Tranexamic Acid and Ethamsylate for Reducing Blood Loss in Patient Undergoing LSCS at High Risk for Postpartum Hemorrhage

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Abstract:

Background: The aim of this study is to assess the efficacy of tranexamic acid (1 gm) and ethamsylate (1 gm) in reducing blood loss in patients undergoing LSCS at high risk for postpartum hemorrhage.

Methods: This clinical trial was conducted at El Galaa Maternity Teaching Hospital. The study included 64 women who were at high risk of postpartum hemorrhage.

Results: There was significant statistical difference in the vital data before and after placental delivery between the two groups. Group 1 (the case group) This group consists of 32 patients received 1gm Tranexamic acid and 1gm Ethamsylate Intravenous slowly in the 2 minutes. Group 2 (the control group):This group consists of 32 patient received a placebo plus the routine prophylaxis intravenous 10 IU Oxytocin in the 2 minutes.

Conclusion: The use of tranexamic acid and ethamsylate in cases of cesarean section is effective as a prophylaxis against post-partum hemorrhage.

Keywords: Tranexamic acid, Ethamsylate, Post-partum hemorrhage

Introduction

Postpartum hemorrhage (PPH) is classically defined as blood loss of 500 mL or more within 24 hours after delivery (1). Estimates of its incidence in the literature vary widely, from 3 % to 15 % of deliveries (2).

About one in five of these hemorrhages progresses to a severe form that may endanger the mother’s life or at least her future fertility and exposes her to the risks of transfusion, surgery, and intensive care admission (3).

PPH remains a leading cause of maternal mortality and accounts for about one quarter of all maternal deaths worldwide. Its risk factors include previous PPH, prim parity, obesity, prolonged or augmented labor, multiple pregnancy, previous cesarean delivery, polyhydramnios, and macrosomia (4).

Tranexamic acid is a synthetic derivative of the amino acid lysine that exerts its antifibrinolytic effect through the reversible blockade of the lysine binding sites on plasminogen molecules. Intravenous administration of tranexamic acid has been routinely used for treating and preventing bleeding with good results (5).

Ethamsylate is a synthetic haemostatic drug indicated in cases of capillary bleeding. It exerts haemostatic action by acting on the first step of haemostasis by improving platelet adhesiveness and restoring capillary resistance. It decreases bleeding time and increases platelet aggregation. It reduces capillary bleeding when platelets are adequate. The drug exerts anti-hyaluronidase action and improves capillary wall stability. It inhibits PGI-2 synthesis and correct abnormal platelet function. Side effects; headache, nausea, rash and fall in blood pressure, occurs only after I.V. administration (6).

Patient and methods:

This clinical trial was conducted at El Galaa Maternity Teaching Hospital in the time between March 2018 and July 2018. The study was approved by the Ethics Board of Al-Azhar University.
This study included 64 pregnant women who were admitted for cesarean section at high risk for post-partum hemorrhage.

All patients were subjected to the following after taking a written consent from each patient:

- **History taking:**
  - Searching for any risk factor of post-partum hemorrhage:
    - History of present pregnancy (abdominal enlargement, rupture of membranes, etc.).
    - Past history of PPH.
    - Exclude any medical disorder (metabolic disease, Thrombocytopenia, Hypertension, Diabetes mellitus, Cardiac disease, etc).
    - Menstrual history (to be sure of her LMP and this date is reliable).

- **General examination**
  - With particular emphasis on fever in cases of premature rapture of membranes
  - Pulse rate and volume.

- **Abdominal examination with particular emphasis on uterine contraction and abdominal enlargement.**

- **Obstetric ultrasound to document viability of pregnancy and to ensure the gestational age.**

- **CBC or hematocrit preoperative.**

- **Coagulation profile.**

- **Liver function test and kidney function test**

**Inclusion criteria**

1. Women undergoing elective lower segment caesarean section.
2. Patient having one or more risk factors for PPH.
3. Age ranging from (20-35).
4. Gestational age ≥ 37 Weeks by LMP or documented early ultrasound.
5. Informed written consent from the patient.
6. General anesthesia for all patients included in the study.

**Exclusion criteria**

1. History of venous thrombosis (DVT and/or Pulmonary embolism) OR arterial thrombosis (angina pectoris, myocardial infarction, stroke).
2. History of epilepsy or seizure.
3. Any known cardiovascular, renal or liver disease.
4. Autoimmune diseases.
5. Sickle cell disease.
7. Placenta previa.
8. Morbidly adherent placenta.
10. Eclampsia, HELLP syndrome.

**Sample size:**

A sample of 32 cases per group was calculated using power and sample size calculation program version 3 using mean difference of blood loss 154.1 ± 217.6 α error 0.05 power of study 80%.

**Results:**

The current study was conducted at El Galaa Teaching Maternity Hospital during the period between March 2018 and July 2018. A total of 64 women who were high risk or postpartum hemorrhage undergoing lower section cesarean section.

**Table 1: comparison between two groups regarding change in Hb level (peripartum changes):**

<table>
<thead>
<tr>
<th>Group</th>
<th>Hb</th>
<th>Mean</th>
<th>Std. Error</th>
<th>95% Confidence Interval</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>Pre</td>
<td>11.066</td>
<td>0.133</td>
<td>10.801</td>
<td>11.331</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>10.806</td>
<td>0.130</td>
<td>10.546</td>
<td>11.066</td>
</tr>
<tr>
<td>Placebo</td>
<td>Pre</td>
<td>10.772</td>
<td>0.133</td>
<td>10.507</td>
<td>11.037</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>9.325</td>
<td>0.130</td>
<td>9.065</td>
<td>9.585</td>
</tr>
</tbody>
</table>
Our results show that tranexamic acid and ethamsylate significantly reduced bleeding during and after cesarean section. The study group’s total blood loss: (149.22 ±54.74ml) was significantly less than control group (353.75 ±115.56 ml) (p<0.001).

In our study the study group included 32 women, while the control group included 32 women.

In our study, there was no significant difference as regard patient characteristics (age, weight, BMI, parity and gestational age between study and control groups.

In our study postoperative hemoglobin was significantly higher in study group than control group (p<0.001). Reduction in hemoglobin was significantly less in study group than control group (p<0.001). In addition, postoperative hematocrit was significantly higher in study group than control group (p<0.001): reduction in hematocrit was significantly less in study group than in control group (p<0.001).

In our study, there was significant statistical difference in the vital data before and after placental delivery between the two groups.

These results support other studies.

In one study in 2013 the patients’ characteristics in the two groups were similar, with no statistical difference between the two groups. The study group included 88 women who received tranexamic acid, whereas the control group included 86 women who did not receive it (7).

In the previous study, tranexamic acid significantly reduced the quantity of blood loss from the end of CS to 2 h postpartum: (46.6 ± 42.7 ml) in the study group versus (84.7 ± 80.2 ml) in the control group (p <0.01). It also significantly reduced the quantity of total blood from placental delivery to 2 h postpartum to (379.2 ± 160.1 ml) in the study group to (441.7 ± 189.5 ml) in the control group (p = 0.02) (7).

In the same study PPH stopped in 65 women (75.6 %) in the control group and in 81 (92.0 %) in the TXA group (p <0.01). No significant abnormal vital signs were observed after TXA administration. Mild, transient side effects occurred more often in the TXA group than in the control group (7).

In another study in 2009 the patients’ characteristics in the two groups were similar, with no statistical difference between the two groups. The study group included 45 women who received tranexamic acid, whereas the
In the previous study tranexamic acid significantly reduced the quantity of blood from the end of CS to 2 h postpartum: (28.02 ±5.53 ml) in the study group versus (37.12±8.97 ml) in the control group (p=0.001), Hb 24 h after CS was significantly greater in tranexamic group than control group (12.57+1.33 in the tranexamic group and 11.74+1.14 in the control group, p=0.002) (8).

In the same study tranexamic acid statistically reduced blood loss from end to 2 h after CS and its use was not associated with any side effect or complications. Consequently, tranexamic acid can be used safely and effectively to reduce bleeding resulting from CS (8).

In another study the patients’ characteristics in the two groups were similar, with no statistical difference between them. The study group included 356 women who received tranexamic acid, whereas the control group included 356 women who did not receive it (9).

In the previous study tranexamic acid significantly reduced quantity of total blood from placental delivery. It was (241.61±6.77 ml) in the study group and (510.66±7.72 ml) in the control group (p = 0.0001) (9).

In the study of Senturk et al., the patients’ characteristics in the two groups were similar, with no statistical difference between them. The study group included 101 women who received tranexamic acid, whereas the control group included 122 women who did not receive it (10).

In the previous study of Senturk et al., tranexamic acid significantly reduced the quantity of blood loss. The mean preoperative Hb value was (11.66 ± 1.02), and the post-operation mean was (10.55 ± 0.97) in study group, while these values were (11.86 ± 1.32) and (10.52 ± 1.24), respectively, for control group. The mean difference between the pre- and post-operative Hb values was 1.11 ± 0.62 in the study group and 1.27 ± 0.66 in the control group. There was a significant difference (p = 0.034) when Hb loss of two groups was compared (10).

In the study of Shahid and Khan, the patients’ characteristics in the two groups were similar, with no statistical difference between the two groups (11).

In that study, tranexamic acid significantly reduced the quantity of blood loss from placental delivery to the end of LSCS which was (356.44 ± 143.2 ml) in the TXA group versus (710.22 ± 216.72 ml) in the placebo group (p < 0.001). It also reduced the quantity of blood loss from the end of LSCS to 2 hours postpartum, which was (35.68 ± 23.29 ml) in the TXA group versus (43.63 ± 28.04 ml) in the placebo group (p = 0.188), was not significant. No complications or side effects were reported in either group (11).

Points of strength in our study includes: small dose of tranexamic acid and ethamsylate is needed to control blood loss, it is easy to calculate allowable blood loss, and the use of ethamsylate for the first time to reduce blood loss in obstetrics in high-risk patients.

Point of weakness in my study was the small number of cases. References


