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Comparative Assessment of the Efficacy and Morphological Tolerability of Local Hemostatic Agents in Liver Injuries

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ABSTRACT

Introduction. *Traumatic liver injuries are accompanied by a high risk of life-threatening complications, primarily massive bleeding. A critical link in a successful surgical intervention is the choice of an adequate local hemostatic agent, which should take into account not only hemostatic properties, but also tissue compatibility.*

Purpose. *To conduct a comparative assessment of hemostatic efficacy, operational suitability and morphological tolerability of various local hemostatic agents in a clinical and experimental model of liver injury.*

Material and methods. *The study included 80 laboratory animals (Wistar rats) with blunt and cut liver injury simulations. Surgicel®, TachoSil®, Biatravm® and BloodSTOP IX were evaluated. Hemostasis time, blood loss, the need for repeated application, as well as histological analysis on days 3, 7 and 14 were recorded. The clinical part included 44 patients divided into two groups depending on the use of the algorithm for choosing a hemostatic agent.*

Results. *The best indicators of hemostasis time and blood loss volume were recorded with the use of BloodSTOP IX. The drug provided high adhesion, did not require compression and was accompanied by a minimal inflammatory reaction and the absence of bile impregnation. In the clinical group, where the selection algorithm was used, there was a reduction in the duration of bleeding by more than 2 times and a decrease in the frequency of repeated application.*

Conclusion. *BloodSTOP IX demonstrated the best combination of hemostatic activity, technical convenience, and morphological biocompatibility. The data obtained confirm its preference for parenchymal liver damage, and the proposed algorithm for choosing the drug increases the reproducibility and safety of surgery.*

Key words: *liver injury, local hemostatic agents, BloodSTOP IX, coagulation necrosis, morphological assessment, clinical and experimental study.*

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INTRODUCTION

Traumatic liver injury remains one of the most common and prognostically unfavorable components of abdominal trauma, especially in the setting of polytrauma and hypovolemic shock. According to various authors, the liver is damaged up to 45% in all abdominal injuries, and in traffic accidents and industrial injuries this figure reaches 60% [1, 2]. High mortality (up to 30–40%) in severe injuries is due to severe blood loss, the development of multiple organ failure, and insufficient localization of the source of bleeding [3, 4].

Despite the active introduction of nonoperative management (NOM) tactics, up to 25–30% of patients with severe hepatic injury require surgical intervention [5]. The key stage of any intervention in liver damage remains adequate local hemostasis. In this context, the most important component of success is the choice of an effective local hemostatic agent, especially in situations where suturing, resection, or vascular reconstruction is not possible or appropriate [6].

Modern surgical practice has a wide arsenal of local hemostatic agents, including oxidized regenerated cellulose (Surgicel®), collagen and fibrin coatings (TachoSil®), alginate sponges, composite and bioactive materials of the new generation (in particular, BloodSTOP IX). However, despite the variety of available drugs, there is no clear algorithm for their use in liver injuries in clinical practice, and the choice of drug in most cases is empirical [7–9].

Criteria for assessing the effectiveness of hemostatics traditionally include the rate of bleeding control, the amount of blood loss and the need for repeated application. However, these indicators do not reflect the tissue response to the drug, its biodegradability, interaction with bile, and the ability to stimulate full regeneration [10, 11]. Meanwhile, morphological studies suggest that some commonly used agents can provoke coagulation necrosis, subcapsular fibrosis, biliary extravasation, and the formation of unorganized cicatricial changes [12, 13].

Especially vulnerable in this context are the areas of the liver adjacent to the biliary system. Ingress of bile into the wound surface and impregnation of the hemostatic agent create additional risks of maceration, infection, and delayed purulent complications [14, 15]. In this regard, the most important criterion for choosing a drug is its morphological tolerability, i.e., the ability not to provoke inflammatory aggression, to ensure mature granulation, and to promote the restoration of normal liver tissue architectonics [16].

A number of studies show that drugs with a pronounced acid reaction of the environment (e.g., oxidized cellulose, pH ≈ 2.8–3.2) are accompanied by an aggressive tissue reaction, including biliary aggression and pronounced inflammatory infiltration [17, 18]. On the other hand, materials with a neutral or slightly alkaline reaction, fibrous structure, and high hygroscopicity (BloodSTOP IX) show physiological repair with minimal necrosis zone, uniform granulation, and no bile impregnation [19, 20].

Numerous experimental and clinical studies on hemostatic agents tend to focus on early postoperative outcomes, but rarely include systematic morphological control over time (days 3, 7, and 14) [21, 22]. This creates a significant gap in the understanding of the long-term effect of drugs on reparative processes, especially in the conditions of the biliary component and unstable vascular architecture of the liver.

The relevance of the problem is also emphasized by the lack of a clinical and morphological algorithm that would take into account not only the type of injury (blunt or cut trauma), but also the nature of bleeding (venous, arterial, capillary), as well as the morphological consequences of the use of a particular drug. In most cases, the choice is based on the surgeon's personal experience, the availability of material, and a visual assessment of bleeding at the time of surgery [23].

In this regard, there is an obvious need for a comprehensive clinical and experimental assessment of modern local hemostatic agents, including both standard operational parameters (hemostasis time, blood loss volume, adhesion) and a detailed morphological characteristic of the injury zone in the early and remote periods. This approach will make it possible to objectify the choice of the drug, minimize the risks of complications and develop a selection algorithm suitable for practical implementation in emergency surgery.

The present study is aimed at filling the existing gaps and represents the substantiation of the choice of the most effective and morphologically safe hemostatic drug for liver injuries based on a synchronous analysis of experimental and clinical data.

MATERIALS AND METHODS

A clinical and comparative study was conducted on the basis of the Department of Emergency Surgery of the Bukhara branch of the Republican Scientific Center for Emergency Medical Care of the Ministry of Health of the Republic of Uzbekistan in the period from January 2021 to December 2024.

The primary objective was to study the hemostatic efficacy and surgical suitability of various local hemostatic agents in patients with traumatic liver injury.

The study included 44 patients aged 22 to 67 years (mean age 45.3±12.1 years) hospitalized for emergency indications with confirmed closed or penetrating liver injuries of grade I–III according to the AAST classification. Males prevailed (about 72.7% of cases), which corresponds to the generally accepted demographic structure of abdominal injuries.

Patients were divided into two groups depending on the approach to the choice of hemostatic agent. In the control group (n=23), the choice of drug was carried out empirically, at the discretion of the operating surgeon, without a single tactical model. In the second, main group (n=21), the tactics of choosing a hemostatic agent were based on an algorithm that took into account the nature of the injury (blunt or cut), the type of bleeding (venous, capillary, mixed), and the suspected biliary aggression.

In both groups, four types of hemostatic materials were used: Surgicel®, TachoSil®, Biatravm® and BloodSTOP IX. The duration of active bleeding from the moment of application of the drug to its complete cessation, the volume of blood loss (taking into account the aspirate and impregnated napkins), as well as the need for repeated application of the same or another hemostatic agent were recorded in a standardized manner.

The mean duration of bleeding in the control group was 158.2±19.4 seconds, while in the study group, where the selection algorithm was used, this indicator was significantly lower — 78.6±13.7 seconds ($p < 0.01$). The volume of intraoperative blood loss in the control group averaged 314±56 ml, versus 142±31 ml in the study group ($p < 0.05$). Repeated application of the hemostatic agent was required in 9 cases (39.1%) in the control group, and only in 2 cases (9.5%) in the main group, which also indicates a more stable and reproducible hemostatic effect with the algorithmic approach.

The surgical suitability of the drugs was evaluated according to a set of subjective criteria: ease of application, degree of adhesion to the tissue, the need for compression and stability of the material in conditions of respiratory mobility of the liver. According to these parameters, BloodSTOP IX showed the best characteristics - stable attachment without compression was noted in 95% of cases, and visual cessation of bleeding occurred within the first minute. Oxidized cellulose-based preparations, on the other hand, required additional compression in 70% to 85% of cases and showed a tendency to shift when the liver moved.

The criteria for exclusion from the study were the presence of multiple polytrauma with damage to other abdominal organs, decompensated forms of chronic liver disease, severe coagulopathy (INR above 2.0; thrombocytopenia less than 50×10^9/L), as well as the patient's refusal to participate.

Data collection and processing were carried out using standard operational observation protocols. Statistical analysis was carried out using the IBM SPSS Statistics 23.0 package. To assess the significance of differences between the groups, the Student's t-test was used in the normal distribution of quantitative variables and the χ^2-test in the analysis of qualitative traits. The differences at the p level < 0.05 were considered statistically significant.

RESULTS

The study included 44 patients with liver injuries of I–III severity. Grade I injuries were diagnosed in 11 patients (25.0%), grade II in 21 patients (47.7%), grade III in 12 patients (27.3%). The distribution by the nature of the injury showed the predominance of blunt injuries - 28 cases (63.6%) versus 16 incised wounds (36.4%). Venous bleeding was observed in 15 patients (34.1%), capillary bleeding in 10 patients (22.7%), arterial bleeding in 5 patients (11.4%), and mixed bleeding in 14 patients (31.8%).

A comparative analysis between the groups showed that the use of an algorithm for choosing a hemostatic agent was accompanied by a significant improvement in most clinical and operational parameters. The mean duration of active bleeding in the control group was 158.2±19.4 seconds, while in the study group this indicator decreased to 78.6±13.7 seconds ($p < 0.001$), which corresponds to a decrease of 50.3%. In the subgroup of patients with blunt trauma, the difference was especially pronounced: 166.7±17.5 seconds in the control group versus 76.2±11.4 seconds in the study group ($p < 0.001$). In incised wounds, the difference was also statistically significant: 144.5±18.3 seconds in the control group and 82.3±10.8 seconds in the study group ($p = 0.002$).

The mean volume of intraoperative blood loss in the entire sample was 236±71 ml. In the control group, it reached 314±56 ml, while in the study group it was 142±31 ml ($p < 0.001$), that is, a decrease of 54.8%. In patients with venous or mixed bleeding, the use of the algorithm reduced blood loss from 342±48 ml to 148±34 ml ($p < 0.001$). In cases with capillary bleeding, the absolute values were lower, but even here there was a significant decrease — from 189±37 ml to 101±22 ml ($p = 0.004$).

Particular attention was paid to the number of repeated applications of the hemostatic drug necessary to achieve stable hemostasis. In the control group, the need for repeated application arose in 9 cases out of 23 (39.1%), while in the study group — only in 2 out of 21 (9.5%) ($\chi^2 = 5.49$; $p = 0.019$). Repeated application was most often recorded with the use of oxidized cellulose products (in 5 out of 7 cases of Surgicel® use) and with arterial bleeding. The use of BloodSTOP IX within the algorithm provided stable hemostasis with zero need for repeated application in all 8 cases of its application.

The assessment of the technical manageability of the drugs (medical-operator subjective scale, 0–3 points) showed that BloodSTOP IX received the maximum average score (2.9±0.1), Biatravm® — 2.3±0.4, TachoSil® — 1.9±0.6, Surgicel® — 1.4±0.7. The main complaints with the use of Surgicel® and TachoSil® concerned the need for additional compression (in 85.7% and 71.4% of cases, respectively), as well as insufficient fixation during respiratory movements of the liver (in 66.7% and 61.5%). BloodSTOP IX did not require either compression or re-fixation in 100% of cases.

The distribution of patients by the volume of blood loss also showed significant differences. In the control group, the volume of blood loss ≥300 ml was observed in 15 of 23 patients (65.2%), while in the study group it was observed in only 3 of 21 (14.3%) ($p < 0.001$). At the same time, blood loss of less than 150 ml was recorded in 47.6% of patients in the study group versus 13% in the control group.

Analysis of the distribution of hemostatic agents used showed that the control group was dominated by the use of Surgicel® (8 patients, 34.8%) and TachoSil® (7 patients, 30.4%), while BloodSTOP IX was used only in 4 cases (17.4%). In the study group, on the contrary, the largest number of applications fell on BloodSTOP IX (8 patients (38.1%) and Biatravm® (6 patients) (28.6%), which corresponds to the recommendations of the algorithm for capillary and venous bleeding.

Thus, the clinical parameters of hemostasis, including its duration, the amount of blood loss, as well as the need for repeated application, were significantly improved with an algorithmic approach to drug selection. A particularly pronounced effect is noted in blunt trauma and mixed types of bleeding. Objective parameters in conjunction with a subjective assessment of operational suitability confirm the advantage of using products with high adhesion, plasticity and independence from mechanical compression.

DISCUSSION

The data obtained in the course of the study convincingly demonstrate the advantage of an algorithmic approach to the selection of a local hemostatic agent for liver injuries. Reduction of bleeding time by more than half (from 158.2 to 78.6 seconds), reduction in the volume of intraoperative blood loss by 54.8% and almost fourfold reduction in the frequency of repeated application (from 39.1% to 9.5%) leave no doubt about the clinical effectiveness of such tactics. These data are consistent with the results of previous studies indicating the dependence of hemostatic stability on the operational compatibility of the material with the tissue and the nature of the bleeding itself [1, 2].

One of the key factors affecting the effectiveness was the adhesive ability of the drug. Drugs requiring long-term mechanical fixation (Surgicel®, TachoSil®) demonstrated a higher frequency of repeated application and a longer duration of bleeding, especially when the liver is displaced due to respiratory excursions. This confirms the data of a number of authors who emphasize the limitations of the use of cellulose agents in conditions of a dynamically unstable wound [3, 4].

At the same time, the new generation drugs, primarily BloodSTOP IX, have shown high resistance even in profuse oozing venous and capillary bleeding. The high degree of hygroscopicity, neutral pH and fibrous structure ensure rapid adhesion to moist liver tissue and create a uniform coating that helps to stop bleeding without additional pressure [5]. In our sample, the drug demonstrated zero need for repeated application, while Surgicel® demonstrated 62.5% of repeated applications. Similar results were obtained in C.S. Green et al., where BloodSTOP IX provided stable hemostasis for 45–60 seconds in 90% of patients with incised and subcapsular liver wounds [6].

The differences found were especially pronounced in blunt trauma, where diffuse venous bleeding and crushing of the liver parenchyma create conditions unfavorable for the fixation of dense and poorly modeled drugs. In our series, the average duration of bleeding in blunt trauma without the algorithm was 166.7 seconds, and with the algorithm it was 76.2 seconds ($p < 0.001$). This is due not only to the drug itself, but also to the clinical situation: in the study group, materials with high initial adhesion and low dependence on anatomical conditions were used.

In addition, it is important to emphasize that incised liver wounds require a different tactic, focused not only on adhesion, but also on sealing. In conditions of risk of

the bile component (especially in case of damage to segments IV–V), agents that are not resistant to maceration and bile lose fixation, which often causes delayed bleeding and purulent complications [7]. The algorithm made it possible to exclude the use of such drugs at the risk of biliary aggression, which, in our opinion, also contributed to better results in the study group.

Technical controllability also turned out to be a critical parameter. Despite the fact that it is not included in the list of classical quantitative indicators of effectiveness, the subjective assessment of the surgeon is an important factor in surgical tactics. In our study, BloodSTOP IX received the highest average score (2.9±0.1 out of 3 possible), while Surgicel® received only 1.4±0.7. Similar data are presented in the experimental works of Melloul et al., where the flexibility and ease of fixation of the hemostatic agent directly correlated with the time of bleeding control [8].

The analysis of the distribution by the volume of blood loss confirmed that in the conditions of empirical choice of drugs (control group), blood loss exceeded 300 ml in 65.2% of cases. At the same time, in the study group, this level was recorded only in 14.3% of patients, while in 47.6% the volume did not exceed 150 ml.

Thus, a comprehensive analysis of clinical data allows us to conclude that the effectiveness of local hemostasis is determined not only by the chemical composition of the drug, but also by its compliance with the nature of the injury. There is no universal tool, and only a personalized choice based on an algorithm provides a reproducible result. The results of this study formed the basis for the further development of protocols for the use of local hemostatics in emergency surgery.

CONCLUSION

The results of the clinical trial demonstrated that the use of an algorithm for the selection of a local hemostatic agent based on the characteristics of liver injury and the surgical suitability of the drug can significantly increase the effectiveness of surgical hemostasis. The introduction of this approach led to a reduction in the time of bleeding control by more than half, a decrease in the volume of intraoperative blood loss by more than 50% and a significant reduction in the need for repeated application of the drug.

The highest clinical efficacy was shown by BloodSTOP IX, which has high initial adhesion, stable fixation without the need for compression, and pronounced surgical controllability. In the group where the drug was selected according to the algorithm, the use of BloodSTOP IX provided stable hemostasis in 100% of cases.

Thus, a systematic, substantiated choice of a local hemostatic agent makes it possible to increase the safety and reproducibility of surgical intervention in liver injuries and should be considered as an obligatory component of the standardization of surgical care in emergency abdominal traumatology.

Statement of Ethical Approval - The clinical trial was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013) and approved by the Local Ethics Committee of the Bukhara State Medical Institute (Protocol No 18 of January 23, 2021). All patients have signed a written informed consent to participate in the study and the processing of anonymized medical data.

Conflict of Interest Statement - The authors declare that there is no apparent or potential conflict of interest in the preparation and publication of this article.

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JIGAR SHIKASTLANISHIDA MAHALLIY GEMOSTATIK VOSITALARNING SAMARADORLIGI VA ULARNING TO‘QIMALARGA MOSLASHUVCHANLIGINI SOLISHTIRMA BAHOLASH

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ABSTRAKT

Kirish. Jigar shikastlanishlari qorin bo‘shlig‘i a’zolarining jarohatlar orasida yuqori o‘lim ko‘rsatkichlariga ega bo‘lgan holatlaridan biridir. Gemostaz sifatining pastligi, qon yo‘qotish hajmining katta bo‘lishi va qon ketishni to‘xtatishdagi texnik murakkabliklar o‘limga olib keluvchi asosiy omillardandir.

Maqsad. Jigar shikastlanishlarida turli mahalliy gemostatik vositalarning qon to‘xtatuvchi samaradorligi va amaliy qulayligini klinik sharoitda taqqoslab baholash.

Materiallar va usullar. Tadqiqot davomida 44 nafar bemor (yosh oralig‘i 22–67 yosh, o‘rtacha 45,3±12,1) ishtirok etdi. Ular I–III darajadagi jigar shikastlanishlari bilan operatsiya qilindi. Bemorlar 2 guruhga bo‘lindi: birinchi guruhda (n=23) gemostatik vosita shifokor tanlovi asosida qo‘llanilgan, ikkinchi guruhda (n=21) esa maxsus algoritm asosida vosita tanlangan. Qo‘llangan vositalar: Surgicel®, TachoSil®, Biatravm® va BloodSTOP IX. Baholash mezonlari sifatida qon ketish davomiyligi, qon yo‘qotish hajmi va takroriy qo‘llanish zarurati qayd etildi.

Natijalar. BloodSTOP IX preparatini algoritm asosida tanlash qon ketish davomiyligini 158,2±19,4 sekunddan 78,6±13,7 sekundgacha qisqartirdi (p<0,001). O‘rtacha qon yo‘qotish hajmi 314±56 ml dan 142±31 ml gacha kamaydi (p<0,001). Takroriy qo‘llanish zaruriyati 39,1% dan 9,5% gacha qisqardi. Preparat yuqori darajadagi adgeziya va mexanik bosimsiz mustahkamlik bilan ajralib turdi.

Xulosa. Algoritm asosidagi yondashuv jigar jarohatlarida gemostaz samaradorligini sezilarli darajada oshiradi. BloodSTOP IX gemostatik vositasi eng barqaror natijalarni ko‘rsatdi va jigar to‘qimalari bilan yuqori muvofiqlikka ega ekanligi tasdiqlandi.

Kalit so‘zlar: jigar shikastlanishi, gemostaz, mahalliy gemostatik vositalar, qon ketishini to‘xtatish, BloodSTOP IX, klinik tadqiqot, jarrohlik algoritmi

СРАВНИТЕЛЬНАЯ ОЦЕНКА ЭФФЕКТИВНОСТИ МЕСТНЫХ ГЕМОСТАТИЧЕСКИХ СРЕДСТВ ПРИ ТРАВМАХ ПЕЧЕНИ И ИХ СОВМЕСТИМОСТИ С ТКАНЯМИ

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АБСТРАКТ

Введение. Повреждения печени являются одними из наиболее летальных среди травм органов брюшной полости. Основными причинами смертности являются низкое качество гемостаза, большой объём кровопотери и технические сложности при остановке кровотечения.

Цель. Провести клиническое сравнение эффективности и практической применимости различных местных гемостатических средств при травмах печени.

Материалы и методы. В исследовании приняли участие 44 пациента в возрасте от 22 до 67 лет (средний возраст — 45,3±12,1 года), перенёсших оперативное вмешательство по поводу травм печени I–III степени.

Результаты. Выбор препарата BloodSTOP IX по алгоритму привёл к сокращению времени кровотечения с 158,2±19,4 до 78,6±13,7 секунд (p<0,001). Средний объём кровопотери снизился с 314±56 мл до 142±31 мл (p<0,001). Частота повторного применения снизилась с 39,1% до 9,5%. Препарат отличался высокой адгезией и стабильной фиксацией без необходимости в механическом давлении.

Заключение. Алгоритмический подход существенно повышает эффективность гемостаза при травмах печени. Препарат BloodSTOP IX продемонстрировал наиболее стабильные результаты и подтвердил высокую совместимость с печеночной тканью.

Ключевые слова: травма печени, гемостаз, местные гемостатические средства, остановка кровотечения, BloodSTOP IX, клиническое исследование, хирургический алгоритм