Therapeutic Hypothermia after Resuscitation from Cardiac Arrest

SBU ALERT REPORT NO 2006-02 • 2006-02-15 • WWW.SBU.SE/ALERT

Summary and Conclusions

TECHNOLOGY AND TARGET GROUP: Sudden cardiac arrest is not uncommon as a complication of coronary heart disease (ischemic heart disease). Most cases of cardiac arrest occur out-of-hospital. In Sweden, approximately 10 000 people per year experience cardiac arrest. Treatment outcomes among this patient group have not improved substantially in the past 20 years. Only 4% of those affected are discharged alive from the hospital following cardiopulmonary resuscitation and treatment. The outcome of treatment depends partly on the time that has elapsed between cardiac arrest and the reestablishment of stable circulation. Most patients who are resuscitated from cardiac arrest are unconscious and require care at an intensive care unit. Lowering the body temperature (induced hypothermia) after resuscitation from cardiac arrest is a treatment method intended to limit the damage, mainly to the brain, that occurs when blood circulation ceases. Body temperature is lowered to 32–34 degrees, which usually requires sedation of the patient, administration of muscle relaxants, and the subsequent use of ventilator treatment. In Sweden, an estimated 1300 people per year are admitted to hospital alive following resuscitation from cardiac arrest. The potential target group for therapeutic hypothermia includes people who are unconscious after resuscitation from cardiac arrest and whose condition would suggest a risk for tissue damage due to oxygen deficiency. Most would be patients with coronary heart disease. Criteria have not been established for selecting patients for therapeutic hypothermia, so the size of the potential target group for this treatment method cannot be estimated.

PRIMARY QUESTION: This assessment is based on a systematic literature review. The question is whether treatment that lowers the body temperature by 3 to 5 degrees after resuscitation from cardiac arrest can increase the chance for survival or reduce the risk for permanent functional impairment.

PATIENT BENEFIT: Two randomized controlled clinical trials have assessed the effects of hypothermia after resuscitation from cardiac arrest. Survival and neurological function were used as outcome measures. One of the studies found an association between hypothermia and improvements in survival and neurological function. The second study showed that patients in the therapeutic hypothermia group could be discharged to a lower care level than the patients in the control group. Regarding study quality and relevance, the first study was rated high and the second study was rated low. Regarding complications or side effects, no significant differences were reported between the study and control groups.

ETHICAL ASPECTS: The most important ethical question concerns the fact that the method has not been adequately assessed. Even if the method appears to have a positive effect it must be thoroughly assessed so the benefits from the healthcare resources consumed can be appropriately weighed against the benefits of providing care for other patient groups.

ECONOMIC ASPECTS: The costs for therapeutic hypothermia consist partly of investment and operational costs for hypothermia equipment and partly of staff costs for the extra 1 to 2 days of intensive care associated with treatment. During therapeutic hypothermia, the patient must be placed on a ventilator. The cost effectiveness of treatment cannot be calculated since the effects of treatment are uncertain.

SBU's appraisal of the evidence

The scientific evidence is insufficient* to show that treatment with induced hypothermia after resuscitation from cardiac arrest improves survival or lowers the risk for permanent functional impairment. Although the scientific evidence is too weak to support reliable conclusions, the method appears to be promising and potentially may be of clinical importance. However, it is essential to continue testing this method in Sweden under scientifically acceptable conditions so that its benefits, risks, and cost effectiveness can be assessed. Until adequate scientific evidence is available, therapeutic hypothermia should be used only within the framework of well-designed, prospective, and controlled trials.

Criteria for Evidence Grading SBU's Conclusions, see page 2

Criteria for Evidence Grading SBU's Conclusions

Evidence Grade 1 – Strong Scientific Evidence. The conclusion is corroborated by at least two independent studies with high quality and internal validity, or a good systematic overview.

Evidence Grade 2 – Moderately Strong Scientific Evidence. The conclusion is corroborated by one study with high quality and internal validity, and at least two studies with medium quality and internal validity.

Evidence Grade 3 – Limited Scientific Evidence. The conclusion is corroborated by at least two studies with medium quality and internal validity.

Insufficient Scientific Evidence. No conclusions can be drawn when there are not any studies that meet the criteria for quality and internal validity.

Contradictory Scientific Evidence. No conclusions can be drawn when there are studies with the same quality and internal validity whose findings contradict each other.

References

1. Friberg H, Herlitz J, Rubertsson S, Wieloch T. Terapeutisk hypotermi efter hjärtstopp - ny länk i kedjan som kan rädda liv. Läkartidningen 2004;101(30-31):2412-6. Review.
2. Nolan JP, Morley PT, Vanden Hoek TL, Hickey RW, Kloeck WG, Billi J et al; International Liaison Committee on Resuscitation. Therapeutic hypothermia after cardiac arrest: an advisory statement by the advanced life support task force of the International Liaison Committee on Resuscitation. Circulation 2003;108(1):118-21.
3. Herlitz J, Bang A, Gunnarsson J, Engdahl J, Karlson BW, Lindqvist J et al. Factors associated with survival to hospital discharge among patients hospitalised alive after out of hospital cardiac arrest: change in outcome over 20 years in the community of Goteborg, Sweden. Heart 2003;89(1):25-30.
4. Hypothermia after Cardiac Arrest Study Group. Mild therapeutic hypothermia to improve the neurologic outcome after cardiac arrest. N Engl J Med 2002;346(8):549-56.
5. Bernard SA, Gray TW, Buist MD, Jones BM, Silvester W, Gutteridge G et al. Treatment of comatose survivors of out-of-hospital cardiac arrest with induced hypothermia. N Engl J Med 2002;346(8):557-63.
6. Holzer M, Bernard SA, Hachimi-Idrissi S, Roine RO, Sterz F, Mullner M; on behalf of the Collaborative Group on Induced Hypothermia for Neuroprotection After Cardiac Arrest. Hypothermia for neuroprotection after cardiac arrest: systematic review and individual patient data meta-analysis. Crit Care Med 2005;33(2):414-8. Review.
7. Hachimi-Idrissi S, Corne L, Ebinger G, Michotte Y, Huyghens L. Mild hypothermia induced by a helmet device: a clinical feasibility study. Resuscitation 2001;51(3):275-81.
8. Part 7.5: Postresuscitation Support. Circulation 2005;112(24_suppl):IV84-IV88.

SBU – The Swedish Council on Technology Assessment in Health Care

SBU is an independent public authority which has the mandate of the Swedish Government to comprehensively assess healthcare technology from medical, economic, ethical, and social standpoints. SBU Alert is a system for identification and early assessment of new methods in health care.

P.O. Box 5650, SE-114 86 Stockholm, Sweden • alert@sbu.se

This summary is based on a report prepared at SBU in collaboration with:

- Prof. **Björn Biber**, Sahlgrenska University Hospital, Göteborg,
- Prof. **Anders Waldenström**, Norrland University Hospital, Umeå.

This report has been subjected to external review.
The complete report is available only in Swedish.