# Preoperative warming versus no preoperative warming for maintenance of normothermia in women receiving intrathecal morphine for cesarean delivery: a single blinded, randomized controlled trial.

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Judy Munday is identified as the principal and corresponding author, based on the criteria specified by the International Committee of Medical Journal Editors [1] and was responsible for initiation of the project, study design, data collection, data analysis, write up of results and writing of the final manuscript. Sonya Osborne contributed to the research protocol, study design, and review of final manuscript. Patsy Yates contributed to the research protocol, study design, and review of final manuscript. David Sturgess contributed to the study protocol, review of results and of the final manuscript. Lee Jones provided statistical review and review of the final manuscript. Edward Gosden reviewed the protocol, contributed to statistical review and reviewed the final manuscript.

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**Abbreviated Title:** Preoperative warming for cesarean delivery

**Abstract**

***Introduction***

Rates of hypothermia for women undergoing spinal anesthesia for cesarean delivery are high and prevention is desirable. This trial compared the effectiveness of pre-operative warming versus usual care amongst women receiving intrathecal morphine, which is thought to exacerbate perioperative heat loss.

***Methods***

A prospective, single-blinded, randomized controlled trial compared 20 minutes of forced air warming (plus intravenous fluid warming) versus no active preoperative warming (plus intravenous fluid warming) in 50 healthy American Society of Anesthesiologists (ASA) graded II women receiving intrathecal morphine as part of spinal anesthesia for elective cesarean delivery. The primary outcome of maternal temperature change was assessed via aural canal and bladder temperature measurements at regular intervals. Secondary outcomes included maternal thermal comfort, shivering, mean arterial pressure, agreement between aural temperature, and neonatal outcomes (axillary temperature at birth, Apgar scores, breastfeeding and skin-to-skin contact). The intention-to-treat population was analyzed with descriptive statistics, general linear model analysis, linear mixed model analysis, Chi-square test of independence, Mann-Whitney, and Bland Altman analysis. Full ethical approval was obtained, and the study was registered on the Australia and New Zealand Clinical Trials Registry (Trial No: 367160, registered at http://www.ANZCTR.org.au/).

***Results***

Intention-to-treat analysis (n=50) revealed no significant difference in aural temperature change from baseline to the end of the procedure between groups: $F$ (1, 47) = 1.2, $p$ =0.28.

There were no other statistically significant differences between groups in any of the secondary outcomes.

***Conclusions***

A short period of pre-operative warming is not effective in preventing intraoperative temperature decline for women receiving intrathecal morphine. A combination of preoperative and intraoperative warming modalities may be required for this population.

**Introduction**

Women undergoing cesarean delivery are a vulnerable but often overlooked population in guidelines for perioperative temperature management. Inadvertent perioperative hypothermia, defined as the unintentional cooling of core temperature to below 36ºC during surgery,[2] has detrimental physiological effects which have been well-studied in the non-pregnant population. These include increased blood loss,[3] higher wound infection rates,[4] immune function suppression,[5] prolonged drug action[6, 7], increased duration of recovery stays[8] and increased hospital stay,[4] increased costs,[9] shivering[10,11] and, importantly, discomfort. Impacts upon neonatal outcomes, such as temperature at birth,[12] umbilical vein[12] and arterial pH[13] and Apgar scores[13] have been demonstrated in some studies as well a relationship between neonatal hypothermia and hypoglycaemia.[14] Hypothermia is often undetected until the postoperative phase, causing significant disruption to postoperative care, as well as maternal-newborn bonding and feeding, whilst rewarming is applied.

Rates of perioperative hypothermia amongst women undergoing cesarean under spinal anesthesia have been estimated as being as high as between 32%[15] to 80%.[16] In addition, perioperative hypothermia appears to be exacerbated by intrathecal morphine.[15, 17,18,19] Since, in clinical practice, spinal anesthesia, commonly utilizing intrathecal morphine, often comprises standard care for this population, it is important that health care providers establish pre-emptive measures to reduce the occurrence of hypothermia, shifting the emphasis from treatment to prevention for all women undergoing caesarean delivery.

Guidelines for the general adult population advise 30 minutes of preoperative warming.[2] A shorter period may be more clinically acceptable and practical, while still reducing intraoperative core temperature decline. Horn et al. tested passive warming versus 10, 20 or 30 minutes of preoperative forced air warming, in a randomized controlled trial of 200

patients undergoing laparoscopic surgery under general anesthesia, finding that 10 minutes of preoperative warming resulted in significantly improved core temperature.[20] An optimum warming period of 20 minutes was recommended where clinically possible.[20] Fifteen minutes of preoperative warming before induction of epidural anesthesia, plus continuation of forced air warming during surgery, has also shown efficacy at reducing hypothermia in a population of women receiving epidural anesthesia but who did not receive opioids.[12]

This single blinded, randomized controlled trial compared the effect of a period of 20 minutes of preoperative forced air warming alongside intraoperative intravenous (IV) fluid warming with usual clinical care (IV fluid warming and no preoperative forced air warming) in women receiving intrathecal morphine during elective cesarean delivery on the primary outcome of maternal temperature change from baseline to the end of the procedure. Secondary outcomes – for exploratory analysis only – included temperature decline assessed over time, hypothermia, maternal thermal comfort, mean arterial pressure (MAP), shivering, agreement between aural canal and bladder temperature measurements, neonatal axillary temperature at birth, Apgar scores at 1 and 5 minutes, skin-to-skin contact at birth, breastfeeding at birth and upon discharge from hospital and incidence of wound complications.

## Methods

### *Study Design*

Women with singleton pregnancies booked for elective cesarean delivery at term under spinal anesthesia with intrathecal morphine were enrolled in this pragmatic, single-blinded randomized controlled study, following hospital and university ethics approval, and informed consent. Exclusion criteria included known allergy to morphine, known impaired thermoregulation or thyroid disorders, vascular disease or poor cutaneous perfusion, ASA

score >II, history of preeclampsia or eclampsia, planned Intensive Care Unit (ICU) admission, tympanic membrane/aural canal that was not visible on otoscopy and baseline temperature ≥37°C. The study was registered on the Australia and New Zealand Clinical Trials Registry (Trial No: 367160, registered at http://www.ANZCTR.org.au/ on 10th October 2014 by the principal investigator Judy Munday).

***Study Protocol***

After informed consent, and otoscopy, participants were randomly assigned to either the control or the intervention group. The randomization schedule was computer–generated, utilising fixed-size blocks (at www.randomisation.com) of five per block and placed within sequentially numbered opaque envelopes. An independent coordinator generated the allocation sequence, and allocation to groups was concealed from the blinded outcome assessor.

Participants in the control group received usual care consisting of no active warming during the admission and preoperative period. Participants in the intervention group received 20 minutes of full body preoperative warming in which perioperative midwives independent of the study applied a forced-air warming device (Cocoon™) set to 43°C in the preoperative waiting area, prior to entering the operating room for induction of spinal anesthesia. The investigator remained in the operating theatre and did not access the preoperative waiting area to ensure blinding. A delay of more than 20 minutes between the end of the preoperative warming and transfer to theatre was considered a protocol deviation. Patients were monitored during the intervention to assess for adverse side effects related to warming, such as diaphoresis or nausea and vomiting.

All women received intravenous fluid warming (compound sodium lactate) warmed to 38.5° C (via Biegler™ fluid warmer), were covered with a warmed cotton blanket and surgical drapes, and received standardized intraoperative anesthetic medication and intravenous

fluids. After induction of spinal anesthesia, a temperature sensing indwelling urinary catheter (Mon-a-Therm™) was inserted. All patients received spinal anesthesia (or combined spinal-epidural anesthesia with no opioids via the epidural catheter) in the sitting position at the L3-4 interspace, with 2.2 to 2.4 mL hyperbaric 0.5% bupivacaine, intrathecal morphine 100 mcg, and intrathecal fentanyl 15 to 20 mcg. Block height was tested using ice, and the procedure commenced once a sensory block above T4 was achieved. Intravenous carbetocin 100 mcg was administered at delivery. Rectal paracetamol 1 g and diclofenac 100 mg were administered at the end of the procedure. Variations to the protocol were documented and recorded. Ambient preoperative holding bay and operating room temperature was recorded via thermostat. At the end of the procedure, all patients were covered with a warmed cotton blanket and a reflective foil blanket, prior to transfer to PACU. If temperature decline, or temperature $\leq$ 35.5° C (as per institutional guidelines), shivering or cold discomfort was experienced in PACU, further warmed blankets were offered and/or forced air warming commenced as per routine care.

Maternal temperature was measured using both a calibrated Genius™ aural canal thermometer (cited as reading a mean of -0.4° C less than pulmonary artery measurement)[21] and a Mon-a-Therm™ indwelling urinary catheterization (cited as providing accuracy to within 0.1° C of pulmonary artery measurement)[22] at the following time points: baseline, pre-spinal, post-spinal, every 15 minutes and at the end of the procedure, on arrival to PACU, then every 15 minutes until ready for discharge from PACU. Maternal thermal comfort was measured using a 100mm Visual Analogue Scale (VAS), used in a number of studies measuring patient thermal comfort.[23-27] Shivering was assessed via a three-point scale used in previous studies in this population,[28,29] in the absence of a validated shivering scale. Mean arterial pressure (MAP) was measured at baseline, pre-spinal, post-spinal and at the end of the procedure, however only baseline, pre-spinal and post-spinal measurements were analyzed due to the individual difference in the use of vasopressors in response to clinical

need; which was not specified in the anesthetic protocol. An independent midwife assessed neonatal axillary temperature, and Apgar scores, at 1 and 5 minutes after birth. Duration of skin-to-skin at birth, feeding intention, breastfeeding and timing of feed at birth were recorded, as well as breastfeeding at 10 days postnatally which was determined retrospectively from the Universal Postnatal Contact Survey. Wound infection and dehiscence upon hospital discharge, and patient concerns with the post-natal wound (at 10 days) were also determined via chart review. Demographic data collection included maternal age, parity and gravidity. Surgical variables such as intraoperative blood loss, volume of intravenous fluid infusion, anesthetic medication (including any which deviate from the agreed protocol) duration of procedure, preoperative and operating room (OR) ambient temperature were also recorded. This manuscript adheres to the CONSORT criteria for the reporting of RCTs.[30]

### *Statistical Analysis*

Descriptive statistics were generated to summarize sample characteristics, and hypothermia prevalence. Data are expressed as means and standard deviations, median and range or as frequencies and percentages as indicated. A general linear model was used to assess the primary outcome of aural temperature change between groups, with adjustment for baseline temperature and surgery duration.

An exploratory analysis of secondary outcomes was undertaken, using linear mixed model analysis (to allow for fixed effects of baseline temperature, time and group, and a random intercept for repeated measures) for aural temperature decline from immediately after spinal insertion until the end of the procedure. Linear mixed model analysis was also used to assess thermal comfort between groups at repeated time points. Pearson Chi-Square test of independence with Continuity Correction was used to analyse hypothermia incidence, shivering and neonatal outcomes, with the Mann-Whitney U Test used for non-parametric

mean arterial pressure data. Bland-Altman analysis (using MedCalc™) examined agreement[31] between aural canal and bladder temperature, and to provide a means to establish the accuracy of the aural canal measurements used for the primary analysis. SPSS™ software (version 22) was utilised for all other data analysis: $p < 0.05$ was considered statistically significant for the primary outcome, and $p < 0.01$ for the secondary outcomes.

All analyses were performed on the Intention-to-Treat (ITT) population, which included all participants in the groups to which they were assigned, irrespective of protocol deviations.

A required sample size of 15 participants in each group was calculated, based on a repeated measures design with the initial temperatures being the same and the temperature decline being 0.4°C greater in the unwarmed group than the warmed group when measured 45 minutes after commencement of surgery. A standard deviation of 0.4°C was used in the calculation, based on the data reported by Chung et al.[32] A type I error rate of 0.05 and a power of 90% were specified. The sample size was inflated from a total of 30 to a total of 50 to allow for attrition.

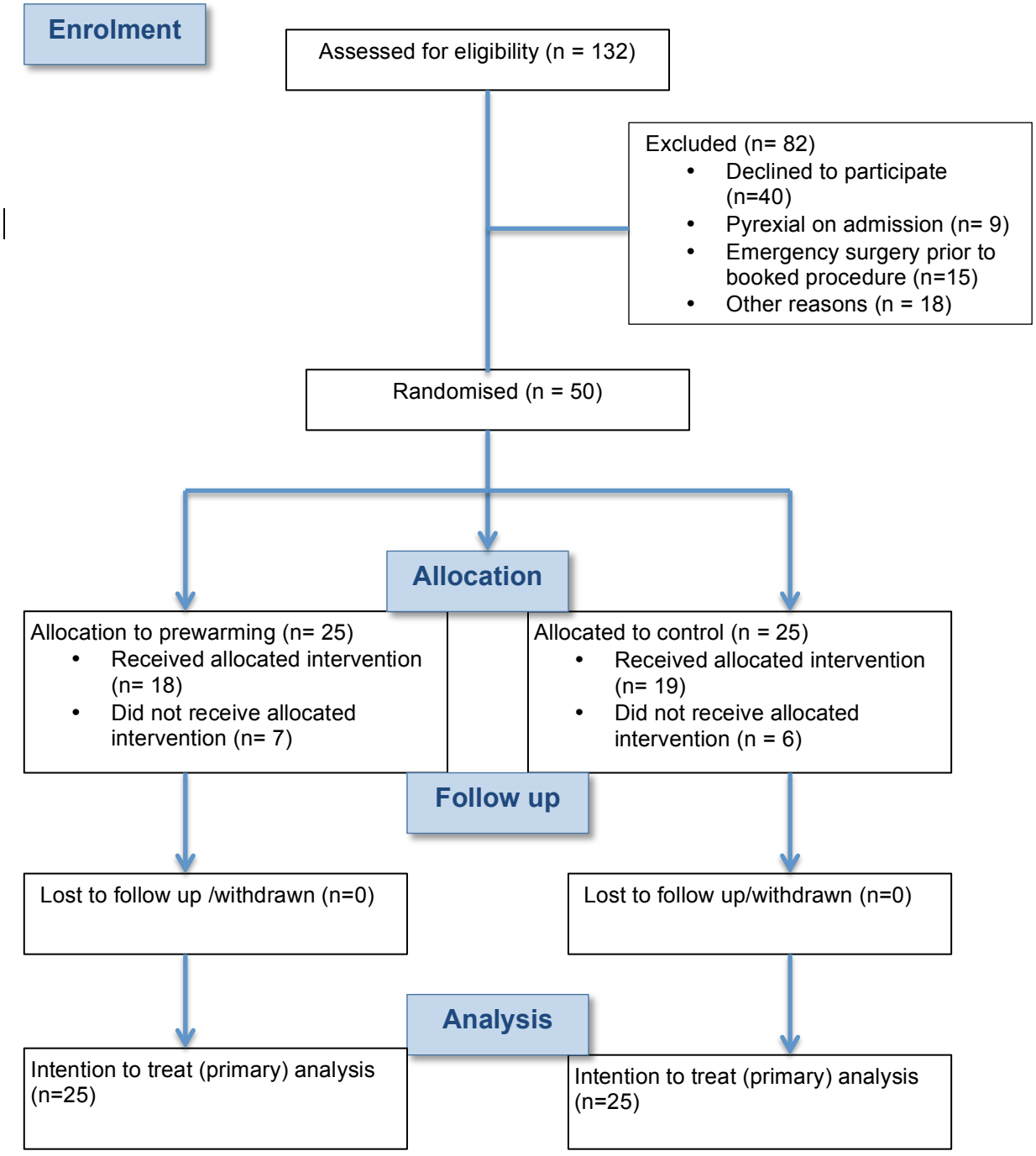


**Figure 1:** Study Flow-chart

## Results

Patients were enrolled in the study between February 2015 and February 2016. All 50 patients completed the study (Figure 1), however there were 13 protocol deviations: seven in the preoperative warming group and six in the control group. Three patients in the pre-operative warming group had suspected bladder injury and received methylene blue dye; from the point of this occurrence bladder temperature for these patients was disregarded. Maternal baseline characteristics, as well as surgical and anaesthetic variables, were similar across treatment groups apart from baseline temperature (Table 1). In the warming group, four patients experienced sweating. Due to this, one patient ceased the warming period two minutes early by request. No other adverse events related to the warming intervention were reported.

### Primary outcome

Intention-to-treat analysis revealed no significant difference in aural temperature change from baseline to the end of the procedure between groups: $F$ (1, 47) = 1.2, $p$ =0.28, partial eta squared = 0.03) (Table 2).

### Secondary outcomes

Although the preoperative warming group experienced higher intraoperative mean temperatures, from the insertion of spinal anesthesia until 30 minutes, this was not statistically significant and by 45 minutes temperatures in both groups were the same, when analysed using linear mixed model analysis, and controlling for baseline temperature (Figure 2). There were no statistically significant differences in hypothermia incidence between the groups (see Table 2).

Maternal thermal comfort did not differ between groups at any time point (Table 3). There was no clinically significant differences in MAP between groups or differences in

postoperative outcomes. No patients experienced wound infection or dehiscence, assessed at discharge, in either group. On follow-up, one patient in the control group had a post-natal wound infection (10 days post-partum). Neonatal outcomes were also similar between groups.

Bland-Altman analysis indicated that, apart from one outlier, differences between aural canal (Genius™) and bladder (Mon-a-Therm™) temperature measurement devices appear to be consistent as temperature changes. The mean difference between devices was 0.04°C (SD 0.25). The limits of agreement ranged from 0.93—0.86°C, however only two paired measurements exceeded a difference of 0.5 °C, conventionally cited as a clinically acceptable measurement variation (Figure 3).

**Table 1:** Maternal baseline, surgical and anesthetic data

| Variable | Pre-operative warming: median, (range) (n=25) | Control: median, (range) (n=25) | P value |
|---|---|---|---|
| **Age (yrs)** | 31 (23-41) | 36 (19-40) | 0.07 |
| **BMI** | 22.9 (16.2-38.2) | 23.8 (17.6-40.3) | 0.90 |
| **Gravidity** | 2 (1-7) | 2 (1-6) | 0.31 |
| **Parity** | 2 (1-5) | 2 (1-5) | 0.80 |
| **ASA I**<br>**ASA II** | 21<br>4 | 19<br>6 | 0.48 |
| **Estimated blood loss (mls)** | 400 (200-700) | 400 (200-600) | 0.93 |
| **Surgical duration (mins)** | 46 (31-76) | 46 (27-72) | 0.68 |
| **Intraoperative Intravenous Fluid (mls)** | 1500 (800-2100) | 1500 (800-2050) | 0.98 |
| **Baseline temperature (°C)** | 36.6 (35.7-36.9) | 36.8 (35.9-36.9) | *0.05** |
| **Mean arterial pressure (MAP)** | 86 (69-100) | 85 (71-96) | 0.53 |
| **Spinal Time (mins)** | 12 (6-31) | 14 (8-22) | 0.37 |
| **Clean up time (mins)** | 9 (4-15) | 10 (5-14) | 0.61 |
| **Preoperative ambient temperature (°C)** | 23 (22-25) | 24 (23-26) | 0.22 |
| **OR Ambient Temperature (°C)** | 21.4 (20.2-23) | 21.5 (20.6-22.6) | 0.21 |

BMI: Body Mass Index

ASA: American Society of Anesthesiologists

MAP: mean arterial pressure

OR: operating room

**Table 2:** Temperature change (°C): baseline-end of procedure and hypothermic patients at each time point

| | **Temperature change °C (baseline – end of procedure): mean (SD) number** | | |
|---|---|---|---|
| | **Intervention** | **Control** | **P value** |
| **Intention-to- treat** | 0.5 (SD 0.32) (n=25) | 0.7 (SD 0.57) (n=25) | 0.28 |
| **Hypothermic patients (by group) at each time point** | | | |
| | **Intervention (n=25)** | **Control (n=25)** | |
| **Baseline** | 3 (12%) | 1 (4%) | |
| **Pre Spinal** | 0 | 0 | |
| **Post Spinal** | 0 | 0 | |
| **OR 15 minutes** | 4 (16.7%) | 6 (25%) | |
| **OR 30 minutes** | 6 (24%) | 9 (36%) | |
| **OR End Procedure** | 11 (44%) | 12 (48%) | |
| **PACU Arrival** | 12 (48%) | 16 (64%) | |

Hypothermia: defined as a temperature of <36°C

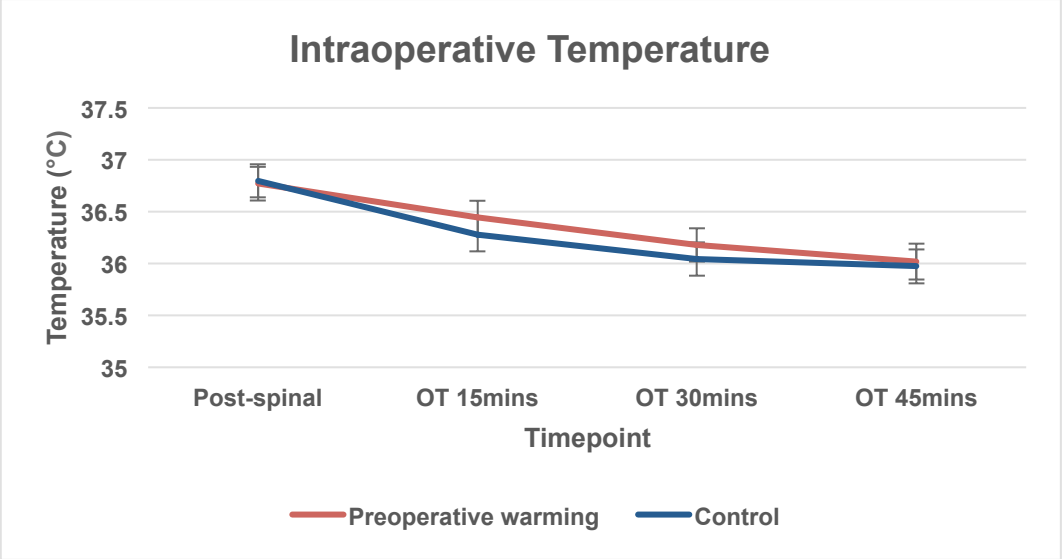


**Figure 2:** Intraoperative temperature (°C)

**Table 3:** Secondary Maternal and Neonatal Outcomes

| Variable | Preoperative warming (n=25) | Control (n=25) | P value |
|---|---|---|---|
| **Mild shivering*** | 3 (12%) | 8 (32%) | 0.09 |
| **Intense Shivering** | 0 | 3 (12%) | n/a |
| **Any shivering*** | 3 (12%) | 8 (32%) | 0.09 |
| **MAP (Pre-spinal)#** | 97 (70-113) | 97 (84-116) | 0.69 |
| **MAP (Post-spinal)#** | 89 (68-112) | 85 (56-118) | 0.03 |
| **Overall maternal thermal comfort** | 5.4 (95%CI 5.1-5.7) | 5.2 (95%CI 4.9-5.5) | 0.58 |
| **PACU: arrival to ready to discharge (mins)** | 37 (30-76) | 39 (27-81) | n/a |
| **Warmed in PACU** | 17 (68%) | 20 (80%) | 0.52 |
| ***Neonatal Outcomes*** | | | |
| **Axillary temperature (°C)**** | 36.8 (36.0-37.3) | 36.6 (36.2-37.3) | 0.26 |
| **Apgar at 1 min#** | | | |
| ***Apgar 7*** | 1 (4%) | 1 (4%) | 0.92 |
| ***Apgar 8*** | 4 (16%) | 3 (12%) | |
| ***Apgar 9*** | 20 (80%) | 20 (80%) | |
| ***Apgar 10*** | 0 | 1 (4%) | |
| **Apgar at 5 mins##** | | | |
| ***Apgar 8*** | 1 (4%) | 0 | 0.74 |
| ***Apgar 9*** | 24 (96%) | 24 (96%) | |
| ***Apgar 10*** | 0 | 1 (4%) | |
| **Special Care Nursery (SCN) admission** | 0 | 0 | n/a |
| **Intensive Care Nursery (ICN) admission** | 0 | 1 | 1 |
| **Respiratory distress** | 3 (12%) | 5 (20%) | 0.7 |

| | | | |
|---|---|---|---|
| **Intention to breastfeed** | 21 (84%) | 23 (92%) | 0.3 |
| **Breastfed at delivery** | 21 (84%) | 22 (88%) | 0.5 |
| **Skin-to-skin >30 minutes** | 12 (48%) | 7 (28%) | 0.23 |
| **Breastfed 10 days postnatally** | 13 (81%) | 17 (85%) | 1 |

* median (range) # number (%) **Fisher's Exact Test, ## median, range, *** Estimated marginal means, linear mixed model analysis

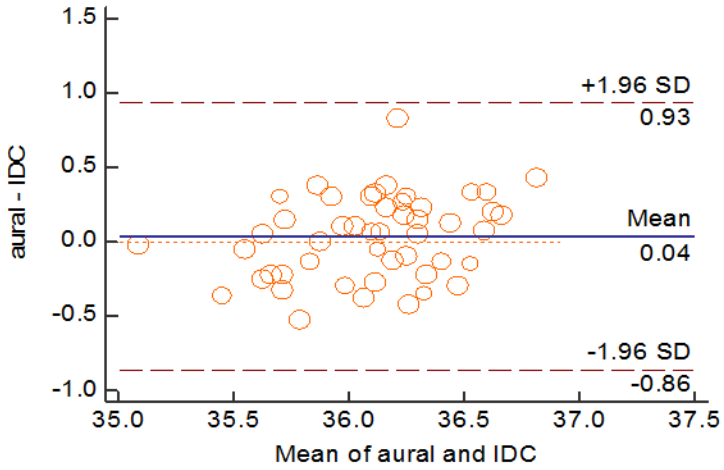


**Figure 3:** Bland-Altman Plot – Agreement between aural (Genius™) and bladder (Mon-A-Therm™) temperature

## Discussion

Twenty minutes of full body preoperative warming, prior to spinal anesthesia with intrathecal morphine for cesarean delivery, does not result in a significant decrease in intraoperative maternal temperature decline. Despite the decreased core to periphery heat gradient that is proposed to result from preoperative warming[12] by the end of the procedure both groups experienced temperature decline with similar end of procedure temperatures.

The results of our study contrast with Horn et al.'s findings that 15 minutes of upper body preoperative warming 43°C, continued intraoperatively, resulted in over 1°C difference between control and intervention group at the end of surgery, in favor of warming.[12] However, ambient temperature was higher in Horn's study, and surgical duration was slightly less than our study (Table 1). In addition, their population received epidural anesthesia with no opioids, which may contribute to the marked differences between their warmed and unwarmed groups.[12] Similarly, De Bernardis et al. also found temperature declined less when women received pre-operative warming that continued intraoperatively, (versus the control group receiving IV fluids warmed only to 37°C). All patients received spinal anesthesia with 80mcg intrathecal morphine.[33]

When considered in conjunction with the results from other comparable studies[12,32,33] several key variations appear important: the use (and dose) of intrathecal morphine, surgical factors including ambient temperature and surgical duration, and the use of pre-operative strategies that are both multi-modal and continued intraoperatively. Although it has been proposed that increased heat loss may occur with intrathecal morphine due to cephalic spread decreasing the temperature set-point, the reasons for this remain unconfirmed. Given current evidence, it cannot be said with certainty that intrathecal morphine blunts the response to warming.

Both groups in our study received IV fluid warming (as per National Institute for Health and Care Excellence (NICE) guidelines that fluids of ≥500mls should be warmed to 37°C or more), [2] in the form of crystalloid co-loading at the time of spinal anesthesia, as is usual care in our institution. This may help to maintain temperature during the period of intravascular volume shift that occurs during spinal anesthesia.[18] However, it is evident that IV fluid warming alone is not sufficient to prevent hypothermia in most patients, as indicated by the incidence of hypothermia in the control group in this study, again further suggesting that multi-modal interventions are likely to be of the most benefit.[18]

Both researchers and clinicians have questioned whether forced air warming is tolerable or practical for obstetric patients.[34,35] While this study did not assess tolerability in any meaningful way beyond recording adverse events related to warming, or patient symptoms of sweating, nausea or discomfort, it appears that patients largely found the duration and 43°C setting tolerable. Only one patient asked to cease the intervention two minutes early, which compares favourably with results from Fallis et al's study of upper-body intraoperative forced air warming, where 14 patients decreased the temperature of the forced air warmer from 43°C to a lower setting.[24] Research into obstetric patient's preferences for warming interventions may be warranted.

The intensity and incidence of shivering may indicate the severity of hypothermia. In our study, no pre-operatively warmed patients, as opposed to 3 patients in the control group, experienced severe shivering. Warmed IV fluids were found to be effective at reducing shivering in recent meta-analysis.[36] Non-thermogenic factors, such as catecholamines resulting from pain or anxiety, may also contribute to shivering,[37,38] and larger studies of the impact of combined warming strategies incorporating pre-operative warming upon shivering are warranted.

This study was designed to test a pragmatic approach to warming by using a short pre-operative full body warming regime, based on evidence of the optimal duration of effective pre-operative warming.[12,20] Warming was applied in the preoperative waiting area before women entered the operating room (OR). Our study protocol specified no greater than a 20 minute time delay between the end of the warming regime and entry to the OR, but some participants experienced longer delays, which reduced power of the study to detect a difference between groups. The benefits of preoperative whole body warming may be evident if warming is continued into the OR, through induction of neuraxial anesthesia, to the commencement of the surgical skin preparation.[12,32]

The use of aural canal thermometry is not without controversy, and disagreement exists as to the accuracy of this method. However, this method is not invasive and therefore may be more acceptable to patients. Our study used measures to assess and increase the reliability of aural canal thermometry, including checking the visibility of the tympanic membrane via otoscopy, using one outcome assessor, and using an additional measurement of bladder temperature (cited as providing an acceptable near-core measurement). Temperature decline was assessed until the end of the procedure, while other studies also report temperature in PACU.[39] Temperatures measured after arrival in the PACU were not analyzed because some patients received postoperative warming interventions; any measurements beyond the arrival temperature into PACU would therefore be confounded.

In conclusion, based on the intention-to-treat results of this study, a short period of preoperative forced air warming, in conjunction with intraoperative IV fluid warming, is not effective at preventing temperature decline in women that receive intrathecal morphine for cesarean delivery. These results do not correspond with the benefits reported for women undergoing cesarean delivery who have received pre-operative warming that continues

intraoperatively or have not received intrathecal opioids. However, as intrathecal opioid administration is common practice in many institutions, effective methods of preventing perioperative hypothermia in this population warrant further exploration; combined warming interventions are likely to be of the most benefit.

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