● Original Article

Present State of the Art and guidelines for future development of Hyperbaric Medicine in Europe. The Consensus Conference System of the European Committee for Hyperbaric Medicine.

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「高圧医学ヨーロッパ委員会」は，ヨーロッパにおける高圧医学の利用を調整する目的で1989年に設立された。その目的の一つは，高圧医学に関する基礎的な問題について，広範で国際的なコンセンサスを達成する「コンセンサス会議」を組織することである。

高圧チェンバーを集中的治療に使うという方法は，ヨーロッパではもう30年以上前に始まった；これまでの経験では，高圧酸素(HBO)の臨床的有用性を確認するに十分である。「コンセンサス会議」の意図は，HBOの適応についてコンセンサスを得るために，得られた臨床結果を対比することであるが，これは次の三つの優先順位に基づく。

a）高圧施設への搬送が強く推奨される適応で，HBOによる生存の可能性が高いと認められるもの。これには，患者をできるだけ早く最寄りの高圧施設に搬送することも含まれるタイプ1の推奨事項)。

b）高圧施設への搬送が推奨される適応で，HBOは治療の重要部分を構成し，患者生命維持には影響を与えないかもしれないが，重篤な障害を防ぐのには重要であると認められるもの。高圧施設への搬送が患者の生命を危険にさらさない場合に限られている。(タイプ2の推奨事項)

c）高圧施設への搬送が任意である適応で，HBOは補助的な療法と考えられ，治療結果を改善する可能性があるもの。(タイプ3の推奨事項)

The European Committee for Hyperbaric Medicine was founded in 1989 with the scope to harmonize the use of Hyperbaric Medicine in Europe. One of its primary goals is to organize Consensus Conferences aimed at achieving vast and international consensus on basic issues concerning hyperbaric medicine.

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 therapeutical interest. The scope of the Consensus Conference System is to confront the obtained clinical results in order to reach a consensus in the definition of recongnized 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 transeferd 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 constitues 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

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important for the prevention of serious disorders. This implics that the transfer to a Hyperbaric Facility is made, unless this represent 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 always 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. It is not always appropriate nor necessary that, in similar conditions, 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.

Clinical experience has an unquestionable vale 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.

The ECHM Consensus Conference System is aiemd at identifying 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 dcnied. In other situations, where sufficient evidence in favour of HBO is not available, it is neccessary to start evaluation procedures based on multicentric studies and on clearly defined protocols, as approved by a suitable ethical committee. Only after the completion of such will it be possible to accept a new indication.

The ECHM organized the First European Consensus Conference on Hyperbaric Medicine in Lille, on 19-21 September 1994, with the aim to establish an agreement on the situation of Hyperbaric Medicine in Europe with regard to the different aspects that characterize a medical discipline: field of application, opcrational rules and procedures, training of dcdicated personnel, effectiveness evaluation, research.

Six basic questions were posed and an International Jury of Hyperbaric as well as Multidisciplinary Experts were called to evaluate the position papers presented by the most prominent experts is the field of baromedical sciences with the scope to formulate official recommendations.

The six questions posed in Lille were the following:

1. Which Treatment for Decompression Illness?
2. Which Emergency Indications for Hyperbaric Therapy?
3. Which Chronic Indications need Hyperbaric Therapy as an adjunctive treatment?
4. Which Safety Regulations for the design and use of medical hyperbaric chambers and of medical equipment for hyperbaric use?
5. Which initial Training and which Continuing Education for personnel employed in Clinical Hyperbaric Medicine?
6. Which Research to expect and plan for the next five year period?

The Lille Conference was followed by other two dedicated conferences, the first about Decompression Disorders, which was held in Marseille in May 1996 and the second on Crush Injuries and Muscolo-skeletal Trauma, held in Milano in September 1996, which corroborated the initial findings and

recommendations made in Lille.

Following to the above indicated Consensus Conferences, the current State of the Art and General Guidelines for Clinical Hyperbaric Medicine in Europe are the following:

DECOMPRESSION DISORDERS

- On-site 100% oxygen first aid treatment is strongly recommended (Type 1 recommendation).
- On-site fluid administration for the first aid of decompression accidcnts is recommended (Type 2 recommendation).
- Therapeutical 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 recalcitrant cases (Type 3 recommendation). Deep, not surface-oriented, mixed gas or saturation diving require special treatment protocols.
- 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 stabilization or no further amelioration is achieved (Type 2 recommendation).

EMERGENCY INDICATIONS FOR IIYPERBARIC OXYGEN THERAPY

I. 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 potential 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 primary Hyperbaric Oxygen Therapy (Type 1 recommendation).
- Carbon Monoxide Intoxications presenting with consciousness alterations, clinical neurological, cardiac, respiratory or psychologiacl 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 12 hours and HBO. Until the results of randomized studies are available HBO remains optional (Type 3 recommendation).

III. Gas Embolism

- Whichever 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 Necrotising 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 crushing 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 2nd 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. Ophtalmological Disorders

- HBO is optional in acute ophtalmologiacal ichemia (type 3 recommendation).

HYPERBARIC OXYGEN THERAPY IN CHRONIC INDICATIONS

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 Chronic Critical Ischemia as defined by the European Consensus Conference on Critical Ischemia*, if transcutancous oxygen pressure readings under hyperbaric coditions (2.5 ATA, 100% Oxygen) are higher than 100 mmHg (Type 2 recommendation).
- In the arteriosclerotic patient the use of HBO is recommended in case of Chronic Critical Ischemia*, if transcutaneous oxygen pressure readings

under hyperbaric coditions (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 (Sccond European Consensus on Critical Ischemia : Circulation 1991, 84, IV-1-IV-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-cxtraction and 10 sessions post-extraction.
- HBO is strongly recommended in soft tissue radionecrosis (Type 1 recommendation). HBO is optional in radionecrotic lesions of the intestine (Type 3 recommendation).
- HBO is optional in spinal cord radionecrosis (Type 3 recommendation).

III. Osteomyelitis

- HBO is recommended in chronic reftactory 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) ans sternal osteomyelitis, HBO should be started simultaneously with antibiotics and surgical treatment (Type 2 recommendation).

IV. Other indications

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

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 emegency or intensive treatment of a patient under hyperbaric conditions.

- Conscience troubles, respiratory insufficiency, hemodynamic instability should not constitute an abstacle to the administration of Hyperbaric Oxygen Therapy (Type 1 recommendation).
- Accepting a patient for hyperbarc treatment, in a situation requiring emergency or intensive care treatment, requires that the following is assured, even under hyperbaric conditions: administration of parenteral pefusion treatment, hemodynamic monitoring and treatment, respiratory monitoring, possibility to assure adequate ventilation to respiratory compromised patients, hyperbaric oxygen effects 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 connection. (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, intratissutal Oxygen Pressure monitoring, Laser Doppler flow monitoring are presentlt considered as the most valid monitoring instruments to evalate 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.

TRAINING AND EDUCATION POIJCIES 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 trainig 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 shoul be the same for diving medicine and hyperbaric medicine students. The first commn 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 specialities, 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 a 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.
- 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 on Training Center for each european linguistic area (Type 1 recommendation).
- The possibility to create a European Baromedical Institute should be considered.

WHICH RESEARCH TO EXPECT AND PLAN FOR THE FUTURE?

- It is strongly recommended that quality reseach protocols are put in place to assure and reinforce the credibility of hyperbaric ohygen 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 multicentric 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).

REFERENCES

1) Proceedings of the 1st European Consensus Conference on Hyperbaric Medicine. Lille 19-21 September 1994. ECHM and University of Lille School of Medicine, 1994
2) Proceedings of the 2nd European Consensus Conference on the Treatment of Decompression Accidents in Recreational Diving. Marscille 9-11 May 1996. ECHM and University of Lille School of Medicine, 1996
3) Proceedings of the International Joint Meeting on Hyperbaric and Underwater Medicine, ECHM, EUBS, ICHM, DAN, Milano 4-8 September, 1996. ECHM and Istituro Ortopedico Galeazzi, Milano 1996