Randomized Control Trial Assessing Effectiveness of Perioperative Warming Measures in Parturients Undergoing Cesarean Delivery

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Temperature Project Protocol

• Title of the proposed study: Randomized Control Trial Assessing Effectiveness of Perioperative Warming Measures in Parturients undergoing Cesarean Delivery

• Name and academic rank of the applicant: Stacy Norrell, MD, Assistant Professor

• Background: Inadvertent Perioperative hypothermia (IPH) can lead to many complications including shivering, decreased wound healing, infection, coagulopathy, higher risk for transfusion, and overall patient discomfort and neonatal hypothermia (1). This problem is complicated in the obstetric population by the presence of a baby that can also be directly affected by maternal hypothermia. IPH during cesarean delivery has been reported as high as fifty percent (6). However, there is a paucity of studies that compare the efficacy of the various available methods currently in use. In this proposed study, we will determine and compare the efficacy of two warming regimens on prevention of IPH in cesarean delivery of parturient and their newborn.

As noted, hypothermia often causes shivering in the patient, which is known in itself to cause many problems. Not only does it make the patient uncomfortable, it increases myocardial oxygen demand by as much as 100-200% (5). It also reduces the ability of the mother to bond with the baby due to the inability of the mother to hold the baby. Even if the mother is not shivering so severely that holding is prohibited, the hypothermic mother does not provide a warm environment during skin to skin bonding time for the baby to be able to regulate its own body temperature. This can lead to hypothermia in the baby as well, which can also worsen the condition of the baby.

This problem is complicated by the use of neuraxial anesthesia, which is the preferred method of anesthesia for cesarean section, for many reasons. However, neuraxial anesthesia causes significant vasodilation, further worsening the potential for hypothermia. This is compounded by the inability of the mother, who is insensate from the T4 level down, to feel just how cold they may be. Therefore, they are less likely to assist by notifying the anesthesiologist in the operating room or nurse in the recovery room how cold they are once the anesthetic is in place.

For the above reasons, the purpose of the study to investigate what method or methods are the most effective in achieving and maintaining normothermia. This is clinically relevant and important to determine so as to improve outcomes for both mother and baby.

• Hypothesis: We hypothesize that the efficacy of lower body warming will have the greatest effect on body temperature of the parturient measured at arrival at PACU and improvements in all of the other study parameters.

• Study Design: We will enroll 100 patients who are scheduled for elective cesarean section under neuraxial anesthesia. Demographic data will include maternal age, gestational age, ASA class and BMI.

Patients will be randomized into 2 study arms:

1. Control arm:
    a. Preop: Use of full body forced air warming pre-operative at ambient (32˚C) for at least 30 minutes and fluids from warmed cabinet set at 45˚C
    b. Intraop: Use of upper body forced air warming intra-operative at ambient (32˚C) and IV fluids at room temperature
2. Study Arm 2:
    a. Preop: Use of full body forced air warming pre-operative at ambient (32˚C) for at least 30 minutes and fluids from warmed cabinet set at 45˚C

b. Intraop: Use of upper body and lower forced air warming intra-operative at 32 and 42˚C respectively and IV fluids with hotline fluid warmer set at 42˚C

Data collections include:

1. Temperature measurement using (the same) digital oral thermometer for the following timeline:
    a. on arrival to the Pre-operative area
    b. 10 minutes after neuraxial anesthetic
    c. within 10 minutes of neonate delivery
    d. 1 hour after neuraxial anesthetic
    e. arrival to PACU
    f. 4 hours after neuraxial anesthetic
    (for consistency we will perform all temperature measurements orally and with the same type of thermometer)
2. Shivering degree (on arrival to PACU, after 30 minutes in PACU and after administration of meperidine, if it applies)
    - 0 = no shivering
    - 1 = shivering> localized to the core and neck
    - 2 = shivering including> the upper extremities
    - 3 = total body shivering
    - Maternal thermal comfort/ Numeric rating score (0-10)
3. Use of meperidine in PACU to reduce shivering and dose given
4. Quantity of IV fluids administered intraoperatively
5. Perioperative blood loss
6. Coagulation Studies
7. Hospital Length of Stay
8. APGARs of the baby
9. Umbilical artery pH recorded at birth
10. Neonate blood sugar
11. Use of skin to skin, length of time of this maneuver
12. Any adverse events in the neonate

Total duration of the study will be the time required for completion of 100 patients, 50 per study arm. After consent is obtained, the patients will be randomly allocated into one of the two study arms. The sequence of the allocation will be pre decided by an outside participant and will be provided to the investigator in a sealed envelope. Our institution averages 163 cesarean sections per month, 84 primary and 79 repeat. Through this research days allocation, I have been provided 1 day a month to dedicate to this project. Daily there are approximately 6-9 cesarean sections. If I also try to recruit help and work post call and pre call, I hope to gather about 15 patients a month. At this rate, I could complete my data gathering in about 7 months.

Our outcome measures to determine the effectiveness of intervention include:

Primary outcomes

1. Change in maternal core body temperature from preoperative/beginning of surgery to postoperative/end of surgery
2. Incidence of women with hypothermia (core temperature < 36 °C)
3. Neonate status as determined by APGARs, Umbilical Artery pH, and Neonate blood sugar
4. Maternal Coagulopathy

Secondary outcomes

1. Incidence of shivering (severity) and need for meperidine

2. Maternal thermal comfort
3. Perioperative blood loss
4. Hospital Length of Stay

- Statistical Analysis as determined by our statistician Zhang Xu, "We will conduct Kolmogorov–Smirnov test to examine distributions of continuous variables. Normally distributed data will be summarized as mean and standard deviation. The paired t test will be used for comparing temperatures of different time points. The two-sample t test will be used for comparing means between two arms. If data have skewed distribution, we will report quartiles and use the Wilcoxon rank sum test for two-sample comparisons.

  Frequencies and incidence rates of hypothermia, shivering and need for meperidine will be reported for each arm. Associations between these outcomes and study arm will be evaluated by Fisher's exact test. The study is exploratory, therefore, we will not employ adjustment method for multiple testing. We will report two-sided p values. P values less than 0.05 will be considered as significant."

• Feasibility: Entirely feasibly done on the labor and delivery floor. Everything is available and the nursing staff is already aware of our desire to do this project and in agreement that it would be beneficial.

• Expected Outcomes: We anticipate that our current measures to maintain normothermia throughout the perioperative process are insufficient for obstetric patients undergoing cesarean delivery nor to prevent adverse effects of hypothermia in mother and neonate. We expect to need to provide the measures in study arm 2 to begin to see improved outcomes and lack of detrimental occurrences.

• IRB protocol status: In IRB review.

• Name of the mentor: Maya Suresh, MD

References:

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