Does Hyperbaric Oxygen Therapy Have a Role to Play in the New Era of Value-Based Wound Care?

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Sat, Sept 8th
10:24 AM - 10:36 AM
Pooled data of 3 trials with 118 patients showed HBOT, in conjunction with revascularization:

- Improves healing rate and decreases major amputation in DFUs in exchange for an increase in minor amputations
- Increases QUALYs among DFU patients

HBOT trials, alone among advanced therapeutics (e.g. Becaplermin, Bioengineered skin), has conducted trials which are generalizable to real world patients (particularly those with vascular disease)

- HBOT (alone among advanced therapeutics) improves tissue PO2.

Arterial Supply is the Final Common Denominator

• Arterial supply is the final common denominator for healing in nearly all chronic wound problems.

• Out of 1,172 RCTs, ONLY those trials involving Hyperbaric oxygen included patients with ischemia, or showed the ability to enhance angiogenesis.

• HBOT remains unique in the literature.

• The small subset of patients who need and can also benefit from advanced are those who have adequate arterial supply.
  • The epidemic of diabetes equates to an epidemic of vascular disease.
HBOT Improves Wound PO2 Baseline Indicating Angiogenesis: High Thigh Amputation

Wound response at 1 ATA at weekly intervals during HBOT

PO2 (mm Hg)

Time (min)

Week 0

8 Mo follow-up

Courtesy of Paul Sheffield, PhD
HBOT not Effective in treating DFUs? (2013)

Retrospective analysis of DFUs with HBDOT (N=6,259 individuals) NHC now Healogics centers:

- **HBOT treated DFUs less likely to heal** (OR: 0.68, 95% CI: 0.63-0.73)
- **HBOT treated DFUs more likely to be amputated** (OR: 2.37, 95% CI: 1.84-3.04) *Could not tell major from minor amputations!*
- Wagner 3 DFUs had less healing with HBOT (OR: 0.66 [0.59-0.73])
- **Wagner 3 had more amputations with HBOT** (OR: 1.41, 95% CI: 1.10-1.80)

**Concerns:**

- 77.2% of HBOT treated DFUs ≤ Wagner 2 – should not have been treated at all and should not have been eligible for the study
- 83% of eligible subjects excluded because they healed or had amputation within 28 days (how many of these got HBOT?)
- No covariates in database to properly adjust the cohorts (or demonstrate that the patients got the necessary work up)

And HBOT is Expensive:

- Total cost of care for 5,571 patients: $29,249,500.
- There were 23 patients who each had care totaling over $100,000.
- Extrapolating our data would yield of a cost of at least ~$25 billion to heal these wounds on the OUTPATIENT side.
- A conservative estimate was that 30% of those costs were spent on HBOT.
- OIG report from 10/2000: (38%) of hospital and physician Medicare charges were paid for inappropriate or excessive treatments.
- $11.1 million was paid for treatments with questioned quality . . . resulting from abuse of current coverage policy . . .

Diabetic Foot ulcers –
the Short Version:

• **They Die**: 5 year survival after a major amputation (BKA) is 37% with kidneys function, 14% on dialysis.

• They get multiple amputations before they die:
  • After a major amputation there is a 22% per year ipsilateral amputation rate.
  • 10% per year contralateral (opposite side).

• The costs of caring for them are staggering:
  • Rehab and care costs are high in part because most never use a prosthesis due to problems with balance and low cardiac output.


Only lung cancer is more fatal than a diabetic major amputation.

What is it worth to save one BKA?
Non diabetics with PAD also do badly

- Among chronic limb ischemia patients, 76% (174) underwent bypass for ischemic tissue loss
- 17 never healed
- 13 limbs required major amputations (BKA, AKA)
- 63% required <3 months for complete healing
- Median time to healing = 86 days

Even with revascularization, ischemic legs stay ischemic, take a long time to heal or perhaps never heal.

But no one thinks we should close the cath lab. Why?

1997 (20 years ago), the University of Texas, Houston and Memorial Hermann Hospital Hyperbaric Program developed a limb salvage protocol with the invasive cardiologists.

- Patients with non-healing wounds were screened with Transcutaneous oximetry (TCOM) and an oxygen challenge to find those who needed angiography and endovascular revascularization.
- TCOM was repeated a week after revascularization.
- Patients whose TCOM increased by 30 mmHg were allowed to heal.
- HBOT was used only in patients whose TCOM values failed to improved by 30 mmHg.
- TCOM was far more accurate than ABI as an indicator of endovascular success.

Two decades ago, endovascular revascularization of these patients was controversial. Providing HBOT to the patients with less stellar responses ensured a good outcome and avoided the criticism of vascular surgery.
Any guesses why this protocol did not catch on?

This protocol reduced amputation rates and turned the invasive cardiologists into supporters of HBOT because they knew if they could not achieve optimal flow, there was still something to offer patients with ischemic ulcers that might prevent a major amputation. As a result, HBOT was viewed as an important adjunct to revascularization.

Choosing Wisely for HBOT in Diabetic foot ulcers: A Mathematical Paradigm

<table>
<thead>
<tr>
<th>Time in days</th>
<th>30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current per CMS</td>
<td></td>
</tr>
<tr>
<td>Initial visit to wound care professional</td>
<td></td>
</tr>
<tr>
<td>Provide appropriate Conservative care</td>
<td></td>
</tr>
<tr>
<td>No measurable signs of healing</td>
<td></td>
</tr>
<tr>
<td>Confirms HBOT is needed</td>
<td></td>
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</tbody>
</table>

Possible wasted time

Future state

WHI at initial visit Predicts failure of conservative care

In-chamber TCOM >200 Reliability = 74%

HBOT predictive model suggests 20-40 HBOT will improve healing likelihood: Fig 2, R² = 22.8

Re-evaluate after 30 days for benefit from HBOT

C stat 0.65

Predict failure to heal spontaneously
Prevent inappropriate use of HBOT here

Predict benefit from HBOT here: Prevent wasted use of HBOT

*Predict futile HBOT: TCOM <100, patient with renal failure and 2 or more DFUs have <30% chance of benefit

- Patient age
- Years of diabetes
- Wagner grade
- Transcutaneous oximetry
- Pack/year smoking history

Fife et Al, Wound Rep Reg (2007) 15 322-331
Some Waste is easy to Cut . . .

1. When we provide HBOT to patients who were going to get well anyway. (Unnecessary = Wasteful)

2. When we give patients more treatments than they need to achieve the desired benefit (Excessive = Wasteful)

3. When we provide HBOT to patients who can’t be helped. (Futile = Wasteful)

(\textit{p<0.0001} compared to non-RF). If 2 or more ulcers, only 30% improved. Should we provide HBOT to patients with renal failure and >2 Wagner 3 ulcers? (Remember, their 5 year life expectancy is 14%)
The Value Proposition for HBOT

- Minor amputations in exchange for avoiding major amputations (i.e. most distal amputation possible).
- Wound closure in marginally perfused tissue in the shortest period of time (and avoidance of repeat operations).

- Vascular screening, revascularization and HBOT only if indicated by physiological studies.
- HBOT if indicated by physiological studies using the fewest number of treatments possible.
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