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Оригинальная статья

ПРИМЕНЕНИЕ САМОРАСШИРЯЮЩЕЙСЯ ПОЛИУРЕТАНОВОЙ ПЕНЫ ДЛЯ ОСТАНОВКИ ПРОДОЛЖАЮЩЕГОСЯ ВНУТРИБРЮШНОГО КРОВОТЕЧЕНИЯ В УСЛОВИЯХ ВОЕННЫХ КОНФЛИКТОВ И ЧРЕЗВЫЧАЙНЫХ СИТУАЦИЙ: ИЗ ОПЫТА ПРОВЕДЕНИЯ ТАКТИКО-СПЕЦИАЛЬНЫХ УЧЕНИЙ

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Резюме. *Цель исследования* – оценить возможность, эффективность и безопасность применения отечественной пенополиуретановой композиции (ППК) в остром эксперименте, выполненном в рамках проведения тактико-специальных учений (ТСУ).
Материалы и методы исследования. Тактико-специальные военно-медицинские учения «Очаг», ежегодно проводящиеся в учебном центре Военно-медицинской академии (ВМА) им. С.М. Кирова, направлены на апробацию передовых технологий здравоохранения, применение которых перспективно в плане сохранения жизни и здоровья военнослужащих. Для моделирования тактической обстановки формируют скоординированную по времени систему войсковых этапов эвакуации раненых – от оказания медицинской помощи на условном поле боя в рамках концепции тактической медицины до оказания первичной врачебной медико-санитарной помощи в медицинском взводе и выполнения оперативных вмешательств в рамках тактики контроля повреждений в операционной, развернутой в палатке медицинской роты.
Результаты исследования и их анализ. Все животные дожили до окончания эксперимента, внутреннее кровотечение было остановлено. В серии анализов крови, к 90-й минуте эксперимента, было отмечено появление небольшого количества веществ, входящих в состав разработанной пены.
Таким образом, был получен первый опыт применения данной технологии при оказании медицинской помощи в тактическом временно́м диапазоне. Для оценки эффективности и безопасности данной ППК спланировано проведение доклинических и клинических исследований.

Ключевые слова: *военные конфликты, гемостаз, животные, лапаротомия, продолжающееся внутрибрюшное кровотечение, саморасширяющаяся полиуретановая пена, тактико-специальные учения, чрезвычайные ситуации, эксперимент*

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Original article

USAGE OF SELF-EXPANDING POLYURETHANE FOAM FOR RESOLVING OF ONGOING INTRA-ABDOMINAL HEMORRHAGING IN CONDITIONS OF MILITARY CONFLICT AND EMERGENCY SITUATIONS BASING ON AN EXPERIENCE OF TACTICAL-SPECIAL EXERCISES

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Summary. *Investigation purpose* – to evaluate the opportunity, efficiency and safety of usage of national polyurethane foam composition (PFC) during acute experiment taken in the frameworks of conducting of tactical-special exercises (TSE).

Materials and methods of the investigation. Tactical-special military-medical exercises "Ochag" are conducted annually and directed to testing of advanced health care technologies which are perspective for saving solders life and health. For modeling of tactical conditions a time coordinate system of troop system of evacuation of injured was created – from the time of provision medical treatment on artificial battlefield on the frameworks of tactical medicine till the time of provision of primary medical-sanitary treatment in medical platoon and providing of surgery in the frameworks of tactical control of injures in surgical room deployed in a tent of medical company.
Investigation results and their analysis. All animals survived till the end of the experiment, internal hemorrhaging was resolved. Till the 90th minute of experiment an appearance of small values of substances included in the developed foam was noticed in a series of blood analyzes.
This way the first experience of this technology usage during medical treatment provision in tactical time range was got. For assess of this PFC a conducting of pre-clinical and clinical researches was planned.

Key words: *animals, emergency situations, experiments, hemostasis, laparotomy, military conflicts, ongoing intra-abdominal hemorrhaging, self-expanding polyurethan foam, tactical-special exercises*

Conflict of interest. The authors declare no conflict of interest

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Introduction

Continued internal bleeding is one of the main causes of death of the wounded and injured in military conflicts and emergencies. Two-thirds of the war wounded die from continuous intracavitary bleeding (CICB), which cannot be stopped by means of external compression or other available means of hemostasis [1, 2]. The same number of victims die from internal bleeding in man-made emergencies. For example, 68% of the victims who suffered abdominal injuries during the earthquake in China (2008) died from CICB [3].

Care for such bleeding implies prompt medical evacuation to surgical care with urgent surgical intervention if possible. At the same time, both in military operations and in emergencies, medical evacuation is usually not fast enough, which leads to a fairly high mortality rate. Currently, to reduce the intensity of CICB in the prehospital period the following options are provided: "tolerable" hypotension; restrictive infusion therapy; early infusion of blood and its components, including lyophilized plasma; early injection of tranexamic acid; in intrapelvic bleeding — application of antishock pelvic belt [4].

Over the past twenty years a large number of experimental studies aimed at the development and implementation of intracavitary hemostasis, based both on the principle of mechanical compression of damaged organs by increasing intra-abdominal pressure, and on the principles of contact hemostasis due to the chemical properties of injected drugs, have been conducted. The meaning of intracavitary hemostasis is the introduction of a special composition into the abdominal cavity by laparocentesis, which due to its physical and chemical properties has a direct or indirect effect on the source of bleeding, thereby leading to its stopping. The injected preparation is extracted at the surgical stage during laparotomy. At the same time, the final stopping of bleeding from the damaged organ or vessel is performed.

Along with such most well-known foreign means of intracavitary hemostasis as ResQFoam (Arsenal Medical, USA), F.O.A.M. (Critical Innovations, USA), which are in the phase of preclinical and clinical trials, domestic analogues promising for application in complex conditions of military conflicts and emergencies, i.e. in cases when the terms of the victim delivery to the surgeon may significantly exceed the "golden hour", appeared.

Until now, the possibilities of intracavitary hemostasis in simulated emergencies have not been studied.

The aim of the investigation was to evaluate the possibility, efficiency and safety of the domestic polyurethane foam composition (PFC) application in an acute experiment performed within the framework of tactical and special training (TST).

Materials and methods of research. The tactical-special military-medical exercises "Ochag" which are annually conducted at the training center (town Krasnoye Selo) of the Kirov Military Medical Academy (MMA) are aimed at testing the advanced medical technologies which are promising to preserve life and health of servicemen. To simulate the tactical situation, a time-coordinated system of troop stages of wounded evacuation is formed: from providing medical aid on the conventional battlefield within the concept of tactical medicine to providing primary medical care in a medical platoon and performing surgical interventions within the damage control tactics in the operating room deployed in the tent of a medical company.

In the context of this work, the subplot of the exercise, conducted from May 23 to 27, 2022, involved: inflicting a wound to the abdomen on a sedated animal (pig); delivering it to a medical platoon; injecting PFC into the animal's abdomen; evacuating the animal to the medical company (surgical care phase) by ambulance, followed by surgical stopping of bleeding.

In the medical platoon deployed in the tent of the battalion's infirmary on the basis of the protected ambulance vehicle "Lensa" in the ZSA-P configuration, the animals were treated by resident doctors using the "MAPTA" protocol (Bleeding, Asphyxia, Respiratory Disorders, Transport Immobilization and Temperature, First Aid Kit) developed by the Department of Military Field Surgery (MFS), and the functions of stretcher-bearers, operating nurses and surgical assistants were performed by MMA cadets. Diagnostics of ongoing intra-abdominal bleeding was performed using a wireless ultrasound machine ELS-MED (Russia). For remote consultations the medical platoon doctor used augmented reality glasses (HoloLens, USA), allowing the specialists of the Medical Support Coordination Center (in our case - professor of the Military Field Surgery Department of the MMA) to see and hear in real time all events occurring in front of the operator, to prompt and correct his actions (Fig. 1).

After assistance and introduction of PFC into the abdominal cavity, the animals were evacuated to the medical company, where the first animal underwent laparotomy with foam extraction and definitive bleeding arrest as part of the SMART training cycle by residency trainees. One of the animals, 60 min after PFC injection, was additionally injected through the previously performed laparocentesis access 1 balloon of Macroflex assembly foam (Makroflex, Estonia) in the hospital ward for research purposes. The study was performed twice during the two days of the exercise.

Toxicological analysis of venous blood samples was performed by reversed-phase liquid chromatography-mass spectrometry (LCMS) with registration of positive ions.

Animal preparation

After starvation the day before the experiment, three animals (Large White pig, 35-47 kg in weight) were intramuscularly injected with Tiletamine and Zolazepam (Zoletil®, France) at a dose of 10 mg/kg. After delivery to the conditional battlefield, the wound was applied to the abdomen (right upper quadrant) from the traumatic pistol PB-4-1ML "Wasp" (New Weapon Technologies, Russia) from a distance of 1 m with a cartridge of 91 J.

Рис. 1. Оказание помощи условно раненому (свинья с нанесенным пулевым ранением живота) в палатке медпункта батальона на базе защищенного санитарного автомобиля «Линза» в варианте комплектации ЗСА-П в ходе проведения ТСУ «Очаг-2022». Диагноз проникающего ранения живота поставлен с помощью беспроводного аппарата УЗИ. Ведущий хирург реанимационно-хирургической группы оснащен очками дополненной реальности для проведения телемедицинской консультации из Центра

Fig. 1. Providing medical care to a simulated wounded person (a pig suffered from a gunshot wound to the abdomen) in a frame tent of the battalion's aid station on the basis of a medical armored vehicle «Lens» in its full version during the military medical exercises «Hearth-2022». A penetrating abdominal wound was diagnosed by using wireless ultrasound. The leading surgeon of the resuscitation and surgical group is equipped with augmented reality glasses for telemedicine consultation from the Center

The animals were brought on a stretcher to the medical platoon, constantly evaluating the adequacy of anesthesia and sedation throughout the experiment and administering additional medication as necessary. Airway clearance was restored by tracheal intubation. Respiratory function was maintained using a MA-110 ventilator (Muraco, Japan). Jugular vein was catheterized for maintenance infusion therapy and administration of drugs under ultrasound guidance. After an abbreviated abdominal ultrasound examination and confirmation of the presence of fluid in the abdominal cavity, we administered PFC.

Brief information about the polyurethane foam composition

The original PFC was developed by Locus Ltd (Sarov) within the framework of the research work carried out under the aegis of the academic strategic leadership program "Priority 2030". During the development of the foam the following requirements were observed: low temperature (<42 °C) on the surface of the foam during its formation; low toxicity; self-sterilization at the time of mixing the components; high percentage (70-80%) of closed cell structure providing sufficient elasticity and expansion factor; controlled process of mixing the components.

The polyurethane foam composition consists of two components - polyol (A) and isocyanate (B). The latter is represented by isocyanic acid esters R-N=C=O, where R is an aliphatic, aromatic, alkyl-aromatic or heterocyclic radical. Among isocyanates, toluene diisocyanate (TDI) and methylenediphenyl diisocyanate (MDI) are the most widely used. Toluene diisocyanate is widely used in construction technologies as a filler or technical adhesive — TDI forms a solid foam, but is toxic, and therefore excluded from the choice when creating the tested PFC. In place of TDI, a flexible polyurethane foam based on the less toxic MDI was included in the matrix.

The polyol component consists of polyols (polyethers), foaming agents, catalysts, and foaming regulators. Polyesters are sources of hydroxyl (-OH) groups, which react with isocyanate to form a polyurethane structure. The choice of the structure of the starting polyol or mixture of polyols determines the final properties of the foam. Carbon dioxide gas (CO_2), which forms when water reacts with isocyanate (chemical foaming), is chosen as the foaming agent. The advantage of water-foamed PFC lies in the lower boiling point of the gas inside the foam cells compared to foam foamed with volatile liquids. Catalysts speed up reactions between isocyanate and polyol and between isocyanate and water and are also important for complete completion of the reaction (foam curing). Foam regulators (component A) keep the raised foam in optimal condition by regulating the cell size; foam stabilizers (component B) stabilize the formed cells. The ratio of components A and B required for optimal expansion of the foam during mixing was 3.75:1.

Time characteristics are important in the process of foam formation. Mixing of component A and component B was carried out immediately prior to application for about 10 seconds. Foam formation time is (40±10) s, and polymerization time is (20±5) min.

Technique of introducing self-expanding PFC

Introduction of the self-expanding polypropylene foam into the abdominal cavity was carried out by laparocentesis.

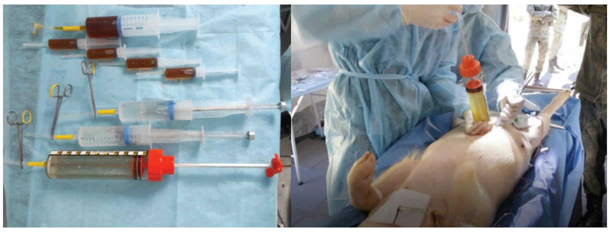

Рис. 2. Отечественная саморасширяющаяся пенополиуретановая композиция для остановки продолжающегося внутрибрюшного кровотечения: А – внешний вид на этапе подготовки к введению (шприцы различной емкости, содержащие 2 основных компонента полиуретановой пены); Б – введение *ex tempore* приготовленной смеси в брюшную полость животного путем лапароцентеза

Fig. 2. Russian prototype of self-expanding polyurethane foam composition to control ongoing intra-abdominal bleeding: A – appearance at the stage of preparation (syringes of various capacities containing 2 main components of polyurethane foam); B – intraabdominal injection of the ex-tempore prepared mixture via laparocentesis

In the experiment it was performed in the medial region of the abdomen, 2 cm below and to the left of the prepuce sac, by a 2 cm incision with opening of the peritoneum under visual control. A delivery system was then inserted into the abdominal cavity.

The delivery system was a complex of one 320 ml syringe (or two 160 ml syringes) of component A and two 20 ml syringes of component B with an adapter-conductor ensuring delivery of the PFC into the abdominal cavity through the above-described access. The syringe is additionally equipped with a system for mixing the PFC components (Fig. 2). After the introduction of the PFC into the abdominal cavity, a clothespin was placed on the incision area to seal it. Subsequently, venous blood was drawn to assess the toxicokinetics of the polymer foam matrix elements. Blood sampling, registration of blood pressure (BP) and temperature values were performed every 30-60 min. A rectal sensor was used to measure core temperature.

Medical Evacuation

After intra-abdominal injection of the PFC, the animal was placed in the sanitary vehicle "Lensa", where it was transported accompanied by anesthesiologist to the next stage of medical evacuation — to the medical company of the team, where we performed laparotomy, foam extraction, revision

Рис. 3. Эвакуация животного после введения пенополиуретановой композиции в защищенном санитарном автомобиле «Линза»

Fig. 3. Simulated casualty evacuation by an armored medical vehicle «Lens» after intraabdominal polyurethane foam injection

of abdominal cavity, hemostatic effect and adhesion degree to the organs, checked foam uniformity, fragmentation degree upon extraction from the abdominal cavity (Fig. 3). The volume of the extracted foam was measured, and its expansion and hygroscopicity coefficients were calculated. The animal was removed from the experiment at the end of a day of practical training, during which residents of the departments of surgical profile practiced techniques of various surgical interventions.

Results of the study and their analysis. All animals were able to perform a complete examination protocol. When laparocentesis was performed, liquid blood was noted in the abdominal cavity, which indicated the penetrating nature of the wound with probable damage to the parenchymatous organs. Despite this, hemodynamics remained stable with systolic BP not lower than 100-110 mm Hg. After foam insertion into the abdominal cavity BP values fluctuated within the limits of previous values. Core temperature throughout the experiment also remained unchanged at 36.3-36.5 °C.

Time spent on preparation for the introduction of the foam was 3-4 min; for laparocentesis (without local anesthesia) — up to 5 min; for the introduction of the foam itself — less than 1 min (delay in the rate of mixing and introduction could lead to freezing of the foam in the syringe). After injection of the foam, there was a significant increase in the circumference of the biobject's abdomen not only due to expansion of the foam itself, but also due to significant gas formation during reaction of the foam components. Total exposure time of the foam in the abdominal cavity was 180 min. The foam expansion coefficient was 1:5. At the time of laparotomy there were no signs of ongoing bleeding. There was a marginal wound of the right lobe of the liver, in one case — a loop of the small intestine. Hygroscopic coefficient was 20%; the volume of explanted foam from the abdominal cavity was 1200-1450 ml; we observed poor adhesion to the abdominal cavity organs — the foam was extracted as a single block without traumatization of organs and without intestine deserosion. Significant foam fragmentation was not observed, but in one of the three cases a 50 ml foam fragment ended up between the loops of the small intestine, which affected the laboriousness and time of its extraction. In another case, a bullet from a traumatic gun was trapped by the foam and was removed along with it (Fig. 4).

LCMS results showed a rapid increase in the level of acylated MDI product (MDI-NH2-Ac) in the blood samples of both animals, followed by a smooth decline. However, its concentration was minimal and 6.5 times lower in the PFC than in the animal who was additionally injected with assembly foam (control). The peak of MDI concentration in the animal's blood was observed by the 90th minute from the moment of intra-abdominal injection of the foam. Rapid rise of MDI level was probably the result of contact of still unpolymerized foam with blood in the abdominal cavity and its penetration into the systemic bloodstream. As the foam solidified and began its softening phase with loss of elasticity, the remaining unreacted components were gradually absorbed.

Discussion

This experimental study, conducted for the first time in a military medical exercise, demonstrated the possibility and prospects of using intracavitary hemostasis techniques in the stages of medical evacuation. It was shown that in the presence of a special syringe, prepared ampoules with component A and component B introduction of PFC into the abdominal cavity can be carried out within 10 minutes. Achieving intracavitary hemostasis in this time frame (the best option - in the pre-hospital period of medical care) will significantly reduce mortality with CIB, which currently can be stopped only by laparotomy in the surgical phase of care. A similar approach to achieving intracavitary hemostasis can be applied in the case of mass casualties during combat operations and in man-made and natural emergencies. It represents a pure implementation of the damage control concept, which implies temporary closure of a bleeding wound followed by prompt delivery of a patient to a surgeon [5].

The concept of early intracavitary hemostasis was first described 20 years ago by J. Holcomb et al. who studied the possibility of achieving hemostasis in small animals by intra-abdominal injection of fibrin glue [6]. Among the developments in this area, the self-expanding ResQFoam PPK (Arsenal Med., USA) and domestic foam, consisting of polyol and isocyanate components (tested over 1300 different modifications), which showed excellent results in experiments (over 600 pigs) in terms of survival in different lethal models of damage: severe liver injury, spleen, iliac artery damage, etc. A 70-90% three-hour survival rate has been shown in severe liver injury models compared with 8% in controls [7, 8]. In the iliac arterial injury model, foam showed >50% survival compared with zero survival in the control group [9]. In addition to the positive effect, a number of undesirable effects were noted: a significant increase in intra-abdominal pressure, which can potentially lead to hypoperfusion of abdominal organs due to the development of abdominal compartment syndrome; formation of local sites of small intestinal damage (similar to intra-abdominal hemorrhages); increase in intra-abdominal temperature >42 °C; residual polyurethane in the abdomen after extraction of a single conglomerate from the abdominal cavity [5]. In addition, this foam also appears to have increased toxicity, since the start date of the REVIVE clinical trial to study the efficacy and safety of ResQFoam is constantly postponed.

Рис. 4. Внешний вид пенополиуретановой композиции, извлеченной из брюшной полости животного в ходе лапаротомии. В центре полиуретанового блока видна пуля от пистолета «Оса», которой было нанесено ранение

Fig. 4. The appearance of a polyurethane foam composition, extracted from the abdominal cavity of an animal during laparotomy. There is a bullet from the «Osa» pistol seen in the center of the polyurethane block

The PFC we are using has a systemic resorptive effect, which requires additional study in full laboratory trials and modification of its structure. Our earlier studies of the first modification of PFC on rabbits did not show a sufficient level of efficacy [10].

Thus, despite serious developments in this area, none of the intracavitary hemostasis agents in the world is used due to either insufficient efficacy or insufficient safety. In a recent paper, an international panel of experts recommended the use of only an antishock pelvic belt for stopping CIB in complex conditions, starting from the moment of injury or wounding, 92.6% of experts and resuscitative endovascular aortic balloon occlusion (REBOA), 75.0% of experts. At the same time, only 14.8% of the experts were in favor of the use of PFC. None of the 27 experts advocated carbon dioxide insufflation into the abdominal cavity as one of the possible methods to achieve intracavitary hemostasis, [11]. In 78.6% of cases, the experts agreed that invasive means of intracavitary hemostasis, which include REBOA and PFC, should be used only by trained medical personnel. The recommendations for prehospital care of war wounded (USA, 2018) state that despite the high potential for clinical use in the future, the use of PFC needs further serious study [12].

Overall, despite a number of limitations related to the small number of animals and the lack of proper laboratory monitoring, the study demonstrated the feasibility of a hemostatic composition for stopping CIB, which is important for saving the lives of patients during prolonged medical evacuation in war and emergency situations.

Conclusion

In view of the high clinical significance of the CIB problem due to the high frequency of lethal outcomes among the injured and wounded in the pre-hospital period, the search for new ways to achieve early intracavitary hemostasis is required. Self-expanding PFC injected through a puncture of the abdominal wall can be an effective prospective means of achieving temporary hemostasis during CIB in difficult conditions, when rapid delivery of the patient to a surgical hospital is not possible. In the long term, injected foam will increase the duration of "safe" transportation of the victim by stopping bleeding and temporary stabilization of hemodynamics. Numerous features and possible adverse effects of such compositions require further research and search for the optimal — effective and safe — chemical composition of the applied agents.

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