Lille 2016

ECHM consensus conference

The European Committee for Hyperbaric Medicine (ECHM) is geared at promoting the continuous improvement of the quality of care and safety in hyperbaric medicine. One of the tools used to reach this target is the organization of consensus conferences to issue widely accepted guidelines. Up to now, nine such conferences have taken place, issuing recommendations which have reached a large audience.

Two of these consensus conferences were especially focused on the organization, indications and quality of care in Hyperbaric Medicine and took place in 1994 and 2004. Ten years after the last one, it is now time to review and update these guidelines according to the advances in medical knowledge and the experience gained in clinical practice during the intervening years.

The 1994 guidelines were defined by a jury from expert reports and discussion with the conference audience. In 2004, report of the guidelines was improved by grading the recommendations both by the level of evidence supporting the recommendation and the importance for practice of the said recommendation. This time, ECHM wishes to take the process one step further by reporting recommendations not only with their confidence level but also by the evidence supporting the recommendation and by the actual audience's levels of confidence in the said recommendations.

1. EBM methodology and hyperbaric medicine

Evidence Based Medicine (EBM) methodology has gained widespread acceptance and is now an integral part of modern medical practice. The approach and tools used in EBM involve using double-blind randomized prospective controlled clinical studies to provide answers to specific questions, grading rather than providing a general estimation of results to conclude clinical

studies and finally collecting results into a meta-analysis to smooth variations between studies.

Research is usually focused on 3 directions :

1- levels of evidence (i.e. the quality of available data)

2- interpretation of the evidence (i.e. what the data suggests and the level of agreement of the data regarding a particular problem)

3- type or strength of the recommended practice (i.e. the extent to which a physician is able to recommend a particular procedure 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 reach the same conclusions.

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

Level A : at least 2 concordant, large, double-blind, controlled randomized studies with no or little methodological bias

Level B : double-blind controlled, randomized studies but with some 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 any existing evidence

Unfortunately, this method only provides clinically useful recommendations when high quality randomized controlled clinical studies have been carried out. Where no such data is available, as in the field of HBOT, no firm recommendations (level A or B) can be issued and physicians are left without any guidelines. In those cases, the search for a consensus within experts is the method most widely chosen. The expert consensus method is considered the best surrogate to EBM methods to assess procedures under the following circumstances :

1- where a particular procedure, unsupported by a high level of evidence, has become universally accepted to such an extent that it would be considered a violation of accepted standards of care to deny a patient the benefit of the said therapy for the purpose of a study

2- 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 able to assess any single procedure
3- where providing the said therapy is so appropriate that it would be grossly inappropriate to consider withholding it in order to establish proof of effectiveness
4- where there is currently no higher level of evidence, but experts are able to report, not only from their own experience but also by producing comprehensive literature reviews from which consensus can provisionally be reached, pending the outcome of future studies.

Even if an enormous effort has been made by the hyperbaric medicine community in order to achieve a high quality in clinical studies, we have to admit that in our field, many questions lack the evidence required for definite answers to be available. It is therefore hardly surprising to note that to this day, only a small proportion of therapy procedures conventionally used in hyperbaric medicine is supported by the highest level of evidence. Each therapy has its own imperatives. Physicians should remember that where therapy is concerned, clinical decision-making is usually based on the existence of evidence, rather than on the level of evidence required for establishing proof. No evidence of a benefit is not the same as evidence of no benefit. Finally, there is a hierarchy in levels of evidence : from the evidence which is strong enough to support clinical decision-making, through to the highest level, where evidence is supported by many extensive clinical studies. A number of pathologies for which HBOT is indicated have not undergone the stringent scrutiny of double-blind randomized prospective controlled clinical study but the considerable amount of available data in favour of the use of HBOT for these pathologies justifies their choice as indications. Obviously the results of current or future research can alter the current list of indications. Lastly the actual conception of clinical studies is essential to assess the effectiveness of therapy such as HBOT, all the more so when ethical considerations further complicate the issue. Here clostridial myonecrosis is a significant example. There are no double-blind randomized prospective controlled clinical studies with human subjects in this field but the scientific and medical community does agree, in view of the microbiology, animal experimentation and considerable clinical experience, that HBOT has transformed the vital and functional prognosis of this terrible gangrene disease –

so much so that such a study would now be considered pointless, dangerous and in contradiction with medical ethics.

2. Methodology of the ECHM consensus conferences

Consensus conferences aim to create an objective and complete review of current literature and knowledge on a particular topic or field. This method has the advantage of involving a varied group of experts, thus increasing objectivity. Participants in consensus conferences are selected from a broad range of relevant backgrounds to make sure every aspect of the chosen topic is taken into consideration and ensure maximum objectivity. The opportunity to meet with other experts in the same field and share comments and information is also a valuable aspect of consensus meetings.

In a consensus conference, experts present their review of the literature relating to a specific topic before a jury and an audience. Thereafter, the jury meets in private to discuss the presentations, and presents its findings in a consensus statement that includes recommendations for clinical practice based on the evidence presented. These recommendations are published in one or several medical journal(s).

Using Evidence-Based Medicine methodology for consensus conferences helps jury members to reach an agreement and gives greater strength to the recommendations issued. Thus, each jury member assesses the literature and the evidence presented by the experts and grades them according to their quality.

In the ECHM consensus conferences, all jury members use the same widely approved grading scale.

Basic studies (tissular, cellular or subcellular level)

1. Strong evidence of beneficial action
2. Evidence of beneficial action
3. Weak evidence of beneficial action
4. No evidence of beneficial action or methodological or interpretation bias precluding any conclusion

Animal studies with control group

1. Strong evidence of beneficial action
2. Evidence of beneficial action
3. Weak evidence of beneficial action
4. No evidence of beneficial action or methodological or interpretation bias precluding any conclusion

Human studies

1. Strong evidence of beneficial action based on at least 2 concordant, large, double-blind, controlled randomised studies with no or only weak methodological bias.
2. Evidence of beneficial action based on double-blind controlled, randomised studies but with some methodological bias, or concerning only small sample, or one study only.
3. Weak evidence of beneficial action based only on uncontrolled studies: (historic control group, cohort study,...)
4. No evidence of beneficial action (case report only) or methodological or interpretation bias precluding any conclusion.

Jury conclusions are made according to the level of supporting evidence :

Type I : Strongly recommended - Recommendations or Standards are supported by level 1 evidence
Type II : Recommended - Recommendations or guidelines are supported by level 2 evidence
Type III : Optional - Statements are supported only by level 3 evidence

During the last consensus conference (Lille, December 2004), for instance, after having listened to the experts and with the support of literature reviewers, the jury graded the existing evidence using the scale we have defined here. 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's discussions and decisions on conditions not considered as accepted

indications for HBOT more transparent, reports were also provided for levels D, E, and F with the jury's assessments of the existing evidence.

3. 2016 ECHM consensus conference methodology

As for the previous consensus conferences, ECHM have asked a panel of well recognized experts in each field to provide reports based on an exhaustive survey of the available literature, present a synthesis of the evidence and a proposal for recommendations (Table 1).

However, in order to take into account the changes proposed to improve the quality of the guidelines provided for this work, we are adding 2 new stages to our methodology :

- all the reports have been circulated between experts and each one has been asked to assess the clinical importance and evidence level of each proposed recommendation (Delphi method)
- during the conference, reports and expert opinions will be presented and discussed. The audience will then vote on each recommendation and the agreement between audience participants will be measured and reported. Final consensual recommendations with weighted evidence and audience confidence will then be issued.

We expect the use of this methodology to make every individual reading the conference conclusions to be able to make an immediate assessment of the strength of each statement and how it may be applied within his own practice.

Strength of Recommendation (Consensus-Based)	Level of Evidence (Based on Grading of Recommendations Assessment, Development and Evaluation System)
Level 1 = Strong recommendation = "We recommend…"	Grade A = High level of evidence
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	The true effect lies close to our estimate of the effect
Level 2 = Weak recommendation = "We suggest…"	Grade B = Moderate level of evidence
The course of action is considered appropriate by the majority of experts but some degree of dissensionexistsamongst the panel. The desirable effects of adherence to the recommendation probably outweigh the undesirable effects	The true effect is likely to be close to our estimate of the effect, but there is a possibility that it is substantially different
Level 3 = Neutral recommendation = "It would be reasonable…"	Grade C = Low level of evidence
The course of action could be considered appropriate in the right context	The true effect may be substantially different from our estimate of the effect
No recommendation	Grade D = Very low level of evidence
No agreement was reached by the group of experts	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

Table 1 : Consensus basis and GRADE scaling for recommendations