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# A Study to Observe Blood Loss Reduction by Tranexamic Acid Before and After Caesarean Section

Delphine Supriya[1], M. Mumtaj[2]

Government Thanjavur Medical College & Hospital, Thanjavur. Tamilnadu, India

**Correspondence Author:** M. Mumtaj, Government Thanjavur Medical College & Hospital, Thanjavur. Tamilnadu, India

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**Conflicts of Interest:** Nil

## Abstract

**Introduction:** Tranexamic acid ,an antifibrinolytic is said to be beneficial in reducing blood loss during caesarean section.

**Aim:** To assess the role of tranexamic acid in controlling blood loss during caesarean section.

**Materials and methods:** This study was conducted to clinically observe the blood loss reduced by tranexamic acid during and after caesarean section.300 patients were selected for the study, 150 as study group and 150 as Control group.

**Results**: Age incidence-44.3% of the cases belong to the age group 25-29 years.57% of the cases were primigravida and 29% of the cases were 2nd gravida.93% of the cases were emergency cases and 7% of the cases were elective cases. There was no statistically significant difference in the subjective characters in between the two groups.

**Conclusions**: Tranexamic acid significantly reduced the blood loss from placental delivery to 2 hour post partum.There was statistically significant fall in blood pressure and rise in PR and significant change in RR in the control group compared to the study group. Hb level was significantly reduced in the control group compared to the study group postoperatively but without significant increase in the need for blood transfusion. Incidence of vomiting was higher in the study group and wound infection was higher in the control group but without statistical significance. This vomiting may be drug related and wound infection may be related to blood collection in the wound. None of the patients in both the groups had thromboembolic complications postoperatively. Neonatal outcome was similar in both the groups.

**Keywords:** tranexamic acid, blood loss, caesarean section, postoperative

## Introduction

Delivery by caesarean section (CS) is one of the most commonly performed obstetric surgeries all over the world. Nevertheless, it certainly exposes women to the inherent risk of abdominal surgery; injury to the pelvic structures, infection and the need for blood transfusion.

Obstetric blood loss is one of the most feared complications of childbirth. Blood loss during caesarean section is twice than that of vaginal delivery. Physiologically, towards the end of pregnancy, the uterus is perfused at a rate of 500-750 ml/minute.

This massive hyper-perfusion results in an average blood loss of approximately 1000 ml during each Caesarean section.

During placental delivery the fibrinolytic system gets activated which lasts for about 6-10 hours. This may lead to postpartum bleeding. In a similar way, the fibrinolytic activity in the endometrium of patients with dysfunctional uterine bleeding may also be high. Hence the use of antifibrinolytics proves to be beneficial in reducing the blood loss during caesarean section and in DUB related menorrhagia. Postpartum haemorrhage contributes to 25%

of global maternal death. As it is preventable in most situations ample steps can be taken to reduce its incidence. The present study observes the role of Tranexamic acid, an antifibrinolytic in reducing blood loss during and after caesarean section.

**Aim of the study**

1. To evaluate the efficacy of preoperative parenteral tranexamic acid in reducing the blood loss during and after caesarean section.

2. To compare it with the amount of blood loss in patients who did not receive tranexamic acid prior to caesarean section.

**Materials and Methods**

The subjects of this prospective randomised placebo controlled study were 300 pregnant women who were admitted in the labour ward and planned for caesarean section in the time period from July 2016 to June 2017 ( 1 year ).

In all patients detailed history – medical history, obstetric history were taken. Vital parameters checked and basic investigations done. Weight of the patient checked. Detailed general examination and obstetric examination done. Gestational age confirmed by USG.150 patients were placed in group A and 150 patients were placed in group B. All patients were counselled and informed consent obtained.

Group A received **:**1. Injection Tranexamic acid 1gm slow intravenous infusion over 5 min –20 minutes before skin incision. 2. Oxytocin 10 units in intravenous infusion immediately after the delivery of the baby.

Group B received **:**Oxytocin 10 units in iv infusion alone immediately after the delivery of the baby.

**Inclusion Criteria** :

1. Primigravida and multigravida
2. More than 38 weeks of gestation.
3. Elective and emergency cases.

**Exclusion Criteria**

Women with risk factors for PPH were not included in this study.

1. Haemoglobin < 8gm%
2. Twin pregnancy
3. Polyhydramnios
4. EFW > 4 kg
5. Previous H/O PPH
6. Fibroid complicating pregnancy
7. Preeclampsia
8. Placenta previa
9. Abruptio placenta
10. Induced labour
11. Prolonged and obstructed labour
12. Heart disease complicating pregnancy
13. Renal / liver disease patients
14. Patients on anticoagulants
15. Previous H/O thromboembolism

**Methods**

Group A and Group B patients received the injections as above mentioned. In each case the following parameters were noted.

1. Preoperative PR / BP / RR / Hb%/Hct
2. Intra operative blood loss from placental delivery to end of surgery.
3. Post operative blood loss from the end of surgery to 2 hours post partum.
4. Post operative PR, BP, RR, Hb%/Hct
5. Side effects of the drug
6. Maternal needs for blood transfusion were noted.
7. Post operative period and the maternal outcome till discharge were noted.
8. Neonatal outcome was also noted.

**Measurement of Blood loss**

In our study blood loss was measured by measuring the blood in the suction container after placental delivery and by weighing the swabs before and after surgery.

1 gm of swab weight = 1 ml of blood.

(Bonica and Lyter 1951 / Harding 1984)

Swab+C-mat weight – Swab+C-mat weight

Total blood loss = after surgery(gm) before surgery(gm) (ml)

+ Blood in the suction container (ml)

+ Diaper soakage upto 2 hrs post partum (weighted before and after surgery).

Eventhough this gives only the approximate amount of bloodlost it is the only practically possible and feasible method. So thesemethods were used in our study.

After collecting all the data, the data were tabulated in amaster chart and analysed. Data analysis was done with the help ofcomputer using Epidemiological information package (2008).

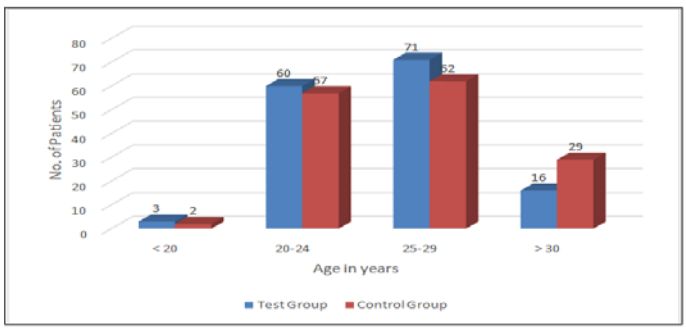
Using this software frequencies, percentage, mean, StandardDeviation, chisquare and 'p' values were calculated. Kruskul Wallischi square test was used to test the significance of differencebetween quantitive variables and Yate's test for qualitative variables.

A 'p' value less than 0.05 is taken to denote significant relationship.

**Results and Statistical Analysis**

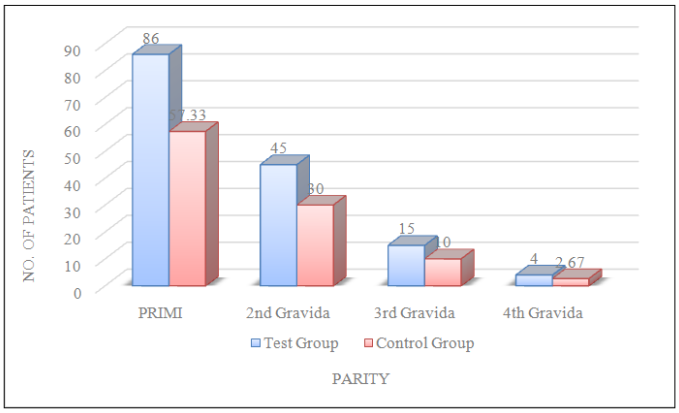
**Distribution of age in the study groups** in TABLE 1

i)



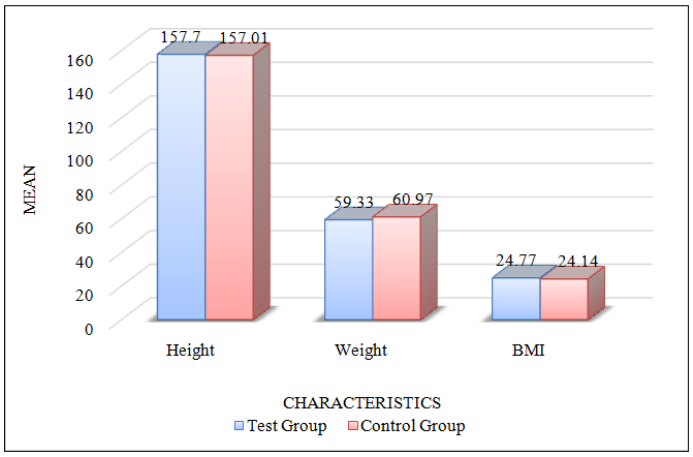

**Parity distribution among the study group in TABLE:2**

ii)



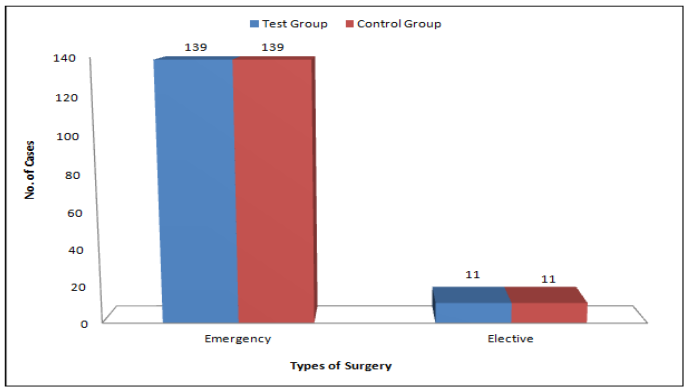

**Comparison of Subjective Characteristics of the study samples in TABLE:3**

iii)




**Comparison of types of Surgery done between the two groups in TABLE:4**

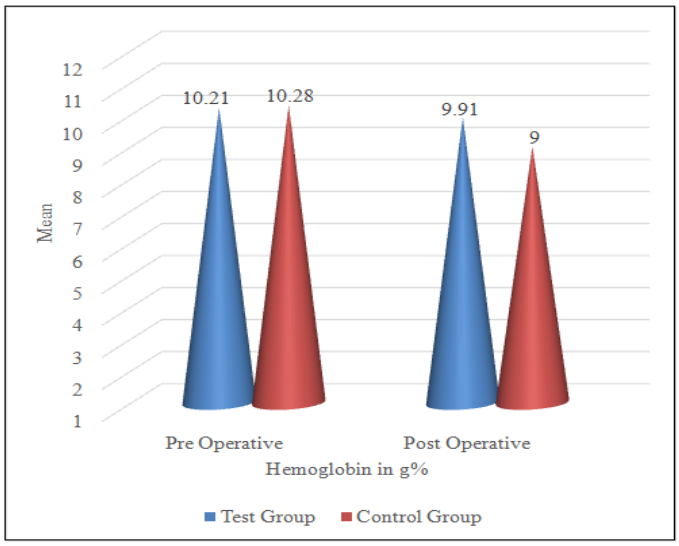
iv)



**Change in vital parameters pre and postoperative in TABLE:5**

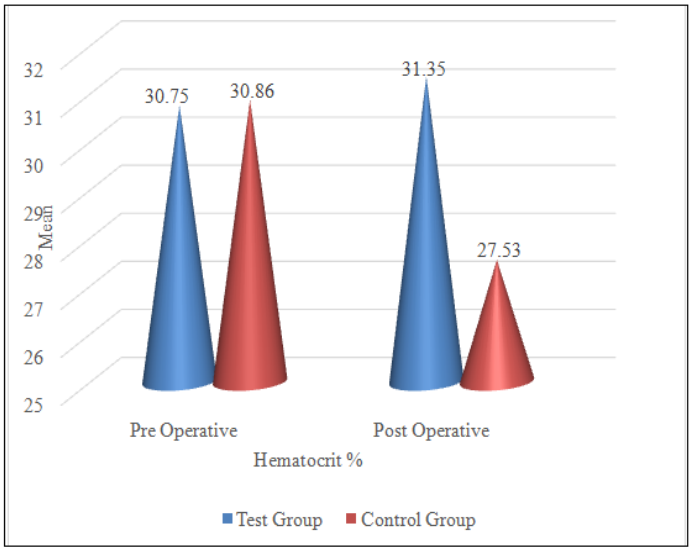
**Comparison of changes in hemoglobin% between the groups in TABLE:6**

v)




**Comparison of hematocrit between two groups in TABLE:7**

vi)



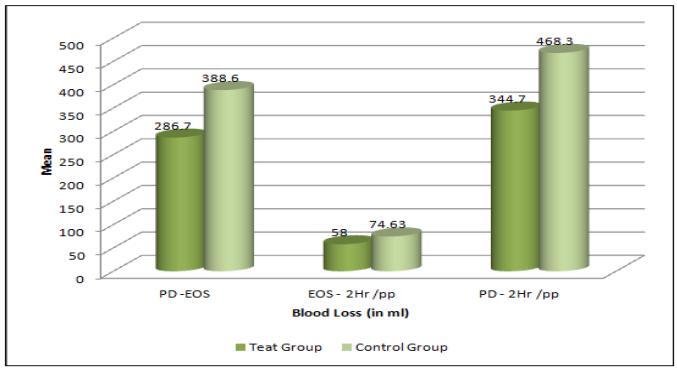

**Comparison of blood loss between two groups in the study in TABLE:8**

vii)

PD - Placental Delivery

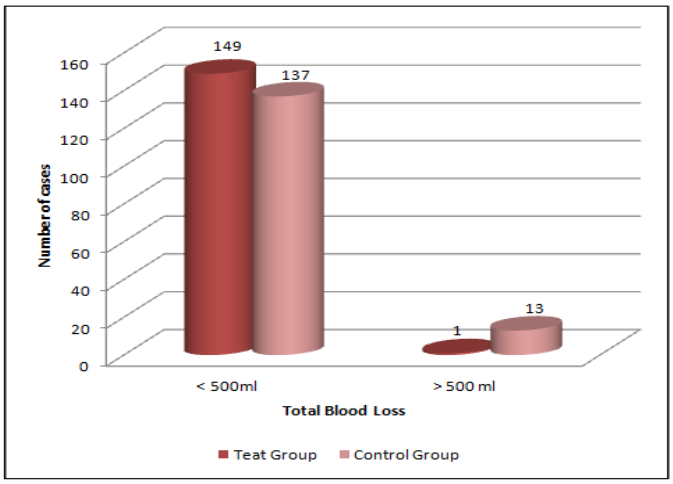
EOS - End of surgery

2hr PD- 2 hours postpartum



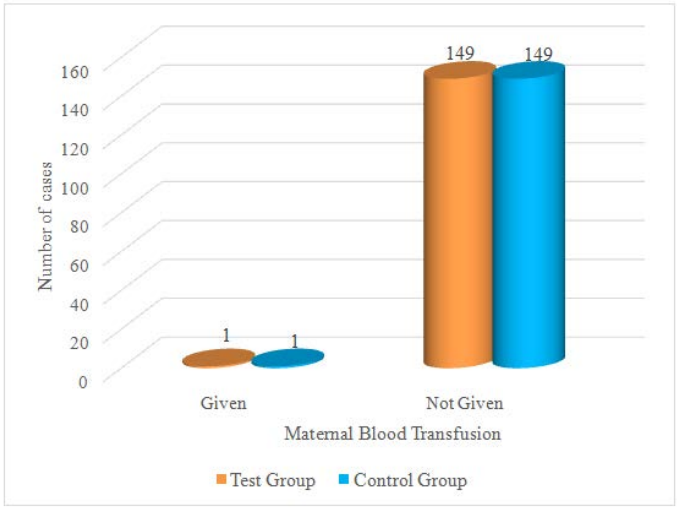

**Comparison of total blood loss proportion between the groups in TABLE:9**

viii)



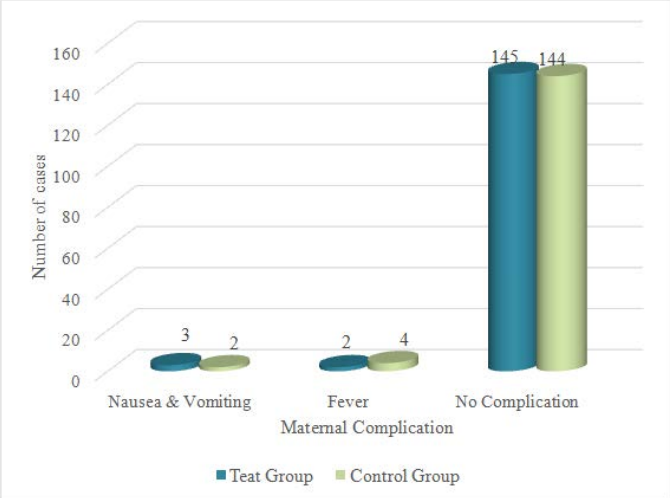

**Comparison of maternal blood transfusion between the groups in TABLE:10**

ix)



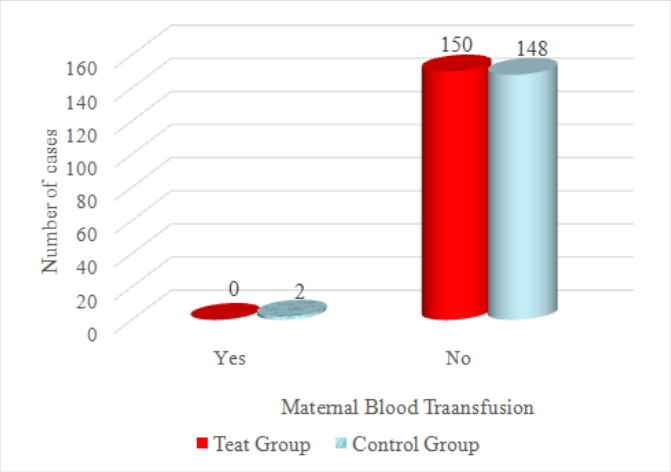
**Comparison of maternal complication between the groups in TABLE:11**

x)




**Comparison of hospital stay after 8th POD between the groups in TABLE:12**

xi)




**Comparison of NICU admission of the infant after birth between the groups in TABLE:13**

**Discussion**

As obstetric blood loss contributes to one fourth of global maternal death, death resulting from PPH should be avoided. As prevention can always be better than cure, the same is true regarding PPH also – an antifibrinolytic agent like tranexamic acid has been used prophylactically in our study to observe its efficacy in reducing blood loss during and after caesarean section.

**Maternal age** :In our study, the age group of patients included varied from 18 to 35 years. Maximum percentage of patients belong to the age group of 25-29 years.( 47.3% of group A and 41.3% group B) . In a study conducted by department of Obst & Gynae Medical college and SSG hospital, Baroda, Gujarat,2013 the mean age was 25 years.

**Antenatal Care** : In our study, 98% of test group and 95% of control group were booked. In a similar study conducted by International Medical Communication Department, Daiichi Pharmaceutical Co. Ltd,Tokyo, Japan,2004, 66% of study group and 68% of control group were booked. Proper antenatal care is important to identify the high risk factors in the antenatal period itself and to correct them thereby reducing the incidence of PPH.

**Parity :**In our study, primigravida were more in both groups than second or third gravida. All were Singleton pregnancies. In the study group 57.3% were Primigravidas and 30% were 2nd gravidas, 10% were third gravidas and . In control group – 58% were Primigravidas and 28.6% were 2nd gravidas, 12% were third gravidas and 1.33% were fourth gravidas . In a similar study conducted by Department of obst & Gynec Medical College and SSG hospital, Baroda, Gujarat second gravidas were 70% and primigravidas were 30%.

**Subjective characters :**In our study mean height was 154.7 cm in test group and 157.01 cm in control group. Mean weight was 59.3 kg in test group and 60.97 kg in control group. Mean BMI was 24.77 in test group and 24.14 in control group. In a similar study conducted by the Department of Obstetrics & Gynecology of Peking Union Medical College hospital, Chinese academy of Medical Sciences, Beijing 100730, China, in 2008, where mean height was 161 cm and mean weight was 72 kg.

**Type of Surgery :**In our study, 92.67% of study group and control group were emergency cases. 7.33% of test and control group were elective cases. Both were comparable in the two groups.

**Vital parameters :**In our study Pulse Rate increases and systolic Blood Pressure decreases significantly in the control group when compare with test group post operatively. Also Respiratory Rate increases post operatively more in control group than in test group. In a similar study conducted by International Medical Communication department, Daiichi Pharmaceutical Co. Ltd, Tokyo, Japan also there was a statistically significant change in vital parameters.

**Blood loss in TABLE:14**

**Haemoglobin change in TABLE:15**

In our study statistically significant fall in Hb% occurred after surgery in control group than with test group.

**Total blood loss of more than 500 ml and need for maternal blood transfusion in TABLE:16**

In our study, one patient in test group and 1 patient in control group had total blood loss of more than 500 ml who needed blood transfusion. This need was not statistically significant. In a similar study conducted by University Department of Obstetrics & Gynaecology in 2009, Rosie Maternity hospitals, Robinson way Cambridge – CB2 – 2SW – UK, 2 patients in study group and 5 patients in control group had more than 500 ml of total blood loss and needed blood transfusion. This was also without statistical significance.

**Maternal complications other than blood loss**:

In our study, 3 patients in test group and 2 patients in control group had vomiting in the immediate post operative period which may be related to the drug. But this increased incidence of vomiting in test group was not statistically significant. 2 patients in test group and 4 patients in control group had fever on 3rd post operative day. In the Test Group, 1patient with fever had dysuria and urine culture was positive for E.coli and treated with antibiotics and discharged on 8th POD. Another patient had breast engorgement as the baby was admitted in NICU for 1 day observation and discharged .Among 4 patients, who had fever on the 3rd POD in control group – 2 had breast engorgement as their babies were admitted in NICU.One baby was discharged on 1st POD and another one was on 5$^{th}$ POD. After the discharge of the babies, fever subsided in both patients. Remaining two patients in control group with fever had purulent wound discharge on 5th POD when the dressing was changed.Pus culture and sensitivity done and treated with appropriate antibiotics and daily dressing and discharged on 15th and 16th POD.

. None of the patients in both groups had thromboembolic complications postoperatively.

**Neonatal Outcome :**In our study, neonatal outcome were comparable in both groups. One baby in group A needed NICU admission for HIE stage I and the indication for LSCS was unengaged head with foetal distress and discharged on 5th POD. 2 babies in group B needed NICU admission for HIE Stage I and for transient tachypnoea of the newborn the indications for LSCS being unengaged head with foetal distress in one and previous LSCS with PROM in another. They got discharged on 1st and 5$^{th}$ POD respectively. The inference was that tranexamic acid use was not associated with any impact on neonatal outcome in our study. In a similar study conducted by Department of Obs & Gyn King's College hospital, London,2010, there was no significant difference in the neonatal outcome between study and control groups.

**Conclusion**

Tranexamic acid injection, an antifibrinolytic agent when given as 1 gram intravenous infusion prophylactically 20 minutes before skin incision appears to reduce the blood loss during and after caesarean section effectively.Some

studies demonstrated that tranexamic acid minimally increases the risk of thromboembolism but without statistical significance. But no evidence of thrombosis was observed in our study. Further , there has been a significant reduction of blood loss and incidence of postpartum haemorrhage with the use of tranexemic acid, thus making it a very promising drug for obstetric use.

**TABLES**

TABLE: 1

| Age in years | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| Less than 20 | 3 | 2 | 2 | 1.3 |
| 20 – 24 | 60 | 40 | 57 | 38 |
| 25 – 29 | 71 | 47.3 | 62 | 41.3 |
| 30 and above | 16 | 10.7 | 29 | 19.4 |
| Total | 150 | 100 | 150 | 100 |
| Mean ± SD | 25.4 ± 3.4 | | 25.9 ± 4.3 | |
| p | Not Significant (p = 0.2251) Unpaired 't' test | | | |

TABLE : 2

| PARITY | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| PRIMI | 86 | 57.33 | 87 | 58 |
| 2nd Gravida | 45 | 30 | 43 | 28.67 |
| 3rd Gravida | 15 | 10 | 18 | 12 |
| 4th Gravida | 4 | 2.67 | 2 | 1.33 |
| Total | 150 | 100 | 150 | 100 |
| p | Not significant (p=0.88) Chisquare test for proportions | | | |

TABLE: 3

| Characteristics | Test Group (N=150) | | Control Group (N=150) | | P value | Statistical test done |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | |
| Height (in cm) | 154.7 | 7.582 | 157.01 | 13.99 | 0.0742 | Unpaired 't' test |
| Weight (in Kg) | 59.33 | 5.344 | 60.97 | 6.385 | 0.0584 (NS) | |
| BMI | 24.77 | 2.427 | 24.14 | 2.750 | 0.054 (NS) | |

TABLE :4

| TYPES OF SURGERY | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| Emergency | 139 | 92.67 | 139 | 92.67 |
| Elective | 11 | 7.33 | 11 | 7.33 |
| Total | 150 | 100 | 150 | 100 |
| p | Not significant (p=0.99) Chi square test. | | | |

TABLE:5

| Parameter | Number of cases in | | | | P Value | Statistical test |
|---|---|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | | | |
| | Mean | SD | Mean | SD | | |
| **Pulse Rate (in bpm)** | | | | | | |
| Pre-operative | 78.69 | 4.78 | 77.90 | 3.72 | 0.112 (NS) | Unpaired t test |
| Post-Operative | 79.96 | 5.90 | 81.67 | 6.59 | 0.018 | Unpaired t test |
| Change | 1.27 | 6.94 | 3.77 | 7.30 | 0.002 | Mann Whitney U |
| % of Change | 1.91 | 8.94 | 5.04 | 9.50 | 0.003 | Mann Whitney U |
| **Systolic Blood pressure (in mm of Hg)** | | | | | | |
| Pre-operative | 109.87 | 10.30 | 116.67 | 8.57 | <0.0001 | Unpaired t test |
| Post-Operative | 111.65 | 9.97 | 113.01 | 11.62 | 0.227 (NS) | Unpaired t test |
| Change | 1.79 | 12.58 | -3.65 | 15.17 | 0.0013 | Mann Whitney U |
| % of Change | 2.36 | 12.33 | -2.58 | 12.51 | 0.0012 | Mann Whitney U |
| **Diastolic Blood pressure (in mm of Hg)** | | | | | | |
| Pre-operative | 71.60 | 4.35 | 71.93 | 3.96 | 0.318 (NS) | Mann Whitney U |
| Post-Operative | 70.87 | 3.46 | 73.53 | 4.80 | <0.0001 | Mann Whitney U |
| Change | -0.73 | 5.80 | 1.60 | 5.92 | 0.002 | Mann Whitney U |
| % of Change | -0.68 | 7.52 | 2.48 | 8.09 | 0.003 | Mann Whitney U |
| **Respiratory Rate (per minute)** | | | | | | |
| Pre-operative | 20.31 | 16.51 | 15.05 | 1.01 | <0.0001 | Mann Whitney U |
| Post-Operative | 15.13 | 1.25 | 15.15 | 0.95 | 0.876 | Unpaired t test |
| Change | -5.17 | 16.61 | 0.11 | 1.33 | <0.0001 | Mann Whitney U |
| % of Change | -8.60 | 22.77 | 1.12 | 8.83 | <0.0001 | Mann Whitney U |

TABLE:6

| Hemoglobin in g% | Number of cases in | | | | P Value | Statistical test |
|---|---|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | | | |
| | Mean | SD | Mean | SD | | |
| Pre-operative | 10.21 | 0.47 | 10.28 | 0.51 | 0.435 (NS) | Unpaired t test |
| Post-Operative | 9.91 | 0.44 | 9.00 | 0.5 | <0.0001 | Unpaired t test |
| Change | -0.3 | 0.5 | -1.28 | 0.68 | <0.0001 | Mann Whitney U |
| % of Change | -2.80 | 4.78 | -12.28 | 6.19 | <0.0001 | Mann Whitney U |

TABLE:7

| Hematocrit % | Number of cases in | | | | P Value | Statistical test |
|---|---|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | | | |
| | Mean | SD | Mean | SD | | |
| Pre-operative | 30.75 | 1.52 | 30.86 | 4.29 | 0.141 (NS) | Mann Whitney U |
| Post-Operative | 31.35 | 7.35 | 27.53 | 3.62 | <0.0001 | Mann Whitney U |
| Change | 0.59 | 7.11 | -3.3 | 5.7 | <0.0001 | Mann Whitney U |
| % of Change | 1.91 | 21.84 | -9.9 | 14.1 | <0.0001 | Mann Whitney U |

TABLE:8

| Blood loss (in ml) | Number of cases in | | | | P Value | Statistical test |
|---|---|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | | | |
| | Mean | SD | Mean | SD | | |
| PD- EOS | 286.7 | 49.97 | 388.6 | 49.33 | <0.0001 | Mann Whitney U |
| EOS – 2hr/PP | 58.00 | 10.00 | 74.63 | 12.21 | <0.0001 | Mann Whitney U |
| PD – 2hr/pp | 344.7 | 50.39 | 468.3 | 69.42 | <0.0001 | Mann Whitney U |

TABLE:9

| Total blood loss | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| ≤ 500 ml | 149 | 99.3 | 137 | 91.3 |
| > 500 ml | 1 | 0.7 | 13 | 8.7 |
| Total | 150 | 100 | 150 | 100 |
| P | Significant (0.0013 ) Fishers exact test | | | |

TABLE: 10

| Maternal blood transfusion | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| Given | 1 | 0.7 | 1 | 0.7 |
| Not given | 149 | 99.3 | 149 | 99.3 |
| Total | 150 | 100 | 150 | 100 |
| p | Not Significant (0.99) Fishers exact test | | | |

TABLE:11

| Maternal complication | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| Nausea & Vomiting | 3 | 2 | 2 | 1.33 |
| Fever | 2 | 1.33 | 4 | 2.67 |
| No complication | 145 | 96.67 | 144 | 96 |
| Total | 150 | 100 | 150 | 100 |
| p | Not Significant (0.988) Fishers exact test | | | |

TABLE:12

| Hospital stay after 8th POD | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| Yes | 0 | 0 | 2 | 1 |
| No | 150 | 100 | 148 | 99 |

TABLE:13

| NICU admission | Number of cases in | | | |
|---|---|---|---|---|
| | Test Group (N=150) | | Control Group (N=150) | |
| | (n) | % | (n) | % |
| Yes | 1 | 0.7 | 2 | 1.3 |
| No | 149 | 99.3 | 148 | 98.7 |
| P value | Not Significant (0.999) Fishers exact test | | | |

TABLE:14

| SEVERAL STUDIES | YEAR | AMOUNT OF BLOOD LOSS IN` ML |
|---|---|---|
| OUR STUDY | 2017 | T-344.7<br>C-468.3 |
| SJD Lakshmi et al -PSG IMSR | 2015 | T-347.17<br>C-517.72 |
| HY Wang et al | 2015 | T-367.11<br>C-567.12 |
| SK BHATIA et al | 2015 | T-367.02<br>C-464.6 |
| AH YEHIA et al | 2014 | T-369.5<br>C-606.8 |
| A SHAHID et al | 2013 | T-356.44<br>C-710.22 |
| MEHMET B. SENTRÜK et al | 2012 | T-345.91<br>C-654.81 |
| L SEKHAVAT et al | 2009 | T-355.8<br>C-478.3 |
| G MAYUR et al | 2007 | T-372.71<br>C-469.70 |

TABLE:15

| SEVERAL STUDIES | YEAR | MEAN FALL IN HAEMO GLOBIN |
|---|---|---|
| OUR STUDY | 2017 | T-0.3<br>C-1.28 |
| SJD Lakshmi et al -PSG IMSR | 2015 | - |
| HY Wang et al | 2015 | - |
| SK BHATIA et al | 2015 | T-0.5<br>C-0.9 |
| AH YEHIA et al | 2014 | - |
| A SHAHID et al | 2013 | - |
| MEHMET B. SENTRÜK et al | 2012 | T-0.5<br>C-2.1 |
| L SEKHAVAT et al | 2009 | - |
| G MAYUR et al | 2007 | - |

TABLE:16

| SEVERAL STUDIES | YEAR | >500 ML BLOOD LOSS |
|---|---|---|
| OUR STUDY | 2017 | T-0.7%<br>C-8.7% |
| SJD Lakshmi et al -PSG IMSR | 2015 | T-3.3%<br>C-60% |
| HY Wang et al | 2015 | T-2.9%<br>C-23.3% |
| SK BHATIA et al | 2015 | T-4%<br>C-16% |
| AH YEHIA et al | 2014 | T-31.1%<br>C-63.2% |
| A SHAHID et al | 2013 | - |
| MEHMET B. SENTRÜK et al | 2012 | T-3.5%<br>C-12.8% |
| L SEKHAVAT et al | 2009 | T-3.1%<br>C-9.9% |
| G MAYUR et al | 2007 | T-10%<br>C-28% |

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**Illustration Captions:**

i) Distribution of age in the study groups

ii) Parity distribution among the study group

iii) Comparison of Subjective Characteristics of the study samples.

iv) Comparison of types of Surgery done between the two groups.

v) Comparison of changes in hemoglobin% between the groups

vi) Comparison of hematocrit between two groups

vii) Comparison of blood loss between two groups in the study.

viii) Comparison of maternal blood transfusion between the groups.

ix) Comparison of maternal blood transfusion between the groups

x) Comparison of maternal complication between the groups

xi) Comparison of hospital stay after $8^{th}$ POD between the groups