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First Results of a Randomized Controlled Trial of Hemoblock in Patients with Large Incisional Hernias

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ABSTRACT When penetrating into the cell, local anesthetics affect some structures and processes, in addition to blocking sodium channels, leading to the development of cell damage. The aim of the article was to study the damaging effect of bupivacaine on the sciatic nerve and biceps femoris in rats.

AIM OF STUDY Analysis of the first results of a randomized clinical trial (RCT) for the use of Hemoblock in patients with large incisional hernias and postoperative ultrasound (US) monitoring.

OBJECTIVES Improving the results of surgical treatment of patients with large incisional hernias.

MATERIAL AND METHODS Design of a simple blind randomized controlled trial with a 90 percent study power, α-error equal to 0.05 and β-error equal to 0.10. For this purpose, the total number of subjects is planned to be 66. Currently, there are 18 patients in the study, 10 in the comparison group (B), and 8 in the main group (A). Surgery is plastic prosthetic mesh implant in the sublay retromuscular position. We applied Hemoblock 15 ml retromuscularly and 15 ml subcutaneously in group B. Wounds were drained by vacuum suction drains. Postoperatively — monitoring of a wounds by ultrasound examination on day 3, 7, 10, 12, 15, 18, and 21 after the removal of drains. The average age was 58.5±6.3 in group B and 55.6±11.7 years in group A (U=36.5, p>0.05), BMI 33.6±3.44 and 32.2±5.19 kg/m^2 respectively (U=35, p>0.05), the width of the hernia defect was 11±1.7 cm and 11.1±1.0 (U=33, p>0.05), length 13.6±2.7 cm and 12.5±3.3 cm (U=29.5, p>0.05), the area was 118±22.7 cm^2 and 108.1±24.1 cm^2 respectively (U=28.5, p>0.05). The average ASA was 2.2 in group B and 2.0 in group A.

RESULTS AND DISCUSSION Median of follow-up for all patients was 30 days. Significant differences obtained in the duration of postoperative wound drainage — 4.2±0.9 days in group B versus 2.5±0.5 days in group A (U=4, p<0.01). In patients of group A, the amount of discharge by drainage and the level of CRP and albumin were lower. On ultrasound examination of the postoperative wound, starting from the 10th day, a significantly smaller volume of fluid accumulations was revealed in patients of this group, and from the 15th day fluid accumulations were not detected. In group B, one patient had seroma IIIc (according to Morales-Condo, 2012), 8 patients had IVa seroma, and one patient had IVb seroma spontaneously opened through the postoperative wound, which required debridement of the cavity on an outpatient for 21 days. In group A, only 3 patients had IVa seroma. The number of punctures was 23 in group B, and 3 in group A (χ^2=8.654, p=0.04, Fisher's exact two-sided test (F) =0.00654, p<0.05). Hospital stay was 8.9±0.6 days in group B and 8.0±0.5 days in group A (U=11.5, p<0.05).

CONCLUSION According to preliminary data using local haemostatic agent Hemoblock allows: 1) to reduce the duration of postoperative wound drainage, 2) to reveal the period of inflammatory exudative processes in the postoperative wound, 3) to reduce the number of puncture interventions after incisional hernia repair, 4) to reduce the severity of pain and the need for analgesics, 5) to reduce the hospital stay time.

Keywords: seroma, puncture, plastic surgery, mesh implant, incisional hernia, complications

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BMI — body mass index
CRP — C-reactive protein
IAP — intra-abdominal pressure

INTRODUCTION

Prevention of wound complications during plastic surgery of large postoperative ventral hernias is an important part of improving the results of surgical treatment of patients [1].

The causes of such complications are multifactorial, but the inevitable dissection of the tissues of the anterior abdominal wall is always recognized as the main reason, which leads to the opening of a large number of lymphatic collectors, small blood vessels, capillaries, lymph, blood flow out on the wound surface, aseptic serous inflammation occurs [2].

Seromas are one of the most common complications after plastic surgery of postoperative hernias [3]. Their frequency varies widely, reaching values of up to 60% by some authors [4–6].

Verified patient seroma increases the risks of subcutaneous fat flap necrosis, infection, reduces the ability of tissues to repair. Seromas over the aponeurosis are capable of self-opening to the outside with subsequent divergence of the sutures of the postoperative wound, the formation of a long non-healing wound surface. Seromas in the area of the endoprosthesis in the retromuscular space can lead to the separation of the mesh prosthesis, the formation of the so-called meshoma (from the English

word *mesh*) [7]. This leads to an increase in the duration of stay of the patient in the hospital and increases the economic burden on the medical organization [6]. A large number of ways to prevent this complication [8-15] suggests that the problem is relevant and has not been resolved to this day. Capillary bleeding and lymphorrhea cause hematomas and seromas in the postoperative period. One promising method for intraoperative hemostasis and lymphostasis is a local hemostatic drug Hemoblock [16, 17].

The aim of our study was to analyze the first results of a randomized clinical trial of the use of the local hemostatic Hemoblock in patients with large postoperative ventral hernias and ultrasound monitoring of the postoperative wound.

MATERIAL AND METHODS

To achieve this goal, we chose the design of a simple blind randomized controlled trial. Based on a preliminary demographic study [18], we determined that to obtain a representative sample that could provide a 90 percent study power with α-error of 0.05 and β–error of 0.10, it would be required the total number of subjects is 66. The study implies the presence of two groups (*A*, the main group and *B*, the comparison group), as well as blinded patient. Voluntary informed consent of the patient to participate in the study was obtained in writing. The study was approved by the Local Ethics Committee of Omsk State Medical University.

For an objective comparison of the selected groups of patients, randomization was performed. Random distribution was performed according to the fishbowl method with replacement. Inclusion criteria: 1) satisfactory condition of the patient; 2) the absence of cancer; 3) consent to participate in the study; 4) large postoperative hernias of the anterior abdominal wall (hernial defect ≥10 cm in diameter and / or area of hernial defect ≥100 cm^2) according to the classification of *EHS*, 2009 (hernias *W*3); 5) age 25–75 years. Non-inclusion criteria: 1) age over 75; 2) decompensated concomitant diseases; 3) patient's refuse. Exclusion criteria: 1) the patient refuses to participate in the study at any of its stages.

If the patient met the inclusion criteria, he was offered to participate in the study. This article presents the first results of our study, which currently includes 18 patients (8 in group *A* and 10 in group *B*).

The operation of the choice was plastic hernia defect mesh prolene prosthesis in *sublay retromuscular* position. After dissection of the skin and subcutaneous fat over herniation/ defect (with excision of the previous operational scar) hernial sac was isolated and dissected. Posterior leaflets of the rectus sheaths were dissected, sutured continuously with monofilament Monoplus 2/0 with a long period of absorption (180-210 days), retromuscular space was formed where the mesh prolene prosthesis Esfil standard (Lintex, Russia) was put of a size to cover the 3 cm hernia defect in each direction, the prosthesis was fixed with eight transoneurotic monofilament ligatures *Proline* 3/0. Hemostasis was performed. The drainage tube was installed into the retromuscular (subaponeurotic) space. At this stage, a randomization procedure took place.

When distributing the patient to group *B* (comparison), the anterior leaflet of the rectus sheath was sutured using the "small byte" technology with a Sterelin-loop polypropylene thread. Hemostasis was performed, a drainage tube was installed in the subcutaneous tissue (over aponeurotic space). The wound was sutured by layers. An aseptic dressing was applied. Drainage tubes were connected to the *UnoVac* vacuum aspiration system (*Unomedical*, Denmark). The operation sheme is shown in the Figure.

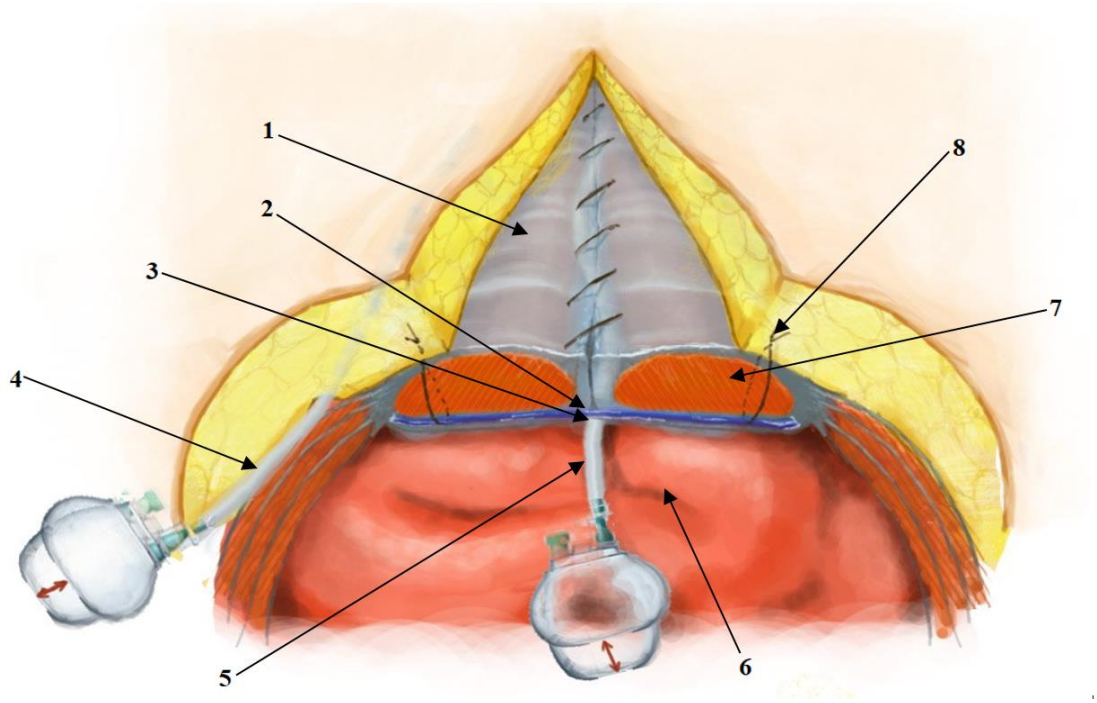

Figure. Plasty of a hernial defect with a mesh implant in sublay retromuscular mode. Vacuum-suction drainage of the sub- and supraponeurotic space (illustration by N.D. Chzhan): 1 — sutured anterior sheet of the vagina of the rectus abdominis muscles, 2 — mesh implant in the retromuscular space, 3 — the sutured posterior sheath of the vagina of rectus abdominis, 4 — vacuum suction drainage in the subcutaneous fat, 5 — vacuum-suction drainage in the retromuscular space, 6 — intestinal loops, 7 — abdominal rectus muscles, 8 — transaponeurotic ligatures that fix the mesh implant

When distributing the patient to group *A* (main) after installing the drainage into the retromuscular space, the local hemostatic preparation Hemoblock was applied with an exposure of 2 minutes in a volume of 15 ml. After that, the anterior leaflet of the rectus sheath was also sutured, hemostasis was performed, the drain was installed in the subcutaneous tissue, and the local hemostatic preparation Hemoblock was applied again with an exposure of 2 minutes in a volume of 15 ml. The wound was sutured in layers. An aseptic sticker was applied. All surgical interventions were performed by the head of the surgical department with 25 years of experience.

METHODS OF STATISTICAL PROCESSING OF MATERIAL

The data were prospectively collected in the *Microsoft Office Excel* 2016 database. The descriptive analysis includes the calculation of average values, standard deviations and proportions. In the analysis, to evaluate the differences between two independent samples by the level of a characteristic in subgroups, non-parametric criteria were used to calculate *p*-values (Mann – Whitney U-test for numerical data and χ^2 Pearson with Yates correction for relative indicators, as well as two-tailed Fisher's exact test). A p value <0.05 was considered a statistically significant difference between the compared groups. All calculations were performed using the *Statistica* 6.1 licensed statistical analysis software package.

PATIENT DEMOGRAPHICS

Patient groups were comparable by age, body mass index (BMI), concomitant pathology, the size of hernia defects. The demographic data of patients by groups are presented in Table 1 and 2. Thus, the mean age was 58.5 ± 6.3 years in group B and 55.6 ± 11.7 years in group *A* (U = 36.5, p > 0.05), mean BMI was 33,6 ± 3.44 kg/m^2 and 32.2 ± 5.19 kg/m^{2,} respectively (U = 35, p > 0.05), mean hernia history was 11.7 ± 10.6 months and 23.5 ± 19.0 months (U = 25, p > 0.05), mean width of the hernial defect was 11 ± 1.7 cm and 11.1 ± 1.0 cm (U = 33, p > 0.05), the length was 13.6 ± 2.7 cm and 12.5 ± 3.3 cm (U = 29.5, p > 0.05), mean area was 118 ± 22.7 cm^2 and 108.1 ± 24.1 cm^2, respectively (U = 28.5, p > 0.05). Under general anesthesia 8 patients (80%) of Group B and all 8 patients (100%) of Group *A* were operated, spinal anesthesia was used in 2 patients (20%) of Group *B*. The degreeof operational and anesthetic risk was assessed according to *ASA*, the average value was 2.2 in Group *B* and 2.0 in Group *A*. All patients received antibiotic prophylaxis with 1st generation cephalosporins 30 minutes before surgery. Postoperative antibiotic therapy was not required in any of the groups. Prevention of venous thromboembolic complications was carried out in accordance with the protocol, using compression stockings of the 2nd class, early activation of patients, which began 6 hours after surgery, low molecular weight heparins in prophylactic doses according to indications. Intra-abdominal pressure (IAP) was measured in all patients with the Crohn method before surgery, during the tightening of aponeurosis leaflets and 2 hours after the intervention. The indication for removal of drainage was the amount of discharge less than 20 ml/day.

Table 1

Distribution of patients by gender, age and comorbidity

Index	Group A	%	Group B	%
Total	8	100	10	100
Women	5	62.5	8	80
Men	3	37.5	2	20
High risk hypertension	5	62.5	7	70
Coronary heart disease	0	0	3	30
Type 2 diabetes	3	37.5	0	0
Pulmonary diseases[1]	0	0	0	0
Hepatic diseases[2]	0	0	0	0
Urolithiasis[3]	1	12.5	1	10
Obesity of 1 degree (BMI = 30 - 35 kg/m^2)	1	12.5	5	50
Obesity of 2 degree (BMI = 35 - 40 kg/m^2)	4	50	4	40
Lower extremities varices	1	12.5	0	0
Anticoagulants	1	12.5	1	10
Cholelithiasis	4	50	8	80
Oncology	1	12.5	2	20
Smoking	1	12.5	0	0
No pathology	1	12.5	0	0

Notes: [1] COPD, Bronchial asthma; [2] Hepatitis B, C

Table 2

Location and reducibility of hernias

Hernias	Group A	%	Group B	%
M1	0	0	1	10
M2	1	12.5	0	0
M3	3	37.5	3	30
M1-2	1	12.5	0	0
M2-3	1	12.5	3	30
M3-4	1	12.5	3	30
M3-5	1	12.5	0	0
Reducible	6	75	8	80
Non-reducible	2	25	1	10
Partially reducible	0	0	1	10

RESULTS AND DISCUSSION

The median follow-up for all patients was 30 days. The duration of surgical intervention, the width, length and area of the implanted mesh materials, the level of IAP did not statistically significantly differ in both groups (Table 3). Significant differences were obtained in the duration of postoperative wound drainage which was 4.2 ± 0.9 days in Group *B* versus 2.5 ± 0.5 days in Group *A* ($U = 4$, $p < 0.01$). Every day prior to the removal of the drain, a discharge was taken for microscopy and biochemical analysis separately from the drainage under and over the aponeurosis. Microscopy showed the number of red blood cells, lymphocytes, segmented neutrophils. In biochemical analysis , the levels of C-reactive protein (CRP) and albumin from the drains. A detailed description and comparative statistical analysis of the drainage was carried out for 2 days, since during this time, all patients of both groups underwent drainage under the same conditions (Table 4). In the future, the drainage conditions changed due to the fact that the quantity and quality of the discharge changed, in some patients the drainage was removed. In Group *A*, drainage was completed in all patients on the 2nd day, in Group *B* in 10 patients was performed for 3 days, in 8 patients – for 4 days, in 3 patients – for 5 days, in one patient – for 6 days. We noted statistically significant*ly* less amount of discharge by drainage and levels of CRP and albumin in patients of Group *A*. Also, in patients of this group, the type of the discharge changed from serous-hemorrhagic to serous by the 2nd day with the appearance of segmented neutrophils and lymphocytes in it, which did not occur in patients of Group *B*, where the type of the discharge changed only by day 4.

Table 3

Distribution of patients according to the surgery duration, mesh size and IAP

Index	Group A	Group B	U	p
Duration of intervention (min)	74.3 ± 19.6	77.5 ± 19.8	38	> 0.05
Mesh width (cm)	16.9 ± 1.0	16.3 ± 0.8	27.5	> 0.05
Mesh length (cm)	18.2 ± 3.5	20.2 ± 2.0	29.5	> 0.05
Area (cm)	247.8 ± 38.1	248.8 ± 51.7	33	> 0.05
IAP before surgery	4.3 ± 1.8	4.7 ± 1.7	35	> 0.05
IAP intraoperatively	6.4 ± 1.6	5.9 ± 1.1	33	> 0.05
IAP after surgery	5.6 ± 1.4	6.0 ± 1.2	33	> 0.05

Table 4

Comparative characteristics of indicators of discharge

Day 1							
Over the aponeurosis				Under the aponeurosis			
Index	A	B	U, p	Index	A	B	U, p
Number of patients	8	10	-	Number of patients	8	10	-
Discharge volume (ml)	37.5 ± 11.7	82.0 ± 44.2	U = 9.5, p <0.01	Discharge volume (ml)	38.7 ± 11.3	91 ± 51.5	U = 8, p <0.01
CRP	3.5 ± 1.8	7.7 ± 3.0	U = 14, p <0.05	CRP	4.0 ± 2.4	8.3 ± 2.6	U = 10, p <0.01
Albumin	29.0 ± 4.9	37.3 ± 5.6	U = 8, p <0.01	Albumin	28.9 ± 2.6	37.4 ± 5.5	U = 7, p <0.01
Type	s/g	s/g*	-	Type	s/g	s/g	-
Red blood cells	+++	+++	-	Red blood cells	+++	+++	-
Segments	-	-	-	Segments	-	-	-
Lymphocytes	-	-	-	Lymphocytes	-	-	-
Day 2							
Over the aponeurosis				Under the aponeurosis			
Index	A	B	U, p	Index	A	B	U, p
Number of patients	8	10	-	Number of patients	8	10	-
Drainage volume (ml)	27.5 ± 14.9	68.0 ± 22.5	U = 5, p <0.01	Drainage volume (ml)	27.5 ± 13.9	93.0 ± 77.2	U = 4, p <0.01
CRP	2.7 ± 1 , 0	16.8 ± 9.1	U = 0, p <0.01	CPR	3.3 ± 1.9	17.0 ± 8.5	U = 0, p <0.01
Albumin	27.1 ± 3.5	36.6 ± 5.9	U = 6, p <0.01	Albumin	28.1 ± 3.1	37.9 ± 8.5	U = 4, p <0.01
Type	from**	s / g	-	Type	from	s / g	-
Red blood cells	-	+++	-	Red blood cells	-	+++	-
Segments	85.8 ± 6.0	-	-	Segments	88.2 ± 5.8	-	-
Lymphocytes	14.2 ± 6.0	-	-	Lymphocytes	11.8 ± 5.8	-	-

Notes: s/g — serous and hemorrhagic; s — serous

In the postoperative period on days 3, 5, 7, 10, 12, 15, 18 and 21 after removal of the drainage, all patients underwent ultrasound monitoring of the postoperative wound, which determined the amount of fluid accumulation in the wound. Monitoring data are presented in Table 5. As can be seen from this table, the first study on the 3rd day in patients of Group *A* revealed a significantly smaller volume of fluid accumulations than in patients of the other group. However, the figures of day 5 and 7 do not differ significantly from each other, which is probably due to the peak of exudative processes in the postoperative wound in both groups. However, we have noted a more rapid decline of exudative inflammatory processes in the post-operative wound in patients Group *A*. Starting from the 10th day, a significantly smaller volume of fluid accumulations was determined in patients of this group, and from the 15th day, fluid accumulations were not detected at all.

Table 5

Dynamics of ultrasound indicators in the postoperative period

Day	The volume of liquid accumulations (ml) in group A	The volume of liquid accumulations (ml) in group B	Criterion U, p-value
3	2.5 ± 4.6	16.0 ± 12.7	U = 13, p ≤ 0.01
5	24.7 ± 14.0	34.0 ± 19.5	U = 25.5, p> 0.05
7	25.0 ± 16.0	45.0 ± 45.3	U = 36, p> 0.05
10	8.7 ± 9.9	56.0 ± 28.0	U = 3, p <0.01
12	3.75 ± 5.2	32.7 ± 21.3	U = 8.5, p <0.01
15	0	25.0 ± 29.3	-
18	0	60	-
21	0	10	-

Seromas were evaluated according to *S. Morales-Conde* classification [19]. In particular, seromas of type 0, I and II are the so-called incident, a clinically significant fluid accumulation detected by ultrasound (type 0 seromas in almost 100% of cases) and clinically (wound asymmetry, palpation fluctuation, which do not cause pain or discomfort to the patient – seromas of type I and II), the difference between type I and II only in the duration of the exudation persistence (type I – less than 1 month , type II – more than 1 month). Seromas of III type include all of the above and in addition to this persistence for 6 months (III*a*), significant aesthetic discomfort (III*b*), restriction of daily activity of the patient (III*c*), associated pain (III*d*), surface infection (III*e*). This is the so-called minor complication. The most important difference of type III is the prescription of only medications to relieve symptoms. The need to puncture drainage immediately changes this seroma to IVa type, spontaneous emptying through the wound (IV*b*), deep infection (IV *c*), recurrence of herniation, associated with seroma (IV*d*), mesh infection associated with seroma (IV*e*). In our study (Table 6), in Group *B* one patient had the III*c* seroma, 8 patients had IV*a* seroma , one patient had IV*b* seroma, which spontaneously opened and required readjustment its cavity for 21 days outpatiently. In Group *A*, only 3 patients had IV*a* seroma, requiring a single puncture. In Group *B*, the number of punctures was 23, in Group *A* — 3 ($\chi^2 = 8.654$, $p = 0.04$, Fisher's exact two-tailed test (F) = 0.00654, p <0.05).

Table 6

Characteristics of seromas and punctures

Type of seroma	Group A		Punctures, Abs.	Discharge, ml	Group B		Punctures, Abs.	Discharge, ml
	Abs.	%			Abs.	%		
III*c*	—	—	—	—	1	10	—	—
IV*a*	3	37.5	3	46.7±5.8	8	80	19	61.6±21.7
IV*b*	—	—	—	—	1	10	4	77.5±31.0

Postoperative analgesia was performed using a visual analogue scale questionnaire. The duration of analgesia with non-steroidal anti-inflammatory drugs in group *B* was 4.2 ± 0.6 days and was longer than in Group *A* — 3.1 ± 0.3 days (U = 7.5, p <0.05). Tramadol was used in all patients after surgery for 1.8 ± 0.4 days in Group *B* and 1.9 ± 0.3 days in group *A* (U = 37, p > 0.05). Promedol was required in 10 patients from Group *B* within 1.5 ± 0.7 days, in Group *A* — 5 patients within 24 hours. The duration of the patient's stay in the bed was 8.9 ± 0.6 days in Group *B* and 8.0 ± 0.5 days in Group *A* (U = 11.5, p <0.05).

CONCLUSION

At present, the research continues, the total number of subjects is planned to be increased to 66, but even the preliminary data of Hemoblock use and ultrasound monitoring of postoperative wound allows you to:

1) reduce the duration of drainage after the operation wound,

2) reduce the period of inflammatory-exudative processes in the postoperative wound,

3) significantly reduce the number of puncture interventions in the area of the postoperative wound in order to evacuate fluid accumulations, reduce the risk "large complications", such as spontaneous drainage of seroma through the postoperative wound

4) reduce the severity of pain and the need for analgesics by reducing the duration of draining and the number of puncture interventions,

5) reduce the duration of inpatient treatment due to faster rehabilitation of patients after plastic surgery of a large postoperative ventral hernia.

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