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Use of negative pressure wound therapy in patients with early deep implant-associated spine infection

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ABSTRACT

BACKGROUND: Implantable metal fixators are widely used in modern spine surgery for surgical treatment of a wide spectrum of pathologies: degenerative pathology, neoplasms, spinal deformities, traumas. The increasing number of operations entails an increase in the number of complications, including implant-associated infection (IAI). The rate of IAI, according to the literature, accounts for up to 20% of cases. The treatment of such complications represents a significant burden on the healthcare system, since patients require multiple revision interventions, antibacterial therapy and other treatment measures requiring a comprehensive interdisciplinary approach. A single, generally accepted algorithm for treatment of deep spinal IAI has not yet been developed, but the use of negative pressure treatment systems (vacuum therapy) is becoming increasingly widespread. Despite the good results of the method reflected in the literature, the evidence base for treating deep IAI remains limited.

AIM: To evaluate the results of negative pressure wound therapy (NPWT) treatment of early deep implant-associated spine infection.

MATERIALS AND METHODS: An observational retrospective study included 28 patients with early deep implant-associated spine infection treated with surgical debridement combined with NPWT method in 2019–2023, among them 16 (57.1%) female and 12 (42.9%) male. Obtained data are presented as mean and standard deviation. Comparison of laboratory blood parameters at different time points was made using Wilcoxon W-test. Differences were considered significant at $p < 0.05$.

RESULTS: In all patients, the remission of infection was achieved. The fixator was retained in 18 (64.3% of total) cases, partially removed in 1 case (3.6%), completely removed in 8 cases (28.6%), and replaced in 1 case (3.6%). On average 5.7±2.83 NPWT dressings were required to achieve the clinical cure. In 27 cases (96.4% of total) the wound was closed with the help of secondary sutures, in 1 case (3.6%) plastic surgery was provided. The average duration of antibiotic therapy was 38.2±18.1 days, the number of hospital days was 42.1±23.31. Relapse was noted in 1 (3.6%) patient with preserved metal structure one month after discharge. During microbiological tests, positive results (growth of microflora) were recorded in 26 (92.9% of total) patients, negative — in 2 cases (7.1%). Among these, in 19 (67.9%) cases, a change of leading pathogen occurred during treatment period.

CONCLUSION: NPWT is an effective and safe method that can be characterized by good clinical results.

Keywords: implant-associated spinal infection; surgical site infection; deep early implant-associated spinal infection; NPWT system; vacuum therapy; negative pressure therapy; transpedicular fixation.

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Применение системы лечения отрицательным давлением у пациентов с ранней глубокой имплантат-ассоциированной инфекцией позвоночника

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АННОТАЦИЯ

Обоснование. Имплантируемые металлоконструкции широко используются в современной вертебрологии для оперативного лечения широкого спектра заболеваний: патологии дегенеративного генеза, новообразований, деформаций позвоночника, а также травм. Возрастающее число таких операций влечёт за собой рост количества осложнений, в том числе имплантат-ассоциированной инфекции (ИАИ), составляющей, по данным различных источников, до 20% случаев. Лечение таких осложнений представляет собой значительную нагрузку на систему здравоохранения, поскольку пациенты нуждаются в неоднократных ревизионных вмешательствах, антибактериальной терапии и иных лечебных мерах, требующих комплексного междисциплинарного подхода. До сих пор не разработан единый общепринятый алгоритм лечения глубокой ИАИ области позвоночника, однако всё более широкое распространение получает использование систем лечения отрицательным давлением (вакуум-терапия, ЛОД-терапия). Несмотря на отражённые в литературе хорошие результаты применения метода, доказательная база по вопросу лечения глубокой ИАИ остаётся скудной.

Цель. Оценить результаты лечения пациентов с ранней глубокой имплантат-ассоциированной инфекцией позвоночника с применением вакуум-терапии.

Материалы и методы. Проведён обсервационно-ретроспективный анализ лечения 28 пациентов с ранней глубокой имплантат-ассоциированной инфекцией позвоночника методом хирургической санации дебридмента в сочетании с лечением отрицательным давлением (вакуум-терапия) за период 2019–2023 гг. Число женщин составило 16 (57,1%), мужчин — 12 (42,9%). Средний возраст — 43,6 года. Полученные данные представлены в виде средних значений и стандартного отклонения. Лабораторные показатели крови обработаны с помощью критерия Уилкоксона. Значимыми считались значения при p <0,05.

Результаты. У всех пациентов в процессе лечения достигнута ремиссия инфекции. Из них металлоконструкция сохранена у 18 (64,3%), частично удалена — у 1 (3,6%), полностью удалена — у 8 (28,6%), заменена — у 1 (3,6%). Для клинического излечения в среднем потребовалось 5,7±2,83 ЛОД-перевязки. В 27 (96,4%) случаях рана зажила наложением вторичных швов, в 1 (3,6%) — потребовала выполнения пластики. Средний срок антибиотикотерапии составил 38,2±18,1 дня, число койко-дней — 42,1±23,31. Рецидив был отмечен у 1 (3,6%) пациента с сохранённой металлоконструкцией через один месяц после выписки. Положительный рост микрофлоры получен у 26 (92,9%) пациентов, отрицательный — у 2 (7,1%). Из них в 19 (67,9%) случаях в ходе лечения происходила смена микроорганизмов.

Заключение. ЛОД-терапия представляет собой эффективный и безопасный метод лечения, обеспечивающий стойкие хорошие клинические результаты.

Ключевые слова: имплантат-ассоциированная инфекция позвоночника; инфекция области вмешательства; глубокая ранняя имплантат-ассоциированная инфекция позвоночника; VAC-система; вакуумная терапия; лечение отрицательным давлением; транспедикулярная фиксация.

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BACKGROUND

The importance of implantable metal fixators, which annually increases the number of spine surgeries, is beyond doubt [1]. Implantable metal fixators are used in modern vertebrology for the treatment of various disorders, including degenerative diseases, neoplasms, spinal deformities, and injuries [2, 3]. The overall number of spinal surgeries grew from 78 per 100,000 population in 1999 to 120 per 100,000 population in 2013 [4]. According to the Moscow Healthcare Department (as of 20072017), the absolute increase is from 4,252 to 8,032 each year (88.9%) [1]. However, as the number of surgeries increases, so does the incidence of associated complications, including implant-associated infections (IAIs) [5, 6]. According to various sources [3, 4, 7–9], the incidence of IAIs reaches 20%; moreover, their clinical significance is further increased due to high disability and mortality rates in patients with unfavorable treatment outcomes [10].

The treatment of IAIs, including vertebrological ones, poses a significant burden of healthcare systems [11]. These patients require multiple revision surgeries [6, 7], long-term antimicrobial therapy [12, 13], and (in some cases) costly medications, equipment, and consumables [14]. According to medical and economic analyses, each case of spinal IAI treatment is associated with 14 additional postoperative inpatient days and a 3–4-fold increase in expenses compared to the primary surgery that caused the IAI [2]. In the United States, the five-year average treatment expenses in these patients are estimated as $64,356–88,353, with the average costs per case without IAIs being $47,366 [15]. The annual treatment costs for the entire healthcare system in the United States reach $1.8 billion [16].

The use of implantable medical devices (including the metal fixators used in vertebrology), as well as other factors such as diabetes mellitus, obesity, hypertension, immunodeficiency, viral diseases (HIV, hepatitis B and C), smoking [1], malignancies, and prior chemotherapy [12], increase the risk of infectious complications [4, 17]. Metal fixation devices are a suitable substrate for microbial colonization (including opportunistic pathogens) and subsequent microbial biofilm formation [16, 18]. According to available data, the incidence of surgical site infections (SSIs) after microdiscectomy with and without metal fixation devices is up to 8.7% and 0.6–5.0%, respectively [1]. Yudistira et al. [4] observed a comparable incidence of IAIs with internal vertebrology devices, whereas Pappalardo et al. reported an incidence of 18% [19]. Karanadze et al. found a significant ($p < 0.05$) increase in the risk of SSIs in the presence of metal fixators [1].

Other risk factors for spinal IAIs include the type of trauma, urgency [1] and duration of surgery, intraoperative blood loss [17], multilevel spinal fixation [16], lesion location [12], and surgical approach. In particular, high-risk procedures include lumbar spine surgeries and surgeries with a dorsal approach [2, 20].

According to the generally accepted classification, IAIs are classified as superficial (affecting the skin and subcutaneous tissue) and deep (affecting deeper tissues below the aponeurosis) [9]. In terms of the time to onset, infections are classified as early (<3 months) or late (>3 months) [2, 15].

Early IAIs are characterized by hyperthermia, acute pain, local hyperemia, delayed wound healing, purulent discharge, and (in some cases) acute neurological deficit.

The diagnosis of early IAIs is rarely challenging and is based on physical examination findings, laboratory tests (including microbiology testing), and computed tomography, magnetic resonance imaging, and (in some cases) ultrasound findings [6]. In contrast, the diagnosis of late IAIs is difficult due to their subtle clinical presentation, which includes chronic pain syndrome, signs and symptoms of metal fixators' instability, and neurological deficit. Bone destruction of varying severity and location also contributes to the clinical presentation. Thus, the definite diagnosis requires both microbiological and histological findings for intraoperative biopsy samples [3].

IAIs necessitate comprehensive treatment involving various approaches, such as systemic antibiotic therapy, surgical debridement of the infection site, and implant removal (in the case of vertebrological IAIs, the latter must be balanced against the risk of spinal instability) [5, 19]. The treatment of early spinal IAIs generally provides better outcomes [15]. Notably, there is currently no unified algorithm for the treatment of deep IAIs; several surgical debridement procedures followed by long-term etiotropic antibiotic therapy in the postoperative period are typically recommended. Many authors recommend negative pressure wound therapy (NPWT) and/or an inflow/outflow system [11, 21]. Given the absence of a unified treatment protocol, the treatment option is typically determined by the surgeon's preferences and experience, as well as the capabilities of the medical institution or its specialty department [6].

Despite their effectiveness, continuous-flow washing systems are not widely used due to the high risk of catheter-associated infections [15, 22].

NPWT systems began to be used for the treatment of spinal IAIs after data on their advantages in similar pathologies located elsewhere became available [7, 8]. There is currently no consensus on the exact mechanism of action of NPWT systems in wound healing [5]. Constant negative pressure prevents microorganism adhesion to metal fixator (or bone tissue) surfaces, enhances tissue perfusion, and promotes angiogenesis. Moreover, it stimulates exudate removal from the surgical wound [2], reduces local edema [13, 23] and wound cavity size, and promotes fibrinolysis and granulation tissue formation [6, 24], creating favorable conditions for secondary healing [19] or flap surgery [21]. Given its benefits, NPWT has quickly gained recognition in the treatment of spinal IAIs. According to studies, NPWT reduces the wound size, wound healing time, number of revision surgeries [13], and length of

hospital stay, as well as improves clinical outcomes [21] in infectious complications after spine surgery.

However, despite significant research in this field [2], there is no uniform therapeutic approach and limited data on the use of NPWT in spinal IAIs, indicating that this subject requires further investigation.

The study aimed to assess the outcomes of NPWT in patients with early deep spinal IAIs.

MATERIALS AND METHODS

Study design

An observational, retrospective case series was performed.

Eligibility criteria

Inclusion criteria:

- primary spine surgery with transpedicular fixation;
- infectious (pyoinflammatory) complications in the form of a deep spinal IAI three months after the primary surgery;
- IAI treatment using negative pressure wound therapy (NPWT);
- long-term follow-up for at least 12 months after discharge.

Non-inclusion criteria:

- primary vertebrological intervention without transpedicular fixation;
- non-infectious complications (with any duration of follow-up) and/or IAI >3 months (late IAI) after the primary surgery;
- superficial IAI;
- inflow/outflow system as the primary treatment method;
- long-term follow-up <12 months after discharge.

Exclusion criteria:

- Therapy switching from NPWT to a washing system.

Study setting

The study included 28 patients: 16 females (57.1%) and 12 males (42.9%). The mean age was 43.6 years (min 17 years, max 88 years). All patients had a deep early IAI (<3 months after the primary surgery). Hospitalization (transfer) to a specialty department within 1 week was required in 5 patients (17.9% of the total number), within 1–2 weeks in 3 patients (10.7%), within 2 weeks to 1 month in 10 patients (35.7%), and within 1–3 months in 10 patients (35.7%). Table 1 presents the distribution of patients by the time to IAI after the primary surgery.

Primary vertebrological intervention was performed in 7 patients (25.0% of the total number) for degenerative-dystrophic changes of the spine, 12 patients (42.9%) for spinal deformity, 7 patients (25.0%) for a simple vertebral fracture, and 2 patients (7.1%) for vertebral spondylitis. Lesions or deformity apexes were distributed as follows: cervical spine (C1–C7) in 5 patients (17.8%), thoracic spine (Th1–Th12) in 8 patients (28.6%), thoracolumbar transition (Th12–L1) in 1 patient (3.6%), lumbar spine in 8 patients (28.6%), lumbosacral spine (L5–S1) in 3 patients (10.7%), and sacral spine in 4 patients (14.3%). All primary interventions (100.0%) were performed with a dorsal approach.

The average duration of primary surgery was 4 hours and 20 minutes (min 30 minutes, max 8 hours and 45 minutes), and the average blood loss was 737.5 mL (min 50 mL, max 1,800 mL). Prior spine surgeries were performed in 3 patients (10.7% of the total number), and revision surgeries (prior to the primary surgery, but before the initiation of NPWT) in 7 patients (25.0%).

Concomitant diseases classified as risk factors were reported in 19 patients (67.9%) (Table 2).

Clinical, laboratory, and X-ray examinations were performed in all patients during the preoperative period. Clinical signs and symptoms corresponding to IAIs are summarized in Table 3.

Computed tomography was performed to determine the borders of bone lesions and better view the metal fixators' installation site, whereas magnetic resonance imaging was used to assess the infection depth and purulent leakages/wound pockets. In the case of wound discharge or fistula, microbiology testing was performed with pathogen

Table 1. Distribution of patients by the time to implant-associated spinal infection after primary surgery with transpedicular fixation

Time to IAI	Absolute number of patients, *n*	%
<7 days	17	60,7
7 days to 2 weeks	6	21,4
2 weeks to 1 month	5	17,9

Note: IAI, implant-associated infection.

Table 2. Risk factors and comorbidities in study participants (*n* = 28)

Condition	Absolute number of patients, *n*	%
Hypertension	11	39,3
Age over 60 years	9	32,1
Smoking	9	32,1
Chronic infections	6	21,4
Diabetes mellitus	5	17,9
Coronary artery disease	4	14,3
Hepatitis C	3	10,7
Rheumatoid arthritis	1	3,6
Protein metabolism disorders	1	3,6
Obesity	1	3,6
Cerebral palsy with lower paraplegia	1	3,6

Table 3. Clinical symptoms in patients with early deep implant-associated spinal infections (*n* = 28)

Clinical symptoms	Absolute number of patients, *n*	%
Hyperemia/hyperthermia	21	75,0
Wound dehiscence	21	75,0
Edema	14	50,0
Pain	10	35,7
Purulent discharge	6	21,4
Neurological deficit	6	21,6
Fever	6	21,4
Infected hematoma/abscess	4	14,3
Wound edge necrosis	1	3,6

identification and antibiotic susceptibility assessment. Sampling was performed before surgery, after each surgical debridement (with an NPWT sponge replacement) from several areas, and postoperatively (at least three times). A histological examination of intraoperative biopsy samples was performed to confirm the acute infection and inflammation.

In the case of fistula, intraoperative fistulography was performed following preliminary microbiological sampling and triple antiseptic treatment of the surgical site. For this purpose, 1% brilliant green solution was injected into the fistulous tract using an intravenous catheter. Comprehensive treatment of spinal IAIs always included debridement of the lesion and adjacent tissue cavities (if any), fibrin plaque removal, necrectomy (including bones and soft tissues), granulation tissue removal around metal fixation devices, subsequent debridement, antibiotics, and implant retention (DAIR, at least 4 L), pulse lavage of the surgical wound with an antiseptic solution, and NPWT system placement (*Renasys Go and Renasys Ez*, Smith & Nephew). A polyurethane sponge adjusted to the wound cavity size was placed in the wound and attached to the skin with a film. A port installation window was made in the film, and a container for wound exudate collection was connected to the port. Wound drainage was performed at a constant pressure of 90–120 mm Hg. Surgical debridement with NPWT dressing changes was repeated every 3–5 days until the infection and inflammation resolved (as evidenced by clinical and laboratory findings). Notably, gradual wound suturing was performed in addition to NPWT as the wound was cleansed and filled with granulation tissue, to reduce its length and volume. A polyurethane NPWT sponge strip was placed over the closed wound, and the treatment continued for an additional 3–5 days.

In early deep infections, the metal fixator was preserved as long as possible (ideally, until a solid fusion formed). Implants were removed in the case of treatment failure, metal fixators' instability, or progressive deterioration of the patient's overall health status due to persistent infection with a high risk of fatal outcome.

In the postoperative period, all patients received systemic etiotropic antimicrobial therapy (based on laboratory data on the pathogen) and empiric therapy with broad-spectrum antibiotics (prior to receiving laboratory data on the pathogen). Antibiotic therapy continued until the IAI resolved completely, as evidenced by a triple negative bacterial culture, improved blood parameters (WBC, C-reactive protein [CRP], ESR, and fibrinogen [Fb]), complete wound healing, and improved overall health status.

Statistical analysis

IBM SPSS Statistics 26 was used for statistical analysis of study findings. Data are presented as mean and standard deviation (m ± SD). The Wilcoxon test was used to determine the significance of differences in laboratory blood parameters, which are used to assess the severity of inflammation at different time points. *P*-values of <0.05 were considered significant.

Ethics approval

The study followed the ethical standards of the *World Medical Association's Declaration of Helsinki*, as revised by the Ministry of Health of the Russian Federation. The patients provided informed consent for participation in the study and the publication of anonymized study findings.

RESULTS

Surgical debridement of the lesion with NPWT resulted in remission of infection in all cases (*n* = 28).

Transpedicular fixation was preserved in 18 cases (64.3%). Eight patients (28.6%) had all of their metal fixators removed. In one patient (3.6%) with lumbopelvic fixation, transverse connector instability in the lumbar spine was detected during the third surgical debridement with NPWT dressing change. As a result, the transverse connector was removed while other metal fixators components were left intact (partial removal). Subsequently, this patient required six more vacuum dressing changes to fully eliminate the infection. The other metal fixators' components did not show any signs of instability till the end of the follow-up. One patient (3.6%) with Th1–Th7 dorsal transpedicular fixation, Th3–Th5 interbody fusion with a cage and autobone, and posterior fusion with autobone required replacement of the metal fixator (refixation using a new system with a cage, with complete removal of previously placed metal fixator). This was due to persistent infection despite timely debridement with six NPWT dressing changes and the failure to achieve a solid thoracic fusion. Sustained remission of the infection was achieved with seven additional NPWT dressings.

The number of vacuum dressing changes during treatment ranged from 1 to 20. Patients with preserved and removed metal fixators required 1–11 changes (mean 5.5) and 5–13 changes (mean 6.6), respectively. Across all

Table 4. Laboratory blood parameters at admission and after treatment

Number of vacuum dressing changes	Blood parameters							
	WBC		C-reactive protein		ESR		Fibrinogen	
	M±σ	WT	M±σ	WT	M±σ	WT	M±σ	WT
0 (at admission)	11,19±4,32	–	119,79±96,92	–	56,00±9,21	–	5,85±1,65	–
1	8,24±3,11	**<0,001**	37,50±47,83	**0,017**	40,60±15,76	**0,021**	4,62±0,82	**0,005**
2	7,84±3,15	**0,017**	47,13±32,99	**0,028**	40,32±14,80	**<0,001**	5,39±1,66	0,31
3	7,68±3,02	0,182	30,00±38,06	**0,008**	43,31±16,28	**0,002**	6,66±1,83	0,5
4	8,36±3,77	0,182	33,86±43,61	**0,018**	38,90±17,93	**0,011**	4,97±1,31	**0,018**
5	8,20±2,87	0,08	77,40±70,32	0,144	41,60±18,19	0,08	7,93±2,19	0,285
6	7,75±3,29	0,104	34,75±6,60	0,144	45,11±22,54	0,109	5,69±1,44	–

Note: WT, Wilcoxon test. The significance of differences in parameters between a specific time point and baseline is presented. *P-values* < 0.05 are given in semi-bold.

groups, patients required an average of 5.7 ± 2.83 dressing changes to eliminate the infection.

In all cases, the surgical wound healed by secondary intention, with 27 patients (96.4%) receiving secondary sutures and one patient (3.6%) receiving soft tissue flap surgery. In one patient with soft tissue grafting, four consecutive necrectomies resulted in a significant musculocutaneous wound defect along the posterior aspect of the neck. This necessitated wound grafting with a rotation thoracodorsal myofasciocutaneous flap with a vascular pedicle harvested from the *latissimus dorsi* muscle.

Table 4 shows the descriptive statistics and asymptotic significance of differences in primary laboratory inflammation parameters compared to baseline.

In 27 patients (96.4%), there were no relapses of infection within one year after discharge. Only one patient with preserved metal fixator required readmission one month after discharge due to reinfection, which manifested as a fistula in the surgical scar area and X-ray signs of implant instability. The infection and inflammation resolved after surgical debridement with metal fixator removal, with no signs of neurological deficit or other spinal disorders.

Microbial growth was reported in 26 patients (92.9%). The bacterial culture was negative in two patients (7.1%), despite clinical signs of inflammation. Monomicrobial infection was observed in 23 patients (82.1%), and polymicrobial infection in 5 patients (17.9%). Overall, the study identified 69 different microorganism species, with 36 (52.2%) Gram-positive bacteria, 32 (46.4%) Gram-negative bacteria, and one (1.4%) *Candida spp.* The species composition of identified pathogens is presented in Table 5.

Changes in dominant pathogens during treatment, surgical debridement, and NPWT dressing changes were observed in 19 patients (67.9%). The number of these changes per patient ranged from 1 to 8 (mean 2.4). In four cases (14.2%), a monomicrobial culture was replaced by a two- orthree-component polymicrobial culture (three cases and one case, respectively). A polymicrobial culture was replaced by a monomicrobial culture in two patients (7.1%); in two more patients, the dominant pathogen was replaced in microbial associations. Only two of the nine polymicrobial communities identified during follow-up consisted solely of Gram-positive pathogens, whereas others included both Gram-positive and Gram-negative pathogens.

Clinical laboratory signs of improvement from the initiation of vacuum therapy to complete wound healing were reported within 7–112 days (mean 42.1 ± 23.31 days). The average duration of antimicrobial therapy (all courses) was 38.2 ± 18.1 days.

There were no complications associated with vacuum therapy during the study.

DISCUSSION

In this study, primary surgeries were most commonly performed for scoliosis, with degenerative-dystrophic changes being the second most common cause. This distribution is somewhat different from published data [4]. In the majority of cases (60.7%), early infections occur within the first week after primary spine surgery with metal fixation devices. Less commonly, spinal IAIs are observed within 2 weeks or 1 month after surgery (21.4% and 17.9%, respectively) (Table 1). According to available data, only 17.9% of patients are promptly (within 7 days) transferred or admitted to a specialty department as soon as the first clinical signs of inflammation appear. In 71.4% of cases, patients are admitted to a specialty department within 1–3 months. This is due to attempts of physicians who performed the primary surgery to treat the infection using stepwise necrectomies, air dressing, and inflow/outflow drainage in combination with etiotropic antibiotic therapy, or systemic antibiotic therapy without surgical debridement. The clinical signs of early spinal IAI were obvious in all cases, and the diagnosis was not difficult. The most common clinical manifestation in our study was wound dehiscence with hyperemia and hyperthermia (75.0%) (Table 3).

Table 5. Pathogen species composition in patients with early deep implant-associated spinal infections

Microorganism type		Absolute number of patients, *n*		%	
Staphylococcus aureus	*MSSA*	7	3	10,1	4,3
	MRSA		4		5,8
Staphylococcus epidermidis	*MSSE*	9	1	13	1,4
	MRSE		8		11,6
Enterococcus faecalis			6		8,7
Staphylococcus haemolyticus (MR)			3		4,3
Staphylococcus hominis (MR)			5		7,2
Staphylococcus warneri (MR)			2		2,9
Staphylococcus lentus (MR)			1		1,4
Corynebacterium spp.			1		1,4
Clostridium perfringens			1		1,4
Acinetobacter baumannii			8		11,6
Pseudomonas aeruginosa			6		8,7
Klebsiella pneumoniae			7		10,1
Escherichia coli			3		4,3
Proteus mirabilis			3		4,3
Enterobacter cloacae	*complex*	3	2	4,3	2,9
	disolvens		1		1,4
Aeromonas hydrophila			1		1,4
Burkholderia cepacia			1		1,4
Pantoea dispersa			1		1,4
Candida spp.			1		1,4
Total			**69**		**100**

Our findings are generally consistent with other studies, which show that early IAIs have distinct clinical manifestations [3] and typically occur within several days to three weeks after primary surgery with metal fixation devices [6, 25].

The most common patient-associated risk factors in our study were cardiovascular diseases (39.3%), smoking (32.1%), age over 60 years (32.1%), and chronic infections (21.4%) (Table 2).

As mentioned earlier, thoracic and lumbar surgeries and dorsal approach are associated with a high risk of spinal infections [2, 20]. Ventral approach was not used in any of the 28 patients in this study, indicating that dorsal approach may be associated with greater risk of IAIs in this anatomic area. The proportion of patients with primary thoracic and lumbar surgeries in our study was similar (25% vs 28.6%); however, their potential impact on IAI development remains unclear due to the relatively small sample size.

Surgical debridement in combination with NPWT in patients with early deep spinal IAIs resulted in 100% positive outcomes and promoted wound healing without grafting in 96.4% of cases. Metal fixators was preserved in 67.9% of cases (including the patient with partial metal fixator removal); only 3.6% of patients had infection relapse within one month after discharge. Notably, a relapse was observed in an immunocompromised patient with risk factors (hepatitis C, 60 years old) and delayed (two months after infection) initial presentation to a specialty department. The inflammation resolved after metal fixator removal with a single NPWT dressing application. A persistent infection despite six NPWT dressing changes was observed in one patient with preserved recently installed metal fixator. This patient required removal of the fixator, which would inevitably result in thoracic spinal instability and neurological deterioration. To prevent these complications, radical surgical debridement was performed, followed by transpedicular system and cage replacement. This approach to the treatment of an early deep IAI resulted in remission. Metal fixators could not be preserved in 8 cases (28.6%) despite several stepwise necrectomies and vacuum dressing changes; thus, the metal fixator was removed to achieve a favorable outcome. The proposed treatment protocol ensured sustained remission of the infection, with no further reactivation in the long term.

Thus, three treatment options with surgical debridement and NPWT as key components are available in spinal IAIs. These include preservation of metal fixator, radical surgery

with fixation device removal, and radical surgery with metal fixator replacement.

Despite ongoing efforts to reduce the impact of patient-associated risk factors and advancements in surgical techniques, the selection of a specific treatment approach in deep spinal IAIs in the presence of metal fixator in real-world practice remains debatable [11]. Existing guidelines for the treatment of infections are primarily based on retrospective analyses and small samples [23]. Radical surgical debridement with removal of metal fixator, which eliminates the persistent source of infection (including by removing microbial biofilms from metal fixation devices [26]), resulting in sustained remission and reduced risk of recurrence in the long term, appears to be the best therapeutic approach. However, surgeons rarely use this approach as the first-line therapy in deep spinal IAIs [4]. This is due to the risks associated with removal of metal fixator for the prevention of recurrent infection, which are considered unacceptable by some practitioners [13]. This is supported by published data [11] on the treatment of 267 patients who received continuous surgical wound drainage for spinal SSIs. By the end of the study, metal fixators were preserved in 231 patients (86.5%) and only needed to be removed in 37 patients (13.5%). Removal of metal fixators is more commonly used in late chronic infections (>3 months) [23], with X-ray signs of fusion and a minimal risk of spinal instability. According to published data, in late spinal SSIs, metal fixators are removed in 65.6–84% of cases [2, 14]. In early deep IAIs, preserved metal fixation devices are a priority [4], because their early removal may cause spinal instability, new-onset or worsening neurological deficit, progressive deformity, or false joint formation [11]. These complications may result in disability and deterioration of the patient's condition up to a fatal outcome [10], or require multiple revision surgeries in the future [13]. One exception are cases of early infection, where preserved metal fixator prevents the elimination of infection [4], and cases of extensive resection, where the fixation device cannot be removed and its complete or partial replacement is required.

According to medical history data, surgical debridement alone is insufficient for successful treatment of early deep spinal IAIs with preserved metal fixator. Multiple stepwise necrectomies are required, with equipment and techniques ensuring continuous drainage of the lesion, such as NPWT systems. Stepwise debridement and dressing changes must be performed until the wound heals completely and clinical laboratory remission of the infection is confirmed. To achieve remission in this study, an average of 5.7 ± 2.83 NPWT dressing changes were required. Notably, blood tests showed a significant decrease in inflammatory markers already after the first dressing change (Table 4). Our values are slightly higher than those obtained in other studies, where complete wound healing in early deep IAIs required an average of 2.7–4.7 NPWT dressing changes [23]. For example, Wang et al. reported infection remission after an average of 2.8 dressing changes [27]. Shapovalov et al. achieved favorable outcomes in deep early IAIs of the lumbar spine after 4.1 ± 1.73 NPWT dressing changes (maximum 8 changes) [6]; comparable findings were reported by Rickert et al. [25]. Some studies report even lower values of 0.7 [8] to 2.2 [28] dressing changes. The high average number of NPWT dressing changes in our study is most likely due to the prevalence of antibiotic-resistant pathogens (Table 5) with constantly changing species composition. We most commonly observed a shift from Gram-positive to Gram-negative pathogens. As reported in our previous work, *MRSE* and *E. faecalis* were the most prevalent during Weeks 1 and 2 of treatment, whereas *P. aeruginosa* and *A. baumannii* were the most prevalent during Weeks 3 and 4. *E. faecalis* and *P. aeruginosa* were detected with similar prevalence during Month 2 and were subsequently replaced by multidrug-resistant Gram-negative pathogens [24]. Changes in dominant pathogens made previously prescribed etiotropic antibiotic therapy ineffective. Therefore, sampling from several intraoperative sites, continuous monitoring of pathogen species composition, and timely modifications of antimicrobial therapy are crucial for successful treatment in patients with spinal IAIs.

Another factor responsible for the high number of NPWT dressing changes is gradual wound suturing during NPWT and a single NPWT dressing application to the closed wound. This approach is based on practical experience with NPWT, where NPWT system removal with immediate wound closure in deep spinal IAIs results in infection reactivation in the early postoperative period in the vast majority of cases. Attempts to preserve metal fixator in combination with a polymicrobial antibiotic-resistant infection, one or several IAI risk factors, and reduced restorative capacity of the body were also associated with a high number of vacuum dressing changes, which is consistent with other publications [4, 6].

The average duration of NPWT in our study was 42.1 ± 23.31 days (range: 7–112 days), which is nearly twice as short as in the study by Kurra et al. (77 days; range: 7–235 days [8]) and 1.5 times longer than in the study by Shapovalov et al. (29.1 ± 10.06 days; range: 14–55 days [6]). Notably, the number of inpatient days in our study was greater in patients with removed metal fixators than those with preserved devices. This is due to a larger number of attempts to preserve the implant and difficulties with infection treatment, which necessitated extended inpatient care and follow-up.

Treatment outcomes in our study are generally consistent with other studies. According to these data, NPWT in patients with spinal SSIs results in 80–100% favorable outcomes. For example, one study reported 98.36% positive outcomes in the treatment of early spinal IAIs, with metal fixators preserved in 83.46% of cases [2]. Notably, these high values were likely because the study included patients with early superficial spinal infections. According to Rickert et al., NPWT with subfascial sponge placement produced 100% favorable outcomes with preserved metal fixators [25]. Wang

et al. reported comparable findings [27]. In another study, NPWT enabled preserving metal fixation devices in 75.5% of cases [11]. In yet another study, metal fixation devices were preserved in 64% of cases. According to the authors, three or more vacuum dressing changes reduce the risk of recurrent infection: two and three NPWT dressing changes resulted in reinfection in 13.5% and 0% of cases, respectively. The incidence of persistent IAIs during NPWT with preserved metal fixators in this study was 7.5% [13] vs 3.6% in our study, which may be due to different sample sizes.

Khanna et al. reported that stepwise surgical debridement without NPWT decreases the likelihood of preserving metal fixators (62.7%, 25.9%, 16.7%, and 0% after the first, second, third, and fourth intervention, respectively) [29]. Dolotin (citing Ho et al.) reported a high incidence of reinfection (up to 50%) in patients with preserved metal fixators who received DAIR [9, 30]. A retrospective cohort study found that debridement with systemic antimicrobial therapy is insufficient to eliminate infection, with preserved metal fixators in 35% of cases in early spinal IAIs and 54% of cases in late spinal IAIs [31].

Study limitations

One limitation of this study is the small sample size, necessitating further research in larger patient populations. Despite this limitation, the study demonstrated the efficacy and safety of surgical debridement in combination with NPWT in early deep spinal IAIs. The proposed technique allowed preserving metal fixators in more than 50% of cases and resulted in sustained remission of the infection and inflammation in 100% of cases.

CONCLUSION

NPWT in combination with surgical debridement in patients with early deep spinal infections results in a significant proportion of favorable clinical outcomes. Negative pressure facilitates wound cleansing and filling with granulation tissue, reducing the size of the wound cavity and promoting wound closure. All these factors contribute to preservation of metal fixators in more than 50% of cases. Notably, preservation of the fixators in early infections requires multiple debridement procedures with NPWT dressing changes. The number of these interventions varies widely depending on comorbidities, restorative capacity of the body, pathogen resistance, frequency of changes in species composition, and other factors, with an average of 5.7 ± 2.83 dressing changes.

ADDITIONAL INFO

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ДОПОЛНИТЕЛЬНО

Вклад авторов. Все авторы подтверждают соответствие своего авторства международным критериям ICMJE (все авторы внесли существенный вклад в разработку концепции, проведение исследования и подготовку статьи, прочли и одобрили финальную версию перед публикацией).

Источник финансирования. Авторы заявляют об отсутствии внешнего финансирования при проведении исследования и подготовке публикации.

Конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с проведённым исследованием и публикацией настоящей статьи.

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