Hyperbaric Oxygen Therapy
Overview & Insights
Special Focus on the Diabetic Foot

Jeffrey A. Niezgoda, MD
FACHM, MAPWCA, CHWS

jniezgoda@webcme.net

Hyperbaric Oxygen Therapy is NOT

Healing Difficult Wounds

Hyperbaric Oxygen Therapy
Definition:
Inhaled 100% Oxygen delivered to the Patient Completely Enclosed in a Pressurized Environment

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net
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Hyperbaric History

Henshaw 1662
- Built the first chamber “Domicilium”
- Pressure Theory for Disease Treatment
  - Acute disease responded to increased pressure
  - Chronic disease treated with “rarified air”

D. Jourdanet 1862

Fontaine 1879
- Mobile hyperbaric operating room
- 2 ATA compressed air (42% oxygen equivalent)

Paul Bert 1878
- Oxygen Toxicity

Orville J. Cunningham
- 1928 Cleveland
- Treated Mr. Timkin (Timkin Rollerbearing Company) for uremia
- Steel Ball Hospital
  - 6 stories
  - 72 rooms
  - Grand Piano, Smoking lounge

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jniezgoda@webcme.net
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Ite Boerema 1956
- Cardiothoracic Surgeon
- First use of chamber for cardiac surgery
- Publication “Life Without Blood”

Hyperbaric quackery, unfortunately, gained ascendancy in the early 1970’s

Recent HBO Trends
- Research & Publications
  - Stem Cells and Mechanisms
  - ACHM Radiation Registry
- Integration of HBOT into Wound Care Clinics
  - Wound Care Adjunct
  - 1000-1250 HBO centers
- New Indications
  - DFU
  - ISSHL & CRAO

Mechanism of Action
Hyperbaric Oxygen Therapy

Oxygen Dosing / ATA
Atmospheres Absolute

<table>
<thead>
<tr>
<th>O₂</th>
<th>1 ATA</th>
<th>Sea Level</th>
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<tbody>
<tr>
<td>O₂</td>
<td>2 ATA</td>
<td>33 Feet Sea Water</td>
</tr>
<tr>
<td>O₂</td>
<td>3 ATA</td>
<td>66 FSW</td>
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Oxygen Dosing / ATA
Atmospheres Absolute

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<thead>
<tr>
<th>ATA</th>
<th>mmHg</th>
<th>(VOL %)</th>
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<tr>
<td>1.0</td>
<td>760</td>
<td>2.09</td>
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<tr>
<td>1.5</td>
<td>1140</td>
<td>3.26</td>
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<tr>
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<td>1520</td>
<td>4.44</td>
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<tr>
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<td>1900</td>
<td>5.62</td>
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<td>3.0</td>
<td>2280</td>
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</table>

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jniezgoda@webcme.net
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Normobaric Conditions

Hyperbaric Conditions

Normobaric Conditions

Hyperbaric Conditions

Normobaric

Hyperbaric

Tissue Oxygenation

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jnierzoda@webcme.net
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Emergent Indications
- Decompression Sickness
- Gas Embolism
- Gas Gangrene
- Acute Ischemia
- Extreme Anemia
- Carbon Monoxide
- Cyanide (Smoke Inhalation)
- Thermal Burns

HBO Chamber Types

Elective Indications
- Radiation Injury
- Chronic Osteomyelitis
- Diabetic Wounds
- Problem Wounds

Side Effects
- Barotrauma (Otic, Pulmonary, Odontic)
- Oxygen Toxicity (CNS, Pulmonary, Ocular)
- Hypoglycemia
- Claustrophobia
- Congestive Heart Failure

Contraindications
- ABSOLUTE
  - Untreated Pneumothorax

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jnieszgoda@webcme.net
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Contraindications

➢ ABSOLUTE
  • Untreated Pneumothorax

➢ RELATIVE
  • Claustrophobia
  • Fever
  • CHF, COPD
  • High FIO2
  • Chemotherapeutic Agents

Capillary density increases when hyperbaric oxygen is breathed.

Smith, Ketchum: 1970

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net
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**HBOT and Angiogenesis**
- Irradiated rabbit mandible model: Significantly increased vascularity via microangiograms in the HBO2 treated group
- Significantly greater angiogenesis in mice implanted with Matrigel plugs when treated with HBO2

**Bacterial Induced Dermal Necrosis**

**Experimental Design**
I/R injury and HBO treatment

- 4 hours Hypoxia/Hypoglycemia
- 20 hours Normoxia/Normoglycemia

- HBO at 2.5 ATA

**HBO down-regulates hypoxia/hypoglycemia-induced VCAM-1 expression**


**HBO increases PDGFR and EGFR expression human dermal fibroblasts**


Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS

jniezgoda@webcme.net
The Effect of Hyperbaric Oxygen Therapy on a Burn Wound Model in Human Volunteers


**HBO Therapy in a Human Burn Model**


Study Type: prospective, randomized, blinded trial

Methods: standardized wound model

Control gp: 8.75% oxygen at 2.4 ATA bid x 3 days

HBO gp: 100% oxygen at 2.4 ATA bid x 3 days

Measurements:
- wound size
- hyperemia
- exudation
- epithelialization

Outcome:
- Wound size- 35% reduction in lesion size (day 2) p < 0.05
- Hyperemia- 42% reduction in wound hyperemia by laser-doppler (day 2) p < 0.03
- Exudation- 22% reduction in exudate (day 2) p < 0.04
- Epithelialization- no difference in time to complete epithelialization NS
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Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net

Summary of HBO Mechanisms

Enhanced WBC Killing
Growth Factor Stimulation
Decreased Edema
Tissue Hyperoxygenation
Cellular Proliferation
Platelet Deformability
Neovascularization
Antioxidant Prevents IRI

HBOT in DFU

Prospective RCT of 94 patients with DFU
- Wagner Grade 2, 3, and 4
- Randomized to HBOT vs Placebo Control
- HBOT (N=48) Complete Healing
  - 25/48 (52%)
- Placebo Control Group (N=42)
  - 12/42 (29%) P=0.03
- Patients completing >35 HBOTxs
  - HBOT Group 23/38 (61%)
  - Control 10/37 (27%) P <0.009


HBOT in DFU

Prospective randomized study of 70 patients using HBO treatment in DFU
- 35 Patients each group
- HBOT Group
  - 3 of 35 (8.6%) patients major amputation
  - 1AKA, 2BKA
- Control Group
  - 11 of 33 (33.3%) patients major amputation
  - 4AKA, 7BKA
- P=0.016


Non randomized comparative study
- 184 consecutive patients with DFU
- HBOT adjunctive to standard of care

Results
- 115 (63%) Healed
- 31 (17%) No improvement
- 38 (20%) Amputation
  - 9 (4.9%) Major (BKA)
  - 29 Minor


Study Summary

Longitudinal observational data from the National Healing Corporation.
- The study goal was to compare the effectiveness of HBO to other therapies for DFU
  - prevention of lower extremity amputation
- Statistical analysis
  - Propensity Scores to determine the “propensity” that an individual was selected to receive HBO
  - Statistically controlled variables that might influence the selection of a therapy and thus to mimic the “even” distribution of variables seen in a RCT

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Results
- 6,259 DFU with adequate lower limb arterial perfusion, and foot ulcer extending through the dermis
  - Propensity score–adjusted models, individuals receiving HBO were less likely to heal DFU
    - hazard ratio, 0.68; 95% confidence interval, 0.63–0.73
  - And more likely to have an amputation
    - hazard ratio, 2.37; 95% confidence interval, 1.84-3.04
  - HBO was not found to improve the likelihood that a wound might heal or to decrease the likelihood of amputation in any of these analyses

Conclusion
- Use of HBO neither improved the likelihood that a wound would heal nor prevented amputation in a cohort of patients defined by Centers for Medicare and Medicaid Services eligibility criteria.
- The usefulness of HBO in the treatment of diabetic foot ulcers needs to reevaluated.

Study Criticisms
- Excluded cohort had a higher rate of lower extremity amputations compared to literature
  - Suggests basic wound care was poorly conducted
- Detailed selection criteria for HBOT were not reported
  - Questions if HBOT patients were medically appropriate
- Included Wagner Grade 2 DFU
  - RCT evidence reports HBOT efficacy in Wagner 3/4 DFU
- Propensity and Sensitivity Analysis was inadequate to account for confounding variables
- Practice protocol of 1 company cannot be generalized

Clinical Correlations

HBOT Utilization Algorithm
- Patient & Wound Assessment
- Standard Wound Care
- Follow up and Monitoring

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net
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Vascular Assessment
- Physical Examination
- ABI
- TCOM
- Duplex Ultrasonography
- Contrast Angiography

Palpable Pulses!
- In patients with PAD (as detected by ABI) 74% had a palpable pulse
- More than two thirds of the patients within the study group with evidence PAD had a palpable pulse
- The sensitivity of a non-palpable pulse for the diagnosis of PAD was 26%
- Pulse palpation is not sensitive for the detection of PAD when compared to ABI

Ankle Brachial Index

Ankle Systolic Pressure
Brachial Systolic Pressure
- Both ankle and brachial systolic pressures should be taken using a hand-held Doppler instrument
- For both arm and leg, use higher of 2 pressures
- The ABI is 95% sensitive and 99% specific for PAD

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jnierzoda@webcmee.net
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Transcutaneous Oximetry
Is not the same as Pulse Oximetry!

TCOM Clinical Guidelines
- 37 Patients undergoing BKA
- Preoperative TCOM evaluation
  - $P_{TCO_2} = 0$ torr / All Failed
  - $P_{TCO_2} > 30 - 40$ torr / 15 of 19 Healed
  - $P_{TCO_2} > 40$ torr / All Healed

Transcutaneous Oximetry in Prediction of Healing

The Vascular Center
- Exercise Testing
- Non-Invasive Imaging
- Angiography

The Vascular Center
- Exercise Testing
- Non-Invasive Imaging
- Angiography

TcPO2 Response to Percutaneous Transluminal Angioplasty (PTCA)
As compared to unsuccessful response (UR), a successful response (SR) to PTCA shows a significant increase in TcPO2 beginning the first week following the procedure and steadily increases over subsequent weeks.

TCOM During HBOT
- Results: Overall 75.6% improved after HBO
  - Improved: 34 treatments (mean)
  - Not improved: 24 treatments (mean)
- Baseline TcPO2 (air 1 ATA) has almost no predictive value - multiple cut-off scores analyzed
- Single best discriminator of success or failure - TcPO2 during HBO2 > 200 mm Hg
  - Reliability 74%
  - Positive Predictive Value (PPV) - 58% (221 pts)

Advanced Modalities Utilization Algorithm
- Patient & Wound Assessment
  - Control of Major Chronic Disease Conditions
  - Nutritional Management
  - Vascular Interrogation & Intervention
- Close Follow-up
  - Basic wound care strategies have been implemented
  - 4 week treatment end point
  - Percent wound area reduction = 50%

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jnieszgoda@webcme.net
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CMS Coverage Indication
Diabetic Foot Ulcer
- Lower extremity wound due to Diabetes
  - Type I or Type II DM
- Wagner Grade III or higher
- Failed standard wound care
  - No measurable signs of healing for 30 days
  - Decrease in volume or size
  - Decrease in exudate
  - Decrease in necrotic tissue

Clinical Algorithm HBOT in DFU

The Future of HBOT
- Industry Contraction
  - CMS Looking at Overutilization
  - Centers of Excellence
- Shift to Free Standing - Outpatient Centers
- New Indications
  - Stem Cell Augmentation

Stem Cells & HBOT


The Future of HBOT
- Industry Contraction
  - CMS Looking at Overutilization
  - Centers of Excellence
- Shift to Free Standing - Outpatient Centers
- New Indications
  - Stem Cell Augmentation
  - Acute Brain Injury
  - Acute Ischemias
- Certifications

Case Studies

Jeffrey A. Niegoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net
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Initial Presentation

- 48 year old male PMH of HTN, IDDM, CRI
- Left 1st MTP plantar foot ulcer 2 weeks
- Presented to WCC
  - Debridement, Offloading, Antimicrobial Topical
  - Vascular Center Referral
    - ABIs .9 BLE
    - Dietary Referral
    - X-ray Negative for Osteo

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net
Initial Presentation

- 63 year old male PMH of CAD, IDDM
- Right plantar foot ulcer 2 months duration
- Presented to ED with cellulitis and distal foot ischemia
- Admitted
  - IV ABX
  - Surgical debridement
  - Open TMA
  - TCOM Evaluation

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net
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Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net
DFU Necrotizing Fasciitis

- 48 year old male PMH of IDDM
- 3 month history of plantar ulcer
- Presented with septic left foot, fever
- Admitted
  - IV ABX
  - Surgical débridement
  - Operative diagnosis of necrotizing fasciitis
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7-11

9-13

11-26

Thank You…

Jeffrey A. Niezgoda, MD, FACHM, MAPWCA, CHWS
jniezgoda@webcme.net