IOSR Journal of Nursing and Health Science (IOSR-JNHS)
e-ISSN: 2320–1959.p- ISSN: 2320–1940 Volume 7, Issue 6 Ver. VII. (Nov.-Dec.2018), PP 28-38
www.iosrjournals.org

Impact of Hyperbaric Oxygen Therapy and Wound Care on Clinical Outcomes for Patients with Diabetic Foot Ulcer

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Abstract: *Diabetic Foot Ulcer is the greatest costly and disturbing complication of diabetes mellitus which can lead to infection, gangrene, amputation, and even death if the necessary carefulnessis not provided.This study aimed to determine the impact of hyperbaric oxygen therapy (HBOT) and wound care on clinical outcomes for patients with diabetic foot ulcer. A quasi-experimental study was conducted on 120 patients with diabetic foot ulcer grade II according to Wagner-Meggitt classification. Three tools were usedfor collecting data:Tool (I): Diabetic foot ulcer patient's profile, Tool (II): Ulcer wound healing assessment, Tool III: Pain visual analogue scale.Results of the present study revealed thatHealing using HBOT and wound dressing wasmorerapid than that in the traditional dressing. No significant differences were found between the extent of ulcer healing in experimental group (1) and control group. The healing parameters related to ulcer depth, floor,tissue formations, ulcer discharge and skin area' characteristic around the ulcer in the experimental group (1) and control group was significantly faster than experimental group (2) throughout the 20 days follow up dressing periods. Accordingly, using HBOT as an adjuvant therapy with another wound care method to improve healing in persons with DFU is crucial.*

Keywords: *Clinical outcome, Diabetic foot ulcer (DFU), Hyperbaric Oxygen Therapy (HBOT),*

Date of Submission: 27-11-2018 Date of acceptance: 08-12-2018

I. Introduction

Diabetes is a complex, chronic illness which requires continuous medical care [(1).] It is one of the most important public health problems nowadays, due to its high morbidity and mortality levels [(2)]. Diabetes is classified into two broad etiopathogenic categories; Type (1) Diabetes, Type (2) Diabetes. [(3)]. It is manifested by marked hyperglycemia and common symptoms which include polyuria, polydipsia, loss of body weight, fatigue, skin and mucosal infections [(4)].

The goals of therapy for type 1 or type 2 Diabetes Mellitus (DM) are to eliminate symptoms related to hyperglycemia, prevent long-term microvascular and macrovascular complications, and allow the patient to achieve as normal a lifestyle as possible[(5)]. One of the most commoncomplications of DM is diabetic foot ulcers (DFU) as it is the most costly and devastating complication of diabetes mellitus. The most frequent underlying etiologies of DFU are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease [(6)].

Diabetic foot ulcers are complex, chronic wounds; it is believed that every 30 second, a limb is lost in the world as consequences of diabetes and DFU. Many classifications of Diabetic foot ulcer are presented. However, the most commonly used classification systems are the Wagner-Ulcer Classification system [(7)].

Numerous studies have shown that proper management of DFU can greatly reduce, delay, or prevent complications such as infection, gangrene, amputation, and even death [(8, 9)]. Moreover, the primary goal in the treatment of DFUs is to obtain wound closure and prevent infection. [(9)].

Standard care for DFU is ideally provided by a multidisciplinary team by ensuring glycemic control, adequate perfusion, local wound care and regular debridement, off-loading of the foot, control of infection by appropriate antibiotics and management of comorbidities [(10)].Another treatment of DFU is hyperbaric oxygen therapy (HBOT) which is an adjunctive treatment for diabetic foot. The exact mechanism of HBOT remains poorly understood. Some studies have reported that HBOT improved wound tissue hypoxia, enhanced perfusion, reduced edema, down regulated inflammatory cytokines, and promoted fibroblast proliferation, collagen production, and angiogenesis[(11)]. In addition, it is demonstrate that HBOT stimulating vasculogenic stem cell mobilization from bone marrow and recruited them to the skin wound [(12)]. It may reduce the risk of lower-extremity amputation and improve healing in people with diabetes with foot ulcers [(13,14)].

Jain (2009) defines hyperbaric nursing "the diagnosis and treatment of human response to actual or potential health problems in the altered environment of the hyperbaric chamber." Moreover, the role of hyperbaric nurses is multifunctional pre, during, and after HBOT, but ultimately their goal is to provide cost-effective, quality patient care according to established standards [(15)]. The nursing role is the cornerstone for management of diabetic foot ulcer through the selection of appropriate wound dressing care, which enhance the wound healing and save the limb from threating consequences if left without proper care and decrease unnecessary cost on the patient. This in addition to teaching and guiding the patient to control blood sugar level to optimal level by utilizing hypoglycemic agents, following diabetic foot regimen and performing exercises and most of all instructing patient about proper foot care hygiene and continuous health teaching and follow up care once ulcer has healed[(16,17)].

Aim of the Study: This study aimed to determine the impact of hyperbaric oxygen therapy and wound care on clinical outcomes for patients with diabetic foot ulcer

Research Hypothesis: Diabetic patients with foot ulcer who receive hyperbaric oxygen therapy and wounds care will ultimately have good clinical outcome in comparison with other groups of patients who will not receive such recommended intervention.

II. Materials and Method

Materials

Research Design: A quasi experimental study design was used to conduct this study.

Setting: The present study was carried out at the Vascular and Diabetic Foot Ulcer Unit, Wound Dressing Room and Oxygen Therapy Unit at Alexandria Vascular Center (AVC).

Subjects: The study subjects were a convenience sample of one hundred and twenty diabetic patients (120) complicated with foot ulcer grade II. The total number of the subjects is alternatively assigned into three equal groups (two experimental groups and one control group)

- Group 1: Experimental group that included 40 patients received hyperbaric oxygen therapy and wound care that done by the researcher.

- Group 2: Experimental group that included 40 patients received wound care that done by the researcher without hyperbaric oxygen therapy.

- Group 3: Control group that included 40 patients received routine hyperbaric oxygen therapy and hospital wound care.

Tools: Three tools were used in assessment and management of these patients.

Tool (I): Diabetic foot ulcer patient's profile (DFUPP)

This tool elicited patient's profile regarding diabetic foot ulcer. It comprised three parts to collect data:

Part I: Patients' Biosociodemographic characteristics, clinical data, laboratory investigations, anthropometric measures.

Part II: Assessment of the affected foot: this includes data related to foot and foot ulcer as;

a. Assessment of the affected foot: The foot was assessed for the following parameters: Skin, nails, edema site, foot color, foot skin's hydration, skin's temperature, skin's sensation, other skin lesions, deformities and pulsation.

b. Assessing the morphology of ulcer: The foot was assessed for the following parameters: number of ulcers, site of the ulcer, wound size, depth of ulcer, ulcer floor condition.

Part III: Intra Hyper Baric Oxygen Chamber Observation Check List (IHBOCOCL).

This part was developed by the researcher after review of relevant literature to observe and assess the following parameters: Ear barotrauma, oxygen toxicity, hypoglycemia, claustrophobia:

Tool (II): Ulcer wound healing assessment (UWHA)

It was adopted from **Yakout R** (2009) in order to evaluate and documented the extent of wound healing for all groups [(18)]. It included two parts:

Part I: Wound healing observation checklist (WHOCL)

The feature of wound healing may vary from complete to partial healing or incomplete healing.

1. **Complete healing**: it consists of two items; 0 = presence of healthy granulation tissue with new blood vessels, fibroblasts, and epithelial cells which is bright pink to red in color, and scar formation (which is replacement of damaged cells with fibrous scar tissue). 1 = complete epithelialization of the entire wound ulcer.

2. **Partial healing**: it scores as; 0 = repairing connective tissue and formation of granulation tissue within the wound space but not completely forming a fibrous scar.1 = decrease of wound size and its depth without formation of fibrous scar tissues.

3. **Incomplete healing**: non-healing wounds have traditionally been defined as those that fail to progress through an orderly sequence of repair in a timely fashion. Also it indicates no improvement in wound characteristics. It scores as; 0 = no repair connective tissue and formation of granulation tissue within the wound space.

1 = no decrease of wound size and its depth; 2 = no formation of fibrous scar tissue.

Part II: Photographic pictures for evaluation of wound healing (PPEWH): Colored photographs were taken on initial assessment, then tenth day, and twenty day to document and comparable different stages of wound healing process for all groups.

Tool III: Pain visual analogue scale (PVAS)

The visual analogue scale (VAS) is a simple and frequently used method for the assessment of variations in the intensity of pain. This scale is starting at the left side with 0 no pain and 10 indicate worst pain.

Method

- An official letter from the Dean of the Faculty of Nursing was addressed to the director of the Alexandria Vascular Center (AVC) to carry out the study.
- Content validity forPart I and II of tool I was done, part III of tool I of the study was developed by the researcher based on review of the recent related literature and tested for content validity by 3 experts of hyperbaric oxygen therapy unit of Alexandria Vascular Center, and modifications were done accordingly.
- A pilot study was initially carried out prior to the actual data collection phase on five patients for each of the experimental study group to check clarity, feasibility and applicability of tools and determine obstacles that may be encountered during period of data collection, accordingly, needed modifications were done.
- General and specific guidelines were designed in an appropriate booklet with colored pictures and simple illustration, and were given to every patient immediately post initial assessment.
- The researcher provided general and specific health guidelines to the two experimental groups during the study time. The health guidelines were given on the first day of the study and were re-emphasized almost at each time of dressing until the patient's discharge from the study. The contents of these guidelines included: Nutritional guidelines, exercise guidelines, foot care, instruction to patients to take their insulin dose post hyperbaric oxygen therapy session, to leave things outside chamber, and teaching patients how to perform Valsalva maneuver.
- The general and specific guidelines were tested for content validity by 5 experts in the field of Medical - Surgical nursing members in the Faculty of Nursing of Alexandria University; andof hyperbaric oxygen therapy unit members of Alexandria Vascular Center; and the necessary modifications were done.Both were designed in an appropriate booklet with colored pictures and simple illustration, and were given to every patient immediately post initial assessment.
- The researcher received training on how to assess dorsalis pedis, and posterior tibial pulsation, and how to do wound debridement by a specialist in vascular surgery before data collection.
- The patients who met the subjects' selection criteria were eligible for the study, and were assigned alternatively into one of the three groups.
- Photos were taken at the initial visit for documentation for patients who fulfilled the sample selection criteria.
- An initial assessment of the patients' ulcer morphology was done at the dressing room in the out-patient clinics in the AVC for 20-30 minutes for every patient using the tool I part II.
- The steps followed by the researcher before performing the dressing for both experimental groups with foot ulcer consisted of:Preparation of the environment, preparation of the equipment and supplies, Preparation of the patients, and maintenance of aseptic technique.
- The healing of ulcer was evaluated for the three groups by using tool II part I. Wound evaluation was done every ten days for all groups. The researcher estimated the time and extent of healing; complete healing, partial healing, or no healing. In addition, if any signs of infection or persistent necrosis were present, the researcher referred the patient to a physician and excluded him from the study sample.
- Data collection started at the beginning of February 2016 and ended of September 2017.

Ethical considerations:

Written consent of the participants was obtained after explaining the purpose of the study and ensuring that their participation was strictly voluntary. Confidentiality, privacy and anonymity of the participants and their responses were assured.

Statistical analysis:Count and Percentage; used for describing and summarizing qualitative data of socio demographic characteristics.Minimum, maximum, arithmetic mean (X), Standard Deviation (SD); they were used as measures of central tendency and dispersion respectively for normally distributed quantitative

data.Analytical Statistics; Chi square(x^2); It was used to test the associations between two qualitative variables or to detect difference between two or more proportions.Fisher's Exact test and Monte Carlo; It was used whenever the expected frequency in any of the cells of 2x2 tables falls below 5.

III. Results

Table (1): Shows Frequency distribution of patients in Experimental and control groups in relation to biosociodemographicdata. The results revealed that, more than one third of the patients (45%, & 62.5% respectively) who had diabetic foot ulcer were in the age group between (40-50 years) in the two **experimental groups.** More than one-half of the patients were males in **G1** and **G3** (57.5% and 70% respectively), while the majority of them (75%) were females in **G2**. As for level of education, 75% in **G1** and 40% in **G3** had a university education, while 60% in **G2** only were read and write.

Figure (1):Diabetic Foot Ulcer Size in Experimental and Control Groups before and after Follow up Dressing Periods (Mean, Standard deviations, Minimum, Maximum) The figure conveyed a significant reduction in the ulcer size between the three groups before dressing ,between the 10^{th} and 20^{th} day as well as after 20 days, were p value were <0.001.

Figure (2):Frequency distribution of patients in the Experimental and Control groups in relation to diabetic foot ulcer depth before and after follow up dressing periods. Regarding **G1**, the figure revealed significant differences in the ulcer depth after 10 days and 20 days of the follow up period P<.001. Concerning **G2**, no significant difference in depth of ulcer before dressing and after 10 days was found. Regarding **G3,** no significant differences in ulcer depth were noted in initial assessment of ulcer and after 10 days, while a significant improvement in ulcer depth was observed after 20^{th} days of follow up period (p <0.001).

Figure (3):Frequency distribution of patients in Experimental and Control groups in relation to amount o

foot ulcer discharge before and after follow up dressing periods: In relation to **G1**, the figure illustrated that before dressing and after 10 days47.5% of patients' ulcer discharge was small in amount. At the end of follow up after 20 days; less than one-half 47.5% of patients' ulcer had no discharge. Significant differences were found between the two periods where P<0.001.Regarding **G2,** the figure denoted that; before dressing, 55% of patients had profuse discharge, 75% of them had moderate discharge after the 10^{th} of dressing follow up, while 40% of them had small amount of discharge and 40% of them had no discharge after 20 days post dressing follow up. Significant differences were found between the two periods where P<0.001.Concerning **G3,** 55% of the patients had profuse discharge before dressing, significant improvement was noted after 10 days of dressing follow up periods, 65% had moderate discharge, while 47% of them the ulcer discharge became small after 20 days of dressing. Significant differences between two periods were noted (P<0.001).Significant differences were found between the two periods where P (<0.034, 0.001, 0.001 respectively).

Table (2):Frequency distribution of patients in Experimental and Control groups in relation to intra hyperbaric oxygen chamber observation. In relation to ear barotrauma, the results revealed that, (37.5%, 67.5% respectively) of patients in G1 and G3 had dizziness at first week of dressing. While (22.5%, 65% respectively) of them in G1 and G3 complained of pain. On the other hand, (57.5%, 79% respectively) of patients in G1 &G3 had lost their hearing.Regarding oxygen toxicity, none of patients had oxygen toxicity in G1 or G3.Regarding hypoglycemic signs, (35% and 27.5% respectively) of patients in G1 and G3 had confusion at the first week, while at the second week (35% and 7.5% respectively) still had confusion due to hypoglycemia. Regarding claustrophobia, all patients in G1 and G3 had fear of restrictions at the first week, significant improvement at second week to become (25% and 22.5% respectively), while (65% and 75% respectively of patients at G1 and G3 had fear of suffocation. On the other hand, at the second week the percentage decreased to 22.5% of patients in G1 and 2.5% in G3.

Figure (4,5,6):Frequency distribution of patients in Experimental and Control groups in relation to the foot ulcer healing. The figure shows that in the G1 (wound dressing with HBOT) after 10 days100% of patients showed partial healing, and no cases had complete ulcer healing. By the end of the 20^{th} day55% of them had complete healing of their ulcer. Regarding G2 (wound dressing without HBOT), the highest percent of (100% and 72.5% respectively) of patients had partial healing after 10 days as well as 20 days after dressing period. In relation to G3 (staff wound dressing with HBOT) the result showed that, after 10 days 97.5% of patient's ulcer were healed, and55% of them had complete healed after 20 days dressing. The results portrayed significant progress in the ulcer healing among the three groups after 10 days and 20 days follow up periods where (p value <0.001, <0.001, <0.001 respectively) for the three groups.

Table (3): Frequency distribution of patients in Experimental and Control in relation to the severity of pain before and after follow up dressing period using Pain Visual Analogue Scale (VAS). Regarding G1, the present results revealed that (45%, 50%, 40% respectively) of patients reported no pain before dressing as well as after 10 and 20 days after dressing. No significant differences were reported along the dressing periods. In relation to G2, 40% of the patients reported no pain before dressing and through the days of

dressing periods. the same results also apply in G3, where (47.5%, 42.5% respectively) of patients reported no pain before dressing and through the 10, 20 days after dressing. No significant differences were found between the two periods where P (<0.001, 0. 549, 0.174 respectively)

Table (1):Frequency distribution of patients in Experimental and control groups in relation to biosociodemographic data n=(120).

Biosociodemographic data	Experimental groups					
	G1 With hyperbaric oxygen (n=40)		G2 Without hyperbaric oxygen (n=40)		G3 Control (n=40)	
	No.	%	No.	%	No.	%
Age (years)						
20 < 30	14	35.0	7	17.5	14	35.0
30 < 40	0	0.0	2	5.0	0	0.0
40 < 50	**18**	**45.0**	**25**	**62.5**	12	30.0
50 ≤ 60	8	20.0	6	15.0	**14**	**35.0**
Sex						
Male	**23**	**57.5**	10	25.0	**28**	**70.0**
Female	17	42.5	**30**	**75.0**	12	30.0
Marital status						
Single	**22**	**55.0**	4	10.0	5	12.5
Married	15	37.5	5	12.5	11	27.5
Divorced	2	5.0	**24**	**60.0**	0	0.0
Widow	1	2.5	7	17.5	**24**	**60.0**
Level of education						
Illiterate	1	2.5	6	15.0	8	20.0
Read & write	1	2.5	**24**	**60.0**	0	0.0
Primary	0	0.0	0	0.0	0	0.0
Preparatory	0	0.0	1	2.5	15	37.5
Secondary	8	20.0	5	12.5	1	2.5
University	**30**	**75.0**	4	10.0	**16**	**40.0**
Occupation						
Manual	1	2.5	**21**	**52.5**	**23**	**57.5**
Clerical	**17**	**42.5**	6	15.0	11	27.5
House wife	8	20.0	0	0.0	1	2.5
Retired	0	0.0	9	22.5	0	0.0
Student	14	35.0	4	10.0	5	12.5
Others	0	0.0	0	0.0	0	0.0
Residence						
Urban	**39**	**97.5**	**33**	**82.5**	**30**	**75.0**
Rural	1	2.5	7	17.5	10	25.0
Onset &duration of ulcer						
1 to < 7 days	8	20.0	0	0.0	0	0.0
7 days to < 14 days	10	25.0	**18**	**45.0**	11	27.5
14< 21 days	8	20.0	15	37.5	**16**	**40.0**
More than 21 days	**14**	**35.0**	7	17.5	13	32.5

*MCP= Monte Carlo P ≤ 0.05

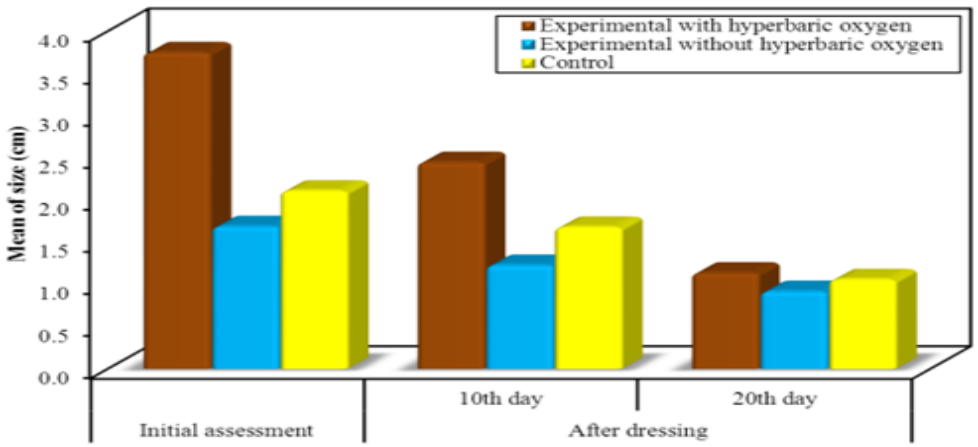

Fig. (1): Diabetic Foot Ulcer Size in Experimental and Control Groups before and after Follow up Dressing Periods (Mean, Standard deviations, Minimum, Maximum)

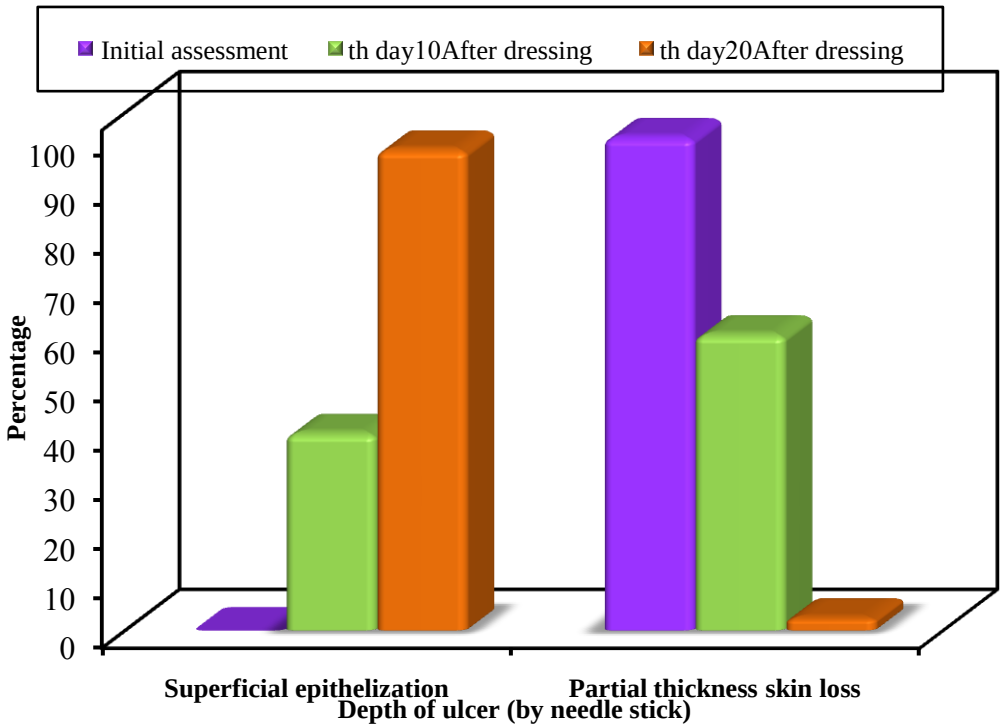

Figure (2):Frequency distribution of patients in the Experimental and Control groups in relation to diabetic foot ulcer depth before and after follow up dressing periods.

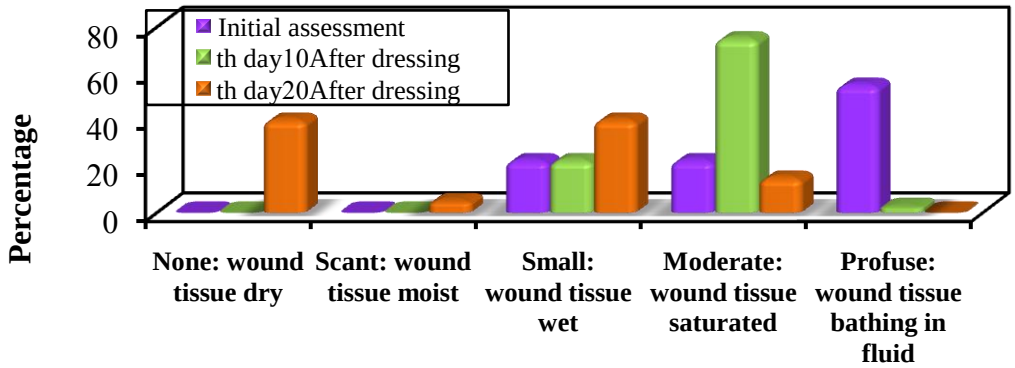

Figure (3):Frequency distribution of patients in Experimental and Control groups in relation to amount o foot ulcer discharge before and after follow up dressing periods:

Table (2): Frequency Distribution of Patients in Experimental and Control Group in Relation to intra Hyperbaric Oxygen Chamber Observation. n = (80).

Intra hyperbaric oxygen chamber observation	G1 Experimental with hyperbaric oxygen (n = 40) group		G3 Control (n = 40) group		χ^2	p
	No.	%	No.	%		
Ear barotrauma						
Dizziness						
1st week	**15**	**37.5**	**27**	**67.5**	7.218*	0.007*
2nd week	1	2.5	0	0.0	1.013	FEp=1.000
3rd week	0	0.0	0	0.0	–	–
Pain						
1st week	**9**	**22.5**	**26**	**65.0**	14.679*	<0.001*
2nd week	0	0.0	0	0.0	–	–
3rd week	0	0.0	0	0.0	–	–
Loss of hearing						

1st week	**23**	**57.5**	**28**	**70.0**	1.352	0.245
2nd week	0	0.0	7	17.5	7.671*	FEp=0.012*
3rd week	9	22.5	12	30.0	0.581	0.446
Oxygen toxicity						
Twitching of perioral						
1st week	0	0.0	1	2.5	1.013	FEp=1.000
2nd week	0	0.0	0	0.0	–	–
3rd week	0	0.0	0	0.0	–	–
Twitching small muscles						
1st week	0	0.0	0	0.0	–	–
2nd week	0	0.0	0	0.0	–	–
3rd week	0	0.0	0	0.0	–	–
Hypoglycemia						
Confusion						
1st week	**14**	**35.0**	**11**	**27.5**	0.524	0.469
2nd week	**14**	**35.0**	3	7.5	9.038*	0.003*
3rd week	1	2.5	0	0.0	1.013	FEp=1.000
Dizziness						
1st week	1	2.5	8	20.0	6.135*	FEp=0.029*
2nd week	**10**	**25.0**	**11**	**27.5**	0.065	0.799
3rd week	3	7.5	3	7.5	0.00	FEp=1.00
Claustrophobia						
Fear of restrictions						
1st week	**40**	**100.0**	**40**	**100.0**	–	–
2nd week	10	25.0	9	22.5	0.069	0.793
3rd week	1	2.5	0	0.0	1.013	FEp=1.000
Fear of suffocation						
1st week	**26**	**65.0**	**30**	**75.0**	0.952	0.329
2nd week	9	22.5	1	2.5	7.314*	0.007*
3rd week	1	2.5	0	0.0	1.013	FEp=1.000

***MCP= Monte Carlo p ≤ 0.05**

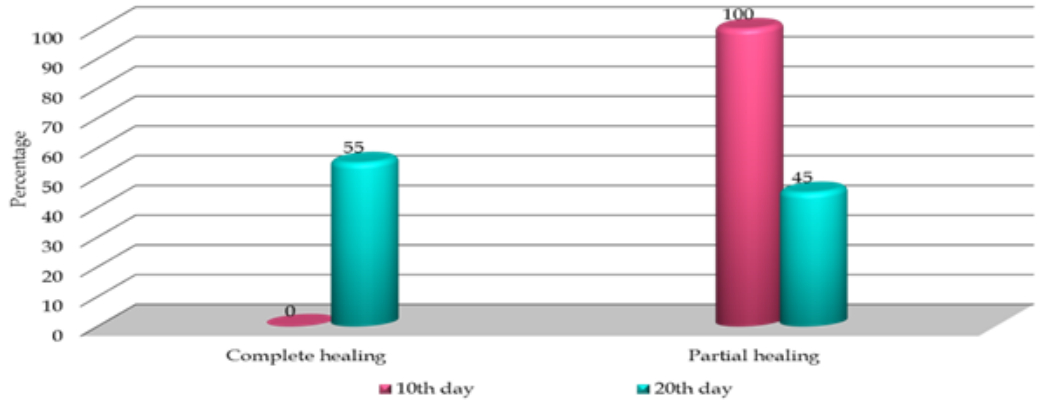

Fig. (4): Frequency Distribution of Patients in G1 in Relation to the Foot Ulcer Healing.

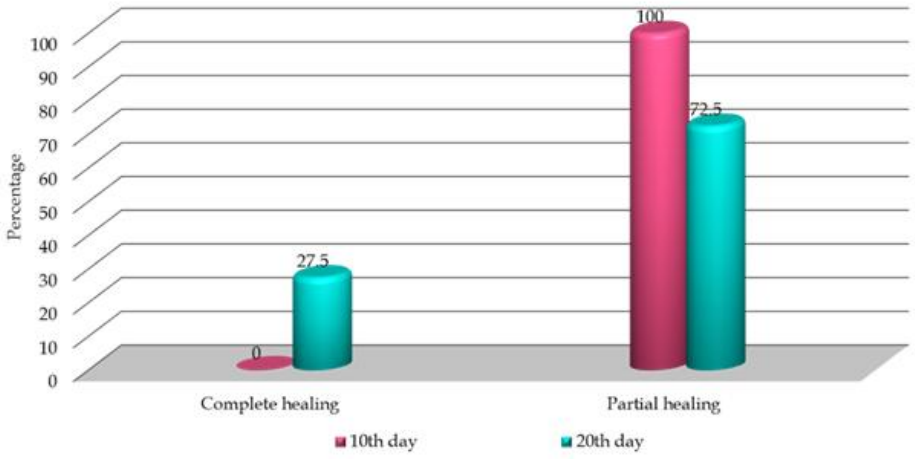

Fig. (5): Frequency Distribution of Patients in G2 in Relation to the Foot Ulcer Healing.

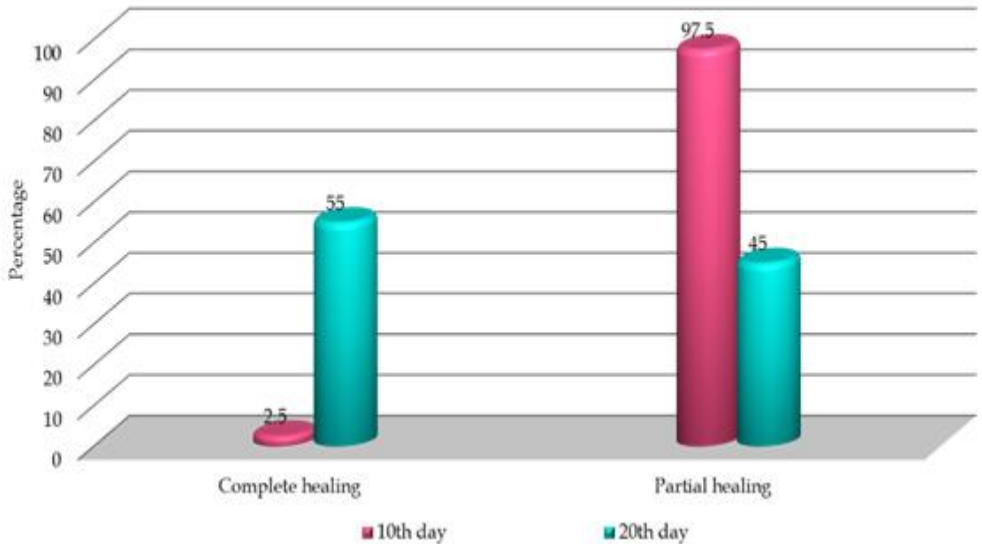

Fig. (6): Frequency Distribution of Patients in G3 in Relation to the Foot Ulcer Healing.

Table (3): Frequency Distribution of Patients in Experimental and Control in Relation to the Severity of Pain Before and After Follow up Dressing Period Using Pain Visual Analogue Scale (VAS) n=120.

Severity of pain evaluation	Experimental group				G3 Control (n=40)		χ^2	p
	G1 With hyperbaric oxygen (n=40)		G2 Without hyperbaric oxygen (n=40)					
	No.	%	No.	%	No.	%		
Before dressing (Initial assessment)								
No pain	**18**	**45.0**	**16**	**40.0**	**19**	**47.5**		
Mild (1–3)	3	7.5	5	12.5	4	10.0	2.907	^{MC}p=
Moderate (4 – 6)	7	17.5	4	10.0	3	7.5		0.841
Severe (7 – 10)	**12**	**30.0**	**15**	**37.5**	**14**	**35.0**		
After 10 days of dressing								
No pain	**20**	**50.0**	**16**	**40.0**	**17**	**42.5**		
Mild (1–3)	5	12.5	3	7.5	3	7.5	5.109	^{MC}p=
Moderate (4 – 6)	7	17.5	7	17.5	4	10.0		0.530
Severe (7 – 10)	**8**	**20.0**	**14**	**35.0**	**16**	**40.0**		
After 20 days of dressing								
No pain	**16**	**40.0**	**16**	**40.0**	**17**	**42.5**		
Mild (1–3)	**9**	**22.5**	3	7.5	3	7.5	11.528	0.073
Moderate (4 – 6)	10	25.0	9	22.5	5	12.5		
Severe (7 – 10)	5	12.5	**12**	**30.0**	**15**	**37.5**		
p_1	0.001*		0.549		0.174			

F,p: F and p values for ANOVA test

IV. Discussion

Diabetic foot ulcers may take months, or years to heal, failure to heal or recurrence of ulcer causes significant pain and discomfort to the patient and his family and increases the cost in the health care services[(6)]. HBOT for DFUs has been shown to improve healing rates and decrease the number of major amputations in the diabetic patients[(19)].

The results of present study revealed that there were statistical significant differences in the biosociodemographic characteristics between the **G1** and **G3**. The highest percentage of patients between both experimental groups were among the age group 40 to less than 50 years. These results are supported by Almobarak et al (2017) who reported that the incidence of diabetic foot ulceration increases in the middle age and in older persons with diabetes [(20)]. These findings may be due to the fact that diabetic patients in this age are at risk for developing complications of diabetes specially foot ulceration if their condition is not under control.

Regarding sex and occupation, the results revealed that; the majority of the patients in **G1** and **G3** were males and they were workers. This may be because most of the males in the studied groups were working as chefs, builders, laborers or security persons, which necessitated long hours of standing on their feet. Moreover,

males are often the sole earning member of the family, the increase in foot ulcers resulting from continuous pressure on the feet. This finding is in accordance with Allison (2016) who found that men are at risk for developing lower extremity problems more than women[(21)].

In relation wound size, the majority of the patients in group one and control group had significant decreased ulcer size by ten and twenty days compared to the initial size as well as the length, width and depth of these ulcers. The wound surface was intact and covered by bright beefy red tissues with healthy surrounding. This is possible due to higher oxygen concentration, which is detrimental to anaerobic bacteria thus contributing to subsequent wound healing. This result was an agreement with Stoekenbroeka et al. (2014) who proved that adjunctive HBOT improved wound healing in patients with DFU, in addition it is reduced the risk of amputation of the affected limb and they assert that at least 20 of HBOT sessions are required to be effective in decreasing wound size and improving the skin around it[(22)].

In relation to side effects that may occur during HBOT, the researcher observe that none of the studied patients shown any oxygen toxicity either twitching of perioral area or twitching of muscles. Some of them had different side effects as ear barotrauma appearing as dizziness, pain and loss of hearing and this may be due to the change in pressure of middle ear. In addition, confusion, fear of restrictions and/or suffocation occurred in the oxygen chamber. These side effects were decreased in the latest sessions of HBOT by teaching patients techniques to decrease them as middle ear clearing techniques and appropriate compression (valsava's maneuver). Claustrophobia may be managed with coaching and anxiolytic medications. Intolerance of a mono-place chamber may warrant referral to the closest multi-place chamber facility[(23, 24)].

Concerning the wound healing process, the majority of the studied patients in **G1** and **G3** had complete healing with healthy granulation tissue and formation of fibrous scar with highly significant relation between the three periods. This is in accordance with Chen et al (2014) who found that neovascularization in patient's ulcer tissue after HBOT at the early stage of wound healing. HBOT also stimulated granulation tissue formation on day 7; however, this effect was reversed on days 14. Neovascularization is involved in both angiogenesis and vasculogenesis[(25)].

In relation to wound healing in **G2**, more one half of patient had complete wound healing at 20 days of wound dressing periods, this finding agree with Mohamed et al (2017), who found that conservative therapy had failed and there were less than 50 percent of wound closure by four weeks, in addition, clinicians should consider advanced techniques such as HBOT to treat diabetic foot ulcer[(26)].

Daily wound care was safe for patients since it permitted daily inspection of the wound, in the protocol of the patient's wound care it gave a chance to assess morphology of wound daily and assess the foot for sensation, pulsation, skin temperature, color and any skin abnormalities. This is in accordance with Thomas and Dabiri et al (2016) who emphasized that daily dressing technique permitted daily inspection of wound so any signs of infection or discharge were detected immediately. Moreover, if wound became infected, culture can be obtained and can determine the type of microorganism and specific antibiotic to be prescribed if needed. In addition, they reported that daily wound care was effective in healing process[(27)].

The findings of the present study showed that, in comparing the results of the three groups in relation to severity of pain that assessed by used visual analogue scale (VAS). It was found that less than one half of patients in **G1** and **G3** in initial assessment had pain and there was are significant decreased in pain severity after 10 and 20 days wound dressing with HBOT. This could be attributed to the fact that HBOT promotes the blood circulation in the feet and reduces the ischemic or neuropathic pain, this possibly due to the effect of cleaning the ulcer during dressing which lead to better blood circulation promotion of healthy granulation tissues in wound bed and regression of inflammation and edema[(28)]. On the contrary, patients in **G2** had persistent pain on VAS.

Based on the results of the present study, HBOT should be applied for DFU together with another foot wound care techniques, which provide humidity to the wound, as the studied patients recorded positive effect after using HBOT in relation to decreased discharge, complete healing, healthy areas around wound, and improved sensory functions [(29-33)].The result obtained fulfilled the aim of the study; the proposal and the hypothesis were tested and accepted.

V. Conclusion

From the findings of the present study, it can be concluded that:

- Healing using HBOT and wound dressing was more rapid than that in the traditional dressing.
- No significant differences were found between the extent of ulcer healing in experimental group (1) and control group.
- The healing parameters related to ulcer depth, floor (granulation and epithelization) tissue formations, ulcer discharge (type and amount) and skin area' characteristic around the ulcer in the experimental group (1) and control group was significantly faster than experimental group (2) throughout the 20 days follow up dressing periods.

- Pain intensity was much lower in the experimental group (1) and control group than in the experimental group (2) through follow up dressing periods.
- Hyperbaric oxygen therapy did not interfere with the patient' ordinary daily activities, but it needs well-educated patients for understanding the benefits of HBOT to manage diabetic wound ulcer. It is also expensive and could not be tolerated by some patients.

VI. Recommendations

Based on the results' findings of the present study, the following recommendations are suggested:

- The importance of using HBOT as an adjuvant therapy with another wound care method to improve healing in persons with DFU.
- The nurse should be considered a crucial and an influential collaborator with the treating physician in the management of patients with diabetic foot ulcer.
- Training programs for nurses who work in hyperbaric oxygen chambers should be established.
- Emphasis should be placed on the education of eligible patients and their families about HBOT in relation to its function and benefits, adverse side effects, and compliance to therapy; this will help to develop a positive attitude, fuel motivation and create a sense of concordance.

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Hassan N". Impact of Hyperbaric Oxygen Therapy and Wound Care on Clinical Outcomes for Patients with Diabetic Foot Ulcer". IOSR Journal of Nursing and Health Science (IOSR-JNHS) , vol. 7, no.06 , 2018, pp. 28-38.