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

Ефекат локалне примене транексаминске киселине на појаву постопера-
тивног хематома након операције ингвиналне херније
Лихтенштајновом техником

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

Ефекат локалне примене транексаминске киселине на појаву постопера-
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SUMMARY

Introduction/Objective The objective of the study is to determine whether the local application of tranexamic acid (TXA) by pouring of 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. Hundred and twenty patients were divided into two groups, one group of patients who were given TXA during surgery, and the other one 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 level of erythrocytes, hemoglobin, and platelets were monitored.

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 ($p < 0.001$). 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 statistically significant difference in the level of platelets before and after surgery in compared groups.

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

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

САЖЕТАК

Увод/Циљ Циљ студије је био да се утврди да ли локална примена транексаминске киселине (TXA) поси-
пањем смањује учесталост појаве постоперативног
хематома у рани, тј. појаве постоперативног крва-
рења у рани након операције ингвиналне херније
Лихтенштајновом техником.

Методе Спровели смо проспективну, рандомизи-
рану, дупло слепоу клиничку студију. Стотину дваде-
сет болесника је било 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 постопера-
тивног крварења и преоперативном и постоператив-
ном 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, ко-
јој је ординиран плацебо ($p < 0.001$). Учесталост по-
јављивања постоперативног хематома у групи, која је
третирана са TXA била 3,8%, док је учесталост у дру-
гој групи била 13%. Постоји 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 постопера-
тивни пад тромбоцита.

Кључне речи: операција ингвиналне херније; тра-
нексаминска киселина; хематом; хемоглобин; ери-
троцити; тромбоцити

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 in patients with postoperative bleeding, excluding cardiac surgery patients [3]. There are various definitions of post-operative

haemorrhage, however our scope of interest is bleeding in the wound after the inguinal hernia surgery using the Lichtenstein technique, manifesting as haematoma 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 tranexamic acid (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 this drug has shown many advantages, and as it is most commonly cited, 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 uncertain data on adverse effects since the drug manufacturer itself suggests avoiding the drug in certain patient groups, as a potential health risk [4, 5]. Several studies, systematic reviews, and meta-analyses tackled 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, orthopaedics, 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 [17], a larger amount of seroma after breast mastectomy and axillary dissection [18], and poor tendon healing [19]. However, 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, who were at increased risk of bleeding due to the medications they were using [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 in 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 with the active substance - tranexamic acid.

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

The criteria for not being included in 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 heparin therapy, which does not include preoperative one-time prevention, patients with acute disease, exacerbation of the chronic disease, patients on dialysis and patients with haematological diseases excluding anaemic syndrome, which meets the conditions for introduction to general endotracheal anaesthesia, patients with proven connective tissue disease.

The exclusion criteria were an intraoperative deviation from standard surgery, which includes increased bleeding and more excessive tissue trauma, which could be the cause of bleeding that might present a false-positive result by 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 the order of patient's surgery procedure, together with the second number, 1 or 2 indicating recipient of a placebo or drug. The ward nurse, in the operation block and the lead researcher were the only one who were familiar with the numbers and its correlation. Thereupon, the patients underwent standard pre-operative preparation, had blood drawn, were operated on, and received standard therapy.

The standard procedure of Lichtenstein technique was performed for the repair of the inguinal hernia. Each patient was operated using a uniform method, and the surgery was performed by five experienced general surgeons, each with over five years of specialised experience. For hernioplasty, polypropylene mesh of the consistent type, characteristics, size 6x11 or 8x15 cm, depending on the size of the inguinal canal, was used for all patients. Prior inserting, the mesh was shaped accordingly and subsequently fixed along the outer lower edge in continuous manner 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, and the mesh was fixed along the inner upper edge of the mesh and with two single sutures, created a new internal inguinal ring on the previously incised mesh. 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 standardised manner, as a standard procedure in open inguinal hernia repairs.

TXA or placebo was prepared out of the operating room, by the previously authorised person, who hasn't introduced the surgical team with its content. Depending on this, either a medication solution was prepared by drawing two ampoules of tranexamic acid, 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 was poured with the solution, without removal of the residues for 1 minute, at least. Further on, 8ml of solution was poured on the entire site below the aponeurosis of musculus obliquus externus, without removal of the residues. Afterwards, additional 4ml of solution was poured on the layers above the closed fascia, without removal of the residues for 1 minute, at least. Intraoperative, prior to using the solution, the homeostasis 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 should 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 analysed the differences in the blood count in the control and observed groups. We monitored the number of erythrocytes, haemoglobin and platelets as easily measurable components involved in coagulation cascade.

On the first postoperative day, patients were examined in detail in order 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. Simple random sampling system and tables of random numbers, was used for randomisation of the patients. Analytical statistics methods were used in the study to identify empirical distributions, methods for assessing the significance of the difference depending on the type of data, the Chi-square test and t-test for independent samples. The SPSS 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 approved by the Ethics Committee of the Đorđe Joanović Zrenjanin General Hospital (protocol code 01-133/56 and 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 experimental group the average age was 64 years. There is no statistically significant difference between the observed groups ($p = 0.076$). The age structure is shown in Table 1.

Figure 1 shows the gender structure of the observed groups, where it was also noted that there is 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 occurred 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 $4.71 \times 10^{12}/l$ in the control group while postoperatively it was $4.58 \times 10^{12}/l$. Moreover, in the experimental group, the values were $4.81 \times 10^{12}/l$ and $4.52 \times 10^{12}/l$, preoperatively and postoperatively. The results are shown in Figure 3.

Statistically significant difference was not observed in the mean haemoglobin level preoperatively and postoperatively in the observed groups ($p = 0.924$). The mean value of haemoglobin 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 is statistically significantly lower in the group of patients who were administered TXA, in comparison to the group that was given a placebo ($p = 0,030$). The mean value of platelets preoperatively was $235.45 \times 10^9/l$ in the control group, while

postoperatively it was $209.27 \times 10^9/l$, while in the experimental group, the values were $232.90 \times 10^9/l$ and $220.06 \times 10^9/l$, preoperatively and postoperatively. the results are shown in figure 5.

DISCUSSION

The gender distribution disclosed that men predominate in both experimental and in the control group. The obtained data coincides with the results of other studies, explaining it 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 mediate roughly between the values of the Burchart and Agarwal studies [22, 23].

There is a small number of studies dealing with the use of TXA in abdominal surgery and abdominal wall surgery [24, 25, 16]. 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 [26], while 800,000 such operations were performed in the United States of America [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 rare 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% (8 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% (2 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 (MI), stroke, pulmonary thromboembolism (PTE), or deep vein thrombosis (DVT) 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 from 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. The plasma concentration after topical application of TXA is the same or lower than the tissue concentration, so far no information is available on this. 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 haemoglobin. 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 haemoglobin 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 showed a different result in his study when he measured preoperative and postoperative haemoglobin 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 Zhong's study [12, 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 was 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 a postoperative bleeding. Further on, the results demonstrated that

TXA does not affect the level of erythrocytes and haemoglobin before and after surgery. However, it was proven that the impact of administering TXA led to the lesser drop of the platelet count prior to/ and post-surgery.

Conflict of interest: None declared.

Paper accepted

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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

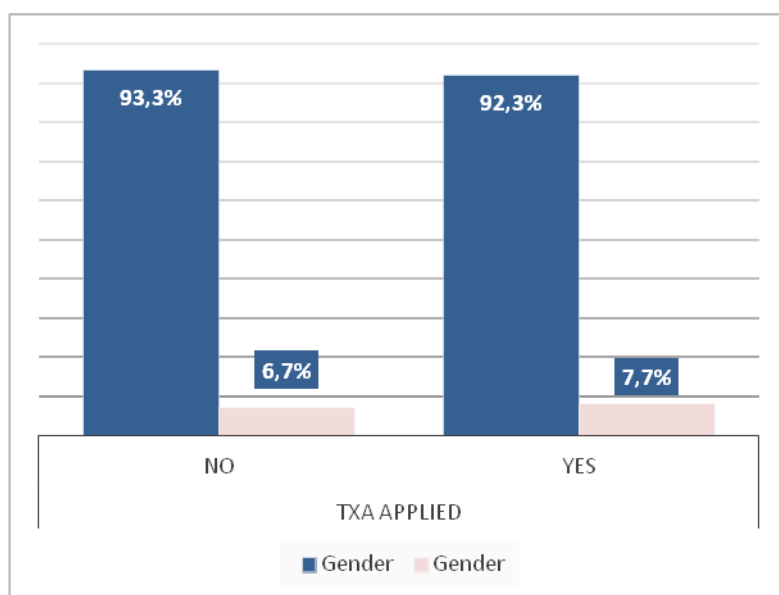


Figure 1. Sex structure of the observed groups

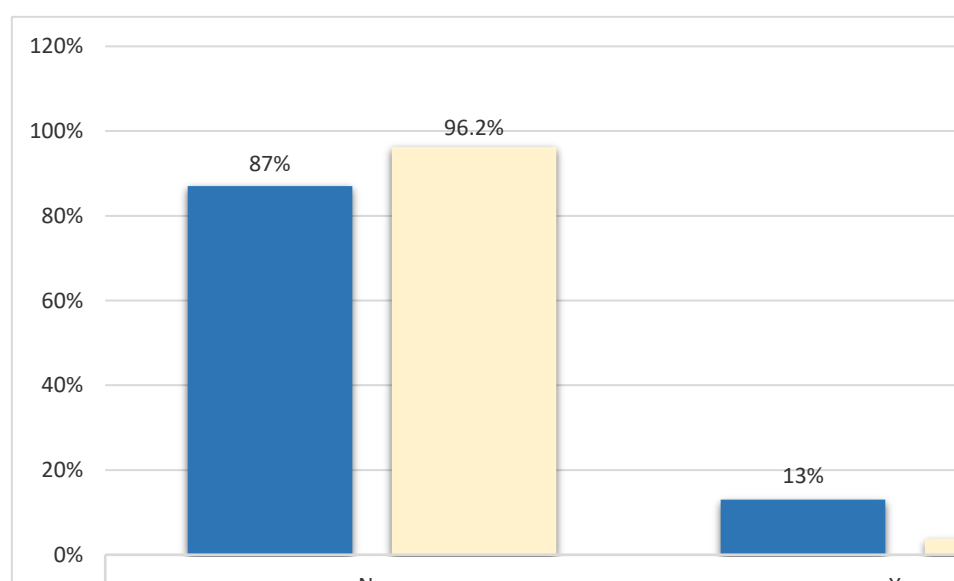


Figure 2. Frequency of occurrence of postoperative hematoma;

TXA – tranexamic acid

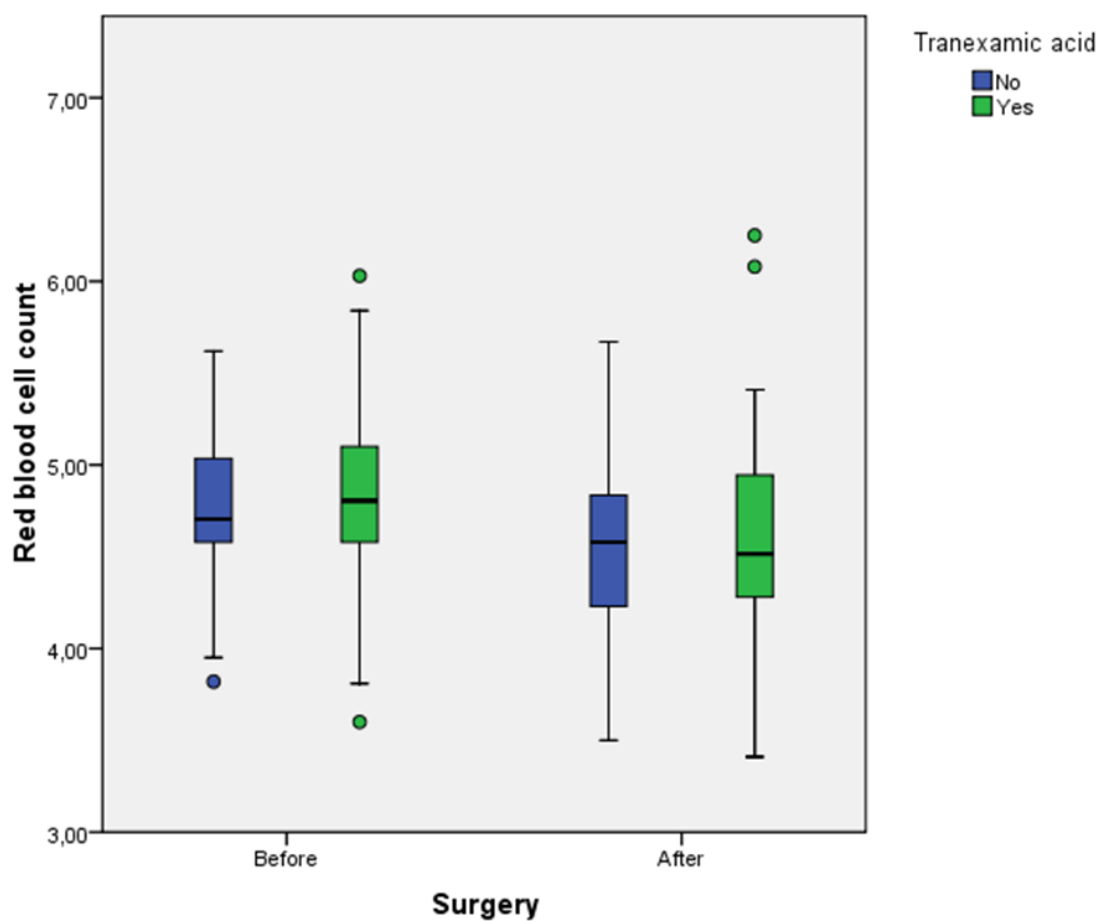


Figure 3. Preoperative and postoperative number of red blood cells in the observed groups

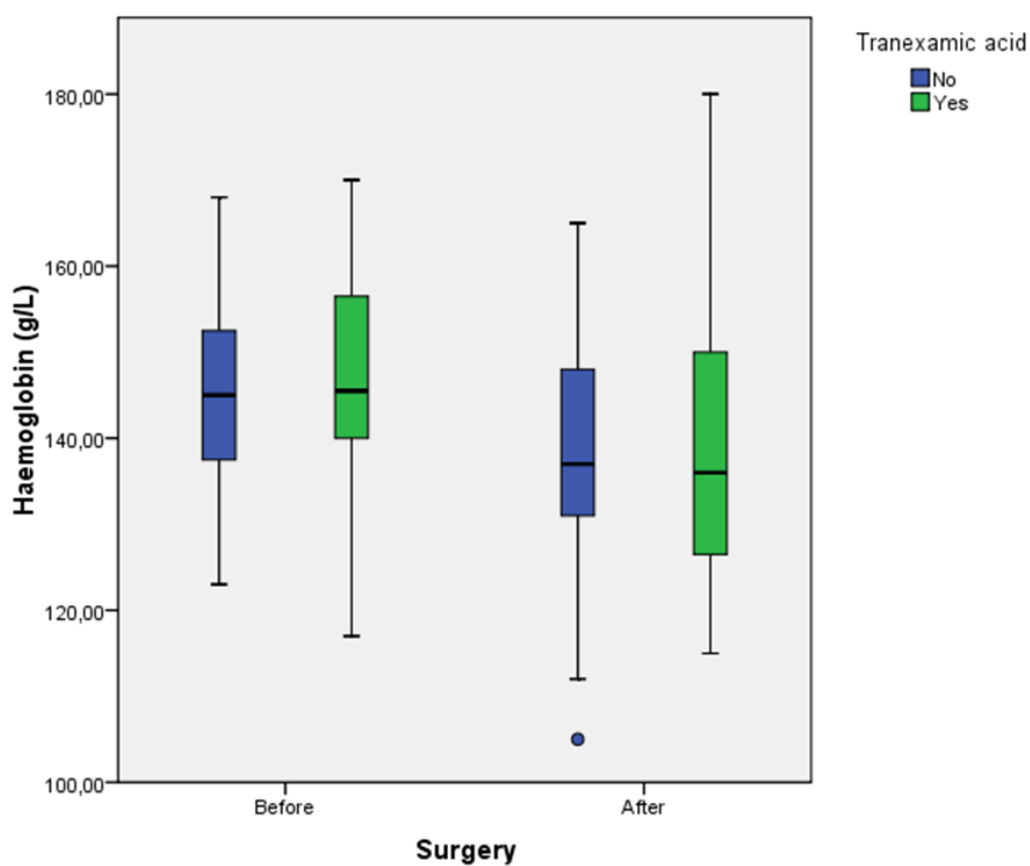


Figure 4. Preoperative and postoperative level of hemoglobin in the observed groups

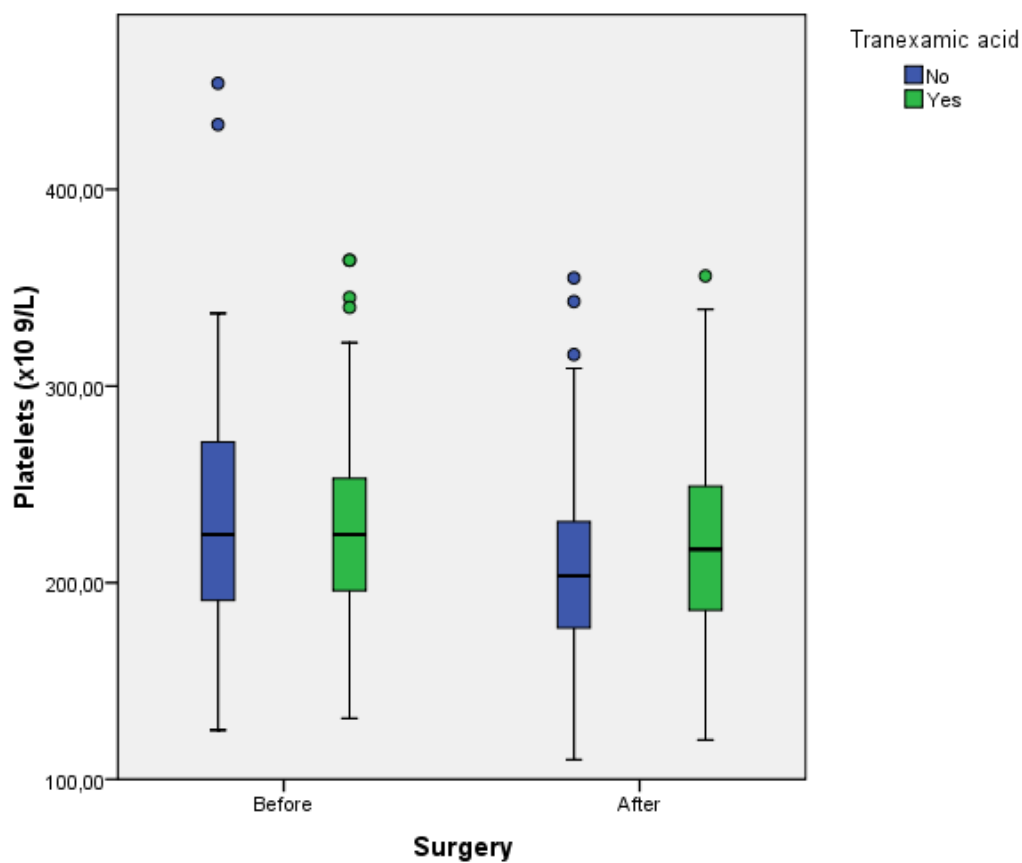


Figure 5. Preoperative and postoperative level of platelets in the observed groups