

Should Haemoglobin be Considered a Criterion for Case Selection in Palatoplasty? - A Prospective Study Report

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ABSTRACT

Aim: The study aimed to find a correlation between the haemoglobin (Hb) and packed cell volume (PCV) levels during the pre and post Palatoplasty in patients with cleft palate and the fistula occurrence after the Palatoplasty surgery.

Methods: A prospective study was conducted on 50 patients with unilateral cleft lip, alveolus and palate (UCLAP) bilateral cleft lip, alveolus and palate (BCLAP), isolated cleft palate (CP) who reported to the Craniofacial unit for Palatoplasty. Hb & PCV levels evaluated pre and post Palatoplasty were correlated with the occurrence of post-surgical fistula.

Results: The patients with fistula present (FP) and fistula absent (FA) after Palatoplasty were compared with respect to pre-operative and post-operative Hb. The pre-op p-value=0.5944 & post-op p-value=0.8010 through t-test. The pre-operative and post-operative Hb was compared to the FP and FA groups by paired t-test, FP group p-value=0.7013 & FA group p-value=0.0923. Both showed no significant difference. A Similar result was found with respect to PCV values and fistula occurrence.

Conclusion: No significant correlation was found between Hb & PCV levels and post-surgical fistula occurrence. Also, literature doesn't show evidence of anaesthetic complications secondary to low Hb levels. Hence, deferring the surgery based on Hb and PCV levels should be reconsidered.

Key words: Cleft Palate, Hemoglobin, PCV, Palatoplasty, Complications, Fistula

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INTRODUCTION

Cleft lip and palate is one of the most common craniofacial deformities with the incidence of 9.3 per every 10,000 babies born in a year. Complications following palatoplasty comprise of bleeding, infection, fistula, haemorrhage, respiratory compromise. Cleft palate with or without lip involved generally require a series of surgeries for functional and aesthetic correction. There are an array of procedures and protocols followed worldwide with each having their own pros and cons. Nevertheless, it is of general consensus that the procedures performed should lead to a good speech restoration with minimum effect on growth of the patients.

A successful surgery entails a procedure that fulfils the aims decided and occurs without any impediments; also

there is a complete recovery in a reasonable amount of time, without any complications. Various local and systemic factors are known to influence healing. The nutritional factors can be assessed with the help of laboratory investigations. The Haemoglobin levels points towards the oxygen carrying capacity of blood [1]. Lower Hb levels may lead to reduced oxygenation of tissues leading to delayed or impaired healing.

Due to the difficulty in feeding in the cleft palate patients, the failure to thrive runs upto almost 49%. Low weight and Hb levels in these patients are common occurrences. Timely surgical repair helps this situation by enabling to feed the child better. Presently the quest is to discover the possible reasons causing palatal fistula, so as to reduce their incidence in the future. There is also evidence in the literature that packed cell volume of the patients is considered necessary in patient selection for surgery. Therefore, this study was done to evaluate the relationship of Hb and PCV levels during and after palatoplasty with fistula formation [2,3].

MATERIAL AND METHODS

A prospective study was conducted where 50 patients who underwent palatoplasty surgery for cleft palate from the period of Craniofacial surgery unit of a private dental hospital at Dharwad, India were studied. Ethical clearance was priorly received from institutional ethical committee. Informed consent was obtained from all the patients participating in the study. The study subjects were operated by a single surgeon using Veau Wardill Kilner V-Y Pushback Technique. The inclusion and exclusion criteria were pre-defined [4]. The patients of unilateral cleft lip, alveolus and palate, Bilateral cleft lip, alveolus and palate and isolated cleft palate were included. They belonged to the age range of 9 months-16 years irrespective of the gender. Patients with associated syndromes or systemic problems were excluded. Also, patients who were operated previously for cleft palate were not considered for the study.

Hb and PCV levels were evaluated in all the patients pre-operatively and 5 days post operatively. Common protocols were followed for all the patients pre and post surgically. All patients received 3 days pre-op oral antibiotic of cefixime (age and weight appropriate dose was given) and 3 days-post op injectible antibiotic of cefixime. They were followed up regularly at 1 week, 1 month and 3 months post discharge. The data hence collected was statistically analysed. The comparisons of patients with fistula present and fistula absent with respect to pre op & post op Hb and PCV and their differences was done by t-test [5,6].

RESULTS

Fifty patients were included in the Present study, where 12 (24%) patients presented with fistula and 38(76%) patient presented with no fistula.

The mean age of the patients was 3.03 years; FP group patients being 2.82 years and FA group patients being 3.10 years.

The FA and FP patients were further divided into 3 groups: (a) 9 months to 5 years- 40 patients; (b) 6 years to 11 years- 6 patients; (c) 12 years to 17 years- 4 patients Out of the 50 patients; 28 were males (56%) and 22 were females (44%).

The FP group consisted of 7 males and 5 females and FA group had 21 males and 17 females. Statistical evaluation with chi-square test $P=0.834$, therefore the correlation of gender with the formations of fistula was not significant.

The size of the fistula that was recorded in these patients ranged from 0.2mm-1.9mm. Anatomically mid-palatal region i.e.at the junction of hard and soft palate was 50%, which therefore was the most common site for fistula occurrence, 42% in the anterior palate and 8% in the soft palate.

The patients with UCLAP, BCLAP and CP were included in the study who were to beoperated for palatoplasty. UCLAP was the most common type of in both FP and FA groups 50% and 56.3% respectively. Association between

type of cleft and status of fistula was insignificant ($P=0.9481$).

Statistical Analysis

The Hb levels in these patients pre-operatively ranged from 8.2gm% -13.2gm% (mean - 9.93gm%); and during the post-operative period the Hb levels ranged from 7.8gm%- 13gm% (mean= 9.72gm%). The comparison of Hb as a parameter in patients with FP and FA during pre-op, post-op and the difference as per the t-test, found p-value 0.5944 pre-op & 0.8010 pre-op therefore making it not significant. The pre-op and post-op Hb was also compared in the FP and FA groups by paired t-test, FP group p-value=0.7013 & FA group p-value=0.0923, hence showing it to be not significant.

Also the pre and post-operative PCV were compared to fistula occurrence i.e., in FP and FA groups by t test, pre-op PCV levels p-value was found to be 0.5189 & PCV levels during post-op p-value was 0.6267. This was not significant. Paired t-test was done to compare the pre-op and post-op PCV in FP & FA groups, in FP group p value=0.5703 & FA group p-value=0.2179 was obtained. Therefore, PCV values were not significant in fistula occurrence. Hence, the pre-op and post-op Hb & PCV levels in blood based on t-test (paired and unpaired) were not significantly associated with post-palatoplasty fistula formation.

DISCUSSION

Cleft palate in infants comes with myriad of problems. The lack of normal attachment of musculature in the palate and the bony defect are seen in these patients. The biggest problem these babies face is poor nourishment due to inability to form an intra-oral suction which is necessary for breast feeding and due to inability to swallow. The rate of failure to thrive of upto 49% was seen in these patients. The incidence oro-nasal communication is associated with middle ear infection, speech anomalies, nasal regurgitation, maxillary hypoplasia. Early management of cleft palate helps the babies to catch up on the nutritional and oro-motor development.

We found an fistula incidence of 24% in our study, while found higher fistula occurrence rate of 35.4% when operated by the humanitarian groups which was could be due to limited resources and multiple surgeons involvement. Cleft palate could be present independently or in association with unilateral or bilateral cleft lip and /or alveolus. In our study we found there to be no correlation between the type of cleft and the fistula occurrence post-operatively, but there are studies which have found the incidence of post-op fistula to be to higher in patients with BCLAP meanwhile came across higher fistula incidence in cleft lip-cleft palate than in cleft palate.

The commonest site of fistula occurrence amongst the subjects of our study was mid palate region, similar observation was made by J Murthy in their study.

A meta-analytic study found single stage procedures presented with lesser likelihood of the occurrence of fistula than the two stage procedures. Also the Furlow double-opposing Z-plasty have decreased fistula rates when compared to the von Langenbeck and V-Y pushback techniques. It was also seen that patients who underwent single stage palatoplasty have more hypernasalance as compared to two stage palatoplasty. Our study involved a single surgeon and all patients were operated using Veau Wardill Kilner V-Y Pushback palatoplasty in a single stage repair.

The age of the patients involved in our study ranged from 9 months to 17 years, which did not reflect any influence over the fistula occurrence statistically. But literature states that early intervention of cleft palate helps in better speech outcome.

Post-surgical fistula might have many factors participating in causing complications. One such factor is Hb and which is the indicator of oxygen carrying capacity of the blood. In our study we found 24% of the patients presented with a fistula as compared to 1.5 % fistula rate as reported by Mahboubi and 13.6% rate seen by Schonmeyr. This could be attributed to smaller sample size of our group. In our study we also found that the Hb and PCV levels of the patients pre and post-operatively, also the change in their levels over the period of surgery did not play a significant role in causing fistula in the patients who underwent palatoplasty also found that it was not necessary to maintain normal hematocrit values to support healing, as long as peripheral perfusion of oxygen is maintained.

Patients who are considered for a surgery need to be cleared by the paediatricians and the anaesthetist prior to the surgery. While a surgeon primarily is concerned about the surgery to occur without any complications and healing occurring uneventfully, the paediatrician and the anaesthetists overlook the systemic wellbeing. Low Hb means a decreased oxygen reserve which is required for maintenance of vital organs due to the systemic insults that might occur when the patient goes under general anesthesia in their study found that patients with Hb 7-10 gm% tolerated anaesthesia well and recovered rapidly. In fact Kotur states that anaesthesiologists' preoperative estimation of Hb% may not be necessary of a clinically normal patient if the proposed surgery does not involve major blood loss and the patient does not have associated cardiac and pulmonary diseases.

There are literatures upholding the 'rule of 10' as the criteria for cleft lip repair the attention on how this rule might not be completely valid and that it might need to be revised and updated. We found that there is a lack of defined criteria for considering patients for palatoplasty unlike that for lip. Also the information available in literature is of the patients who were operated upon therefore, it is difficult to estimate the percentage of people who were not accepted for surgery based on their haematological values.

LIMITATION AND SUGGESTIONS

Limitation of our study was that there was small sample size. Although the number of subjects was statistically sufficient, a larger number would have helped with even distribution in the age group of the subjects.

CONCLUSION

We find that cleft palate patients stand to benefit more from undergoing palatoplasty than facing risks. In our study we found that Hb and PCV levels of the patients operated for cleft palate did not have a correlation with the fistula occurrence. From our study we suggest that deferring the surgical intervention because of anaesthetic or surgical complications secondary to low Hb or PCV levels should be made redundant. Study recommends that there is a need for formulation of criteria for selection of patients for palatoplasty.

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