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RESEARCH

A Randomized Controlled Trial to Improve Outcomes Utilizing Various Warming Techniques during Cesarean Birth

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ABSTRACT

Objective: To examine the effect of various warming methods during cesarean birth (CB) on maternal core body temperature, maternal hypothermia, and other maternal and neonatal outcomes.

Design: Three-arm randomized controlled trial.

Setting: Perinatal unit in a large community hospital in the mid-Atlantic United States.

Participants: Two hundred twenty-six (226) pregnant women undergoing planned CB.

Methods: Women were randomly assigned to one of three groups (usual care, warmed fluids, or warmed underbody pad). Warming treatments began preoperatively and continued for 2 hours postoperatively. Study nurses measured outcomes at defined intervals.

Results: Both warming techniques affected maternal temperatures and the incidence of hypothermia. The warmed fluids group had significantly higher temperatures in the operating room, whereas the warmed underbody pad group had significantly higher temperatures in the recovery room. Although none of the other outcomes was statistically different among groups, the findings have implications for practice. Apgar scores were proportionately lower in the usual care group, and maternal request for additional warming was proportionately higher in the usual care group.

Conclusion: This study adds information on ways to maintain maternal normothermia during surgery. By understanding maternal hypothermia during CB, nurses can use best practice to obtain optimal maternal and neonatal outcomes.

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Hypothermia is a known complication of abdominal surgery and may increase surgical wound infections, hypertension, cardiac complications, coagulopathy, and bleeding (Eddy, Morris, & Cullinane, 2000). Previously, researchers found that as many as 77% of patients undergoing abdominal surgery develop hypothermia during the procedure (Ellis-Stoll, Anderson, Cantu, Englert, & Carlile, 1996). Intraoperative hypothermia develops in response to exposure to cool ambient environmental temperatures in the operating room (OR), exposure of the abdominal cavity, and infusion of room-temperature intravenous (IV) fluids (Butwick, Lipman, & Carbalho, 2007). Spinal anesthesia demonstrates a negative correlation between block levels and core temperature (Frank, El-Rahmany, Cattaneo, & Barnes, 2000) by exacerbating intraoperative hypothermia due to peripheral vasodilatation caused by the inhibition of vasomotor function. In addition, the lack of movement in the large muscles resulting from the administration of regional anesthesia retards the body's ability to respond to alterations in the core temperature during surgery. Postoperative hypothermia is a recognized risk factor for compromised recovery and contributes to increased mortality rate in adult intensive care units. This finding has particular significance given that the rate of postoperative hypothermia hovers around 35% in adult critical care (Karalapillai et al., 2009).

Cesarean birth (CB) is the most common surgical procedure in the United States and comprises 32.8% of all U.S. births (Hamilton, Martin, & Ventura, 2012). Maternal hypothermia after planned cesarean (MHAPC) is a known complication of

Warmed cloth blankets and forced warm air blankets offered to women who complain of being cold or experience shivering are ineffective.

CB (Fallis, Hamelin, Symonds, & Wang, 2006) and occurs in nearly 50% of all cases (Butwick, Lipman, & Carvalho, 2007). Surprisingly, very few researchers have examined MHAPC in the last three years (Holloran, 2009).

Common practices in the clinical setting reflect recognition of the problem of MHAPC. Two common technologies available in many birthing suites, warmed cloth blankets and forced warm air blankets, enable nurses to provide exogenous heat to women who complain of being cold or experience shivering during the first few postpartum hours. However, neither type of blanket improves outcomes (Butwick et al., 2007; Fallis et al., 2006), most likely due to disturbances in the body's thermal homeostasis from regional anesthesia.

Conversely, several simple preventative nursing interventions may be effective. Yokoyama et al. (2009) showed that warming the operating room (OR) and using prewarmed (41°C) intravenous fluids reduced the occurrence of MHAPC. In that study, maternal core temperature, neonatal Apgar scores, and blood gas values improved significantly with warmed IV fluids during CB. Although the postpartum reactionary interventions were ineffective, simple preoperative and perioperative prevention methods produced significant benefits for mother and baby.

The paucity of published studies about MHAPC identifies a critical gap in the knowledge related to CB and its association with adverse maternal and neonatal outcomes. Much remains unknown about this clinical phenomenon, its implications for outcomes, and its effective management. We designed this study to fill that gap and examined thermal variance in women undergoing planned CB under spinal anesthesia. A three-arm clinical trial was conducted to determine if the interventional use of warmed IV fluids or warmed underbody pad versus usual care reduced the likelihood of maternal hypothermia intraoperatively or during the first 4-hours postpartum. We hypothesized that usual care practices in isolation would be related to lower core temperatures and increased levels of hypothermia, maternal shivering, pain, thermal discomfort, delayed initial breast feeding, delayed maternal/neonatal bonding, and adverse neonatal outcomes including hypothermia, lower Apgar scores, and lower cord pH values. We used the Consolidated Standards for Reporting Trials (CONSORT) guidelines to frame the reporting of the study (Schulz, Altman, & Moher, 2010).

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Methods

Design

A parallel group three-arm randomized controlled trial consisting of a usual care group, a warmed fluids treatment group, and a warmed underbody pad treatment group tested the hypothesis. The study team aimed to have an equal number of participants in each group. The study protocol did not change after recruitment began.

Participants, Sample Size, and Setting

Women were eligible for participation if they presented for planned singleton CB during the study period. Exclusion criteria included unplanned CB, failure to receive postoperative Duramorph, or planned postpartum tubal ligation during CB. An a priori power analysis conducted by a statistician consultant indicated that 50 to 100 women per treatment group would be sufficient to show differences in maternal hypothermia among groups.

This study was conducted in a large community hospital in the mid-Atlantic United States. The hospital provides comprehensive perinatal care and manages approximately 4600 births annually. The team that designed and implemented the study consisted primarily of a study coordinator and four Labor & Delivery (L&D) nurses. The chief of obstetrics and chief of obstetric anesthesia approved and supported the study. A small number of postpartum nurses participated in patient monitoring throughout the study period. Study nurses recruited participants, revealed the assigned treatment group from the sealed envelopes, provided primary care, and collected data. The study ended after 11 months because we met our recruitment goal.

Randomization and Blinding

We used the Research Randomizer website to generate the simple random allocation sequence. The names of the treatment groups were placed into envelopes per the randomization sequence, sealed, and labeled with a sequential participant number. Once a patient consented to participate, a study nurse opened the envelope to reveal the name of the assigned group. The nature of the