

**AUTOLOGOUS VERSUS ALLOGENEIC BLOOD
TRANSFUSION: A COMPARATIVE STUDY
OF THE PERI-OPERATIVE OUTCOMES
IN A TERTIARY CARE HOSPITAL
IN SOUTH INDIA**

Dr. Angel Mary Sam

MD THESIS

2020-2022



**SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES
AND TECHNOLOGY, TRIVANDRUM**

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A THESIS SUBMITTED BY

Dr. Angel Mary Sam

TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND
TECHNOLOGY, TRIVANDRUM.

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

MD in Transfusion Medicine

2020-2022

DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr. Angel Mary Sam hereby certify that I had personally carried out the work depicted in the thesis titled, **“AUTOLOGOUS VERSUS ALLOGENEIC BLOOD TRANSFUSION: A COMPARATIVE STUDY OF THE PERI-OPERATIVE OUTCOMES IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA”**.

No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.



Dr. Angel Mary Sam

Date: 19th July 2022



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

CERTIFICATE BY THE RESEARCH GUIDE

Name of the Guide: Dr. Debasish Gupta

Division/Department: Professor & Head, Dept. of Transfusion Medicine

This is to certify that Dr. Angel Mary Sam, Department of Transfusion Medicine of this institute has fulfilled the requirements prescribed for the MD degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, “**Autologous Versus Allogeneic Blood Transfusion: A Comparative Study of The Peri-Operative Outcomes in A Tertiary Care Hospital in South India.**” was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Dr. Debasish Gupta

Date: 20th July 2022.



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

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Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Manikandan S.

Division/Department: Professor, Dept. of Neuroanesthesia

This is to certify that Dr. Angel Mary Sam, Department of Transfusion Medicine of this institute has fulfilled the requirements prescribed for the MD degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "**Autologous Versus Allogeneic Blood Transfusion: A Comparative Study of The Peri-Operative Outcomes in A Tertiary Care Hospital in South India.**" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Dr. Manikandan S.

Date: 21.7.2022



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तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Krishnakumar K.

Division/Department: Professor, Dept. of Neurosurgery

This is to certify that Dr. Angel Mary Sam, Department of Transfusion Medicine of this institute has fulfilled the requirements prescribed for the MD degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "**Autologous Versus Allogeneic Blood Transfusion: A Comparative Study of The Peri-Operative Outcomes in A Tertiary Care Hospital in South India.**" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Krishnakumar K

Dr. Krishnakumar K.

Date 25 July 2022



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Prasanta Kumar Dash

Division/Department: Professor, Dept. of Cardiothoracic and Vascular Anesthesia

This is to certify that Dr. Angel Mary Sam, Department of Transfusion Medicine of this institute has fulfilled the requirements prescribed for the MD degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, “**Autologous Versus Allogeneic Blood Transfusion: A Comparative Study of The Peri-Operative Outcomes in A Tertiary Care Hospital in South India.**” was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Dr. Prasanta Kumar Dash

Date 21.7.22



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CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Vivek V. Pillai

Division/Department: Professor, Dept. of Cardiothoracic & Vascular Surgery

This is to certify that Dr. Angel Mary Sam, Department of Transfusion Medicine of this institute has fulfilled the requirements prescribed for the MD degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

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Clearance was obtained from the Institutional Ethics Committee for carrying out the study.


Dr. Vivek V. Pillai

Date 21.7.22



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Amita R.

Division/Department: Assistant Professor, Dept. of Transfusion Medicine

This is to certify that Dr. Angel Mary Sam, Department of Transfusion Medicine of this institute has fulfilled the requirements prescribed for the MD degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, “Autologous Versus Allogeneic Blood Transfusion: A Comparative Study of The Peri-Operative Outcomes in A Tertiary Care Hospital in South India.” was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.


Dr. Amita R.

Date 25/7/22



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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APPROVAL OF THE THESIS

The thesis entitled

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The Peri-Operative Outcomes in A Tertiary Care Hospital in South India**

Submitted by

Dr. Angel Mary Sam

for the degree of

MD in Transfusion Medicine

of

**SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND
TECHNOLOGY, TRIVANDRUM**

is evaluated and approved by

.....
(Name & Signature of the Guide)

.....
(Name & Signature of Thesis Examiner)

Dr. DEBASISH GUPTA
Professor & Head
Department of Transfusion Medicine
Sree Chitra Tirunal Institute for
Medical Sciences and Technology
Thiruvananthapuram - 695 011

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LIST OF ABBREVIATIONS

AAA	Abdominal Aortic Aneurysm
AABB	American Association of Blood Banks (old) Association for the Advancement of Blood & Biotherapies (new)
ANH	Acute Normovolemic Hemodilution
BCSH	British Committee for Standards in Hematology
BSH	British Society for Hematology
FFP	Fresh Frozen Plasma
FNHTR	Febrile Non-Hemolytic Transfusion Reaction
Hb	Hemoglobin
HCT	Hematocrit
HIV	Human Immunodeficiency Virus
HTLV	Human T-Cell Lymphotropic Viruses
ICS	Intra-operative Cell Salvage
ICU	Intensive Care Unit
INR	International Normalized Ratio
IRAAA	Infra-renal Abdominal Aortic Aneurysm
IVF	Intravenous Fluid
JPAC	Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee
MSBOS	Maximum Surgical Blood Order Schedule
NACO	National Aids Control Organization
NBTC	National Blood Transfusion Council

PAD	Pre-deposit (Pre-operative) Autologous Donation
PBM	Patient Blood Management
PC	Platelet concentrate
PCS	Post-operative Cell Salvage
PRBC	Packed Red Blood cell Concentrate
PRC	Packed Red Cells
RBC	Red Blood Cell
RDP	Random Donor Platelet concentrate
TAAA	Thoraco-Abdominal Aortic Aneurysm
TAD	Transfusion Associated Dyspnea
TTI	Transfusion Transmissible Infection

SYNOPSIS

Autologous blood transfusion is known to have advantages over allogeneic transfusion by preventing transfusion reactions, transfusion transmissible infections (TTIs), alloimmunization, metabolic disturbances, and coagulopathies. Also, the need for blood far exceeds the allogeneic blood supply.

In this study, we aim to bring out the peri-operative effects of autologous blood transfusion undergoing various Neurosurgical and Vascular surgical procedures in our hospital. Our secondary objectives are to compare the requirement of allogeneic blood and blood components in patients between the autologous transfusion group and the allogeneic transfusion group, to compare the hematological (hemoglobin, hematocrit, coagulation profile) investigations pre- and post-transfusion, to compare the mean duration of Intensive Care Unit (ICU) stay, post-operative infections and other outcomes between the two groups, and also to assess the influence of autologous blood transfusion in the Blood Centre inventory.

A randomized controlled trial was carried out in the Neurosurgery and Cardiothoracic and Vascular surgery departments of our institute over a period of 15 months. We allocated the patients receiving autologous transfusion to Group I and those who received conventional allogeneic transfusion were clustered as Group II for analysis. We employed Acute Normovolemic Hemodilution (ANH), Pre-deposit Autologous Donation (PAD) and Intra-operative Cell Salvage (ICS) as various modalities for autologous blood collection. Those patients in the autologous transfusion group in whom autologous blood did not suffice, allogeneic transfusion was provided. Data was collected and statistical analyses were performed by using a statistical software package SPSS, version 20.0.

Out of a total of 2207 patients who underwent surgical procedures in the departments of Neurosurgery and Vascular surgery, 141 patients were selected and randomized into 2 groups as mentioned above.

In order to study the safety of autologous blood collection, we compared the heart rate, mean arteriolar pressure (MAP) and SPO₂ before and after blood collection among the

patients who underwent ANH and PAD. We concluded that ANH and PAD can be safely carried out without drastic changes in the vital signs recorded.

We elicited that out of the total 71 patients who underwent autologous transfusion, 43 (60.6%), i.e., the majority received exclusive autologous blood transfusion. A detailed analysis was done separately for the neurosurgical and vascular surgical patients and it depicted that autologous transfusion has significantly reduced the requirement for allogeneic blood transfusion.

On comparing the hemoglobin, hematocrit, platelet count and INR between the group which received autologous transfusion and one which received conventional allogeneic transfusion, it was seen that they were comparable. All parameters remained within normal limits itself.

Post-operative outcomes like duration of ICU stay, re-exploration due to bleeding, hours of mechanical ventilation from the time of intubation and post-operative infections upto 5 days post- surgery were compared between the group receiving autologous blood and that receiving allogeneic blood. There was no statistically significant difference between the groups in the neurosurgical patients as well as those vascular surgical patients who underwent ANH.

But it was seen that there was a significant decrease observed in the duration of ICU stay and the need for re-exploration due to post-operative bleeding in those thoraco-abdominal aortic aneurysm patients who utilized autologous intra-operatively salvaged blood compared to their allogeneic controls.

Also, transfusion reactions were observed in a few patients who received allogeneic transfusion while none were reported among the patients who received exclusive autologous transfusion.

The Blood Centre inventory was also saved to a significant extent by employing the autologous transfusion programme.

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INTRODUCTION

Blood transfusion is a ubiquitous treatment that is commonly practiced in modern medicine. “Blood for blood” is an age-old maxim that is still being followed perioperatively all over the world. Extensive surgical procedures are becoming quite frequent and are associated with major blood loss requiring large volumes of blood. This continues to increase the need for intra- and post-operative replacement of blood and its components.

Blood transfusion may be either autologous or allogeneic. The word autologous arises from the Greek words *autos* which means self and *logus* which means relation. Thus, autologous means ‘related to self’. Autologous blood transfusion is the process of collecting blood from an individual and transfusing back to the same person when a requirement for blood or blood components arises. Here, the donor and the recipient are the same people ^[1,2]. The term allogeneic arises from *allo-* which means different and the Greek word *genea* which means race. Thus, allogeneic donation means blood and blood components collected from an individual and intended for transfusion to another individual. Allogeneic transfusion, also known as homologous blood transfusion, involves the transfusion of blood or blood components obtained from a compatible donor to a patient.^[2]

Primary concerns about allogeneic transfusions ascended from the transmission of viruses such as the hepatitis viruses, human immunodeficiency virus (HIV), and human T-cell lymphotropic viruses (HTLV). Reliable screening tests have abridged the risk of infection from transfusion, but have further raised the cost of each unit. Allogeneic blood transfusion is not completely safe, even after advances in blood screening and collection techniques as it may be associated with complications such as hemolytic transfusion reactions, transfusion transmissible infections (TTIs), alloimmunization, metabolic disturbances, coagulopathies, and immune suppression. It also increases the economic and psychological burden on patients and their families. ^[3,4]

Autologous blood transfusion can avoid these serious adverse effects, alleviate blood shortages, and save blood resources and is hence increasingly being recognized as a suitable adjunct to conventional allogeneic transfusion practice.

There are four methods of autologous transfusion. They are Preoperative (Pre-deposit) Autologous Donation (PAD), Acute Normovolemic Hemodilution (ANH), Intraoperative Cell Salvage (ICS) and Post-operative Cell Salvage.^[5]

Autologous transfusion reduces the need for allogeneic transfusion and can be safely carried out in elective surgery, by proper planning between the surgeon, anesthetist, and transfusion medicine specialist, and thereby deciding the method of autologous blood collection.^[6] The most important driving forces for the use of autologous blood transfusion are to avoid the risk of transfusion transmissible infections (TTI) and to protect an increasingly scarce resource.

The most prominent benefits of autologous blood transfusion are that it can promptly provide patients with blood that has an identical type, quickly replenish the patient's blood volume, and improve oxygen carrying capacity, maintaining effective blood circulation.^[7]

In this new era during which patient blood management (PBM) using multimodal methods of plummeting obligation on allogeneic blood are becoming routine, autologous blood transfusion remains a valuable means for blood conservation perioperatively.^[9] PBM programmes vary in scope, cost, and effectiveness. Initiating a full-fledged programme comprising all possible specialties and interventions may be challenging in a hospital with no capability to consider beforehand.

ANH and cell salvage are becoming more cost-effective alternatives to PAD. PAD should be reserved for patients with limited availability of compatible blood (eg, patients with IgA deficiency, multiple red cell alloantibodies, or antibodies to a high-frequency antigen) or when sufficient time for regeneration of the collected red cell mass is attainable after collection. Due to personal reasons and/or public insight into blood safety, certain patients may still insist on PAD for their surgical procedures. Many facilities encourage such patients to donate sufficiently early, allowing for an erythropoietic response. Regardless of the reason for donation, it is important for hemoglobin optimization before and after the donation. Advanced planning and evaluation of the patient are important for PAD to be of benefit for PBM. Donating as early as possible, donating the minimal amount, and being evaluated for and receiving iron replacement therapy with or without erythropoietin before the donation is important strategies for avoiding allogeneic transfusions. Cell salvage and

ANH are essential elements of a program for limiting allogeneic blood exposure in surgical patients. The particular techniques a hospital chooses to undertake will often depend on the type and number of surgical cases, preferences of the surgeon, and personnel resources. Standards are to be maintained, which will help ensure that the patient undergoes therapy utilizing skilled, competent personnel trained in proper procedures and equipment operation to avoid procedure-associated morbidity.^[10]

While autologous blood transfusion is usually the purview of the anaesthesiologist, transfusion medicine specialists have become increasingly involved with the technique as part of comprehensive patient blood management programs. They should be mandatorily involved in the approval of protocols, technical aspects of blood collection as well as storage, and quality assurance. Under many circumstances, a member of the transfusion service should be available in the operating room to assist with the procedure. ^[8]

In this study, the peri-operative outcomes of autologous and allogeneic blood transfusions in neurosurgical and vascular surgery patients will be compared; also, the influence of autologous blood transfusion in the Blood Centre inventory will be evaluated. This study will also bring out how autologous blood transfusion has aided in conserving precious allogeneic blood due to an acute shortage of voluntary blood donors during the COVID-19 pandemic.




AIMS & OBJECTIVES

Primary Aim

To study the effects of autologous blood collection and transfusion in patients undergoing Neurosurgical and Cardio-vascular surgical procedures in our hospital

Secondary Objectives

1. To compare the requirement of allogeneic blood and blood components in patients between the autologous transfusion group and the allogeneic transfusion (control) group
2. To compare the hematological (Hemoglobin, Hematocrit, coagulation profile) investigations pre- and post-transfusion between the autologous group and allogeneic transfusion group.
3. To compare the mean duration of Intensive Care Unit (ICU) stay, post-operative infections and other outcome measures between patients in the two groups.
4. To assess the influence of autologous blood transfusion in the Blood Centre inventory.



REVIEW OF LITERATURE

History of Blood Transfusion

The circulation of blood was discovered by English physician William Harvey in 1628. In 1665, physician Richard Lower performed the first recorded successful blood transfusion in England: transfusion of blood between dogs.^[12] In 1667, Jean-Baptiste Denis and Richard Lower separately reported successful blood transfusions from lambs to humans in France and England respectively. Blood transfusion from animals to humans was prohibited by law within 10 years because of reactions. The first human blood transfusion was performed in 1795 by American physician Philip Syng Physick in Philadelphia, but this information was not published.^[11]

In 1818, James Blundell who was a British obstetrician performed the first successful transfusion of human blood to his patient as a treatment for excessive blood loss due to postpartum hemorrhage. He used the patient's husband as a donor and withdrew approximately four ounces of blood from the vein in his arm and, using a syringe, he successfully transfused the wife. Between 1825 and 1830, he performed 10 transfusions, five of which proved to be beneficial to his patients, and he published these results. He also devised “the impellor” for performing transfusions. Blundell is regarded as the Father of Modern Blood Transfusion.^[11,12]

Later, in 1840, Samuel Armstrong Lane was aided by consultant Dr. Blundell, at St. George's School in London to carry out the first successful whole blood transfusion to treat a patient with hemophilia.^[11]

Between 1873 and 1880, US physicians began to transfuse milk (from cows, goats, and humans). But there was an increased frequency of adverse reactions to milk and hence saline infusion replaced milk as a “blood substitute” in 1884.^[11,13]

The most remarkable discovery was made by Karl Landsteiner, an Austrian physician, in 1900. He discovered the first three human blood groups and named them as A, B, and C. Blood type C was later renamed as O. His colleagues Alfred Decastello and Adriano Sturli discovered AB, the fourth type, in 1902. The Nobel Prize for Medicine was awarded to Karl Landsteiner in 1930 for this discovery.^[5, 11, 12, 14]

Hektoen, in 1907 suggested that the safety of transfusion could be improved by crossmatching blood between donors and patients to exclude incompatibilities. The first

blood transfusion after blood typing and crossmatching was performed by Reuben Ottenberg in New York. He also observed the mendelian inheritance of blood groups and documented the universal utility of group O donors. ^[11,14]

In 1908, a French surgeon named Alexis Carrel developed a method to prevent clotting of blood by sewing the vein of the recipient directly to the vein of the donor. This vein-to-vein or direct method, known as anastomosis, proved unfeasible for blood transfusions. But this paved the way for successful organ transplantation. Carrel received the Nobel Prize in 1912 for the same. ^[12,13]

Roger Lee, who was a physician at the Massachusetts General Hospital, along with Paul Dudley White, demonstrated in 1912 that it was safe to give group O blood to patients of any blood group, and that blood from all groups can be transfused to group AB patients. The terms "universal donor" and "universal recipient" were hence coined. ^[15]

Around 1914, long-term anticoagulants, including sodium citrate, were developed. Anticoagulation allowed for longer preservation of blood. Richard Lewisohn used sodium citrate as an anticoagulant at Mt. Sinai Hospital in New York in 1915. ^[12] In addition, Richard Weil demonstrated the feasibility of refrigerated storage of such anticoagulated blood. Although this was a great advancement in the field of transfusion medicine, it took 10 years for sodium citrate use to be accepted. Francis Rous and J.R. Turner introduced a citrate-glucose solution in 1916 that permitted the storage of blood for several days after collection. ^[15] Allowing blood to be stored in containers for later transfusion helped the changeover from the vein-to-vein method to indirect transfusion. This discovery also paved way for the establishment of the first blood depot by the British during World War I. Oswald Robertson, an American Army officer, is accredited for creating blood depots. ^[15] Robertson received the AABB Landsteiner Award in 1958 as the developer of the first blood bank.

The very first blood bank was established in 1932 in a Leningrad hospital. In 1937, Bernard Fantus, director of the therapeutics at the Cook County Hospital in Chicago, established the first hospital blood bank in the United States. In creating a hospital laboratory that can preserve and store donor blood, Fantus coined the term "blood bank." Within a few years, hospital and community blood banks begin to be established across the United States. Some of the earliest are in New York, San Francisco, Miami, and Cincinnati. ^[11, 12, 15]

Later, the Rh blood group system, which is the second most important following the ABO system, was discovered between 1939 and 1940 by Karl Landsteiner, Alexander Wiener, Philip Levine, and R.E. Stetson. It was soon recognized as the cause of the majority of transfusion reactions. ^[5,11,12,15] Identification of the Rh factor took its place next to the discovery of ABO as one of the most important breakthroughs in the field of blood banking.

History of Autologous blood transfusion

The idea of transfusing back the own blood of the patient was stated for the first time by Eulenburg and Landois, in 1866. They proposed to treat gas poisonings by suggesting that the blood would be withdrawn and then transfused after the poisonous gases have been eliminated. ^[16]

However, the first originally sourced autologous blood transfusion was performed by the German surgeon Friedrich von Esmarch. The blood which was shed during exarticulation of the thigh at the hip joint was collected by him in a washbowl, and after defibrinating, was reinjected back into the severed femoral vein. However, in spite of further cases of autologous blood transfusion performed for various indications in different countries, the method was unable to gain a grip in the treatment of acute blood loss. ^[16]

F.C. Grant, the neurosurgeon at the University Hospital of Pennsylvania, made the first report on pre-deposit autologous blood transfusion in 1921. The patient was a 42-year-old man having a rare blood type who was to be operated on for a cerebellar tumor. 500 ml of autologous blood was collected, kept in 0.2% sodium citrate solution in a refrigerator, and transfused following suboccipital exploration. Clinically, there was a promising postoperative course, and 'autotransfusion' was appraised as a life-saving procedure. ^[17]

The first case of intraoperative blood salvage was performed on a 42-year-old man with left occipital meningioma. Due to massive bleeding, the tumor could not be removed even by two-staged operations. In a 3rd stage operation, 600 ml of autologous blood was collected with a homemade suction apparatus and was replaced intraoperatively. Hence, they could remove the tumor weighing about 120 grams. This was reported by L.E. Davis and H. Cushing in 1925. No adverse effects were noted. Intraoperative blood salvage was performed in 23 cases and it provided beneficial effects in all except one. In ten of the cases, the procedure was assessed as a life-saving treatment. ^[18]

The first description of acute hemodilution was first put reported by Kronecker in 1886.^[19] Clinical use of hemodilution in surgical practice began with reports in the late 1950s and early 1960s by Neptune and Panico describing the use of bloodless prime in open heart surgery.^[20] Early reports which utilized heparinized autologous blood through venous drainage cannulas with the subsequent return at the conclusion of bypass, indicated that the use of blood collected during surgery could be used to decrease blood use.^[21]

Types of Autologous Blood Collection

1. Pre-operative (Pre-deposit) Autologous Donation

The term pre-deposit autologous donation (PAD) refers to the collection and subsequent storage of blood where the person from whom the blood is collected is intended also to be the recipient. This modality is planned for the clinical benefit of that person by contemplating an expected loss of a significant amount of blood resulting from, for example, elective surgery.^[22,23]

As per the British Committee for Standards in Haematology, Transfusion Task Force 2007 guidelines^[22], PAD is recommended for

- Rare blood groups where allogeneic blood is difficult to obtain
- Children with scoliosis (Evidence obtained from at least one randomized controlled trial)
- Patients at serious psychiatric risk if blood transfusion is thought to be likely to cover their elective surgery (Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.)
- Patients who refuse to consent to allogeneic transfusion but who would consent to PAD

According to the AABB PBM recommendations, PAD should be reserved for those patients for whom there is inadequate availability of compatible blood (eg, patients with IgA deficiency, or patients with an antibody to a high-frequency antigen or with multiple red cell alloantibodies). Sufficient time should be obtainable after collection so that

regeneration of the collected red cell mass can be allowed. Due to personal reasons and/or public perception of blood safety, a handful of patients still insist on PAD for their forthcoming surgical procedure. ^[10]

The National Blood Transfusion Council (NBTC), under the Ministry of Health and Family Welfare, Govt. of India put forward the National Aids Control Organization (NACO) guidelines ^[23] which state that:

- Autologous pre-deposit procedure requires the consent of the donor-patient and a request from the treating physician.
- The records of all units collected for autologous use should be maintained.
- Pre-deposit unit should be labelled "For Autologous Use Only" segregated and used solely for this purpose. The donor-patient's signature should be on the label.
- Precaution should be taken to identify the donated unit and donor-patient before the transfusion procedure.
- If the blood collected for autologous transfusion is not used for the donor-patient, it should be discarded.

NACO suggests that rigid criteria required for donor selection are not applicable for autologous donation. Whenever requirements for donor selection or collection cannot be applied, suitable guidelines applicable for the individual donor-patient should be established in consultation with their physician and medical officer of the blood centre.

The individual guidelines should be recorded in the procedure manual of the blood centre and clinical records of the donor-patient. The suitable guidelines include:

- The volume of blood collected should be proportionate to the donor-patient's weight and volume of preservative used.
- There should not be any age limits for autologous transfusion procedures.
- The hemoglobin concentration of donor-patient should not be less than 11 g/dl and Haematocrit not less than 33% and must not fall below 10 g/dl., at the end of this autologous programme. However, this level may be adjusted to higher or lower values by the medical officer based on the clinical condition of the donor.
- Iron supplementation should be started much in advance of this programme and must continue sufficiently to replenish iron stores.

- Donation of pre-deposit autologous transfusion should not be undertaken when donor-patient has, or is being treated for bacteremia or has any local skin lesions.
- Pre-deposit donation for autologous transfusion should not be drawn from donor-patient within 72 hours of the anticipated operation or transfusion.
- The frequency of phlebotomy for a number of autologous transfusion units should be determined by the blood bank medical officer and donor-patient's physician.
- Phlebotomy for autologous units should not be undertaken more frequently than every three days and at least 72 hours prior to surgery.
- Transfusion of the autologous units should be under medical supervision.

With regard to testing of units, NACO guidelines state that:

- ABO grouping and Rh(D) typing for the PAD units should be determined.
- The tests for irregular antibodies and infectious disease tests should be done at least on the first unit collected from the patient-donor.
- Any abnormal test results should be reported to the patient's physician.
- Blood should be discarded if the test result is positive for any mandatory TTI test.

The following information should be provided on a label or tag attached to the blood container.

- Name of the blood bank (collecting facility) and its manufacturing license number.
- Name of the patient and the hospital where he is hospitalized
- Patient's hospital registration number and other details (Ward-Bed or any other identifying information);
- ABO and Rh(D) type;
- Date of collection and expiry;
- HIV/HCV/HBsAg status; VDRL test; Malaria Parasite
- Notice that the unit is 'For Autologous Use Only'.

The patient's blood sample should be accompanied by pre-transfusion requisition form for autologous transfusion as per the requirements to confirm the ABO and Rh blood group.

Advantages of PAD:

- This modality virtually eliminates the risks of viral transmission and immunologically mediated hemolytic, febrile, or allergic reactions. ^[24]

- Prevents immunomodulation, which is the decrease in cellular immune function that have been documented after allogeneic transfusions. [25]

Disadvantages of PAD:

- Blood that is collected may be discarded if not used by the donor-patient [23] because the amount drawn may exceed the median routinely needed to avoid additional allogeneic transfusions.
- Leftover blood cannot be used for other patients because most autologous donors do not meet the stringent health requirements for allogeneic blood donation.
- Administrative or clerical errors can occur during labelling and/or storage leading to mismatched transfusions.

In PAD, regardless of the reason for donation, it is important for hemoglobin optimization before and after the donation. Advanced planning and evaluation of the patient is important for PAD to be of benefit for PBM. PAD is most effective when collection occurs 4 to 6 weeks before surgery to allow sufficient interval for red cell regeneration. [10] Donating as early as possible, donating the minimal amount, and being evaluated for and receiving iron replacement therapy with or without erythropoietin before donation are important strategies for avoiding allogeneic transfusions.

Erythropoietin and iron can be administered to promote the formation and maturation of erythrocytes in patients from whom large volumes of blood is collected to prevent pre-operative anemia. Studies have revealed that the combined use of erythropoietin along with iron promotes hematopoiesis in a short period of time [26]. The preoperative erythropoietin administration increases hemoglobin levels, lessens the requirement for blood transfusion, and also contributes to their recovery [27]. Dai *et al* suggest that optimized PAD by adjusting the physical condition by supplementation of crystalloid intravenous fluid (IVF) and intraoperative administration of erythropoietin is a safe and effective method for patients who are scheduled to undergo elective cardiac surgery [28].

2. Acute Normovolemic Hemodilution (ANH)

Acute normovolemic hemodilution (ANH) is defined as the withdrawal of whole blood from a patient immediately before surgery, either before or shortly after the induction of anesthesia, and simultaneous replacement with a suitable volume of crystalloid or colloid

intravenous fluids, alone or in combination, in order to maintain the circulating volume.^[29] ANH is also known as intraoperative hemodilution. Generally, a predetermined volume of autologous whole blood is withdrawn (1 or 2 units) from the patient and is stored in the operating room just before a surgical procedure, replacing the removed blood volume with three times crystalloid or equal volume of colloid solution. Then, towards the end of the surgery, the blood units are transfused back to the patient.^[5]

The key goal of this technique is to create relative anemia in the patient so that the blood that is shed during the surgical procedure would effectively have a reduced red cell content. Once the threat of further blood loss is reduced, the ANH blood could be transfused back to the patient. This technique helps to avoid or limit allogeneic red cell transfusion. Also, the ANH whole blood may provide, to a small extent, platelets and coagulation factors that would aid hemostasis.^[10]

Studies demonstrate that the ANH method of autologous blood collection helps in adequate dilution of the blood, thereby reducing the hematocrit, and in turn reducing RBCs lost in acute blood loss during surgery^[30,31,32]. This modality has been commonly used in postpartum hemorrhage, cancer, and orthopedic surgeries – like joint replacement and also in spine surgery. These are surgeries that often have a large volume of blood loss, and hence these patients often require blood transfusions^[33,34,35].

The British Committee for Standards in Hematology Blood Transfusion Task Force recommends that ANH should be considered only when the potential blood loss is likely to be greater than 20% of the total blood volume of the individual. Also, they recommend that this technique should be executed only when the pre-operative hemoglobin concentration is greater than or equal to 11 g/dL.^[29]

Age is not a factor in recruiting patients for this procedure. But, in patients, more than 45 years of age added precaution should be exercised in view of the risk of underlying ischemic heart disease. Patients with severe myocardial disease of any cause, for example, moderate to severe left ventricular impairment, severe aortic stenosis, unstable angina, critical left main stem disease or the equivalent, should only undergo hemodilution over and above that is necessarily incurred during cardiopulmonary bypass with extreme caution.^[29]

The BCSH also suggests that patients undergoing ANH need not be screened routinely for viral markers. In order to protect staff from the risks of transmission of TTIs universal precautions are to be observed. Also, the fate of all units must be documented.

According to the BCSH guidelines ^[29], the following points are important while carrying out ANH:

- Blood may be collected into a single bag with CPD-A1 anticoagulant. Appropriate bag volume selection is important to maintain anticoagulant to blood ratios.
- A regularly calibrated balance should be used to measure the volume of blood drawn.
- Skin should be cleaned thoroughly using chlorhexidine (in alcohol) or equivalent.
- The donor tubing should be clamped, for example with “non-toothed” Spencer Wells forceps, before the guard is removed from the needle. The clamp should remain in place until after the venipuncture. This prevents air from entering the bag and possibly contaminating the donation.
- The blood bag should be labelled during donation. The label affixed to the blood bag should include the following information: Surname, First name, Date of birth, Hospital number, Date and time of collection, Responsible Medical Officer, and UNTESTED BLOOD: FOR AUTOLOGOUS USE ONLY
- The blood bag should be agitated gently throughout the collection procedure in order to mix blood with the anticoagulant.
- Blood collected during hemodilution must remain with the patient and should not be kept in a blood refrigerator. It may be kept for up to 6 hours at room temperature, preferably in an insulated box or other container to minimize temperature fluctuations. The container should be labelled with the patient’s full details with a warning that it must not be used for another patient.
- Pre-transfusion checks of identity are mandatory and should be equivalent to the standard procedures for administration of allogeneic blood by the hospital.
- In general, all such blood should be used in the operation theatre itself. If ANH blood is to be taken along with the patient to a recovery area or ward, a written procedure should be in place to guarantee that the blood is handled and administered to the patient appropriately.
- Any unused autologous blood is to be disposed off as hazardous waste; the fate of all units must be documented.

- It should be ensured that no autologous blood is transferred to the general blood supply.
- The number of units of blood and total volume removed from the patient must be recorded in the patient's case notes. Whenever allogeneic blood is given, the reasons must be documented clearly in the patient's notes.
- Serious adverse events should be reported to the hospital transfusion committee and to any appropriate national reporting system.
- Regular audit of procedures should be undertaken under the aegis of the hospital transfusion committee. Audit and comparison with allogeneic blood usage is to be facilitated by the regular recording of autologous blood use in theatre.

The safety of ANH mainly depends on the maintenance of normovolemia. In all patients, care must be taken to match the continuous replacement of volume with crystalloids or colloids with the removal of blood. In older patients and where cardiac disease may be suspected, additional care is necessary. ^[32]

Advantages of ANH

- 1) ANH dilutes the blood thereby reducing the concentration of erythrocytes in blood circulation during surgery. In turn, this reduces erythrocyte loss and improves the tolerance of the body, reducing actual blood loss during the surgery ^[32].
- 2) It is the only method that provides fresh autologous whole blood – functions of platelets and clotting factors are not affected much ^[5,10].
- 3) Blood that is collected is maintained at the point of care reducing the risk of blood mismatch because of administrative errors. ^[29]
- 4) Blood is readily obtainable for patients with Rh D negative traits, rare blood groups, irregular antibodies, or with other blood cross-matching disparities.
- 5) It effectively prevents postoperative bleeding and anemia, and provides a safe and effective autologous transfusion method. ^[36,37]

Disadvantages of ANH

- 1) There is an acute and significant reduction in hematocrit leading to hemodynamic instability and a possibility of myocardial ischemia in susceptible patients. ^[38]
- 2) Additional training is required for anesthetic personnel.

Extreme hemodilution (target hematocrit <20%) is likely to be more efficacious in reducing allogeneic transfusion requirements, but the risks are correspondingly greater. This procedure should be restricted to relatively healthy patients with a low risk of ischemic heart disease and must be supervised by an expert anaesthetist using appropriate monitoring techniques.^[29]

ANH is most often used in cardiac bypass surgery where the immediate postoperative transfusion of 'fresh whole blood' containing platelets and clotting factors is seen as an advantage. Reported hazards of ANH include fluid overload, cardiac ischemia and wrong blood into patient errors.^[2] ANH has also been successfully used in lung cancer patients^[39], dealing with hemorrhage in orthopedic surgery and postpartum hemorrhage in the Rh(D) negative patients. It also provides a safe and effective mode of blood transfusion^[34,35].

3. Intra-operative Cell Salvage (ICS)

Intraoperative cell salvage (ICS) is the process of recovering red blood cells from blood lost in the operative field and returning them to the patient.^[40] In simpler terms, it is the collection and reinfusion of blood spilled during surgery.^[2]

The AABB guidelines recommends that intraoperative or postoperative autotransfusion should be performed in surgeries where a large amount of bleeding (more than 20% total volume) is anticipated.^[10]

In the operating room, once a sufficient volume of shed blood is recovered, and the patient loses sufficient blood to require transfusion, the salvaged blood can be centrifuged and washed in a closed, automated system. Red cells suspended in sterile saline solution are produced, which must be transfused to the patient within 4 hours of processing.^[2] During this process, the plasma, platelets, red cell stroma, contaminants, and anticoagulant are removed. The washed red cells are transferred to a separate bag, which is then administered to the patient in much the same way that allogeneic blood would be administered.^[10] The red cells are transfused through a 200 µm screen filter, as in a standard blood administration set, except in those instances where a leucodepletion filter is indicated.^[2] Ideally, the recovered autologous red cell product should have a hematocrit of at least 45% to 55%. Substantial volumes of red cells can be recovered for reinfusion in those cases undergoing increased blood loss. Intraoperative blood recovery may be considered for

several surgical procedures, including cardiothoracic, orthopedic, neurosurgery, obstetrics, gynecology, urology, and vascular procedures. ^[10]

Commercially available, largely automated devices are available for ICS and are now widely used in hospitals for both elective and emergency surgery with significant blood loss. It is being widely practiced in the management of major traumatic or obstetric haemorrhage. The machines must always be used and maintained according to the manufacturer's instructions by appropriately trained staff. A 2010 Cochrane Collaboration review of randomised trials of ICS, mainly in cardiac and orthopaedic surgery, showed a 20% reduction in donor blood exposure (an average saving of 0.7 units per patient). Much useful information about clinical indications and use of ICS, policies for implementation, staff training/competency assessment and patient information has been prepared by the UK Cell Salvage Action Group (UKCSAG).^[2]

According to JPAC guidelines ^[2], the indications for ICS in adults and children (for whom low-volume processing bowls are available) are as follows:

- Surgery where the anticipated blood loss is >20% of the patient's estimated blood volume.
- Elective or emergency surgery in patients with risk factors for bleeding (including high-risk Caesarean section) or low pre-operative Hb concentration.
- Major hemorrhage.
- Patients with rare blood groups or multiple blood group antibodies for whom it may be difficult to provide donor blood.
- Patients who do not accept donor blood transfusions but are prepared to accept, and consent to, ICS (this includes most Jehovah's Witnesses).

ICS should not be used when contents of the bowel contaminate the surgical site. Also, blood should not be aspirated from infected surgical fields. Due to concerns about cancer cell reinfusion and spread, ICS is not recommended in patients having surgery for malignant disease. However, extensive clinical experience suggests this is not a significant risk although it is recommended to reinfuse leuco-depleted the red cells by making it pass through a leucodepletion filter. ^[29,41]

The BCSH guidelines for ICS are as follows [29]:

❖ SELECTION OF PATIENTS:

- Cell salvage is appropriate where there is a clean wound.
- The technique is applicable to open heart surgery, vascular surgery, total joint replacements, spinal surgery, liver transplantation, ruptured ectopic pregnancy and some neurosurgical procedures.
- Some Jehovah's Witnesses may accept transfusion of autologous cells salvaged by a continuous circuit device: specific consent to the procedure should be sought in this instance.

❖ CONTRAINDICATIONS:

- Cell salvage techniques should not be used in the presence of bacterial contamination of the surgical field.
- Malignant disease has been considered a contraindication but recently published work suggests that the risk of dissemination of malignant disease is minimal.
- Blood containing fat or amniotic fluid should not be salvaged because of the risk of embolism and DIC.
- Topical clotting agents such as collagen, cellulose, gelatin, and thrombin, and topical antibiotics or cleansing agents used in the operative field should not be aspirated into a cell salvage device.
- Complications have been reported in patients with sickle cell disease.

❖ Patients undergoing cell salvage need not be screened routinely for viral markers.

❖ All blood salvage devices should be used in strict compliance with the manufacturers' instructions.

❖ Blood for reinfusion must be labelled according to the specifications given for ANH.

❖ All cell salvage procedures and volumes of blood reinfused must be recorded in the patient's case notes.

❖ Whenever allogeneic blood is transfused, the reasons must be documented in the patient's notes.

Advantages of Intra-operative cell salvage

- Reduces or eliminates the need for allogeneic blood transfusion and the associated risks of infectious and non-infectious complications.^[41]
- Studies comparing cell salvaged with allogeneic blood have demonstrated increased mean erythrocyte viability ^[42] and increased 2,3-disphosphoglycerate (2,3-DPG) and adenosine triphosphate (ATP) levels in salvaged blood. ^[43,44] The mean erythrocyte viability has been reported to be as high as 88% with cell salvage.^[45]
- Salvaged RBCs maintain their normal biconcave disc shape, but allogeneic blood assumes an echinocyte shape (after 14 days), which is thought to impair its ability to cross the capillary beds. ^[46]
- It has also been postulated that cell salvage may have immunostimulatory effects, which may reduce postoperative infection.^[42]

Disadvantages of Cell Salvage ^[47]

- Initial equipment cost
- Cost of disposables
- Complex device – staff training and competency
- Delay in processing red cells
- Risk of bacterial contamination
- Red cell lysis due to ‘skimming’
- Complications like air and fat embolism, and electrolyte imbalance.

Complications of cell salvage

Complications associated with the use of cell salvage are rare and studies have shown no increase in complications in patients receiving cell salvage.^[48]

Potential complications include electrolyte imbalance, air embolism, pyrexia with rigors, infection, fat embolism, microaggregates causing micro-embolism, and salvaged blood syndrome. Salvaged blood syndrome is the activation of intravascular coagulation with increased capillary permeability leading to acute lung injury and renal failure. This syndrome is related to the dilution of salvaged blood with large volumes of saline solution, and forms deposits of cellular aggregates when used with the fixed volume bowl system.^[47]

Other complications include hemolysis, and increased amounts of free hemoglobin, which can lead to renal damage. Moreover, salvaged blood contains no platelets or coagulation factors. Hence, in cases of massive hemorrhage, it is likely that the patient will require allogeneic blood components like platelets, fresh-frozen plasma, and cryoprecipitate. Coagulation factor deficiency should be anticipated after more than 2 litres blood loss with continued bleeding. [47,48]

Point of care testing (including thromboelastography), laboratory testing (including prothrombin time, fibrinogen, and platelet count), or both should be carried out and blood product replacement considered according to local protocols. [49]

In 2006, a Cochrane Collaboration meta-analysis of studies published up to 2003 of the use of cell salvage for minimizing allogeneic blood transfusion found that cell salvage was efficacious in reducing the requirement for allogeneic blood transfusion in elective surgeries. Overall, the use of cell salvage reduced exposure to allogeneic blood transfusion by 39%, with an average saving of 0.67 units per patient. Cell salvage was found to be the most effective in orthopedic surgery and had no negative impact on morbidity or mortality. In patients who had received autologous salvaged blood, there was a decreased incidence of myocardial infarction and reduced postoperative infections. [48]

There is evidence that autologous transfusion results in increased survival after esophagectomy when compared with allogeneic blood transfusion. [50] This may be due to the lack of immunomodulatory effects of salvaged blood compared with allogeneic blood.

At present, the application of intraoperative or postoperative autologous transfusion has widely expanded. Its application in surgeries with a small amount of bleeding in healthy adults can moderately improve early postoperative hemoglobin levels and tissue oxygenation [51]. Intraoperative or postoperative cell salvage can also be combined with PAD in elective major surgeries to improve the effect of blood transfusion and the prognosis of patients [52].

The application of intraoperative or postoperative cell salvage in cancer surgery remains controversial as some clinicians fear that it may cause cancer cell proliferation and metastasis [53,54]. However, other studies have revealed that it can be safely applied to certain tumor surgeries [55], with the required specific assessments before and during surgery such as tumor metastasis and recurrence, and the use of a leukocyte filter [56].

The AAGBI guidelines recommend the use of cell salvage in cases where patients have objections to receiving allogeneic blood transfusions.^[41] There are many case reports of the successful use of cell salvage in Jehovah's Witness patients undergoing major surgery, including radical prostatectomy,^[57] living donor liver transplants,^[58] renal cell carcinoma extending into the right atrium,^[59] and gynae-oncology surgery.^[60]

ICS is now widely used in women at high risk of postpartum hemorrhage during Caesarean section and in the management of major obstetric hemorrhage and is supported by many specialists and national guideline groups. Concerns about amniotic fluid embolism have not been observed in practice. But, gross fluid contamination should be aspirated before the collection of blood and the harvested red cells should be reinfused through a leucodepletion filter. ^[2, 61]

4. Post-operative Cell Salvage (PCS)

Postoperative cell salvage (PCS) involves the recovery and reinfusion of shed blood from surgical drains and/or wounds. It is largely used in cardiac and orthopedic surgical cases where the volume of shed blood may be significant. Blood recovered postoperatively may be washed or unwashed. The minimum volume for reinfusion is considered to be 200mL.^[10]

For the unwashed product, blood is collected into a device where it is filtered. Once a sufficient volume is reached, the filtered blood is transferred to an infusion bag for administration. For the washed product, once sufficient shed blood is collected in the surgical drain, it is further processed by washing and then transferred to a bag for reinfusion. ^[10]

Although controversial, reinfusion without washing is more commonly applied, particularly for joint replacement surgery.^[62] In the absence of washing, the product has a hematocrit ranging from 20% to 30% and contains activated clotting and complement factors, inflammatory mediators, cytokines, and fat particles that can increase the risk for febrile reactions.^[10] Despite these negative effects, unwashed postoperative recovered blood has been shown to reduce allogeneic blood transfusions in orthopedic surgery ^[62,63], but has been less effective in reducing such transfusion in cardiac surgery.^[63]

Improved product quality and safety—hematocrit ranging from 60% to 80% with the removal of contaminants—can be achieved by using devices that wash and concentrate the

postoperative wound drainage blood (eg, CardioPAT, OrthoPAT, Haemonetics, Braintree, MA). However, the higher costs associated with these devices and the maintenance of competency by nursing staff may be a disadvantage for some institutions. [10]

PCS is relatively less expensive, has the potential to reduce exposure to donor blood, and is also acceptable to some Jehovah's Witnesses. It remains unclear whether it adds significantly to a comprehensive blood conservation programme that includes preoperative optimization of hemoglobin, hemostatic/antifibrinolytic measures during surgery, and strict postoperative transfusion thresholds. [2]

Autologous blood transfusion in Neurosurgery

Literature depicts that pre-donated autologous blood transfusion is acceptable and safe predominantly in scoliosis surgery. It significantly reduces the subsequent requirement of allogeneic transfusion. Although the cost is currently more than allogeneic transfusion, with the increase in the costs of the latter and the decrease in potential donors which is anticipated, pre-donation of autologous blood will become comparatively cost-effective. [64]

ANH has been proven as a safe, effective, and affordable method of blood transfusion in patients undergoing intracranial surgery. Complications associated with homologous blood transfusion can be avoided with autologous blood transfusion. [65,66]

Evidence to support the use of cell salvage in neurosurgery is limited. A prospective observational study comprising 472 patients who underwent intracranial surgery found that the use of cell salvage resulted in a reduction in the use of allogeneic blood transfusion by 74%. In 25% of patients who required blood transfusions, the use of allogeneic blood was avoided altogether. [67]

Autologous blood transfusion in Cardio-vascular Surgery

The total transfusion is an index of the demand for blood, which is a scarce resource. It is also a marker of the number of donors to whom patients are being exposed to. This exposure was highest for patients with ruptured thoraco-abdominal aortic aneurysms

(TAAAs), followed by patients treated without ANH, and least in patients treated with ANH. [68]

When a systematic review of five randomized controlled trials (RCTs) was looked into, it was found that there was not enough evidence to recommend the routine use of cell salvage during elective abdominal aortic aneurysm (AAA) or aorto-femoral bypass surgery. [69] These findings were contradicted by a meta-analysis of five RCTs in 2007, which found that cell salvage reduced the risk of exposure to allogeneic blood transfusion by 37% in patients undergoing elective AAA repair. [70]

In vascular surgery, the use of a combination of methods of blood conservation has been demonstrated to be effective. A small multi-centre, prospective, randomized study found that cell salvage in combination with ANH decreased the exposure to allogeneic blood transfusion from 80.0% to 33.7%. [71]

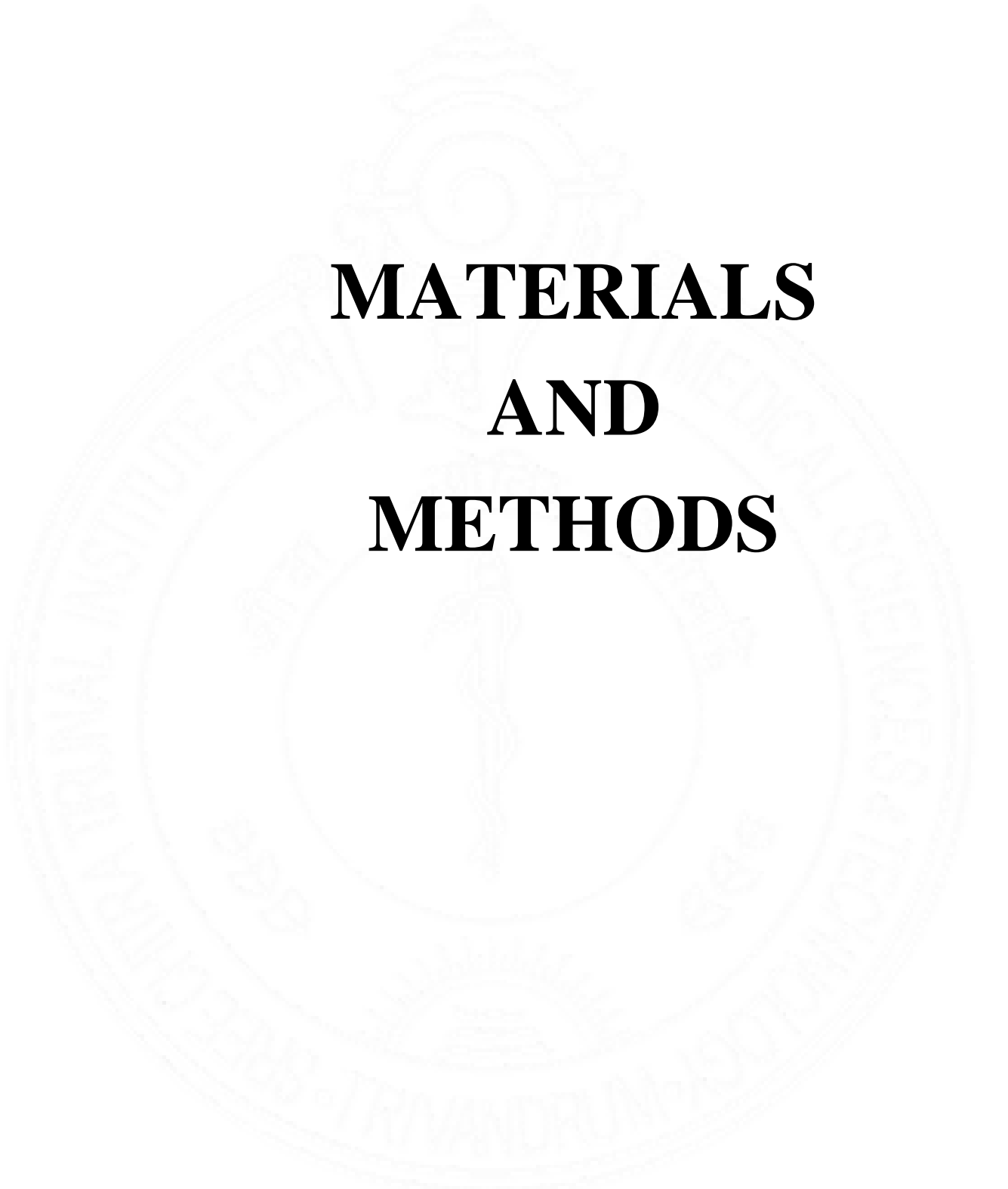
Development trends and challenges of autologous blood transfusion

Autologous blood transfusion techniques and concepts need to be further explored and researched urgently, especially with respect to blood collection methods and timing, in order to highlight the role of autologous blood transfusion in a clinical transfusion setting. Blood cell separation technology (apheresis) began in the 1980s. It has been widely used in clinical practice mainly for the collection of hematopoietic stem cells, granulocyte collection, plasmapheresis, plateletpheresis, blood component removal, and other therapeutic uses [72]. Apheresis technology is widely used for allogeneic blood component collection such as platelets, plasma, and erythrocytes. This technique can be used to collect red cells, platelet concentrate, and plasma, according to the requirement of the patient as a part of PAD. These components can be stored separately according to their respective preservation requirements so as to maintain their normal physiological activity. [73] Also, another advantage is that as only concentrated blood components are collected, the blood volume in patients before and after the collection does not vary significantly. Using the blood apheresis technique, 2 or more units of red blood cells can be collected at a time. In a comparative study in which 2 units of red blood cells were collected in two ways: by

whole blood collection and by apheresis, it was revealed that in the apheresis collection, only the concentrated blood components were collected and hence the blood volume of the patient did not fluctuate significantly before and after collection, thereby ensuring added safety. Compared to the whole blood collection, patients who underwent apheresis collection had fewer days of hospitalization and faster recovery of the post-operative hemoglobin levels. However, presently, the collection of more than 2 units of autologous erythrocyte or other blood components using a blood apheresis system has not been reported. [73]

Another challenge is that while utilizing the existing techniques, the shelf-life of platelets is short-lived. To tackle this, platelet cryopreservation technology has continuously gained more attention all over the world. In order to avoid damaging the platelet membrane during cryopreservation which affects platelet function, a cryoprotectant Dimethyl sulfoxide (DMSO) is added. DMSO also acts as an enhancer of cell fusion and permeability. [74] The application of DMSO in the cryopreservation of apheresis platelets is included in the 1998 European "Blood Component Preparation, Application and Quality Assurance Guidelines". Literature reveals that DMSO with a final concentration of 6% was added, platelets in long-term storage at -80°C had a considerable quality and stability of function. [75] Therefore, this strategy can be implemented in the future in order to extend the platelet shelf-life, and ensure that autologous platelets maintain their physiological function.

The existing autologous blood transfusion technology does not completely satisfy the clinical requirements of transfusion. Hence, application of new technology like apheresis and platelet preservation technique and new concepts can be applied in autologous blood transfusion, in the near future.



MATERIALS AND METHODS

A Randomized Control Trial was conducted by the Department of Transfusion Medicine in collaboration with the departments of Neuroanesthesia, Neurosurgery, Cardiac-anesthesia and Cardio-Thoracic & Vascular Surgery (CTVS) in Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum. The sample size of the study was 141 patients who underwent various neurosurgical and vascular surgical procedures in this institution during a period of 15 months from January 2021 to March 2022.

The various inclusion and exclusion criteria were as follows:

Inclusion criteria [10,22,29]:

1. Age – 18 years and above
2. Patients undergoing elective neurosurgical or vascular surgical procedures.
3. Patients with an anticipated blood loss of more than 20% of the total blood volume.
4. Pre-operative Hemoglobin more than 11g% for ANH; greater than or equal to 12.5 g% for Pre-deposit autologous donation.
5. For ANH and Pre-deposit autologous donation:
 - a. Surgical cases with Maximum Surgical Blood Order Schedule (MSBOS) of 1, 2 and 3 units of blood
 - b. American Society of Anesthesiology [ASA] score I or II
6. For Intra-operative cell salvage:
 - a. MSBOS 4 units and above
 - b. ASA score of III, IV and V
7. Platelet count more than $100 \times 10^9/L$;
8. Normal coagulation profile; and
9. Stable cardiac function.
10. Normal renal and liver functions

Exclusion criteria:

1. Patients under 18 years of age.
2. Emergency surgical procedures
3. Patients with
 - High grade malignant diseases,
 - Acute and chronic infectious diseases,
 - Autoimmune diseases,
 - Metabolic diseases,
 - Respiratory diseases,
 - Liver and kidney diseases,
 - Unstable cardiovascular conditions,
 - Fever, and
 - Use of perioperative corticosteroids and other drugs affecting immune function.

Written informed consent was obtained for participation in the study from all eligible candidates after explaining the purpose and design of the study.

The patients were allocated into two groups by randomization using computer generated random numbers; Group I (71 patients) receiving autologous transfusion and Group II (70 patients) who received allogeneic blood transfusion only. In those cases, in which autologous blood did not suffice, additional allogeneic blood was used for the autologous transfusion group (Group I).

In Group I, autologous blood transfusion was performed. In this study, we have utilized Pre-deposit autologous donation (PAD), Acute Normovolemic Hemodilution (ANH) and Intra-operative Cell Salvage (ICS) modalities for autologous transfusion. However, ANH was performed in the maximum number of cases. PAD was carried out exclusively in neurosurgical patients mainly those who were to undergo spine surgeries and in those patients in whom compatible blood was difficult to be found. In vascular surgical patients we employed ANH alone in those cases with MSBOS of 1, 2 and 3 units and ICS in cases with MSBOS \geq 4 units of blood. ICS was not performed in neurosurgical cases owing to the cost factor as well as dissemination of any malignancy of intracranial lesions that were undetected prior to surgery. In those patients in whom autologous blood was insufficient to meet the blood loss, allogeneic blood was administered.

Post-operative Cell Salvage was not used as there could be increased rates of contamination, air and fat embolism, and other complications with the method.

In Group II, after induction of anesthesia, surgery was allowed to proceed and allogeneic blood was transfused when blood loss was estimated to be $\geq 20\%$ of their total blood volume.

Modalities of autologous blood collection employed in this study:

1. Acute Normovolemic hemodilution (ANH)

- Performed in the operating room
- After induction of anesthesia
- Autologous whole blood was collected in 350 mL single blood bags which contained 49mL CPD-A anticoagulant.
- Volume of blood to be collected was based on MSBOS; Also, the maximum volume that could be collected was determined by the formula adopted from the BCSH guidelines ^[29]:

$$V = EBV \times (H_o - H_f / H_{av})$$

Where V = Volume of blood collected, EBV = Patient's estimated blood volume (70ml/kg), H_o = Patients initial Hematocrit, H_f = Patient's final (Desired) Hematocrit after hemodilution (30%), and H_{av} = Average of initial and final Hematocrit.

- Vascular access: Either anti-cubital vein or internal jugular vein
- Simultaneous infusion of crystalloid in the ratio 1:3 (blood: crystalloid) – mainly normal saline; in some instances, Ringer lactate was also used. If there was hypotension, intravenous colloid (Hydroxy ethyl starch) was administered.
- Volume of blood collected in the blood bag was assessed using Blood Collection Monitor; it also helped in continuous mixing of blood with anticoagulant. (Image 1)
- Vitals were monitored continuously; during any intractable hypotension, bleeding was stopped.

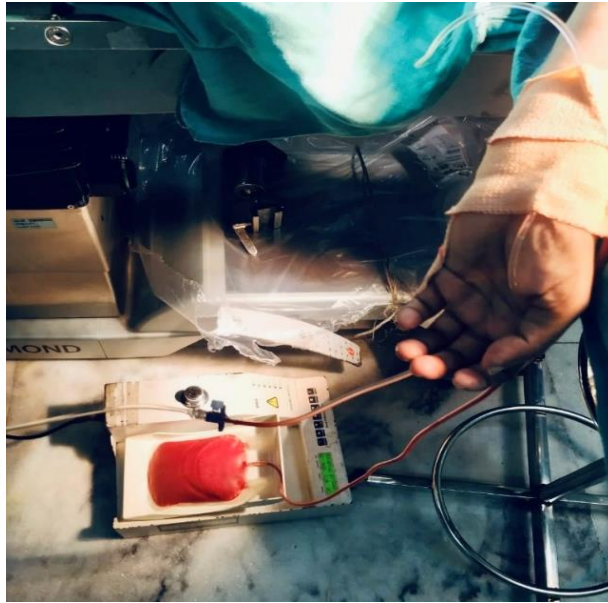


Image 1: Autologous whole blood is collected in the operating room after anesthesia induction

- Autologous whole blood units were labelled using the assigned green coloured stick-on label. The bags were sequentially labelled with the patient's name, age, gender, hospital number and date and time of collection. The label stated "AUTOLOGOUS BLOOD". (Image 2)



Image 2: Autologous whole blood collected by ANH and labelled

- Blood was stored in the operating room itself and transfusion was given within 6 hours from the time of collection – the last unit collected being the first to be transfused in order to obtain more functional platelets as well as clotting factors. Also, the fresher units would be more diluted; more concentrated blood could be given at the end.
- Hemoglobin levels were monitored using Arterial Blood Gas (ABG) analysis before the start of surgery, after ANH, at maximum surgical blood loss, and also post-transfusion.
- TTI testing was not performed. However, every patient admitted for surgery in our institute undergoes routine testing for HIV, Hepatitis B and C.

2. Pre-deposit Autologous Donation (PAD)

- Performed either in the Blood Centre or in the ward in which the patient was admitted. (Image 3)
- Blood was collected from two weeks prior and up to 72hrs before the surgery.
- Autologous whole blood was collected in 350 mL triple bags and was separated into packed red cells (PRC) and Fresh frozen plasma (FFP) universally. Also, platelet concentrate was prepared from the last unit collected.
- Labelling of PRC and other components were done as per guidelines.
- Storage of autologous units – separate compartments allotted to prevent mixing up with allogeneic units.
- Autologous blood donation was planned according to the date of surgery.
- Iron supplementation was started ahead of blood collection and was continued until discharge from hospital
- Transfusion was given as per routine protocol which is followed for allogeneic transfusions.
- Blood pre-donated in the Blood Centre underwent routine investigations like blood grouping, typing and antibody screening as per NACO guidelines.^[23]
- TTI testing performed – Malaria, Syphilis, Hepatitis B, Hepatitis C and HIV.^[23]



Image 3: Autologous blood being collected from a donor-patient in the Blood Centre

3. Intra-operative Cell Salvage (ICS)

- Performed in the operating room after a sufficient volume of blood is shed intra-operatively.
- Equipment used was Cell Saver by Sorin Xtra (Image 4)



Image 4: Cell saver equipment - Sorin Xtra used in this study

- The salvaged blood was centrifuged and washed in a closed, automated system. Red cells suspended in sterile saline solution were produced and transfused to the patient within 4 hours of processing. (Image 5)
- TTI testing was not performed in the units collected.



Image 5: Cell Saver being used by a thoracoabdominal aortic aneurysm patient

All patients in the study who had a blood loss above 20% of their total blood volume were given transfusion. In Group I (Autologous Transfusion Group), either pre-deposit autologous blood, blood collected by ANH, or autologous blood collected using Cell Saver was used for transfusion. Group II (Allogeneic transfusion group) received conventional allogeneic blood for replacement intraoperatively, depending on the blood loss.

However, in the event of excessive blood loss, autologous transfusion was started early and if the blood loss exceeded the autologous blood donation, allogeneic blood was also given. The autologous blood units which were not re-transfused were discarded.

During surgery, ECG, heart rate, arterial blood pressure, oxygen saturation, temperature, urine output, and blood loss were monitored. Blood collected in suction bottles and drapes was also included in the total calculated blood loss.

Preoperative hemoglobin, hematocrit, and coagulation profile (platelet count and PT-INR) were recorded as baseline values. The hemoglobin values were measured again at maximum surgical blood loss and after re-transfusion in Group I, whereas in Group II, hemoglobin was measured at maximum surgical blood loss and after transfusion of allogeneic blood.

Demographic data of all the study population was recorded. Hemodynamic changes like mean arterial pressure and heart rate before and after donation, complications, and any additional allogeneic blood requirement in the autologous transfusion group were noted. Pre- and post-operative investigation results like Hb, hematocrit, platelet count and PT-INR, intraoperative transfusion requirement, the volume of blood lost during the surgery, duration of ICU stay, re-exploration for bleeding, hours of mechanical ventilation, and post-operative infections up to 5 days post-surgery if any, in both groups were compared. Units of Autologous blood discarded were recorded.

Statistical Analysis

Categorical and quantitative variables were expressed as frequency (percentage) and mean \pm SD respectively. An independent t-test was used to compare quantitative parameters between categories. Mann-Whitney U test was used to compare ordinal parameters between groups. Fisher's exact test was used to find associations between categorical variables. Paired t-test was used to compare quantitative parameters before and after the intervention. For all statistical interpretations, $p < 0.05$ was considered the threshold for statistical significance. Statistical analyses were performed by using a statistical software package SPSS, version 20.0.



RESULTS

A total of 2207 patients underwent surgical procedures in the departments of Neurosurgery and Vascular surgery during the period January 2021 to March 2022. After excluding those subjects who did not meet the eligibility criteria and did not give consent, a total number of 141 patients were selected and randomized into Group I consisting of 71 patients who underwent autologous transfusion, and Group II comprising 70 patients who obtained conventional allogeneic transfusion. We employed pre-deposit autologous donation (PAD), acute normovolemic hemodilution (ANH) as well as intra-operative cell salvage (ICS) as modalities of autologous blood collection.

Among this, the total number of male patients were 102 (72.3 %) and female patients were 39 (27.7%). The patients were all between 18 to 70 years of age with a mean age of 48±14 years. Age, gender, weight and pre-operative laboratory investigations are depicted in Table 1. An age-wise distribution is illustrated in Figure 1.

Table 1: Comparison of the demographics and pre-operative characteristics for patients who received autologous transfusion (Group I) and conventional allogeneic transfusion (Group II)

Variable		Group I (n=71)	Group II (n=70)	p
Age (years) [Mean±SD]		48.5 ± 13.4	47 ± 13.8	0.516*
Gender	Male N (%)	51 (72%)	51 (73%)	0.891#
	Female N (%)	20 (28%)	19 (27%)	
Weight (kg) [Mean±SD]		68.3 ± 11.7	66.9 ± 10.0	0.426*
<i>Base-line pre-operative investigations</i>				
Hb (g/dL)		13.4 ± 1.1	13.7 ± 1.1	0.099*
Hematocrit (%)		40.4 ± 3.3	41.2 ± 3.2	0.099*
Platelet count (lakhs/cumm)		2.7 ± 0.8	2.8 ± 0.8	0.492*
INR		1.1 ± 0.1	1.1 ± 0.1	0.936*

*T-test; #Chi-square test,

INR = International Normalized Ratio

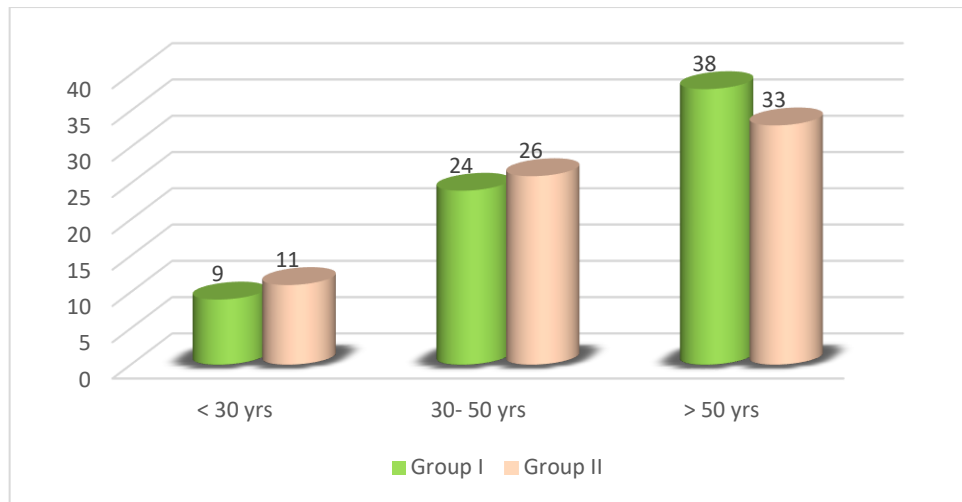


Figure 1: Age-wise distribution of study participants among the groups (Group I – Autologous transfusion; Group II – Allogeneic transfusion)

Cases subjected to autologous transfusion

The various cases which were subjected to autologous transfusion are described in tables 2 and 3.

Table 2: Neurosurgical cases which underwent autologous transfusion

Modality	Diagnosis	No. of cases	Total
ANH	Intracranial Meningioma	23	34
	Schwannoma	7	
	AV Malformation	4	
PAD	Spine surgeries	5	9
	Intracranial Meningioma	3	
	Clival chordoma	1	

ANH= Acute Normovolemic Hemodilution, PAD = Pre-deposit Autologous Donation

Table 3: Vascular surgical cases which underwent autologous transfusion

Modality	Diagnosis	No. of cases	Total
ANH	Infra-renal abdominal aortic aneurysm	14	22
	Thoracic mass lesion excision	4	
	Carotid aneurysm	3	
	Subclavian artery aneurysm	1	
Intra-operative Cell Salvage (ICS)	Thoraco-abdominal aortic aneurysm	6	6

Effect of autologous blood collection on heart rate, mean arteriolar pressure and SPO₂

The effect of autologous blood collection on the heart rate, mean arteriolar pressure (MAP) and SPO₂ were analyzed for those patients who underwent ANH and PAD. There was a statistically significant difference in the MAP among the neurosurgical and vascular surgical patients who underwent ANH ($p < 0.01$). There was no statistically significant difference in the heart rate and SPO₂ among any of the groups. (Tables 4,5 and 6)

Table 4: Comparison of heart rate pre- and post- autologous blood collection

Surgery		Pre-collection		Post-collection		Mean difference	Paired t	p
		Mean	SD	Mean	SD			
Neuro-surgery	ANH (n=34)	78.9	9.6	75.5	10	3.4	1.77	0.085
	PAD (n=9)	77.4	4.4	76.1	7.9	1.3	0.67	0.522
Vascular surgery	ANH (n=22)	82.9	10.4	80	12.7	2.8	1.28	0.216

Table 5: Comparison of Mean arteriolar pressure (MAP) pre- and post- autologous blood collection

Surgery		Pre-collection		Post-collection		Mean difference	Paired t	p
		Mean	SD	Mean	SD			
Neuro-surgery	ANH (n=34)	95.7	7	84.9	10.5	10.9	5.96	<0.01
	PAD (n=9)	94	6.1	93	4.6	1	0.83	0.43
Vascular surgery	ANH (n=22)	95.6	10.1	88.4	12.5	7.2	3.9	<0.01

Table 6: Comparison of SPO₂ pre- and post- autologous blood collection

Surgery		Pre-collection		Post-collection		Mean difference	Paired t	p
		Mean	SD	Mean	SD			
Neuro-surgery	ANH (n=34)	97.1	1.6	97.4	1.4	0.2	0.58	0.565
	PAD (n=9)	96.9	1.4	97.2	1.2	0.3	0.47	0.65
Vascular surgery	ANH (n=22)	97	1.5	97.3	1.1	0.4	0.79	0.437

Requirement of allogeneic blood and blood components among the autologous transfusion group

Out of the total 71 patients who underwent autologous transfusion, 43 (60.6%) received exclusive autologous blood transfusion, whereas 28 (39.4%) received additional allogeneic transfusion. (Figure 2) Cases in the autologous group which required additional allogeneic blood have been described in Table 7.

Table 7: Cases in the autologous transfusion group which required additional allogeneic blood

	Diagnosis	No. of patients who received additional allogeneic transfusion			
		Intra-operatively alone	Post-operatively alone	Both intra- and post-operatively	TOTAL (%)
Neuro-surgery	Intracranial Meningioma (n=26)	6	3	0	9 (34.6)
	Schwannoma (n=7)	1	-	1	2 (28.6)
	AV Malformation (n=4)	0	0	0	0
	Spine surgeries (n=5)	0	0	0	0
	Clival chordoma (n=1)	-	-	1	1 (100)
Vascular Surgery	Infra-renal abdominal aortic aneurysm (IRAAA) (n=14)	3	3	2	8 (57.1)
	Thoracic mass lesion (n=4)	1	0	0	1 (25)
	Carotid aneurysm (n=3)	0	1	0	1 (33.3)
	Subclavian artery aneurysm (n=1)	0	0	0	0
	Thoraco-abdominal aortic aneurysm (TAAA) (n=6)	-	-	6	6 (100)

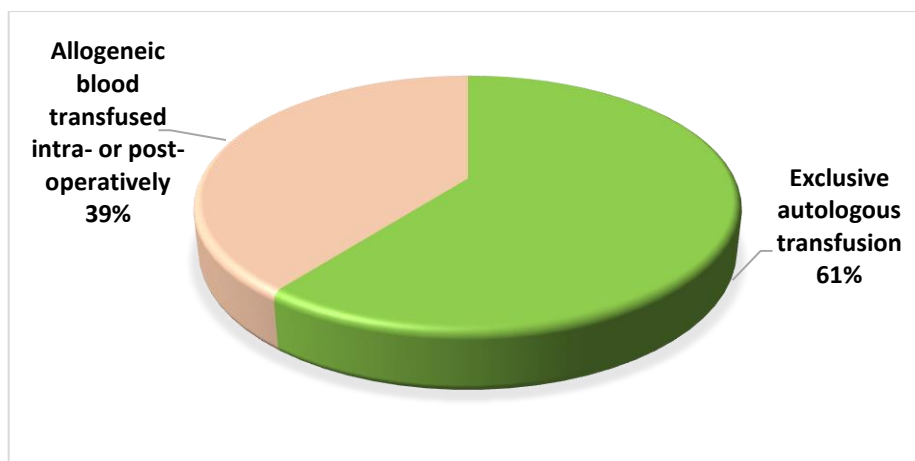


Figure 2: Transfusion requirement among autologous transfusion group (n=71)

A. Allogeneic transfusions in the Neurosurgical patients

Case-wise allogeneic transfusion requirement among the neurosurgical patients in Group I (autologous transfusion group) is shown in Figure 3.

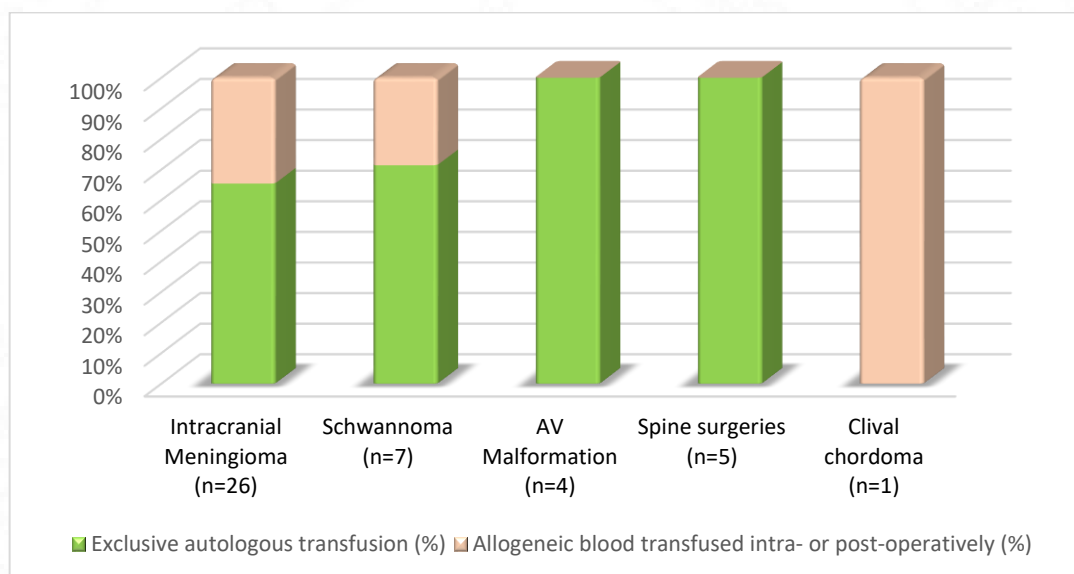


Figure 3: Transfusion requirements among neurosurgical patients in the autologous transfusion group

Among the neurosurgical cases, only 9 out of 43 patients (20.9%) from Group I required additional allogeneic blood intra-operatively. (Figure 4)

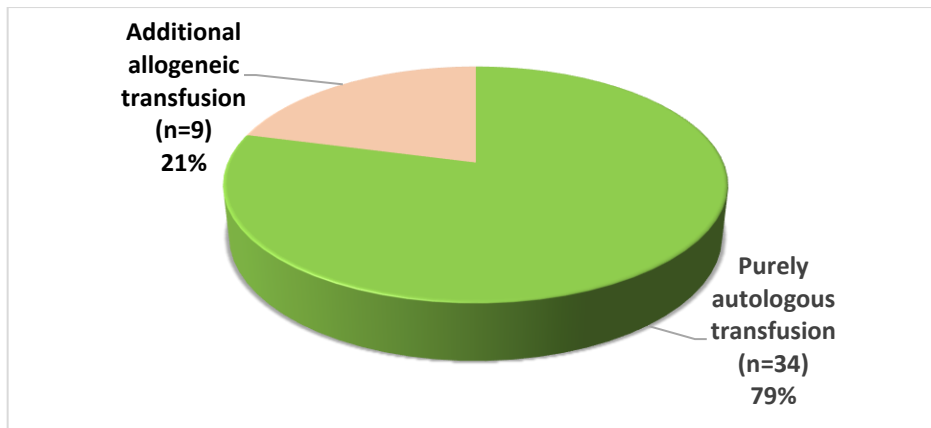


Figure 4: Intra-operative transfusion requirements among the autologous group in Neurosurgery

The mean intra-operative requirement of allogeneic blood components was calculated for those patients who received additional allogeneic blood from Group I and for Group II. (Table 8, Figure 5)

Table 8: Comparison of the intraoperative requirement (no. of units) of allogeneic blood and blood components in neurosurgical cases between autologous (group I) and allogeneic transfusion (group II) groups

Blood component	Group I (n= 9)		Group II (n=46)	
	Mean	SD	Mean	SD
PRBC	1.7	1.1	2	0.9
FFP	0.7	0.5	0.7	0.9
PC (RDP)	0.5	0.4	0.5	0.8
Cryoprecipitate	0	0	0	0

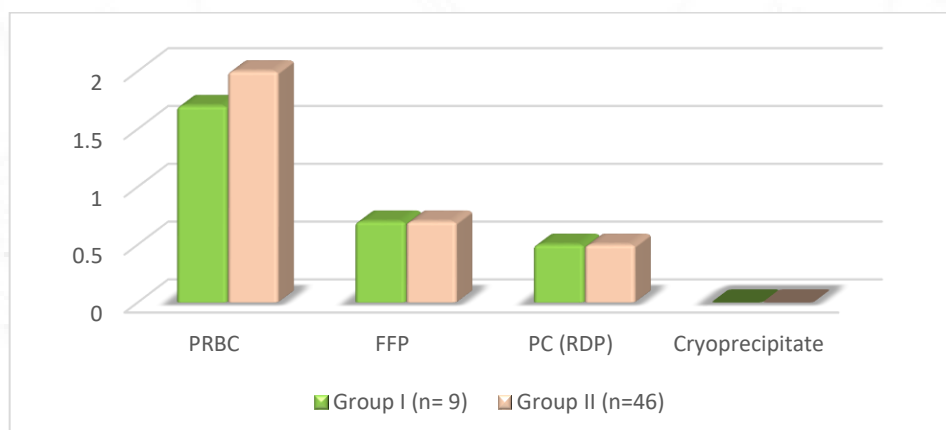


Figure 5: Intraoperative requirement (no. of units) of allogeneic blood and blood components in neurosurgical cases between the two groups

In the post-operative period, 5 (11.6%) patients in the autologous group and 5 (10.9%) in the allogeneic group received additional allogeneic PRBCs. It was noted that the mean requirement was higher in the autologous group which received additional allogeneic blood. (Table 9, Figure 6)

Table 9: Comparison of the post-operative requirement (no. of units) of allogeneic blood and blood components in neurosurgical cases

Blood component	Group I (n= 5)		Group II (n=5)		p
	Mean	SD	Mean	SD	
PRBC	1.2	0.4	1	0	0.34
FFP	0	0	0	0	-
PC (RDP)	0	0	0	0	-
Cryoprecipitate	0	0	0	0	-

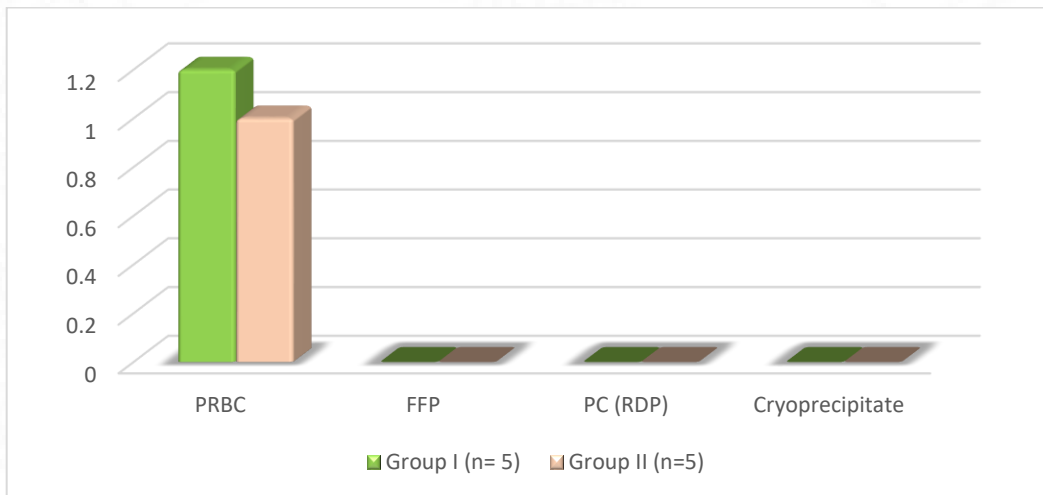


Figure 6: Comparison of post-operative allogeneic blood and blood component requirement (no. of units) in neurosurgical cases between autologous and allogeneic transfusion groups

B.1. Allogeneic transfusions in the Vascular surgical patients (excluding TAAA patients)

Case-wise allogeneic transfusion requirement among the vascular surgical patients in Group I (autologous transfusion group) who underwent ANH is shown in Figure 7.

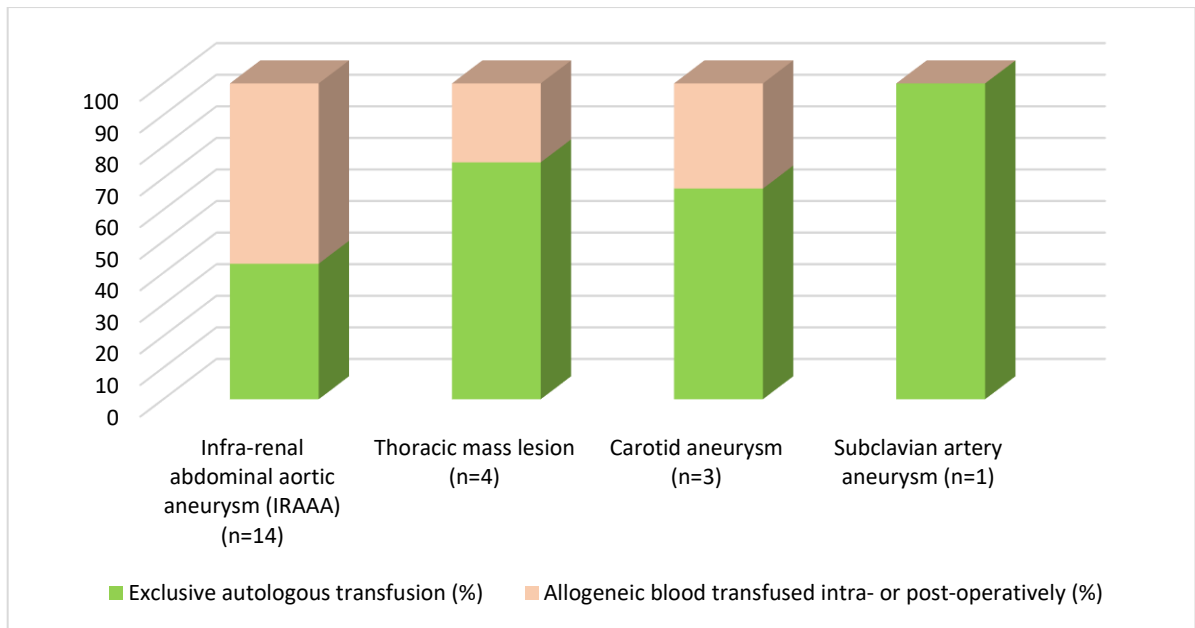


Figure 7: Transfusion requirements among Vascular surgical patients in the autologous transfusion group who underwent ANH

Out of the 22 patients in the ANH autologous group (Group I), only 6 (27.3%) patients required allogeneic blood transfusion in addition to the autologous blood intraoperatively. (Figure 8)

There were 19 patients in the allogeneic transfusion group (Group II).

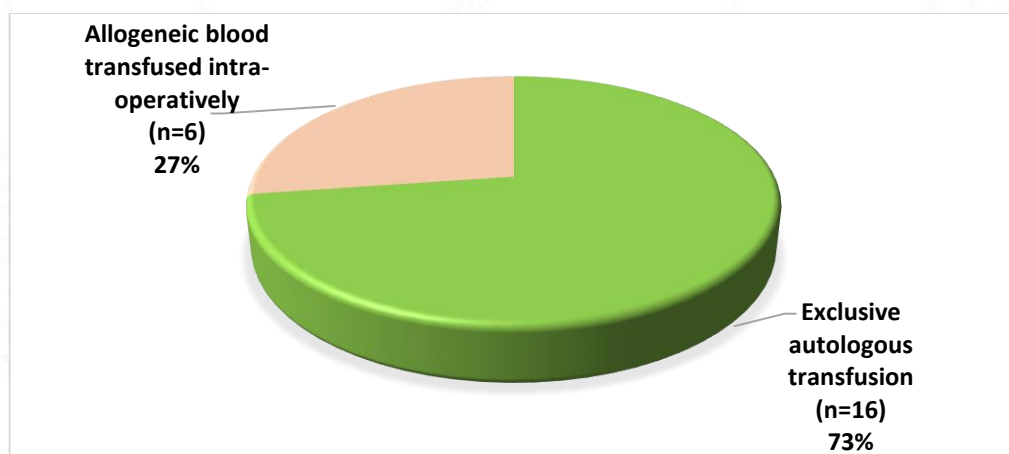


Figure 8: Intra-operative transfusion requirements in the autologous group among patients who underwent ANH in Vascular surgery

The mean intra-operative requirement of allogeneic blood components was calculated for those patients who received additional allogeneic blood from Group I and for Group II. (Table 10, Figure 9). Statistically significant difference was observed in transfusion of PRBC intraoperatively, between the two groups.

Table 10: Comparison of intraoperative allogeneic blood and blood component utilization in vascular surgical cases between autologous (ANH) and allogeneic transfusion groups

Allogeneic Units	Group I (n=6)		Group II (n=19)		Z [#]	p
	Mean	SD	Mean	SD		
PRBC	1	0	2.3	0.9	3.02	0.002
FFP	1	0	1.2	0.8	0.54	0.59
PC (RDP)	0.2	0.4	1.6	2.1	1.55	0.12
Cryoprecipitate	0	0	0	0	-	-

[#]Mann-Whitney U test

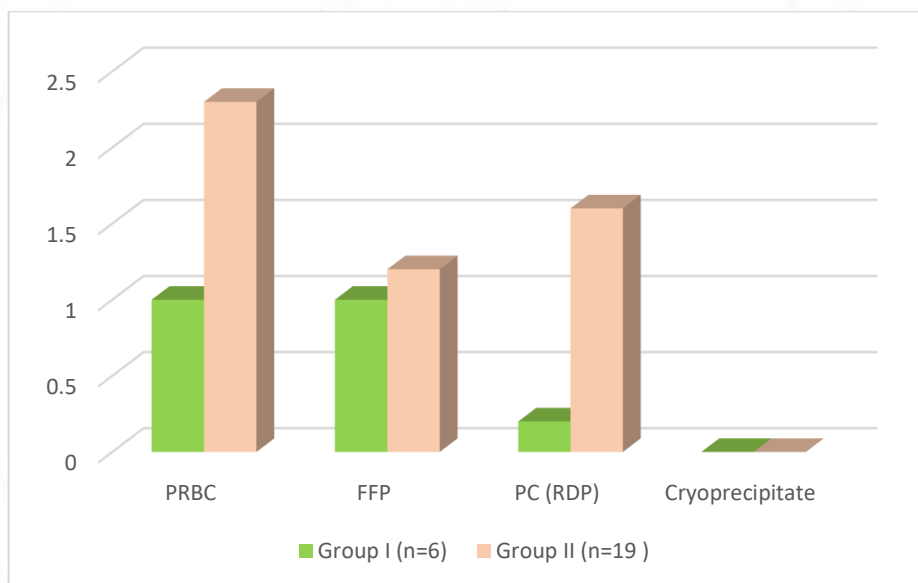


Figure 9: Comparison of intraoperative allogeneic blood and blood component utilization in vascular surgical cases between autologous (ANH) and allogeneic transfusion groups

Likewise, during the post-operative period, 6 (27.3%) out of 22 patients from the autologous group (Group I) were transfused with allogeneic blood/components. In Group II, 10 (52.6%) out of 19 patients received additional blood/components post-operatively.

There was no statistical significance between the two groups with respect to transfusion of any blood component. (Table 11, Figure 10)

Table 11: Comparison of post-operative allogeneic blood and blood component requirement (no. of units) in vascular surgical cases between autologous (ANH) and allogeneic transfusion groups

Allogeneic Units	Group I (n=6)		Group II (n=10)		Z [#]	p
	Mean	SD	Mean	SD		
PRBC	1	0	1.3	0.5	0.92	0.35
FFP	0	0	0	0	-	-
PC (RDP)	0.5	0.8	0.9	1	0.65	0.51
Cryoprecipitate	0	0	0	0	-	-

[#]Mann-Whitney U test

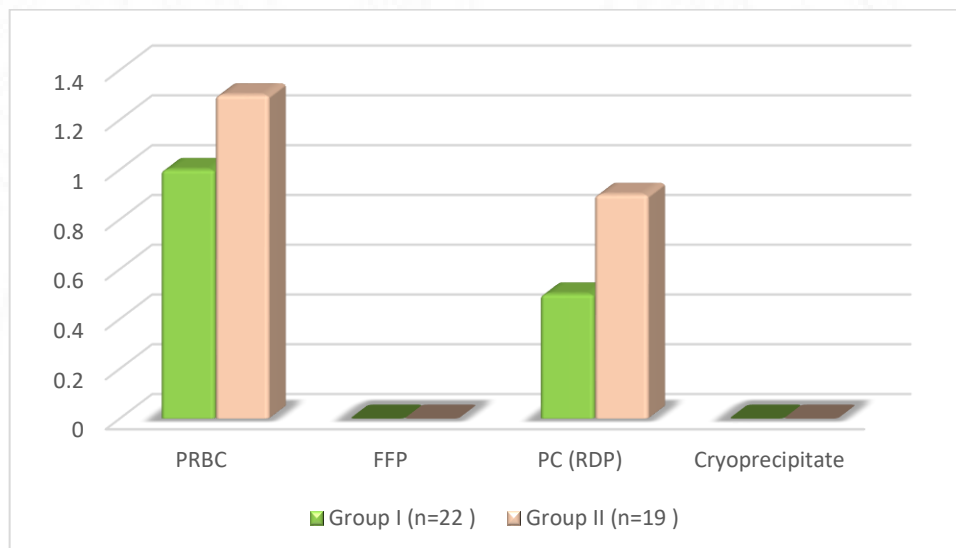


Figure 10: Comparison of post-operative allogeneic blood and blood component utilization in vascular surgical cases between autologous (ANH) and allogeneic transfusion groups

B.2. Allogeneic transfusions in the Vascular surgical patients (TAAA patients) who used Intraoperative Cell Salvage (ICS)

There were 6 patients with Thoraco-abdominal aortic aneurysm (TAAA) who underwent open repair, in whom intraoperative cell-salvage was practiced (Group I). All of the patients in Group I needed additional allogeneic blood. 5 patients who underwent the same procedure were in the allogeneic transfusion group (Group II). There was a significant difference between the two groups with respect to intra-operative transfusion of allogeneic

PRBC, FFP, RDP and Cryoprecipitate in all the four groups. ($p < 0.01$ for PRBC, FFP, RDP transfusions; $p < 0.05$ for Cryoprecipitate transfusion) (Table 12, Figure 11)

Table 12: Comparison of intraoperative allogeneic blood and blood component utilization in Thoraco-abdominal aortic aneurysm (TAAA) cases between autologous (ICS) and allogeneic transfusion groups

Allogeneic Units	Group I (n=6)		Group II (n=5)		Z [#]	p
	Mean	SD	Mean	SD		
PRBC	3.5	2.1	5.8	1.3	3.06**	0.002
FFP	2.5	2	3.4	0.9	3.12**	0.002
PC (RDP)	4	2.3	4.2	1.3	2.96**	0.003
Cryoprecipitate	0.8	1	1.2	1.1	2.53 *	0.012

Mann-Whitney U Test

**Significant at 0.01 level, *Significant at 0.05 level

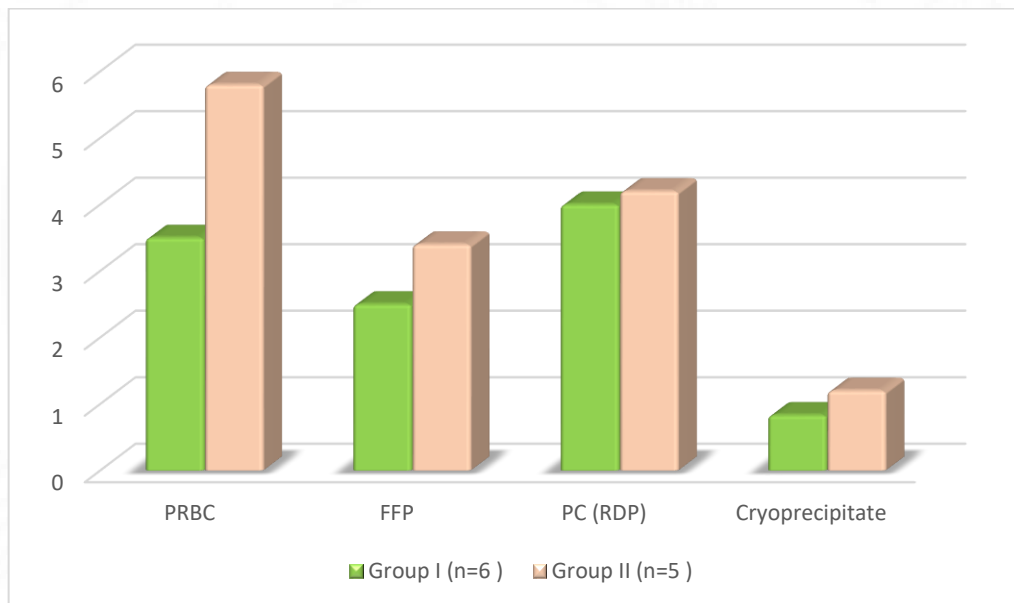


Figure 11: Comparison of intraoperative allogeneic blood and blood component utilization in Thoraco-abdominal aortic aneurysm (TAAA) cases between autologous (ICS) and allogeneic transfusion groups

In the post-operative period, there was a statistically significant difference with respect to PRBC transfusion ($Z=2.27$ and $p=0.023$) between the two groups. (Table 13)

Table 13: Comparison of post-operative allogeneic blood and blood components (no. of units) in Thoraco-abdominal aortic aneurysm (TAAA) cases between autologous (Group I) and allogeneic (Group II) transfusion groups

Allogeneic Units	Group I (n=6)		Group II (n=5)		Z #	p
	Mean	SD	Mean	SD		
PRBC	1.5	0.8	1.2	0.8	2.27 *	0.023
FFP	0.7	1	0	0	-	-
PC (RDP)	1	1.7	0.6	1.3	0.44	0.661
Cryoprecipitate	0	0	0	0	-	-

Mann-Whitney U Test

*Significant at 0.05 level

It was noted that the group which was transfused with autologous salvaged blood had more requirement of allogeneic blood and its products in the post-operative period. (Figure 12)

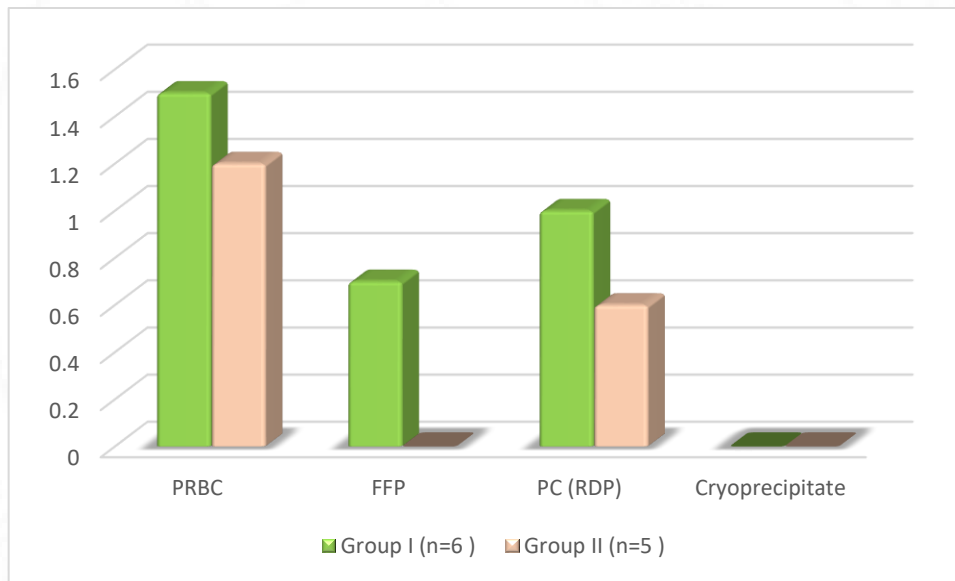


Figure 12: Comparison of post-operative allogeneic blood and blood component utilization in Thoraco-abdominal aortic aneurysm (TAAA) cases between autologous (ICS) and allogeneic transfusion groups

Comparison of the effect of transfusion on hemoglobin, hematocrit, platelet count and INR between autologous and allogeneic groups

We further did a comparison between patients receiving autologous and allogeneic transfusion based on their hemoglobin, hematocrit (HCT), platelet count and INR, as described below.

1. Neurosurgery patients receiving autologous blood (collected by ANH) vs Allogeneic blood

A t-test was performed between the two groups by grouping on the basis of Hb-value pre-operatively, on the day of the surgery (Day 0), one day after surgery (Day 1) and 5th day of the surgery (Day 5). There was no significant difference between the two groups prior to surgery. Day 0, day 1 and day 5 indicated significant difference in the Hb values between two groups with $t = 2.75$ with $p = 0.007$, $t = 2.53$ with $p = 0.013$ and $t = 4.05$ and $p < 0.01$ respectively. (Table 14, Figure 13)

Table 14: Comparison of hemoglobin pre- and post-operatively in patients between autologous transfusion and allogeneic transfusion group for Neurosurgery

	Group I (ANH Autologous)			Group II (Allogeneic)			t	p
	Mean Hb (g/dL)	SD	N	Mean Hb (g/dL)	SD	N		
Pre-operative	13.5	1.2	34	13.7	1.1	46	0.69	0.491
Day0	10.6	1.0	34	11.3	1.2	46	2.75**	0.007
Day1	10.4	1.1	34	11.2	1.4	46	2.53*	0.013
Day5	10.3	1.2	34	11.4	1.3	46	4.05	p<0.01

**:- Significant at 0.01 level, *:- Significant at 0.05 level; Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

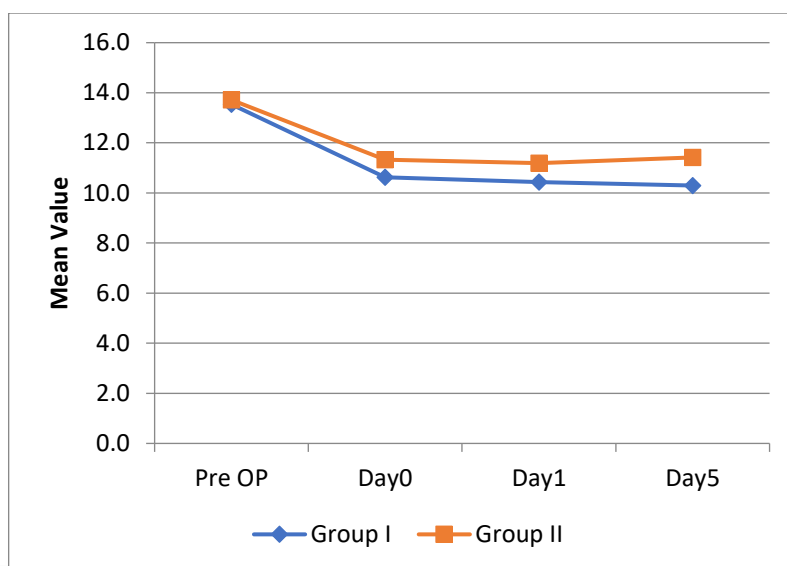


Figure 13: Comparison of hemoglobin (g/dL) pre- and post-operatively in patients between autologous transfusion and allogeneic transfusion group for Neurosurgery

Similarly, as done for hemoglobin, a similar analysis was applied to the hematocrit (HCT), platelet count and INR.

Between group comparison for Group I (ANH autologous) and Group II (allogeneic), the hematocrit value did not show any difference for the pre-operative value but there was a significant difference in the hematocrit on the day of the surgery, 1 day after surgery and 5 days post-surgery with p-values being $p < 0.007$, $p < 0.014$ and $p < 0.01$ respectively. (Table 15, Figure 14)

Table 15: Comparison of hematocrit (HCT) pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Neurosurgery

	Group I (Autologous)			Group II (Allogeneic)			t	p
	Mean HCT (%)	SD	N	Mean HCT (%)	SD	N		
Pre-operative	40.6	3.7	34	41.1	3.2	46	0.69	0.491
Day0	31.9	3.0	34	34.0	3.7	46	2.75**	0.007
Day1	31.3	3.4	34	33.6	4.3	46	2.52*	0.014
Day5	30.9	3.5	34	34.2	3.8	46	4.04	p<0.01

**Significant at 0.01 level, *Significant at 0.05 level; Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

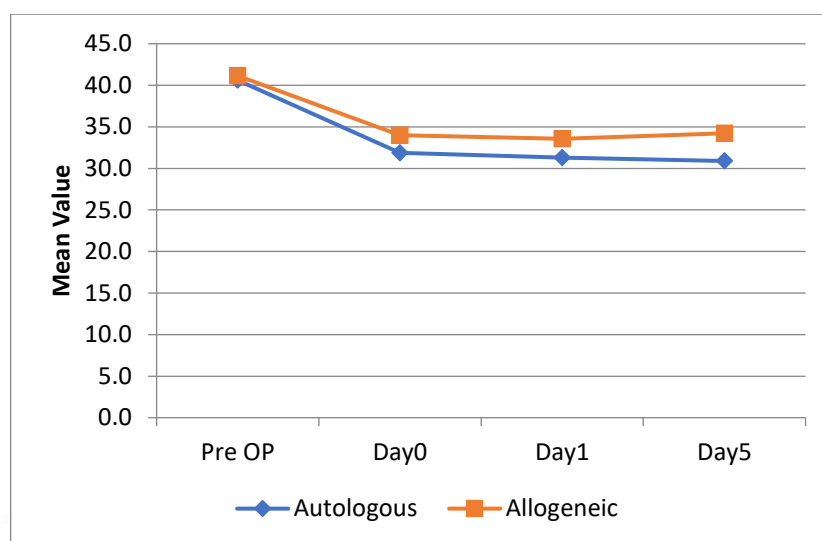


Figure 14: Comparison of hematocrit (%) pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Neurosurgery

With regard to the platelet count, it was noted that there was no significant difference in the pre-operative, day 1 post surgery and fifth day post-surgery values between the autologous and allogeneic group. The platelet counts on the day of the surgery showed significant difference with $t = 2.28$ with $p = 0.025$. (Table 16, Figure 15)

Table 16: Comparison of Platelet count pre- and post-operatively in patients between autologous transfusion and allogeneic transfusion groups in Neurosurgery

	Group I (Autologous)			Group II (Allogeneic)			t	p
	Mean Platelet count (lakhs/mm ³)	SD	N	Mean Platelet count (lakhs/mm ³)	SD	N		
Pre-operative	3.1	0.7	34	2.8	0.9	46	1.29	0.199
Day0	2.9	0.7	34	2.5	0.9	46	2.28*	0.025
Day1	2.9	0.7	34	2.6	0.9	46	1.99	0.052
Day5	3.0	0.7	34	2.8	0.9	46	1.1	0.275

*Significant at 0.05 level; Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

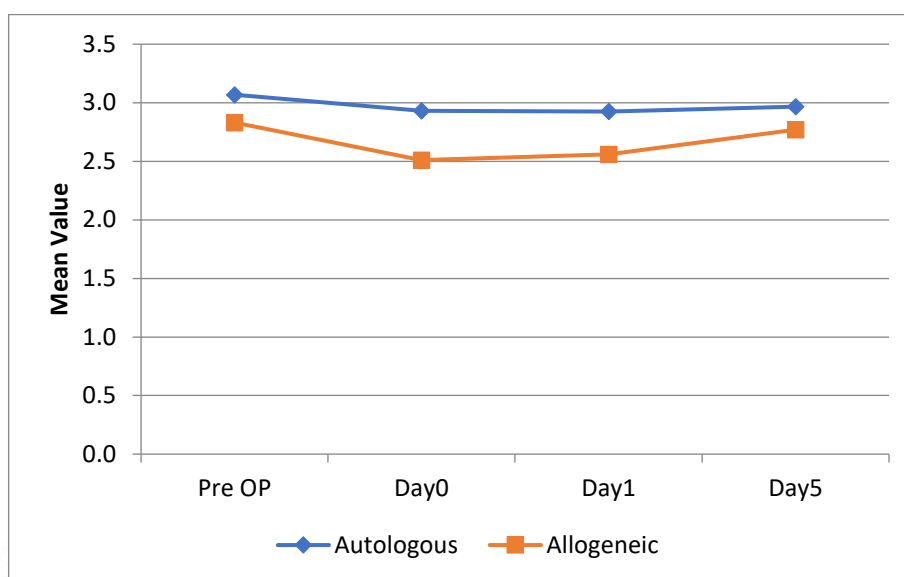


Figure 15: Comparison of Platelet count (lahks/cumm) pre- and post-operatively in patients between autologous transfusion and allogeneic transfusion groups in Neurosurgery

Likewise, regarding INR value, there was a significant difference between the ANH autologous and allogeneic group only on Day 1 with $t = 2.11$ and $p = 0.038$. There was no significant difference in the other days when compared. (Table 17, Figure 16)

Table 17: Comparison of INR pre- and post-operatively in patients between autologous transfusion and allogeneic transfusion group in Neurosurgery

	Group I (Autologous)			Group II (Allogeneic)			t	p
	Mean	SD	N	Mean	SD	N		
Pre-operative	1.04	0.07	34	1.06	0.06	46	1.33	0.189
Day0	1.06	0.08	34	1.04	0.05	46	1.1	0.275
Day1	1.06	0.06	34	1.03	0.05	46	2.11*	0.038
Day5	1.07	0.08	34	1.06	0.05	46	1.21	0.228

* Significant at 0.05 level; Day0= on the day of surgery, Day1= one day after surgery, Day5= 5 days after surgery

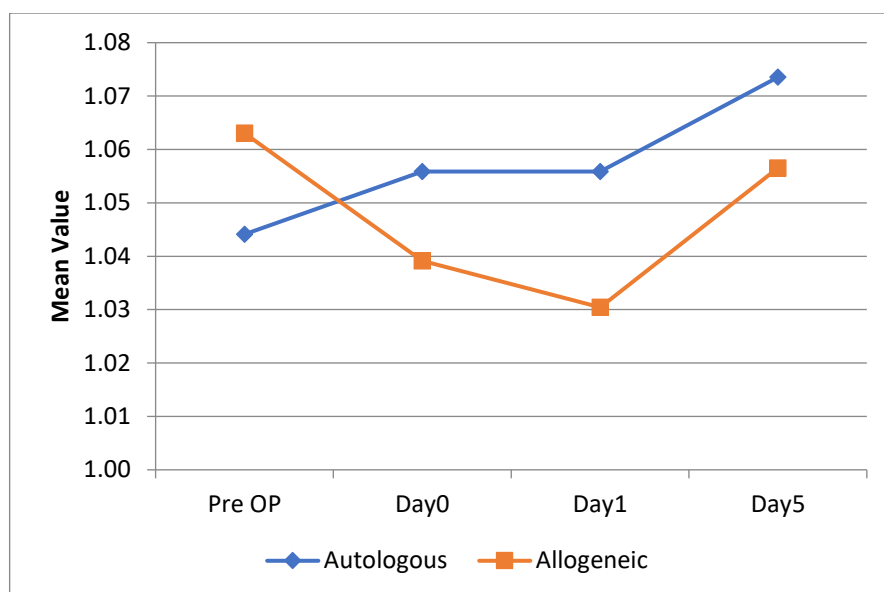


Figure 16: Comparison of INR pre- and post-operatively in patients between autologous transfusion and allogeneic transfusion group in Neurosurgery

2. Neurosurgery patients receiving pre-deposit autologous blood

The mean hemoglobin, hematocrit, platelet count and INR was calculated for the pre-operative, Day 0, 1 and 5 for the group which received autologous blood collected by PAD. (Table 23) Comparison with allogeneic group was not done as a matching group was not present.

Table 18: Mean pre- and post-operative Hemoglobin, hematocrit, platelet count and INR in group which underwent autologous transfusion of pre-deposited blood

Transfusion		Hemoglobin (g/dL)		Hematocrit (%)		Platelet count (lakhs/mm ³)		INR	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-deposit Autologous	Pre-op	12.8	0.71	38.5	2.1	2.7	0.7	1.05	0.07
	Day 0	11	1.3	33.1	4	2.7	0.7	1.06	0.05
	Day 1	10.7	1.8	32.1	5.3	2.7	0.7	1.06	0.05
	Day 5	11	1.3	33	4	2.7	0.8	1.06	0.02

Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

3. Vascular surgery patients receiving autologous blood (collected by ANH) vs Allogeneic blood [Thoraco-abdominal aortic aneurysm cases excluded]

When a group comparison between patients receiving ANH autologous transfusion and allogeneic transfusion among the vascular surgery patients was deduced, there was no statistically significant difference in the pre-operative hemoglobin. The Hb value on the day of the surgery (Day 0), Day 1 and Day 5 showed significant group difference. (Table 19, Figure 17)

Table 19: Comparison of hemoglobin pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

	Group I (Autologous)			Group II (Allogeneic)			t	p
	Mean Hb (g/dL)	SD	N	Mean Hb (g/dL)	SD	N		
Pre-operative	13.8	0.9	22	13.8	1.1	19	0.24	0.815
Day0	10.3	0.9	22	10.9	0.6	19	2.24*	0.031
Day1	9.3	1.2	22	10.6	0.8	19	3.92	<0.01
Day5	8.7	1.6	22	10.2	1.2	19	3.32**	0.002

**:- Significant at 0.01 level, *:- Significant at 0.05 level; Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

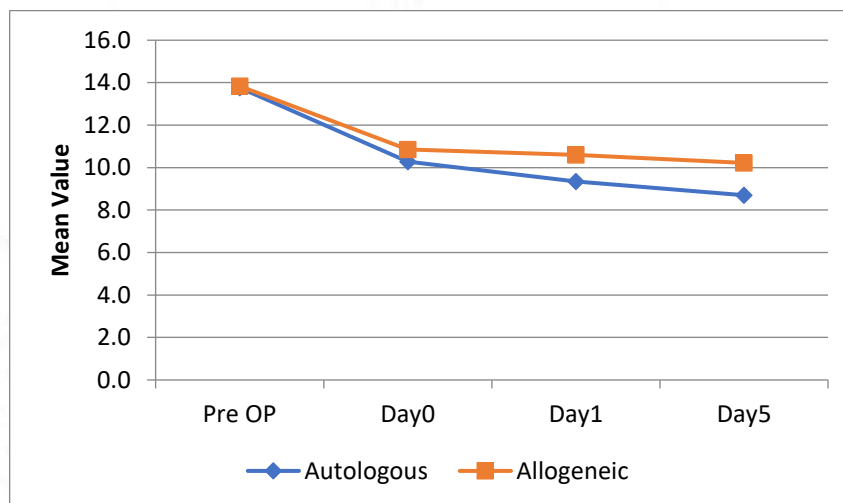


Figure 17: Comparison of hemoglobin (g/dL) pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

A group comparison was performed to understand the difference in the hematocrit between the ANH autologous and allogeneic groups. It was noted that there was no significant difference in the pre-operative value. A difference was noted on the day of the surgery (Day 0) with $t = 2.24$, $p = 0.031$, one day after the surgery (Day 1) with $t=3.92$ and $p < 0.01$ and the fifth day post-surgery (Day 5) with $t = 3.32$ and $p = 0.002$. (Table 20, Figure 18)

Table 20: Comparison of hematocrit pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

	Group I (Autologous)			Group II (Allogeneic)			t	p
	Mean HCT (%)	SD	N	Mean HCT (%)	SD	N		
Pre-operative	41.3	2.7	22	41.5	3.3	19	0.24	0.815
Day0	30.8	2.8	22	32.6	1.9	19	2.24*	0.031
Day1	28.0	3.5	22	31.8	2.4	19	3.92	p<0.01
Day5	26.1	4.9	22	30.7	3.7	19	3.32**	0.002

** - Significant at 0.01 level, * - Significant at 0.05 level; Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

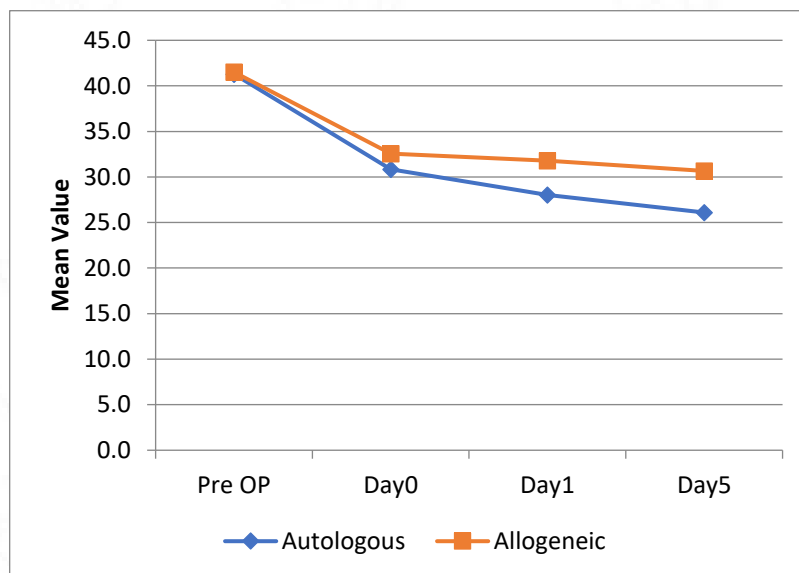


Figure 18: Comparison of hematocrit (%) pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

A comparative analysis between the two groups on platelet counts pre-operatively, on the day of surgery (Day 0), one day after surgery (Day 1) and five days post-operatively (Day 5) represented that there was no statistically significant difference ($p > 0.05$). (Table 21, Figure 19)

Table 21: Comparison of platelet counts pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

	Group I (Autologous)			Group II (Allogeneic)			t	p
	Mean (lakhs/mm ³)	SD	N	Mean (lakhs/mm ³)	SD	N		
Pre-operative	2.4	0.7	22	2.8	0.8	19	1.64	0.109
Day 0	2.2	0.8	22	2.5	0.8	19	1.14	0.260
Day 1	2.2	0.8	22	2.5	0.8	19	1.26	0.216
Day 5	2.1	0.8	22	2.6	0.8	19	2	0.053

Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

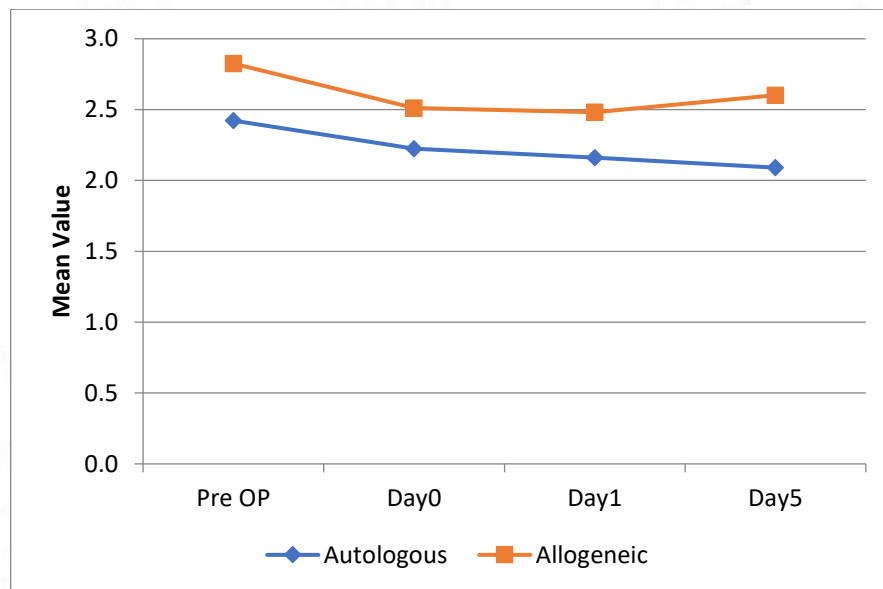


Figure 19: Comparison of platelet counts (lakhs/cumm) pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

Statistically significant difference in the INR between the ANH autologous transfusion group and the allogeneic transfusion group was seen in day 5 post surgery ($p = 0.021$). There was no statistical difference with respect to the pre-operative, Day 0 and 1 value ($p > 0.05$). (Table 22, Figure 20)

Table 22: Comparison of INR pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

	Group I (Autologous)			Group II (Allogeneic)			t	p
	Mean INR	SD	N	Mean INR	SD	N		
Pre-operative	1.09	0.06	22	1.06	0.06	19	1.56	0.127
Day0	1.06	0.07	22	1.05	0.05	19	0.55	0.584
Day1	1.05	0.07	22	1.06	0.05	19	0.66	0.515
Day5	1.03	0.05	22	1.06	0.05	19	2.41*	0.021

*Significant at 0.05 level; Day0= on the day of surgery, Day1= one day after surgery, Day5 = 5 days after surgery

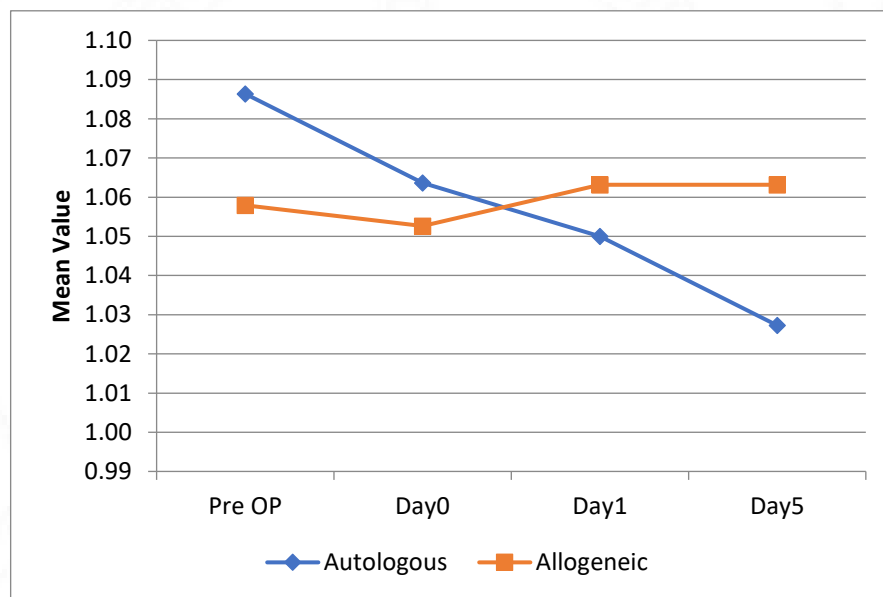


Figure 20: Comparison of INR pre- and post-operatively in patients between ANH autologous transfusion and allogeneic transfusion group in Vascular surgery

4. Vascular surgical Thoraco-abdominal aortic aneurysm (TAAA) patients who underwent autologous transfusion (intra-operative cell salvage-ICS) vs allogeneic transfusion

A comparison for TAAA patients was also made between those patients who received autologous (intra operative cell salvage -ICS) and allogeneic blood transfusion. The Hb value on post-operative day 5 alone was found to be significantly different (p=0.012). (Table 23, Figure 21)

Table 23: Comparison of Hemoglobin pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

	Group I (Autologous-ICS)			Group II (Allogeneic)			t	p
	Mean Hb(g/dL)	SD	N	Mean Hb(g/dL)	SD	N		
Pre-operative	12.7	0.8	6	13.7	0.9	5	1.98	0.079
Day0	9.3	0.6	6	9.2	0.4	5	0.08	0.936
Day1	8.7	0.9	6	8.2	1.0	5	0.92	0.381
Day5	8.1	0.9	6	9.5	0.4	5	3.14*	0.012

*Significant at 0.05 level; Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

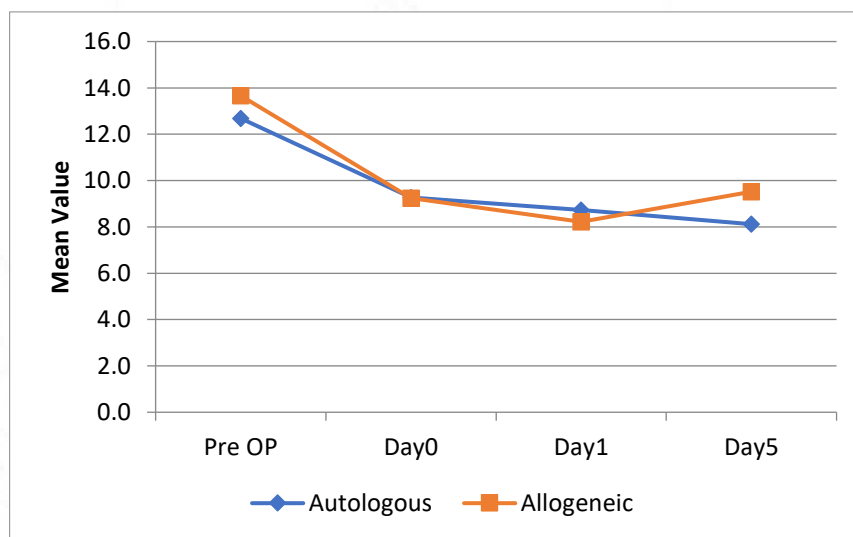


Figure 21: Comparison of Hemoglobin pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

Likewise, a comparison of hematocrit pre-operatively, on the day after surgery (Day 0), one (Day 1) and five (Day 5) days following surgery represented that there was a statistically significant difference between the group receiving intra-operatively salvaged blood and that receiving allogeneic blood on Day 5 post-operatively ($p=0.012$). (Table 24, Figure 22)

Table 24: Comparison of Hematocrit pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

	Group I (Autologous-ICS)			Group II (Allogeneic)			t	p
	Mean HCT (%)	SD	N	Mean HCT (%)	SD	N		
Pre-operative	38.1	2.3	6	41.0	2.6	5	1.98	0.079
Day0	27.8	1.9	6	27.7	1.2	5	0.08	0.936
Day1	26.2	2.6	6	24.7	3.0	5	0.92	0.381
Day5	24.4	2.8	6	28.6	1.1	5	3.14*	0.012

*Significant at 0.05 level; Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

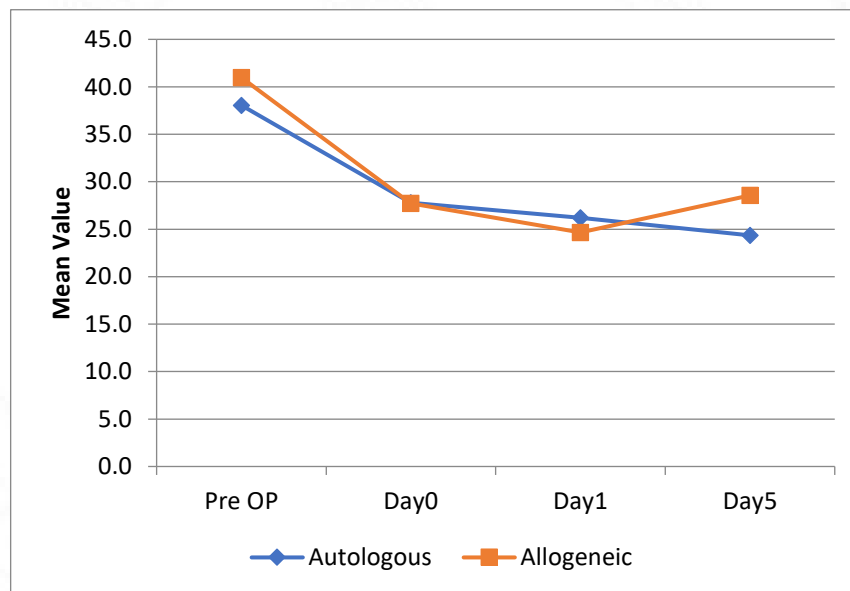


Figure 22: Comparison of Hematocrit pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

There was no statistically significant difference in the platelet count with respect to the pre-operative, Day 0, 1 and 5 values between the autologous and allogeneic transfusion groups. (Table 25, Figure 23)

Table 25: Comparison of platelet counts pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

	Group I (Autologous-ICS)			Group II (Allogeneic)			t	p
	Mean (lakhs/mm ³)	SD	N	Mean (lakhs/mm ³)	SD	N		
Pre-operative	2.0	0.4	6	2.9	0.7	5	1.78	0.065
Day0	1.7	0.5	6	2.2	0.7	5	1.12	0.292
Day1	1.6	0.5	6	2.0	0.7	5	1.12	0.293
Day5	1.5	0.5	6	2.0	0.6	5	1.49	0.170

Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

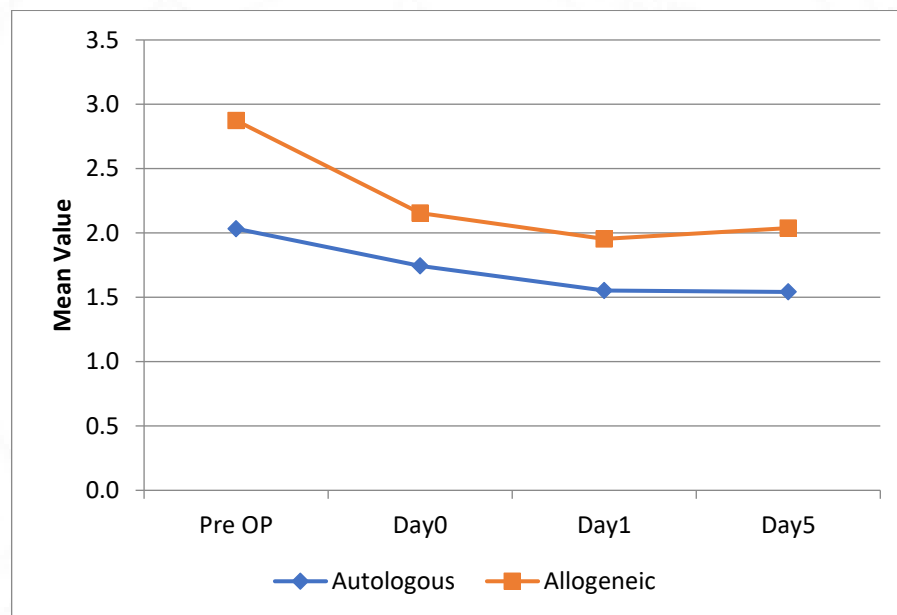


Figure 23: Comparison of platelet counts pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

Comparison of INR pre-operatively, on the day after surgery (Day 0), one (Day 1) and five (Day 5) days following surgery depicted that there was no statistically significant difference between the groups receiving intra-operatively salvaged blood and that receiving allogeneic blood on Day 0, 1 and 5 post-operatively. (Table 26, Figure 24)

Table 26: Comparison of INR pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

	Group I (Autologous-ICS)			Group II (Allogeneic)			t	p
	Mean INR	SD	N	Mean INR	SD	N		
Pre-operative	1.08	0.10	6	1.06	0.05	5	0.47	0.649
Day0	1.28	0.08	6	1.28	0.08	5	0.07	0.946
Day1	1.28	0.08	6	1.26	0.05	5	0.58	0.579
Day5	1.25	0.10	6	1.26	0.05	5	0.19	0.852

Day0 = on the day of surgery, Day1 = one day after surgery, Day5 = 5 days after surgery

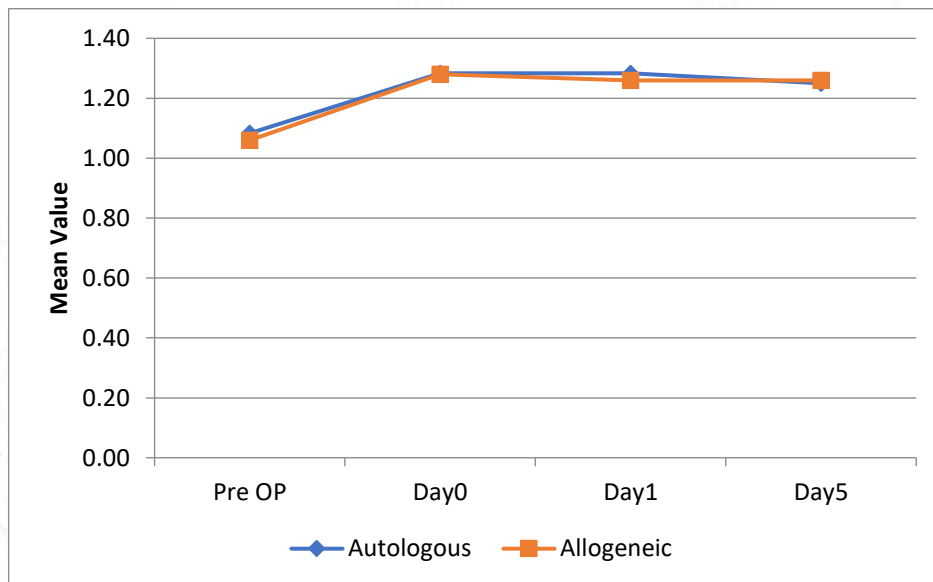


Figure 24: Comparison of INR pre- and post-operatively between patients who received intra-operatively salvaged autologous transfusion vs allogeneic transfusion

Effect on Blood Loss

Further, analysis was performed to compare blood loss between patients in the two groups. It was found that there was no statistically significant difference in blood loss in neurosurgical or vascular surgical patients. (Table 27, Figure 25)

Table 27: Comparison of blood loss (in mL) between patients in the two groups

Surgery	Group I			Group II			t	p
	Mean	SD	N	Mean	SD	N		
Neurosurgery	1104.4	367.7	43	1242.6	377.7	46	1.92	0.059
Vascular surgery (excluding TAAA)	1344.5	479.8	22	1555.8	442.8	19	1.46	0.153
Vascular surgery → TAAA	2713	677.34	6	2860.0	322.88	5	0.44	0.669

TAAA = Thoraco-abdominal aortic aneurysm

Figure 25 illustrates a slightly higher blood loss in the group which underwent conventional allogeneic blood transfusion practice (Group II) compared to the group which received autologous transfusion (Group I).

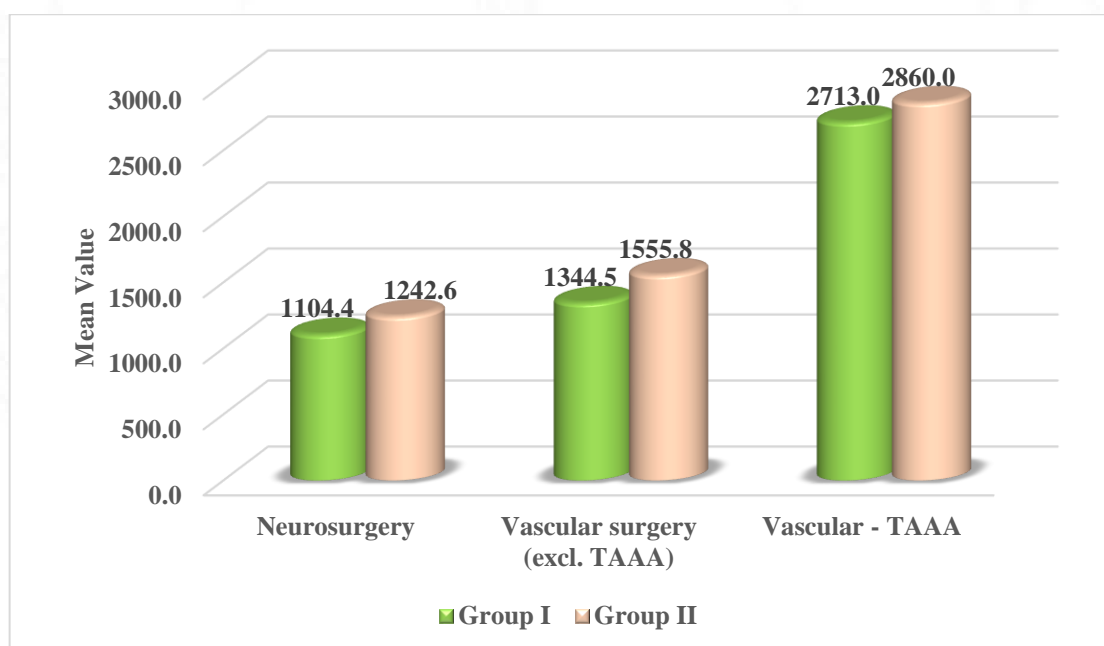


Figure 25: Comparison of blood loss (in mL) between patients in the two groups

Post-operative Outcomes

Post-operative outcomes like duration of ICU stay, re-exploration due to bleeding, hours of mechanical ventilation from the time of intubation and post-operative infections upto 5 days post- surgery were compared between the group receiving autologous blood (Group I) and that receiving allogeneic blood (Group II). (Tables 28, 29)

Table 28: Post-operative outcomes for Neurosurgical patients who received autologous blood vs allogeneic transfusion

	Group I (n= 43)	Group II (n=46)	p
ICU duration of stay (days)	2.9 ± 0.7	2.7 ± 0.9	0.246 #
Re-exploration for Bleeding N(%)	0	1 (2.2)	-
Mechanical ventilation (hours)	8.3 ± 2.6	8.4 ± 2.6	0.875#
Post-operative infection** N (%)	1 (2.3)	3 (6.5)	0.220 \$

ICU = Intensive care unit; ** Upto 5 days post-operatively;
Mann-Whitney U Test, \$ Fisher's Exact Test

Table 29: Post-operative outcomes for vascular surgical patients who received ANH autologous blood vs allogeneic transfusion

	Group I (n= 22)	Group II (n=19)	p
ICU duration of stay (days)	2.7 ± 0.8	2.8 ± 1	0.989 #
Re-exploration for Bleeding N(%)	1 (4.5)	2 (10.5)	0.430 \$
Mechanical ventilation (hours)	9.8 ± 4.6	9.8 ± 3.7	0.869 #
Post-operative infection** N (%)	1 (4.5)	2 (10.5)	0.430 \$

ICU = Intensive care unit; ** Upto 5 days post-operatively;
Mann-Whitney U Test, \$ Fisher's Exact Test

Statistically significant difference was observed in the TAAA patients between the two groups with respect to duration of ICU stay (p=0.002) and re-exploration due to bleeding (p=0.048). (Table 30)

Table 30: Post-operative outcomes for vascular surgical patients who received intra-operatively salvaged autologous blood (TAAA cases) vs allogeneic transfusion

	Group I (n= 6)	Group II (n=5)	p
ICU duration of stay (days)	2.7 ± 1.1	6.2 ± 0.8	0.002 #
Re-exploration for Bleeding N(%)	1 (16.7)	2 (40)	0.048 \$
Mechanical ventilation (hours)	33.5 ± 10.4	39.6 ± 11.1	0.370 #
Post-operative infection** N (%)	0	1 (20)	0.357 \$

ICU = Intensive care unit; ** Upto 5 days post-operatively;
Mann-Whitney U Test, \$ Fisher's Exact Test

Transfusion Reactions

In Group I, transfusion reactions were observed in 2 patients – 1 patient with Febrile non-hemolytic transfusion reaction (FNHTR) and another with a FNHTR with allergic transfusion reaction. Both these patients suffered the reaction after receiving additional allogeneic blood over the autologous transfusion.

In Group II, transfusion reactions were observed in 3 patients – 1 neurosurgical patient had an allergic reaction, 2 patients who underwent vascular surgical procedures, 1 had Transfusion associated dyspnoea (TAD) and 1 suffered a FNHTR.

Effect on Blood Centre Inventory

159 blood units were collected by autologous transfusion. (Table 31)

Table 31: Autologous blood units collected

		No. of units
Neurosurgery	Pre-deposit	13
	ANH	59
Vascular surgery	ANH	40
	Intra-operative cell salvage (equivalent units)	47
	Total	159

DISCARDS:

2 PRBC (1.26%), 9 FFP and 2 RDP which were collected as pre-deposit were discarded.

1 (0.62%) whole blood unit collected by ANH in a vascular surgical patient was also discarded.

Hence, a total of 156 allogeneic red cell units were saved.



DISCUSSION

This was a randomized controlled trial that was carried out over a period of 15 months in 141 patients who underwent various neurosurgical and vascular surgical procedures in our institute. The patients were allocated into two groups – Group I which received autologous transfusion and Group II which received conventional allogeneic transfusion as per institute protocols.

In our study, the maximum number of autologous transfusions among the neurosurgical cases were employed in patients with meningioma. Likewise, Patil *et al*, in their study bring out that the maximum number, of neurosurgical cases that utilized autologous blood transfusion successfully, was that of meningioma. ^[66] This shows the feasibility of employing autologous transfusion, especially ANH, in meningioma cases. Similarly, among the vascular surgical cases, the maximum number was seen in infra-renal abdominal aortic aneurysm cases. A study by Wolowczyk *et al* on the effects of ANH among aortic aneurysm cases reports that autologous transfusion was safe and successful in patients with infra-renal abdominal aortic aneurysm. ^[76]

In our study, the effect of autologous blood collection was assessed by comparing the difference in hemodynamic parameters like heart rate and mean arteriolar pressure (MAP), and also the percentage saturation of oxygen (SPO₂) pre- and post- blood collection. It was found that there was no significant difference in heart rate or SPO₂ from the baseline values of the patients. However, despite showing a statistically significant difference in the MAP pre- and post- autologous blood collection in those patients who underwent ANH among the neurosurgical and vascular surgical patients, the MAP values remained within normal physiological limits. Likewise, Oppitz *et al* report that there was a significant difference in the MAP post autologous collection in neurosurgical patients following ANH, but just as seen in our study, the values were within the normal physiological range. ^[30] This depicts that PAD and ANH can be safely carried out without causing any hemodynamic instability under the supervision of trained blood centre and anesthesia personnel respectively. Studies carried out in India by Patil *et al* and Naqash *et al* also brought out that there was no statistically significant difference in mean arterial pressure and heart rate before and after autologous blood collection by ANH and hence is a safe procedure. ^[66,77]

An exception was noted in 2 (2.8%) of our patients who underwent ANH (1 neurosurgical and 1 vascular surgical) in whom hypotension not responding to intravenous (IV) crystalloids or colloids was observed and vasopressors were initiated. Segal *et al*, in a

meta-analysis of 42 studies reported that only 0.85% experienced hypotension during acute hemodilution. [78]

Regarding the requirement of additional allogeneic blood in the autologous transfusion group, it was found in our study that the majority (60.6%) received autologous transfusion alone. Similar reports have been put forward by Guo *et al*, Patil *et al* and Naqash *et al*. [35,66,77] In our study, only 20.9% of the neurosurgical patients and 27.3% of the vascular surgical patients who underwent ANH required additional intra-operative allogeneic blood component transfusion. Also, the number of intra-operative allogeneic units transfused by the neuro- and vascular surgical patients in the autologous group was lesser compared to those in the allogeneic transfusion group. A multicenter study by Goldberg *et al* also concludes that there was a significant association between ANH and reduced perioperative RBC transfusion in cardiac surgery. They also mention that the larger the volumes of ANH, the more profound the reduction in allogeneic blood transfusion. Their findings suggest that the volume of ANH could be an important feature of blood conservation strategy. [33]

Contradictory to the intra-operative findings it was noted in our study that the post-operative allogeneic transfusions were slightly higher among the neurosurgical patients who underwent ANH and PAD, and also TAAA patients who were transfused with intra-operatively salvaged autologous blood. But, in the vascular surgical group which underwent ANH, the post-operative allogeneic blood component usage was also lower compared to their controls who received conventional allogeneic transfusion. But, Segal *et al* report in their meta-analysis that the risk of allogeneic transfusion was similar among patients receiving ANH and those receiving usual transfusion practices. [78]

Among the neurosurgical patients, autologous transfusion was feasible in cases like intracranial meningioma, schwannoma, arterio-venous malformations, and spinal surgeries. Multiple studies show successful autotransfusion in meningiomas, intra-cranial aneurysms, and spine surgeries, hence making them suitable for autologous transfusion. [30,66,77] It was noted in our study that clival chordoma, being locally invasive, was not ideal for autologous transfusion as there is a very high propensity for uncontrolled bleeding which in turn may require many units of additional allogeneic blood and blood products. [79] In our study, the patients in the allogeneic transfusion group who underwent clival chordoma excision also suffered rapid and increased blood loss. Chin *et al* report the

increased risk of internal carotid artery injury in endoscopic endonasal surgeries like that of clival chordoma excision which in turn can lead to increased blood loss and massive transfusion. [80]

Among the patients from vascular surgery, it was noted in our study that ANH was feasible in infra-renal abdominal aortic aneurysms, thoracic mass lesions, carotid as well as subclavian artery aneurysm. Intra-operative requirement of allogeneic PRBC, FFP, and RDP was lesser in the group in which ANH and autologous transfusion were practiced. But, in the post-operative period, the requirement of additional allogeneic PRBC was noted to be slightly higher than the group which received conventional allogeneic transfusion, but was not statistically significant. Droz *et al* reported in their study that just as in our study, the intra-operative allogeneic transfusion requirement was reduced in patients who underwent ANH. But, contradictory to our study, they observed that there was a decrease in allogeneic blood transfusion in these patients during the post-operative period also. [81]

The intraoperative allogeneic blood and blood product utilization in thoraco-abdominal aortic aneurysm (TAAA) cases showed that despite marked blood loss, the group which received intra-operatively salvaged blood required significantly lesser units of allogeneic blood and blood products. But, just as in the case with the group which underwent ANH, those aneurysm patients who received intra-operatively salvaged blood utilized more units of blood and blood products in the post-operative period. Alvarez *et al* also describe that cell salvage did not reduce the amount of peri-operative allogeneic transfusions in abdominal vascular surgeries. [69] A review article by Shantikumar *et al* which took into consideration 23 studies also found that cell salvage autotransfusion in abdominal aortic aneurysm surgery has significantly reduced the requirement of allogeneic blood transfusion in both elective cases as well as in ruptured aneurysms. [82] Torella *et al* suggest that a combination of ANH and ICS would suffice all the intra-operative blood necessity and may render crossmatching unnecessary, even in aortic aneurysm surgery. [83]

We compared hematological parameters like hemoglobin, hematocrit, platelet count, and INR values between the autologous and allogeneic transfusion groups. Among the neurosurgical and vascular surgical patients who underwent ANH, there was a statistically significant decrease in post-operative hemoglobin and hematocrit values in both autologous and allogeneic transfusion groups. The autologous transfusion group had a lower mean Hb and HCT compared to the allogeneic group. A similar observation was

made by Oppitz *et al* among neurosurgical patients.^[30] This could be due to the liberal use of allogeneic PRBCs in the latter group compared to the restrictive transfusion practice seen in the former group in order to minimize allogeneic transfusions. But, in our study, the mean post-operative values on the day of surgery, the first day, and the fifth day after surgery in both groups were within the normal physiological range. This finding is similar to that reported by Dai *et al* who mentions that hemoglobin and hematocrit levels were within the normal range before and after autologous blood donation, transfusion, and before discharge in patients undergoing elective cardiac surgery.^[28]

On analysis of the TAAA cases which underwent ICS and conventional allogeneic transfusion, the pre-and post- transfusion Hb and hematocrit values were comparable between the two groups in our study. It was also noted that in both the groups there was a significant decrease in the mean Hb and hematocrit values in the post-operative period when compared to the pre-operative values. Similarly, Cheriyan *et al* report in a meta-analysis that there was a moderate drop in hemoglobin levels post-operatively in patients receiving salvaged blood compared to those who did not receive it.^[84] This depicts that the use of ICS has no added advantage on the Hb and hematocrit levels of the patient. Contrary to our finding, Liu *et al* reported that no significant differences were noted in neither hemoglobin nor hematocrit levels in the post-operative period between the group which received salvaged autologous blood and the group which received a routine allogeneic transfusion.^[85]

Taking into consideration the platelet count and INR, it has been noted that despite having few statistically significant differences between the autologous and allogeneic groups among the neurosurgical and vascular surgical patients, all the values were within the normal range. Smith *et al*, in their study regarding coagulation test changes associated with ANH in cardiac surgery, found that the platelet counts, as well as PT/INR values, were within the normal range.^[86] A similar report was made by Mladinov *et al* among thoracic aortic aneurysm patients.^[87] Droz *et al* describe that in their study, that ANH in open aortic aneurysm repair had beneficial outcomes related to coagulation such as a rise in platelet count and a decrease of international normalized ratio (INR).^[81]

We also compared blood loss between the two groups and found that the mean volume of blood lost intra-operatively remained comparable in the group that received autologous blood as well as in those who received purely allogeneic transfusions. This finding is

consistent with a study by Oppitz *et al* who reported that intraoperative blood loss and operative time were comparable between neurosurgical patients who underwent autologous as well as allogeneic transfusions. [30] Guo *et al*, in their study, found that perioperative blood loss was not significantly different between groups that received autologous and allogeneic transfusion. [35]

Various post-operative outcomes like duration of ICU stay, need for re-exploratory surgery due to post-operative bleeding, duration of mechanical ventilation, and rate of post-operative infection were compared between the autologous and allogeneic transfusion groups. All these outcomes were comparable among the patients who underwent neurosurgical and vascular surgical procedures in whom ANH and PAD were carried out. A similar observation was made by Oppitz *et al* stating that the incidence and grade of complications and length of hospital stay were similar between groups that obtained autologous transfusion by ANH and their allogeneic controls. [30] An observation by Dai *et al* reported that the duration of ICU stay was significantly reduced in those patients who underwent autologous transfusion. [28] Wolowczyk *et al*, in their study, bring out that only 18% of the patients in the ANH group had post-operative complications compared to 45% in the allogeneic transfusion group. [76] Another study by Droz *et al* illustrates that those patients who underwent ANH for open abdominal aneurysm repair had a shorter hospital stay compared to their controls who received allogeneic transfusion. [81] Mladinov *et al* in their study describe that peri-operative outcomes like mean ICU stay, duration of mechanical ventilation, re-operation for post-operative bleeding, and need for renal replacement therapy were comparable in those thoracic aortic aneurysm repair patients in whom ANH was performed vs. not performed. [87]

Senarslan *et al* describe that similar in-hospital morbidity and mortality rates were noted in patients who utilized ICS as well as those patients who did not. [88] But, in our study, in the TAAA patients who utilized ICS it was shown that the mean ICU stay duration and requirement for re-exploration for post-operative bleeding were reduced significantly compared to those patients who received conventional allogeneic transfusion. A 16-year retrospective study with 2012 patients by Kiser *et al* comparing “low Cell Salvage” (salvaged units <40, and “high cell salvage” (salvaged units \geq 40) portrays that there was an incremental risk of renal failure and 30-day mortality proportional to the number of salvaged cell units. [89]

In those patients who received autologous transfusion alone, there were no transfusion reactions reported. A similar observation was made by Dai *et al* where there were no adverse reactions during the autologous blood transfusion process in elective cardiac surgery patients.^[28] The various transfusion reactions reported were FNHTR, allergic transfusion reaction, and TAD – all in patients who received allogeneic blood/ blood product transfusion. A meta-analysis by Segal *et al* also illustrates that there were no transfusion reactions in those patients who obtained autologous blood alone. In their study also, they encountered transfusion reactions in patients who required additional blood or blood products.^[78]

We discarded 1 whole blood unit collected by ANH from a patient with a thoracic mass lesion after his intra-operative frozen section biopsy revealed a high-grade spindle cell carcinoma. No other units collected by ANH were discarded. On the other hand, 2 PRBC, 9 FFP, and 2 RDP units which were collected by PAD and separated were discarded. An Italian national survey reported by Catalano *et al* portrays that about 50% of the pre-deposited autologous blood was discarded as they were not used.^[90] A multi-center study by García-Erce *et al* also highlights the high discard rates (38%) of pre-deposit autologous blood in patients undergoing spinal surgery.^[91] In our study also, the discards were of spinal surgery patients. Autologous blood discards can also cause an added financial burden to the patient.^[92] Hence, it is ideal to employ PAD in patients with rare blood groups or those who have any alloantibodies in whom it is difficult to obtain allogeneic blood.^[22] In our study, one case of meningioma had alloantibody anti-e, against e-antigen, a high prevalence antigen belonging to the Rh blood group system. We collected 2 units of autologous blood as PAD and proceeded with the surgery. The 2 autologous units were transfused. The patient did not require any additional allogeneic blood.

The autologous blood transfusion programme made a marked impact on our blood inventory by helping us to save precious allogeneic blood to be used by patients who were not fit for autologous blood collection and transfusion. Moreover, this study was carried out during the global COVID-19 pandemic. Even amidst a dire acute shortage of blood donors, the autologous transfusion service catered to the needs of the patients and the postponement of surgeries due to the reason of “blood shortage” could be avoided in our institute. Hence, it was also proven that autologous blood transfusion can be safely carried out during an acute shortage of blood or during any pandemic situation.



SUMMARY

A randomized controlled trial was carried out among patients undergoing surgical procedures in neurosurgery and vascular surgery over a period of 15 months. Our main aim was to study the effects of autologous blood collection and transfusion among our study participants. 141 patients were categorized into Group I and II which comprised patients who received autologous and allogeneic transfusions respectively.

We employed PAD, ANH and ICS as the autologous blood collection modalities. Pre-deposited autologous blood was collected and stored in the blood centre. ANH was performed in the operating room and blood was kept there until transfusion. ICS was performed only in TAAA cases as they almost always experienced massive blood loss.

We studied the effects of autologous blood collection in our study subjects and found that autologous blood collection is a safe procedure and can be carried out by trained personnel.

Also, when we compared the requirement of allogeneic blood, it was also seen that the majority of the patients who underwent autologous transfusion did not require additional allogeneic blood. The mean requirement of allogeneic blood among those in the autologous transfusion group who required additional allogeneic blood was comparable or in some cases, even lesser than in the control group who received allogeneic transfusion alone. We observed that ICS played a great role in reducing allogeneic blood transfusions.

We also studied the effect of autologous transfusion on Hb, hematocrit, platelet count and INR and found that all these parameters were within normal limits and not significantly different from the allogeneic transfusion group.

On studying the post-operative outcomes like duration of ICU stay, need for re-exploratory surgery due to post-operative bleeding, duration of mechanical ventilation, and rate of post-operative infection, we observed that all these outcomes were comparable between the autologous and allogeneic transfusion groups among the patients who underwent neurosurgical and vascular surgical procedures in whom ANH and PAD were carried out. But, the TAAA patients who utilized ICS had a reduced mean ICU stay duration and requirement for re-exploration for post-operative bleeding compared to those patients who received conventional allogeneic transfusion alone.

There were no transfusion reactions in those patients who were given autologous transfusion alone.

We observed that ANH is an ideal modality of auto-transfusion. It reduces the overall requirement of allogeneic blood components. PAD, on the other hand, requires keen planning and has more probability of blood discards which augments the economic burden. ICS can be advantageous in those patients expected to bleed massively by decreasing the intraoperative allogeneic blood transfusion.

Autologous blood transfusion aids in preventing postponement of surgeries due to acute blood shortage or unavailability of crossmatch compatible blood, as in the case with rare blood groups or alloimmunization to red cell antigens. It also helps in maintaining Blood Centre inventory.



CONCLUSION

- Acute normovolemic hemodilution (ANH) and pre-deposit autologous donation (PAD) can be carried out safely without any significant hemodynamic changes in the donor-patient.
- The requirement of allogeneic blood and blood components intra-operatively are much lesser in those patients who received autologous blood transfusion. Blood loss was comparable between patients undergoing autologous as well as allogeneic transfusions.
- Hemoglobin, hematocrit levels and parameters of coagulation like platelet count and INR values were within the normal range before and after autologous blood donation and transfusion.
- Duration of ICU stay, need for re-exploratory surgery due to post-operative bleeding, duration of mechanical ventilation and rate of post-operative infection were similar in both the autologous and allogeneic transfusion groups.
- Autologous blood transfusion aided in saving Blood Centre inventory to a significant extent.



LIMITATIONS

1. Our institute does not have various surgical specialties like Orthopedics and Obstetrics & Gynecology, but is limited to Neurosurgery and Cardiothoracic and Vascular Surgery. Hence the study population was limited to these two specialties only.
2. The study was carried out during a short period, that too amidst the COVID-19 pandemic. Thus, the number of participants recruited for the study was less.
3. We followed up with the patients only up to 5 days post-operatively, failing inability to assess the long-term effects.
4. Even though we were able to strike a balance between the groups on known factors, we are unable to account for unmeasured confounders.



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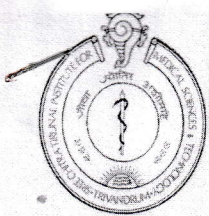
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ANNEXURE



Technical Advisory Committee (Clinical Studies)
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2020/1093

Date: 21.08.2020

Project title: AUTOLOGOUS VERSUS ALLOGENEIC BLOOD TRANSFUSION: A COMPARATIVE STUDY OF THE PERI-OPERATIVE OUTCOMES IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA

Principal Investigator:	
Dr. Angel Mary Sam, Junior Resident, Department of Transfusion Medicine, SCTIMST	Degree: MBBS
Co-Principal Investigator(s):	
Dr. Debasish Gupta, Professor and Head, Dept. of Transfusion Medicine SCTIMST	Degree: MD Transfusion Medicine
Dr. Manikandan S., Professor and Head, Dept. of Neuroanaesthesia, SCTIMST	Degree: MD Anaesthesia, PDCC Neuroanaesthesia
Dr. Krishnakumar K., Professor, Dept. of Neurosurgery, SCTIMST	Degree: MS General Surgery MCh Neurosurgery
Dr. Prasanta Kumar Dash, Professor, Dept. of Anaesthesia, SCTIMST	Degree: MD Anaesthesia PDCC Neuro and Cardiac Anaesthesia
Dr. Vivek V. Pillai, Additional Professor, Department of CTVS, SCTIMST	Degree: MS General Surgery MCh CTVS, Fellow- AATS Graham EHM Valve
Dr. Amita R., Assistant Professor, Dept. of Transfusion Medicine, SCTIMST	Degree: MD Pathology DNB Pathology

Members who participated in the TAC meeting on 20/06/2020

Dr Harikrishnan S (Chairman)
Dr Manikandan S
Dr Narayanan Namboodiri
Dr Jayadevan E R
Dr Sylaja P N
Dr Ramshekhar N Menon
Dr Unnikrishnan K P
Dr Syam K
Dr Sanjay G
Dr Deepti A N
Dr Sabarinath Menon
Dr Jayanand Sudhir B
Dr Srinivas G (Member Secretary)

Dr Sabarinath Menon, Dr Ramshekhar N Menon, Dr Sylaja P N, Dr Deepti A N, Dr Manikandan S, Dr Narayanan Namboodiri, Dr Srinivas G, Dr Sanjay G, Dr Harikrishnan S, Dr Unnikrishnan K P, Dr Syam K and Dr Jayadevan E R stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#1072, 1087, 1089, 1092, 1093, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1103, 1107, 1108, 1111, 1113, 1114, 1116, 1118, 1119, 1120, 1121, 1122, 1123, 1127, 1129, 1130)

Risk Classification of the project (Minimum/ Moderate/ High): High

Requirement of DSMB: Yes

Recommended members of DSMB:

1. Dr. Rupa Sreedhar, Professor Senior Grade, Department of Anesthesia, SCTIMST
2. Dr. Subin Sukesan, Associate Professor, Department of Anesthesia, SCTIMST
3. Dr. George C. Vilanilam, Additional Professor, Department of Neurosurgery, SCTIMST
4. Dr. Dinoop K. P., Assistant Professor, Department of Microbiology, SCTIMST
5. Dr. Soumya Ramanan V., Assistant Professor, Department of CTVS, SCTIMST

Recommendations of TAC:

Recommended for consideration of IEC in the light of the responses received from the investigator
The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.


Dr Srinivas G

MEMBER SECRETARY
TAC (Clinical Studies)

Note for IEC **SCTIMST**

Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).

Appendix-1

1. Three types of autologous transfusion: Acute normovolemic hemodilution (ANH), Intra-operative Cell salvage and pre-deposit autologous transfusion For ANH: 15-20ml/kg will be collected after induction of anaesthesia This will be 900-1000ml in 60-70 kg patients with simultaneous infusion of crystalloids. Feasibility of ANH.

Answer: In Acute normovolemic hemodilution (ANH) modality, blood will be collected based on the body weight, total blood volume, haemoglobin concentration, initial haematocrit and expected final haematocrit. It will not be performed by exclusively taking into consideration the patient's body weight alone. Moreover, the purpose of this method is to bring down the haematocrit of the patient by withdrawing his/her blood and induce hemodilution by simultaneous infusion of crystalloids or colloids. This will cause loss of diluted blood during surgery and hence the net blood loss is minimized. The patients will also have their own blood in its original concentration, which can be used instead of allogeneic blood. So, for example, if a moderately built, male patient planned for ANH weighs 60 kgs and has a haemoglobin concentration of 15g/dL and haematocrit of 45%, his blood volume will be about 4200 mL (70mL/kg). The volume of the blood collected will be determined by the following formula:

$$V = EBV \times (H_o - H_f) / H_{av}$$

Where V = Volume of blood collected, EBV = Patient's estimated blood volume (70ml/kg), H_o = Patient's initial Hematocrit, H_f = Patient's final (Desired) Hematocrit after hemodilution (30%), and H_{av} = Average of initial and final Hematocrit.

So, in this example, if we want to bring down the haematocrit to 35%, the volume of blood which can be collected will be 1050 mL (by substituting the above formula). We use 350mL blood bags for blood collection. So, 350 mL will be considered as one unit of blood. In this patient we can withdraw up to 3 units of whole blood. For each unit of blood collected, the patient's haemoglobin will drop by 1g/dL. So, in this case, if 3 units of blood is collected, his haemoglobin level will drop to 12g/dL and hemodilution will cause further drop. This is totally safe for the patient as he will be hemodynamically stabilized with the simultaneous infusion with crystalloids/colloids. The blood loss will be relatively less during surgery and 3 units of his own blood is readily available for transfusion when need arises. Hence, ANH is a feasible modality and is practiced worldwide.

2. For Vascular surgery patients: Intra-operative Cell salvage using Cell saver will also be used (i) Is this method already being used in some of the patients in the Institute? If no, is the equipment available and are the Staff experienced in the technique? (ii) What will be the approximate cost of disposables per patient? How will it be charged?

Answer: Yes, this modality is currently being used at least more than twice a month in the department of CTVS, mainly for Vascular surgery cases in which massive blood loss is anticipated, e.g. cases of aortic aneurysm surgeries. Rates are already fixed by the institute and the patient will be charged accordingly (Code: DSATR12- Rs.8000/-).

[One unit of allogenic Packed Red Cells cost Rs. 1300. Using Cell Saver, we can collect 5 to 7 units of blood at least, thereby making the charges comparable, with an added advantage that the patient receives his/her own blood and is free from any adverse effect of allogeneic transfusion.]

3. For Acute normovolemic hemodilution, what is the reason for performing autotransfusion in the reverse order: last collected unit will be transfused first?

Answer: As time elapses, the activity of the platelets and other clotting factors tend to decrease. In order to provide the most active blood components to the patient, it would be best to transfuse the last collected unit first which has more viable platelets and clotting factors than the first collected unit. This ensures better haemostasis and has beneficial effect on the patient.

4. Group II: The hemoglobin values will be measured again after blood drainage, hemodilution, at maximum surgical blood loss and after re-transfusion Group I: hemoglobin will be measured at maximum surgical blood loss and after transfusion of allogeneic blood Is it feasible to measure hemoglobin at maximum surgical blood loss. Is haemoglobin normally measured multiple times during surgery?

Answer: Yes, it is feasible to measure haemoglobin multiple times and it is normally measured like that. All these patients have central venous and arterial accesses established by the anaesthetists. They routinely perform Arterial Blood Gas (ABG) analysis multiple times during the surgery, from which haemoglobin levels can be assessed, on which the red cell transfusions are based on.

5. Brief review of status of research and development in the subject The international, national and current status and Expertise available have to be indicated.

Answer:

International

In a quasi-experimental trial by Yang et al in China in 2017, they came to the conclusion that patients undergoing excision of intracranial meningioma, ANH is an effective procedure to reduce the need for allogeneic transfusions. (Medicine. 2017 Sept; 96(38): 8093-8095)

J.I Spark et al, in the study conducted in UK titled "Allogeneic versus autologous blood during abdominal aortic aneurysm surgery" concluded that cell salvage autologous blood can safely replace, or at least decrease, exposure to homologous blood transfusion, with a reduction in the mean hospital stay. (Euro J Vasc Endovasc Surg. 1997 Dec; 14(6):482-486)

National

H. Patil et al, in "Clinical Experience of Autologous Blood Transfusion in Neurosurgery: Prospective Study in Central India" brought out that autologous blood transfusion is a safe, effective, and affordable method of blood transfusion in patients undergoing intracranial surgery. Complications associated with homologous blood transfusion can be avoided with autologous blood transfusion. (World Neurosurg. 2018 Jul; 115: 539-543)

In the 2000, preoperative autologous donation and Acute normovolemic haemodilution were found to be very safe, viable and practicable alternatives to allogenic transfusion by YV Machave. (Med J Armed Forces India. 2000 Apr; 56(2): 93-94)

Sankalp India foundation, based in Bangalore is providing opportunities for autologous blood donation/transfusion (<http://www.sankalpindia.net/book/autologous-blood-donation>)

The National Blood Transfusion Council of India (NBTC) under the MoHFW, GoI also advocates the importance of Autologous blood transfusion and has put forward guidelines regarding patient selection and the procedure to be carried out. (Standards for Blood Banks & Blood Transfusion Services. NACO. 2007; 83-86)

Importance of the Proposed Project in the Context of Current Status:

There is a huge shortage of voluntarily donated blood as compared to the requirement. COVID- 19 has also made an additional impact on the already existing blood shortage. So, if those patients who will be able to accept autologous transfusions can go about with it with lesser or no allogeneic transfusion requirement, the existing allogeneic blood available in the Blood Centre can be easily used by those patients who do not fit into the criteria for autologous blood transfusion

Expertise available

The autologous blood transfusion programme was in existence in our institute as a part of the patient blood management practice. Of late, there has been a decline in this practice. With this thesis project we are trying to revive the practice.

1. Pre-deposit autologous donation will be carried out in the blood bank or ward as per patient willingness. The blood collection procedure is exactly the same as how it is being done on blood donors and the staff are experts in phlebotomy. Stock will be maintained in the blood bank.
 2. ANH will be carried out only in the presence of Anaesthesiology experts and hence all the hemodynamic parameters will be monitored and stabilized as and when required. Moreover, Autologous transfusion is a part of curriculum on blood conservation and patient blood management and hence they have expertise in the procedure
 3. Intraoperative Cell Salvage is already being done on vascular surgery patients who undergo massive blood loss. The perfusionists in our operating rooms are well trained to operate the Cell Saver.
6. Which are the surgeries that have >20% loss of blood? There is sufficient literature on this. Should a prospective study, that too high risk, be done? The investigator may be called for a presentation

Answer: 20% of the estimated blood volume of a 60kg person would come around 840mL. This loss is not unusual in our surgical departments as we carry out a good number of major surgeries. Hence this is not of any high risk. Moreover, autologous blood transfusion is being practiced worldwide, especially in those patients who do not consent for allogeneic blood transfusion. Investigator is ready to give a presentation before the members of the TAC at any date of their convenience.



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेंद्रम - 695 011, केरल, भारत
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
TRIVANDRUM - 695 011, KERALA, INDIA
(एक राष्ट्रीय महत्व का संस्थान, विज्ञान एवं प्रौद्योगिकी विभाग, भारत सरकार)
(An Institution of National Importance, Department of Science and Technology, Government of India)
टेलीफॉन नं./Telephone No.: 0471-2443152 फैक्स/Fax: 0471-2446433, 2550728
ई-मेल/E-mail: sct@sctimst.ac.in वेबसाइट/Website: www.sctimst.ac.in



Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1591 /NOVEMBER-2020

28.12.2020

Dr. Angel Mary Sam
Pursuing MD (Transfusion Medicine)
Department of Transfusion Medicine
SCTIMST, Thiruvananthapuram

Dear Dr. Angel Mary Sam,

Thank you for submitting documents related to your proposal titled **“AUTOLOGOUS VERSUS ALLOGENEIC BLOOD TRANSFUSION: A COMPARATIVE STUDY OF THE PERI -OPERATIVE OUTCOMES IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA (IEC/1591)”** to the IEC for review.

The following documents were reviewed:

1. Covering letter addressed to Chairman, IEC, SCTIMST dated 27.08.2020
2. Check list (No check list attached)
3. TAC Approval with Comments and responses
4. Singed IEC Application Form
5. Project Proposal
6. Proforma
7. Project Proposal
8. Signed CV of PI, Dr. Angel Mary Sam with TCMC Registration number
9. Signed CV of Dr. Debasish Gupta with WBMC Number
10. Signed CV of Dr. Manikandan with TCMC Number
11. Signed CV of Dr. Krishnakumar with TCMC Number
12. Signed CV of Dr. Prasanta Kumar Dash with TCMC Number
13. Signed CV of Dr. Viviek Pillai with TCMC Number
14. Signed CV of Dr. Amita with TCMC Number
15. Information Sheet in English
16. Information Sheet in Malayalam
17. Informed Consent Form in English
18. Informed Consent Form in Malayalam
19. Declaration Form
20. DSMB Members list with signature

The following members of the Students Sub-Committee of the Institutional Ethics Committee participated in the discussions held between August 23-October 29, 2020 at the offices and residences of the members

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
5.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
6.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
7.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,



Mala Ramanathan

Member Secretary, IEC

PLAGIARISM REPORT



Document Information

Analyzed document	Auto vs Allo transfusion (Plagiarism).docx (D142260155)
Submitted	7/21/2022 5:30:00 AM
Submitted by	
Submitter email	amita.rnair@sctimst.ac.in
Similarity	2%
Analysis address	a.rnair.sctims@analysis.orkund.com



PROFORMA**Autologous Versus Allogeneic Blood Transfusion: A Comparative Study Of The Peri-Operative Outcomes In A Tertiary Care Hospital In South India****1. Patient Details:**

Group I		Group II	
Age		Gender	
Weight		Blood Group	
Diagnosis/ Procedure			
Date of surgery			

The proforma is divided into Part A, Part B and Part C which consists of the pre-operative, intraoperative and post-operative data respectively.

PART A (Pre-Operative Data)**A.1 Investigations**

DATE					
Hb			LFT		
TC			ALP		
DC			SGOT/ SGPT		
Platelet			LDH		
Hematocrit			Total protein		
ESR			S. Albumin		
FBS			S. Globulin		
PPBS			A/G ratio		
HbA1C			S. Bilirubin Total/ Direct		
RFT			Coagulation Profile		
S. Creatinine			PT		
S. Urea			INR		

Na ⁺			APTT		
K ⁺			Lipid Profile		
Cl ⁻			Tot. Chol.		
Ca ²⁺			TG		
Phosphorous			HDL		
Ammonia			LDL		
			VLDL		
			ABG		

SEROLOGY	
• HIV	
• HBsAg	
• HCV	
• VDRL	
Culture & Sensitivity	
• <u>Blood</u>	• <u>Urine</u>

A.2. Total Blood Volume =

A.3. Total body surface area =

A.4. Total Plasma Volume =

A.5. Planned modality of blood transfusion:

- Autologous []
 - i. Pre-deposit
 - ii. Acute Normovolemic Hemodilution
 - iii. Intraoperative cell salvage

- Allogenic []

A.5.a. If Pre- deposit autologous donation being done,

	1 st Collection (/ /20)		2 nd Collection (/ /20)	
	<i>Before donation</i>	<i>After donation</i>	<i>Before donation</i>	<i>After donation</i>
Heart Rate				
Blood Pressure				
Mean Arteriolar Pressure				
Respiratory Rate				
SPO₂				
Temperature				

Reactions, if any, during/after donation:

A.5.b. Volume of Blood collected as pre-deposit=

A.5.c. No. of blood units collected =

PART-B (Intraoperative Data)

B.1. If Acute Normovolemic Hemodilution (ANH) is performed,

	1 st unit Collection		2 nd unit Collection	
	<i>Before collection</i>	<i>After collection</i>	<i>Before collection</i>	<i>After collection</i>
Heart Rate				
Blood Pressure				
Mean Arteriolar Pressure				
Hb				
SPO₂				
Volume infused				

Reactions, if any, during/after blood collection:

.....

B.2. Temperature

Pre-Operative	Intraoperative	Postoperative

B.3. Volume of blood lost =

B.4. Urine Output =

B.5. Fluid infusion volume=

B.6. Modality of Blood Transfusion (Encircle the appropriate)

<i>Allogenic Blood</i>	<i>Autologous Blood</i>			
		Pre-deposit	ANH*	Intra-operative cell salvage
a) No. of Units used:	a) Units collected	NA		
	b) Volume collected (mL)	NA		
b) Volume used:	c) Units Used			
	d) Volume used (mL)			

*Acute Normovolemic Hemodilution

B.7. Operative time =

B.8. No. of Blood units saved in Blood Bank Inventory (if autologous transfusion practiced) =

B.9. No. of autologous blood units discarded=

PART-C (Postoperative Data)

C.1 Investigations

DATE								
Hb								
TC								
DC								
Platelet								
Hematocrit								
ESR								
FBS								
PPBS								
HbA1C								
RFT								
S. Creatinine								
S. Urea								
Na ⁺								
K ⁺								
Cl ⁻								
Ca ²⁺								
Phosphorous								
Ammonia								
LFT								
ALP								
SGOT/ SGPT								
LDH								
Total protein								
S. Albumin								
S. Globulin								
A/G ratio								

S. Bilirubin Total/ Direct								
Coagulation Profile								
PT								
INR								
APTT								
Lipid Profile								
Tot. Cholesterol								
TG								
HDL								
LDL								
VLDL								
ABG								

Culture & Sensitivity	
• <u>Blood</u>	• <u>Urine</u>

C.2. Total no. of days in ICU =.....

C.3. Infections post-operatively within 5 days.....

C.4. Hours of Mechanical ventilation

C.5. Re-exploration due to bleeding



**Sree Chitra Tirunal Institute For Medical Sciences And Technology,
Thiruvananthapuram -11**

Department Of Transfusion Medicine

INFORMATION SHEET

Title of the study:

Autologous Versus Allogeneic Blood Transfusion: A Comparative Study Of The Peri-Operative Outcomes In A Tertiary Care Hospital In South India

1. What is this study about?

Patients who undergo surgery may require blood transfusion to compensate for the excess blood loss. The blood for transfusion may be obtained either from the blood bank which is collected from voluntary blood donors (allogeneic blood) or on fulfilling certain eligibility criteria your own blood (autologous blood) may be used.

In this study we plan to compare the peri-operative outcomes of the patients who receive solely autologous blood versus those who receive allogeneic blood.

Once you consent to be a part of this study, you will be randomly allocated to either of the two groups for blood transfusion, the details of which are given below.

We hope to include in this study about 140 patients undergoing surgery and receiving transfusion in this hospital.

2. What are the advantages and disadvantages of autologous blood transfusion?

When your own blood is transfused back to you there is least chances of acquiring transfusion transmitted infections (like HIV, Hepatitis B and C, Malaria and Syphilis) and development of allergic reactions. Studies have also shown that the post- operative infections and hospital stay is considerably reduced when your own blood is used for transfusion. In patients who have rare blood groups or antibodies it becomes difficult to find compatible blood units in the blood bank. Autologous blood donation solves that problem.

The disadvantages are that not all patients will satisfy the eligibility criteria for donation of autologous blood. Also, it requires a proper planning well ahead of the surgery and hence cannot be practiced for emergency surgeries. Allogeneic blood might be required in addition to your own blood if there is unanticipated blood loss. Iron supplementation may be required in some patients to maintain the hemoglobin levels.

3. What are the advantages and disadvantages of allogeneic blood transfusion?

The main advantage of allogeneic blood is that it is readily available in the blood bank to meet even emergency requirements.

Although we take all precautionary measures, there underlies a possibility of the transmission of transfusion transmissible infections. Also, allogeneic blood carries a risk of allergic reactions which are usually mild but can sometimes be fatal. There is a risk for immunological response to the donor antigens (alloimmunization).

4. If I take part in this study what will I have to do?

Once you give consent to take part in this study, you will be randomly allotted into the group receiving either autologous blood or allogenic blood.

If you are allotted into the Autologous transfusion group, blood will be collected from you by either of the following three modalities depending on your general health condition and the type of surgery.

- i) Donation of your blood units in the blood bank one or two weeks prior to your surgery and then utilizing the pre-donated units during or after your surgery, as per the requirement. In this case, routine investigations (blood grouping, typing, antibody screening and, HIV, Hep B, Hep C, Malaria and Syphilis testing) will be carried out in the blood bank. You will also be given Iron tablets to help maintain your haemoglobin levels.
- ii) Collection of your blood immediately prior to your surgery, in the Operation Theatre and replacing the collected volume with intravenous fluids to maintain your blood volume. The collected blood will be transfused when a need for blood arises during or after surgery.
- iii) The blood that you lose during surgery would be collected into a cell saver machine which will filter and the washed unit will be transfused back to you.

All these modalities will be carried out under strict medical supervision.

You should also be aware that you will be given conventional allogenic blood in case the autologous blood collected does not suffice for your requirements.

5. If I do not require my blood, can someone else have it?

In case you do not need transfusion of your own blood it cannot be given to another patient.

6. Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

7. What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you.

8. Will you have to pay if you participate in this study?

Charges for blood transfusion (allogenic or autologous) are already in existence in our hospital and you will be charged accordingly.

9. Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please contact:

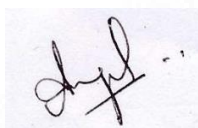
- Dr. Angel Mary Sam, Junior Resident, Department of Transfusion Medicine, SCTIMST (Ph: 9495477504/ 0471-2524636 email: angelmary.sam@sctimst.ac.in)
- Dr. Debasish Gupta, Professor and Head, Department of Transfusion Medicine, SCTIMST (Ph: 0471-2524177, email: dgupta@sctimst.ac.in)

Name of the Principal Investigator: *Dr. Angel Mary Sam*

Address and Contact Details:

Junior Resident, Department of Transfusion Medicine, SCTIMST

Ph: 9495477504/ 0471-2524636, email: angelmary.sam@sctimst.ac.in



Signature of the PI:

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of the SCTIMST-IEC. The phone number is: 0471-2524234 and the email id is: iec.mem.sec@sctimst.ac.in

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി

ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ വിഭാഗം

കാര്യവിവരണപത്രം

പഠനശീർഷകം: സ്വന്തം രക്തവും (ഓട്ടോലോഗസ്) അന്യരുടെ രക്തവും (അലോജനിക്) രക്ത പകർച്ചകൾ തമ്മിൽ: തെക്കേ ഇൻഡ്യയിലെ ഒരു ടെർഷ്യറി പരിചരണ ആശുപത്രിയിലെ ശസ്ത്രക്രിയയാനന്തരഫലങ്ങളുടെ താരതമ്യം

1. എന്തിനെപ്പറ്റിയാണ് ഈ പഠനം?

ശസ്ത്രക്രിയയ്ക്ക് വിധേയരാവുന്ന രോഗികൾക്ക് അമിതമായുണ്ടാകുന്ന രക്തനഷ്ടം പരിഹരിക്കാൻ രക്തം പകരേണ്ടിവരും. സ്വയമേവ രക്തം ദാനം ചെയ്യുന്നവരിൽനിന്ന് രക്തബാങ്കിൽ ശേഖരിക്കുന്ന അന്യരുടെരക്തം (അലോജനിക് രക്തം) അല്ലെങ്കിൽ ചില യോഗ്യതാ മാനദണ്ഡങ്ങൾ പൂർത്തിയാക്കുന്ന താങ്കളുടെ സ്വന്തം രക്തമോ (ഓട്ടോലോഗസ് രക്തം) പകർച്ചയ്ക്കായി ഉപയോഗിക്കും.

ഈ പഠനത്തിൽ പൂർണ്ണമായും സ്വന്തം രക്തം സ്വീകരിക്കുന്ന രോഗികളെയും അലോജനിക് രക്തം സ്വീകരിക്കുന്ന രോഗികളെയും തമ്മിൽ ശസ്ത്രക്രിയാസമയത്തെ ഫലങ്ങൾ താരതമ്യം ചെയ്യാൻ ഈ പഠനത്തിൽ ഞങ്ങൾ ആസൂത്രണം ചെയ്യുന്നു.

താങ്കൾ ഈ പഠനത്തിന്റെ ഭാഗമാകാൻ സമ്മതിച്ചാൽ, താങ്കളെ ക്രമാനുഗതമല്ലാതെ രക്തപകർച്ചയ്ക്കുള്ള താഴെ വിശദമാക്കിയിട്ടുള്ള രണ്ട് സംഘങ്ങളിലൊന്നിൽ ഉൾപ്പെടുത്തും.

ഈ ആശുപത്രിയിൽ ശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകുന്ന, രക്ത പകർച്ച സ്വീകരിക്കുന്ന 140 രോഗികളെ ഈ പഠനത്തിലുൾപ്പെടുത്താമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നു.

2. സ്വന്തം രക്തം സ്വീകരിക്കുന്നതിന്റെ നേട്ടങ്ങളും കോട്ടങ്ങളും എന്തെല്ലാം?

താങ്കളുടെ സ്വന്തം രക്തം തിരിച്ച് സ്വീകരിക്കുമ്പോൾ രക്തപകർച്ചയിലൂടെ ഉണ്ടാകുന്ന അണുബാധയ്ക്കും (എച്ച്ഐവി, ഹെപ്പറ്റൈറ്റിസ് ബിയും സിയും, മലേറിയയും സിഫിലിസും) അലർജി പ്രതികരണങ്ങളുണ്ടാകുന്നതിനും വളരെ കുറഞ്ഞ സാധ്യതയെ ഉള്ളൂ. രക്തപകർച്ചയ്ക്ക് താങ്കളുടെ സ്വന്തം രക്തം ഉപയോഗിക്കുമ്പോൾ ശസ്ത്രക്രിയാനന്തര അണുബാധയും ആശുപത്രിവാസവും കാര്യമായി കുറയ്ക്കുന്നതായി പഠനങ്ങൾ കാണിക്കുകയും ചെയ്യുന്നു. അപൂർവ്വ രക്തഗ്രൂപ്പുകളോ ആന്റി ബോധികളോ ഉള്ള രോഗികൾക്ക് ചേരുന്ന രക്തം രക്തബാങ്കുകളിൽനിന്നും ലഭിക്കാൻ ബുദ്ധിമുട്ട് കൂടിവരുന്നു. സ്വന്തം രക്തം ദാനം ചെയ്യുമ്പോൾ ആ പ്രശ്നം പരിഹരിക്കപ്പെടും.

എല്ലാ രോഗികളും സ്വന്തം രക്തം ദാനം ചെയ്യുന്നതിന് രക്തദാനത്തിന്റെ മാനദണ്ഡങ്ങൾ പ്രകാരം യോഗ്യരാകുന്നില്ല എന്നതാണ് കോട്ടം. തന്നെയുമല്ല, ശസ്ത്രക്രിയയ്ക്കുവളരെമുമ്പേ കൃത്യമായ ആസൂത്രണം ആവശ്യമാകയാൽ അടിയന്തിര ശസ്ത്രക്രിയകളിൽ നടപ്പാക്കാനും കഴിയില്ല. അപ്രതീക്ഷിതമായ രക്തനഷ്ടമുണ്ടായാൽ താങ്കളുടെ രക്തത്തോടൊപ്പം അല്ലോജനിക് രക്തവും ആവശ്യമായി വന്നേക്കാം. ചുവന്നരക്താണുവിന്റെ നിലവാരം നിലനിർത്താൻ അയണിന്റെ പോരായ്മ നികത്തേണ്ടതായും വരും.

3. അല്ലോജനീക് രക്തം സ്വീകരിക്കുന്നതിന്റെ നേട്ടങ്ങളും കോട്ടങ്ങളും എന്തെല്ലാം?

അന്യരുടെ രക്തം സ്വീകരിക്കുന്നതിലെ പ്രധാനനേട്ടം അടിയന്തിര സാഹചര്യങ്ങളിലെ ആവശ്യങ്ങൾക്കു പോലും അത് രക്തബാങ്കുകളിൽ ലഭ്യമാണെന്നുള്ളതാണ്.

നമ്മൾ എല്ലാ മുൻകരുതൽ നടപടികളും സ്വീകരിക്കുന്നുണ്ടെങ്കിലും പകരാനിടയുള്ള അണുബാധകൾക്കുള്ള സാധ്യത രക്തപ്പകർച്ചയിൽ നിലനിൽക്കുന്നു. തന്നെയുമല്ല, സാധാരണ ലഘുവായതെങ്കിലും ചിലപ്പോൾ മാതൃകവുമായേക്കാവുന്ന അലർജി പ്രതികരണങ്ങളുടെ അപായ സാധ്യതയും അന്യരുടെ രക്തത്തിൽ ഉണ്ട്. രക്തദാനം ചെയ്യുന്നവരുടെ ആന്റിജനുകളുടെ ഇമ്മ്യൂണോളജിക്കലായ പ്രതികരണങ്ങളുടെ (അല്ലോഇമ്മ്യൂണൈസേഷൻ) അപായ സാധ്യതയുമുണ്ട്.

4. ഞാൻ ഈ പഠനത്തിൽ പങ്കെടുക്കുകയാണെങ്കിൽ എന്തു ചെയ്യണം?

താങ്കൾ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിച്ചുകഴിഞ്ഞാൽ താങ്കളെ ക്രമാനുഗതമല്ലാതെ സ്വന്തം രക്തം സ്വീകരിക്കുന്നവരുടെയോ അന്യരുടെ രക്തം സ്വീകരിക്കുന്നവരുടെയോ സംഘത്തിൽ ഉൾപ്പെടുത്തും.

താങ്കളെ സ്വന്തം രക്തപകർച്ച സ്വീകരിക്കുന്നവരുടെ സംഘത്തിൽ ഉൾപ്പെടുത്തിയാൽ താങ്കളിൽ നിന്നും മൂന്ന് രീതികളിൽ ഒന്നുവഴി താങ്കളുടെ ആരോഗ്യത്തെ അടിസ്ഥാനമാക്കിയും ശസ്ത്രക്രിയയുടെ സ്വഭാവത്തിനും അനുസരിച്ച് രക്തം ശേഖരിക്കും.

- i. താങ്കളുടെ ശസ്ത്രക്രിയയ്ക്ക് ഒന്നോ രണ്ടോ ആഴ്ചകൾക്കു മുമ്പ് താങ്കളുടെ രക്തം രക്തബാങ്കിന് സംഭാവന ചെയ്യുകയും അത് താങ്കളുടെ ശസ്ത്രക്രിയയ്ക്കോ ശേഷമോ അവശ്യാനുസരണം ഉപയോഗിക്കുകയും ചെയ്യും. ഈ കാര്യത്തിൽ രക്തബാങ്കിൽ പതിവ് പരിശോധനകൾ (രക്തഗ്രൂപ്പ് നിർണ്ണയം, തരംതിരിക്കൽ, ആന്റി ബോഡി പരിശോധന, എച്ച്ഐവി, ഹെപ്പറ്റൈറ്റിസ് ബി, ഹെപ്പറ്റൈറ്റിസ് സി, മലേറിയയും സിഫിലിസും) എന്നിവ നടത്തും. താങ്കൾക്ക് ചുവന്നരക്താണുവിന്റെ നിലവാരം നിലനിർത്താൻ അയൺ ഗുളികകളും നൽകും.
- ii. താങ്കളുടെ ശസ്ത്രക്രിയയ്ക്കു തൊട്ടുമുമ്പ് ശസ്ത്രക്രിയാമുറിയിൽ വച്ച് താങ്കളുടെ രക്തം ശേഖരിക്കുകയും താങ്കളിൽനിന്നും ശേഖരിച്ച രക്തത്തിനുപകരം രക്തത്തിന്റെ അളവ് നിലനിർത്താൻ ദ്രാവകം കുത്തിവയ്ക്കുകയും ചെയ്യും. ശേഖരിച്ച രക്തം ശസ്ത്രക്രിയാസമയത്തോ ശേഷമോ ആവശ്യം വരുമ്പോൾ പകരുകയും ചെയ്യും.
- iii. ശസ്ത്രക്രിയാസമയത്ത് താങ്കൾക്ക് നഷ്ടമാകുന്ന രക്തം ഒരു സെൽസേവർ യന്ത്രത്തിൽ ശേഖരിച്ച് അത് അരിക്കുകയും കഴുകുകയും ചെയ്ത് താങ്കളിലേയ്ക്ക് തിരിച്ച് പകരും. ഈ മൂന്ന് രീതികളും നടപ്പാക്കുന്നത് കർശനമായ വൈദ്യ മേൽനോട്ടത്തിലായിരിക്കും. താങ്കളുടെ സ്വന്തം രക്തം തികയാതെ വന്നാൽ സാമ്പ്രദായികമായി അന്യരുടെ രക്തവും നൽകുമെന്നതും താങ്കൾ അറിഞ്ഞിരിക്കണം.

5. എനിക്ക് എന്റെ രക്തം ആവശ്യം വന്നില്ലെങ്കിൽ മറ്റാർക്കെങ്കിലും അത് നൽകാനാകുമോ?

താങ്കളുടെ രക്തം താങ്കൾക്ക് പകരേണ്ടി വന്നില്ല എങ്കിലും അത് മറ്റൊരു രോഗിക്ക് നൽകാനാവില്ല.

6. പഠനമാരംഭിച്ച ശേഷം താങ്കൾക്ക് പിൻമാറാനാകുമോ?

താങ്കളുടെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയായുള്ളതും സമ്മതം പിൻവലിക്കാൻ ഏതു സമയത്തും താങ്കൾക്ക് സ്വാതന്ത്ര്യമുള്ളതുമാണ്. താങ്കളുടേതായ ചെയ്താലും ഈ ആശുപത്രിയിലെ താങ്കളുടെ പതിവ് ചികിത്സയെ ഒരുതരത്തിലും ബാധിക്കില്ല.

7. പഠന സംബന്ധിയായി എന്തെങ്കിലും പരിക്ക് താങ്കൾക്കുണ്ടായാലേന്ത് സംഭവിക്കും?

ഈ പഠനത്തിൽ താങ്കൾക്ക് പരിക്കൊന്നും ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല, പക്ഷേ താങ്കൾക്കെന്തെങ്കിലും പാർശ്വഫലങ്ങളോ പ്രശ്നങ്ങളോ ഉണ്ടായാൽ താങ്കൾക്ക് ഒരു ചിലവുമുണ്ടാകാതെ ചികിത്സിക്കും..

8. പഠനത്തിനായി താങ്കൾ പണംമുടക്കണോ?

രക്തപ്പകർച്ചയ്ക്ക് (സ്വന്തരക്തമോ അന്യരുടെ രക്തമോ) നമ്മുടെ ആശുപത്രിയിൽ പണം ഈടാക്കുന്നുണ്ട്, താങ്കൾ അതിനനുസരണമായി പണം നൽകേണ്ടിവരും

9. താങ്കളുടെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായിരിക്കുമോ?

ഈ പഠനത്തിന്റെ ഫലങ്ങൾ ഒരു വൈദ്യശാസ്ത്ര ജേർണലിൽ പ്രസിദ്ധീകരിച്ചേക്കാം പക്ഷേ താങ്കളെ പേരുകൊണ്ട് പ്രസിദ്ധീകരണത്തിലോ പ്രദർശനത്തിലോ തിരിച്ചറിയാനാകില്ല. എന്നാലും പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിച്ചാൽ താങ്കളുടെ ചികിത്സാരേഖകൾ പഠനവുമായി ബന്ധപ്പെട്ടയാളുകൾ താങ്കളുടെ അധികമായ സമ്മതമില്ലാതെ അവലോകനം ചെയ്തേക്കാം.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ബന്ധപ്പെടുക

- ഡോ. ഏയ്ഞ്ജൽ മേരി സാം, ജൂനിയർ റസിഡന്റ്, ഡിപ്പാർട്ട്മെന്റ് ഓഫ് ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ, **SCTIMST** (ഫോൺ: 9495477504/ 0471-2524636 4177) ഇമെയിൽ angelmary.sam@sctimst.ac.in
- ഡോ. ദേബശീഷ് ഗുപ്ത, ഹെഡ് ഓഫ് ദ ഡിപ്പാർട്ട്മെന്റ് ഓഫ് ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ, **SCTIMST** (ഫോൺ 0471-2524177) ഇമെയിൽ dgupta@sctimst.ac.in

പ്രധാന ഗവേഷകയുടെ പേര് ഡോ. എയ്ഞ്ജൽ മേരി സാം

മേൽവിലാസവും ബന്ധപ്പെടാനുള്ള വിശദാംശങ്ങളും

ഡോ. ഏയ്ഞ്ജൽ മേരി സാം,

ജൂനിയർ റസിഡന്റ്,

ഡിപ്പാർട്ട്മെന്റ് ഓഫ് ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ **SCTIMST**

(ഫോൺ: 9495477504/ 0471-2524636 4177) ഇമെയിൽ angelmary.sam@sctimst.ac.in

പ്രധാന ഗവേഷകയുടെ ഒപ്പ്

പഠനത്തിന്റെ നൈതിക അനവാദവുമായി ബന്ധപ്പെട്ട സംശയങ്ങൾക്ക് **SCTIMST-IEC** മെമ്പർസെക്രട്ടറി, മാല രാമനാഥൻ (ഫോൺ. 0471-2524263) ഇമെയിൽ iec.mem.sec@sctimst.ac.in



Sree Chitra Tirunal Institute For Medical Sciences And Technology, Trivandrum.

Department Of Transfusion Medicine

INFORMED CONSENT FORM

Name of the patient:

Hospital No.:

Date of Birth/ Age (in years):

Contact Number:

I _____ Age: _____, son/daughter of _____ hereby declare that I have read the information sheet provided to me regarding the study: *Autologous Versus Allogeneic Blood Transfusion: A Comparative Study Of The Peri-Operative Outcomes In A Tertiary Care Hospital In South India* and have clarified any doubts that I had. []

- I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights. []
- I also understand that neither I, nor my doctors, will have any choice for allocating me into the autologous transfusion group or the allogeneic transfusion group. []
- I also understand the benefits and potential risks of blood transfusion. []
- I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the study. I agree to this access. []
- I understand that my identity will not be revealed in any information released to third parties or published. []
- I voluntarily agree to take part in this study. []
- I received a copy of this signed consent form. []

Name:

Name of witness:

Signature:

Relation to participant:

Date:

Date:

Signature:

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Name and Signature of Person Obtaining Consent (For Principal Investigator)

Witness:

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി

ട്രാൻസ്ഫ്യൂഷൻ മെഡിസിൻ വിഭാഗം

സമ്മതപത്രം

പഠനത്തിൽ പങ്കെടുക്കുന്നയാളുടെ പേര് ആശുപത്രി നമ്പർ

ജനനതീയതി/വയസ്സ് മാസങ്ങളിൽ/വർഷത്തിൽ)

ബന്ധപ്പെടാനുള്ള നമ്പർ.....

(പ്രസക്തമായ കോളങ്ങളിൽ ശരിയടയാളമിടുക)

സ്വന്തം രക്തവും (ഓട്ടോലോഗസ്) അന്യരുടെ രക്തവും (അലോജനിക്) രക്ത പകർച്ചകൾ തമ്മിൽ: തെക്കേ ഇൻഡ്യയിലെ ഒരു ടെർഷ്യറി പരിചരണ ആശുപത്രിയിലെ ശസ്ത്രക്രിയാനന്തരഫലങ്ങൾ താരതമ്യം എന്ന പഠനസംബന്ധമായി എനിക്കു തന്ന കാര്യവിവരണപത്രം വായിക്കുകയും മനസ്സിലാക്കുകയും എന്റെ സംശയങ്ങൾ പരിഹരിക്കുകയും ചെയ്തു. []

- എന്റെ പങ്കാളിത്തം സ്വമേധയായാണെന്നും, എന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളോയോ ബാധിക്കാതെ ഏതു സമയത്തും പങ്കെടുക്കുന്നതിനുള്ള എന്റെ അനുവാദം പിൻവലിക്കാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. []
- എനിക്കോ എന്റെ ഡോക്ടർക്കോ സ്വന്തം രക്തം സ്വീകരിക്കുന്നവരുടെ ഗ്രൂപ്പിലേയ്ക്കോ അന്യരുടെ രക്തം സ്വീകരിക്കുന്നവരുടെ ഗ്രൂപ്പിലേയ്ക്കോ എന്നെ നിശ്ചയിക്കാൻ കഴിയില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു[]
- രക്തപ്രകർച്ചയുടെ നേട്ടസാധ്യതകളും അപായങ്ങളും ഞാൻ മനസ്സിലാക്കുന്നു []
- പഠന സംഘാംഗങ്ങൾക്കും എത്തിക്സ് കമ്മിറ്റി അംഗങ്ങൾക്കും പഠനത്തിൽനിന്നും ഞാൻ പിൻമാറിയാലും ഈ പഠനവുമായി ബന്ധപ്പെട്ട ആരോഗ്യരേഖകൾ എന്റെ അനുവാദം കൂടാതെ പരിശോധിക്കാമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിന് ഞാൻ സമ്മതിക്കുന്നു.
- എന്റെ വ്യക്തിപരമായ വിവരങ്ങൾ മൂന്നാം കക്ഷികൾക്കോ പ്രസിദ്ധീകരണത്തിനോ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []
- ഞാൻ സ്വമേധയാ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. []
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. []

പേര്
ഒപ്പ്
തീയതി

സാക്ഷിയുടെ പേര്
രോഗിയുമായുള്ള ബന്ധം
ഒപ്പ്

സമ്മതപത്രം വാങ്ങുന്ന ആൾ

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണ പദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര്

ഒപ്പ്

തീയതി

പ്രധാന ഗവേഷകൻ

സാക്ഷി



DATA SHEETS

A. GROUP I

1. Data Sheet of Patients in Autologous Transfusion Group under Neurosurgery who underwent ANH						Pre-Operative investigations					
Sl no	Age	Gender	Weight	Blood group	Diagnosis	Pre op Hb (g/dL)	Pre op HCT (%)	Pre op Platelet (lakhs/cumm)	PT (sec)	INR	APTT (sec)
1	49	M	82	O+	Schwannoma	15.6	46.8	2.12	14.6	1.1	31.1
2	65	F	51	O+	Meningioma	13.4	40.2	1.87	14	1.0	29
3	63	M	74	O+	Meningioma	12.1	36.3	2.55	14.3	1.0	27.3
4	35	M	58	A+	Schwannoma	13.3	39.9	3.27	15.1	1.1	30.2
5	60	M	75	B+	AVM	12.8	38.4	3.98	13.8	1.0	31.4
6	50	M	65	B+	Meningioma	13.2	39.6	2.79	15	1.1	28.5
7	46	M	82	A+	Meningioma	13.1	39.3	2.9	14.7	1.1	29.1
8	41	M	75	A neg	Meningioma	16.4	49.2	1.54	14.6	1.1	30.3
9	57	F	54	O+	Schwannoma	11.9	35.7	3.65	14.2	1.0	30.6
10	54	M	76	O neg	Meningioma	12.4	37.2	2.98	14	1.0	31.2
11	50	F	60	O+	Meningioma	12.8	38.4	3.67	13.9	1.0	30.8
12	53	F	61	O+	Schwannoma	13.4	40.2	4.31	14	1.0	27.1
13	54	M	78	A+	Meningioma	14.2	42.6	4.45	16.1	1.2	30.5
14	36	F	67	B+	Meningioma	13.6	40.8	3.78	15.3	1.1	31
15	52	F	70	B neg	Meningioma	12.8	38.4	2.79	14.2	1.0	29.9
16	54	M	62	A+	Meningioma	13.2	39.6	3.22	14.2	1.0	30.3
17	22	M	65	O+	Schwannoma	13.6	40.8	1.98	14.7	1.1	30.3
18	28	M	72	B+	AVM	15.1	45.3	2.6	15.3	1.1	29.5
19	48	F	61	O+	Meningioma	12.6	37.8	3.12	16.4	1.2	30.6
20	52	M	79	O+	Meningioma	13.4	40.2	2.77	14.9	1.1	31.2

21	48	M	67	AB+	Meningioma	12.9	38.7	4.1	14.2	1.0	30.8
22	34	M	79	O+	Meningioma	13.9	41.7	3.98	13.6	1.0	31
23	58	F	65	AB neg	Schwannoma	12.9	38.7	2.99	13.9	1.0	29.9
24	19	M	89	B+	AVM	14.2	42.6	3.7	14.3	1.0	30.3
25	31	F	76	A+	Meningioma	13.6	40.8	2.67	13.6	1.0	29.5
26	48	M	70	A+	Meningioma	14	42	2.95	15.3	1.1	30.6
27	42	F	54	O+	Meningioma	11.9	35.7	3.12	14.7	1.1	31.2
28	26	M	69	O+	Meningioma	14.6	43.8	3.76	13.6	1.0	30.8
29	61	M	82	B+	Meningioma	13.1	39.3	2.7	14.1	1.0	31
30	33	M	75	A neg	Meningioma	16.4	49.2	1.91	14.3	1.0	30.2
31	58	F	54	O+	Schwannoma	11.9	35.7	3.78	15.2	1.1	31.4
32	52	M	76	B+	Meningioma	12.4	37.2	2.79	13.1	0.9	28.5
33	39	M	82	O+	AVM	16.4	49.2	3.22	13.6	1.0	29.1
34	60	F	75	B+	Meningioma	13.1	39.3	2.32	14.3	1.0	27.7

Intra-operative Data														
Sl no	Units of blood collected	Heart Rate		Mean Arterial Pressure		SPO2		Hemoglobin			Complications during collection	Autologous units transfused	Autologous units discarded	Blood Loss (mL)
		Pre-collection	Post-collection	Pre-collection	Post-collection	Pre-collection	Post-collection	after ANH	at Max Surg Blood Loss	after transfusion				
1	2	96	82	88	74	99	99	12.5	9.2	12.2	0	2	0	1350
2	2	94	92	96	84	98	95	10.9	6.4	10.2	0	2	0	1900
3	2	86	87	104	94	99	93	9.6	7.6	10.3	0	2	0	1400
4	2	77	98	106	100	99	97	10.4	8.6	10.8	0	2	0	1150
5	1	96	87	100	96	97	99	11.2	9.6	10.5	0	1	0	800
6	2	86	73	104	76	96	96	10.6	7.1	9.7	0	2	0	1800
7	2	97	88	96	92	98	97	10.2	8.1	11.7	0	2	0	1750
8	2	88	75	96	98	98	98	13.7	10.2	11.8	0	2	0	1300
9	1	76	68	98	86	97	98	10	7.6	9.8	0	1	0	1350

10	2	68	96	100	52	95	97	10.1	8.3	10.6	Intractable Hypotension	2	0	1050
11	2	78	64	96	86	98	95	10.2	7.9	9.8	0	2	0	1400
12	2	66	68	84	88	97	98	10.8	8.1	10.2	0	2	0	950
13	2	79	70	82	74	97	97	11.4	8.9	11.7	0	2	0	1500
14	2	68	76	104	98	96	99	10.8	8.9	11.4	0	2	0	1250
15	1	78	64	88	76	99	96	11	9.2	10.1	0	1	0	1100
16	1	67	75	98	94	95	97	11.9	7.3	10.4	0	1	0	2100
17	2	78	69	97	74	93	98	11.1	9.8	11.7	0	2	0	1100
18	1	77	69	86	88	97	98	13.6	11.4	12.6	0	1	0	750
19	2	87	75	90	84	99	97	10.1	7.4	9.7	0	2	0	1800
20	2	77	69	89	73	96	99	10.8	8.3	10.5	0	2	0	1450
21	2	79	70	82	74	97	98	11	8.6	10.8	0	2	0	1600
22	2	68	76	104	98	98	99	11.6	9.1	11.2	0	2	0	1550
23	2	78	64	88	76	98	99	10.6	7.4	9.6	0	2	0	1900
24	1	67	75	98	94	97	97	12.9	11.5	12.6	0	1	0	600
25	2	77	89	98	72	99	97	10.9	7.4	9.7	0	2	0	1750
26	2	66	60	109	84	95	98	11.6	8.1	10.3	0	2	0	1600
27	1	78	62	99	74	94	98	9.3	6.4	9.1	0	1	0	1400
28	2	77	69	86	88	98	97	11.2	8.6	10.8	0	2	0	1570
29	2	97	88	96	92	96	99	10.2	8.6	11.7	0	2	0	1300
30	2	88	75	96	98	97	95	13.1	9.1	11.8	0	2	0	1780
31	1	76	68	98	86	99	98	10.1	7.1	9.8	0	1	0	1850
32	2	68	79	100	88	99	97	9.6	7.9	10.6	0	2	0	1300
33	1	76	68	98	86	97	98	14.9	12	13.2	0	1	0	800
34	2	68	79	100	88	95	97	10.6	7.8	9.6	0	2	0	1500

SI No	Post-Operative Investigations																	
	D0 Hb	D0 HCT	D0 Platelet	D0 PT	D0 INR	D0 APTT	D1 Hb	D1 HCT	D1 Platelet	D1 PT	D1 INR	D1 APTT	D5 Hb	D5 HCT	D5 Platelet	D5 PT	D5 INR	D5 APTT
1	11.8	35.4	1.99	15.3	1.1	28.5	11.6	34.8	2.11	16.1	1.2	28.1	11.7	35.1	2.01	15.1	1.1	30.1
2	10.1	30.3	1.76	14.2	1.0	29.1	9.9	29.7	1.78	14.8	1.1	32	9.5	28.5	1.79	14.6	1.1	30
3	10.2	30.6	2.09	13.8	1.0	30.3	10	30	2.16	14.9	1.1	29.6	9.7	29.1	2.2	14.8	1.1	29.8
4	10.9	32.7	3.09	15.3	1.1	30.2	10.2	30.6	3.21	15	1.1	31	10.4	31.2	3.22	14.7	1.1	27.3
5	10.5	31.5	3.88	13.9	1.0	31.2	10.3	30.9	3.82	14.3	1.0	29.7	10.9	32.7	3.78	13.2	0.9	29.9
6	9.4	28.2	2.43	14.6	1.1	30.8	9.1	27.3	2.45	15	1.1	32.1	8.2	24.6	2.6	14.3	1.0	28.4
7	11.2	33.6	2.53	13.8	1.0	31.2	11.3	33.9	2.55	14.6	1.1	29.6	10.7	32.1	2.58	15	1.1	31.2
8	11.5	34.5	1.42	14.3	1.0	30.8	11.6	34.8	1.59	14.2	1.0	31.2	11.1	33.3	1.97	14.4	1.0	32.1
9	9.5	28.5	3.61	15.2	1.1	27.1	9.3	27.9	3.7	14	1.0	30.8	9.6	28.8	3.77	13.7	1.0	29.6
10	10.5	31.5	2.93	14.4	1.0	30.5	10.3	30.9	2.96	14.1	1.0	31.1	9.8	29.4	3.02	15	1.1	31.2
11	9.5	28.5	3.45	14	1.0	31	9.2	27.6	3.21	15	1.1	29	8.2	24.6	3.22	15.8	1.2	30.8
12	10.3	30.9	4.19	13.8	1.0	29.9	10.4	31.2	4.25	14.2	1.0	27.3	10.7	32.1	4.24	14.7	1.1	31.1
13	11.4	34.2	4.36	15.9	1.2	31.2	11.5	34.5	4.33	14	1.0	29.7	10.9	32.7	4.29	14	1.0	29
14	11.4	34.2	3.78	14.8	1.1	30.8	11.2	33.6	3.6	14.6	1.1	32.1	10.7	32.1	3.71	14.8	1.1	28.6
15	10.1	30.3	2.68	14.6	1.1	31.2	10.3	30.9	2.66	14.2	1.0	29.6	10.5	31.5	2.98	14.9	1.1	26.9
16	10.2	30.6	3.1	13.7	1.0	30.8	10	30	2.98	14.3	1.0	31.2	9.7	29.1	3.04	15	1.1	32.1
17	11.5	34.5	1.88	14.2	1.0	31.1	11.3	33.9	1.86	15	1.1	30.3	11	33	1.89	14.3	1.0	30.4
18	12.6	37.8	2.4	14.1	1.0	29	12.3	36.9	2.33	14.6	1.1	29.5	12.5	37.5	2.45	15.8	1.2	31.1
19	9.6	28.8	3.05	14.5	1.0	27.3	9.4	28.2	2.98	14.2	1.0	30.6	9.1	27.3	2.97	14.7	1.1	30.1
20	10.6	31.8	2.77	16	1.2	30.2	10.2	30.6	2.65	14	1.0	31.2	10.4	31.2	2.78	14	1.0	30.8
21	10.7	32.1	3.9	15.8	1.2	31.4	10.1	30.3	3.97	14.1	1.0	32.1	10.2	30.6	3.97	14.3	1.0	31.1
22	11	33	3.67	15.6	1.2	28.5	11.3	33.9	3.87	14.6	1.1	29.6	11.1	33.3	3.88	15	1.1	29
23	9.2	27.6	2.99	13.6	1.0	30.8	9.4	28.2	2.67	14.2	1.0	31.2	9.1	27.3	2.66	14.4	1.0	28.6
24	12.4	37.2	3.67	12.9	0.9	27.1	12.5	37.5	3.78	14.3	1.0	30.8	12.2	36.6	3.55	14.9	1.1	26.9
25	9.5	28.5	2.45	16.6	1.2	29.9	9.1	27.3	2.56	15	1.1	31.1	8.6	25.8	2.78	15	1.1	30
26	10.3	30.9	2.79	15.6	1.2	31.2	10	30	2.66	14.6	1.1	29	9.8	29.4	2.45	14.3	1.0	29.8
27	8.9	26.7	2.89	14	1.0	30.8	8.5	25.5	2.76	14.2	1.0	27.3	8.7	26.1	2.66	15.8	1.2	27.3

28	10.5	31.5	3.78	14.3	1.0	31.2	10	30	3.33	14	1.0	29.7	10.1	30.3	3.77	14.7	1.1	29.9
29	11.7	35.1	2.5	15.2	1.1	30.8	11.6	34.8	2.67	14	1.0	30.8	11	33	2.8	16.2	1.2	28.4
30	11.5	34.5	1.91	14.7	1.1	31.2	11.1	33.3	1.76	16.1	1.2	31.2	10.4	31.2	1.9	15.6	1.2	31.2
31	9.7	29.1	3.6	14.3	1.0	30.8	8.6	25.8	3.8	15.3	1.1	30.8	9.8	29.4	3.1	14.3	1.0	32.1
32	10.5	31.5	2.66	13.7	1.0	31.1	10.3	30.9	2.8	14.2	1.0	32.9	10.2	30.6	2.89	14.1	1.0	28.4
33	13	39	3.1	13.8	1.0	33	13.2	39.6	3.13	15	1.1	31	13.5	40.5	3.21	14.3	1.0	31
34	9.5	28.5	2.35	14.2	1.0	31.2	9.7	29.1	2.5	14.8	1.1	30.1	10.1	30.3	2.76	15	1.1	30.6

SI No	Additional Allogeneic Transfusion (units)								ICU Stay (days)	Post-op Infection within 5 days	Transfusion reaction	Re-exploration for bleeding	Mechanical Ventilation (hours)
	Intra-operative				Post-operative								
	PRBC	FFP	Platelets	Cryoprecipitate	PRBC	FFP	Platelets	Cryoprecipitate					
1	0	1	0	0	0	0	0	0	3	0	0	N	9
2	3	1	1	0	0	0	0	0	4	0	0	N	10
3	0	0	0	0	0	0	0	0	2	0	0	N	7
4	0	0	0	0	0	0	0	0	2	0	0	N	8
5	0	0	0	0	0	0	0	0	2	0	0	N	4
6	0	0	0	0	1	0	0	0	3	0	0	N	9
7	0	0	0	0	0	0	0	0	2	0	0	N	8
8	0	0	0	0	0	0	0	0	3	0	0	N	9
9	1	1	0	0	0	0	0	0	4	0	0	N	13
10	0	0	0	0	0	0	0	0	2	0	0	N	9
11	0	0	0	0	1	0	0	0	3	0	0	N	8
12	0	0	0	0	0	0	0	0	3	0	0	N	10
13	0	0	0	0	0	0	0	0	2	0	0	N	9
14	0	0	0	0	0	0	0	0	3	0	0	N	11
15	1	0	0	0	0	0	0	0	4	0	0	N	8
16	1	0	0	0	0	0	0	0	2	0	0	N	9
17	0	0	0	0	0	0	0	0	3	0	0	N	9
18	0	0	0	0	0	0	0	0	3	0	0	N	7
19	0	0	0	0	1	0	0	0	3	0	0	N	8
20	0	0	0	0	0	0	0	0	4	0	0	N	7
21	0	0	0	0	0	0	0	0	3	0	0	N	7
22	0	0	0	0	0	0	0	0	3	0	0	N	8
23	0	0	0	0	0	0	0	0	2	0	0	N	9

24	0	0	0	0	0	0	0	0	2	0	0	N	4
25	0	0	0	0	0	0	0	0	4	0	0	N	9
26	0	0	0	0	0	0	0	0	3	0	0	N	8
27	2	1	0	0	0	0	0	0	3	0	0	N	9
28	0	0	0	0	0	0	0	0	4	0	0	N	6
29	0	0	0	0	0	0	0	0	2	0	0	N	7
30	0	0	0	0	0	0	0	0	3	1	0	N	8
31	1	0	0	0	1	0	0	0	4	0	0	N	11
32	0	0	0	0	0	0	0	0	2	0	0	N	10
33	0	0	0	0	0	0	0	0	3	0	0	N	7
34	0	0	0	0	0	0	0	0	2	0	0	N	7

2. Data Sheet of Patients in Autologous Transfusion Group under Neurosurgery who underwent PAD						Pre-Operative investigations						
Sl	Age	Gender	Weight	Blood group	Diagnosis	Pre op Hb	Pre op HCT	Pre op Platelet	PT	INR	APTT	
1	48	F	73	AB+	Meningioma	12.1	36.3	3.2	14.6	1.1	30.8	
2	55	M	66	O+	Clival chordoma	12.8	38.4	3.56	14.2	1.0	31.2	
3	46	F	80	AB neg	Meningioma	12.7	38.1	2.43	14.0	1.0	30.8	
4	18	M	78	B+	Spine	14.1	42.3	1.79	13.9	1.0	28.1	
5	31	M	62	B+	Spine	13.2	39.6	2.2	14.0	1.0	30.5	
6	36	M	78	A+	Spine	12.2	36.6	3.22	16.1	1.2	31.6	
7	49	M	98	O+	Meningioma	12.9	38.7	3.78	15.3	1.1	29.9	
8	23	M	84	O+	Spine	13.5	40.5	2.6	14.1	1.0	29.8	
9	31	F	72	B neg	Spine	11.9	35.7	1.82	14.3	1.0	30	

Pre-Deposit Blood Collection									
Sl	Hb Pre-collection	Heart Rate		Mean Arteriolar Pressure		SPO2		Units Collected	Complications during collection
		Pre-collection	Post-collection	Pre-collection	Post-collection	Pre-collection	Post-collection		
1	13.2	78	80	82	88	98	98	2	0

2	15	74	76	96	98	97	98	2	0
3	13.5	76	70	96	92	95	97	1	0
4	14.9	88	94	102	98	98	95	1	0
5	14	74	79	96	92	97	98	1	0
6	13.8	79	68	86	85	97	97	1	0
7	14.4	78	72	96	94	96	99	2	0
8	15	74	76	96	98	99	96	2	0
9	12.5	76	70	96	92	95	97	1	0

Sl. no	Intra-operative data									Blood Loss (mL)
	Hemoglobin (g/dL)		Autologous units transfused			Autologous units discarded				
	at Max Surg Blood Loss	after transfusion	PRBC	FFP	Platelets	PRBC	FFP	Platelets		
1	8.6	11.9	2	2	1	0	0	0	1950	
2	7.5	10.4	2	1	1	0	1	0	2300	
3	7.5	9.7	1	0	0	0	1	1	1200	
4	12.6	13.4	1	0	0	0	1	0	560	
5	11.7	12.5	1	0	0	0	1	0	750	
6	10.7	11.8	1	0	0	0	1	0	400	
7	9.6	12.2	2	0	1	0	2	0	1000	
8	12	13.2	1	1	0	1	1	1	650	
9	10.4	no transfusion	0	0	0	1	1	0	250	

Sl. no	Post-Operative Investigations																	
	D0 Hb	D0 HCT	D0 Platelet	D0 PT	D0 INR	D0 APTT	D1 Hb	D1 HCT	D1 Platelet	D1 PT	D1 INR	D1 APTT	D5 Hb	D5 HCT	D5 Platelet	D5 PT	D5 INR	D5 APTT
1	11.6	34.8	3.2	15.0	1.1	32.1	11.5	34.5	3.3	13.8	1.0	32.1	11.6	34.8	3.2	14.9	1.1	31.1
2	10.2	30.6	3.4	15.8	1.2	29.6	7.5	22.5	3.3	15.3	1.1	29.6	9.2	27.6	3.4	15.0	1.1	29
3	9.7	29.1	2.47	14.7	1.1	31.2	9.5	28.5	2.53	13.9	1.0	31.2	9.5	28.5	2.47	14.3	1.0	28.6
4	13.5	40.5	1.5	14.0	1.0	30.8	13.2	39.6	1.67	14.6	1.1	30.8	13.2	39.6	1.5	15.0	1.1	30

5	12.6	37.8	2.13	14.8	1.1	31.1	12.8	38.4	2.13	14.7	1.1	31.1	12.5	37.5	2.13	14.6	1.1	29.1
6	11.3	33.9	3.04	14.9	1.1	32.1	11.5	34.5	3.04	14.8	1.1	29	11.5	34.5	3.2	14.6	1.1	27.9
7	10.5	31.5	3.66	14.4	1.0	33.1	10.6	31.8	3.66	14.9	1.1	28.6	10.9	32.7	3.76	14.5	1.0	29.7
8	9.8	29.4	2.67	14.3	1.0	27.1	9.7	29.1	2.67	15.0	1.1	30	10	30	2.58	14.5	1.0	30.2
9	10.1	30.3	1.87	14.2	1.0	29.6	10	30	1.87	15.1	1.1	29.1	10.5	31.5	1.92	14.4	1.0	30.2

SI No	Additional Allogeneic Blood Transfusion (units)								ICU stay (days)	Post-op Infection within 5 days	Transfusion reaction	Re-exploration for bleeding	Mechanical Ventilation (h)
	Intra-operative				Post-operative								
	PRBC	FFP	Platelets	Cryoprecipitate	PRBC	FFP	Platelets	Cryoprecipitate					
1	1	0	0	0	0	0	0	0	4	0	0	N	10
2	4	3	3	0	2	0	3	0	5	0	Allergic + FNHTR	N	20
3	1	0	0	0	0	0	0	0	2	0	0	N	9
4	0	0	0	0	0	0	0	0	2	0	0	N	5
5	0	0	0	0	0	0	0	0	2	0	0	N	6
6	0	0	0	0	0	0	0	0	2	0	0	N	6
7	0	0	0	0	0	0	0	0	3	0	0	N	9
8	0	0	0	0	0	0	0	0	2	0	0	N	7
9	0	0	0	0	0	0	0	0	2	0	0	N	5

3. Data Sheet of Patients in Autologous Transfusion Group under Vascular surgery who underwent ANH						Pre-Operative Investigations					
SI	Age	Gender	Weight	Blood group	Diagnosis	Pre op Hb (g/dL)	Pre op HCT (%)	Pre op Platelet (lakhs/cumm)	PT (seconds)	INR	APTT (seconds)
1	22	M	55	B+	Carotid aneurysm	14.1	42.3	3.76	15.3	1.1	30.8
2	63	F	42	AB+	Carotid aneurysm	12.9	38.7	2.04	15.1	1.1	31.2
3	65	M	55	B+	Carotid aneurysm	14.1	42.3	1.68	13.9	1.0	30.8
4	36	M	74	A+	IRAAA	14.6	43.8	1.96	14.8	1.1	31

5	64	M	67	O+	IRAAA	15.4	46.2	1.87	14.9	1.1	29.9
6	64	M	70	O+	IRAAA	15.3	45.9	2.07	14.6	1.1	32.1
7	60	M	50	B+	IRAAA	13.8	41.4	2.11	14.8	1.1	29.6
8	51	M	78	O+	IRAAA	13.9	41.7	1.88	14.7	1.1	31.2
9	57	M	90	A+	IRAAA	14.7	44.1	1.97	13.9	1.0	31.1
10	58	M	92	B neg	IRAAA	13.9	41.7	1.83	14.6	1.1	29
11	63	M	86	O+	IRAAA	12.8	38.4	2.43	13.8	1.0	30.8
12	60	M	63	O+	IRAAA	12.8	38.4	3.13	14.9	1.1	31.2
13	59	M	70	A+	IRAAA	13.1	39.3	1.87	15.1	1.1	30.8
14	63	M	65	B+	IRAAA	12.4	37.2	2.3	14.6	1.1	27.1
15	59	M	55	O neg	IRAAA	13.4	40.2	1.69	13.9	1.0	30.5
16	60	M	70	A+	IRAAA	15.3	45.9	2.31	14.6	1.1	31
17	57	M	50	B+	IRAAA	13.8	41.4	2.06	16.1	1.2	29.9
18	53	F	48	A neg	Subclavian artery aneurysm	12.7	38.1	2.22	14.6	1.1	27.1
19	50	M	62	O neg	Thoracic mass lesion	14	42	3.67	13.8	1.0	30.8
20	57	F	66	B+	Thoracic mass lesion	13.5	40.5	2.97	15.3	1.1	31.2
21	26	F	56	O+	Thoracic mass lesion	12.6	37.8	4.12	16.1	1.2	30.5
22	29	F	57	O+	Thoracic mass lesion	13.7	41.1	3.35	14.8	1.1	31.2

SI No.	Intra-operative data													
	Units of blood collected	Heart Rate		Mean Arteriolar Pressure		SPO2		Hemoglobin			Complications during collection	Autologous units transfused	Autologous units discarded	Blood Loss (mL)
		Pre-collection	Post-collection	Pre-collection	Post-collection	Pre-collection	Post-collection	after ANH	at Max Surg Blood Loss	after transfusion				
1	2	87	78	100	96	97	98	11.7	8	11.3	0	2	0	1200
2	1	85	72	104	94	95	97	10.5	6.8	9.2	0	1	0	1100
3	2	87	93	84	86	98	95	11.7	8	10.2	0	2	0	1850

4	2	85	80	94	92	96	99	12.2	8.5	9.6	0	2	0	2100
5	3	86	83	98	96	99	96	12.6	8.9	12.1	0	3	0	1980
6	2	65	71	108	102	96	96	12.9	9.2	11.8	0	2	0	2000
7	2	98	102	86	52	98	97	11.4	7.7	10.5	Intractable hypotension	2	0	1700
8	2	69	54	98	80	98	98	11.5	7.8	10.2	0	2	0	1650
9	2	98	66	112	97	95	97	12.3	8.6	10.6	0	2	0	1900
10	2	78	78	105	102	98	99	11.5	7.8	10.2	0	2	0	1400
11	2	87	76	99	84	97	97	10.4	6.7	9.7	0	2	0	1300
12	2	76	77	87	94	99	97	10.4	6.7	11	0	2	0	1450
13	2	86	83	98	96	95	98	10.7	7	10.8	0	2	0	1100
14	2	85	72	104	94	94	98	10	6.3	9.7	0	2	0	950
15	2	65	71	108	102	98	97	11	7.3	10.1	0	2	0	1200
16	2	65	71	106	102	96	99	12.9	9.2	11.8	0	2	0	1000
17	2	98	102	86	74	99	95	11.4	7.7	10.5	0	2	0	1200
18	2	94	104	96	92	97	98	10.3	6.6	9.6	0	2	0	950
19	1	81	77	78	74	97	98	12.8	11.4	no transfusion	0	0	1	450
20	1	92	88	86	72	95	97	11.1	10.1	12.6	0	1	0	500
21	1	79	94	88	84	97	97	10.2	7.2	10.9	0	1	0	1800
22	1	77	69	78	80	99	98	11.3	10.1	11.6	0	1	0	800

SI No.	Post-Operative Investigations																	
	D0 Hb	D0 HCT	D0 Platelet	D0 PT	D0 INR	D0 APTT	D1 Hb	D1 HCT	D1 Platelet	D1 PT	D1 INR	D1 APTT	D5 Hb	D5 HCT	D5 Platelet	D5 PT	D5 INR	D5 APTT
1	10.9	32.7	3.74	15.8	1.2	31.4	10.7	32.1	3.65	14.2	1.0	30.8	10.5	31.5	3.58	13.8	1.0	27.1
2	8.8	26.4	1.98	14.2	1.0	27.1	8.6	25.8	1.89	13.8	1.0	27.1	9	27	1.82	15.3	1.1	30.5
3	9.8	29.4	1.44	14.7	1.1	31.4	8.5	25.5	1.35	15.3	1.1	30.5	6.9	20.7	1.28	14.2	1.0	30.2
4	9.2	27.6	1.72	13.8	1.0	31.2	7.9	23.7	1.63	14.2	1.0	30.2	6.3	18.9	1.56	15.3	1.1	31.4
5	11.7	35.1	1.63	15.3	1.1	30.8	10.4	31.2	1.54	15.6	1.2	31.4	8.8	26.4	1.47	14.2	1.0	30.5
6	11.4	34.2	1.83	14.1	1.0	30.5	10.1	30.3	1.74	14	1.0	28.5	8.5	25.5	1.67	14.1	1.0	31

7	10.1	30.3	1.87	14.5	1.0	31	8.8	26.4	1.78	14.3	1.0	29.1	7.2	21.6	1.71	14	1.0	29.9
8	9.8	29.4	1.64	16	1.2	29.9	8.5	25.5	1.55	15.2	1.1	27.7	6.9	20.7	1.48	14.5	1.0	31.2
9	10.2	30.6	1.73	15.6	1.2	29.6	8.9	26.7	1.64	13.9	1.0	31.3	9.2	27.6	1.57	14.2	1.0	30.2
10	9.8	29.4	1.59	14	1.0	27.1	8.5	25.5	1.5	14.5	1.0	30.8	8.8	26.4	1.43	15.1	1.1	31.4
11	9.3	27.9	2.19	14.3	1.0	30.5	8	24	2.1	15.3	1.1	31.2	6.4	19.2	2.03	14	1.0	28.5
12	10.6	31.8	2.89	15.2	1.1	30.2	9.3	27.9	2.8	15.6	1.2	30.8	9	27	2.73	14.3	1.0	30.8
13	10.4	31.2	1.63	13.8	1.0	31.4	9.1	27.3	1.54	14	1.0	27.1	8.4	25.2	1.47	15.2	1.1	27.1
14	9.3	27.9	2.06	15.4	1.1	29.6	8	24	1.97	14.3	1.0	30.5	6.8	20.4	1.9	14.2	1.0	30.5
15	9.7	29.1	1.45	14	1.0	31	8.4	25.2	1.36	15.2	1.1	31	7.9	23.7	1.29	14.1	1.0	29.8
16	11.4	34.2	2.07	14.5	1.0	29.7	10.1	30.3	1.98	14.2	1.0	29.9	8.5	25.5	1.91	14.5	1.0	27.3
17	10.1	30.3	1.82	14.2	1.0	32.1	8.8	26.4	1.73	15.6	1.2	31.2	8.2	24.6	1.66	14	1.0	29.9
18	9.2	27.6	2.02	15.3	1.1	28.5	8.7	26.1	2.04	14	1.0	31.6	9	27	1.97	14.3	1.0	30.8
19	11.3	33.9	3.54	14.6	1.1	27.3	11	33	3.6	14.3	1.0	30.2	11.2	33.6	3.53	15.2	1.1	27.1
20	12.5	37.5	2.86	14.8	1.1	30.2	12.4	37.2	2.9	13.6	1.0	31.4	12.5	37.5	2.83	14	1.0	31.2
21	10.6	31.8	4.01	14.2	1.0	30.8	10.7	32.1	3.98	15	1.1	28.5	10.9	32.7	3.91	14.2	1.0	32.1
22	10	30	3.24	15.1	1.1	30.2	10.2	30.6	3.26	14.2	1.0	29.3	10.5	31.5	3.19	15.2	1.1	29.5

SI no	Additional Allogeneic Transfusion (units)								ICU stay (days)	Post-op Infection within 5 days	Transfusion Reaction	Re-exploration for bleeding	Mechanical Ventilation (h)
	Intra-operative				Post-operative								
	PRBC	FFP	Platelets	Cryoprecipitate	PRBC	FFP	Platelets	Cryoprecipitate					
1	0	0	0	0	0	0	0	0	2	0	0	N	7
2	0	0	0	0	0	0	0	0	1	0	0	N	8
3	0	0	0	0	2	0	2	0	3	0	0	N	7
4	1	1	0	0	0	0	0	0	3	0	0	N	11
5	1	1	0	0	0	0	0	0	2	0	0	N	9
6	0	0	0	0	0	0	0	0	2	0	0	N	9
7	0	0	0	0	1	0	0	0	3	0	0	N	14
8	1	1	1	1	2	0	1	0	3	0	0	Y	28
9	0	0	0	0	0	0	0	0	4	0	0	N	10
10	1	1	0	0	0	0	0	0	2	1	0	N	10

11	0	0	0	0	1	0	0	0	3	0	0	N	9
12	0	0	0	0	0	0	0	0	2	0	0	N	8
13	0	0	0	0	0	0	0	0	2	0	0	N	11
14	0	0	0	0	2	0	0	0	3	0	0	N	11
15	1	1	0	2	1	0	0	0	4	0	0	N	13
16	0	0	0	0	0	0	0	0	2	0	0	N	9
17	0	0	0	0	0	0	0	0	3	0	0	N	8
18	0	0	0	0	0	0	0	0	3	0	0	N	6
19	0	0	0	0	0	0	0	0	4	0	0	N	8
20	0	0	0	0	0	0	0	0	4	0	0	N	6
21	1	1	0	0	0	0	0	0	2	0	0	N	7
22	0	0	0	0	0	0	0	0	2	0	0	N	7

4. Data Sheet of Patients in Autologous Transfusion Group under Vascular surgery who underwent ICS						Pre-Operative Investigations					
Sl	Age	Gender	Weight	Blood group	Diagnosis	Pre op Hb	Pre op HCT	Pre op Platelet	PT	INR	APTT
1	65	M	46	A+	TAAA	13.5	40.5	1.45	14	1.0	30.8
2	54	M	63	O+	TAAA	11.9	35.7	1.67	16.1	1.2	31.2
3	66	M	62	O+	TAAA	12.5	37.5	2.01	15.3	1.1	30.8
4	43	M	60	B+	TAAA	11.8	35.4	2.54	14.2	1.0	27.1
5	56	M	59	O+	TAAA	12.8	38.4	1.98	14.2	1.0	30.5
6	65	M	70	B+	TAAA	13.6	40.8	2.55	15.9	1.2	31

Intra-operative							
Sl	Hemoglobin		Autologous blood collected		Autologous units transfused		Blood Loss (mL)
	at Max Surgical Blood Loss	After Transfusion	Volume (mL)	Equivalent number of units	Volume (mL)	Equivalent number of units	
1	5.2	9.8	1320	6	1320	6	2020
2	4.9	9.7	2800	13	2800	13	3500
3	6.5	9.2	950	4	950	4	2150

4	7	8.1	2300	10	2300	10	3460
5	5.9	10.1	1800	8	1800	8	2950
6	7.1	9.2	1270	6	1270	6	2200

SI no	Post-Operative Investigations																	
	D0 Hb	D0 HCT	D0 Platelet	D0 PT	D0 INR	D0 APTT	D1 Hb	D1 HCT	D1 Platelet	D1 PT	D1 INR	D1 APTT	D5 Hb	D5 HCT	D5 Platelet	D5 PT	D5 INR	D5 APTT
1	9.7	29.1	1.20	17.4	1.3	38	9.2	27.6	1.06	16.8	1.3	31.4	8.4	25.2	1.08	16.9	1.3	33
2	9.6	28.8	1.03	16.8	1.3	34.2	9.2	27.6	0.85	17.2	1.3	32.9	7.6	22.8	1.01	17.7	1.4	30.5
3	9.0	27	1.87	15.9	1.2	36.3	8.1	24.3	1.76	16.5	1.2	31.1	7.5	22.5	1.59	16.3	1.2	34.1
4	8.2	24.6	2.31	17	1.3	31.4	7.3	21.9	2.01	17.1	1.3	34.2	6.9	20.7	1.58	16.6	1.2	32.4
5	9.9	29.7	1.75	18.3	1.4	32.9	9.5	28.5	1.5	18.2	1.4	36.3	9.3	27.9	1.65	17.2	1.3	33.1
6	9.2	27.6	2.31	15.8	1.2	31.1	9.1	27.3	2.14	16.2	1.2	32	9	27	2.34	14.7	1.1	31.7

SI no.	Additional Allogeneic Transfusion (units)								ICU stay (days)	Post-op Infection within 5 days	Transfusion Reaction	Re-exploration for bleeding	Mechanical Ventilation (h)
	Intra-operative				Post-operative								
	PRBC	FFP	Platelets	Cryoprecipitate	PRBC	FFP	Platelets	Cryoprecipitate					
1	2	1	5	0	1	0	0	0	4	0	0	N	26
2	5	5	6	2	3	2	4	0	6	0	FNHTR	Y	52
3	2	1	3	0	1	0	0	0	7	0	0	N	28
4	7	5	6	2	2	2	2	0	5	0	0	N	38
5	2	1	0	0	1	0	0	0	7	0	0	N	24
6	3	2	4	1	1	0	0	0	8	0	0	N	33

B. GROUP II

5. Data sheet of Neurosurgery patients in the group which underwent allogeneic blood transfusion						Pre-Operative investigations					
Sl	Age	Gender	Weight	Blood group	Diagnosis	Pre op Hb	Pre op HCT	Pre op Platelet	PT	INR	APTT
1	45	M	65	A+	Meningioma	13.4	40.2	4.31	14	1.0	27.1
2	54	F	45	B+	Meningioma	14.2	42.6	4.45	16.1	1.2	30.5
3	36	M	78	B+	Meningioma	13.6	40.8	3.78	15.3	1.1	31
4	64	M	90	A+	Meningioma	14.6	43.8	3.76	13.6	1.0	30.8
5	21	M	67	A+	Meningioma	13.1	39.3	2.7	14.1	1.0	31
6	35	M	86	O+	Meningioma	16.4	49.2	1.91	14.3	1.0	30.2
7	54	M	67	O NEG	Meningioma	11.9	35.7	3.78	15.2	1.1	31.4
8	56	M	65	O+	Meningioma	13.8	41.4	2.11	14.8	1.1	29.6
9	62	M	46	O+	Meningioma	13.9	41.7	1.88	14.7	1.1	31.2
10	19	F	60	A+	Meningioma	14.7	44.1	1.97	13.9	1.0	31.1
11	29	M	68	B+	Meningioma	13.9	41.7	1.83	14.6	1.1	29
12	33	F	60	O+	Meningioma	12.8	38.4	2.43	13.8	1.0	30.8
13	48	F	73	A+	Meningioma	12.8	38.4	3.13	14.9	1.1	31.2
14	52	M	79	B+	Meningioma	12.7	38.1	2.22	14.6	1.1	27.1
15	63	F	81	A+	Meningioma	14	42	3.67	13.8	1.0	30.8
16	49	F	57	B+	Meningioma	13.5	40.5	2.97	15.3	1.1	31.2
17	47	M	70	O+	Meningioma	12.6	37.8	4.12	16.1	1.2	30.5
18	39	M	77	O+	Meningioma	13.7	41.1	3.35	14.8	1.1	31.2
19	46	M	54	O+	Meningioma	11.9	35.7	3.78	15.2	1.1	31.4
20	38	M	68	AB+	Meningioma	13.8	41.4	2.11	14.8	1.1	29.6
21	59	M	71	O+	Meningioma	13.9	41.7	1.88	14.7	1.1	31.2
22	64	F	54	A+	Schwannoma	14.7	44.1	1.97	13.9	1.0	31.1
23	59	F	86	A+	Schwannoma	14	42	2.95	15.3	1.1	30.6
24	23	M	63	O+	Schwannoma	11.9	35.7	3.12	14.7	1.1	31.2
25	27	M	70	O+	Schwannoma	14.6	43.8	3.76	13.6	1.0	30.8
26	29	M	65	O+	Schwannoma	15.6	46.8	2.12	14.6	1.1	31.1
27	33	M	55	B+	Schwannoma	13.4	40.2	1.87	14	1.0	29
28	48	M	70	O+	Schwannoma	12.1	36.3	2.55	14.3	1.0	27.3
29	52	F	54	B+	Schwannoma	13.9	41.7	1.88	14.7	1.1	31.2
30	34	M	68	O+	Schwannoma	14.7	44.1	1.97	13.9	1.0	31.1
31	58	M	71	B+	Schwannoma	12.8	38.4	3.56	14.2	1.0	31.2
32	19	M	54	O+	Schwannoma	14.6	43.8	3.76	13.6	1.0	30.8
33	31	M	79	A+	AVM	13.1	39.3	2.7	14.1	1.0	31
34	48	F	62	B NEG	AVM	16.4	49.2	1.91	14.3	1.0	30.2
35	33	M	61	B+	AVM	11.9	35.7	3.78	15.2	1.1	31.4

36	36	M	78	A+	AVM	13.8	41.4	2.11	14.8	1.1	29.6
37	64	F	67	O+	AVM	13.2	39.6	1.88	14.7	1.1	31.2
38	21	F	70	B+	Clival Chordoma	12.1	36.3	2.55	14.3	1.0	27.3
39	35	M	62	O+	Clival Chordoma	13.9	41.7	1.88	14.7	1.1	31.2
40	54	M	65	B+	Spine	14.7	44.1	1.97	13.9	1.0	31.1
41	46	M	72	A+	Spine	14.2	42.6	4.45	16.1	1.2	30.5
42	60	M	54	O+	Spine	13.6	40.8	3.78	15.3	1.1	31
43	54	M	86	O+	Spine	14.6	43.8	3.76	13.6	1.0	30.8
44	44	M	63	O+	Spine	13.2	39.6	3.22	14.2	1.0	30.3
45	53	F	61	O NEG	Spine	13.6	40.8	1.98	14.7	1.1	30.3
46	48	M	67	O+	Spine	15.1	45.3	2.6	15.3	1.1	29.5

Post-Operative Investigations																			Blood Loss (mL)
SI	D0 Hb	D0 HCT	D0 Platelet	D0 PT	D0 INR	D0 APTT	D1 Hb	D1 HCT	D1 Platelet	D1 PT	D1 INR	D1 APTT	D5 Hb	D5 HCT	D5 Platelet	D5 PT	D5 INR	D5 APTT	
1	10.5	31.5	3.71	14.7	1.1	31.2	10.7	32.1	3.77	14.9	1.1	31.2	10.6	31.8	3.98	14.9	1.1	31.2	1200
2	11.3	33.9	3.85	13.9	1.0	31.1	11.5	34.5	3.91	14.6	1.1	27.1	11.3	33.9	4.12	14.6	1.1	27.1	1100
3	10.7	32.1	3.18	14.6	1.1	29	8.2	24.6	3.24	14.7	1.1	31.2	9.8	29.4	3.45	14.7	1.1	31.2	1450
4	11.7	35.1	3.16	13.8	1.0	30.8	11.9	35.7	3.22	13.6	1.0	30.8	12.2	36.6	3.43	14.7	1.1	31.2	1200
5	10.2	30.6	2.1	14.9	1.1	31.2	10.4	31.2	2.16	13.6	1.0	30.8	10.7	32.1	2.37	13.9	1.0	31.1	1350
6	13.5	40.5	1.31	14.6	1.1	27.1	13.7	41.1	1.37	14.1	1.0	31	14	42	1.58	14.6	1.1	29	1900
7	9	27	3.18	14.7	1.1	31.2	9.2	27.6	3.24	13.9	1.0	31.1	9.5	28.5	3.45	13.8	1.0	30.8	1400
8	10.9	32.7	1.51	13.6	1.0	30.8	11.1	33.3	1.57	14.2	1.0	31.2	11.4	34.2	1.78	14.9	1.1	31.2	1150
9	11	33	1.28	14.6	1.1	31.1	11.2	33.6	1.34	14.7	1.1	31.2	11.5	34.5	1.55	14.6	1.1	27.1	1050
10	11.8	35.4	1.37	14	1.0	29	12	36	1.43	13.6	1.0	30.8	12.3	36.9	1.64	14.3	1.0	30.2	1800
11	11	33	1.23	14.3	1.0	27.3	11.2	33.6	1.29	13.9	1.0	31.1	11.5	34.5	1.5	13.6	1.0	30.8	1750
12	9.9	29.7	1.83	13.9	1.0	31.1	7.9	23.7	1.89	14.6	1.1	29	9.6	28.8	2.1	14.9	1.1	31.2	1300
13	9.9	29.7	2.53	14.2	1.0	31.2	10.1	30.3	2.59	13.8	1.0	30.8	10.4	31.2	2.8	14.2	1.0	30.8	1350
14	9.8	29.4	1.62	13.6	1.0	30.8	10	30	1.68	14.9	1.1	31.2	10.3	30.9	1.89	14.2	1.0	31.2	1050
15	11.1	33.3	3.07	14.1	1.0	31	11.3	33.9	3.13	14.6	1.1	27.1	11.6	34.8	3.34	14.7	1.1	31.2	1400
16	10.6	31.8	2.37	14.3	1.0	30.2	10.8	32.4	2.43	13.9	1.0	31.1	11.1	33.3	2.64	13.6	1.0	30.8	1700
17	9.7	29.1	3.52	13.6	1.0	30.8	9.9	29.7	3.58	14.6	1.1	29	10.2	30.6	3.79	13.9	1.0	31.1	1500
18	10.8	32.4	2.75	13.9	1.0	31.1	10.6	31.8	2.81	14.1	1.0	31	10.9	32.7	3.02	14.9	1.1	31.2	1250
19	9	27	3.18	14.6	1.1	29	7.8	23.4	3.24	14.3	1.0	30.2	9.3	27.9	3.45	14.6	1.1	27.1	1100
20	10.9	32.7	1.51	16.1	1.2	30.5	11.4	34.2	1.57	13.6	1.0	30.8	11.7	35.1	1.78	14.7	1.1	31.2	2100
21	11	33	1.28	15.3	1.1	31	11.2	33.6	1.34	14.9	1.1	31.2	11.5	34.5	1.55	13.6	1.0	30.8	1900
22	11.8	35.4	1.98	14	1.0	29	11.5	34.5	2.04	14.2	1.0	30.8	11.6	34.8	2.25	14.7	1.1	31.2	1200
23	11.3	33.9	2.86	14.3	1.0	27.3	11.1	33.3	2.9	13.6	1.0	31	11.5	34.5	3.11	13.6	1.0	30.8	1300
24	9.4	28.2	3.03	13.9	1.0	31.1	9.1	27.3	3.07	13.9	1.0	29.9	8.4	25.2	3.28	13.9	1.0	31.1	1250
25	12.6	37.8	3.67	14.2	1.0	31.2	12.2	36.6	3.71	14.3	1.0	30.3	12.2	36.6	3.92	13.9	1.0	31.1	1100
26	12.5	37.5	2.03	14.7	1.1	31.2	12.6	37.8	2.07	14	1.0	29	12.5	37.5	2.28	14.6	1.1	29	1200
27	11.6	34.8	1.78	13.6	1.0	30.8	11.2	33.6	1.82	14.3	1.0	27.3	11.1	33.3	2.03	14.7	1.1	31.2	1100
28	10.7	32.1	2.46	13.9	1.0	31.1	10.5	31.5	2.5	13.9	1.0	31.1	9.9	29.7	2.71	13.6	1.0	30.8	1240

29	12.5	37.5	1.79	14.6	1.1	29	12.2	36.6	1.83	14.2	1.0	31.2	12	36	2.04	13.9	1.0	31.1	1560
30	12.3	36.9	1.88	14.7	1.1	31.2	12.6	37.8	1.92	14.7	1.1	31.2	12.6	37.8	2.13	14.6	1.1	29	1300
31	11.5	34.5	3.47	13.6	1.0	30.8	9.1	27.3	3.51	13.6	1.0	30.8	10.8	32.4	3.72	14.7	1.1	31.2	1110
32	12.6	37.8	3.67	13.9	1.0	31.1	12.3	36.9	3.71	13.9	1.0	31.1	12.6	37.8	3.92	13.6	1.0	30.8	1000
33	12.5	37.5	2.61	14.6	1.1	29	12.4	37.2	2.65	14.6	1.1	29	12.6	37.8	2.86	13.9	1.0	31.1	500
34	15.8	47.4	1.82	13.8	1.0	30.8	15.7	47.1	1.86	14.7	1.1	31.2	15.9	47.7	2.07	14.6	1.1	29	800
35	11.3	33.9	3.69	14.9	1.1	31.2	11.2	33.6	3.73	13.6	1.0	30.8	11.4	34.2	3.94	14.7	1.1	31.2	950
36	13.2	39.6	2.02	14.6	1.1	27.1	13.1	39.3	2.06	14.0	1.0	30.5	13.3	39.9	2.27	14.9	1.1	31.2	600
37	11.5	34.5	1.79	14.2	1.0	31.2	11.5	34.5	1.83	14.2	1.0	29.9	11	33	2.04	14.6	1.1	27.1	1200
38	11.5	34.5	2.46	14.7	1.1	31.2	11.7	35.1	2.5	14.3	1.0	27.3	11.3	33.9	2.71	14.2	1.0	31.2	1950
39	12.3	36.9	1.79	13.6	1.0	30.8	12.2	36.6	1.83	13.9	1.0	31.1	12.4	37.2	2.04	14.9	1.1	31.2	1800
40	11.4	34.2	1.88	13.9	1.0	31.1	11.5	34.5	1.92	14.2	1.0	31.2	11.5	34.5	2.13	14.6	1.1	27.1	750
41	11.3	33.9	4.36	13.9	1.0	31.1	11.5	34.5	4.4	14.7	1.1	31.2	11.2	33.6	4.61	14.3	1.0	30.2	800
42	11.4	34.2	3.69	14.2	1.0	31.2	11.4	34.1	3.73	14.3	1.0	30.2	11.5	34.4	3.94	14.6	1.1	27.1	1100
43	12.0	36.0	3.67	14.7	1.1	31.2	12.0	35.9	3.71	13.6	1.0	30.8	12.1	36.2	3.92	14.2	1.0	31.2	1200
44	10.4	31.2	3.13	14.3	1.0	30.2	10.4	31.1	3.17	13.9	1.0	31.1	10.5	31.4	3.38	14.9	1.1	31.2	450
45	11.7	35.1	1.89	13.6	1.0	30.8	11.7	35.0	1.93	14.6	1.1	29	11.8	35.3	2.14	14.6	1.1	27.1	700
46	12.0	36.0	2.51	13.9	1.0	31.1	12.0	35.9	2.55	13.6	1.0	30.8	12.1	36.2	2.76	14.3	1.0	30.2	1000

SI no	Allogeneic Transfusion (units)								ICU stay (days)	Post-op Infection within 5 days	Transfusion Reactions	Re-exploration for bleeding	Mechanical Ventilation (hours)
	Intra-operative				Post-operative								
	PRBC	FFP	Platelets	Cryoprecipitate	PRBC	FFP	Platelets	Cryoprecipitate					
1	2	1	0	0	0	0	0	0	3	0	0	N	8
2	3	1	1	0	0	0	0	0	3	0	0	N	11
3	3	2	1	0	1	0	0	0	2	0	0	N	7
4	2	1	0	0	0	0	0	0	3	0	0	N	7
5	2	1	0	0	0	0	0	0	4	0	0	N	9
6	2	0	0	0	0	0	0	0	3	0	0	N	10
7	3	2	2	0	0	0	0	0	2	0	0	N	9
8	4	2	2	0	0	0	0	0	2	0	0	N	9
9	2	0	0	0	0	0	0	0	3	0	0	N	10
10	2	0	0	0	0	0	0	0	2	0	0	N	7
11	1	0	0	0	0	0	0	0	3	0	0	N	8
12	2	1	0	0	1	0	0	0	2	0	0	N	7
13	2	0	0	0	0	0	0	0	2	1	0	N	9
14	3	2	0	0	0	0	0	0	3	0	Allergic	N	8
15	2	0	0	0	0	0	0	0	4	0	0	N	9
16	4	2	2	0	0	0	0	0	5	0	0	N	12
17	3	1	0	0	0	0	0	0	4	0	0	N	9
18	2	1	0	0	0	0	0	0	5	0	0	N	9
19	3	1	0	0	1	0	0	0	3	0	0	N	7
20	4	2	2	0	0	0	0	0	2	0	0	N	8
21	2	0	0	0	0	0	0	0	2	0	0	N	10

22	1	0	0	0	0	0	0	0	2	0	0	N	11
23	1	0	0	0	0	0	0	0	2	0	0	N	12
24	2	2	0	0	1	0	0	0	3	0	0	N	11
25	1	0	0	0	0	0	0	0	2	1	0	N	10
26	2	0	0	0	0	0	0	0	3	0	0	N	12
27	1	0	0	0	0	0	0	0	2	0	0	N	10
28	2	1	0	0	0	0	0	0	2	0	0	N	9
29	2	0	0	0	0	0	0	0	3	0	0	N	10
30	2	1	0	0	0	0	0	0	3	0	0	N	9
31	2	1	0	0	1	0	0	0	4	0	0	N	11
32	1	0	0	0	0	0	0	0	2	0	0	N	8
33	2	2	1	0	0	0	0	0	2	0	0	N	6
34	2	0	0	0	0	0	0	0	2	0	0	N	5
35	1	0	0	0	0	0	0	0	2	0	0	N	7
36	2	0	0	0	0	0	0	0	2	0	0	N	8
37	2	1	1	0	0	0	0	0	2	0	0	N	6
38	3	2	2	0	0	0	0	0	4	1	0	Y	18
39	3	2	2	0	0	0	0	0	5	0	0	N	8
40	1	0	0	0	0	0	0	0	2	0	0	N	4
41	1	0	0	0	0	0	0	0	2	0	0	N	5
42	1	0	0	0	0	0	0	0	2	0	0	N	5
43	1	0	0	0	0	0	0	0	3	0	0	N	5
44	1	0	0	0	0	0	0	0	3	0	0	N	4
45	1	0	0	0	0	0	0	0	2	0	0	N	6
46	1	0	0	0	0	0	0	0	2	0	0	N	5

6. Data sheet of Vascular surgery patients in the group which underwent allogeneic blood transfusion (excl. TAAA)						Pre-Operative investigations						Intra-operative		
Sl	Age	Gender	Weight	Blood group	Diagnosis	Pre op Hb	Pre op HCT	Pre op Platelet	PT	INR	APTT	Hb at Max Surg Blood Loss	Hb after transfusion	Blood Loss (mL)
1	48	M	76	B+	IRAAA	14.2	42.6	4.45	16.1	1.2	30.5	9.4	11.6	1980
2	52	F	60	A+	IRAAA	13.6	40.8	3.78	15.3	1.1	31	7.5	10.9	2200
3	63	F	61	O+	IRAAA	14.6	43.8	3.76	13.6	1.0	30.8	8.8	10.4	2000
4	63	M	78	B+	IRAAA	16.4	49.2	1.91	14.3	1.0	30.2	10.6	11.9	2100
5	65	M	67	O+	IRAAA	11.9	35.7	3.78	15.2	1.1	31.4	6.1	10.7	1900
6	70	M	70	O+	IRAAA	13.8	41.4	2.11	14.8	1.1	29.6	8	10.6	1700

7	59	M	62	AB+	IRAAA	13.9	41.7	1.88	14.7	1.1	31.2	8.1	10.6	1800
8	64	M	65	B+	IRAAA	14.7	44.1	1.97	13.9	1.0	31.1	8.9	10.3	1400
9	59	M	54	B+	IRAAA	12.8	38.4	3.56	14.2	1.0	31.2	7	10.8	1600
10	23	M	68	A+	Thoracic mass lesion	11.9	35.7	3.12	14.7	1.1	31.2	6.8	10.9	1200
11	27	F	71	A+	Thoracic mass lesion	14.6	43.8	3.76	13.6	1.0	30.8	12.2	12.6	750
12	51	F	54	O+	Thoracic mass lesion	13.2	39.6	2.2	14.0	1.0	30.5	10.3	11.9	900
13	46	M	86	O+	Thoracic mass lesion	12.8	38.4	2.79	14.2	1.0	29.9	8.6	11.9	1400
14	24	M	49	B+	Thoracic mass lesion	13.2	39.6	3.22	14.2	1.0	30.3	9.1	10.4	1250
15	56	M	56	ANEG	Subclavian aneurysm	13.6	40.8	1.98	14.7	1.1	30.3	8.9	11.5	1700
16	43	M	67	B+	Carotid aneurysm	15.1	45.3	2.6	15.3	1.1	29.5	9.6	10.9	1100
17	54	F	76	O+	Carotid aneurysm	13.9	41.7	1.88	14.7	1.1	31.2	9.3	10.4	1300
18	48	M	60	O+	Carotid aneurysm	14.7	44.1	1.97	13.9	1.0	31.1	9.8	10.9	1100
19	49	F	62	AB+	Subclavian aneurysm	14	42	2.95	15.3	1.1	30.6	7.6	10.2	2180

Sl no.	Post-Operative Investigations																	
	D0 Hb	D0 HCT	D0 Platelet	D0 PT	D0 INR	D0 APTT	D1 Hb	D1 HCT	D1 Platelet	D1 PT	D1 INR	D1 APTT	D5 Hb	D5 HCT	D5 Platelet	D5 PT	D5 INR	D5 APTT
1	11.4	34.2	3.88	13.6	1.0	30.8	10.2	30.6	3.85	13.8	1.0	30.8	9.5	28.5	3.97	13.8	1.0	27.1
2	10.6	31.8	3.21	13.9	1.0	31.1	10	30	3.18	14.9	1.1	31.2	9.1	27.3	3.3	15.3	1.1	30.5
3	10.5	31.5	3.19	14.6	1.1	29	10.1	30.3	3.16	14.6	1.1	27.1	8.4	25.2	3.28	14.2	1.0	30.2
4	11.5	34.5	1.34	13.8	1.0	30.8	11.2	33.6	1.31	15.3	1.1	31.4	11.3	33.9	1.43	15.3	1.1	31.4
5	10.6	31.8	3.21	14.9	1.1	31.2	10.3	30.9	3.18	14.2	1.0	30.5	9.7	29.1	3.3	14.2	1.0	30.5
6	10.4	31.2	1.54	14.6	1.1	27.1	10.5	31.5	1.51	14.2	1.0	31.1	10.3	30.9	1.63	14.1	1.0	31
7	10.7	32.1	1.31	15.3	1.1	31.4	10.2	30.6	1.28	14.1	1.0	31	10	30	1.4	15.3	1.1	31.4
8	10.1	30.3	1.4	14.2	1.0	31.3	9.4	28.2	1.37	14.6	1.1	29	8.7	26.1	1.49	14.9	1.1	31.2
9	10.5	31.5	2.99	14.1	1.0	31	9.9	29.7	2.96	14.1	1.0	31	9.1	27.3	3.08	14.9	1.1	31.2
10	10.6	31.8	3.04	14.6	1.1	29.3	10.2	30.6	3.01	14.3	1.0	30.2	10.4	31.2	3.13	14.6	1.1	27.1
11	12	36	3.68	14.1	1.0	31	11.8	35.4	3.65	14.9	1.1	31.2	11.9	35.7	3.77	14.9	1.1	31.2
12	11.9	35.7	2.12	14.3	1.0	30.2	12	36	2.09	14.9	1.1	31.2	12.1	36.3	2.21	14.8	1.1	29.6
13	12.1	36.3	2.71	13.6	1.0	30.8	12.4	37.2	2.68	14.6	1.1	27.1	12.2	36.6	2.8	14.7	1.1	31.2
14	10.2	30.6	3.14	14.9	1.1	31.2	10.3	30.9	3.11	14.1	1.0	31	9.9	29.7	3.23	14.2	1.0	30.5
15	11.2	33.6	1.9	14.9	1.1	31.2	11	33	1.87	15.3	1.1	31.4	11.3	33.9	1.99	14.1	1.0	31
16	10.8	32.4	2.45	14.6	1.1	27.1	11.2	33.6	2.42	14.9	1.1	31.2	11.5	34.5	2.54	14.6	1.1	29
17	10.4	31.2	1.78	14.3	1.0	30.2	10.5	31.5	1.75	14.8	1.1	29.6	10.3	30.9	1.87	13.8	1.0	30.8
18	10.7	32.1	1.96	14.6	1.1	27.1	10.4	31.2	1.93	14.7	1.1	31.2	10.1	30.3	2.05	14.9	1.1	31.2
19	10	30	2.87	14.9	1.1	31.2	9.8	29.4	2.84	14.6	1.1	29	8.4	25.2	2.96	14.6	1.1	27.1

Sl no.	Allogeneic Transfusion (units)								ICU stay (days)	Post-op Infection within 5 days	TRANSFUSION REACTION	Re-exploration for bleeding	Mechanical Ventilation (hours)
	Intra-operative				Post-operative								
	PRBC	FFP	Platelets	Cryoprecipitate	PRBC	FFP	Platelets	Cryoprecipitate					
1	3	2	2	0	2	0	2	0	3	0	0	N	11
2	3	2	2	0	1	0	0	0	4	1	0	N	9
3	2	1	0	0	2	0	2	0	4	0	0	N	9
4	2	1	1	0	1	0	0	0	3	0	0	N	14
5	4	2	5	0	2	0	2	0	6	0	TAD	Y	22
6	2	1	0	0	0	0	0	0	2	0	0	N	10
7	2	1	0	0	1	0	0	0	2	0	0	N	10
8	2	2	2	0	1	0	0	0	2	0	0	N	11
9	3	2	3	0	0	0	0	0	2	0	0	N	11
10	4	2	6	0	0	0	0	0	3	0	0	N	8
11	1	0	0	0	0	0	0	0	2	0	0	N	7
12	1	0	0	0	0	0	0	0	2	0	0	N	7
13	3	1	6	0	0	0	0	0	2	0	0	N	8
14	1	0	0	0	0	0	0	0	2	1	0	N	6
15	2	1	0	0	0	0	0	0	2	0	0	N	8
16	2	0	0	0	1	0	2	0	3	0	0	N	7
17	2	0	0	0	1	0	1	0	3	0	0	N	7
18	2	2	2	0	0	0	0	0	3	0	0	N	8
19	3	2	2	0	1	0	0	0	3	0	0	Y	14

7. Data sheet of Vascular surgery patients – TAAA cases – in the group which underwent allogeneic blood transfusion						Pre-Operative investigations						Intra-operative		Blood Loss (mL)
						Hemoglobin						at Max Surg Blood Loss	after transfusion	
Sl	Age	Gender	Weight	Blood group	Diagnosis	Pre op Hb	Pre op HCT	Pre op Platelet	PT	INR	APTT			
1	64	M	58	A+	TAAA	12.8	38.4	2.79	14.2	1.0	29.9	6.4	9.1	3200
2	59	M	75	B+	TAAA	13.2	39.6	3.22	14.2	1.0	30.3	5.7	9.8	2450
3	68	M	65	B+	TAAA	13.6	40.8	1.98	14.7	1.1	30.3	6.2	10.3	2600
4	53	M	82	A+	TAAA	15.1	45.3	2.6	15.3	1.1	29.5	6.1	9.3	2950
5	57	M	75	A+	TAAA	13.6	40.8	3.78	15.3	1.1	31	6.8	9.5	3100

Sl. No.	Post-Operative Investigations																	
	D0 Hb	D0 HCT	D0 Platelet	D0 PT	D0 INR	D0 APTT	D1 Hb	D1 HCT	D1 Platelet	D1 PT	D1 INR	D1 APTT	D5 Hb	D5 HCT	D5 Platelet	D5 PT	D5 INR	D5 APTT
1	9	27	2.07	16.9	1.3	33	7	21	1.87	17.4	1.3	38	9.2	27.6	1.95	17.2	1.3	32.9
2	9.5	28.5	2.5	17.7	1.4	30.5	9.4	28.2	2.3	16.8	1.3	34.2	9.2	27.6	2.34	16.5	1.2	31.1
3	9.8	29.4	1.26	16.3	1.2	34.1	9	27	1.06	15.9	1.2	36.3	10	30	1.23	17.1	1.3	34.2
4	9	27	1.88	16.5	1.2	31.1	8.2	24.6	1.68	16.5	1.2	31.1	9.4	28.2	1.77	16.8	1.3	34.2
5	8.9	26.7	3.06	17.1	1.3	34.2	7.5	22.5	2.86	17.1	1.3	34.2	9.8	29.4	2.9	15.9	1.2	36.3

Sl. No.	Allogeneic Transfusion (units)								ICU stay (days)	Post-op Infection within 5 days	Transfusion Reaction	Re-exploration for bleeding	Mechanical Ventilation (hours)
	Intra-operative				Post-operative								
	PRBC	FFP	Platelets	Cryoprecipitate	PRBC	FFP	Platelets	Cryoprecipitate					
1	6	4	4	2	2	0	3	0	7	0	0	Y	54
2	5	4	6	2	0	0	0	0	6	1	0	N	37
3	4	2	3	0	1	0	0	0	5	0	FNHTR	N	30
4	7	4	5	2	1	0	0	0	6	0	0	N	29
5	7	3	3	0	2	0	0	0	7	0	0	Y	48