

Indications For Hyperbaric Oxygen Therapy – An Introduction

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1

Disclosure

I have no relevant financial relationships with commercial interests to disclose

2

Objectives

- What is Hyperbaric Medicine?
- Current FDA Approved Indications
- Off-label diagnoses

3

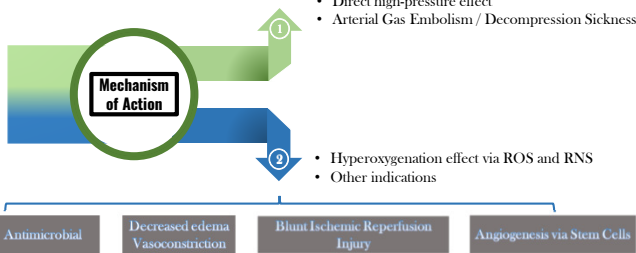
Hyperbaric Medicine

- The application of hyperbaric oxygen (HBO₂) to treat itemized medical and surgical conditions.
- Deeply connected to dive medicine (undersea medicine)
- Intra-nasal delivery of 100% oxygen to patients at higher-than-atmospheric pressures (> 1.4 atmosphere absolute)
- HBO₂ can be considered as a drug
 - ✓ Different diseases require different dosing of oxygen and regimen
 - ✓ Dose (blood level) is measured in partial pressure - PaO₂

Gesell L, Ed. (2008). Hyperbaric Oxygen Therapy Indications. Durham, NC, Undersea and Hyperbaric Medical Society.

4

Scientific Rationale



5

FDA / UHMS Approved Indications

Emergent	Urgent	Routine
<ul style="list-style-type: none"> • Arterial gas embolism • Acute carbon monoxide poisoning • Central retinal artery Occlusion • Decompression illness • Exceptional (acute) severe anemia • Impending skeletal compartment syndrome 	<ul style="list-style-type: none"> • Acute peripheral insufficiency • Crush injuries • Compromised graft / flap • Gas gangrene • Idiopathic sudden sensorineural hearing loss • Intracranial abscess • Necrotizing Fasciitis 	<ul style="list-style-type: none"> • Acute thermal burns • Chronic refractory osteomyelitis • Diabetic foot ulcers • Osteoradionecrosis • Soft tissue radiation injury

Moon R et al. Part I Indications. Undersea and Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indication. 14th Edition. Best Publishing Company. 2019
 U.S. Food & Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Updated July 26, 2021. Accessed January 3, 2023. <https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts>

6

FDA Approved Indications

7

Osteoradionecrosis (ORN)

- 2 - 22% of patients with oral cancer treated with radiation therapy develop jaw bone necrosis (osteoradionecrosis)
- **Osteoradionecrosis** is a vasculopathy
- HBO increases angiogenesis in irradiated tissue
- 310 out of 371 (83.6%) showed improvement following HBO₂ for ORN in 14 papers
- 30 / 10 protocol. Emphasis on interval debridement/alveoloplasty/reconstruction

Angiogenesis in Irradiated Tissue

Beech A, Furrer J. Use of the Integra skin regeneration system in an intraoral mandibular defect in osteoradionecrosis. *Int J Oral Maxillofac Surg.* 2016;45:1159-61.
 Marx RE, Eher WJ, Tayapongsk P, Pierce LW. Relationship of oxygen dose to angiogenesis induction in irradiated tissue. *Am J Surg.* 1990;160(5):519-524.
 Mounsey RA, Brown DH, ODwyer TP, Gallane PJ, Koch GH. Role of hyperbaric oxygen therapy in the management of mandibular osteoradionecrosis. *Laryngoscope.* 1993;103(6):605-608.

8

Soft Tissue Radiation Injury: Radiation Cystitis

- History of pelvic radiation and usually > 6 months post radiation
- **Hemorrhagic cystitis** is often serious and life-threatening
- 84% with partial or complete resolution in recent review article of 16 papers
- Improved success rate with early intervention.
- Recurrence occurs and are mostly responsive to HBO₂
- 40 to 60 treatments

Radiation-induced cystitis treated with hyperbaric oxygen therapy (RICH-ART): a randomised, controlled, phase 2-3 trial

Background: Late radiation cystitis is an adverse effect of cancer treatment with radiotherapy in the pelvic region. Symptoms of late radiation cystitis can be treated with the Hyperbaric Oxygenation System (HOS). Previous reports indicate that hyperbaric oxygen therapy reduces symptoms from late radiation cystitis, but the evidence is predominantly based on non-randomised and retrospective studies. We aimed to assess whether hyperbaric oxygen therapy would mitigate symptoms of late radiation cystitis.

Methods: We did a randomised, controlled, phase 2-3 trial (RICH-ART: Radiation Induced Cystitis treated with current standard care). This report reports the primary outcome of hyperbaric oxygen therapy in late radiation cystitis. Secondary outcomes included quality of life, and microscopic appearance of the bladder in stable hyperbaric oxygen therapy responders. Hyperbaric oxygen therapy was compared with current standard care. The report reports the primary outcome of hyperbaric oxygen therapy in late radiation cystitis. Secondary outcomes included quality of life, and microscopic appearance of the bladder in stable hyperbaric oxygen therapy responders. Hyperbaric oxygen therapy was compared with current standard care. The report reports the primary outcome of hyperbaric oxygen therapy in late radiation cystitis. Secondary outcomes included quality of life, and microscopic appearance of the bladder in stable hyperbaric oxygen therapy responders.

Cattinai J, Shah A, McFarland M, Kichani S, Hoeding JN, Myers JB. Scoping Review and Meta-analysis of Hyperbaric Oxygen Therapy for Radiation-Induced Hemorrhagic Cystitis. *Curr Urol Rep.* 2018;19(6):38. Published 2018 Apr 13. doi:10.1007/s11934-018-0790-3
 Ajayi OD, Gaskill Z, Kelly M, Logue CJ, Hendricksen SM. A comparison of two hyperbaric oxygen regimens: 2.0 ATA for 120 minutes to 2.4 ATA for 90 minutes in treating radiation-induced cystitis. Are these regimens equivalent? *Undersea Hyperb Med.* 2020;47(4):581-589. doi:10.22607/10.12.2020.7

9

Soft Tissue Radiation Injury: Radiation Proctitis

- 5-10% of patients treated with radiation therapy for pelvic malignancy develop chronic **radiation proctitis**
- Radiation injury can affect any part of the GI tract.
- Hyperbaric oxygen therapy is an effective modality to reduce bleeding in radiation proctitis (1B evidence)
- 40 - 60 treatments

CLINICAL PRACTICE GUIDELINES

The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Treatment of Chronic Radiation Proctitis

Jan M. Pappas, M.D.* Jon D. Vogel, M.D.† Maher A. Abbas, M.D.‡
 Daniel J. Feingold, M.D.† Scott R. Steele, M.D., M.B.A.‡

On behalf of the Clinical Practice Guidelines Committee of The American Society of Colon and Rectal Surgeons

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 2 Anschutz Medical Campus, University of Colorado Denver, Denver, Colorado
 3 Cleveland Clinic Foundation, Cleveland, Ohio

Hyperbaric oxygen therapy is an effective treatment modality to reduce bleeding in patients with CRP. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Onych DP, Nelson H. Radiation injuries of the colon and rectum. *Surg Clin North Am.* 1993;73(5):1017-1035. doi:10.1016/0039-6109(16)46138-4
 Pappas JM, Vogel JD, Abbas MA, Feingold DJ, Steele SR. Clinical Practice Guidelines Committee of The American Society of Colon and Rectal Surgeons. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Treatment of Chronic Radiation Proctitis. *Dis Colon Rectum.* 2018;61(10):1135-1140. doi:10.1097/DCR.0000000000001209

10

74 y.o male with symptomatic radiation proctitis
 40 hyperbaric oxygen treatments at 2.4 ATA

16 Rectum: Inflammation 18 Rectum: Inflammation 20 Rectum: Inflammation

40 hyperbaric oxygen treatments at 2.4 ATA

1 Rectum: Inflammation 2 Rectum: Inflammation 3 Rectum: Inflammation

11

Intracranial Abscess

- Consider adjunctive HBO₂ for **Intracranial abscess** in these settings
 - Multiple abscesses
 - Abscesses in deep or dominant location
 - Surgery is contraindicated
 - No response to surgical and antibiotic treatments
 - Concomitant skull osteomyelitis
- Response determines number of moon R et al. Part I. Indications. Undersea and Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indication. 14th Edition. Best Publishing Company, 2019

- 50 yo, presented with altered mental status, headache, fever and bizarre behavior 4 weeks after treatment for acute subarachnoid hemorrhage. Isolated *E. Coli* and possibly *Shigella spp*
- Recurrent right frontal abscess and persistent fever despite 2 stealth-aided bur aspiration + ongoing Vancomycin, Meropenem.
- Added 26 HBO₂ treatments

12

Intracranial Abscess

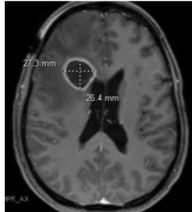


Fig. 1 50 years old female (patient), axial gadolinium-enhanced T1-weighted MRI demonstrating a single large right frontal lobe intracerebral abscess measuring with associated ventriculitis and surrounding vasogenic edema.

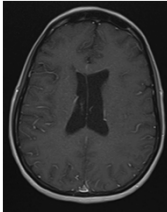


Fig. 2 An axial gadolinium-enhanced T1-weighted MRI (same patient) performed 4 months after second aspiration, combined antibiotic and HBO₂ therapy demonstrating no residual brain abscess

13

Central Retinal Artery Occlusion (CRAO)

- Emergent HBO₂ for **central retinal artery occlusion**
- Painless loss of vision (LP, HM)
- HBO₂ use in CRAO is a level IIb AHA classification of evidence
- Goal is to increase oxygen concentration enough to adequately perfuse the retinal choroidal circulation and maintain viability until natural recanalization and reperfusion occurs

Conditions for which hyperbaric chambers are cleared for marketing by the FDA

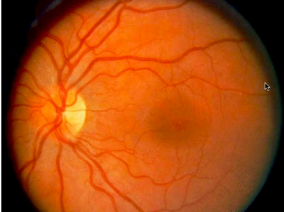
FDA clearance of a medical device includes a determination that the device has the same intended use as, and is as safe and effective as, another legally U.S.-marketed device of that type. As of July 2022, the FDA has cleared hyperbaric chambers for the following disorders:

- Skin graft flap at risk of tissue death
- Vision loss (when sudden and painless in one eye due to blockage of blood flow)
- Wounds (non-healing, diabetic foot ulcers)

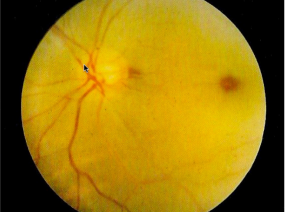
U.S. Food & Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Updated July 26, 2021. Accessed January 3, 2023. <https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts>

14

Normal



CRAO



Lim J, et al. American Academy of Ophthalmology. CME Resources. Retinal Artery Occlusion. Updated December 5, 2022. Accessed January 3, 2023

15

Therapies for CRAO

Therapy	Effectiveness	Source
IV Tissue plasminogen activator	47.0%	Huang L et al. (2022). A systematic review and meta-analysis.
Intra-arterial plasminogen activator	50.4%	Page PS et al. (2018). A Systematic Review and Meta-Analysis.
Hyperbaric oxygen treatment	66%	Murphy-Lavoie H et al (2019). Arterial Insufficiencies CRAO. p 22 - 25. UHMS HBOT indications, 14 th Edition. Moon R. BPC

16

Foot Ulcers

Diabetic Patient

- 50-70% of all non traumatic amputations occur in diabetics
- 5-year survival rates in patients with **diabetic foot ulcer** after a major amputation is 70%
- HBO₂ is effective in healing diabetic foot ulcers and preventing major amputations (proximal to ankle)
- 35 to 40 treatments
- Coverage only for > Wagner grade 2 ulcers & evidence of at least 30 days of ongoing wound care

Non-Diabetic Patient

- Gray zone, even for patients with severe peripheral arterial disease
- Evidence of low tissue oxygenation and/or poor microcirculation may not suffice
- HBO₂ can be offered post surgery following a flap or graft procedure if there are concerns for "compromised flap/graft"

Moulik PK, Monga R, Gill GV. Amputation and mortality in new-onset diabetic foot ulcers stratified by etiology. *Diabetes Care*. 2003;26(2):491-494. doi:10.2337/diacare.26.2.491
 Armstrong DG, Sverdlow MA, Armstrong AA, Coats MS, Fialdo WV, Bitt SA. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. *J Foot Ankle Res*. 2020;13(1):16. Published 2020 Mar 24. doi:10.1186/s13047-020-00383-2
 Sharma, R., Sharma, S.K., Madgal, S.K., et al. Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials. *Sci Rep* 11, 2189 (2021).

17



Pre-HBO₂ Treatments



+ 35 HBO₂ Treatments

18

Compromised Flap/graft

- **Compromised flap/graft** occurs in 5-10%
- Irradiated wound bed, hypoxic wound bed, excessively large harvested graft, random flap ischemia, venous or arterial insufficiency, trauma and ischemia-reperfusion injury
- HBO₂ enhances O₂ diffusion, reduces necrosis and promote angiogenesis
- HBO₂ decreases expression of ICAM-1 and alters nitric oxide synthase
- 5 to 20 treatments

HBO ₂ started	Success Rate
Immediately	98%
10 hours	56%
48 hours	14%

Deng BH, Shen XH, Li AM, et al. Efficacy of early intervention with HBO after skin grafting. *J Clin Rehabil Tissue Eng Res.* 2007;11(4): 156-157.

HBO ₂ started	Flap Healing
< 12 hours	100%
12-48 hours	71%
> 48 hours	50%

Qi Y, Lin SH, Jiang YH, et al. The effect of hyperbaric oxygen therapy in 38 cases of skin flap transplantation. *J Rare & Uncom Dis.* 2009;16(3): 30-33.

Wilson AJ, Chang CS, Kanchwala S. Management of flaps. *Neurocritical Care Management of the Neurological Patient.* 2018;439-445.
 Ibarra JA, Sisti GL, Sushoda KK, Resnora WR. Hyperbaric oxygen downregulates ICAM-1 expression induced by hypoxia and hypohyemia: the role of NOS. *Am J Physiol Cell Physiol.* 2000;278(2):C292-C302. doi:10.1152/ajpcell.2000.278.2.C292.
 Zhou YY et al. *Undersea and Hyperbaric Medicine.* 2014; 41(3): 209-216.

19

Acute Carbon Monoxide Poisoning

- **Carbon monoxide (CO)**, a colorless, odorless gas produced by incomplete combustion of carbon containing compounds is the leading of poisoning death in the United States
- CO binds to heme proteins and cytochrome oxidases in the electron transport chain
- Symptoms vary and are neither related to the level of COHgb nor predictive of outcome
- CO can lead to end-organ damage and delayed neurological sequelae (DNS)

SYMPTOM	PERCENTAGE OF PATIENTS
Headache	91
Dizziness	77
Weakness	53
Nausea	47
Difficulty in concentrating or confusion	43
Shortness of breath	40
Visual changes	25
Chest pain	9
Loss of consciousness	6
Abdominal pain	5
Muscle cramping	5

*Data are from Ely et al.,¹³ Myers et al.,¹⁶ and Burney et al.¹⁵

Centers for Disease Prevention and Control. Carbon Monoxide Poisoning. National Center for Environmental Health. Reviewed November 16, 2022. Accessed September 9, 2023.

20

What's up with HBO in CO poisoning?

- HBO₂ dramatically reduces the 1/2 life of CO bound to heme proteins- rapid detoxification
- HBO₂ provides enough dissolved O₂ in the bloodstream to prevent further hypoxic insult
- HBO₂ improves neurological outcomes even when COHgb has normalized prior to treatment in the chamber

Moon R et al. Part I. Indications. *Undersea and Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indication. 14th Edition.* Best Publishing Company. 2019.

21

Acute Carbon Monoxide Poisoning

DNS: Delayed Neuropsychiatric Syndrome

22

Sudden Idiopathic Sensorineural Hearing Loss

- **Sensorineural loss** is the most common type of hearing loss
- Occurs when there is damage to the inner ear or retro-cochlear area
- 30dB or greater over at least 3 contiguous frequencies within a 72-hr period. Idiopathic
- Two-fold etiopathology → Inflammation and Hypoxia
- ENT to initiate steroid therapy
- Hyperbaric medicine to initiate HBO₂

University of Minnesota
<http://www.mvcmc.com/anatomy/ear/>

Moon R et al. Part I. Indications. *Undersea and Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indication. 14th Edition.* Best Publishing Company. 2019.

23

Sudden Idiopathic Sensorineural Hearing Loss

Presentation

- 40 year-old female
- Sudden onset left sided hearing loss (Day 0)
- Primary care physician → Low dose steroids → No improvement (Day 6)
- ENT evaluation and initiation of high dose steroids + intratympanic steroids (Day 11)
- Hyperbaric medicine evaluation and initiation of HBO₂ (Day 11)

Treatment

- Oral steroids
 - Prednisone 60mg x 7 days, 40mg x 4 days, 20mg x 3 days
- Intratympanic steroid injections
 - Dexamethasone 10mg/mL, series of 4 over 2 weeks
- Hyperbaric oxygen treatment
 - 10-20 dives

24

Sudden Idiopathic Sensorineural Hearing Loss

Clinical Practice Guideline: Sudden Hearing Loss (Update) Executive Summary

Outcome

Pre-HBO₂ **Steroids and 10 HBO₂**

Chandrakumar SS, Tsai Do BS, Schwartz SR, et al. Clinical Practice Guideline: Sudden Hearing Loss (Update). *Otolaryngol Head Neck Surg*. 2019;161(11_suppl):S1-S45.

25

Arterial Gas Embolism

Bubble Obstructing End-Arterial Flow in a Cerebral Vessel, causing Distal Ischemia. The obstruction causes the metabolic process of neurons to fail. Sodium and water enter the vessel, and cytotoxic edema develops. The surface of the bubble generates a foreign-body response through cellular and humoral immune mechanisms. The bubble also mechanically irritates the arterial endothelium. Both processes result in vasogenic edema and greater impairment of perfusion. The neuronal injury extends beyond the area of obstruction.

Muth and Shank. Primary Care: Gas Embolism. *N Engl J Med* 2000; 342: 476-482.

26

Arterial Gas Embolism

- Hyperbaric oxygen is the primary treatment option for **Arterial Gas Embolism (AGE)**
- Idiopathic AGE can occur in any invasive procedure
- Management include:
 - ABCs and rapid neurological assessment
 - ACLS protocols
 - Oxygen!
 - IV access
 - Labs and Imaging
 - Detailed neurological examination
- Place foley catheter for acute urinary retention
- Consider DVT prophylaxis
- Lidocaine has neuroprotective role in iatrogenic cerebral AGE
- Expect hemoconcentration and leukocytosis
- Cardiac biomarkers
- CT head for neurological symptoms
- EKG to check for arrhythmias

27

Arterial Gas Embolism

66 y.o female transferred from an outside hospital when she was noted to have gas bubble in her right ventricle wall after PICC line placement for initiating chemotherapy

Pre-HBO₂ **After 1 HBO₂**

28

Gas Gangrene

- Gas Gangrene**
- Clostridium perfringens* is the leading cause, and it thrives in oxygen tension < 30 mmHg
- Severe pain precedes other symptoms
- Surgical exploration, gram stain, culture
- HBO₂ at 3.0 atmosphere absolute (ATA) inhibits alpha toxin
- 3 HBO₂ in 24 hours then BID until infection is under control

Moon R et al. Part 1 Indications. Undersea and Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indication. 14th Edition. Best Publishing Company, 2019

29

Necrotizing Soft Tissue Infection (NSTI)

- NSTI is a relatively rare, life-threatening condition
- Associated with rapid tissue destruction, sepsis, multi-organ failure
- Average mortality 25 - 39%
- Management = Surgical debridement + antibiotics + intensive care.
- Adjuvant HBO₂ is added in severe cases

	N	HBO Mort.	Non-HBO Mort.	OR
Gas gangrene	1450	19% (234/1233)	46.2% (98/217)	3.52 (2.57-4.81)
Necrotizing fasciitis	552	20.7% (57/276)	43.5% (12/278)	2.96 (2.0-4.39)

Clark LA, Moon RE. Respiratory Care Clinics of North America. 1999

30

Acute Traumatic Ischemias

- Acute traumatic ischemia and other acute insufficiencies
- Trauma + Tissue hypoxia
- Crush injuries and Skeletal muscle compartment syndrome

Crush Injury:

- ✓ Gustillo IIB and IIC, certain IIA and IIIA
- ✓ Early application (4-6 hrs) is recommended
- ✓ 2 - 3 times daily in initial 24 hours
- ✓ Demarcation of viable tissue is indicator for when to stop HBO₂

Impending Skeletal compartment Syndrome:

- ✓ Not indicated for suspected or established comp. syndrome
- ✓ Does not defer fasciotomy
- ✓ BID treatments for first 24 - 36 hours, then daily until symptoms resolve

Bouachour G, Cronier P, Gouello JP, Toulemonde JL, Taha A, Akquier P. Hyperbaric oxygen therapy in the management of crush injuries: a randomized double-blind placebo-controlled clinical trial. *J Trauma*. 1996;41(2):333-339.

31

Acute Peripheral Arterial Insufficiency

Acute Peripheral Arterial Insufficiency

- Frostbite
- Embolic disease
- Purpura fulminans (e.g., meningococemia)

85 y.o male sustained frostbite to both hands after falling on a snow bank at sub-zero ambient temperature.

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    graph TD
      A[Re-warming initiated] --> B[He is not a candidate for TPA]
      B --> C[HBO2 initiated]
      C --> A
      D[40 minutes]
      subgraph Cycle
        A
        B
        C
      end
      D --- Cycle
    
```

32

Acute Peripheral Arterial Insufficiency: Frostbite

Pre-HBO₂

After 13 HBO₂

33

Other FDA Approved Indications

- Adjunctive measure for Chronic refractory osteomyelitis
- Decompression Illness (Decompression Sickness and Dive-related arterial gas embolism)
- Acute severe anemia when blood transfusion is contra-indicated
- Adjunctive measure for Acute thermal burns (2nd and 3rd degree)

Moon R et al. Part I Indications. Undersea and Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indication. 14th Edition. Best Publishing Company, 2019
 U.S. Food & Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Updated July 26, 2021. Accessed January 3, 2023. <https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts>

34

Off-label Diagnoses

35

Diagnosis	Notes
Fibromyalgia	Two RCT (Yildiz, 2004 and Efrati, 2015) suggest fewer tender points and pain meds required. Further research required
Concussion	Ambivalent results from 5 RCTs. Most recent RCT suggest improvement at 13 weeks may be lost afterwards (Weaver, 2018)
Long COVID	No RCT. Very limited studies. 1 consecutive study reports fatigue score improvement after 10 HBOT (Robbins, 2021)
Complex Regional Pain Syndrome	Limited studies, mostly case reports. 1 RCT reported decreased pain, edema and increased movement (Kilrap, 2004)
Pyoderma Gangrenosum (PG)	PG has a hypoxic component. HBO ₂ can be considered in the context of non-healing chronic wound. Not covered by insurance
Operative Pre-conditioning	Very promising, multiple RCT (Alex, 2005; Yogaratham, 2010; Li, 2011). Needs a current RCT

36

Diagnosis	Notes
Acute Coronary Syndrome	Limited evidence that HBO ₂ reduces major cardiac event. Studies have poor inclusion criteria, need a RCT
Acute Ischemic Stroke	11 RCTs, no good evidence to show HBO ₂ improves clinical outcomes (Bennett MH, et al, 2014)
Multiple Sclerosis	12 RCTs, no clinical significant benefit. No study designed to test efficacy of HBO ₂ against alternative best practice (Bennett M & Heard R, 2010)
Cerebral Palsy	Mixed results. HBO ₂ may improve gross motor function. Further research is required (Bennett M & Newton H, 2007)
Autism	"Very weak" evidence. Few studies, mixed result (Martin's review, 2015)
Neonatal Hypoxic Encephalopathy	Animal models show HBO ₂ reduces brain injury, limited and poorly designed human studies (Liu Z, et al, 2006)
Acute long bone fractures	HBO ₂ increases new bone formation in animal studies. RCT Human studies are required (Bennett M, et al, 2012)

37

Summary

- Hyperbaric oxygen therapy is a systemic treatment option that entails breathing >99.9% oxygen in an environment with a pressure > than 1.4 atmosphere absolute
- FDA website has approved indications, each supported by quality research
- Insurance coverage exist for indications on the FDA list of diagnoses
- Distinguishing between emergent, urgent and routine-based indications is critical to obtaining the best clinical outcome
- Off label use is common, but with little supporting research
- Ongoing research to expand the role of HBO₂ in Inflammatory Bowel Disease and acute graft-versus-host disease

38