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## ORIGINAL ARTICLE

# Complications associated with the negative pressure therapy in the treatment of the diabetic foot ulcers: Retrospective case series

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### KEYWORDS

Diabetic foot ulcers;  
Negative pressure therapy;  
Complications;  
Diabetic foot;  
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Peri wound maceration

### Abstract

**Introduction:** Torpid evolution of diabetic foot ulcers (DFU) is a complex problem of health of patients and causes an increase in costs for the health system. Negative pressure therapy (NPT) is a treatment that accelerates healing by a negative pressure flow applied to the wound to stimulate a series of physiological processes in chronic wounds.

**Patients and methods:** We performed a retrospective case series study that evaluated the complications associated to NPT in the treatment of DFU in patients from the Diabetic Foot Unit of the Universidad Complutense de Madrid from 2011 to 2015.

**Results:** Fifty-seven (83.8%) patients who underwent NPT were analyzed and complications during the time that NPT was maintained were collected. Skin maceration of wound borders was found in 49% of the patients, bleeding (14%), necrosis (12%), local infection (7%) and local pain (2%).

**Discussion:** The peri wound maceration was the most frequent complication and the most easily resolved. After resolution of the complications, 80% of the patients obtained a favorable result with the therapy, so it can be concluded that NPT is an effective and safe therapy for the treatment of DFU.

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## PALABRAS CLAVE

Úlcera de  
piediabético;  
Terapia de presión  
negativa;  
Complicaciones;  
Pie diabético;  
Necrosis;  
Maceración  
perilesional

## Complicaciones asociadas a la terapia de presión negativa en el tratamiento de las úlceras de pie diabético: serie de casos retrospectiva

### Resumen

**Introducción:** El retraso en la cicatrización de las úlceras de pie diabético supone un problema complejo en la salud de los pacientes y provoca un aumento de costes para el sistema sanitario. La terapia de presión negativa (TPN) es un procedimiento terapéutico que acelera la cicatrización, empleando un flujo de presión negativa para estimular una serie de procesos fisiológicos en las heridas crónicas.

**Pacientes y métodos:** Se realizó un estudio observacional retrospectivo en el que se evaluaron las complicaciones asociadas a la TPN en el tratamiento de las úlceras de pie diabético, con pacientes de la Unidad de Pie Diabético de la Universidad Complutense de Madrid, entre los años 2011 y 2015.

**Resultados:** Mediante la revisión de historias clínicas se obtuvo una muestra de 68 pacientes que fueron sometidos a esta terapia, de los cuales 57 (83,8%) presentaron alguna complicación durante el tiempo que mantuvieron la TPN. En el 49% de los pacientes se encontró maceración perilesional, seguida de sangrado (14%), necrosis (12%), infección local (7%) y dolor local (2%).

**Discusión:** La maceración perilesional fue la complicación más frecuente, pero también la que más fácilmente se solventó, mediante la aplicación de apósitos barrera y otras terapias que favorecen el control del exudado de la herida. Tras la resolución de las complicaciones, en el 80% de los pacientes se obtuvo un resultado favorable con la terapia, por lo que se puede concluir que la TPN se considera una terapia efectiva y segura en el tratamiento de las úlceras de pie diabético.

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## Introduction

The most common etiologies for DFU are diabetic neuropathy and peripheral arterial disease. Strict ischemic foot is only about 10% of all DFU, being neuropathy involved in 90% of cases. However, in the last years the incidence of neuroischemic ulcers has increased, being actually the most common ulcer types in the diabetic foot.<sup>1</sup> The delay of healing of DFU is a complex health problem that affects diabetic patients, increases the costs of health systems and decreases quality of life of patients with DFU.<sup>2,3</sup> One of the most evidence based therapies to fasten wound closure is negative pressure therapy (NPT).<sup>4-7</sup> It is a noninvasive therapy based on the application of a pressure over the base of the wound with the idea to accelerate healing of wounds of different etiology.<sup>2,3,8</sup>

NPT consists in the application of sub atmospheric pressure, with a 50–175 mm Hg pressure range, in a continuous or intermittent fashion and with or without the instillation of a drug over the complex wound.<sup>9,10</sup> NPT improves wound conditions and creates a good environment for healing activating the mechanisms of normal healing: granulation tissue proliferation, increased local hyperemia, reduction of edema, bacterial load and exudate, control of metalloprotease levels, and healing of wound in a wet environment.<sup>2,3,8,9</sup>

Main indications for this therapy are: chronic wounds, acute and traumatic wounds, dehiscence, flaps and grafts.<sup>2,3,9,10</sup> Contraindications are: soft tissue infections, osteomyelitis, necrotic tissue, malignancy and non-explored fistula.<sup>9-11</sup>

Although in the scientific literature there are several studies about the effectiveness of NPT<sup>12</sup>, very few of them explain the complications associated with this therapy that are mainly derived from its use in non indicated cases. Commonly described adverse effects are usually minor and include pain during dressing changes, tissue necrosis, perilesional tissue erosion and periwound maceration.<sup>13-15</sup> Major adverse effects can also occur such as allergic reactions, infection, sepsis or osteomyelitis that require immediate discontinuation of the therapy.<sup>16-18</sup>

The objective of the present study is to describe the most common complications observed with the application of NPT in patients with DFU.

## Patients and methods

A retrospective case series study was performed in patients with DFU treated with NPT in the Diabetic Foot Unit of Universidad Complutense de Madrid, between January 2011 and November 2015.

Inclusion criteria included patients, independently of their gender, older than 18 years with a DFU that after surgical debridement required treatment with NPT. Patients with some contraindications for the application of NPT previously reported were excluded. In accordance with Spanish law of patients security and data protection all information was securely and anonymously treated.

All patients underwent surgical debridement of their FDU, removing nonviable devitalized tissue and afterward NPT was applied with a polyurethane sponge in the

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