EFFICIENCY OF USING POLYACRYLIC ACID SILVER SALT IN DECOMPRESSION AND STABILIZATION SURGERY ON THE LUMBAR SPINE INVOLVING 1 TO 3 SEGMENTS

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Objective. To determine possible effect of the preparation of an incomplete polyacrylic acid silver salt on the volume of intraoperative and postoperative blood loss in open posterior surgery on the spine involving up to three segments.
Material and Methods. Study design: randomized prospective multicenter cohort analysis. Level of evidence – IIb. The study was based on 90 patients aged 27 to 65 years who underwent decompression and stabilization surgical interventions on the lumbar spine through posterior median approach using transpedicular fixation system with fixation of up to three vertebrae. A comparison of perioperative blood loss volume in patients with local application of polyacrylic acid silver salt and without it was performed.
Results. The volume of inraoperative blood loss (the sample was described using the mean value and standard deviation $M \pm \sigma$) in the study group was 258.1 ± 164.5 ml (min 90; max 890), in the control group – 405.5 ± 157.9 ml (min 190; max 950). The postoperative blood loss through drainage ($M \pm \sigma$) was 81.500 ± 77.046 ml (min 20; max 400) in the study group, 151.560 ± 74.745 (min 20; max 600) in the control group. Comparison of both intraoperative and postoperative blood loss according to the Mann-Whitney U-test confirms the high statistical significance of differences ($p < 0.01$), which suggests the effectiveness of the preparation.
Conclusion. The use of incomplete polyacrylic acid silver salt in decompression and stabilization interventions on the lumbar spine involving 1 to 3 segments can effectively reduce the volume of blood loss both during surgery and in the postoperative period.
Key Words: spine surgery, transpedicular fixation, blood loss.
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The reduction of intraoperative blood loss is one of the most accessible and vivid criteria of decreasing traumaticity of surgeries. Minimally invasive interventions, which make it possible to reduce blood loss by means of using special technical facilities (retractor systems, video equipment, etc.), are not available in all clinical units and rather expensive. Nowadays, there is an active search for topical hemostatic agents, which would be applicable in various types of surgeries and would combine clinical efficiency with accessibility and low price. At the same time, the majority of materials intended for topical application (hemostatic sponges, powders, glues, including Surgiflo, Surgicel, etc.), despite their high efficiency, cannot be used in case of a large wound surface, and the market cost of the most commonly used topical hemostatic materials varies in wide ranges: sponges cost from 3,400 to 14,548 roubles per unit, hemostatic matrices with thrombin cost from 13,268.2 to 24,378.2 roubles per a bottle, and surgical glue kit with preparation instructions costs 11,700 roubles per unit (according to the data of online pharmacies as of 09.02.2018).

Polyacrylic acid (PAA) partial silver salt is one of the hemostatic substances meeting the requirements of medical institutions in terms of the efficiency–cost ratio; its preparations are authorized for use abroad and in Russia, moreover, the nature of the drug's active substance, besides the basic (hemostatic) activity, ensures also bactericidal and bacteriostatic activities because of silver ions present. Their application in clinical practice is limited to works of general (abdominal) surgery, there are only some publications referring to ophthalmology, obstetrics and gynaecology [1–3].

The drug's mechanism of action includes several successive steps. At the beginning, the active substance binds with plasma proteins, first of all with albumin, thus forming a polyacrylic matrix structure containing albumin molecules in the cells of the polyacrylic matrix [4]. This structure forms several layers on the wound surface, and the reduced silver ions produce bactericidal effect. Then the polyacrylic matrix is plasmolyzed and substituted with fibrin. The drug is simple in application: a wound surface is covered with surgical drapes wetted with its solution, and no precise dosing is required. Its safety makes it possible to foresee positive effects in the spine surgery, especially

in interventions involving traumatizing approaches.

The objective of the study was to determine possible effects of the drug based on the PAA partial silver salt on the volume of intraoperative and postoperative blood loss in open posterior surgery on the spine involving up to three segments.

Material and Methods

The following three medical centers were involved in the randomized, prospective, multicenter study:

– National Medical Research Centre for Traumatology and Orthopaedics n.a. N.N. Priorov, Moscow, Russia (Center 1);

– Chair of Traumatology, Orthopaedics and Disaster Surgery of the I.M. Sechenov First Moscow State Medical University, Moscow, Russia (Center 2);

– N.V. Sklifosovsky Scientific Research Institute of First Aid, Moscow, Russia (Center 3).

The data on 180 patients aged 20–80 years were included into the study according to the following criteria:

– process localized in the region from L1 to S1 (inclusive);

– multilevel (at least three segments) spinal stenosis combined with degenerative scoliosis or spinal fracture;

– decompression and stabilization surgery was performed through the open posterior approach involving skeletonization of the vertebral arches and instrumented fixation of up to three spinal motion segments;

– absence of haematological disorders according to the parameters of complete and biochemical blood tests and coagulograms obtained prior to surgery.

The exclusion criteria were as follows: co-existing chronic, infectious or tumor diseases, divergence of one or several coagulogram parameters (prothrombin time, prothrombin index according to Quick, INR, APTT, fibrinogen).

Patients were selected continuously in each participating center within the year 2018. All the patients were divided into two equal groups (study and control groups), each containing 90 patients, moreover, each center studied the equal number of patients (n = 60, including 30 patients in the control group and 30 patients in the study group). The study group contained 30 consecutively operated patients who met the inclusion criteria (gender-blind). Totally, this group contained 53 males (58.8 %) and 37 females (41.2 %). The formation of the study group was completed, when the mentioned number of patients was treated (5 emergency interventions and 25 elective surgeries for each center). The control group included patients, who were admitted later, the group was formed by the method of sex-stratified randomization; each group contained the equal number of patients: 15 males (50 %) and 15 females (50 %) in each center. The data of the medical centers (the volume of the data available was correspondingly extended) included into the study made it possible to stratify the study group according to the type of surgical interventions: elective (for degenerative stenoses) and emergency (for spinal injuries) surgeries. The comparability of the study and control groups according to this parameter was ensured by equal (for the groups) ratio of interventions – 5:1 (data on the number of patients for each center are presented in Tables 1, 2). The mentioned ratio was one of the conditions of pseudo randomization, which was observed both in the final comparison groups and in the groups of patients, who had been treated in each center taken individually.

All the participants of the study had signed the informed consent statement.

The patients were operated on by surgeons, who had great experience (from 12 to 25 years) in carrying out decompression and stabilization surgeries on the spine. During every intervention for decompression of the spinal cord and spinal roots, bone structures were resected involving hemilaminectomy or interlaminectomy on the same level. Intraoperative blood loss was measured by collecting the draining blood with a separate vacuum aspirator. Solutions used for cleaning the intraoperative wound were collected separately. When the approach to the spine was performed and the stable hemostasis of the wound walls was achieved, the aspirating blood was collected into a separate container during the decompression of the spinal cavity. Because of this, the volume of blood lost during local bleedings from the bone tissue and Batson's epidural venous plexus was not taken into consideration. Hemostasis during the intervention involving bone structures and spinal cavity was performed using bone wax and bipolar coagulation. Cell Saver registering the volume of the collected (drainage-associated) blood automatically was used to a limited extent in 13 (7.22 %) patients because of a low (<1 l) expected volume of loss of the circulating blood volume and availability of blood substitutes (both auto- and donor ones). During surgery interventions, blood substitution was performed only if medically required, but it did not exceed one dose (300 ml) of packed red blood cells and two doses (600 ml) of fresh frozen plasma (auto- or donor ones).

Therefore, the total blood loss to be estimated during the study referred to diffuse muscular bleeding arising at the stages of the approach and intraoperative wound suturing (which in all cases was carried out with wound drainage left) was estimated as a volume of postoperative blood loss. The indication to remove the wound drainage was the decrease of the daily blood loss to 25 ml/day or less.

The main difference between the study and control groups was the application of the drug based on the PAA partial silver salt according to the following procedure: in the process of skeletonization of the vertebral arches, the wound surface was covered with a surgical drape wetted with a 1 % solution of the PAA partial silver salt (standard drug form), the exposure time was from 2 to 5 min (the duration was estimated visually depending on the intensity of diffuse bleeding). The same procedure was used to apply the drug for the second time before the wound suturing. During the similar stages in the control group, hemostasis was performed using hemostatic sponges and surgical drapes

wetted with a 3 % hydrogen peroxide solution.

Mono- and bipolar electrocoagulation was used during different stages of interventions in the both groups.

Statistical processing was carried out using the IBM SPSS Statistics v. 22.0 software package. The study parameters (volumes of the intra- and postoperative blood losses) were checked for normality of distribution according to the Kolmogorov–Smirnov test; all groups revealed asymptotic significance $p < 0.001$, thus indicating non-normal distribution. The significance of differences of the study parameters between the groups was estimated using the Mann–Whitney U-test. The homoscedasticity was checked using the White's test ($p < 0.05$). The differences were considered significant at $p < 0.05$. The results were presented as $M \pm \sigma$, where M is the mean value and is the root-mean-square deviation.

Table 1
Total numeric distribution of patients of each participating center per comparison groups

Groups	Center 1	Center 2	Center 3	Total
Study				
Elective surgeries	25	25	25	75
Emergency surgeries	5	5	5	15
Total	30	30	30	90
Control				
Elective surgeries	25	25	25	75
Emergency surgeries	5	5	5	15
Total	30	30	30	90

Table 2
Control group formation: number of patients before and after the randomization in each center participating in the study

Surgeries	Center 1	Center 2	Center 3
Elective			
Total number	61	69	82
After the randomization	25	25	25
Emergency			
Total number	12	15	9
After the randomization	5	5	5

Results

Statistical analysis determined that the volume of the intraoperative blood loss (the sample was described using the mean values and root-mean-square deviations $M \pm \sigma$, ml) was 258.1 ± 164.5 ml (min 90; max 890) in the study group and 405.5 ± 157.9 (min 190; max 950) in the control group. On the other hand, the drainage-associated blood loss in the postoperative period ($M \pm \sigma$, ml) was 81.50 ± 77.046 (min 20; max 400) in the study group and 151.56 ± 74.745 (min 20; max 600) in the control group. The comparison of both intraoperative and postoperative blood loss according to the Mann–Whitney U-test confirmed a high statistical significance of the differences ($p < 0.01$), which made it possible to assess the efficiency of the used preparation.

The data on the estimated blood loss in patients in the study and control groups are presented in Table 3.

Discussion

Nowadays, there is no a well formulated demand for new hemostatic facilities in traditional orthopaedics. This is partly because less traumatic surgical approaches are more preferable, when the intervention, especially planned ones, are accompanied with minimal blood loss, and the organism restores blood volume by its own resources in the majority of patients; with the exception of surgeries carried out for advanced injuries and extensive damages, which are accompanied with large losses of the circulating blood volume. Because of this reason, many trauma orthopaedists consider a special use of additional hemostatic facilities as unnecessary, with the exception of those who perform surgeries, when large blood loss is definitely foreseen (e.g., total endoprosthesis of major joints or hypervascular tumors of the skeleton).

The use of the drug based on the PAA partial silver salt in traumatology and orthopaedics is not discussed in literature; the information search using the following key words as traumatology, orthopaedics, endoprosthetics, acute injury, as well as by the name of the drug gave no results. At the same time, there is optimistic information on its use in other fields of surgery, first of all, in abdominal.

A.A. Polyantsev et al. [5] used the drug based on the PAA partial silver salt for the first time for endoscopic hemostasis in 20 patients aged 25–67 years and showed that recurrent bleeding was observed in three cases only. No postoperative complications were observed, with the exception of the mentioned recurrences.

A.I. Andreev et al. [6] obtained a long-lasting hemostatic effect in 23 patients (88.5 %) out of 26 patients with acute calculous cholecystitis (11) and acute adhesive intestinal obstruction (15). The drug was applied twice within 4 min in two out of the three patients with recurrent bleeding; a repeated surgical intervention was required in one patient (bleeding in the region of the bed of the removed gall bladder).

No complications were observed in the postoperative period, with the exception of the mentioned above.

One of the most sprawling studies was carried out in four medical centers in different regions of the Russian Federation [4]. The study included 89 patients of the general surgery, who had been operated on through the open and laparoscopic approaches to the abdominal cavity. The following results were obtained. In the Hospital Surgery Clinic of the Ivanovo City Hospital no. 4, long-lasting hemostasis was achieved at the open surgeries in 39 patients, wherein the drug (25–50 ml, 2–3 min exposition) was applied on a middle-size surgical drape, which in its turn was laid upon a wound dried with a dry surgical drape. In the Surgical Center of the Central Hospital no. 1 of the JSC Russian Railways (Moscow), the drug proved to be effective in 85.2 % of cases (23 patients). A total of 27 patients aged from 30 to 76 years (males and females) were treated with the drug, 16 patients of them had oncologic pathology, 11 patients had acute surgical pathology of the abdominal cavity organs, great vessels, and skeleton bones. In two cases (7.4 %) of the follow-up, recurrent bleedings were observed, in two more cases (7.4 %) the drug was inefficient (one patient had septic shock related to chronic cholangitis, under low unstable pressure, the continuing bleeding from abdominal adhesions was stopped with tamponade and platelets based on fibrinogen and thrombin; in the other patient, the bleeding from the ureter continued because it was connected with the aortic aneurysm, so a repeated intervention was required). In the Endoscopy Department of the Chelyabinsk Regional Hospital no. 3, the preparation was successfully used during endoscopic interventions in eleven males aged from 46 to 77 years. In the Endoscopy Department of the Central Hospital of Kineshma (Ivanovo Region), the efficiency of the PAA partial silver salt was demonstrated in 12 patients in comparison with epsilon-aminocaproic acid.

V.F. Chikaev et al. [7] operated on patients for hernias of the anterior abdominal wall and noted that, when the studied drug was applied as a topical hemostatic agent after the main stage of the surgery before the closure of the surgical wound, the volume of the drainage-related blood in the postoperative period was lower than that in patients, who did not receive it, i.e. 10 ml/day and 30–40 ml/day respectively, which resulted in later drainage removal in the control group.

As far as surgical vertebrology is concerned, the situation differs from that in general traumatologic surgery. At present, there are two main approaches to the spinal column. Open approaches are mastered by a limited number of spine surgeons, moreover, their use is not always efficient and safety because of the anatomical features [8]. Posterior approaches are technologically simpler for the majority of specialists and can be applied on all levels, because they cover anatomical structures from the occipital bone and craniovertebral junction to the sacrum, nevertheless, they involve large blood loss and a lot of complications due to the necessity to separate significant muscular masses from the bone structures [9]. When they are treated with instruments (wound retractors, hooks, mirrors, electrocoagulator), local bleeding arises inevitably from small blood vessels, as a rule, of low volume, but they must be stopped.

A rare surgical complication is a damage of segmental arteries located in hard-to-reach areas of the intraoperative wound and it is difficult to ligate vessels, so the choice of hemostatic facilities is limited. As a rule, the operating surgeon has the following facilites at his/her disposal: a coagulator, temporary clamping of muscular tissues together with deep blood vessels, tamponade of the wound with a gauze material, as well as facilities which are not specific hemostatic agents (3 % hydrogen peroxide solution). Hemostatic sponge, judging by our experience, is not always effective, because it is not fixed properly on the bleeding area, so the effect is reduced to minimum. Bone wax is a restrictively-specific hemostatic agent, it acts against one type of bleeding only, from the cells of cancellous bones.

Despite the intensive development and distribution of various systems for minimally invasive dorsal surgery, it is economically impossible to equip with them all the existing hospitals and departments; and it takes certain expenditures, including organizational, to get surgeons aware of new technologies of surgical interventions, especially in vertebrology.

So, vertebrology is still that field of traumatology and orthopaedics, where the use of simple and efficient hemostatic facilities is of great importance. They should meet the following requirements:

– topical action (e.g., to be applied with surgical drapes wetted with the drug on a bleeding vessel in the intraoperative wound);

– absence of systemic effect upon coagulation properties of blood;

– pronounced hemostatic effect in the absence of adverse events (no sensitivity reactions and toxicity)

A pronounced effect under conditions of hemodilution (when the concentrations of blood coagulation factors and plasma proteins in blood in general are reduced) is an additional requirement to hemostatic drugs. The mentioned situation can be observed in case of large blood loss and/or long-running operations, when it is necessary to replenish the total blood volume not only by means of erythrocytic and plasma components, but also by means of infusion solutions (of crystalloids and colloids).

The discussed drug meets the abovementioned requirements. The data we obtained confirm its effect on the decrease of perioperative (intra- and postoperative) blood loss which arises in case of diffuse muscular bleeding. Despite the absence of the data on its application in case of another spinal pathology, our data make it possible to speak with confidence about the applicability of the drug based on the PAA partial silver salt for hemostasis in surgery for degenerative changes and spinal injuries in order to stop diffuse muscular bleeding from the intraoperative

Table 3
Volume of blood loss in the study and control groups, ml

Patients	Study group		Control group		Patients	Study group		Control group		Patients	Study group		Control group	
	a	b	a	b		a	b	a	b		a	b	a	b
1	320	50	430	100	31	250	100	550	150	61	100	90	240	125
2	450	150	550	80	32	200	50	350	120	62	110	80	280	165
3	270	50	380	250	33	150	50	300	100	63	120	70	230	140
4	630	100	470	100	34	250	120	700	200	64	130	85	310	150
5	500	30	600	80	35	100	50	300	100	65	100	90	220	200
6	420	60	720	150	36	150	50	550	170	66	90	85	230	180
7	300	200	440	100	37	100	70	450	200	67	125	80	250	170
8	720	400	650	400	38	150	50	300	100	68	130	90	300	190
9	350	20	730	250	39	170	100	350	150	69	115	70	290	150
10	400	50	450	70	40	120	50	370	120	70	110	70	210	150
11	550	70	400	50	41	180	100	300	100	71	105	80	200	140
12	890	150	370	50	42	200	100	370	150	72	95	90	330	180
13	350	80	950	200	43	250	100	450	150	73	100	85	320	170
14	400	50	810	100	44	150	50	550	200	74	135	75	290	200
15	250	20	550	120	45	180	80	300	120	75	100	90	410	190
16	500	200	600	70	46	120	70	370	100	76	180	90	400	180
17	380	50	440	30	47	280	100	290	100	77	200	115	380	205
18	600	70	350	40	48	200	100	250	150	78	190	105	370	145
19	450	40	400	100	49	150	90	270	100	79	175	95	380	200
20	430	80	510	90	50	150	70	350	170	80	180	90	400	155
21	350	30	550	20	51	300	100	300	150	81	170	100	290	165
22	540	100	480	100	52	150	50	290	180	82	180	105	280	195
23	450	50	420	80	53	130	80	300	170	83	175	75	310	205
24	400	30	570	140	54	200	70	450	150	84	185	70	320	210
25	350	20	550	100	55	100	50	600	200	85	150	85	300	180
26	500	50	610	600	56	150	70	800	250	86	200	95	208	130
27	670	90	750	180	57	280	100	220	140	87	210	100	250	190
28	300	30	500	200	58	150	50	270	100	88	180	95	315	205
29	350	50	550	100	59	100	50	190	100	89	185	110	280	210
30	430	70	390	80	60	250	80	350	150	90	190	85	240	195

Data on patients are divided into three columns with bold white lines for convenience of table handling;
a — intraoperative blood loss; b — postoperative blood loss.

wound walls. Surely, the drug acting exclusively as a local hemostatic agent is not efficient to reduce bleeding from other anatomic structures, when other methods should be used (bone wax and bipolar electrocoagulation).

Conclusion

Vertebrology is a sphere of orthopaedics, and it has a practical demand for new hemostatic agents. Polyacrylic acid partial silver salt can be considered as such an agent and successively used in surgical vertebrology. Its use in decompression and stabilization surgery on the lumbar spine involving 1–3 segments makes it possible to efficiently reduce the volume of blood loss both intraoperatively and in the postoperative period. Moreover, the volume of blood loss in the study group was statistically less ($p < 0.05$), although different methods of hemostasis combined with each other were used in the control group.

Limitation of the result reliability. The results of the study are presented without analysis of the impact of such factors as traumaticity of manipulations, level of the arterial blood pressure during the surgery, the fixation length (from one to three segments), intake of anticoagulants, and some other factors, on the volume of blood loss. Nevertheless, taking into account sufficiently narrow criteria of inclusion/exclusion and randomization of the patients when selected into a control group, it is possible to speak with a certain confidence about uniform characteristics of the patients.

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