

Therapeutic hypothermia with endovascular cooling

Background

Therapeutic hypothermia save more and better lives for comatose survivors after cardiac arrest (1, 2), and is now an international recommended treatment (3). However, how to optimal induce and maintain hypothermia is one of the main questions that still need to be discussed. Although the convincing positive results, the HACA-study (1) was criticised because the time from restoration of spontaneous circulation until the target temperature was reached exceeded eight hours. It has been stressed that the earlier hypothermia is initiated, and the earlier the target temperature is reached, the greater

the chance of a positive outcome (4). Therefore, strategies and devices that both can induce and control hypothermia faster and better are needed.

Endovascular cooling

Today in Vienna and Helsinki, the two places delivering the majority of the patients to the HACA-study (1), they use an intravascular method for producing controlled mild hypothermia, CoolGard 3000 with an Icy-catheter. This is an external heat exchange control device. There are four major components to the CoolGard 3000 system with Icy-catheter as follows:

- The CoolGard 3000 Temperature Control System (figure 1)
- The Icy Intravascular Heat Exchanger Catheter (figure 2 and 3)
- CoolGard 3000 Tubing Pack for connection between the catheter and the temperature control system with in-line disposable heat exchanger (figure 1 and 2)
- Temperature probes (bladder, figure 2)

The objective is to circulate chilled sterile saline to the indwelling venous catheter that is placed percutaneously in the patient. Data from the temperature monitor are integrated into the system via software that controls the temperature of the sterile saline to be circulated through the catheter to maintain the desired body temperature.

The Icy central venous heat exchange catheter is a triple lumen intravascular catheter (figure 3). The shaft of the catheter has three cooling membranes. Two of the catheter's lumens

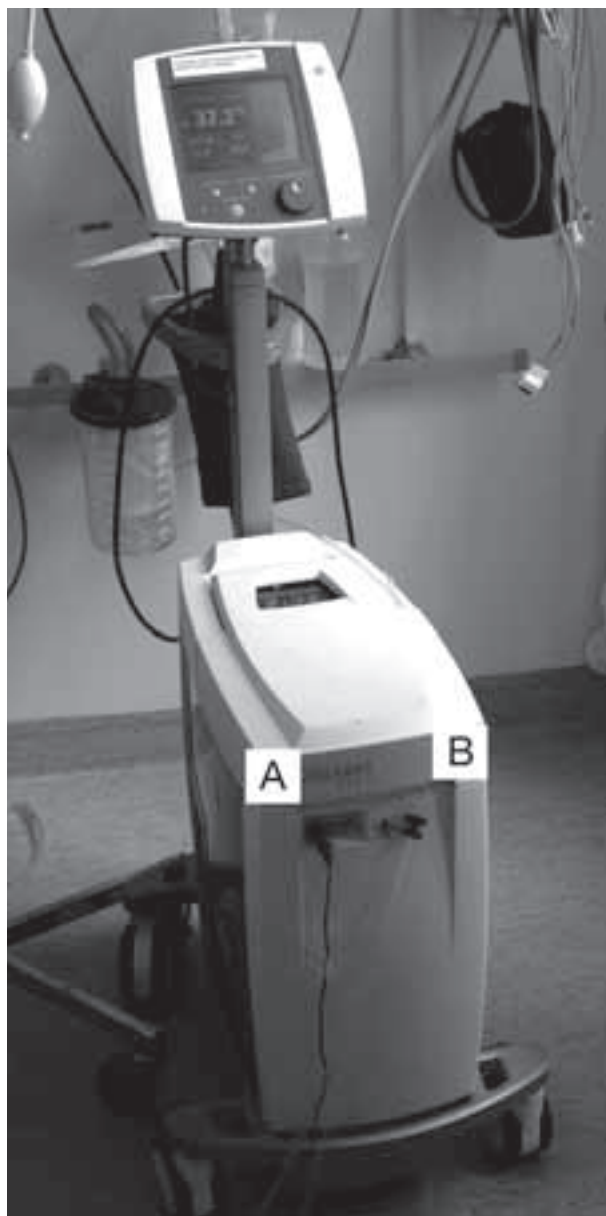


Fig. 1. Coolgard 3000 A: Bladder temperature control via a urine catheter. B: The in- and outflow lumen from the tubing pack that is connected to the Icy-catheter (filled with saline).

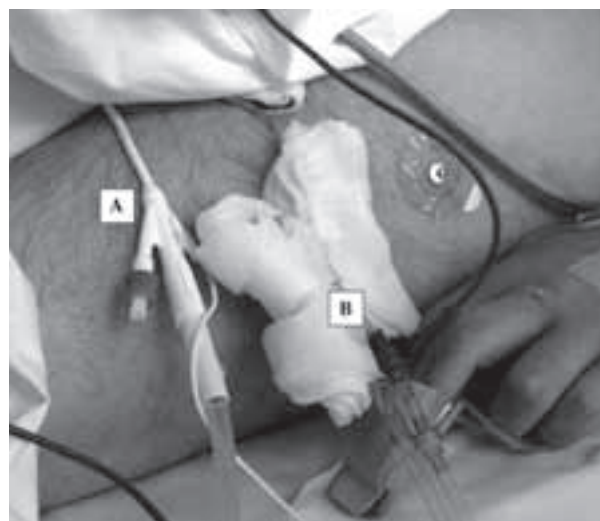


Fig. 2. Icy-catheter inserted into the femoral vein of a patient. A: Urine catheter with bladder temperature control connected to the Coolgard. B: The in- and outflow lumen from the Icy catheter connected to the tubing pack in the Coolgard (because they are very cold they have to be isolated from the skin of the patient).

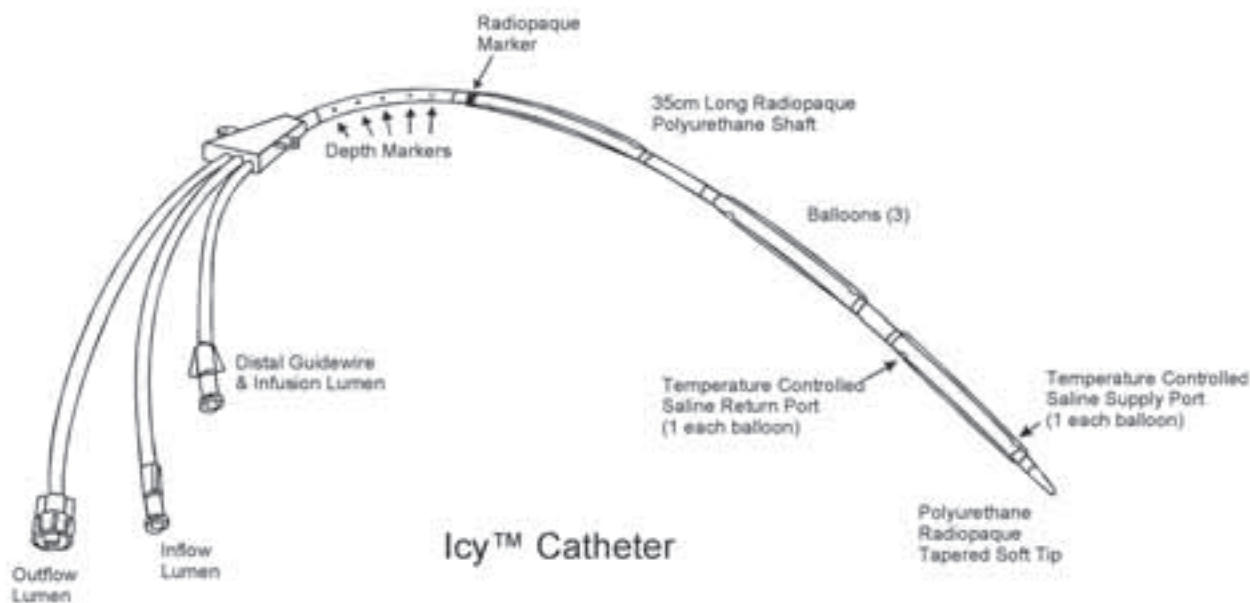


Fig. 3. Icy-catheter

are used to circulate sterile saline to exchange heat with the central venous blood supply. The inflow lumen/outflow lumen forms a closed-loop system through which the chilled saline circulates. The third lumen is a standard guidewire lumen that can be used as an infusion lumen.

Practical use

The Icy-catheter (8.5 Fr, 38 cm) is inserted into the inferior vena cava via the right or left femoral vein using Seldinger technique as a regular central venous line placement. Alternatively you can use another catheter, the Cool-line, placed in the subclavian or jugular internal vein, but this is a smaller catheter and a effective. Recently, another catheter (Fortius) was developed to allow more rapid cooling (2-4 °C per hour). After installing the tubing pack and the set-up procedure of the CoolGard, the catheter can be connected and cooling can be initiated. The use and safety of the CoolGard system has been documented (5-7).

Own experience

At Ullevaal University Hospital we have during the last year tried the CoolGard system in more than 20 patients (for cardiac arrested patients, but also for temperature control and normothermia in patients with brain trauma). It is easy to use and provides very rapid and stabile temperature control.

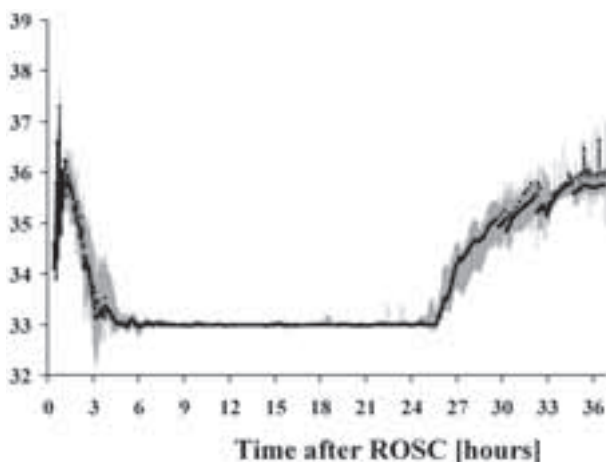


Fig. 4. Temperature profile using Icy-catheter and Coolgard in 19 patients with cardiac arrest (from F. Sterz, Vienna).

In the post-cardiac arrest period therapeutic hypothermia with CoolGard and/or other cooling techniques is part of a standardised treatment protocol. Using CoolGard, the target temperature of 33°C will be reached in a few hours. Combination with initial rapid ice cold saline infusion (8) is of great benefit, resulting in earlier initiation of hypothermia treatment and a further reduction of the time to reach the target temperature. We have had no major problems with this the Coolgard technique.

Two other hospitals in Norway (Haukeland University Hospital in Bergen and Rogaland Central Hospital in Stavanger) also use the CoolGard system. In the near future we may have some results to publish.

Advantages and disadvantages

The advantages of endovascular cooling are 1) a rapid and controlled decrease in core temperature (1-2 °C per hour with Icy-catheter (figure 4) and even faster when combined with infusion of ice cold saline), 2) a stable control of the target temperature (figure 4), 3) no skin injuries that may appear after external cooling, and 4) less or no shivering compared to external cooling. 5) re-warming is easy and well-controlled (figure 4), using the same system with a chosen constant rate, for example 0.5 °C per hour as recommended (3). Both maintenance of a stable target temperature and the controlled re-warming is very desirable.

Finally, when you have inserted the catheter and started the machine, hypothermia and temperature control result without further interventions (Figure 4). Therefore, the staff can focus on other important parts of the intensive care for these critically ill patients. This is a practical and valuable benefit and maybe the main advantages of the CoolGard system. Furthermore, patient and system data are stored in the software, allowing recall and graphical display (figure 4). Using a special program, data can be transferred and archived on a standard laptop.

On the other hand, it is an invasive procedure, which may lead to complications, for instance bleeding from the insertion

place, or displacement. When inserted after PCI, bleeding occur because of the combined use of heparin, GIIb/IIIa-inhibitors (abciximab) and clopidogrel. This is normally not a dramatic bleeding and easy to handle. The main consideration, however, with this product, is the economical aspect. The price for the CoolGard, the tubing Pack and the Icy-catheter has to be considered before using this technique; each patient treated equipment costs for around 1000 Euros.

The Coolheart Registry

The Coolheart Registry, www.coolheart.com, is a pan-European registry conducted under the auspices of the European Resuscitation Council. Its commercial sponsor is Alsium Corporation, the producer of CoolGard/Icy-catheter. The intent of the Registry is to document the clinical use and outcome of mild resuscitative hypothermia in patients after cardiac arrest with a special focus on endovascular cooling. Five centres in four different countries are now (January 2004, altogether 120 patients) registering patients anonymously in the Coolheart Registry. In Vienna they have treated more than 80 patients with this technique, their results are promising (personal comment from Prof. F. Sterz) and an international paper is soon to be submitted. In Norway, the Norwegian Data Security Control has not yet approved registration into such a registry (January 2004). We hope, however, to join this registry in the near future.

Future perspectives

The most important strategy for comatose resuscitated patients is to have a standardised treatment protocol including therapeutic hypothermia, with the goal of saving both the brain and the heart. We do not know the ideal technique for cooling and there are a lot of unsolved issues regarding therapeutic hypothermia. How long, how cold, how fast the re-warming, the optimal cooling technique, as well as side effects and

contraindications are today still largely unanswered questions. Therefore, international collaboration and registration of such treatment is of utmost importance. Only through scientific evaluation of the treatment procedures and cooling techniques can these important questions be answered in the future. Registration and scientific evaluation of results after endovascular cooling, is part of this.

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