

**ASSESSMENT OF INTRAOPERATIVE BLOOD LOSS
DURING ORAL AND MAXILLOFACIAL SURGICAL
PROCEDURES AND ITS IMPLICATIONS**

Dissertation

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Of

MASTER OF DENTAL SURGERY

In

ORAL AND MAXILLOFACIAL SURGERY

By

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BATCH: 2018-2021

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I hereby declare that this dissertation entitled “ASSESSMENT OF INTRAOPERATIVE BLOOD LOSS DURING ORAL AND MAXILLOFACIAL SURGICAL PROCEDURES AND ITS IMPLICATIONS” is a bonafide and genuine research work carried out by me under the guidance of **Dr. Hemant Gupta**, Professor & Head, Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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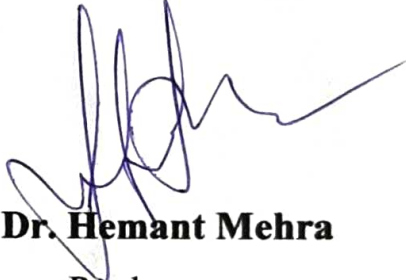
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LIST OF ABBREVIATIONS

Hb	:	Haemoglobin
HCT	:	Haematocrit
PCV	:	Packed cell volume
RBC	:	Red blood cell
EBL	:	Estimated Blood loss
ABL	:	Actual Blood loss
SPSS	:	Statistical Package for Social Sciences

ABSTRACT

Background of the study: Despite the enormous revolution in the field of medical science; intraoperative haemorrhage remains one of the major surgical complications experienced in day to day surgical practice. Hence, this study was performed to quantify the intraoperative blood loss and to evaluate its influence on the blood parameters.

Aim and Objectives: To estimate blood loss during oral and maxillofacial surgical procedures and to establish correlation between gravimetric/volumetric estimation of blood loss with changes in pre-operative and post-operative values of haematocrit, haemoglobin, body weight and RBC count.

Material and Method: 30 patients were enrolled in the study. During the surgery, Gravimetric method of blood loss estimation was used based on the assumption that 1ml of blood weighs 1.06 gm and volumetric estimation was done by measuring the amount in the suction bottle. Preoperative and immediate postoperative haematocrit, haemoglobin, RBC count and body weight were assessed. Patient's characteristics, duration of surgery and intraoperative fluids given were also recorded. This EBL was compared with ABL which was calculated from a modification of the Gross formula: $\text{Actual blood loss} = \text{Blood volume} \left[\frac{\text{Haematocrit}(i) - \text{Haematocrit}(f)}{\text{Haematocrit}(m)} \right]$. Bivariate analyses was performed using paired t test for comparison of pre and post value change and correlation among continuous variable was assessed using Pearson correlation test. Level of statistical significance was set at p-value less than 0.05.

Results: Significant reduction was found between mean preoperative and mean postoperative haematocrit, haemoglobin, body weight and RBC count. Blood loss was found to consistently increase with duration of surgery. The study revealed significant difference between the clinical measurement of blood loss using the gravimetric and volumetric method i.e. EBL and the blood loss calculated by the Gross formula using the haematocrit values i.e. ABL.

Conclusion: The study concluded that gravimetric/volumetric estimation was a reliable method to determine intraoperative blood loss.

KEYWORDS: Intraoperative blood loss, Haematocrit, Haemoglobin, EBL, ABL.

INTRODUCTION

Introduction

Of the many battles the surgeon encounters during years in practice, none is more demoralizing and critical than uncontrolled hemorrhage. The loss of circulating fluid volume can lead to homeostatic imbalance, therefore recognition, assessment and monitoring of blood loss via a reliable parameter is of prime importance to enable the surgeon decide upon definitive fluid replacement protocol.

An adult human has 4-7 litres of blood in his/her circulation; thus the loss of 350-500ml of blood might be negligible. In response to blood loss, stimuli from the baroreceptors trigger the cardiovascular centers to stimulate sympathetic responses to increase cardiac output and vasoconstriction. This prompts the heart rate to increase to about 180-200 contractions per minute restoring cardiac output to normal levels. Vasoconstriction of the arterioles increases vascular resistance whereas constriction of the veins increases venous return to the heart. Both these mechanisms increase blood pressure. Sympathetic stimulation also triggers the release of epinephrine and norepinephrine which enhance both cardiac output and vasoconstriction. If blood loss is less than 20% of total blood volume, these responses together would usually return blood pressure to normal and redirect the remaining blood to the vital organs and tissues.⁵ However, after losing 30% (or more) of the blood volume, symptoms of hypovolemic shock might develop. A blood loss greater than 40% blood loss is life threatening and resuscitation is generally essential for survival. Significant loss of intravascular volume may lead sequentially to hemodynamic instability, decreased tissue perfusion, cellular hypoxia and organ damage and may even cause death.¹

Blood supply to the face is very generous.² Maxillofacial surgical procedures can be classified as minor, intermediate, major or supra major cases based on the type and duration of the procedures. These procedures may be associated with excessive blood loss from the facial microvasculature and major blood vessels within the operation field of the surgeon. The extensive network of vessels in maxillofacial region makes the control of bleeding difficult during the surgery. Quite often, the lesions also invade the walls of the vessels or lie close to these vessels making them vulnerable to injury during surgery with consequent loss of blood. Furthermore, a significant amount of bleeding can occur during dissection of the capillary-rich skin, subcutaneous tissue and muscles in the maxillofacial region.³

The potential blood loss and estimated number of blood products required should therefore be predetermined using many factors. These include haemoglobin or haematocrit levels, body weight of the patient especially for pediatric cases, extent of lesion, age and gender as well as the type and extent of procedure.³

It is important not only to measure the patient's blood losses but also to be able to address them with the appropriate means of correction. Loss of blood in the intraoperative period is of concern to both the surgeon and the anesthesiologist. Head and neck surgical operations are often associated with major blood loss requiring substitution, usually by homologous blood transfusion since other sparing techniques such as hemodilution and intraoperative blood recuperation are usually insufficient. The accurate and timely estimation of blood loss is difficult and results in imprecise quantitative and qualitative replacement.

Accurate assessment of blood loss is necessary as underestimation can lead to delayed replacement which results in hypoperfusion, decreased haemoglobin, delayed recovery and increased morbidity and mortality. Overestimation of blood loss can lead to unnecessary transfusion, volume overload and cardiac failure.

The urgency for replacement depends on many factors including amount of blood loss, duration of surgery and response of the patient to the operative procedures. It is therefore appropriate to emphasize that accurate replacement of blood loss during operative procedures depends on the accurate measurement of blood loss as it occurs.¹ The anaesthetist and surgeon armed with this knowledge of blood loss estimation are in a stronger position to influence the cardiovascular homeostasis of their patient.

The most commonly used methods of determining operative blood loss are gravimetric and volumetric i.e. the weighing of all swabs and pads before and after use and recording the weight difference and measuring blood suctioned from the operative field. Inaccuracies are due mainly to measuring tissues or fluids other than blood.⁴ Other methods being the patient weighing, colorimetric, blood volume measurement using radioactive isotopes, photometry, electrolytic conductivity, urine strip method etc.¹

However, what all of these methods lack is a practical and accurate real-time intraoperative EBL assessment. For minor surgical procedures in which major blood loss is not expected, inaccurate measurement is trivial. For maxillofacial surgeries in which major blood loss is expected, allogenic blood transfusion is often the mainstay for intraoperative and postoperative hemodynamic management, making accurate determination of blood loss a necessity.

The purpose of this study was to assess the amount of blood loss and to provide theoretical support for the most reliable method of blood loss estimation, thereby addressing the need for immediate replacement of lost blood and also to evaluate relationship between the amount of blood loss and blood parameters.^{1,3}

AIMS

&

OBJECTIVES

Aims and Objectives

Aim

The aim of this study is to estimate the amount of blood loss during oral and maxillofacial surgical procedures and to establish correlation between gravimetric/volumetric estimation of blood loss with changes in pre-operative and post-operative values of haematocrit, haemoglobin, body weight and RBC count.

Objectives

The objectives of this study are-

- To assess intra-operative blood loss
- To establish correlation between gravimetric/volumetric estimation of blood loss by using changes in haematocrit values
- To compare pre and post operative haemoglobin, body weight and red blood cell count
- To evaluate blood loss and transfusion requirements by comparing haemoglobin and haematocrit values

**REVIEW
OF
LITERATURE**

Review of Literature

Hercus VM, Reeve TS, Tracy GD, Rundle FF (1961)⁶ measured blood loss using gravimetric method of blood loss estimation in a total of 412 cases. The surgery included 255 cases of thyroidectomy and neck surgery and 52 vascular, 48 abdominal, 28 urological and 29 breast operations. The difference in weight between each blood stained sponge and the average weight of a dry one of a similar size was recorded in grams and was taken to represent milliliters of blood lost. Some additional allowance was made for blood on gowns and large drapes and other sites. Dry swabs and sponges were used in all cases. The amount of saline used was measured and the suction bottle was accurately calibrated and the volume was measured. In few cases the surgeon measured blood volume immediately after operation using red cells tagged with ⁵¹Cr. They checked the accuracy of measured blood losses (and replacement). In radical mastectomy the blood loss was considerable ranging from 380 to 3200 ml. In subtotal gastrectomy the blood loss ranged from 200 to 1800 ml. and during prostatectomy 150 to 2750 ml. They found that in long operations especially or when the blood loss was severe, assessment of blood loss was wildly misleading. They concluded that accuracy of replacement during excessive haemorrhage could be checked postoperatively by determining the patient's blood volume to minimize the risk of over or under transfusion.

Gardiner AJS, Dudley HAF (1962)⁷ compared four methods for accurate measurement of blood loss giving their advantages and disadvantages. The first method was subjective visual estimation in which for less amount of blood loss, the surgeons and anaesthetists were quite reliable and they become more so when some objective measure was also available in the operating theatre but as the amount of blood loss increased, the estimation became increasingly unreliable. The second method was blood volume analysis post trauma or surgery. The accuracy of this method was found different with the different tracer used and was slightly better with red cell labels such as ⁵¹Cr than with plasma labels such as T-1824 or radio-iodinated human serum albumen but this method is inappropriate for routine application. The third method was gravimetric method of blood loss estimation in which unused and used sponges were weighed and the difference was used to calculate amount of blood loss although it had large inherent errors, particularly loss from evaporation and also patient weighing which was unreliable and

included error and difficult determination of the weight of excised viscera and dressings. The fourth method was extraction-dilution analysis in which blood was extracted by various means from the absorptive materials and suction effluent and any constant chemical or physiochemical property was used as a yardstick for measurement of its concentration in the resulting solution. The early results which were obtained by measuring some derivative of haemoglobin such as acid hematin were inaccurate. An alternative technique was to exploit the fact that the electrical conductivity of blood is constant and addition of blood to water will produce changes in the electrical conductivity of the mixture which may be measured using a wheatstone bridge, provided other electrolytes are not present this was an extremely accurate method but the commercial equipment were expensive and home made apparatus was not very accurate. The advent of powerful domestic washing machines has made the complete extraction of blood from gauzes simpler and by a simple adaptation the concentration of blood in the resulting solution was continuously determined by optical densitometry but both conductometric and optical techniques have the disadvantage that as the volume of blood added to the system increases, it itself alters the volume of the solvent and thus influences the final concentration.

Thornton JA, Saynor R, Schroeder HG, Taylor DG, Verel D (1963)⁸ compared blood loss during cardiac surgery measured by gravimetric, colorimetric, patient weighing and red cell volume studies. Gravimetric measurements (based on the assumption that 1ml of blood weighs 1g) of blood loss estimation was used in case of mitral valvotomy performed on 120 patients of both gender with age ranging from 20 to 60 years. The results of gravimetric and colorimetric methods were compared in the same subjects and was found to be in a close relationship. The results of blood loss calculated from the loss in patient's weight during the surgery were compared with the gravimetric measurement of blood loss. When the blood losses as estimated by colorimetric method were compared with blood loss measured by red cell volume studies, the latter indicated that there is an even greater blood loss. It was concluded that all methods agree closely but that the red cell volume studies suggest a concealed blood loss at the operation site, not measured by other methods. The colorimetric method described here offer simple and practical means of estimating blood loss during surgery and was introduced as routine during all major surgical procedures requiring blood replacement. It was emphasized that blood loss

measured in this way represented the minimum amount of whole blood that should be replaced by transfusion.

Thornton JA (1963)⁹ compared various methods of estimation of blood loss together with their advantages and disadvantages. He gave the following methods- Subjective or visual estimation which can be considered as the most unreliable method. Gravimetric method which involves either preoperative and postoperative patient weighing or by weighing of unused and blood soaked swabs and calculating the difference together with the suction volume. Electrolyte conductivity method, though it gives a continuous reading but is dependant on the constancy of the electrolyte content of the blood. Colorimetric method in which blood can be extracted by various means from the swabs and the concentration of the resultant solution can be used to determine the actual blood loss. Radioactive method of blood loss estimation using radioisotopes. The researcher concluded that the gravimetric method and colorimetric method of blood loss estimation were the most commonly used and relatively reliable techniques when compared to the other methods for determining blood loss during surgery.

Davies JWL (1966)¹⁰ researched on the various methods of assessing blood loss in shocked and injured patients and provided the following methods- First- Assessment from the amount of tissue damage. 4 categories were given-(1) Small wounds (less than 1 hand of tissue damage) show blood loss of rarely more than 20 per cent of blood volume. (2) Moderate wounds (between 1 and 3 hands of tissue damage), blood loss of between 20 and 40 per cent of blood volume. (3) Large wounds (between 3 and 5 hands of tissue damage), blood loss of about 40 per cent of blood volume. (4) Very large wounds (more than 5 hands of (tissue damage), blood loss of 50 per cent or more of blood volume. Second- By measurement of limb volume. Third- By measurement of plasma volume. Fourth- By measurement of red cell volume. Fifth- By simultaneous estimates of red cell and plasma volume. Sixth-By the use of semi automatic instruments. The researcher added that blood lost during surgical procedures can also be directly measured by weighing soaked swabs and aspirate or more accurately by estimation of the haemoglobin or electrolyte content of aspirate and the fluid in which all blood stained items have been washed. A retrospective estimate of blood loss can be obtained from haemoglobin or haematocrit values estimated during the second week after injury. The researcher concluded that

by comparison of measured losses with the extent and severity of injury and using these serial blood volume estimation information, there can be better management of future patients.

Bond G (1969)¹¹ described the sources of error and elimination of inaccuracy in the haemoglobin-dilution technique. The sources of error were classified as : 1) Error due to dilution of the known volume of water by the (unknown) volume of blood. 2) Error due to inadequate mixing or non-uniformity of the haemoglobin solution due to-(a) Inadequate destruction of blood clot (b) Incomplete haemolysis of blood. (c) Dead space in washing machines. 3)Error associated with the inaccurate measurement of large volumes of water. 4) Errors associated with the determination of haemoglobin of blood and of the aqueous solution of haemoglobin. 5) Errors associated with variability of the haemoglobin of the blood shed due to surgery due to:(a) Physiological response to acute haemorrhage (haemodilution) (b) Haemodilution due to associated induced or other vasodilatory hypotension. (c) Haemodilution due to anaesthesia itself. (d) Intravenous fluid infusions. (e) Blood transfusion. The haemoglobin-extraction-dilution method of operative blood loss assay was investigated for its associated sources of error. Discrepancies occur from three main sources: defective technique, faults in making simple measurements and failure to allow for the marked variability of haemoglobin of the shed blood that may occur during anaesthesia and surgery. The author concluded that any one of these errors may introduce inaccuracy sufficient to invalidate the technique even as a rough guide to blood loss volume. Strict attention to the appropriate precautions can reduce such error to a total level of less than two per cent.

Mahler D and Davies RM (1972)⁴ used the technique of Perometer for blood loss estimation during surgical excision of burned areas and taking of autografts in 31 surgical procedures in 18 burn patients whose burns varied from 8 to 70 percent of body surface, mostly full thickness. The age ranged from 3 years to 65 years and the range of preoperative haemoglobin levels was 9.3g percent to 14.6g percent. The perometer consisted of a washing machine into which 40 litres of water was introduced together with perosol, a haemolysing agent and all swabs, pads and linen soaked with blood and any aspirated fluids were collected in the tank where the blood was washed out and haemolysed to oxyhaemoglobin. The solution was circulated continuously from the washing machine via the copper filter through a measuring cell of a photometer which

registered the solution's haemoglobin content. The measuring cell was set at the patient's preoperative haemoglobin value enabling the photometer to register directly the quantities of blood lost by the patient. There were 2 scales available: a low range which read 5-600ml. and a high range which read upto 5 litres of blood loss. They experienced that the perometer gives accurate, immediate and continuous monitoring of the blood loss during operation and the speed of intravenous transfusion can be continuously regulated. Errors of inadequate mixing, incomplete haemolysis, dead spaces in the washing machine or inaccuracy in measurement of water could be the potential criticism. They concluded that the use of perometer when fitted with a suitable filter is the most satisfactory method available for measuring blood loss during surgery on burned patients.

Hang C, Weiler RL(1986)¹² provided the usefulness of technique of blood loss estimation using haematocrit method than simply calculating by the volume of suction. The researcher explained the drawback of the common way of estimating blood loss in the operating room by subtracting the amount of irrigation fluid used from the total volume of blood and fluid in the suction bottle as this technique requires a record of irrigation fluid and so it may lead to omissions or inaccuracy. The author reminds the usefulness of the micro haematocrit method to determine the packed cell volume of the blood and fluid in the suction bottle to estimate blood loss.

Karmo FR, Milan MF, Stein S and Heinsimer JA (1998)¹³ conducted a prospective study from December 1995 to August 1996. 43 women patients were enrolled in the study who underwent lipoplasty by the plastic surgeons using Tumescence technique. Haemoglobin and whole blood volume were calculated from the infranatant portion of the lipoplasty aspirate. The results of 38 patients were obtained. The mean volume of lipoplasty aspirate material was 2901ml. The mean haemoglobin concentration in aspirate was 0.42gm/dl. The mean whole blood volume in lipoplasty aspirate per case was 36ml. The volume of whole blood loss estimated was 12.4 ml in each 1000ml. of lipoplasty aspirate. The mean preoperative haemoglobin was 13.93 gm/dl. The mean postoperative haemoglobin was 13 gm/dl. The mean fall in haemoglobin on the seventh postoperative day was 0.93 gm/dl. They concluded that blood loss using tumescence technique was remarkably low compared to the early 'dry method' and 'wet method' and with

the use of this technique large volume lipopasty procedures can be done minimizing the need for blood transfusion.

Dulguerov P, Quinodoz D, Allal AS, Tassonyi E and Beris P (1998)¹⁴ conducted a retrospective study of patients operated in the Otolaryngology-Head and Neck surgery Department of the University of Geneva between 1990 and 1995 to study the blood loss and transfusion requirements. 227 patients (41 women and 186 men, average age was 58 years) were included in the study. The different type of surgical operations were classified into 5 groups- First group-Neck dissections, second group-Oral and pharyngeal operations, third group-Laryngectomies, fourth group-Maxillofacial operations and fifth group-Parotidectomies. The estimated intraoperative blood loss, the number of blood units transfused during or after surgery, the age of the patient, his/her cardiac and pulmonary medical history, the preoperative and postoperative hemoglobin and haematocrit, and the delay between diagnosis and actual surgery were reviewed. Neck dissections are usually classified as either radical or functional (also called modified radical neck dissection), unilateral or bilateral. All bilateral radical neck dissection patients required transfusion, while only a quarter of the unilateral radical neck dissection patients were transfused. The composite resection patients were transfused in 92% of the cases and 8 out of 10 patients with partial mandibular resection required blood transfusion. Only 27% of glossectomy cases underwent transfusion. In the laryngectomy group, the total laryngectomy or pharyngolaryngectomy patients associated with neck dissection were transfused in 35% of cases. Only 1 out of 20 cases of partial laryngeal surgery underwent transfusion. The operations for paranasal sinus primaries were divided into maxillectomy cases associated or not with a cranio-facial resection, who all necessitated a transfusion, and the lateral rhinotomy cases for which a transfusion took place only in 15% of cases. For the total parotidectomies the rate of transfusion was 4%. There was no transfusion for a superficial parotidectomy. Patients who had undergone previous radiation therapy had a higher blood loss, but the difference was not significant, for any of the procedures. . The researchers concluded that there are 3 categories of surgical procedures for Head and Neck cancer, according to their probability of requiring a blood transfusion . In the first category with a high transfusion probability, a transfusion is necessary in at least 80% of the patients. This category includes the bilateral radical neck dissections, the maxillectomy operations with or without a cranio-facial resection, the composite resections, and

the partial mandibulectomy procedures. For the second category, the probability is low, inferior to 5%. These operations are partial laryngectomies, parotidectomies, the functional neck dissections (unilateral or bilateral), and total laryngectomies without an associated neck dissection. In the third category, the transfusion probability is moderate, between 15 and 40%. The procedures involved are total laryngectomy with a neck dissection, glossectomy, unilateral radical neck dissections, and lateral rhinotomy. For the moderate transfusion probability operations, patients requiring a transfusion were significantly older. Also, transfused patients had a lower preoperative hemoglobin (124g/l), when compared to patients not requiring a transfusion (Hb: 150g/l) and the difference was significant. The average preoperative haemoglobin and haematocrit for the transfused patients were respectively, 133.4 g/l and 40%. The average postoperative hemoglobin and haematocrit for the transfused patients were 101.9 g/l and 31% respectively. The transfusion requirements of Head and Neck' surgical procedures could be safely met by an autotransfusion protocol, given the average delay of 3 weeks between diagnosis and surgery.

Yu CNF, Chow TK, Kwan ASK, Wong SL, Fung SC (2000)¹⁵ conducted a prospective study on 32 Chinese patients undergoing surgery to correct dentofacial deformities at a public hospital in Hong Kong from 1 December 1997 to 1 December 1998. 9 men and 20 women were involved in the study. The mean preoperative haemoglobin level for the men was 142.6(14.9)g/l and for the women was 123.7(5.6)g/l (normal ranges, 140-180g/l and 115-155g/l for men and women, respectively). Data from the demographic information, operating time, intraoperative estimated blood loss for each orthognathic procedure, mean arterial pressure, mean heart rate and blood transfusion were recorded. The orthognathic procedures performed included Lefort I osteotomies which comprised a simple osteotomy cut (one or two pieces cut) and multiple segmentalised cut (three or four pieces cut), anterior maxillary segmental osteotomy, mandibular ramus osteotomies such as bilateral sagittal split osteotomies and vertical subsigmoid osteotomies and anterior mandibular osteotomies which included Hofer's osteotomy and genioplasty. The operating time was calculated for each type of orthognathic procedure. The intraoperative estimated blood loss was calculated by weighing the surgical gauze swabs and measuring the contents of suction bottle (with adjustment made for the amount of saline irrigation used). The haemoglobin level and the hematocrit value (packed cell volume) were obtained on the

preoperative day and first postoperative day. Most patients needed double jaw surgery. The mean estimated blood loss was approximately 617.6ml. The average drop in the haematocrit value was 15.4% and the crossmatch to transfusion ratio was 29. The two-tailed Pearson correlation test was used to assess the bivariate correlation between estimated blood loss and operating time and the change of haematocrit value.

Law N L, Ng KFJ, Irwin MG and Man JSF (2001)¹⁶ conducted a prospective, randomized study to compare coagulation and blood loss during anaesthetic maintenance with target-controlled intravenous propofol infusion vs. inhaled isoflurane. 38 ASA I-III patients undergoing head and neck surgery were allocated randomly to receive either inhaled isoflurane at end-tidal concentration 1-1.5% (group I, n=20) or target-controlled infusion (TCI) of propofol at target-concentration 2-5 µg/ml. (group P, n=18). Thrombelastography on re-calcified whole blood was performed pre-induction and at 15,30,60,90,120 min post-induction and 30 mins. after anesthesia in both groups. Blood loss was estimated from weighing swabs and the volume in the suction bottles. Induced hypotension was not used and perioperative body temperature was similar between groups. There were no significant differences in thrombelastographic coagulation (R-time, K-time, maximum amplitude and angle) or fibrinolytic variables (lysis index at 30 and 60 min) at all times between groups. Total blood loss was also not significantly different (median group I:350ml, range 20-1200ml; group P:200ml, range 50-800ml). Shortening of R-time and widening of angle developed over time in both groups (P<0.05 groups I and P, repeated measures ANOVA). They concluded that maintenance of anaesthesia with propofol TCI at 2-5µg/ml does not cause detectable coagulation changes on thrombelastography nor increase surgical blood loss when compared to inhaled isoflurane.

Sehat KR et al (2004)¹⁷ reported that with hip and knee procedures the surgeon should always account for what are labeled as 'hidden' blood losses. These numbers have been attributed to intraoperative haemolysis and the extravasation of blood into the soft tissues. This can account upto 1140 ml in total knee arthroplasty and 840 ml in total hip arthroplasty.

Elipe Naveen and Ponniah M (2006)¹⁸ conducted a study to assess the accuracy of perioperative blood loss estimation. 50 patients undergoing major surgeries were enrolled in this

study. Normovolemia was maintained and no RBCs were transfused. At any point in time perioperatively, the attending anaesthesiologist estimated the blood loss upto then, the clinically Estimated Blood Loss (EBL). Simultaneously a blood sample was sent to the laboratory and the haematocrit was tested. The Gross formula (Actual blood loss= Blood volume [Haematocrit(initial)-Haematocrit(final)/Haematocrit(mean)]) was used to calculate the actual blood loss (ABL). In 64% of cases the blood loss was underestimated. The Bland and Altman plot suggests that clinical estimation is more inaccurate as the average blood loss increases ($p < 0.05$). The 95% confidence intervals for the differences (between ABL and EBL) were -719.93 ml to +1265.61ml. Interclass Correlation Coefficient for the data was 34% further confirming poor correlation between the EBL and the ABL. They concluded that in the perioperative period clinical estimation of blood loss is inaccurate and alone should not be used to determine the need for red blood cell transfusions.

Lee M H et al (2006)¹⁹ compared gravimetric and laboratory methods of quantifying blood loss during animal surgery. Intraoperative blood loss was first quantified by measuring irrigation fluid and the weight of surgical sponges. Blood loss was determined as the weight difference between the sterile saline solution used and gauze pre and postoperatively. A highly significant correlation was found between the laboratory method and the gravimetric method, supporting the use of weight measurement as an accurate option.

Stricker PA et al (2010)²⁰ documented the incidence of clinically important problems, particularly related to blood loss and performed a risk factor analysis. Records of all patients who underwent craniofacial reconstruction surgery at the Children's Hospital of Philadelphia between December 1, 2001 and January 1, 2006 were reviewed. Data were collected from the electronic anesthesia record, intensive care unit (ICU) progress notes, and discharge summary. All intraoperative laboratory values and all laboratory values obtained upon arrival in the ICU were recorded. A multivariable analysis was performed to evaluate associations between elements of intraoperative management and the following clinical outcomes: intraoperative hypotension, intraoperative metabolic acidosis, presence of a postoperative coagulation test abnormality and postoperative administration of hemostatic blood products. Data for 159 patients were reviewed. The mean volume of packed red blood cells transfused intraoperatively was 51 ml/kg).

Multivariable analysis revealed that intraoperative administration of albumin was strongly correlated with both an increased incidence of postoperative coagulation derangements and postoperative administration of hemostatic blood products) while intraoperative administration of fresh frozen plasma (FFP) in patients to have extensive blood loss improved postoperative laboratory measurements of coagulation.

Kathariya R, Devanoorkar A, Jain H(2013)¹ compiled various ways to measure intraoperative haemorrhage. Following are the various methods used for measurements of intraoperative blood loss: 1) Visual estimation- Some found underestimation was common, others overestimation, and still others found inconsistencies but without any particular pattern. 2) Gravimetric: A) Patient weighing-a special accurate weighing table is used to amount the pre- and post-operative weight of the patient. B) Swab weighing- weighing of unused swabs before surgery, which are re-weighed immediately after surgery. From their variance in weight between the two, blood loss is calculated. 3) Volumetric- the content of any fluid to be introduced into the operative field is accounted pre-operatively and any surfeit fluid present in the aspirator jar after the surgery is surmised to be blood. 4) Colorimetric- washing of bloodstained swabs, instruments, drapes, scrubs, gloves etc., two or three times and then collecting the fluid left after the washing along with the contents present in the aspirator jar. This fluid is amassed in a container holding an agent which alters hemoglobin to a more permanent pigment such as methemoglobin or cyanomethemaglobin. 5) Labelled red cells- a sample of patient's blood is incubated with Cr 51, after which the red cells are washed, measured for gamma radiation on a scintillation counter and are returned to the cardiovascular system. 6) Blood volume measurement- In this, a known quantity of dye or radioactive tracer is injected into a vein. After a delay of a few minutes, which permits the dye to be evenly distributed throughout the cardiovascular compartment, a sample of blood is withdrawn. From the dilution of the injected substance in the blood sample, post surgery, the blood volume is calculated. 7) Photometry-portable photometer for hemoglobin detection, HemoCue photometer are used. 8) Electrolytic conductivity- consisted of a water-filled tub, containing an agitator, which extracts the electrolytes from the blood sponges and clothes. A suction pump transfers blood from the operating table directly into the tub. A conductivity bridge measures changes in conductants. 9) Urine strip method- Blood was collected prior to the operation, immediately post-operation and 24-hour post-operation. Total

Hb and number of red blood cells were measured. Volume of irrigating fluid used during the surgery was recorded. The treated irrigating fluid was diluted into various concentrations and filled in the plate and tested by the urine strip. Various other techniques of blood loss estimation are also there. The author concluded that no method is considered the gold standard since each method has its own advantages and disadvantages so considering a specific method is dependent on operators' choice, feasibility and cost-benefit ratio.

Faverani L P et al (2013)²¹ conducted a study to assess intra-operative blood loss and blood transfusion requirements in patients undergoing orthognathic surgery. 45 patients (18 males and 27 females; mean age 29.29 years, range 16-52 years) undergoing orthognathic surgery were assigned to one of two groups according to procedure type- rapid maxillary expansion or double jaw orthognathic surgery. Pre-operative hemoglobin and haematocrit levels and intra-operative blood loss were measured. There was a substantial individual variation in pre and post-operative hemoglobin values (10.3-17 and 8.8-15.4 g/dl, respectively; $p < 0.05$). Mean haematocrit values were 41.53% pre-operatively (range 31.3-50.0%) and 36.56% post-operatively (range 25-43.8%) ($p < 0.05$). Mean blood loss was 274.60ml (range 45-855ml). Only 2 patients required blood transfusion. Blood loss was greater in patients undergoing double-jaw orthognathic surgery (group 2) than in those undergoing rapid maxillary expansion (group 1).

Chen HS, Tsung Lai SS, Tsung Lee K, Er Lee H, Hsu KJ (2014)²² conducted a study to assess intraoperative blood loss during an osteotomy of the bilateral vertical ramus. Bilateral vertical ramus osteotomy was performed on 37 patients with mandibular prognathism. All the data were recorded such as patient's characteristics, operative time, intraoperative blood loss, pre-surgical and post-surgical changes in blood constituents (RBC count, haemoglobin and haematocrit). The mean operative time was approximately 255.5 minutes and mean blood loss of 105.9 ml. The maximum blood loss was 320ml which resulted in a 1.7g/dl decrease in the Hb value and a 5.6% decrease in haematocrit. The minimum blood loss was 50ml which resulted in a 1g/dl decrease in the Hb value and a 3.2% decrease in haematocrit. Male patients had a longer operative time (42.5 minutes) and greater blood loss (19.5ml) than female patients. Post surgical reductions in blood constituents were significant in both female and male patients.

Akinbami BO and Obembe BO (2014)³ conducted a study to assess the amount of intra-operative blood loss during oral and maxillofacial surgical procedures and duration of surgery. All cases of maxillofacial surgical procedures done under GA in the MFU theatre, from January 2007 to December 2013 were included in the study. Pre and post operative haematocrit values, number of units of whole blood requested, crossmatched and used, amount of blood loss and duration of surgery were recorded. 139 patients were analyzed. 56 cases involved soft tissues, 83 cases involved hard tissues. Age range was 2 months to 78 years. Isolated unilateral cleft lip had the lowest mean value of estimated blood loss of 10.4ml and also the lowest duration of surgery of 58 minutes. Fractures of mandible had mean blood loss of 352mls and duration was 175 minutes. In this study there was significant relationship between estimated blood loss and duration of surgery for mandibular and zygomatic complex fractures.

Prasant MC, Kar S, Rastogi S, Hada P, Ali FM, Mudhol A (2014)² conducted a comparison of blood loss, quality of surgical field and duration of surgery in maxillofacial cases with and without hypotensive anesthesia. A total of 30 patients were included in the study. Of them 14 patients were in unilateral cleft lip, 10 were in SABG and 6 patients were in Le fort I osteotomy. The patients were randomly divided into two groups, the study group and the control group. In the study group patients, induced hypotension was used in order to maintain systolic pressure of 80-90 mm Hg. In the control group patients, normotensive anesthesia was used. Estimation of blood loss, quality of the surgical field and duration of surgery was calculated for both groups in three types of surgical procedures. Estimated blood loss was found to be significantly less in all the surgical procedures carried out under hypotensive anesthesia ($P < 0.05$). The quality of surgical field was better in cases with induced hypotension but there was no significant difference in duration of the procedures with and without induced hypotension.

Maisa O Al Sebaei (2014)²³ conducted a retrospective study to evaluate the predictors of intra-operative blood loss and to assess the transfusion rate and practices related to orthognathic procedures. 92 patients were included in the study who underwent the following four types of orthognathic procedures: Group 1, Bimaxillary surgery (Le fort I and Bilateral Sagittal Split Osteotomy); Group 2, Bimaxillary surgery with bone grafts; Group 3, Le fort I osteotomies and

group 4, Le fort I osteotomies with bone grafts. The intraoperative blood loss, operative time, age, gender and pre and post operative haemoglobin and haematocrit were assessed. The mean operative time was 5 hours and 32 minutes. The pre-operative haemoglobin and haematocrit were collected from the patient 1-2 days before the surgery and the post-operative haemoglobin and haematocrit were collected 6-24 hrs after the surgery. There was no difference in intraoperative blood loss between the genders or the BMI categories. A mean post-operative haemoglobin drop of 3.0 g/dl in females and 3.7g/dl in males was observed. The patients whose procedures lasted between 1-3hrs. exhibited less intra-operative bleeding compared to the patients whose procedure lasted 3-6hrs or 6-10 hrs. The operative time was significantly shorter for Group 3. 18 of the 92 patients received blood transfusion. The mean intraoperative blood loss was higher among the patients who received transfusions.

Gao FQ, Li ZJ, Zhang K., Sun W and Zhang H (2015)²⁴ conducted a study to determine the most reliable method for calculating blood loss after total knee arthroplasty. 245 patients (29 males and 216 females with age ranging from 56 to 78 years) who underwent primary unilateral total knee arthroplasty from February 2010 to August 2011 were enrolled in the study. The preoperative haemoglobin was 131.25g/l. Blood loss was calculated using four methods: Gross equation, hemoglobin (Hb) balance, the Orthopedic Surgery Transfusion Hemoglobin European Overview (OSTHEO) formula, and Hb dilution. Demographic data, BMI, preoperative diagnosis, type of anesthesia, medical co-morbidities, preoperative autologous blood donation, allogeneic blood transfusion, and pre- and post-operative complete blood count (CBC) including hematocrit (Hct) and Hb levels were evaluated. A large difference was found in the calculated blood loss obtained by the four methods except between Gross equation and Haemoglobin balance. The haemoglobin balance method was found to be the most reliable method of estimating blood loss after total knee arthroplasty.

Algadiem EA, Aleisa AA, Alsubaie HI, Buhlaiqah, Algadeeb JB and Alsneini HA (2016)²⁵ conducted a cross-sectional study to determine the absorptive capacity of surgical gauze along with a case-control study to determine the absorptive capacity of gauze-wetted with saline and supersaturated as compared to dry gauze. Three different sizes of commonly used surgical gauze (10*10 cm, 30*30cm and 45*45cm) were tested for their absorptive capacity and used to

reconstruct the analogue. A measured amount of expired whole blood was spilled into a bowl and a resident was asked to dry the blood. The blood spill was gradually increased. The stains that resulted from the spill were photographed for the visual guide. After the gauze testing was complete, four patterns were selected for each gauze to construct the visual guide. Each pattern represented 25%,50%,75% and 100% saturation. Supersaturation of the gauze was determined by adding more blood to the 100% saturated gauze. This was repeated with pieces of wet gauze. Wetting of the gauze decreased the absorptive capacity to 25% (dry 12ml vs. wet 9ml) in the 10*10cm, 30% (dry 100ml vs. wet 70 ml) into 30*30cm) and 25% (dry 160ml vs. wet 140ml) in the 45*45cm. Supersaturation of the gauze increased the absorptive capacity to 25% (12ml vs. 15ml) in the 10*10cm, 30% (100ml vs. 130ml) in the 30*30cm and 25% (160ml vs. 200ml) in the 45*45 gauze.

Eftekharian HR, Talebi M, Ahzan S, Neydavoodi M and Daneste H (2016)²⁶ conducted a cross-sectional study on 441 (367 males and 74 females) patients referred to Shahid Chamran Hospital, Shiraz, Iran from 2013 to 2016 who underwent maxillofacial operation due to various types of maxillofacial fractures. The data included were demographic characteristics, reasons and sites of fracture, patient's haemoglobin concentration before and after surgery, amount of blood loss during surgery, received blood products during surgery and duration of operation. The amount of blood loss was measured by volume suction devices and also 4*4 gauzes used during surgeries. Paired t-test was used to compare the mean haemoglobin before and after the surgery. The mean duration time of surgery was approx. 2.45 hours. The mean blood loss during the operation surgeries was approx. 141.79cc and a significant linear relation was found between time duration of surgery and amount of blood loss in patients. No significant relation between age and blood loss during surgery was found. No significant correlation between type of maxillofacial fractures, the cause of injury and gender with mean blood loss was found. The mean haemoglobin was 13.63mg/dl and 12.31mg/dl before and after surgery respectively which showed a significant difference. The results of this study demonstrated that there was a decrease in mean haemoglobin concentration after surgery and also the amount of blood loss in patients during surgery was not high enough for blood transfusion.

Fritz DK, Matthews TW, Chandarana SP, Nakoneshny SC and Dort JC (2016)²⁷ conducted a study to evaluate the impact of using the harmonic scalpel on operating time and blood loss in patients undergoing resection for advanced oral cancer. 36 adult head and neck cancer patients with advanced oral cancer requiring primary tumor resection with unilateral or bilateral selective neck dissection from July 2012 to September 2014 were randomized to either the control group (traditional surgery) or the experimental group (harmonic surgery). Patients older than 18 years who were able to provide informed consent were eligible. The control group (traditional surgery) comprised 18 combined oral resections and neck dissections in which standard dissection technique (sharp dissection using scalpel or cutting cautery, surgical ties and/or clips for hemostasis augmented with bipolar and/or monopolar cautery) was used. The experimental group (harmonic surgery) consisted of 18 combined oral resections and neck dissections performed using the harmonic surgery as an adjunct to standard dissection technique. Mean blood loss in the experimental group was 260ml versus 403ml in the control group ($p=0.08$). Mean operative time was 140 minutes in the experimental group and 159 minutes in the control group ($p=0.2$). In this randomized control trial, use of the harmonic scalpel did not effect intraoperative blood loss or operating time in patients undergoing surgery for advanced oral cancer.

Thurer RL, Castro JM, Javidroozi, Burton K and Bernal NP (2017)²⁸ conducted a study to assess accurate measurement of intra-operative blood loss improves prediction of post-operative haemoglobin levels. A novel FDA-cleared mobile application on a tablet computer was used to measure surgical blood loss. Using image-processing algorithms, a novel system accurately measures blood loss by photographing surgical sponges and canisters and calculating their haemoglobin content. A formula to predict post-operative haemoglobin levels was devised and used to calculate post-operative haemoglobin levels in a study group of 167 burn and other wound excision procedures performed on 103 patients using the system. In an historical group (100 similar procedures, 60 patients) clinician estimates of blood loss were used. These predictions were compared with actual values. The formula using measured blood loss in the study group was a better predictor of the actual post-operative day one haemoglobin value ($R^2=0.822$) than was the same formula using visually estimated blood loss used in the historical group ($R^2=0.615$). the mean absolute bias of post-operative day one haemoglobin levels in the study

group was significantly lower than the mean bias in the historical group (study=group, mean 0.4, 95% CI 0.2 to 0.5g/dl; historical group, mean 0.9, 95% CI 0.7 to 1.2 g/dl, $p<0.001$). Blood loss measurements using the novel system are a significantly better predictor of haemoglobin values obtained after surgery than traditional blood loss estimates.

Belousov A, Malygon E, Yavorskiy V (2017)²⁹ gave a short commentary on the factors which play a major role affecting volume of blood loss post surgery and also provided with a formula known as Belousov's formula which calculated the true volume of blood loss. In conditions of acute blood loss, on the basis of calculations of the volume of blood loss and deficit of circulating blood volume, the medical practitioner could quickly assess the patient's condition to assign optimum, adequate and most importantly a timely infusion-transfusion therapy that aim at rapid elimination of circulatory hypoxia, preventing coagulopathy. Estimating blood loss is complicated by several factors including urinary losses and the development of tissue edema, therefore complete blood volume deficit was calculated for determining the volume of infusion solutions and for correction of blood loss. In case of ignorance of the fact and unreasonable transfusion of red blood cells, there will be a direct threat of development of transfusion complication-volume overload. Thus, Belousov's formula was used to calculate the true volume of blood loss especially for infusion therapy during surgical intervention.

Sud S, Dwivedi D, Sawhney S and Panjiyar SP (2018)³⁰ presented a case of a 70-year-old female patient weighing 50 kg suffering from carcinoma of the endometrium undergoing staging exploratory laparotomy. The patient was ASA class-II with a haemoglobin level of 10 g/dl. Maximum allowable blood loss (MABL) calculated was 550 ml. Intraoperatively, the patient had an episode of hypotension as blood pressure dropped from 130/70 mmHg to 85/54 mmHg with heart rate increasing from the basal value of 78 beats/min to 118 beats/min. Blood transfusion was started and the blood loss estimated by the anaesthesia resident was 518 ml (fully soaked six abdominal swabs and 200 ml in suction). Despite adequate blood and fluid resuscitation and control of bleeding at the surgical site, blood pressure continued to be on the lower side (88/45 mmHg) at this juncture. This raised the doubt of discrepancy in estimation. On reassessment of the field of surgery, suction, and abdominal swabs, it was noticed that abdominal swabs were larger in size (21 × 32 cm) than those routinely being used previously (21 × 20 cm). On re-

estimation, the calculated blood loss was 818 ml. There are various methods to measure blood loss which include visual estimation, photometry, colorimetric and gravimetric method and the use of radiolabeled red blood cells (RBC). The author concluded that accurate assessment of blood loss is necessary as underestimation can lead to delayed replacement which results in hypoperfusion, decreased haemoglobin, delayed recovery and increased morbidity and mortality while overestimation of blood loss can lead to unnecessary transfusion, volume overload and cardiac failure. The author suggests to always use a standardized size of abdominal swabs and if there is any change in size, then it should be notified to the anaesthesiologists by nursing staff, as any change will lead to discrepancy in blood loss estimation which can prove fatal not only in a healthy patient but also in pediatric and geriatric patients who have limited cardiopulmonary reserves.

Li B, Li J, Wang S and Liu L (2018)³¹ conducted a study to quantify the perioperative blood loss of elderly patients with intertrochanteric fractures treated by unreamed proximal femoral nail anti-rotation and analyze whether the substantial hidden blood loss was induced by initial trauma or the operation. The clinical data of 123 patients from Jan 2013 to Apr 2017 were analyzed retrospectively. During the surgical procedure when the femur was exposed with the awl, the proximal femoral nail anti-rotation was carefully inserted without the reaming process. Drainage was placed in the incision according to the intra-operative bleeding condition and was removed 24 hours after operation in the light of the drainage condition. The total drainage of post-operation was recorded as visible blood loss. Blood routine of different time points including haematocrit and haemoglobin were obtained on admission day, pre-operatively day, post-operative days one and three. Visible blood loss contained intraoperative blood loss and the volume of drainage after operation. Intraoperative visible blood loss corresponded to the amount of liquid in the suction bottle minus the amount of liquid used to flush the wound and the total volume of blood lost in gauzes and surgical towels. The volume of drainage was obtained and measured as the post-operative visible blood loss. The transfused blood volume was also recorded. Total blood loss was calculated from the change in the haematocrit level and estimated patient's blood volume. The total blood loss from admission day to postoperative day one and three were 693.5 ml and 863.8 ml of which the corresponding hidden blood loss was 86.8% and 89.4% respectively. The mean total blood loss and hidden blood loss from admission day to

preoperative were higher than that from preoperative to postoperative day one. No significant difference between hidden blood loss from admission day to preoperative and hidden blood loss from preoperative to postoperative day three was found. It was concluded that the majority of perioperative hidden blood loss occurred before surgery, it was mainly associated with the initial trauma rather than the operation.

Politis C, Agbaje J O, Lambrichts I (2018)³² reviewed blood loss and transfusion practice in orthognathic surgery in the literature published between 1976 and 2012 and compared these data with more recent developments. The relationship between the duration of surgery and related blood loss and/or transfusion was examined. Articles containing clear information on the operation time, blood loss and transfusion in orthognathic surgery were included. In total, 51 papers and 2 thesis were retained that contained valuable subgroups with information. Both retrospective and prospective studies were accepted no matter if the procedure were done in normotension, mild hypotension, controlled hypotension or any other tension reported. In 22 out of 51 papers, the method of measuring estimated blood loss was missing. In 18, out of 51 papers, the estimated blood loss was measured by deducting the volume of saline used from the total volume in the suction unit and by weighing the sponges. In 6 out of 51 papers, losses in sponges were not included in the estimated blood loss but the irrigation fluid and the fluid collected in suction device was included. In 5 papers/thesis, the calculation was based on a comparison of preoperative and postoperative hematocrit level or blood volume. Several articles found a linear correlation between blood loss and duration of surgery. Blood loss and duration of surgery were found to be weakly related to each other and the most significant factor in deciding when to transfuse was considered one's attitude towards transfusion since the contemporary limit of 7g/dL hemoglobin is a safe margin for healthy persons and the hemoglobin drop can be overestimated due to hemodilution which in return may influence the decision of blood transfusion.

Nowicki PD et al (2018)³³ conducted a prospective study to compare intraoperative estimation of blood loss using various methods and also evaluated a newer triton technique to measure blood loss. A total of 55 pediatric patients who underwent posterior spinal fusion, single-event multilevel surgery or hip reconstruction and whose expected intraoperative estimated blood loss

was >200ml. with age ≤ 18 years were enrolled in the study. The methods used for blood loss assessment included the Triton system (Gauss Surgical), Gravimetric method and Spectrophotometric assay (reference) method. A total of 781 surgical sponges were collected for analysis. The mean preoperative haemoglobin level was 13.2g/dl. The Triton system was used to measure blood loss on sponges and within canisters. Image analysis was performed using both the standard Triton system. All laparotomy sponges were weighed using a calibrated scale and the dry weight of the sponges was subtracted to compute the sanguineous fluid mass contained within using Gravimetric method. The fluid mass was then computed to volume units assuming 1g/ml mean density conversion corresponding to blood loss mixed with irrigation. The measured Spectrophotometric assay (reference method) was determined by direct measurement of the sanguineous effluent extracted from the sponges using a validated extraction method. The mean sponge count per case was 14.2. 1 patient required intraoperative blood transfusion and 19 patients underwent intraoperative cell saver blood transfusion. The average cell saver blood volume returned was 138.6ml. On comparing the estimated blood loss by the gravimetric method and assay (reference) method, the gravimetric method overestimated blood loss. On comparing the estimated blood loss measurement between the Triton system and assay method, a generalized agreement between the two methods was found. The Triton method had a slight overestimation of blood loss. The researchers concluded that the Triton method was found to be highly correlative and accurate in estimating intraoperative blood loss in pediatric orthopaedic surgery patients.

Meesters MI, Burtman D, Van de Van PM, Boer C (2018)³⁴ conducted a retrospective study to evaluate the predictive value of thromboelastometry for postoperative blood loss in adult cardiac surgery with cardiopulmonary bypass. 202 patients with more or less 500ml blood loss after 6 hours of surgery were included in the study. Thromboelastometry was performed before cardiopulmonary bypass and 3 minutes after protamine administration. In 181 patients bleeding <500ml., the average amount of blood loss was 168ml. 6 hours and 410 ml. 24 hours after surgery. In 21 patients with major blood loss i.e. >500ml. the average amount of blood loss was 890 ml. after 6 hours and 1530 ml. after 24 hours. The minor bleeding group received less red blood cell transfusion in the operating room and in the ICU compared to patients bleeding >500ml. The study showed that the preoperative and postoperative thromboelastometric positive

predicting value was poor, however the negative predicting value was high. They concluded that thromboelastometry does not predict which patients are at risk for major postoperative bleeding.

Hong N and Park JY (2018)³⁵ conducted a study to find specific risk factors for delirium especially estimated blood loss during operations. 175 elderly patients (124 women and rest men) who were admitted at the Department of Orthopedic Surgery, Hallym University Sacred Heart Hospital, between May 2013 and May 2014 were enrolled in this study before they underwent surgery. They were all 65 years old at the time of admission. The surgery was about the bone treatment from fracture fixation to artificial joint. The confusion assessment method was used to evaluate the patients for delirium. The amount of perioperative blood loss was estimated using Mercuriali's formula based on preoperative hematocrit and 5th postoperative day hematocrit. The estimated mean volumes of blood loss during operations were found to be larger in delirium patients. It was concluded that risk factors for hyperactive and hypoactive delirium are different and the estimated blood loss volumes during perioperative period might affect hyperactive delirium but they do not seem to affect hypoactive delirium so estimated blood loss can be considered as a risk factor for hyperactive delirium.

Tsai CY, Chang YJ, Wu TJ, Lai JP, Chen TY, Lin SS (2019)³⁶ performed a retrospective study to evaluate the volume of blood loss and operative time associated with management of non growing patients with cleft lip and palate using bimaxillary orthognathic surgery designed by a three dimensional (3D) computer-assisted simulation and navigation for othognathic surgery (CASNOS) system and compare it with the traditional 2D system. A total of 53 (34 men and 19 women, age range-16-33 yrs.) skeletal class III non growing cleft lip and palate patients who underwent bimaxillary osteotomies between January 2010 and September 2017 at the Craniofacial Centre of Kaohsiung Chang Gung Memorial Hospital were included in the study out of which 30 patients were grouped under CASNOS system and 23 patients were grouper under the traditional 2D system. The estimated blood loss for each surgery was assessed by weighing the sponges and measuring the suction volume. The haemoglobin and hematocrit levels were measured in all patients 1 day prior to surgery and one the 1st day postoperatively. The actual blood loss was calculated by the Gross formula. The mean operative time was approx. 469 min. in the 2D group and approx. 384 min. in the 3D group, the difference being not

statistically significant. The mean estimated blood loss was approx. 469.6 ml in 2D group and approx. 506.7ml. in the 3D group, again the difference being not statistically significant. The mean actual blood loss of the 3D group was significantly lower than that of the 2D group, with the mean difference being 289.3ml. The mean preoperative haemoglobin was approx. 14.4g/dl in 2D and 14.0g/dl in 3D group while the mean postoperative Hb value was approx. 1g/dl in the 2D group and approx. 11.5g/dl in the 3D group which showed a statistically significant decrease in the 2D group compared to 3D group. The mean preoperative hematocrit was approx. 43.3% in 2D and approx. 41.9% in the 3D group while the mean postoperative value was approx. 32.7% in 2D and 33.7% in 3D group so a mean decrease in hematocrit on the 1st postoperative day was 24.7% in 2D group and 19.8% in the 3D group which showed significant decrease in the traditional group compared to the CASNOS 3D group. So they concluded that the application of 3D CASNOS approach in orthognathic surgery for the management of complicated class III non growing patients with cleft lip and palate significantly shortened the operating time and reduced the actual blood loss in comparison with the traditional 2D methods.

Anya SU, Onyekwulu FA, Onuora EC (2019)³⁷ conducted a double-blind, prospective, nonrandomized, controlled study to compare visual estimation of intraoperative blood loss with haemoglobin estimation. A total of 60 pregnant patients (age range 21 and 37 years and body weight ranging from 62kg to 95kg) at term undergoing elective caesarian section under spinal anaesthesia at the University of Nigeria Teaching Hospital Enugu, Nigeria were enrolled in this study. In the operation theatre, the patient's haemoglobin level was determined before and after the surgery using the HemoCue201+ and a modified Gross formula was used to calculate the blood loss. The researcher estimated the blood loss visually by counting the blood soaked abdominal mops and gauze pieces and multiplying them by the estimated volume of blood each would hold, fixed size mops and gauzes were used. A fully soaked and dripping abdominal swab (10*10 inch) was taken as containing 100ml of blood while a piece of gauze (4*4 inch) was assumed to contain 10ml. of blood. Blood lost to suction bottles and that lost in and around the operating field mixed with amniotic fluid were also estimated. Abdominal mops and gauze pieces not fully soaked were also estimated using the experience and expertise of the researcher. The mean visually estimated blood loss and HemoCue calculated blood loss were 470ml. and 563ml. respectively. Visual estimation was less than HemoCue calculated blood loss

(underestimation). The mean difference between both the methods was negligible (45.25ml.). The discrepancy between the two methods increased when blood loss was ≥ 500 ml. The study showed that the visually estimated blood loss was closely related to HemoCue calculated blood loss when the quantity of blood loss was < 500 ml. but as the blood loss increases above 500ml. the error margin between visually estimated and HemoCue calculated blood loss widens.

Ghattas PJ³⁸ conducted a clinical trial to provide a concise reproducible method of estimating blood loss. Absorptive materials used commonly in orthopedic procedures were used to measure the amount of saline absorbed at varied levels of saturation. These included a 30*30cm lap sponge, 30*5 lap sponge, 4*4 Raytec, 2*2 surgical pattie and the peanut sponge. Methylene blue dye and normal saline were used to create a colored medium for measure. The solution was then placed into clearly marked graded cylinders. Each material to be tested was placed into the fluid to an approximated percent saturation based on the visual coverage of the material. This was done for 25, 50 and 100% saturation. The change in volume in the cylinder was measured in each trial. The mean of 5 separate trials at each of the saturation intervals was calculated and determined to be the mean absorptive value. The mean absorptive value was greatest for the 30*30 lap sponge at all three intervals of saturation with 61mls of volume absorbed at 100% saturation. The peanut offered the lowest absorptive value with a max of 1ml at 100% saturation. Both 25 and 50% saturation data points could not be reliably be measured as the amount of visual coverage was indiscernible. Through this clinical trial using the volumes absorbed by commonly used materials, the practice of estimating intraoperative blood loss was refined to offer valid endpoints for identifying the need for blood products.

MATERIALS
&
METHOD

Materials and Method

Eligibility criteria

Inclusion criteria:-

- All elective procedures performed under general anesthesia under 60 years of age
- Patients without any systemic disorder
- Patients willing to be included in the study

Exclusion criteria:-

- Surgeries performed under local anesthesia
- Patients with bleeding disorders
- Patients taking anticoagulants
- Acute or chronic anemia
- Haemoglobin below 10 mg/dl
- Patients with sudden and/or massive blood loss (as they require RBC transfusion in an emergent situation often before blood loss could be estimated or haematocrit could be sent)

Materials:-

Armamentarium:

- Pre-weighed and pre-measured dimension Gauge and Sponges
- Weighing machine
- Normal saline
- Syringe
- Calibrated Suction bottle
- Hematological investigations (Hb, HCT, RBC)

Method:-

Study Design:

- Patients reporting to the Out Patient Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow undergoing surgery under general anesthesia were included in this study.

Method of collection of data:

The patients under study were ASA Class I and relatively healthy ASA Class II patients. RBC count, haemoglobin, haematocrit value and body weights were taken pre-operatively and immediate post-operatively for all patients.

Methodology:

1. The pre-operative and post-operative RBC count, haemoglobin, hematocrit values and body weight were recorded.
 2. The intra-operative blood loss was measured in milliliters.
- 30 patients (n=30) were included in the study.
 - After routine laboratory and radiological investigations and written consent, pre-anesthetic evaluation was done. The patient was prepared as per the routine aseptic protocol and under laryngoscopic assisted intubation, general anesthesia was administered.
 - During the surgery Gravimetric method of blood loss estimation was used based on the assumption that 1ml of blood weighs 1.06 gm.
 - Swabs were moistened with known quantities of normal saline. The swabs were weighed as soon as possible after contamination with blood so that the loss by evaporation is minimized⁸. The difference in weight between each blood stained sponge and the average weight of a dry one of similar size was recorded in grams and was taken to represent milliliters of blood lost. Some additional allowance were made for blood on gowns, large drapes and other sites which cannot be weighed on the basis of archive data⁶.
 - Volume of suction was taken as it is an essential and an accurate measure of frank haemorrhage provided the loss is contained. Allowance was made for any fluid used for washing.
 - Intra-operative blood loss was quantified by measuring the amount in the suction bottle and weighing the blood soaked gauge.
 - The actual blood loss was calculated from a modification of the Gross formula given below¹⁸-

Actual blood loss = Blood volume[Haematocrit(i)-Haematocrit(f)/Haematocrit(m)]

Where, Haematocrit(i) = initial haematocrit

Haematocrit(f) = final haematocrit

Haematocrit(m) = mean haematocrit

Blood volume is calculated from the body weight,

Blood volume=Body weight in kgs*70ml/kg

- Therefore, for each patient the clinically EBL and the calculated ABL were used to calculate the difference in blood loss.
- Patient's characteristics, duration of surgery, intra-operative blood loss, pre-surgical and post-surgical changes in blood constituents (RBC count, haemoglobin and haematocrit), number of units of whole blood requested, cross matched and used, procedure were recorded.

Changes in blood constituents due to surgery were calculated and analyzed by a paired *t* test. Pearson's correlation coefficient was used to detect correlation between blood loss and various parameters. A P value of ≤ 0.05 was considered significant.

Parameter assessment:

Patients for surgery were selected irrespective of gender, religion or socio-economic status. The parameters assessed included-

Pre and immediate post-operative-

1. Red blood cell count
2. Haemoglobin
3. Haematocrit
4. Body weight

Intra-operative-

5. Volume of infusion fluid
6. Volume of blood loss

Photographs

Preoperative Photographs:-

PATIENT I.D.	1637		
DATE	11/DEC/2018		
PATIENT NAME:-	ANISH		
AGE/GENDER	18YRS / MALE		
REFERRED BY	BBQ HOSPITAL		
SAMPLE	BLOOD		
PATHOLOGICAL EXAMINATION REPORT			
HEMATOLOGICAL EXAMINATION:			
Hemoglobin	: 11.2	gm/dl	male: 13.5 - 15.5 g female: 11.5 - 13.5 gm Children: 11.5 - 13.5 gm/dl
R.B.Cs. Count	: 5.28	million/cm	4.5 - 5.5 million/cm
P.C.V.	: 34	%	male: 42 - 52 % female: 36 - 46 %

Pre-operative investigations



Pre-operative body weight

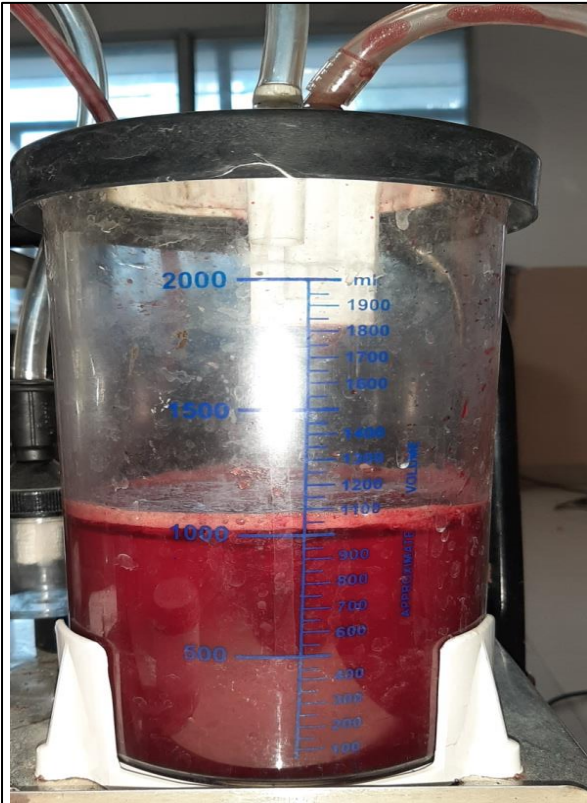


Pre-soaked guage

Intraoperative Photographs:-



Blood soaked guage



Volume of suction

Postoperative Photographs:-

ENT I.D.	1651
ENT NAME:	ANISH
GENDER	18YRS /MALE
REF BY	BBD HOSPITAL
FILE	BLOOD

PATHOLOGICAL EXAMINATION REPORT

PATHOLOGICAL EXAMINATION:

Hemoglobin	:	10.2	gm/dl	male: 13.5 - 15.5 gm/dl female: 11.5 - 13.5 gm/dl Children: 15.5 - 18.5gm/dl
R.B.Cs. Count	:	5.01	million/cm	4.5 - 5.5 million/cm
P.C.V.	:	32	%	male : 42 - 52 % female: 36 - 46 %

Post-operative investigations



Post-operative body weight

RESULTS

Results

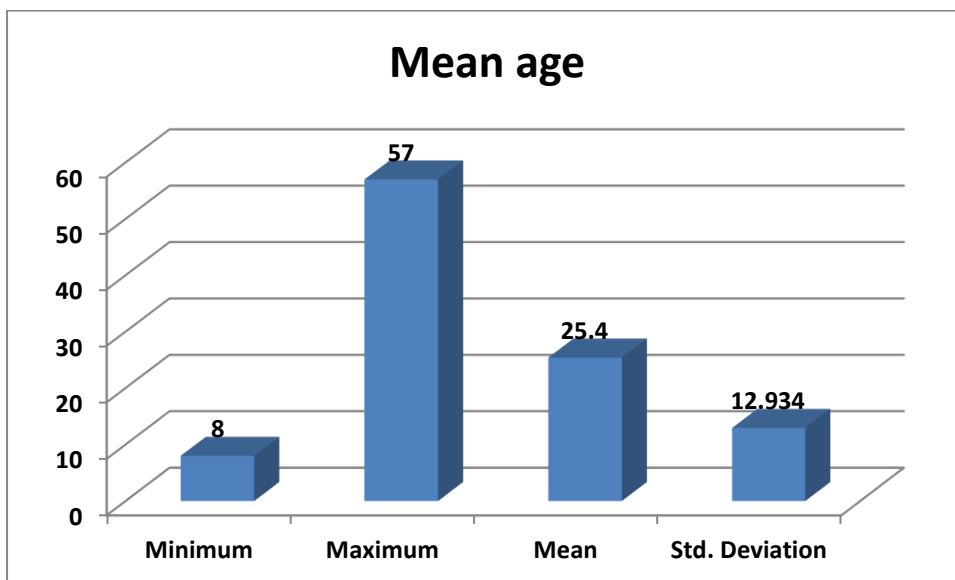
Data was analyzed using SPSS version 21, IBM Inc. Descriptive data was reported for each variable. Descriptive statistics such as mean and standard deviation for continuous variables was calculated.

Summarized data was presented using Tables and Graphs. Shapiro Wilk test was used to check the normality of the data. As the data was found to be normally distributed bivariate analyses was performed using paired t test for comparison of pre and post value change and correlation among continuous variable was assessed using Pearson correlation test. Level of statistical significance will be set at p-value less than 0.05

Table 1: Mean age of the study population

	N	Minimum	Maximum	Mean	Std. Deviation
AGE	30	8	57	25.40	12.934

In this study, mean age of the study population was found to be 25.40 ± 12.93 years.



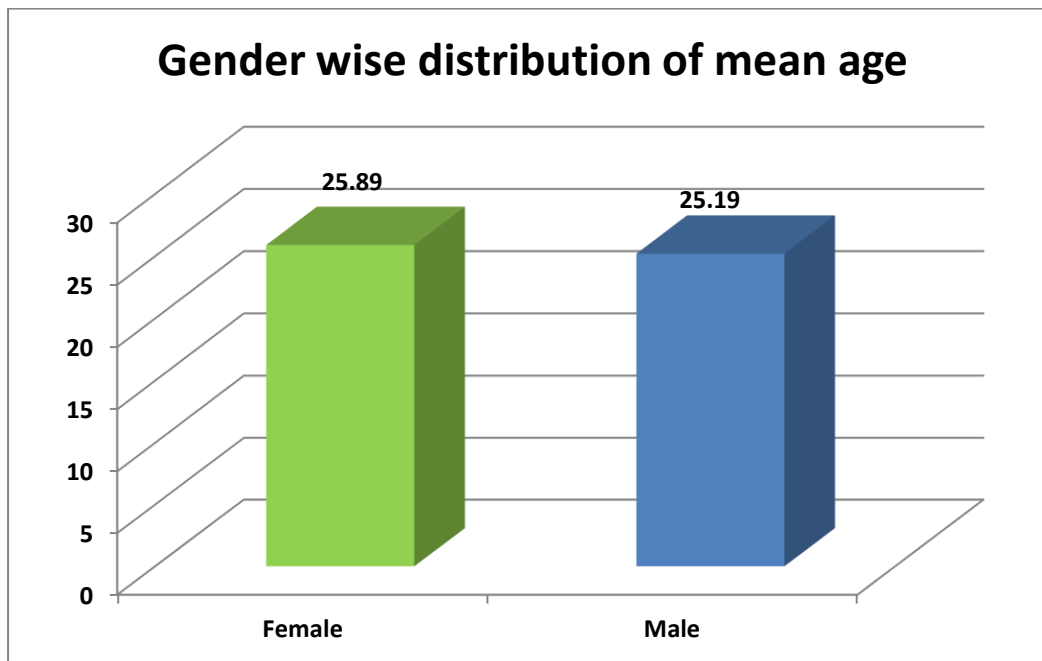
Graph 1:

The present study was conducted on a sample of young to adult patients with age ranging from 8 years to 57 years.

Table 2 : Genderwise distribution of mean age

GENDER	Mean	N	Std. Deviation
Female	25.89	9	14.287
Male	25.19	21	12.679

In this study, among 9 females, mean age was found to be 25.89 ± 14.28 years whereas among 21 male subjects, mean age was found to be 25.19 ± 12.67 years.



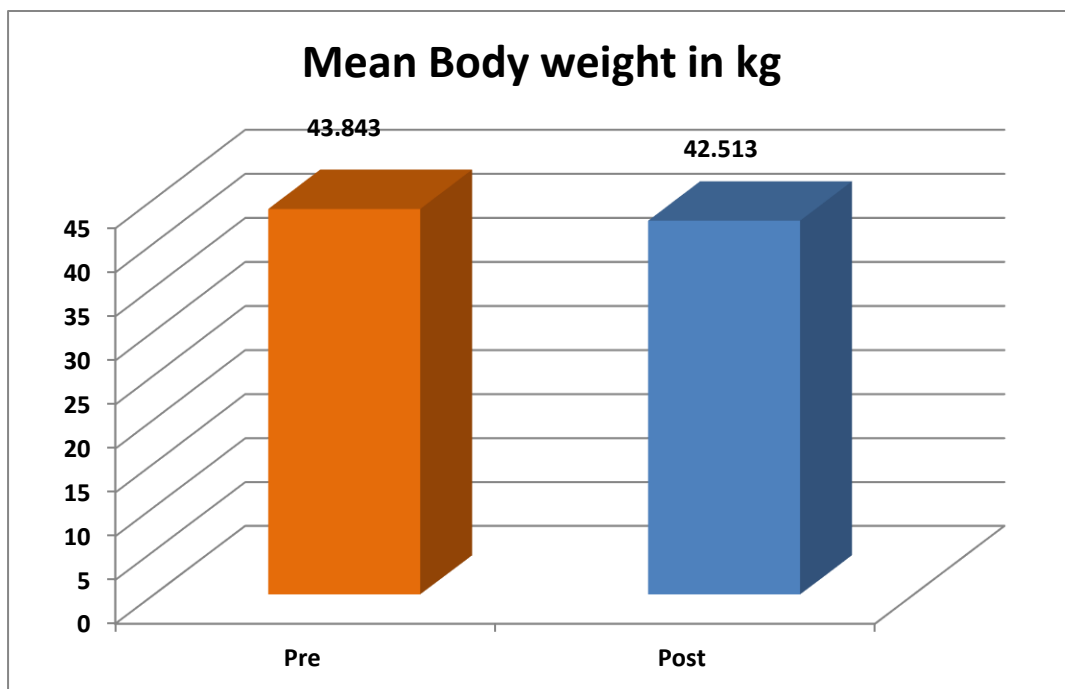
Graph 2:

The present study included 21 males and 9 females with mean age of approximately 25 years.

Table 3: Pre and postoperative comparison of the body weight of the study population

Body weight	Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std deviation
Pre	43.843	30	12.3455	2.2540	1.33	0.86
Post	42.513	30	12.1882	2.2252		
P value	<0.0001 S					

Pre-operative and post-operative comparison of the body weight using Paired t test showed statistical significant difference as $p < 0.05$ i.e body weight decreased significantly post-operatively.



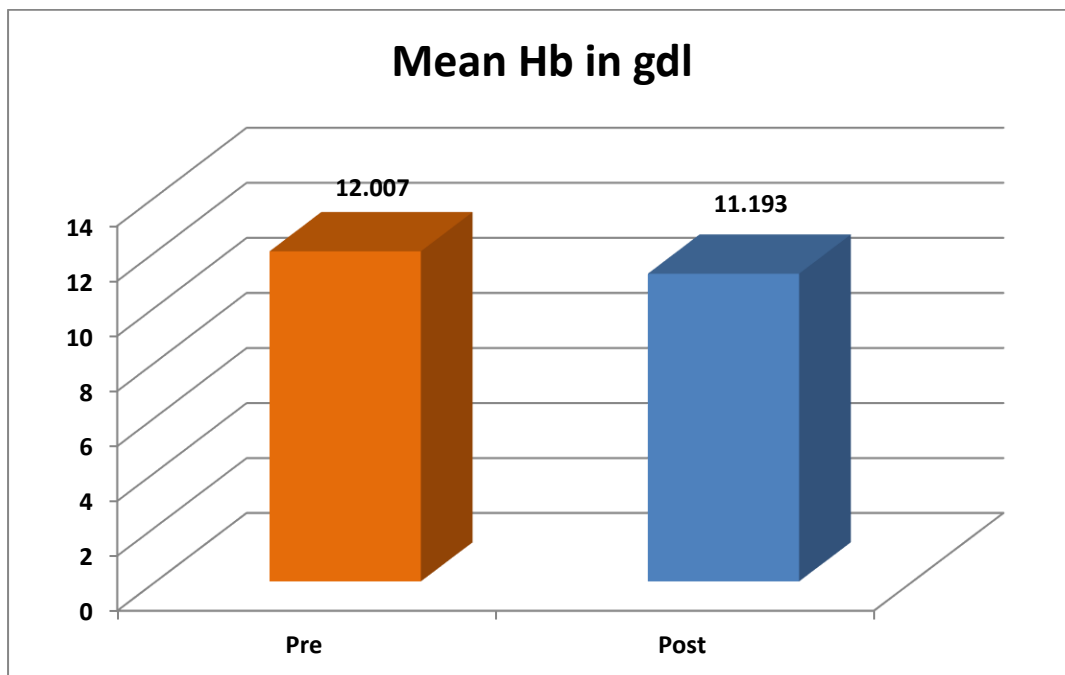
Graph 3:

In the present study, comparison of patient's body weight pre-operatively and post-operatively was done using paired t test which showed significant statistical difference between the body weight.

Table 4: Pre and postoperative comparison of the Hb of the study population

Hb in gdl		Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std deviation
	Pre	12.007	30	1.2329	.2251	0.81	0.52
	Post	11.193	30	1.3120	.2395		
P value	<0.0001 S						

In this study pre and post-operative comparison of the Hb using Paired t test showed statistical significant difference as $p < 0.05$ i.e. Hb decreased significantly post-operatively.



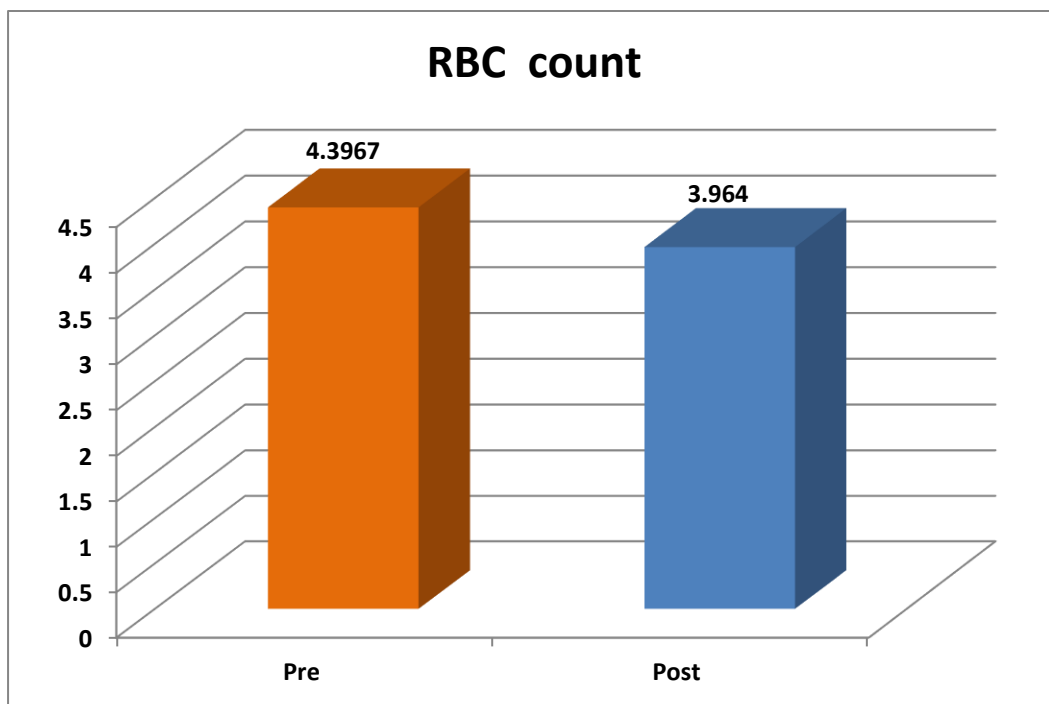
Graph 4:

In the present study, comparison of patient's Hb pre-operatively and post-operatively was done using paired t test which showed significant statistical difference between the Hb values.

Table 5: Pre and post-operative comparison of the RBC count of the study population

RBC in million cm	Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std deviation
Pre	4.3967	30	.49159	.08975	0.43	0.34
Post	3.9640	30	.55085	.10057		
P value	<0.0001 S					

In this study pre and post-operative comparison of the RBC count using Paired t test showed statistical significant difference as $p < 0.05$ i.e RBC count decreased significantly post-operatively.



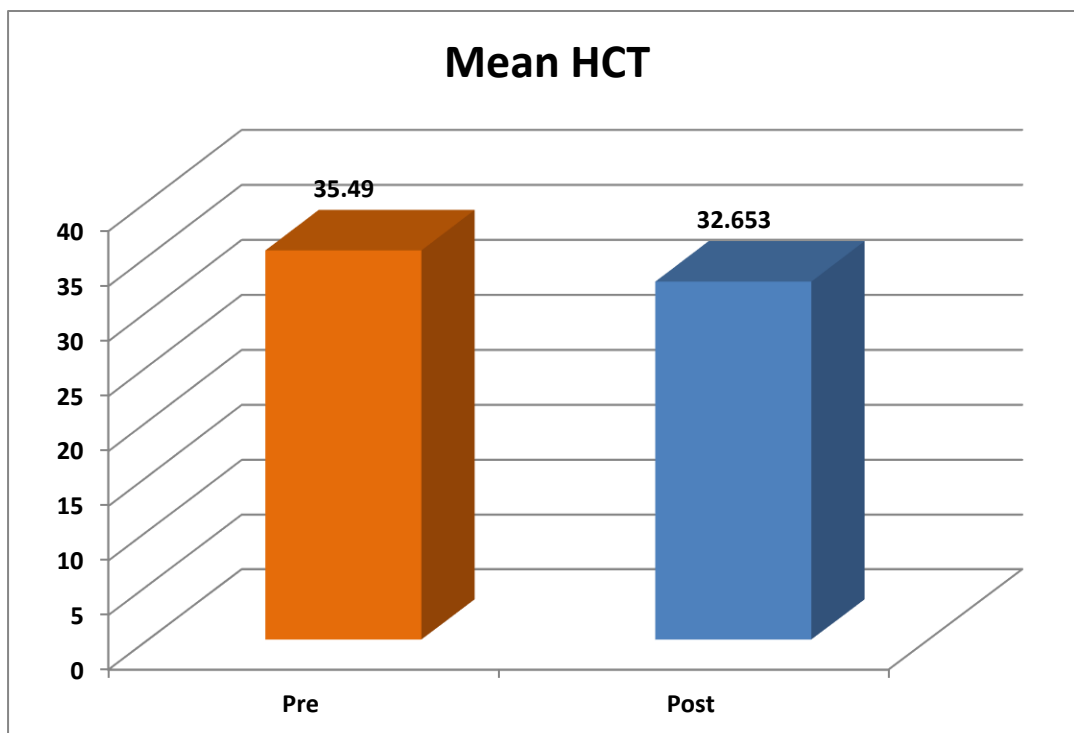
Graph 5:

In the present study, comparison of patient's RBC pre-operatively and post-operatively was done using paired t test which showed significant statistical difference between the RBC counts.

Table 6: Pre and post-operative comparison of the HCT value of the study population

HCT	Mean	N	Std. Deviation	Std. Error Mean	Mean difference	Std deviation
Pre	35.490	30	3.6705	.6701	2.8	1.7
Post	32.653	30	3.7217	.6795		
P value	<0.0001 S					

In this study pre-operative and post-operative comparison of the HCT using Paired t test showed statistical significant difference as $p < 0.05$ i.e HCT decreased significantly post-operatively.



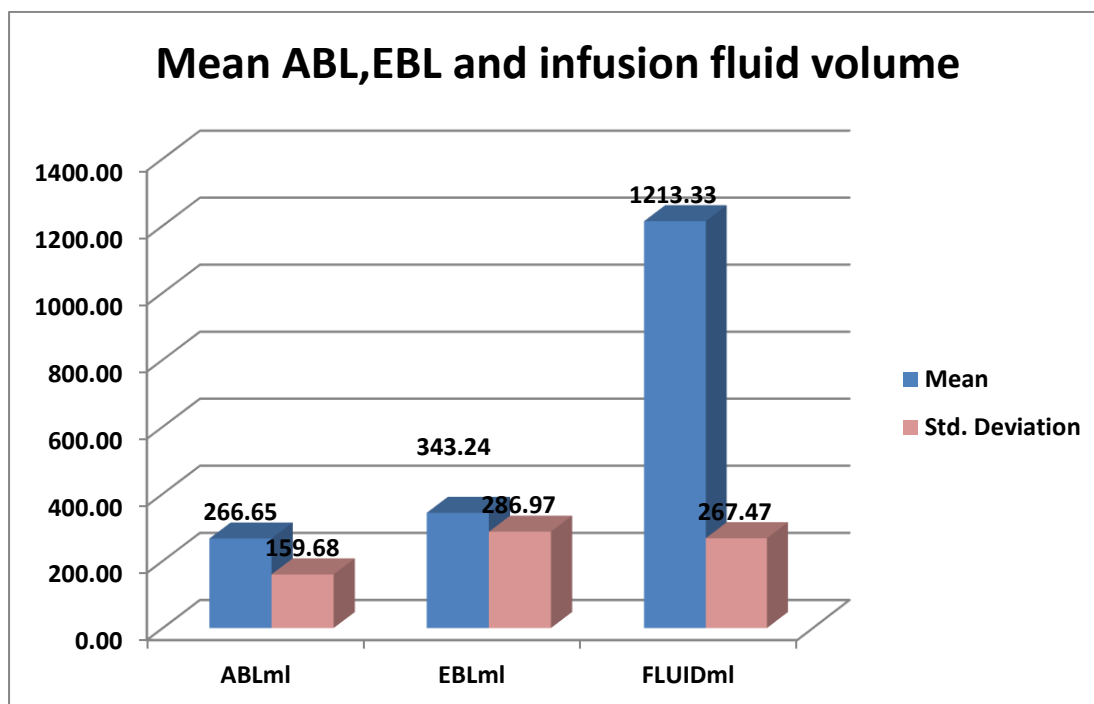
Graph 6:

In the present study, comparison of patient's HCT pre-operatively and post-operatively was done using paired t test which showed significant statistical difference between the HCT values.

Table 7 : Descriptives of actual blood loss, estimated blood loss and total volume of infusion fluid

	N	Minimum	Maximum	Mean	Std. Deviation
ABLml	30	.00	636.77	266.6533	159.68417
EBLml	30	25.40	1350.70	343.2367	286.97094
FLUIDml	30	1000.0	1600.0	1213.333	267.4701

Mean actual blood loss was found to be 266.65±159.68 ml, mean estimated blood loss was found to be 343.23±286.97 ml and mean total infusion fluid volume was found to be 1213±267.47 ml.



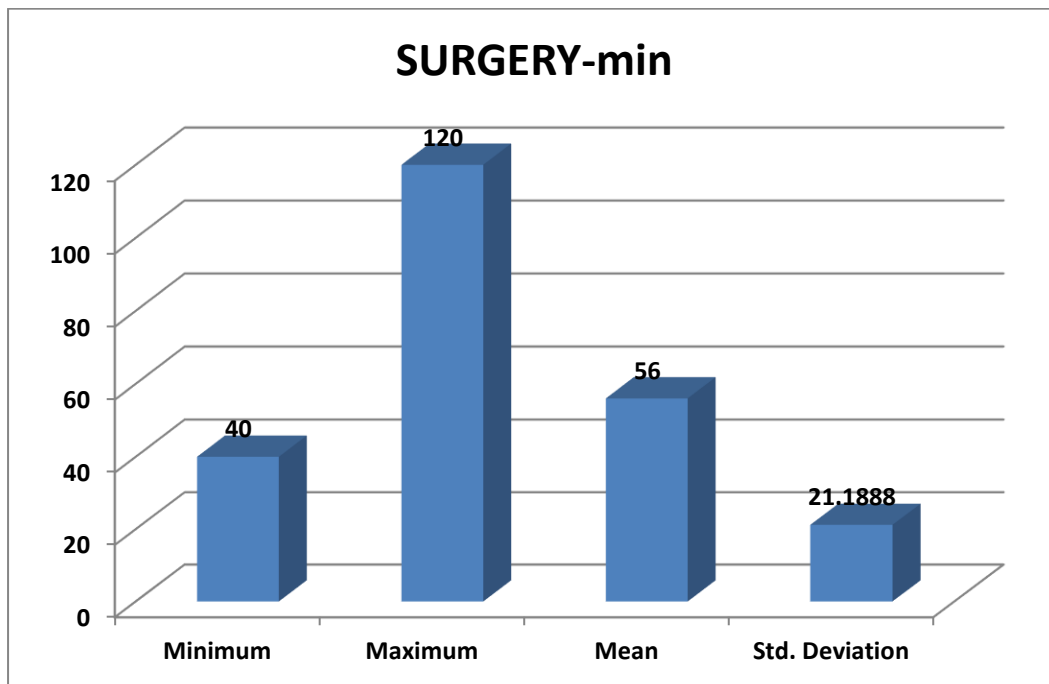
Graph 7:

In the present study, comparison of patient's ABL and EBL post-operatively was done using paired t test which showed significant statistical difference.

Table 8 : Descriptives of surgery time in minutes

	N	Minimum	Maximum	Mean	Std. Deviation
SURGERY-min	30	40.0	120.0	56.000	21.1888

In this study, mean time for performing the surgery was found to be 56 minutes with the SD of 21.18.



Graph 8:

In this study, the time of surgery varied from a minimum of 40 min. to a maximum of 120 min.

Table 9 : Correlation of Body weight, Hb, RBC count and HCT with Actual blood loss

		Weight	Hb	RBC count	HCT
ABLml	Pearson Correlation	.120	.604**	-.047	.832**
	Sig. (2-tailed)	.527	.0001*	.805	.0001*
	N	30	30	30	30

In this study, correlation among body weight, Hb, RBC count and HCT with Actual blood loss was calculated using Pearson correlation. There was a moderate positive correlation between actual blood loss and Hb with p the p value of $< .0001$. Whereas strong positive correlation was found between ABL and HCT with the p value of < 0.0001 . Negative correlation was found between ABL and RBC count though it was not significant.

Table 10 : Correlation of Body weight, Hb, RBC count and HCT with Estimated blood loss

		Weight	Hb	RBC count	HCT
EBLml	Pearson Correlation	.095	.216	.043	.186
	Sig. (2-tailed)	.616	.251	.821	.326
	N	30	30	30	30

In this study, correlation among body weight, Hb, RBC count and HCT with Estimated blood loss was calculated using Pearson correlation. Positive correlation was found between EBL, body weight and RBC count, Hb and HCT though they were not statistically significant.

Table 11: Correlation of Body weight, Hb, RBC count and HCT with infusion fluid volume

		Weight	Hb	RBC count	HCT
FLUID ml	Pearson Correlation	.127	-.169	.134	.035
	Sig. (2-tailed)	.504	.372	.480	.855
	N	30	30	30	30

In this study, correlation among body weight, Hb, RBC count and HCT with Infusion fluid volume calculated using Pearson correlation. Positive correlation was found between EBL, body weight and RBC count and HCT though they were not statistically significant and negative correlation was seen with fluid volume and Hb.

DISCUSSION

Discussion

Blood loss during any surgical procedure is a concern for both the surgeon and the anaesthetist. Precise estimation of blood loss thus becomes crucial for maintenance of intra and postoperative homeostasis.

Excessive bleeding can be distressing and may result in delayed completion of the procedure. Heavy blood loss compromises wound healing and predisposes it to infection. The bleeding risk of any dental procedure varies with how easy it is to access the site and apply haemostatic measures. For a simple procedure, local haemostatic measures are enough to control bleeding from the potential sites of haemorrhage. In contrast, there may be little or no access to bleeding sites following deep head and neck surgeries. Another complication that may arise during surgery is patients with known history of coagulopathies. Such abnormalities are among the major problems encountered in the surgical procedures. Although most of the patients have no intrinsic abnormalities of homeostasis but their underlying disease or therapy of the disease may pose significant bleeding problems.

Several assessments have been proposed for measuring blood loss during surgery. Gatch and Little in 1924 were the first to report the measurement of blood loss during some of the more common operations in general surgery⁴⁴. Blain, in 1929 commenting on his experience with 3000 transfusions noted that “the amount of blood lost during operations is often several times greater than that estimated by the surgeon”. Wangenstein in 1942 used gravimetric method⁴⁶. Jansen H in 1978 introduced the photometric method¹. The Triton system is the most recent method of blood loss assessment³³.

Of various methods that have been tried for estimation of intraoperative blood loss, most popular have been the gravimetric, volumetric, colorimetric, visual estimation methods and measuring the difference between pre and post-operative plasma volumes. Other techniques include spectrophotometry, intraoperative haemoglobin monitoring, electrical conductivity, urine strip method etc. However, none of the method can be considered gold standard. Each method has its own merits and limitations. Intraoperative blood loss estimation is subjective and often unreliable because of inaccuracies in measurement from swabs and drains, intercompartmental

fluid shifts during surgery and the dilutional effects of crystalloids. This study aims to generate a reliable method for estimation of blood loss during surgery using gravimetric and volumetric method.

A total of 30 patients were enrolled in this study. 2 of our patients underwent surgery for malignancy, 6 were trauma patients, 9 patients had undergone surgery for TMJ ankylosis, 5 underwent surgery for treatment of oral submucous fibrosis and 1 for orthognathic surgery. Rest 7 patients underwent surgery for various soft and hard tissue pathologies like ameloblastoma, peripheral giant cell granuloma, fibrous dysplasia, maxillary sinusitis, oroantral fistula repair and correction for residual deformity.

In this study we have used the weight method for calculating blood loss which is scientifically logical and widely applied method for measuring blood loss. Weighing surgical sponges, gauze pads, gowns and drapes and measuring drainage containers are the most commonly employed and reliable direct method for blood loss assessment. It must also be remembered that the weighing method estimates only the minimal blood loss and is the minimal amount of whole blood that should be replaced.

In all the patients we have used infiltration of adrenaline 1:200,000 for upto 15 mins. prior to the surgical incision with normotensive anaesthesia. The meta-analysis of Hardwick et al. has proven that adrenaline infiltration can reduce bleeding during reduction mammoplasties and the outcome, safety and efficacy does not depend on the size/ extent of the lesion or the tissues involved³.

The present study was conducted on a sample of young to adult patients age ranging from 8yrs. to 57yrs. The result failed to show any significant age-related difference in blood loss parameters. This can be explained by the fact that unanticipated blood loss is mostly associated with coagulopathies and other systemic disorders and does not correlate with patient age. Hypothermia and hypocalcemia are factors that may induce coagulopathy. Temperatures less than 34°C and serum ionized calcium concentrations less than 0.9mmol/l have been identified as significant contributors. The ability to effectively warm the patients from a temperature drop that often occurs following anesthesia induction and surgical preparation may explain the lack of association between decreased temperatures and blood loss²⁰. Accurate blood loss assessment is

necessary for patient care in both intraoperative and postoperative settings. Proper critical care includes blood volume management and determination for blood product replacement and is therefore highly dependent on an accurate assessment of EBL. This initiative is especially important in pediatric patients who have a lower haemodynamic reserve as compared to adults.

This study included 21 males and 9 females. No statistically significant differences based on gender were found in the intraoperative blood losses and pre and immediate post-operative haemoglobin and haematocrit changes showing an absence of correlation between gender, severity of hypovolemia and transfusion requirements.

Our analysis revealed a significant association between greater blood volume loss and decreasing weight. The mean preoperative body weight was 43.8 kg which decreased to 42.5 kg postoperatively. Total blood volume in body varies according to body weight (Total blood volume is 90ml/kg in newborn, 80ml/kg in infants, 70ml/kg in children and adults). So just by calculating volume of blood loss, the need for blood replacement cannot be predicted since an adult weighing 70kg with a blood loss of 500ml. shows an insignificant loss and may not require blood transfusion while a 20kg boy with similar blood loss of 500ml. may show a significant loss of blood volume which can even be life threatening⁴⁷. Wang M et al. in their study on Chinese patients investigated the effects of body mass index on blood loss and found that patients with low and normal weight lost more blood per kg of their weight and had higher total transfused volume compared to the obese group⁴¹.

Pre and immediate post-operative comparison of haemoglobin showed significant difference in this study. Post-operative value of haemoglobin decreased with increasing blood loss. According to other studies, most patients are in positive fluid balance postoperatively and experience an initial downward “haemoglobin drift” followed by recovery as this fluid is mobilized. These variations can result in haemoglobin changes of greater than 2g/dl that occur over several days despite a stable red cell mass, making reliance on haemoglobin values alone a poor strategy²⁸.

In this study the mean preoperative haemoglobin value decreased from 12.007gm% to 11.193gm% postoperatively so there was a difference of approximately 1% seen for blood loss upto 1500ml. In some cases the Hb is seen not to alter much with blood loss. In many cases

general anesthesia appears of itself to cause a fall in Hb of the venous blood. This may not be complete until some twenty minutes or more have elapsed from the moment of induction of anesthesia. In many individuals anesthesia in the absence of very marked falls in blood pressure is also associated with fluctuations in venous Hb, such fluctuations are usually falls but occasionally there is a rise in the level of mean operative Hb. In any operation, marked variation in the value of venous Hb can occur in short period of time. The origin of this may be summarized: Hb alterations due to anesthetic drugs and their effects; Hb falls due to haemorrhage and compensatory haemodilution; Hb falls due to infusions and transfusions; Hb falls due to vasodilatory hypotension¹¹.

Further, quite marked fluctuations in Hb can occur throughout the course of the operation due to fluctuations in blood pressure, level of anesthesia and reflex stimulation, infusions, transfusions and perhaps as a result of previous medication. From moment to moment, the haemodilution associated with fluid infusions alters the haemoglobin of the shed blood. The magnitude of such error will be affected by the following factors: Volume of circulating blood and hence also the rate at which haemorrhage is occurring; total volume of infused fluid during the operative period, its rate of redistribution throughout the body and its rate of clearance from the body; the rate at which infusions are administered etc¹¹.

The red blood cell count in this study showed significant reduction postoperatively from mean value of 4.3 million/mm³ to 3.9 million/mm³. As the blood loss increases the RBC count decreases. The replacement of lost blood using fluids during and after surgical operations causes compensatory increase in plasma volume but there is no increase in the number of red cells. Without blood transfusion the red cell volume does not return to normal for several weeks⁹.

Pre and immediate post-operative comparison of haematocrit showed significant difference in this study. There was approximately 3% reduction in the mean pre-operative value of haematocrit from 35.4 % to 32.6% with increased blood loss (for blood loss less than 30% of blood volume or 1500ml). **Elipe and Ponniah** in their study showed that differences in pre and post-operative haematocrit values and deductions of blood loss by the Gross formula are invaluable, the formula stated that actual blood loss equals blood volume multiplied by the difference in pre and post-operative haematocrit values and divided by mean of both haematocrit values; blood volume was calculated by multiplying body weight in kilograms by 70ml/kg.

However, the values are difficult to correlate with exact intraoperative blood loss due to intraoperative blood transfusion and crystalloid infusion as well as post-operative blood losses/ fluid dilutions. Hence, clinical estimates of intraoperative blood loss are more useful. Maximum allowable blood loss can be calculated as a proportion using the patient's preoperative haematocrit and the lowest acceptable haematocrit (usually 25%) by the formula: $\{(preoperative\ haematocrit - 25) / preoperative\ haematocrit\} * estimated\ blood\ volume$. Hence, if the blood loss exceeds the calculated amount, blood transfusion may be required⁴⁷.

The average operating time in this study was 56 min. It did vary with the type of surgery since treatment of malignancies took longer time duration compared to the other soft and hard tissue surgeries. The relationship between operative time and EBL is a strong linear one i.e blood loss consistently increases over time. The majority of blood loss is expected to occur in the beginning of the procedure. Blood loss decreases as the wounds get sutured. The longer surgical time observed in this study could be explained by the complexity of the procedures and surgeon's experience.

The result showed that operation for excision of malignant soft tissue recorded the highest amount of blood loss and the longest duration of surgery on the whole, this was mainly due to the large dimension and extent of the tumor involved. Revascularization of abnormally proliferating cells and local spread of the lesion also contributed to increasing bleeding episode seen in our patients.

It is not surprising that, in the hard tissue surgeries, the duration of surgery and the amount of blood loss were particularly highest for trauma or TMJ ankylosis cases. Treatment of these facial fractures involves the dissection and detachment of soft tissues and the reflection of the mucoperiosteum overlying the bones and these result in appreciable bleeding. Open reduction and internal fixation of these bony segments are actually major surgeries especially when multiple sites are involved and the number of fracture sites will determine the duration of surgery and consequently the amount of blood loss.

Studies have shown that a wider nasal floor mucosa repair in the palate causes more bleeding which is further exacerbated by the diffuse and multiple blood supply of the palate when compared to skin of the lip. On the contrary, the relatively less bleeding seen in operations

involving maxillary tumors may be due to the fact that most of the tumors were removed by intraoral approach. For maxillary lesions, resections were performed after which the defect was covered with sofra-tulle-wrapped gauze while rehabilitation was accomplished with obturators³.

The formula method described by “Gross” for calculation of blood loss is popular among surgeons. As blood loss is occurring, the patient’s circulating volume will tend to fall. However, the simultaneous shift of fluid into the circulating compartment and fluid administered peri-operatively maintain the circulating volume, although with increasingly more dilute blood and the haematocrit gradually falls. The RBC loss, as haemorrhage, continues logarithmically. It was found that the Gross equation closely approximated the logarithmic one unless there was substantial or brisk haemorrhage causing the formula to drift from the normal baseline. The Gross equation reflects actual postoperative blood loss to some extent. However, the Gross equation does not involve Hb-related factors. Actual blood loss and anemia are revealed by the calculated peri-operative volume and the changing haematocrit which may be the limitation of this method²⁴.

The present study revealed large difference between the clinical measurement of blood loss using the gravimetric and volumetric method i.e. EBL and the blood loss calculated by the Gross formula using the haematocrit values i.e. ABL. The result found was significantly different. Between the two, EBL method can be considered more reliable for assessing blood loss in maxillofacial surgical procedures.

Blood is a scarce resource. It is transfused to increase the haemoglobin content and improve oxygen delivery thereby preventing tissue hypoxia. In this study, none of our patients required blood transfusion postoperatively. All the patients lost blood less than 1500ml. which was replaced using crystalloid infusions. As large volume (about 75%) of crystalloid leaves the circulation into the interstitial space, the volume of crystalloids required to replace blood loss is larger than the volume of blood lost so as a rule blood loss needs to be replaced with 3 times the volume of crystalloids⁴⁷.

Apart from maintaining homeostasis, care must be taken to prevent excessive blood losses by avoiding major blood vessels. The approach to a lesion via avascular planes as well as subperiosteal dissections for non-invasive lesions and safety margin sacrifice of tissues in

infiltrative lesions are excellent methods of minimizing intraoperative bleeding³. Considering the fact that blood transfusion carries unwanted side effects and in addition of the usual complications, some studies show an increase in the frequency of the cancer recurrences and a higher incidence of postoperative infections. Also since blood is a limited resource, inappropriate use of blood must be discouraged; although appropriate blood transfusion can be life saving. Blood wastage can be avoided by paying more attention to the expected blood loss and using preset criteria for homologous blood administration.

The accurate assessment of blood loss is absolute necessary since underestimation can lead to delayed replacement resulting into hypoperfusion leading to decreased capillary filling and acidosis which further leads to decreased delivery of oxygen to tissues, resulting in delay in achieving the goals of cellular resuscitation and increased morbidity and mortality while overestimation of blood loss would lead to unnecessary transfusion, volume overload and cardiac failure³⁰.

Possible sources of bias might have been incomplete measurements of blood loss, blood coagulating before reaching the suction system or blood loss resulting from blood extractions (used for laboratory analysis). The assumption must therefore be made that the actual blood loss during any surgical procedure is more than it is measured. The “concealed” haemorrhage revealed by red cell volume studies, does not appear outside the body. It presumably consists of leaking of blood into the tissue spaces around the operation site, in the incision and due to the immobilization of blood in vessels proximal to ligatures. Although this blood is within the body confines it is unavailable blood and is lost to the circulation⁹.

One of the causes of errors in calculating blood loss may be because of the use of slightly variable size of the gauze. To prevent such errors in measuring intraoperative blood loss, it is recommended to always use a standardized size of gauzes and if there is any change in size then it should be notified, as any change will lead to discrepancy in estimation of blood loss which can prove fatal not only in a healthy patient but also in pediatric and geriatric patients who have limited cardiopulmonary reserves³⁰.

Strengths of the current study include an appropriate analysis with uniform method for estimating blood loss in a specific patient population who undergo maxillofacial surgical

procedures leading to high blood loss. This method of blood loss assessment helps minimize variability and bias in the overall result and maybe more applicable to clinical practice. The goal of this study was to provide theoretical and practical support for the most reliable method for blood loss estimation.

Finally to again stress that accurate replacement of whole blood acts as a prophylaxis against circulatory collapse and also aids in decreasing postoperative morbidity. “Less amount of blood is required to prevent hypotension than to correct it”; therefore ideally, blood should be replaced as it is lost, thus helping to maintain cardiovascular homeostasis.

Within the framework of Patient Blood Management as a multidisciplinary and evidence-based treatment concept, the recording of blood loss is becoming increasingly important. PBM is based on three main pillars: 1) Anaemia management 2) Minimizing blood loss and increased use of donor blood saving strategies 3) Rational use of blood reserves^{43,45}

Patients undergoing major maxillofacial surgical procedures are at risk for severe bleeding and may require blood transfusion due to anatomic features of the surgical area (vascular proximity), complexity of surgical procedure, duration of surgery, tumor characteristics, perioperative hypothermia, metabolic derangements and intraoperative dilutional coagulopathy (blood transfusions and fluid administration). It is therefore crucial for both the surgical and anesthesia team to delineate perioperative interventions targeted to minimize perioperative blood loss.

The recording of intraoperative blood loss plays a central role in the daily routine of clinicians. Estimates of blood loss can improve operative management and should become much more widespread. Not only do they make for accuracy in surgical care but also they promote a healthy attitude on the part of surgeon to blood loss and conservation.

CONCLUSION

Conclusion

Within the scope and limitations of this study, the following conclusions were drawn:

- The gravimetric and volumetric estimation of blood loss during surgery is an inexpensive and reliable method and can be used to determine minimal blood loss which needs to be replaced.
- The parameters such as body weight, haemoglobin, haematocrit, RBC count decrease with increase in intraoperative blood loss.
- Blood loss is directly proportional to time of surgery.
- Crystalloid infusions can be safely used to increase depleted circulating volumes upto 1500ml. of blood loss.

The recording of intraoperative blood loss plays a very vital role in the daily routine of clinicians. Based on these estimations, patient's treatment and infusion and transfusion decisions can be made. Consequently for the patient's safety we should aim for the highest possible accuracy of measurement.

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ANNEXURES

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the VIIth Institutional Ethics Sub-Committee

IEC Code: 35

BBDCODS/01/2019

Title of the Project: Assessment of Intraoperative Blood Loss During Oral and Maxillofacial Surgical Procedures and its Implications.

Principal Investigator: Dr. Ishita Srivastava

Department: Oral & Maxillofacial Surgery

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr. Ishita Srivastava,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 10th January 2019.

- | | |
|---|--|
| 1. Dr. Lakshmi Bala
Member Secretary | Prof. and Head, Department of Biochemistry, BBDCODS,
Lucknow |
| 2. Dr. Amrit Tandan
Member | Prof. & Head, Department of Prosthodontics and Crown &
Bridge, BBDCODS, Lucknow |
| 3. Dr. Rana Pratap Maurya
Member | Reader, Department of Orthodontics & Dentofacial Orthopedics,
BBDCODS, Lucknow |
| 4. Dr. Sumalatha M.N.
Member | Reader, Department of Oral Medicine & Radiology,
BBDCODS, Lucknow |

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.

The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala
21/01/19
Member-Secretary
(Dr. Lakshmi Bala) Ethic Committee
Member-Secretary of Dental Sciences
IEC BBD University
Faizabad Road, Lucknow-226028

[Signature]
Principal
Babu Banarasi Das College of Dental Sciences
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BBD City, Faizabad Road, Lucknow (17)

**BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES
(FACULTY OF BBD UNIVERSITY), LUCKNOW**

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled "**Assessment of Intraoperative Blood Loss During Oral and Maxillofacial Surgical Procedures and its Implications.**" submitted by **Dr Ishita Srivastava** Post graduate student from the **Department of Oral & Maxillofacial Surgery** as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on **26th November 2018** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.



Prof. Vandana A Pant
Co-Chairperson



Prof. B. Rajkumar
Chairperson

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad road, Lucknow – 227105 (INDIA)

Patient Information Document (PID)

1. Study title

Assessment of Intraoperative Blood Loss During Oral and Maxillofacial Surgical Procedures and Its Implications.

2. Invitation paragraph

You are requested to take part in this research study, therefore if you agree it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to participate .

3. What is the purpose of the study?

The purpose of this study is to estimate blood loss during oral and maxillofacial surgical procedures and to establish its correlation between gravimetric/volumetric estimation of blood loss with changes in pre op and post op blood values.

4. Why have you been chosen?

You have been chosen for this study as you will be treated for your ailment by surgical procedure as deemed necessary. This will result in some amount of blood loss. As you get the treatment you also fulfill the criteria to be included in the study .

5. Why would you take part?

Your participation in the research is entirely voluntary. However, as the study doesn't warrant any additional procedure or a new procedure to be performed on you apart from one additional blood sample post operatively to do comparisons required for the study. If you participate, you will be given this information sheet to keep and will be asked to sign

a consent form. You won't be asked for any additional follow up visits. The results of the study would help us judge the need of any additional blood to be transfused after a procedure based on time, extent etc. this would eventually help mankind to be treated in a better way. However, during the study you still are free to withdraw at any time and without giving a reason.

6. What will happen to you if you take part?

You will not be under any additional risk throughout the procedure and will not be subjected to any direct benefit from this study but instead the conclusions which come out will help the mankind.

7. What would you have to do?

A preoperative blood investigation is required for all surgeries performed under general anesthesia. You have to go for an additional blood sample immediately after surgery which we ensure, will be performed using a sterile needle.

8. What is the procedure that is being tested?

The blood investigations will be done prior to the surgery. During the surgery, gravimetric/volumetric estimation of blood loss method will be used to calculate accurate amount of blood loss. An additional blood sample will be collected immediately after surgery to assess the changes in blood counts depending on the amount of blood loss and thus the need for blood transfusion will be estimated.

9. What are the interventions for the study?

A pre operative blood investigation is required for pre anesthetic evaluation. An additional blood sample is required post operatively which brings risk of needle stick injury. However, we assure you that the collection of post operative blood sample will be done using sterile syringe. You will not be asked for any additional follow up visits.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

11. What are the possible disadvantages and risks of taking part?

The only disadvantage is an additional prick for collection of blood sample immediately after surgery which risks it to the associated needle stick injury. However, we assure you that the sample collection will be done using sterile syringe.

12. What are the possible benefits of taking part?

There are no monetary benefits as such for taking part in our study, however, the conclusion which comes out will instead help the mankind with better post operative care

.

13. What if new information becomes available?

If additional information becomes available during the course of the research it will not affect your participation as your participation ends as soon as additional blood sample is collected post operatively. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study stops/finishes before the stipulated time, this will be explained to you.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and IEC.

16. Shall I take part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The result of the study will be published in the indexed journal. Your identity will be kept confidential in case of any report/publications

.

18. Who is organizing the research?

This research study is organized by the candidate and Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, BBD University, Lucknow.

19. Will the results of the study be made available after study is over?

Yes, only the data obtained will be published

.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Department and the IEC of the institution.

Thankyou for your participation.

Contact for further information

Dr. Ishita Srivastava

Department of Oral and Maxillofacial Surgery

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BBDCODS, Lucknow.

Dr. Laxmi Bala

Secretary Ethics committee

bbdcods_iec@gmail.com

Name of principal investigator.....

Signature of principal investigator

Date.....

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
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रोगी सूचना दस्तावेज (पीआईडी)

1. अध्ययन शीर्षक

मौखिक और मैक्सिलोफेशियल सर्जिकल प्रक्रियाओं और इसके प्रभावों के दौरान अंतःक्रियात्मक रक्त हानि का आकलन।

2. निमंत्रण पैराग्राफ

आपसे अनुरोध है कि इस शोध अध्ययन में भाग लें, इसलिए यदि आप सहमत हैं तो आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने और दोस्तों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक / परिवार के डॉक्टर से चर्चा करें। हमसे पूछें कि क्या ऐसा कुछ है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं। यह निर्णय लेने के लिए समय निकालें कि आप भाग लेना चाहते हैं या नहीं।

3. अध्ययन का उद्देश्य क्या है?

इस अध्ययन का उद्देश्य मौखिक और मैक्सिलोफेशियल सर्जिकल प्रक्रियाओं के दौरान रक्त के नुकसान का अनुमान लगाना है और पूर्व सेशन में बदलाव और ऑप रक्त मूल्यों को पोस्ट करने के साथ रक्त के नुकसान के ग्रेविमेट्रिक / वॉल्यूमेट्रिक अनुमान के बीच इसके संबंध को स्थापित करना है।

4. आपको क्यों चुना गया है?

आपको इस अध्ययन के लिए चुना गया है क्योंकि आवश्यक समझे जाने पर आपको सर्जिकल प्रक्रिया द्वारा आपकी बीमारी का इलाज किया जाएगा। इससे कुछ मात्रा में रक्त की कमी होगी। जैसा कि आप उपचार प्राप्त करते हैं आप अध्ययन में शामिल होने के मानदंडों को भी पूरा करते हैं।

5. आप क्यों भाग लेंगे?

अनुसंधान में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। हालांकि, जैसा कि अध्ययन किसी भी अतिरिक्त प्रक्रिया या आप पर किए जाने वाले एक नई प्रक्रिया के अलावा एक अतिरिक्त रक्त के नमूने पोस्ट ऑपरेटिव को अध्ययन के लिए आवश्यक तुलना करने के लिए वारंट नहीं करता है। यदि आप भाग लेते हैं, तो आपको रखने के लिए यह सूचना पत्र दिया जाएगा और सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। आपको किसी भी अतिरिक्त अनुवर्ती यात्राओं के लिए नहीं कहा जाएगा। अध्ययन के परिणाम हमें समय, सीमा आदि के आधार पर प्रक्रिया के बाद किसी भी अतिरिक्त रक्त की आवश्यकता का पता लगाने में मदद करेंगे, जिससे अंततः मानव जाति का बेहतर तरीके से इलाज किया जा सकेगा। हालांकि, अध्ययन के दौरान आप किसी भी समय और बिना कारण बताए वापस लेने के

लिए स्वतंत्र हैं।

6. अगर आप हिस्सा लेंगे तो आपका क्या होगा?

आप पूरी प्रक्रिया के दौरान किसी भी अतिरिक्त जोखिम के अधीन नहीं होंगे और इस अध्ययन से किसी भी प्रत्यक्ष लाभ के अधीन नहीं होंगे, बल्कि इसके बजाय जो निष्कर्ष सामने आएंगे वह मानव जाति की मदद करेंगे।

7. आपको क्या करना होगा?

सामान्य संज्ञाहरण के तहत की जाने वाली सभी सर्जरी के लिए एक प्रीऑपरेटिव रक्त जांच आवश्यक है। आपको सर्जरी के तुरंत बाद एक अतिरिक्त रक्त के नमूने के लिए जाना होगा जो हम सुनिश्चित करते हैं, एक बॉझ सुई का उपयोग करके प्रदर्शन किया जाएगा।

8. वह प्रक्रिया क्या है जिसका परीक्षण किया जा रहा है?

सर्जरी से पहले रक्त की जांच की जाएगी। सर्जरी के दौरान, रक्त की हानि विधि के ग्रेविमेट्रिक / वॉल्यूमेट्रिक आकलन का उपयोग रक्त की हानि की सटीक मात्रा की गणना करने के लिए किया जाएगा। रक्त के नुकसान की मात्रा के आधार पर रक्त की मात्रा में परिवर्तन का आकलन करने के लिए सर्जरी के तुरंत बाद एक अतिरिक्त रक्त नमूना एकत्र किया जाएगा और इस प्रकार रक्त आधान की आवश्यकता का अनुमान लगाया जाएगा।

9. अध्ययन के लिए हस्तक्षेप क्या हैं?

पूर्व सवेदनाहारी मूल्यांकन के लिए एक पूर्व ऑपरेटिव रक्त जांच आवश्यक है। ऑपरेटिव रूप से एक अतिरिक्त रक्त के नमूने की आवश्यकता होती है जो सुई की छड़ी की चोट का जोखिम लाता है। हालांकि, हम आपको आश्वस्त करते हैं कि पोस्ट ऑपरेटिव रक्त के नमूने का संग्रह बॉझ सिरिज का उपयोग करके किया जाएगा। आपको किसी भी अतिरिक्त अनुवर्ती यात्राओं के लिए नहीं कहा जाएगा।

10. भाग लेने के दुष्प्रभाव क्या हैं?

इस अध्ययन के रोगियों पर कोई दुष्प्रभाव नहीं है।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

एकमात्र नुकसान सर्जरी के तुरंत बाद रक्त के नमूने के संग्रह के लिए एक अतिरिक्त चुभन है जो इसे संबंधित सुई की छड़ी की चोट के लिए जोखिम देता है। हालांकि, हम आपको आश्वासन देते हैं कि नमूना संग्रह बॉझ सिरिज का उपयोग करके किया जाएगा।

12. भाग लेने के संभावित लाभ क्या हैं?

हमारे अध्ययन में भाग लेने के लिए कोई मौद्रिक लाभ नहीं है, हालांकि, जो निष्कर्ष निकलता है वह मानव जाति को बेहतर पोस्ट ऑपरेटिव देखभाल के साथ मदद करेगा।

13. यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा?

यदि अनुसंधान के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है तो यह आपकी भागीदारी को प्रभावित नहीं करेगा

क्योंकि अतिरिक्त रक्त के नमूने को पोस्टऑपरेशनल तरीके से एकत्र करते ही आपकी भागीदारी समाप्त हो जाती है। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन रुक जाता है तो क्या होता है?

यदि निर्धारित समय से पहले अध्ययन रुक जाता है / समाप्त हो जाता है, तो यह आपको समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

यदि कोई गंभीर प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत होता है, तो संस्थान (एस), और आईईसी को रिपोर्ट करके शिकायतों को नियंत्रित किया जाएगा।

16. क्या मुझे इस अध्ययन में भाग लेना गोपनीय रखा जाएगा?

हां इसे गोपनीय रखा जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन का परिणाम अनुक्रमित पत्रिका में प्रकाशित किया जाएगा। किसी भी रिपोर्ट / प्रकाशन के मानले में आपकी पहचान गोपनीय रखी जाएगी

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18. अनुसंधान का आयोजन कौन कर रहा है?

यह शोध अध्ययन ओरल एंड मैक्सिलोफेशियल सर्जरी, बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज, बीबीडी विश्वविद्यालय, लखनऊ के उम्मीदवार और विभाग द्वारा आयोजित किया जाता है।

19. क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे?

हां, केवल प्राप्त डेटा प्रकाशित किया जाएगा

|

20. अध्ययन की समीक्षा किसने की?

विभाग के प्रमुख और संस्थान के IEC द्वारा अध्ययन की समीक्षा और अनुमोदन किया गया है।

भाग लेने के लिए आपको धन्यवाद।

अधिक जानकारी के लिए संपर्क करें

डॉ। इशिता श्रीवास्तव डॉ। लक्ष्मी बाला

GUARDIAN INFORMATION DOCUMENT

Title : ASSESSMENT OF INTRAOPERATIVE BLOOD LOSS DURING ORAL AND MAXILLOFACIAL SURGICAL PROCEDURES AND ITS IMPLICATIONS

Your child is requested to take part in this research study. It's up to you to decide whether you want your child to take part in the study or not. Kindly read all the information carefully and discuss and clear all your doubts before giving your consent.

The aim of our study is to estimate blood loss during oral and maxillofacial surgical procedures and to establish correlation between gravimetric/volumetric estimation of blood loss with changes in pre op and post op values of haematocrit, haemoglobin, body weight and RBC count.

Taking part in this research is entirely voluntary. It is upto you to decide whether or not to take part. If you allow your child to take part in this study , you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving any reason.

Your child's participation in the study may help others, because his/her participation will help us determine if the study procedure is efficacious.

The information collected about your child will be kept confidential but it may be looked at by people from IEC to check the study is being carried out correctly.

The result of the study will be published in the indexed journal without revealing your identity. There is no sponsorship for the study.

HOD/IEC of institution has reviewed and approved the study.

Thanking you for taking part in study.

Contact address:

Dr. Ishita Srivastava

Department of Oral and Maxillofacial Surgery

isrivastava7@gmail.com

BBDCODS, Lucknow.

Dr. Laxmi Bala

Secretary Ethics committee

bbdcods_ice@gmail.com

Name of the principal investigator -

Signature of principal investigator-

Date:

आईसीएन सूचना विभाग

शोधक: अनिच्छुक रक्त की कमी का पता लगाने के लिए आंरल और मैक्सिलोफेशियल शल्यचिकित्सा प्रक्रियाएं और इसके कार्यान्वयन

आपके बच्चे से अनुरोध है कि वे इस शोध अध्ययन में भाग लें। यह आपको तय करना है कि आप अपने बच्चे को अध्ययन में भाग लेना चाहते हैं या नहीं। कृपया सभी जानकारी को ध्यान से पढ़ें और चर्चा करें और अपनी सहमति देने से पहले अपने सभी संदेहों को दूर करें।

हमारे अध्ययन का उद्देश्य मौखिक और मैक्सिलोफेशियल सर्जिकल प्रक्रियाओं के दौरान रक्त के नुकसान का अनुमान लगाना है और हेमटोक्रिट, हीमोग्लोबिन, शरीर के वजन और आरबीसी काउंट के पूर्व ऑप और मूल्यों में परिवर्तन के साथ रक्त के नुकसान के ग्रेविमेट्रिक / वॉल्यूमेट्रिक अनुमान के बीच संबंध स्थापित करना है।

इस शोध में भाग लेना पूरी तरह से स्वैच्छिक है। यह आपको तय करना है कि आपको हिस्सा लेना है या नहीं। यदि आप अपने बच्चे को इस अध्ययन में भाग लेने की अनुमति देते हैं, तो आपको रखने के लिए यह सूचना पत्र दिया जाएगा और सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं तो आप किसी भी समय और बिना किसी कारण के वापस लेने के लिए स्वतंत्र हैं।

अध्ययन में आपके बच्चे की भागीदारी दूसरों की मदद कर सकते हैं, क्योंकि उसकी / उसकी भागीदारी से हमें यह निर्धारित करने में मदद मिलेगी कि क्या अध्ययन प्रक्रिया प्रभावोत्पादक है।

आपके बच्चे के बारे में एकत्र की गई जानकारी को गोपनीय रखा जाएगा, लेकिन यह आईईसी के लोगों द्वारा देखा जा सकता है कि अध्ययन सही ढंग से हो रहा है।

अध्ययन के परिणाम को आपकी पहचान बताए बिना अनुक्रमित पत्रिका में प्रकाशित किया जाएगा। अध्ययन के लिए कोई प्रायोजन नहीं है।

संस्थान के एचओडी / आईईसी ने अध्ययन की समीक्षा और अनुमोदन किया है।

अध्ययन में भाग लेने के लिए धन्यवाद।

संपर्क पता:

डॉ। इशिता श्रीवास्तव डॉ। लक्ष्मी बाला

आंरल और मैक्सिलोफेशियल सर्जरी सचिव आचार समिति के विभाग

isrivastava7@gmail.com bbdcods_ice@gmail.com

BBDCODS, लखनऊ।

प्रधान अन्वेषक का नाम -

मुख्य अन्वेषक का हस्ताक्षर- दिनांक:

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study

Study Number.....

Subject's Full Name.....

Date of Birth/Age

Address of the Subject.....

Phone no. and e-mail address.....

Qualification

Occupation: Student / Self Employed / Service / Housewife/

Other (Please tick as appropriate)

Annual income of the Subject.....

Name and of the nominees(s) and his relation to the subject..... (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document datedfor the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [] No []**
Not Applicable []
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally Acceptable

Representative:.....

Signatory's Name.....

Date

Signature of the Investigator.....

Date.....

Study Investigator's Name.....

Date.....

Signature of the witness.....

Date.....

Name of the witness.....

Received a signed copy of the PID and duly filled consent form

Signature/thumb impression of the subject or legally

Date.....

Acceptable representative

BBDCCOOS

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

सहमति पत्र

अध्ययन शीर्षक.....
अध्ययन संख्या.....
प्रतिभागी के पूर्ण नाम.....
जन्म तिथि / आयु.....
प्रतिभागी का पता

फोन नं. और ई-मेल पता

योग्यता

व्यवसाय: छात्र / स्व कार्यरत / सेवा / ग्रहिणी

अन्य (उचित रूप में टिक करें)

प्रतिभागी की वार्षिक आय

प्रत्याशीयो के नाम और प्रतिभागी से संबंध...(परीक्षण से संबंधित मौत के मामले में मुआवजे के प्रयोजन के लिए)

1. मेरी पुष्टि है कि मैंने अध्ययन हेतु सूचना पत्र दिनांक को पढ़ व समझ लिया तथा मुझे प्रश्न पुछने या मुझे अध्ययन अन्वेषक ने सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पुछने के समान अवसर प्रदान किए गये।
2. मैंने यहाँ समझ लिया कि अध्ययन में मेरी भागीदारी पूर्णतः स्वैच्छिक है और किसी भी दबाव के बिना स्वतंत्र इच्छा के साथ दिया है किसी भी समय किसी भी कारण के बिना , मेरे इलाज या कानूनी अधिकारों को प्रभावित किए बिना , अध्ययन में भाग न लेने के लिए स्वतंत्र हूँ ।
3. मैंने यह समझ लिया है कि अध्ययन के प्रायोजक , प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को मेरे स्वास्थ्य रिकार्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति की जरूरत नहीं है, चाहे मैंने इस अध्ययन से नाम वापस ले लिया है। हालांकि मैं यह समझता हूँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नहीं दी जायेगी।
4. मैं इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबंध नहीं है।
5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हूँ।

हाँ [] नहीं [] अनउपयुक्त []

6. मैं परीक्षण की अनुमति देता हूँ। मुझे इसके द्वारा यदि कोई परेशानी होती है, इसके बारे में जानकारी दे दी गई है। मैंने रोगी जानकारी सूचना पत्र को पढ़ तथा समझ लिया है।

प्रतिभागी / कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर (या अंगूठे का निशान.....

हस्ताक्षरकर्ता का नाम..... दिनांकअन्वेषक के

हस्ताक्षर दिनांक

अध्ययन अन्वेषक का नाम

गवाह के हस्ताक्षर दिनांकगवाह के

नाम

मैंने पीआईडी और विधिवत भरे सहमति फार्म का एक हस्ताक्षर की नकल प्राप्त की.

प्रतिभागी कानूनी तौर पर प्रतिनिधि का हस्ताक्षर/ अंगूठे का निशान दिनांक.....

BBDCODS

CASE SHEET

DATE:-

OPD NO.:-

PATIENT NAME:-

AGE/SEX:-

FULL PERMANENT POSTAL ADDRESS:-

TELEPHONE NO.:-

CHIEF COMPLAINT:-

FAMILY HISTORY:-

PERSONAL HISTORY:-

HABITS:-

HISTORY OF PAST ILLNESS:-

HISTORY OF PRESENT ILLNESS:-

PAST DENTAL HISTORY:-

SYSTEMIC EXAMINATION:-

LOCAL EXAMINATION:-

INVESTIGATIONS & RECORDS:-

Hb gram%-

RBC count-

PCV-

ESR-

B.T.

C.T.

TLC-

DLC-

POLY-

MONO-

LYMPHO-

EASN.-

Platelet count-

HbSAg-

HIV- I

- II

Blood urea-

Serum creatinine-

DIAGNOSIS:-

TREATMENT:-

PRE-OPERATIVE RECORD

BODY WEIGHT	
HAEMOGLOBIN	
RED BLOOD CELL COUNT	
HEMATOCRIT	

INTRA-OPERATIVE RECORD

EBL	
ABL	
VOLUME OF INFUSION FLUID	
DURATION OF SURGERY	

POST-OPERATIVE RECORD

BODY WEIGHT	
HAEMOGLOBIN	
RED BLOOD CELL COUNT	
HEMATOCRIT	

Urkund Analysis Result

Analysed Document: Ishita Thesis.pdf (D110194440)
 Submitted: 7/6/2021 10:39:00 AM
 Submitted By: hemantmehra121@bbdu.ac.in
 Significance: 7 %

Sources included in the report:

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