

## TCCS IN ACUTE ISCHEMIC STROKE

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Rapid neuroimaging is crucial to an emergency approach to stroke. After diagnosis ischemic stroke there is a need of quick baseline information about hemodynamic changes in brain circulation and stroke etiology including information about occlusion or stenosis of cerebral extra- and/or intracranial arteries and state of collateral flow. For non invasive diagnosis computed tomography (CTA), magnetic resonance angiography (MRA), transcranial Doppler (TCD) and transcranial color coded sonography (TCCS) can be used in acute stroke settings. Each of these modalities has its advantages and limitations. TCCS provides assessment of real time, angle corrected velocity of the flow and direction of flow in main cerebral arteries. In compare with TCD it more precisely diagnoses the place of stenosis, occlusion and collateral flow. It helps in distinguishing hyperperfusion, collateral flow and tortuosity of the vessels. It can be performed bed side, without delaying treatment and it is an ideal method for bed side follow up stroke patients especially to assess reperfusion or reocclusion of the arteries. The lack of sufficient acoustic bone window (15 - 20% cases) is a main limitation of TCCS. It can be partially overcome by using contrast agent. TCCS needs also a trained sonographer and cannot visualize more distal branches of main arteries of the brain.

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### ETHICS IN MODERN CLINICAL RESEARCH

Franz Gerstenbrand

Ethics constitutes altruism, sense of honour, justness, respect for others, solidarity and ability to forgive. Ethics is the part of philosophy dealing with morality. Moral is the search for inner standard. According to Kant the individual should act in a way that his actions can be regarded as a general law, which is the basis of the relation of the individual to a higher order. In the past century the term „moral“ has been replaced by the term „ethics“. Ethical thinking began with the philosophy of Socrates and Plato. Through Aristotle ethics became a science. The Christian ethics was developed by Thomas Aquinas. In the past century various schools arose from regional interpretation (existentialist ethics France, value ethics Germany, American Bioethics, Marxist ethics of the Sowjet way etc.).

Formal ethics is based on metaphysical principles, catholic-theology ethics focuses on the belief in a personal good. Ethical standards are dependent upon the biological surroundings.

Bioethical principles are practised in various forms of medical conduct and physician's obligation as well as in medical research involving human subjects. The principles of biomedical ethics have been developed in order to regulate medical ethical behaviour and were laid down in the Helsinki Declaration 1964 by the World Medical Association. Amendments were effected in several revisions, the last one in Edinburgh, October 2000. The Helsinki principles were thought as a self-controlling of „medical conduct in the treatment of sick persons and research on human beings for the development of better medical procedures“. The use of new medications and the study of this effects on the ill is adapted in the rules of Good Clinical Practice – European Union (EU-GCP), regulated in an extensive paper since 1 June 1991.

Nowadays every clinical trial with experiments on human subjects, every new therapeutic method, the use of new devices and instruments and development in diagnostic methods have to applicate at the local ethics committee. In intensive and detailed discussions the committee has to decide if arguments are against the designed of the project. In a written document the applicant has to be informed. No renowned journal will accept a manuscript dealing with results of clinical trials or new treatment without the proof of ethical committee.

Neuroethics as a new institution in the wide spread field of neurosciences has to deal with different problems such as brain death, end of life decision, allocation of resources, but also with teaching in preand postgraduate programs.

for Neurological Sciences and Continuing Education

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### ETHICS OF CLINICAL TRIALS

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Clinical trials have become important instruments to advance medical knowledge and fulfill regulatory requirements. The randomized controlled trial – the current golden standard – compares the effect of interventions in groups of patients to obtain reliable and generalizable evidence. The trial subject carries the risk hoping for individual or collective medical benefit. Voluntary informed consent is the ethical precondition for participation.

A complex act of prediction is the ethical basis of every comparative interventional trial: balancing the promising but unproven benefits of something new with its associated risks against the established benefits and risks of something known. Only if there is uncertainty (equipose) regarding the comparative advantages of either intervention can a patient be asked to enter into a trial. However, due to cultural differences this ethical principle translates quite differently into research practice with Europeans favouring the uncertainty principle or individual equipose, the US favoring clinical equipose or collective professional uncertainty.

The ethics of clinical research in Europe should be based on national law and should respect the European core values (human rights and dignity) of the Biomedicine Convention of the Council of Europe – representing 42 member states. Moreover, the Declaration of Helsinki has offered ethical guidance to the medical community for decades – and continues to do so.

Today, everyone involved has to contribute to high ethical standards:

- trial subjects: voluntary informed consent, compliance with trial protocol;
- investigators: scientifically valid research protocols; compliance with national laws and international rules; professional and ethical competence;
- research ethics committees: independent and competent assessment of the research protocol and its intended execution at the trial site;
- industry: adherence to scientific, ethical, legal standards/responsibilities;
- state authorities: professional oversight according to the law;
- patient advocacy groups: assurance, support and control.

The current economic divide of our continent is a challenge for the development of common ethical standards for clinical trials in Europe.

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### HYPERBARIC MEDICINE

Franz Gerstenbrand

Dr. Henshaw performed in 1964 the first therapeutic attempts with a pressure chamber using air with a pair of bellows. Two centuries later the idea of pressure chamber therapy was taken up in France and in the USA. In the 1920ies Dr. Orval Cunningham designed the giant project of a pressure chamber of a six-story building with twelve beds on every floor.

Priestly discovered oxygen in 1775. Lavoiser and Seguin (1789) thought it to be toxic, therefore it was hardly used for therapeutic purposes. Dräger planned the first system of HBO for diving accidents, but it was never built. For the treatment of decompression disease Behnke and Shaw used HBO in 1937. The father of modern hyperbaric medicine is considered to be Dr. Boeroma. In 1950 HBO was used in cardiac surgery. Ingvar and Lassen (1965) treated patients with ischemic stroke.

In various medical centres, experiences with high-pressure oxygenation as sole treatment as well as part of a combination of multi-component therapies are known. The first therapeutic results in traumatic and anoxic acute brain injuries of varying degrees of severity have been published. Hyperbaric oxygenation therapy has yielded encouraging results in children with cerebral palsy of different aetiologies.

The effectiveness of oxygen pressure therapy in local and regional acute brain lesions may be explained by considering increased oxygen supply for partly damaged brain tissue. In chronic brain lesions the HBO induces the formation of new ganglion cell networks. Thus, it has not only a functional but also a structural influence, which is as step from neurorehabilitation towards restorative neurology. HBO should be applied as early as possible before secondary changes have occurred.

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