



# The effects of a resistive warming mattress during caesarean section: a randomised, controlled trial

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#### ABSTRACT

**Background:** The adverse effects of inadvertent perioperative hypothermia in the surgical population are well established. The aim of this study was to investigate whether a resistive warming mattress would reduce the incidence of inadvertent perioperative hypothermia in patients undergoing elective caesarean section.

**Methods:** A total of 116 pregnant women booked for elective caesarean section were randomised to either intraoperative warming with a mattress or control. The primary outcome was the incidence of inadvertent perioperative hypothermia, defined as a temperature  $<36.0^{\circ}$ C on admission to the recovery room. Shivering in the perioperative period, severity of shivering and the need for treatment, total blood loss, fall in haemoglobin, incidence of blood transfusion, immediate health of baby, and length of hospital stay were also recorded.

**Results:** The incidence of inadvertent perioperative hypothermia in the mattress-warmed group was significantly lower than in the control group (5.2% vs. 19.0%, P = 0.043); mean temperatures differed between the two groups, 36.5°C and 36.3°C, respectively (P = 0.046). There was also a significantly lower mean ( $\pm$  SD) haemoglobin change in the mattress-warmed group at  $-1.1 \pm 0.9$  g/dL versus  $-1.6 \pm 0.9$  g/dL in the control group (P = 0.007). There was no difference in shivering (P = 0.798).

**Conclusions:** A resistive warming mattress reduced the incidence of inadvertent perioperative hypothermia and attenuated the fall in haemoglobin. The use of resistive mattress warming should be considered during caesarean section.

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## Introduction

The adverse effects of inadvertent perioperative hypothermia (IPH) in the general surgical population are well established.<sup>1–4</sup> Shivering can cause patient discomfort, distress and hypoxia.<sup>5</sup> To date, little research has looked at IPH in patients undergoing caesarean section (CS);<sup>4</sup> what randomised trial data exist generally involve small numbers of patients ranging from 30 to 75.<sup>6–9</sup> Furthermore, in this group of patients, undesirable effects may extend beyond the patients as hypothermia and

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shivering may adversely affect contact with and feeding of the new baby; one study suggested that hypothermia can affect Apgar scores.<sup>6</sup>

The UK National Institute for Health and Care Excellence (NICE) has published guidance on the prevention of perioperative hypothermia.<sup>10</sup> These guidelines refer to elective operations under general or neuraxial anaesthesia, but surgical procedures on pregnant patients including CS were considered outside the remit of the panel.<sup>11</sup> Nevertheless, it is reasonable to infer that women undergoing CS are likely to benefit from warming.<sup>4</sup>

Recent research has shown that few UK obstetric units routinely warm patients undergoing elective CS and intraoperative warming does not appear to be a standard of care.<sup>12</sup> Our own audit data have shown approximately 11% of patients undergoing elective CS become hypothermic and 25% suffer from shivering.<sup>13</sup> An audit from another obstetric unit showed that 50% of patients undergoing elective CS were hypothermic (as defined by NICE) on admission to the recovery

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room.<sup>14</sup> An analysis of our group's previous audits has suggested that all patients undergoing CS with spinal or epidural anaesthesia should receive intraoperative warming.<sup>15</sup>

In the NICE guideline, forced air warming blankets (FAWB) were the only active warming devices recommended as only they had a published evidence base at the time of drafting.<sup>10</sup> FAWB can be obtrusive for awake patients and the authors of the NICE guidance accept that alternative warming devices may also be effective; a small study conducted by our group suggests that warming mattresses (WM) may be as effective as FAWB.<sup>16</sup> Recent NICE medical technology guidance has recommended that a WM produced by a specific manufacturer should be considered as an alternative to FAWB.<sup>17</sup>

The aim of this study was to investigate whether a commercially available under-body resistive WM could reduce the incidence of IPH in women undergoing elective CS. Our null hypothesis was that the use of a resistive WM would not alter the incidence of IPH during elective CS.

### Methods

After obtaining ethical approval from the Local NHS Research Ethics Committee (09/H1107/105), and written informed consent, 116 women undergoing elective CS were enrolled in this randomised, single-blind, interventional study comparing a WM with the current UK standard of care (no warming). The study was conducted at Brighton and Sussex University Hospitals NHS Trust, UK. Women were recruited between February 2010 and July 2011. The trial was prospectively registered with clinicaltrials.gov (ref: NCT01054209) and EudraCT (ref: 2009-016118-26).

All women undergoing elective CS were eligible for recruitment. Women who were unable to fully understand the trial and those aged <16 years at the time of CS were excluded. Potential participants were identified by the investigating team in the pre-assessment clinic attended by all women 24-72 h before their elective CS. Women were given information sheets detailing the protocol and consent procedure. It is standard practice in our institution for haemoglobin (Hb) to be measured at this visit. On the day of surgery, patients were seen by their anaesthetist. Potential participants were then reviewed by the investigating team, consented by one of two investigators (AC or MJD), and allocated a unique trial reference number. After recruitment, participants were randomly assigned to group A (not warmed with mattress) or group B (warmed with mattress) using a randomisation master sheet generated by a web-based randomisation system (http://graphpad.com/quickcalcs/randomN1.cfm). Age, American Society of Anesthesiologists (ASA) grade, gestation, weight, body mass index (BMI) at booking (approximately 10–12 weeks of gestation), and patient temperature at the time of consent were recorded. The data analyst and anaesthetists conducting the cases were blinded to the identity of the two groups, but the investigator responsible for consenting, randomising, collecting data from participants and controlling the WM was not blinded. Participants were not informed of their group allocation.

Temperature was measured non-invasively with a Temporal*Scanner*<sup>™</sup> TAT-5000 temporal artery scanner (Exergen, Watertown, MA, USA) used in previous published trials of IPH. This device has comparable accuracy to bladder temperature monitoring.<sup>18,19</sup>

The operating room temperature at the time of CS was noted. In the operating room, all patients were placed on a full body reusable pressure relieving under-body resistive WM (Inditherm Alpha Systems, OTM1: 1900 mm × 585 mm, Inditherm plc, Rotherham, UK) covered with a cotton sheet (Fig. 1). If the patient was allocated to group B, the mattress was turned on by the investigator and set to 40°C before the patient entered the operating theatre. Anaesthesia was conducted according to the individual clinician's choice, including the use of warmed fluids. In our institution, no patient warming device is used during elective CS and warmed fluids are recommended only when it is expected that >500 mL will be administered.<sup>10</sup> Warmed fluids, if used, were warmed using a Ranger<sup>™</sup> fluid warmer (warming unit model 24500, Standard Flow Disposable Set model 24200, Arizant Inc, Eden Prairie, MN, USA). Women were repeatedly asked about their level of thermal comfort and encouraged to inform investigators of any discomfort at any time. The protocol required temperature to be measured immediately



Fig. 1 Labour ward theatre set-up with warming mattress and control unit

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