Study protocol

Difference in wound temperature in parturients scheduled for elective cesarean delivery with and without preoperative active warming.

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Introduction

Spinal anesthesia is the technique of choice for women undergoing cesarean delivery, because it allows the parturient to experience the moment of birth and facilitates early bonding. However, there are adverse effects such as hypotension and perioperative hypothermia (Munday et al., 2018). There is a high incidence of perioperative hypothermia among women undergoing cesarean delivery with spinal anesthesia (Cobb et al. (2016) Anesth Analg 122:1490-1497) because spinal anesthesia markedly inhibits body auto regulation as a result of suppression of vasomotor response and thermal redistribution from body core to peripheral tissues (Frank et al., 2000).

Low intraoperative wound temperature is known to increase the risk for both mothers and neonates, including wound infections as a result of decreased blood supply by the effect of hypothermia (Torossian et al., 2015), altered clotting function (Torossian et al., 2015), suppression of the immune system (Beilin et al., 1998), extended length of hospital stay and consequently higher costs (Kurz et al., 2009), high risk of bleeding (Rajagopalan et al., 2008) and shivering. Neonates also suffer from perioperative hypothermia (Horn et al., 2002), which is apparent in altered arterial pH and Apgar scores (Yokoyama et al., 2009).

Preoperative active warming has been associated with improved maternal thermal comfort, less shivering and improvement in neonatal acid base status (Horn et al., 2014; Sultan et al., 2015). In this study, we would like to elucidate the effects of prewarming on the wound temperatures during surgery for caesarian section, because low intraoperative wound temperatures might be associated with an increased risk of postoperative wound infections.

Methods

This study is designed as a single-center, single-blinded randomized controlled trial to be conducted at the Klinikum Bremerhaven-Reinkenheide. The study will be conducted after the approval of the ethics committee of the Ärztekammer Bremen. Written informed consent will be obtained from all patients before inclusion into the study.

Study population

Patients scheduled for elective cesarean section.

Inclusion criteria

- Patients scheduled for elective cesarean delivery under spinal anesthesia with a planned surgery duration of at least 30 minutes.
- Gestational age >34 weeks.
- ASA status I or II.
- Age ≥18 ≤ 40.
- Body mass index (BMI): > 20 kg/m2 and < 40 kg/m2.

Exclusion criteria

- Patient refusal.
- Allergies against any medications used for cesarean sections in this study.
- Preoperative fever or known thermoregulation disorders or poorly managed thyroid disorders.
- Patients planned for ICU admission postoperatively and any history of preeclampsia or eclampsia.
- Patients who are unable to understand the study and/or are not capable of making informed decisions.

Randomization

Patients will be randomly allocated into two equal groups:

- Group W: patients receiving standard care and active preoperative warming (intervention group).
- Group C: patients receiving standard care and no active preoperative warming (control).

Randomization is performed by using allocation cards in sealed opaque envelopes.

Study process

Day 0 – Screening and consent

Patients presenting to the anesthesia preop clinic and scheduled for elective cesarean section will be screened for inclusion and exclusion criteria. If criteria are met, patients will be asked if they would be willing to participate in the study. No compensation will be offered for participation in the trial. Once written informed consent has been obtained, patients are considered to be included in the study.

Day 1 – Day of c-section

Preparation

Except for the intervention (active prewarming), medical care during the cesarean section will be standardized based on the standard protocols of our hospital.

All patients will receive Ranitidine 150 mg PO and natrium citrate 20 ml PO as pre-medications approx. One hour before spinal anesthesia. Antibiotics (2g Cefazolin IV) will be applied as per obstetrician orders. Continuous non-invasive measurement of core temperature (SpotOn by 3M, Neuss, Germany) will be initiated before randomization and will be continued until discharge from PACU.

Randomization into group W (prewarming) and C (control, no prewarming) is performed by using prepared, sealed, opaque envelopes. Patients in group W (intervention group) will be warmed preoperatively by using a standard convective patient warmer (mistral air, The 37 Company, Amersfoort, The Netherlands) set to 38°C for at least 20 minutes and receive a standard hospital duvet cover. Patients in group C (control group) will receive a standard hospital duvet cover and no active warming.

SpotOn temperature measurement sensor

Before bringing the patient to the OR, a thermal image will be taken (FLIR ONE PRO, FLIR Systems, Inc., Wilsonville, USA) to document the heat distribution throughout the patient's body. The picture will cover lower half of the patient's body (genital area covered).

Example of a thermal image; skin temperature measured on back of left hand.

Surgery

In the operating room, basic monitors will be applied (pulse-oxymitery, non-invasive blood pressure, ECG 3-Leads). Room temperature will be set to 20°C. Before placing the spinal anesthesia, patient comfort is assessed using 100-mm visual analog scale (Buggy and Crossley, 2000).

Spinal anesthesia will be given at a sitting position at a level of L3-4 using 2.0 to 2.4 mL hyperbaric 0.5% Bupivacaine with addition of intrathecal morphine 200 mcg (hospital standard). Once spinal anesthesia is placed, patients are placed in lithotomy position and active warming with the mistral-air device set to 43°C is initiated with a convective warming blanket under the patient's body (blanket ID 2450). For heat conservation, two warmed blankets will also be applied over the upper half of the body. For surgical reasons, a urinary bladder catheter is placed and a temperature cable will be connected to the temperature sensor in the urinary bladder catheter.

Surgery will be performed according to the hospital standard. The exact time of key time points will be recorded: begin of prewarming, end of prewarming, as well as time points recorded as per hospital policy (e.g. skin incision, delivery suture) After delivery of the baby and extraction of the placenta, ambient room temperature and bladder temperature are recorded. Additionally, a thermal image of the open wound will be obtained. Further surgery will be performed according to the hospital standards. All medications, blood loss and administration of fluids are recorded on the anesthesia chart.

Before the beginning of the wound closure, another set of temperature measurements are taken and another thermal image of the wound is obtained. The remaining parts of the surgery are conducted according to the hospitals standards.

PACU

In PACU, recording of patient temperature is continued throughout the PACU stay. Additionally, we will assess patient thermal comfort at the begin of her stay in PACU and after one hour in PACU (Buggy and Crossley, 2000).

Day 2 – Follow-up

On the day after surgery, study patients will have a follow-up visit. Information about any adverse events will be obtained, and a final assessment of the patients' recollection of their thermal comfort is obtained. This concludes the study.

Outcomes

Primary outcome

- Difference in between the two groups in core temperatures and wound temperature after delivery of the baby and the placenta and before wound closure.

Secondary outcomes

- Difference in core temperature during the perioperative course.
- Difference in core temperature in PACU.
- Difference in patient comfort.
- Difference in baby Apgar score and pH in blood gas analysis.

Statistical analysis

Sample size estimation

Based on preliminary data obtained during testing of the thermal camera, we estimate a difference in wound temperature of 1°C. With a ß-error of 80% and a α-level of 5%, 27 patients per group are required. To compensate for drop-outs, we will include 60 patients in the study (30 per group).

Table 1: Measurements and timepoints

Day 0		Screening	History, demographics, written informed consent
Day 1	T0	Before pre-warming	core temperature, patient comfort, thermal image of lower body
	T1	After prewarming.	core temperature, patient comfort, thermal image of lower body
	T2	After completion of spinal anesthesia	core temperature
	T3	After delivery of baby and placenta	core temperature, thermal image of wound
	T4	Before wound closure	core temperature, thermal image of wound
	T5	Begin PACU	core temperature, patient comfort
	T6	After 1hr in PACU	core temperature, patient comfort
Day 2		Follow-Up	Recolletion of patient comfort

Statistical analysis

Data will be presented as mean ± standard deviation (±SD), median and ranges, or frequencies (number of cases) or percentages where appropriate.

Comparison of numerical variables between the study groups will be done using Student t test for independent samples in comparing 2 groups when normally distributed. Mann Whitney U test for independent samples will be used when not normally distributed. For comparing categorical data, Chi square test will be performed. A probability value (p value) less than 0.05 is considered statistically significant.

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