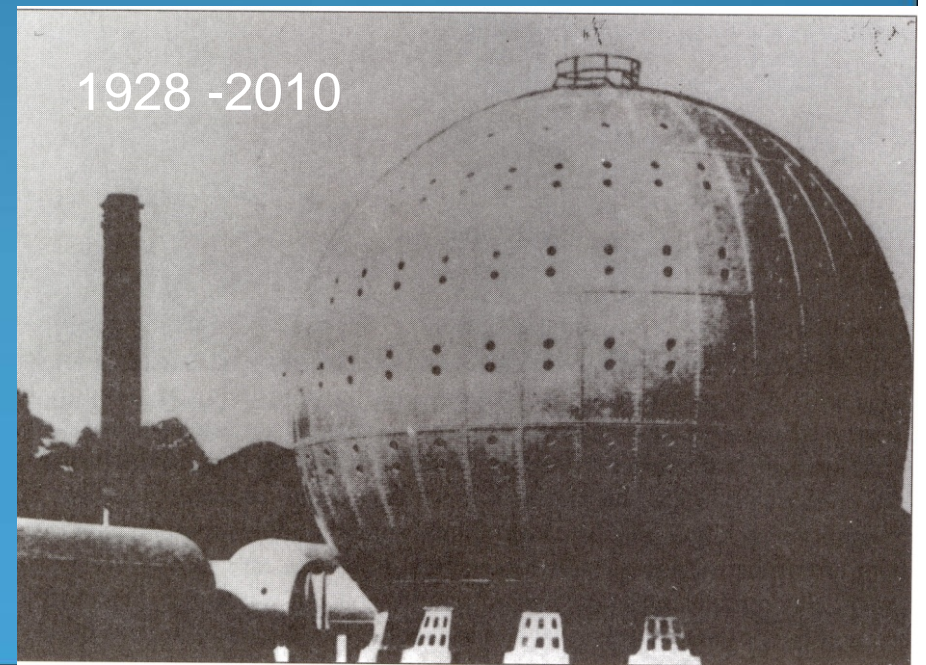


HBOT research in Canada

What is needed for multi-centre trials?

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University of Toronto
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What is needed?

- Solid scientific rationale / hypothesis
- Regulated/standardized approach to therapy across the centers
- Open lines of communication
- Desire to work harder and acquire skills
- Willingness to share the recognition for work done
- Patient population
- Money / time / grantsmanship

Why is it needed?

- We are still a fringe specialty
- The only way to bring HBO into the mainstream of modern medicine is through solid evidence
- If we don't do it, HBO will be even more marginalized in the years to come as new biologics/dressing/modalities come to market (think \$\$\$\$ for new patented technologies)



Don't get upset with the next few slides.

I am your friend but this is how I see it for now.

Don't worry, I have been wrong before

Why do I think that hyperbaric medicine is still in trouble?

- We are having one drug – Oxygen
- We have certain indications for treatment
- We have been around 30 odd years in an organized entity (UHMS) with these indications
- We just starting to understand how and why it may work
- We have only several good randomized trials published
- Some of them show good results, some are negative

Why do I think that hyperbaric medicine is still in trouble?

- We have extremely low quantity of excellent randomized clinical trials to show for over 35 years of work in the field
- We do not know the dose response curve
- Most of our practice is based on clinical experience
- It is an expensive drug
- It has side effects

Why do I think that hyperbaric medicine is still in trouble?

- Most of our colleagues don't know or believe that it really works
- Most of our colleagues wouldn't even know when or where to refer the patient
- Even if they did refer, the patient would not get timely treatment because of waiting lists
- There is non-existent industry sponsorship as there is no patent to be had

What dose would you use?

Aspirin

- 81mg OD
- 325 mg OD
- 500 mg Q6H
- As much as patient tolerate-
the tinnitus in the ears and
passes out from time to time
- It depends...what you are
treating

Amiodarone

- 200 mg OD
- 400 mg OD
- 600 mg OD plus 3000
loading dose
- As much as needed to cause
pulmonary fibrosis and blue
skin

What dose would you use?

HBO for CO poisoning (patient awake on arrival)

- 2.4 ATA x 90 min
- 3 ATA x 120 min
- 3ATA until COHb less than 10%
- 3ATA x 110 min X 3 treatments
- None

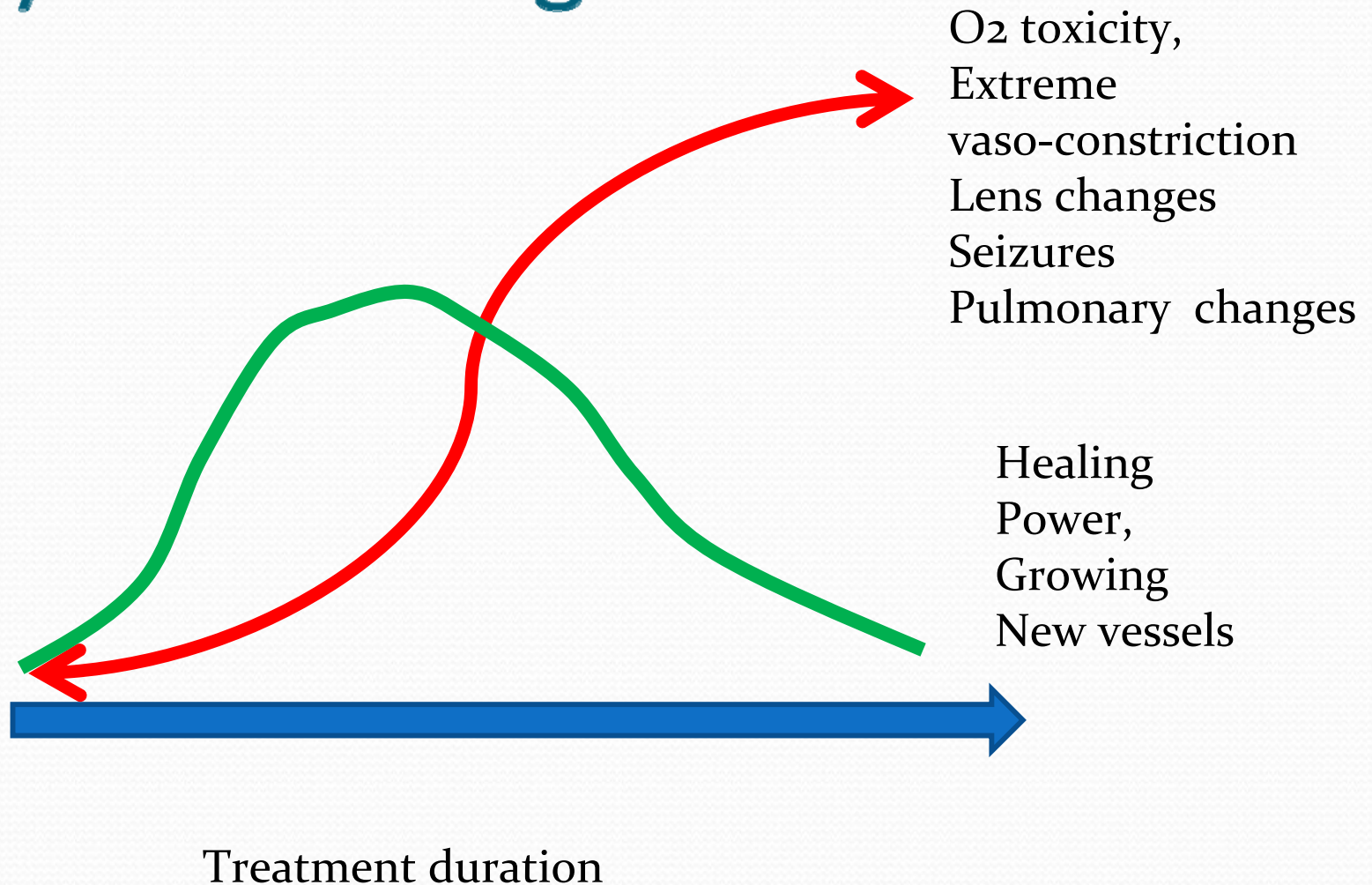
HBO for chronic wound

- 2.4 ATA x 90 min x 30 sessions
- 2.4 ATA x 90 min x 40
- 2.4 ATA x 90 min until is healed
- 2.4 ATA x 90 min until the patient can't drive anymore because of visual side effects

Where is evidence for dosing of HBO?

- Collective wisdom
- Because how it was done before
- Payment structures

Hyperbaric Oxygen is a Drug, it has efficacy and side effects just like any other drug



What has changed since 1978?

- 2008 Some pivotal RCT trials such as proctitis study
- 2005/2006 ground breaking mechanistic studies of Thom, Gallagher shedding light on HBO
- Gradual move over decades towards “evidence based medicine” by payers to control the costs of therapies and to protect the patients
- Increasing urgency to do such quality research or be phased out

Canadian UHMS Chapter

- ? Wonderful opportunity not to be wasted
- ? Beginning of modern approach to HBO in Canada
- ? Perfect timing due to recent basic research
- ? Can we do together what we cannot do alone



Osteomyelitis,
Penetrating
to the dorsum
7 months



RX: 6 weeks of ABX + HBO; Picture 12 weeks after start of treatment

Study Pt 76 year old diabetic professional figure skater



Study Pt After 30 HBOT treatments



Stem cell mobilization by hyperbaric oxygen

**Stephen R. Thom, Veena M. Bhopale, Omaidia C. Velazquez, Lee J. Goldstein,
Lynne H. Thom and Donald G. Buerk**

Am J Physiol Heart Circ Physiol 290:1378-1386, 2006. First published Nov 18, 2005;

doi:10.1152/ajpheart.00888.2005

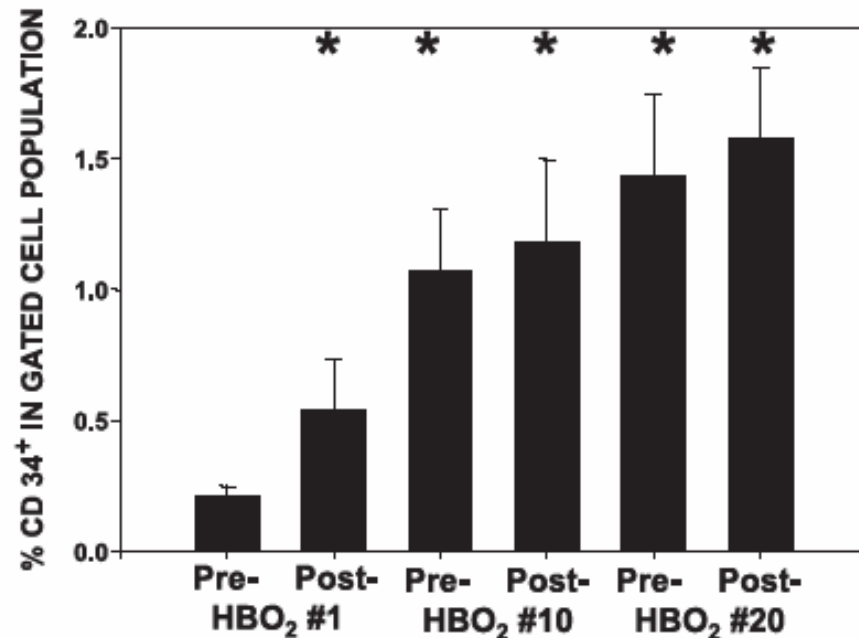


Fig. 4. Mean CD34⁺ population in blood of humans before and after HBO₂ treatments. Data are the fraction of CD34⁺ cells within the gated population using leukocytes obtained from 26 patients before and after their 1st, 10th, and 20th HBO₂ treatment. *Repeated-measures one-way ANOVA, $P < 0.05$ vs. the pre-HBO₂ first treatment value.

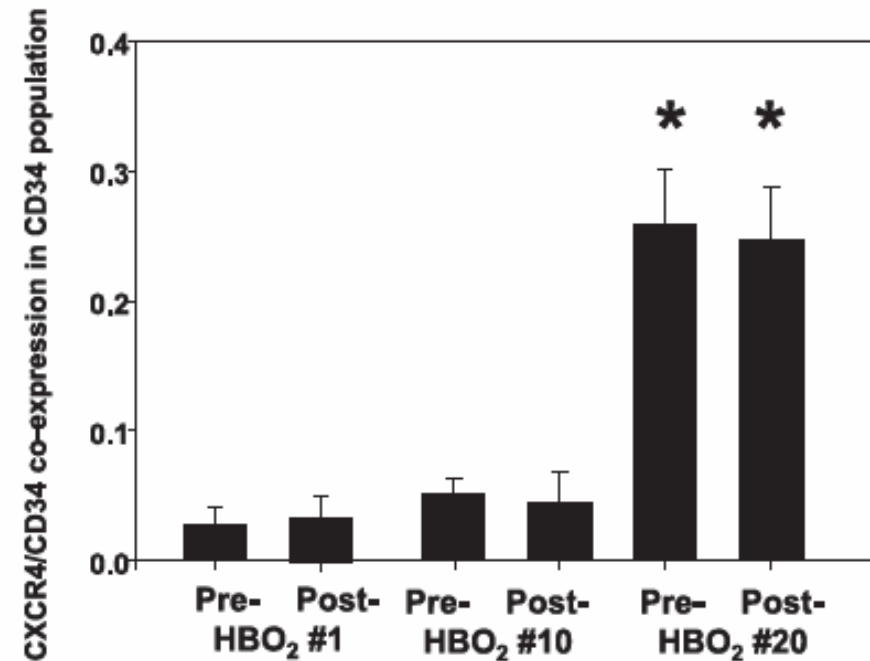
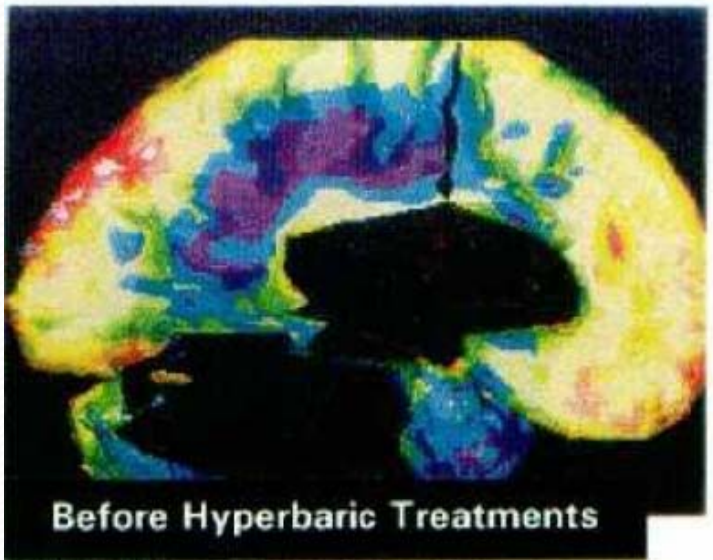
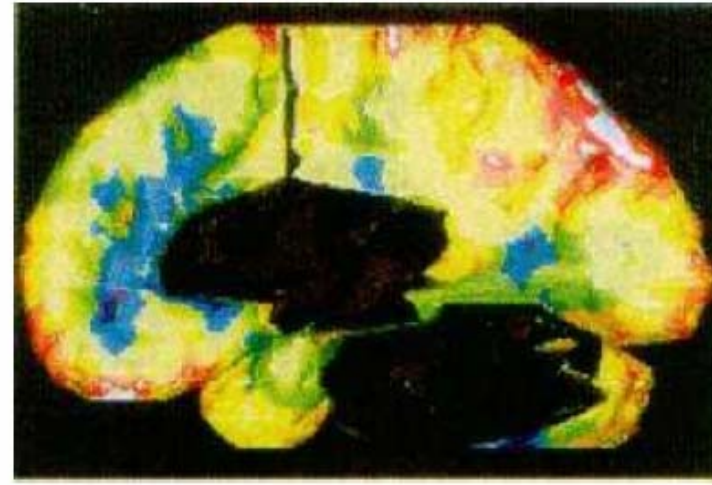
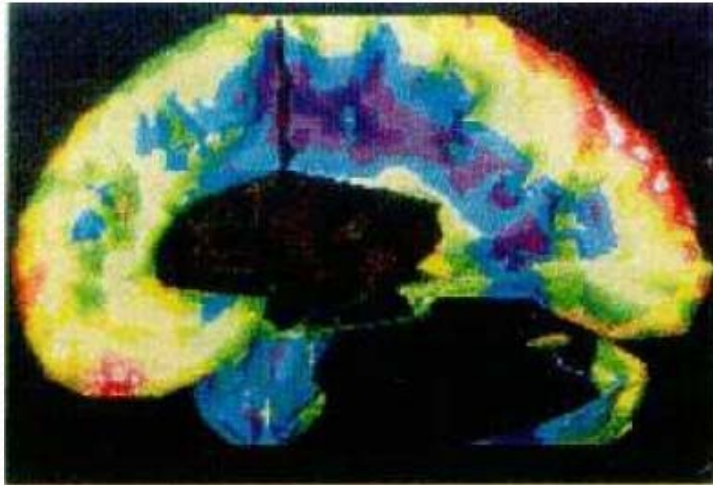
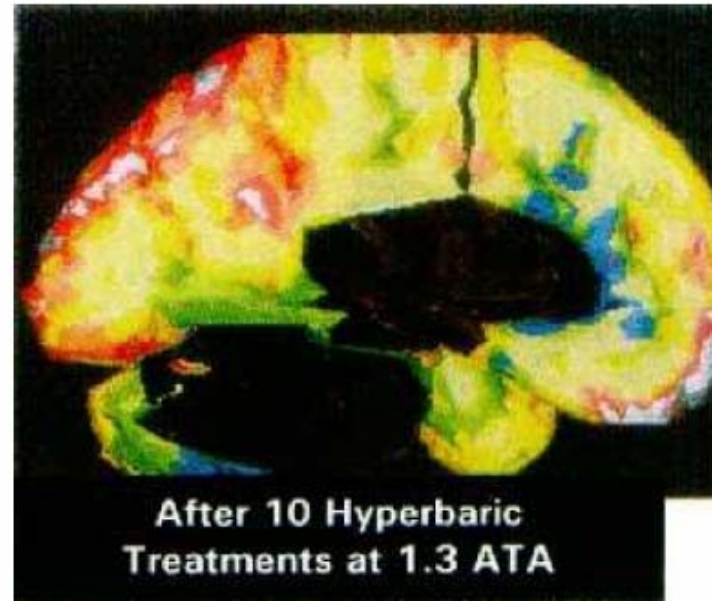


Fig. 5. Proportion of circulating CD34-expressing cells that also express CXCR4 before and after the 1st, 10th, and 20th HBO₂ treatments ($n = 26$ patients). *Repeated-measures one-way ANOVA, $P < 0.05$ vs. the pre-HBO₂ first treatment value.

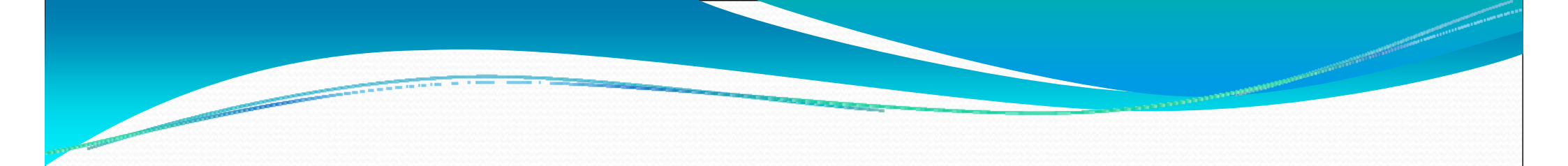
Future looks promising for stem cell therapies in other areas




Before Hyperbaric Treatments



After 10 Hyperbaric
Treatments at 1.3 ATA



HBO may be a major factor in
vascular repair and healing in many
disease states where it is impaired



HBO has a proven record of safety second to none, when compared to biologics and stem cells

Canadian UHMS Chapter offers unique opportunities for research

- Few centers across the country – better referral pattern
- Single payer system (similar patterns of practice)
- Shortage of HBO facilities and waiting lists facilitates patients' participation in placebo controlled trials
- Most facilities are hospital based and not for profit ventures
- Not a single facility can recruit enough patients and carry the financial burden, but together have large catchment pool

Example of states which may respond to HBO and controlled trials are warranted

- Any hypovascular or chronic wound
- Calciphylaxis
- Pyoderma Gangrenosum
- Vascular dementia
- Retinal artery thrombosis
- Studies of using HBO for improved harvesting of progenitor cells from peripheral blood

What needs to be done

- Use UHMS Canada as a communication tool
- Create Research Board of willing participants
- Agree on priorities for research projects (compromise?)
- Write research plan and protocols together / REB approvals
- Conduct a pilot on our own funds to test feasibility of protocols
- Apply to CIHR and other agencies (including specific foundation)
- Use UHMS Canada for raising public and physician awareness.
- Have fun doing it