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STUDY OF EFFICACY OF HBOT IN CASES OF DIABETIC FOOT AND A COMPARATIVE STUDY BETWEEN PATIENTS GIVEN HBOT WITH THAT OF THEM WHO ARE GIVEN ONLY REGULAR DRESSING

General Surgery

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ABSTRACT

BACKGROUND: The term diabetic foot means a group of syndromes & foot lesions in which neuropathy, ischemia and infection lead to tissue break down resulting in morbidity and possible amputation.

The aim of my study is

- To study advantages of Hyperbaric Oxygen Therapy in diabetic foot.
- To compare the duration of healing process of hyperbaric oxygen therapy over regular dressing.
- To study decreased amputation rate in Diabetic foot patients.
- To study Hospital stay in diabetic foot patients.

CONCLUSION

Patients receiving HBOT have a better overall outcome as compared to those treated with only regular dressing.

KEYWORDS

HBOT, Diabetic Foot.

INTRODUCTION

Diabetes Mellitus is a heterogeneous primary disorder of carbohydrate metabolism with multiple etiologic factors that generally involve absolute or relative insulin deficiency or insulin resistance or both leading to hyperglycemia and various long term complications.

The term diabetic foot means a group of syndromes & foot lesions in which neuropathy, ischemia and infection lead to tissue break down resulting in morbidity and possible amputation.

Both neuropathy and vasculopathy are strong independent risk factors for development of diabetic foot ulcers. About 2.5% diabetic men and women will develop a foot ulcer each year.

The Consensus Development Conference on diabetic foot wound care in April 1999 stated that 15% of patients with diabetes will experience foot ulcers in their lifetime.

It also stated that the term "diabetic foot wound", refers to a variety of pathological conditions, the ulcer being the most common and characteristic type of lesion. Between 5 to 15% of diabetic foot ulcers will ultimately require amputation.

At present treatment of diabetic foot ulcer is as below :

- Debridement
- Pressure management
- Antibiotic treatment
- Compression therapy
- Use of specialized wound dressings

Some more recent approaches to treating foot ulcers include

- HBOT
- The application of cultured skin substitutes (Apligraft & Derma graft)
- Electrical stimulation
- Vacuum assisted closure

HYPERBARIC OXYGEN THERAPY (HBOT)

Hyperbaric oxygen therapy (HBOT) is a form of treatment in which a patient breathes 100% oxygen at higher than normal atmospheric pressure.

When there is a restriction in the blood flow due to surgery, illness or injury, the red blood cells block the blood vessel and are unable to transfer oxygen to the cells on the other side of the occlusion. This causes swelling and starves the area of oxygen, causing hypoxia and the tissue begins to break down.

Breathing 100% oxygen under pressure causes the oxygen to diffuse into the blood plasma. This oxygen-rich plasma is able to diffuse up to 4 times further into the tissue. The pressurized environment helps to reduce swelling and discomfort, while providing the body with at least 10 times its normal supply of oxygen to help repair tissue damaged by the original occlusion or subsequent hypoxic condition.

Hyperbaric Oxygen Therapy forces more oxygen into the tissue, encouraging the formation of the new blood vessels. As these new blood vessels develop, the red blood cells start to flow, delivering even more oxygen to the affected area. This creates the optimal environment for the body's natural healing process to repair damage. HBOT is thus a valuable addition to conventional methods of diabetic foot management.

MATERIALS AND METHODS

A comprative study was done in the Dept. of General Surgery, Tertiary health Centre and teaching institute, Mumbai for 2 years 60 cases of diabetic foot, 30 treated with HBOT and 30 with regular dressing. convenient, consecutive, clinic based, consenting sampling of subjects. Patients were randomly divided into two groups using a random number generator.

INCLUSION CRITERIA

- Patients admitted with Diabetic foot.
- Of either sex.
- Adults above age 18.
- Willingness to participate in the study.

EXCLUSION CRITERIA

- Planned revascularization procedure.
- Vascular reconstruction has been performed less than 12 weeks ago.
- Urgent amputation needed.

RESULTS

The study was conducted at a tertiary health Centre and teaching institute in Mumbai. The data presented here is of 60 cases of diabetic foot, either diagnosed for the first time or already diagnosed, who were referred to OPD over a period of 2 years. Only patients with grade 3 in the PEDIS score were selected in the study. 30 patients were treated with hyperbaric oxygen therapy and 30 with regular dressing. Each patient was given a minimum of 5 cycles per week of HBOT and was increased on the basis of severity of wound. Only patient with strict diabetic control and HbA1c <6% were studied.

Patient were followed up for a period of two months with regular assessment of wound with respect to PEDIS score and glycemic

control. Assessment and comparisons of wounds of both the groups was on Day 30 was considered in our study while the incidence of skin grafting in the patients was taken into account on follow up at 2 months.

(1) AGEWISE DISTRIBUTION OF CASES

	Group	N	Mean
Age	HBOT	30	55.13
	Regular Dressing	30	57.67

In our study the mean age of patients receiving HBOT is 55.13yrs while those receiving regular dressing is 57.67yrs.

(2) SEX WISE DISTRIBUTION

		Group		Total
		HBOT	Regular Dressing	
Sex	Male	21	17	38
	Female	9	13	22
Total		30	30	60

In this study out of 60 cases of diabetic foot 38 (63.33%) are male and 22 (36.66%) are female. Male to female ratio is 1:7.

(3) DAYS OF HOSPITALISATION

	Group	N	Mean	Std. Deviation
DAYS OF HOSPITALIZATION	HBOT	30	13.80	3.478
	Regular Dressing	30	44.63	19.866

The above analysis shows that the mean hospital stay of patients treated with HBOT was 13.80 days and of those treated with regular dressing is 44.63 days. Using t test for equality of means we can state that this difference is significant.

(4) PEDIS SCORE

In our study only patients with grade 3 of the PEDIS score were included.

PEDIS score of the patients were recorded one month after either HBOT or regular dressing and compared to see if there was an increase, decrease or no change in the PEDIS score post treatment.

Group Statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean
Pre Hbot Pedis Score	A: HBOT	30	3.00	.000a	.000
	B:Regular Dressing	30	3.00	.000a	.000
Post Hbot Pedisscore	A:HBOT	30	1.07	.254	.046
	B:Regular Dressing	30	1.93	.450	.082

Independent Samples Test				
		t-test for Equality of Means		
		t	Dof	p
POST HBOT PEDIS SCORE	Equal variances assumed	-9.192	58	.000

T-Test

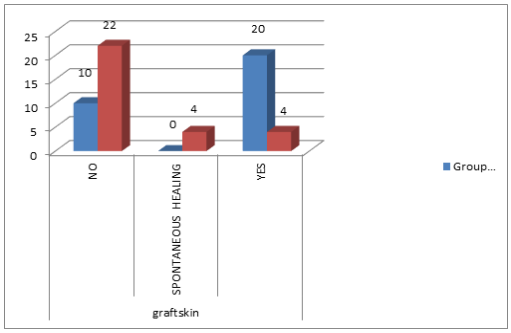
Group A- patients treated with HBOT

Paired Samples StatisticsA					
		Mean	N	Std. Deviation	Std. Error Mean
Pair A	Pre Hbot Pedis Score	3.00	30	.000	.000
	Post Hbot Pedis Score	1.07	30	.254	.046

Paired Samples TestA						
		Paired Differences		t	dof	Sig. (2-tailed)
		Mean	Std. Deviation			
Pair A	Pre Hbot Pedis Score Post Hbot Pedis Score	1.933	254	41.738	29	.000

Group B- Regular Dressing

Paired Samples Statistics[B]					
		Mean	N	Std. Deviation	Std. Error Mean
Pair B	Pre Regular Dressing Pedis Score	3.00	30	.000	.000
	Post Regular Dressing Pedis Score	1.93	30	.450	.082



The above analysis shows that out of 30 patients who had received HBOT,20 patients underwent skin grafting and 10 patients were not grafted. Out of 30 patients receiving regular dressing only 4 patients underwent skin grafting, 4 patients had spontaneous healing and 22 patients were not grafted. This difference in rate of skin grafting was significant.

AMPUTATION

Count				
		Group		Total
		HBOT	Regular Dressing	
Amputation	No	26	16	30
	YES	4	14	30
Total		30	30	60

The above analysis shows that 4 patients of HBOT underwent amputation while 14 patients who were treatedwith regular dressing underwent amputations.

Amputations include great toe amputation, trans metatarsal amputation, below knee amputation or above knee amputation.

DISCUSSION

HBOT is a recently promoted treatment modality for diabetic foot. HBOT has been demonstrated to have an antimicrobial effect and to increase oxygenation of hypoxic wound tissues. This enhances neutrophil killing ability, stimulates angiogenesis, and enhances fibroblast activity and collagen synthesis. Thus, theoretically, HBOT could improve the healing of ischemic foot ulcers in patients with diabetes.

In order to study the efficacy of HBOT we have studied the outcome of HBOT in the treatment of diabetic foot and compared it with regular dressing. The results obtained in this study were compared with previously conducted similar studies.

(1) Days of hospitalization

In our study the mean hospital stay of patients treated with HBOT was 13.80 days and of those treated with regular dressing is 44.63 days. This was statistically significant.

(2) PEDIS score

In our study we used PEDIS score to compare the condition of the wounds before and after HBOT. There was a significant decrease in the PEDIS score post HBOT as compared to the group receiving regular dressing. Thus significant improvement in the healing of diabetic foot ulcers has been supported by our study.

(3) Skin Grafting

In our study the incidence of patients having negative culture report on wound swab was higher in those being treated with HBOT. 4 patients of HBOT and 10 patients of regular dressing had wound positive on day 30 post treatment.

(4) Amputation

In our study, 4 patients of HBOT underwent amputation while 14 patients who were treated with regular dressing underwent amputations (minor or major). Thus a lesser incidence of amputations was seen in patients who had received HBOT.

(5) Complications

In a case series of 11 376 treatment sessions, 17% of all patients reported ear pain or discomfort during compression (60). However, persistent injuries visible in ear microscopy are less common, with

reported incidences between 0.5% and 3.8% (18, 60). In our study one patient studied from seizures and one from tinnitus as a result of HBOT, thus a complication rate of 6% was noted.

Pre HBOT

Post 5 sittings of HBOT

Wound on day 30. Received 10 cycles of HBOT.
Figure 1: Post- below knee amputation patient treated with HBOT.

Pre-HBOT

Post 10 cycles of HBOT
Figure 2: Diabetic foot treated with HBOT.

Pre- HBOT

Post 5 sittings of HBOT

Post 10 cycles of HBOT

CONCLUSION

Diabetic foot ulcer is more common in 40 to 60 year of age group. Diabetic foot ulcer is more common in males. HBOT helps in limb salvage by decreasing amputation rate. HBOT reduces the hospitalization by making healing process faster. HBOT makes ulcer healthy so patient undergoing early skin grafting and early discharge from hospital is possible. Patients receiving HBOT have a better rate of swab negativity as compared to those receiving regular dressing. Patients receiving HBOT have a better overall outcome as compared to those treated with only regular dressing.

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