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Selective resection of the bone with preservation of soft tissues ("empty toe technique") combined with negative pressure wound therapy for treatment of osteomyelitis of the great toe - a case report

Jacek Białecki, Przemysław Pyda, Michalina Hupało-Tatarkiewicz

CASE REPORT

***Abstract*— Diabetic foot ulceration (DFU) is a serious complication of diabetes mellitus and one that is difficult to treat. In many cases of DFU, chronic osteomyelitis occurs in the foot. The present paper describes the course of treatment for chronic osteomyelitis of the great toe with metatarsophalangeal arthritis using selective resection of the bone-preserving the soft tissues (the "empty toe technique"). Following the procedure, to promote surgical wound healing, negative pressure wound therapy (NPWT) was administered for 7 days, with a constant pressure of –120 mmHg. The presented method was found to be effective in treating osteomyelitis in a patient with DFU, partially preserving the function and completely preserving the shape of the treated toe.**

***Keywords*—negative pressure wound therapy, diabetic foot, amputation**

I. Introduction

DIABETES mellitus is a growing public health concern. One of its complications is diabetic foot ulceration (DFU), which occurs in more than 6% of diabetic patients.[1] In many DFU cases, chronic osteomyelitis occurs, often involving the forefoot. In these cases, local treatment combined with targeted antibiotic treatment is used.[2–4] Preserving the function of the limb is a major therapeutic objective. The scope and extent of any surgical intervention depend on the condition of the foot and patient's response to treatment. In many cases, antibiotic treatment proves ineffective due to poor penetration of the antibiotic into the bone, necessitating the use of increasingly radical surgical treatment. Conservative procedures may result in DFU recurrence.[5] Sadly, even small resections may affect the biomechanics of the patient's foot. To avoid extensive amputations, only the infected part of the bone is removed, with the smallest possible margin around the damaged and dead tissue.[6, 7] Only when this way of treatment fails does radical amputation become necessary.

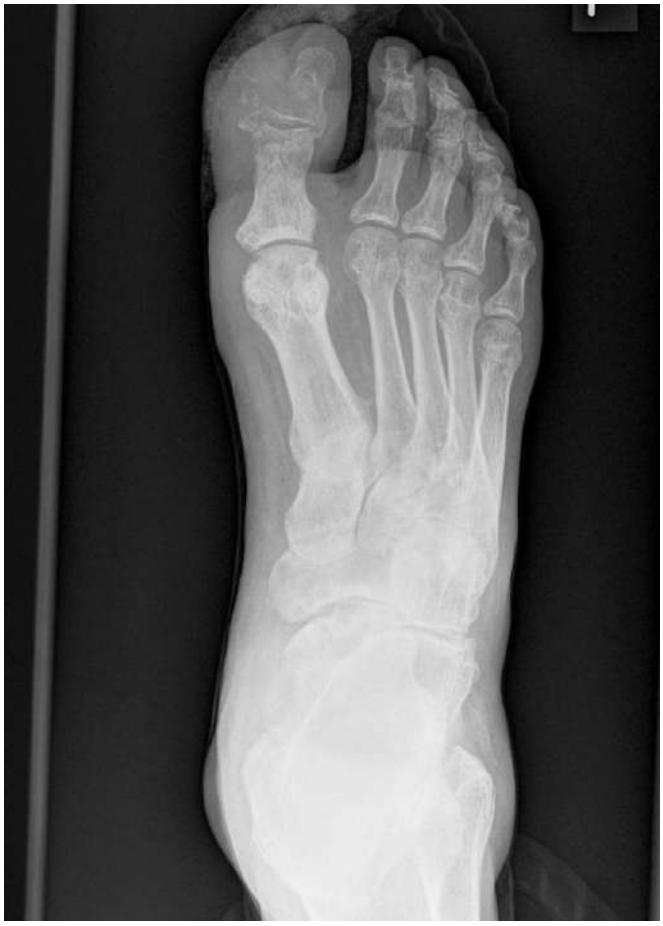

Figure 1. Pre-surgery foot radiograph showing signs of chronic osteomyelitis.

Local surgical treatment of DFU is widely used in combination with negative pressure wound therapy (NPWT), which has proven particularly valuable in assisting the healing of the surgical wound.[8, 9] The subsequent sections of this paper describe the course of treatment for chronic osteomyelitis

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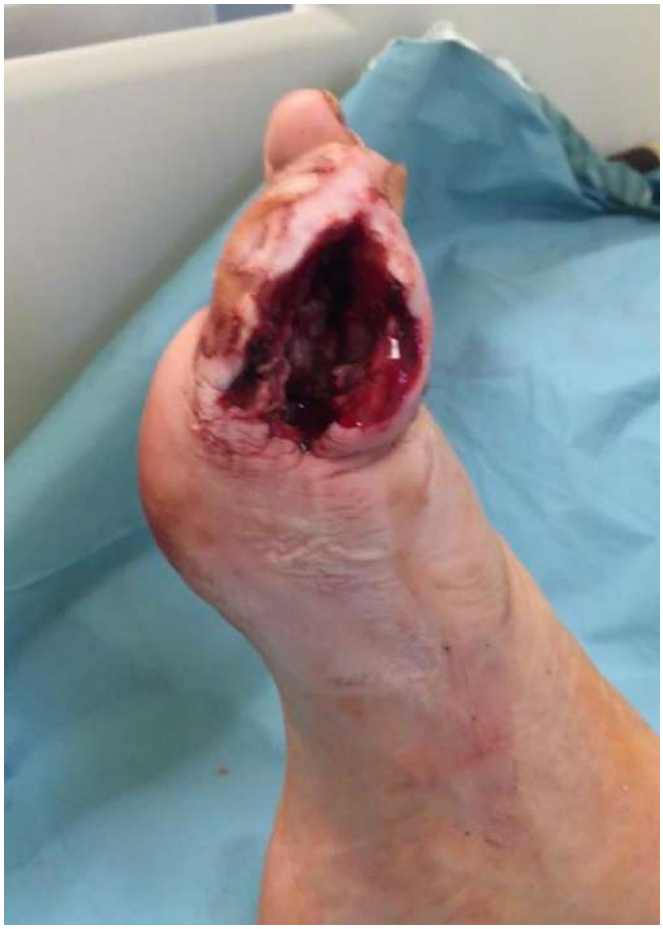

Figure 2. The great toe after the selective resection of both phalanges and the metatarsophalangeal joint (empty toe technique).

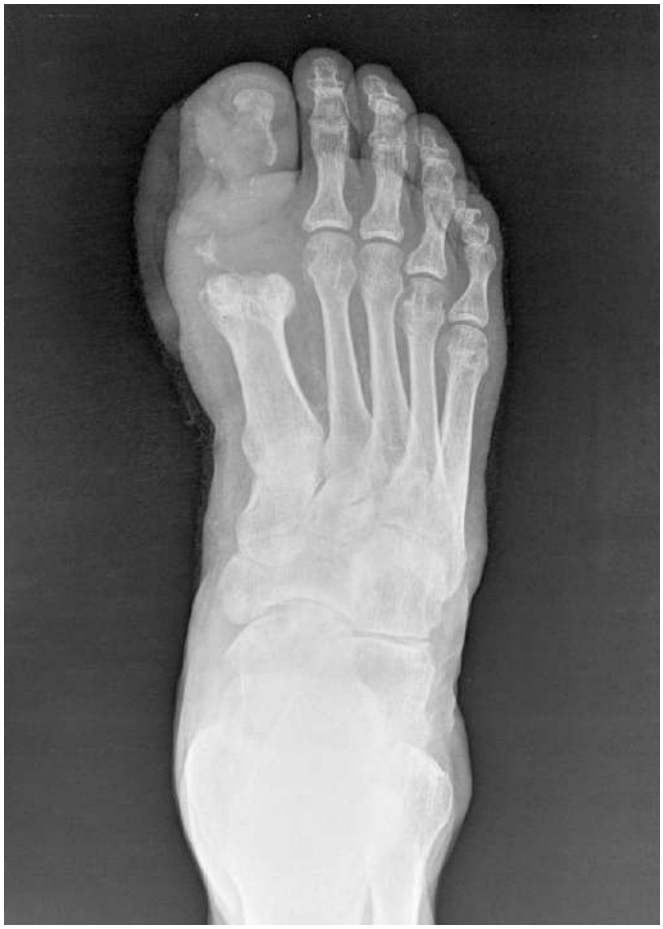

Figure 3. Radiograph of the treated foot on the 1st post-operative day.

of the great toe with metatarsophalangeal arthritis using selective resection of the bone-preserving the soft tissues (the "empty toe technique"), combined with NPWT and antibiotic treatment.

II. Case report

A 44-year old male patient with type 1 diabetes presented with inflammation and phlegmon in the great toe of the right foot. Inflammatory symptoms had intensified over the previous 14 days. Following clinical examination and radiography, chronic osteomyelitis was diagnosed, with an inflammatory reaction in the surrounding soft tissue 1. The patient was scheduled for surgery. On admission, standard first-line antibiotics were started Taromentin 2 x 1,2 g i.v. (1000 mg amoxicillin + 200 mg clavulanic acid) and samples were collected for culture.

The patient was anesthetized with an injection of 2% lignocaine at the base of the great toe. A 3 cm longitudinal incision was made on the lateral surface of the toe. Using this approach, both phalanges and the metatarsophalangeal joint were dissected free and removed. The head of the first metatarsal bone was preserved, with the articular surface removed. Soft tissue in the toe was preserved, with only small portions adjacent to the bone and affected by inflammation removed 2. Following the procedure, the wound was dressed using a non-woven dressing impregnated with Povidone. An X-ray was performed 3.

The radiograph showed a small fragment of the lamina of the distal phalanx remaining after the resection, which had not been visible during the surgery. The dressing was first changed after 24 hours. The next day, NPWT was started. The foam dressing was cut so as to cover the wound without filling the space left by the resected phalanges. The dressing was sealed, and constant negative pressure of –120 mmHg was applied 4.

After 3 days of NPWT, the dressing was removed. The wound was clean and granulating, with no signs of infection. A fresh dressing was applied, and NPWT was continued for 4 subsequent days. 5 days after the procedure, the antibiotic susceptibility test results revealed a Streptococcus agalactiae strain sensitive to Augmentin; therefore, the previous antibiotic treatment was continued until the 9th postoperative day. Throughout the NPWT period, the volume of drained serosanguineous fluid was approx. 50 mL total. NPWT was discontinued on the 9th postoperative day (after 7 days of administration). The wound was clean, granulating abundantly, with no inflammatory discharge 5.

The patient was discharged after 10 days of hospitalization and subsequently treated on an outpatient basis. He was

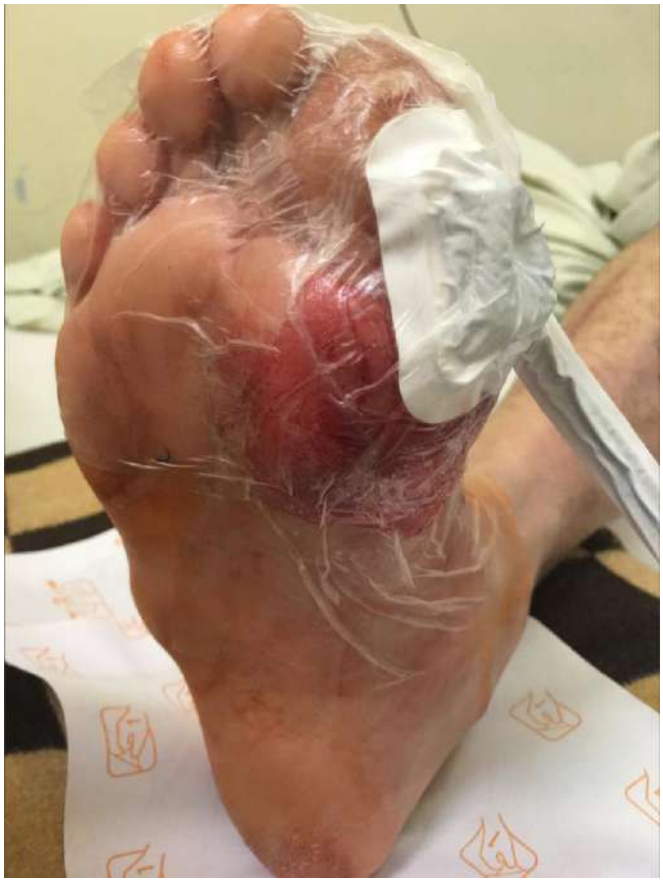

Figure 4. The foot with the NPWT dressing.

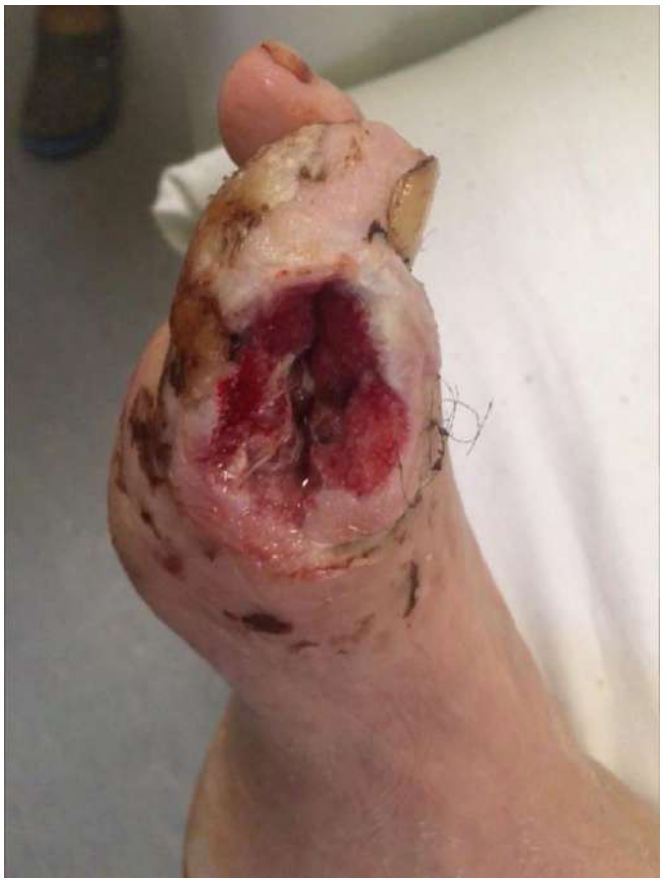

Figure 5. The surgical wound after 7 days of NPWT.

instructed to use a post-operative shoe for 6 weeks. The patient changed his dressings himself and was followed-up periodically at a diabetic foot clinic. Four months after the surgery, the wound was fully healed and the patient reported no complaints 6.

After 6 months, a follow-up examination was performed. The patient was in overall good condition. The surgical scar was pale, with no inflammation 7. The patient reported no pain in the foot or the treated toe. The toe had a normal blood supply and temperature. The patient reported impaired sensation in the toe, indicative of neuropathy, the same as before the onset of inflammatory symptoms. The range of passive dorsiflexion was 30 degrees, plantar flexion – 5 degrees. After flexion, the toe spontaneously returned to the initial position. Soft tissue compactness and elasticity was similar to that found in healthy toes. The toe had no active mobility. The patient reported no significant difficulties in walking. No areas of excessive load, in the form of corns and calluses or other plantar tissue deformations, were found. The arch of the foot was normal. An X-ray was performed 8. In the distal portion of the toe, within the site from which the distal phalanx had been removed, and directly adjacent to the remaining bone fragment seen in the previous radiograph 2, there was an expanding area of extraskeletal bone formation, which seemed to be filling the space from which the distal phalanx had been removed.

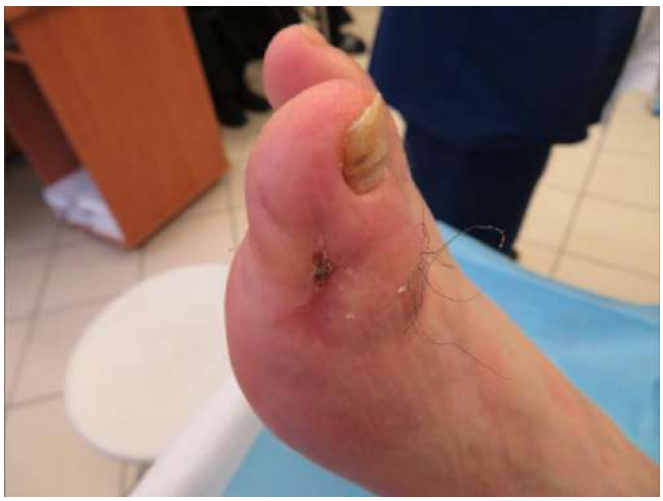

Figure 6. The surgical wound 4 months post-operatively.

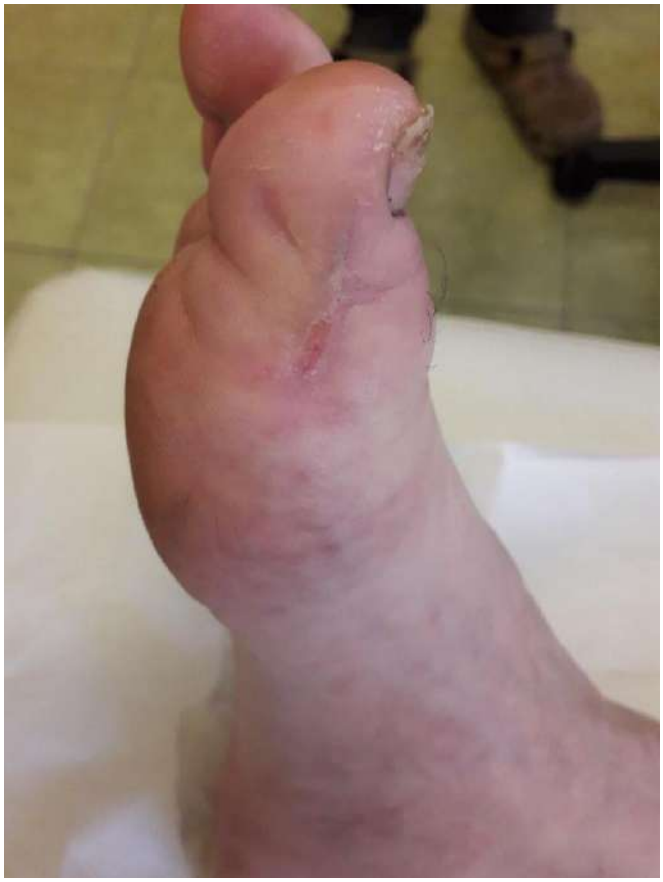

Figure 7. The surgical wound 6 months post-operatively.

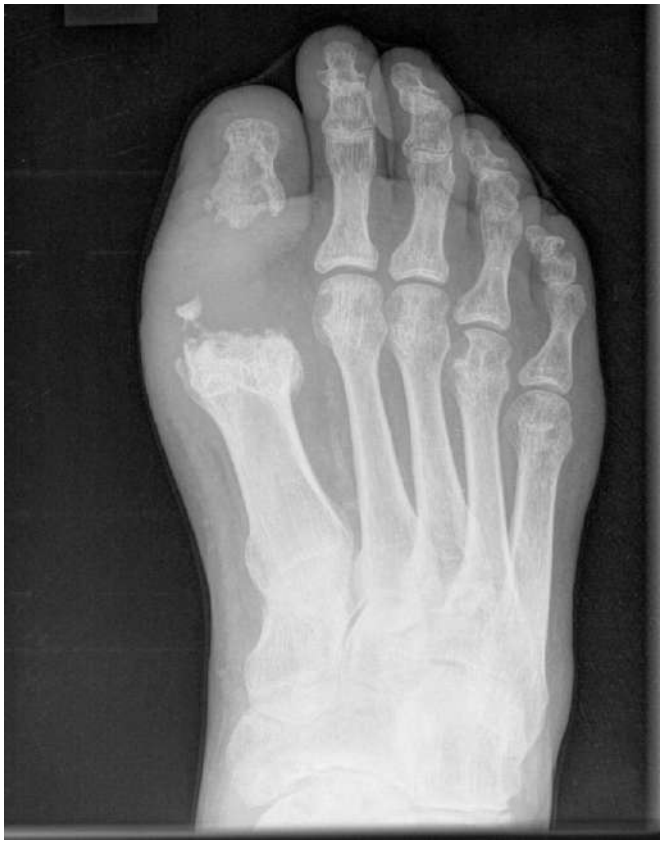

Figure 8. Radiograph of the treated foot 6 months post-operatively, showing an extraskeletal bone formation process.

III. Discussion

The treatment method used, the "empty toe technique", enables the soft tissue of the toe to be preserved despite amputation of the phalanges. Thus, the toe itself is preserved. When only a portion of the phalanges is removed, the toe can be reconstructed using antibiotic-loaded bone cement and stabilized with an external fixator.[10] In the present case, such a course of treatment was not possible, as both phalanges and part of the joint required resection. A decision was made, though, to preserve the soft tissue of the toe. Benefits of this technique for the patients are mainly aesthetic and psychological in nature, as the treatment leaves no external signs of amputation. Preserving the toe may increase the patient's compliance with treatment and willingness to undergo further treatment. In theory, this technique also offers an opportunity for future reconstruction of hard tissue. One question concerns the function of the toe. When DFU is treated surgically, the impact of the treatment on gait mechanics, and on static and dynamic load distribution in the treated foot, is an important consideration.[11, 12] It seems that the "empty" toe does not have a significant stabilizing function. With regard to gait mechanics, the removal or preservation of soft tissue is most likely insignificant. However, preserving the shape of the foot improves the fit of footwear. If the toe is fully amputated, the fit must be ensured e.g. by using filler inserts. Another potential concern is the flaccidity of the "empty" toe, which might cause discomfort for the patient or lead to subsequent mechanical injury. The 6-month follow-up showed that the treated toe retained its shape, compactness, and elasticity despite bone removal, and the patient reported no inconvenience or discomfort.

The surgical wound was healed using NPWT, a common method in DFU treatment. Arguably, it was NPWT that made it possible for the wound to heal. NPWT assists in soft tissue healing by evacuating the discharge, proinflammatory factors, and bacteria, while promoting granulation within the area from which bone was removed. Thus, the "empty" toe is partially filled, regaining some of its compactness and elasticity. The presented "empty toe technique" for selective resection of the bone-preserving the soft tissues, combined with NPWT and antibiotic treatment, is a promising treatment for chronic osteomyelitis affecting toe phalanges and metatarsophalangeal joints. Further studies are warranted to confirm its effectiveness.

References

[1] P. Zhang, J. Lu, Y. Jing, S. Tang, D. Zhu, and Y. Bi, "Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis," *Annals of medicine*, vol. 49, no. 2, pp. 106–116, 2017.

[2] J. L. Lázaro-Martínez, J. Aragón-Sánchez, and E. García-Morales, "Antibiotics versus conservative surgery for treating diabetic foot osteomyelitis. a randomized comparative trial," *Diabetes Care*, p. DC_131526, 2013.

[3] E. Senneville, A. Lombart, E. Beltrand, M. Valette, L. Legout, M. Cazaubiel, Y. Yazdanpanah, and P. Fontaine, "Outcome of diabetic foot osteomyelitis treated non-surgically: a retrospective cohort study," *Diabetes Care*, 2008.

[4] L. Giurato, M. Meloni, V. Izzo, and L. Uccioli, "Osteomyelitis in diabetic foot: A comprehensive overview," *World journal of diabetes*, vol. 8, no. 4, p. 135, 2017.

[5] J. Aragón-Sánchez, "Treatment of diabetic foot osteomyelitis: a surgical critique," *The international journal of lower extremity wounds*, vol. 9, no. 1, pp. 37–59, 2010.

[6] F. Aragón-Sánchez, J. Cabrera-Galván, Y. Quintana-Marrero, M. Hernandez-Herrero, J. Lazaro-Martinez, E. Garcia-Morales, J. Beneit-Montesinos, and D. Armstrong, "Outcomes of surgical treatment of diabetic foot osteomyelitis: a series of 185 patients with histopathological confirmation of bone involvement," *Diabetologia*, vol. 51, no. 11, p. 1962, 2008.

[7] G. H. Van, H. Siney, J.-P. Danan, C. Sachon, and A. Grimaldi, "Treatment of osteomyelitis in the diabetic foot: contribution of conservative surgery," *Diabetes Care*, vol. 19, no. 11, pp. 1257–1260, 1996.

[8] M. Y. Hasan, R. Teo, and A. Nather, "Negative-pressure wound therapy for management of diabetic foot wounds: a review of the mechanism of action, clinical applications, and recent developments," *Diabetic foot & ankle*, vol. 6, no. 1, p. 27618, 2015.

[9] S. Liu, C.-z. He, Y.-t. Cai, Q.-p. Xing, Y.-z. Guo, Z.-l. Chen, J.-l. Su, and L.-p. Yang, "Evaluation of negative-pressure wound therapy for patients with diabetic foot ulcers: systematic review and meta-analysis," *Therapeutics and clinical risk management*, vol. 13, p. 533, 2017.

[10] L. Dalla Paola, A. Carone, C. Morisi, S. Cardillo, and M. Pattavina, "Conservative surgical treatment of infected ulceration of the first metatarsophalangeal joint with osteomyelitis in diabetic patients," *The Journal of Foot and Ankle Surgery*, vol. 54, no. 4, pp. 536–540, 2015.

[11] L. A. Lavery, D. C. Lavery, and T. L. Quebedeax-Farnham, "Increased foot pressures after great toe amputation in diabetes," *Diabetes Care*, vol. 18, no. 11, pp. 1460–1462, 1995.

[12] P. J. Kim, "Biomechanics of the diabetic foot: consideration in limb salvage," *Advances in wound care*, vol. 2, no. 3, pp. 107–111, 2013.

Aplication of NPWT in the surgical treatment of wounds and injuries of various locations - case series

Zarutskii Ya.L., Aslanyan S.A., Plis I.B., Kompaniiets A.O., Goncharuk V.S.

CASE SERIES

***Abstract*— In the modern world, local military conflicts are not uncommon. A feature of local wars is a dynamically changing tactical situation, which can lead to massive losses and more serious injuries. This creates new challenges related to the treatment of combat trauma victims. We analyzed our experience of application of NPWT in complex surgical treatment of combat wounds and injuries of various locations.**

***Keywords*—npwt, gunshot wounds, VAC therapy, combat trauma**

I. Introduction

THE military conflict in the East of Ukraine led to a significant increase in the number of explosive and gunshot wounds, both among the armed forces and the civilian population.[1, 2] In the structure of modern combat surgical trauma, the main part is shrapnel 61.6% and bullet 9.1% gunshot wounds, blast trauma and burns are 27% and 2.3% respectively.[1, 3]

During the Anti-terrorist operation in the east of Ukraine, the largest proportion was head injuries 31.9%, thorax 11.7% abdomen 7.3% and limbs 62.6% (Tab. I).[4]

The problem of the treatment of gunshot wounds and their consequences remains the main task of military field surgery, because of the complexity of diagnosis and treatment, with long hospitalisation terms, accompanied by a large number of complications (12-47%) with a high percentage of disability (4.9-7.3%).[1, 5, 6]

The main task of military surgery in the treatment of gunshot wounds of various locations is to shorten the terms of treatment, the early return of the wounded to duty.[7]

The main method of gunshot wounds treatment still remains primary, repeated and secondary surgical debridement with subsequent application of sterile dressing. The final stage of treatment is the closure of a wound defect by one of the plastic surgery methods according to the "reconstructive ladder".[6, 8, 9]

Large gunshot defects of tissues with complex forms of a wound channel, presence of important anatomical formations on the bottom of wounds create significant difficulties with wound-dressing modeling, their superposition and ensuring adequate outflow of wound exudate.

Considering the foregoing, in the complex surgical treatment and preparation for the closure of the gunshot wounds of the soft tissues of the chest, abdomen and pelvis, the NPWT method rapidly spread.

The aim of the study was to study the results of treatment of victims with gunshot wounds of various localizations by applying NPWT techniques in complex surgical treatment.

Table I
STRUCTURE OF COMBAT TRAUMA (COMBINED TRAUMA ACCOUNTED)

Localization	Total [%]	Soft tissues [%]
Head	31,9	26,3
Neck	1,9	0,9
Spine	1,1	-
Thorax	11,7	9,3
Abdomen	7,3	4,9
Pelvis	2,6	1,5
Limbs	62,6	48,9
Burns	2,7	2,7
Combined	22,7	22,7

II. Materials and methods of research

We carried out the analysis of treatment results of 195 gunshot wounded, who were treated with NPWT method in the National Military Medical Center of the Ministry of Defense of Ukraine in the period from 2014 to 2017.

All the injured were male with an average age 39.6 $\pm$ 5.3 years. In 37.8% there were wounds of soft tissues, in 62.2% of wounds were connected with open gunshot fractures of bones of upper and lower extremities, required immobilization with external fixation. All the wounded came from institutions II and III levels of medical care by air and land medical evacuation within a period of 3 to 20 days from injury.

NPWT was performed with a usage of KCI, HearCo, GomCo, and other VAC systems, in combination with irrigation with antiseptics and antibiotics, with oxygen insufflation, hyperbaric oxygenation, ultrasonic cavitation, NO therapy for additional stimulation of repair processes.

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The NPWT technique is universal and has been used at various stages of wound healing:

1) Immediately after wound debridement to prevent infection.
2) In cases of infectious complications development.
3) As a stage of preparation of wound defects to plastic closure.
4) After reconstructive interventions, as a method of postoperative wound care.

Figure 1. Shrapnel gunshot wound of the head. Surgical treatment of soft tissue defect.

Indications for the use of NPWT in cases with head injuries (n = 6) were infected wounds, temporary closure of soft tissue defects. The purpose of NPWT was: cleansing infected wounds, reducing their size, stimulating granulation tissue and preparing for plastic closure (Fig. 1).

Contraindications to the use of NPWT were: the presence of wounds connected with the oral cavity, penetrating injuries of the ENT organs, osteomyelitis of subordinate bones, necrotic tissue, bleeding or liquorrhea in the wound area. When the bandages come into contact with the main vessels of the head, standard or improvised protectors were used. In the world literature there are reports of the successful use of NPWT in injuries with defects of the dura mater.[1]

NPWT of infected wounds in the neck (n = 3) was used to temporarily close the wounds at the stage of preparation for their plastic closure (Fig. 2).

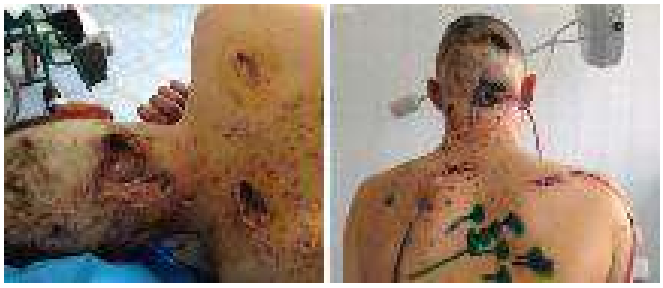

Figure 2. Multiple shrapnel wounds of the head, neck, thorax. NPWT of soft tissues of the neck.

Contraindications to the imposition of vacuum dressings were bleeding in the wound area, the main vessels of the neck in the bottom of wound defects, defects of the esophagus, trachea. The NPWT system was applied with -75 Hg mm.

Indications for the use of NPWT in chest injuries (n = 7) were infected wounds of the chest wall, defects of the chest wall with open pneumothorax, presence of a wound of the chest wall in combination with pleural empyema, temporary

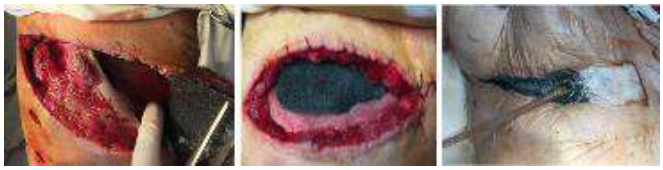

Figure 3. Treatment of pleural empyema after thorax combat injury: left – resec tion of the rib, thoracostomy; middle – closure of chest wall defect with a sponge; right – NPWT of the chest wall defect.

closure of the wound in preparation for thoracoplasty. Contraindications to the application of NPWT were osteomyelitis of the ribs or sternum, excessive necrotic tissue, bleeding in the wound area, unexplored fistula, bronchial fistulas (relative contraindication) (Fig. 3).

We have experience in applying a sponge to an intact pleura, and if the pleura was damaged polyvinyl-alcohol white sponge protectors have been used. In cases of doubt in the viability of the ribs, perforation was performed or, according to indications, the external cortical rib plate was removed and, after evaluation of the blood supply, the closure was completed with a polyurethane sponge. With pleural empyema or pericarditis, NPWT made it possible to accelerate the eradication of the inflammatory focus.

With penetrating wounds of the abdominal cavity (n = 25), indications for NPWT usage were: open wounds of the abdominal cavity and abdominal wall defects (3), abdominal compartment syndrome (3), postoperative complications of the abdominal cavity organs (ischemic abdominal syndrome (2), progressive peritonitis (6), postoperative complications of the wound (10), burns of the abdominal wall (1). The purpose of the NPWT was adequate sanitation of the abdominal cavity, removal of the compartment syndrome, and the tactics of conducting the open abdomen (Fig. 4).

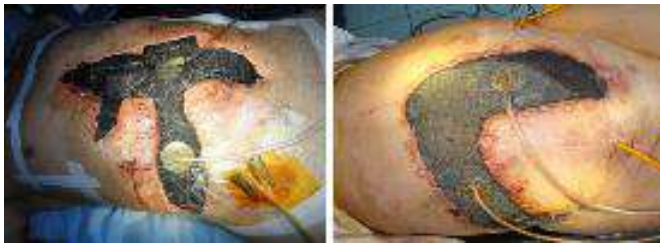

Figure 4. NPWT in abdominal combat wounds: gradual wound closure

Absolute contraindications to the use of NPWT with injuries of the abdomen were: active bleeding, unstable hemostasis, and not a sanitized septic focus; intestinal, bile, urinary fistulas, a large number of necrotic tissues or abdominal wall defects, that did not allow to create a closed space.

Relative contraindications were: violation of the blood clotting, a defect in the wall of hollow abdominal organs (enteroatmospheric fistula).

When forming a vacuum bandage, the sponge should not come into direct contact with the hollow organs. Standard (AV-Thera) or improvised protectors with a polyurethane sponge and an adhesive film were used to prevent complications.

In case of peritonitis, bandages were replaced after 24-48 hours. With abdominal compartment syndrome, IAP monitoring is mandatory 2-4 times a day (no more than 15 mm). In cases of enteroatmospheric fistulas, standard or improvised obturators were used (Fig. 5).

Indications for the NPWT usage in pelvic injuries were infected wounds, which were temporarily closed in the preparation for plastic closure. Contraindications: active foci of osteomyelitis, unexplored fistulas, rectum damage, unreliable hemostasis. With injuries to the pelvic organs (n = 6) and perineum, there were technical problems in achieving tightness of NPWT dressings due to the complex relief of the site.

e have experience of successful application of NPWT with bladder damage and thrombosis of the cavernous bodies of the penis (Fig. 6).

Figure 5. NPWT sn cases of enteroatmospheric fistulas: left – placement of improvised obturator; middle – applying of NPWT; right – wound closure with functioning fistula.

Figure 6. Left – NPWT of perineum wound; middle and right – NPWT of abdominal wall with functional suprapubic cystostomy.

Victims with limb injuries were the most numerous group of clinical observations (n = 147). NPWT was used in the presence of infected wounds and for temporary closure in preparation for plastic closure according to the "reconstructive ladder" introduced in the modern surgical treatment system. Contraindications: foci of osteomyelitis, unexplored fistula, necrotic tissue, active septic process (Fig. 7)(Fig. 8).

When forming NPWT dressings on limbs, the sponge should not be in contact with: large neural trunks (threat of necrosis of nervous tissue), large vessels (threat of hemorrhage). To prevent these complications, standard polyvinylalcohol sponge protectors from poly were used.

In cases of combined wounds with various anatomical and functional sites polyfocal NPWT were used with one or several vacuum devices. In this case, it became necessary to form external improvised or standard bridges for remote localization of injuries, as well as internal bridges, which densely contacted the main sponge with wound defects located nearby. Internal bridges should not be in contact with vessels and nerves.(Fig. 9)

Figure 7. NPWT in treatment of injured lower limb: left - tissue defect in the foot area; middle - tissue defect in the shin area; right - forming closure.

The presence of external fixation devices made it difficult to achieve the tightness of the VAC bandage. When carrying out VAC therapy of large and extensive wounds, there is a threat of thrombosis of large main vessels - therefore, prior to the application of NPWT dressings, the condition of blood circulation by means (ultrasound, doppler, pulse oximeter, etc.) must be determined.

When combined wounds of various anatomical and functional sites were present, we used polyfocal NPWT using one or several vacuum devices. In this case, it became necessary to form external improvised or standard bridges for remote localization of injuries, as well as internal bridges, which densely contacted the main sponge with a number of wound defects located nearby. Internal bridges should not be in contact with vessels and nerves.

Figure 8. Blast injury with traumatic amputation of right lower limb at the level of the middle third of the shin: left – skin necrosis; middle – NPWT of right lower limb stump; right – closure of defect with tension system (TopClosure).

When closing the wound defects, rare stitches were applied, which were externally covered with a gauze cloth, and the skin was protected with a tread. The polyurethane sponge was fixated to the edges of the wound to prevent its displacement.

In cases of deep blind wounds with a narrow wound canal, deep pockets were plugged with separate sponges with close contact with the main sponge which filled the wound channel and had perforated drainage inside. In cases of presence of bones with signs of osteomyelitis, decortication of the bone was performed, followed by application of a polyurethane sponge to the destruction site. This accelerated the elimination of osteomyelitis foci, stimulated regional blood flow and growth of granulation tissue.

At deep extensive defects the sponge was stacked in several layers before the full execution of the wound. When performing NPWT instillation, good results were obtained when placing drainage through the counter aperture directly to the wound surface.

The application of polyvinylalcohol vacuum dressings at low negative pressures was used to manage wounds after autodermoplasty with significant wound exudation, to contain

the split autodermotransplant in the complex relief of the wound surface, to accelerate its integration, and to prevent the traumatization of the graft.

Figure 9. Blast injury with traumatic amputation of right lower limb at the level of the middle third of the shin: left – skin necrosis; middle – NPWT of right lower limb stump; right – closure of defect with tension system (TopClosure).

Features: when NPWT is used for all localizations, monitoring of its status is mandatory, since there is a threat of bleeding. There are six death cases described in the literature, and we have experienced three timely detected bleedings which were successfully ceased.

Indications for NPWT discontinuation were: a change in the phase of exudation to the proliferation phase, wound cleaning, the appearance of active granulations, marginal epithelization, decrease in microbial contamination to 10 or less CFU, a normalization of microcirculation indices.

III. Conclusions

1) The use of NPWT in the complex treatment of gunshot and extensive wounds improves microcirculation, evacuation of exudate, leads to a reduction in the wound defect and its preparation for plastic closure
2) The use of NPWT for the closure of thoracic and abdominal traumatic and postoperative wounds has a curative effect not only on the wound itself, but also on the internal organs of this cavity
3) The NPWT method can be used in the complex surgical treatment of wounds of various locations in all phases of the wound process; The indications for its use are constantly expanding, methods are being developed to reduce contraindications.

References

[1] Y. L. Zarutskii and O. O. Shudrak, "Vkazvki z voenno-polovo hrurgi: dlya medichnogo skladu zbrojnih sil ukraini ta nshih silovih vdomstv," *Kyiv*, pp. 351–373, 2018.
[2] G. E. Samoylenko and O. V. Andreev, "The extensive battle wound features and there plastic closure," *Kharkivsjka khirurghichna shkola*, vol. 78, no. 3, pp. 118–122, 2016.
[3] M. A. Kashtalyan, S. V. Tertishniy, and K. L. Masunov, "Use of vac-therapy in comprehensive treatment of gunshot wounds," *Visnyk morsjkoji medycyny*, no. 2, pp. 187–192, 2016.
[4] I. R. Trutyak, I. M. Hajda, G. A. Prohorenko, V. I. Medzyn, and R. I. Trutyak, "Complications characteristic of the modern combat surgical trauma," *Acta medica Leopoliensia*, vol. 22, no. 3, pp. 50–54, 2016.
[5] R. N. Mikhayusov, "Experience of application of vacuum systems in the treatment of soft-tissue gunshot wounds," *Clinical Surgery*, no. 6, pp. 61–64, 2016.
[6] V. R. Belenky, V. V. Negoduyko, and R. M. Mykhaylusov, "Errors in the primary surgical debridement of soft tissues gunshot wounds," *Surgery of Ukraine*, no. 1, pp. 7–13, 2015.
[7] A. Laksha and D. Los, "The patients with soft tissue gunshot injuries managment," *Chronicle of traumatology and orthopedics*, no. 1-2, pp. 31–36, 2015.
[8] R. Holmgaard, J. Duffy, and F. E. Warburg, "Danish experience with free flaps in war wounds," *Danish Medical Journal*, vol. 64, no. 1, pp. 1–4, 2016.
[9] J. M. Sabino, J. Slater, and I. L. Valerio, "Plastic surgery challenges in war wounded i: Flap-based extremity reconstruction," *Advances in Wound Care*, vol. 9, no. 1, pp. 403–411, 2016.

Xydalba® (*dalbawancyna*)

Skład i postać farmaceutyczna: substancja czynna – dalbawancyna. Xydalba 500 mg proszek do sporządzania koncentratu roztworu do infuzji. Każda fiolka zawiera 500 mg dalbawancyny w postaci dalbawancyny chlorowodorku. Po odtworzeniu każdy mililitr zawiera 20 mg dalbawancyny. Rozcieńczony roztwór do infuzji musi mieć końcowe stężenie od 1 mg/ml do 5 mg/ml dalbawancyny. **Wskazania:** Produkt leczniczy Xydalba jest wskazany w leczeniu ostrych bakteryjnych zakażeń skóry i tkanek miękkich (ang. acute bacterial skin and skin structure infections, ABSSSI) u dorosłych. **Dawkowanie i sposób podawania:** Dorośli: Zalecana dawka dalbawancyny u dorosłych pacjentów z ABSSSI to 1500 mg podawane albo w infuzji jako dawka pojedyncza 1500 mg, albo 1000 mg, a następnie po tygodniu 500 mg. *Pacjenci w wieku podeszłym:* Dostosowywanie dawki nie jest konieczne. U pacjentów z zaburzeniami czynności nerek: Dostosowywanie dawki nie jest konieczne u pacjentów z łagodnymi lub umiarkowanymi zaburzeniami czynności nerek (klirens kreatyniny 30 ml/min do 79 ml/min). Dostosowywanie dawki nie jest konieczne u pacjentów regularnie poddawanych hemodializie (3 razy w tygodniu); dalbawancyna może być podawana bez względu na czas hemodializy. U pacjentów z przewlekłymi zaburzeniami czynności nerek, u których klirens kreatyniny wynosi <30 ml/min i którzy nie są regularnie poddawani hemodializie, zalecany schemat dawkowania dalbawancyny raz w tygodniu należy zmniejszyć do dawki 750 mg, a następnie po tygodniu o 375 mg. U pacjentów z zaburzeniami czynności wątroby: Dostosowywanie dawki dalbawancyny nie jest zalecane u pacjentów z łagodnymi zaburzeniami czynności wątroby (stopień A w klasyfikacji Childa-Pugha). Należy zachować ostrożność, przepisując dalbawancynę pacjentom z umiarkowanymi lub ciężkimi zaburzeniami czynności wątroby (stopień B i C w klasyfikacji Childa-Pugha), ponieważ nie ma danych umożliwiających określenie właściwego dawkowania. Dzieci i młodzież: Nie określono jeszcze bezpieczeństwa ani skuteczności stosowania dalbawancyny u dzieci w wieku od urodzenia do poniżej 18 lat. **Sposób podania:** *Podanie dożylne.* Produkt leczniczy Xydalba musi być odtworzony, a następnie rozcieńczony przed podaniem w infuzji dożylnej przez 30 minut. Należy zapoznać się z instrukcją dotyczącą odtwarzania i rozcieńczania tego produktu leczniczego przed podaniem. **Przeciwwskazania:** Nadwrażliwość na substancję czynną lub na którąkolwiek substancję pomocniczą [mannitol (E421), laktoza jednowodna, kwas solny (do ustalenia pH), sodu wodorotlenek (do ustalenia pH)]. **Specjalne ostrzeżenia i środki ostrożności dot. stosowania:** Reakcje nadwrażliwości: Produkt leczniczy Xydalba należy z ostrożnością podawać pacjentom, o których wiadomo, że są nadwrażliwi na inne glikopeptydy, ze względu na możliwość wystąpienia krzyżowej nadwrażliwości. Jeżeli wystąpi reakcja alergiczna na produkt leczniczy Xydalba, należy przerwać jego podawanie i zastosować właściwe leczenie reakcji alergicznej. Biegunka spowodowana przez *Clostridium difficile:* Podczas stosowania prawie wszystkich antybiotyków obserwowano związane z leczeniem przeciwbakteryjnym zapalenie okrężnicy i rzekomobłoniaste zapalenie okrężnicy, których przebieg może być od łagodnego do zagrażającego życiu. Z tego względu należy brać pod uwagę to rozpoznanie u pacjentów z biegunką występującą podczas lub po zakończeniu leczenia dalbawancyną. W takich przypadkach należy rozważyć przerwanie podawania dalbawancyny i zastosowanie leczenia wspomagającego oraz specyficznego dla zakażenia *Clostridium difficile*. U tych pacjentów nigdy nie należy stosować produktów leczniczych hamujących perystaltykę. Reakcje związane z infuzją: Produkt leczniczy Xydalba podaje się w infuzji dożylnej, z wykorzystaniem całkowitego 30-minutowego czasu trwania infuzji, w celu zminimalizowania ryzyka reakcji związanych z infuzją. Szybkie infuzje dożylne przeciwbakteryjnego glikopeptydu mogą przyczynić się do wystąpienia reakcji przypominających „zespół czerwonego człowieka", który obejmuje nagłe zaczerwienienie górnych części ciała, pokrzywkę, świąd i (lub) wysypkę. Zaprzestanie podawania infuzji lub jej spowolnienie może spowodować ustąpienie tych reakcji. Zaburzenia czynności nerek: Informacje dotyczące skuteczności i bezpieczeństwa stosowania dalbawancyny u pacjentów, których klirens kreatyniny wynosi <30 ml/min są ograniczone. Na podstawie symulacji, dostosowywanie dawki jest konieczne u pacjentów z przewlekłymi zaburzeniami czynności nerek, u których klirens kreatyniny wynosi <30 ml/min i którzy nie są regularnie poddawani hemodializie. Zakażenia mieszane: W przypadku zakażeń mieszanych, jeśli się podejrzewa obecność bakterii Gram-ujemnych, pacjentów należy leczyć odpowiednimi lekami przeciwbakteryjnymi działającymi na bakterie Gram-ujemne. Drobnoustroje niewrażliwe: Zastosowanie antybiotyków może promować namnażanie drobnoustrojów niewrażliwych. Jeżeli podczas terapii wystąpi nadkażenie, należy wdrożyć odpowiednie postępowanie. Ograniczenia danych klinicznych: Dane dotyczące bezpieczeństwa stosowania i skuteczności dalbawancyny w przypadku zastosowania więcej niż dwóch dawek (w odstępie jednego tygodnia) są ograniczone. W kluczowych badaniach w przypadku ABSSSI rodzaje leczonych infekcji były ograniczone jedynie do cellulitisu/róży, ropni i infekcji ran. Brak doświadczenia dotyczącego stosowania dalbawancyny w leczeniu pacjentów z silnie obniżoną odpornością. **Ciąża i laktacja:** Nie ma danych dotyczących stosowania dalbawancyny przez kobiety w ciąży. Badania na zwierzętach wykazały toksyczne działanie na reprodukcję. Xydalba nie jest zalecana w okresie ciąży, o ile nie jest to bezwzględnie konieczne. Nie wiadomo, czy dalbawancyna przenika do mleka matki (mleka ludzkiego). Niemniej dalbawancyna przenika do mleka samic szczurów karmiących piersią i może również przenikać do mleka ludzkiego. Dalbawancyna nie wchłania się dobrze po podaniu doustnym; niemniej nie można wykluczyć wpływu dalbawancyny na florę żołądkowo-jelitową oraz florę jamy ustnej karmionego piersią niemowlęcia. Należy podjąć decyzję o kontynuacji/zaprzestaniu karmienia piersią lub kontynuacji/zaprzestaniu leczenia produktem Xydalba, biorąc pod uwagę korzyści z karmienia piersią dla niemowlęcia oraz korzyści z terapii dla kobiety. Płodność: Badania na zwierzętach wykazały obniżoną płodność. Potencjalne ryzyko, na które narażeni są ludzie jest nieznane. **Działania niepożądane:** Podsumowanie profilu bezpieczeństwa: W fazie 2/3 badań klinicznych dalbawancynę otrzymało 2473 pacjentów. Była ona podawana albo w infuzji jako dawka pojedyncza 1500 mg, albo w dawce 1000 mg, a następnie po tygodniu w dawce 500 mg. Najczęściej występującymi działaniami niepożądanymi występującymi u ≥1% pacjentów leczonych dalbawancyną były: mdłości (2,4%), biegunka (1,9%) oraz bóle głowy (1,3%), i zwykle miały lekkie lub umiarkowane nasilenie. Tabelaryczny wykaz działań niepożądanych: W fazie 2/3 badań klinicznych z zastosowaniem dalbawancyny zidentyfikowano poniższe działania niepożądane. Działania niepożądane podano zgodnie z klasyfikacją układów i narządów oraz według częstości występowania. Kategorie częstości występowania zostały opisane zgodnie z następującymi normami: bardzo częste (1/10), częste (1/100 do <1/10), rzadkie (1/1000 do <1/100), bardzo rzadkie (1/10 000 do <1/1000).

Klasyfikacja układów i narządów	Częste	Rzadkie	Bardzo rzadkie
Zakażenia i zarażenia pasożytnicze		zakażenia grzybicze pochwy i sromu, zakażenia dróg moczowych, infekcje grzybicze, zapalenie okrężnicy wywołane *Clostridium difficile*, kandydoza jamy ustnej	
Zaburzenia krwi i układu chłonnego		anemia, trombocytoza, eozynofilia, leukopenia, neutropenia	
Zaburzenia układu immunologicznego			reakcje anafilaktoidalne
Zaburzenia metabolizmu i odżywiania		zmniejszony apetyt	
Zaburzenia psychiczne	ból głowy	bezsenność	
Zaburzenia układu nerwowego		zaburzenia smaku, zawroty głowy	
Zaburzenia naczyniowe		nagłe zaczerwienienie, zapalenie żył	
Zaburzenia układu oddechowego, klatki piersiowej i śródpiersia		kaszel	skurcz oskrzeli
Zaburzenia żołądka i jelit	mdłości, biegunka	zaparcie, ból brzucha, dyspepsja, uczucie dyskomfortu w jamie brzusznej	
Zaburzenia skóry i tkanki podskórnej		świąd, pokrzywka	
Zaburzenia układu rozrodczego i piersi		świąd sromu i pochwy	
Zaburzenia ogólne i stany w miejscu podania		reakcje związane z infuzją	
Badania		zwiększona aktywność dehydrogenazy mleczanowej we krwi, zwiększona aktywność aminotransferazy alaninowej, zwiększona aktywność aminotransferazy asparaginianowej, zwiększone stężenie kwasu moczowego we krwi, nieprawidłowe wyniki testu czynności wątroby, zwiększona aktywność aminotransferaz, zwiększona aktywność fosfatazy zasadowej we krwi, zwiększona liczba płytek krwi, zwiększona temperatura ciała, zwiększona aktywność enzymów wątrobowych, zwiększona aktywność gamma-glutamylotransferazy	

Opis wybranych działań niepożądanych: *Działania niepożądane związane z klasą leków.* Ototoksyczność jest związana ze stosowaniem glikopeptydu (wankomycyny i teikoplaniny); u pacjentów otrzymujących w skojarzeniu lek ototoksyczny, taki jak aminoglikozyd, ryzyko ototoksyczności może być zwiększone. Zgłaszanie podejrzewanych działań niepożądanych: Po dopuszczeniu produktu leczniczego do obrotu istotne jest zgłaszanie podejrzewanych działań niepożądanych. Umożliwia to nieprzerwane monitorowanie stosunku korzyści do ryzyka stosowania produktu leczniczego. Osoby należące do fachowego personelu medycznego powinny zgłaszać wszelkie podejrzewane działania niepożądane za pośrednictwem krajowego systemu zgłaszania. **Podmiot odpowiedzialny:** Durata Therapeutics International B.V. Spaces Zuidas II, Barbara Strozzilaan 101, 1083 HN Amsterdam, The Netherlands. **Przedstawiciel podmiotu odpowiedzialnego: Angelini Pharma Polska Sp. z o.o.**, ul. Podleśna 83, 05-552 Łazy, Polska, tel. +48227028200, fax +48227028202. **Pozwolenie na dopuszczenie do obrotu:** EU/1/14/986/001. **Kategoria dostępności:** Rpw. **Przed zastosowaniem należy zapoznać się z zatwierdzoną Charakterystyką Produktu Leczniczego.**

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