ISSN 2349-7823

International Journal of Recent Research in Life Sciences (IJRRLS)
Vol. 6, Issue 4, pp: (10-15), Month: October - December 2019, Available at: www.paperpublications.org

The clinical effects of Intermittent Negative Pressure on deteriorated diabetic foot

[1]Osama S. Abbadi, [2]Khalid Hussein Bakheit

[1]Lecturer of biochemistry, Faculty of medicine, Omdurman Islamic University, Sudan.

[2]Associate professor of biochemistry, Faculty of medicine, King Abdulaziz University in Jeddah, Saudi Arabia.

Abstract: **About fifty percent of patients with long standing diabetes mellitus eventually develop the diabetic foot. Millions of diabetic patients are amputated annually at different levels on their feet. The diabetic foot develops either due to neuropathy or micro-vascular diseases. Diabetic foot management includes controlling the diabetes mellitus-(blood glucose level), the choice of a proper foot wear, care of the wound, and, if needed, surgical revascularization or amputation. Negative pressure wound therapy, using NPWT machines, proved its efficacy in draining and closing diabetic foot ulcers. The objective of the study was to determine the effects of applying intermittent negative pressure (INP) in patients with diabetic foot, with and without a preformed ulcer. Six non-ulcer diabetic foot patients were subjected to INP using a foot-shaped plastic cast for ten minutes every two days. Another six patients with wounded diabetic foot were subjected to INP by a traditional cupping kit for five to seven minutes every two days. The study showed that four of the non-ulcer patients-(representing 67%), admitted that the symptoms of diabetic foot were reduced markedly, the remaining two-(representing 33%), stated that there were no improvement in symptoms, but no patient declared to be deteriorated due to the experiment. The patients with foot ulcer had got a great benefit from the INP; their wounds did heal faster than expected. In conclusion, intermittent negative pressure reduced the symptoms of diabetic foot and fastened the healing of diabetic wounds.**

Keywords: **Negative pressure, Diabetic foot, Amputation.**

1. INTRODUCTION

Diabetes is a metabolic disease with high prevalence; more than 150 million people, in different rates and distributions around the globe, have diabetes [1]. The diabetic foot is defined as any foot disorder results directly from chronic diabetes mellitus, and about 15% of the diabetics develop this complication [1], [2]. Roughly, four to four and a half million amputation processes are performed annually because of the deterioration of diabetic foot conditions [2]. The diabetic foot is mainly manifested by its ulcers and skin changes, but the ongoing pathogenesis is usually preceded by slow symptomless progression. According to Volmer-Thole and Lobmann, half of the diabetic foot disorders are attributed to neuropathy, and about one third to the neuro-ischemia; only sixth of the cases of diabetic foot are considered purely vascular [3]. Foot ulcers are almost always present before amputation; in every ten amputees, about nine were having a pre existing ulcer [4]. Simple clinical tests such as the diminished ankle reflex and monofilament screening locates the neuropathy [5]. Loss of vibration sensation is tested through the Biothesiometry [5], [6]. Conservative management of diabetic foot includes regular check for foot, at least once a year, patient education about the disease, selection of appropriate footwear, and care for the present ulcer by debridement and callus removal [7]. Specific care for the foot with vascular pathology includes the surgical revascularization, which is a complex choice with vague outcomes [7]. Unless the foot ulcer is massive or infected, the foot should be given a chance to heal before thinking about surgery, during a month and a half period of proper wound care [8].

The main types of physical managements of diabetic foot could be categorized into three main modalities: pressure offloading techniques, hyperbaric oxygen therapy, and negative pressure wound therapy. Pressure offloading is used at the ulcer stage of diabetic foot disease, along with careful dressing and surgical removal of debris and callus [9].

Offloading, in general, needs more clinical evidence and elaborative explaining in the mechanisms of action. It also needs development to become more suitable to different patients according to their individual needs [10].

Hyperbaric oxygen therapy (HBOT) is a complementary method in the management of the diabetic foot [11], [12], [13], [14]. It involves the delivery of an Oxygen concentration higher than the atmospheric Oxygen, optimally 100%, to the patient in an ambient chamber. Oxygen plays an important role in the physiology of wound healing. It is hypothesized that HBOT acts by enhancing the leucocytes to combat infection and inhibit bacteria and bacterial toxin formation [15], also it kills anaerobic bacteria by the unfavorable high oxygen concentration [15], [16]. High oxygen tension is also a promoter for fibroblasts to produce more collagen fibers; an important protein in the healing process [16]. Although the effect of HBOT is still controversial and the scientific evidence needs more search, reviews showed that the rates and extent of amputations were significantly reduced when HOBT is introduced [12], [13]. Negative pressure wound therapy (NPWT) is a mechanical system that uses the application of negative pressure to heal and drain a preformed ulcer. It is used in the treatment of diabetic foot wound and any chronic ulcerated wound of the foot [17]. The conventional NPWT system is composed of a suction device to give the negative pressure potential, a sucking tube connected between the device and the wound surface, and at the wound surface there is foam gauze shaped to fit the ulcer area, and a plaster cover to ensure the sealing and isolation of the negative pressure area [18]. Gauze is changed in every two to three days to ensure the dryness of the wound. When compared to the most optimum conventional dressing, NPWT proved to be more effective and safe and even the rate of consequent amputation was less [19]. It is evident that NPWT stimulate new vascular formation, and accelerate the formation of granulation tissue. It is hypothesized that NPWT increases local expression of anti-inflammatory factors such as IL-8 and IL-10 and growth factors such as PDGF, VEGF, TGF-β, and PDGF [20]. The molecular responses to NPWT are attributed to the mechano-transduction and chemical transduction of the cells [20], [21]. The main NPWT disadvantages are the uncomfortable settings of the process and the high cost of the kits, though some trials were performed to design a cheaper NPWT for poorer areas of the globe [18]. This study aimed to make simpler, manual device to enhance healing of an ulcer, and improve the general diabetic foot condition before ulcer formation. It uses the same negative pressure theory but with different settings.

2. MATERIALS AND METHOD

This was an Experimental study with an intention to treat (ITT), held in the teacher's diabetic center in Khartoum city for Six weeks. Twelve patients participated in this study: six diabetic foot patients with no ulcers, and six diabetic foot patients with foot ulcers. For non-ulcer diabetic feet, a specially designed boot-shaped plastic cast was manufactured in Aotad® factory for prosthetic limbs. It was made to accommodate the foot until the level of the upper leg; see figure (1). Manual pump with an inverted one-way valve was attached to the boot to give the suction power. By this maneuver, the negative pressure built up inside the boot. No pressure monitor was attached to the boot. The suction was intermittent to avoid pain, edema, and bruises. The application of negative pressure was for ten second, and then a rest period was held for five seconds. Each patient had fifteen minute session every two days. For patients with diabetic foot ulcers, the kit of traditional cupping shown in figure (2) was used. Cups were placed in the site of the ulcer, providing that the cup is covering the ulcers well and beyond. The kit handle was used to deflate the air inside the cup thereby creating the negative pressure. Cups were left on each spot for between ten to twelve seconds. Resting gap was held after each deflation for five seconds. The process was repeated for five to seven minutes on each ulcer. Ulcers with profuse purulent discharge usually took longer time before deflation of the cups. The sessions were performed before the regular wound dressing of the patients. Statistics were carried out by calculators and Microsoft® 2007 office Excel software. The study was considered of minimal intervention nature by local research committee, and verbal consents were taken from the candidates. The procedure was thoroughly explained to candidates including its possible side effects and complications. Patients whom had been photographed were asked for permission.

ISSN 2349-7823

International Journal of Recent Research in Life Sciences (IJRRLS)
Vol. 6, Issue 4, pp: (10-15), Month: October - December 2019, Available at: www.paperpublications.org

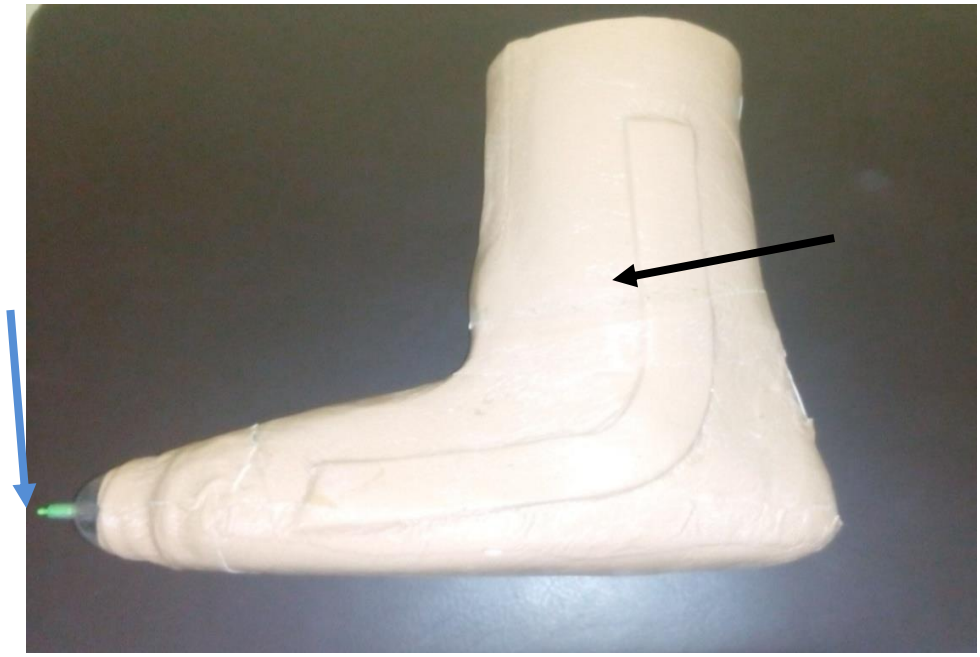

Figure 1: Plastic cast used for the non-ulcer group. Notice the fiberglass bar support (Shown by the black arrow) and the unilateral valve (shown by the blue arrow).

Figure 2: The cupping device. The handle (shown by the blue arrow) contains a small negative pump, will be attached to the cups (shown by the black arrows) directly or by the tube (shown by the red arrow).

3. RESULTS

Among the six non-ulcer patients, four patients appreciated an improvement in sensation; the remaining two said that there was no difference in sensation pre- and post experiment. No patient claimed to be deteriorated after the experiment; see figure (3). Concerning the patients with diabetic foot ulcer, there was great improvement in the draining of wounds before the regular dressing. Change in color of the skin was a good indication for the circulation improvement, revise figure (4). The negative pressure application before dressing had lead to the acceleration of wound healing in five patients; nevertheless, no wound was completely closed during the experiment period, and one patient progressed to left middle toe amputation with wound debridement.

ISSN 2349-7823

International Journal of Recent Research in Life Sciences (IJRRLS)
Vol. 6, Issue 4, pp: (10-15), Month: October - December 2019, Available at: www.paperpublications.org

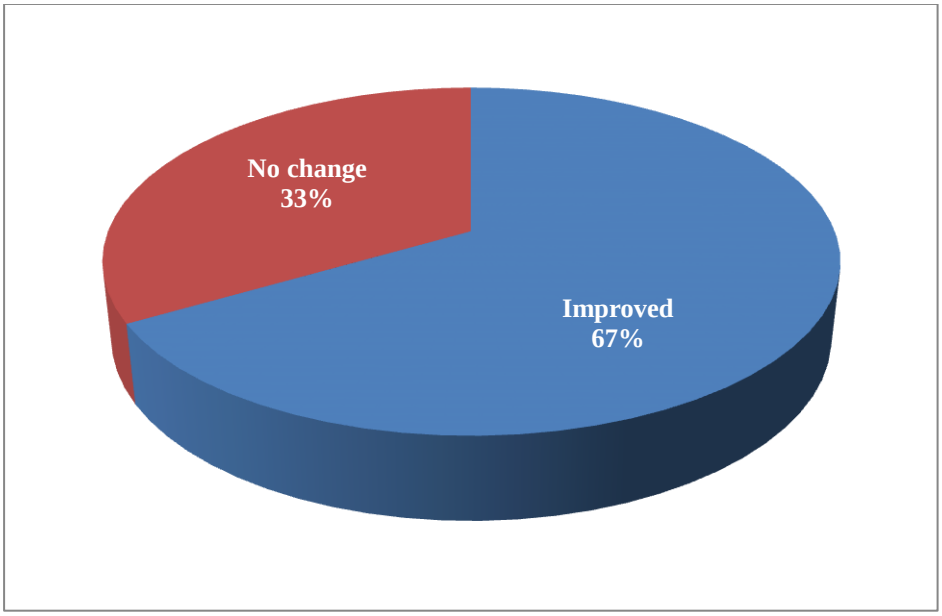

Figure 3: Pie chart showing the percent of patients claimed to be improved after the negative pressure sessions versus the patients who claimed that there were no changes. No patient stated they were deteriorated due to the experiment.

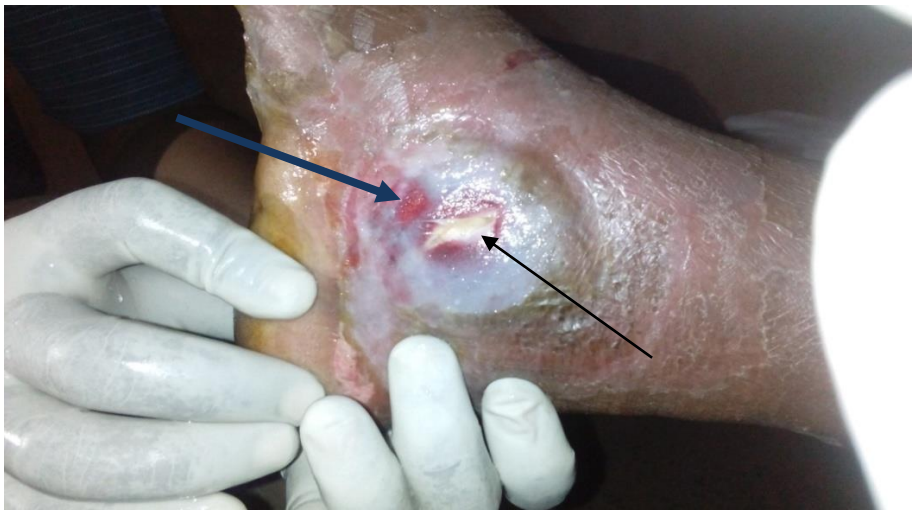

Figure 4: Improved perfusion of the ulcerated foot, as seen by the red erythematous medial malleolus (blue arrow), after using the cups in intermittent sessions. The wound is almost closed (black arrow.)

4. DISCUSSION

To summarize the results, it could be said that two-thirds of the non ulcer patients felt significant improvement in sensation after using the INP boot, and one third felt no difference in symptoms. The patients with foot ulcer had a great benefit from the INP cups, which accelerated the draining of wounds. The positive results obtained by this study are encouraging for further INP experiments. Negative pressure usage in open wound is well known, with different settings, but has not been used in non-ulcer diabetic foot. HBOT [11], [12], [13], [14], and NPWT [17], [18], [19], are both effective for wound management, and the cupping used in this research can be very effective if combined with regular dressing and surgical debridement. Advantages of the plastic suction cast include its cost effectiveness; it costs about 140 USD. For manufacturing, it is also easy to use, not associated with dangerous side effects, and could be used for a short

period of fifteen minutes or less every two days. As a disadvantage, this research recruited few sample size, compared to the high prevalence of diabetes and diabetic foot. It also did not take in consideration the measurement of the applied negative pressure with pressure meters. INP protocol was an act of diligence and not based on a previous literature. It did not involve some important parameters of the diabetic foot prognostics such as doppler ultrasound for vascular flow, biosthesiometry for the vibration, and monofilament test for the touch sensation. Further research should include larger and diverse sample population, involvement of multivariable indicators such as the sensation prognostics, the doppler and oximetry for circulatory estimation, the clinical chemistry laboratory, and Imaging studies; ultrasound, CT scan , MRI, and MRI angiography. Finally, there should be a multi-speciality research containing pathologists, endocrinologists, and surgical clinicians.

5. CONCLUSION

This research aimed to test the healing effects of Intermittent Negative Pressure by means of cubbing device and a costumed plastic foot cast, on diabetic foot patients. The method was tested on candidates with ulcerated and non ulcerated diabetic foot, and it proved to be effective and beneficial in both situations. The advantage of this study was its simplicity and its minimal intervention with the regular treatment of the patient. On the other hand, the sample size was small, the duration of the experiment was short, and no follow up was done to the patients. Further research on this technique is advised, with proper recruitment of a good representative sample population.

REFERENCES

[1] Boulton AJ, “The diabetic foot: a global view. Diabetes Metab Res Rev,” 2000;16(1):2–5.

[2] Aalaa M, Sanjari M, Shahbazi S, Shayeganmehr Z, Abooeirad M, Amini MR, Adibi H, Mehrdad N, “Diabetic foot workshop: Improving technical and educational skills for nurses,” Med J Islam Repub Iran. 2017; 31: 8.

[3] Volmer-Thole M, Lobmann R, “Neuropathy and Diabetic Foot Syndrome,” Int J Mol Sci. 2016; 17(6):917.

[4] Boulton AJ, “The diabetic foot: grand overview, epidemiology and pathogenesis,” Diabetes Metab Res Rev. 2008; 24(l):3-6.

[5] Kasalová Z, “Biothesiometry in the diagnosis of peripheral neuropathies [Czech],” Cas Lek Cesk. 2002;141(7):223-5.

[6] Davis EA, Jones TW, Walsh P, Byrne GC, “The use of biothesiometry to detect neuropathy in children and adolescents with IDDM,” Diabetes Care. 1997;20(9):1448-53.

[7] American Diabetes Association (ADA), “Standards of medical care in diabetes-2010,” Diabetes care. 2010;33(1):11-61.

[8] Brownrigg JR, Apelqvist J, Bakker K, Schaper NC, Hinchliffe RJ, “Evidence-based management of PAD & the diabetic foot,” Eur J Vasc Endovasc Surg. 2013;45(6):673-681.

[9] Edmonds M, “Diabetic foot ulcers: practical treatment recommendations,” Drugs. 2006;66(7):913-29.

[10] Bus SA, “Priorities in offloading the diabetic foot,” Diabetes Metab Res Rev. 2012;28(1):54-9.

[11] Kessler L, Bilbault P, Ortéga F, Grasso C, Passemard R, Stephan D, Pinget M, Schneider F, “Hyperbaric oxygenation accelerates the healing rate of non-ischemic chronic diabetic foot ulcers: a prospective randomized study,” Diabetes Care. 2003; 26(8):2378-82.

[12] Bishop AJ, Mudge E, “Diabetic foot ulcers treated with hyperbaric oxygen therapy: a review of the literature,” Int Wound J. 2014;11(1):28-34.

[13] Duzgun AP, Satir HZ, Ozozan O, Saylam B, Kulah B, Coskun F, “Effect of hyperbaric oxygen therapy on healing of diabetic foot ulcers,” J Foot Ankle Surg. 2008;47(6): 515-9.

[14] Liu R, Li L, Yang M, Boden G, Yang G, “Systematic review of the effectiveness of hyperbaric oxygenation therapy in the management of chronic diabetic foot ulcers,” Mayo Clin Proc. 2013;88(2):166-75.

[15] Bakker DJ, “Hyperbaric oxygen therapy and the diabetic foot,” Diabetes Metab Res Rev. 2000;16 (1):55-8.

[16] Senior C, "Treatment of diabetic foot ulcers with hyperbaric oxygen," J Wound Care. 2000;9(4):193-7.

[17] Schwartz JA, Goss SG, Facchin F, Gendics C, Lantis JC, "Single-use negative pressure wound therapy for the treatment of chronic lower leg wounds," J Wound Care. 2015;24(2): 4-9.

[18] Vaidhya N, Panchal A, Anchalia MM, "A New Cost-effective Method of NPWT in Diabetic Foot Wound," Indian J Surg. 2015;77(2):525-9.

[19] Blume PA, Walters J, Payne W, Ayala J, Lantis J, "Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial," Diabetes Care. 2008;31(4):631-6.

[20] Glass GE, Murphy GF, Esmaeili A, Lai LM, Nanchahal J, "Systematic review of molecular mechanism of action of negative-pressure wound therapy," Br J Surg. 2014;101(13):1627-36.

[21] Engler AJ, Holle AW, "More Than a Feeling: Discovering, Understanding, and Influencing Mechanosensing Pathways," Curr Opin Biotechnol. 2011; 22(5): 648–654.