

I. Study Design:

This will be a randomized controlled double blinded study.

Our study will include 100 patients having elective cesarean section at Cedars-Sinai Medical Center. Patients will be randomized in two groups: the first group will receive active warming with VitaHeat underbody heating mattress in preoperative holding area for 15 min, during the surgery and in PACU; second group will not receive active forced air or resistive mattress warming; both groups will receive the standard patient blankets and warmed intravenous fluids.

The observer and patient will be blinded as to the group assignment. Another anesthesiologist will perform the randomization table and turn the VitaHeat warming mattress on or off.

2. Study Device

VitaHeat will loan the underbody heating mattresses for the duration of the study.

3. Inclusion/Exclusion

Inclusion criteria:

- will be age >18 years,
- singleton pregnancy >37 weeks,
- neuraxial anesthesia,
- healthy afebrile patients.

Exclusion criteria:

- severe uncontrolled medical problems (e.g. uncontrolled diabetes),
- preeclampsia,
- pre-operative temperature >38degrees C,
- BMI>40kg/m2.
- Neonates of uncertain viability
- Nonviable neonates

4. Study Procedures

Patient temperature will be measured with Exergen temporal scanner TAT -5000 at the following events and intervals: in preoperative area, at time of neuraxial block (anesthesia) is placed, at delivery of the fetus, then every 15 min, at application of wound dressing, on arrival to recovery, then q 15 min until normothermia is achieved.

Shivering will be recorded and graded on the following scale as used in previous studies:

0 - no shivering,

1 - shivering not interfering with monitoring or causing distress,

2 - shivering interfering with OR patient monitoring devices (ECG, BP, Pulse oximeter) and causing patient distress.

During the temperature monitoring period we will record patient's vital signs as dictated by standard of care: heart rate, noninvasive blood pressure, pulse oximetry and episodes of interruption of monitoring secondary to a moving artifact. Other recorded variables will be room temperature, humidity, duration of surgery, estimated blood loss, hemoglobin level before surgery and on POD#1.

We will record time of skin-to-skin contact, initiation of breastfeeding, length of hospital stay, and incidence of surgical wound infection. Thermal comfort will be evaluated at the same time points as temperature, using a visual analog scale, in which 0 is the worst imaginable cold, 50 is temperature comfort, and 100 identifies the worst imaginable heat. We will ask the patients to provide a satisfaction score for the quality of care using a scale 0-100, 0=extremely unsatisfied, 100=extremely satisfied.

Neonatal parameters: rectal temperature at delivery and Apgar scores at 1 and 5 minutes will be recorded as routinely measured by the assigned nurse taking care of the neonate in the delivery room.

A review of medical records will be performed to determine the length of hospital stay and surgical wound infection rate.

For patients with no data for their postoperative course (outside of the Cedars-Sinai electronic medical record system) we will contact them via telephone to inquire about postoperative surgical wound infection complications. The call will take place 30 days after cesarean section was performed.

STATISTICS AND DATA HANDLING:

Using results from a previous published study, power analysis was performed to determine the sample size necessary to detect a temperature difference of 0.2 degree C with power 0.8, a type 1 error 0.05 and standard deviation 0.5 degree C. We calculated 50 patients in each group to detect such an effect.

Patients will be randomized in two groups: with or without active warming. A computer generated randomization number will be assigned to each patient, patients will not be aware of their group allocation.

Numeric variables: temperature, blood loss, transfusion rate, time to initiate skin to skin contact or breastfeeding, patient thermal comfort and satisfaction score and length of hospital stay will be compared with a unpaired Student t-test or Mann-Whitney U-test depending on data distribution. Categorical variables: incidence of perioperative hypothermia, shivering, wound infection rate, transfusion rate will be compared with chi-square test or Fisher's exact test.