

Feasibility of an Intravenous Warming Device to Rewarm Cardiac surgery Patients

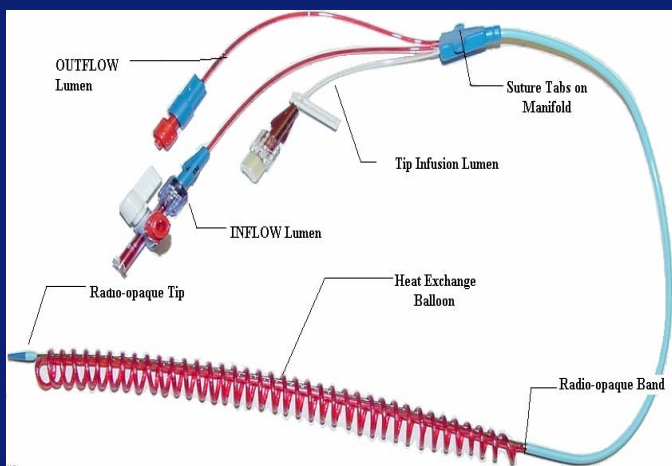
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INTRODUCTION: Hypothermia (core temperature < 36°C) is common after long-lasting surgical procedures. [1-2] Heat loss mainly occurs during anesthesia and surgery and leads to increased risk of morbidity, especially in high risk patients like the elderly, children and victims of trauma. Proper control of body temperature during and after surgery can result in an overall better outcome and reduced hospital stay, thereby a reduction in morbidity and costs can be expected.

OBJECTIVE: To evaluate if the Fortius catheter (see figure 1) is able to rewarm and control steady body core temperature in patients who undergo cardiac surgery with cardiopulmonary bypass (CPB).

Figure 1: Fortius catheter



METHODS: This trial is designed as a prospective, single center feasibility trial (n=10), showing the utility of the CoolGard 3000/Fortius catheter in this specific application. Further randomized studies will be commenced after successful completion of this trial. Both the CoolGard 3000 heat exchange system and Fortius catheter are CE marked for the broader application of maintaining temperature and cooling. Patients eligible for participation in this clinical study are those undergoing elective general anesthesia for CABG and/or valve surgery using cardiopulmonary bypass (CPB) (see table 1). The primary target issues are; time to attaining and the stability of the maintenance of normal body core temperature after CPB.

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

THE MEASURES EMPLOYED:

- Time to normothermia (measured as the time from "off pump" to first attaining a stable core temperature of 37 ± 0.5 °C)
- Average rate of rewarming (°C/h from "off pump" to a core temperature of 37 ± 0.5 °C)
- Temperature stability (average absolute temperature variance from 37 °C for the period of normothermia)

RESULTS: Preliminary results – after 8 patients: at maximum capacity the CoolGard 3000/Fortius catheter does rewarm and maintain steady body core temperature in patients who undergo cardiac surgery with CPB. The average time to normothermia was 2 1/3 hours – ranging from 54 min to 222 min; the average rate of rewarming was 1 °C/hour with a temperature stability of 37 ± 0.4 °C for at least 1.5 to a maximum of 12 hours. Blind positioning of the catheter is critical and needs special attention, especially during introduction by using the left femoral vein.

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.

References:

1. Janke EL, Pilkington SN, Smith DC. 1996. Evaluation of two warming systems after cardiopulmonary bypass. *Br J Anaesth* Aug; 77(2): 268-70.
2. Villamaria FJ et al. 1997. Forced-air warming is more effective than conventional methods for raising postoperative core temperature after cardiac surgery. *J Cardiothorac Vasc Anesth* 11(6): 708-11.