**Heated Humidified Breathing Circuit Rewarming in Hypothermic Patients after Cardiopulmonary Bypass**

NCT03697122

Document Date: 02/25/2019

# Heated Humidified Breathing Circuit Rewarming in Hypothermic Patients after Cardiopulmonary Bypass

## Purpose of the Study

Our primary objective is to assess whether use of Heated Humidified breathing circuits (HHBC) decreases time to normothermia (≥ 36.5 °C).

Our secondary objectives are to assess whether use of HHBC shorten time to extubation, improve coagulopathy, decrease bleeding, and metabolic derangements seen with hypothermia.

We propose the hypothesis that: Rewarming hypothermic patients (≤ 35 °C) admitted to the CTICU following cardiac surgery with CPB, using HHBC in addition to conventional forced air warming blankets will shorten time to normothermia.

## Background & Significance

To reduce the rising cost of cardiac operations, researchers have studied early extubation as a means to shorten ICU length of stay, and favorably influence patients' health outcomes. In the process, various nursing ICU protocols have been developed to facilitate the expedient tracheal extubation of patients, taking into account hemodynamic status, mediastinal drainage, urine output, patient temperature (rewarming from induced hypothermia), and other factors.

Hypothermia on admission to the ICU following CPB is common. Cooling and rewarming during CPB and takes considerable time and contributes to the post-procedural coagulopathy and physiologic perturbations.

Rewarming in the postoperative period after hypothermic CPB is often associated with hemodynamic and ventilatory instability. Temperature changes, PaCO2 values, and mechanical ventilation were observed for the first 12 hours in the ICU in 73 patients who had undergone cardiac surgery with hypothermic CPB. Mean rectal temperature increased from 34.7 to 38.3 degrees C over the first 8 hr after admission to the ICU. The temperature curve was sigmoid rather than linear, and the most rapid rate of temperature increase occurred 2-4 hours after admission. During rewarming, the most common abnormality of PaCO2 on mechanical ventilation was acute respiratory acidosis (PaCO2 greater than 45 mmHg, pH less than 7.35), which occurred in 42% of patients.

After disconnecting from CPB the body is allowed to self-equilibrate. The normal vasoconstriction response is impaired by the administered anaesthesia. Hence, heat distribution takes place from the warm core to the colder periphery. This causes an afterdrop: a decrease in the temperature of the core organs. After-drop may contribute to post-operative complications of hypothermia such as shivering, coagulopathy, increased myocardial stress, increased wound infections,metabolic acidosis, delayed extubation and prolonged ICU length of stay.

The current standard of rewarming patients in the ICU is to use forced air heating blankets. Forced-air blankets reduce the core temperature afterdrop by 60%. However, heat-balance data indicate that this reduction resulted primarily because forced-air heating prevented the typical decrease in body heat content after discontinuation of CPB, rather than by reducing redistribution. They do not lead to clinical relevant changes in deep thigh temperature, or toe perfusion. The extra heat especially favors core temperature. This is underlined by the decrease in postoperative leg blood flow, suggesting that the majority of the warmed blood leaving the heart flows to core organs and not to the periphery.

A recent Cochrane review showed that active warming, particularly forced air warming, appears to offer a clinically important reduction in mean time taken to achieve normothermia (normal body temperature between 36°C and 37.5°C) in patients with postoperative hypothermia. However, high-quality evidence on other important clinical outcomes is lacking; therefore it is unclear whether active warming offers other benefits or harms. High-quality evidence on other warming methods is also lacking; therefore it is unclear whether other rewarming methods are effective in reversing postoperative hypothermia.

Regarding HHBC, Hyungseok et al recently showed that a heated humidifier is more effective in preventing intraoperative core temperature decrease in elderly patients than a heat moisture exchanger alone. Sooyong et al showed that a decrease in core temperature from anesthetic induction to 120 minutes after induction was lower in the HHBC group in patients undergoing hip arthroscopy. Park et al showed that HHBC influences heat redistribution in early period of thyroid surgery and can lessen the magnitude of the decrease in core body temperature. Frank et al showed that the delivery of warmed, humidified O2 via nasal canula accelerates core rewarming rate by approximately two-fold in mildly hypothermic postoperative patients. A recent fellow QI project used HHBC during rewarming of patients in the operating room following DHCA procedures found that it significantly attenuated the temperature afterdrop upon separation from CPB when compared to standard airway circuits.

**Design & Procedures**

Hypothermia (≤ 35 °C) after cardiac surgery using CPB is not uncommon. To avoid complications associated with hypothermia, and due to absence of shivering when patient is sedated, and harmful effects of shivering when patient is awake, clinicians resort to active warming devices. Forced air warming devices are the most commonly utilized, but occassionally heated humidified breathing circuits are used as well. We plan to use both warming devices on study patients, and compare them with a historical cohort that has used forced air warming device only.

On admission to CTICU, if temperature ≤ 35 °C, we will attempt to recruit the patient. Patients are intubated and sedated on admission to the CTICU after cardiac surgery, so informed consent will be obtained from the patient's next of kin or power of attorney. After consent is obtained, the clinical provider will ask the patient's nurse to place a lower body forced air warming device and set to 38 °C, and ask the respiratory therapist to set up and connect a heated humidified breathing circuit.

Admission temperature and other vital signs will be recorded per CTICU standards. Other patient management decisions (ie medication changes, laboratory assessments…etc) per direction of ICU providers. Core temperature and location (esophageal, nasopharyngeal, bladder, rectal, blood) will be recorded every 15-30 minutes until normothermia reached (36.5 °C), then record per CTICU standard. Record active warming methods in nursing flow sheets (i.e. Forced air warming blanket and heated humidified breathing circuit). Record other vital signs, medications, extubation time, hourly chest tube output, and patient data per unit policy. Alert Respiratory therapy once normothermia (36.5 °C) has been achieved for discontinuation of HHBC.

**Selection of Subjects**

For the prospective part of the study:

Inclusion Criteria:
Adult patients (18-85 years old) Admitted to CTICU following cardiac surgery using CPB.
Admission temperature ≤ 35.0 °C.

Exclusion Criteria:
Patients admitted to ICU on ECMO support.

For the retrospective part of the study:

We will be matching the 14 prospective patients who received both ANAPOD and forced warm air with 28 retrospective ones who presented with hypothermia that were treated with forced warm air alone without ANAPOD. Criteria should include:

- Hypothermic Patients (Temp < 35C) undergoing cardiac surgery under CPB who received forced warm air alone.
- Temp at time of ANAPOD application would be our reference point.
- Type of surgery
- Patient's BMI
- Deep hypothermic arrest

**Subject Recruitment and Compensation**

All adult patients (18-85 years old) Admitted to CTICU following cardiac surgery using CPB, with an admission temperature ≤ 35.0 °C will be considered for recruitment.

Both males and females and all demographic groups will be included.

Patients are intubated and sedated on admission to the CTICU after cardiac surgery, so informed consent will be obtained from the patient's next of kin or power of attorney by one of the patient's care providers or study personnel.

Approximately 14 patients will be included in the prospective recruitment of patients. Data will be matched with a historical cohort of 28 patients (2:1 matching).

No compensation will be offered.

**Consent Process**

Typically, patients remain intubated and sedated until hypothermia resolves. Patients will not be able to consent for themselves for this study. Informed consent will be obtained from next of kin / power of attorney.

**Risk/Benefit Assessment**

Heated humidified breathing circuits are being used clinically to avoid / treat hypothermia both in the OR and the ICU. We aim to examine if this clinical practice provides additional benefit to the forced warm air devices. Risks associated with heated humidified breathing air includes: possible inefficient warming of body temperatures, thermal inlury to airways, excessive heathing (hyperthermia).

There is also a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, but this cannot be guaranteed. Those risks can be minimized by frequent monitoring and documentation of both the device temperature as well as the patient temperature every 15-30 minutes to avoid over heating, and make sure active rewarming is stopped when temperature of patient exceeds 36 C.

If patient's power of attorney declined to participate in the study, only forced air warming will be used for active rewarming of patient.

Possible benefit if using warm humidified air is more effective in rewarming patients when combined with forced warm air devices than when using forced warm air devices alone, hypothermia will resolve quicker, potentially minimizing complications associated with hypothermia such as coagulopathy, shivering, metabolic derangements, etc.

**Data Analysis & Statistical Considerations**

Descriptive statistics will be used to evaluate patient demographics and clinical characteristics. Descriptive statistics will be summarized as mean ± (SD) or median (interquartile range) for continuous variables and group frequencies (%) for dichotomous or categorical variables.

As all patients are expected to achieve normotherma within the study period, the primary outcome of time to normothermia will be analyzed as a numeric outcome variable.Following validation of distributional assumptions we will compare the time to normothermia between the two groups via t-test or Wilcoxon rank sum test as appropriate. It is expected that the patients will reach normothermia between 45 minutes and 6 hours after admission to the ICU.

By using a 2:1 matching ratio and a moderate level of variability (SD=1.3 hours) a study of 14 prospectively enrolled patients and 28 retrospectively matched patients would attain 82% power to detect a 1.25 hour difference between time to normothermia in the two groups at alpha level 0.05.

Secondary numeric outcomes such as time to extubation, time to normal PH, and coagulopathy lab values will be analyzed by t-test or Wilcoxon rank sum test as appropriate.Differences in categorical outcomes between treatment groups such as shivering will be analyzed via chi-square or fisher exact tests.As the patients will be matched on key confounders no further adjustment is expected to be necessary, so the moderate sample size should not limit the primary analysis.Potential subgroup analysis may be conducted in an exploratory analysis to determine if the treatment effect of ANAPOD warming is different by procedure type or patient/surgical characteristics.