

Title: Temperature Monitoring in Cardiac Surgery: Agreement Between Different Clinical Methods

NCT number: 04355013

Document date: 27/04/2016

Protocol

Anesthetic management was similar in all patients. Operation room temperature was maintained at 19– 20°C. During the period prior to CPB, no active warming measures were used. After CPB, active warming of the patient was initiated using a convective blanket and heating the infusion fluids and those used in the surgical field to 39°C. During rewarming, the temperature of the arterial outlet line was limited to 37°C (maximum temperature of the heater cooler unit set at <38°C).

Temperature monitoring

After anesthesia induction, the following sites were used for simultaneous measurement of temperature: nasopharynx, via a probe inserted to a depth equal to the distance between the nares and the earlobe (Level 1® Oesophageal Stethoscope Temperature Sensor, Smiths Medical, Kent, UK), pulmonary artery (Continuous Cardiac Output Pulmonary Artery Catheter, Edwards Lifesciences, Irvine, CA), arterial outlet and venous inlet temperature probes (Stockert S5 Perfusion System, München, Germany), forehead using a Tcore™ double-sensor (Drägerwerk AG & Co, Lübeck, Germany), and urinary bladder (with the Level1® 400 series thermistor Foley catheter temperature sensor, Smiths Medical International Ltd, UK). Adequate positioning of sensors was confirmed at intervals throughout the study. 24 temperature measures per patient (1152 pairs of measurements) were recorded at 5-min intervals throughout surgery (8 readings in the pre-CPB period, 8 during the CPB period, and 8 after the weaning from CPB). The initial 10 min measurements in each period were discarded since the forehead sensor needs about 10 min to reach equilibrium. We excluded pulmonary artery measurements during the CPB period.

Statistics The Bland-Altman plot for repeated measures was used to assess concordance between methods. We a priori set the acceptable agreement (i.e., 95% limits of agreement) between methods to be 0.5°C. In addition, the percentage of measurement differences within the range of $\pm 0.5^{\circ}\text{C}$ and the 95% confidence interval for the proportion was estimated using bootstrap percentiles based on 10,000 resamples. Finally, for assessment of reproducibility, the Lin's concordance correlation coefficient (LCCC) was computed and interpreted using McBride's strength-of-agreement criteria for continuous variables (almost perfect: >0.99; substantial: >0.95– 0.99; moderate: 0.90–0.95; poor: < 0.90 were considered statistically significant. MedCalc® statistical software (MedCalc Software, Ostend, Belgium) was used for statistical analyses.

