Original Research Article

New Indian Journal of Surgery
Volume 10 Number 1, January - February 2019
DOI: https://dx.doi.org/10.21088/nijs.0976.4747.10119.7

Hyperbaric oxygen therapy: Trends at Prana Hyperbaric Oxygen Therapy Centre Mumbai, India

Manoj Gupta

Director, Prana Hyperbaric Oxygen Therapy Center, Mumbai, Maharashtra 400092, India.

How to cite this article:

Manoj Gupta. Hyperbaric oxygen therapy: Trends at Prana Hyperbaric Oxygen Therapy Centre Mumbai, India. New Indian J Surg. 2019;10(1):41-48.

Abstract

Background: Hyperbaric Oxygen Therapy (HBO) is an established treatment modality, internationally practiced since a long time ago. International protocols for the practice of hyperbaric oxygen therapy have been established in the United States by the Undersea and Hyperbaric Medical Society and in Europe by the European Committee for Hyperbaric Medicine. In India, HBO seems to be a well-accepted adjunctive treatment for diabetic foot, gas gangrene and post radiation complications. *Objective:* The main aim of this study is to describe the referral patterns, the different indications and patient population treated at the Prana HBO center, and to describe the protocols followed at the center and determine whether these conform to the standards established by the UHMS. *Study Design:* A Descriptive cross sectional study (retrospective record review) was performed to realize the aim and objectives of this study. *Place of Study:* The study was carried out at the Prana HBO Centre, which is owned by the Investigator and located in the Northern parts of Mumbai, in India. *Methods:* The data was collected from all the patient files, which are stored at the center. TCOM data was also collected from the Centre register which is maintained separately. *Observation & Discussion:* A total number of 276 patients were treated at the hyperbaric facility during the study period. These individuals received a total of 2,740 individual treatment sessions. An average of 9.928 (SD=F.2) treatment sessions were thus provided to each patient. One patient received 80 treatment sessions, skewing the data. The median number of treatment sessions was 10, with an inter-quartile range of 5 - 10. TCOM was carried out on diabetic foot patients (67.8%) and in non-healing wound (22.2%). Chronic venous ulcers and compromised skin graft cases TCOM was not advised either by the treating doctor or the wound was so big that, TCOM was not possible. *Conclusions:* Indian perspective requires Standard HBOT facility and registry reporting as a part of healthcare reform to facilitate the acquisition of real-world data for HBOT comparative effectiveness studies, with matched cohorts.

Keywords: Hyperbaric oxygen therapy; India; Clinical and basic research.

Introduction

Hyperbaric Oxygen Therapy (HBO) is an established treatment modality [1], which is internationally practiced since a long time ago. International protocols for the practice of hyperbaric oxygen therapy have been established in the United States by the Undersea and Hyperbaric Medical Society (UHMS) [2] and in Europe by the European Committee for Hyperbaric Medicine (ECHM) [3]. These are generally accepted as the standard of care in the western world and treatment protocols were developed for around 17 indications overall. However, additional indications are accepted by other hyperbaric medical societies. Approximately 53 indications are accepted in China [4,7], twenty in Japan [5] and 72 in Russia [5].

Transcutaneous Oxygen Monitoring (TCOM) is advised (in international guidelines) in all

Corresponding Author: Manoj Gupta, Sailee Hospital & Diagnostic Center, Prathamesh Horizon New MHB Colony, New Link Road, Borivali West, Mumbai, Maharashtra 400091, India.

E-mail: drmanojgupta222@gmail.com

Received on 21|11|2018, **Accepted on** 13|12|2018

peripheral non-healing wounds before treatment in the chamber [9]. The UHMS published standard protocols, which is based on the current available medical evidence [2]. These protocols would typically prescribed the type of patients who should be selected (i.e. establishing a bona fide indication for therapy), and the typical work-up required for evaluation. This would for instance include the use of TCOM for diabetic ulcers of the lower limb [9]. The protocols also describe the range of treatment depth (while breathing 100% oxygen) that would yield a therapeutic tissue oxygen tension for the disease being treated. These typically range from 150 kPa to 280 kPa (depending on the disease being managed). Apart from the treatment depth, the report also describes the typical number of treatments to be provided for each indication, ranging from one session (e.g. for decompression sickness) to as many as 40 sessions (e.g. for radiation-induced lesions).

In Mumbai, HBO seems to be a well-accepted adjunctive treatment for diabetic foot, gas gangrene and post radiation complications [8]. However referring doctors seems to not be aware of the other indications approved by the UHMS and ECHM and they are also seemingly not aware of the standard protocols to be followed even in conditions for which they are aware that HBO is of benefit.

Despite these guidelines being in existence for more than three decades, there are no publications available that describe the actual treatment practices of hyperbaric facilities. Anecdotally, it seems like treatment is provided for off-label indications in almost all hyperbaric facilities and such use creates ethical dilemmas [10]. This is especially the case when treatment is provided to desperate patients (or parents) for non-indications (i.e. "indications" that have been scientifically proven to have no benefit), such as cerebral palsy [11].

Equally problematic would be the non-use of hyperbaric oxygen therapy for established indications, when such treatment modality is readily available. This could be due to a lack of available hyperbaric facilities and/or the lack of awareness about the use of HBO amongst doctors in Mumbai.

The main aim of this study is to describe (report on) the referral patterns to, the different indications and patient population treated at the Prana HBO center, and to describe the protocols followed at the center and determine whether these conform to the standards established by the UHMS. The study therefore had the following objectives, to describe the different indications treated at the Centre, to describe the patient population treated at the Center, to describe the typical treatment protocols followed at the Centre, to compare the protocols followed at the Centre with published international protocols and standards, to describe the referral patterns to the Center.

Study Design

A Descriptive cross sectional study (retrospective record review) was performed to realize the aim and objectives of this study.

Study setting

The study was carried out at the Prana HBO Centre, which is owned by the Investigator and located in the Northern parts of Mumbai, in India. The center has one Sechrist Monoplace hyperbaric chamber and a TCOM machine with 3 electrodes. The oxygen gas supply is from oxygen cylinders of 7000 liters' capacity each. The center has all the requisite certifications and registrations as required by the local authority in Mumbai. The data was collected from all the patient files, which are stored at the center. TCOM data was also collected from the Centre register which is maintained separately. The Investigator is the medical practitioner working in this center and the physician who consulted the patients. The study is limited to the patients who were seen at the Centre during the previous two years.

Inclusion Criterion

The study included all those cases that were given HBO, including cases treated for conditions which were not part of the UHMS list of "approved indications" [2]. The study also included all those cases who were consulted and after investigations (such as TCOM studies) were advised that HBO treatment was not indicated.

Exclusion Criterion

The study excluded all those patients who were consulted by the Investigator but were not treated with HBO, nor they were evaluated for HBO (e.g. by means of TCOM studies).

Data sources

All the data was collected from patient files and the register, which is manually maintained at the center. The collected data was directly captured in an MS excel spread sheet for analysis. Factors associated with following the approved protocols,

association was determined by calculating the Odds Ratio of contingency tables, with 95% confidence intervals. The Chi 2 test was used to determine statistical significance between the two groups. A significance level of 0.05 was used for all these tests.

Addressing potential bias

Because this study was a retrospective record review, it may be subject to information bias, since the information was primarily captured for clinical management purposes and not for research. The data was thus not always captured in a systematic manner.

Ethics review

This study was performed within the scope of international ethical guidelines and legislation. Ethics review and approval was provided by Stellenbosch University (number: U16/06/015) and the ethics committee of the Hyperbaric Society in India

Results

A total number of 276 patients were treated at the hyperbaric facility during the study period. These individuals received a total of 2,740 individual treatment sessions. An average of 9.928 (SD=7.2) treatment sessions were thus provided to each patient. One patient received 80 treatment sessions, skewing the data. The median number of treatment sessions was 10, with an inter-quartile range of 5-10.

The average age of the study participants was 40.899 (SD = 17.21) years; with a range of 2 to 69 years, and the median age was 45 (IQR = 29-54) years Figure 2.

The majority of patients (n=212) treated at the facility were male.

A total of 13 indications were treated at the unit (Fig. 4), of which nine are considered "approved indications" by the UHMS. Autism spectrum disorder, Cerebral palsy, head injuries and stroke have not been classified as approved indications by the UHMS. Level B evidence exists that autism spectrum disorder and cerebral palsy are negative indications for HBO therapy. Level C evidence exists that the acute phase of stroke is a negative indication, but evidence for or against chronic stroke is limited Figure 3.

The unit's compliance with the UHMS recommended number of treatments and treatment depths are depicted in Figures 5 and 6.

All treatments provided at this unit complied with this standard. When considering all the factors associated with compliance (treatment depth, numbers, duration and frequency), the overall compliance with the recommended international protocols is depicted in Figure 7.

Transcutaneous Oxygen Monitoring (TCOM) is usually indicated for all wounds that have a hypoxic component. Indications that would potentially require TCOM measurements include chronic venous ulcers, compromised skin grafts, diabetic foot problems, non-healing wounds and chronic radiation injuries. The application of TCOM for these indications are depicted in the Figure 8.

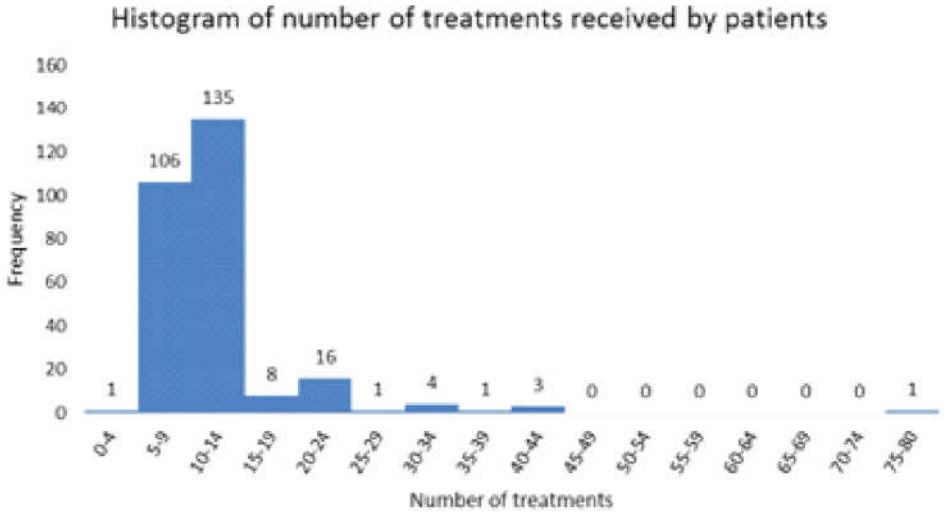

Fig. 1: Shows the distribution of treatment numbers received by patients

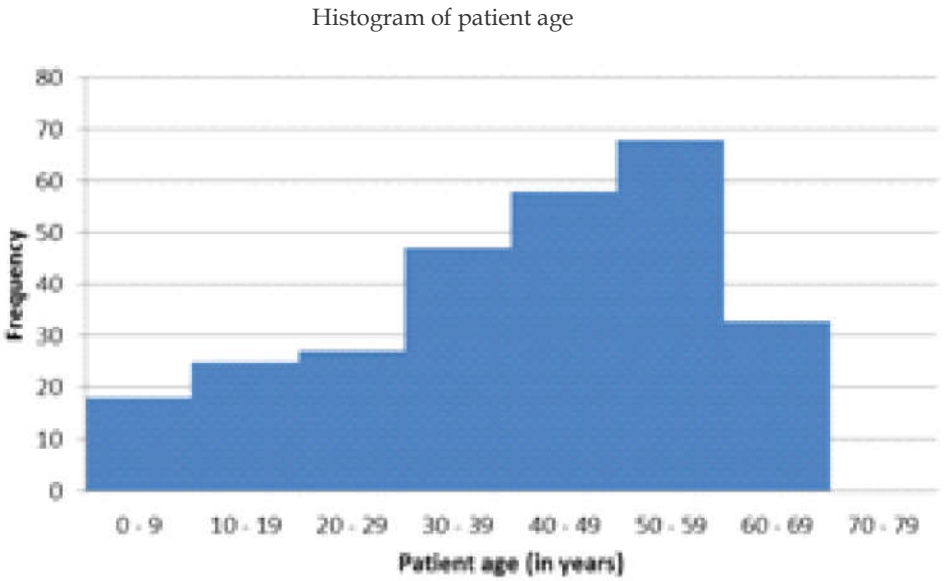

Fig. 2: depicts the age distribution of the study participants.

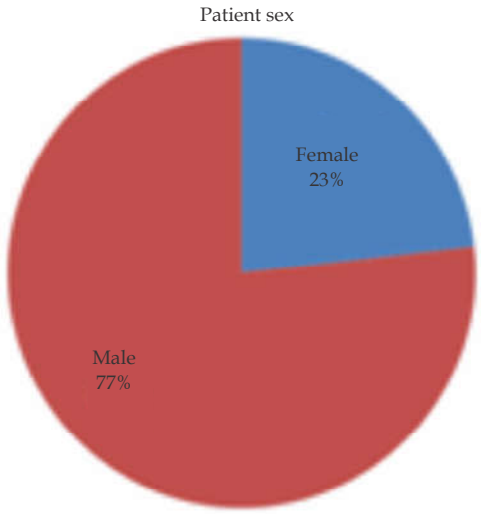

Fig. 3: Patient Sex

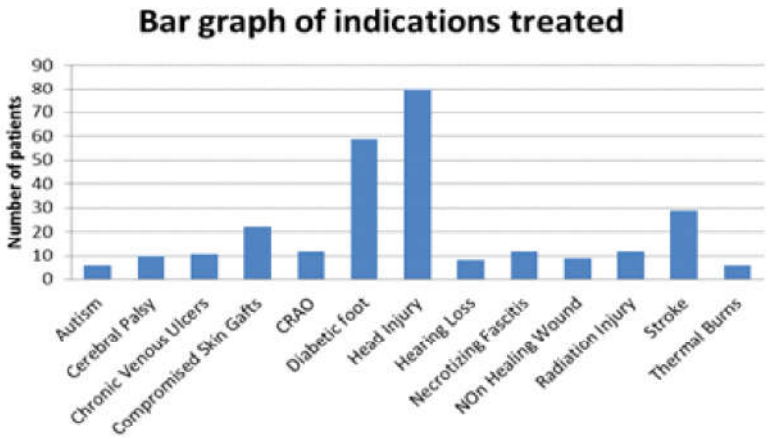

Fig. 4: Bar Graph of Indications treated

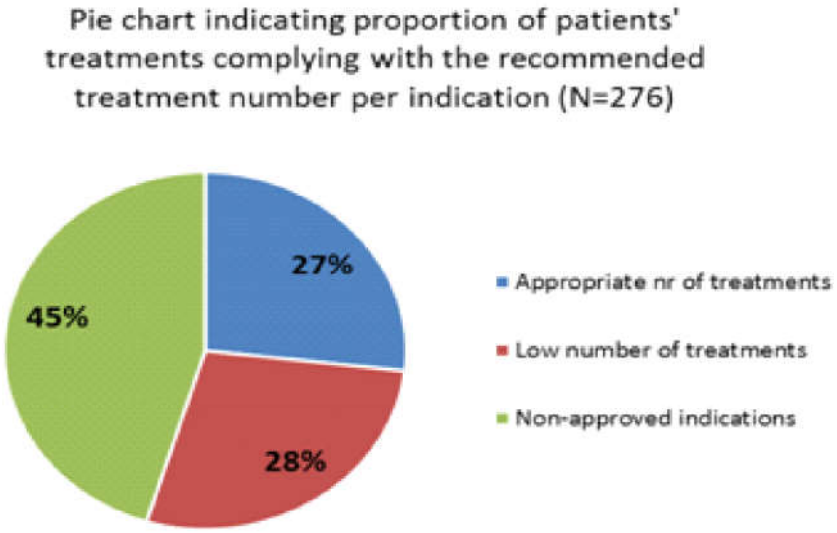

Fig. 5:

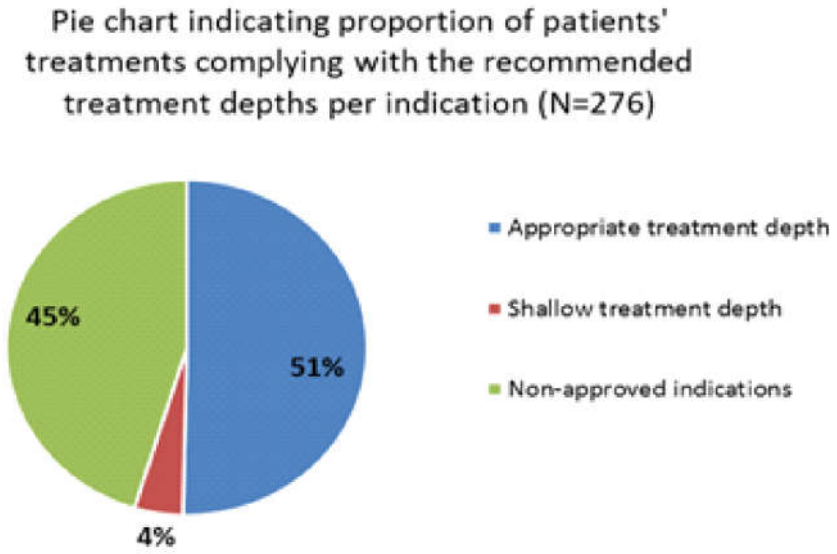

Fig. 6:

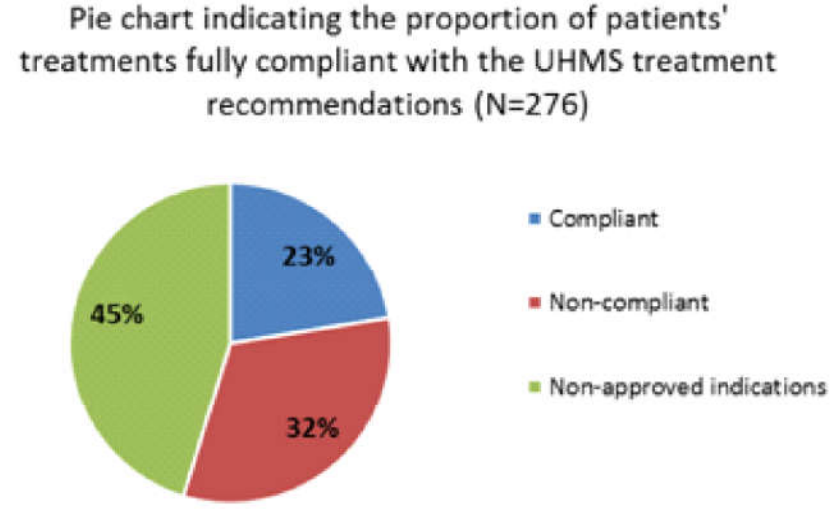

Fig. 7:

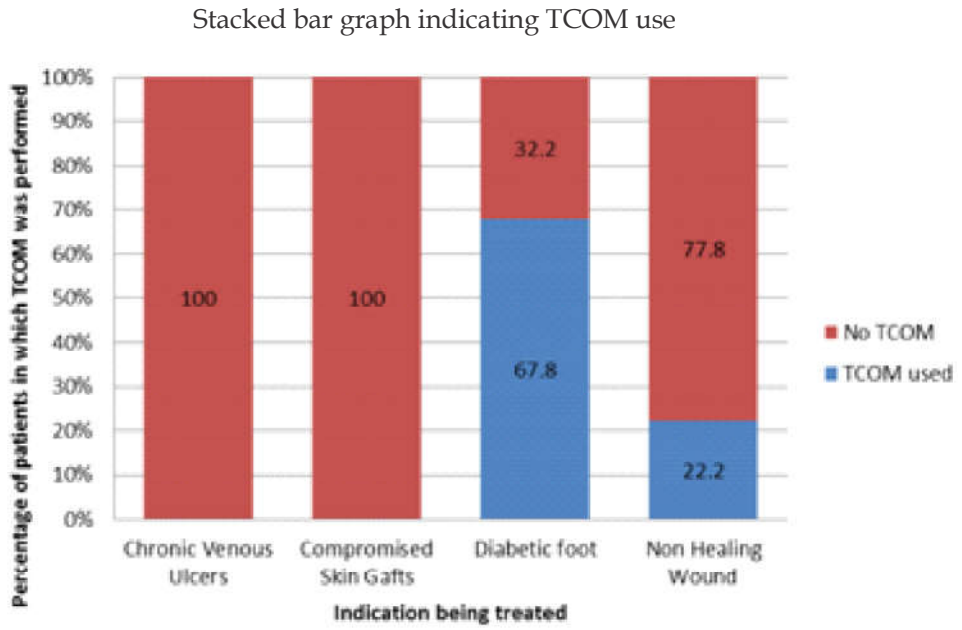

Fig. 8: Indicating TCOM Use

Table 1: Factors associated with overall compliance with the treatment recommendations in patients treated for approved indications (N=151)

Variable Evaluated	N (%)	OR (95% CI)	p-value
Demographic variables			
Female gender	40 (26.5)	1.9 (0.9 - 3.9)	0.086
Age < 10 years	0 (0)	. (. - .)§	.
Age < 20 years	3 (2)	. (1.147 - .)§	0.067
Age < 30 years	15 (9.9)	6.9 (1.9 - 25.6)	0.001
Age < 40 years	48 (31.8)	3.2 (1.6 - 6.6)	0.001
Age < 50 years	84 (55.6)	3.4 (1.7 - 6.8)	<0.001
Age < 60 years	132 (87.4)	4.3 (1.2 - 15.5)	0.017
Age < 70 years	151 (100)	. (. - .)§	.
Age < median age	59 (39.1)	2.8 (1.4 - 5.4)	0.003
Age < mean age	49 (32.5)	3 (1.5 - 6.1)	0.002
Indications			
Diabetic foot ulcers	59 (39.1)	0 (0 - 0.032)§	<0.001
Compromized grafts or flaps	22 (14.6)	. (12.4 - .)§	<0.001
Venous ulcers	11 (7.3)	0.1 (0.0 - 0.96)	0.028
Central Retinal Artery Occlusion	12 (7.9)	. (5.4 - .)§	<0.001
Sudden hearing loss	8 (5.3)	. (3.3 - .)§	<0.001
Necrotizing soft-tissue infections	12 (7.9)	0 (0.0 - 0.4)§	0.002
Non-healing wounds	9 (6)	. (3.8 - .)§	<0.001
Late radiation injury	12 (7.9)	0.7 (0.2 - 2.4)	0.762
Thermal burns	6 (4)	. (2.4 - .)§	0.004
Other treatment-related conditions			
Experiencing ear pain during the treatment	26 (17.2)	1.1 (0.5 - 2.5)	0.887
Not being referred to the unit	13 (8.6)	0.6 (0.2 - 2.1)	0.430
Not completing the planned treatment regime	9 (6)	0 (0 - 0.6)§	0.011

§ Cornfield method used to calculate the Odds Ratio (OR)

Table 2: Referral sources for different indications

Referral source Indication	Internet Search	Burns Specialist	Endocrinologist	ENT Surgeon	General Surgeon	Maxillo Facial Surgeon	Neurologist	Neurosurgeon	Ophthalmologist	Plastic Surgeon	Podiatric Surgeon	Radiation Oncologist	Total
Autism	6												6
Cerebral Palsy	10												10
Chronic Venous Ulcers	2				9								11
Compromised Skin Grafts	2						1			19			22
CRAO									12				12
Diabetic foot	6		5		40						8		59
Head Injury								80					80
Hearing Loss				8									8
Necrotizing Fascitis					9					3			12
Non Healing Wound	2				7								9
Radiation Injury						3						9	12
Stroke	4						25						29
Thermal Burns		6											6
Total	32	6	5	8	65	3	26	80	12	22	8	9	276

Side-effects and complications: None of the patients suffered a serious complication from HBO, such as a pneumothorax, etc. However, some minor side-effects were experienced. A total of 48 (17.39%) of the patients suffered ear pain in the chamber - most likely as a result of mild barotrauma of the ears. However, Barotrauma wasn't noted as a complication for any of these patients. One patient suffered hypoglycemia during a treatment, while eleven patients suffered visual changes related to the HBO.

Discontinuation of treatments: A total of 11 (3.99%) of patients did not complete their planned number of treatments. The reasons for discontinuation of treatments included financial constraints (n=8), inability to tolerate the chamber treatments (n=1), referral to another hospital (n=1) and one patient discontinued treatment for an unknown reason.

Discussion

Transcutaneous treatment is generally indicated in hypoxic wound. In the study TCOM was carried out on diabetic foot patients (67.8%) and in non-healing wound (22.2%). Chronic venous ulcers and compromised skin graft cases TCOM was not advised either by the treating doctor or the wound was so big that, TCOM was not possible.

Hyperbaric oxygenation has become a recognized treatment for a number of disorders although its role in many other conditions remains experimental, controversial or simply unknown to the medical professional at large Most of the current indications for HBO are based on evidence obtained from uncontrolled clinical trials. There are few of the randomized, double blind, and controlled studies that are emphasized these days before recognition of any new therapeutic method or for reevaluation of older well established methods

Un-established indications [11] are conditions in which systematic clinical use of hyperbaric oxygen treatment (HBOT) is not supported by adequate proof of benefit. HBOT is vulnerable to use in many such conditions for various reasons, perhaps the most important being that a placebo or participation effect may create an impression of efficacy. The systematic use of HBOT in un-established indications raises ethical concerns about provision of misleading information, giving false hope, and taking payment for therapy of doubtful benefit. Any practice perceived as unethical or unscientific has the potential to draw the wider field into disrepute. Of substantial contemporary relevance is the use of HBOT in treatment of various forms of chronic brain injury; in particular, cerebral palsy in children and the squeal of mild traumatic brain injury in adults.

HBOT in China [13] has a wide range of indications, involving nearly every system of the human body. However, contraindications are

relatively limited. Although the use of HBOT in China for the clinical treatment of various diseases has been widely studied, the quality of these clinic trials is generally low due to a small sample size and high heterogeneity between studies. Russia [6] has extensive hyperbaric facilities. There are over 60 centers with hyperbaric facilities and approximately 1300 hyperbaric chambers are currently in Russia. Russia has one of the longest lists of indications for hyperbaric oxygen therapy (72 indications). Again the research publication from Russia is inadequate.

In India hyperbaric oxygen facilities are restricted to limited cities. If you consider the population (1.25 billion) v/s HBO facility (only 46 centers with 50 machines), it is grossly inadequate to carry out any kind of research activity. Besides this the HBO treatment is comparatively new in Indian scenario which makes further difficult in convincing the doctors for referral of patients. There are hardly any research papers from India to give any data to referring doctors due to poor research in this field and whatever Indian data is available it is inadequate to support the HBO treatment.

Conclusion

Among advanced modalities of treatment, HBOT has the unique ability to ameliorate tissue hypoxia, reduce pathologic inflammation, and mitigate ischemia reperfusion injury. Most conditions for which it is utilized have few successful alternative treatments, and the morbidity and mortality associated with treatment failure are significant. Although numerous small RCTs provide compelling support for HBOT, However there are significant barriers to trial design.

Indian perspective requires Standard HBOT facility and registry reporting as a part of healthcare reform to facilitate the acquisition of real-world data for HBOT comparative effectiveness studies, with matched cohorts. Predictive models already exist that may be useful in selecting the patients most likely to need HBOT and most likely to benefit from it. Although it is not clear whether patients, payers, or clinicians will support the allocation of healthcare resources by mathematical models, a better paradigm for the appropriate use of HBOT is needed.

Conflict of Interest: The author declares no conflict of interest for this study.

Acknowledgement

Author acknowledge the immense help received from the scholars whose articles are cited and included in references of this manuscript.

References

1. Wound healing: the evidence for hyperbaric oxygen therapy, Mills BJBr J Nurs. 2012 Nov 8-21;21(20):28, 30,32, 34
2. Undersea and Hyperbaric Medical Society, Page V, Hyperbaric Oxygen Therapy Indications, 13th edition, Lindell K. Weaver M.D. Chair and Editor.
3. European code of Good Practice for hyperbaric Oxygen Therapy, prepared by working group <SAFETY> of the COST action, B14, hyperbaric oxygen therapy, May 2004.
4. KK Jain. Textbook of hyperbaric medicine, Fifth revised and updated edition, Pg 496, Table 42.2
5. KK Jain. Textbook of hyperbaric medicine, Fifth revised and updated edition, Pg 500, Table 43.1
6. KK Jain. Textbook of hyperbaric medicine, Fifth revised and updated edition, Pg 501, Table 43.2
7. Yan L, Liang T, Cheng O. Hyperbaric oxygen therapy in China, Med Gas Res. 2015 Feb 18;5:3. doi: 10.1186/s13618-015-0024-4. E Collection 2015.
8. Sahni T, Singh P, John MJ. Hyperbaric oxygen therapy: current trends and applications. J Assoc Physicians India. 2003 Mar;51:280-4.
9. Grolman RE, Wilkerson DK, Taylor J, Allinson P, Zatina MA. Transcutaneous oxygen measurements predict a beneficial response to hyperbaric oxygen therapy in patients with nonhealing wounds and critical limb ischemia. Am Surg. 2001 Nov; 67(11):1072-9; discussion 1080.
10. Chan EC, Brody B. Ethical dilemmas in hyperbaric medicine. Undersea Hyperb Med. 2001 fall; 28(3):123-30.
11. Caroline E. Fife, MD, Kristen A. Eckert, MPhil, and Marissa J. Carter, PhD, An Update on the Appropriate Role for Hyperbaric Oxygen: Indications and Evidence MA Plast Reconstruct Surg. 2016 Sep;138(3):107S–116S. Published online 2016 Aug 25. doi: 10.1097/PRS.0000000000002714(conclusion)
12. Mitchell SJ, Bennett MH. Unestablished indications for hyperbaric oxygen therapy. Diving Hyperb Med. 2014 Dec;44(4):228-34.
13. Yan, Ting Liang and Oumei Cheng. Hyperbaric oxygen therapy in China. Ling, Email author Medical Gas Research 2015;5:3. DOI: 10.1186/ s13618-015-0024-4©Yan et al.; licensee BioMed Central. 2015