

## Original Research Article

# The effect of intravenous tranexamic acid on reduction of seroma after para-umbilical hernioplasty

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### ABSTRACT

**Background:** Para-umbilical hernioplasty is mostly safe but there are possible complications like seroma, wound infection and recurrence. Tranexamic acid is a synthetic derivative of the amino acid lysine that exerts an anti-fibrinolytic action through the reversible blockade of lysine binding sites on plasminogen molecules, used in the prevention and treatment of excessive bleeding both in primary and secondary care. Our study aimed to evaluate the effect of intravenous tranexamic acid injection on reduction of seroma after para-umbilical hernioplasty.

**Methods:** We conduct a prospective controlled trial to compare the effect of intra-operative, intravenous single dose of tranexamic acid by a dose of 10 mg/kg body weight with induction of anaesthesia on the occurrence of local wound complications as seroma, wound infection in addition to time of drain removal and the amounts of drain output, by comparison between two groups.

**Results:** Single intravenous dose of tranexamic acid with induction of anaesthesia reduced drain duration (P-value was 0.001), drain output in 1st day (P-value was 0.008), and drain output in 5th day (P-value was 0.036). Adverse effects were not observed. There were no significant difference in occurrence of seroma (P-value was 0.429), and wound infection (P-value was 1.00).

**Conclusions:** Our study revealed that tranexamic acid showed significant correlation with decrease duration of drains and fewer amounts of drain volumes in first day post-operative.

**Keywords:** Hernioplasty, Para-umbilical, Seroma, Tranexamic acid

### INTRODUCTION

Para-umbilical hernias occur just above or less commonly below the umbilicus. They result from weakness in the linea alba and are more common in women than in men. They rarely occur in children and are most common in adult; it constitutes the 2nd common type of hernias about 22% of all hernias in Egypt.<sup>1</sup>

Para-umbilical hernioplasty is mostly safe but there are possible complications like seroma, wound infection, injury to bowel (when hernia contain loops of bowel), wound dehiscence.<sup>2</sup>

A seroma is an accumulation of fluid in a tissue that can occur after para-umbilical hernioplasty, the fluid called serum leaks out of nearby damaged blood and lymphatic vessels. Cells are typically present in the fluid, which is normally clear. Seroma formation may be associated with an increased risk of infection and breakdown of the surgical site. Surgical drain tubes with bulb suction devices are used after some surgeries to help reduce the risk of seroma formation. These allow for monitoring the volume of fluid leakage, and once drainage becomes minimal, the drains are removed. Seromas can form shortly after surgery if drains are not used, and they may also occur after removal of a drain.<sup>3</sup>

Small seromas often resolve on their own, although left untreated, they can calcify forming hard knots. Larger seromas often require aspiration (removal of fluid), generally accomplished with a needle. Seromas that become infected may require antibiotic therapy and on rare occasions surgery may be necessary to treat a seroma.<sup>4</sup>

Postoperative complications such as wound seroma occur in 5.6% to 42% of cases using the meshes for para-umbilical hernia repair. It can be the reason of postoperative wound infection, suppuration, and hernia recurrence.<sup>5</sup>

Tranexamic acid is a synthetic derivative of the amino acid lysine that exerts an anti-fibrinolytic action, used in the prevention and treatment of excessive bleeding both in primary and secondary care, first described in the 1960s; recent years have seen a resurgence of interest in its use in the management of bleeding and particularly in the context of severe trauma.<sup>6</sup>

When fibrinolysis exceeds coagulation, unwanted surgical bleeding may occur despite adequate haemostasis. Tranexamic acid is the most commonly used medication to prevent fibrinolysis. It acts by blocking the lysine-binding sites on plasminogen, thereby preventing the activation of plasminogen to plasmin.<sup>1</sup> Tranexamic acid can be administered orally or intravenously, Intravenous administration of tranexamic acid during major surgery has been shown to reduce postoperative bleeding by 34 percent. Intravenous dose of tranexamic acid (10mg /kg body weight) was usually given with induction of anaesthesia in para-umbilical hernioplasty.<sup>6</sup> To the best of our knowledge, no up-to-date studies act on the effect of tranexamic acid on seroma formation and wound infection after paraumbilical hernioplasty.

## METHODS

This study included 40 patients divided into two groups with para-umbilical hernioplasty, the study were carried out from January 2018 to January 2019 in Menoufia university hospital (Shebeen Elkom, Egypt) and El zaytoon specialized Hospital (Cairo, Egypt).

This is a prospective study, in which the 40 consecutive patients were divided into two groups:

- Group A: 20 patients received tranexamic acid intravenous injection by adose of 10 mg/kg IV infusion with induction of anaesthesia and were submitted to para-umbilical hernioplasty.
- Group B: 20 patients not received tranexamic acid and were submitted to para-umbilical hernioplasty.

The inclusion criteria were: Uncomplicated para-umbilical hernias and Ages between 21 to 70 years. The exclusion criteria were: Complicated hernias, Hernias

associated with medical diseases affecting co-aggulation profile and pregnancy.

In this study we used the same type and size of polypropylene mesh in repair of para-umbilical hernias and the same surgeon did hernioplasty in both hospitals).

## Clinical assessment

All patients in both groups were subjected to preoperative assessment both clinically and laboratory, all of them were assessed for vital signs, associated medical diseases (diabetes, hypertension, renal, pulmonary, and heart diseases), any anticoagulation such as (low dose aspirin, anti-platelets, warfarin) or cortico-steroids.

## Laboratory assessment

CBC, blood sugar, S. creatinine, liver function tests, and INR were drawn.

## Abdominal and pelvic ultra-sonography

It is very useful in determination of the size of the abdominal wall defect, and shows the hernia contents. All patients of both groups were subjected to hernioplasty and on-lay mesh repair through a transverse incision and a suction drain were inserted in all patients. Both groups were compared according: the time for drain removal, the amount of drain outcome on 1<sup>st</sup>, 3<sup>rd</sup>, 5<sup>th</sup> days, Occurrence of seroma, time of occurrence and its severity during 30 days after removal of drain and Occurrence of wound infection.

## Statistical analysis

The collected data were organized, tabulated and statistically analyzed using SPSS software (Statistical Package for the Social Sciences, version 21, SPSS Inc. USA). Data were described using mean and standard deviation (SD) and frequencies according to the type of the data (quantitative or categorical respectively). Chi-square and fisher exact test were used for comparison of qualitative variables. We used one way Anova test to compare between means of categorical and numerical data. Significance level (P-value) was adopted, i.e.  $p < 0.05$  for interpretation of results of tests of significance.

## RESULTS

As regarding comparison of gender of patients in both groups are found that: In group A 11 males (55% of group) and 9 females(45% of group).while in group B 10 males and 10 females without impact on outcomes of the study with  $p$ -value=0.752 (Table 1).

As regarding comparison of age of patients in both groups are found that: In group A between 23-52 years old while in group B between 21-57 years old without

impact on outcomes of the study. P-value=0.860 (Table 1).

**Table 1: Demographics of studied groups.**

Demographic data	Group A (n=20)	Group B (n=20)	$\chi^2$ (U)*	P value
<b>Age /years</b>				
Mean $\pm$ SD	38.2 $\pm$ 8.3	37.6 $\pm$ 9.4	0.176	0.860
Median	38	39	(U)*	
Range	23-52	21-57		
<b>Gender</b>				
Male	11 $\pm$ 55.0	10 $\pm$ 50.0	0.100	0.752
Female	9 $\pm$ 45.0	10 $\pm$ 50.0		
<b>Diabetes mellitus</b>				
No	15 $\pm$ 75.0	16 $\pm$ 80.0	0.143	0.705
Yes	5 $\pm$ 25.0	4 $\pm$ 20.0		
<b>Hypertension</b>				
No	16 $\pm$ 80.0	15 $\pm$ 75.0	0.144	1.00
Yes	4 $\pm$ 20.0	5 $\pm$ 25.0		

About 25% of patients in group A had diabetes mellitus. While 20% in group B had diabetes without statistically significant difference between both groups (P-value=0.705).

About 20% of patients in group A had hypertension. While 25% in group B without statistically significant difference between both groups (P-value=1.00) (Table 1).

**Table 2: The differences of drain output between two groups.**

Drain	Group A (n=20)	Group B(n=20)	U*	P value
<b>Drain duration in days</b>				
Mean $\pm$ SD	6.4 $\pm$ 1.2	8 $\pm$ 1.6	2.03	0.001
<b>Drain volume (1<sup>st</sup> day) in ml</b>				
Mean $\pm$ SD	106.5 $\pm$ 39.7	157.5 $\pm$ 60.8	2.65	0.008
<b>Drain volume (3<sup>th</sup> day) in ml</b>				
Mean $\pm$ SD	98 $\pm$ 52	104 $\pm$ 56.7	0.35	0.72
<b>Drain volume (5<sup>th</sup> day) in ml</b>				
Mean $\pm$ SD	(n=13) 67.6 $\pm$ 40.2	(n=16) 93.1 $\pm$ 48.6	2,15	0.036

The mean time for drain removal in group A was 6.4 $\pm$ 1.2 less than that for group B which was 8 $\pm$ 1.6.

- Group A: drains were left for more than 5 days in 5 patients (25% of group). While removed on 5<sup>th</sup> day or before in 15 patients (75% of group).
- Group B: drains were left for more than 5 days in 14 patients (70% of group). While removed on 5<sup>th</sup> day or before in 6 patients (30% of group). P-value is 0.001 so tranexamic acid shows positive effect on time of drain stay after operation on this study (Table 2).

In comparison between the two groups in the mean amount of fluid coming through drain in ml, we found the mean of volumes as follow:

- Group A: In the 1<sup>st</sup> day it was 106.5 ml, in the 3<sup>rd</sup> day it was 98 ml and in the 5<sup>th</sup> day it was 67.6 ml.
- Group B: In the 1<sup>st</sup> day it was 157.5 ml, in the 3<sup>rd</sup> day it was 104 ml and in the 5<sup>th</sup> day it was 93.1 ml.

P-value in 1st day is 0.008, 3<sup>rd</sup> day is 0.72 and in 5th day is 0.036 so tranexamic acid shows positive effect on drain amount on 1st and 5<sup>th</sup> days and no impact on drain amount on 3rd days on this study (Table 2).

**Table 3: Methods of treatment of seroma in two studied groups.**

Line of treatment	No	%
<b>Group A</b>		
Suction syringe	2	66.7
Drain guided by ultrasound	1	33.3
<b>Group B</b>		
Suction syringe	3	60.0
Drain guided by ultrasound	2	40.0

In comparison between the two groups in the occurrence of seroma we found that:

In group A: seroma occurred in 3 patients and in group B seroma occurred in 5 patients. P-value of the study is 0.429 so tranexamic acid shows no impact on seroma on this study (Table 4).

In comparison between the two groups in the occurrence of wound infection we found that:

In group A: wound infection occurred in 3 patients and in group B wound infection occurred in 4 patients. P-value=1.00 so tranexamic acid shows no impact on wound infection on this study (Table 4).

In comparison between the two groups in treatment of seroma we found that:

- In group a (3 cases with seroma) 2 cases treated by aspiration syringe and 1 case treated by reapplication of drain guided by ultrasound (Table 3).
- In group b (5 cases with seroma) 3 cases treated by aspiration syringe and 2 cases treated by reapplication of drain guided by ultrasound (Table 3).

There are no complications detected from injection of intravenous tranexamic acid in this study.

**Table 4: Correlation between injection of tranexamic acid and development of seroma and wound infection.**

	Group A (no=20)		Group B (no=20)		Fisher's Exact Test	P value
<b>Occurrence of seroma</b>	No	%	No	%		
Yes	3	15.0	5	25.0	0.625	0.429
No	17	85.0	15	75.0		
<b>Wound infection</b>					0.173	1.00
Yes	3	15.0	4	20.0		
No	17	85.0	16	80.0		

## DISCUSSION

Abdominal wall hernias are one of the most common surgical problems, and mainly caused by any condition that increases the pressure in the intra-abdominal cavity.<sup>7</sup>

All patients of both groups were subjected to hernioplasty and on-lay mesh repair through a transverse incision and a suction drain were inserted in all patients.

In our study, we found that there was no significant relation between age and gender in both groups in occurrence of complications as seroma, wound infection and time of drain removal post-operative and this matches with the study done by Patel et al, in 2014 that showed comparison of intravenous versus topical tranexamic acid in total knee arthroplasty (p-value was 0.342), while Yan-ping et al, that showed risk factors for postoperative seromas in Chinese breast cancer patients, in their study showed significant relation between age and gender in both groups in occurrence of complications as seroma (p-value was 0.004).<sup>8,9</sup>

In this study, we found that there was no significant effect of co-morbidities disease like diabetes mellitus and hypertension on the results of the study (P-value was 0.705, 1.00).

The current study revealed that there was a significant effect of tranexamic acid on drain duration (P-value was 0.001) and this matches with the study done by Suh et al., in 2018 which showed the efficacy of tranexamic acid for hemostasis in patients undergoing high tibial osteotomy (P-value was <0.05).<sup>10</sup>

The current study revealed that there was a significant effect of tranexamic acid on amount of drain output in 1st and 5<sup>th</sup> days post-operative (P-value was 0.008, 0.036 respectively) and non-significant in 3<sup>rd</sup> day (P-value was 0.72) may be due to technical human error as patient do this alone in his home and this matches with the study done by Ausen et al, in 2015 which showed that clinical trial of topical tranexamic acid after reduction mammoplasty had a significant effect on amount of drain output (P-value was 0.038).<sup>13</sup>

The current study revealed that there was no significant effect of tranexamic acid in the development of post-operative seroma (P-value was 0.429) may be due to low dose of tranexamic acid as only single dose as it decrease incidence but not significant and this matches with the study done by Oertli et al, in 1994 which showed that Perioperative and postoperative tranexamic acid reduces the local wound complication rate after surgery for breast cancer had no significant effect on seroma but decrease it (P-value was 0.2).<sup>12</sup>

The current study revealed that there was no significant effect of tranexamic acid in the development of wound infection (P-value was 1.00) and this matches with the study conducted by Ausen et al, in 2015 which showed that clinical trial of topical tranexamic acid after reduction mammoplasty had no significant effect on wound infection (P-value was 0.428).<sup>11</sup>

## CONCLUSION

Our study revealed that tranexamic acid showed significant correlation with decrease duration of drains and less amount of drain volumes in first day post-operative. Our study showed that there is no significant correlation between tranexamic acid and rate of seroma formation.

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