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Original Research Article

A prospective study to evaluate the effects of acute normovolemic hemodilution on perioperative homologous transfusion requirements in patients undergoing major surgery

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ABSTRACT

Background: Acute Normovolemic Hemodilution (ANH) and autologous transfusion can mitigate the harmful effects of banked blood intraoperatively. This study was planned to evaluate its effects on perioperative transfusion requirement, hemodynamic stability and safety profile.
Methods: Hundred patients were randomized to Group 1, where assigned patients received ANH and autologous transfusion after hemostasis; and Group II where assigned patients received homologous transfusion. In group I, 350 to 700 ml of patient's blood was collected before induction of anaesthesia and was kept in the operation theatre at room temperature. This was followed by rapid infusion of calculated Hetastarch. Intraoperative blood loss, amount of transfused blood, serial haemoglobin (Hb) assessment, and change in hemodynamics were carefully monitored. The blood was reinfused once hemostasis was secured at the end of surgery.
Results: It was observed that hemodynamic stability was maintained in both the groups during and after haemodilution. There was no significant change in bleeding and clotting time due to haemodilution. The mean intra-operative blood loss in both groups was comparable. 350 mL and 700 mL blood withdrawn in 27 and 23 patients and 500mL and 1000 mL HES infused respectively. There was an average fall in the mean Hb level by 1.74 gm % and in the mean haematocrit (Hct) level by 6.4 % after haemodilution. The mean 12th and 24th hour Hb and Hct levels were comparable. The requirement of homologous blood transfusion in group I was significantly low ($p<0.0001$). Need for homologous transfusion was 0.72 per patient treated in the Group I.
Conclusions: Acute normovolemic hemodilution is a simple, safe and effective modality to reduce perioperative transfusion of banked blood and should be considered in patients undergoing surgical procedures where major blood loss is expected.

Keywords: Acute normovolaemic haemodilution, Auto transfusion, Blood loss, Blood transfusion, Hetastarch

INTRODUCTION

Blood transfusion is an essential part of perioperative care. With a large burden of trauma and complex surgical procedures like open heart surgery, vascular surgery, organ transplantation being carried out, it is becoming more difficult for the blood bank and health care systems to meet requirements for large quantities of fresh banked blood and other blood components.[1]

A major concern with blood transfusion is the associated infectious complications of homologous blood.[2] Acute Normovolumic Haemodilution (ANH) is a donation that sets aside patient's own blood in anticipation of major intraoperative blood loss, so that it can be re-infused if needed as an autologous transfusion at the conclusion of surgery.[3] This technique reduces the load on the blood bank, while providing safe blood without fear of transmitting diseases. However, there are obvious disadvantages of labeling error, storage problems, increased cost and loss of professional time in paperwork.[3] It is also contraindicated in patients with malignancy, perforated viscera, and in gross contamination or infection.

ANH may be considered in any patient with a haematocrit (Hct) above 33% and Haemoglobin (Hb) above 11 gm%. A decrease of 20-90% in the use of allogenic blood has been reported for a wide spectrum of surgical procedures, particularly when haemodilution is used alongside other blood conservation techniques.[1,2]

This prospective randomized study was carried out to find the efficacy of haemodilution and autologous transfusion during elective surgical procedures where expected blood loss was 500-1500 ml. The aim of this study is to compare the efficacy and safety of ANH with homologous blood transfusion technique on patients undergoing major surgery.

METHODS

After institutional ethics committee approval and obtaining written informed consent, in a period from September 2015 to November 2016, consecutive patients between 20-60 years, with Hb >11 gm%, weighing between 45 to 70 kg, ASA (American Society of Anaesthesiologists) Physical status I and II grade, undergoing elective surgical procedure and likely to be transfused more than 500 ml blood intraoperatively; were enrolled in this prospective randomized study. Patients with coronary artery disease, hypertension and any other cardiac diseases, obstructive or restrictive airway diseases, coagulation disorders, renal diseases, hepatic diseases, haemoglobinopathies or hypoalbuminaemia were excluded. Patient on drugs like beta-blockers and antiplatelet agents/ anticoagulants were also excluded from the study.

After computer-generated randomization, patients were assigned in either Group I (n=50) who underwent ANH and autologous transfusion or II (n=50) which acted as control group in which patient received homologous banked blood depending on the decision of the attending anaesthesiologist. In Group I patients, a predetermined volume of blood was withdrawn prior to surgery and after induction of anaesthesia and normovolaemia was achieved by infusing Hydroxyl Ethyl Starch (HES). Under aseptic precautions the right or left antecubital vein was punctured with a 14-gauge cannula attached to a Citrate Phosphate Dextrose Adenine (CPDA) bag. A standardized protocol of blood collected in ANH was instituted: In patients with Hct >39% or Hb >13 gm%, 700 ml autologous blood was withdrawn and 1000 ml HES infused; and in patients with Hct >33.5 or Hb >11 gm%, 350 ml blood was collected and 500 ml HES infused respectively. After completion of haemodilution, patient's blood sample was collected for estimation of Hb, Packed Cell Volume (PCV), bleeding time and clotting time.

In Group II, homologous banked blood was used for volume replacement when blood loss exceeded 10% of the estimated total blood volume. Total blood volume (in ml) was calculated as 70% of body weight in males and 65% in females respectively.

General Anaesthesia (GA) was given as per standard protocol to all the enrolled patients in either group. Blood loss during the surgical procedure was monitored accurately by swab weighing and calibrated suction bottles. First 10% of the loss was replaced by Ringer lactate in patients undergoing surgery in both the groups and thereafter with autologous and homologous blood depending upon the group.

In patients requiring more blood than the collected autologous blood, homologous banked blood was given. In few surgical procedures where blood loss was expected to be more than 1000 ml, autologous blood was preserved at temperature +2 to +6 degree Celsius and homologous transfusions were given first and thereafter autologous transfusion carried out in reverse order. Hb estimation was done with either HemoCue Beta Haemoglobinometer or B-Haemoglobin microcuvette or by platelet agitator.

Data was analyzed statistically by using the unpaired 't' test. A power analysis based on 95% confidence interval, a sample size of 30 in each group with the total sample size of 60 for 80% statistical power and 5% level of significance was considered. All statistics were performed using the Statistical Package for the Social Sciences (SPSS) version 20. Chi square test was employed, where indicated, to find any associations. $p<0.05$ was taken to indicate statistical significance.

RESULTS

The efficacy and safety of ANH and autologous transfusion compared with homologous transfusion during major elective surgical procedures was studied in 100 patients. Both the groups were comparable with respect to demographics, ASA Physical status grade and the duration of surgery, type of surgery and need for mechanical ventilation (Table 1 and 2).

Duration of surgical procedures was from 2 to 6 hours. Obstetric and gynecological procedures were completed within 2 hours.

The hemodynamic parameters were comparable in the two groups during and after hemodilution with hemodynamic stability maintained throughout the procedure of ANH (Table 3). The mean values of heart rate (HR) and blood pressure were comparable with no significant rise or fall in perioperative hemodynamics in the two groups (Table 3).

Blood loss in both the groups ranged from 400 to 1300 ml and the mean intra-operative blood loss was comparable in the two groups (Table 1). 350 mL of autologous blood was collected in 27- and 700-mL autologous blood in 23 patients with simultaneous infusion of 500 mL and 1000 mL HES respectively.

Table 1: Demographic profile and clinical characteristics of patients in both the group (all values expressed as mean±sd or as expressed otherwise).

Parameter	Group I (n=50)	Group II (n=50)	p-value
Age in years	36.3±8.9	38.5±8.8	0.21
Sex(male/female)	27/23	26/24	
Weight(kg)	58.4±7.3	59.6±7.8	0.42
GA/GA+EA	37/13	46/14	
Asa status (I/II)	28/22	24/26	
Blood loss during surgery(ml)	636.6±197.7	619.8±187.77	0.66

GA-General anaesthesia, EA-Epidural anaesthesia, and ASA-American society of anaesthesiologist

Table 2: The procedures performed in each group.

Operative procedure		Group I	Group II
General	Thyroidectomy	03	04
Surgery	Cholecystectomy	11	11
	Hemicolectomy	02	01
	Radical gastrectomy	02	01
Urological surgery	Nephrectomy	04	04
	Pyelolithotomy	03	05
Orthopaedic surgery	Total hip replacement	04	04
	Dynamic hip screw	07	07
Neurosurgery	Laminectomy	03	02
	Removal of cerebral tumor	02	01
Gynecological surgery	Abdominal hysterectomy	05	05
	Vaginal hysterectomy	04	04
	Exp lap for ruptured ectopic pregnancy	00	01
Total no. of cases		50	50

Preoperative Hb and PCV levels in the two groups were comparable (Table 4). The range of preoperative Hb level in both groups was 11.0-15.5 gm % and Hct was 34-49%. Mean Hb level dropped by 1.74 gm % and mean Hct level by 6.4% after withdrawal of blood and haemodilution. A statistically significant difference was noted in the homologous transfusion requirement in the two groups ($p<0.0001$) (Table 4).

Group I patients required 8 units of banked blood whereas amount of banked blood utilized in Group II was 44 units. Overall 36 units of banked blood were saved due to application of the ANH technique. Perioperative bleeding time and clotting time of all the patients in the two groups was within normal limits at all time points (Table 5). The mean 12^{th} and 24^{th} hours bleeding and clotting time were comparable in the two groups.

Mean amount of homologous banked blood required in Group I was 0.266 units and in Group II was 1.466 units. Mean amount of autologous blood transfusion done in Group I was 1.433 units. In other words, of the total 51 units of blood transfusion in the study group, 43 units were autologous and 8 were homologous. Four patients in the study group required homologous banked blood transfusion post-operatively. One orthopedic patient required two units postoperatively, was noted to have large surgical site haematoma, while the other three patients in group I received one unit each of banked homologous blood transfusion.

The aim of preventing homologous banked blood transfusion could be achieved in 81.8% patients in the ANH group and was statistically significant.

Table 3: Preoperative, post-haemodilution and postoperative haemodynamic measurements in both groups.

	Groups I (mean±sd)	Groups II (mean±sd)	p value
Pre-operative			
HR	78±8.1	79.9±8.1	0.24
SBP	125.2±10.6	123.4±14.2	0.47
DBP	82±6.5	83.6±5.6	0.19
Post haemodilution			
HR	79.7±8.8	-	-
SBP	124.4±13.3	-	-
DBP	81.6±6.03	-	-
Post-operative 12 hours			
HR	79.5±6	78.8±7.1	0.59
SBP	124.5±11.01	122±13.5	0.31
DBP	81.7±5.4	81.3±5.9	0.72
Post-operative 24 hours			
HR	78.1±7.7	78.8±6.07	0.61
SBP	122.6±11.04	120.04±11.5	0.25
DBP	82.2±6.4	83.8±4.7	0.15

HR-heart rate, SBP-Systolic blood pressure, DBP-Diastolic blood pressure

Table 4: Preoperative, post haemodilution and Postoperative hematological measurements in both groups.

	Group I (mean±sd)	Group II (mean±sd)	p value
Pre-operative			
Hb (gm %)	12.9±1.2	12.8±1.1	0.66
PCV (%)	39.9±3.7	39.9±4.4	1
Post haemodilution			
Hb (gm%)	11.1±0.7	--	--
Pcv (%)	33.5±2.6	--	--
Post-operative 12 hours			
Hb (gm %)	12.5±1.1	12.2±1.03	0.16
PCV (%)	38.8±3.9	38.3±4.43	0.55
Post-operative 24 hours			
Hb (gm %)	12.5±1.1	12.2±1.01	0.16
PCV (%)	39.2±4.03	38.5±4.1	0.39
Autologous transfusion (units	1.43±0.504		
Autologous transfusion (ml)	500.6±177.37		
Homologous transfusion (in units)	0.266±0.58	1.466± 0.776	0.0001
Homologous transfusion(ml)	93.36± 204.15	513.33± 271.62	0.0001

Hb- Haemoglobin, PCV-Packed cell Volume

Table 5: Preoperative, post haemodilution and post-operative bleeding time and clotting time in both groups.

	Groups I (mean±sd)	Groups II (mean±sd)	p value
Pre-operative			
Bleeding time	2.07±0.10	2.06±0.08	0.58
Clotting time	4.17±0.22	4.20±0.19	0.46
Post haemodilutio			
Bleeding time	2.10±0.13	--	--
Clotting time	4.21±0.23	--	--
Post-operative 12 hours			
Bleeding time	2.06±0.09	2.05±0.09	0.57
Clotting time	4.18±0.23	4.19±0.19	0.81
Post-operative 24 hours			
Bleeding time	2.04±0.10	2.04±0.08	1
Clotting time	4.22±0.21	4.2±0.18	0.61

DISCUSSION

The present study noted a statistically significant efficacy of ANH as a blood conservation strategy in patients undergoing major surgical procedures with expected blood loss of more than 10% total blood volume. Mehta et al, and Manickam et al, included patients with haemoglobin concentration above 11 and 12 gram% in their study.[4,5]

In the present study, in Group I estimated blood volume was withdrawn from the patients prior to skin incision. Damyanti et al, had also withdrawn blood under general anaesthesia.[6] This was done to avoid transient vaso-vagal attacks which may occur in the conscious patients. The autologous blood was collected via a broad gauge peripheral intravenous cannula. Other researchers have employed radial artery cannulation for rapid collection of blood.[7] However, rapid withdrawal of blood may be deleterious with added concerns of unnecessary arterial cannulation. ANH in this study was achieved by infusion of HES. Rai Sand Watzek et al, in their study achieved ANH with HES and concluded that it was sufficient to maintain normovolaemia.[8,9] A similar procedure was followed by Mehta et al, and Shah et al, who had withdrawn 800-1200 ml blood in CPD bottles and maintained the haemodynamic stability by infusion of 2-3 units of colloid.[4,6]

In this study Bleeding and clotting time estimations were done after haemodilution. Ruttman T-G James MF in their study investigated the effect of in vitro dilution of blood with saline on whole blood coagulation and proved that saline haemodilution has marked effects on increasing the coagulability of whole blood than colloids.[10]

The mean amount of homologous banked blood required in Group I was 0.266 units and in group II was 1.466 units. Mean amount of autologous blood transfusion done in group I was 1.433 units. In other words, 52 units of blood transfusion in the study group 43 were autologous and 8 were homologous. On the other hand, 44 units of homologous were transfusion in the control group. Shah et al, in their autologous group did not require any homologous banked blood and Mehta et al, noted saving 47 units of banked blood in their study.[4,6]

There was no significant difference in the HR and blood pressure at 12 and 24 hours. Similar results were observed by Korula et al, and Mehta et al.[4,5] In this study, there was no significant statistical difference after 12 and 24 hrs in mean haemoglobin concentration and haematocrit value in both groups. Korula et al, also found no significant difference between the haematocrit values post-operatively.[4] In the study by Shah et al, haemoglobin level on Day 3 was significantly higher in the autologous than in than in control group and they attributed it to transfusion of autologous blood after completion of surgery.[6]

Total avoidance of homologous-banked blood transfusion was aimed at and could be achieved in 81.8% patients in the ANH group. This compared with the other studies where the reduction in the homologous banked blood use was noted in 18-90% patients. Mehta et al, observed complete avoidance of banked blood transfusion in the ANH group.[4] Thus in this study, it was found that preoperative haemodilution and autologous transfusion was an effective and safe blood conservation strategy

with statistically significant conservation of homologous banked blood.

This study was fraught with certain limitations. Firstly, authors included only healthy young patients in the study and the results cannot be applied to patients in extremes of age, obese patients and those with comorbidities. Additionally, authors employed conservative threshold of autologous collection and the results would be different with extreme ANH technique. Finally, the cost effectiveness of this technique was not evaluated in terms of reducing health care costs.

CONCLUSION

Acute normovolemic haemodilution was found to be a safe and easy technique well tolerated by healthy patients with optimal preoperative haemoglobin level. The hemodynamic stability, unchanged coagulation parameters and adequate tissue oxygenation; proves the safety profile of this technique. This blood conservation modality should be considered in all patients undergoing major surgical procedures with expected blood loss exceeding 10% of the patient's blood volume.

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