monthly for the later 4 months. All patients were assessed for improvement of difficulty with feedings and nasal regurgitations.

RESULTS

This study evaluated the effectiveness of PRF in reducing postoperative complications in cleft palate surgeries. Key outcome measures included the rates of oronasal fistula, tissue necrosis, and functional results such as velopharyngeal function. Below are the main findings, presented with corresponding tables from the original data.

Postoperative Complications

Oronasal Fistula Formation: The incidence of oronasal fistula formation was significantly lower in the PRF group, with only 5.0% of patients affected, compared to 30.0% in the control group. This substantial reduction demonstrates PRF's potential in minimizing one of the most common complications in cleft palate surgery, which typically impacts postoperative healing and patient outcomes.

Tissue Necrosis Rates: In the control group, tissue necrosis occurred in 35.0% of patients, while only 10.0% of those in the PRF group experienced this complication. The reduction in tissue necrosis among patients treated with PRF reinforces the efficacy of PRF in enhancing tissue regeneration and reducing necrotic outcomes postoperatively.

Wound Dehiscence: The PRF group showed a wound dehiscence rate of only 5.0%, compared to 25.0% in the control group. This finding aligns with the hypothesis that PRF, due to its high concentration of growth factors, promotes better wound integrity and healing, thereby reducing dehiscence.

Functional Outcomes

Velopharyngeal Function: Postoperative assessment revealed that both groups showed similar velopharyngeal function outcomes, with no statistically significant differences. This result suggests that while PRF is beneficial in reducing physical complications, it does not appear to affect functional speech outcomes, as measured by VP function.

Hospital Stay Duration: The duration of hospital stay was comparable between the groups, with both having an average stay of approximately 5 days. This result indicates that PRF did not affect the length of postoperative hospitalization, suggesting its effects may be limited to structural healing improvements rather than overall recovery time.

Overall, the study results show that PRF application during cleft palate surgery significantly reduced the rates of oronasal fistula formation, tissue necrosis, and wound dehiscence. These findings support PRF as a valuable adjunct in cleft palate repair, enhancing tissue healing and minimizing structural complications. However, functional outcomes, such as velopharyngeal function and hospital stay, showed no notable differences, indicating PRF's primary advantage is in reducing structural complications rather than impacting speech or recovery duration.

Table [1]: Comparison of demographics and clinical characteristics between study groups.

Variable		PRF Group	Control Group	P-value
Age [years]		1.6 ± 1.5 [0.8 - 5]	4.1 ± 3.4 [0.8 - 12]	0.012
Weight [Kg]		12 ± 3 [8 - 18]	14 ± 5 [9 - 30]	0.512
Gender	Female	3 [15.0%]	5 [25.0%]	0.429
	Male	17 [85.0%]	15 [75.0%]	
Associated congenital syndrome		0 [0.0%]	0 [0.0%]	----

Table [2]: Comparison of Postoperative Complications Between Study Groups

Complication	Control Group [n = 20]	PRF Group [n = 20]	P-value
Oronasal Fistula	30.0%	5.0%	< 0.001*
Tissue Necrosis	35.0%	10.0%	0.047*
Wound Dehiscence	25.0%	5.0%	0.034*

Table [3]: Functional Outcomes

Variable		PRF Group	Control Group	P-value
Length of Hospital Stay		4.8 ± 2.1 days	4.5 ± 1.8 days	0.648
Follow-up Period [months]		5.3 ± 1.5	5.1 ± 1.3	0.695
VP Function	Mild VPI	25.0%	20.0%	0.677
VP Function	Normal	75.0%	80.0%	

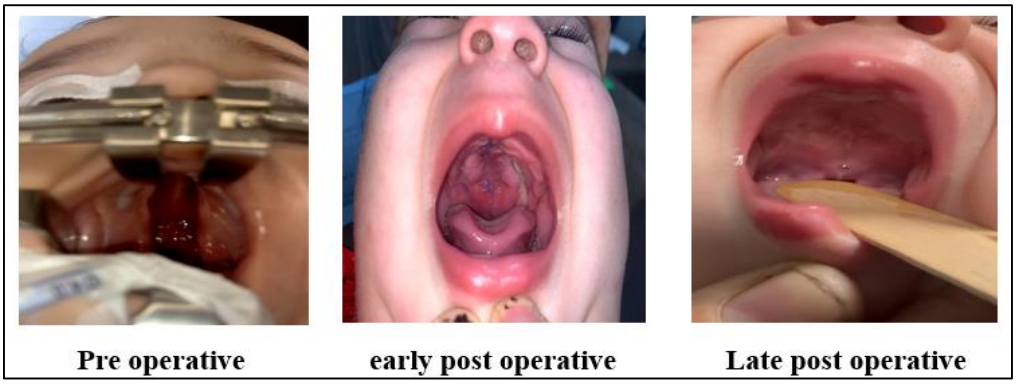

Figure [1]: Nine months old male with cleft of the secondary palate repaired using Bardach's two flaps technique

DISCUSSION

The main findings of the current study were as the following: the rates of postoperative infection and fistula formation were prevalent among the control compared to the PRF group. There were no statistically significant differences between groups in terms of length of hospital stay, follow-up period, and VP function postoperatively.

To our knowledge, this is may be the first study to compare the rate of postoperative complications among patients with cleft palate who underwent surgical repair in combination with PRF.

Soliman *et al*. reported in their prospective cohort study involving children with cleft palate, who underwent surgical repair of the defect using a mixture of bone graft and PRF, that the rate of fistula formation post-operatively was 5.0%, affecting only 2 patients, and wound infection occurred in 10.0% of the included patients [8]. These findings align with the current study as only four patients reported surgical site infection in the PRF group, and none had fistula during the whole period of follow-up.

Our findings were supported by **Al-Mahdi *et al***. who found that PRF used with autologous bone graft among children diagnosed with cleft palate significantly reduced postoperative bone resorption and provided a higher bone density in the long postoperative course [9]. This emphasizes the lower rate of fistula formation in the PRF group in our study.

Our findings were consistent with those of **Shawky and Seifeldin** [10] who conducted a study on 24 patients with unilateral alveolar cleft, using PRF with iliac bone graft to reconstruct the alveolar bone. They evaluated the improvement of bone volume using CT scan postoperatively and after 6 months, finding that bone density was significantly improved among the included patients. These findings were inconsistent with those of **Omidkhoda *et al***., who found no statistically significant benefit added by the addition of PRF to autologous bone graft among children diagnosed with cleft palate and who underwent surgical repair [11].

Thanasut *et al*. conducted a randomized control study involving children with cleft palate, randomized into two groups: the PRF group [mixing particulate cancellous bone and marrow with liquid PRF and covering the graft with PRF membranes] and a control group [PCBM only]. They found that regenerated bone volume and density were not significantly different between both groups, and no postoperative complications were reported in either group [12]. Additionally, the studies conducted by **Anwandter *et al***. and **Wang *et al***. examined the dimensional changes of the alveolar ridge following tooth extraction. These studies investigated the use of PRF for preserving the alveolar socket and found that PRF was ineffective in preventing vertical and horizontal bone loss in the alveolar ridges [13,14].

A study conducted by **Gurler *et al***. on the impact of platelet-rich fibrin [PRF] in conjunction with bone grafting on sinus lifting indicated that the incorporation of PRF did not yield a substantial enhancement in the observed outcomes [15].

Conclusion: This could significantly reduce postoperative complications such as oronasal fistula formation or tissue necrosis following cleft palate repair. These kinds of inclusions by PRF in surgical procedures may give a ray of hope toward better results among the patients and may minimize the need for further surgeries, hence assuring a better quality of life in cases of cleft palate. Further studies are needed to establish PRF as a standard adjuvant in all cleft palate repairs.

Limitations of the Study: Sample Size: The study was conducted among a relatively small group of 40 pediatric patients limiting to some extent the wider applicability of the research outcomes to other populations.

Short Duration of Follow up: A period of six months only post intervention may not be adequate in evaluating the long-lasting effects of PRF application especially in the adversity of complications that develops with time like retardation of maxillary growth.

Unitary Patient Demographics Limitation: The study only enrolled preselected patients with secondary cleft palate and pediatric age group thus the findings may not be applicable to other types or ages of the cleft.

Future Directions

Larger, Multicenter Trials: For subsequent works, it would be prudent to find a larger population with different ethnic groups in several centers and examine the effect of PRF on cleft palate surgeries.

Extended Follow-Up Period: Prolonged [- anti PRF time of six months] follow up would provide important information regarding the short- and long-term effects of the use of PRF following surgical intervention in the growth of the jaws.

Comparative Studies with Other Bioactive Agents: Further studies including the application of PRF and other bioactive agents or different methods of regeneration will be of significance in finding out the best adjunctive management of cleft palate surgery.

Standardization of PRF Application Protocols: Studies on the standardization of PRF preparation and application protocols of PRF should improve the reproducibility and clinical effectiveness of PRP.

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