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Research Article

Hematological profile and transfusion requirement during hysteroscopic myomectomy: A comparative study between oxytocin and tranexamic acid infusion

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KEYWORDS

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Abstract *Background:* Oxytocin is uterotonic drug reducing uterine blood loss. Tranexamic acid reduce blood loss in various settings. Data on their efficacy are limited in gynecological hysteroscopy. This study was conducted to compare the effect of oxytocin versus tranexamic acid on hematological profile and transfusion requirement during hysteroscopic myomectomy (HM).
Methods: Fifty women scheduled for HM were randomly assigned into two groups. Ttranexamic acid (TXA) or oxytocin (OXY). TXA was injected with 15 mg kg^{-1} of tranexamic acid, followed by infusion of 10 mg kg^{-1} h^{-1}. In OXY, 10 Unites of oxytocin were added to 500 mL saline (400 mU/min) during surgery. Spinal anesthesia was induced for all patients. Hemodynamics, hematological data, number of transfusions, serum sodium and central venous pressure were measured.
Results: TXA showed significant decrease of heart rate 30 and 45 min and 1 and 2 h when compared with OXY. Post operative Hb and Hct showed significant decrease ($p < 0.001$) in TXA compared with OXY. CVP in TXA displayed significant increase ($p < 0.001$)

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15 min after spinal blockade and 30 min, 45 min, 1 h and 2 h. Serum sodium showed significant decrease in TXA ($p < 0.001$) compared with OXY nearly throughout study period.
Conclusion: Use of oxytocin during HM was accompanied with stable hemodynamics, hematological profile and less transfusion requirement compared with the use of tranexamic acid.

1. Introduction

Women undergoing HM are prone to significant blood loss, hemodynamic and hematological derangement from distention fluid medium used.

HM using the electro surgery or the Nd YAG laser may be performed in cases of type one submucous fibroids, those greatest diameter is inside the uterine cavity [1–4].

Hysteroscopy is a routine procedure for diagnosis and treatment of abnormal uterine bleeding and infertility assessment [5,6]. Jansen et al. described an overall risk for hysteroscopy of 0.28% and a risk for HM of 0.75% [7]. However, it can result in potentially severe and life threatening complications as reported in some case [8].

Nonconductive and hypotonic fluids such as 5% mannitol, 3% sorbitol, and 1.5% glycine improve visualization during HM when bleeding occurs, and they can be used in diagnostic as well as operative hysteroscopic media [9]. In the last two decades, multiple researches had been promoted on hysteroscopic procedures due to its brief hospital stay, reduced discomfort, low costs and satisfactory short-term results [10].

HM is a challenging surgical procedure for gynecologists and anesthetists, which can result in significant blood loss. Decreasing blood loss and transfusion requirements should improve patient safety, enhance rapid postoperative recovery, and decrease hospital costs.

Tranexamic acid is a synthetic derivative of the amino acid lysine that exerts antifibrinolytic effect through the reversible blockade of the lysine binding sites on plasminogen molecules [11]. Intravenous administration of tranexamic acid has been routinely used for many years to reduce hemorrhage during and after surgical procedures like coronary artery bypass, scoliosis surgery, oral surgery, orthotopic liver transplantation, total hip or knee arthroplasty, and urinary tract surgery [12,13].

Tranexamic acid acts within 2–3 h after oral administration and immediately after intravenous administration, and its half-life is 2–10 h [14].

Oxytocin used to help start or strengthen labor and to reduce bleeding after delivery. Intravenous oxytocin has a very short half-life (4–10 min). Therefore, the potential advantage of an oxytocin infusion at hystroscopic myomectomy is that it maintains uterine contractility throughout the surgical procedure [15].

Although oxytocin is considered to be a safe drug, it can cause tachycardia and hypotension, and it has negative inotropic, antiplatelet, and antidiuretic effects [16].

To the best of our knowledge, this is the first prospective randomized study designed to compare oxytocin with tranexamic acide as regard their effect on hemodynamics, hematological profile and intra operative transfusion requirement during hysteroscopic myomectomy.

2. Patients and methods

This prospective double blind randomized study consisted of 50 women (age range 25–45 years) with symptomatic uterine submucous fibroids scheduled to undergo hysteroscopic myomectomy (HM) performed by one of the authors (Sadek ES) at Mansoura University Hospital, out of them, 47 patients completed the study. The indications for HM in these patients included infertility, menorrhagia and pressure symptoms.

Exclusions criteria included patients with bleeding or coagulation disorders, diabetes mellitus, cardiac disease with evident ischemia, history of myocardial infarctions and congestive heart failure, renal insufficiency as well as any contraindication to spinal anesthesia.

The study was conducted after approval by the local ethical committee of Department of Anaesthesia and Surgical Intensive Care, Faculty of Medicine, Mansoura University. Randomization was done through allocation ratio computer-generated, random number table was used, and the results were kept in sealed envelopes. Envelops were picked to allocate the enrolled patients into two groups, tranexamic acid group (TXA) and oxytocin group (Oxy), each comprised 25 patients. A physician outside the operating team was responsible for the preparation of the blinded injection syringes, randomized the patients appropriately as well as enrolled the patients and assigned them to their respective groups.

All patients have given a written informed consent prior to enrollment.

The day before surgery all patients were evaluated fulfilling full medical history, clinical examination and ECG. Laboratory investigations included complete blood picture and hematocrit, serum creatinine, serum sodium level, serum bilirubin, albumin, SGOT, SGPT, prothrombin time and partial thromboplastin time and blood glucose.

The day of surgery and after arrival to the operating theater a wide bore intravenous cannula (18 G) were inserted through suitable peripheral veins and I.V. midazolam 0.05 mg/kg was given. Preanesthetic monitoring included heart rate, ECG, blood pressure (non-invasive), and peripheral oxygen saturation using Drager (Infinity Kappa, Mexico) monitor with Samsung screen.

Five-hundred milliliter Ringer's solution was infused to all patients as a pre loading 1 h before induction of spinal anesthesia. Spinal anesthesia was performed in sitting position using 2.5 ml 0.5% hyperbaric bupivacaine mixed with fentanyl 20 μg intrathecally after local Lidocaine 2% infiltration. Any hypotension, was treated by intravenous injecting of ephedrine 5–10 mg. Hypotension defined as 20% decrease in blood pressure from pre-induction level or a systolic blood pressure lower than 100 mm Hg. Surgeon was allowed to start surgery when adequate sensory block to *T*10 at the umbilical level was achieved and surgical procedure was performed by the same surgeon for all patients.

Central venous pressure catheter was inserted just before surgery to judge the status of the intravascular volume and trans-compartmental fluid shift using a single lumen catheter (Amecath, France) that inserted in the right internal jugular vein with strict sterile technique using Sildenger technique after local infiltration of Lidocaine 2%. The catheter was then flushed with heparinized normal saline solution and connected to a pressure transducer for central venous pressure monitoring. The position of the catheter was confirmed by antero-posterior chest X-ray just after insertion by C-arm.

Patients in the TXA group were given 15 mg/kg of tranexamic acid (Cyklokapron@; Amoun Pharmaceutical Co., SAE) slowly intravenously 30 min before surgery followed by 10 mg/kg/h infusion in 500 ml Ringer's by infusion pump till the end of the procedure. An equal volume of normal saline syringe in a double blinded manner was intravenously administered to the OXY group 30 min before surgery followed by one ampoule of oxytocin (10 U/mL/amp) (Syntocinon®@; Aventis Pharmaceutical Co.) was added to 500 mL Ringer's solution running at a rate of 400 mU/min by infusion pump till the end of the procedure.

After establishing spinal anaesthesia, resection was carried out under the use of Glycine (1.5%) as a fluid distention media. Resectoscope (26 Fr) (Karl Storz) with a 24 Fr cutting loop under videoscopic screening was used for surgical resection. The flow and the distention pressure were regulated using a Hys-surgimat. The flow rate was kept at 250–400 ml/min with distention pressure was kept between 80 and 100 mm Hg to maintain good visualization. The height of the irrigating fluid reservoir is fixed at 60 cm height from the surgical table. The resected tissues were collected at the end of surgery and weighted. Histopathological examination was carried out for a specimen from the resected tissues.

An accurate method to calculate the actual amount of blood loss during hysteroscopic procedures that use a distention medium was very difficult, so we depend on both hemodynamics (HR and MBP) and pre operative and post operative hemoglobin and hematocrit concentration to assess the blood loss during this study.

Heart rate (HR), ECG monitoring, non–invasive mean blood pressure (MBP), arterial oxygen saturation (SaO2; using pulse oxymetry) and central venous pressure (CVP) were recorded.

The above mentioned parameters were recorded immediately after arrival to the pre anaesthetic room (Basal or preoperative reading), 15 min after spinal blockade, 30 min, 45 min, 1 h, 2 h from the start of resection and 8, 16 and 24 h from the end of the procedure using Drager (Infinity Kappa, Mexico) monitor with Samsung screen.

Hb, Hct, PT and PTT (using Automatic Cell Counter; Sysmex Kx-21, Japan) were measured preoperatively and immediately postoperative. Serum sodium concentration was measured at preoperative (basal), 15 min after spinal blockade, 30 min, 45 min, 1 h, 2 h from the start of resection and 8, 16 and 24 h from the end of the procedure.

The amount of distension fluid medium used in each patient is calculated. The total amount of urine output was calculated by indwelling Foley's catheter, that was inserted to all patients after the spinal blockade. Any complications were noted at the end of the study.

The power of this clinical trial was retrospectively calculated using the G Power analysis program version 3 [17]. Using post-hoc power analysis with accuracy mode calculations with hemoglobin concentration as the primary variant and assuming type-I error protection of 0.05 and an effect size convention of 0.8, a total sample size of 50 patients produced a power of 0.87.

The statistical analysis of data done by using excel program for figures and SPSS (SPSS, Inc, Chicago, IL) program statistical package for social science version 16. To test the normality of data distribution K–S (Kolmogorov–Smirnov) test was done only significant data revealed to be nonparametric. N.B: all tested data revealed to be parametric. The description of the data done in form of mean (±) SD for quantitative data and frequency and proportion for qualitative data.

The analysis of the data was done to test statistical significant difference between groups.

Chi square test was used for qualitative data. Any difference or change showing probability (P) less than 0.05 was considered statistically significant at confidence interval 95%.

3. Results

The flow diagram of participation in this study is shown in Fig. 1. Two patients of TAX Group (one had a severe hemorrhage requiring vasopressor and blood transfusion; one failed blinding) and one of OXY Group (exposed to un blinding) were excluded from the analysis of the study outcomes. In this study, there were no significant differences between TAX group and OXY group with respect to age (25–45 and 26–44 years, respectively), weight (55–88 and 58–82 kg, respectively), and body mass index BMI (20.7–33.3 and 20.5–32.0, respectively). All patients were ASA I and II (ASA I/ASA II = 13/10 and 13/11, respectively). The duration of surgery and the weight of resected tissues also showed no significant intergroup differences (Table 1).

The used distention fluid medium (glycine 1.5%) displayed no significant difference between the studied groups (5195 ± 1855 ml) in TXA group versus (4975 ± 985 ml) in OXY group with p value 0.38 (Table 1).

The total amount of the urine output, at the end of the procedure reflected no difference between the studied groups (465.20 ± 127.58) in TXA group versus (468.80 ± 82.43) in OXY group with a p value 0.91, and no patients taken diuretic therapy (Table 1).

Heart rate demonstrated a significant decrease in TXA group compared with OXY group nearly throughout the study period (p ranged from <0.01 to <0.001) (Table 2).

Mean arterial blood pressure (MBP) showed a significant decrease ($p < 0.02$) in TXA group compared with OXY group 15 min after spinal blockade (Table 2).

Peripheral arterial oxygen saturation (SPO2) was significantly increased in TXA group ($p < 0.03$) compared with OXY group at 8, 16 and 24 h from the end of the procedure (Table 2).

Both the pre operative hemoglobin (Hb) and hematocrit (Hct) concentration were comparable to each other in both groups. Post operative Hb concentration displayed significant decrease ($p < 0.001$) in TXA group compared with oxy group. Also, Hct level showed significant decrease in TXA group compared with the OXY group ($p < 0.001$) (Table 3).

Both pre operative and post operative prothrombine time (PT) and partial thromboplastine time (PTT) were comparable

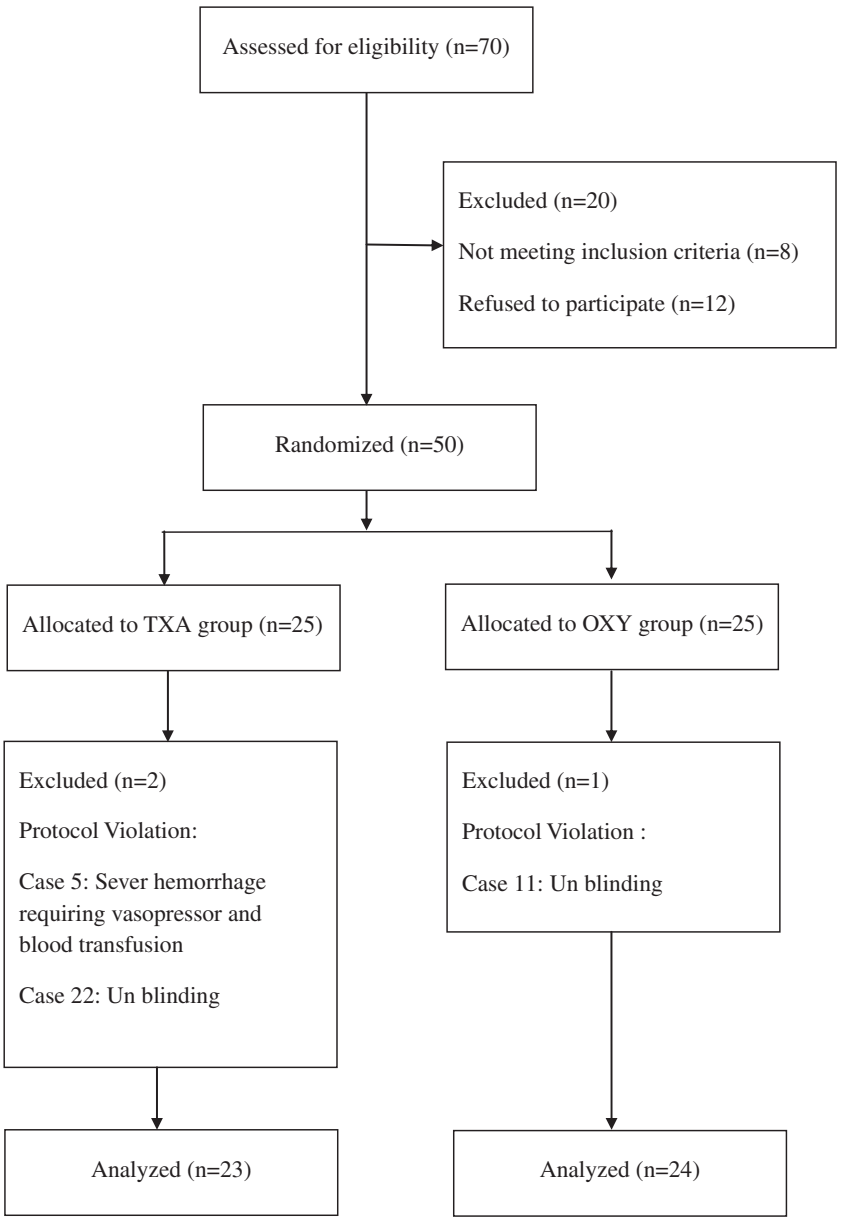

Figure 1 Patients flow diagram.

Table 1 Patients characteristics and duration of surgery (min) of the studied groups. Values are presented as mean ± SD, (number) and (%) for ASA classification.

	TXA group (N = 23)		OXY group (N = 24)		p Value
	N	%	N	%	
ASA					
I	13	56.5	13	54	0.76
II	10	43.5	11	46	
Age (ys)	34.08 ± 6.43		35.24 ± 5.17		0.48
Wt (kg)	68.52 ± 7.13		70.36 ± 6.26		0.33
BMI	26.27 ± 3.28		26.21 ± 2.99		0.94
Duration of surgery (min)	61.24 ± 15.97		61.48 ± 14.47		0.95
Resected Tissues (gm)	179.36 ± 23.77		183.44 ± 27.00		0.57
Total glycine used (ml)	5195 ± 1855		4975 ± 985		0.38
Total urine output (ml)	465.20 ± 127.58		468.80 ± 82.43		0.91

TXA = tranexamic acid and OXY = oxytocin.

Table 2 Hemodynamic data: heart rate (HR, bpm), mean arterial blood pressure (MBP, mm Hg), and peripheral arterial oxygen saturation (SPO2, %) of the studied groups. Values are presented as mean ± SD.

	TXA group ($N = 23$)			OXY group ($N = 24$)		
	HR	MBP	SPO2	HR	MBP	SPO2
Preop	89.28 ± 12.9	126.28 ± 11.48	98.72 ± 1.24	88.72 ± 14.75	131.40 ± 11.54	98.12 ± 1.33
15 min After spinal block	90.56 ± 8.76	104.76 ± 8.81*	99.00 ± 0.82	94.16 ± 14.49	107.96 ± 10.86	99.20 ± 0.82
30 min From start of resection	92.56 ± 7.16*	104.52 ± 6.58	99.56 ± 0.58	102.16 ± 10.71	108.92 ± 6.73	99.68 ± 0.48
45 min From start of resection	94 ± 6.48*	113.16 ± 8.17	100.04 ± 2.13	101.6 ± 9.26	115.52 ± 6.78	99.76 ± 0.44
1 h From Start of resection	93.52 ± 6.31*	127.84 ± 10.47	99.72 ± 0.46	99.04 ± 8.07	125.80 ± 7.21	99.64 ± 0.57
2 h From Start of resection	92.72 ± 5.56*	126.40 ± 6.20	98.36 ± 0.91	96.56 ± 7.024	128.48 ± 6.14	98.36 ± 1.04
8 h	90.28 ± 5.69*	128.16 ± 5.12	98.12 ± 0.78*	93.6 ± 6.15	127.84 ± 5.84	97.64 ± 0.70
16 h	88.72 ± 5.71	126.92 ± 5.80	99.32 ± 0.69*	91.88 ± 5.86	127.28 ± 6.52	98.44 ± 1.00
24 h	87.56 ± 6.48*	127.40 ± 5.69	99.52 ± 0.59*	91.2 ± 5.62	129.12 ± 7.02	98.88 ± 1.05

TXA = tranexamic acid and OXY = oxytocin.
p Is significant if < 0.05.
* Significant difference with the same value in the other group.

Table 3 Hematological data: Hemoglobin (Hb, g/dL) and Hematocirt (Hct, %) and Prothrombine time (PT, s), Partial thromboplastine time (PTT, s) and Patients who underwent transfusion of the studied groups. Values are presented as mean ± SD and number (percentage).

	TXA group ($N = 23$)	OXY group ($N = 24$)	p Values
Preoperative			
Preop Hb	11.95 ± 0.78	11.81 ± 0.74	0.51
Preop Hct	39.76 ± 2.20	39.80 ± 2.33	0.95
Preop PT	11.84 ± 0.90	11.80 ± 0.71	0.86
Preop PTT	29.56 ± 2.86	29.68 ± 1.93	0.86
Postoperative			
Post op Hb	10.18 ± 0.62*	11.13 ± 0.70	< 0.001
Post op Hct	32.68 ± 2.41*	38.16 ± 1.86	< 0.001
Post op PT	12.12 ± 0.73	12.12 ± 0.53	1.00
Post op PTT	29.80 ± 2.38	30.12 ± 1.59	0.58
Patients who underwent transfusion	5 (21.7%)	1 (4.1%)	0.09

TXA = tranexamic acid and OXY = oxytocin.
p Is significant if < 0.05.
Data are given as number (percentage) of each group.
* Significant difference with the same value in the other group.

in both group and showed no significant difference between the groups (Table 3).

Also, the number of patients whose underwent RBCs transfusion displayed no significant difference between the two groups. Five patients in TXA group (21.7% of the total number of the group) and one patient in OXY group (4.1% of the total number of the group) underwent RBCs transfusion (Table 3).

Regarding central venous pressure in TXA group revealed a highly significant increase ($p < 0.001$) at 15 min after spinal blockade and at 30 min, 45 min, 1 h and 2 h from the start of resection (Fig. 2).

Sodium level concentration showed a highly significant decrease in TXA group ($p < 0.001$) compared with OXY group nearly throughout the study period (Fig. 3).

4. Discussion

In the present study, oxytocin and tranexamic acid were compared as regard their effect on hematological profile and their ability to decrease the need for blood transfusion during HM. Patients in both groups demonstrated a comparable demographic characteristics. This clinical study showed that the use of oxytocin during HM resulted in stable hematological parameters (Hb, Hct, PT and PTT) and significant decrease of Hb and Hct concentration with the use of tranexamic acid in comparable to oxytocin. In addition, only one patient required blood transfusion in OXY group. Oxytocin was associated with significant increase in HR compared with tranexamic acid with nearly comparable MBP and SPO2. One of the considerable results of this study, was the protective effect of oxytocin against absorption of distension fluid medium during HM, that proved by the significant increase in central venous pressure as well as significant decrease in serum sodium concentration in TXA group compared with OXY group.

Most of the surgical procedures consuming a distention fluid medium to provide a good visualization were accompanied with a serious complication of fluid absorption and sever bleeding [18]. Hence, our interest in this study was to compare the efficacy of oxytocin and tranexamic acid as regard the

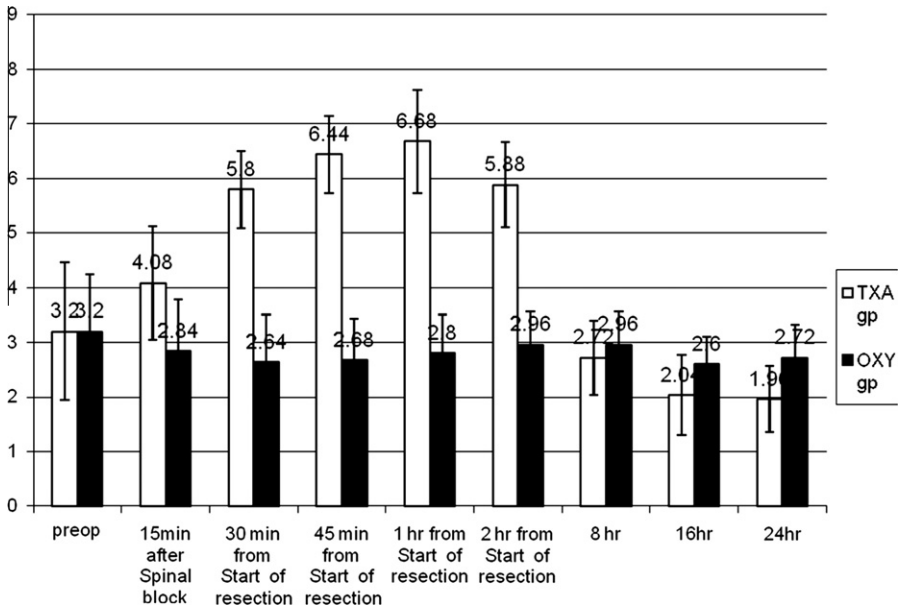

Figure 2 Central venous pressure (CVP) (mm Hg) of the studied groups, white column (□) (TXA) $n = 23$ and black column (■) (OXY) $n = 24$.

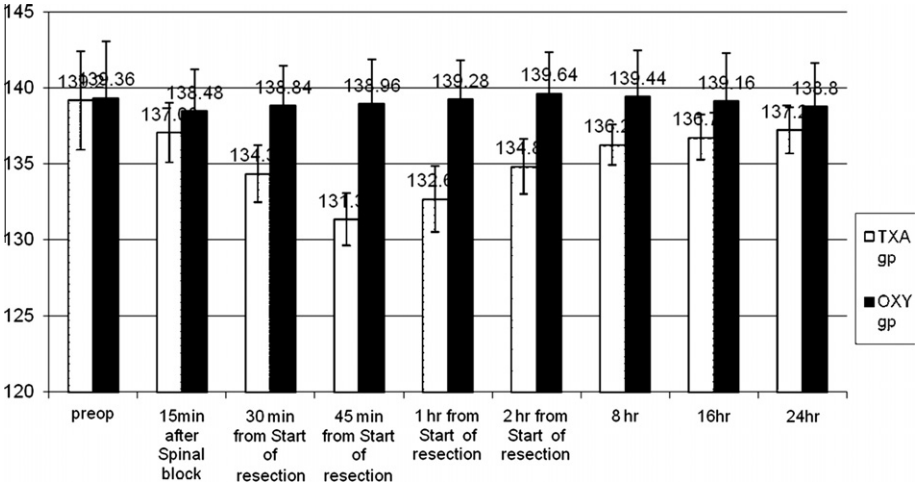

Figure 3 Serum sodium concentration (Na+) (meq/L) of the studied groups, black column (■) (OXY) $n = 24$ and white column (□) (TXA) $n = 23$.

maintenance of the hemodynamics and hematological profile within the physiological range.

As regard hemodynamic changes, a lot of studies have been proved that there were many causes to the maternal hemodynamic alteration during delivery, including uterine contraction, stress factor, relieve of the aorto-caval compression and blood loss, but many studies consider the uterotonic drugs (oxytocin) have a dominant effect [19,20].

This study showed that, heart rate was significantly reduced in tranexamic acid group than oxytocin group nearly at all time of the study period. But with highly significance ($p < 0.001$) observed at 30 and 45 min from the start of resection, most probably due to the actual increase of heart rate that might be occur with the oxytocin group at these time of readings. This result was in accordance with the previous study [21] which state that an intravenous bolus five unites of oxytocin injected in pregnant women undergoing an elective caesarean section under spinal anaesthesia produced an elevation of heart rate from 85 to 119 with a p value < 0.003. Another study [22] compared oxytocin given either by bolus or infusion, proved a significant increase in heart rate which is so rapid within (30 s) with bolus injection but with steady manner of increase by infusion.

Regarding mean arterial blood pressure (MBP), it was showed significant decrease with tranexamic acid group ($p < 0.02$) compared with the oxytocin group at 15 min after spinal blockade. Which could be attributed to the effect of spinal blockade, that needed to be treated with ephedrine and fluid therapy. However, this decrease was not continue and restricted only at this time of the study.

The significant decrease of hemoglobin (Hb) and hematocrit (Hct) values ($p < 0.001$) in the post operative period in TXA group compared with the OXY group, we believe, is a result of the uterotonic effect of oxytocin which might be more effective in reducing surgical blood loss than the anti fibrinolytic effect of tranexamic acid. Another explanation for significant decrease in Hb and Hct values in TXA group could be explained by the dilutional effect of the absorbed irrigate fluid, especially when this result was supported by the significant increase in central venous pressure (CVP) ($p < 0.001$) which occurs at the same time of the study period in TXA group. This significant increase in CVP with TXA group compared with the OXY group, caused by the possibility of absorption of significant amount of irrigating fluid, make the oxytocin an ideal uterotonic drug used during HM decrease the problem of fluid over load. This result was in accordance with the result of the previous study that used oxytocin drip during hysteroscopic myomectomy [23]. However, the significant increase in CVP in TXA group was within the physiological ranges.

Dilutional effect of fluid absorption on Hb and Hct values are in a agreement with previous findings, that in surgical patients, low Hct and Hb together with elevated CVP are usually encountered as a result of excess fluid absorption [24]. On the other hand, our results are contradictory to the previous studies, those proved significant increase of Hb and Hct when tranexamic acid used versus placebo to reduce intra operative blood loss and transfusion requirement [25–27].

Preoperative and post operative prothrombine time (PT) and partial thromboplastine time (PTT) were comparable in both group, indicating that tranexamic acid and oxytocin have no draw back on the coagulation pathway in the current study. This is in agreement with the previous findings that showed no significant changes, both in the preoperative as well as the post operative values of PT and PTT when tranexamic acid was used versus placebo in pediatric craniosynostosis surgery [27]. Similarly, another study carried out in total knee arthroplasty proved the same results [28].

In this study five patients need RBCs transfusion during surgery (one unit for each patient) in the TXA group, where as only one patient required one unite RBCs transfusion in OXY group. So, it was no significant difference between both group in the issue of the blood transfusion. Previous study was in agreement with our result, when it used tranexamic acid versus placebo to decrease the total number of transfusion unites during total hip replacement surgery [25]. On the other hand, different studies were demonstrated a significant decrease ($p < 0.001$) in the number of the transfused RBCs unites when used tranexamic acid to decrease blood loss and transfusions during total knee arthroplasty [25].

As regard sodium level concentration, it showed highly significant decrease ($p < 0.001$) in TXA group compared with OXY group, which could be explained with the dilutional effect of the irrigate fluid absorption, however, it did not accompanied with any symptoms related to fluid over load (nausea, vomiting, irritability, etc.), neither it need any diuretic therapy. This result was in accordance with a previous study [18] that proved significant decrease in serum sodium concentration in 40 out of 46 patients underwent transcervical resection of the endometrium using 1.5% glycine as an irrigating solution. Youn et al (2011) [9], in his case report, demonstrated extreme hyponatremia with moderate acidosis during hysteroscopic myomectomy as a result of excess absorption of fluid distention media.

This current study had certain limitations, includes inability to accurately measure the actual blood loss. Also we could not use a different dose of the drugs (especially tranexamic acid) so the efficacy of the drug and the severity of bleeding were varied which might have its effect on the total blood loss and total transfusion requirement. Other limitations includes, no drug combination groups were used. We recommend further and continuous investigations to reach to the best regimen that could has an effective haemostatic effect in such procedures.

5. Conclusion

Maintaining physiological hemodynamics and hematological profile are crucial in most of all surgeries. According to the measured variables with the positive and negative findings of the studied drugs, we can conclude that, oxytocin is more effective in reducing the transfusion requirement than tranexamic acid in the current study with more stable hematological and hemodynamic profile. Future studies in this field should continue, trying to exclude limitations and drawbacks of this study through use of different doses of tranexamic acid as well as including drug combination group.

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Conflict of interest

No conflict of interest emerged during the implementation of this work. The paper had not been presented at any congress before.

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