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Original Research Article

SAFETY AND HEMODYNAMIC ALTERATIONS ASSOCIATED WITH ACUTE NORMOVOLEMIC HEMODILUTION IN COMPARISON TO CONVENTIONAL HOMOLOGOUS BLOOD TRANSFUSION AMONG PATIENTS WHO WERE POSTED FOR HYSTERECTOMY

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Abstract

Background: The increasing need for extensive surgical procedures, often involving major blood loss, necessitates intraoperative and postoperative blood replacements. The risks of allogeneic blood transfusion include blood-borne infections, haemolytic reactions, and immunological complications. Acute normovolaemic haemodilution (ANH) is cost-effective, convenient, and safe but is underutilised in patients undergoing hysterectomy. This study aimed to compare haemodynamic alterations between patients receiving acute normovolaemic haemodilution (ANH) and those receiving conventional homologous blood transfusion during elective hysterectomy. **Materials and Methods:** This randomised controlled study included 60 patients who underwent elective total abdominal hysterectomy at the Department of Gynecology, Government Theni Medical College Hospital, during the study period. Data were analysed using Microsoft Excel 2010 and SPSS 20.0, with parametric tests, normality tests, chi-squared tests, and ANOVA for categorical variables. Statistical significance was set at $p < 0.05$. **Result:** There were no significant differences in age, ASA grade, or weight between the groups ($p < 0.05$). Therefore, the two groups were comparable. The study found no significant differences in heart rate, systolic blood pressure, diastolic blood pressure, arterial pressure, haemoglobin levels, haematocrit levels, platelet count, bleeding time, clotting time, aPTT, INR, or sodium and potassium levels between the two groups during the preoperative and postoperative periods. However, the haemodilution group experienced greater decreases in systolic blood pressure, diastolic blood pressure, arterial pressure, and haematocrit levels. The changes were similar in both groups. **Conclusion:** Acute normovolaemic dilution is a safe alternative to homologous blood transfusion, with no significant changes in haemodynamic parameters, and a 30% haematocrit cut-off is safe.

INTRODUCTION

The need for extensive surgical procedures which are often associated with major blood loss, is on the rise; hence, the need for intraoperative and postoperative replacement of blood continues to surge. Although blood and blood products are safer now than before, there are still many risks of allogeneic blood transfusion, such as the transmission of blood-borne infections, haemolytic reactions, and immunological complications, ranging from subtle allergic reactions to anaphylactic shock and immunosuppression in some cases.[1,2] For these reasons, several strategies to reduce or eliminate the need for homologous blood transfusion have been introduced. Messmer and Sunder Plassman were the first to study several blood conservation strategies including autologous withdrawal of blood for re-infusion in the peri-operative period. Autologous transfusion can be done by preoperative autologous blood donation (PABD), acute normovolemic haemodilution (ANH), or intraoperative blood salvage.[3]

Acute normovolaemic haemodilution (ANH) is defined as the process of removing whole blood from the patient immediately before surgery and maintaining normovolaemia (circulating volume) by simultaneous replacement using a suitable volume of acellular fluids such as crystalloids or colloids. It is performed shortly before or after anaesthesia induction. This can be considered in patients undergoing surgery in which substantial blood loss is anticipated.[4] Thus, hemodiluted blood with fewer blood cells is lost during surgery, and once haemostasis is achieved at the end of the surgery, the saved blood is re-infused into the patient. Acute normovolaemic haemodilution (ANH) is convenient for patients as a blood procurement technique because it is very simple to perform and is the only technique that provides fresh whole blood for use in the operating room. Moreover, acute normovolemic haemodilution is very cost-effective in comparison to autologous donation or intraoperative cell savage as the blood obtained from the patient needs no filtering, washing and storage in a blood bank.[5]

As the blood is re-transfused immediately, there is no scope for biochemical changes associated with blood storage. In addition, platelet function is preserved when compared to that of blood; similarly, the risk of hypothermia associated with cold storage is avoided.[6] Furthermore, ANH eliminates the risk of a transfusion-related clerical error that could lead to the transfusion of incompatible blood and its grave consequences. However, ANH remains underutilised because of the perception that it may prolong the time at the operating table and require additional monitoring and personnel.[7] The hysterectomy has become a common obstetric surgery in India and one study reported a prevalence of roughly 17 per 1000 women according to District Level Household Survey (DLHS) data.[8]

The need for blood transfusion is common in women who undergo hysterectomy because the surgical procedure is associated with significant blood loss. Acute normovolaemic haemodilution is a safe, effective, and economical alternative strategy that can be ideally used in patients who undergo hysterectomy to alleviate the need for homologous blood transfusion and transfusion-associated risks. Moreover, there is a paucity of data regarding the use of ANH in hysterectomy, particularly in our country.

Aim

This study aimed to compare haemodynamic alterations between patients receiving acute normovolaemic haemodilution (ANH) and patients receiving conventional homologous blood transfusion during elective hysterectomy at the Government Theni Medical College Hospital.

MATERIALS AND METHODS

This randomised controlled study was conducted on 60 patients who underwent elective total abdominal hysterectomy at the Department of Gynecology, Government Theni Medical College Hospital during the study period. The study was approved by the institutional ethics committee before initiation, and informed consent was obtained from all patients.

Inclusion Criteria

Patients aged > 18 years who were scheduled for elective total abdominal hysterectomy, preoperative haemoglobin level >11 g %, and preoperative haematocrit level >30% were included.

Exclusion Criteria

The presence of cardiac, pulmonary, renal, or liver disease; uncontrolled hypertension; coagulation disorders; hypoalbuminaemia; presence of infection; and unwillingness to provide consent to participate were excluded.

Statistical Analysis

All data were entered initially into Microsoft Excel 2010 and then spreadsheets were used for analysis, and statistical analysis was performed using SPSS version 20.0. Parametric tests, such as Student's t-test, were used to compare the means of continuous variables after ensuring that the variable followed a normal distribution. Tests for normality, such as the Kolmogorov-Smirnov test, were used. The chi-square test was used to compare various categorical variables, while Yates's correction for continuity was used in the chi-square test to reduce the error in the approximation. Factorial repeated measures ANOVA was employed to test for differences in changes in various (continuous) independent variables, such as haemodynamic parameters and coagulation profile variables, between the haemodilution group and the control group (between-subjects factor). A p-value of <0.05 was used to reject the null hypothesis in all statistical tests of significance.

RESULTS

There were no significant differences in age or ASA grade between groups ($p < 0.05$). Therefore, the two groups were comparable. The difference in mean weight between the two groups was not statistically significant ($p > 0.05$); hence, both groups had comparable body weights [Table 1].

T1- Before Hemodilution/Time after Induction in the Control Group, T2- At the End of Hemodilution /40 mins after Induction in the Control Group, T3- Start of Surgical Closure, T4: 3 h postoperatively.

There was no statistically significant difference in mean heart rate between the groups throughout the preoperative and postoperative periods.

There was a statistically significant difference in the mean systolic blood pressure (SBP) between the two groups only at the end of haemodilution, as there was a fall in SBP in the haemodilution group but not in the control group. There was a statistically significant variation in the mean systolic blood pressure (SBP) over time in both groups, and subjects in the haemodilution group experienced a greater decrease in systolic blood pressure (decline in T3) than

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subjects in the control group, and this difference was statistically significant.

There was a statistically significant difference in the mean diastolic blood pressure (DBP) between the two groups only at the end of haemodilution, as there was a decrease in DBP in the haemodilution group. There was a statistically significant variation over time in mean diastolic blood pressure (DBP) in both groups, and subjects in the haemodilution group experienced a greater decrease in diastolic blood pressure than subjects in the control group, and this difference was statistically significant.

There was a statistically significant difference in the mean arterial pressure between the two groups only at the end of haemodilution, as there was a decrease in MAP in the haemodilution group. There was a statistically significant variation in the mean arterial pressure (MAP) over time in both groups. However, there was no statistically significant difference in MAP changes between the two groups.

The statistically significant difference in mean haemoglobin levels (Hb) between the two groups present at the baseline was maintained throughout the preoperative and postoperative periods, except at the end of haemodilution, where this difference diminished because of the greater decrease in haemoglobin levels in the haemodilution group than in the control group.

The statistically significant difference in the mean haematocrit levels (HCT) between the two groups at baseline was maintained throughout the preoperative and postoperative periods. There was a statistically significant variation in HCT over time in both groups, and subjects in the haemodilution group experienced a greater decrease in HCT than subjects in the control group at the end of haemodilution, and this difference was statistically significant.

For platelet count, bleeding time, clotting time, activated partial thromboplastin time (aPTT), and INR, there was no statistically significant difference between the mean levels of these parameters between the two groups from the baseline, throughout the preoperative and postoperative periods. Although there was significant variation in these variables over time, these changes were similar in both groups.

Mean sodium and potassium levels were not significantly different between the mean levels of these parameters between the two groups from the baseline throughout the preoperative and postoperative periods, except that there was a fall in sodium levels in T1 and T2 in both groups before returning to preoperative levels [Table 2 and 3].

Table 1: Comparison of age, ASA grade and weight between groups

		Control	Haemodilution	P value
Age	31 to 40 years	6 (20)	7 (23.3)	0.415
	41 to 50 years	16 (53.3)	20 (66.7)	
	51 to 60 years	6 (20)	2 (6.7)	
	>60 years	2 (6.7)	1 (3.3)	
Mean age		48.53±8.803	44.60±5.230	0.051
ASA grade	Grade I	20 (66.7)	21 (70)	0.781
	Grade II	10 (33.3)	9 (30)	
Weight		58.60±3.440	56.03±6.578	0.063

Table 2: Comparison of various parameters among the groups at various time

		Control group	Haemodilution Group	P value
Mean heart rate	Pre-op	83.1±3.9	84.4±11.5	0.561
	T1	85.2±4.2	90.4±15.8	0.086
	T2	90.9±4.4	90.0±12.7	0.714
	T3	88.3±4.4	90.1±15.6	0.538
	T4	89.6±5.4	89.6±10.5	1
Systolic blood pressure	Pre-op	123.8±12.3	128.1±6.8	0.097
	T1	125.4±18.4	124.5±8.5	0.802
	T2	118.7±16.6	112.5±11.6	0.048
	T3	119.2±14.8	119.6±11.1	0.914
	T4	122.5±10	124.1±5.3	0.121
Diastolic blood pressure	Pre-op	77.9±9.2	81.7±6.8	0.07
	T1	81.6±14.1	78.7±7.8	0.334
	T2	77.3±13	70.6±8.2	0.02
	T3	79.5±10.1	78.0±6	0.489
	T4	82.4±8.1	82.2±4.9	0.909
Mean arterial pressure	Pre-op	92.8±9.2	96.2±5.3	0.085
	T1	96.0±15.1	94.2±8.2	0.575
	T2	90.9±13.8	84.8±9	0.048
	T3	93.4±11.3	92.2±7.2	0.616
	T4	95.7±7.9	97.1±5	0.415
Hemoglobin Levels	Pre-op	10.3±0.4	11.2±0.5	<0.001
	T1	10.1±0.3	10.7±0.8	<0.001
	T2	9.3±0.6	9.6±0.8	0.152
	T3	9.6±0.4	10.4±1.3	0.001
	T4	10.2±0.4	10.8±1.0	0.003
Hematocrit values	Pre-op	31.3±1.0	35.7±5.1	<0.001
	T1	30.7±1.1	34.2±4.4	<0.001

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	T2	28.8±1.3	31.3±4.5	0.004
	T3	29.3±1.2	31.8±3.8	0.001
	T4	30.6±1.0	33.2±3.7	0.001
Platelet count	Pre-op	2.85±0.29	2.92±1.01	0.686
	T1	2.66±0.35	2.73±0.68	0.592
	T2	2.48±0.41	2.51±0.62	0.865
	T3	2.46±0.39	2.33±0.50	0.243
	T4	2.58±0.29	2.31±0.49	0.053
Bleeding time	Pre-op	136±18	127±28	0.127
	T1	132±13	126±16	0.112
	T2	118±15	117±14	0.667
	T3	121±19	121±19	0.937
	T4	120±21	114±30	0.401
Clotting time	Pre-op	7.2±1.1	7.5±1.1	0.23
	T1	7.2±1.1	7.9±0.8	0.058
	T2	7.8±1.0	7.7±1.0	0.684
	T3	7.7±1.1	7.9±1.1	0.483
	T4	8.1±1.0	8.0±0.9	0.729
Activated partial thromboplastin time	Pre-op	34.4±2.8	35.9±2.8	0.057
	T1	35.8±2.7	36.4±2.6	0.142
	T2	37.5±2.9	37.1±2.7	0.592
	T3	36.9±2.8	37.1±2.5	0.757
	T4	37.7±2.7	37.9±2.6	0.754
International normalized ratio	Pre-op	1.105±0.059	1.130±0.048	0.079
	T1	1.194±0.040	1.206±0.039	0.236
	T2	1.251±0.056	1.261±0.070	0.513
	T3	1.274±0.056	1.293±0.040	0.06
	T4	1.246±0.048	1.242±0.047	0.735
Sodium levels	Pre-op	141.5±1.4	140.8±1.2	0.059
	T1	141.0±1.2	140.2±1.8	0.078
	T2	139.7±1.6	140.4±2.0	0.164
	T3	139.9±2.2	140.3±1.5	0.419
	T4	141.5±1.5	141.1±1.0	0.232
Potassium levels	Pre-op	4.1±0.1	4.2±0.2	0.084
	T1	4.0±0.1	4.1±0.2	0.067
	T2	4.0±0.3	4.1±0.3	0.3
	T3	4.0±0.2	4.1±0.2	0.063
	T4	4.2±0.2	4.1±0.2	0.1
Blood sugar	Pre-op	94.8±9.2	97.8±26.5	0.56
	T1	104.3±8.8	102.3±26.4	0.705
	T2	116.3±7.9	114.7±21.3	0.701
	T3	128.4±4.0	125.3±18	0.366
	T4	136.8±6.4	129.1±17.3	0.56

Table 3: Comparison of various parameters among the groups

		Mean	**P value**
Heart rate	Over time	9.069	<0.001
	Variation	2.143	0.088
Systolic blood pressure	Over time	7.721	0.001
	Variation	3.663	0.01
Diastolic blood pressure	Over time	11.244	<0.001
	Variation	2.634	0.044
Mean arterial pressure	Over time	11.26	0.001
	Variation	2.24	0.076
Haemoglobin levels	Over time	52.62	<0.001
	Variation	2.69	0.04
Haematocrit values	Over time	41.546	0.001
	Variation	2.948	0.028
Platelet count	Over time	12.554	0.002
	Variation	2.243	0.061
Bleeding time	Over time	5.966	<0.001
	Variation	0.742	0.568
Clotting time	Over time	7.492	<0.001
	Variation	2.315	0.052
Activated partial thromboplastin time	Over time	7.621	0.001
	Variation	1.238	0.306
International normalised ratio	Over time	100.19	0.001
	Variation	0.653	0.627
Sodium levels	Over time	15.243	0.001
	Variation	2.115	0.189
Potassium levels	Over time	2.279	0.087
	Variation	2.15	0.102

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Blood sugar	Over time	108.21	<0.001
	Variation	1.657	0.198

Table 4: Comparison of blood loss between the groups of the study

		Mean ± SD	P value
Estimated blood volume (EBV)	Control	3809.0±223.6	0.063
	Haemodilution	3642.2±427.6	
Estimated allowable blood loss (EABL)	Control	487.1±126.5	<0.001
	Haemodilution	701.8±151.7	
Blood loss (BL)	Control	736.7±204.7	0.058
	Haemodilution	825.0±144.3	

DISCUSSION

The mean age ± S.D of the patients in the control group was 48.53 ± 8.8 and in the haemodilution group it was 44.6 ± 5.23 years but this minor difference in mean age between the two groups was not statistically significant (p>0.05). The majority were aged 41–50 years. These findings were similar to those of Gokhale et al., who compared ANH with PABD in gynaecological surgeries as 46% were in the 41 to 50 years age group.[9] In our study, the mean weight ± S. D. of the patients in the control group was 58.6 ± 3.4 and in the haemodilution group it was 56.03 ± 6.57 Kg but this minor difference in mean weight between the two groups was not statistically significant (p>0.05). This finding can be compared to Mirhasemi et al., who reported the mean weight of patients posted for gynaecological surgeries as 56 ± 6.57 Kg.[10]

In our study, the majority were ASA grade 1, followed by grade 2, and patients in the control and haemodilution groups were almost equally distributed according to ASA grading. There were no statistically significant differences in the changes in heart rate between the two groups. These findings are like that of Goodnough et al., in which there were no significant variations in HR between the 2 groups.[11]

Our study found significant differences in systolic blood pressure (SBP) and diastolic blood pressure (DBP) between the two groups after haemodialysis. The haemodilution group experienced a greater decrease in SBP and DBP, while the control group experienced a decrease in DBP. The mean arterial pressure (MAP) also showed significant differences between the two groups, with a decrease in MAP in the haemodilution group. However, no significant difference was found in MAP changes between the two groups. These findings can be corroborated with that of Santoso et al., in which except for arterial pH and oxygen consumption, there was a fall in perfusion indices including blood pressure and there was tachycardia reported.[12]

In contrast, Naqash et al. reported that there were no statistically significant changes in heart rate and mean blood pressure between the controls and ANH groups.[13] Also, Firodiya et al. reported a statistically significant fall in blood pressure but it can be considered that it was clinically insignificant as the fall in BP was only 3 mmHg.[14]

Our study found a significant difference in the mean haemoglobin levels between the two groups at baseline, which remained throughout the preoperative and postoperative periods. However, at the end of haemodilution, the difference diminished due to a greater decrease in haemoglobin levels in the haemodilution group than in the control group. These differences became statistically significant over time. This contradicts the findings of Naqash et al., as they observed no statistically significant variation in mean haemoglobin levels between the two groups.[13]

In our study, there was a statistically significant variation in HCT over time in both groups, and subjects in the haemodilution group experienced a greater decrease in HCT than subjects in the control group (2.9% vs. 1.9%) at the end of haemodilution, and this difference was statistically significant. According to Rehm et al., the intraoperative HCT was 30.5% in controls and 21.9% in the ANH group, while the postoperative HCT was 25.7% vs. 27.2% in the control and ANH groups, respectively; platelet count, bleeding time, clotting time, activated partial thromboplastin time (aPTT), and INR, there was no statistically significant difference between the mean levels of these parameters between the two groups from baseline, throughout the preoperative and postoperative period.[15]

Although there was significant variation in these variables over time, these changes were similar in both groups. These findings can be compared to that of Jones et al., as they reported that there was a significant change in platelet count, bleeding time, and clotting time in patients who had ANH undergoing radical prostatectomy though they did not include the control group.[16]

Also, Messmer et al., reported that there is no change in the coagulation profile associated with ANH, mean sodium and potassium levels there was no statistically significant difference between the mean levels of these parameters between the 2 groups from the baseline, throughout the preoperative and postoperative period except that there was a fall in sodium levels in T1 and T2 in both groups before rising back to preoperative levels, estimated allowable the mean EABL ± S.D of the patients in the control group was 487.1 ± 126 ml and in a haemodilution group it was 701.8 ± 151 ml and this difference in mean EABL between the two groups was statistically significant (p 0.05) though blood loss was higher in the haemodilution group.[3]

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CONCLUSION

Acute normovolaemic dilution is a safe alternative to homologous blood transfusion, as there were no significant changes in haemodynamic parameters and coagulation profile. There was a decrease in haemoglobin level and haematocrit values at the end of haemodilution, but it reverted to normal levels after re-infusion. A haematocrit cutoff of 30% can be safely used as a limit for normovolaemic haemodilution.

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