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CO2 Water Bath as a treatment Option in Diabetic Foot Ulcer Patients

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Abstract:

Background: A persistent, dangerous consequence of diabetes mellitus is diabetic foot ulcers (DFU). A number of complicated factors interact to cause diabetic foot. These factors include immune system and metabolic disturbances, peripheral neuropathy, and peripheral artery disease. The purpose of this study is to compare patients with DFU obtaining standard therapy versus those receiving carbon dioxide therapy.

Methods: 95 patients with DFU (mean age 55.6 ± 11.6 years; 59 men, 36 female) divided into two groups by randomized double-blind study, The CO2 therapy group (study group) will be treated with advance dressings, CO2 therapy, and antibiotics, while the traditional therapy group (control group) will get treatment only by advance dressings and antibiotics. Demographics data was taking, also, the size, color and sensation of the ulcerative area were all evaluated and compared between two groups.

Results: There are highly significance changes in the size, color, and sensation of the ulcerative region in study group after CO2 therapy according to the results but no significant changes in demographic data between the two groups.

Conclusion: The efficiency of CO2 water bath technique in treating ischemic feet has no deference between male and female and in other demographic deference in both groups, suggesting its potential use as a physiotherapy intervention for ischemic feet.

Keywords: DFU: Diabetic foot ulcer, CO2: carbon dioxide.

INTRODUCTION:

Diabetes mellitus (DM) is defined as a group of metabolic disorders that result in excess Hyperglycemia, which results either from a defect in the secretion of the hormone insulin or the action of insulin, or both (1) Diabetes mellitus is caused by a deficiency of β cells. The pancreas stops producing insulin in sufficient quantity or stops producing it completely, and this is known as Diabetes mellitus – type1 (DMT1) Insulin- dependent diabetes mellitus (IDDM), or when the body is unable to use that substance effectively, this represents Diabetes mellitus – type 2 (DMT2), which is not dependent on Insulin, Noninsulin-dependent diabetes mellitus (NIDDM) (2). The incidence of diabetes with foot complications has increase significantly during the last decade. A severe diabetic foot infection has approximately. A 25% risk of in the end requiring a major lower limbs amputation (3). At least 592,000 patients with diabetes mellites were living, with a

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lower limb's amputation in.2005, and 60% of these were major amputations. The number of people living with an amputation is has been increase by 70% by 2020 (4). Peripheral vascular disease is common in patients with diabetes mellites, in the development of ulceration, peripheral vascular disease separately is rarely a cause of ulceration: as with neuropathy, a combination of risk factors with less trauma more commonly causes ulceration (5). The diagnosis of diabetic foot infection is depended on clinical feature (i.e., redness, warmth., induration, pain/tenderness, and loss of function) (6). There are substitutional signs that propose infection (e.g., purulent and nonpurulent discharge, fetid odor, necrosis, undermining of wound edges, poor granulation tissue and lack of wound healing) (6). Several types have been published internationally; Wagner's classification, the Texas classification, Mike Edmonds' classification and the PEDIS classification Wagner classifies lesions in six grades of increasing severity,0-5 Grades 1 to 3 are depended on neuropathic ulcers of increasing severity based on to depth. and infection, while grades 4 and 5 are vascular lesions (7).

MATERIAL AND METHOD:

95 patients with DFU (mean age 55.6 ± 11.6 years; 59 men,36 female) with mean age of 55.6 ± 11.6 years and range between 40-70 years old, the patients will select by etiology and wound extension and by randomized double-blind will divide into 2 groups CO2 therapy group (study group) that using advance wound care, antibiotics and CO2 water bath, while the other group (control group) using advance wound care, antibiotics and plan water bath. The two groups were treated by debridement the wound, removed the dead tissue and dressing the wound, also the two groups was selected according to several exclusion and inclusion criteria. We take demographic data (age, residence, occupation) form the participant also physical examination for ulcer was done by Wagner's classification including: Ulcer (wound) assessment and sensory, examination of the foot ulcer [size of ulcer, color, and depth of ulcer also position of ulcer]. The foot of patients. was immersed in CO2-riched water (depth of 20–30 cm., 37–38°C, duration for 30 minutes) 3 times in week for the next 3 months **(8,9)**.

Ethical Consent:

Participants will be given both written and verbal information describing the nature of the study. Sufficient time will be allowed for participants to provide their consent.

Statistical of the study:

For statistical analysis, a paired T-test and two-way ANOVA test was performed to compare the variables prior to and after treatment and between the groups. The level of significance was set at P < 0.05.

RESULTS:

According to the age distribution of study sample in study group and control group are $(55.6 \pm 11.6, 55.7 \pm 10.7)$ respectively, also according to sex distribution are (48 (29 M, 19F), 47 (29 M, 18 F)) respectively, BMI (mean kg/m2 ± SD) (30.5 ± 4.3, 28.9 ± 5.0) respectively, according to Wound age (average months ± SD) (8.8 ± 14.3, 7.6 ± 8.2) respectively, also according to wound numbers are (50, 47) respectively. According to size, colure and sensation there are highly significant difference between the study group and control group also there is high significant difference in study group before

and after CO2 water bath treatment as in figure (1), also in wound area and depth there is high significant changes in study group after treated with CO2 water bath as in figure (2).

DISCUSSION:

Diabetic foot ulcers are a common complication of diabetes mellitus, and early intervention is key to preventing further complications such as amputations and cardiovascular disease (10). The results of our research confirmed that application of CO2 in water bath led to improvement in blood flow as in (11) and there was significantly improved the healing of DFU (12,8,9). Wounds in study group patients that received CO2 therapy healed significantly rapidly compared with the control group . After CO2 therapy, 66% of the wounds recover completely compared with 0% in the placebo group. CO2 water bath therapy has been reported to show potential benefits in accelerating the wound recover process of diabetic foot ulcers (DFUs) by Lower pH levels (13) In addition, CO2 has an anti-inflammatory effect change in CO2 concentration affect the intermediate metabolism. Arise in the CO2 concentration bring about arise in serum phosphorus and in the lactic dehydrogenize (14). Alkhawaja S take 100 patients with different diabetic foot lesion from minor lesion.to gangrenous wounds were diabetic mellites patient with foot ulcer have good response and from one hundred patient 60% patient complete cure after CO2 water bath therapy, This study highly similar to our study (12). The rise in CO2 concentration within the tissue and peripheral blood vessels causes pre capillary arterioles to dilated, thereby opening capillary that were functionally closed the same is true also when CO2 is applied to the skin, area changes after an increase in flow depend on the endothelium, mainly through a NO-dependent mechanism but also through vascular smooth muscle cell contraction and relaxation (15)

Shalan et al. performed an observational study on 22 diabetic patients with chronic wounds (8). There was no control group. They put their patients' feet into CO2-riched water bath 1 daily for 30 minutes, for 15 days they show improved blood flow (confirmed by Doppler flowmeter) and recover in wound color. There was no significant recover in wound area reduction this against the result of our study that showed there was highly significant change in the area of the ulceration (p < 0.005). The authors rightfully assumed that CO2 therapy would probably recover wound healing if the treatment lasted longer 3 years later, Abdulhamza et al,2018. conducted a study using the same device as Alkhawaja and Shalan. (12,8,9).

Abdulhamza et al. 2018 performed a study similar to ours except theirs was not double blind (9). They included 100 diabetic mellites patients with chronic feet wounds separated into study and control groups. The study group received both standard treatment and CO2 therapy. CO2 therapy was managed as gas in water bath. as.in our study. The patients put their feet in CO2-riched water for.30 minutes,3 times per week for 3 months.

The strength of our study is its methodology, because it was designed as a controlled double-blind randomized study, to our knowledge, our study, Alkhawaja and Shalan are the only ones investigating application of gaseous CO2 in water bath on diabetic wound recover, but Shalan had no control group (12,8,9).

Limitations of our study are there is some wounds needs more or frequent session than other so need more than 3 moth to complete healing as in figure (3) the wound takes 6 months to complete healing.

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Figures:



Figure (1): Mean size, color and sensation of wound for pre. and post therapy in both. groups. The number of asterisks (*) corresponds to the level of statistical significance (* p < 0.05, ** p < 0.005., ***p < 0.0005.). All values refer to mean \pm standard deviation (SD).



Figures (2): show wounds. prior to and after CO2 therapies in study group.



Figure (3): show wounds prior to and after CO2 therapies in 6 months duration of treatment with CO2 water bath.

CONCLUSION:

Significantly increased cutaneous blood flow in ischemic feet, and improved subjective symptoms. Moreover, the artificial carbon dioxide footbath induced rise in cutaneous blood flow in the feet was found to be reproducible. The same was true of the improvement in subjective symptoms. These results demonstrate the effectiveness of this method in the treatment of ischemic feet, and indicates it is potential utility as a form of physiotherapy in the treatment of ischemic feet. Further studies need to be

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carried out on related topics, including optimum carbon dioxide concentration and the general effects of carbon dioxide foot bathing on the body.

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