(e) ISSN Online: 2321-9599

(p) ISSN Print: 2348-6805

Original Article

The Therapeutic Potential of Hyperbaric Oxygen Therapy in Diabetic Limb Care

[1]Naval Khurana, [2]Ajay Kumar Agrawal

[1]Assistant Professor, Department of General Surgery, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, India;
[2]Professor, Department of General Surgery, Gold Field Institute of Medical Sciences & Research, Faridabad, Haryana, India

ABSTRACT:
Background: The current study was undertaken with the aim of investigating the presentation patterns of patients with diabetic limb conditions in the surgical outpatient department (OPD) and emergency casualty settings. It also sought to assess the effectiveness of existing treatment options for preserving diabetic limbs, while simultaneously evaluating the extent of healthcare resource utilization and the associated impact on health-related quality of life for these patients. **Methods**: This study was a prospective randomized controlled trial conducted over a span of two years within a hospital setting. The research involved a total of 202 patients, all of whom were dealing with various diabetic limb issues. These patients were divided into two groups: one group receiving standard care, and the other group undergoing treatment with hyperbaric oxygen therapy (HBOT). **Results**: Notably, the study group exhibited a significant reduction in the percentage of isolated bacteria among the study subjects. According to culture sensitivity reports, the most frequently isolated organism in both study groups was E. coli. **Conclusion**: Diabetic wounds pose a significant challenge for surgeons when it comes to healing. Among the various factors contributing to the poor healing of diabetic wounds, one crucial factor is ischemia. Hyperbaric oxygen therapy (HBOT) plays a vital role in addressing this issue. By providing oxygen at pressures greater than 1 atmosphere absolute (ata), HBOT delivers 100% oxygen, which effectively promotes and accelerates wound healing in diabetic patients.
Keywords: HBOT, diabetic foot, diabetes mellitus, amputation

Corresponding author: Ajay Kumar Agrawal, Professor, Department of General Surgery, Gold Field Institute of Medical Sciences & Research, Faridabad, Haryana, India

Received: 09-02-2014 Revised: 11-03-2014 Accepted: 20-03-2014

This article may be cited as: Khurana N, Agrawal AK. The Therapeutic Potential of Hyperbaric Oxygen Therapy in Diabetic Limb Care. J Adv Med Dent Scie Res 2014;2(2):238-242.

INTRODUCTION

Diabetic foot ulcers represent a prevalent and severe complication of diabetes. The treatment of these ulcers typically necessitates prolonged hospital stays and frequent outpatient consultations. Additionally, the loss of mobility imposes a substantial burden on both the patient and the healthcare system.[1] Even at renowned medical centers, a significant proportion (19-35%) of these ulcers are reported as nonhealing. Consequently, despite advancements in diabetic foot ulcer treatment, there remains a demand for innovative treatment strategies and approaches to address this persistent issue.Diabetes has been on a concerning rise in India. In 1995, India had 19.6 million diabetic patients, and projections indicate a substantial increase, with an estimated 56.2 million diabetic patients in the country by 2025. On a global scale, the prevalence of diabetes is expected to reach 300 million by 2025, with 74 million cases in developed countries and a staggering 226 million in developing countries, representing 75% of all diabetics.

Furthermore, it is alarming to note that a significant proportion of non-traumatic lower limb amputations, ranging from 40% to 60%, are directly attributable to diabetes. A striking 86% of diabetic-related foot amputations are preceded by foot ulcers, which themselves are often triggered by trauma. The prevalence of foot ulcers in diabetic patients ranges from 4% to 10%, highlighting the substantial impact of diabetes on lower limb health[2].

Hyperbaric oxygen therapy (HBOT) has garnered attention as an effective treatment for diabetic foot wounds, with the first controlled trial for this application reported over 20 years ago in Diabetes Care. Supporters have suggested that the scientifically proven effects of HBOT, such as improving tissue oxygenation in wounds, enhancing blood flow, reducing swelling, dampening the activity of inflammatory cytokines, stimulating fibroblast proliferation, promoting collagen synthesis, and encouraging angiogenesis, all make it a valuable addition to clinical practice for challenging wounds like diabetic foot ulcers. Additionally, HBOT is recognized for its potential in eliminating stubborn

soft tissue and bone infections. This is achieved through various mechanisms, including the destruction of microorganisms, bolstering the function of white blood cells and macrophages, and augmenting the effectiveness of antimicrobial treatments.The potential clinical realization of these beneficial effects of hyperbaric oxygen therapy (HBOT), despite its costliness, could significantly reduce the risk of lower-extremity amputations in diabetic patients with foot wounds. Therefore, it is crucial to thoroughly assess the clinical effectiveness of HBOT in the context of diabetic foot ulcers. However, given the strong motivation of both patients and clinicians to prevent the devastating outcome of amputation, there exists a considerable risk of bias in poorly designed trials[3].

To establish the actual benefits of HBOT, it is imperative to conduct well-designed clinical trials that rigorously minimize the influence of preexisting biases on patient allocation, the diligence of foot care, and other critical management decisions. This approach is essential to ensure that the true clinical impact of HBOT on diabetic foot ulceration is accurately assessed.Most of the existing reports regarding the effect of hyperbaric oxygen therapy (HBOT) for the treatment of diabetic foot wounds have been comprised of case series or nonrandomized trials, often suffering from significant methodological limitations[4]. While these studies are considered a weak source of evidence, the noteworthy aspect is the consistency of positive results they demonstrate. In recent years, there has been a notable increase in the number of randomized controlled trials.A systematic review published in the Cochrane database in 2004, based on the findings of four such trials, concluded that "HBOT significantly reduced the risk of major amputation and may improve the chance of healing at 1 year." However, it also emphasized the need for caution in interpretation due to the small number of studies, limited patient numbers, and methodological and reporting inadequacies.A more recent systematic review and meta-analysis, which encompassed 10 studies (including 6 that were not randomized controlled trials), found that HBOT was associated with a reduced risk of amputation (odds ratio 0.24 in seven studies) and an increased likelihood of wound healing (odds ratio 10.0 in six studies). These findings highlight the potential benefits of HBOT in the treatment of diabetic foot wounds[5]. Therefore, the present study was conducted to investigate the presentation patterns of diabetic limb patients in surgical outpatient departments and emergency casualties, assess the efficacy of available treatment options for preserving diabetic limbs, and evaluate the utilization of healthcare resources and health-related quality of life.

MATERIALS AND METHODS

This study, spanning a two-year duration, was conducted within a hospital setting and followed a prospective randomized controlled design. It involved a total of 202 patients who presented with various diabetic limb conditions. These patients were managed using either standard care or hyperbaric oxygen therapy (HBOT). The inclusion criteria encompassed patients already diagnosed with type 1 or 2 diabetes mellitus, those with limb ulcers present upon admission to the hospital, and ulcers within the range of 0.25 to 25 cm2 in area. In cases where multiple ulcers were present on a limb, only the largest ulcer was considered for the study. Patients aged 18 years and above were included, as were those with diabetes diagnosed at the time of hospital admission[6]. Conversely, individuals below the age of 18, those from whom informed consent could not be obtained, and uncooperative patients were excluded from the study. Contraindications to HBOT included acute respiratory disease, a history of spontaneous pneumothorax, non-stabilized epilepsy, concurrent therapy with steroids, pregnancy, and Eustachian tube dysfunction. This study was initiated to comprehensively investigate the patterns of diabetic limb presentation in surgical outpatient departments and emergency casualties, assess the effectiveness of available treatment options for preserving diabetic limbs, and evaluate the utilization of healthcare resources and health-related quality of life among these patients.

Following admission and the initial application of standard wound care, patients were additionally administered hyperbaric oxygen therapy (HBOT) in selected cases. This HBOT involved patients spending 46-90 minutes within a hyperbaric chamber set at 2 atmospheres absolute (ata) pressure, where they breathed 100% oxygen. The duration of HBOT varied, spanning 2 to 4 weeks based on the specific patient and case requirements.[7]To facilitate a comparative analysis, the patients were divided into two groups: one that received HBOT therapy in addition to standard care and another that received standard care alone. This allocation was carried out using an odd and even number method of assignment. The study then proceeded to compare both groups with regard to various parameters, including the rates of wound healing, the average time required for healing, the rate of amputation in both groups, and the duration of hospital stays. This comprehensive evaluation aimed to assess the efficacy of HBOT as an adjunctive therapy in the treatment of diabetic limb conditions.

RESULTS

In this study, we conducted an analysis of the demographic characteristics of the study subjects. It was observed that the mean age of the individuals in the study group was 54.2 years, while in the control group, it was slightly higher at 55.2 years. The gender distribution in the current study was relatively consistent between the two groups, with a male-to-female ratio of 3:1 noted in both groups.

Table 1: Age distribution

Parameter	Study group	Control group
Age(yr)	54.2	55.2
Range	40-70	42-70
Sex(m:f)	3:1	3:1
Duration(yr)	9.6	10.0
Typeofdiabetes		
IDDM	14%	20%
NIDDM	86%	80%
neuropathy	16%	19%
Distalpulsations		
absent	10%	8%

The average duration of diabetes was found to be quite comparable in both groups, with a mean of 9.6 years in the study group and 10.0 years in the control group. A significant majority of the study subjects in both groups were diagnosed with non-insulin-dependent diabetes mellitus, constituting 86% in the study group and 80% in the control group. Notably, approximately 10% of subjects in the study group and 8% in the control group exhibited the absence of distal pulsations.

Additionally, the study group demonstrated a noteworthy reduction in the percentage of bacteria isolated among the study subjects. According to culture sensitivity reports, the most commonly isolated organism in both groups was Escherichia coli (E. coli). This information provides valuable insights into the clinical characteristics and microbiological aspects of the study population.

Table 2: Bacteria isolated

Bacteria isolated	Study group (on admission)	Control group (on admission)	Study group (after 2weeks)	Control group (after 2 weeks)
E.COLI	84	106	4	32
STAPHAUREUS	8	8	2	4
KLEBSIELLA	60	66	2	22

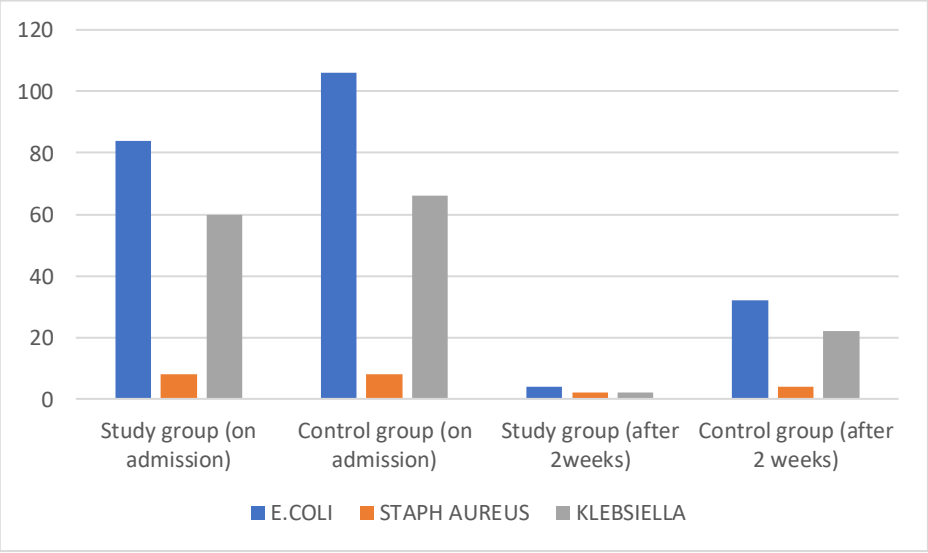

Table 3: Clinical parameters

Parameters		Study group	Control group	Level of Significance
Hospital stay	Average	25.22days	35.31days	P<0.05, HS
	Range	16-36days	20-54days	
Surgical revision procedure	Redebridements	8	40	
Amputations	Major	0	6	P<0.05.HS
	Minor	2	10	
Indications for major amputation	Spreading infection	2	12	--
	Gangrene	0	4	--

Follow-up cultures conducted after 14 days revealed a notable difference between the study and control groups. In the study group, there was a faster and more effective control of the infection compared to the control group.[8] This suggests that the addition of hyperbaric oxygen therapy (HBOT) to the treatment regimen played a positive role in managing the infection.Furthermore, the mean hospital stay in the study group was 25.22 days, indicating a shorter duration of hospitalization. In contrast, the control group had a comparatively longer mean hospital stay of 35.31 days. These findings highlight the potential benefits of HBOT in terms of more efficient infection control and a reduced hospitalization period, ultimately contributing to better patient outcomes.

DISCUSSION

In this study, we conducted a comprehensive assessment of the demographic characteristics of the study subjects. It was observed that the mean age of the participants was 54.2 years in the study group and slightly higher at 55.2 years in the control group. The male-to-female ratio was consistent at 3:1 in both groups. The average duration of diabetes was relatively similar, with a mean of 9.6 years in the study group and 10.0 years in the control group. The majority of the study subjects in both groups were diagnosed with non-insulin-dependent diabetes mellitus, comprising 87% in the study group and 80% in the control group. Notably, approximately 10% of subjects in the study group and 8% in the control group exhibited the absence of distal pulsations.

Microbiological analysis revealed that the study group exhibited a significant reduction in the percentage of bacteria isolated among the study subjects. According to culture sensitivity reports, Escherichia coli (E. coli) was the most commonly isolated organism in both groups.[9] Subsequent cultures conducted after 14 days demonstrated a faster control of infection in the study group compared to the control group. Additionally, the mean hospital stay in the study group was 24.22 days, whereas it was comparatively longer in the control group, where the mean hospital stay was 34.31 days. These findings underscore the potential benefits of hyperbaric oxygen therapy (HBOT) in terms of infection control and reduced hospitalization duration, with the ultimate aim of improving patient outcomes.The study outcomes revealed significant differences between the study and control groups with respect to the need for surgical revision procedures (re-debridement) and amputations. In the study group, only 8 subjects required surgical revision procedures, whereas this was the case for 40 subjects in the control group. Major amputations were reported in 6 subjects in the control group, while minor amputations were performed for 10 subjects in the control group. Additionally, the control group experienced a higher incidence of infection spread (12 cases) and gangrene (4 cases). In contrast, the study groups did not exhibit these complications, with the exception of one case involving a minor amputation and another case of infection.

The lower amputation rate was notably lower in the HBOT group at 8.6%, whereas the control group had a significantly higher amputation rate of 33.3%. These findings emphasize the potential benefits of hyperbaric oxygen therapy (HBOT) in reducing the need for surgical revisions and amputations, thereby mitigating the severity and spread of infection and gangrene, and ultimately improving the clinical outcomes for patients[10].

In the comparison between the study and control groups, several key parameters were evaluated, including the average period for healing, rates of amputation, and the number of debridements required. The results clearly indicated that the study group exhibited a significant reduction in the number of debridements and amputations required, as well as a shorter mean hospital stay. Moreover, the study group demonstrated a faster control of infection, as supported by the culture sensitivity reports.

These findings highlight the beneficial impact of hyperbaric oxygen therapy (HBOT) in terms of reducing the need for surgical interventions, amputations, and hospitalization duration. The evidence suggests that HBOT plays a crucial role in enhancing the healing process and minimizing the severity of infections, ultimately leading to improved clinical outcomes for the patients under study.

CONCLUSION

Diabetic wounds present a considerable challenge for surgeons, primarily due to their poor healing characteristics. Ischemia, or insufficient blood supply, is a significant factor contributing to the difficulties in healing these wounds. Hyperbaric oxygen therapy (HBOT) plays a pivotal role in addressing this issue. By delivering oxygen at pressures greater than 1 atmosphere absolute (1 ATA), HBOT provides 100% oxygen to the tissues, which in turn accelerates the process of wound healing. HBOT also stimulates the development of new blood vessels (neoangiogenesis), enhances bactericidal activity, and fosters a faster healing response in diabetic wounds, as well as chronic non-healing wounds in general.The findings of this study strongly support the conclusion that the standard care of wounds combined with HBOT is superior to standard wound care alone. This combined approach significantly reduces the need for redebridements and amputations, thereby minimizing the associated morbidity. Importantly, the study also reveals a substantial decrease in the duration of hospital stay, leading to an overall reduction in healthcare expenditures and the effective utilization of hospital resources. These outcomes underscore the potential benefits of incorporating HBOT into the management of diabetic wounds, ultimately improving patient outcomes and reducing the burden on the healthcare system.

REFERENCES

1. Baroni G, Porro T, Faglia E, Pizzi G, Mastropasqua A, Oriani G, Favales F: Hyperbaric oxygen in diabetic gangrene treatment. Diabetes Care 1987; 10: 81– 86
2. Gill AL, Bell CN: Hyperbaric oxygen: its uses, mechanisms of action and outcomes. QJM 2004; 97: 385– 395
3. Barnes RC: Point: hyperbaric oxygen is beneficial for diabetic foot wounds. Clin Infect Dis 2006; 43: 188– 192
4. Cimşit M, Uzun G, Yildiz S: Hyperbaric oxygen therapy as an anti-infective agent. Expert Rev Anti Infect Ther 2009; 7: 1015– 1026
5. Kranke P, Debus S: Hyperbaric oxygen therapy for chronic wounds. Cochrane Database Syst Rev 2004; 1: CD004123
6. Goldman RJ: Hyperbaric oxygen therapy for wound healing and limb salvage: a systematic review. PM R 2009; 1: 471– 489
7. Oriani G,Favales F, Pizzi GL, Aldeghi A, Faglia E. Hyperbaric oxygen in diabetic gangrene. J Hyperb Med. 1990;5:171–
8. Wattel F, Mathieu D, Fossati F, Nevie're R, Coget JM. Hyperbaric oxygen in the treatment of diabetic foot. Undersea Biomed Res. 1990;17:160–1
9. Zamboni WA,Pfeifer MA. Evaluation of hyperbaric oxygen for diabetic wounds: A prospective study. J Hyperb Med. 1997; 24:175–9.
10. Kalani M, Lind F, Brismar K. Hyperbaric oxygen (HBO) therapy in the treatment of diabetic foot ulcers. Long term follow-up. J Diabetes Compl. 2002;16:153–8.