

# Consensus Conference

## Tenth European Consensus Conference on Hyperbaric Medicine: recommendations for accepted and non-accepted clinical indications and practice of hyperbaric oxygen treatment

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### Abstract

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The tenth European Consensus Conference on Hyperbaric Medicine took place in April 2016, attended by a large delegation of experts from Europe and elsewhere. The focus of the meeting was the revision of the European Committee on Hyperbaric Medicine (ECHM) list of accepted indications for hyperbaric oxygen treatment (HBOT), based on a thorough review of the best available research and evidence-based medicine (EBM). For this scope, the modified GRADE system for evidence analysis, together with the DELPHI system for consensus evaluation, were adopted. The indications for HBOT, including those promulgated by the ECHM previously, were analysed by selected experts, based on an extensive review of the literature and of the available EBM studies. The indications were divided as follows: Type 1, where HBOT is strongly indicated as a primary treatment method, as it is supported by sufficiently strong evidence; Type 2, where HBOT is suggested as it is supported by acceptable levels of evidence; Type 3, where HBOT can be considered as a possible/optional measure, but it is not yet supported by sufficiently strong evidence. For each type, three levels of evidence were considered: A, when the number of randomised controlled trials (RCTs) is considered sufficient; B, when there are some RCTs in favour of the indication and there is ample expert consensus; C, when the conditions do not allow for proper RCTs but there is ample and international expert consensus. For the first time, the conference also issued 'negative' recommendations for those conditions where there is Type 1 evidence that HBOT is not indicated. The conference also gave consensus-agreed recommendations for the standard of practice of HBOT.

### Key words

Medical conditions and problems; Evidence; Systematic review; Symposium; European Committee for Hyperbaric Medicine

### Introduction

The European Committee for Hyperbaric Medicine (ECHM) has in its objectives the continuous improvement in the quality of care and the safety of hyperbaric medicine.<sup>1</sup> One of the tools used to reach this target is the organization of consensus conferences to issue guidelines which could be recognized and accepted as widely as possible. Two such consensus conferences have been organized previously in 1994 and 2004. In 1994, the guidelines were elaborated by a jury from expert reports and discussion with the conference audience.<sup>2</sup> In 2004, the guidelines report was improved in grading the recommendations both by the level of evidence supporting the recommendation and their importance for clinical practice.<sup>3</sup> Twelve years on, it was time to review and update these guidelines based on the advances in medical knowledge and the experience gained in clinical practice during that period. For the 2016 guidelines, ECHM wished to go a step further in reporting not only recommendations with their clinical importance and evidence level, but also how confident the conference audience was in those recommendations. A preliminary report with the short list of indications for hyperbaric oxygen treatment (HBOT)

was published recently.<sup>4</sup> Here, we present the full report, including methodology and detailed recommendations given at the conference. Additional files with literature queries and analysis of published evidence using the GRADE system can be found on the ECHM website ([www.ECHM.org](http://www.ECHM.org)).

### Methodology

Evidence based medicine (EBM) methodology has gained a widespread acceptance and is presently an integral part of modern medical practice. The approach and tools used in EBM involve using scientific evidence to provide answers to specific questions. However in the real world, there are different levels of evidence depending on the source of information and the design of the study (e.g., from case reports to randomised controlled trials RCTs). This results in the concept of a pyramid of evidence with a decreasing chance of bias as the methodological rigour improves moving up the pyramid. For interested readers, we provide a useful reference on EBM.<sup>5</sup>

The process of issuing new recommendations for clinical practice is typically based on three components: 1) the

level of evidence (i.e., the quality of available data;) 2) the interpretation of the evidence (i.e., what the data suggest and how concordant these data are regarding a particular problem) and 3) the type or strength of the recommended practice (i.e., the extent to which a physician is able to recommend a particular intervention on the basis of the first two considerations). This method may be used either by an individual physician or by a group of experts who could be expected to arrive at the same conclusion.

For clinical research, the various levels of evidence are the following:

- Level A: At least two concordant, large, double-blind RCTs with no or little methodological bias;
- Level B: Double-blind RCTs but with methodological flaws, studies with only small samples or one study only;
- Level C: Consensus opinion of experts;
- Level D: Only uncontrolled studies with no consensus opinion of experts;
- Level E: No evidence of beneficial action, or methodological or interpretation bias precluding any conclusion;
- Level F: Procedure not indicated by existing evidence.

Even though the hyperbaric medicine community has made considerable effort to achieve high quality clinical studies, we must recognize that many questions remain with insufficient evidence to give a definite answer. Therefore, it is hardly surprising that, from the current list of clinical indications for HBOT, only a small number of clinical entities in which HBOT is conventionally used is supported by the highest level of evidence. Physicians should remember that clinical decisions are usually based on some level of evidence that is less than absolute proof and that no evidence of a benefit is not the same as evidence of no benefit. In the view of the ECHM, there are some clinical situations in which it is extremely difficult or even virtually impossible to undertake high quality, controlled trials, for example:

- Using HBOT in a particular condition, unsupported by a high level of evidence, is so logical that it has become universally accepted to such an extent that it would be grossly inappropriate to consider omitting it to establish proof of efficacy or even that it would be considered a violation of accepted standards of care to deny a patient the benefit of the therapy for the purpose of a study (e.g., HBOT for decompression illness (DCI) or arterial gas embolism (AGE));
- where the disease or condition of interest is so complex or where there are so many variables that it would be impossible to design a study sufficiently powerful to assess any single procedure (e.g., HBOT and gas gangrene);
- where no current higher level of evidence exists, but experts are able to report, not only from their own experiences but also by producing comprehensive literature reviews from which consensus can

provisionally be reached, pending the outcome of future studies (e.g., HBOT and neuroblastoma).

In such situations, an alternative approach should be sought. In the opinion of the ECHM, the search for a consensus by experts is a way to convert the best evidence available into clinical guidelines.

ECHM consensus conferences aim to create an objective and complete review of the current literature and knowledge on a particular topic or field. This method has the advantage of involving a diverse group of participants from a broad range of relevant backgrounds to provide consideration of all aspects of the chosen topic and maximum objectivity. The opportunity to meet with other experts in the same field and share comments and information is also a valuable aspect of these meetings. At a consensus conference, experts present their reviews of the literature relating to a specific topic before a jury and an audience. Thereafter, the jury gathers in a secluded place to discuss the presentations, and presents its finding in a consensus statement that includes recommendations for clinical practice based on the evidence that was presented. These recommendations are published in one or more medical journals.

The application of EBM methodology to the consensus process helps the jury members to reach a consensus and strengthens the recommendations. Thus, each jury member assesses the literature and the evidence presented by the experts and grades these according to their quality. In the ECHM conferences, each jury member used the same grading scale (from 1 to 4) for the level of evidence as follows:<sup>2,3</sup>

For both basic studies (tissue, cellular or subcellular level) and for animal studies with a control group:

- Level 1: Strong evidence of beneficial action;
- Level 2: Evidence of beneficial action;
- Level 3: Weak evidence of beneficial action;
- Level 4: No evidence of beneficial action or methodological or interpretation bias preclude any conclusion.

For human studies:

- Level 1: Strong evidence of beneficial action based on at least two concordant, large, double-blind, RCTs with no or only weak methodological bias;
- Level 2: Evidence of beneficial action based on double-blind RCTs but with some methodological bias, or concerning only small samples, or only a single study;
- Level 3: Weak evidence of beneficial action based only on uncontrolled studies (historical control group, cohort study);
- Level 4: No evidence of beneficial action (case reports only) or methodological or interpretation bias preclude any conclusion.

Jury conclusions have been made according to the level of supporting evidence (Table 1):

**Table 1**

Consensus-based and GRADE scaling for recommendations; GRADE – Grading of Recommendations Assessment, Development and Evaluation System

<b>Strength of recommendation (consensus-based)</b>	<b>Level of evidence (based on GRADE system)</b>
<p>Level 1 = Strong recommendation = “<i>We recommend...</i>”            The course of action is considered appropriate by the large majority of experts with no major dissension. The panel is confident that the desirable effects of adherence to the recommendation outweigh the undesirable effects.</p>	<p>Grade A = High level of evidence            The true effect lies close to our estimate of the effect.</p>
<p>Level 2 = Weak recommendation = “<i>We suggest...</i>”            The course of action is considered appropriate by the majority of experts but some degree of dissension exists amongst the panel. The desirable effects of adherence to the recommendation probably outweigh the undesirable effects.</p>	<p>Grade B = Moderate level of evidence            The true effect is likely to be close to our estimate of the effect, but there is a possibility that it is substantially different.</p>
<p>Level 3 = Neutral recommendation = “<i>It would be reasonable...</i>”            The course of action could be considered appropriate in the right context.</p>	<p>Grade C = Low level of evidence            The true effect may be substantially different from our estimate of the effect.</p>
<p>No recommendation            No agreement was reached by the group of experts.</p>	<p>Grade D = Very low level of evidence            Our estimate of the effect is just a guess, and it is very likely that the true effect is substantially different from our estimate of the effect.</p>

- Type 1 recommendation, which means “*strongly recommended*”, recommendations or standards are supported by Level 1 evidence;
- Type 2 recommendation, which means just “*recommended*”, recommendations or guidelines are supported by Level 2 evidence;
- Type 3 recommendation, which means “*optional*”, statements are supported only by Level 3 evidence.

During the 2004 ECHM consensus conference, after having listened to the experts and with the assistance of literature reviewers, the jury graded the existing evidence using the scale we have described above (levels from A to F).<sup>3</sup> Conditions where the use of HBOT was supported by level A, B or C evidence were considered as accepted indications. However, in order to make the jury discussion and decision on conditions not considered accepted indications for HBOT more transparent, the levels D, E, and F were also reported with the jury’s evaluation of the existing evidence.

For the 2016 European Consensus Conference, the ECHM decided to adopt the modified GRADE system for evidence analysis,<sup>7,8</sup> together with the DELPHI system for consensus evaluation.<sup>9,10</sup> As for the previous conferences, ECHM asked a panel of experts in each field to prepare reports based on a literature survey, a synthesis of the evidence for each and a proposal for recommendations (Table 1).<sup>6-8</sup>

In order to take into account the changes proposed to improve the quality of guidelines elaboration, we introduce two additional steps:

- All the reports were circulated within the expert group and each expert was asked to weight the clinical importance and the level of evidence each proposed recommendation (Delphi method).

- During the conference, reports and expert opinions were presented and discussed. The audience then voted on each recommendation and the agreement between audience participants was measured and reported. Final consensual recommendations with weighted evidence and audience confidence were then issued.
- We expect that, using such a methodology, every individual reading the conference conclusions will be immediately able to assess the strength of each statement and how it could be applied in their own practice.

## Results

Recommendations on the clinical indications for HBOT have been presented separately for accepted indications (Table 2), non-accepted indications (Table 3) and those conditions in which HBOT is not recommended (Table 4).

### ACCEPTED INDICATIONS

#### *Carbon monoxide (CO) poisoning*

- We recommend HBOT in the treatment of CO poisoning (Type 1 recommendation, Level B evidence).
- We recommend 100% oxygen be applied immediately to any CO poisoned person as a first aid treatment (Type 1 recommendation, Level C evidence).
- We recommend HBOT for every CO poisoned person who presents with altered consciousness alteration, clinical neurological, cardiac, respiratory or psychological signs whatsoever the carboxyhaemoglobin level at the time of hospital admission (Type 1 recommendation, Level B evidence).
- We recommend HBOT in CO-poisoned pregnant women whatever their clinical presentation and

**Table 2**

Recommendations on the indications accepted for HBOT (there was no Level A evidence)

Condition	Level of evidence		Agreement level
	B	C	
<b>Type 1</b>			
CO poisoning	X		Strong agreement
Open fractures with crush injury	X		Strong agreement
Prevention of osteoradionecrosis after dental extraction	X		Strong agreement
Osteoradionecrosis (mandible)	X		Strong agreement
Soft tissue radionecrosis (cystitis, proctitis)	X		Strong agreement
Decompression illness		X	Strong agreement
Gas embolism		X	Strong agreement
Anaerobic or mixed bacterial infections		X	Strong agreement
Sudden deafness	X		Strong agreement
<b>Type 2</b>			
Diabetic foot lesions	X		Strong agreement
Femoral head necrosis	X		Strong agreement
Compromised skin grafts and musculo-cutaneous flaps		X	Strong agreement
Central retinal artery occlusion (CRAO)		X	Strong agreement
Crush Injury without fracture		X	Agreement
Osteoradionecrosis (bones other than mandible)		X	Agreement
Radio-induced lesions of soft tissues (other than cystitis and proctitis)		X	Agreement
Surgery and implant in irradiated tissue (preventive treatment)		X	Agreement
Ischaemic ulcers		X	Agreement
Refractory chronic osteomyelitis		X	Agreement
Burns, 2nd degree more than 20% BSA		X	Agreement
Pneumatosis cystoides intestinalis		X	Agreement
Neuroblastoma, stage IV		X	Agreement
<b>Type 3</b>			
Brain injury (acute and chronic TBI, chronic stroke, post anoxic encephalopathy) in highly selected patients		X	Agreement
Radio-induced lesions of larynx		X	Agreement
Radio-induced lesions of the CNS		X	Agreement
Post-vascular procedure reperfusion syndrome		X	Agreement
Limb replantation		X	Agreement
Selected non-healing wounds secondary to systemic processes		X	Agreement
Sickle cell disease		X	Agreement
Interstitial cystitis		X	Agreement

carboxyhaemoglobin level at hospital admission (Type 1 recommendation, Level B evidence).

- It would be reasonable to treat patients with minor CO poisoning either by 12 hours normobaric oxygen or HBOT (Type 3 recommendation, Level B evidence).
- We do not recommend treating with HBOT asymptomatic patients seen more than 24 hours after the end of CO exposure (Type 1 recommendation, Level C evidence).

*Open fractures with crush injury*

- We recommend HBOT in the treatment of open fractures and/or with crush injury (Type 1 recommendation, Level

B evidence).

- We recommend early application of HBOT following severe open fractures because it can reduce complications such as tissue necrosis and infection. Gustilo 3B and 3C injuries are considered indications for HBOT and less severe injuries should be considered for treatment when host- or injury-related risk factors are present (Type 1 recommendation, Level B evidence).
- We suggest that HBOT may offer benefit in crush injuries with open wounds but without fracture, where tissue viability is at risk or where there is significant risk of infection (Type 2 recommendation, Level C evidence).

- It would be reasonable to provide HBOT for closed crush injuries where tissue viability is clinically judged to be at risk (Type 3 recommendation, Level C evidence).
- It would be reasonable to provide HBOT for closed crush injuries where there is a potential for compartment syndrome, but where compartment syndrome requiring fasciotomy is not established and where it is possible to monitor progress and response to treatment either clinically or via compartment pressure or oxygenation monitoring (Type 3 recommendation, Level C evidence).
- We recommend that HBOT centres treating crush injury should have equipment for transcutaneous oximetry measurement (TCOM) under pressure as this has predictive value in some situations (Type 1 recommendation, Level B evidence).

#### *Radionecrosis or radition-induced lesions*

- We recommend HBOT in the treatment of mandibular osteoradionecrosis (Type 1 recommendation, Level B evidence).
- We recommend HBOT for the prevention of mandibular osteoradionecrosis after dental extraction (Type 1 recommendation, Level B evidence).
- We recommend HBOT in the treatment of haemorrhagic radiation cystitis (Type 1 recommendation, Level B evidence).
- We recommend HBOT in the treatment of radiation proctitis (Type 1 recommendation, Level A evidence).
- We suggest HBOT in the treatment of osteoradionecrosis of other bone than the mandible (Type 2 recommendation, Level C evidence).
- We suggest HBOT for preventing loss of osseointegrated implants in irradiated bone (Type 2 recommendation, Level C evidence).
- We suggest HBOT in the treatment of soft-tissue radionecrosis (other than cystitis and proctitis), in particular in the head and neck area (Type 2 recommendation, Level C evidence).
- It would be reasonable to use HBOT for treating or preventing radio-induced lesions of the larynx (Type 3 recommendation, Level C evidence).
- It would be reasonable to use HBOT in the treatment of radio-induced lesions of the central nervous system (Type 3 recommendation, Level C evidence).

#### *Decompression illness (DCI)*

- We recommend HBOT in the treatment of DCI (Type 1 recommendation, Level C evidence).
- We recommend 100% normobaric oxygen first aid (Type 1 recommendation, Level C evidence).
- We recommend intravenous fluid resuscitation with non-glucose containing crystalloid solutions (Type 1 recommendation, Level C evidence).

- We recommend HBOT/recompression therapy tables (US Navy Treatment Table 6 or helium/oxygen (Heliox) Comex Cx30 or equivalent) for the initial treatment of DCI (Type 1 recommendation, Level C evidence). US Navy Treatment Table 5 can be used as the first recompression schedule for selected mild cases.
- We recommend appropriate HBOT treatment tables for residual manifestations of DCI (Type 1 recommendation, Level C evidence).
- We recommend the use of low-molecular weight heparin for the prophylaxis of deep venous thrombosis for immobile or paralyzed cases of DCI (Type 1 recommendation, Level C evidence).
- We suggest the use of lignocaine (lidocaine) and Heliox recompression tables for serious neurological DCI (Type 2 recommendation, Level C evidence).
- We suggest oral tenoxicam (or similar NSAID) for appropriately selected DCI cases (Type 2 recommendation, Level B evidence).

#### *Gas embolism*

- We recommend HBOT in the treatment of gas embolism (Type 1 recommendation, Level C evidence).
- We recommend the use of HBOT in cases of arterial and venous gas embolism with neurological and/or cardiac manifestations. Even if a short interval (< 6 h) between embolism and hyperbaric treatment is associated with a better outcome, response to hyperbaric treatment with substantial clinical improvement has been observed in many case reports with a longer interval and even in small series of patients after 24 hours or more (Type 1 recommendation, Level B evidence).
- We recommend the immediate administration of 100% oxygen in case of noticed embolism. However, even if the signs/symptoms resolve, because secondary deterioration can occur later, HBOT is still recommended (Type 1 recommendation, Level B evidence).
- We do not recommend high pressure treatment tables (>405 kPa) because of lack of good evidence. Consideration of the use of heliox or nitrox at higher pressure must be undertaken by each unit based on experience and logistic arguments (Type 2 recommendation, Level B evidence).
- We suggest the use of adjunctive therapy for isolated AGE, such as lidocaine (Type 2 recommendation, Level B evidence) aspirin and/or NSAID (Type 3 recommendation, Level C evidence).
- It would be reasonable to use anticoagulants as adjunctive therapy for isolated AGE (Type 3 recommendation, Level C evidence).

#### *Anaerobic and mixed bacterial infections*

- We recommend HBOT in the treatment of anaerobic and mixed bacterial infections (Type 1 recommendation, Level C evidence).

- We recommend HBOT for the treatment of necrotizing soft tissue infections in all locations, particularly perineal gangrene. (Type 1 recommendation, Level C evidence).
- We recommend HBOT be integrated in a treatment protocol combined with immediate and adequate surgery and antibiotics targeting the most probable anaerobic and aerobic involved bacteria (Type 1 recommendation, Level C evidence).
- We recommend HBOT be integrated in the treatment protocol of intra-cranial abscess when one of the following criteria is met: multiple abscesses; abscess in a deep or dominant location; compromised host; contra-indication to surgery, lack of response or further deterioration in spite of standard treatment (Type 1 recommendation, Level C evidence).
- We suggest HBOT be integrated as a second-line measure in the treatment of other anaerobic or mixed anaerobic-aerobic tissue infections such as pleuropulmonary or peritoneal infection (Type 2 recommendation, Level C evidence).

*Sudden deafness (idiopathic sudden sensorineural hearing loss, ISSNHL)*

- We recommend HBOT in the treatment of ISSNHL (Type 1 recommendation, Level B evidence).
- We recommend HBOT combined with medical therapy in patients with acute ISSNHL who present within two weeks of disease onset (Type 1 recommendation, Level B evidence).
- We do not recommend the use of HBOT alone or combined with medical therapy in patients with ISSNHL who present after six months of disease onset (Type 1 recommendation, Level C evidence).
- It would be reasonable to use HBOT as an adjunct to corticosteroids in patients presenting after the first two weeks but not later than one month, particularly, in patients with severe and profound hearing loss (Type 3 recommendation, Level C evidence).

*Delayed wound healing*

- We suggest using HBOT in the treatment of diabetic foot lesions (Type 2 recommendation, Level B evidence).
- We suggest using HBOT in the treatment of ischaemic ulcers (Type 2 recommendation, Level C evidence).
- It would be reasonable to use HBOT in the treatment of selected non-healing wounds secondary to systemic processes (Type 3 recommendation, Level C evidence).
- We recommend HBOT in ischaemic lesions (ulcers or gangrene) without surgically treatable arterial lesions or after vascular surgery:
  - a. In the diabetic patient, the use of HBOT is recommended in the presence of a chronic critical ischaemia as defined by the European Consensus Conference on Critical Ischemia (see note below),

if TCOM readings under hyperbaric conditions (253 kPa, 100% oxygen) are higher than 100 mmHg (Type 1 recommendation, level A evidence).

- b. In the arteriosclerotic patient, HBOT is recommended in case of a chronic critical ischaemia (see note below), if TCOM readings under hyperbaric conditions (253 kPa, 100% oxygen) are higher than 50 mmHg (Type 2 recommendation, Level B evidence).
  - c. Note: Chronic critical ischaemia can be recognised when there is: periodic 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.<sup>11</sup>
  - d. However, despite the strong agreement on the validity of the criteria listed above to properly select patients for HBOT, the jury acknowledges the fact not all hyperbaric centres are able to perform TCOM under hyperbaric conditions (253 kPa, 100% oxygen). Therefore, owing to this limitation, we suggest HBOT in diabetic foot ulcers (grade 3 and above of Wagner classification, stage B, grade 3 and above of University of Texas classification) that have failed to respond to adequate basic wound care after four weeks (Type 2 recommendation, Level B evidence).
- For the same reason as above, it would be reasonable to use HBOT in delayed-healing (chronic), non-diabetic wounds and in recurrent, multiple non-healing wounds due to vasculitis (especially those who have not responded to immunosuppressive therapy) (Type 3 recommendation, Level C evidence).
  - We recommend, as standard of care, that HBOT should always be used as part of a holistic, multidisciplinary, treatment plan with ongoing wound care on a regular basis and not as a stand-alone therapy (Type 1 recommendation, Level B evidence).
  - We recommend that, prior to HBOT, standard wound care has been provided during at least four weeks (including appropriate debridement, vascular screening for significant peripheral arterial disease and/or local wound hypoxia, adequate offloading and infection management) (Type 1 recommendation, Level C evidence).
  - We recommend that, prior to HBOT, vascular screening, including imaging procedures, is undertaken in order to evaluate if any revascularization procedure is indicated (Type 1 recommendation, Level C evidence).
  - We recommend the use of TCOM as the best technique to monitor the local tissue pressure of oxygen and to select patients for HBOT (Type 1 recommendation, Level C evidence).
  - We suggest that the therapeutic dose of HBOT (pressure, time and length of treatment course) should be adapted to patient, type of chronic wound and evolution (Type 2 recommendation, Level C evidence).

- It would be reasonable to consider HBOT as part of a multi-interventional approach in the treatment of chronic calciphylaxis (Type 3 recommendation, Level C evidence).

#### *Compromised skin graft and flap*

- We suggest using HBOT in the treatment of compromised skin graft and flap (Type 2 recommendation, Level C evidence).
- We recommend HBOT in all cases of compromised skin grafts and flaps as soon as possible after the diagnosis of compromised grafts/tissues (Type 1 recommendation, Level B evidence).
- We suggest tissue viability be evaluated by clinical judgement and more objective methods including measurement of TCOM or assessment of capillaries by laser Doppler (Type 1 recommendation, Level B evidence).
- We suggest HBOT at a pressure between 203 and 253 kPa for at least 60 minutes per session (preferably 90–120 min), repeated two or three times in first day, then twice per day or once daily until tissues declared alive or necrotic (Type 2 recommendation, Level C evidence).
- We recommend HBOT be used both pre- and post-operatively in cases where there is an increased risk for compromised skin grafts and flaps, e.g., irradiated or infected wound bed, immuno-compromised patient (Type 1 recommendation, Level C evidence).

#### *Limb replantation*

It would be reasonable to consider HBOT for limb replantation (Type 3 recommendation, Level C evidence).

#### *Post-vascular procedure reperfusion syndrome*

It would be reasonable to consider HBOT for post-vascular procedure reperfusion syndrome (Type 3 recommendation, Level C evidence).

#### *Refractory chronic osteomyelitis*

- We suggest HBOT be used in the treatment in chronic refractory osteomyelitis (Type 2 recommendation, Level C evidence).
- We suggest compromised hosts be identified as, in particular, they may benefit from HBOT (Type 2 recommendation, Level C evidence).
- We suggest HBOT protocol be individualized based on the condition and compliance of the patient (Type 2 recommendation, Level C evidence).
- We recommend the effects of HBOT be evaluated repeatedly during and after treatment using the same diagnostic methods as used pre HBOT. HBOT treatment should last at least 11–12 weeks, approx. 60 sessions,

before any significant clinical effect should be expected. (Type 1 recommendation, Level C evidence).

#### *Femoral head necrosis (FHN)*

- We suggest HBOT be used in the treatment of the initial stage of FHN (Type 2 recommendation, Level B evidence).
- We suggest daily treatment of  $\geq 60$  min, 100% oxygen, 5–6 days a week, and 4–5 weeks per cycle, at 243–253 kPa, at the initial stage of FHN (Type 2 recommendation, Level B evidence).
- We suggest scheduling MRI and orthopaedic clinical evaluation at 3–4 weeks from the end of the HBOT cycle (Type 2 recommendation, Level C evidence).
- We do not recommend HBOT be used as an isolated treatment but be integrated in a multidisciplinary protocol including minimizing weight-bearing, weight reduction, physiotherapy where applicable and smoking cessation through the HBOT course (Type 1 recommendation, Level C evidence).

#### *Burns*

- We suggest HBOT be used in the treatment of second degree burns  $>20\%$  body surface area (BSA) (Type 2 recommendation, Level C evidence).
- We recommend that only highly specialised HBOT centres, in the immediate vicinity of a burns centre, treat burns as an adjunct to classical burns care, taking care of optimal monitoring and fluid management. (Type 1 recommendation, Level C evidence).
- We suggest that the most benefit is obtained in severe scald burns patients ( $>20\%$  BSA), with a large proportion of partial-thickness burns (Type 2 recommendation, Level C evidence).
- We suggest that burns to the face (ear, nose), neck, hands and fingers and perineum may benefit even if the total surface burned is  $<20\%$  (Type 2 recommendation, Level C evidence).
- We suggest that HBOT be initiated within six (at the most eight) hours after the burn injury, and that two sessions per day (at 253 kPa, 100% oxygen) be given for a minimum of three days (Type 2 recommendation, Level C evidence).

#### *Central retinal artery occlusion (CRAO)*

- We suggest considering HBOT for patients suffering from CRAO, to be applied as soon as possible (Type 2 recommendation, Level C evidence).

#### *Pneumatosis cystoides intestinalis*

- We suggest HBOT in the treatment of pneumatosis cystoides intestinalis (Type 2 recommendation, Level C evidence).

**Table 3**

Recommendations on the non-accepted indications for HBOT; all have only Level D evidence

Condition	Level of evidence			Agreement
	A	B	C	
Post sternotomy mediastinitis		X		Agreement
Malignant otitis externa		X		Agreement
Acute myocardial infarction		X		Agreement
Retinitis pigmentosa		X		Agreement
Facial (Bell's) palsy		X		Agreement

**Table 4**

Recommendations on those indications for which HBOT should not be used; no Level A evidence

Condition	Level of evidence			Agreement
	A	B	C	
Autism spectrum disorders		X		Agreement
Placental insufficiency			X	Agreement
Multiple sclerosis		X		Agreement
Cerebral palsy		X		Agreement
Tinnitus		X		Agreement
Acute phase of stroke			X	Agreement

*Sickle cell disease*

- It would be reasonable to consider HBOT as a second-line treatment in sickle cell disease crisis in addition to opioids (Type 3 recommendation, Level C evidence).
- It would be reasonable to consider HBOT as an adjunct to standard wound care in patient with non-healing skin ulcer due to sickle cell disease (Type 3 recommendation, Level C evidence).

*Interstitial cystitis*

- It would be reasonable to consider HBOT for interstitial cystitis (Type 3 recommendation, Level C evidence).

*Brain injury in highly selected patients*

- It would be reasonable to consider HBOT in acute moderate-severe traumatic brain injury (TBI) patients and in a highly selected group of patients with chronic TBI who have clear evidence of metabolically dysfunctional brain region(s) (Type 3 recommendation, Level B evidence).
- We recommend HBOT use in TBI to be used only in the context of an investigational study protocol approved by an ethics committee and performed according to clinical research good practice (Type 1 recommendation).
- We do not recommend HBOT use in the acute phase of stroke (Type 1 recommendation, Level C evidence).

- It would be reasonable to consider HBOT in the frame of an investigational clinical study in a highly selected group of patients with chronic stroke who have clear evidence of metabolically dysfunctional brain regions that are mismatching with the necrotic brain regions (Type 3 recommendation, Level C evidence).
- It would be reasonable to use HBOT as an adjunctive measure in the treatment of post anoxic encephalopathy after near hanging (Type 3 recommendation, Level C evidence).

*Neuroblastoma*

- We suggest HBOT in the treatment of neuroblastoma stage IV (Type 2 recommendation, Level C evidence).

NON-ACCEPTED INDICATIONS (TABLE 3)

Owing to very low levels of evidence (Grade D), no specific recommendations on HBOT are given for the following clinical conditions:

- Post sternotomy mediastinitis
- Malignant otitis externa
- Acute myocardial infarction
- Retinitis pigmentosa
- Facial (Bell's) palsy

CONDITIONS FOR WHICH HBOT IS NOT INDICATED (TYPE 1 INDICATION, TABLE 4)

Evidence of lack of clinical effect of HBOT allows Type 1 recommendations to be given for not using HBOT in:

- Autism spectrum disorders (Type 1 recommendation, Level B evidence)
- Placental insufficiency (Type 1 recommendation, Level C evidence)
- Multiple sclerosis (Type 1 recommendation, Level B evidence)
- Cerebral palsy (Type 1 recommendation, Level B evidence)
- Tinnitus (Type 1 recommendation, Level B evidence)
- Acute phase of stroke (Type 1 recommendation, Level C evidence).

PRACTICE OF HYPERBARIC OXYGEN TREATMENT

- We recommend that all European hyperbaric facilities comply as a minimum with the European Code of Good Practice and this ECHM list of clinical indications for HBOT as the basis for accreditation processes and national reimbursement policies.
- We recommend conditions in which HBOT is considered not to be indicated are discussed in a benefit/risk balance for each specific patient before using HBOT.
- We recommend medical education and training of hyperbaric centre medical staff comply with the standards developed and mutually agreed by ECHM and

- the European Diving Technology Committee (EDTC).
- We recommend education and training of hyperbaric centre non-medical staff comply with the standards developed by the European Baromedical Association for nurses, operators and technicians (EBAss) and agreed by ECHM.
  - We recommend physicians involved in hyperbaric centres are trained and participate in clinical as well as basic research.
  - We recommend the hyperbaric community at large increases its participation in the research effort in order to improve the level of evidence supporting the ECHM recommendations.

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