The Effect of Platelet Rich Fibrin in Bardach Two Flaps Palatoplasty Technique for Primary Cleft Palate Repair; A Comparative Study

Thesis

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بسم الله الرحمن الرحيم

وَاتَّقُوْا اللّٰهَ وَيُعَلِّمُكُمُ اللّٰهُ

وَاللّٰهُ بِكُلِّ شَيْءٍ عَلِيمٌ

صدق الله العظيم

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List of Abbreviations

Abbr.	Full-term
AEP	: Alveolar extension palatoplasty
BCLP	: Bilateral Cleft lip and palate
bFGF	: Basic Fibroblastic Growth Factor
CBC	: Complete blood count
CCC	: Cleft Care Center
CP	: Cleft palate
CTGF	: Connective tissue growth factor
DPOI	: Daily postoperative oral intake
ENT	: Nose, and throat care
FDP	: Fibrinogen degradation products
FLACC	: Face, Legs, Activity, Cry, and Conslobility
GBR	: Guided bone regeneration
GTR	: Guided tissue regeneration
IGF	: Insulin like growth factor
IV	: Intravenous
Kcal	: Kilocalories
L-PRF	: Leucocyte and PRF

MSC : Mesenchymal stem cells

NAT : Nucleic acid Amplification Testing

NG group : Nasogastric tube group.

NS : Non-significant (NS)

OME : Otitis media with effusion

PDGF : Platelet-derived growth factor

PLLA : Poly- (L—lactic) acid

P-PRF : Pure platelet-rich fibrin

PRF : Platelet Rich Fibrin

PRP : Platelets rich plasma

RBCs : Red blood cells

RCT : Randomized controlled clinical trial

SCTG : Sub-epithelial connective tissue graft

SPSS : Statistical Program for Social Science

TGF- β : Tumor growth factor-beta

UCLP : Unilateral cleft palate

VEGF : Vascular endothelial growth factor

VWK : Veau-Wardill-Kilner

WBCs : White blood cells

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Abstract

Background: Wide cleft palates and relatively wide cases with deficient palatal tissues are significant contributors to postoperative palatal fistula. Trails to optimize healing in such cases were carried out. Use of absorbable membranes was carried out to act as a scaffold attracting cellular action and revascularization. **Aim of the Work:** To assess the effect of using Platelet Rich Fibrin (PRF) to aid primary cleft palate repair in dimensionally challenging CPs, and to assess its effect on healing, postoperative pain, and early postoperative oral function recovery. **Patients and Methods:** The study was conducted after approval of the Research Ethical Committee at Faculty of Dentistry, Ain Shams University. **Patients selection:** Fourteen patients presenting with primary cleft palate (CP) larger than ten millimeters at the widest area, were selected from those attending the Cleft Care Center (CCC), Oral and Maxillofacial Department, Faculty of Dentistry, Ain Sham University. All should fulfill these ***Inclusion criteria: Cleft related criteria:*** Unilateral, bilateral cleft lip and palate and isolated cleft palates. Patients must have hard palate cleft (Post-incisive foramen cleft), Gap width at the posterior edge of the hard palate is at least 10mm, Relatively deficient tissues, where ratio of palatal width to the sum of palatal tissue at the posterior edges of palatal shelves is at least 0,5, Primary cleft palate repair (no previous attempts of CP repair). **Results:** The present study showed highly significant regression in postoperative pain score upon using PRF as adjunct to the surgical repair. The daily postoperative pain score in each day of the successive 3 postoperative days in the study group showed significantly less pain as compared to the control group. **Conclusion:** Surgical technique remains the paramount for achieving anatomical closure in cleft lip and palate cases. AEP provides a dependable surgical technique for missing the possibilities of fistula formation in primary and secondary CP repair. PRF can be considered as a biologically useful adjunct in CP surgery. Nutrition is an aspect that is affected in infants following CP surgeries. Monitoring pain and nutrition using graded scores provide valuable information regarding the general condition of the patients with CP in the early postoperative phase. The ad vocation of PRF combined with AEP proved worthy of further research and investigation. Further investigations to assess the outcomes in CP surgeries are worthy requested. **Recommendations:** AEP is a technique that should receive more support for cleft center. This is attributed to its rule in minimizing the occurrence of palatal fistula. A paradigm shift towards more nutrition based analysis is strongly recommended in the field of CP management. Further studies with a large study sample are needed to evaluate the effect of PRF in the surgical management of challenging wide CP. Effect of PRF on postoperative pain had been surgically explained. Biological explanation is vitally required to describe the detailed effect of PRF on soft tissue healing. Using a graded numerical scales aids in quantifying and assessment of postoperative pain in infants. Close follow up following CP surgery is essential. This is not only to focus on the physical status, but rather to provide parental guidance and ensure postoperative nutritional support. The use of nasogastric tubes postoperatively in CP patients should be decreased on case to case basis.

Key words: Cleft palates, postoperative palatal fistula, Platelet Rich Fibrin (PRF)

Introduction

Palatogenesis takes place during weeks 8-12 in human intrauterine life. Palatal formation takes place by merging of both the frontonasal and maxillary prominences. Frontonasal prominence gives rise to the median palatine process. Whereas, the maxillary prominences gives rise to the lateral palatine processes. All three derived elements are initially widely separated. During the eighth week of gestation, they start fusion from anterior to posterior. By the end of the eight week, the palate is completely formed. [1,2]

The fusion of these processes may be interrupted at any point. Interruption of palatogenesis results in cleft palate, which appears as an oronasal opening of variable presentations. The earlier the interruption, the more anatomically significant the cleft defect. [2]

Our aim was to prevent the drawback, following primary closure of cleft palate (CP). especially in dimensionally challenging CP. Dimensionally challenging CP is a term that was widely used. That is why studies were concerned with setting specific criteria of dimensionally challenging CPs. Furthermore, studies were concerned with investigating the effects of dimensionally challenging CP on the surgical outcomes.

Review of Literature

The overall incidence of oral clefts (excluding bifid uvula) is estimated to be 1 in 750 live births, making clefts the second most common congenital defect after clubfoot. [3] About 30% of oral clefts are accompanied with syndromes and 70% are non-syndromic. [4] The subdivision into non-syndromic and syndromic is important. The incidence of CP among families in non-syndromic CL/P and CP rarely occur again with incidence rate of (2-6%) [5,6]. While syndromic cases have a strong association with specific genetic mutations with a higher inheritance risk (passed down through families). [4]

Cleft palate presentation differs, but it had been categorized in various classification systems. These classifications helped documentation, communicating, comparing, and analyzing results. The classification by Davis and Ritchie divides cleft lip and palate into 3 groups, according to the extent of the cleft, as follows: group I - Clefts anterior to the alveolus (unilateral, median, or bilateral cleft lip), group II - Postalveolar clefts (cleft palate alone, soft palate alone, soft palate and hard palate, or submucous cleft, and group III- Complete palatal cleft. [7]

The Veau classification system comprises 4 groups, which are as follows: group I – Defects of the soft palate only, Group II – Defects involving the hard palate and soft palate, group III – Defects involving the soft palate to the alveolus, usually involving the lip, group IV – Complete bilateral clefts. [5]

The International Confederation of Plastic and Reconstructive Surgery classification system uses an embryonic framework to divide clefts into 3 groups, with further subdivisions to denote unilateral or bilateral cases, as follows: group I – Defects of the lip or alveolus, group II – Clefts of the secondary palate (hard palate, soft palate, or both), group III – Any combination of clefts involving the primary and secondary palates [(6)].

The challenge in management of CP is the sequlae of the congenital anomaly as well as those of the surgical intervention itself. Cleft palate adversely affects the appearance, speech, hearing, feeding, and facial growth. [(6)] Surgical intervention can neutrally, positively, or even negatively affect these functions. For speech, the anomaly adversely affects the sound production. Cleft palate patients suffer from failure to produce high pressure and air escape due to lack of structural seal between oral and nasal cavities, along with the resultant hypernasality. In addition, lacking enough palatal surface area for articulation in special sounds also adds the suffering cleft palate patient. [(8)]

Hearing disabilities are co-factors in speech problems. Diminished hearing capabilities and even hearing loss are associated with cleft palate. CPs negatively affects hearing. The pathophysiology of this negative effect is attributed to the pertinent anatomy of the middle ear.

The middle ear is a cavity formed as an extension of naso-pharynx by a connecting channel known as Eustachian tube. [(8)] The Eustachian tube is the ventilator of the middle ear, it acts to neutralize