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The negative pressure effect on the lower limbs in patients with Peripheral arterial disease

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Abstract: **Peripheral arterial disease (PAD) is a common complication of diabetes mellitus. It is the main factor attributed to the diabetic foot ulcer and the subsequent foot amputation. The current management for PAD includes the use of hyperbaric oxygen to improve the perfusion to the lower limbs. Negative pressure recently had been experimented as a new method to enhance the lower limb circulation, but only studied in healthy non diabetics. This research aimed to study the effects of applying intermittent negative pressure (INP) with a simple manual device to diabetic patients with PAD. A costumed plastic cast, designed to accommodate the foot and leg, was used to deliver the negative pressure to six patients with PAD. The process involved ten seconds of INP and five seconds as rest, and repeated for ten minutes daily for four weeks. The right lower limb was the test and the left was used as a control. The arterial flow magnitude was measured by a portable Doppler machine from the posterior tibial artery and dorsalis pedis artery. Five of the six patients, representing 83% of the patients, agreed that the Plastic cast improved their PAD associated symptoms; however, the mean difference of the Doppler vascular scoring between the test and control was insignificant, so it had been concluded that applying INP to the diabetic patients with PAD improved their symptoms.**

Keywords: **Diabetes, Peripheral arterial disease, Negative pressure.**

I. INTRODUCTION

One of the most common metabolic disorders worldwide is Diabetes mellitus. Diabetic foot is any foot pathology that results directly from diabetes or its long term complications. The two causative factors of diabetic foot are diabetic neuropathy and peripheral vascular diseases [1]. About 15% of the diabetic foot patients present with foot ulceration and fifth of those might face amputation [2], [3]. The ulcer of diabetic foot is caused by the impaired sensations and affected arterial perfusion. It is the peripheral arterial disease (PAD) that has a strong association to diabetic foot ulcers, rather than the micro-vascular disease [4]. One of each two diabetic foot ulcer patients has also accompanying PAD [4], [5]. A good general definition of PAD is the occurrence of infra-inguinal arterial occlusion due to atherosclerosis [4]. Presence of both PAD and foot ulcer implies bad prognosis, because wound healing is delayed, and risks of amputation and death are increased [4], [6], [7]. In fact, the 2008 EURODIALE study of Prompers et al concluded that a diabetic foot ulcer accompanied with a PAD is a completely different entity than the foot ulcer alone [6], for all of these reasons, the presence of the PAD is considered as one of the poor prognostic values for the ulcer progression [7]. The 2015 International Working Group on the Diabetic Foot- IWGDF, recommended to examine the diabetic patient at least once every year for PAD, by good notes of history and clinical examination, even if no symptoms are present. Palpation of the popliteal, posterior tibial, and dorsalis pedis arteries is important both for diagnosis, management, and evaluation of the diabetic foot. PAD could be excluded simply by comparative examination of the pulses; the ankle-brachial index – ratio between the rate of Posterior tibial artery to the brachial artery, of 0.9-1.3, will exclude the presence of PAD, as well as a toe brachial index of 0.75 or more [4]. Arterial Doppler ultrasound is an excellent, non-invasive method of diagnosis. If the dorsalis pedis artery has an apparent tri-phasic waveform, this would be against the presence of PAD. The skin

perfusion test is another simple modality of diagnosis of PAD: if a skin perfusion pressure test was ≥40mmHg, the healing probability increases by one fourth, likewise if a toe pressure test recorded 30mmHg or more [4]. Angiography (Radiographic vascular imaging) of the lower limb is definitive in diagnosing PAD. This could be performed through CT angiography, MRI angiography, or from inside (intra-arterial) angiography. Together with colored Doppler ultrasound, angiography gives excellent anatomical information [4]. This will be very beneficial when considering the revascularization surgery for the management of foot ulcers combined with PAD.

The current management choices for diabetic foot involve the non-invasive foot orthotics, also known as Pedorthics, and surgical choice, either by debridement (removing dead tissue), revascularization, or both. All should be enforced with patient education about the care of diabetic foot, and the importance of controlling the causative etiology, Diabetes mellitus. The surgical choice is complicated and its results are unpredictable, because the vessels are originally diseased, the diabetes is already usually advanced, and collateral vessels are also weak [8]. The pedorthics, on the other hand, dug their way successfully to be an important part in the management of diabetic foot ulcer [9], but have no role in treatment of PAD. This thesis aimed to invent a new method that is simple, could be performed at bedside, and lead to improvement of both the diabetic foot ulcer and PAD. All the focus of research concerning diabetic foot was on how to treat the foot wound. The PAD is not of great weight in clinical trials, mainly because it is a hidden entity of diabetic complications. The non-surgical intervention of diabetic foot involves the above mentioned pedorthics, hyperbaric oxygen therapy, and the negative pressure modalities. In 2015, Lavery et al performed a three months clinical trial to compare the effects of three pedorthic aids in healing a foot ulcer: shear-reducing foot beds, total contact casts, and healing sandals. Total contact cast was the most effective and lead to the healing of about seventy percent of ulcers, it also had the fastest healing period [10]. The superiority of total contact cast over all other off-loading methods was demonstrated earlier in 2001 by Armstrong et al [11]. Used for more than forty years, hyperbaric oxygen therapy is effective in healing wounds, but it is linked to a number of side effects due to increased Oxygen concentration, let alone the long uncomfortable procedure that takes between one and two hours, for each session [12], [13], [14].

The use of Negative pressure wound therapy, abbreviated NPWT, became popular since 2000. It involves the placement of a foamy material at the wound surface. A suction tube is attached to the foam surface, which in turn attached to a suction machine. An adhesive tape is applied to the skin to seal the whole area, thereby creating a vacuum when the machine is switched on. The goal of the procedure is to suck out the fluid in the wound, which gives the area a chance to heal properly [12]. NPWT is postulated to augment capillary reformation in the wound area, drain harmful fluid accumulation, create in isolated medium for healing, and stimulate the re-growth of lost tissue [12], [15]. Despite that the above assumed roles are still uncertain; the effect of NPWT is proven by the obvious healing results, especially in diabetic foot ulcer [16]. The NPWT is not exclusive for the diabetic wound; it also proved effective in healing wounds-either recent or chronic, in accelerating the healing of skin grafts, and improving the condition of bed sores [12], [15]. The use of intermittent negative pressure (INP) is recently introduced to improve PAD; Sundby et al performed a study in 2016 on healthy individuals with an INP technique resulted in enhancement of the peripheral circulation [17]. With another group of scientists, Sundby proved the efficacy of INP in healing foot ulcers[18]. The apparatus used on Sundby et al was an electric INP generator and a vacuum chamber shaped like the foot and leg[17,18]. The research showed good results improving circulation. The focus of diabetic foot studies was on how to heal an existing ulcer and improve patient's quality of life, but the underlying vascular pathology is overlooked. The most difficult part of using a negative pressure modality in the foot and leg is how to form a vacuum around such part of the body. The effort in this thesis is on how to deliver a convenient, easy, and healthy method to put the foot and leg in a vacuum state, hoping that it will improve both the PAD and diabetic foot, with or without a preformed ulcer. INP method used in the later studies was modified in our research; we used very short durations (One seconds INP, two seconds venting, and two seconds rest), unlike the former INP protocol (ten seconds INP, seven seconds venting) [18].

II. MATERIALS AND METHOD

Six diabetics with lower limb vascular complications and PAD were chosen. None of them have a pre-existing ulcer. Patient's data was collected by paper questionnaire. Bed-side tests included the arterial blood flow measurement via a portable Doppler ultrasound device. A plastic template was custom designed in Aotad factory for prosthetic limbs, Khartoum, Sudan. It is in a shape of a long neck shoe, reaching about ten centimeters below the knee; see figure (1). Through an opening in the anterior part of the boot, suction was performed by a manual pump attached to a valve. By this maneuver, the negative pressure builds up inside the box. Barometric scale was not introduced into the boot, so the suction was held and adjusted according to the patient's subjective reaction to the suction. 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 a ten minute session per day. All patients were tested on the right lower limb, and the left was a control. The arterial flow was taken from the posterior tibial and dorsalis pedis arteries pre- and post- sessions, and the magnitude of the voice was given a score from zero, which equals to absent pulse, to ten, which is a completely normal pulse. Methods of measuring the posterior tibial and dorsalis pedis arteries are demonstrated in figure (2). Patients were then monitored for twenty minutes for any possible side effects or complications.Statistics analysis was done by calculators and Microsoft® Excel (2007) software .Consents were taken from all patients, and the possible side effects and complications were thoroughly explained for them.

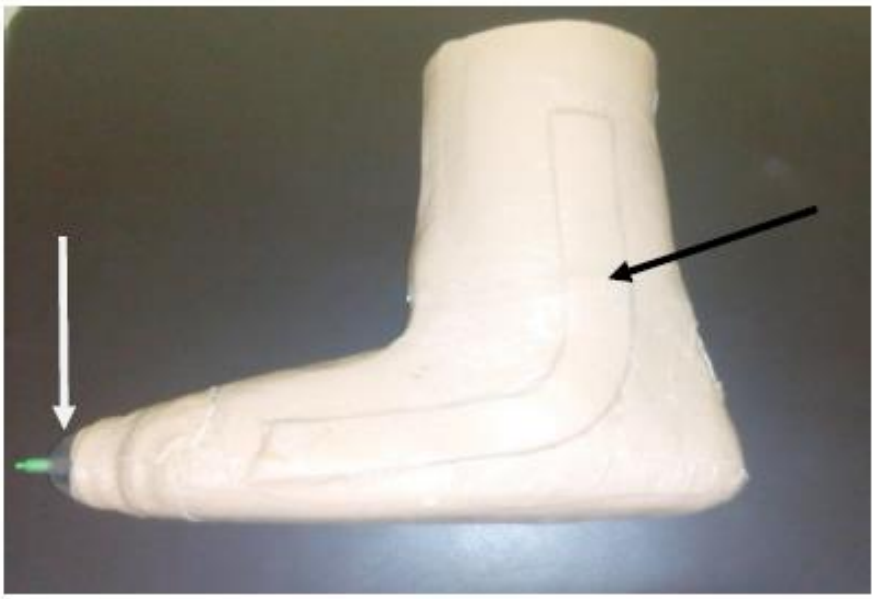

Fig 1: The plastic cast, demonstrating the one way valve cup with a white arrow and the extra fiberglass support with a black arrow. Photo from Abbadi and Bakheit [19], after permission.

Fig 2: Locating and measuring the flow of the posterior tibial artery (a) and dorsalis pedis artery (b) with a portable Doppler device.

III. RESULTS

Five of the six patients were satisfied by the post- experiment results. They stated that the feet felt less painful and less swollen. Dependent edema that builds up after walking for a distance was markedly less. The sixth patient stated that there was no improvement in the PAD after using the boot. No patient claimed to deteriorate after the experiment. See figure (3). The Doppler measurements scored a mean of (8.2 +/- 1.5) for Posterior tibial artery pre- testing and (8.7 +/- 1.64) post test. The standard error (SE) for the two means was (0.4536) and the T-test value was 1.1023, giving a P-value of (0.8519). For the dorsalis pedis artery, the mean flow index was (8.3 +/- 1.64) pre testing and (8.8+/- 1.96) after the test. The standard error for the two means was 0.5216 and the T-test value was 0.3067, giving a P-value of (0.6173). In both cases, the Null hypothesis was not rejected. Revise table (1) below.

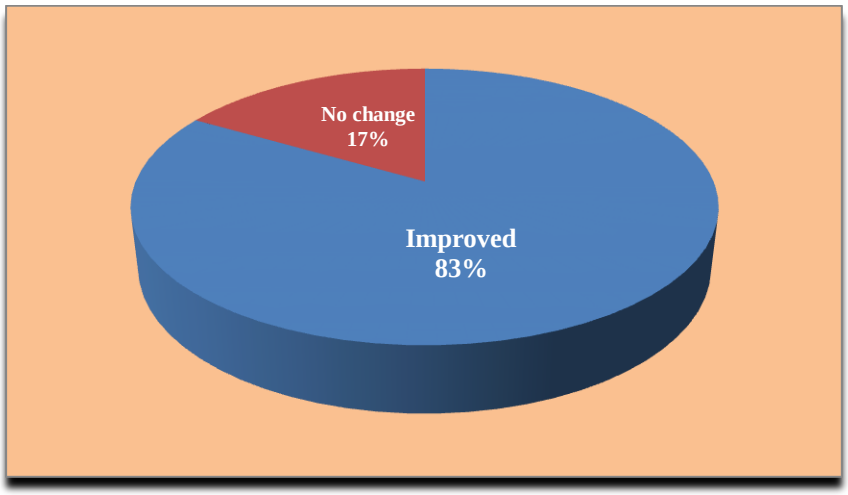

Fig 3: A pie chart demonstrating the percent of the patients reported to be improved versus the patient who stated that there was no improvement from the experiment.

TABLE 1: Shows the values of the Posterior tibial and dorsalis pedis arteries flow indices before and after the INP sessions in the six patients. Arithmetic means, Standard deviations, and 95% Confidence intervals of each category are also shown. SD; standard deviation, CI; confidence interval.

Patient's Index	Posterior Tibial score pre-test	Posterior Tibial score post-test	Dorsalis pedis score pre- test	Dorsalis pedis score post- test
#1	9	8	9	9
#2	9	9	9	7
#3	8	10	8	9
#4	7	8	8	9
#5	8	8	9	10
#6	8	9	7	9
Mean	8.2	8.7	8.3	8.8
SD	0.75	0.82	0.82	0.98
95% CI	6.7– 9.70	7.06– 10.00	6.66– 9.94	6.84– 10.00

IV. DISCUSSION

To summarize the results, it had been found that five of the six patients, resembling a percent of (83%), stated that their PAD symptoms were improved after the INP sessions. The mean arterial flow index for the posterior tibial artery was (8.2) before the INP sessions, and (8.7) after the sessions, and for the dorsalis pedis artery, it was (8.3) before INP, and (8.8) after the sessions, however, the statistic difference between the Posterior tibial and dorsalis pedis arteries flow before and after the INP, was not significant. Therefore it is fair to say that the subjective results are quite satisfying while the tangible results are disappointing. Nevertheless, the symptoms improvement is of great benefit, because it gives the experiment and the device the trust of candidates for further improvements. The results come in pace with the 2016 Sundby et al conclusion, where INP was tested in healthy volunteers, and it proved to improve the lower limbs blood flow[17]. In fact, the device that had been used in our experiment could be considered as the manual version of Sundby et al device, the differences being the absence of the automated machine and the pulse and oxygen saturation sensors. The improvement of symptoms was expected, while the change in vascularity needs more than a few weeks. The symptoms improvement is likely to be caused by improved circulation and warming of the feet by the increased blood flow. The major pitfalls and limitations of the study were that it was not pre-discussed with an expert endocrinologist or a surgeon, and depended mainly on the obtained literature. The plastic device used was not properly sealed, and needed to be re-vacuumed several times during some sessions. It also cannot be worn by markedly obese patients. Pressure measurement manometer was not installed because they were not found except in physics laboratories attached to large powered vacuum devices. The polyethylene material, from which the device made, caused the feet to sweat profusely. The sessions were relatively long and needed more than forty minutes to finish. The Oximeter was omitted from the experiment due to technical difficulties, which deprived us from a very good and informative index. The sample size was not satisfying, considering that the PAD is a prevalent complication of diabetes. The doppler machine that had been used was small and do not contain the imaging and wavelength measurement facilities. Furthermore, all the experiment candidates were of mild PAD, to avoid serious complications.

For further research in the PAD, it is suggested to set up a better diagnostic build up in the Sudan, because the PAD diagnosis is a matter of the physician's experience and doppler ultrasound is seldom done due to its relatively high cost. The plastic cast should be proposed to a research committee to study its efficacy in PAD management. Sundby et al device[17] should be made available for usage, with trained nursing and medical staff to operate. The diabetes complications research should be well funded, particularly in sub-Saharan Africa, where diabetes is increasing in incidence. And finally, more studies should be established concerning the pathogenesis of the PAD and all the diabetic complications.

V. CONCLUSION

Peripheral arterial disease-PAD is a direct path to foot ulcer and amputation. Intermittent negative pressure was applied to the lower limbs of six patient previously diagnosed with PAD. The INP improved the patients symptomatically; however there was no significant improvement in the Doppler vascular readings.

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