Nurse Approach in the Treatment of Piabetic Foot Ulcers with the Management of Negative Pressure Therapy

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ABSTRACT
The global increase of Diabetes Mellitus represents serious complications for those who suffer from it, the most frequent complications are diabetic foot ulcers and amputations derived from them. Currently, negative pressure therapy (NPT) is used as an advanced therapy for the treatment of this type of ulcers. This novel therapy promises numerous advantages for the nursing approach to patients with diabetic foot ulcers. Therefore, the objective of this narrative review is to prove the effectiveness of the negative pressure therapy as a treatment for diabetic foot ulcers. The search of the articles was carried out in several scientific databases with the help of a searching chain, which combined the keywords and boolean operators. 16 studies were selected, which indicated that NPT as a treatment for diabetic foot ulcers provides benefits such as promoting the formation of granulation tissue, healing and closing of the ulcer in a shorter time, as well as reducing ulcer depth and area and even decreases the bacterial load, the rate of amputations and re-ulcerations. Hence, NPT is an effective therapy that should be applied to clinical practice.

Keywords: "Diabetic Foot Ulcer", "Diabetic Foot", "Negative Pressure Therapy"; "V.A.C.", "Vacuum Assisted Closure".

Introduction
DM is a public health problem classified as one of the four non-communicable diseases worldwide. According to the World Health Organization (WHO), the number of people suffering from DM has increased from 108 million of the adult population in 1980 to 422 million in 2014, so the prevalence of diabetes has increased from 4.7 % in 1980 to 8.5% in 2014 [1,2]. Furthermore, it is estimated that in 2035 these data will continue to increase to 592 million people with diabetes, due to its high incidence in industrialized countries [3].

The most frequent complications derived from DM are retinopathies, nephropathies or neuropathies, such as diabetic foot [4]. The Society of Angiology and Vascular Surgery defines diabetic foot as "A clinical alteration of neuropathic origin and induced by hyperglycemia, in which, with or without coexistence of ischemia, and previous traumatic trigger; produces injury and / or ulceration of the foot" [5].

The prevalence of PD ranges from 1.5% - 4.8% of the population worldwide and it is estimated that around 20% of diabetics will suffer at least one PD ulcer throughout their life, which may lead to a amputation. It is also considered that at 5 years the re-ulceration rate is 70% and those adult users have a 50% probability of losing the opposite limb in the 3 years after the previous amputation [5]. This complication causes a deterioration in the quality of life of people due to the disability and morbidity that it causes, in addition to being the primary cause of loss of limbs or non-traumatic amputations. Likewise, the diabetic foot gives rise to a high impact on the family, personal, social and economic burden for the health system, since it is the main reason for hospitalization in diabetics [5].

Treatment for diabetic foot ulcers always follows the same algorithm, which begins with prevention and health education by relieving foot pressure and managing diabetes, in order to prevent its onset. Later, when the ulcer is present, it is a matter of debriding the non-viable tissue and controlling the bacterial load, inflammation, humidity, exudate and pain, for which the cure is used in a humid environment. As the severity of the ulcer increases or becomes stagnant and the above procedures cease to be effective, advanced therapies are resorted to, with amputation and skin grafts being used as a last resort in acute or urgent chronicles [5,6].

There are several advanced therapies for the treatment of diabetic foot ulcers, including negative pressure therapy, a novel therapy that is currently used to treat complex acute wounds and chronic stagnant wounds in the healing process [7].

TPN was first used in 1993 by Fleischmann, who applied TPN with a foam dressing to 15 users with open fractures in order to generate granulation tissue and wound healing. Although it was Morykwas and Argenta in 1997 who designed a pored polyurethane foam dressing that interacted connected to a vacuum reservoir by applying pressure to the wound surface. Subsequently, the company Kinetic Concepts Inc. created a vacuum assisted closure system, commonly known as VAC® (Vacuum Assisted Closure), whose main property is to create a humid environment...
that favors healing [7].

This therapy consists of a non-invasive and active system, which distributes controlled subatmospheric pressure on the surface of the ulcer. The ulcer bed is covered by a polyurethane or polyvinyl sponge adapted to the ulcer area, which in turn is covered by a transparent adhesive film dressing that seals it tightly. The film dressing is connected by means of a suction tube to a vacuum pump where the negative pressure to be applied to the surface of the ulcer is adjusted (the pressure usually ranges between –75 and –125 mmHg continuously or intermittently), thus draining the exudate into a container or collection bag located in the vacuum pump [8, 9].

The Effects Demonstrated when Applying the TPN are [5,9,10]:
- Eliminate exudate.
- Reduce bacterial load.
- Reduce tissue edema.
- Stimulate the formation of granulation tissue.
- Reduce depth and ulcer area.
- Promote tissue proliferation.
- Increase local blood flow.
- Stimulate the healing of the perilesional tissue and the approach of the edges to each other, allowing the ulcer to close.

According to the scientific literature, TPN is indicated in surgical wounds, vascular, diabetic or pressure ulcers, burns, necrotic wounds, grafts, open abdominal incisions and infected wounds. However, this therapy is contraindicated in the presence of necrosis in the ulcer bed, untreated osteomyelitis, non-enteric or unexplored fistulas, malignant lesions, and wounds with exposure of veins, nerves, or organs in the insertion area [11,12]. TPN also entails complications such as bleeding or necrosis, perilesional maceration, with infection and local pain being the most frequent and to a lesser extent. Despite finding studies that indicate the effectiveness of negative pressure therapy compared to other types of therapy as an effective and safe means for the treatment of diabetic foot ulcers, the evidence and studies found are scarce, so there is a great limitation [10, 13-15].

Material and Methods
The elaboration of this work was carried out by means of a bibliographic search in scientific databases between the month of November 2019 and March 2020, in order to carry out a narrative review of the literature. The studies selected to prepare this narrative review were identified in the Scopus, Pubmed / Medline, Cochrane and Web Of Science (WOS) databases. The key words in this review are: "diabetic foot ulcer", "diabetic foot", "negative pressure therapy", "V.A.C.", "Vacuum Assisted Closure". From the keywords, a search string was designed, in which the following boolean operators were used ("VAC" OR "VAC therapy" OR "negative pressure" OR "Vacuum Assisted Closure" OR "negative pressure therapy" OR "NPWT" OR "negative pressure wound therapy") AND ("diabetic foot" OR "diabetic wound" OR "diabetic ulcer" OR "diabetic foot ulcer").

The Criteria that have been Taken into Account for the Selection of the Relevant Studies are the Following:

**Inclusion Criteria:**
- Studies whose participating subjects are patients with diabetic foot ulcers over 18 years of age.
- Studies using negative pressure therapy as treatment.
- Studies published in databases or scientific journals.
- Scientific articles whose publication is between the year 2014-2019.
- Articles published in English or Spanish.

**Exclusion Criteria:**
- Studies whose subjects are patients under 18 years of age.
- Studies that do not provide relevant data.
- Studies that apply negative pressure therapy associated with another type of therapy.
- Articles that study negative pressure therapy comparing different types of dressings.
- Articles published in books or non-scientific web pages.
- Articles published in a language other than Spanish or English.
- Articles published prior to 2014.

In the first search, from the previously designed search string, a total of 1230 articles were found. Subsequently, applying the inclusion and exclusion criteria, 699 articles were obtained, of which only 75 were relevant to the review. After eliminating those duplicate and non-relevant articles analyzed in full text, 16 articles were selected to be included in this narrative review (Table 1).

**Table 1: Search strategy**

<table>
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<th>SCOPUS</th>
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<th>PUBMED / MEDLINE</th>
<th>COCHRANE</th>
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<tr>
<td>Articles evaluated in full text</td>
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<tr>
<td>Articles included in the narrative review</td>
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<td></td>
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To carry out the narrative review, 16 articles were used that studied TPN as a treatment for PD ulcers.

**Discussion**

TPN is a novel therapy, which is beginning to be used more frequently in the treatment of diabetic foot ulcers, although it remains unknown due to its lack of knowledge by nursing personnel. The different studies included in this review demonstrate that TPN is an effective and safe therapy compared to conventional therapies. Regarding the characteristics of ulcers, most authors indicate that TPN promotes the reduction of the ulceral area, as well as its depth, however one of the authors has greater reduction was observed with wet therapy than with TPN [10,15-18, 21,22].

A study also indicates that TPN has an anti-inflammatory effect,
which reduces inflammation and local edema, and other authors argue that TPN reduces bacterial load and infection [18,26]. There are also several articles that mention the decrease in tissue oxygenation when applying TPN in the ulcerated bed, which favors the stimulation of blood flow and its closure [24,25].

Regarding healing and closure of the ulcer, TPN favors the appearance of granulation tissue, which allows the edges to come closer until the ulcer closes completely [16,19-21,26-29]. What is more, the TPN shows a greater number of healed ulcers compared to the rest of the therapies in a shorter time and a lower expenditure of resources [10, 15,18-23, 28,29].

The costs of treatment for diabetic foot ulcers are controversial, according to Driver et. al, the cost of TPN was higher than the cost of wet therapy when total ulcer healing was achieved, however, the cost of TPN was lower if complete healing was not achieved [17]. However, according to Vaidhya, et al, the cost was lower in the PNT compared to the conventional bandage [23]. Other authors indicate that TPN is a cost-effective treatment compared to standard therapies [10].

The main complication of diabetic foot is amputation, it has been observed that the use of TPN as a treatment for this type of ulcers reduces the number of amputations, although one of the articles mentions that they are reduced major amputations, but no significant differences were found in minor amputations [10,18,19,21,29]. It has also been observed that the reulceration rate and re-amputation is lower applying the TPN [15,29].

Authors like Liu et al. they also include the reduction of adverse affects when using TPN in PD ulcers [10].

According to the articles included, most indicate that TPN is effective and safe [10,18,19, 21-23,26]. However, one of them mentions that there are no significant differences in safety and another in effectiveness compared to other types of therapy. Although authors such as Colak et al [15,21]. indicate that the effectiveness of TPN is the same as in other therapies, however, its effectiveness is greater if TPN is applied to infected ulcers [28].

Regarding the level of user satisfaction with the different treatments, the satisfaction of those patients treated with TPN is greater than with the cure in a humid environment and conventional dressings [16,18].

The following limitations have been found in this narrative review:

TPN is a novel therapy with little research. Most research on TPN is applied to abdominal wounds, fistulas, and complex vascular ulcers. Several of the articles dealing with diabetic foot ulcers do not have good methodological quality and the conclusions cannot be generalized, because clinical trials use small samples, are not representative and are not randomized. TPN is a great advance in the treatment of diabetic foot ulcers, therefore future research of higher methodological quality should be carried out to indicate the short and long-term effectiveness, the adverse effects of using this therapy and the costs associated with its use.

Conclusions

The TPN provides numerous advantages, since it favors the formation of the granulation tissue, reduces the depth and the area of the ulcers, which results in the healing and closure of the ulcers in a shorter time and even decreases the bacterial load and the rate of amputations and reulcerations. TPN compared to conventional therapies has shown better results in terms of speed, effectiveness, and healed ulcers. TPN should be adopted in clinical practice, since it is a therapy that provides numerous benefits for patients. What's more, most studies show successful results and improve patients' quality of life.

References

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