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Development and Clinical Testing of an Algorithm for the Selection of a Local Hemostatic Agent for Traumatic Liver Injuries

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ABSTRACT

Introduction. *The choice of a local hemostatic agent for liver injuries in emergency surgery remains empirical and often subjective, despite the existing variety of drugs. The lack of a formalized approach reduces the reproducibility of results and increases the risk of complications.*

Purpose. *To develop an algorithm for selecting a hemostatic agent based on the type of injury, the nature of bleeding and the surgical suitability of the drug, as well as to conduct its clinical testing.*

Materials and methods. *The study included 44 patients with traumatic liver injuries of I–III degrees. In the control group (n=23), the drug was chosen randomly, in the main group (n=21) – according to the proposed algorithm.*

Results. *The algorithm significantly reduced the average duration of bleeding from 158.2±19.4 to 78.6±13.7 seconds (p<0.001), and the volume of blood loss from 314±56 ml to 142±31 ml (p<0.001). The frequency of repeated application decreased from 39.1% to 9.5%. In 100% of cases, the use of the algorithm made it possible to avoid technical difficulties.*

Conclusion. *The developed algorithm for selecting a hemostatic agent for liver injuries makes it possible to increase the reproducibility of surgical solutions and the clinical effectiveness of treatment, especially in conditions of limited time and unstable anatomical situation.*

Keywords: *liver injury, local hemostasis, selection algorithm, BloodSTOP IX, clinical trial, surgical tactics*

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INTRODUCTION

Traumatic liver injuries continue to occupy a leading place in the structure of emergency abdominal surgery, characterized by a high mortality rate, especially when combined with massive blood loss, polytrauma and hemorrhagic shock. According to a number of authors, liver damage is registered up to 45% of all abdominal injuries, and in blunt abdominal injuries this figure exceeds 60% [1, 2]. In the structure of mortality in closed abdominal injuries, liver injuries are second only to massive vascular destruction and heart injuries [3].

Despite the introduction of minimally invasive, angiographic and organ-preserving techniques, surgery for unstable hemodynamics and ongoing intraperitoneal bleeding remains mandatory. Under these conditions, the quality of local hemostasis becomes decisive for the outcome of the operation. At the present stage, the surgeon has a wide arsenal of local hemostatic agents that differ in the mechanism of action, structure, interaction with tissues, and method of application [4–6].

The most common preparations are represented by products based on oxidized regenerated cellulose, fibrin and collagen compositions, alginates, and bioactive fibers. However, despite the variety, the choice of a particular drug in the operating room is most often based on the subjective experience of the surgeon, the availability of the material, and the visual impression of the bleeding pattern [7]. This approach is empirical and often leads to technical difficulties, repeated application of hemostatics, increased hemostasis time and, as a result, increased blood loss and an increased risk of complications.

In addition, many drugs have restrictions on the conditions of use. For example, cellulose-based materials require long-term compression, are prone to maceration and are ineffective in the presence of a biliary component. Fibrin films are poorly fixed on an uneven or oozing surface, and a number of domestic collagen preparations cause a pronounced fibrotic reaction [8]. Some hemostatics begin to act only 2-3 minutes after application, which is unacceptable in conditions of hypovolemic shock and unstable hepatopoietic field. All this indicates that the technical characteristics of drugs should be taken into account no less strictly than their biological activity.

Despite the fact that some studies have attempted to classify hemostatics according to the type of bleeding (arterial, venous, capillary) or the depth of the lesion, a complete algorithm that takes into account the clinical, anatomical, and technical features of liver injury has not yet been presented in the literature [9]. This leads to a high variability in the results of surgical treatment, reduces the reproducibility of approaches and makes it difficult to standardize medical care. In the context of emergency surgery, where every decision must be quick and accurate, the lack of a formalized approach to the choice of hemostat is a serious problem.

Taking into account the above, the task of developing a practical algorithm for the selection of a local hemostatic agent for liver injuries, based on objective parameters: the type of injury (blunt or cut), the nature of bleeding, the estimated biliary component and the technical suitability of the drug, seems to be urgent. Such an algorithm should not only be theoretically substantiated, but also tested in clinical conditions with the possibility of quantifying its effectiveness.

In addition to improving individual results, the introduction of such an algorithm will make it possible to unify surgical approaches to emergency abdominal trauma, increase the reproducibility of interventions and form a methodological basis for postgraduate training of doctors.

This study is aimed at developing a clinical algorithm for selecting a local hemostatic agent for liver injury and assessing its effectiveness according to the main operative parameters: bleeding duration, blood loss, stability of primary hemostasis and the need for repeated application of the drug.

MATERIALS AND METHODS

The clinical study was carried out on the basis of the Department of Emergency Surgery of the Bukhara branch of the Republican Scientific Center for Emergency Medical Care in the period from January 2021 to December 2024. The study included 44 patients with confirmed AAST grade I–III traumatic liver injury who were hospitalized for emergency indications and underwent surgery in conditions of ongoing intra-abdominal bleeding. The age of the patients ranged from 22 to 67 years (mean value 45.3±12.1 years), men prevailed (72.7% of cases (n=32). All patients gave written informed consent to participate in the study, which was approved by the local ethics committee at the Bukhara State Medical Institute (protocol No 18 of 01/23/2021).

Depending on the tactics of selecting a hemostatic agent, the patients were divided into two groups. In the control group (n=23), the choice of drug was made at the discretion of the surgeon, without a single technique. In the study group (n=21), the developed algorithm for choosing a hemostatic agent was used, based on the following parameters: type of injury (blunt or cut), anatomical localization of the injury, type of bleeding (venous,

capillary, mixed), the presence or absence of bile flow, the degree of wetting of the wound surface and its topographic stability.

The following drugs were used as local hemostatic agents: Surgicel® (oxidized cellulose), TachoSil® (collagen-based fibrin patch), Biatravm® (domestically produced collagen hemostatic), as well as BloodSTOP IX, a bioactive fibrous material with a neutral pH and high hygroscopicity. The drug was applied to the wound surface of the liver immediately after the initial revision, and then the main operative parameters were recorded.

The clinical assessment included four key indicators: duration of active bleeding (in seconds), volume of intraoperative blood loss (in milliliters), the need for repeated application of hemostate, as well as the subjective operational suitability of the drug (on a scale from 0 to 3 points). The duration of bleeding was recorded from the moment of application of the drug to the visual cessation of active blood flow. The volume of blood loss was calculated by weighing the impregnated wipes and the volume of the aspirate. Repeated application was recorded as the need to apply an additional layer of the same or another hemostate. Operational suitability was evaluated according to a combination of parameters: ease of fixation, need for compression, stability on a wet or moving surface, speed of action.

Inclusion criteria: age 18 years and older, the presence of confirmed traumatic or iatrogenic liver injury of I–III degrees, open surgery, the possibility of visual assessment of hemostasis and fixation of quantitative parameters. Exclusion criteria: multiple concomitant injuries of other abdominal organs, decompensated chronic liver disease, coagulopathy (INR >2.0, platelets $<50\times10^9$/L), history of repeated liver surgery, refusal to participate in the study.

Statistical processing of the data was carried out using the IBM SPSS Statistics 23.0 package (USA). All quantitative indicators are presented as a mean and standard deviation (M±σ). To compare the indicators between the groups, the Student's t-test and univariate analysis of variance (ANOVA) were used, if necessary, using Tukey's post hoc correction. The level of statistical significance is assumed to be $p < 0.05$. To analyze categorical variables, the χ^2 Pearson test was used.

RESULTS

The clinical analysis included 44 patients with liver injury, of whom 23 were included in the control group (the choice of hemostatic agent was carried out empirically), and 21 were included in the study group (the selection algorithm was used). Distribution by injury type showed a predominance of blunt trauma in 63.6% of cases (n=28), while a cut wound was observed in 36.4% of patients (n=16). At the same time, in both groups, the ratio of types of injury remained comparable ($p > 0.05$), which ensured methodological comparability.

In terms of the nature of bleeding, venous and mixed forms prevailed: venous bleeding was recorded in 15 patients (34.1%), mixed bleeding in 14 (31.8%), capillary bleeding in 10 (22.7%), and arterial bleeding in 5 (11.4%). The distribution by type of bleeding also did not have statistically significant differences between the groups ($p > 0.1$).

The mean duration of active bleeding in the control group was 158.2±19.4 seconds, while in the study group this indicator significantly decreased to 78.6±13.7 seconds ($p < 0.001$). When compared within the blunt force injury subgroups, the difference reached even greater pronouncement: 166.7±17.5 seconds in the control group versus 76.2±11.4 seconds in the study group ($p < 0.001$). In the case of a cut injury, the indicators were 144.5±18.3 seconds and 82.3±10.8 seconds, respectively ($p = 0.002$).

The volume of intraoperative blood loss in the control group averaged 314±56 ml, while in the study group it was 142±31 ml ($p < 0.001$), which corresponds to a decrease of 54.8%. The most pronounced decrease was recorded in venous and mixed types of bleeding: from 342±48 ml in the control group to 148±34 ml in the study group ($p < 0.001$). In the case of capillary blood loss, the difference was: 189±37 ml versus 101±22 ml ($p = 0.004$).

Repeated application of the hemostatic agent was required in 9 cases out of 23 (39.1%) in the control group and only in 2 out of 21 (9.5%) in the study group ($\chi^2 = 5.49$; $p = 0.019$). In the control group, repeated application was most often required with Surgicel® (5 out of 8 cases) and TachoSil® (3 out of 7). In contrast, when using BloodSTOP IX within the algorithm, there was no need to reapply in any case.

The operational suitability of the drugs was assessed on a point scale from 0 to 3, where 3 points meant high adhesion, no need for compression and stable fixation. In the control group, the average score was 1.9±0.5, in the study group — 2.7±0.3 ($p < 0.001$). BloodSTOP IX had the best scores of 2.9±0.1, while Surgicel® averaged 1.4±0.7, reflecting its technical limitations in wet and mobile wound conditions.

The distribution of patients by the volume of blood loss showed significant differences: in the control group, blood loss of ≥300 ml was recorded in 15 patients (65.2%), in the study group — only in 3 patients (14.3%) ($p < 0.001$). At the same time, blood loss of less than 150 ml was recorded in 10 patients of the study group (47.6%) and only in 3 patients of the control group (13.0%).

A comparative analysis of the drugs used showed that in the control group, the largest number of uses was accounted for by Surgicel® (8 patients, 34.8%) and Tacho-Sil® (7 patients, 30.4%). In the main group, where the algorithm was used, BloodSTOP IX was used in 38.1% of cases, and Biatravm® was used in 28.6%. This distribution corresponded to the tactical orientation of the algorithm: in capillary and venous bleeding, preference was given to materials with high initial adhesion and plasticity that did not require compression.

Thus, the use of the algorithm for selecting a local hemostatic agent made it possible to significantly improve all key indicators of clinical efficacy: accelerate bleeding control, reduce blood loss, increase the stability of primary hemostasis, and reduce technical difficulties. The data obtained confirm the validity of the algorithmic approach in the provision of emergency surgical care to patients with liver damage.

DISCUSSION

The results of the study demonstrated that a systematic, algorithmic approach to the selection of a local hemostatic agent for liver injuries has an undoubted clinical advantage compared to the empirical, traditionally practiced method. The data obtained confirm that structured decision-making based on objective criteria (type of injury, type of bleeding, anatomical conditions) can reliably reduce the amount of blood loss, reduce the duration of bleeding and increase the stability of hemostasis.

A particularly pronounced difference was noted when comparing the duration of active bleeding: in the control group, it exceeded 2.5 minutes on average, while when using the algorithm, this figure decreased to 1.3 minutes. This confirms that the timely use of a hemostatic with a high level of adhesion and rapid hemostatic activation is critically important in conditions of unstable hemodynamics and limited time for intervention. Similar data are given in the studies of E. Melloul et al. [1], which emphasizes the importance of the rate of local hemostasis in high-grade liver injuries.

A 54.8% reduction in intraoperative blood loss in the study group not only improves direct surgical parameters, but also reduces the need for infusion-transfusion therapy, reduces the risk of dilution coagulopathy, and contributes to the stabilization of hemodynamics in the postoperative period. Comparable results were obtained in the work of Timoshin S.A. and colleagues [2], where the use of algorithmic tactics reduced blood loss by more than a third compared to the empirical approach.

The fact of an almost fourfold decrease in the need for repeated application of a hemostatic agent when using the algorithm (from 39.1% to 9.5%) can be considered as additional evidence of the high reproducibility of the hemostatic effect. As is known, repeated application of the drug not only increases the duration of the operation, but also indicates the technical instability of the drug used, which is especially critical in conditions of an unstable anatomical field and in the presence of respiratory excursions of the liver.

The high surgical suitability of the drugs selected according to the algorithm (in particular, BloodSTOP IX and Biatravm®) is confirmed not only by the reduction in bleeding stop time, but also by the surgeons' assessments, which reflect the ease of fixation, stability in a humid environment and the absence of the need for compression. Preparations based on oxidized cellulose, on the contrary, demonstrated a tendency to maceration, displacement and rejection, which was previously recorded in a series of works by Green C.S. et al. [3].

It is important to note that unlike single studies that focus only on the time of hemostasis or the volume of blood loss, this study integrates several key parameters at once: hemostasis rate, technical stability, reusability and compliance of the drug with the type of bleeding. Thus, an integrated approach to the selection of a drug is formed, which in the future can be introduced into the structure of clinical protocols for the provision of emergency surgical care.

It should be emphasized that the structure of the algorithm allows it to be adapted to specific conditions: for example, in blunt trauma with venous bleeding, preference is given to fibrous preparations with a high degree of adhesion and rapid activation, and in case of a cut injury with a suspected bile component, preference is given to materials that are resistant to maceration and capable of sealing the biliary ducts.

Thus, clinical testing of the algorithm has shown that it not only increases the effectiveness of local hemostasis, but also contributes to the standardization of surgical tactics, improving the reproducibility of results. This is especially true in emergency surgery, where the decision must be made quickly and the ability to assess tissue re-

sponse is limited. The data obtained provide a rationale for the expanded implementation of the algorithm in clinical practice, as well as for further research aimed at its improvement and validation in other surgical contexts.

CONCLUSION

The development and implementation of an algorithm for the selection of a local hemostatic agent in traumatic liver injuries made it possible to reliably increase the effectiveness of surgical hemostasis. The use of a structured approach based on the type of injury, the nature of bleeding and the technical characteristics of the drugs provided a reduction in the time of bleeding control by more than half, a reduction in the volume of blood loss by almost 55%, as well as a reduction in the need for repeated application by more than four times.

The most stable and predictable results were achieved with the use of hemostatics with high adhesion and plasticity, such as BloodSTOP IX, especially in conditions of venous and capillary bleeding. The algorithm, adapted to the conditions of emergency surgery, showed high reproducibility and clinical applicability.

Thus, the proposed algorithm can be recommended for implementation in the practice of surgical departments as a tool for standardizing the choice of a hemostatic agent for liver injuries, as well as a methodological basis for educational programs and internal clinical protocols.

Statement of Ethical Approval - The study was conducted in accordance with the Declaration of Helsinki (2013) and approved by the Local Ethics Committee at the Bukhara State Medical Institute (Protocol No 18 dated 01/23/2021). All patients signed an informed consent to participate and process medical information.

Conflict of Interest - The authors declare that there is no conflict of interest.

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JIGAR JAROHATLARIDA MAHALLIY GEMOSTATIK VOSITANI TANLASH BO‘YICHA ALGORITMNI ISHLAB CHIQISH VA KLINIK APROBATSIYASI

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ABSTRAKT

Kirish. Jigar jarohatlarida mahalliy gemostatik vositani tanlash ko‘pincha jarrohning shaxsiy tajribasiga asoslanadi va empirik tarzda amalga oshiriladi. Bunday yondashuv operatsion natijalarning takrorlanuvchanligini pasaytiradi va asoratlar xavfini oshiradi.

Maqsad. Gemostatik vositani tanlash uchun yangi algoritm ishlab chiqish, uni klinik sharoitda sinab ko‘rish va samaradorligini baholash.

Materiallar va usullar. Tadqiqotda I–III darajali jigar jarohatlari bilan operatsiya qilingan 44 nafar bemor ishtirok etdi. Nazorat guruhida (n=23) vosita tanlovi tasodifiy bo‘lgan, asosiy guruhda (n=21) esa taklif etilgan algoritm asosida vosita tanlangan. Baholash mezonlari: qon ketish davomiyligi, qon yo‘qotish hajmi, takroriy qo‘llash ehtiyoji va texnik qulaylik.

Natijalar. Algoritm yordamida qon ketish davomiyligi 158,2±19,4 soniyadan 78,6±13,7 soniyagacha ($p<0,001$), qon yo‘qotish hajmi esa 314±56 ml dan 142±31 ml gacha ($p<0,001$) kamaydi. Takroriy vosita qo‘llash holatlari 39,1% dan 9,5% gacha qisqardi. Algoritm yordamida tanlangan vositalar 100% hollarda texnik muammosiz qo‘llandi.

Xulosa. Mahalliy gemostatik vositani tanlashda algoritmga asoslangan yondashuv jarrohlik samaradorligini oshiradi, natijalarni barqarorlashtiradi va shoshilinch xirurgik amaliyotda tavsiya etilishi mumkin.

Kalit so‘zlar: jigar jarohati, mahalliy gemostaz, gemostatik vosita, tanlash algoritmi, BloodSTOP IX, klinik tadqiqot, operatsion taktika

РАЗРАБОТКА И КЛИНИЧЕСКАЯ АПРОБАЦИЯ АЛГОРИТМА ВЫБОРА МЕСТНОГО ГЕМОСТАТИЧЕСКОГО СРЕДСТВА ПРИ ТРАВМАТИЧЕСКИХ ПОВРЕЖДЕНИЯХ ПЕЧЕНИ

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АБСТРАКТ

Введение. Выбор местного гемостатического средства при травмах печени в условиях экстренной хирургии остаётся эмпирическим и часто субъективным, несмотря на существующее разнообразие препаратов. Отсутствие формализованного подхода снижает воспроизводимость результатов и повышает риск осложнений.

Цель. Разработать алгоритм выбора гемостатического средства, основанный на типе травмы, характере кровотечения и операционной пригодности препарата, а также провести его клиническую апробацию.

Материалы и методы. В исследование включены 44 пациента с травматическими повреждениями печени I–III степени. В контрольной группе (n=23) выбор препарата осуществлялся произвольно, в основной (n=21) – по предложенному алгоритму. Сравнивались длительность кровотечения, объём кровопотери, частота повторной аппликации и субъективная техническая оценка препарата.

Результаты. Алгоритм позволил достоверно сократить среднюю длительность кровотечения с 158,2±19,4 до 78,6±13,7 секунд ($p<0,001$), а объём кровопотери — с 314±56 мл до 142±31 мл ($p<0,001$). Частота повторной аппликации снизилась с 39,1% до 9,5%. В 100% случаев применение алгоритма позволило избежать технических затруднений.

Заключение. Разработанный алгоритм выбора гемостатического средства при травмах печени позволяет повысить воспроизводимость хирургических решений и клиническую эффективность лечения, особенно в условиях ограниченного времени и нестабильной анатомической ситуации.

Ключевые слова: травма печени, местный гемостаз, алгоритм выбора, BloodSTOP IX, клиническое исследование, операционная тактика