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Original Research Article

Study of the efficacy of hyperbaric oxygen therapy in chronic wounds in diabetic patients

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ABSTRACT

Background: Diabetic patients are prone to chronic wounds that are difficult to heal due to impaired blood flow, immune dysfunction, and prolonged hyperglycemia. Hyperbaric oxygen therapy (HBOT) has been proposed as an adjunctive treatment for diabetic wounds. This study aimed to evaluate the efficacy of HBOT in treating chronic wounds in diabetic patients.
Methods: A prospective observational study was conducted at Sassoon General Hospital, Pune, Maharashtra from July 2022 to March 2024. A total of 34 diabetic patients with chronic non-healing ulcers were consecutively recruited and randomized into two groups: the test group (standard wound care + HBOT) and the control group (standard wound care only). Primary parameters included wound healing rate and reduction in ulcer area, while secondary parameters involved infection rates, time to appearance of serous discharge, and hospital stay duration. Data were analyzed using statistical package for the social sciences (SPSS) 26.0, with significance set at $p<0.05$.
Results: The HBOT group showed a significantly greater reduction in ulcer area, granulation tissue formation was notably faster compared to the control group. Infection rates were lower in the HBOT group, with a higher proportion of sterile cultures on day and HBOT patients also had a shorter hospital stay compared to controls.
Conclusions: HBOT significantly improved wound healing rates, infection control, and reduced hospital stay duration in diabetic patients with chronic wounds.

Keywords: Hyperbaric oxygen therapy, Diabetic wounds, Wound healing, Chronic wounds, Infection control

INTRODUCTION

Diabetes mellitus (DM) is a global health challenge with an increasing prevalence, significantly impacting patient quality of life and imposing a substantial burden on healthcare systems. Chronic wounds, particularly diabetic foot ulcers (DFUs), are a common complication in diabetic patients due to peripheral neuropathy, impaired immunity, and vascular complications.[1,2] Among various approaches for managing chronic wounds in diabetic patients, hyperbaric oxygen therapy (HBOT) has gained attention as a potential treatment for enhancing wound healing processes by improving oxygen supply to hypoxic tissues and promoting cellular repair mechanisms.[3]

The pathogenesis of chronic wounds in diabetes is complex, with factors such as hyperglycemia, peripheral neuropathy, and impaired microcirculation playing significant roles.[4] Chronic hyperglycemia leads to glycation of proteins, impaired function of leukocytes, and compromised wound healing capacity.[5] Furthermore, poor circulation restricts oxygen delivery, leading to tissue hypoxia that hinders the natural wound healing process, contributing to chronic, non-healing wounds that are highly susceptible to infections.[6] This hypoxic state is particularly detrimental as oxygen is essential for fibroblast function, collagen synthesis, and bacterial defense.[7]

HBOT involves breathing 100% oxygen at pressures greater than atmospheric levels, typically 1.5 to 3.0 atmospheres absolute (ATA), allowing for the delivery of higher oxygen concentrations to blood and tissues.[8] This therapeutic approach increases oxygen partial pressures in wound tissues, which enhances the ability of leukocytes to destroy bacteria and stimulates angiogenesis, collagen deposition, and epithelialization.[9,10] Increased oxygen levels in the wound area also promote the activity of fibroblasts and endothelial cells, essential for effective wound repair and tissue regeneration.[11]

Numerous studies have shown that HBOT can significantly reduce healing time and improve outcomes for chronic wounds in diabetic patients. For instance, a randomized controlled trial by Londahl et al demonstrated that HBOT reduced amputation rates and improved healing in diabetic foot ulcers compared to standard wound care.[12] Additionally, a meta-analysis by Abidia et al found that patients receiving HBOT experienced better wound healing rates than those receiving conventional treatment alone.[13] This evidence suggests that HBOT can be an effective adjunctive treatment for chronic wounds in diabetic patients by addressing the underlying hypoxia that impairs wound healing.[14]

Despite its promising outcomes, HBOT is not without limitations. The therapy is resource-intensive, requiring specialized equipment and trained personnel, which limits its availability in many healthcare settings, especially in low-resource areas.[15] Furthermore, the therapy is associated with potential side effects, such as barotrauma, oxygen toxicity, and temporary myopia, which may limit its applicability for some patients.[16,17] Additionally, patient compliance and accessibility to HBOT facilities can pose challenges in managing chronic diabetic wounds through this method.[18]

Professional organizations, including the Undersea and Hyperbaric Medical Society (UHMS), have outlined specific indications for HBOT in the management of diabetic foot ulcers. According to these guidelines, HBOT is recommended as an adjunctive treatment for patients with Wagner grade 3 or higher foot ulcers who have not responded to conventional wound care therapies.[19] The use of HBOT in clinical practice, however, is often guided by individual patient needs, wound characteristics, and healthcare provider expertise.[20]

METHODS

Study design

This study was conducted as a prospective observational study, designed to evaluate the effectiveness of HBOT for chronic wounds in diabetic patients. By using an observational design, the study collected data in real-time without altering treatment conditions, which improved the study's external validity. The prospective approach reduced recall bias and helped establish a clearer link between HBOT and wound healing outcomes.

Study setting

The study took place in a tertiary care center known for its extensive healthcare services and advanced treatment facilities. The surgery ward, equipped for HBOT, provided an ideal setting for treating diabetic patients with chronic wounds.

This setting allowed access to a relevant patient population and ensured that the study was conducted in a real-world clinical environment.

Study duration

The study spanned from July 2022 to March 2024 to allow adequate time for patient recruitment, treatment, follow-up, and data collection. The extended duration enabled observation of both short- and long-term effects of HBOT. This timeframe also accommodated any unforeseen delays due to patient health variations or logistical challenges.

Participants – inclusion and exclusion criteria

Participants included diabetic patients aged 18 and older with chronic non-healing ulcers fit for HBOT. Exclusion criteria involved minors, patients lacking consent, those with peripheral vascular disease, discharge against medical advice, or contraindications to HBOT. These criteria ensured a focused and homogeneous study population.

Study sampling

Participants were recruited consecutively as they presented to the surgery ward with chronic diabetic wounds. Consecutive sampling reduced selection bias, ensuring that all eligible patients during the study period were considered. This method enhanced the study's representativeness of the patient population.

Study sample size

A sample size of 34 participants was determined using power analysis with a 95% confidence level and an alpha of 0.05. The estimated effect size was based on previous research on HBOT efficacy in wound healing. The sample size included allowances for potential dropouts to ensure reliable results.

Study groups

Participants were randomly assigned to a control group (standard wound care) or a test group (standard wound care + HBOT) using a computer-generated randomization. This random assignment minimized bias and allowed direct comparison of HBOT's additional efficacy over standard care.

Study parameters

Primary study parameters included wound healing rate, wound size reduction, and time to closure. Secondary parameters involved pain levels, infection rates, and wound-related complications like amputation. These parameters directly reflected treatment efficacy and clinical outcomes.

Study procedure

After informed consent, participants underwent baseline assessments before randomization into either the control or test group. HBOT sessions were conducted in a multiplace chamber at 2.5 atmospheres, 90 minutes per session, five days a week for up to six weeks. The control group received only standard wound care.

Study data collection

Data were gathered through initial medical evaluations, baseline assessments, and ongoing weekly monitoring. Variables such as wound size, infection status, and discharge type were recorded in case report forms and securely stored in an electronic database to ensure consistency and accuracy.

Data analysis

Data were analyzed using statistical package for the social sciences (SPSS) 26.0 with descriptive and inferential statistics. Chi-square and t-tests compared categorical and continuous variables between groups, while repeated measures analysis of variance (ANOVA) assessed wound healing progress. Significance was set at $p<0.05$, with multivariate regression to adjust for confounders.

Ethical considerations

The study obtained ethical approval from the Institutional Review Board, and informed consent was secured from all participants. Privacy and confidentiality were strictly maintained, and participants could withdraw anytime. The study adhered to the Declaration of Helsinki guidelines to protect participant rights and well-being.

RESULTS

Age distribution among study groups

The study on the efficacy of HBOT in chronic wounds in diabetic patients shows that the age distribution of the participants is skewed towards middle-aged individuals. The highest frequency of patients falls within the 41-50 age group (14 patients), followed closely by the 51-60 age group (13 patients), and a smaller number of participants are in the 30-40 age range (5 patients). This suggests that chronic wounds requiring HBOT are more prevalent in older diabetic patients, particularly those in their 40s and 50s.

Gender distribution among study groups

The study's gender distribution indicates that a larger proportion of the participants were male, with 64.7% (22 participants) being male, while 35.3% (12 participants) were female. This suggests that males may be more affected by chronic wounds requiring hyperbaric oxygen therapy in diabetic patients, or that they may be more likely to seek treatment, as represented in this study's sample of 34 patients.

Distribution of the duration of diabetes in patients

The distribution of the duration of diabetes in two groups shows that the majority of patients had diabetes persisting between 6 to 15 years. Specifically, 12 patients each fall into the 6-10 years and 11-15 years categories, indicating that duration of diabetes in this study population often persist for more than 6 years. A smaller number of patients, 10 in total, had diabetes for 0-5 years.

Distribution of hemoglobin levels among study groups

The distribution of hemoglobin (Hb) levels among the study participants indicates that the majority, 21 patients, had HB levels between 7-10 g/dl, which may suggest mild to moderate anemia. The remaining 13 patients had slightly higher HB levels between 11-12 g/dl, which is closer to the lower end of the normal range. This distribution highlights that a significant portion of the study population may have anemia, a common complication in diabetic patients, which could potentially influence the healing of chronic wounds and the efficacy of HBOT.

Distribution of HbA1c levels among study groups

The distribution of HbA1c levels among the study participants reflects varying degrees of glycemic control, with the majority of patients showing poor control of their diabetes. Specifically, the highest frequency of participants (11 patients) had HbA1c levels between 9.5-10.4%, indicating significantly elevated blood sugar levels. Fewer participants had better glycemic control, with 8 patients each in the 6.5-7.4% and 8.5-9.4% ranges. Only 1 participant had an HbA1c level between 10.5-11.4%. This distribution suggests that most participants had poorly controlled diabetes, which is a critical factor in the development and persistence of chronic wounds, and may impact the effectiveness of HBOT.

Albumin levels among study groups

The albumin (ALB) levels among the study participants indicate that most of them have low albumin levels, which could be a sign of poor nutritional status or chronic illness. Specifically, 18 participants had albumin levels between 2.53 g/dl, and 16 participants had levels between 3-3.5 g/dl. Since albumin is a marker of protein status and plays a crucial role in wound healing, these low levels suggest

that many participants may be at a nutritional disadvantage, which could affect their recovery and the overall efficacy of HBOT in treating their chronic wounds.

Table 1: Distribution of HbA1c levels among study groups.

HbA1c	Frequency
6.5-7.4	8
7.5-8.4	6
8.5-9.4	8
9.5-10.4	11
10.5-11.4	1

Comparison of granulation tissue formation between the interventional groups

Table 2 show the growth of healthy granulation tissue in cases and controls from day 0 to day 28. By day 7, 11 cases (64.7%) in test group had developed a healthy granulation tissue compared to the control group where only 2 cases had developed healthy granulation tissue, which was statistically significant with a p-value of 0.004. By day 14, 16 cases (94.1%) in test group had a healthy granulation tissue as compared to 10 (58.8%) in Control group who had developed a healthy granulation tissue. By 21 days, all the 35 patients both in test and control group had developed healthy granulation tissue, of score 4. Thus overall difference was statistically significant ($p<0.05$) within 7 days.

Table 2: Hypothesis test summary indicating distribution of granulation tissue formation across the categories of interventional groups.

S. no.	Null hypothesis	Test	Sig.	Decision
1	The formation of granulation tissue is the same across categories of interventional groups	Indepen-dent-samples, Mann-Whitney U test	0.004	Reject the null hypothe-sis.

Reduction in ulcer area (% of reduction)

The area of the ulcers reduced significantly in the patients who received HBOT when compared to those who received conventional dressing. The area of ulcer is compared from the time of admission to the time of discharge, wherein healthy granulation tissue has formed and the patient is deemed fit for discharge (graftable wound). The mean percentage of reduction in surface area of ulcers was 72.61 in the test group while in the control group it was 40.11. The p value calculated by t-test was found to be very significant with a p value of <0.000002.

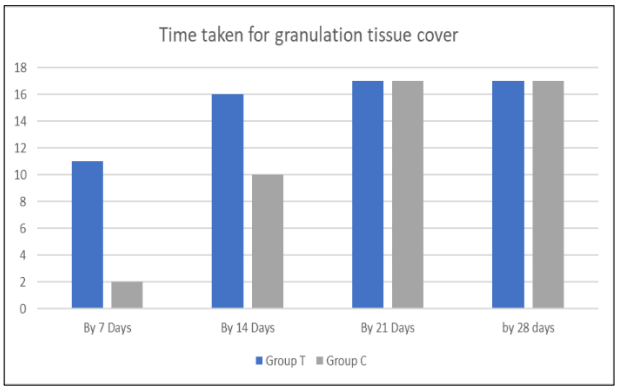

Figure 1: Time taken (in days) for granulation tissue cover of visual score 4.

Time taken for appearance of serous wound discharge

The time taken for appearance of serous wound discharge between cases and controls at the end of each week. By 7 days, serous discharge was seen in a greater number of patients treated with HBOT as compared to control group i.e., 12 versus 2 (70.5% versus 11.7%). By 14 days also, serous discharge was seen in a greater number of patients in cases group as compared to control group i.e. 17 versus 10 (91.4% versus 58.8%). The result was statistically significant with a p value of 0.001 within 7 days.

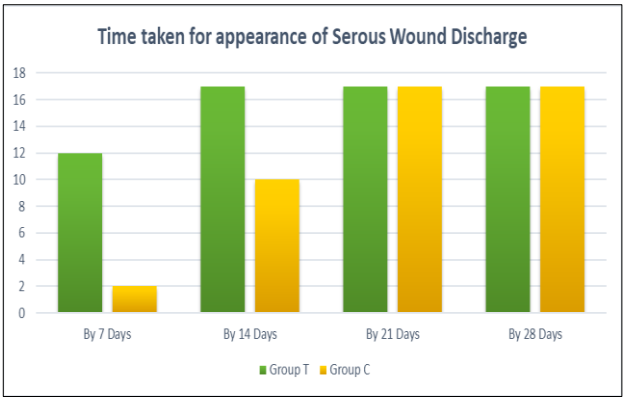

Figure 2: Time taken for appearance of serous wound discharge.

Wound swab culture on day 7

The commonest organism associated with diabetic foot ulcer was *Staphylococcus aureus*, which was cultivated in the cultures of 6 patients. Of these, 1 were isolated from the test group and 5 were isolated from the control group. The other common organisms were *Citrobacter, Klebsiella, Pseudomonas aeruginosa* and *Escherichia coli*.

A total of 9 patients had no growth during their hospital stay of which 7 belonged to the study group and 2 belonged to the control group.

Table 3: Wound swab culture.

Organism	Group T		Group C	
	N	%	N	%
Citrobacter	4	23.5294118	3	17.6470588
E. coli	2	11.7647059	1	5.88235294
Klebsiella	2	11.7647059	4	23.5294118
Pseudomonas	1	5.88235294	2	11.7647059
S. aureus	6	35.2941176	5	29.4117647
Sterile growth	7	41.1764706	2	11.7647059
Total	35	100	35	100

Table 4: Mean duration of hospital stay.

Parameters	Group T		Group C		P value
	Mean	SD	Mean	SD	
Hospital stay	12.70	4.46	20.94	4.53	<0.000 001

Figure 3: Wound on day 1 (above) and on day 14 (below) of HBOT therapy.

Mean duration of hospital stay

Table 4 shows the comparison of mean duration of hospital stay between cases and controls (mean was calculated by adding the no. of days patients were admitted and dividing the sum with the total no. of patients). The mean duration of hospital stay in the patients treated with HBOT for diabetic foot ulcer is 12.70 days while the patients treated with conventional dressing stayed longer in the hospital with a mean duration of stay of 20.94 days. Thus, the duration of stay was significantly shorter for cases as compared to controls with p value <0.000001.

Number of HBOT sessions among study groups

The distribution of the number of HBOT sessions among the study participants indicates that most patients required a relatively low number of sessions to achieve their treatment outcomes. Specifically, 12 participants had 6-10 sessions. A smaller number of participants needed more extensive treatment, with 4 patients receiving 11-15 sessions and only 1 patient requiring 15-20 sessions as that patient had a wound size of 9×9 cm. This suggests that a majority of patients responded to HBOT within a limited number of sessions, highlighting the potential efficiency of the therapy in treating chronic wounds in diabetic patients.

Figure 4: Wound on (a) day 1 and (b) on day 7 of HBOT therapy.

DISCUSSION

This study examined the efficacy of HBOT in managing chronic wounds in diabetic patients, highlighting significant outcomes across various clinical parameters. The findings underscore HBOT's potential as an effective adjunct therapy in accelerating wound healing, improving infection control, and reducing hospital stays.

The age distribution in this study showed that middle-aged individuals, specifically those in the 41-50 (41.2%) and 51-60 (38.2%) age groups, comprised the largest proportion of patients. This aligns with previous studies showing that older adults with diabetes are more prone to chronic wounds, likely due to prolonged diabetes duration and associated comorbidities.[1] Furthermore, the study noted a higher prevalence of chronic wounds among males, who made up 64.7% of participants. This male predominance may reflect a higher incidence of foot ulcers in men or greater healthcare-seeking behavior, as documented in other chronic wound studies.[2]

The duration of diabetes among participants highlighted that 70.6% had diabetes for more than six years, with most in the 6-10 (35.3%) and 11-15 (35.3%) year ranges. This supports findings that prolonged diabetes correlates with a higher risk of non-healing wounds, as extended hyperglycemia contributes to vascular and immune

dysfunction, impairing wound healing.[3] Patients with chronic diabetes often develop peripheral neuropathy and decreased tissue perfusion, key factors in the development of chronic wounds.[4]

The majority of participants exhibited Hb levels between 7-10 g/dl (61.8%), indicating mild to moderate anemia, which is common in diabetics with chronic wounds. Low hemoglobin levels may exacerbate tissue hypoxia, delaying wound healing.[5] Additionally, albumin levels revealed that 52.9% had levels between 2.5-3 g/dl, reflecting poor nutritional status. Given albumin's role in wound healing, low levels are linked to delayed recovery and increased infection risk, further emphasizing the challenges faced by diabetic patients in wound healing.[6]

The distribution of HbA1c levels highlighted poor glycemic control in the majority of participants, with 32.4% showing levels between 9.5-10.4%, indicative of significantly elevated blood glucose. Poorly controlled diabetes is a known risk factor for delayed wound healing and increased infection rates, as hyperglycemia impairs leukocyte function and compromises local immunity.[7] The high prevalence of poor glycemic control in this study likely contributed to the chronic nature of the participants' wounds, underscoring the need for stringent glucose management in diabetic wound care.

One of the most compelling findings was the accelerated formation of healthy granulation tissue in the HBOT group. By day 7, 64.7% of HBOT-treated patients showed healthy granulation compared to only 11.7% in the control group ($p=0.004$). By day 14, 94.1% in the HBOT group exhibited significant granulation, versus 58.8% in the control group. This rapid development of granulation tissue reflects HBOT's role in enhancing tissue oxygenation, a crucial factor in the wound-healing cascade.[8] Previous studies have shown that increased oxygen levels in wound sites stimulate angiogenesis and collagen synthesis, expediting tissue repair.[9] This study's results align with these findings, further supporting HBOT as an effective therapy in diabetic wound management.

HBOT demonstrated a notable impact on ulcer size reduction, with a mean percentage decrease in ulcer area of 72.61% in the HBOT group compared to 40.11% in the control group ($p<0.000002$). This substantial reduction underscores HBOT's efficacy in improving wound healing outcomes. The oxygen-rich environment provided by HBOT likely facilitates cellular metabolism and fibroblast proliferation, essential for tissue regeneration.[10] Such findings are consistent with prior studies showing HBOT's effectiveness in reducing ulcer size in diabetic patients, highlighting its value as an adjunct therapy in reducing wound burden.[11]

The appearance of serous discharge, indicative of wound healing progression, occurred earlier in the HBOT group. By day 7, 70.5% of HBOT patients had serous discharge compared to only 11.7% in the control group ($p=0.001$). This rapid shift to serous discharge in HBOT patients may reflect faster granulation and lower infection rates, suggesting enhanced healing dynamics in the HBOT environment.[12] Serous discharge in wound healing represents reduced infection and inflammation, marking a key milestone in the recovery process.[13]

Wound culture results on day 7 showed a higher prevalence of sterile cultures in the HBOT group (41.2%) compared to the control group (11.8%), indicating that HBOT may play a role in reducing bacterial load in chronic wounds. The most common pathogen, Staphylococcus aureus, was present in both groups but was more prevalent in the control group. HBOT's bactericidal effect, due to oxygen's toxic impact on anaerobic bacteria, may explain the lower infection rates observed in the HBOT group.[14] Studies have suggested that HBOT can enhance phagocytic activity, improving infection control in chronic wound settings.[15]

A significant reduction in hospital stay was noted for HBOT-treated patients, with a mean duration of 12.7 days compared to 20.94 days in the control group ($p<0.000001$). This shorter stay implies a faster overall healing rate for HBOT patients, potentially lowering healthcare costs and resource utilization. The reduced hospital time is advantageous for patients and healthcare facilities, affirming HBOT's clinical value in promoting efficient wound management.[16]

Number of HBOT sessions

The study found that most patients responded to HBOT within 6-10 sessions, suggesting that HBOT achieves effective outcomes in relatively few sessions. Only a minority required more extensive treatment, emphasizing the therapy's efficiency in diabetic wound care. This finding aligns with studies demonstrating HBOT's efficacy within short treatment cycles, indicating that rapid healing responses are achievable with targeted HBOT interventions.[17]

While HBOT showed clear benefits, certain limitations must be acknowledged. The relatively small sample size (34 participants) may limit the generalizability of the results. Additionally, as a single-center study, the findings may not be fully representative of broader populations with varying healthcare access and demographics. However, the results provide valuable insights into HBOT's role in chronic wound care, suggesting that incorporating HBOT into diabetic wound management protocols may enhance healing outcomes. Clinically, HBOT could serve as a valuable adjunct to conventional wound care in diabetic patients, especially those with poorly controlled diabetes or low albumin levels, who are at higher risk for non-healing wounds. By accelerating wound healing, reducing infection, and shortening hospital stays, HBOT may improve patient quality of life and reduce healthcare burdens associated with chronic wound management.

CONCLUSION

In conclusion, this study supports the efficacy of HBOT in treating chronic wounds among diabetic patients. The significant improvements in wound healing, infection control, and hospital stay duration observed in the HBOT group suggest that HBOT is a promising adjunctive therapy for diabetic wound management. Future research with larger, multicenter trials may further establish HBOT's role and cost-effectiveness, potentially guiding clinical guidelines for chronic wound care in diabetic populations.

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