

Helsinki of 1964 with its different amendments was created by the World Medical Association to regulate medical research involving human subjects. As of May 1st, 2004, the clinical trial directive 2001/20/EC makes compliance with the ICH-GCP guidelines (International Conference for Harmonization - Good Clinical Practice) obligatory for EU-member states. The advice of independent Ethics Committees (IEC) helps in balancing the benefit /risk assessment for the patient. Western ethical rules demand strict observation of the basic principles of human rights and dignity when applying modern technology for medical purposes. Randomized control clinical trials producing the highest quality of evidence are increasingly influencing medical practice. The quality of evidence depends on properly designed, executed, interpreted and published trials. Studies can suffer from various forms of bias undermining internal validity. The results of trials comparing patient groups in order to identify and quantify causal associations are valid for the patient population investigated thus determining external validity. Review articles, editorials, meta-analyses, consensus statements and guidelines can be helpful for interpreting trial data, however all are vulnerable to publication bias. Underreporting of negative results, non-publication of unwanted results and unprofessional citation practices have all been recognized as factors distorting evidence. An obligatory register for all clinical trials has been advocated repeatedly in order to counteract publication bias. An EU register for clinical trials is in preparation but will only be accessible to regulatory authorities. Public perception can introduce another source of bias; emergency research, research in children and research in patient not able to consent is still widely afflicted by these negative attitudes. Conflicts of interest have surfaced as another disturbing influence. Financial conflicts of interest have recently prompted regulatory and political action. And last but not least, a less recognized conflict of interest is medical research conducted in poor countries for the primary benefit of wealthier regions thereby violating basic ethical and scientific principles. Cases of scientific fraud and misconduct have been addressed by several leading medical journals. It is up to the medical community to face the challenges of bias, conflicts of interest and fraud. Ethics committees and professional societies have to contribute to the process of promoting scientific integrity and true professionalism. Recognizing and rejecting biased evidence will dry up its sources and pave the way for unbiased and soundly based evidence in medicine. Evidence-based Medicine in its last consequence can only achieve its true aim, i.e. the best available treatment for individual patients, through judicious application of evidence based knowledge together with experience based medicine by experienced physicians. This will preserve the value of experience-based medicine rooting in thousands of years of caring for the health needs of human beings.

Hyperbaric oxygenation therapy. An effective approach to special neurologic disorders

SS3-1

Introduction

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Dr Henshaw, a British physician, performed in 1664 the first therapeutic attempts with a pressure chamber. His pressure chamber was operated by a pair of bellows. Only two centuries after the first attempt, the pressure chamber therapy was taken up in France and later in the USA it reached its climax in the early twenties of the last century, with the largest pressure chamber constructed by Cunningham. This giant project consisted of a six storied-building, where each level held 12 beds, but it never came in function. Priestly discovered oxygen in 1775. In 1789 Lavoiser and Seguin distributed the idea of toxic properties of oxygen, which refrained the therapeutic purposes. The Draeger manufactory developed 1917 a system of hyperbaric oxygenation for treating diving accident victims, but the apparatus was never built. Behnke and Shaw used the system of hyperbaric oxygenation for treatment of decompression disease in 1937. The Dutch physician Dr Boerema is considered as the father of modern hyperbaric medicine. In the 1950s he was the first to perform cardiac surgery under hypothermia and HBO with elongated asyctic periods. In animal experiments he could show that with the help of HBO organ functions of pigs could be sustained without blood supply. In 1965 Ingvar and Larsen were the first using the HBO method for treatment of ischemic stroke. In the last 8 years hyperbaric oxygenation from the field of neurology has drawn varying degrees of attention. An explanation could be the non-selected indication for treatment of neurological diseases, the absence of neurologists in the HBO-centers and the occurrence of some accidents within the pressure chamber system in the past. But in the last few years neurology has rediscovered hyperbaric oxygenation. Undoubtedly the standard indication for HBO is decompression therapy of diving accident victims with commonly neurological complications. In various HBO-centers first experiences with HBO as basic therapy for acute and chronic neurological conditions, as well as part of multi component treatment were gained. First therapeutic results are presented for traumatic brain injury of moderate severity and for acute stroke. In chronic neurological conditions like in state after anoxic accidents and in cerebral palsy positive therapeutic results are published. It is progress, that neurology is considering HBO in therapy in acute as well as in chronic neurological conditions. The explanations of HBO in acute states of brain damage is the interaction in the metabolism of partly damaged brain cells under the principle that oxygen under pressure is supporting the functions even without blood supply, in chronic neurological conditions with HBO the dendrite system seems to be activated.

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HBO in cerebral hypoxic lesions caused by cerebrovascular obstruction: Experimental and clinical investigations

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Background: A cerebral energy crisis resulting from thromboembolic events and/or obstructive vessel disease needs therapeutic intervention to reduce secondary damage of brain tissue, especially so called 'penumbra'-regions. Increased

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