HYPERBARIC OXYGEN IN THE ACUTE TREATMENT OF SUDDEN IDIOPATHIC SENSORINEURAL HEARING LOSS

A RANDOMISED, PROSPECTIVE STUDY OF HBO AFTER FAILURE OF PREVIOUS MEDICAL TREATMENT

COST Action B14
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COST
European Cooperation in the field of Scientific and Technical Research
FACTS:

- Sudden sensorineural hearing loss ("sudden deafness") is a frequent disease
  - 5 to 20 / 100,000 per year
  - Only in 20% a causal factor can be identified (vascular, viral, traumatic, auto-immune, tumor)

- Sudden deafness is not a banality
  - Bilateral hearing is important for spatial orientation
  - Psychosocial isolation of deaf people
  - Tinnitus is frequent and can be psychologically devastating
FACTS:

- Treating "Sudden Deafness" is frustrating:
  - General consensus: treat early and aggressively
  - Treatments are generally not very successful
  - About 50% of patients spontaneously recover to a functional hearing level
  - No treatment has fully proven its value
    - Spontaneous recovery rate is still controversial
    - Placebo-controlled studies: most medication equivalent to placebo
    - General "shotgun" approach = "give everything"
How to treat a disease without a cause?

- **Vascular**: thrombosis, embolus, bleeding, vasospasm, rheological disturbance?
- **Viral infection**: (echovirus, adenovirus, mumps virus, coxsackie virus)?
- Inner ear trauma?
- Auto-immune disease?
- Retrocochlear tumor?
All treatments aim at improving blood supply to the cochlear inner hair cells.
Improving oxygen supply

Oxygen supply to inner hair cells occurs via diffusion from stria vascularis to endolymph fluid

- Increase blood flow to a. cochleovestibularis
- Increase oxygen content of blood

Hyperbaric Oxygen Therapy?
Hyperbaric Oxygen Therapy

- Respiration of 100% oxygen under pressure (2.5 Atmospheres)
- Increases dissolved oxygen in plasma
- Provides high oxygen pressure gradient for increased diffusion
- Oedema reduction by arteriolar vasoconstriction
- Decreases ischemia-reperfusion effects
Hyperbaric Oxygen Therapy

- Has been sporadically used in this indication for about 20 years
- Use limited by need for pressure chamber
- Few prospective studies (when started early after onset, results often "blurred" by spontaneous recovery)
- Efficacy of about 50% in cases refractory to a classical drug therapy course (Lamm et al. – meta-analysis, 1998)
COST: Cooperation in Science and Technology

- European Commission programme
- To stimulate development of scientific networks in Europe
- Promoting multicentric clinical and experimental research
- In domains with large socio-economical impact
COST B14: Hyperbaric Oxygen Therapy

- HBO Experts from 15 European Countries
- 5 Working Groups on selected clinical research
- Collaboration with independent experts in each research area
- Consensus Protocol for Multicentric Study
- Coordination and monitoring of Study
The COST B14 Sudden Deafness Study

- To establish the clinical efficacy of HBO in the treatment of Sudden Deafness, not responsive to a classical medical treatment. Prospective, randomised, controlled study.
  - Main endpoint:
    - changes in auditory function, as tested by tonal and speech audiometry
  - Secondary endpoints:
    - changes in intensity and pitch of tinnitus, if present
    - changes in feeling of fullness to the ear
    - establishment of the safety of HBO: presence of side effects and complications
The COST B14 Sudden Deafness Study

**Study Setup:**
- Patients will first receive "standard" drug therapy
- "Non-responders" will be randomised to:
  - HBO therapy (10 daily sessions)
  - Placebo therapy (placebo oral medication, 3x/day, 10 days)

**Randomisation:**
- Telephone randomisation service
- Patient and audiologist will be blinded
- Cross-over possible if no result after placebo or HBO
Study outline

- Estimated patient sample = 400 (2x200)
- Duration of study: 3 years
This study is an ENT study!

- Help evaluate a "new" therapeutic modality for Sudden Deafness!
- Give "refractory" Sudden Deafness patients a real chance to improve hearing!
- No pharmaceutical (commercial) interest involved!
- Reasonable workload for each participating ENT specialist.