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EFFICACY OF TOPICAL TRANEXAMIC ACID ON BLOOD LOSS DURING OPEN MYOMECTOMY A RANDOMIZED CONTROLLED TRIAL

Gynaecology

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ABSTRACT

Objectives: To assess efficacy of topical tranexamic acid in reducing intra-operative blood loss in open myomectomy surgeries.
Materials and methods: 100 women who underwent open Myomectomy were randomly divided into two groups. The first group received 2 gm topical tranexamic acid applied on myoma bed after myomectomy and the second group received topical placebo.
Results: Topical tranexamic acid application significantly reduced intra-operative blood loss compared to placebo (305.24 ± 56.21 ml vs 523.57± 62.38 ml) and it was statistically significant (P < 0.0001).
Conclusion: Topical application of tranexamic acid significantly reduced intra-operative blood loss during open Myomectomy.

KEYWORDS

Myomectomy, blood loss, tranexamic acid

INTRODUCTION:

Uterine fibroids are common benign gynecologic tumors and 25% to 30% of women would be diagnosed at a time during their lives[1]. There are several strategies for the treatment of fibroids, but myomectomy remains the most common and the most efficient uterus-sparing treatment[2]. Nevertheless, this procedure is associated with known risks, chief of which is excessive perioperative blood loss which sometimes necessitates a hysterectomy. Many strategies have been used to manage blood loss including mechanical tourniquets, administration of haemostatic agents, autologous donation and minimally invasive procedures[3-5]. However, blood transfusions were still required to treat anemia in many cases. Traditionally, tranexamic acid has been administered intravenously in surgical settings. Safety concerns associated with intravenous administration of tranexamic acid includes thrombosis, increased seizure risk, and renal impairment[6]. Topical application of tranexamic acid provides a high drug concentration at the site of the wound and a low systemic concentration. Studies from cardiac and orthopedic surgeries have shown an equal or superior effect of topical compared with intravenous tranexamic acid on both bleeding and transfusion requirement[7]. The present study was aimed at evaluating the role of topical tranexamic acid application for prevention of blood loss during open Myomectomy.

MATERIALS AND METHODS:

The present study was conducted at KAPV Govt medical college hospital from April 2019 to February 2020 after approval from the Medical Ethics Committee. One hundred women seeking treatment for symptomatic leiomyomas and scheduled to undergo abdominal myomectomy with myoma staging from (3 to 6) were selected and Informed consent was obtained. Women with cardiac, hepatic, renal or thromboembolic disease were excluded from the study. The participants were randomly allocated to two groups (50 patients in each group)

Group A - 2 gm of tranexamic acid acid (20 ml) with 100 ml of normal saline soaked mop applied on the myoma bed

Group B - 120 ml of normal saline (placebo) soaked mop applied on the myoma bed

All participants underwent ultrasound examination to assess the number and location of myomas. Preoperative Hb was checked for all patients. Under general anesthesia abdomen was exposed and Uterus was inspected for the number, location, and shape of myomas. Intracapsular enucleation of myomas were performed. A mop soaked with 2 g tranexamic acid (20 ml) diluted in 100 ml of normal saline or placebo (120 ml of normal saline) used to compress the myoma bed for 5 min. At the end of the operation, the amount of bleeding was measured based on the number of mops used and the blood in the suction container. Hemodynamic variables were monitored. In addition, the patient's Hb was determined 24 h after surgery. The Primary outcome measure was the determination of Intraoperative blood loss and the secondary outcome measures included the need for blood transfusion and change in Hb levels. Data are expressed as mean ± standard deviation. All outcomes were assessed using Chi-squared test and independent t-test, P < 0.05 was considered statistically significant. statistical analyses were done using SPSS version 16.0 statistical software.

Results: The mean age, Number of myomas, Uterine size and preoperative Hb were comparable in both the groups (Table 1).

Table 1 Demographic pattern

	Group A (tranexamic acid)	Group B (placebo)	P value
Age(years)	42.40 ± 4.79	42.32 ± 5.31	>0.05
No. of myomas	4.20 ± 0.49	4.17 ± 0.78	>0.05
Uterine size(weeks)	19.29 ± 2.14	19.32 ± 2.72	>0.05
Hb(g/dL)	11.35 ± 0.41	11.29 ± 1.35	>0.05

The mean intra-operative blood loss in the topical tranexamic acid group was 305.24 ± 56.21 ml and in the Placebo, group was 523.57± 62.38 ml. The difference was statistically significant (P > 0.0001). The incidence of blood transfusion was increased in Placebo group 27 (54%) patients compared with 11 (22%) patients in Tranexamic acid group.

The mean haemoglobin levels reduction in the placebo group was higher than the tranexamic acid group (- 3.6 ± 1.84 vs - 1.85 ± 0.82 g/dL) and was statistically significant (P > 0.0001) The incidence of blood transfusion was increased in Placebo group 27 (54%) patients compared with 11 (22%) patients in tranexamic acid group and was statistically significant (P > 0.0001) (Table 2).

Table 2. Primary outcome

	Group A (tranexamic acid)	Group B (placebo)	P value
Mean blood loss(ml)	305.24 ± 56.21	523.57± 62.38	<0.0001
Hb reduction(g/dl)	-1.85 ± 0.82	-3.6 ± 1.84	<0.0001
Blood transfusion	11 (22%)	27 (54%)	<0.0001

Haemodynamic parameter changes were comparable in both the groups. No major intraoperative or postoperative adverse effects were noted in any group.

DISCUSSION:

in our study the use of topical tranexamic acid in the myoma bed after myomectomy helps to reduce the blood loss during open Myomectomy and statistically significant increase in blood transfusion in placebo-group compared with topical tranexamic acid group. Tranexamic acid, which acts as antifibrinolytic agent, is famous for proven success in reducing peri- and postoperative blood loss and widely used in surgical procedure[7]. Konig et al[8]reported that topical application of tranexamic acid for patients undergoing primary total hip arthroplasty is effective and safe. Fu et al[9] conducted a meta-analysis from 22 RCTs and showed that tranexamic acid is beneficial for patients undergoing total knee arthroplasty, which can significantly

reduce total blood loss. Hany F. Sallam et al in their study reported that topical tranexamic acid application is a safe and reliable method to help decrease blood loss during and after the abdominal hysterectomy[10]. Nahla W.Shady et al reported that topical tranexamic acid safe and reliable method to help decrease blood loss during open myomectomy[11].

CONCLUSION:

This study concluded that topical application of tranexamic acid significantly reduced intra-operative blood loss, postoperative haemoglobin decline and transfusion requirements during open Myomectomy.

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