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Predictor Variables of Intraoperative Blood Loss during Cleft Palate Surgery

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Cleft palate surgery, Intra-operative blood loss, Predictor variables

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ABSTRACT

Study design: Cross-sectional study

Objectives: To determine the predictor variables associated with blood loss during cleft palate surgery.

Method: This was carried out for 12 months. Pre-operative records of each participant were taken including the age, sex, BMI, haematocrit, haemoglobin concentration, the length of the cleft defect and the width. Blood loss was determined using colorimetric method of measurement. The blood loss was calculated using the appropriate formula. Multiple regression analysis was done to determine the predictors of increased blood loss. Statistical analysis was carried out with IBM SPSS version 23.0 (2015) with statistical significance assessed at a p-value of ≤ 0.05, and a 95% confidence interval.

Result: A total of 39 participants were recruited for this study, with a median age of 24 (IQR: 21–48) months. The mean length of the defects was 32.1±2.6 mm while the mean duration of surgery was 118.1±38.1 mm. The median value of the intra-operative blood loss was 40.2(IQR: 26.7–60.5). The duration of surgery and the age of the patient were the only statistically significant variables in regression analysis (p<0.0001).

Conclusion: Predictor variables of increased intra-operative blood loss were the duration of surgery and the age of the patient.

INTRODUCTION

Cleft surgery is one of the commonest surgical procedures in some oral and maxillofacial surgery centres. An audit of oral and maxillofacial procedures under general anaesthesia in a South-Western tertiary hospital[1] showed that cleft surgery was the most frequent procedure performed. This was similar to finding from another study in the South-South of Nigeria.[2] This increase in the number of cleft surgeries may be due to the rise in awareness of the deformities, the demystification of the condition, the campaign against stigmatisation, and improvement in the available treatment expertise.

Cleft repairs, like every other surgery, involve loss of blood which has to be estimated to ensure the patient's optimisation and survival. A previous study showed that up to 10% of the patients that underwent cleft surgeries were transfused,[3] however, there is a paucity of studies on the predictors of intra-operative blood loss in cleft palate surgery. Also, despite the high volume of cleft surgeries in Nigeria, a search of the literature showed only one study reported an in-depth assessment of blood loss in cleft surgery. Therefore, this study seeks to address the knowledge gaps by determining the predictor variables associated with blood loss in cleft palate surgery.

MATERIALS AND METHODS

This cross-sectional study was carried out for 12 months at the Department of Oral and Maxillofacial Surgery, University of Benin Teaching Hospital (UBTH), Benin City. The study population comprised all patients with cleft palate that presented at the hospital and were scheduled for cleft repair under general anaesthesia within the study period. The selection criteria include the presence of congenital cleft palate in ASA 1 or 2 patients, aged between 18 months and 5 years. Patients with pre-operative haemoglobin lower than 10 mg/dl or haematocrit of less than 30% were excluded as well those with history of coagulopathy. Ethical approval for this study was obtained from the Ethics and Research Committee of the hospital and a total of 39 participants were recruited. A written consent was obtained from parents whose children/wards met the inclusion criteria and who agreed to participate in the study.

Pre-operative records of each participant were taken including the age, sex and the BMI (using RGZ-120@ height and a weighing scale) The haematocrit, haemoglobin concentration, estimated blood volume (EBV) and the allowable blood loss (ABL) were also recorded. The cleft defect was classified for each participant using Veau's classification.

Intra-operatively, 2 ml of blood sample was collected from each participant (for colorimetric measurement of blood loss) during cannulation under light sedation. After intubation and drapping, dingman retractor was placed to gag the mouth open to aid access and visibility. The length of the cleft defect was measured (in mm) with the aid of a Castro Viejo calliper from the most anterior point to the most posterior point of the defect. The width of the cleft was similarly measured (in mm) at the junction of the hard and soft palates, and also at the widest point of the defect for Veau type 4.[4]

Surgical markings were placed and the sites infiltrated with 2% Xylocaine with 1:100,000 epinephrine (of 2-3 ml) was used to infiltrate the surgical sites to aid haemostatic control. Surgical repairs of the cleft were done using appropriate surgical technique (von Lagenbeck, Wardil-Kilner-Veau, Bardach or Furlows) in each case based on the type of the defect.

Post-operatively, duration of surgery **(**time from the first incision to the placement of the last suture was recorded (in minutes). Blood loss was mopped up with standard surgical gauze and suctioned into a collection bottle throughout the procedure. The suction tube was irrigated with normal saline after the procedure so that blood in the conduit could be added to the one already in the suction bottle taking note of the volume of saline used for irrigation. Also, the blood-stained instruments and gloves of the operators were wiped clean with moistened swabs. [5,6,7,8,9]

Afterward, all these (the used gauze and the contents in the suction bottle) were collected in a large container (Sample B) and taken to the hospital chemical pathology laboratory for colorimetric analysis. At the laboratory, two separate solutions of 5% NaOH (100 ml and 2 litres) were prepared by a qualified laboratory scientist by adding distilled water to 5g of NaOH (Loba Chemie@)) up to 100 ml and 2 litres marks respectively. Then, 1 ml of venous blood taken pre-operatively (sample A) was brought to 1:100 dilution with 5% sodium hydroxide (NaOH) solution (solution A), while 2 litres of the same prepared solution was added to Sample B (the used gauze and the contents in the suction bottle in the large container) (Solution B).[5,6,7,8,9] Both solutions (A&B) were allowed to soak for 24 hours for the haemoglobin content of the red cells to be released.[9,10]

After this, 10 ml of each of the solutions (A and B) was taken and centrifuged for 10 minutes at 3000rpm, and the optical densities were read with a spectrophotometer at 550nm wavelength. Colorimetric blood loss was calculated using the formula; [5,6,7,8,9]

$$\textbf{Total blood loss(ml)} = \frac{\textbf{Optical Density of Solution B X 2000}}{\textbf{Optical Density of Solution A X100}}$$

All data collected were entered into a spreadsheet on the passworded personal computer and then coded and processed using statistical software.

Descriptive statistics, tables and figures were applied in presenting and analysing the socio-demographic and clinical characteristics of the study participants. Quantitative variables were expressed in mean ± SD, median/interquartile range or percentage (%) as appropriate. Shapiro-Wilk test was used to evaluate the normality of continuous variables. The relationship of blood loss with the independent variables (age, BMI, the extent of cleft defect and duration of surgery) was assessed using Spearman's correlation coefficient.[11] Multiple regression analysis was used to evaluate the significant predictor variables influencing bleeding.[4]

A p-value of ≤ 0.05 was considered statistically significant for this study, with a 95% confidence interval. The statistical analysis was carried out using IBM SPSS Statistics 23.0 (2015).

RESULTS

A total of 39 participants were recruited for this study. There were 12 (30.8%) males and 27 (69.2%) females (Table 1). The age range of the study participants was 18 months to 5 years, with a median age of 24 (IQR:21-48) months, and a mean BMI of 16.6 ± 2.8 kg/m^2. The participants were taken in for surgery with an HB concentration of at least 10g/dl and a PCV of at least 30%. The mean HB and PCV were 11.5 ± 1.0g/dl and 34.4 ± 2.7 respectively (Table 2). Two-thirds of the participants (69.2%) had type 2 Veau's defects, while most repairs (51.3%) were carried out using Wardill-Kilner-Veau's technique.

The mean length and width of the defect were 32.1 ± 2.6mm and 11.0 ± 1.1mm respectively (Table 2). And the average duration of surgery was 118.1 ± 38.1 minutes. The median value of the blood loss was 40.2 (IQR:26.7-60.5) ml using the colorimetric method, while the visual estimation was 70.0 (IQR: 45.0-90.0) ml.

Spearman's Correlation analysis (Table 3) showed the relationship between the amount of blood loss using the colorimetric method of assessment and the following clinical variables; Duration of surgery, Age, Weight and the BMI of the participants, Length of the defect and the Width of the defect. There was a statistically significant relationship between the blood loss and the clinical variables

(Table 3) like; Duration of surgery (ρ =0.722; *p* <0.001), Length of the defect (ρ =0.571; *p* <0.001) and the BMI (ρ =-0.351; *p*= 0.028).

Multiple regression analysis was further used to evaluate the predictor variables that influence the amount of intra-operative blood loss as measured by the colorimetric method (Table 4). The result showed that the Age of the participants (β = 0.499; *p*=0.032) and the Duration of Surgery (β = 0.571; *p*=0.001) were the significant predictors of increased intra-operative blood loss. However, the length of the defect (β = 0.286; *p*=0.133) and the BMI (β = 0.049; *p*=0.722) also came up as predictors of increased blood loss but were not statistically significant. The male gender was associated with a loss of 4.95ml of blood more than the female which was not statistically significant (*p*=0.522).

The standardised coefficient (β) showed that the Duration of surgery has the highest effect (β=0.571) as a predictor of increased intra-operative blood loss. The overall measure of the strength of association between blood loss and the independent variables was 0.565. And the subject per variable (SPV) was 5.6.

Table 1: Socio-demographic Characteristics of the Study Participants

Variable	Frequency (Percentage) N=39
Sex	
Male	12 (30.8)
Female	27(69.2)
Age (in months) *	24 (IQR:21-48)
Weight (kg)*	12.5 (11.5-15.0)
BMI (kg/m^2)	16.6 ± 2.8

*Not normally distributed, presented in median. (IQR= Inter Quartile Range).

Table 2: Clinical and Perioperative Parameter

Variable	Frequency (Percentage) N=39
Hb (g/dl)	11.5 ± 1.0
Types of Veau's defect	
1	1 (2.6%)
2	27 (69.2%)
3	9 (23.1%)
4	2 (5.1%)
Technique	
von Langenbeck's	7 (17.9%)
Bardach's	11 (28.2%)
Double opposing Z plasty	1 (2.6%)
Wardill-Kilner-Veau's	20 (51.3%)
Duration of Surgery (mins)	118.1 ± 38.1
Length of Defect (mm)	32.1 ± 2.6
Width of Defect (mm)	11.0 ± 1.1
Blood Loss (ml)	
Colorimetry Measurement	40.2 (IQR:26.7-60.5)

Table 3: Spearman's Correlation Coefficient (ρ) Between Blood Loss and Clinical Variables

Variable	Spearman's Correlation Coefficient (ρ)	*p* Value
Age (months)	0.010	0.954
Duration of Surgery (mins)	0.722	<0.001*

BMI (kg/m^2)	-0.351	0.028*
Weight (kg)	-0.152	0.355
Length of the defect (mm)	0.571	<0.001*
Width of the defect (mm)	0.299	0.065

*Statistically significant

Table 4: Multiple Linear Regression Analysis for the Predictor Variables of Blood Loss

Variable	Un-standardised Coefficients (B)	Standardised Coefficients (Beta)	*t* value	*p-value*
Sex†	-4.952	-0.099	-0.647	0.522
Age (months)	0.788	0.499	2.241	0.032**
Duration of Surgery (min)	0.351	0.571	3.853	0.001**
Weight(kg)	-2.277	-0.295	-1.467	0.152
BMI (kg/m^2)	0.410	0.049	0.360	0.722
Length (mm)	0.629	0.286	1.542	0.133
Width (mm)	-0.030	-0.005	-0.037	0.970

*Model Parameters: R^2=0.565, p<0.001; **statistically significant, † males were the reference group.

DISCUSSION

The most prevalent congenital orofacial defect is cleft lip and palate, and as a result, cleft repair is among the most often carried out surgical treatments under general anaesthesia in some maxillofacial centres.[1,2] The whole blood volume of an infant is about 70 to 80 ml per kilogram body weight; which indicates a limited haemodynamic capacity.[4] Palatoplasty requires flap procedures and is associated with intra-operative blood loss which is of importance, especially in children who are more prone to systemic derangement at relatively lower blood loss. There is paucity of study on the predictor variables associated with intra-operative blood loss in cleft palate repair, hence the need for this study.

Following the selection criteria, children between the ages of 18 months and 5 years were recruited for the study. The median age was 24 (IQR:21-48) months. The median value of the blood loss as measured by the colorimetric method was 40.2 (IQR:26.7-60.5) ml. Variables assessed to determine their impact in influencing the amount of blood loss in cleft repair include the participants' age, sex, weight, BMI and the length and the width of the defects. This study showed that there were certain predictor variables of intra-operative blood loss. Regression analysis identified the duration of surgery as a predictor of increased intra-operative blood loss (p < 0.001). The longer a surgical procedure is or the longer it takes to control intra-operative bleeding, the longer would be the duration of the surgery and the more the amount of blood that would be lost. This is why ensuring prompt effective haemostatic control (by using suitable agents like adrenaline, gel foam, surgicel, application of pressure or coagulation with diathermy), to give a clear field of operation ultimately reduces both duration of surgery and the amount of blood loss. Further, analysis showed that with every one-minute increase in the duration of surgery the odds of increasing blood loss was 1.1%. This finding is in agreement with previous studies.[4,12,13,14,15] Kim et al., found prolonged operation times as a predictor of more blood loss in cleft palate patients.[4]

Apart from the duration of surgery, the age of the cleft participant was another significant predictor variable of increased intra-operative blood loss identified in this study. It is known that with an increase in age there is more developed musculature and vascularity, hence more bleeding is expected when an incision is made. Therefore, the older the patient, the more the amount of blood that is lost, which is similar to the findings from other studies.[4,16] This could be the reason why certain authors have advocated for palatoplasty at an early age to minimise blood loss and the duration of surgery.[4] The odds of increasing blood loss with every one-month increase in age was 1.8%.

This study also identified the BMI and the length of the defect as predictor variables of increased intra-operative blood loss, but these were not statistically significant (p > 0.05). The BMI is a reflection of the patient weight which is often dependent on the bone and the muscle mass. A high muscle mass is indicative of a well-developed and well-vascularised muscle which tends to bleed more when incised. Increased length of the defect also indicates a need for a longer incision line during repair which means more tissue bleeding, thereby increasing blood loss. However, this finding is in contrast to that of another study that showed that the width of the cleft, rather than the length, was a predictor of more blood loss.[4] This same analysis showed that the male gender was associated with increased (4.95 ml) blood loss, though not statistically significant ($p > 0.05$). The male gender has a higher BMI than the female which is a function of the bone and the muscle mass as highlighted above, and therefore associated with more blood loss. Veau type of the defect and Surgical technique as factors were tested in the regression model and removed as these factors were not statistically significant and reduced the proportion of variance in the dependent variable (Blood Loss) which can be predicted from the independent variables. The standardised coefficient (β) showed that the Duration of surgery has the highest effect (β=0.571) as a predictor of increased intra-operative blood loss.

In conclusion, the predictor variables of intra-operative blood loss in cleft palate surgery are the duration of surgery and the age of the patient.

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None

CONFLICT OF INTEREST

None declared.

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