Effect of Hyperbaric Oxygen Therapy on Quality of Life for Patients with Diabetic Foot Ulcers

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Abstract: Foot ulcers are a significant source of morbidity, mortality and diminished quality of life (QOL) for patients with diabetes. Hyperbaric oxygen therapy (HBOT) has been proposed as a possible treatment. Aim: this study aims to evaluate the effect of HBOT on QOL for patients with diabetic foot ulcers. Methods: A quasi-experimental design was used. This study was conducted at the HBOT unit and surgical outpatient clinics, affiliated to Naser Institute Hospital. Sample: A purposive sample included 46 adult patients with diabetic foot ulcers. Tools: 1) Patients` interviewing sheet to assess QOL domains: physical, psychological, social and spiritual (pre/post tests), 2) Strauss wound classification scoring system (Pre/post tests), 3) Wound symptoms chart (pre/post tests), 4) Hamiltons anxiety rating scale and 5) Numerical rating pain scale (pre/post tests). Results: Statistically significant differences were found between QOL domains before and after HBOT among the studied patients. Moreover there is an obvious improvement regarding wound ulcers healing added to significant reduction in the anxiety and pain levels post treatment sessions. Conclusion: HBOT had a positive effect on the improvement of QOL for patients with diabetic foot ulcers, which is possibly attributable to better ulcers healing. Recommendations: Further studies should be done to assess the long term success of HBOT and to follow up patient's QOL.

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1. Introduction

Foot ulcers are a common and serious complication of diabetes mellitus. Diabetic foot ulcers (DFUs) are estimated to affect 15% of people with diabetes during their lifetime. Ulcer is often due to combination of diabetic neuropathy and peripheral vascular disease which decreases supply of oxygen to the affected extremity. So they can be classified as either neuropathic (found in 80-85% of all patients) and ischemic which involved in 50% of lower extremity amputation. Epidemiologic data suggest that foot ulcers precede 85% of amputations and 9-20% of diabetic patients undergo a second ipsilateral or controlateral amputation within 1 year after amputation. Moreover five year mortality following amputation varies between 39 and 68% (Fife et al., 2007 and Wu, 2010).

The decrease in sensory input from lower limbs due to neuropathy, increase foot injury and reinjury. Pedal injury can come from sources of heat or cold as well as poorly fitting shoes. Once the foot is injured, the ulcer becomes chronic because of re-injury hypoxia. Microvascular and macrovascular complications of diabetes diminish blood flow to the extremities, limiting the gradient of oxygen pressure in the tissue. Oxygen is an essential controlling factor for bacterial killing, fibroblast growth, angiogenesis, collagen synthesis, epithelialization and other biochemical processes essential for wound healing (Lyon, 2008 and Cucco, 2011).

QOL is a vague, ethereal construct that reflects an individuals' perspective on life satisfaction regardless of the situation. It can be profoundly altered by the presence of a delayed wound healing. A review of the literature confirms that the presence of unhealed DFUs negatively affects on patients QOL which incorporates such variables as pain, suffering, financial healthcare costs, strain on personal resources and overall impact on life and activities of daily living (**Spilsbury** *et al.*, **2007**, **King,2009 and Vissink** *et al.*, **2009**).

HBOT may be a noninvasive alternative for the treatment of diabetic foot ulcers. Many of the studies examining the role of HBOT in treatment of diabetic ulcers have been retrospective, non randomized and non controlled. Results of these studies suggest that it may accelerate wound healing and reduce amputation. It was defined as adjunctive treatment that involves administration of 100% oxygen at atmospheric pressure greater than 1 atmosphere absolute (ATA) within a hyperbaric chamber: monoplace chamber for one patient lying, multiplace chambers for multi patients either seated or supine and topical chamber treated (**Rakel et al., 2006 and Kemp & Hermans, 2011**).

Inhalation of pure oxygen at higher pressure causes plasma and hemoglobin to become supersaturated, so enhancing oxygen delivery to all tissues, in addition to the drives oxygen directly through skin rising oxygen level in all tissues. A typical session lasts between 60 and 90 minutes and not more than 120 minutes, with one session daily. Prescribed pressure and time will be determined by type of pathogen at wound site and other factors such as the degree of revascularization around the affected tissues. Each session consists of three phase: compression (takes between 6-10 minutes and sometimes 30 minutes to raise pressure inside the chamber), and decompression (decreased pressure to normal, takes between 6-10 minutes but can last as long as 30 minutes) (**Heyneman & Lawless-Liday, 2002 and Londahi et al., 2011**).

The exposure to HBOT increases tissue oxygen levels so, increased cellular proliferation, improved collagen synthesis and increased angiogenesis. It increases the killing ability of leukocytes and is lethal certain anerobic bacteria. Edema in the to the periwound area is decreased through the action of vasoconstrictive oxygen and the leukocyte-bacterial killing ability. HBOT enhances phagocytosis of bacteria and inhibits toxin formation (Zhang et al., 2008)

Significance of the Study:

Foot ulcers are a significant source of morbidity, mortality and diminished QOL for diabetic patients so, there is a tremendous need for treatments that will reduce the human and economic burden and loss associated. As tissue hypoxia is one of the pathophysiological characteristics of diabetic ulcers, HBOT has been considered as a therapeutic strategy for the reduction of tissue hypoxia and enhancing wound healing which result in the improvement of the QOL measures (**Rakel et al., 2006 and Ogunlesi, 2010**).

Aim of the Study:

This study aimed to evaluate the effect of Hyperbaric oxygen therapy (HBOT) on quality of life (QOL) for patients with diabetic foot ulcers. This aim was achieved through the following:

- Assessing the QOL domains (physical, psychological, social and spiritual) for the studied patients.
- Evaluating the effect of HBOT on DFUs healing and QOL domains for the studied patients.

Hypothesis:

It was hypothesized that HBOT will be helpful in improving the QOL for patients with diabetic foot ulcers.

Operational definitions : Diabetic foot ulcer wound:

Means any break in the cutaneous barrier

extending through the full thickness of the dermis, and did not heal after one month.

Undergoing:

Means pre, during and post treatment sessions.

Quality of life (QOL):

Means state of contentment in a conscious individual due to their satisfaction in physiological, psychological, social and spiritual aspects of life.

Subjects and Methods:

A quasi-experimental design was used for the conduction of this study.

Setting:

The study was carried out at the HBOT unit and surgical outpatient clinics, affiliated to Naser Institute Hospital.

Subjects:

A purposive sample include 46 adult patients from both sexes with diabetic foot ulcers (neuropathic and ischemic).

Inclusion criteria:

- Patients with diabetic foot ulcers wounds (neuropathic and ischemic) that fail to respond to optimal conventional medical and surgical treatment in a reasonable time frame.
- All patients received standard wound care.
- Patients did not receive HBOT previously.
- No comorbid condition with normal level of vital signs
- Strauss wound score less than 8 or higher wound.
- Blood glucose test within normal level.
- Time scheduled of each HBOT session from 60-90 minutes, with 100% oxygen for respiration at pressure greater than 1 atmosphere absolute (ATA).
- Patients agree to participate in the study and to complete the treatment sessions.

Tools of data collection:

Patient's interviewing sheet (pre/post tests), it was designed by the researcher, in the light of relevant references to determine patient's QOL domains regarding to HBOT. It was written in simple Arabic language and included the following:

Characteristics of the studied patients which included: age, educational level, income and wound types.

Quality of life domains assessment sheet for patients with HBOT (pre/post tests). It included the following:

Physical domain:

Problems with physical activities, pain work, activities of daily living, sleep disturbance, difficult in bathing, discomfort from band aging/dressing, immobility outside the home.

Psychological domain:

Emotional status, information about HBOT treatment (definition - indications – complications – contraindications – safety measures – physical preparations) , anxiety, frustration, fear from complications, body image and unpleasant odor from the wound.

Social domain:

Social relations, leisure time activities, need assistance, traveling problems.

Spiritual domain:

Follows religious, vision for the future, enjoying with the life and wound considered as a punishment.

Patiens` answers were categorized as satisfactory (1) or un satisfactory (zero)

Good QOL (75%-100%) Average QOL (60% - < 75%). Poor QOL (less than 60%)

2. Strauss wound classification scoring system (Pre/post tests). It was adopted from

Strauss (2000), the validity of this scoring system was 4.60 (range = 1-5) as determined by expert validity. The value of Cronbach's and which used to assess the reliability $\alpha = 0.83$ which means the results obtained by using the wound scoring was reliable.

It is formed of five variables: Appearance, size, depth, infection and perfusion. The total score ranged from 0-10. Score of less than 8 = problem wound, score of 8 and more = healthy wound.

According to wound assessment, the following classification was adopted: Good (2 points), Average (1 point) and poor (zero).

3. Wound symptoms chart (pre/post tests).

It was adopted from Naylor and Grey (2006) to assess the wound symptoms experienced by the patients (wound pain, dressing pain, leakage of exudates, wound bleeding, smelt and itching). The scoring system was as follows:

Not at all = 1, little bit = 2, somewhat = 3, quiet a bit = 4 and very much = 5. It was filled by the researcher.

4. Hamilton's anxiety rating scale (pre/post tests)

It was developed by Max Hamilton (1959) and modified by the researchers to determine patient's anxiety level. It was formed of fourteen variables: anxious mood, tension, insomnia, cognitive change, depression, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic, symptoms, somatic (muscular) and the behavior at interview. The total score ranged from 0-42. According to patient's response, the following classification was adopted: no anxiety (zero), mild anxiety (0-<25), moderate anxiety (25-<31.5) and severe anxiety (31.5-42).

5. Numerical rating pain scale (pre/post tests).

It was used to determine patient's pain intensity before and after treatment sessions. The scale ranged from 0-10. According to patient's responses, the following classification was adopted: 0 (none), 1-3 (mild), 4-6 (moderate) and 7-10 (severe) (Krebs *et al.*, 2007 and Jacques, 2011).

Content validity: It was ascertained by a group of experts including: hyperbaric oxygen experts, general surgery staff and medical surgical nursing staff. Their opinions were elicited regarding to the tool format layout, consistency and scoring system. The content tools were tested regarding to the knowledge accuracy, relevance and competence.

Ethical considerations and human rights:

In the planning stage, approval was obtained from director of the Hyperbaric Oxygen Therapy Unit at Nasr Institute. The studied patients were informed about the procedure and their rights according to medical research ethics to withdraw from the study at any time, then, written informed consent was obtained from them.

Pilot study:

A pilot trial was carried out on 10% of the studied patients to test the clarity and practicability of the tools in addition to the subjects and setting. Pilot subjects were later included in the study as there was no radical modifications in the study tools.

Procedure of the study:

- Sampling was started and completed within one year.
- Number of treatment sessions and pressure level were determined by the physician. Treatment course = 30 sessions which were classified as follow: one session daily for 6 days/week.
- The treatment course may be repeated according to patients` wound healing assessment.
- Purpose of the study was simply explained to patients who agreed to participate in the study

prior to any data collection.

- The researchers starts to collect data from the patients on the same day of scheduling for the treatment sessions using the pre-constructed tools.
- Quality of life domains assessment sheet was filled in and completed by the researchers pre treatment sessions .
- Strauss wound classification scoring system, wound symptoms chart, anxiety rating scale and numerical rating pain scale were filled in and completed by the researchers pre treatment sessions (pre test).
- Filling in the tools, according to the patients` understanding and health condition.
- The researchers contacted the patients two days weekly. Patients were informed to be in contact with the researchers by telephone for any guidance.
- Weekly wound assessment by physician in the unit of HBOT to assess wound condition.
- Traditional dressing was made in the surgical outpatient clinics according to physician order.
- Post test was done after completion of the treatment sessions by six months later using the pre- constructed tools . .

Statistical analysis

Data were presented using numbers, percentages, means and standard deviations and t-test. Level of significance was threshold at 0.05.

Limitation of the study:

Cost of the treatment sessions was high in addition, therapeutic regimen to control blood glucose level along the treatment sessions was limited among the studied patients, so they taken long time to complete the treatment sessions.

3. Results

Table (1): Presents characteristics of the studied patients. Results revealed that more than two fifths of them with the age between 40-<50 years and had highly level of education (45.7% and 43.5% respectively). Moreover, majority of them had highly income (80.4%). In relation to wound types, nearly one third of them had neuropathic wound and more than two thirds of them had ischemic wound (32.6% and 67.4%, respectively).

Table (2): Reveals QOL domains among diabetic foot ulcers patients. As detected, post treatment had a higher mean percent than pre treatment regarding QOL domains: physical = 2.84 ± 0.4 , with t = 9.7, psychological = 2.87 ± 0.4 , with t = 12.5, social = 2.77 ± 0.5 with t = 10.8 and spiritual = 2.89 ± 0.4 with t = 11.9.

Table (3): Presents wound types and QOL progress among patients post treatment . significant differences were observed among the two types of wounds, where as ischemic wound had a higher percent of improvement than neuropathic wound in relation to the QOL domains (physical, psychological, social and spiritual).

Table (4): Shows wound symptoms among patients pre/post treatment sessions. As noticed significant improvement was indicated post treatment regarding to dressing pain, exudates, bleeding, wound smell, itching and wound pain, with t = 16.3, 16.3, 30.8, 50.0, 48.2 & 21.1, respectively.

Figure (1): Illustrates Strauss wound classification scoring system among patients pre/post treatment. Significant differences were observed Pre/post treatment, where as more improvement was noticed post treatment (85% represented poorly wound and 93% represent healthy wound, respectively).

Figure (2): Presents level of pain among the studied patients pre/ post treatment . significant differences were observed among Pre/post treatment, , where as more reduction in pain level was indicated post treatment .

Figure (3): Shows anxiety level among patients pre/post treatment. As shown more than two fifths (74%) of patients had severe anxiety followed by nearly one third of them (31%) had moderate anxiety and less than one fifth (14%) of them had mild anxiety pre treatment. Significant reduction in patients' anxiety level was indicated post treatment.

Table (1): Characteristics of the studied patients

Items	No	%
Age (vears)		
Less than 40	7	15.2
40 - less than 50	21	45.7
50-60	18	39.1
X±SD	47.8±6.3	
Educational level		
High	20	43.5
Moderate	16	34.8
Low	10	21.7
Sex		
Male	25	54.3
Female	21	45.7
BMI		
Under weight (less than 18.5kg	14	30.4
Normal weight (18.5 – 25 kg)	5	10.9
Over weight (more than 25 kg)	27	58.7
Income		
High (enough)	37	80.4
Low (not enough)	9	19.6
Wound types		
Neuropathic	15	32.6
Ischemic	31	67.4

	Pre – treatment		Post – treatment			
Items	Good	Average	Poor	Good	Average	Poor
	%	%	%	%	%	%
Physical	18.0	20.0	62.0	87.0	10.0	3.0
X±SD		1.56 ± 0.8		2.84 ± 0.4		
	r	Γ value = 9.7.	, p < 0.05 , Si	ignificant		
					•	
Psychological	11.0	19.0	70.0	89.0	9.0	2.0
X±SD		1.41 ± 0.7			2.87 ± 0.4	
		T value = 12.5	, p < 0.05 , S	ignificant		
Social	10.0	19.0	71.0	83.0	13.0	5.0
X±SD		1.39 ± 0.7			2.77 ± 0.5	
T value $= 10.8$, p < 0.05 , Significant						
Spiritual	25.0	35.0	40.0	91.0	7.0	2.0
X±SD		1.85 ± 0.8			2.89 ± 0.4	
T value = 11.9 , p < 0.05 , Significant						

Table (2): Presentation of QOL domains among patients with diabetic foot ulcers pre/post treatment sessions (n=46)

Table (3): Presentation of wound types and QOL progress post treatment among the studied patients

OOL domains	Ischemic wound %	Neuropathic wound %	
Physical	86.3	71.4	
Psychological	92.1	75.3	
Social	76.1	69.4	
Spiritual	91.3	87.1	
X±SD	84.8 ± 8.1	72.0 ± 3.0	
T- value	t = 9.8 , p < 0.05 , Significant		

Significant at p < 0.05

Table (4): Presentation of wound symptoms pre/post treatment sessions among studied patients

Items	Pre-treatment %	Post-treatment %
Pain with dressing	100.0	38.0
Exudates	88.0	20.4
Bleeding	78.9	18.0
Wound smell	91.0	15.6
Itching	85.3	16.0
Pain from wound	85.0	25.0
X±SD	88.6 ± 7.8	21.6 ± 9.4
T- value	t = 37.2, p < 0.05, Significant	

*Significant at p < 0.05











Figure (3): Presentation of anxiety level pre /post treatment sessions among patients .

4. Discussion:

The current study aimed to evaluate the effect of HBOT on QOL for diabetic foot ulcers patients. In the present study, findings regarding to patients characteristics revealed that, more than two fifths of them with the age between 40-<50 years. This finding was supported by Spilsbury et al. (2007) and Ogunlesi (2010) who mentioned that, the physiological changes with ageing place patients at higher risk of poor wound healing as: reduced skin elasticity and collagen replacement, declines of the immune system making the patients more susceptible to infection added to the presence of other chronic diseases which affect the circulation and oxygenation to wound. On the same lien, findings revealed that majority of the studied patients had highly income. This result could be attributed to the fact that HBOT is expensive according to Zhang et al. (2008), HBOT in the treatment of diabetic foot ulcers was cost effective adjunct to standard wound care particularly on a long term basis.

As regards OOL domains among patients with diabetic foot ulcers. The current study results revealed that mean percent of QOL domains post treatment sessions was higher than pre treatment. These findings were supported by Lin et al. (2006) who stated that some studies have shown that patients with diabetic foot ulcers have a decreased QOL. King (2009) reported that, various factors have been implicated in decreased QOL: Frequency and regularity of dressing changes that affect daily routine, continued fatigue due to lack of adequate sleep, restricted mobility, pain, wound infection, social isolation, depression and reduction in activity levels. Kemp and Hermans (2011) stated that, HBOT improve OOL (e.g. patients being independent and ambulant).

Concerning satisfactory information about HBOT among the studied patients. The present study results detected that significant differences were present between pre/post treatment sessions regarding patients HBOT information. These findings were in agreement with El-Shamaa et al. (2008) who reported that less than three fourths of the studied patients, their knowledge about HBOT were poor pre guidelines. Also he emphasized that the patients before treatment sessions should be informed about the removable items as safety measures (e.g., jewelry, dental spacers, ear plugs, hair clips, canvas splints, contact lenses, combustion materials, static electricity items, discharge sparks objects that must not be permitted in or near HBO chamber, no synthetic rubber, plastic (including Styrofoam) or metal items can be taken into the chamber. Moreover, food should be leave outside the chamber and vitamin E should be increased in the

diet (Marques *et al.*, 2004). In the same context, patients' information about physical preparation, plays a vital role in the successful outcome of the treatment added to information about treatment side-effects can help patients to judge benefits of the treatment (Londahi *et al.*, 2011).

Regarding wound symptoms assessment in relation to dressing pain, exudates, bleeding, wound smell, itching and wound pain. Significant improvement was detected post treatment sessions as regards wound healing. The previous findings were in accordance with Cucco (2011) who stated that improperly or incompletely assessed wound creates all types of problems including incorrect treatment. Fife *et al.* (2007) concluded that, there was an improvement in wound symptoms after HBOT on a study done for patients with diabetic foot ulcers. Moreover, there was a statistical significant negative correlation between wound symptoms severity and QOL after treatment sessions.

In relation to strauss wound classification scoring system among patients pre/post treatment sessions. More improvement on wound healing post treatment was noticed. The previous finding was in agreement with **Lin et al.** (2006) who mentioned that there was a positive correlation between the strauss wound classification score and QOL indicating that HBOT has the advantage of reducing wound size and decreasing amputation rates after therapy. **Rakel et al.** (2006) summarized that application of HBOT had a positive effect on wound healing and patients felt that their lives were no longer affected, evidently, the healthier wound associated with higher QOL.

Concerning wound types and QOL post treatment sessions, results of the current study revealed that ischemic wound healing had the higher percent of improvement than neuropathic wound in relation to the QOL domains among the studied patients. The previous finding was in accordance with **Brem & Tomic – Canic (2007) and Zhang et** *al.* (2008).

Considering anxiety level pre treatment sessions, more than two fifths of patients had severe anxiety. The present study result was in agreement with **Heyneman & Lawless-Liday (2002)** who reported that patients with HBOT which is considered as a new therapy may react with a lot of fears, insecurity, alienation, feelings of strangeness, rejection and many other negative reactions So, he recommended by the reassurance of patients and the provision of diversion during treatment sessions, added to antianxiety medications as ordered. Moreover, **Mohamed** *et al.*(2011) stated that health team had the responsibility to explain to patients and heir families what to expect during and after a treatment session. *He also* concluded that teaching patients is a vital part in the treatment.

Conclusion:

In the light of the present study, it can be concluded that HBOT in conjunction to standard treatment had a true beneficial effect on improving the QOL for patients with diabetic foot ulcers, possibly attributable to better ulcers healing.

Recommendations:

- HBOT should be generalized for all patients with diabetic foot ulcers.
- Educational programs should be held about QOL for diabetic foot ulcers patients with HBOT.
- Prospective studies are needed to assess the long-term success of HBOT and follow up patients' QOL.

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