

Efficacy of Hyperbaric Oxygen Therapy in the Treatment of Vasculitic Skin Ulcers in Systemic Lupus Patients

Intsar S. Waked, PT.D. and Samah H. Nagib, PT.D.

Department of Surgery, Faculty of Physical Therapy, Cairo University, Giza, Egypt.

ABSTRACT

The purpose of this study was to evaluate the effectiveness of hyperbaric oxygen therapy (HBOT) on Vasculitic skin ulcers in systemic lupus patients. Forty patients with systemic lupus erythematosus (SLE) had foot or leg ulcer referred by dermatologist were participated in this study. Their age ranged from 25 to 40 years. Patients were classified into two groups of equal number; group (A) received HBOT, at 2 atmospheres absolute (ATA) for 90 minutes/session, five times/week for 4 weeks in addition to local wound care, while group (B) received local wound care only. Ulcer surface area and ulcer volume were measured as well as Doppler ultrasonography was used to assess the improvement in the macrocirculation response before and after the treatment program for both groups. Results of this study revealed a highly significant differences between both groups, regarding ulcer surface area, ulcer volume and Doppler finding at the end of treatment program (P values < 0.01) On conclusion, the present study revealed that HBOT is considered safe and effective treatment method that promote healing of the ulcer in systemic lupus patients.

Key words: Hyperbaric oxygen therapy, Systemic lupus erythematosus, Vasculitis skin ulcer, local wound care, Doppler ultrasonography.

INTRODUCTION

Systemic lupus erythematosus, (SLE), is a systemic autoimmune disease (or autoimmune connective tissue disease) that can affect any part of the body. As occurs in other autoimmune diseases, the immune system attacks the body's cells and tissue, resulting in inflammation and tissue damage. It is a Type III hypersensitivity reaction caused by antibody-immune complex formation^{1,11}.

SLE most often harms the heart, joints, skin, lungs, blood vessels, liver, kidneys, and nervous system. The course of the disease is unpredictable, with periods of illness (called flares) alternating with remissions. The disease occurs nine times more often in women than in

men, especially in women in child-bearing years ages²².

SLE is treatable through addressing its symptoms, mainly with cyclophosphamide, corticosteroids and immunosuppressants; there is currently no cure. SLE can be fatal, although with recent medical advances²³.

Vasculitis is an inflammatory process affecting the vessel wall and leading to its compromise or destruction and subsequent hemorrhagic and ischemic events. Cutaneous vasculitis may present as a significant component of many systemic vasculitic syndromes such as rheumatoid vasculitis, systemic lupus vasculitis, anti-neutrophil cytoplasmic antibody (ANCA)-associated primary vasculitic syndromes (Wegener granulomatosis, Churg-Strauss syndrome, microscopic polyangiitis)³.

Vasculitis is a heterogeneous group of diseases characterized by inflammatory processes of the blood vessel wall resulting in the alteration of blood flow and vascular damage. The vessels involved are of different sizes (arteries, arterioles, venules, capillaries)⁶. Resulting syndromes are the consequence of tissue ischemia, vascular damage and systemic inflammation. Most vasculitis is mediated by the vascular deposition of immune complexes (IC), abnormal cell-mediated immune responses, antibodies against endothelial cells or against lysosomal enzymes of neutrophils²⁹.

Vasculitis may be primary or secondary to connective tissue and intestinal diseases, medications, tumors. Vasculitic skin ulcers are clinical manifestations of ischemic injury, and are usually treated medically by controlling the underlying disease with immunosuppressants¹⁸.

When normal circulation is compromised or obstructed, normal cellular function is affected and some cells may die. If normal circulation is not restored quickly, long-term injury may result². Cutaneous nonhealing ulceration is a threatening manifestation of vasculitis. They are usually

treated by medical therapy with systemic anti-inflammatory drugs, steroids and immunosuppressants. Not always, the ulcers heal with systemic treatment; for this reason and because of the beneficial effects of oxygen on healing of infected vasculitic lesions, it was decided to treat this patient's refractory ulcer using the hyperbaric oxygen (HBO)¹⁶.

Low oxygen tension around the wound is one of several critical factors, which mutually enhance the progression of a chronic ulcer. In an hypoxic environment, wound healing is halted by decreased fibroblast proliferation collagen production, and capillary angiogenesis. Hypoxia also allows growth of anaerobic organisms, further complicating wound healing. (HBO), provides a significant increase in tissue oxygenation in the hypoperfused, infected wound. It influences the rate of collagen deposition, angiogenesis, and bacterial clearance in wounds. The greatest benefits are achieved in tissues with compromised blood flow and oxygen supply. Oxygen gives the body the ability to rebuild itself, detoxifies the blood, and strengthen the immune system²⁴.

Hyperbaric medicine is the fascinating use of barometric pressure for delivering increased oxygen dissolved in plasma to body tissues. (HBO) involves intermittent inhalation of 100% oxygen under a pressure exceeding that of the atmosphere, that is greater than 1 atmosphere absolute (ATA). (HBO) significantly reduces the length of the patient's hospital stay, amputation rate, and wound care expenses. Thus, it is a cost-effective⁸. (HBOT) is used as primary or adjuvant therapy in various clinical conditions, including cutaneous vasculitic ulcers that are resistant to immunosuppressive therapy⁶.

The aims of this study was to assess the effectiveness of HBOT for vasculitic skin ulcer in Systemic lupus patients.

SUBJECTS, MATERIAL AND METHODS

Subjects

Forty patients from both sex participated in this study (33 female and 7 male), who had vasculitic skin ulcer in foot or leg referred by physician of dermatology. The study was done

in out clinic of Nasser institute. The patients were randomly classified into 2 groups of equal number. Group (A) (Study group): received hyperbaric oxygen therapy in addition to local wound care while Group (B) (Control group): received local wound care only.

Inclusion criteria

All the forty patients had SLE complicated with grade III foot or leg ulcer¹². Ulcers with surface area less than ten cm² were included in this study. Subjects with ulcer duration less than one year were only chosen for this study. The patient's age ranged from 25 to 40 years. Elapsed time since the beginning of the systemic lupus disease was less than 2 years. All patients received the same medication (immunosuppressive drug). A diagnosis of (SLE) was considered and confirmed, according to the diagnostic criteria laid down by American College of Rheumatology, for the presence of antinuclear antibodies (1:1280, homogeneous appearance), anti-dsDNA (normal < 30), anti-Sm (normal <30), anti-Sm/RNP (normal <30), lupus anticoagulant (normal 0-1.3) and anticardiolipin antibodies (normal up to 20).

Exclusion criteria

Patients were excluded if they had one or more of the following: acute sinusitis, otitis media, pneumonia, pregnancy, active cancer, pneumothorax, Diabetes, cardiac disease, renal failure, myocardial infarction or emphysema, claustrophobia.

Ethical consideration

The experimental protocol was explained in details for each patient before the initial assessment and informed written consent were obtained from all participant. The trial protocol was approved by the meeting of the department of surgery, faculty of physical therapy, Cairo University. There was no harm inflicted on the patients. On the contrary, all had benefited from the final results of the study.

Material and Methods

**Measurement procedures:*

1- Initial session for patient selection, history was taken through personal, present, past and family history. Ulcer surface area selection was done. The selected surface areas of the

ulcer were measured initially as the following: the ulcer perimeter was traced using pointed pen on a clean transparent film then two perpendicular lines were drawn with a tape measurement using the maximum open wound areas at these lines and the results of the two measurements were multiplied to obtain the rough surface area of the ulcer in square centimeters⁵.

2- Wound surface area (WSA) & Computer Image analysis for the wound tracing; for each subject, a baseline tracing of the ulcer perimeter was drawn on a sterile disposable transparency. The sterile transparent film was positioned as flat as possible across the wound to trace accurately the outline of the epithelial edge. Computer and scanner were used to objectively measure the ulcer surface areas through entering the tracings to the computer using the scanner and using a program of surface area calculation (AutoCAD program). This measurement was done for both groups before and after one month of treatment⁵.

3- Ulcer volume assessment; a syringe of five cubic centimeters filled with normal saline was used. The patient was positioned in a comfortable position that allows the wound to be filled with the saline solution maximally, prone lying position with knee flexed 90 degree and the ankle in neutral position for ulcers in the planter aspects, crock lying position was chosen for ulcers in the dorsal aspects and side lying position was chosen for the ulcers on the malleoli. The saline is injected into each wound until its filling. The amount of saline injected was detected in cubic centimeters. These measurements were conducted for each patient before and after one month of the treatment in both groups using the same patient's position⁵.

4- Ultrasonic Doppler flowmetry was used to examine the macrocirculation response in the lower limb blood vessels²⁷ before and after one month of the treatment in both groups.

***Treatment procedures:**

For HBOT group (A):

- Apply local wound care for each ulcer in the form of (cleaning, debridement if needed, antimicrobial agent (Mundidone), dressing)²¹.

- First a single test hyperbaric exposure was done for each patient.
- Before the patient entered the chamber of HBOT, he was instructed to remove or not use the following; Makeup, Perfume, Hair spray, oils or Wigs , Nail polish, Alcohol or petroleum-based products, Metallic items (like jewelry, watches and coins), Flammable materials, Hearing aids, synthetic fabrics, or hard contact lenses. Underwear items with metal, such as under wire bras, not use tobacco or smoke over the course of therapy, not drink carbonated drinks (such as sodas) for two hours before treatments. Then the patient worn cotton garment²⁶.
- Patient entered monoplace chamber of HBOT that constructed from clear acrylic plastic so allows easy visualization of the patient and manufactured by (Patterson Companies, Inc., St.Paul, MN). The chamber with increased pressure at 2 ATA atmospheres absolute for 90 minutes, five times / week for 4 weeks. In the chamber, the patient inhales 100% oxygen. Treatment usually runs for 20 sessions²⁵.
- Once the patient become comfortable, the pressure slowly increased and the temperature also temporarily raised. When reach the right pressure, the temperature would be adjusted to the patient comfort. The patient may feel fullness in his ears because of the increased pressure, that be relieved by the Valsalva maneuver by asking patient to bear down.
- Careful monitoring for the patient during the treatment sessions.
- The treatment has three steps¹⁰:
Compression: slowly increase the pressure in the chamber to the prescribed level. The temperature may get warmer. Compression usually takes about ten to fifteen minutes.
Treatment: When the pressure reaches the prescribed level, the treatment begins. This step takes about 90 minutes.
Decompression: After the treatment was completed, the pressure begins to decrease in the chamber back to normal. Patient may feel cool at this time, and the patient had a blanket for warming after session. Patient may feel some pressure in his ears again and this relieved by drinking or swallowing.

Decompression usually takes about ten to fifteen minutes also. The total treatment time is usually 2 hours.

For control group:

Local wound care was done for each patient as following; Debridement, for removal of microorganisms, necrotic tissues and foreign bodies when needed. Irrigation of the wound with normal saline. Apply antimicrobial agent (Mundidone) then the wound was dressed. All the dressings were changed once daily²¹.

Statistical analyses

Statistical analyses were performed using a personal computer running SPSS 16.0 (SPSS, Inc. Chicago, IL) for Windows 7 (Microsoft, Inc., Redmond, WA). Descriptive statistics were done based on the raw data for each component of the dependent variable and for the patients demographic data. Paired Student t tests were used to compare the ulcer surface area and ulcer volumes before and after the study within the each group. Two-tailed unpaired Student t tests were used to analyze continuous numeric data, including age, duration of systemic lupus disease, and duration of ulcer, ulcer surface areas, ulcer volume measurements between both groups, whereas the Mann Whitney U (Wilcoxon rank sum) test was used to analyze categorical data, including gender, Doppler findings, family & past history between both groups. Statistical

significance was defined at the 5% ($P < .05$) level.

RESULTS

Data concerning the patients' demographic and clinical characteristics included sex, age, duration of systemic lupus disease, as well as of ulcer, initial ulcer size and volume have been collected at the beginning of the study. Follow up evaluation of ulcer size and volume has been performed at the end of treatment.

The results were presented as follow:

- I- Demographic characteristics of the patients.
- II- Results of group (A) HBOT.
- III- Results of group (B) control group.
- IV- Comparative analysis between groups (A) and (B).

I- Demographic characteristics of the patients.

The mean and standard deviation of demographic characteristics of all patients in both groups (A and B) were represented in table (1).

As shown in table (1), there were no statistical significance differences ($P > 0.05$) observed between both groups concerning general characteristics (age, duration of ulcer as well as of systemic lupus disease, initial ulcer size and volume).

Table (1): Statistical analysis of the demographic characteristics of all patients for both groups (A and B).

Variables	Groups	Range		X±SD	P-value
		Min	Max		
Age (yrs)	A	25	39	33.05±4.58	.924*
	B	25	40	32.90±5.22	
Duration of Disease (months)	A	12	24	17.80±3.488	.549*
	B	12	24	18.45±3.30	
Duration of ulcer (week)	A	4	48	28.70±13.24	.838*
	B	12	48	29.50±11.3	
Ulcer size (Pre) (cm ²)	A	2.5	6.1	4.5±.950	.802*
	B	2.4	5.9	4.42±.925	
Ulcer volume (Pre) (C ³)	A	2.1	4.6	3.03±.727	.397*
	B	1.9	4.9	3.25±.8894	

X=mean, SD=Standard Deviation,
*Non-Significant ($P > 0.05$),

Min=Minimum, Max=Maximum,
Cm²=Centimeter square,

P-value=Probability level,
C³=Cubic centimeter.

The frequency, percentage of ulcer site, sex, past history, family history of all patients in both groups (A and B) were represented in

table (2). The results revealed statistical non significance ($P > 0.05$) differences between two groups.

Table (2): The frequency and percentage of ulcer site, sex, past history, family history of all patients in both groups (A and B).

Variables	Group		P-value	Sig.
	A	B		
Site of ulcer				
• foot	16	17	.681	NS
• leg	4	4		
Sex				
• female	16	17	.681	NS
• male	4	3		
Past history				
• positive	12	13	.747	NS
• negative	8	7		
Family history				
• positive	11	10	.755	NS
• negative	9	10		

NS=Non significant

II- Results of group (A) (HBOT group):

As shown in table (3) the mean value and standard deviation of ulcer surface area and ulcer volume at the beginning of the study (pre) were $4.5 \pm 0.959\text{cm}^2$ and 3.03 ± 0.727

cm^3 respectively, while they were $1.6 \pm 1.236\text{cm}^2$ and $0.90 \pm 0.5262\text{cm}^3$ respectively post treatment. Fig (1) represents the percentage of improvement of group A (HBOT group).

Table (3): The statistical analysis of mean differences of ulcer surface area and ulcer volume in HBOT group (A) pre and post-treatment.

Statistics	Ulcer surface area (cm ²)		Ulcer volume (cm ³)	
	Pre	Post	Pre	Post
Mean	4.5	1.6	3.03	0.90
S.D±	0.959	1.236	0.727	0.5262
t- value	9.721		11.193	
P-value	<0.01		<0.01	
Level of significance	HS		HS	

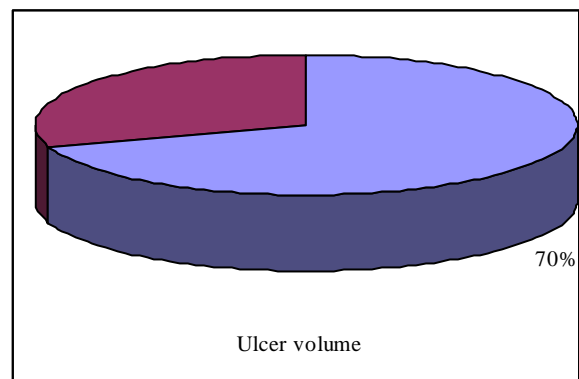
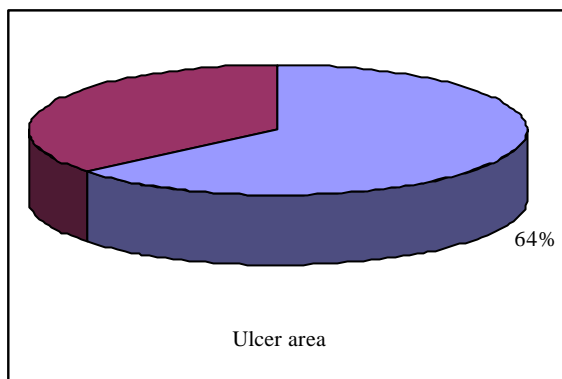


Fig. (1): Represent the percentage of improvement of group A (Treatment).

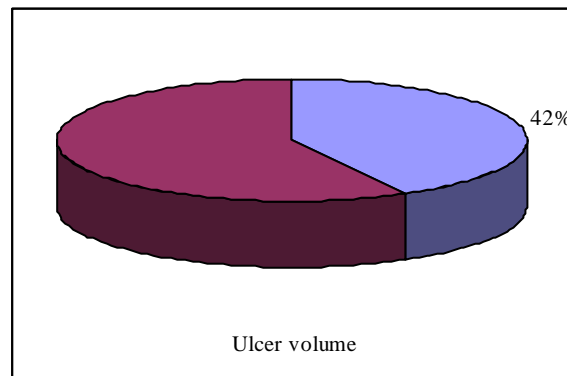
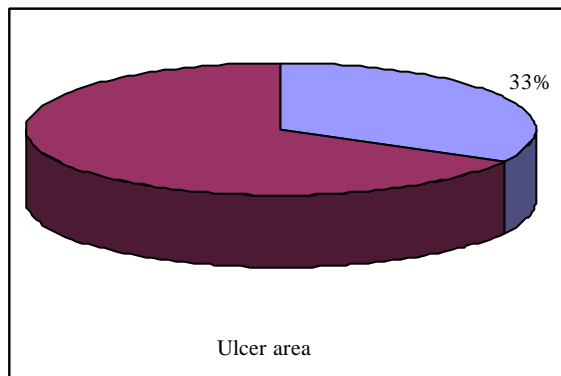
III- Results of group (B) (Control):

As shown in table (4) the mean value and standard deviation of ulcer surface area and ulcer volume at the beginning of the study (pre) were $4.425 \pm 0.925\text{cm}^2$ and 3.25 ± 0.8894

cm^3 respectively, while they were $2.955 \pm 1.091\text{cm}^2$ and $1.870 \pm 0.552\text{cm}^3$ respectively after treatment (post). Fig (2) represents the percentage of improvement of group B (Control).

Table (4): The statistical analysis of mean differences of ulcer surface area and ulcer volume in Control group (B) pre and post-treatment.

Statistics	Ulcer surface area (cm ²)		Ulcer volume (cm ³)	
	Pre	Post	Pre	Post
Mean	4.425	2.955	3.25	1.870
S.D±	0.925	1.091	0.8894	0.552
t- value	5.644		5.65	
P-value	<0.05		<0.05	
Level of significance	S		S	

**Fig. (2): Represents the percentage of improvement of group B (Control).**

IV a -Comparative analysis of the mean differences of ulcer surface area, ulcer volume between both groups (post treatment):

Table (5) showed the mean differences of ulcer surface area, ulcer volume between

both groups post treatment and it showed that there were highly statistically significant differences between both groups at the end of the study with P value <0.01.

Table (5): Statistical analysis of the mean differences of ulcer surface area, ulcer volume between both groups post- treatment.

Statistics	Ulcer surface area (cm ²)		Ulcer volume (cm ³)	
	Post 1	Post 2	Post 1	Post 2
Mean	1.6	2.955	0.90	1.870
S.D±	1.236	1.091	0.5262	0.552
t- value	-3.675		-5.695	
P-value	<0.01		<0.01	
Level of significance	HS		HS	

IV b- Comparative analysis of doppler findings between both groups A and B at end of the treatment:

Comparing the percentage and frequency of Doppler results at end of treatment (Post) between group A (HBOT group) and group B (control group) were analyzed in table (6) as the following:

The cross tabulation and Mann Whitany test revealed statistical significant difference (P<0.05) between two groups, there were 16

patients with 80% who reported improvement in doppler findings, for group A, while there were seven patients with 35% who reported improvement in doppler findings for group B. There were four patient with 20 % who reported "No changes" in doppler findings for group A, while there were 9 patients with 45% reported "No-changes" in doppler findings, and four patients with 20% reported worsen of their condition in doppler findings for group B. Figs (3 a, b).

Table (6): Comparative analysis of doppler findings between both groups (A&B), at the end of treatment.

	Group		P-value
	Group A N (%)	Group B N (%)	
Improvement	16(80%)	7(35%)	0.003
No-Changes	4(20%)	9(45%)	
Worsen	----	4(20%)	

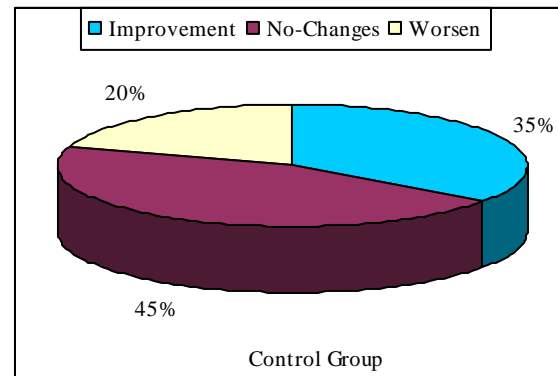
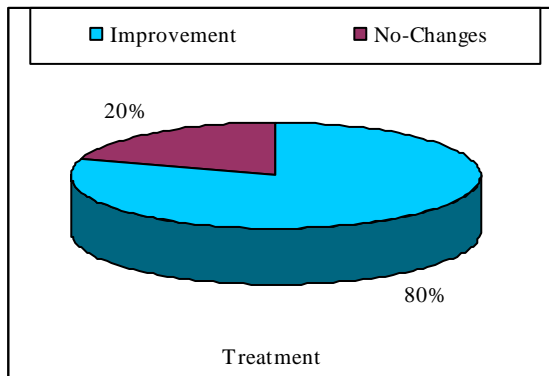


Fig. (3): Represents comparative analysis of doppler findings between both groups (A and B), at the end of treatment.

DISCUSSION

This study was applied to evaluate the effectiveness of HBOT in vasculitic skin ulcers in systemic lupus patients. Patients were divided into two groups of equal number, group A (HBOT) received hyperbaric oxygen therapy in addition to local wound care while group B (Control) received only local wound care.

Results of the study revealed that there was a highly significant differences between both groups regarding wound surface area, ulcer volume and doppler findings after the treatment (P values <0.01). Also the results of this study revealed that the percentages of improvement in HBOT group regarding to ulcer area, ulcer volume, Doppler findings were 63%, 70% and 80% respectively while in the control group were 33%, 42%, 35% respectively. This confirms the effectiveness of HBOT in treating vasculitic skin ulcer and this may be due to the increased wound oxygen tension achieved with HBOT promotes wound healing, increases the host antimicrobial defenses and has a direct bacteriostatic effect on anaerobic microorganisms. Also the concentrated oxygen encourages the growth of new blood vessels. All these effects help to accelerate healing and prevent future problems.

The results of this study were in agreement with Kalani, et al.¹³, who reported that Adequate tissue oxygen tension is an essential factor in infection control and wound healing. A daily sessions of oxygen breathing at 2.5-bar increased pressure in a hyperbaric chamber, has beneficial actions on wound healing including antimicrobial action, prevention of edema and stimulation of fibroblasts. Also they concluded that HBOT seems to accelerate the rate of healing, reduce the need for amputation, and increase the number of wounds that are completely healed on long-term follow-up.

Kulikovsky, et al.¹⁵, stated that oxygen is an essential component of wound healing, and the rate of healing can be directly linked to the level of tissue oxygenation. According to Mogford and Mustoe²⁰, wound ischemia is, arguably, the most common cause of wound-healing failure. HBOT is a treatment for hypoxic wounds. It utilizes oxygen as a drug and the hyperbaric chamber as the mechanical tool for elevating its concentration at the target area.

Cimit, et al.⁴, showed that HBOT acts as a bacteriostatic agent against anerobic bacteria by increasing the formation of free oxygen radicals. HBOT restores the bacterial-killing capacity of leukocytes in hypoxic wounds by increasing tissue oxygen tensions. In addition,

HBOT acts synergistically with a number of antibiotics.

Wu²⁸, revealed that HBOT works by elevating the plasma oxygen level. Fibroblasts synthesize and modify collagen, and both these activities require relatively high partial pressures of oxygen. Hyperbaric oxygen can promote healing by stimulating fibroblast activity and collagen formation. Increasing oxygen tensions also has a direct and toxic effect on anaerobes.

Heng, et al.⁹, also concluded that HBOT is effective in stimulating angiogenesis with enhanced healing of necrotic wounds. The growth of new blood vessels in damaged tissues (angiogenesis) is another permanent effect of hyperbaric oxygen treatment boosting oxygen delivery to the hypoxic tissues. It is the most significant clinical benefit in the healing improvement of certain hypoxic wounds.

Gallagher, et al.,⁷ reported that recent evidence indicates, that tissue-level hyperoxia achieved by therapeutic hyperbaric oxygen protocols (HBOT) can increase the mobilization of endothelial progenitor cells (EPC) from the bone marrow into peripheral blood. They are the key cellular effectors of postnatal vasculogenesis and play a central role in wound healing.

Lyon¹⁷, also stated that those who received HBO as part of their wound care regimen healed faster than those who received standard treatment or growth factor therapy only.

Kuffler¹⁴, revealed that HBOT has important effects on the biology of cytokines and other mediators of inflammation. HBO2 causes cytokine down-regulation and growth factor up-regulation. HBO2 transiently suppresses stimulus-induced proinflammatory cytokine production and affects the liberation of TNFa (tumor necrosis factor alpha) and endothelins.

Also the results of the study revealed no side effects reported by any patient in HBOT group during and after treatment period. On conclusion, the present study revealed that HBOT is considered an effective treatment method that promotes healing of the Vasculitic skin ulcer in systemic lupus patients.

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المخلص العربي

فاعلية الأوكسجين ذو الضغط العالي في علاج قرح الجلد الناتجة عن الالتهاب الوعائي في مرضي الذئبة الحمراء الجهازية

يهدف هذا البحث إلي دراسة تأثير الأوكسجين ذو الضغط العالي علي قرح الجلد الناتجة عن الالتهاب الوعائي في مرضي الذئبة الحمراء الجهازية . وقد أجريت هذه الدراسة علي أربعين متطوعاً ممن تتراوح أعمارهم بين 25 الي 40 سنة ممن يعانون من قرح في الرجل أو القدم نتيجة مرضهم بالذئبة الحمراء الجهازية. وقد تم تقسيمهم عشوائياً إلي مجموعتين متساويتين في العدد ، المجموعة الأولى (أ) : تلقت الأوكسجين ذو الضغط العالي (ضعف الضغط الجوي) لمدة 90 دقيقة في الجلسة بواقع 5 جلسات أسبوعياً وذلك لمدة شهر . بالإضافة إلي الروتين العلاجي للجروح بينما المجموعة الثانية (المجموعة الضابطة) : عولجت بالروتين العلاجي للجروح وقد تم قياس مساحة وحجم القرح قبل وبعد العلاج للمجموعتين وكذلك استخدام دوبلر الموجات الصوتية لمعرفة التحسن في المجموعتين بعد العلاج . وقد أظهرت النتائج فروق ذات دلالة إحصائية بين المجموعتين بعد العلاج بالنسبة لمساحة و حجم القرح وأيضا نتاج الدوبلر وطبقاً لهذه النتائج يمكن أن نستخلص أن للأوكسجين ذو الضغط العالي تأثير فعال و امن في علاج قرح الجلد لمرضي الذئبة الحمراء الجهازية . الكلمات الدالة : الأوكسجين ذو الضغط العالي، الذئبة الحمراء الجهازية، الالتهاب الوعائي، قرح الجلد،الروتين العلاجي للجروح ، دوبلر الموجات فوق الصوتية .