Original Research Article

Role of hyperbaric oxygen therapy in diabetic limb

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Abstract

Background: The present study was conducted to study the pattern of presentation of patients with diabetic limb in surgery opd and casualty, to evaluate the efficacy of available treatment options salvaging the diabetic limb, and to evaluate the amount of health care resource utilization, health care related quality of life. **Material and methods:** It was a hospital based, prospective randomized control study, conducted at department of General Surgery, Government Medical college and Hospital Nagpur during June 2012 to October 2014 among 101 patients with various diabetic limb are being managed with standard care and with HBOT. **Results:** The distribution of bacteria isolated is shown in the table number 2. Study group shows singificant reduction in the percentage of bacteria isolated among the study subjects. According to culture sensitivity reports most commonly isolated organism was E.coli in both the groups. **Conclusion**: Diabetic wounds are one of the most dreaded wounds to heal for any surgeon. Amongst various factors involved in poor healing of diabetic wounds one important factor is ischaemia HBOT by delivering oxygen at more than 1 ata delivers 100% oxygen and so helps in accelerating wound healing.

Keywords: HBOT, diabetic foot, diabetes mellitus, amputation

Introduction

Diabetic foot ulcers are a common and serious complication of diabetes[1-2]. Treatment often requires long-term hospital admissions and frequent outpatient visits. Furthermore, loss of mobility poses a great burden on the patient and the health care system[3]. At centers of excellence, 19–35% of ulcers are reported as nonhealing[4-6]. Thus, despite improvements in healing diabetic foot ulcers, there is still a need for new treatment strategies and methods. India had 19.4 million diabetics in 1995. India will have 57.2 million patients in 2025. The world wide prevalence of diabetes will be 300 million in 2025 of which 72 million will be in developed countries and 228 million in developing countries, i.e. 75% of diabetics will be in developing countries. 40% - 60% of all non traumatic lower limb amputation are due to diabetes, 85% of diabetic related foot amputation are preceded by foot ulcer, 4 out of 5 ulcer in diabetics are precipitated by trauma, 4% -10% is the prevalence of foot ulcer in diabetics.

Hyperbaric oxygen therapy (HBOT) has been promoted as an effective treatment for diabetic foot wounds, and the first controlled trial for this indication was reported (in Diabetes Care) over 20 years ago[1].Advocates have suggested that the experimentally demonstrated effects of HBOT on improving wound tissue hypoxia, enhancing perfusion, reducing edema, downregulating inflammatory cytokines, promoting fibroblast proliferation, collagen production, and angiogenesis make it a useful adjunct in clinical practice for "problem wounds," such as diabetic foot ulcers[2,3]. HBOT is also touted for eradicating difficult to treat soft tissue and bone infections by mechanisms that include killing microorganisms, improving leukocyte and macrophage function, and enhancing the effect of antimicrobials[4]. If realized clinically, these beneficial effects, although requiring expensive technology, might powerfully reduce the risk of lower-extremity amputation in diabetic patients with foot wounds. Thus, rigorously assessing the clinical effectiveness of HBOT in diabetic foot ulceration is an important enterprise. But, because both patients and clinicians are strongly motivated to avoid the devastating outcome of amputation, there is a high potential for bias in poorly designed trials. Proof of benefit requires properly conducted clinical trials that minimize the possibility that preexisting prejudices will influence the allocation of patients, diligence of foot care, or other key management decisions.Most of the published reports on the effect of HBOT for treating diabetic foot wounds have been case series or nonrandomized trials with major methodological limitations. Although these are a poor source of evidence, the consistency of positive results is noteworthy. More recently, several randomized controlled trials have been conducted. A Cochrane database systematic review published in 2004 concluded, based on results from four such trials, that "HBOT significantly reduced the risk of major amputation and may improve the chance of healing at 1 year" but, "… the small number of studies … modest numbers of

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patients, methodological and reporting inadequacies … demand a cautious interpretation"[5]. A more recent systematic review and meta-analysis that included 10 studies (6 of which were not randomized, controlled trials) concluded that HBOT reduces the risk of amputation (odds ratio 0.24, seven studies) and increases the likelihood of wound healing (odds ratio 10.0, six studies) [6].Hence the present study was conducted to study the pattern of presentation of patients with diabetic limb in surgery opd and casualty, to evaluate the efficacy of available treatment options salvaging the diabetic limb, and to evaluate the amount of health care resource utilization, health care related quality of life.

Material and methods

It was a hospital based, prospective randomized control study, conducted at department of General Surgery, Government Medical college and Hospital Nagpur during June 2012 to October 2014 among 101 patients with various diabetic limb are being managed with standard care and with HBOT.

Inclusion criteria

Patients with already diagnosed type 1 and2 diabetes mellitus, Limb lesion in form of ulcer present at the time of admission, Ulcer area 0.25-25cm^2, if more than one ulcer present on the limb only the largest is considered for the study, Patients with age more than 18 years, and Patients with diabetes diagnosed at the time of admission to the hospital were included in the present study.

Exclusion criteria

Patients with age less than 18 years of age, Informed consent not obtained, Uncooperative patient

Contraindication to HBOT:

Acute respiratory disease, History of spontaneous pneumothorax, Non stabilized epilepsy, Associated therapy with steroids, Pregnancy, Eustachian tube dysfunction

Methodology

After admission with standard care of the wound patient also received 45-90 minutes of HBOT at 2 ata with the patient breathing 100% oxygen inside the chamber in selected cases. HBOT given to patients for 2 to 6 weeks depending on the cases.Patients were allocated to two groups as those receiving HBOT therapy in addition to standard care and those receiving standard care alone based on odd and even number method of allocation.

Both groups were compared with respect to healing rates, average time required for healing, rate of amputation in both groups and hospital stay.

Results

In the present study we assessed demographic characteristics of the study subjects. We observed that the mean age of the study subjects was 55.2 years in study group and 56.2 years in control group. The male: female ration in the current study was 3:1 in both groups. (Table 1)

Table 1: Age distribution

Parameter	Study group (n=101)	Control group(n=101)
Age(yr)	55.2	56.2
Range	40-70	42-70
Sex(m:f)	3:1	3:1
Duration(yr)	9.8	10.2
Type of diabetes		
IDDM	13%	20%
NIDDM	87%	80%
neuropathy	16%	19%
Distal pulsations		
absent	10%	8%

The mean duration of diabetes was 9.8 years and 10.2 years in either group. Majority of the study subjects had non insulin dependent diabetes mellitus (87% and 80% in either groups). Distal pulsations were absent among 10% and 8% subjects in either groups. The distribution of bacteria isolated is shown in the table number 2. Study group shows significant reduction in the percentage of bacteria isolated among the study subjects. According to culture sensitivity reports most commonly isolated organism was E.coli in both the groups. (Table 2) (Figure 1-3)

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	42	53	2	16
STAPH AUREUS	4	4	1	2
KLEBSIELLA	30	33	1	11

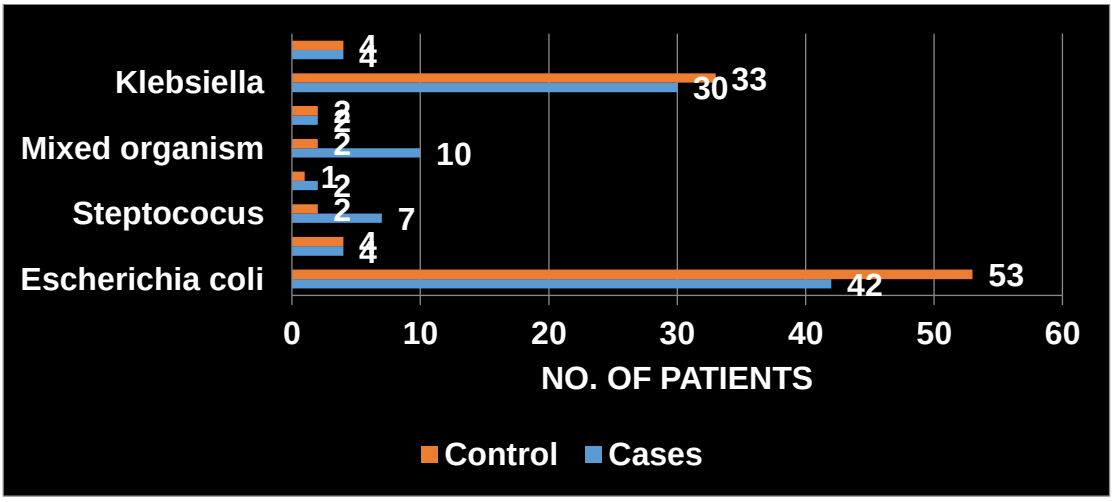

Fig 1: Bacteriology on admission

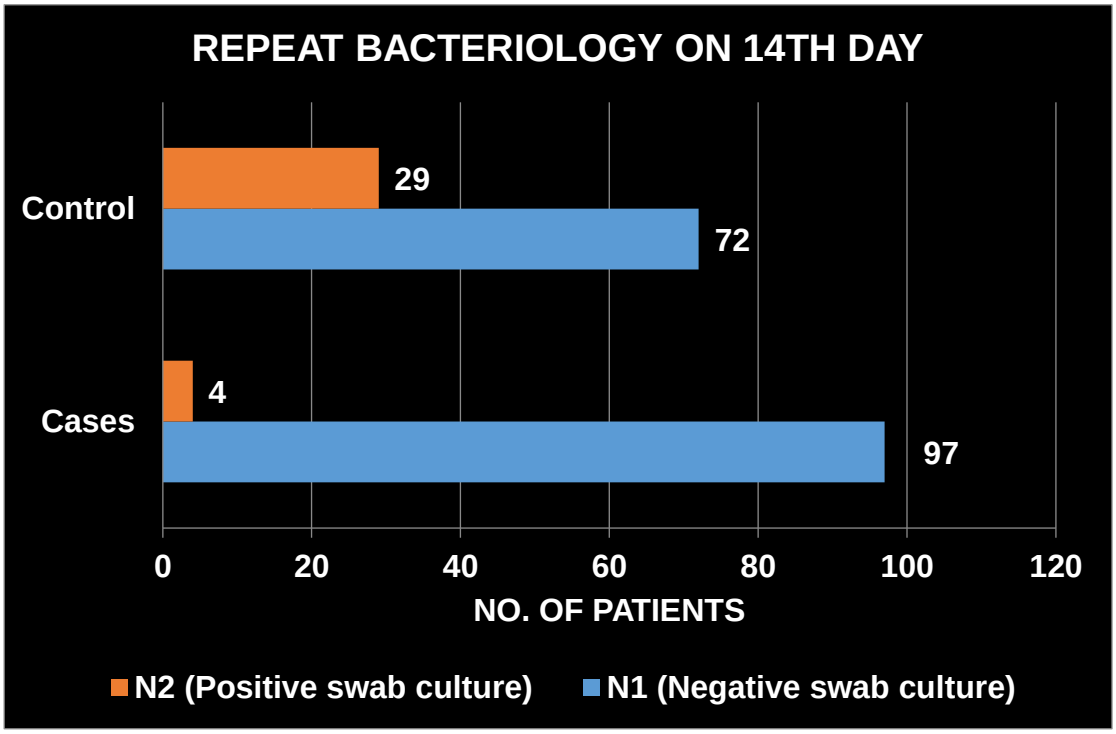

Fig 2: Bacteriology on 14th day

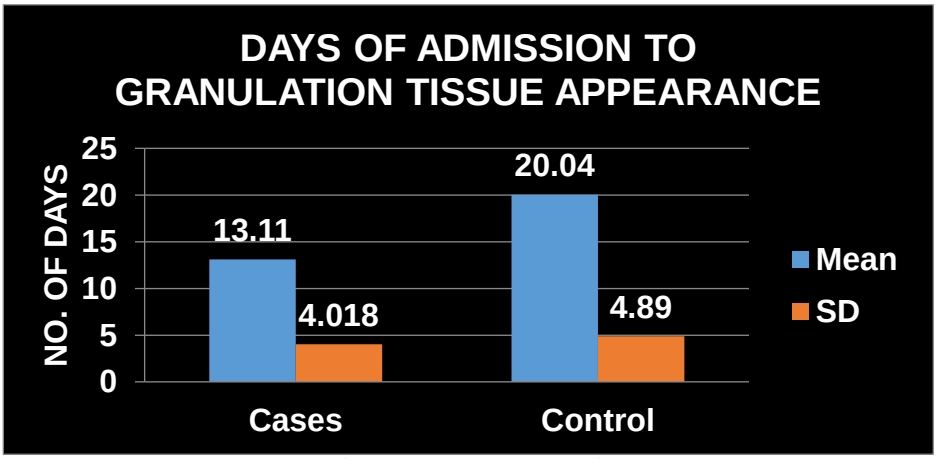

Fig 3: Mean days of admission to appearance of granulation tissue

Cultures were repeated after 14 days and it was noticed that there was a faster control of infection in study group as compared to control group. Mean hospital stay was 24.22 days in study group, while it was comparatively greater in control group (34.31 days). (Table 3)

Table 3: Clinical parameters

Parameters		Study group (n=101)	Control group (n=101)	Level of Significance
Hospital stay	Average	24.22 days	34.31 days	P<0.05,HS
	Range	16-38 days	20-52 days	
Surgical revision procedure	Redebridements	4	20	
Amputations	Major	0	3	P<0.05.HS

	Minor	1	5	
Indications for major amputation	Spreading infection	1	6	--
	Gangrene	0	2	--

Surgical revision procedure (re debridement) was needed among 8 subjects in study groups, while among 20 subjects in control group. (Figure 4)

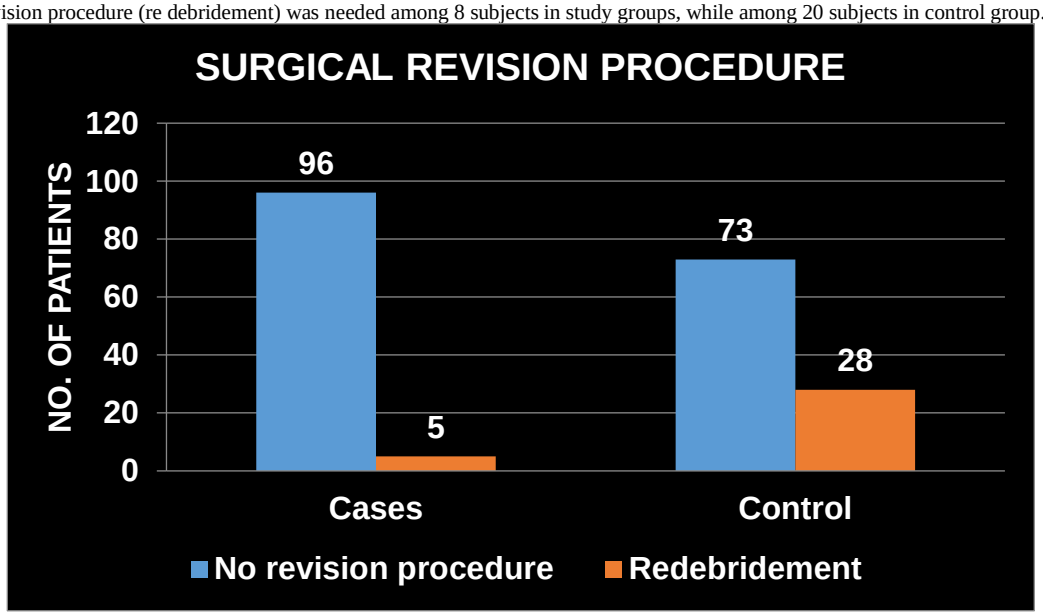

Fig 4: Surgical revision procedure

Major amputations were seen in 3 subjects in control group, while minor amputations were seen in 5 subjects in control group. Spread of infection and gangrene was seen in control group (6 cases and 2 cases respectively). In study groups we did not observed any of these complications, except 1 case with minor amputation and 1 case with infection. (Table 4)

Table 4: Healing

	Healed/ Studied	% P=0.03	Subset >35 txs	% **P= 0.009**
HBOT	25/48	52%	23/38	61%
Placebo	12/42	29%	10/37	27%

Discussion

In the present study we assessed demographic characteristics of the study subjects. We observed that the mean age of the study subjects was 55.2 years in study group and 56.2 years in control group. The male: female ration in the current study was 3:1 in both groups. The mean duration of diabetes was 9.8 years and 10.2 years in either group. Majority of the study subjects had non insulin dependent diabetes mellitus (87% and 80% in either groups)

Distal pulsations were absent among 10% and 8% subjects in either groups. The distribution of bacteria isolated is shown in the table number 2. Study group shows significant reduction in the percentage of bacteria isolated among the study subjects. According to culture sensitivity reports most commonly isolated organism was E. coli in both the groups. Cultures were repeated after 14 days and it was noticed that there was a faster control of infection in study group as compared to control group. Mean hospital stay was 24.22 days in study group, while it was comparatively greater in control group(34.31 days).

Surgical revision procedure (re debridement) was needed among 8 subjects in study groups, while among 20 subjects in control group. Major amputations were seen in 3 subjects in control group, while minor amputations were seen in 5 subjects in control group. Spread of infection and gangrene was seen in control group (6 cases and 2 cases respectively). In study groups we did not observed any of these complications, except 1 case with minor amputation and 1 case with infection. Lower Amputation Rate was 8.6% in HBOT group, while it was 33.3% in control group.

Table 5: Study and different parameters

Study	Total no .of patients	No. of healing patients	Healing rate
ORIANI et al[7]	62	59	95%
BARONI et al[1]	18	16	98%
WATTEL et al[8]	59	52	88%
ZAMBONI et al[9]	5	4	80%
KALANI et al [10]	17	13	76%

Improved Healing Rates were observed among study subjects (75.6% HBOT group)as compared to 46.7% in Non-Treated group. Randomized, double blinded, placebo controlled study using 40 treatments 94 patients with Wagner grade 2,3, or 4 ulcers of >3 months duration Complete healing of the ulcer at 1 year.The study and control groups were compared for average period for healing,

rates of amputation, number of debridement required. It was evident that study group showed significant reduction in terms of decrease in number of redebridements and amputation required and mean hospital stay.There was faster control of infection in study group as compared to control group as evident by the culture sensitivity reports.

Conclusion

Diabetic wounds are one of the most dreaded wounds to heal for any surgeon. Amongst various factors involved in poor healing of diabetic wounds one important factor is ischaemia HBOT by delivering oxygen at more than 1 at a delivers 100% oxygen and so helps in accelerating wound healing.It also stimulates neoangiogenesis and bactericidal activity and promotes faster healing of diabetic wounds or infact any of chronic non healing wounds. So as per this study we could conclude that standard care of the wound with HBOT is superior to standard care of wound alone and there is a significant reduction in terms of redebridements and amputations required and morbidity associated with it. Significant decrease in the duration of hospital stay has resulted in overall reduction in expenditures and effective utilization of hospital resources.

Conflict of Interest: Nil Source of support: Nil

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