Intravenous device feasible for controlled cooling and rewarming of individuals with abnormal body core temperature

A. Struijs[1], F. De Ruiter[1], A. Weijerse[1] , J. Klein[2] , A.J.J.C. Bogers[1]

[1]Department of Cardio-Thoracic Surgery, Erasmus University Medical Center, Rotterdam, The Netherlands
[2] Department of Anaesthesiology, Erasmus University Medical Center, Rotterdam, The Netherlands

Summary

We conducted a prospective single centre trial, to evaluate the ability of the FORTIUS® catheter combined with the COOLGARD® 3000 system to rewarm and maintain steady body core temperature in patients who undergo cardiac surgery with the use of cardio-pulmonary bypass. It appeared that in this population the FORTIUS® /COOLGARD® 3000 combination was able to rewarm safely and maintain steady body core temperature. The mean time to normothermia was 140 minutes and the mean rate of rewarming was 1ºC/ hour with a temperature stability of 37 ± 0.4 ºC for at least 1.5 to a maximum of 12 hours. Warming with this combination appeared to be a new, promising and safe technique, allowing controlled rewarming directly after cardio-pulmonary bypass during and after operation. It appeared to minimize the risk of afterdrop, temperature fluctuations and hyperthermia. Correct "blind" positioning of the FORTIUS® catheter appeared to be critical.

Introduction

The importance of maintaining body core temperature is widely known. Hypothermia (core temperature < 36 ºC) is common after long-lasting surgical procedures. Heat loss mainly occurs during anaesthesia and surgery and leads to increased risk of morbidity, especially in high risk patients like the elderly, children, victims of trauma etc. Proper control of body temperature during and after surgery can result in an overall better outcome and reduced hospital stay which can thereby be expected to reduce morbidity and costs.

Evidence that general hypothermia is of benefit to patients undergoing cardiopulmonary bypass (CPB) has existed since the 1940's. Not withstanding the development of warm blood cardioplegia and beating heart techniques, hypothermic CPB remains a standard method used in open-chest cardiac surgery. CPB is done with a blood oxygenator system ("the pump") that has high heat exchange capabilities.

Upon completion of the cardiac procedure, the blood is rewarmed nearly to normothermia before discontinuing the bypass pump. After disconnection from the bypass pump, it is common for patient's body temperature to spontaneously drop by 2º to 5ºC in the absence of interventions to the contrary (Jani et al, 1986). This is thought to occur due to thermo-dilution of core blood as peripheral vascular beds vasodilate post-operatively. Hence the patient would once again be hypothermic (termed "afterdrop").

The effects of this "afterdrop" are varied. Hypothermia predisposes the patient to cardiac arrhythmia, increases systemic vascular resistance, precipitates shivering, which increases oxygen consumption and carbon dioxide production, and impairs coagulation. Furthermore, hypothermia causes a decrease in cardiac output by producing bradycardia along with the increase in peripheral vasoconstriction (Zwischenberger et al, 1987)(Breisblatt et al, 1990)(Ralley et al, 1988).

Proper temperature control also requires that the patient will not become hyperthermic. As normal self-regulating mechanisms struggle to become re-established, shivering and other warming measures may produce "rebound" hyperthermia. Stevens & Fitzsimmons (1995) also found that approximately 40% of the cardiopulmonary bypass patients reached hyperthermia four hours or more after arrival in the ICU. To avoid this complication, Stevens and her group recommend discontinuation of active rewarming efforts at 36.0ºC, and administration of

acetaminophen to reduce additional temperature increase upon achievement of normothermia. The concern of hyperthermia is that increased metabolic demand results in greater cardiac work. Hence a device that warms a patient should, ideally, be able to prevent hyperthermia.
The trend in post-operative care for patients recovering from Coronary Artery Bypass Grafting (CABG) is to seek early extubation and ambulation. This is termed the "fast-track" approach. The development of the fast track recovery of CABG patients was driven primarily by a desire to allow higher throughput in existing centers capable of supporting CABG. Fast-track recovery produced shorter intubation time, and reduced intensive care and overall lengths of stay. This approach involves optimization of all aspects of the CABG procedures from the anaesthetics used to the post-operative care. It has been shown, however, that this can be done without increasing morbidity or mortality. Average USA postoperative lengths of stay for isolated, primary elective CABG were 6.4 days in 1997 with more complex cases averaging 10.5 days. Some authors report that the "Ultra-Fast Track" procedures results in 70% of patients being discharged in less than or equal to 4 days (Walji et al, 1999).
Typically patients are cared for in a cardiac surgery recovery area by cross-functional teams with the aim being extubation within 4-6 hours after the termination of the procedure. (Westaby et al, 1993)(Øvrum E et al, 2000). "Safe extubation requires that the patient be alert and cooperative, be hemodynamically stable and warm, is not bleeding, and has adequate respiratory function". The maintenance of normothermia is one of many homeostatic functions that must return. In focused trials it has been shown that, with attention to temperature management post-operatively, the recovery team can eliminate postoperative shivering which resulted in the lowering of oxygen uptake, carbon dioxide production, and required ventilatory volumes (Joachimsson et al, 1987)(Ralley et al, 1988).
Variation in external conditions such as room temperature and humidity, patient size, and concurrent pharmacologic treatments affect both the core temperature and the speed at which it changes.
In effect, the thermal challenge after CPB is to restore the patient to normothermia quickly, but without allowing an overshoot of the target temperature. Measures used historically for temperature control are effective in different applications, and each has its disadvantages.

Rewarming Post-Coronary Artery Bypass.

The most commonly used warming techniques are external and "passive"; that is, they rely primarily on the body's own heat-producing mechanisms to restore normal temperature. Applying heated or reflective blankets, using radiant heat sources from overhead or near the bed, and raising the room temperature are uncomplicated, inexpensive and readily available. However, they are labor-intensive and can be uncomfortable for nursing staff and visitors.
"Active" rewarming methods such as heated mattresses and forced-air tents seem to be more effective and faster at raising the core temperature; but they too require substantial management by hospital staff, and still leave the temperature fluctuating around a desired target. Villamaria et al (1997) reported, in a randomized controlled trial, that both forced air warming devices and more conventional warm blankets and overhead heating lamps showed similar performance. They reported rewarming rates of 0.25 ºC per hour. In a randomized controlled trial, the use of warming blankets in a typical recovery area resulted in a 0.5 ºC/h increase in core temperature (Janke et a, 1996). The rate for the Bair Hugger system was 0.75 ºC/h.
The Fortius catheter combined with the use of the Cool Guard® is a simple procedure for maintaining body temperature in the operation theater. Heat loss during operation can be already reduced by several procedures, such as external devices, supplying warm fluids or other methods for reducing heat loss. The FORTIUS catheter is superior because its ability to control the body core temperature during a longer period of time without interfering with accessibility for the surgeon or disturbing fluid balances.

Methods

This trial is designed as a prospective, single center study. The total number of patients enrolled into this trial is 20. This trial is a feasibility trial showing the utility of the CoolGard 3000/Fortius catheter in this specific application. Further randomized studies will be commenced after successful completion of this feasibility trial. Both the CoolGard 3000 heat exchange system and Fortius catheter are CE marked for the broader application of intravascular heating and cooling.

There are four major components to the CoolGard system with Fortius catheter:

- The CoolGard 3000 Temperature Control System
- The Fortius Intravascular Heat Exchanger Catheter placed preferably in the left femoralis vein.
- CoolGard Tubing Pack for connection between the catheter and the temperature control system with in-line disposable heat exchanger
- Temperature probes

Patients eligible for participation in this clinical study are those undergoing elective general anaesthesia for CABG and or valve surgery using cardiopulmonary bypass, age range 40-80 years, ASA classification I-IV and after having given their written informed consent. Patients requiring emergency operations, those with bleeding disorders, history of thrombosis, pregnancy and any clinical condition, which does not justify study participation in the investigator's opinion were excluded. The patients were followed up for 24 hours after surgery under normal circumstances. Anamnesis and history (also on thrombosis and bleeding), previous anaesthesia, concomitant disease, concomitant medication, vital signs, body weight, BMI, temperature, laboratory results were collected. Patients are pre-medicated with lorazepam (1-2 mg). A Foley bladder catheter with an inbuilt YSI-400 temperature probe was inserted prior to anaesthesia and connected to the CoolGard 3000. The Fortius catheter was introduced into the right or left femoral vein after induction had taken place. Anaesthesia was induced by midazolam (0.1 mg/kg bw), sufentanil (2-3 μg/kg bw) and the muscle relaxant pancuronium (0.12 mg/kg bw). After intubation of the trachea, anesthesia is maintained with propofol (2-3 mg/kg/h). Just before incision, a bolus of sufentanil (1 μg/kg) is given. Cefacidal is given with induction (2 g) and 1 gram is given when CPB is started. The position of the catheter was checked by X-ray. The catheter was connected to the CoolGard 3000 via the Start-up Kit. The system was set to run with a set point of 34 ºC selected, as soon as the patient is anesthetized and it is convenient to do so. This will permit the electronic recording of the patient during surgery and the Fortius catheter assisted in the cooling of the patient. After CPB was stopped, the set-point of the CoolGard 3000 was set to 37 ºC. A secondary thermometer is used to check patient temperature in accordance with the labelling of the CoolGard 3000 throughout the rewarming period.

The primary target criteria were the time taken to attain normal body core temperature after CPB and the stability of the maintenance of the normal core temperature. The measures employed will be:

1. Time to normothermia. Measured as the time from "off pump" to first attaining a stable (i.e. prolonged for more than 30 minutes) core temperature of 37± 0.5 ºC.
2. Average rate of rewarming. Measured as ºC/h from "off pump" to a core temperature of 37± 0.5 ºC.
3. Temperature stability. Measured as the average absolute temperature variance from 37 ºC for the period of normothermia (i.e. once core temperature 37± 0.5 ºC and until CoolGard 3000 function ceased).

Results

Twenty patients were asked to participate in this study. Eight patients refused to participate because of the invasive procedure. In four patients the placement of the catheter could not be performed without the help of continuous X-ray that was not available. We present the preliminary results of 8 patients enrolled in the study. The patient characteristics are shown in table 1. The mean time to normothermia was 140 minutes and the mean rate of rewarming was 1ºC/ hour with a temperature stability of 37 ± 0.4 ºC for at least 1.5 to a maximum of 12 hours. There was no afterdrop, temperature fluctuation nor hyperthermia.

Table 1: Patients' characteristics (n=8)

	BMI	Age (yr)	Gender (m/f)	Surgery
1	29	58	M	AVR + CABG
2	26	68	M	MVR
3	33	72	M	CABG
4	22	71	M	AVR
5	24	56	M	MVR
6	25	57	M	MVR
7	23	53	M	MVR
8	26	66	F	MVR + CABG

Conclusions

Based on current evidence intravenous warming with the CoolGard 3000/Fortius catheter is a promising new therapy. In patients after cardiac surgery this catheter minimizes the risk of afterdrop, temperature fluctuations and hyperthermia. In addition, with the CoolGard 3000/Fortius it is possible to start the process of rewarming directly after CPB when the patient is still in the operation room. Correct "blind" positioning of the FORTIUS® catheter is critical.

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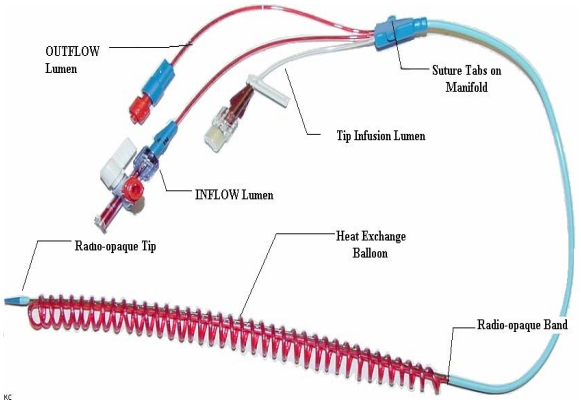
OUTFLOW
Lumen
Suture Tabs on
Manifold
Tip Infusion Lumen
INFLOW Lumen
Radio-opaque Tip
Heat Exchange
Balloon
Radio-opaque Band