

Clinical evolution of patients with infection associated with orthopedic devices in treatment with continuous negative pressure

Evolución clínica de los pacientes con infección asociada a dispositivos ortopédicos en tratamiento con presión negativa continua

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Abstract

Objective: To describe the use of negative pressure therapy with (TPNi) and without instillation (TPNs) as adjuvant treatment in the management of orthopedic device-associated infections (IADO). **Method:** Analytic observational study of records of patients with IADO managed with TPNi and TPNs with 0.9% saline solution, in patients > 18 years, operated on in 2018-2021. Clinical characteristics of infection, infectious agent as well as sociodemographic variables were evaluated. TPN was performed with the V.A.C. VERAFLORTM system. Analysis with chi-square, Fisher and t-Student. Statistically accepted value $p < 0.05$. **Results:** Sample 40 patients. 75% male. Fractures 42.5% exposed and 57.5% closed. 92.5% applied prophylactic antibiotic (30-120 min). 35% plate implants, 12.5% centromedullary nail, 10% knee prosthesis and 12.5% hip. 47.5% bleeding < 500 mL. 72.5% surgical time of 2-4 hours. Previous hospitalization time, TPNs 3 weeks 55.9% and 4 weeks 26.5%; TPNi, 3 weeks 50% and 4 weeks 33.3%. Conservation of the implant 73.5% TPNs and 50% TPNi ($p = 0.341$). Wound closure 91.2% with TPNs and 100% with TPNi ($p = 1.000$). **Conclusions:** The use of TPNs and TPNi were useful as adjuvant treatments in the management of IADO, in addition they allowed to preserve the implant and wound closure in a large part of the patients.

Keywords: Orthopedic fixation devices. Prosthesis-related infections. Postoperative complications. Orthopedic equipment.

Resumen

Objetivo: Describir el uso de la terapia de presión negativa con (TPNi) y sin instilación (TPNs) como tratamiento adyuvante en el manejo de infecciones asociadas a dispositivo ortopédico (IADO). **Método:** Estudio observacional analítico de expedientes de pacientes con IADO manejados con TPNi y TPNs con solución salina al 0.9%, mayores de 18 años, operados en el periodo 2018-2021. Se evaluaron las características clínicas de infección, el agente infeccioso y las variables sociodemográficas. La TPN se realizó con sistema V.A.C. VERAFLORTM. Para los análisis se emplearon las pruebas χ^2 , Fisher y t de Student. Valor estadísticamente aceptado: $p < 0.05$. **Resultados:** La muestra fue de 40 pacientes, el 75% masculinos. Fracturas: 42.5% expuestas y 57.5% cerradas. En el 92.5% se aplicó antibiótico profiláctico (30-120 min). Implantes: 35% placas, 12.5% clavo centromedular, 10% prótesis de rodilla y 12.5% cadera. El 47.5% con sangrado < 500 mL. En el 72.5% un tiempo quirúrgico de 2-4 horas. Tiempo de hospitalización previa: TPNs 3 semanas 55.9% y 4 semanas 26.5%; TPNi 3 semanas 50% y 4

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semanas 33.3%. Conservación del implante: 73.5% TPNs y 50% TPNi ($p = 0.341$). Cierre de herida: 91.2% con TPNs y 100% con TPNi ($p = 1.000$). **Conclusiones:** El uso de TPNs y TPNi fue útil como tratamiento adyuvante en IADO, y además permitieron conservar el implante y el cierre de la herida en la mayoría de los pacientes.

Palabras clave: Fijación interna. Infecciones periprotésicas. Complicaciones posquirúrgicas. Implantes ortopédicos.

Introduction

Health care-associated infections are considered a public health problem, both in developed and developing countries. Surgical site infections, including those associated with orthopedic devices (IADO)^{1,2}, are classified as Health care-associated infections. IADOs are rare, but when they occur, they are serious, with a slow progression and cause prolonged disability, high Health care costs, and loss of well-being. IADOs can have various causes, but the primary one is contamination during the surgical procedure³⁻⁷. It also depends on the damage caused to the soft tissues, especially in traumatic orthopedic surgical procedures^{5,8,9}.

The incidence of IADOs varies from country to country, as well as depending on the surgical procedure performed. Argüelles Martínez et al.⁴ found in their study that the most frequent periprosthetic infection was that of the knee. Carvajal and Londoño¹⁰ found that surgical site infections secondary to orthopedic implants had higher frequencies in surgical procedures involving the patella, tibia, and fibula, but were lower in forearm surgical procedures and joint replacements.

In general, the treatment of IADOs consists of cleaning and aggressive debridement. For over 30 years, subatmospheric pressure therapy has been used as an adjunct in the treatment of wound infections, as well as deep infections^{8,11-14}. Negative pressure therapy (NPT) has two modalities: with permanent or intermittent pressure^{14,15}.

NPT is not the panacea for treating both deep and superficial wound infections. Its success depends on the follow-up and care of the infection, the duration of use, and its combined management with aggressive surgical treatment involving serial washes and antibiotic therapy^{12,16,17}.

The success in treating surgical site infections in orthopedic surgery is observed in cases involving osteosynthesis material or joint replacement. With the introduction of NPT, several studies show its success, as over 43% of cases preserve the implant, and infection eradication reaches 76-83% when combined with permanent instillation^{18,19}.

Due to the fact that the use of NPT with instillation (NPTi) with antiseptic results in shorter treatment times than patients who are only managed with surgical washing and systemic antibiotics, reducing both costs and resources, the objective of this study was to describe the use of NPT with and without instillation as an adjunctive treatment in the management of infections associated with orthopedic implants, as well as to describe the hospital's experience with this therapy, the clinical evolution, and the microbiological characterization of patients with this type of infection.

Method

An analytical, observational, cross-sectional, and retrospective study was conducted on patients with IADO who were treated with either NPTi or NPT without instillation (NPTw) with saline solution. Prior to its implementation, this study was reviewed and approved by the health research and ethics committees, with the registration number R-2019-2105-046.

The sampling technique was non-probabilistic, at the researcher's discretion, but a sample size calculation was not performed as all patients who met the inclusion criteria from January 2018 to May 2021 were considered. Patients over 18 years of age with surgical wound infections who received NPT as an adjunct to treat IADO, without distinction of sex, and who had a complete clinical file were included. Patients with incomplete clinical records and those who did not receive NPT as an adjunctive treatment were excluded. Patients who abandoned NPT before the clinical condition was healed or those who did not receive NPT properly were eliminated.

Data were collected from the hospital's clinical services database, identifying those who presented surgical wound infections. Variables collected from the clinical records included age, sex, comorbidities, smoking, and body mass index (BMI), as well as clinical signs (fever, fistula, induration, and redness of the wound) and laboratory values indicative of infection (leukocyte count, hemoglobin, hematocrit, C-reactive protein [CRP], sedimentation rate, and proteins), previous management history (open fractures, implant

placement, prophylactic antibiotics during the initial surgery, transoperative bleeding, and type of procedure), initial surgery time, infection evolution time, and bacteriological data (etiologic agent, antibiotic resistance, and antibiotic sensitivity). Open fractures were categorized according to the Gustillo-Anderson classification.

The decision to apply NPTi was at the surgeon's discretion. Surgical procedures were performed by senior medical professionals with experience in managing bone infections, and they had prior training in negative pressure system placement.

Before applying the NPT, all patients underwent aggressive surgical debridement, predominantly aiming to conserve the implant as long as no loosening was observed. Once the wound bed was prepared, an open-cell reticulated polyurethane foam sponge (V.A.C.® GranuFoam™) was placed. For wound closure, an acrylic adhesive cover was used, which connected to the suction tube of the V.A.C. VERAFLOR™ system. Instillation was performed with 0.9% saline solution, with an instillation time of 3 hours, 30 minutes of suction, and 15 minutes of retention. The suction pressure was set at a continuous pressure of 125 mmHg.

NPT was changed every 7 days, with sponge and container replacement. Each sponge change included taking a culture from the wound bed. The criterion for discontinuing NPT was having two negative cultures, with granulation tissue present and no purulent exudate.

In the statistical analysis, qualitative variables were expressed as frequencies and percentages, while numerical variables were expressed as mean and standard deviation (SD). For inferential analysis, the chi-square test was used for associations between polytomous variables, and Fisher's exact test was used for dichotomous variables. For associations between quantitative variables, the Student's t-test was applied. A p-value of < 0.05 was considered statistically significant.

Results

During the study period, 2033 patients presented fractures, and hip or knee joint replacement was performed on 1503 patients, of which only 60 were identified with orthopedic implant-associated infections (IADO) who used negative pressure therapy (NPT) as an adjunct treatment. However, 20 had to be excluded because NPT was not applied properly, leaving a sample of 40 patients. Of the final sample, 75% were

Table 1. Sociodemographic Variables (n = 40)

Variables	n (%)
Sex	
Male	30 (75)
Female	10 (25)
Weight	
Underweight	5 (12.5)
Normal weight	12 (30)
Overweight	20 (50)
Obesity grade I	3 (7.5)
Comorbidity	
Diabetes mellitus	12 (30)
Systemic arterial hypertension	6 (15)
None	22 (55)

Table 2. Orthopedic Diagnoses (n = 40)

Diagnoses	n (%)
Open fracture	
IIIA	4 (10)
IIIB	9 (22.5)
IIIC	4 (10)
Closed fracture	23 (57.5)
Osteoarthritis	
Gonarthrosis	2 (5)
Coxarthrosis	4 (10)

male. The mean age was 43.2 years (SD, 16.8; range: 19-76). A total of 55% had no comorbidities. 50% were overweight, 30% had normal weight, and 12.5% were underweight (Table 1); the mean BMI was 25 (SD, 0.8; range: 10-40). Among the orthopedic diagnoses, 42.5% of the sample had an open fracture (Gustilo and Anderson), and 57.5% had a closed fracture. 11.8% had chronic degenerative conditions (Table 2).

When describing the surgical management history of the patients who developed IADO, regarding the surgical risk according to the ASA (American Society of Anesthesiologists) classification, it was found that 92.5% were ASA II, and 17.5% were ASA III. The prophylactic antibiotic administration time was 30 to 120 minutes before surgery in 92.5%. The most widely administered antibiotic was cephalexin (52.5%). The most widely used orthopedic implants were plates (35%), intramedullary nails (12.5%), and minimal osteosynthesis (12.5%). Surgical bleeding of < 500 mL was reported in 47.5%, and > 500 mL in 50%. The surgical time was < 2 hours in 25%, 2-4 hours in 72.5%, and > 4 hours in 2.5% (Table 3).

Table 3. Surgical History in Patients with Infections Associated with Orthopedic Devices (n = 40)

Antecedents	n (%)
Surgical risk	
ASA II	33 (82.5)
ASA III	7 (17.5)
Antibiotic prophylaxis time	
30-120 min	37 (92.5)
> 120 min	3 (7.5)
Prophylactic antibiotic	
Cefalexin	21 (52.5)
Cefalotin	9 (22.5)
Ceftriaxone	10 (25)
Orthopedic implant	
Plate	14 (35)
Centromedullary nail	5 (12.5)
Minimal osteosynthesis	5 (12.5)
Knee prosthesis	4 (10)
Hip prosthesis	5 (12.5)
Pedicule screws	2 (5)
Surgical bleeding	
< 500 mL	19 (47.5)
500-999 mL	20 (50)
1000-1400 mL	1 (2.5)
Surgical time	
< 2 hours	10 (25)
2-4 hours	29 (72.5)
> 4 hours	1 (2.5)

Regarding the clinical signs of patients with IADO, induration (17.5%), redness (95%), fistula (25%), and fever (42.5%) were observed. The time to onset of infection was < 3 months in 72.5%, 3-24 months in 17.5%, and > 24 months in 10% (Table 4).

Among the initial laboratory values, CRP levels were 5-10 mg/dL in 35%, 11-20 mg/dL in 60%, and 21-50 mg/dL in 5%. Total protein levels were altered in 57.5% of the patients (Table 4).

Initial radiographs showed segment-bone interface in 7.5% and osteolysis in 12.5% (Table 4).

Regarding the hospitalization time before NPT use and its type, for NPT without instillation (NPTw), it was 1 week in 2.9%, 2 weeks in 5.9%, 3 weeks in 14.7%, 4 weeks in 41.2%, 5 weeks in 20.6%, 6 weeks in 8.8%, and 7 weeks in 5.9%; for NPT with instillation (NPTi), it was 4 weeks in 50%, 5 weeks in 33.3%, and 6 weeks in 16.7% (p = 0.864) (Table 5).

Regarding the type of NPT used, 85% used NPTw, and 15% used NPTi. Regarding the usage time, for NPTw, 14.7% used it for 2 weeks, 55.9% for 3 weeks, 26.5% for 4 weeks, and 2.9% for 5 weeks; for NPTi, 16.7% used it for 2 weeks, and 50% for 3 weeks.

Table 4. Clinical Signs, Laboratory Values, and Initial Radiological Findings in Patients with Infections Associated with Orthopedic Devices (n = 40)

Variables	n (%)
Time of onset of infection	
< 3 months	29 (72.5)
3-24 months	7 (17.5)
> 24 months	4 (10)
Induration	
Yes	33 (82.5)
No	7 (17.5)
Temperature	
< 37°C	14 (35)
37-37.9°C	9 (22.5)
38-38.5°C	16 (40)
> 38.5°C	1 (2.5)
Redness	
Yes	38 (95)
No	2 (5)
Fistula	
Yes	10 (25)
No	30 (75)
Radiographs	
No radiographic signs	32 (80)
Segment-bone interface	3 (7.5)
Osteolysis	5 (12.5)
C-reactive protein	
5-10 mg/dL	14 (35)
11-20 mg/dL	24 (60)
21-50 mg/dL	2 (5)
Total proteins	
Altered	23 (57.5)
No alteration	17 (42.5)

Regarding the type of NPT used, 85% received NPTw, and 15% received NPTi. Regarding the duration of use, for NPTw, 14.7% used it for 2 weeks, 55.9% for 3 weeks, 26.5% for 4 weeks, and 2.9% for 5 weeks; for NPTi, 16.7% used it for 2 weeks, 50% for 3 weeks, and 33.3% for 4 weeks. Implant preservation was observed in 73.5% of patients with NPTw and 50% with NPTi, while the implant had to be removed in 26.5% of patients with NPTw and 50% with NPTi (p = 0.341). Wound closure was performed in 91.2% of patients with NPTw and 100% with NPTi (p = 1.000) (Table 5).

When associating initial and final laboratory values with the type of NPT, with NPTw, the initial hemoglobin had a mean of 11.35 ± 3.4 mg/dl and with NPTi, 9.2 ± 1.9 mg/dl (p = 0.042). The final hemoglobin had a mean of 13.1 ± 1.4 mg/dl with NPTw and 12.3 ± 1.5 mg/dl with NPTi (p = 0.251). The initial leukocyte count was

Table 5. Association of Negative Pressure Therapy Type with Duration of Use, Implant Preservation, Wound Closure, and Hospitalization Time (n = 40)

Variables	NPTw (n = 34) n (%)	NPTi (n = 6) n (%)	Total n (%)	Significance*
Duration of use				
2 weeks	5 (14.7)	1 (16.7)	6 (15)	0.958
3 weeks	19 (55.9)	3 (50)	22 (55)	
4 weeks	9 (26.5)	2 (33.3)	11 (27.5)	
5 weeks	1 (2.9)	0	1 (2.5)	
Preservation of orthopedic implant				
Yes	25 (73.5)	3 (50)	28 (70)	0.341
No	9 (26.5)	3 (50)	12 (30)	
Wound closure				
Yes	31 (91.2)	6 (100)	37 (92.5)	1.000
No	3 (8.8)	0	3 (7.5)	
Previous hospitalization time				
1 week	1 (2.9)	0	1 (2.5)	0.864
2 weeks	2 (5.9)	2 (33.3)	4 (10)	
3 weeks	5 (14.7)	1 (16.7)	6 (15)	
4 weeks	14 (41.2)	0	14 (35)	
5 weeks	7 (20.6)	1 (2.5)	8 (20)	
6 weeks	3 (8.8)	2 (5)	5 (12.5)	
7 weeks	2 (5.9)	1 (12.5)	3 (7.5)	

*Significance: $p < 0.05$.

NPTi: Negative Pressure Therapy with Instillation; NPTw: Negative Pressure Therapy without Instillation.

13,097 $\pm$ 4641.7 per field with NPTw and 13,133.3 $\pm$ 4195.6 per field with NPTi ($p = 0.985$), and the final count was 7,758.8 $\pm$ 1578.6 per field with NPTw and 7,966.7 $\pm$ 242.2 per field with NPTi ($p = 0.475$). The initial C-reactive protein (CRP) was 2.7 $\pm$ 0.6 with NPTw and 2.7 $\pm$ 0.5 with NPTi, and the final CRP was 1.1 $\pm$ 0.4 with NPTw and 1.2 $\pm$ 0.4 with NPTi ($p = 0.915$). The initial total proteins were 5.9 $\pm$ 0.9 with NPTw and 6.3 $\pm$ 1.0 with NPTi ($p = 0.366$), and the final total proteins were 6.5 $\pm$ 0.7 with NPTw and 6.2 $\pm$ 0.4 with NPTi ($p = 0.258$) (Table 6).

Discussion

IADO present a significant challenge for orthopedic surgeons; the costs associated with their treatment are six to seven times higher compared to non-infected procedures²⁰. In this study, it was observed that the use of Negative Pressure Therapy (NPT) in IADO allows for the preservation of the orthopedic implant in a large percentage of patients. Most authors who have used NPT for treating IADO report that in a large percentage (75-85%) of cases, the orthopedic implant is retained^{16,17,21,22}. In contrast to the literature, the percentage of implant preservation in this study was similar to what has been reported, but only with NPTw (73.5%), while among patients treated with NPTi, only half preserved the implant, but without statistical

significance, possibly due to group heterogeneity. Webb²³ argues that the use of NPTi shows favorable results, but studies of higher quality are needed to guarantee the efficacy of this therapy. West et al.²⁴ note that instillation may help eradicate infections in surgical sites with a high risk of infection, facilitating implant preservation, but could cause long-term tissue damage due to the toxicity of the instillation solution used. In this study, instillation was performed only with saline solution to avoid toxicity in surrounding tissues.

The use of NPTw and NPTi should be considered as an adjunctive treatment, for limited periods, and in carefully selected patients^{11,12}. In this study, NPT was applied to patients who exhibited persistent IADO after initial treatment and who showed no clinical improvement. The length of hospitalization varied depending on associated factors. It is important to note that the population to which both NPTw and NPTi were applied had, to a large extent, hospitalizations of more than 4 weeks before the application of NPT. These types of therapies have shown their effectiveness in managing deep infections¹³. Falci et al.²⁵ identify potential variables for surgical wound contamination as the clinical condition of patients (ASA), the type of surgical procedure, and the duration of the surgery. Ángeles-Garay et al.⁹ report risk factors for developing surgical site infections, including smoking history, low weight,

Table 6. Initial and Final Laboratory Values of Patients with Orthopedic Device-Associated Infections Treated with Negative Pressure Therapy (n = 40)

Parameters	NPTw (Mean $\pm$ SD)	NPTi (Mean $\pm$ SD)	Significance*
Initial Hemoglobin	11.35 $\pm$ 3.4	9.2 $\pm$ 1.9	0.042
Final Hemoglobin	13.1 $\pm$ 1.4	12.3 $\pm$ 1.5	0.251
Initial Leukocytes	13,097.1 $\pm$ 4641.7	13,133.3 $\pm$ 4195.6	0.985
Final Leukocytes	7,758.8 $\pm$ 1578.6	7,966.7 $\pm$ 242.2	0.475
Initial C-reactive Protein	2.7 $\pm$ 0.6	2.7 $\pm$ 0.5	0.871
Final C-reactive Protein	1.1 $\pm$ 0.4	1.2 $\pm$ 0.4	0.915
Initial Total Proteins	5.9 $\pm$ 0.9	6.3 $\pm$ 1.0	0.366
Final Total Proteins	6.5 $\pm$ 0.7	6.2 $\pm$ 0.4	0.258

*Significance: $p < 0.05$.

NPTi: Negative Pressure Therapy with Instillation; NPTw: Negative Pressure Therapy without Instillation.

inadequate handwashing techniques, blood transfusions during surgery, contaminated surgeries, hospital stays of 8 to 14 days, and the presence of venous catheters and urinary catheters for 1 to 3 days. This study did not aim to identify risk factors for the development of IADO, but as comorbidities, half of the patients studied had diabetes mellitus or systemic hypertension, and most patients had normal weight or overweight, with only small percentages having obesity or underweight. More than half of the patients presented a closed fracture, with a smaller proportion having an exposed fracture (Gustillo-Anderson III). Regarding surgical risk, 82.5% of the patients were ASA II. The surgical time in the primary surgery was between 2 and 4 hours for 72.5%, and in more than half of the cases, the surgical bleeding was less than 1000 mL.

Regarding laboratory values after NPT and NPTi application, a significant reduction was observed in the leukocyte count ($p = 0.475$), CRP ($p = 0.915$), and total proteins ($p = 0.258$).

Izadpanah et al.¹⁷ establish that factors contributing to NPT failure in patients with postoperative infections after osteosynthesis include late infection manifestations (> 4 weeks), bacterial mixture, significant soft tissue injury, and high CRP values (> 20 mg/L). This study only showed laboratory values at the end of the NPT treatment, where a decrease in CRP was observed, but it was not statistically significant, possibly due to the small sample size.

The strength of this study lies in comparing 2 NPT techniques, and it also demonstrated the effectiveness of these therapies as adjuncts in the treatment of IADO, allowing implant preservation in a large percentage of patients. The weaknesses of the study include the

heterogeneity between the groups and the small number of patients, which is why the statistical values were not significant. Furthermore, patients were not followed up, but this will be addressed in future studies, along with a cost study involving a larger number of patients, with a 12-month follow-up. It is also important to note that this therapy was administered after surgical debridement and antibiotic therapy, so a comparison of hospital stay reduction times was not made, suggesting the use of NPT from the beginning for IADO management without comparing it to patients managed without NPT.

Conclusions

The use of NPTw and NPTi was useful as an adjunct treatment in the management of IADO and also allowed for the preservation of the orthopedic implant and definitive closure of the surgical wound in a large portion of the patients. In this study, there was no significant difference in the outcomes when comparing both NPT techniques. The choice between NPTw and NPTi is left to the discretion of the surgeon. More randomized clinical trials with a larger number of patients and longer follow-up are required, as well as applying NPT at the start of treatment to demonstrate its effectiveness in eradicating IADO and determine which NPT technique is best.

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Conflicts of interest

None declared.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

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