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Role of Tranexamic Acid in Reducing Blood Loss During Abdominal Myomectomy

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Abstract--- Background: *Leiomyoma is benign, monoclonal tumor of the smooth muscle cells of the myometrium. This study aimed to reducing blood loss during myomectomy using either intravenousor topical method.* ***Methods:*** *This study was randomized controlled trials included 60 women undergoing abdominal myomectomy for symptomatic uterine leiomyomas in Department of Obstetrics and Gynecology, at Zagazig University Hospital during the period study year October 2019 to April 2020. Study inclusion criteria were women who attended the outpatient gynecology clinic, seeking treatment for symptomatic leiomyomas and scheduled to undergo abdominal myomectomy with myoma staging from (3 to 6) according to FIGO staging. The primary outcome was intra-operative, postoperative and all blood loss estimation.* ***Results:*** *There was statistically significant difference between the studied groups regarding blood loss with higher blood loss either intraoperative, postoperative and overall blood loss on control than topical than intra venous tranxamic acid group (p-value= 0.8, 0.9 and 0.9) respectively. Regarding need for blood transfusion where (50.0%) of the control group needed blood transfusion while only (10.0%) of intravenous and topicaltranexamic acid groups needed blood transfusion (p-value= 0.003*).* ***Conclusions:*** *Intravenous and topical tranexamic acid safe and reliable method to help decrease blood loss during open myomectomy without serious side effects.*

Keywords--- *Myomectomy, Tranexamic Acid,Uterine Leiomyomas.*

I. INTRODUCTION

Uterine leiomyomas represent the most common benign tumours encountered in women, originating from myometrium smooth muscle cells. These tumours are estrogen dependent and grow during the reproductive period with incidence of approximately 70% in the general population. Approximately 20-40% of women with fibroids experience significant symptoms and consult gynecologic care. However, their true prevalence is probably under-estimated[1].

Leiomyoma is benign, monoclonal tumor of the smooth muscle cells of the myometrium. It is much denser than normal myometrium. It affects mostly women during reproductive age; rarely found before menarche and

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usually regress after menopause. Large and medium leiomyomas grew more than small ones, and intramural leiomyomas grew more than subserous or submucosal ones. Measured rates of growth were similar for different races and ethnic groups via MRI [2].

Leiomyoma can appear as symmetrical, well-defined, hypoechoic, and heterogeneous masses by sonography and transvaginalsonography is reasonably reliable for uteri <375 ml3 in total volume or containing four leiomyomas or fewer[3].

Surgery is the mainstay of therapy for leiomyomas. Indications for surgical therapy are abnormal uterine bleeding, pressure symptoms, Infertility or recurrent pregnancy loss. It includes; Laparotomy (hysterectomy and myomectomy), endoscopy (hysteroscopic myomectomy, laparoscopic myomectomy or hysterectomy or uterine artery occlusion or myolysis).

Abdominal myomectomy is the surgical removal of fibroids through an abdominal incision-either longitudinal or transverse cut. It is an option for women who have not completed childbearing or wish to retain their uterus[4].

Bleeding during myomectomy is one of the major complications which can result in significant morbidity and mortality. Despite advances in reducing excessive haemorrhage during the procedure, it still remains a major challenge for gynecologic surgeons [1]. The risk of bleeding depends on the number, the size and the position of fibroids removed[5].

Several interventions have been developed to control bleeding during this operation such as dissection and embolization of uterine artery, use of mechanical tourniquets, use of uterotonic medications such as oxytocin, Carbetocin, ergometrine, misoprostol and manipulation of the coagulation cascade with antifibrinolytic treatment, especially aprotinin, tranexamic acid, epsilon-aminocaproic acid, desmopressin and recombinant factor VIIa[1].The aim of this study is reducing blood loss during myomectomy using either intravenous or topical method.

II. METHODS

This study was randomized controlled trials included 60 women undergoing abdominal myomectomy for symptomatic uterine leiomyomas in Department of Obstetrics and Gynecology, at Zagazig University Hospital during the period study year October 2019 to April 2020. Study inclusion criteria were women who attended the outpatient gynecology clinic, seeking treatment for symptomatic leiomyomas and scheduled to undergo abdominal myomectomy with myoma staging from (3 to 6) according to FIGO staging, Age 18-45 years. Exclusion criteria were: Patients undergone vaginal or laparoscopic myomectomy. Patients received preoperative embolization or gonadotrophin releasing hormone analogue. Cervical and broad ligament myoma. Myoma staging from (0, 1 or 2) according to FIGO staging **[7-9].** Patients with cardiac, hepatic, renal or thromboembolic disease. Patients had an allergy to tranexamic acid).Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University.

All participants underwent a detailed history, general examinations, body mass index (BMI) was calculated, abdominal and vaginal examinations, and pelvic ultrasound examination was undertaken for all participants to assess the number and location of myomas and the largest myoma diameter. Investigations, CBC, PT, PTT, ALT, AST and serum creatinine, was performed preoperatively for both groups, and CBC was repeated on the first and third postoperative day. The participants who fulfilled the eligibility criteria were explained about the study with the beneficial and possible adverse effects of tranexamic acid.

Randomization was done using computer program by randomized 60 patients in 3 groups each group comprised of 20 patients. Group I: 20 patients received 110 ml normal saline intravenous just before skin incision. Group II: 20 patients received 1g tranexamic acid (2 ampoules of kapron 500mg 5ml) intravenous just before skin incision. Group III: 20 patients received 2g topical tranexamic acid (4 ampoules of kapron 500 mg 5ml) applied on myoma bed after myomectomy.

Intervention

All participants was received general anesthesia and immediately prior to the operation and just before skin incision. The 1st group was received 110 normal saline by slow intravenous injection at the approximately rate of 1ml per minute. The 2nd group was received 1g tranexamic acid (10 ml) in 100 ml saline infusion by slow intravenous injection at an approximate rate of 1 ml per minute. The abdomen was exposed through a midline or Pfannensteil incision, after skin incision, the subcutaneous fat and abdominal fascia was opened crosswise, and the rectus muscle was opened on the midline. The parietal peritoneum was opened longitudinally to reach the pelvic cavity. Uterus was inspected for the number, location, and shape of myomas and other pelvic organs was inspected for associated pathology. Uterine incisions on top of myoma was performed vertical incision using monopolar diathermy. Intracapsul are nucleation of myomas was performed by gently dissecting between the myoma and the pseudo capsule. The myoma was grasped by Collins forceps and gently enucleated out.

The 3rd group was received a gauze soaked with 2 gmtranexamic acid (20 ml) diluted in 100 ml of sodium chloride 0.9% or placebo (120ml of sodium chloride 0.9%) was used to compress the myoma bed for 5 minutes. To ensure a sufficiently high concentration, the tranexamic acid was diluted only to a volume sufficient to moisten a large wound surface. 20 ml moisten at least 1500 cm2. Myoma bed then closed by 1 or 2 layers of interrupted vicryl sutures (Vicryl 1–0 polyglactin 910; Egycryl, Taisier CO, Egypt). At the end of the surgery, 1 intra-peritoneal suction drain was routinely used in all patients the drains was removed on the second postoperative day unless otherwise indicated. Number and size of myomas was recorded. Myoma size represented the mean size of each myoma. Enucleated myomas was sent to histopathology.

Blood Loss Estimation

Intraoperative blood loss was measured by adding the volume of the contents of the suction bottle and the difference in weight (in grams) between the dry and the soaked operation sheets and towels (1g = 1ml). Postoperative blood loss was measured through intra-peritoneal suction drain which measured every 12 hour and on removing the drain. After that, the total blood loss was calculated by the addition of intraoperative and postoperative

blood loss. Hb, Hct level was measured in first and third postoperative day for require of blood transfusion.The number of transfusion requirments was recorded according to intraoperative blood loss and postoperative Hb and Hct.

Study outcome

The primary outcome was estimate the efficacy of tranexamic acid in reducing blood loss during abdominal myomectomy. Including total blood loss level, transfusion rate, and drainage volume.

Secondary outcomes; was estimation the efficacy of tranexamic acid either intravenous or topical in reducing blood loss after myomectomy. Frequency of blood transfusion. Change in preoperat and immediate postoperative Hb.

Statistical Analysis

Data were entered checked and analyzed using Epi-Info version 6 and SPP for Windows version 8 **(Dean, 2006)**.

III. RESULTS

There was no statistically significant difference between the studied groups in age, BMI, gravidity, parity and age grouping, previous scar, largest myoma size, stage and total number of myomas **Table (1) Figure (1)**.

Table 1: Demographic Criteria of the Study Groups

Variable	Group (A) No. (20)	Group (B) No. (20)	Group (C) No. (20)	F-test	P
Age (years)					
Mean ± SD	35.1±4.6	35.8±6.6	35.0±4.5	0.1	0.8
(range)	(27-41)	(23-43)	(27-41)		
BMI					
Mean ± SD	27.2±3.8	27.3±3.1	27.1±3.9	0.1	0.9
(range)	(23.3-36)	(23-33)	(23.3-36)		
Gravidity					0.

Mean ± SD (range)	3.1±1.3 (1-5)	3.6±1.2 (1-6)	3.5±1.1 (1-6)	0.3	6
Parity Nulliparous Multiparous	2 (10.0%) 18 (90.0%)	4 (20.0%) 16 (80.0%)	2 (10.0%) 18 (90.0%)	χ^2= 1.1	0.6
Age grouping <35 years 35-39 years >39 years	10 (50.0%) 4 (20.0%) 6 (30.0%)	4 (20.0%) 10 (50.0%) 6 (30.0%)	6 (30.0%) 10 (50.0%) 4 (20.0%)	χ^2= 6.3	0.2

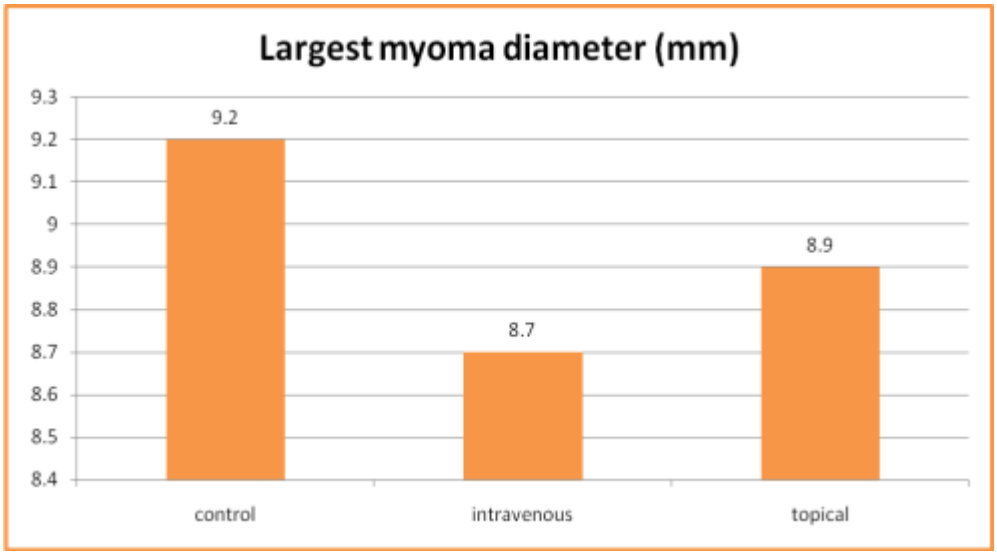

Figure 1: Bar Chart for Comparing Largest Myoma diameter among the Three Studied Groups

There was statistical significant difference between the studied groups regarding blood loss with higher blood loss either intraoperative, postoperative and over all blood loss on control than topical than intra venous tranxamic acid group **Figure (2)**.

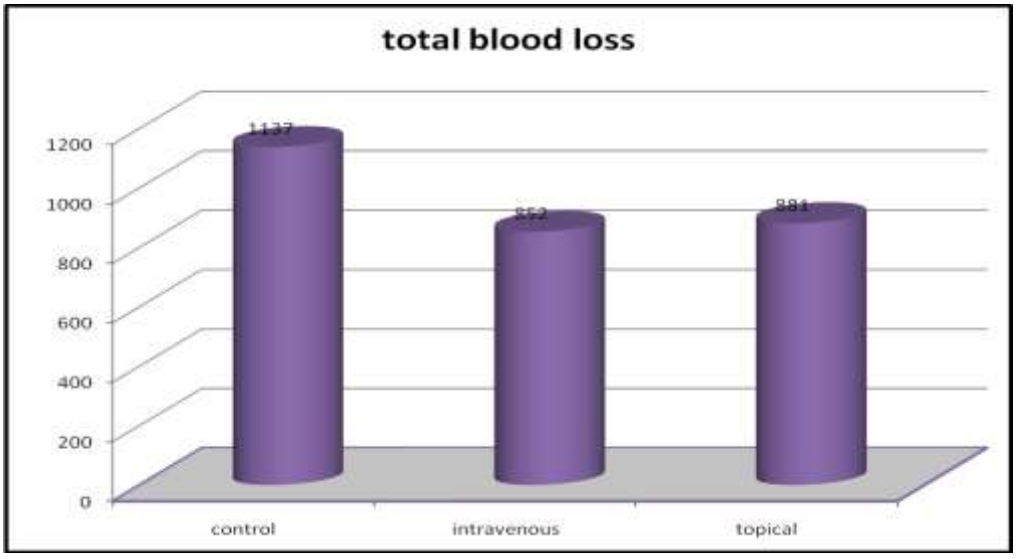

Figure 2: Bar Chart for Comparing the Total Blood Loss between the Studied Groups

There was statistical significant difference between the studied groups in hemoglobin postoperative with higher level among intravenous group than topical tranexamic acid group than control group. But regarding preoperative hemoglobin, there was no statistically significant difference between the studied groups. There was statistical significant difference decrease in hemoglobin postoperatively in the three studied groups but this decrease was more among control then topical then intra venous tranexamic acid groups **Table (2)**.Regarding HCT, there was statistical significant difference between the studied groups in HCT postoperative with higher level among intravenous group than topical tranexamic acid group than control group. But regarding preoperative HCT, there was no statistical significant difference between the studied groups. Also, there was statistical significantly decrease in HCT postoperative in the three studied groups but this decrease was more among control then topical then intra venous tranexamic acid groups. Additionally, that there was statistical significant difference between the studied groups regarding need for blood transfusion where (50.0%) of the control group needed blood transfusion while only (10.0%) of intravenous and topical tranexamic acid groups needed blood transfusion **Table (2)**.

Table 2: Mean and Standard Deviation of Hemoglobin and Hematocrit (HCT) Pre- and Post-operative and the Need for Blood Transfusion among the Three Studied Groups

Mean hemoglobin	**Group (A) No. (20)**	**Group (B) No. (20)**	**Group (C) No. (20)**	**F-test**	**P**
Preoperative hemoglobin					
Mean ± SD	11.4±0.8	11.2±0.7	11.1±0.2	2.5	0.08
(range)	(10.5-12.5)	(10-12.5)	(10.2-12.4)		

Postoperative hemoglobin Mean ± SD (range)	10.1±0.8 (9.8-11)	10.8±0.7 (9.4-11.8)	10.5±0.4 (9.8-11.6)	3.6	**0.03***
P-Value^	**0.001****	**0.005***	**0.003***		
PreoperativeHCT Mean ± SD (range)	33.86±2.3 (29.8-36.7)	33.67±2.8 (29.8-35.9)	33.78±2.6 (29.8-35.7)	1.6	0.5
Postoperative HCT Mean ± SD (range)	30.14±3.7 (26.2-33.8)	32.38±2.8 (28.4-35.4)	31.9±4.6 (27.9-34.8)	3.2	**0.04***
P-Value^	**0.001****	**0.008***	**0.006***		
Need for blood transfusion	**Group (A)** **No. (%)**	**Group (B)** **No. (%)**	**Group (C)** **No. (%)**	**test** **χ^2**	**P**
Yes	10 (50.0%)	2 (10.0%)	2 (10.0%)	11.9	**0.003***
No	10 (50.0%)	18 (90.0%)	18 (90.0%)		

P-Value^ for comparing pre & postoperative

* Statistically significant difference ($P \leq 0.05$)

**Statistically highly significant difference ($P \leq 0.001$)

There was high statistical significant difference between the studied groups regarding operative time where intravenous tranexamic acid group had the least operative time followed by topical group then the control group had the longest operative time. Regarding hospital stay where control group stayed more than topical more than intravenous tranexamic acid groups **Table (3)**. **Figure (3).**

Table 3: Mean and Standard Deviation of Operative Time among the three Studied Groups

Variable	Group (A) No. (20)	Group (B) No. (20)	Group (C) No. (20)	F-test	P
Operative time(minutes)					
Mean ± SD	111±19.7	72.5±7.3	110±19.1	7.6	**0.001****
(range)	(90-145)	(60-85)	(90-135)		

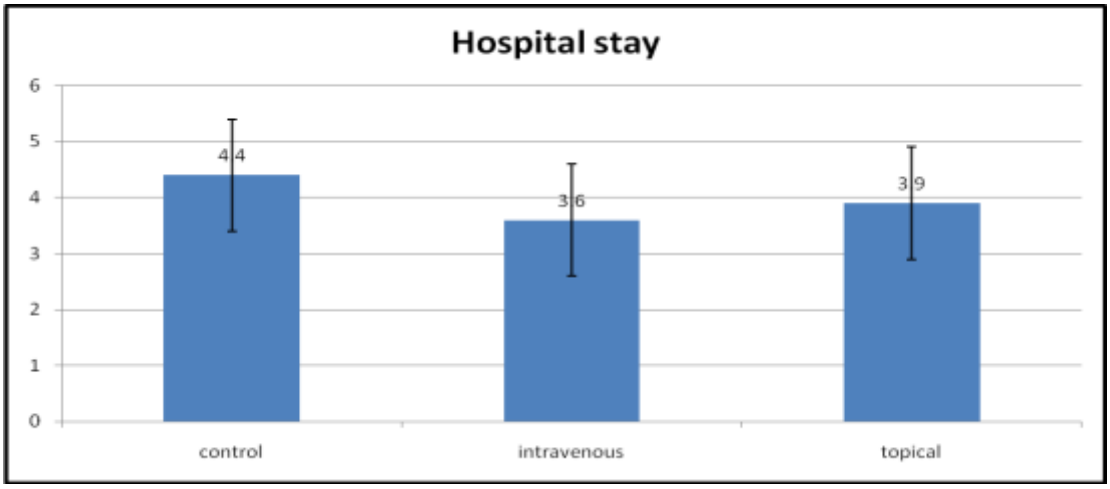

Figure 3: Bar Chart for Comparing Hospital Day among the Studied Groups

There was no statistical significant difference between the studied groups regarding nausea, vomiting and diarrhea **Table (4)**.

Table 4: Frequency and Percentage of Side Effects among the Three Studied Groups

Side effects	Group (A) No. (%)	Group (B) No. (%)	Group (C) No. (%)	test χ^2	P
Nausea	3 (15.0%)	5 (25.0%)	4 (20.0%)	1.9	0.3
Vomiting	1 (5.0%)	2 (10.0%)	1 (5.0%)		
Diarrhea	1 (5.0%)	2 (10.0%)	1 (5.0%)		
Absent	15 (75.0%)	11 (55.0%)	14 (70.0%)		

IV. DISCUSSION

The current study showed that there was no statistically significant difference between the studied groupsin age, BMI, gravidity, parity and age grouping where the age and BMI of the control, intravenous tranexamic acid and topical tranexamic acid groups were (35.1±4.6**,** 35.8±6.6 and 35.0±4.5 years), (27.2±3.8, 27.3±3.1 and 27.1±3.9) respectively and (90.0%) of the first and third groups were multiparous while (80.0%) of the second group were multiparous. Also there was no statistically significant difference between the studied groups regarding presence of previous scar (p-value =0.1), largest myoma size (p-value =0.3), stage and total number of myomas (p-value =0.7 and 0.6), this was in consistence with many previous studies as **Shady et al. [5]**whose study included 105 patients were randomized to 3 groups each group comprised of 35 patients. Group I: (received 1 g IV normal saline), Group II: (received 1 g tranexamic acid IV) and found that there was no significant difference between the three groups with respect to their age (35.54± 4.0, 3, 35.46 ± 4.6 and 35.8 ± 4.7, p-value=0.9) , weight (p-value=1), Hight (p-value=0.3), body mass index (BMI) (25.69 ± 2.21, 25.33 ± 2.21 and 25.43 ± 2.22, p-value=0.7), parity ranged from zero to five (p-value=0.9), myoma number, myoma stage, size of the largest myoma, uterine size, initial hemoglobin and history of the previous scar (**p-value=0.005*, 0.001** and 0.001****) for each variable.

Also, the present study was in agreement with **Sallam and Shady**[3]where 129 patients were included in their study and randomized to three groups: Group I (43) patients received 110 ml normal saline IV just before skin in scion], Group II [43 patients received 1 g tranexamic acid (2) ampoules of kapron 500 mg 5ml. Amoun company) IV just before skin in scion], and Group III [43 patients received 2 g topical tranexamic acid (4 ampoules of kapron 500 mg 5ml) and reported that there was no significant difference between the three groups with respect to their age, weight, height, body mass index (BMI) , uterine size, indication of hysterectomy, initial hemoglobin and history of previous scar, diabetes mellitus (DM), and hypertension (HTN)with (p-value= 0.8, 0.9, 0.3, 0.7, 0.9, 0.7,0.8, 0.7 and 0.9) respectively.

Shaaban et al. [6] study was in similarity with our results as the mean age of patients was 35 years and 34.6 years in both TA and control groups, respectively. No statistical difference was noted regarding the mean number of myomas (4.87 in study group versus 5.11 in control group, respectively) or the mean size of myomas (9.96 cm and 10.48 cm in both groups, respectively). Both groups were also matching regarding body mass index (BMI) parity and preoperative Hb level.

Concerning blood loss as a primary outcome of our study, the current study reported that there was statistically significant difference between the studied groups regarding blood loss with higher blood loss either intraoperative, postoperative and overall blood loss on control than topical than intra venous tranxamic acid group (p-value= 0.8, 0.9 and 0.9) respectively this was in similarity with **Shaaban et al.** [6]who showed lower total amount of blood loss (407 mL) when compared to the control group (677 mL). This total blood loss was the sum of blood lost during the period of surgery and postoperative period; both were significantly lower in study group and were 40% lower than in the control group ($P < 0.01$).

Similarly, another study by **Sallam and Shady** [3]reported that both Group II and Group III showed great

reduction in intraoperative and postoperative blood loss (blood in the intra-abdominal drain) compared with Group I **(P = 0.0001, 0.0001, 0.0001, 0.0001)**, so the overall estimated blood loss in groups II and III showed highly reduction compared with Group I **(609.19 ± 119.14 versus 401.74± 121.67 versus 395.35 ± 117.61, P = 0.0001)**. Also, there was reduction in postoperative bleeding in Group III compared with Group II (P = 0.001). However, no significant difference in intraoperative and overall estimated blood loss between groups II and III (P = 0.631 and 0.804, respectively). Total blood loss (500 ml) was 69.8% in Group I compared with (14.0%) in Group II and (16.3%) in Group III P = 0.0001.

Additionally, **Shady et al.** [5] found that both TA groups showed a great reduction in intraoperative and post-operative blood loss (blood in the intraabdominal drain) compared with saline group **(P = .0001, .0001, .0001, .0001)**, so the overall estimated blood loss in group II and III showed highly reduction compared with group I **(1080 ± 126.07 versus721.71 ± 211.78 versus 683.71 ± 214.92, P = .0001)**. However, no significant difference in overall estimated blood loss either intraoperative or post-operative between group II and III (P = .402, 0.423, and .287 respectively).

Finally, in a randomized trial conducted by **Wang et al.** [**7**]**,** tranexamic acid was compared with placebo in patients undergoing open myomectomy. Tranexamic acid was found to be associated with reduced total blood loss.

The most probable explanation for the effect of TA to be pronounced only in this group is that excessive tissue trauma associated with dissection of multiple myomas induce excessive fibrinolysis that can be improved by the use of TA, It is well known that concentration of plasminogen activator is increased 30 minutes after the start of the operation and suppression of the elevation in plasminogen activator by TA to enhance the effectiveness of the patients' own hemostatic mechanisms. Consequently, fibrinolysis is inhibited, and excessive or recurrent bleeding is reduced. It's anticipated that this effect is exaggerated with excessive tissue trauma as that associated with dissection of multiple uterine fibroids[4]**.**

Oppositely, the only randomized controlled studies comparing the effect of preoperative intravenous TA and placebo on women undergoing myomectomy and found no significant difference were **Caglar et al.,** [**8**] included 100 women and found that Intra-operative blood loss (ml) = 654 ± 460 **(81–2005)** versus 820 ± 558 **(213–2544)** P =0 .12 with no significant difference between preoperative intravenous TA and placebo groups, and **Ngichabe et al.** [**9**]investigated the adjunctive use of TA along with intra-myometrialornipressin during open myomectomy to assess for intraoperative blood loss. A total of thirty-four patients were randomized to two groups; 17 received ornipressin only and 17 received TA and ornipressin. There was no difference in blood loss between the groups with a median blood loss in the ornipressin (n = 17) and ornipressin plus tranexamic acid arms of 398 ml (IQR: 251–630) ml and 251 ml (IQR: 158–501) ml respectively P = 0.361.

Regarding secondary outcomes as hemoglobin and hematocrit levels, the need for blood transfusion, operative time and the hospital stay; this study found that there was statistical significantly between the studied groups in hemoglobin and HCT postoperatively with higher level among intravenous group than topical tranexamic acid group than control group groups **(p-value= 0.03* and 0.04*)** respectively. But regarding preoperative hemoglobin and HCT, there was no statistically significant difference between the studied groups (p-value= 0.08 and 0.5) respectively and women in TA groups had a smaller drop in hemoglobin and HCT levels after surgery compared with control. Also there was statistically significant difference between the studied groups regarding need for blood transfusion where (50.0%) of the

control group needed blood transfusion while only (10.0%) of intravenous and topical tranexamic acid groups needed blood transfusion **(p-value= 0.003***), this was in agreement with **Shaaban et al.** [6] who found that postoperative Hb and hematocrit levels were significantly higher in the study groups (9.09% and 29.00% vs 8.23% and 26.77%, respectively).

Similarly, **Sallam and Shady** [3]were in consisted with our study and reported that the mean postoperative hemoglobin concentration was higher in topical and intravenous TA than in control (10.16 ± 0.74 g/dl and 10.17 ± 0.79 vs. 9.71 ± 0.74 g/dl, respectively). P = 0.008 and similarly, women in TA groups had a smaller drop in hemoglobin levels after surgery compared with control **(0.3 vs. 0.8 g/dl; P = 0.0001)**, but there was no significant difference in the incidence of blood transfusion (p-value= 0.499).

Shady et al. [5]found that the incidence of blood transfusion was significantly increased in control group , 19 (54.3%) patients compared with 6 (17.1%) patients in group II, and 7 (20%) patients in group III (P = 0.001 and 0.003 respectively). However, no significant difference in the incidence of blood transfusion between topical and intravenous TA (p = 0.759). But regarding postoperative Hb, there was no statistically significant difference (9.83 ± 0.63 versus 10.02 ± 0.81 versus 10.03 ± 0.797 p=0.4).

Oppositely, **Caglar et al.** [8] found no significant difference between TA and control groups regarding post-operative Hb (9.97 ± 1.5 ranged from (7.1 to13.2) versus 9.76 ± 1.4 ranged from (7.3 to13.0) P = 0.44) and Blood transfusion 0.3 ± 0.8 ranged from (0 to 3) versus 0.3 ± 0.7 ranged from (0 to 3) (P = 0.6).

On concern with operative time and hospital stay, the following study found that there was highly statistically significant difference between the studied groups regarding operative time and hospital stay where intravenous tranexamic acid group had the least operative time followed by topical group then the control group had the longest operative time and the control group stayed more than topical more than intravenous tranexamic acid groups **(p-value =0.001**)** with no statistically significant difference between the studied groups regarding nausea, vomiting and diarrhea, this was similar to the findings of **Shaaban et al.** [6]who found shorter duration of surgery (75.9 vs 86.7 minutes for control group; P – value=0 .04) and also in **Caglar et al.** [8]**,** operative time was statistically significant (73 ± 22) ranged from (40 to145) versus (84 ± 29) ranged from (40 to150) (P = 0.03).

In contrast to our results**, Sallam and Shady** [3]found that there was no significant difference was observed operation time, duration of hospital stay, nausea, vomiting and diarrhea between the groups (P = 0.907, 0.174, 0.1, 0.8 and 0.7 respectively) and also **Ngichabe et al.** [9]showed no significant change in operative time between the groups.

Shady et al. [5]found that there was a significant reduction in operative time in group II compared with group I and group III **(p = .0001 and 0.0001)**. However, no significant difference between group I and group III in relation to operative time (p =0.911) with no significant difference between the three groups related to their hospital stay, post-operative hemoglobin, the incidence of nausea, vomiting, and diarrhea (P = 0.752, .446, .102, .87 and 1.00 respectively.

V. CONCLUSIONS

Intravenous and topical tranexamic acid safe and reliable method to help decrease blood loss during open

myomectomy without serious side effects. Further prospective studies with different protocols (varying the duration of administration, quantity, route, etc.) are necessary to confirm these findings. more subjects (larger sample size) can further orient future clinical practices.

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