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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

The effect of topical application of tranexamic acid on the occurrence of postoperative hematoma after inguinal hernia repair using the Lichtenstein technique

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SUMMARY

Introduction/Objective The objective of the study was to determine whether the local application of tranexamic acid (TXA) by pouring over the surgical wound reduces the incidence of postoperative hematoma and the occurrence of postoperative bleeding in the wound following inguinal hernia repair using the Lichtenstein technique.

Methods We conducted a prospective, randomized, double-blind clinical study in the period from June 2024 to February 2025. One hundred and twenty patients were divided into two groups, one group of patients who received TXA during surgery, and the other group where a placebo was administered. Subsequently, the groups were compared and analyzed by sex and age structure, the frequency of postoperative hematoma, and the pre- and postoperative levels of erythrocytes, hemoglobin, and platelets were recorded.

Results The results indicate that in the group where TXA was administered, postoperative hematoma occurred statistically significantly less often than in the group with a placebo ($p < 0.05$). The frequency of postoperative hematoma in the group of patients who were treated with TXA was 3.8%, while the frequency in the group of patients who were treated with a placebo was 13%. There was a statistically significant difference in the levels of platelets before and after surgery in the compared groups.

Conclusion We found that the topical application of TXA reduces the occurrence of postoperative hematoma, and thus the occurrence of postoperative bleeding, as well as reduces the postoperative drop in platelets.

Keywords: inguinal hernia repair; tranexamic acid; hematoma; hemoglobin; erythrocytes; platelets

INTRODUCTION

Postoperative bleeding is one of the most common complications of surgical procedures. According to some reports, more than 300 million patients undergo surgery annually [1]. Bleeding can be merely a clinical sign, without any consequences, but it can also be significant, with varying consequences, and it occurs within the first 7 days in 77.7% of cases [2]. This affects the patient's morbidity and mortality, quality of life, and speed of recovery. According to a study conducted by Roshanov, mortality occurs in 5.8% of cases among patients with postoperative bleeding, excluding cardiac surgery patients [3]. There are various definitions of postoperative hemorrhage; however, our scope of interest is bleeding in the wound after inguinal hernia surgery using the Lichtenstein technique, manifesting as hematoma, i.e., bruising and/or swelling and out-of-range blood test results. The drug that is standardly used to prevent or stop bleeding is TXA. This agent is routinely used intravenously and orally, according to the manufacturer's recommendations, and has its own indications and contraindications [4, 5].

Systemic administration of TXA has shown many advantages, and most commonly cited are reduced postoperative bleeding and a reduced need for blood transfusion [6–9]. However, the idea of using TXA in the form of a local application emerged because there is unclear data on adverse effects since the drug manufacturer suggests avoiding the drug in certain patient groups, as a potential health risk [4, 5]. Several studies, systematic reviews, and meta-analyses addressed this topic, including the local application of TXA [10, 11–16]. So far, local application of TXA has been applied in various fields of surgery, such as otorhinolaryngology, maxillofacial surgery, orthopedics, breast surgery, spinal surgery, thoracic surgery, urology, and plastic surgery. However, some studies have described side effects following the local application of TXA, such as impaired wound healing, a larger amount of seroma after breast mastectomy and axillary dissection, and poor tendon healing [17, 18, 19]. Two studies also described that it enhances bone healing [20, 21]. Only one study investigated a similar topic regarding the local application of TXA during inguinal hernia repair, with a small number of patients at increased risk of bleeding due to

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the medications they used [16]. For this reason, our study aimed to test whether the local, more precisely topical application of TXA affects the reduction in the frequency of postoperative hematoma, i.e., bleeding after inguinal hernia repair using the Lichtenstein technique.

METHODS

A prospective, randomized, double-blinded study was conducted in the period from June 2024 to February 2025. The sample size consisted of 120 patients, divided into two groups. Both groups were treated in a standard way, one group (control) was intraoperatively treated with a placebo solution, and the other (experimental) with a solution containing TXA.

The criteria for inclusion in the study were: age over 18 years and males and females with one-sided inguinal hernia.

The criteria for exclusion from the study were: patients with an inguinoscrotal hernia, patients with a recurrent inguinal hernia after open surgery, patients who did not stop their regular antiplatelet therapy, patients on permanent low-molecular-weight heparin therapy, excluding preoperative one-time prevention, patients with acute disease, exacerbation of chronic disease, patients on dialysis, and patients with hematological diseases excluding anemic syndrome, which meets the conditions for introduction to general endotracheal anesthesia, patients with proven connective tissue disease.

The exclusion criteria also included an intraoperative deviation from standard surgery, which included increased bleeding and excessive tissue trauma, which could be the cause of bleeding that might present a false-positive result for the drug under investigation.

Upon admission to hospital treatment, the patient was assigned two numbers, the first number, which was the serial number, related to the name, surname, and order of patient's surgical procedure, together with the second number, 1 or 2, indicating the recipient of a placebo or drug. The ward nurse, in the operation block and the lead researcher was the only person who was familiar with the numbers and their correlation. Thereupon, the patients underwent standard preoperative preparation, had blood drawn, were operated on, and received standard therapy.

The standard procedure of the Lichtenstein technique was performed for the repair of the inguinal hernia. Each patient was operated on using a uniform method, and the surgery was performed by five experienced general surgeons, each with over five years of specialized experience. For hernioplasty, polypropylene mesh of the same type, characteristics and size 6 × 11 cm or 8 × 15 cm, depending on the size of the inguinal canal, was used for all patients. Prior to inserting, the mesh was shaped accordingly and subsequently fixed along the outer lower edge continuously with a monofilament, non-absorbable suture of thickness 2.0 in the region of the inguinal ligament, from the tubercle to 2–4 cm above the internal inguinal ring. The mesh was further fixed with 3–5 single sutures of the same material along the inner upper edge and with two single sutures on the previously incised mesh to create a new internal inguinal ring. Access to the inguinal canal, preparation and management of the hernial sac, reconstruction of the posterior wall of the inguinal canal, and closure of the inguinal canal were performed in a standardized manner, as a standard procedure in open inguinal hernia repairs.

TXA or placebo was prepared outside the operating room, by the previously authorized person, who did not inform the surgical team about its content. Depending on this, either a medication solution was prepared by drawing two ampoules of TXA, i.e., 10 ml of solution at a concentration of 500 mg / 5 ml, into a 20 ml syringe, followed by adding 10 ml of sterile 0.9% saline solution, or just 20 ml of 0.9% saline solution as a placebo in a syringe of the same specifications.

The professional did not inform anyone about the contents of the syringe. During the operation, the hernia sac or its residues were poured over with the solution, without removal of the residues for at least 1 minute. Further on, 8 ml of solution were poured on the entire site below the aponeurosis of *musculus obliquus externus*, without removal of the residues. Afterwards, an additional 4 ml of solution were poured on the layers above the closed fascia, without removal of the residues for at least 1 minute. Intraoperative, prior to using the solution, hemostasis was achieved by surgical means.

The described methods achieved the effect of a double-blind study.

Postoperatively, the occurrence of hematoma in the operated region was monitored until the postoperative day 7, when most of the bleeding would be visualized [2]. The appearance of a hematoma was considered statistically significant if the width was greater than 2 cm along the entire lower and upper edge of the postoperative wound.

In addition, changes in the blood count were monitored preoperatively and postoperatively, the day before and after the operation. In this way, we analyzed the differences in the blood count in the control and observed groups. We monitored the number of erythrocytes, hemoglobin, and platelets as easily measurable components involved in the coagulation cascade.

On the first postoperative day, patients were examined in detail to record possible complications and hematoma at the site of the operative wound. Also, laboratory analyses were repeated, i.e., blood test results. The wound was then bandaged, and if the treatment was without complications, the patients were discharged for further home and outpatient follow-up.

After discharge, patients were examined after seven days to record clinical signs of bleeding, and other complications.

In the study, among the methods of descriptive statistics, the measure of central tendency, the arithmetic mean, measures of variability and the standard deviation, as well as relative numbers, were used. A simple random sampling system and tables of random numbers were used for randomisation of the patients. Analytical statistics methods were used to identify empirical distributions and methods

Table 1. The age structure of the observed groups

	Tranexamic acid applied							
	No				Yes			
	Mean	Standard deviation	Minimum	Maximum	Mean	Standard deviation	Minimum	Maximum
Age (years)	63.85	11.85	23	85	59.46	13.94	27	87

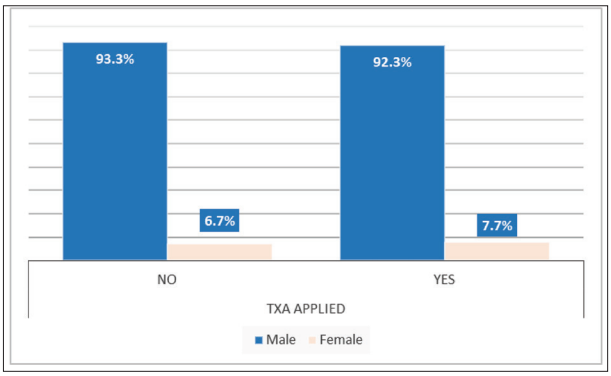

Figure 1. Sex structure of the observed groups

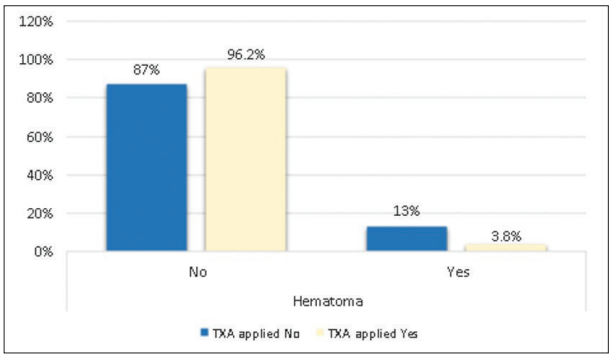

Figure 2. Frequency of occurrence of postoperative hematoma; TXA – tranexamic acid

for assessing the significance of the difference depending on the type of data, the χ^2 test, and t-test for independent samples. The IBM SPSS Statistics (IBM Corp., Armonk, NY, USA) program was used for statistical data processing.

Ethics: Informed consent was obtained from all subjects involved in the study. The study was conducted in accordance with the Declaration of Helsinki, and was approved by the Ethics Committee of the Đorđe Joanović Zrenjanin General Hospital (protocol code 01-133/56, date of approval April 10, 2024).

RESULTS

By comparing the demographic characteristics of the patients in both groups, we did not find a statistically significant difference. In the group of patients who received TXA, the average age was 59 years, while in the control group the average age was 64 years. There was no statistically significant difference between the observed groups ($p = 0.076$). The age structure is shown in Table 1.

Figure 1 shows the sex structure of the observed groups, where it was also noted that there was no statistically significant difference ($p = 0.834$). Men were predominant in both groups of patients, 92.3% in the experimental group and 93.3% in the control group.

A statistically significant lower frequency of postoperative hematoma was observed in the group that received TXA during surgery ($p < 0.05$). It was observed that in the experimental group, hematoma appeared in 3.8% of patients, while in the control group, hematoma occurred in 13% of patients. The data are shown in Figure 2.

A statistically significant difference in the number of red blood cells before and after surgery between groups ($p = 0.672$) was not observed. The mean value of red blood cells preoperatively was 4.71×10^{12}/l in the control group, while postoperatively it was 4.58×10^{12}/l. Moreover, in the experimental group, the values were 4.81×10^{12}/l and

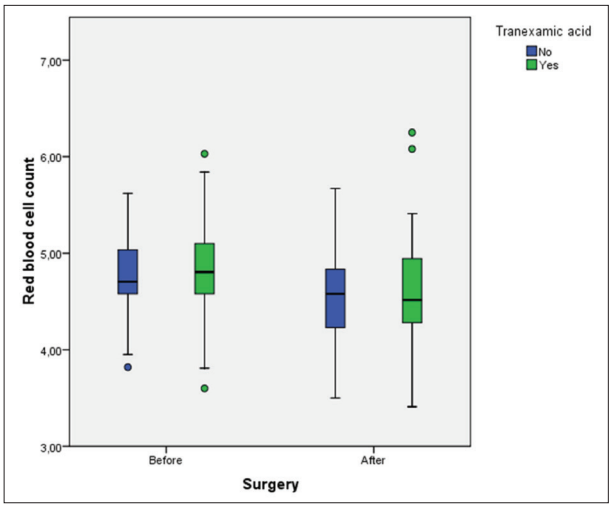

Figure 3. Preoperative and postoperative number of red blood cells in the observed groups

4.52×10^{12}/l preoperatively and postoperatively. The results are shown in Figure 3.

A statistically significant difference was not observed in the mean hemoglobin level preoperatively and postoperatively in the observed groups ($p = 0.924$). The mean value of hemoglobin preoperatively was 145.2 g/l in the control group, while postoperatively it was 137.93 g/l. In the experimental group, the values were 146.23 g/l and 139.31 g/l preoperatively and postoperatively. The values are shown in Figure 4.

The decrease in platelet count was statistically significantly lower in the group of patients who were administered TXA, compared to the group that was given a placebo ($p = 0.030$). The mean value of platelets preoperatively was 235.45×10^9/l in the control group, while postoperatively it was 209.27×10^9/l; in the experimental group, the values were 232.90×10^9/l and 220.06×10^9/l preoperatively and postoperatively. The results are shown in Figure 5.

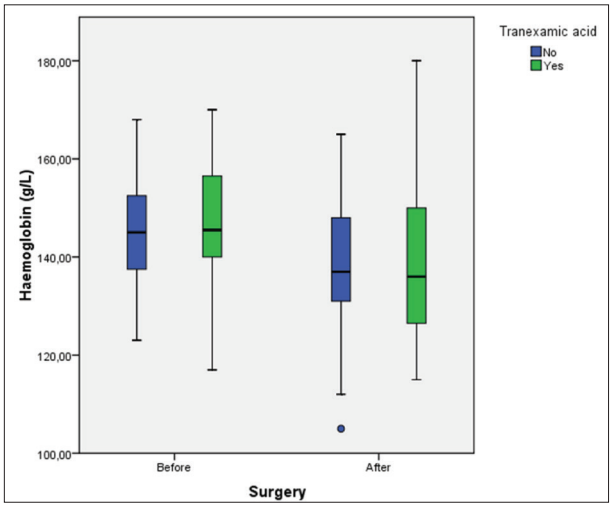

Figure 4. Preoperative and postoperative level of hemoglobin in the observed groups

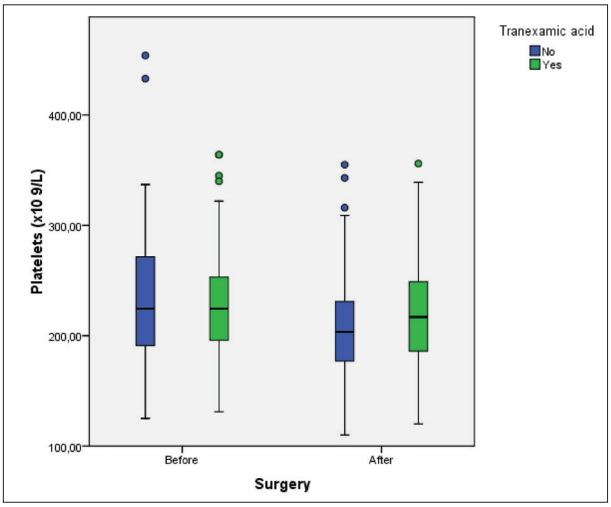

Figure 5. Preoperative and postoperative level of platelets in the observed groups

DISCUSSION

The sex distribution disclosed that men predominated in both the experimental and the control group. The obtained data coincide with the results of other studies, explaining this by the fact that men are exposed to heavier physical efforts through work and physical training. Regarding the age distribution, the results of our study fall roughly between the values of the studies by Agarwal [22] and Burcharth et al. [23].

There is a small number of studies dealing with the use of TXA in abdominal surgery and abdominal wall surgery [16, 24, 25]. The number of subjects in the studies is small, and the possibilities are large, considering the number of operations and potential complications related to postoperative bleeding. Inguinal hernia repair is one of the most common surgeries in the world, and the most common technique for surgery is the Lichtenstein technique. Thus, according to some reports, 275,000 such operations were performed in Germany, while 800,000 such operations were performed in the United States of America in one year [26, 27].

Bleeding is one of the most common complications of this surgery, and it can lead to other complications, such as swelling, hematoma, mesh infection and pain. Hematoma as a sign of bleeding is described with varying frequency, from 1.4–13.6%, depending on the author and the definition of the observed complication [26, 27, 28]. These complications can result in slower patient recovery, additional surgical procedures or reoperations, slower return to regular daily activities and work duties, disability, more expensive treatment, and very rarely death. When this number of complications is multiplied by the number of operations and the percentage of their occurrence, it can be concluded that the prevention of bleeding can have great benefits for the patient and the health system. Hematoma as a sign of postoperative bleeding is the most common complication, which can be easily monitored clinically. Through our study, we determined that the frequency of hematomas in the group that did not receive TXA was 13% (eight patients), according to the given criteria. Of these, one patient had significant clinical bleeding, prolonged hospitalization, monitoring and replacement of blood products, while the frequency of occurrence of hematoma in the group that received TXA was 3.8% (two patients). Comparing these two groups, we found that there is a statistically lower incidence of hematoma in the experimental group. Therefore, it can be concluded that there was less intra- and/or postoperative bleeding in this group. Several other studies have shown similar results [9, 10, 11, 14, 16].

TXA is a potent antifibrinolytic agent, as it blocks the lysine binding site on the plasminogen molecule, thereby preventing its interaction with fibrin. This inhibits the activation of the plasminogen molecule and its conversion to plasmin. This inhibition disrupts the activation of plasminogen and its conversion to plasmin, consequently impeding fibrinolysis and preserving the integrity of the blood clot, thus reducing the risk of bleeding. Moreover, during the application of higher doses of TXA during cardiac surgery, convulsions may occur due to the antagonistic effect on GABA(A) receptors. The primary elimination route is renal, with over 95% of the drug excreted through kidneys. After oral administration, 30–50% of the drug is absorbed and 90% of the drug is excreted from the body within 24 hours when TXA is administered intravenously, while during oral administration 39% of the drug is excreted during the same period. The apparent elimination half-life is close to 2 hours when TXA is administered intravenously, while the mean terminal half-life is approximately 11 hours. Similar pharmacokinetic properties of TXA when administered topically are not available [4, 5].

The mechanism of action of TXA theoretically increases the risk of thromboembolic events, so it is not recommended in patients where this risk is increased [4, 5]. However, in practice, this risk has not been confirmed, as shown in a large number of studies [8, 9, 11]. No increased frequency of vascular side effects such as myocardial infarction, stroke, pulmonary thromboembolism (PTE), or deep vein thrombosis was shown. There was no risk of acute renal failure either. Even a protective effect against such side effects has been shown. However, there was an

increased risk of seizures when high doses of TXA were used in cardiac surgery [8, 29].

The mechanism of action of TXA during local application is the same as during systemic application of TXA, the stabilization of the formed coagulum on severed venous and arterial blood vessels and capillaries. The methods of application are different, by spraying, pouring, local infiltration and covering the surface with gauze and fabric soaked with TXA. Spraying and pouring of tissue (topical application) are most recommended due to surface coverage and ensuring sufficient contact of tissue and TXA. The concentrations used are very different, ranging 1–100 mg/ml, where even the lowest concentration is 100 times higher than the minimum required concentration of TXA in plasma to achieve a beneficial effect, which is 10 μg/ml. So far, no information is available on whether the plasma concentration after topical application of TXA is the same or lower than the tissue concentration. It has not been shown that a greater number of adverse reactions, which we mentioned earlier, occur with topical application of TXA compared to systemic application of TXA or when it is not used at all [9, 10, 11].

We compared the blood count before and after surgery, more precisely the level of erythrocytes and the level of hemoglobin. We wanted to determine whether topical application of TXA affects the level of these two blood count indicators. The results showed that TXA did not affect the level of erythrocytes and hemoglobin postoperatively in the experimental and control groups. From this, it can be concluded that these are not the factors that influence the less frequent occurrence of hematoma in the group where TXA was applied. Kushwaha et al. [12] showed a different result in his study when he measured preoperative and postoperative hemoglobin levels, and when he observed a statistically significant difference in the group where TXA was applied topically compared to the group that received saline solution. Both groups received systemic saline instead of TXA, which was similarly shown in a study by Zhong et al. [13].

On the other hand, the study indicated that the local application of TXA affects the postoperative platelet level, reduces the decline, i.e., consumption, in comparison to the group of patients who were not prescribed TXA, which is contrary to some other studies [13]. It is not clear by which exact mechanism the local application of TXA affects systemic platelet level, however, one possible mechanism is more efficient formation of clot and thrombus on severed blood vessels, thereby reduced consumption of platelets during their formation. Certainly, determining the mechanism of action remains a subject for further research, and this knowledge could be applied in preoperative preparation of all patients, especially for those with lower platelet count.

No adverse reactions during topical application of TXA were recorded, which is consistent with the experience of other authors [9, 10, 11]. The influence of TXA can be indirectly applied to other areas of surgery and invasive procedures. Also, there are still a lot of doubts that need to be resolved, such as, for example, the specific mechanism of action of TXA at the local level, required concentrations, method of application, and length of contact with the tissue.

CONCLUSION

The study determined that the topical application of TXA during inguinal hernia repair using the Lichtenstein technique statistically significantly reduces the occurrence of postoperative hematoma, indicative of postoperative bleeding. Furthermore, the results demonstrated that TXA does not affect the level of erythrocytes and hemoglobin before and after surgery. However, it was proven that the impact of administering TXA led to a lesser drop in the platelet count prior to and post-surgery.

Conflict of interest: None declared.

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Ефекат локалне примене транексаминске киселине на појаву постоперативног хематома после операције ингвиналне хернije Лихтенштајновом техником

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САЖЕТАК

Увод/Циљ Циљ студије је био да се утврди да ли локална примена транексаминске киселине (*TXA*) посипањем хируршке ране смањује учесталост појаве постоперативног хематома, тј. постоперативног крварења у рани након операције ингвиналне хернije Лихтенштајновом техником.

Методе Спровели смо проспективну, рандомизирану, дупло слепу клиничку студију. Сто двадесет болесника било је подељено у две групе; једној групи је апликована *TXA* током операције, а другој плацебо. Даље, групе су поређене и анализиране према полу, старосној доби, учесталости постоперативног крварења и преоперативном и постоперативном нивоу еритроцита, хемоглобина и тромбоцита.

Резултати Резултати указују да се постоперативни хематом појављивао статистички значајно ређе у групи којој је ординирана *TXA* у односу на групу којој је ординиран плацебо ($p < 0,05$). Учесталост појављивања постоперативног хематома у групи која је третирана са *TXA* била је 3,8%, док је учесталост у другој групи била 13%. Постојала је статистички значајна разлика у нивоу тромбоцита пре и после операције међу поређеним групама.

Закључак Утврдили смо да локална примена *TXA* смањује појаву постоперативног хематома и самим тим постоперативног крварења, као и постоперативни пад тромбоцита.

Кључне речи: операција ингвиналне хернije; транексаминска киселина; хематом; хемоглобин; еритроцити; тромбоцити