FIRST EUROPEAN CONSENSUS CONFERENCE ON HYPERBARIC MEDICINE

LILLE , 19 - 21 September 1994

RECOMMENDATIONS OF THE JURY*

The scope of this first European Consensus Conference was to establish an agreement on the situation of Hyperbaric Medicine in Europe in 1994 with regard to the different aspects that characterize a medical discipline: field of application, operational rules and procedures, training of dedicated personnel, effectiveness evaluation, research.

Starting from these points the Jury, with the support of the Conference experts and rapporteurs, was called to formulate recommendations that could answer to the 6 following questions, after each one of them had been discussed and debated during monothematic workshops:

Members of the Jury : E.M. Camporesi, New York (USA), A. Gasparetto, Rome (Italy), M. Goulon, Paris (France), L.J. Greenbaum, Bethesda (USA), E.P. Kindwall, Milwaukee (USA), M.Lamy, Liege (Belgium), D. Linnarsson, Stockholm (Sweden), J.M. Mantz, Starsbourg (France), C. Perret, Lausanne (Switzerland), P. Pietropaoli, Ancona (Italy), H. Takahashi, Nagoya (Japan), C. Voisin, Lille (France).

INTRODUCTION

The use of hyperbaric chambers in intensive care started in Europe more than 30 years ago; the present experience is sufficient to identify those clinical conditions where hyperbaric oxygen (HBO) has a therapeutic interest. Therefore the first scope of the Conference is to confront the obtained clinical results in order to search a consensus in the definition of recognized indications for HBO, according to three levels of priority:

a) Situations where the transport to a hyperbaric facility is strongly recommended because it is recognized that HBO positively affects the prognosis for survival. This implies that the patient is transferred to the nearest hyperbaric facility as soon as possible (type 1 recommendation).

b) Situations where the transport to a hyperbaric facility is recommended because it is recognized that HBO constitutes an important part of the treatment of that given condition, which, even if it may not influence the prognosis for patient's survival, it is nevertheless important for the prevention of serious disorders. This implies that the

transfer to a hyperbaric facility is made, unless this represents a danger to the patient's life (type 2 recommendation).

c) Situations where the transfer to a hyperbaric facility is optional, because HBO is regarded as a additional treatment modality which can improve clinical results (type 3 recommendation)

Establishing a similar list is not an easy task, as in almost the totality of cases, the choice of an indication for treatment is based on clinical experience and not on controlled studies. Is it necessary, in similar conditions, that the validity of a given indication is again put under discussion and that the results of controlled prospective studies are awaited before defining lists of indications for Hyperbaric Oxygen therapy? This Jury does not think that this is appropriate. Clinical experience has an unquestionable value when it is the result of multiple agreeing observations, collected during many years and independently confirmed by different groups. In other words, it seems justified that indications for which there is unanimous consensus of the leading experts are accepted without further evidence.

A criticism to a similar attitude, which can lead to accept a treatment without any formal evidence of its efficacy, is that it can expose the patient to unknown potential damage. But we can answer that the choice of any treatment modality, be it medical or surgical, is always based on a careful evaluation of its risk / benefit ratio as compared to the patient's specific conditions . There are circumstances where clinical experience shows that the benefits of treatment are of such magnitude that the potential side-effects can be considered negligible. Serious carbon monoxide intoxication, for instance, is a condition where it would seem unreasonable to withdraw HBO because of the potential pulmonary oxygen toxicity effects. In situations such as the latter, the choice is simple; but it may be more complicated when the expected advantage is not as evident. In these situations the issue is the objective evaluation of the real interest and usefulness of the treatment modality.

The Jury has attempted to identify those clinical situations for which the efficacy of Hyperbaric Oxygen Therapy is unanimously recognized and where the evidence of beneficial effects of the treatment is such that the treatment should not be ethically denied. In other situations, where sufficient evidence in favour of HBO is not available, it is necessary to start evaluation procedures based on multicentre studies and on clearly defined protocol, as approved by a suitable ethical committee. Only after the completion of such studies will it be possible to accept a new indication.

Professor Claude PERRET - President of the Conference Jury

QUESTION 1: WHICH TREATMENT FOR DIVING DECOMPRESSION ACCIDENTS ?

The primary cause of DCI is the separation of gas in the body tissues (bubbles).

- The best prophylaxis is achieved by adequate ascent/decompression procedures.
- DCI is best classified descriptively.
- On-site 100% oxygen first aid treatment is strongly recommended (Type 1 recommendation).
- On-site fluid administration for the first aid of decompression accidents is recommended (Type 2 recommendation).
- Therapeutic recompression must be initiated as soon as possible (Type 1 recommendation).
- Aside immediate recompression treatment tables which may be used on the site of the accident, the *"low pressure oxygen treatment tables"* are recommended as the treatment tables of first choice (Type 1 recommendation). High pressure oxygen/inert gas tables can be used in selected and/or resistant cases (Type 3 recommendation). Deep, not surface-oriented, mixed gas or saturation diving accidents require special treatment protocol.

Adjunctive pharmacological treatment is controversial but :

- I.V. fluid therapy is recommended (Type 2 recommendation)
- The use of steroids and anticoagulants, although widely adopted without any apparent adverse effect, is considered optional (Type 3 recommendation)

The continuation of a combined Hyperbaric Oxygen Therapy and rehabilitation treatment is recommended until clinical stabilisation or no further improvement is achieved (Type 2 recommendation)

Comments:

The minimal consensus obtained reflects the heterogeneous nature of the different conditions grouped under the definition "Decompression Illness", even if they share the same pathophysiological basis.
It must be remembered that the majority of the scientific papers on the subject refers to military or commercial diving. Considering the treatment results of these accidents, the role of pressure and the importance of the time factor in limiting the delay to recompression are unquestionable and consequently justify the need for hyperbaric chambers on the very site where commercial or military diving is performed.
The recent significant development of recreational diving, notwithstanding the stringent safety rules and procedures, is similarly accompanied by the occurrence of decompression accidents, based on the same pathophysiological mechanisms, but the situation is entirely different with regard to the start of therapeutic recompression procedures, as the interval to recompression is consistently longer, with the consequence that the efficacy of recompression may be compromised and impaired.
As a further consequence the therapeutic procedures are applied at different stages of the same illness, characterized by a multi-factorial evolution.
Thus, a reliable comparative analysis of the therapeutic results become delicate and risky, as it deals with different procedures applied to heterogeneous conditions.
Answering these pending questions will only be possible after further studies conducted with adequately modified approaches

QUESTION 2 : WHICH ACUTE INDICATIONS FOR HYPERBARIC OXYGEN THERAPY ?

1 - General:

- Hyperbaric Facilities accepting emergency indications in potentially Intensive Care requiring patients should be hospital based and located in or immediately near-by the hospital Intensive or Emergency Care Department.
- Technical competence and personal skills at the hyperbaric facility must be adequate and such that any potentiel accident - derangement - problem will not be likely to interfere with the decision to accept an indication for Hyperbaric Oxygen Therapy.
- Hyperbaric Oxygen Therapy must be seen as part of a therapeutical continuum, without any interruption of the chain of treatment. It cannot be considered as an isolated treatment modality.
- Hyperbaric Oxygen Therapy implies the administration of oxygen under pressures not lower than 2 ATA and for times not shorter than 60 minutes.

II - Carbon Monoxide (CO) Intoxication

- Carbon monoxide intoxications must be treated with normobaric oxygen as a first aid treatment (Type 1 recommendation)
- Carbon monoxide intoxications presenting with consciousness alterations, clinical neurological, cardiac, respiratory or psychological signs must be treated with Hyperbaric Oxygen Therapy, whatever the carboxyhemoglobin value may be (Type 1 recommendation)
- Pregnant women must be treated with Hyperbaric Oxygen Therapy, whatever the clinical situation and the carboxyhemoglobin value may be (Type 1 recommendation).
- In minor carbon monoxide intoxication cases there is a choice between normobaric oxygen therapy for at least 12 hours and HBO. Until the results of randomized studies are available HBO remains optional (Type 3 recommendation).

III - Gas Embolism

- Whatever is the symptomology of air embolism, Hyperbaric Oxygen Therapy is strongly recommended, The minimal treatment pressure must not be lower than 3 ATA (Type 1 recommendation)

IV - Anaerobic or mixed bacterial Necrotizing Soft Tissue Infections

- Hyperbaric Oxygen Therapy is strongly recommended in the treatment of anaerobic or mixed bacterial necrotising soft tissue infections (myonecrosis, necrotizing fasciitis, necrotizing cellulitis, etc ...). HBO therapy should be integrated in a treatment protocol comprising adequate surgical and antibiotic therapy (Type 1 recommendation). The sequential order for HBO, antibiotics and surgery is a function of the conditions of the patient, of the surgical possibilities and of hyperbaric oxygen availability.

V - Acute Soft Tissue Ischemia

- HBO is recommended in limb crush trauma and reperfusion post-traumatic syndromes (Type 2 recommendation)
- HBO is optional in post-vascular surgery reperfusion syndromes (Type 3 recommendation)
- HBO is recommended in compromised skin grafts and myo-cutaneous flaps (Type 2 recommendation)
- HBO is optional in the re-implantation of traumatically amputated limbs (Type 3 recommendation)
- In every case the measurement of transcutaneous oxygen pressure is recommended as an index for the definition of the indication and of the evolution of treatment (Type 2 recommendation)

VI - Post-anoxic encephalopathy

- HBO is optional for the treatment of cerebral anoxia (Type 3 recommendation)

VII - Burns

- HBO is strongly recommended when the burn is associated to carbon monoxide intoxication (type 1 recommendation).
- In the absence of a carbon monoxide intoxication, HBO is optional when burns exceed 20% of body surface and are of 2^{nd} degree or more (Type 3 recommendation)
- If burned areas are less than 20% of body surface, HBO therapy is not advised.

VIII - Sudden Deafness

- HBO, together with other treatment measures, such as hemodilution, is recommended in sudden deafness (Type 2 recommendation). However, the respective efficacy of the two treatment modalities is not known at the moment.

IX - Ophthalmological Disorders

- HBO is optional in acute ophthalmologiacal ischemia (type 3 recommendation)

QUESTION 3 : WHICH CHRONIC INDICATIONS NEED HYPERBARIC OXYGEN AS AN ADJUNCTIVE TREATMENT ?

I - Ischemic lesions (ulcers or gangene) without surgically treatable arterial lesions or after vascular surgery:

- In the diabetic patient, the use of HBO is recommended in the presence of a chronic critical ischemia as defined by the European Consensus Conference on Critical Ischemia*, if transcutaneous oxygen pressure readings under hyperbaric conditions (2.5 ATA, 100% Oxygen) are higher than 100 mmhg (Type 2 recommandation)
- In the arteriosclerotic patient the use of HBO is recommended in case of a chronic critical ischemia*, if transcutaneous oxygen pressure readings under hyperbaric conditions (2.5 ATA, 100% Oxygen) are higher than 50 mmhg (Type 2 recommendation)

Chronic Critical Ischemia:
periodical pain, persistent at rest, needing regular analgesic treatment for more than two weeks, or ulceration or gangrene of foot or toes with ankle systolic pressure <50 mmhg in the non-diabetic or toes systolic pressure <30 mmhg in the diabetic (Second European Consensus on Critical Ischemia: Circulation 1991, 84, IV, 1-26)

II - Radionecrotic lesions:

- HBO is strongly recommended in osteoradionecrosis (Type 1 recommendation). The most frequently adopted treatment protocol implies 20 HBO sessions pre-surgery and 10 sessions post-surgery.
- HBO is strongly recommended as a preventive treatment for dental extraction in irradiated or osteonecrotic bone (Type 1 recommendation). The most frequently adopted treatment protocol implies 20 HBO sessions pre-extraction and 10 sessions post-extraction.
- HBO is strongly recommended in soft tissue radionecrosis (Type 1 recommendation), except in radionecrotic lesions of the intestine where HBO has to be considered only as optional (Type 3 recommendation).
- HBO is optional in spinal cord radionecrosis (Type 3 recommendation).

III - <u>Osteomvelitis</u>

- HBO is recommended in chronic refractory osteomyelitis defined as osteomyelitic lesions persisting more than six weeks after adequate antibiotic treatment and at least one surgery (Type 2 recommendation).
- In cranial (except the mandible) and sternal osteomyelitis, HBO should be started simultaneously with antibiotics and surgical treatment (Type 2 recommendation).

IV - <u>Other indications</u>

- Multiple Sclerosis and Pigmentous Retinitis are not recognized indications for Hyperbaric Therapy at the moment, but various research protocole are currently underway.

Comments:

Only the indications generally accepted by the leading representatives of the discipline have been discussed.

Other Consensus Conferences, dedicated to the evaluation of certain particular aspects of the treatment of a disease for which HBO is aiready used or to new indications, seem aiready necessary. In fact the present recommendations should not prejudice the possible extension of the indications for Hyperbaric Oxygen Therapy. For example, chronic ophtalmological disorders, foeto-placentar insufficiencies, certain mycotic and parasital infections, peripheral arteriopathies, certain dermatological disorders, spinal and cerebral contusions are part of the HBO indications for which the evaluation is being currently conducted.

QUESTION 4 : WHICH SAFETY REGULATIONS FOR THE DESIGN AND USE OF MEDICAL HYPERBARIC CHAMBERS AND OF MEDICAL EQUIPMENT FOR HYPERBARIC USE?

I - Minimal Prerequisites for the design of medical hyperbaric chambers and for medical equipment aimed at the emergency or intensive treatment of a patient under hyperbaric conditions :

- Consciousness level disturbances, respiratory insufficiency, hemodynamic instability should not constitute an obstacle to the administration of Hyberbaric Oxygen Therapy (Type 1 recommendation).
- Accepting a patient for hyperbaric treatment, in a situation requiring emergency or intensive care treatment, requires that the following is assured, even under hyperbaric conditions: administration of parenteral perfusion treatment, hemodynamic monitoring and treatment, respiratory monitoring, possibility to assure adequate ventilation to respiratory compromised patients, hyperbaric oxygen effect monitoring, with special regard to transcutaneous oxygen pressure monitoring (Type 1 recommendation).
- In order to minimize the risk of fire, no medical equipment and instrumentation should be used in a hyperbaric chamber unless:
    - it has specifically been designed for this use and its safety has been adequately controlled
    - it has been specifically modified for use under hyperbaric conditions and its safety has been adequately controlled
    - the equipment and instrumentation not specifically adapted for hyperbaric use is kept outside the hyperbaric chamber and only parts of the equipment, such as electrodes and probes, are used inside, with appropriate and safety-controlled trans-hull penetrations to assure electrical connections (Type 1 recommendation).
- Mechanical ventilation under hyperbaric conditions requires special adaptations. No specific ventilator which can assure all the possibly required ventilatory modes and can be considered ideal for hyperbaric use presently exists.

II - Minimal Prerequisites for the design of medical hyperbaric chambers and for medical equipment for the treatment of chronic patients under hyperbaric conditions :

- A minimal monitoring capability, adequate for the conditions of any given patient, is necessary for the administration of Hyperbaric Oxygen Therapy to chronic patients. In particular it is strongly recommended that the principal hemodynamic parameters are non-invasively monitored (Type 1 recommendation).
- Transcutaneous oxygen pressure monitoring, tissue oxygen pressure monitoring, Laser Doppler flow monitoring are presently considered as the most valid monitoring instruments to evaluate the efficacy of hyperbaric oxygen therapy (Type 2 recommendation).

III - Use of Oxygen-pressurized hyperbaric chambers

- Their use is possible, but only if very stringent safety measures are adopted (Type 1 recommendation).

IV - Safety Recommendations to be foreseen at European Union level

- Hyperbaric Chambers are considered as type II b instruments and are subject to directive 93.42CE of 14 June 1993 regarding medical instrumentation (Type 1 recommendation).

V - Safety Regulations must be respected upon designing and using hyperbaric chambers and all medical instrumentation used in hyperbaric chambers :

- Fire is the principal danger in hyperbaric conditions. Every preventive measure must be taken to avoid the risk:
    - the chamber must be built with non-burning materials
    - any greasy or oily materials must be avoided inside the chamber
    - the concentration of oxygen in the chamber must be kept at normal levels (outboard dumping systems, forced ventilation, etc..) (Type 1 recommendation).

- Maximized fire prevention must be adapted to any given case and hyperbaric installation, as no universally valid system exists at the moment.

QUESTION 5 : WHICH INITIAL TRAINING AND WHICH CONTINUING EDUCATION FOR PERSONNEL EMPLOYED IN CLINICAL HYPERBARIC MEDICINE?

- The identity of the physical and physiological phenomena involved in both diving and hyperbaric medicine allows us to strongly recommend that a common training curriculum is designed for medical personnel involved in diving as well as in hyperbaric medicine. In this regard the European Committee for Hyperbaric Medicine and the Medical Sub-Committee of the European Diving Technology Committee are invited to cooperate (Type 1 recommendation).
- The respect of the European Standards concerning the initial training and the continuing education of personnel, contained in the attached document, is strongly recommended (Type 1 recommendation).
- The initial training should be planned in a modular fashion. Initial training of medical doctors should last not less than 200 hours. Certain teaching modules should be the same for diving medicine and hyperbaric medicine students. The first common module concerns safety. Other optional modules should be added as a function of the specific orientation of the course towards diving or hyperbaric medicine. Hyperbaric Medicine candidates may come from different medical specialties, but should undergo a testing stage in hyperbaric medicine before starting the official training. The preparation and discussion of a thesis or paper in hyperbaric medicine is a necessary prerequisite for the completion of the training. The final diploma must be released by an University (Type 1 recommendation).
- The Medical Director of a Hyperbaric Medicine Facility, being responsible for all the activities performed in the Center, should have adequate training in both hyperbaric medicine and enterprise management (Type 2 recommendation).
- It is strongly recommended that the European Committee for Hyperbaric Medicine and the Medical Sub-Committee of the European Diving Technology Committee closely cooperate with the goal to constitute a European Authority to control and validate training in diving and hyperbaric medicine (Type 1 recommendation).
- There should be at least one Training Center for each European linguistic area (Type 1 recommendation).
- The possibility to create a European Baromedical Institute should be considered.

QUESTION 6 : WHICH RESEARCH TO EXPECT AND PLAN FOR THE NEXT FIVE YEAR PERIOD ?

- It is strongly recommended that quality research protocols are put in place to assure and reinforce the credibility of hyperbaric oxygen therapy (Type 1 recommendation).
- It is strongly recommended that doctors operating in hyperbaric centers are trained to basic and clinical research methods (Type 1 recommendation).
- It is strongly recommended that hyperbaric facilities and specialists associate into multidisciplinary teams (Type 1 recommendation).
- It is strongly recommended that information and personnel exchange policies between hyperbaric facilities are implemented (Type 1 recommendation).
- It is strongly recommended that a network of multicentre clinical research is implemented (Type 1 recommendation).
- It is strongly recommended that a structure for coordination and information is created (Type 1 recommendation).
- It is strongly recommended that Reference Centers as well as a European Ethical and Research Commission are constituted, within the European Committee for Hyperbaric Medicine (Type 1 recommendation).

Comments:

The implementation of these recommendations suggest the need to create a European Ethical and Research Commission as well as of a Coordination and Information Structure with the following primary goals:

1. establishment of a directory of centers and teams involved in Hyperbaric Medicine Research
2. establishment of a network of consultants (epidemiologists, methodologists, engineers, etc..)
3. organisation of seminars and workshops dedicated to clinical research training
4. coordination of Reference Centers, after approval of the same by the European Ethical and Research commission (EERC)
5. monitoring and assuring the achievement of the planned goals, as defined by the EERC