Clinical Approaches to the Prevention of Inadvertent Perioperative Hypothermia

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This work is being submitted as partial fulfilment of its requirements for the award of the degree of Doctor of Philosophy by Publication of the University of Portsmouth

Statement

I declare that none of the work presented in this thesis has been submitted for any other equivalent qualification.

For all the papers I was either the first or senior author and/or chief investigator. I contributed to all aspects of the undertaking of the research: design, data collection, analysis and writing of the text.

Whilst registered as a candidate for the above degree, I have not been registered for any other research award, t/he results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

Notes

Annex 1 was not a peer-reviewed publication but has been included to give perspective to the narrative.

Annex 2: the abstract to this paper was peer-reviewed and accepted for presentation at the European Society of Anesthesia Annual Scientific Meeting 2016 and will be published in a supplement to the European Journal of Anesthesia. However, I have included the full paper which we are submitting to the British Journal of Anaesthesia.

Annexes 11 and 13 are 'grey' literature publications

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Abbreviations

CG: Clinical guideline

CPW: Carbon polymer warming

CS: Caesarean section

FAW: Forced-air warming

Hb: Haemoglobin

IPH: Inadvertent perioperative hypothermia

ITS: Ingestible Temperature Sensor

NICE: The National Institute for Health and Care Excellence

OTP: Oesophageal temperature probe

PAC: Pulmonary artery catheter

RCT: Randomised Controlled Trial

RHM: Resistive heating mattress

RWB: Resistive warming blanket

TAS: Temporal artery scanner

UC: Urinary catheter

ZFD: Zero flux device

Abstract

The contribution of this programme of research has been to improve perioperative temperature management in daily clinical practice.

The papers presented in this thesis represent a logical and coordinated programme designed to provide theatre teams with information that will allow them to make clinically, environmentally and financially informed decisions about the most effective means of preventing inadvertent perioperative hypothermia.

The areas in which this research has contributed include:

- determining the accuracy of new and minimally invasive temperature measurement devices
- determining the relative effectiveness of warming devices
- the safety of warming devices
- increasing the number of patients who benefit from perioperative warming
- the adoption of best perioperative warming practice

1.0   Background: Statement of the problem

Under normal circumstances deep body temperature is maintained within the very narrow range required for the optimisation of physiological processes. Both general anaesthesia and central neural blockade impair thermal homeostasis.   General anaesthetic agents reduce vasoconstriction thresholds; this causes peripheral vasodilation that results in a redistributive hypothermia, as the warm central circulation tends to equilibrate with the cooler peripheral tissues. Central neural blockade (epidural and spinal anaesthesia) impairs temperature regulation by reducing conscious sensitivity to cold, reducing vasoconstriction thresholds and blocking the efferent nerves which control vasoconstriction.

The resulting hypothermia is associated with adverse clinical outcomes which include: postoperative shivering and discomfort; an increased incidence of adverse cardiac events; infection and pressure damage to the skin; higher blood loss and rates of transfusion; and longer hospital stays. The clinical problem that needs to be addressed is how to prevent this inadvertent perioperative hypothermia (IPH) in the most effective, safe and economical way.

2.0   Review of the Literature

2.1   Review Methodology

A basic computer and library-based search of the literature was undertaken in 1998 prior to an anaesthetic conference we had arranged in the French Alps. Appropriate to the setting, the talk was entitled "Skiing: it's cold and dangerous out there". As part of this, and more appropriate to the nature of conference, the perioperative consequences of hypothermia were examined. Evidence of the adverse effects of IPH was only just emerging at this point and it was these early, randomised, controlled trials that captured my interest and prompted my subsequent series of studies.

Over the intervening 17 years, this knowledge and understanding of the literature has been expanded by a number of means including further database searches, electronic table of content alerts from relevant journals, CiteTrack alerts, in the role of reviewer for medical journals and following-up primary references from talks, reviews and published papers.

With an understanding of the physiology, pathophysiology and consequences of IPH it is possible to construct a framework through which we can optimise its prevention and treatment, thereby improving outcomes for patients.

2.2   The Consequences of Inadvertent Perioperative Hypothermia

Although the body can tolerate significant deviations, it operates best within very narrow physiological limits. While it can operate reasonably well at core temperatures of 36-40 ˚C, most metabolic pathways work optimally in the range 36.5˚C-37.5 ˚C. It is interesting to note that even poikilothermic animals keep their temperatures within narrow limits through behavioural regulation to the extent that they will go so far as to 'generate' a fever when injected with dead bacteria[1], and goldfish can be trained to press a lever to reduce the temperature when swimming in warm water[2].

Before the early 1990s, IPH was recognised as a consequence of anaesthesia, but not so much as a problem. This was possibly for two, linked,

reasons. The first is that the performance of warming devices at the time was inadequate, so people didn't think they could do anything about IPH even if it was a problem. The second was, because warming devices were inadequate, no-one had seen the benefits of the prevention of IPH so anaesthetists did not even understand that it might be worth warming patients.

This all changed with the development of forced-air warming (FAW). Whilst the advent of an effective technology was important in itself, of possibly more significance was the fact that the manufacturers established a research base which, at the same time as it showed the effectiveness of the device, delineated the adverse effects of IPH. In addition to the widely recognised discomfort associated with simply feeling cold and shivering, the adverse effects uncovered included:

- an increase in morbid cardiac events[3]
- increased rates of infection[4-6]
- a longer time spent in the recovery room[7,8]
- longer stays in hospital[7]
- increased blood loss and transfusion rates[9-12]
- higher risk of pressure damage to skin[13]
- higher overall complication rates[12,14]

While the underlying mechanisms for these adverse effects have not been fully elucidated, there are a number of studies which point to the reasons behind the clinical observations associated with IPH:

- Increased plasma levels of catecholamines[15] and sympathetic nervous system activation[16,17]
- Reduced subcutaneous oxygen levels[18]
- Reduced clearance of anaesthetic drugs[19]
- Increased shivering: this is common after anaesthesia and, the colder the patient, the more frequent and more intense the shivering with a consequent increase in metabolic demand[20]. This is despite the response being blunted by some anaesthetic agents[21-23].
- Impaired immune function[24-27]
- Altered glucose handling[28]

- Increased plasma cortisol levels[15]: though not necessarily higher in cold patients
- Coagulopathy[29]

The mechanisms and the pathophysiological observations may be related as follows:

1. **Morbid Cardiac Events:** In 1997, Frank et al[3] demonstrated that patients becoming hypothermic intraoperatively had higher rates of myocardial infarction and clinically significant arrhythmias such as ventricular tachycardia perioperatively. This could be explained by a rise in circulating catecholamines causing tachycardia and vasoconstriction both of which are likely to raise the heart's metabolic demand in relation to its oxygen delivery[15]. Shivering-which is more common in cold patients-also increases metabolic demand[20].

2. **Increased rates of infection:** Kurz et al[4] in their study published in 1996 showed that hypothermic elective surgical patients had both increased postoperative infections and prolonged hospitalisations. A subsequent study looking at emergency laparotomies reproduced this finding[6]. The reasons behind this include not only the impairment of the immune system[24-27] but also the activation of the sympathetic nervous system[15-17] which produces vasoconstriction and, consequently, decreased subcutaneous tissue oxygen levels[18]. The importance of blood flow to the area of the incision can be inferred from Melling et al's[5] study which showed that simply warming the operative site prior to incision reduced the incidence of wound infection.

3. **Longer time spent in the recovery room**: Data from Kurz et al's study[8] suggested that the delayed return to the ward even in reasonably fit patients resulted from substantial postoperative thermal discomfort which could take many hours to resolve.

4. **Longer stays in hospital:** Kurz et al[7] showed that perioperative normothermia shortened hospitalization. While their primary focus was on the role of surgical site infections in prolonging recovery, it was more notable that hospital stay was prolonged (by standardised discharge criteria) in the hypothermic patients even in the absence of infection. In these patients they

noted that the healing of the incision was slower due to reduced deposition of collagen and that it was significantly longer before they could tolerate an oral diet.

5. **Increased blood loss and transfusion rates**[9-12]: This is a very consistent finding in studies of IPH. While the rheology of blood is adversely affected by hypothermia[30] (which may, in part, account for the increase seen in myocardial damage), it is the reduction in coagulability due to the decreased efficiency of the enzymes in the clotting cascade that results in increased blood loss[29]. This tendency to increased blood loss is seen in studies where the mean temperature difference between the warmed and controlled groups is as little as 0.5 ˚C[11,12]. Moreover, while the National Institute for Health and Care Excellence (NICE) guideline defined IPH as a core temperature of less than 36.0 ˚C, significantly higher blood loss and transfusion rates were seen in one study[11] in which both control and treatment groups had mean core body temperatures above this level (36.1 ˚C and 36.5 ˚C respectively)[*]. This demonstrates both the exquisite sensitivity to temperature of the clotting cascade, and that there are benefits from maintaining normal (i.e.≥36.5 ˚C) core body temperatures in surgical patients. This is despite the evidence that P-selectin expression is enhanced under hypothermic conditions implying that the effect on the clotting cascade outweighs the resulting increase in platelet and leucocyte aggregation.

6. **Higher risk of pressure damage to skin**[13]**:** This finding is probably multifactorial and similar in aetiology to that of infection as outlined above. While the physical effect of pressure reduces blood flow to the areas of the body in contact with the bed or operating table, this is exacerbated by vasoconstriction[15] and impaired immune function[24-27].

7. **Higher overall complication rates**: Although this is really an aggregation of complications outlined above, it is notable that while most studies had a single primary aim, many of them also found adverse effects within their secondary endpoints[7,12,14].

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[*] see section 2.4 for an explanation of this apparent contradiction

With the establishment that outcomes can be improved by maintaining normothermia and that only small falls in core temperature result in complications[11,12], it becomes essential to measure body temperature accurately. In other words, effective body temperature management requires accurate temperature measurement. The following section deals with the measurement of core body temperature.

2.3   Perioperative Temperature Measurement

Before determining how we measure body temperature, it is necessary to define what it is we actually want to measure. For this purpose, the body is nominally divided into two components, the 'outer' or 'shell' and the 'deep' or 'core'[31,32].

The term 'core' is used to collectively refer to various measures of deep body temperature. As such, a single core temperature does not exist. The core component is tightly regulated and consists of the internal environment that houses the vital organs such as heart, liver and brain. The superficial shell structures show significant variations in temperature both within themselves and in comparison with the core, the latter typically being 2-4 ˚C warmer than the former at rest in a thermoneutral environment[33].   So, while the core temperature does not give an accurate overview of whole body heat content, it does provide "the best single indicator of thermal status in humans[31]". Moreover, it is reductions in core temperature that have been associated with adverse clinical effects in the perioperative period.

In terms of measurement, the perioperative period presents a number of specific challenges:
- As little as 0.5 ˚C reduction in core temperature can have adverse clinical consequences[11,12]
- Patients pass through a number of different areas (preoperative holding bay, anaesthetic room, theatre, recovery, ward) over a relatively short space of time
- Patients' level of consciousness will vary

- Access to the patient may be difficult at times

There is therefore a need for an accurate, easy to use, non-invasive, reusable or cheap and transferable thermometer that functions in both conscious and unconscious patients[34].

None of the devices available when we began our studies of IPH fulfilled all these criteria (see Table 1 below).

Table 1. Analysis of the cost, logistics and utility of different measures of 'core' temperature

Thermometer Type	Accuracy	Ease of use	Invasiveness	Awake patients	Asleep	Cost	Reusable
Oral	Good	Easy	Low	Yes	No	Low/Medium	Yes/No
Tympanic thermocouple	Good	Difficult	Medium	Yes	Yes	High	Yes
Oesophageal/Nasopharyngeal	Good	Moderate	Medium	No	Yes	Medium	No
Pulmonary Artery	Good	Difficult	High	No	Yes	High	No
Rectal	Moderate/good	Moderate	Medium	Possibly	Yes	Medium	No
Bladder	Variable	Difficult	Medium/High	If catheterised	Yes	High	No
Aural canal	Poor	Easy	Low	Yes	Yes	Low	Yes
Skin surface strips	Poor	Easy	Low	Yes	Yes	Low	No

From this, in broad terms it can be concluded that accurate thermometers are either too invasive or difficult to use routinely, or are not suitable for both awake and anaesthetised patients.

The need therefore remains to continue research in the perioperative setting on new or, as yet, unevaluated temperature measurement technologies.

2.4   The development of guidelines for the prevention of IPH and the optimisation of clinical practice

In 2008 the National Institute for Health and Care Excellence (NICE) published Clinical Guideline 65, Hypothermia: prevention and management in adults having surgery[35]. This document has, for the most part, defined clinical practice since then.

As one of the clinical experts on the guideline development group, I was in a particularly strong position to see both the positive aspects of the document and some of its shortcomings. Whilst it was an excellent synthesis of the available literature, as is so often the case, there were significant gaps in that literature.

On the positive side, we were able to show that IPH is associated with adverse effects, that preventing IPH reduced the number complications and that forced-air warming (FAW) was an effective means of reducing its incidence.

However, there were other areas where conclusions were extrapolated from studies which were not necessarily directly applicable:
- Most of the studies were carried out in the US and mainland where clinical practice can vary significantly from the UK. These disparities may mean that the incidence of both IPH and its complications are different in the UK
- Whilst the guideline made the recommendation that warming should be used on all patients having operations lasting an hour or longer, this was back calculated from studies where the average length of surgery was at least twice this time
- Similarly, the recommendation that all infusions of 0.5 L or more of intravenous fluid should be warmed was extrapolated from studies where significantly greater volumes were administered.
- The definition of perioperative hypothermia as ≤36.0 ˚C was one of consensus rather than evidence. Up until this time, studies had looked at warming *versus* no warming. As a consequence, core body temperatures of patients in the control arms of the studies underpinning the NICE guideline typically fell to 35.5 ˚C or less[3,4,7]. It was not therefore possible to clearly establish the core temperature below which complications developed. However, subsequent studies, not available to the guideline development group, compared two different warming techniques. Some of these suggest that a difference in core temperature of as little of 0.5 ˚C-even when the mean

core temperature in the control group was ≥36.0 ˚C-is sufficient to have significant clinical consequences[11,12†].

- Mean core body temperature was the outcome measure used to compare the effectiveness of warming devices rather than the incidence of IPH. While mean temperatures are an indication of device effectiveness, they do not directly relate to the aim of the guideline which is to prevent IPH as defined by a core temperature of ≤36.0 ˚C.

- Most of the studies compared FAW with no warming. There was little evidence in terms of comparisons between FAW and other warming technologies. It was not therefore possible to delineate the relative effectiveness or complication rates between devices.

- Most of the core body temperature drop initially seen in patients when they are anaesthetised is due to the core-peripheral redistribution of heat[33]. While prewarming can mitigate the effects of this redistribution, it was not comprehensively reviewed during the development of the guideline.

It is concluded that preventing IPH leads to significant improvements in patient outcomes. Therefore, research into accurately measuring temperature, safely warming patients and translating these findings into clinical practice should generate clinical benefits.

[†] See section 2.2.5

3.0   Research Question:

What are the most effective, safe and economical means of measuring temperature in the clinical setting and preventing IPH in patients undergoing surgery?

3.1   Experimental Hypotheses:

H1: Inadvertent perioperative hypothermia is a common clinical problem in UK operating theatre practice

H2: New technology may provide accurate measurement of core body temperature throughout the perioperative period
- H2.1: Temporal artery scanners
- H2.2: Radiofrequency capsules and zero-flux thermometer

H3: Alternative warming technologies, such as carbon polymer mattresses, are as, or more, effective than forced air warming

H4: Alternative technologies, such as carbon polymer mattresses and blankets, may provide effective and economical warming in settings which do not come under the current guidelines:
- H4.1: Caesarean Section
- H4.2: Day-surgery

H5: Forced-air warming interferes with laminar flow by affecting temperature gradients in operating theatres, thereby potentially increasing the risk of surgical site infection

H6: The provision of information and tools in addition to NICE guideline 65 is necessary to optimise the prevention of IPH in clinical practice

4.0 Papers and Commentary

4.1   H1: Inadvertent perioperative hypothermia is a common clinical problem in UK operating theatre practice

Abstract: GAT Audit Prize Submission 2003: A series of three audits of peri-operative hypothermia and the effect of various warming strategies

In the light of the increasing evidence that perioperative temperatures <36 °C can have detrimental effects, we carried out an audit to determine the incidence of perioperative hypothermia in our institution.

We found that 28% of a series of 149 consecutive, elective surgical patients arrived in recovery with a core temperature (determined by infra-red tympanic measurement) of <36 °C. In particular, it was noted that the incidence was 35% amongst urological patients.

We then re-audited the temperatures of patients undergoing transurethral resection of prostate and bladder tumours. In this group the incidence of post-operative hypothermia was 44%. Hypothermia was associated with a larger weight of resection, volume of irrigation fluid used and length of operation.

For the third audit we looked at the association between the method of patient warming and post-operative temperature. For 116 consecutive patients we found that 38% had a temperature of <36°C in recovery. However this incidence was only 16% in those patients aggressively warmed (fluid warming, forced-air warming blanket and irrigation fluid warmed in a hot cabinet) whereas it was 44% amongst the other patients.

As a consequence of these audits, aggressive warming has become standard care for these patients and the order for blankets and fluid warmers increased to ensure that they are available for all patients. We are also setting-up a prospective trial to see if the rate of complications is higher in those patients who still become hypothermic and whether these patients can be identified pre-operatively and targeted for further intervention.

Our preliminary work consisted of a series of three audits to determine whether IPH was a significant clinical problem in our practice.

The hospital where we carried out the audits is a typical, district general hospital and, as such, could be considered reasonably representative of UK practice.

The first audit of 149 patients showed that 28% had a core temperature of <36 ˚C in recovery indicating that IPH, if accurately measured, was a clinical problem in our practice.

Of note was the fact that the mean temperature was 36.3 ˚C. Taken in isolation, this figure would indicate that IPH was not an issue. This audit therefore reinforced the importance of detailing the proportion of patients who are hypothermic as these are the ones who are more likely to suffer the adverse effects.

At the time of these audits, most of the work on IPH had been done on patients who had received a general anaesthetic. The finding that there was a significant number of patients undergoing regional anaesthetic who became hypothermic was therefore a novel one (see Table 2 below).

Table 2. IPH by Anaesthetic Technique in Lister Hospital audit.

Anaesthetic Technique	Number	%	Number with Core Temperature <36 ℃	% with Core Temperature < 36 ℃
General	112	75	24	21
Regional	24	16	10	42
Both	9	6	6	66
IV Sedation	2	1.5	1	50
Missing Data	2	1.5	0	N/A
Total	149	100	41	28

IPH was particularly prevalent in certain specialities (see Table 2).

Table 3. IPH by speciality in Lister Hospital audit.

Speciality	Number	% of total	Number with Core Temperature < 36 $^{\circ}$C	% with Core Temperature < 36 $^{\circ}$C
Plastics	13	9	3	23
Orthopaedics	27	18	10	37
Max Fax	6	4	0	0
Gynaecology	15	10	5	33
General Surgery	29	20	7	24
Urology	23	15	8	35
ENT	35	23	8	23
Missing Value	1	1	0	N/A
total	149	100	41	28

One of the specialities with a high incidence of IPH was urology and we therefore concentrated our subsequent audits on these patients.

In these we demonstrated that:

- The incidence of IPH was <20% if the patients had been aggressively warmed
- Patients having surgery under regional block had similar rates of IPH to those having it under GA
- Irrigation fluids warmed through a specialist device were no more effective at preventing IPH than those that had simply been kept in a warming cabinet
- Warming practice was both inconsistent and not fully effective

From this we inferred that there was a significant, clinical problem with our practice; a practice which was typical of the UK. As a consequence, there was a need to bring the adverse consequences of IPH to a wider audience and to establish the most effective and safe ways of preventing it.

On this basis, we published an editorial in the British Medical Journal[36] which detailed the issues facing anaesthetists and surgeons and emphasised the importance of perioperative warming which, at that time, was still not fully appreciated. In our audit we found that FAW was used in only 19% of cases and fluid warming in 7%.

We concluded:

> "Perioperative warming can be cost effective and reduce a patient's discomfort by cutting the incidence of wound infections, length of stay in hospital, and shivering. It may also reduce the rate of allogenic blood transfusions and its associated risks."

At that time, there was no guidance on perioperative warming available. Our paper encouraged uptake of FAW, outlined its cost-effectiveness and provided impetus to the subsequent setting up of the NICE guideline development group for "The management of inadvertent perioperative hypothermia in adults[35]".

H1: The hypothesis that IPH was a problem in UK clinical practice was accepted.

In the next section, studies to determine the best methods of measuring core temperature in clinical practice will be discussed.

4.2   H2: New technology may provide accurate measurements of core body temperature throughout the perioperative period:

In order to manage core body temperature effectively, it is essential to measure it accurately.

4.2.1 H2.1 Temporal Artery Scanner

Abstract: A study to compare the accuracy and suitability of two methods of temperature measurement in the perioperative setting

Background and Goal of Study: Closer management of perioperative temperature can improve patient outcome but is reliant on the accuracy of temperature measurement. An ideal temperature monitor would be accurate, non-invasive and able to produce readings throughout the perioperative period. Oesophageal probes (OP) are widely used but can produce unreliable data, such as when they are sited in the nasopharynx. Furthermore there is a small risk of nasal trauma on insertion and they are not suitable for pre- or post-operative use. The temporal artery scanner (TAS) is a novel, non-invasive temperature monitor which can be used throughout the perioperative period but its accuracy has not been tested in this setting. The gold standard comparator for any evaluation of temperature measurement devices would be the pulmonary artery catheter (PAC). However, these have high rates of associated complications so we used urinary catheters (UC) with integral temperature thermistors as their accuracy with respect to PAC has been demonstrated during surgery. Our goal was determine the accuracy and suitability of the two methods of temperature measurement (OP and TAS) during surgery by comparing them to temperatures obtained from the bladder.
Materials and Methods: Fifteen patients were recruited to a prospective comparative study. OP and UC thermistors were inserted after induction of anaesthesia. Non-invasive TAS measurements were taken using the Exergen thermoscan. For each patient we recorded temperatures using each of the three methods at six time-points during surgery.

Results and Discussion: Observed body temperatures were similar for UC (median 36.2 C [range 35.3 −38.2 ˚C]) and TAS (36.2 ˚C [35.6 −37.6 ˚C]] (p=0.188 by Wilcoxon test), but OP values were lower (36.1 ˚C [35.5 - 38.3 ˚C]] (p<0.05). As expected, correlations between the techniques were high (Spearman s rho = 0.70 comparing Bladder and TAS and 0.64 comparing Bladder and OP; all p<0.001). Bland-Altman limits-of-agreement analysis showed that TAP gave similar results to Bladder whereas the OP values suggested greater bias and imprecision.

Conclusion: The temporal artery scanner appears to avoid the bias associated with oesophageal thermistors when measuring temperatures intra-operatively and so may be helpful during the thermal management of patients in the perioperative period.

The temporal artery scanner (TAS) is a non-invasive thermometer which can be employed throughout the perioperative period for all operations during which the anaesthetist has access to the head. If accurate, it would therefore be both cheap and simple to use which is likely to improve perioperative temperature monitoring.

It uses multiple readings of skin surface temperature as it is passed across the forehead using infrared light. The theory behind it is that the peak recording will come from the temporal artery which, as a branch of the carotid, is a surrogate for core temperature.

In 1999, Exergen introduced it into clinical practice. Whilst they did produce a document outlining studies undertaken for patients in the general hospital setting[37], there was nothing demonstrating its accuracy in the perioperative period.

We therefore undertook a study comparing it with bladder and oesophageal thermometers[38]. We concluded that the observed body temperatures were similar for urinary catheters and temporal artery but oesophageal values were lower and that Bland-Altman limits-of-agreement analysis showed that TAP gave similar results to Bladder whereas the OP values suggested greater bias and imprecision.

Whilst we published this study as an abstract[38] and presented it at the European Society for Anesthesia annual meeting, retrospectively, we became conscious that it was flawed and more valuable for its lessons in research than its data.

The first issue was our assumption that bladder temperature was a better reflection of core temperature than oesophageal temperature. Whilst this may be the case in certain circumstances, combined with the second problem - the enrolment of patients undergoing gynaecological surgery – it does not hold. This is because during the procedures we included, the bladder is exposed so urinary catheter measurements are influenced by the ambient temperature thereby rendering them inaccurate.

The lessons we drew from this were that we needed to read the literature more closely surrounding our assumptions before designing a study and that more careful planning of our recruitment strategy was necessary.

4.2.2 H2.2: Zero-flux thermometers and radiofrequency capsules.

Abstract: A study to determine the accuracy of zero-flux and ingestible thermometers in the perioperative setting

Jack J.M., Ellicott H., Densham I., Harper CM. A study to determine the accuracy of zero-flux and ingestible thermometers in the perioperative setting. Abstract accepted for presentation at Euroanaesthesia 2016. To be published in the EJA (see Annex 3)

Relevance of research: Accurately monitoring core temperature during anaesthesia is a cornerstone of good practice. Relatively invasive devices such as oesophageal temperature probes and pulmonary artery flotation catheters allow accurate measurement of core temperature. However these are not appropriate for many patients. There is a need for accurate non-invasive measurement of core temperature.

Background and Goal of Study: This study was designed to compare the accuracy of two new non-invasive core temperature thermometers, the 3M SpotOn™ Temperature Monitoring System zero flux device (ZFD) and the CorTempR Wireless Ingestible Temperature Sensor (ITS) with the oesophageal temperature probe (OTP) which is the current introperative standard.

Materials and Methods: 20 patients scheduled for elective surgical procedures under general anaesthesia were recruited to the study. Prior to induction patients ingested an ITS, and after induction a ZFD was attached above their right eyebrow. During surgery temperature on each device was recorded every minute. Data were compared using Bland Altman analysis.

Results and Discussion: The ITS experienced considerable interference from equipment used in the operating theatre, including diathermy and fluoroscopy, rendering around 30% of its readings unsuable. These were removed from subsequent analysis. The bias for the ZFD compared to OTP was 0.024 and the 95% limits of agreement -0.47 to 0.52. 97.7% of readings are within +/-0.5 ˚C of the probe reading. With erroneous readings removed, the bias for the ITS when compared with the probe was 0.42 and the 95% limits of agreement -2.4 to 3.2. 75.4% of readings were within +/-0.5 ˚C of the OTP reading. Bland Altman analysis found good concordance between the ZFD and OTP.

Conclusions: The results of this study suggest the ZFD is an accurate non-invasive measure of core temperature, whereas the ITS is not suitable for perioperative practice.

More recently, a different method of non-invasive temperature measurement has been developed commercially. The zero-flux thermometer uses a small heating element to warm the skin surface on the forehead. It works on the principle that when the measured temperature flux drops to zero, it is in equilibrium with the underlying anatomical structures-in this case the brain-which will give an accurate reflection of core temperature. While neither as simple nor cheap as the temporal artery scanner, it does potentially offer a way of accurately measuring temperatures in all patients including those who are awake (having procedures under regional anaesthesia) in whom it is neither possible nor desirable to pass an oesophageal probe.

Radiofrequency capsules swallowed by the patient have been available for a number of years. Their accuracy has not, however, been studied in patients undergoing surgery. While not suitable for operations on the bowel for example, they do offer a consistent way of collecting data over a much larger part of the patient journey. Our previous work has suggested that patients with fractured hips have a higher mortality if they become hypothermic at any point between admission and their arrival in recovery postoperatively. With one of these capsules, we could, theoretically monitor these patients right through from admission through to recovery thereby gathering accurate temperature data which will allow us to identify the points at which they are most likely to become hypothermic and provide active warming as necessary.

Based on the hypothesis that the ZFD and ITS thermometers provided accurate measurements of core temperature, we designed a study which compared them with oesophageal readings in patients who were not undergoing bowel or laparoscopic (where the insufflated gas in the abdomen would affect the accuracy of the capsule readings) surgery.

Core temperature drops of 0.5 ˚C have a clinically significant effect on outcomes such as blood loss[‡]. Therefore, to be clinically useful, a new thermometer needs to be accurate to within ±0.5 ˚C of the current standard, in this case oesophageal.

For the ZFD, we found that the bias compared to probe was 0.024. The 95% limits of agreement were -0.47 to 0.52 and 97.7% of readings are within +/-0.5 ˚C of the probe reading. This then confirms the findings of the one previous trial of the technology[39]; that it is sufficiently accurate for clinical use.

For the capsule compared to the probe, the bias was 0.42 and the 95% limits of agreement are -2.4 to 3.2. And only 75.4% of readings are within +/-0.5 ˚C of the probe reading. Looking at the Bland-Altman plots, it can be seen that while the capsule is reasonably accurate over a narrow range (which corresponds to normal, core body temperature), the high bias and wide limits of agreement are mainly generated from its marked tendency to over-read at high temperatures and under-read at low temperatures.
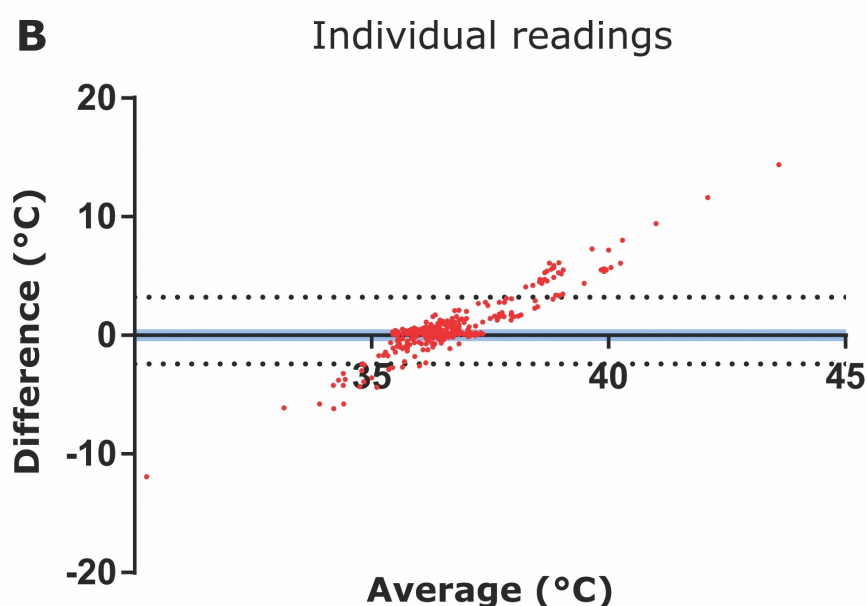
Figure 1: Bland-Altman plot of temperature readings from OTP vs ITS (all patients): shaded area indicates ±0.5 ˚C. Dotted lines represent 95% confidence intervals.

[‡] See sections 2.2.5 and 2.4

From this study, we concluded that the ZFD is sufficiently accurate to be used in clinical practice but, outside the limits of normal core temperature, but that the ITS is not.

H2: The hypothesis that new technology may provide accurate measurements of core temperature throughout the perioperative period is partially accepted and partially rejected. Neither the TAS nor ITS demonstrated adequate performance in this setting. However, the ZFD appears to be both clinically acceptable and sufficiently accurate so, for this device, the hypothesis is accepted.

Just as new technologies may improve temperature measurement, new heating devices may allow us to optimise patient warming in clinical practice. The next section will deal with this area of research.

4.3 H3: Alternative warming technologies may be as, or more, effective than FAW

NICE guideline 65[35] was only able to recommend FAW as this was the only technology with an adequate evidence base at the time of writing. Whilst the guideline showed an overall economic benefit with its recommendations, investment in the technology was associated, as we pointed out in our editorial[36], with significant ongoing costs. This extra cost is due to the disposable nature of the blankets. Although reusable warming devices are associated with a significant start-up cost, they can still work out cheaper in the long term[40].

4.3.1 Resistive heating mattresses may be as, or more, effective than forced-air warming

Abstract: Comparison of resistive heating and forced-air warming to prevent inadvertent perioperative hypothermia

John M, Crook D, Dasari K, Eljelani F, El-Haboby A, Harper CM. Comparison of resistive heating and forced-air warming to prevent inadvertent perioperative hypothermia. British journal of anaesthesia. 2016;116(2):249-54 (Annex 4)

Background: Forced-air warming is a commonly used warming modality, which has been shown to reduce the incidence of inadvertent perioperative hypothermia (<36 °C). The reusable resistive heating mattresses offer a potentially cheaper alternative, however, and one of the research recommendations from the National Institute for Health and Care Excellence was to evaluate such devices formally. We conducted a randomized single-blinded study comparing perioperative hypothermia in patients receiving resistive heating or forced-air warming.

Methods: A total of 160 patients undergoing non-emergency surgery were recruited and randomly allocated to receive either forced-air warming (n=78) or resistive heating (n=82) in the perioperative period. Patient core temperatures were monitored after induction of anaesthesia until the end of surgery and in the recovery room. Our primary outcome measure was the incidence of hypothermia at the end of surgery.

Results: There was a significantly higher rate of hypothermia at the end of surgery in the resistive heating group compared with the forced-air warming group (P=0.017). Final intraoperative temperatures were also significantly lower in the resistive heating group (35.9 compared with 36.1 °C, P=0.029). Hypothermia at the end of surgery in both warming groups was common (36% forced air warming, 54% resistive heating).

Conclusion: Our results suggest that forced-air warming is more effective than resistive heating in preventing postoperative hypothermia

One technology with the potential to be a more economic means of warming patients came onto the market around the time that the NICE guideline was published. This was the Inditherm carbon-polymer resistive heating mattress (RHM). Furthermore, the NICE health and technology guidance 7[40] for which I was an expert advisor, concluded that, if as clinically effective as FAW, this device would also save

significant amounts of money. A preliminary audit showed an acceptable level of effectiveness where around 10% of patients suffered from IPH compared with a rate of 15-20% that we had found in previous audits of FAW. From this we concluded that a randomised, controlled trial comparing the effectiveness of the RHM with FAW was warranted

We randomised 160 patients undergoing operations that would require warming according to NICE guidelines, to either FAW or RHM. We found a high rate of IPH overall and there were significantly more patients (54%) in the RHM group that were cold at the end of surgery, than in the FAW group (36%; P=0.017).

Final intraoperative temperatures were also lower in the resistive heating group (35.9 compared with 36.1 °C, P=0.029). Even though statistically significant, the clinical significance of this figure is questionable, highlighting the issue with using mean temperatures as a primary outcome measure. This is in contrast to the figures for IPH, which certainly are clinically important. It is most likely that this is a statistical anomaly because the study was powered to find differences in the incidence of IPH rather than clinically significant differences (>0.5˚C) in core temperature. There may, however, be a group of patients who are more prone to IPH and more difficult to rewarm when they have become hypothermic.

Looking purely at the primary outcome measure-the incidence of IPH at the end of surgery-this study demonstrates that FAW is superior to the RHM. However, in clinical terms it is important to look beyond that figure to the high rates of IPH in both groups. The implication here is that following current warming guidelines leads to unacceptable levels of IPH. In the future, recommendations should encompass additional approaches that have been shown to be effective such as prewarming[41] and combining FAW and the RHM[12].

H3: The hypothesis that resistive heating mattresses may be as, or more, effective than forced-air warming is rejected as its performance did not match that of the established technology.

While new technologies may not be as effective as FAW in general, in-patient operating theatres, there are other situations where they may prove more suitable either for economic or logistical reasons. During Caesarean Section it is logistically difficult to use FAW because of the large surgical field. As a consequence, their upper body and heads would need to be covered to provide an adequate surface area for effective heat transfer. This is both uncomfortable and makes holding the baby difficult. We therefore tested the hypothesis that the RHM might be an effective alternative.

H4: Alternative technologies, such as carbon polymer mattresses and blankets, may provide effective and economical warming in settings which are not currently covered by national guidance

4.4.1 H4.1: Carbon polymer mattresses for warming patients undergoing Caesarean Section.

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

Background: The adverse effects of IPH 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 IPH 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 IPH, defined as a temperature <36.0 °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 IPH 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 (± SD) haemoglobin change in the mattress-warmed group at −1.1 ± 0.9 g/dL versus −1.6 ± 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 IPH and attenuated the fall in haemoglobin. The use of resistive mattress warming should be considered during caesarean section.

Caesarean section (CS) is a major operation. However, it was specifically excluded from the remit of NICE CG65 because it came under the remit of a different grouping within the organisation.

The evidence-base is even more limited in this field than it is for adult general surgery. There are three main reasons for this.

1. It can be more difficult to obtain ethical approval for trials in obstetrics where the impact on the baby as well as the mother has to be considered.
2. The FAW technology itself presents certain difficulties in CS. It is noisy, bulky and awkward. Obstetric operating theatres are relatively busy and noise as it is due to the need to look after both mother and baby. Furthermore, it can be difficult to position the blanket in such a way that allows the mother to hold the baby comfortably after delivery.
3. As most of these operations are conducted under regional anaesthetic, the patient's own perception is often that they are warm due to the vasodilatory and thermoregulatory blocking effects of the drugs even when they are actually hypothermic.

As a consequence, standard practice for this procedure is not to warm the patient. We hypothesised that a carbon polymer warming (CPW) mattress would reduce the incidence of IPH in patients undergoing CS without adding to the noise or interfering with the maternal-baby bonding.

We undertook a trial where we randomised 116 patients to either standard practice (no warming) or CPW mattress[23]. We found that there was a lower incidence of IPH in the CPW mattress group (5.2% vs. 19.0%, P = 0.043) and higher mean temperatures (36.5 °C vs. 36.3 °C (P = 0.046)). We also found that there was a significantly lower mean haemoglobin (Hb) drop in the CPW group at 1.1 ± 0.9 g/dL versus 1.6 ± 0.9 g/dL in the control group (P = 0.007).

We drew a number of conclusions from this:

- Again, while we see clinically unimportant differences in mean temperatures at the end of surgery, the differences in the rate of IPH is significant.
- That the mattresses, as anticipated, did not have an adverse impact on the theatre environment or mother-baby contact. In fact, anecdotally, a number of mothers in the CPW mattress group commented on how much they liked the warmth.
- That, while statistically significant, the reduced drop in Hb seen in the warmed group was not clinically significant.

In terms of future warming research, there are two main things to take from this. First, it would be worth measuring patient satisfaction and thermal comfort as outcome. Second, while the difference in blood loss was not clinically significant in this group of patients, it may be in emergency CS where rates of blood loss and transfusion are much higher. Specific trials in this procedure are therefore warranted.

H4.1: In the case of using carbon-polymer warming mattresses to warm patients undergoing CS, the hypothesis that this alternative to FAW is effective is accepted.

While this section has demonstrated the utility of new technology in warming patients undergoing major operations, the next study investigated its use and effectiveness during minor surgery.

H4: Alternative technologies, such as carbon polymer mattresses and blankets, may provide effective and economical warming in settings which are not currently covered by national guidance

4.4.2 H4.2: Carbon polymer blankets for warming patients undergoing day-surgery procedures

Abstract: A Randomised Controlled Trial To Determine The Influence of Carbon-Polymer Resistive Warming Blankets On The Incidence Of Perioperative Hypothermia During And After Short, Day-Case Operations

Sharma M-PD, M. Eljilani, F. Harper, C Mark. A Randomised Controlled Trial To Determine The Influence of Carbon-Polymer Warming Blankets On The Incidence Of Perioperative Hypothermia During And After Short, Day-Case Operations. Journal of One Day Surgery. 2014;24(4):92-9 (Annex 6)

The purpose of our study was to determine whether a reusable warming blanket could reduce the incidence of inadvertent perioperative hypothermia in patients undergoing short surgical procedures. Patients were randomised to either standard care (no warming) or standard care plus warming with an electric carbon-polymer resistive warming blanket (RWB) on arrival in the operating theatre. Core temperatures were measured with an oesophageal thermistor. The primary outcome measure was the incidence of perioperative hypothermia (defined as a core temperature <36 $^{\circ}$C) at the end of surgery. Of the patients in the warming group, 24% (9/37) were hypothermic at the end of surgery compared to 39% (13/33) in the standard care group (p=0.20). Although the evidence from this study is not conclusive, these results suggest that warming patients with a RWB during short, surgical procedures may reduce the incidence of inadvertent perioperative hypothermia although further studies would be necessary to confirm this.

NICE CG65 concluded that active warming was not justified for patients having operations that take less than 60 minutes such as hernia repairs and diagnostic laparoscopies. The economic basis for this is that the rate of complications is lower and while the cost remains the same. This presupposes that FAW with its disposable costs would be used. Reusable devices may, however, offer a cost-effective solution.

Furthermore, these conclusions were reached through extrapolation of data from studies of longer operations. None of the papers included in the analysis specifically looked at short procedures.

The RWM works well for many procedures such as Caesarean section for the reasons outlined above and because there is a fixed operating table in the theatre. However, in day-care units the patient is often anaesthetised, operated and recovered on the same trolley. The problem here is that the trolleys are often an irregular shape which makes satisfactory fitting of the mattress difficult and that several mattresses would be required to account for the high throughput of patients thus offsetting the economic benefits.

We therefore concluded that the most appropriate device for this setting would be a reusable RWB. We randomised 60 patients to either standard care (no warming) or RWB.

We found that 24% (9/37) patients in the RWB group were hypothermic at the end of surgery compared to 39% (13/33) in the standard care group (p=0.20)[22]. Although this is not conclusive, these results suggest that the use of RWB could reduce the incident of IPH in patients undergoing short operations.

On average, around 8-10 patients are operated on every day in each of our day-surgery theatres. To use a FAW blanket on each of them would therefore cost £60-£140 (depending on type of blanket and number of patients). A RWB and control unit cost (depending on the number and types of blanket purchased) around £1500, equivalent to the price for 10-25 days of FAW. It can therefore be seen that it is possible to provide warming for these patients at a reasonable cost. A larger trial would be required to determine whether the difference was due to chance or a real difference. It is also unclear whether warming would actually provide any economic benefits. It would certainly be worth investigating patient satisfaction and comfort outcomes as significant improvements in these might justify the costs.

H4: The hypothesis that RWBs were effective at warming patients undergoing day-surgery procedures was accepted

The effectiveness of FAW has been demonstrated in numerous studies and, in some, it has superior performance compared to other technologies. However, efficacy must be balanced with safety. The next study investigates the mechanism behind the theoretical risk of wound contamination by FAW and compares it to other warming devices.

4.5 H5: FAW interferes with laminar flow by affecting temperature gradients, thereby potentially increasing the risk of surgical site infection

Abstract: Effect of forced-air warming on the performance of operating theatre laminar flow ventilation

Forced-air warming exhaust may disrupt operating theatre airflows via formation of convection currents, which depends upon differences in exhaust and operating room air temperatures. We investigated whether the floor-to-ceiling temperatures around a draped manikin in a laminar-flow theatre differed when using three types of warming devices: a forced-air warming blanket (Bair Hugger™); an over-body conductive blanket (Hot Dog™); and an under-body resistive mattress (Inditherm™). With forced-air warming, mean (SD) temperatures were significantly elevated over the surgical site vs those measured with the conductive blanket (+2.73 (0.7) °C; $p < 0.001$) or resistive mattress (+3.63 (0.7) °C; $p < 0.001$). Air temperature differences were insignificant between devices at floor ($p = 0.339$), knee ($p = 0.799$) and head height levels ($p = 0.573$). We conclude that forced-air warming generates convection current activity in the vicinity of the surgical site. The clinical concern is that these currents may disrupt ventilation airflows intended to clear airborne contaminants from the surgical site.

Whilst the benefits of FAW have, as discussed in the introduction, been clearly demonstrated, one aspect of its safety has recently come under scrutiny.

Orthopaedic and other implant surgery is usually carried out in laminar flow operating theatres whereby clean, filtered air comes into the theatre through a canopy above the patient and is directed down to the floor before passing out through wall vents. In theory, the air around the operative site is kept clean thereby reducing the risk of infection-although the results of studies regarding its effectiveness are contradictory[42,43].

FAW works, as its name suggests, by forcing air warmed by an element through a specially designed blanket. Whilst this air could, theoretically, be recycled through

the warming device it is generally vented through small holes in the base of the blanket. It was therefore suggested that this might interfere with the laminar flow air currents in operating theatres[44,45].

In terms of infection risk, the key element is that the air, instead of heading down to the floor and out of the room, actually rises from the 'dirty' areas below the level of the wound and even below the operating table. We hypothesised that alterations in temperature gradients may contribute to this effect.

We therefore undertook a mannequin study whereby we arranged high-sensitivity thermometers around an operating theatre and recorded the temperature. We looked at the temperature gradients found with no warming, with CPW blankets, a CPW mattress and a FAW blanket.

We found that, even in the face of an air flow of around 8000 m^3/h there were temperature gradients of up to 6 ˚C 30cm above the patient with FAW which was significantly higher than that seen with the other devices[46].

It could be argued that in daily practice, there will be more impact on airflow from, for example theatre personnel and equipment trolleys, than in our study. However our study did demonstrate that FAW generates significant temperature gradients above the wound site and therefore confirmed our hypothesis.

Although the clinical significance of this remains unclear[47,48], the study adds to the theoretical basis for using other technologies to provide active warming in laminar flow operating theatres.

H5: The hypothesis that FAW interferes with laminar flow by affecting temperature gradients is accepted; therefore it may increase the risk of surgical site infection.

Much research has been undertaken in the field of IPH and many of its results have been synthesised into guidelines. However, dissemination of these findings and a system of monitoring and quality improvement is needed in order for patients to

derive its clinical benefits. The next section explores the means of translating this research into daily practice.

4.6   The provision of information and tools in addition to NICE guideline 65 is necessary to optimise the prevention of IPH in clinical practice

Abstract: Peri-operative warming devices: performance and clinical application

Since the adverse consequences of IPH have been recognised, there has been a rapid expansion in the development of new warming equipment designed to prevent it. This is a review of perioperative warming devices and a critique of the evidence assessing their performance. Forced-air warming is a common and extensively tested warming modality that outperforms passive insulation and water mattresses, and is at least as effective as resistive heating. More recently developed devices include circulating water garments, which have shown promising results due to their ability to cover large surface areas, and negative pressure devices aimed at improving subcutaneous perfusion for warming. We also discuss the challenge of fluid warming, looking particularly at how devices' performance varies according to flow rate. Our ultimate aim is to provide a guide through the bewildering array of devices on the market so that clinicians can make informed and accurate choices for their particular hospital environment.

Other publications:

Harper CM, McNicholas T, Gowrie-Mohan S. Maintaining perioperative normothermia. Brit Med J. 2003;326(7392):721-2 (see Annex 9)

Harper CM, Andrzejowski JC, Alexander R. NICE and warm. Br J Anaesth. 2008;101(3):293-5. (see Annex 10)

John M, Harper M. Inadvertent peri-operative hypothermia: guidance and protecting patients. British Journal of Healthcare Management. 2014;20(5):206-11 (see Annex 11)

Theron P, Harper C. Inadvertent Perioperative Hypothermia Mini-topic Review. NHS library for health 2009 (see Annex 12)

Chakladar A, Harper CM. Keeping the right temperature during surgery - anaesthetists are warming to advice on inadvertent hypothermia. Hospital Healthcare Europe 2009/10 [Internet]. 2010 1st February 2011 (Annex 13)

Harper CM. Perioperative temperature management audit standards. In: Colvin JR, Peden CJ, editors. Raising the Standard: a compendium of audit recipes 3rd ed. London: Royal College of Anaesthetists; 2012 (Annex 14)

Harper CM. Warming Devices. In: Davey A, Diba A, editors. Ward's anaesthetic equipment. 5th ed. London: Elsevier Saunders; 2011. p. 513-23 (see Annex 15)

Many of the most important papers describing the adverse effects of IPH were published between 1996-2001[3-5,7,10,11,13,26]. However, as we demonstrated in our audits[49] practice lagged behind the evidence. We hypothesised that this was because awareness of these papers and the potential benefits of warming remained low so we published an editorial in the British Medical Journal highlighting the issue to the broad range of clinicians who are ultimately responsible for the care of patients during the perioperative period[36]. At the time of writing, this article has been cited over 50 times.

Five years later, in 2008, the NICE Clinical Guideline 65[35], Hypothermia: prevention and management in adults having surgery was published. But even then, practice varied and was suboptimal[50]. So, while it was a landmark in the recognition of the importance of perioperative thermal management, more was required to highlight the clinical benefits of warming.

The clinical guideline document itself is a long and highly detailed synthesis of the evidence which few people would have the time or inclination to read through. The executive summary provided bullet-point highlights of the most important findings. And there was a rigid protocol for use in clinical practice.

To help disseminate these findings and optimise the guideline's impact we published an editorial in the British Journal of Anaesthesia[51] which, at the time of writing, has been cited on 35 occasions, to provide a narrative context which highlighted some of its strengths and weaknesses.

Since then, we have published book chapters[52], reviews in anaesthetic publications[53,54] and the NHS Library of Health[55]. We have also generated audit templates and tools[56] to aid the implementation of the guideline and maximise its impact.

As a result of these publications, I have received numerous enquiries regarding the use of the audit tools, the implementation of guidance in clinical practice and from manufacturers of warming devices asking for advice regarding the design and testing of their products.

H6: The hypothesis that the provision of information and tools in addition to NICE guideline 65 is necessary to optimise the prevention of IPH in clinical practice is accepted.

5.0 Conclusions

5.1 Summary

The ultimate aim of our research programme has been to reduce the number of patients suffering from IPH. In this thesis I have attempted to demonstrate how a multi-faceted approach has had a potentially significant clinical impact by:

- demonstrating the extent to which IPH is a problem
- determining the accuracy of temperature measurement devices suitable for awake, as well as anaesthetised, patients
- showing that, while new warming technology may not be as effective as forced-air warming, it has the potential to bring the benefits of perioperative warming to hitherto unwarmed patient groups
- providing evidence of the mechanism behind potential safety issues with forced-air warming
- bringing my own and other people's work to the attention of a wider audience and providing the information and tools to reduce the incidence of IPH clinical practice

5.2 Limitations

The most significant limitation of our research is that it was not carried out under carefully controlled conditions. This was, however, a very conscious decision. Instead, we chose a pragmatic focus; one that would reflect everyday practice and therefore be more universally applicable to the clinical environment.

Another potential limitation is in our choice of outcome. First, we chose to use the incidence of IPH (which is an indication of the number of people at risk of its adverse effects) as our primary outcome measure rather than, as in older studies, mean, core temperatures (which is more of a statistical construct). However, this is also a strength of the studies as this outcome is more clinically relevant and is also the outcome that links more closely with the recommendations of the NICE CG65.

Finally, unlike the earlier studies which compared warmed with unwarmed patients, we have chosen to compare warming with current clinical practice and recommendations. This is because the benefits of warming have already been clearly established so our focus should now be on finding the optimum warming techniques for different groups of patients. It would be unethical to withhold warming where it is recommended.

5.3 Areas for further research

The most striking finding from our paper comparing FAW blankets with CPW mattresses is that, even in the more effective, FAW group, the incidence of IPH was 36%. This is clearly going to have a significant, clinical effect and is an unacceptably high percentage. Further research should therefore concentrate on finding ways to further reduce these rates of IPH. These could include prewarming or using multiple warming devices for which there is some limited evidence in the literature already[12,41,57]. Alternatively, it could include untried methods of warming such as providing exercise bikes for patients in the preoperative area.

Another area of research into perioperative warming that needs to be definitively addressed is that of the potential of FAW to increase infections, most notably implant infections, following orthopaedic arthroplasty surgery. The data are conflicting[44,47,58]. We are currently at a preliminary stage in setting up a multicentre RCT of FAW *vs.* resistive heating in patients with fractured neck of femurs to investigate this prospectively.

It is also important to establish the core temperature at which complications occur. As mentioned earlier, the current definition is one of consensus rather than evidence. Further studies are needed to establish where this threshold lies.

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Annex 1: GAT Audit Prize Submission 2003: A series of three audits of peri-operative hypothermia and the effect of various warming strategies

GAT AUDIT PRIZE 2003: A series of three audits of peri-operative hypothermia and the effect of various warming strategies.

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In the light of the increasing evidence that peri-operative temperatures <36°C can have detrimental effects, we carried out an audit to determine the incidence of peri-operative hypothermia in our institution.

We found that 28% of a series of 149 consecutive, elective surgical patients arrived in recovery with a core temperature (determined by infra-red tympanic measurement) of <36°C. In particular, it was noted that the incidence was 35% amongst urological patients.

We then re-audited the temperatures of patients undergoing transurethral resection of prostate and bladder tumours. In this group the incidence of post-operative hypothermia was 44%. Hypothermia was associated with a larger weight of resection, volume of irrigation fluid used and length of operation.

For the third audit we looked at the association between the method of patient warming and post-operative temperature. For 116 consecutive patients we found that 38% had a temperature of <36°C in recovery. However this incidence was only 16% in

those patients aggressively warmed (fluid warming, forced-air warming blanket and irrigation fluid warmed in a hot cabinet) whereas it was 44% amongst the other patients.

As a consequence of these audits, aggressive warming has become standard care for these patients and the order for blankets and fluid warmers increased to ensure that they are available for all patients. We are also setting-up a prospective trial to see if the rate of complications is higher in those patients who still become hypothermic and whether these patients can be identified pre-operatively and targeted for further intervention.

Annex 2: Harper CM, Crook D. A study to compare the accuracy and suitability of two methods of temperature measurement in the peri-operative setting. Eur J Anaesthesiol. 2008;25(Suppl 44):3AP1-4.

3AP1-4 A study to compare the accuracy and suitability of two methods of temperature measurement in the peri-operative setting

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Background and Goal of Study: Closer management of peri-operative temperature can improve patient outcome[1] but is reliant on the accuracy of temperature measurement. An ideal temperature monitor would be accurate, non-invasive and able to produce readings throughout the peri-operative period. Oesophageal probes (OP) are widely but can produce unreliable data, such as when they are sited in the naso-pharynx. Furthermore there is a small risk of nasal trauma on insertion and they are not suitable for pre- or post-operative use. The temporal artery scanner (TAS) is a novel, non-invasive temperature monitor which can be used throughout the peri-operative period but its accuracy has not been tested this setting. The 'gold standard' comparator for any evaluation of temperature measurement devices would be the pulmonary artery catheter (PAC). However, these have high rates of associated complications so we used urinary catheters (UC) with integral temperature thermistors as their accuracy with respect to PAC has been demonstrated during surgery[2]. Our goal was determine the accuracy and suitability of the two methods of temperature measurement (OP and TAS) during surgery by comparing them to temperatures obtained from the bladder.

Materials and Methods: Fifteen patients were recruited to a prospective comparative study. OP and UC thermistors were inserted after induction of anaesthesia. Non-invasive TAS measurements were taken using the Exergen thermoscan. For each patient we recorded temperatures each of the three methods at six time-points during surgery.

Results and Discussion: Observed body temperatures were similar for UC [median 36.2 C (range 35.3 − 38.2 °C)] and TAS [36.2 °C (35.6 − 37.6 °C)] (p=0.188 by Wilcoxon test), but OP values were lower [36.1 °C (35.5 - 38.3 °C)] (p<0.05). As expected, correlations between the techniques were high (Spearman's rho = 0.70 comparing Bladder and TAS and 0.64 comparing Bladder and OP; all p<0.001). Bland-Altman limits-of-agreement analysis showed that TAP gave similar results to Bladder whereas the OP values suggested greater bias and imprecision.

Conclusion(s): The temporal artery scanner appears to avoid the bias associated with oesophageal thermistors when measuring temperatures intra-operatively and so may be helpful during the thermal management of patients in the peri-operative period.

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Citation: C. Harper, D. Crook. A study to compare the accuracy and suitability of two methods of temperature measurement in the peri-operative setting. *Eur J Anaesthesiol 2008*; **25 (Suppl 44):** 3AP1-4

Presentation Time: Saturday, May 31, 2008 3:15 PM - 4:45 PM
Session Info: 03 - Monitoring: equipment and computers - 3AP1
Room: Hall A1 - ROW 2B

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Annex 3: Jack J.M., Ellicott H., Densham I., Harper CM. A study to determine the accuracy of zero-flux and ingestible thermometers in the perioperative setting.

A study to determine the accuracy of zero-flux and ingestible thermometers in the perioperative setting.

Relevance of research: Accurately monitoring core temperature during anaesthesia is a cornerstone of good practice. Relatively invasive devices such as oesophageal temperature probes and pulmonary artery flotation catheters allow accurate measurement of core temperature. However these are not appropriate for many patients. There is a need for accurate non-invasive measurement of core temperature.

Background and Goal of Study: This study was designed to compare the accuracy of two new non-invasive core temperature thermometers, the 3M SpotOn™ Temperature Monitoring System zero flux device (ZFD) and the CorTempR Wireless Ingestible Temperature Sensor (ITS) with the oesophageal temperature probe (OTP) which is the current introperative standard.

Materials and Methods: 20 patients scheduled for elective surgical procedures under general anaesthesia were recruited to the study. Prior to induction patients ingested an ITS, and after induction a ZFD was attached above their right eyebrow. During surgery temperature on each device was recorded every minute. Data were compared using Bland Altman analysis. Results and Discussion: The ITS experienced considerable interference from equipment used in the operating theatre, including diathermy and fluoroscopy, rendering around 30% of its readings redundant. These were removed from subsequent analysis. The bias for the ZFD compared to OTP was 0.024 and the 95% limits of agreement -0.47 to 0.52. 97.7% of readings are within +/-0.5C of the probe reading. With erroneous readings removed, the bias for the ITS when compared with the probe was 0.42 and the 95% limits of agreement -2.4 to 3.2. 75.4% of readings were within +/-0.5C of the OTP reading. Bland Altman analysis found good concordance between the ZFD and OTP.

Conclusions: The results of this study suggest the ZFD is an accurate non-invasive measure of core temperature, whereas the ITS is not suitable for perioperative practice.

The agreement between zero-flux and ingestible thermometry in the peri-operative setting.

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Abstract:

Relevance of research: Accurately monitoring core temperature during anaesthesia is a cornerstone of good practice. Relatively invasive devices such as oesophageal temperature probes and pulmonary artery flotation catheters allow accurate measurement of core temperature. However these are not appropriate for many patients. There remains a need for accurate monitors of core temperature that can be used in awake patients

Background and Goal of Study: This study was designed to compare the accuracy of two core temperature thermometers that can be used in awake patients: the 3M SpotOn™ Temperature Monitoring System Zero Flux Device (ZFD) and the CorTempR Wireless Ingestible Temperature Sensor (ITS). We compared the readings from these with the oesophageal temperature probe (OTP), which is the current introperative standard.

Materials and Methods: 30 patients scheduled for elective surgical procedures under general anaesthesia were recruited to the study. Prior to induction patients ingested an ITS, and after induction a ZFD was attached above their right eyebrow. During surgery temperature on each device was recorded every minute. Measurements were compared using Bland-Altman analysis.

Results: The ITS experienced considerable interference from equipment used in the operating theatre, including diathermy and fluoroscopy, rendering 39% of its readings invalid. These were removed from subsequent analysis. The bias for the ZFD compared to the OTP was 0.02°C and the 95% limits of agreement -0.47°C to 0.52°C. 97.7% of readings were within 0.5°C of the OTP reading. With the unusable readings removed, the bias for the ITS when compared with the OTP was 0.42°C and the 95% limits of agreement -2.4°C to 3.2°C. 75.4% of readings were within 0.5°C of the OTP reading.

Conclusions: The results of this study suggest the ZFD is sufficiently accurate for clinical use, whereas the ITS is not suitable for perioperative practice.

Introduction

The importance of good perioperative temperature management in optimising patient outcomes has been established for some time now[1-3]. In 2008, the National Institute for Health and Clinical Excellence (NICE) published Clinical Guideline 65 (CG65) on Perioperative hypothermia (inadvertent): The management of inadvertent perioperative hypothermia in adults[4]. This was a landmark in recognising the benefits of keeping patients warm around the time of surgery.

While NICE CG65 did not review methods of temperature measurement, it did emphasise the necessity of monitoring it regularly. Of note, CG65 is currently under review and, this time, thermometry has been included in the remit.

The gold standard of temperature measurement is the pulmonary artery catheter (PAC). However, this is rarely used in clinical practice as it is difficult to place and associated with many complications and its use is not recommended in routine practice[5].

Urinary bladder and oesophageal temperatures are sufficiently accurate[6] but are unsuitable for the many patients undergoing surgery either awake or without urinary catheters. Although non-invasive and relatively cheap means of measuring temperature (such as aural canal probes and infrared scanners) exist, they are neither accurate nor consistent enough to distinguish the 0.5°C differences which may have a significant effect on patient outcomes[6].

In this study we planned to determine whether two methods of core temperature measurement were sufficiently accurate to be employed in the perioperative period. While the measurments for the study were undertaken in patients while they were anaesthetised, both these monitors can, and have, been used in awake patients.

The first is a new method is zero-flux thermometry. This is completely non-invasive, involving no more than placing an adhesive pad to the forehead. Connected up to a

monitor, the zero-flux device (ZFD) equilibrates with the patient's core temperature and gives a constant read-out. A small proof of concept trial was published in 1980[7]. While a preclinical trial[8] and a study in cardiac surgical patients[9] have shown good performance of this device, the commercially available device has not been tested to date in the general surgical population.

The second is the CorTemp wireless intestinal temperature monitoring system (ITS). This consists of an ingestible pill and an external receiver. It has been tested over several days in laboratory protocols[10] and in various sports to look for both hypothermia and hyperthermia[11 12]. Its accuracy has not, however, been tested in hospital patients.

The existing data regarding both ZFD and ITS are equivocal. There exists a need for accurate, non-invasive measurement of core temperature in the intraoperative setting. This study investigated these two methods of measuring core temperature, to assess whether or not they are sufficiently accurate for routine clinical use in elective surgery. The comparator we used was an oesophageal temperature probe (OTP).

Methods

The study was registered at http//www.clinicaltrials.gov (NCT number: NCT02121574), reviewed and approved by the NRES Committee East of England - Norfolk (Ref: 14/EE/1016), and conducted in accordance with the Ethical Principles for Medical Research Involving Human Subjects outlined in the Declaration of Helsinki.

Written informed consent was obtained from all subject. All aspects of patient privacy and confidentiality were conserved.

4

Patients eligible for inclusion were those over 18 years of age listed for elective surgery, with sufficient mental capacity and command of spoken and written English to give informed written consent.

Exclusion criteria were as follows: the inability to give informed consent, contraindication to insertion of oesophageal probe (carcinoma of the oesophagus or pharynx, previous oesophageal surgery, oesophageal stricture or varices, pharyngeal pouch), subjects underoing open intra-abdominal surgery to remove a portion of the gastrointestinal tract, abnormal gastrointestinal pathology to prevent safe use of ITS.

Subjects were informed of the study at preoperative assessment clinic with recruitment posters, and given a patient information sheet. Written informed consent was sought on the morning of surgery at anaesthetic pre-assessment.

Upon arrival in the anaesthetic room, subjects ingested the ITS with 50ml of water. OTP and ZFD were administered post induction of anaesthesia. The ZFD electrode was attached above the right supraorbital ridge after cleaning with a 2% chlorhexidine/alcohol wipe.

Recording commenced after transfer into operating theatre and before the start of surgery. Temperature was recorded simultaneously by each device every minute for the duration of the procedure. Upon completion of surgery the OTP and ZFD were removed, while the ITS would have been excreted by the patient over the following days.

Statistics

GraphPad Prism 6 was used to produce Bland-Altman plots of the ITS vs OTP and ZFD vs OTP. 95% limits of agreement were calculated taking into account the repeated measurement per patient[13].

Results

30 patients were recruited to the study of which 29 completed it. This included 7 male (24%) and 22 female (76%) subjects. The mean age was 54 (range 19-85) years, weight 74.7 (range 48-104) kg, mean height 1.67 (range 1.50-1.88)m, BMI 26.4 (range 19.7-36.0)kg/m^2.

Surgical specialties studied included Urology, Vascular, Gynaecology, Spinal, Maxillofacial, Otorhinolaryngology and Breast.

One subject was excluded due to dislodgement of the OTP, which could not be resited due to the nature of surgery. Mean measurement duration was 41.9 (range 10-165) minutes.

2511 individual time points were measured with each device. The ITS temporarily ceased to function with use of both surgical diathermy and fluoroscopic imaging. These erroneous results, which consisted of 983 (39%) readings, were removed from subsequent analysis.

The bias for the ZFD compared to OTP was 0.02°C and the 95% limits of agreement -0.47°C to 0.52°C. 97.7% of readings erre within ±0.5°C of the probe reading. Bland Altman analysis found good concordance between the ZFD and OTP (Figures 1 and 2).

Figure 1: Bland-Altman plot of OTP vs ZFD (average values for all patients: shaded area indicates ±0.5°C)

Figure 2: Bland-Altman plot of OTP vs ZFD (all values: shaded area indicates ±0.5°C)

With the invalid readings removed, the bias for the ITS when compared with the OTP was 0.42°C and the 95% limits of agreement -2.4°C to 3.2°C. 75.4% of readings were within +/-0.5°C of the OTP reading (Figures 3 and 4).

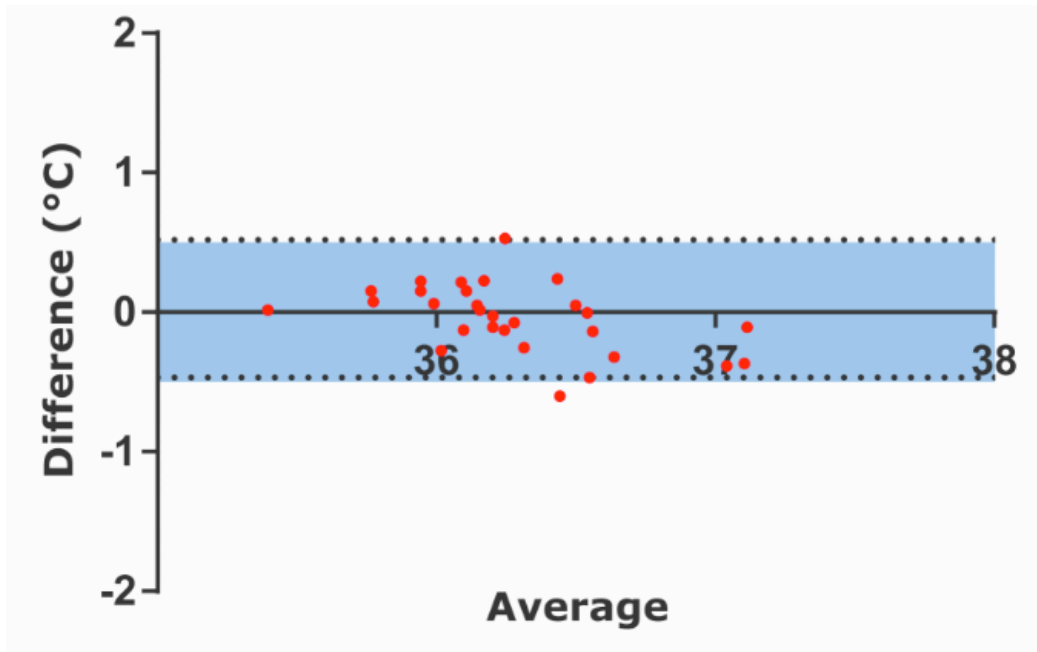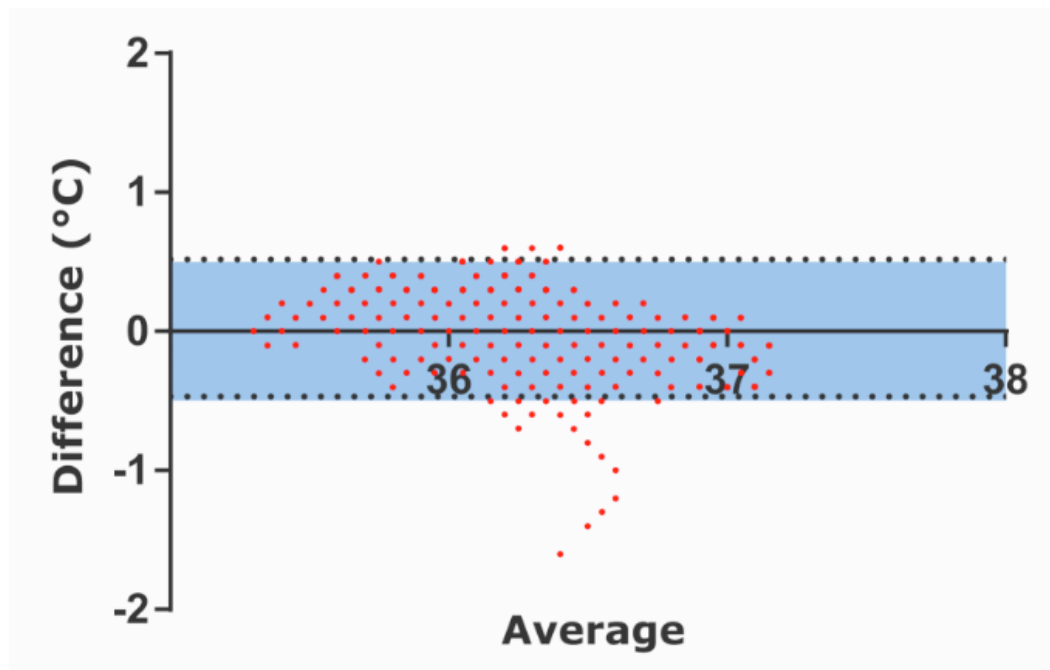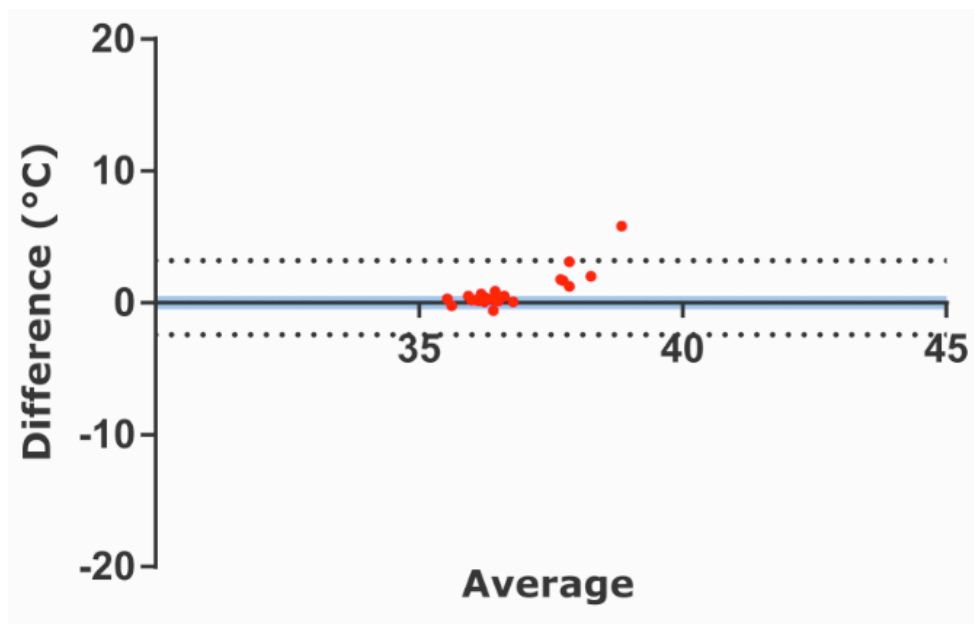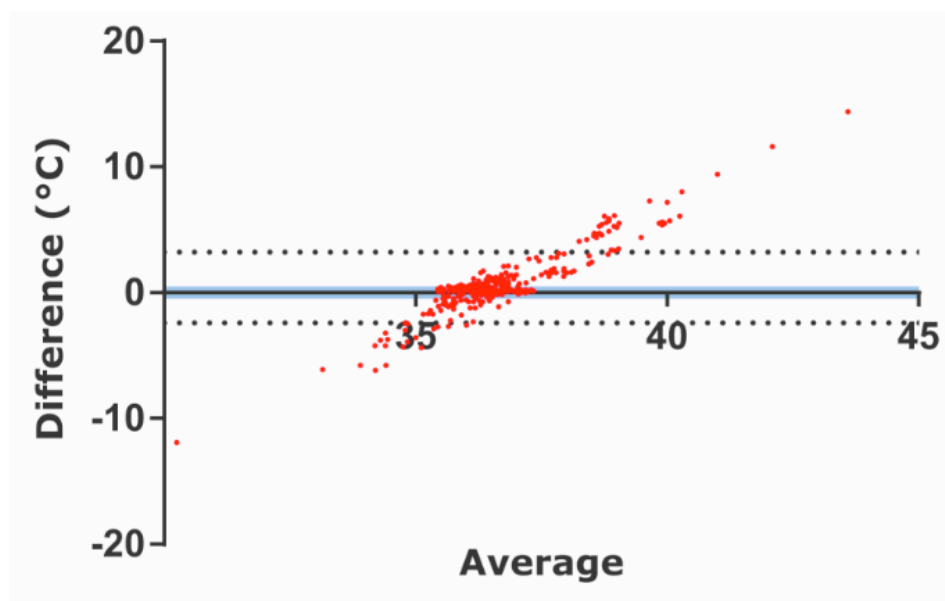Figure 3: Bland-Altman plot of OTP vs ITS (average values for all patients: shaded area indicates ±0.5˚C)

Figure 4: Bland-Altman plot of OTP vs ITS (average values for all patients: shaded area indicates ±0.5˚C)

Discussion

The ZFD has been shown to be a practical and reliable substitute for OTP, providing continuous, accurate real time readings after a typical 3-5 minute "warm up period".

The ZFD malfunctioned for a 29 minute period during breast surgery, which was thought to be due to the close proximity (approximately 30cm) of surgical diathermy.

The ITS was unreliable, with diathermy or fluoroscopy resulting in no readings taken, or readings that were obviously erroneous. Investigators noted the duration when either were in use and removed these specific values from analysis. It is theoretically possible this process introduced investigator bias, although investigators adhered to a protocol for this occurrence.

With the ITS, the Bland-Altman plots (Figure ..) suggest that it has a reasonable degree of accuracy around a normal body temperature of 37°C but rapidly becomes insufficiently accurate for clinical purposes both above and below this temperature.

Intraoperatively, the ITS was impractical and labour intensive. The accompanying external device used to read the ITS required close proximity to the capsule, approximately 60cm or less, typically requiring the operator to reach over the patient under the surgical drapes, requiring a read button to be pressed to obtain a temperature. The most convenient solution was to rest the device on the patient's shoulder, which may be unacceptable to many clinicians. The degree of involvement required by this device in its current format would render it impractical for a lone anaesthetist to measure temperature every minute for the duration of surgery. In everyday practice, every 30 minutes in accordance with current guidelines may be workable.

Weaknesses in the study

A potential investigator bias may have been introduced when removing erroneous readings from the ITS.

Conclusions

The ZFD appears to be a reliable, practical and accurate continuous measure of core temperature during elective surgery that could be used for awake patients. As such it potentially represents a big step forward for perioperative temperature management. The ITS has insufficient accuracy and reliability for routine use in elective surgery, and is likely too impractical for routine use.

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Annex 4: John M, Crook D, Dasari K, Eljelani F, El-Haboby A, Harper CM. Comparison of resistive heating and forced-air warming to prevent inadvertent perioperative hypothermia. British journal of anaesthesia. 2016;116(2):249-54

Comparison of resistive heating and forced-air warming to prevent inadvertent perioperative hypothermia

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Abstract

Background: Forced-air warming is a commonly used warming modality, which has been shown to reduce the incidence of inadvertent perioperative hypothermia (<36°C). The reusable resistive heating mattresses offer a potentially cheaper alternative, however, and one of the research recommendations from the National Institute for Health and Care Excellence was to evaluate such devices formally. We conducted a randomized single-blinded study comparing perioperative hypothermia in patients receiving resistive heating or forced-air warming.

Methods: A total of 160 patients undergoing non-emergency surgery were recruited and randomly allocated to receive either forced-air warming ($n=78$) or resistive heating ($n=82$) in the perioperative period. Patient core temperatures were monitored after induction of anaesthesia until the end of surgery and in the recovery room. Our primary outcome measures included the final intraoperative temperature and incidence of hypothermia at the end of surgery.

Results: There was a significantly higher rate of hypothermia at the end of surgery in the resistive heating group compared with the forced-air warming group ($P=0.017$). Final intraoperative temperatures were also significantly lower in the resistive heating group (35.9 compared with 36.1°C, $P=0.029$). Hypothermia at the end of surgery in both warming groups was common (36% forced air warming, 54% resistive heating).

Conclusions: Our results suggest that forced-air warming is more effective than resistive heating in preventing postoperative hypothermia.

Clinical trial registration: NCT01056991.

Key words: equipment; hypothermia; temperature; warming devices

Inadvertent perioperative hypothermia (IPH), defined as a core temperature <36°C,[1] is associated with numerous adverse patient events, including greater intraoperative blood losses,[2] increased postoperative wound infection rates,[3 4] pressure ulcers,[5] cardiac events,[6] hospital costs, and lengths of stay.[7] A plethora of warming devices and techniques[8] have been developed to protect patients, including prewarming[9] and the use of fluid warmers,[10] water mattresses,[11] negative pressure devices,[12] forced-air warming,[13] and resistive heating.[14] Of these, the most commonly used modality is the forced-air warming blanket (FAWB). Use of a FAWB has been recommended by the National Institute for Health and Care Excellence (NICE) for all patients at high risk of IPH and those undergoing surgeries lasting >30 min.[1] However, they are single-use and therefore have ongoing, cumulative costs, which have been recognized in the NICE technology guidance on the Inditherm mattress.[15] They can also be difficult to

Editor's key points

- Many methods and devices are available to prevent peri-operative hypothermia, but their relative effectiveness is uncertain.
- This study compared a forced-air warming device (Bair Hugger™) with a resistive heat mattress (Inditherm) in patients undergoing surgery of >30 min duration.
- Body temperatures were very slightly higher after surgery in patients receiving forced-air warming.
- Although statistically significant, the clinical relevance of this is not established; perioperative hypothermia occurred in a high proportion of patients in both groups.

position in such a way that satisfies both anaesthetist and surgeon. Carbon-polymer resistive heating mattresses (RHMs) provide a silent, reusable warming system, which does not interfere with the surgical field and could provide a solution to the aforementioned problems. The mattress uses resistive heating, whereby a low-voltage electric current passes through a carbon-based conductive polymer to generate a uniform heating surface.[15]

A review of the literature comparing the efficacy of resistive heating with forced-air warming shows mixed results, with one non-clinical study favouring resistive heating,[16] six showing equivalence in performance,[17–22] and three clinical studies favouring forced-air warming.[23–25] The aim of our study was to compare the efficacy of the carbon-polymer mattress (posterior resistive heating) with the forced-air warming blanket (anterior forced-air warming) in preventing IPH in patients undergoing non-emergency surgery. Our study was a response to the NICE CG65 research recommendations calling for further assessments to compare the warming capacity of forced-air warming (FAW) with alternative devices.[1] This was a pragmatic study insofar as the use of warming and the mix of operations were intended to reflect everyday clinical practice.

Methods

We initially performed a pilot study to assess larger scale feasibility by recruiting 40 patients undergoing elective surgery under general anaesthesia, where the anaesthetist judged that warming during the operation was appropriate. The only exclusion criteria were patients less than the age of 18 yr or presenting as an emergency. In the pilot study, 5% of patients were hypothermic on admission to the recovery room. Using the online calculator (http://www.cct.cuhk.edu.hk/stat/proportion/tspp_sup.htm) set to an α of 0.05 and a power of 0.8, we calculated that 59 patients in each arm or a total of 118 would be needed to show the RWM to be non-inferior. Taking the results for the incidence of IPH at the end of surgery, from the pilot phase, a total sample size of 120 patients would be required to show non-inferiority.

We therefore recruited a further 120 patients using exactly the same criteria and methods as the pilot before pooling all of the results for final analysis[26] (Fig. 1).

The study received local research ethics committee approval (REC reference 05/Q1907/166) and was registered with ClinicalTrials.gov (Identifier NCT01056991). Written informed consent was obtained from all patients.

Patients were randomized via computer-generated codes to receive warming using either a FAWB (Bair Hugger 750; Actamed,

Wakefield, UK) or RHM (Inditherm; Inspiration Healthcare, Rotherham, UK).

General anaesthesia was induced i.v. and maintained with inhaled volatile agents in all patients. If indicated, tracheal intubation was facilitated with a non-depolarizing muscle blocker. Fresh gas flows were reduced to ≤1 litre min⁻¹ within 15 min of inducing anaesthesia. All patients received warmed fluids (Ranger; Actamed, Wakefield, UK), and the operating theatre temperature was maintained between 20 and 22°C. The patients who were allocated to the FAWB group received forced-air warming via the Bair Hugger 750 Warming Unit set to the maximal setting (43°C). The most appropriate style of blanket was used for each patient. Patients allocated to the RHM group received resistive heating from lying supine on the mattress in theatre set to the maximal setting of 40°C. Patient warming in the RHM group commenced as soon as the patient was positioned on the operating table; in the FAWB group, it was started immediately after surgical draping. In both groups, it was maintained until the end of the operation.

Pre-induction and recovery room temperature measurements were obtained from all patients using a temporal artery thermometer (TAT 5000; Exergen, Watertown, MA, USA). After induction of anaesthesia, an oesophageal probe (Thermistor 400; Mallinckrodt, Cornamaddy, Ireland) was inserted to measure patient core temperature immediately after induction, at the start of surgery, every 15 min for the first hour, and then every 30 min thereafter until the end of surgery. The probes were maintained and calibrated according to the manufacturer's instructions. Primary outcomes included the postoperative core temperature and the incidence of IPH at the end of the operation. The secondary outcome measure was the estimated blood loss based on suction volume, swab weight, and surgical opinion.

Data analysis was performed using SPSS 16.0 for Mac (SPSS Inc., Chicago, IL, USA). Continuous data distributions were examined for normality by visual inspection of frequency histograms. Normally distributed data are presented as mean (SD) and were compared using Student's unpaired *t*-test. Where data distributions were skewed, we used medians, ranges and interquartile ranges (IQRs) and the Mann–Whitney *U*-test. Categorical data were analysed using the χ^2 test or Fisher's exact test as appropriate. Owing to the limited number of planned comparisons, no adjustment for multiple testing was made. A value of $P<0.05$ was considered statistically significant.

Results

Overall, 160 patients were randomized to receive intraoperative warming from either FAWB (*n*=78) or RHM (*n*=82). One patient allocated to the RHM group in whom a clear surgical cause of bleeding resulted in an excess of 5 litre blood loss was excluded from the final analysis. There were no reports of burns or other intraoperative complications related to the warming devices used. The groups were well matched (Table 1), and the rates of pre-induction hypothermia were low (RHM=6%, FAWB=1%). There was no significant difference in pre-induction starting temperatures between the RWM and FAWB groups (*P*=0.133). The mean (SD) patient core temperature before knife to skin was 36.0 (0.4)°C for the RHM group and 36.0 (0.5)°C for the FAWB group.

Mean, final intraoperative temperatures were significantly (*P*=0.029) higher in the patients warmed with forced-air warming (36.1°C) compared with resistive heating (35.9°C; Table 2). In keeping with the core temperature results, the incidence of hypothermia (defined as core temperature <36°C) at the end of surgery was significantly (*P*=0.017) lower in patients warmed with FAWB (36%)
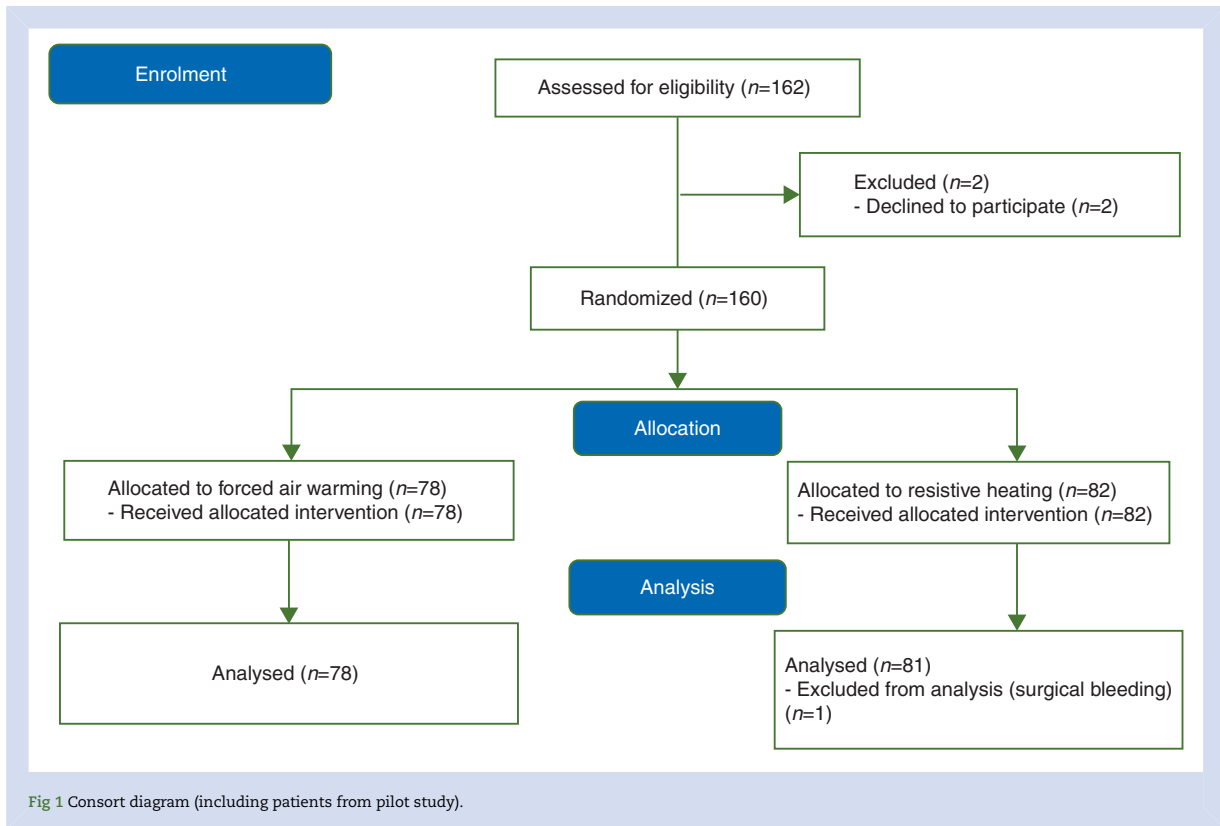
Fig 1 Consort diagram (including patients from pilot study).

Table 1 Patient characteristics and surgical specialties. Values are mean (SD), median (interquartile range [range]), or number (proportion) as appropriate

	Resistive heating (n=81)	Forced-air warming (n=78)
Patient characteristics		
Age (yr)	55 (18–93)	54 (21–89)
Sex (male/female)	17/64	23/55
BMI (kg m^{-2})	28 (24–32 [19–52])	25 (23–30 [19–41])
ASA grade I	30 (37%)	31 (40%)
ASA grade II	42 (52%)	38 (49%)
ASA grade III	9 (11%)	9 (12%)
Anaesthetic time (min)	15 (12–21 [5–85])	15 (12–22 [5–60])
Total operative time (min)	88 (67–115 [25–200])	85 (65–110 [30–230])
Surgical specialties		
Gynaecology	33 (41%)	19 (24%)
General	29 (36%)	37 (47%)
Ear, nose, and throat	6 (7%)	3 (4%)
Vascular	4 (5%)	9 (12%)
Breast	5 (6%)	5 (6%)
Maxillofacial	3 (4%)	0 (0%)
Urology	0 (0%)	3 (4%)
Orthopaedics	1 (1%)	2 (3%)

compared with RHM (54%). Both of our primary outcome measures therefore favour forced-air warming over resistive heating in preventing postoperative hypothermia for our patient population.

There was no significant difference (P=0.055) in the estimated intraoperative blood loss between the RHM and FAWB groups. The median (IQR) blood loss was in fact the same for both the resistive heating 0.1 (0.1–0.3) litre and forced air warming groups 0.1 (0–0.2) litre. However, a single extreme outlier in the mattress cohort was excluded from analysis because during the procedure in question, there was a surgical cause of excessive bleeding (>5 litre).

Table 2 Perioperative core temperatures and blood loss estimates for patients in the resistive heating and forced-air warming groups. Values are mean (SD), median (interquartile range [range]), or number (proportion) as appropriate. IPH, inadvertent perioperative hypothermia

Parameter	Resistive heating	Forced-air warming	P-value
Pre-induction temperature (°C)	36.7 (0.4)	36.8 (0.4)	0.133
Starting temperature (°C)	36.0 (0.4)	36.0 (0.5)	0.676
Final temperature (°C)	35.9 (0.6)	36.1 (0.5)	0.029
Recovery room temperature (°C)	36.5 (0.4)	36.6 (0.5)	0.015
IPH at knife to skin	35 (43.2%)	33 (42.3%)	0.924
IPH at the end of surgery	44 (54.3%)	28 (35.9%)	0.017
IPH on admission to recovery room	8 (9.8%)	4 (5.6%)	0.370
IPH at any time	50 (61.7%)	44 (56.4%)	0.159
Total amount of fluid (litres)	1.00 (1.0–1.5 [0–3])	1.00 (1.0–1.5 [0–4])	0.672
Estimated blood loss (litres)	0.1 (0.05–0.3 [0–1.1])	0.1 (0–0.2 [0–1])	0.055
Blood transfusion rate	2 (2.5%)	0 (0%)	0.258

Discussion

Our study showed that the use of FAW in elective adult patients was associated with higher core temperatures in patients at the end of surgery and on admission to the recovery room when compared with a resistive warming mattress. There was, however, no significant difference in the overall number of patients who experienced hypothermia at any stage perioperatively between the two groups.

Since the publication of the NICE perioperative hypothermia guidelines,[1] FAW has been the gold standard with which all other methods of warming need to be compared. We set out to clarify whether resistive heating was non-inferior to FAW because the published evidence has shown contrasting results. An early study by Leung and colleagues[23] showed that intraoperative upper-body FAWB was more effective than resistive heating in maintaining core temperatures for patients undergoing laparotomies. However, the resistive heating pad used in this earlier study covered only 104 cm×45 cm, which limited its warming capacity. Later trials involving full-length resistive heating mattresses with a greater surface area available for warming[19 21] suggested equivalence in performance. Our results, however, show the RHM to be inferior to the FAWB in preventing IPH at the end of surgery as measured using oesophageal temperature monitoring.

The FAWB protects patients from inadvertent perioperative hypothermia both through heat transfer and by preventing radiant and convective heat loss from exposed anterior surfaces. The RHM lacks this added protective effect, which may have contributed to the inferior performance.

Posterior surface warming in the supine position is also limited by the restricted perfusion in dependent capillaries and subsequent reduced ability to distribute heat to the rest of the body. The construction of the mattress used in the present study is such that it has inherent pressure-relieving properties.[27] This both increases the surface area in contact with the warming element and reduces the risk of pressure heat necrosis,[28] which has dogged previous such devices. However, although the performance appears to be superior to older devices, this construction is still insufficient to compensate for the restriction on the amount of heat that can be generated safely. For the warming devices used in our study, the maximal temperature available for posterior surface resistive heating was 40°C, compared with 43°C for forced-air warming.

Inadvertent perioperative hypothermia has been shown to increase intraoperative blood loss and the relative risk for transfusion,[29] most probably because of the negative effect on platelet function and the enzymes of the coagulation cascade. Our results, however, did not show any significant difference in the estimated intraoperative blood loss or transfusion rate between the RHM and FAWB groups. It is important to stress that this result was reached after the exclusion of a patient who received resistive underbody heating and bled excessively during surgery (>5 litre). The excluded patient was undergoing gynaecological surgery and suffered from what was considered a predominantly surgical bleed as opposed to bleeding from a temperature-related coagulopathy. Although the exclusion of these data undermines the strength of our secondary outcome results, we considered this patient to be an extreme and unrepresentative outlier. If this outlier is included in our statistical analysis, a significant difference in intraoperative blood loss favouring forced air warming is reached (P=0.042).

After induction of anaesthesia, the reduction in core temperature is primarily caused by a core-to-peripheral redistribution of body heat that is most marked during the first intraoperative hour.[30] Here lies both the weakness and potential strength of the RHM.

It is a weakness insofar as it appears to transfer less heat to the patient than forced-air warming; therefore, it takes longer to bring the patient's temperature back to normal. The average overall anaesthetic and surgical time in our study for the RHM group was 88 (67–118) min. When the operative time was much longer, as in the study of Egan and colleagues[19] (average surgical time of 222 mins in RHM group), a greater proportion of patients had core temperatures >36°C at the end of surgery in comparison to our results (58 *vs* 46%, respectively).

The only effective means of preventing this redistributive heat loss after induction of anaesthesia is through prewarming.[9] Although we did not use the mattress for prewarming in this study, it is very simple and presents no additional cost, which is a potential strength of the system. Wong and colleagues[4] showed that 2 h of preoperative warming with an RHM was effective in reducing both the reduction in core temperature and the complications associated with bowel resection surgery when patients also received forced-air warming during surgery. Even if not used for prewarming, the RHM allows warming before and during induction of anaesthesia without interfering with the process or disturbing the patient. Our rates of hypothermia after induction were surprisingly high in both groups (43% in the RHM group, 42% in the FAWB group). This will lengthen the time required to achieve normothermia, which strengthens the

argument for prewarming, especially given that times as short as 10 min have been shown to be effective with FAW.[31]

Given the high rates of IPH in both groups, if prewarming is not carried out, alternative strategies to maintain normothermia would seem to be necessary. One option available is to combine resistive heating and forced-air warming during surgery. A small study of 20 patients from Engelen and colleagues[32] showed that this combination can achieve higher intraoperative core temperatures when compared with forced-air warming alone.

The findings from our study, which was designed to reflect everyday clinical practice, are timely, because the review of the NICE hypothermia guideline has now been scheduled. The limitations of our study included the practical inability to blind the treatment groups, which could have introduced bias. Patient warming was also started at different times depending on the warming device used. Warming with the RHM started as soon as the patient was positioned on the operating table, whereas warming with the FAWB commenced later on, after surgical draping. Nevertheless, this accurately reflects how these two devices are used in real life.

Although the difference in core temperature at the end of surgery was statistically significant, it is important to view the results in their clinical context. The final mean temperatures for the resistive heating and forced-air group were 35.9 and 36.1°C, respectively, and whether this translates into a clinically significant difference was not assessed.

The blood loss volumes were estimations, based on the opinions of different surgical teams. Furthermore, we excluded a patient who suffered from excessive surgical bleeding. Another limitation is that the type of FAWB was not standardized.

Nonetheless, we feel that our study reflected fairly the performance of the two tested warming devices in everyday clinical practice throughout a wide range of non-emergency surgical operations and, as such, provides the best possible information on which to base purchasing decisions.

In summary, our results suggest that forced-air warming is more effective than posterior surface resistive heating; however, both warming modalities failed to prevent postoperative hypothermia in an alarmingly high proportion of patients. Further trials should be undertaken to assess the effectiveness of combining FAWB with RHM in order to prevent IPH in this patient population.

Authors' contributions

Study initiation: K.D.
Study design: D.C., C.M.H.
Ethical approval: K.D.Patient recruitment: M.J., K.D., F.E., A.E., C.M.H.Data collection: M.J., K.D., F.E., A.E., C.M.H.
Data analysis: M.J., D.C.
Writing of the manuscript: M.J., D.C., C.M.H.

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Declaration of interest

M.J., D.C., K.D., F.E., A.E.: no conflict of interest declared. C.M.H. has received loans of equipment from various manufacturers of warming devices, including Inditherm, Augustine Biomedical, Arizant, and Mölnlycke. He has also received expenses and an honorarium for sitting on an advisory board for Mölnlycke.

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Annex 5: Chakladar A, Dixon MJ, Crook D, Harper CM. The effects of a resistive warming mattress during caesarean section: a randomised, controlled trial. International Journal of Obstetric Anesthesia. 2014;23(4):309-16.

ORIGINAL ARTICLE

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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°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 ± 0.9 g/dL versus -1.6 ± 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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Keywords: Anaesthesia, obstetric; Caesarean section; Complications, hypothermia; Complications, anaemia; Equipment, warming devices; Temperature, monitoring

Introduction

The adverse effects of inadvertent perioperative hypothermia (IPH) in the general surgical population are well established.[1–4] Shivering can cause patient discomfort, distress and hypoxia.[5] To date, little research has looked at IPH in patients undergoing caesarean section (CS);[4] what randomised trial data exist generally involve small numbers of patients ranging from 30 to 75.[6–9] Furthermore, in this group of patients, undesirable effects may extend beyond the patients as hypothermia and shivering may adversely affect contact with and feeding of the new baby; one study suggested that hypothermia can affect Apgar scores.[6]

The UK National Institute for Health and Care Excellence (NICE) has published guidance on the prevention of perioperative hypothermia.[10] 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.[11] Nevertheless, it is reasonable to infer that women undergoing CS are likely to benefit from warming.[4]

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.[12] Our own audit data have shown approximately 11% of patients undergoing elective CS become hypothermic and 25% suffer from shivering.[13] 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

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

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.[10] 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.[16] Recent NICE medical technology guidance has recommended that a WM produced by a specific manufacturer should be considered as an alternative to FAWB.[17]

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 TemporalScanner™ 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.[18,19]

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.[10] Warmed fluids, if used, were warmed using a Ranger™ 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

after the patients receiving neuraxial anaesthesia were positioned supine (baseline), or immediately after induction of general anaesthesia (GA), upon knife to skin, and every 15 min thereafter. Temperature was also measured on delivery of the infant(s), when the dressing was applied to the wound, on arrival in to the recovery room and then 30 min after admission to recovery. Shivering at any time and need for treatment in the perioperative period were noted. All patients received routine postoperative care and blood was drawn on postoperative day one or two to measure haemoglobin in line with hospital policy; no additional blood tests were performed on account of this study.

All participants wore standard NHS (open back) gowns which were folded over their chest during surgery. Immediately following surgery, postoperatively these gowns were changed if they were wet or soiled. Otherwise, women were transferred to the recovery room in the original gowns and were covered with a cotton sheet and blankets, as required.

The primary aim of this study was to determine whether a resistive electric WM reduced the incidence of postoperative hypothermia (defined as core temperature <36.0°C on admission to the recovery room) in women undergoing elective CS. Secondary aims included ascertaining differences in the incidence of shivering, severity of shivering and need for treatment, estimated blood loss (EBL), incidence of blood transfusion, immediate health of baby (Apgar score at 1 and 5 min), time taken to initiate breast feeding (if choosing to do so) and length of hospital stay. For non-singleton pregnancies, the Apgar score of the first-delivered infant was analysed. Shivering was graded as 0 to 3 (0 = no shivering; 1 = intermittent, low intensity (mild) shivering; 2 = moderate shivering; 3 = continuous severe shivering).[6] Treatment of shivering was based on patient need rather than an observed grade.

Statistical analysis

Estimates of the prevalence of hypothermia vary across the literature; recent internal audit and published research suggest an incidence of hypothermia of 60–70% during elective CS.[7] As greater awareness of the issue of hypothermia amongst clinicians may have reduced this rate, we predicted a reduction of 50% for the endpoint of hypothermia (defined as core temperature <36.0°C) when the warming mattress was used. Using an online sample-size calculator (http://department.obg.cuhk.edu.hk/researchsupport/statmenu.asp) and standard criteria (power = 80%, type 1 error = 0.05) we calculated that 58 women in each group would be sufficient to detect such an effect.

Data are presented as mean ± standard deviation (SD) or median [range]; however, ranges are given for certain continuous variables such as theatre temperature and temperature on admission to the recovery room.

Parametric continuous variables were compared using unpaired, 2-tailed, Student's t tests, non-parametric variables with 2-tailed Mann–Whitney U tests and discrete variables with chi-square tests. Incidence of IPH and shivering were compared using 2-tailed Fisher's exact tests. Statistical tests were conducted using SPSS Version 18.0 (SPSS Inc., Chicago, IL, USA). Data were analysed on an intention to treat basis. A P value <0.05 was considered statistically significant.

Results

Between February 2010 and July 2011, 119 women were enrolled and randomised; 116 completed the study, three women were not studied as their surgery was postponed (Fig. 2). Patient characteristics, operative times, time from end of surgery to admission to recovery, use of warmed fluids, and volume of intravenous fluids infused were similar in the two groups (Table 1). Spinal anaesthesia was employed in 57 out of 58 women in each group. One woman in the mattress-warmed group had an epidural and one woman in the control group had a general anaesthetic. Baseline temperature measurements and the operating theatre temperature were similar in the two groups (Table 2).

The incidence of IPH and shivering in the two study groups is shown in Table 2. There was a statistically significant lower incidence of IPH in women warmed with a mattress. Three out of 58 women (5.2%) receiving mattress warming were hypothermic on admission to recovery compared to 11 out of 58 women (19.0%) in the control group (P = 0.043). Women in the warmed group were warmer (36.5°C) compared to the control group (36.3°C) on admission to the recovery room (P = 0.046) and 30 min after (P = 0.046).

There was no significant difference between the two groups in the incidence of shivering, severity of shivering or need for treatment (Table 2), preoperative Hb concentration, EBL, incidence of blood transfusion (Table 3), Apgar scores, time to breast feeding, or length of hospital stay. No participant required treatment for shivering. There was a significant difference in postoperative Hb concentration fall in the mattress-warmed group compared to control (1.1 vs. 1.6 g/dL, P = 0.007).

One woman randomised to the control group was inadvertently warmed by the mattress and another women randomised to the control group was noted to be pyrexial on admission to the labour ward but apyrexial at the start of surgery and on admission to the recovery room. Data from both women were analysed on an intention to treat basis. Analyses excluding data from these women did not alter our findings. One participant (mattress-warmed group) had a temperature of 39.6°C on arrival in the recovery room, having been normothermic throughout her surgery and 30 min later.
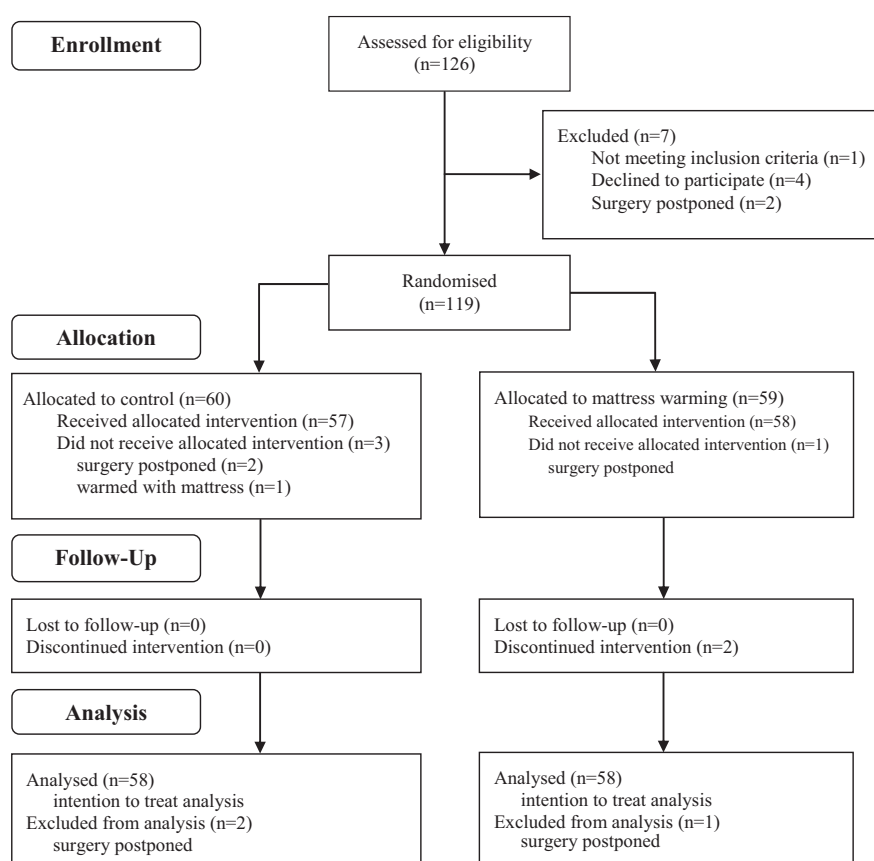
Fig. 2 CONSORT flow diagram

Table 1 Patient demographics and operation details

	Mattress warmed ($n = 58$)	Control ($n = 58$)	P value
Age (years)	33.6 ± 5.8	34.3 ± 5.9	0.493
ASA physical status			0.175
1	37 (63.8%)	44 (75.9%)	
2	21 (36.2%)	13 (22.4%)	
3	0	1 (1.7%)	
Weight at booking (kg)	70.1 ± 14.0	69.6 ± 18.4	0.902
Body mass index at booking (kg/m^2)	24.8 ± 4.4	25.7 ± 5.9	0.364
Gestational age (weeks)	38.3 ± 1.7	38.5 ± 0.8	0.389
Pregnancy			0.393
Singleton	53 (91.4%)	49 (84.4%)	
Twins	5 (8.6%)	9 (15.5%)	
Length of operation[*] (min)	44 [23–104]	42 [24–75]	0.621
Fluid warming	51 (87.9%)	55 (94.8%)	0.322
Volume fluid infused (L)	2.0 [1.0–3.5]	2.0 [0.75–3.5]	0.888
Dressing time[†] (min)	12 [3–33]	11 [5–23]	0.599

Data are mean ± SD, median [range] or number (%). ASA: American Society of Anesthesiologists. [*]Length of operation: time from knife-to-skin to application of surgical skin dressing; [†]Dressing time: time from application of surgical skin dressing to admission to recovery area.

Two women randomised to receive mattress warming did not receive the full intervention due to feeling uncomfortably warm. One woman had a temperature of 37.4°C immediately post-spinal but this had dropped to 36.6°C at skin incision; in these cases the ambient theatre temperatures were 24.0°C and 25.0°C, respectively. This amounts to a 3.4% rate thermal discomfort when a WM was used as per our protocol.

Table 2   Patient body temperatures and cold-related outcomes

	Mattress warmed (n = 58)	Control (n = 58)	P value
Operating theatre temperature (°C)	23.0 ± 1.6 [20.0–26.0]	22.9 ± 2.0 [18.0–27.0]	0.753
Patient temperature (°C)			
Preoperative	36.7 ± 0.3	36.6 ± 0.4	0.251
Post-anaesthesia	36.8 ± 0.4	36.7 ± 0.4	0.629
Knife to skin	36.5 ± 0.3 (n = 58)	36.4 ± 0.4 (n = 58)	0.134
Knife to skin + 15 min	36.5 ± 0.4 (n = 58)	36.5 ± 0.4 (n = 58)	0.234
Knife to skin + 30 min	36.6 ± 0.4 (n = 52)	36.4 ± 0.4 (n = 48)	0.169
Knife to skin + 45 min	36.5 ± 0.4 (n = 25)	36.3 ± 0.4 (n = 25)	0.11
Knife to skin + 60 min	36.6 ± 0.2 (n = 5)	36.5 ± 0.3 (n = 7)	0.487
Knife to skin + 75 min	36.5 ± 0.2 (n = 2)	35.8 (n = 1)	0.242
Dressing*	36.5 ± 0.4	36.4 ± 0.4	0.079
Recovery admission	36.5 ± 0.5 [35.8-39.6]	36.3 ± 0.4 [35.8-37.2]	0.046
Recovery admission + 30 min	36.6 ± 0.6	36.4 ± 0.4	0.046
Incidence of IPH	3 (5.2%)	11 (19.0%)	0.043
Incidence of shivering	10 (17.2%)	8 (13.8%)	0.798
Intensity of shivering			
Grade 1	8 (13.8%)	5 (8.6%)	
Grade 2	2 (3.4%)	3 (5.2%)	

Data are mean ± SD [range] or number (%). IPH: inadvertent perioperative hypothermia. *Dressing temperature: temperature on application of surgical skin dressing.

Table 3   Haemoglobin levels, blood loss, and transfusion

	Mattress warmed (n = 58)	Control (n = 58)	P value
Preoperative Hb (g/dL)	11.7 ± 1.0	11.7 ± 1.0	0.97
Lowest postoperative Hb (g/dL)	10.6 ± 1.0	10.2 ± 1.3	0.052
Day of postoperative Hb measurement	2 [0–3]	2 [0–3]	0.362
Estimated blood loss (L)	0.5 [0.1–2.5]	0.6 [0.2–4.0]	0.557
Blood transfusion needed	2 (3.4%)	3 (5.2%)	1.00
Discharge Hb (g/dL)	10.6 ± 1.0	10.3 ± 1.3	0.064
Change in Hb (g/dL)	−1.1 ± 0.9	−1.6 ± 0.9	0.007

Data are mean ± SD, median [range], or number (%). Hb: haemoglobin.

Five women required red blood cell transfusions. Seven units were transfused in the control group; four of the seven units administered in the control group were given intraoperatively to a woman who had a massive obstetric haemorrhage with an EBL of 4000 mL. Four units were transfused in the mattress-warmed group; two units each to women estimated to have bled 2500 mL and 2000 mL, respectively. There was no incidence of IPH in the transfused women.

Discussion

This randomised, controlled trial is, to date, the largest prospective study examining the effects of warming during elective CS and the first to investigate the effectiveness of an under-body resistive WM on the incidence of IPH. We found a reduction in the incidence of hypothermia and attenuation in the perioperative fall in Hb concentration, but no effect on shivering. We chose to base our outcomes on the incidence of IPH rather than

temperature as this is the clinical standard defined by NICE.

The potential mechanisms by which WM reduce IPH include reduced peripheral heat redistribution and consequent vasodilatory heat loss after neuraxial and general anaesthesia, attenuation of linear phase heat loss, and reduced conductive heat loss. In our two groups, there was no difference in measured temperatures until admission to the recovery room. This suggests that significantly more heat was lost by unwarmed women between the time of dressing application and admission to recovery room (Table 2) despite comparable transit times. This can be explained by a prewarming effect of the WM which reduces heat redistribution when patients are exposed and washed at the end of the surgery.

The rate of IPH after elective CS in our institution is lower than previously reported.[14] This may be because the mean operating theatre temperature was higher than the minimum of 21°C recommended by the NICE guideline;[10] most women in both groups received warmed

fluids which mitigate temperature decrease during elective CS;[8] and the WM may have provided passive insulation for the control group. Furthermore, one of the authors (CMH) was part of the NICE guideline development group and so the importance of preventing IPH is high in our institution. This may produce a pre-existing attention bias or institutional Hawthorne effect.[20]

There was a non-significant difference in mean temperatures between the groups in our study. Any difference in outcomes may be explained by a 'hypothermic threshold' below which complications are more likely. The definition of IPH used (<36°C) is a consensus definition.[10] A study in the general surgical population has shown significant differences in infection and blood loss between groups whose mean temperatures were 36.5°C and 36.2°C,[21] indicating a possible advantage in keeping core temperature normal (36.5–37.5°C).

Although there was no difference in EBL (which is known to be an imperfect, subjective measure), we did find a significantly greater reduction in the objectively measured Hb concentration in the unwarmed group. While Hb concentration can be affected by a number of variables, the most important, the volume of intravenous fluid infused, was equal in both groups. This statistical significance remained ($P = 0.046$ vs. 0.007) even in post hoc analysis where patients defined as having postpartum haemorrhage (>1 L) were excluded. Red cell transfusion is an independent risk factor for postoperative morbidity and mortality,[22–24] so even small Hb decreases could be important if they drop the concentration below transfusion thresholds. Furthermore, the effect may be greater in emergency procedures where blood loss is often higher. Although the study was not powered for this outcome, it adds to the evidence that avoiding hypothermia attenuates blood loss.

The incidence of shivering was lower than expected at 13.8% compared to 35% seen previously in our and other institutions.[5,8,25,26] However, our study was underpowered to evaluate it. We note a trend towards an increased incidence in the WM group which we cannot explain. Previous studies have shown mixed effects of patient warming on shivering,[6,7,25,27] presumably because it is physiologically complex.[5] Although commonly attributed to core hypothermia, it is often seen after neuraxial anaesthesia with normal core body temperatures. This is due to non-thermogenic causes which are exacerbated by the reduced shivering threshold associated with neuraxial blockade.[5,28,29]

There was no difference in neonatal outcome as measured by Apgar scores. The impact of hypothermia on neonatal outcome is contentious.[6,7] A recent study, demonstrated improvements in umbilical pH and Apgar score at one but not at 5 min with reduced maternal temperature decrease.[9] The clinical significance is not clear. The authors postulate that delivery of relatively warmer blood to the placenta causes rightward shift of the oxygen–haemoglobin dissociation curve and greater oxygen delivery to the fetus.

Although forced air warming blankets were the only devices recommended in the NICE clinical guideline they have revised their technological advice to include the Inditherm mattress used in our trial.[10,17] It is difficult to position an upper-body FAWB effectively in such a way that it does not interfere with mother and baby skin-to-skin contact. Although patient comfort was not measured in this study, patients in both groups commented on the comfort of the WM and this would have been an interesting patient-centred measure.

Our study has several weaknesses. A single investigator completed the randomisation procedure and all measurements for each participant. It was single-blinded as blinding the investigator was logistically difficult. Care was taken to not inform the participant of their group assignment but it is likely that the warmed patients would have known their group, although the clinical impact of this would have been minimal. All but one participant was ASA class 1 or 2. However, higher ASA grades are associated with more adverse consequences from IPH so any benefits are likely to be greater in more complicated patients. Our protocol did not exclude women with fever; one participant, allocated to the control group, had a temperature of 38°C on admission and was included on an intention to treat basis. Non-singleton pregnancies were also included and were distributed equally between the two groups.

The mode of anaesthesia and drug doses were not standardised. All participants who had spinal anaesthesia received intrathecal diamorphine. The participant who received an epidural was randomly allocated to the control group and the participant who received a general anaesthetic was in the mattress-warmed group. Neither developed IPH or shivering, nor were there differences in other outcomes. By not limiting the inclusion criteria nor standardising anaesthetic technique, we believe the results of this study are more relevant to clinical practice.

The incidence of IPH in the control group (19%) was lower than expected (50% in previous audits), which means our study was underpowered to detect a difference in IPH due to the warming mattress. As this increased the risk of a false negative, this makes the positive result all the more noteworthy. Our ethical approval was based upon the original power and sample-size calculation and we were unable to extend the recruitment process.

We recruited women undergoing elective CS; however, we feel that a WM may have greater utility in women undergoing emergency obstetric operations. Although not evaluated, in our experience, emergency procedures have greater potential for heat loss as they are often longer, have greater blood loss and require

more intravenous fluid and blood transfusions. Future studies should look at the effects of an electric WM during emergency CS to confirm the possible beneficial effect on Hb. In such studies it will be important to measure intraoperative blood loss accurately and evaluate patient-centred outcomes, such as comfort.

In conclusion, although our study demonstrated that use of an electric under-body resistive WM reduced the incidence of IPH, compared with standard measures, the clinical significance remains uncertain. However, as an electrical WM is re-useable, easy to clean, unobtrusive, has low running costs, provides additional pressure care, can permanently reside on the operating table and so can easily be integrated into emergency care and is acceptable to patients, we suggest that obstetric units consider having them in their operating theatres.

Disclosures

Acknowledgements

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Annex 6: Sharma M-PD, M. Eljilani, F. Harper, C Mark. A Randomised Controlled Trial To Determine The Influence of Carbon-Polymer Warming Blankets On The Incidence Of Perioperative Hypothermia During And After Short, Day-Case Operations. Journal of One Day Surgery. 2014;24(4):92-9.

The Journal of
One-Day Surgery

A randomised controlled trial to determine the influence of carbon-polymer warming blankets on the incidence of perioperative hypothermia during and after short, day-case operations

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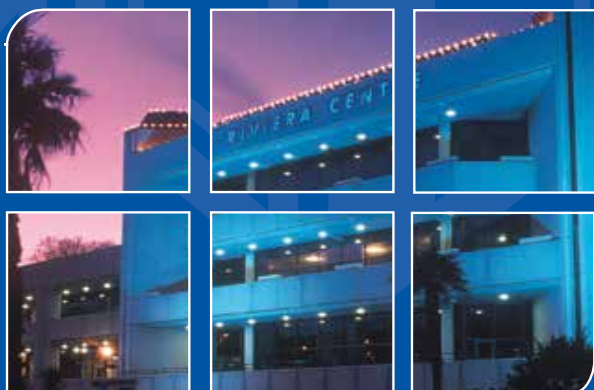
A randomised controlled trial to determine the influence of carbon-polymer warming blankets on the incidence of perioperative hypothermia during and after short, day-case operations

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Keywords: *Day Surgery, Hypothermia, Patient Warming, Perioperative.*

Summary

The purpose of our study was to determine whether a reusable warming blanket could reduce the incidence of inadvertent perioperative hypothermia in patients undergoing short surgical procedures. Patients were randomised to either standard care (no warming) or standard care plus warming with an electric carbon-polymer blanket on arrival in the operating theatre. Core temperatures were measured with an oesophageal thermistor. The primary outcome measure was the incidence of perioperative hypothermia (defined as a core temperature <36°C) at the end of surgery. Of the patients in the warming group, 24% (9/37) were hypothermic at the end of surgery compared to 39% (13/33) in the standard care group (p=0.20). Although the evidence from this study is not conclusive, these results suggest that warming patients with an electric blanket during short, surgical procedures may reduce the incidence of inadvertent perioperative hypothermia although further studies would be necessary to confirm this.

Introduction

It is critical for the health of the human body to maintain a core temperature of 36.5 – 37.5°C. This narrow range allows enzymes to function at their optimum temperature and so maintain normal physiological parameters. Hypothermia has been associated with increased perioperative blood loss and coagulopathy, altered drug metabolism and secondary delay in post-anaesthetic recovery, post-operative shivering and increased oxygen consumption. These alterations may lead to myocardial ischaemia, cardiac arrhythmias, delays in wound healing and an increased risk of surgical wound infection and a longer hospital stay.[1,2]

Guidance published by the National Institute for Health and Care Excellence (NICE) in 2008[3] recommended that all patients having surgery under general and/or regional anaesthesia that would last more than 30 minutes should be actively warmed using forced-air warming blankets on the basis that this is a cost-effective way of reducing complications.

The lower limit of 30 minutes was, however, extrapolated from studies of longer operations. There is very little data on the prevalence of and the intra-operative management of inadvertent perioperative hypothermia (IPH) and its consequences in day surgery procedures. An audit in our institution found that 60% of our patients were becoming clinically hypothermic during such procedures. Although the incidence of complications from day surgery is very low, feeling cold and shivering are unpleasant so it would be reasonable to do more to keep these patients warm simply on the grounds of comfort.

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The original NICE guideline recommended the use of forced-air warming (FAW) to prevent IPH as, when the guideline was being written, no other available methods had sufficient evidence for their effectiveness. However, the FAW blankets are single-use and therefore can be costly in both environmental and financial terms, particularly in the high-turnover environment of the Day Surgery Unit (DSU).

Advances in medical technology have led to the development of novel patient-warming devices such as electric carbon-polymer blankets and mattresses. Recent Technology Guidance from NICE recommended that electric carbon-polymer blankets (ECB) be considered either as an adjunct or alternative to FAW due to their cost-effectiveness.[4] However, these are not suitable for use in many DSUs as they are designed for operating tables and do not fit onto the operating trolleys that are frequently used in DSUs. The electric blankets, on the other hand, are lightweight and less cumbersome during transfer from the anaesthetic room to the operating theatre. Furthermore they do not interfere with cleaning and draping the operative site. so can be turned on as soon as the patient is anaesthetised, as opposed to the FAW devices which are turned on only once the patient is draped.

We therefore designed our study with a view to determining the effectiveness of a low- cost strategy for keeping patients warm during short procedures using a medical-standard electric warming blanket compared to standard care alone as defined by NICE (no active body warming). The primary outcome measure of this study was the proportion of patients who were hypothermic (core body temperature <36°C) at the end of surgery.

Methods

Ethical approval was sought and granted (10/H1107/5) and the trial was registered at clinicaltrial.gov (NCT01285206)

The study design was a randomised, controlled trial with the primary outcome measure being hypothermia (core body temperature <36ºC) at the end of surgery, defined as the application of the dressing. Recent audits in our institution had shown an incidence of IPH of 60% and it was this figure that was used in our sample size calculations. The study was powered to 80% (Type 2 error) and the p-value taken as 0.05 (Type 1 error), for a sample size of 70 patients.

Patients were given a Patient Information Sheet regarding the trial at the pre-assessment clinic, with the opportunity of reading the information and contacting the research team to ask questions greater than 24 hours prior to their procedure. On the day of the procedure the trial was explained in detail to the patients, any questions answered and written consent obtained. Patients were randomised using a computer generated sequence. Allocations were placed in sealed envelopes, by an external delegate, to avoid allocation bias.

All patients scheduled for day surgical procedures in the supine position were eligible for inclusion. The major exclusion criterion was inability to fully understand the trial or the language and give informed consent.

Patients randomised to the intervention arm received, in addition to standard care, an electric warming blanket (Hot Dog™ B103; Augustine Temperature Management, Eden Prairie, MN, USA). This was turned on straight after the patient was positioned on the operating table and removed immediately after application of surgical dressing to skin. Patients in the control arm were treated according to standard practice based on NICE guidance with passive insulation in the form of blankets and sheets. If 500 ml or more of intravenous fluids were administered, this was were warmed beforehand for all patients.

Core temperature was measured using a nasopharngeal probe (Temprecise; De Royal, Powell, TN, USA), immediately post-induction, on knife to skin (KTS) and every 15 minutes until the end of the procedure which was taken as application of the surgical dressing. We also recorded temperatures pre-induction and in recovery using an infrared temporal artery thermometer (TAT 5000; Exergen, Watertown, MA, USA).

Demographic data are presented as mean (SD) or median (IQR). Between-group differences were assessed using 2-tailed Fisher's Exact tests, 2-tailed Mann–Whitney U tests or Student's t-Tests as appropriate using IBM SPSS software v20 (SPSS IBM, New York, U.S.A)

See CONSORT Diagram, overleaf.

Results

Between January and September 2011, 70 participants were recruited into the study. All patients recruited met the inclusion criteria. No participants had to be excluded from the study. Patients were similarly matched demographically and in terms of intraoperative characteristics except that the warming group were, on average about 10 years older than the controls [Table 1].

For the primary outcome of core temperature at the end of surgery, 24% (9/37) of patients randomised to the warming blanket arm were hypothermic compared to 39% (13/33) of patients managed in accordance to routine measures (p = 0.20). There was no significant difference in temperatures at the end of surgery (36.2 C vs 36.2 C, p = 0.84) between the two groups.

Figure 1 shows the development of mean core temperatures over the course of the procedures and Figure 2 shows the incidence of IPH against time.

We also recorded the incidence of IPH (Table 2) and temperature (Table 3) using the non- invasive thermometer before and after the anaesthetic (where it was not possible to take oesophageal temperature measurements).

CONSORT diagram.

Assessed for eligibility (n = 83)

Excluded
– Did not meet inclusion criteria (n = 10)
– Refused to participate (n = 11)
– Other reasons (n = 2)

Randomised (n = 70)

Allocated to intervention group (n = 37)
– Received allocated intervention (n = 37)
– Did not receive allocated intervention (n = 0)

Allocated to standard care (n = 33)
– Received standard care (n = 33)
– Did not receive standard care (n = 0)

Lost to follow-up (n = 0)
Discontinued intervention (n = 0)

Lost to follow-up (n = 0)
Discontinued contact (n = 0)

Analysed (n = 37)
Excluded from analysis (n = 0)

Analysed (n = 33)
Excluded from analysis (n = 0)

Enrolment · **Allocation** · **Follow-up** · **Analysis**

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Table 1 Demographic data and intra-operative characteristics of patients included in the study. Values are number (portion), mean is ± SD and median (IQR [range]).

	Electric Warming Blanket (n = 37)	Routine (n = 33)
ASA 1	12 (33%)	15 (45%)
ASA 2	22 (59%)	15 (45%)
ASA 3	3 (8%)	3 (10%)
Male	14 (38%(	16 (48%)
Active fluid warming	26 (70%)	18 (54%)
Overnight admission	5 (14%)	2 (6%)
Body Mass Index: kgm^{-1}	26.6 ± 5.3	28.6 ± 6.6
Age: years	55.1 ± 16.8	44.1 ± 17.5
Induction to application of dressing: min	40 (0-71)	28 (13-90)
Dressing to discharge from recovery: min	45 (15-88)	35 (19-105)
Volume of fluid given: litres	1.0 (0.2-2.0)	1.0 (0.3-2.0)

*ASA: American Society of Anaesthesiologists Physical Status Classification System.

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Figure 1 Comparison of core temperatures between the two study groups throughout the study period
x- axis = time; y-axis = temperature (ºC)
Core Temperature versus Time: Electric Blanket (circle) and Standard Care (square).
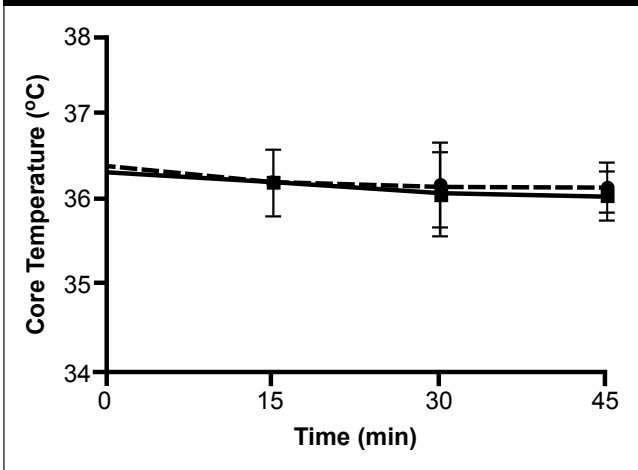
Figure 2 Comparison of incidence of inadvertent peri-operative hypothermia (IPH) (core temperature) between the two study groups throughout the study period.
x-axis = time; y-axis = IPH
Percentage (%) Patients with IPH versus Time: Electric Blanket (circle) and Standard Care (square).
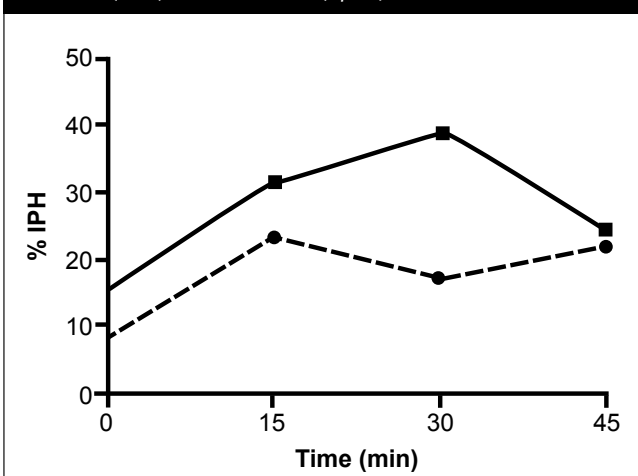
Shivering was only seen in two patients, both in the active warming group.

Discussion

Heat loss immediately post-induction of anaesthesia and for the first hour of surgery (i.e. our sample population and indeed most day surgery procedures) comes mainly from redistribution.[5] This constitutes the majority of our sample (DSU) population. It is therefore important that effective warming is initiated as soon as possible and preferably before induction

Although not reaching statistical significance, the results of the study suggest that using an electric carbon-polymer warming blanket (EWB) during short-duration surgery does reduce the proportion of patients developing IPH intra-operatively. Further research with larger scale trials is warranted.

The reasons for our findings not reaching significance may be due to the lower incidence of IPH in the control arm than was seen in the baseline audit (incidence of IPH 60%) which we used to power the trial. The incidence of IPH in our control arm was similar to previously published work. Hoyle and Andrzejowski found 40% of their day-case patients became hypothermic, a figure that rose to 52% when the surgery lasted an hour or more.[6]

Using the incidence of IPH from the control arm of our study (39%) we can calculate that for a power of 80% and a p-value of 0.05, a future study would require 150 patients in each arm. However, rather than repeating a larger study using the same methodology, as we already know that patients become hypothermic during short/ day surgery procedures it may be worth investigating interventions to reduce the rate of IPH further. It has been shown that 10–20 minutes of prewarming is sufficient to transfer significant amounts of heat.[7]

Our study has shown that the EWB does reduce the incidence of IPH in short/ day surgery procedures. It is flexible, reusable and easy to use and transport between the anaesthetic room and operating theatre. Therefore, we suggest that further studies which look at the benefits of prewarming patients for short/ day surgical procedures should employ this (EWB) technology.

Another limitation in our study was that we were only able to measure temperatures preoperatively and postoperatively, in PACU, with temporal artery thermometer, which are considered less accurate than the nasopharyngeal temperature probe. However, it is interesting to note that the mean temperatures in PACU were actually lower in the treatment group. This may be artefact due to the different measurement technique, but consideration should be given to the possibility that patients warmed for short operations may lose heat more rapidly in the immediate postoperative period. If this is the case then it might be beneficial to keep the electric (carbon polymer) blanket on the patient and connect it to a second controller in PACU. It may also be reasonable to assume that an additional period of prewarming, as outlined above, would render postoperative warming in recovery unnecessary.

The incidence of shivering (2.8%) was surprisingly low, especially considering that our previous audits showed it to be in the region of 17%. It is therefore not possible to draw any conclusions from this study about the effect of warming on this parameter.

Unfortunately some of the demographics between the two groups were dissimilar, for example age. However, evidence suggests that age is not an important risk factor for the incidence of hypothermia either intraoperatively or postoperatively so this should not affect the validity of our findings.[3] On reviewing our results we also noticed

Table 2 Prevalence of inadvertent peri-operative hypothermia: non-invasive temperature measurements. Values are number (portion).

	Electric Warming Blanket (n=37)	Routine Practice (n=33)	P-value
Admission to day surgery unit*	3 (8.1%)	1 (3.0%)	0.616
Pre-induction	2 (5.4%)	1 (3.0%)	1.000
Admission to recovery	9 (24.3%)	5 (15.2%)	0.384
Recovery at time: 15mins	8 (22.2%)	14 (12.1%)	0.348
Recovery at time: 30mins	5 (22.7%)	1 (5.9%)	0.206
Recovery at time: 45mins	3 (42.9%)	0 (0.0%)	0.236
Discharge from recovery	6 (24.0%)	0 (0.0%)	0.028
Anytime	10 (27%)	5 (15.2%)	0.258

*IPH; Inadvertent Perioperative Hypothermia (Temperature <36.0°C)

Table 3 Details of observed cases: non-invasive temperatures at set intervals during the study period. Presented as mean ± SD. Temperatures in °C.

	Electric Warming Blanket (n = 37)	Routine (n = 33)	P-value
Pre-operative	36.5 ±0.5	36.7 ±0.4	0.044
Pre-induction	36.5 ±0.5	36.6 ± 0.4	0.680
Arrival to recovery	36.4 ± 0.4	36.4 ± 0.4	0.812
Recovery: 15 mins	36.3 ± 0.4	36.4 ± 0.5	0.795
Recovery: 30 mins	36.2 ± 0.4	36.5 ± 0.5	0.046
Recovery: 45 mins	36.1 ± 0.4	36.6 ± 0.5	0.098
Recovery: discharge	36.4 ± 0.5	36.6 ± 0.4	0.093

that the mean average duration of surgery between the two groups was different, 40 minutes in the intervention group and 28 minutes in the routine care group. This may have effected the statistical significance of our results.

We did not specifically study patient comfort. Even when the warming method employed does not transfer significant amounts of heat, such as blankets from a warming cabinet, patients report that it makes them feel better. Certainly our own anecdotal experience from using the EWB for prewarming of patients undergoing major surgery confirms this.

In conclusion, this study suggests that intraoperative warming with an electric, carbon- polymer blanket may reduce the incidence of perioperative IPH and a larger study

would be justified. Beyond the initial purchase cost, these systems are inexpensive to run and maintain so should be considered by day surgery units as an alternative to either no warming or FAW. Further, larger studies are needed to validate our findings, to also investigate the effects of prewarming and postoperative warming in PACU and should also focus on patient comfort as an outcome.

With increasing numbers of high-risk patients and more complex procedures being undertaken in an outpatient setting [9] it is important that units develop warming protocols. Electric, carbon-polymer blankets should be considered in this context at they provide a potentially cost and clinically effective means of warming patients and reducing the incidence of IPH.

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Apology

The Editor wishes to apologise to Dr Valori, who was one of the distinguished speakers at the BADS 25th ASM in Scarborough. Dr Valori's first name is Roland, not Raymond, as recorded in JODS 24.3.

Annex 7: Dasari KB, Albrecht M, Harper M. Effect of forced-air warming on the performance of operating theatre laminar flow ventilation*. Anaesthesia. 2012;67(3):244-9.

Original Article

Effect of forced-air warming on the performance of operating theatre laminar flow ventilation*

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Summary

Forced-air warming exhaust may disrupt operating theatre airflows via formation of convection currents, which depends upon differences in exhaust and operating room air temperatures. We investigated whether the floor-to-ceiling temperatures around a draped manikin in a laminar-flow theatre differed when using three types of warming devices: a forced-air warming blanket (Bair Hugger™); an over-body conductive blanket (Hot Dog™); and an under-body resistive mattress (Inditherm™). With forced-air warming, mean (SD) temperatures were significantly elevated over the surgical site vs those measured with the conductive blanket (+2.73 (0.7) °C; p < 0.001) or resistive mattress (+3.63 (0.7) °C; p < 0.001). Air temperature differences were insignificant between devices at floor (p = 0.339), knee (p = 0.799) and head height levels (p = 0.573). We conclude that forced-air warming generates convection current activity in the vicinity of the surgical site. The clinical concern is that these currents may disrupt ventilation airflows intended to clear airborne contaminants from the surgical site.

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Patient warming systems are widely used to prevent unintentional peri-operative hypothermia based on the established benefits of reduced blood loss and transfusion [1], improved wound healing [2], reduced duration of hospital stay [3], improved survival [4] and reduced surgical site infection rates [5]. However, patient warming systems also release excess heat into the operating theatre that may generate convection currents even within a laminar flow system. It is possible that convection currents could disrupt the intended ceiling-to-floor theatre airflows and therefore impede the ventilation system's ability to clear contaminants from the surgical site.

There are two distinct categories of patient warming technology, forced-air and conductive heating. Forced-air devices deliver a heated airflow to a disposable coverlet that vents the hot air over the patient's body [6]. Conductive heating devices employ an electrically heated pad in contact with the patient's body [7]. Both types of devices appear to be comparably effective for the prevention of accidental peri-operative hypothermia [8–14], although forced-air devices are less efficient in transferring the applied heat to the patient than conductive devices [15]. Therefore, we might expect forced-air devices to generate a greater excess heat load on the ventilation system.

When considered in combination with other established sources of ventilation disruption such as surgical lights and personnel [16], even moderate changes in the excess heat load are of clinical importance. For example, convection currents due to forced-air warming occur in the vicinity of the surgical site. They are formed in the downstream 'wake' created by overhead lights and regions of blocked ventilation flow created by drapes and/or personnel. Convection currents were not observed when conductive patient warming devices were used [17]. McGovern et al. postulated that the observed disruption was due to excess heat as the result of patient warming excess heat, yet they made no measurements of ventilation field temperature nor did they establish the 'thermal' basis of such disruption.

Conceptually, the thermal basis of laminar flow disruption is the opposition of downward ventilation air currents by buoyancy-driven hot air convection currents. We assessed ventilation performance by measuring changes in ventilation field temperatures using a forced-air blanket (Bair Hugger™ 525; Arizant Healthcare Inc., Eden Prairie, MN, USA), with an over-body conductive blanket (Hot Dog™ B103; Augustine Temperature Management, Eden Prairie, MN, USA) and an under-body resistive mattress (Inditherm™ OTM1, Rotherham, UK) as controls. Our (null) hypothesis was that the use of forced-air warming would result in ventilation field temperatures similar to the conductive patient warming devices.

Methods

Experiments were conducted in a partial-walled ultra-clean operating theatre (ExFlow 90, Howorth, UK; Validation certification QA ref AA719/1/SM) used for orthopaedic surgery (Royal Sussex County Hospital, UK). A manikin was placed in the supine position and a general surgical drape applied with the head end tented to form an anaesthesia screen (Fig. 1). The foot end of the drape was raised and folded over to create an air channel that directed the forced-air warming exhaust out of the ventilation field. A lower-body patient warming device (either the Bair Hugger, Hot Dog or Inditherm) was introduced under the drape (Fig. 2).

Ventilation field temperatures (Fig. 1) were measured floor-to-ceiling using 24 thermistors (KIMO KH200 Temperature and Humidity Loggers; Kimo,
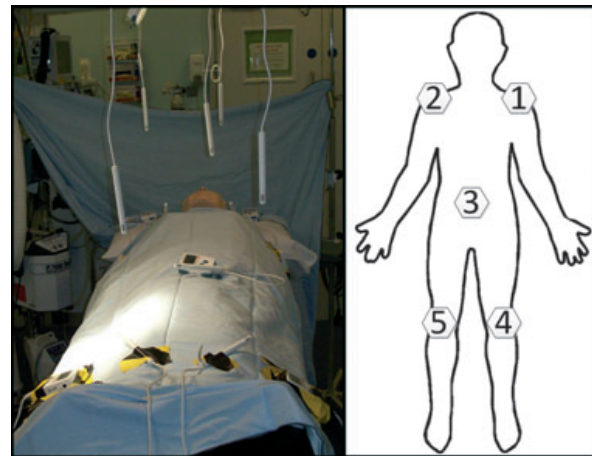
Figure 1 Manikin with raised foot drape and thermistors placed at 5 heights (floor, table, patient, head, overhead supply plenum) across five locations shown as (1) left shoulder; (2) right shoulder; (3) surgical site (abdomen); (4) left knee; and (5) right knee.

Montopon, France) placed across five heights:- floor ($\sim$5 cm above the floor); table (on the drape, $\sim$60 cm from the floor); patient (2 cm above the dummy, $\sim$80 cm from the floor); head (25 cm above the dummy, $\sim$105 cm from the floor); ceiling (high level in the laminar flow, $\sim$210 cm from the floor); and five locations (left shoulder, right shoulder, surgical site (abdomen), left knee, right knee); 24 locations resulted instead of 25 as it was not possible to measure the surgical site location at table height.

With each of the three patient warming devices, ventilation field temperatures were recorded at 60-s intervals for: (1) a 20-min 'control' period with the patient warming device turned off; (2) a 'transition' period of $\sim$10 min when the patient warming device was turned on but had not thermally equilibrated with the ventilation environment; and (3) a 20-min 'steady-state' period when the patient warming device had thermally equilibrated and ventilation field temperatures had stabilised.

Air temperature differences from the overhead supply were computed by subtracting the time series of ventilation field temperatures at each location and height from the corresponding time series obtained at ceiling height for that location. Increases in air temperature were assessed as the average of this differenced time series for each location, height, time period
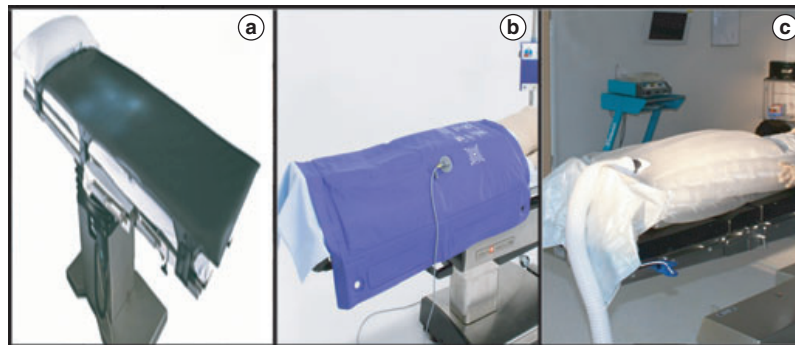
Figure 2 Patient warming devices evaluated: (a) under-body resistive mattress (Inditherm); (b) over-body conductive fabric blanket (Hot Dog); and (c) forced-air blanket (Bair Hugger).

(i.e. control, transition, steady state) and patient warming device.

Two separate classes of ANOVA models were fitted to the data. The first class assessed whether increases in air temperature were significantly different between patient warming devices when compared across control and steady-state periods for a given height. Formally, this difference between patient warming devices was assessed via the interaction term of an ANOVA model having 'increase in air temperature' as the response and 'blocking effects of period' (two levels: control and steady state) and 'environment' (three levels: forced-air warming run, conductive fabric run, and resistive mattress run) as the factors. Inclusion of a separate 'warming device' main effect in the model was not possible because it is perfectly correlated with the 'environment blocking term'. In other words, the main effect of warming device cannot be distinguished from, say, a 2 °C increase in overall environmental theatre temperature due to the time of day. Furthermore, we were interested in temperature increases by warming device for the steady-state period vs control period (which is the effect measured by the interaction term). The p value of interest is therefore the significance of the model interaction term when compared with an additive model using a log-likelihood ratio test.

A second class of ANOVA model was fitted to the temperature data for heights having a significant interaction term as described in the first model class. The purpose of this second model was to assess increase in air temperature vs control by location for a given height. Formally, an ANOVA model with interactions was fitted

to the data for each significant height having increase in air temperature as the response and the following predictors: (1) 'environment blocking term' (three levels: forced-air run, conductive fabric run, and resistive mattress run); (2) 'location' (three levels: shoulder, surgical site which was always the abdomen, and knee); and (3) 'period' (two levels: control and steady state). It was necessary to pool the right and left measurements at the knee and shoulder locations to form replicates for inference. Means and standard errors are the maximum likelihood parameter estimates and p values were computed by applying t-tests to model parameter contrasts.

Results

Figure 3 shows an example of the temperature recordings obtained over the course of an experiment, with control, transition and steady-state periods highlighted.

The measured increase in air temperature vs control for each device by location and height (Fig. 4) showed forced-air warming to result in the greatest temperature increase at the patient height locations; for locations at the other heights (floor, table, head), there appeared to be no significant differences in air temperature between warming devices. This was confirmed by ANOVA; increases in steady-state air temperature vs control were significantly different between warming devices at the patient height ($p = 0.012$), but not at the other heights of floor ($p = 0.339$), table ($p = 0.799$) and head ($p = 0.573$).

A second class of ANOVA models was fitted to the patient height data to determine the specific effects of
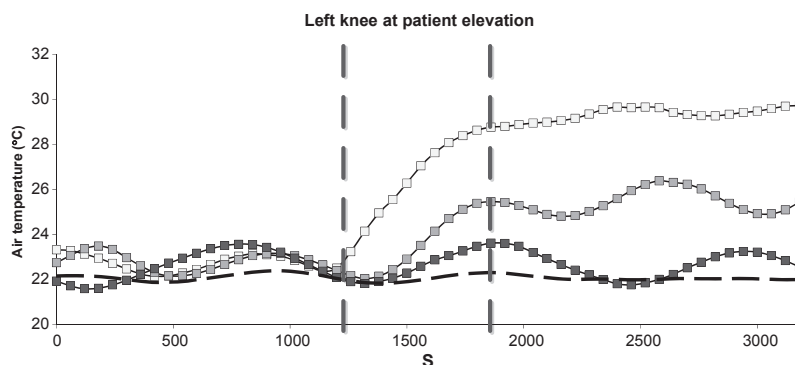
Figure 3 Absolute air temperature measurements for a single location (1 of 24) showing control period with patient warming device off (time = 0 to ~1200 s); transition period after turning device on (time = ~1200 s to ~1700 s) and steady state (from time = ~1700 s). Note the slightly varying temperature from the overhead supply. Temperature differences from the overhead supply were computed for the steady-state data and analysed for device comparisons. (■) resistive mattress, (▣) conductive blanket, (▢) forced-air, (━) average overhead supply.
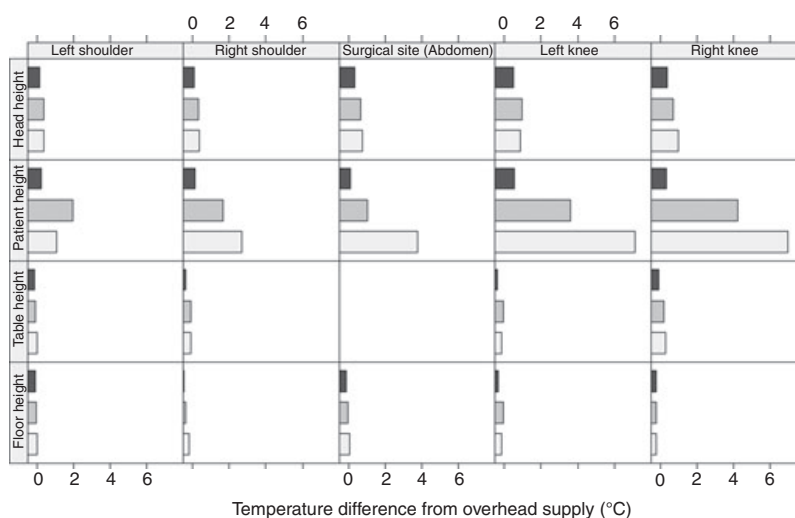
Figure 4 Steady-state increase in air temperature from the overhead supply for each patient warming device by location and elevation. (■) resistive mattress, (▣) conductive blanket, (▢) forced-air

each patient warming device by location; these models were not applied to the floor, table, and head height data as there were no significant temperature differences vs control. There were significant differences in mean (SD) patient height air temperature vs control between warming devices at the locations of: knee, with forced-air 3.2 (0.5) °C (p < 0.001) higher than conductive fabric and 6.6 (0.5) °C (p < 0.001) higher than the resistive mattress; surgical site, with forced-air 2.7 (0.7) °C (p < 0.001) higher than conductive fabric

and 3.6 (0.7) °C (p < 0.001) higher than the resistive mattress; and shoulder, with forced-air 1.7 (0.5) °C (p = 0.01) higher than resistive mattress. Differences were not significant between forced-air and conductive fabric at the shoulder location. Furthermore, conductive fabric air temperatures were significantly higher than the resistive mattress by 1.6 (0.5) °C (p = 0.001) and 3.5 (0.5) °C (p < 0.001) for the locations of shoulder and knee, respectively; these differences were not significant at the surgical site.
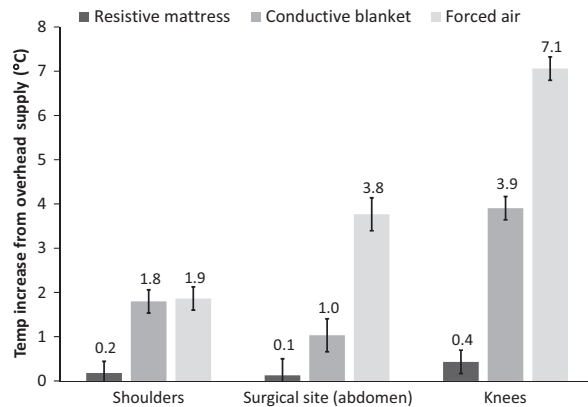
Figure 5 Average temperature increase from overhead supply at patient height by location. Right and left measurements for the shoulder and knee were pooled to allow for an estimate of dispersion. Error bars are SD.

Discussion

Our result rejects the null hypothesis, as we found forced-air warming to generate increased ventilation field temperatures vs both conductive warming devices. This finding suggests that forced-air warming technologies release significantly higher levels of excess heat than conductive warming technologies. Furthermore, forced-air warming temperature elevations were found to be the greatest above and around the surgical site. This finding is of concern because temperature elevations are the direct result of hot air-pockets moving upwards and against the downward laminar airflow currents. We can surmise this because air has a high transmissivity (i.e. low infrared absorption) [18]; thus, any temperature elevations are the result of convection current activity.

McGovern et al. used neutrally buoyant detergent bubbles released into theatre and found that forced-air warming appears to have a profound impact on laminar ventilation air-flows: there was large-scale dispersion of bubbles from the floor to the ceiling [17]. Our findings differ, in that we observed convection current activity directly above the patient and minimal activity elsewhere with forced-air warming. These differences could be due to the arrangement of the drapes; in our study, we raised the foot end of the drape to channel the forced-air warming exhaust outside the ventilation environment, whereas this channel was not present in the study of McGovern et al. in which the foot end of the drape extended to the floor. Therefore, the mass-flow of forced-air exhaust appears to play a critical role in the degree of ventilation disruption. Further studies are warranted to investigate whether specialised draping arrangements can lessen the risks of convection current formation. Both studies, however, confirmed that conductive warming technologies have little or no impact on ventilation airflows.

Although we attempted to mimic real conditions to a certain extent by having two people walk around within the laminar flow area, in a working operating theatre there are more people and many other ways by which the system might be disrupted [16, 17]. Another limitation of our study is that the definitive effects of this excess heat on clinical outcomes are presently unknown. Any future study might focus on particular types of surgery (e.g. that for device or joint implantation) where even small increases in airborne contamination are likely to be of more relevance [19]. Our findings may in part explain some aspects of the results of national studies over past 10 years, in which laminar flow ventilation has demonstrated either similar [20] or even higher [21, 22] infection rates than its conventional counterpart.

Balanced against these considerations, the prevention of hypothermia reduces the incidence of adverse events. Forced-air warming has been used on millions of patients and has been shown to be effective for managing unintended peri-operative hypothermia. The choice of warming device depends on a number of factors including the evidence base for the technology, cost, noise and even complaints from surgeons that they themselves become too warm [23]. Disruption of laminar flow should be one further objective factor guiding the proper choice.

Competing interests

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Annex 8: John M, Ford J, Harper M. Perioperative warming devices: performance and clinical application. Anaesthesia. 2014;69(6):623-38.

Review Article

Peri-operative warming devices: performance and clinical application

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Summary

Since the adverse consequences of accidental peri-operative hypothermia have been recognised, there has been a rapid expansion in the development of new warming equipment designed to prevent it. This is a review of peri-operative warming devices and a critique of the evidence assessing their performance. Forced-air warming is a common and extensively tested warming modality that outperforms passive insulation and water mattresses, and is at least as effective as resistive heating. More recently developed devices include circulating water garments, which have shown promising results due to their ability to cover large surface areas, and negative pressure devices aimed at improving subcutaneous perfusion for warming. We also discuss the challenge of fluid warming, looking particularly at how devices' performance varies according to flow rate. Our ultimate aim is to provide a guide through the bewildering array of devices on the market so that clinicians can make informed and accurate choices for their particular hospital environment.

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Introduction

Accidental peri-operative hypothermia, defined as a core body temperature < 36 °C [1], is both common and preventable. Patients undergoing general anaesthesia are at increased risk of hypothermia due to inhibition of thermoregulatory control, increased heat loss to the environment and absent behavioural responses [2]. Adverse outcomes associated with peri-operative hypothermia are well documented and include cardiac morbid events [3], greater intra-operative blood loss [4], thermal discomfort [5], increased postoperative wound infection rates [6] and prolonged recovery ward and hospital stay [6, 7].

To address these potentially avoidable complications, the National Institute for Health and Care Excellence (NICE) published a clinical guideline in 2008 addressing the prevention and management of accidental peri-operative hypothermia [1]. Forced-air and intravenous fluid warmers were the only devices recommended. It was acknowledged that other warming devices might be as effective, but there was insufficient evidence at the time to warrant their recommendation.

Methods

A literature search was performed using the PubMed database for articles published from 1980 up to and including 2012. The following title and abstract keywords were used: warm; warming; warmer; warmed AND intra-operative; peri-operative; surgery; blanket; mattress; forced air; devices; electric; system; fluid;

water; hypothermia; normothermia. We selected relevant randomised controlled trials, clinical studies and when necessary, additional literature to aid discussion.

Intravenous fluid warming devices

It has been calculated that the administration of 1 l intravenous fluid at room temperature (21 °C) decreases core body temperature by 0.25 °C [2]. To maintain normothermia, fluid warmers are designed to deliver fluid around body temperature (37 °C), and their use has been recommended for all intra-operative infusions $\geq$ 500 ml in adults [1]. Administration of warmed intravenous fluids in conjunction with standard heat conservation measures has been shown to reduce the incidence of accidental peri-operative hypothermia significantly in gynaecological [8] and abdominal [9] surgery, as well as associated complications during orthopaedic lists [10]. In obstetric practice, the use of intra-operative warmed fluid is also associated with significantly higher Apgar scores in the newborn infant following caesarean section [11].

There are several fluid warming devices available on the UK market [12] and their heating methods include passing intravenous tubing through heating blocks (dry warming system), counter-current heat exchange, water bath, convective air systems and insulators.

The ability of these devices to deliver heated fluid is dependent on the warming method, the flow rate and the length of tubing between warmer and patient.

Flow rate limitations on heating capacity

Anaesthetists deliver fluid over a wide range of flow rates, varying from millilitres per hour in certain paediatric cases to litres per minute during adult resuscitation. A major problem in delivering warmed fluid at low flow rates is the considerable heat loss that occurs between the warmer and the patient [13]. Difficulties in delivering warm fluid at faster flow rates include a limited time and surface area for heat exchange and a high resistance to flow through the warming apparatus [14].

Low flow rates

Of the simulated clinical studies evaluating fluid warmer performance (at or including lower flow rates of <0.5 l.h^{-1}), the Hotline® counter-current water heat exchanger (Level 1 Technologies Inc, Rockland, MA, USA) consistently delivers the warmest fluid outlet temperatures when compared directly against dry warming devices [15–18]. The Hotline heat exchanger is incorporated into the delivery tubing by circulating warmed water around a central delivery channel [19]. This system prevents the loss of heat from fluid to environment seen at low flow rates with conventional delivery tubing.

To circumvent this problem using dry warming apparatus, attempts at insulating the distal delivery tubing have been made, with limited success [17]. The dry wall warmers Flotem (DataChem, Indianapolis, IN, USA) and DW1000A (Baxter Healthcare, Valencia, CA, USA) provide modest distal fluid temperatures of > 32 °C at minimum flow rates of 300 and 730 ml.h^{-1}, respectively. It is also worth noting that the Warmflo® fluid warmer (dry cassette heat exchanger) (Nellcor Tyco Healthcare, Gosport, UK), although not assessed directly against counter-current warming, has been shown to deliver fluid at comparable temperatures at low flow rates [20].

Another way to minimise heat loss across the tubing between warmer and patient at low flow rates is to incorporate small warming units near the patient. The efficacy of two of these warmers, the Buddy lite™ (Belmont Instruments, Boston, MA, USA) and enFlow™ (GE Healthcare, Munich, Germany), has been assessed recently. Both devices adequately warmed fluid at the tested flow rates (25–100 ml.min^{-1}), although the Buddy lite outperformed the enFlow between 25 and 75 ml.min^{-1}, whilst the enFlow was more effective at rates > 75 ml.min^{-1} [21].

Importantly, distal fluid temperatures only rarely achieved the recommended 37 °C at low flow rates of < 0.5 l.h^{-1}, and were only reported when the fluid passed through counter-current water heat exchange apparatus [16] or the Warmflo device [20].

High flow rates

At faster flow rates above 9 l.h^{-1}, the Level 1® infusor (Level 1 Technologies Inc, Rockland, MA, USA) was found to achieve higher distal temperatures in laboratory studies when evaluated against heating blocks, air convective fluid warming, heating elements, steel foil heat exchangers and water bath warmers [14, 18,

22–25]. The Level 1 system incorporates a counter-current water heat exchanger via a large-bore thermally conductive aluminium tube interface, which is designed to maximise heat transfer without compromising flow [24]. However, the recommended delivery fluid temperature of 37 °C was still only rarely achieved at these flow rates [18]. Other types of counter-current water warming system, such as the Hotline, are not as effective at these higher flow rates and have been shown to underperform compared with the Ranger® dry heat warmer (Arizant, Wakefield, UK) [26].

In studies assessing the warming ability of apparatus other than the Level 1 infusor at flow rates > 9 l.h^{-1}, the Fenwal® (Travenol Ltd, Compton, Berkshire, UK) dry warming system and Fluido® (Datex-Ohmeda, Hatfield, UK) infrared warming system were superior [23, 27]. The Fenwal warmer uses a thin polythene bag between two heating plates to warm fluid, and achieved delivery temperatures of > 32 °C at a flow rate of 9 l.h^{-1} [26]. The Fluido warmer was only assessed in one laboratory study, but of interest, it is the only device that maintains a delivery temperature (35 °C) close to that of the core body over a wide range of flow rates (8.4–26.7 l.h^{-1}). This was attributed to heat delivery via infrared lamps that varies according to changes in flow [23].

Testing the warming capabilities of devices at rapid flow rates to mimic resuscitation scenarios places certain devices outside the manufacturers' recommended flow rate range. The Bair Hugger® fluid warmer (Augustine Medical, Eden Prairie, MN, USA) and Hotline device are both recommended for use at low to moderate flow rates (1 and 5 l.h^{-1}), which may account for their reduced performances at higher rates [23, 26].

To date, there have been no comprehensive studies comparing the performance of different intravenous warming devices, and meta-analysis is unlikely to produce meaningful results due to the heterogeneity of the studies in this area. Variations in starting fluid temperature, composition, flow rate and ambient temperature make comparisons between studies challenging. In all but one [14] of the laboratory studies where the capacity of the device to warm red cells was investigated [17, 18, 25, 26], the red cells tested were in fact diluted with crystalloid, making the inferences less clinically relevant.

Warming cabinets

An alternative method to providing warmed intravenous fluid is by the use of warming cabinets. By pre-warming and administering fluid through conventional giving sets, this method has been suggested as a cheaper and simpler option than using in-line fluid warming devices. Encouragingly, pre-warmed fluid administration has been shown in a laboratory study to achieve distal temperatures comparable to the Astotherm® (Futuremed, Granada Hills, CA, USA) and, if the pre-warmed bag is also insulated, the Ranger fluid warmer [28].

In the few clinical studies comparing these two methods, the use of pre-warmed fluid was found to be as effective as the Astotherm [29] and the Hotline fluid warmer [30] in preventing peri-operative hypothermia during short surgical procedures and elective caesarean section, respectively. When compared with administering fluids at room temperature, the use of pre-warmed fluid was also associated with significantly improved peri-operative patient core temperatures [29–31].

The main setback with the use of pre-warmed fluids is the potential cooling effect that lower flow rates through long thin tubing [13] has on the delivery fluid temperature. Their suitability in paediatric cases has therefore been questioned [31].

Safety concerns

A number of safety concerns have been raised with the use of fluid warmers, particularly with regard to the risk of air embolus, delivery fluid contamination and potential thermal damage to transfused blood cells.

Air embolus has been a particular concern when using devices designed to deliver warmed fluid rapidly and there has been a reported fatality from the use of the Level 1 infusor [32]. Laboratory studies comparing the air eliminating capabilities of fluid warmers during pressurised infusions have identified the Ranger apparatus as superior to the Level 1 infusor when 50–400 ml of air has been introduced [33, 34]. The superior capacity of the Ranger in comparison with the Level 1 infusor has been attributed to the threefold larger surface area of its gas permeable membrane within the air purging element [33]. Both these devices were, however, much more efficient at eliminating air when compared with the Warmflo and Gymar® (B+P Beatmungsprodukte GmbH, Neunkirchen-Seelscheid,

Germany) apparatus, which only removed 3% and 1%, respectively, when 200 ml air was introduced [33].

Devices utilising counter-current warming systems where warmed non-sterile water flows around an inner sterile infusion lumen can potentially introduce infections and cause dilutional electrolyte disturbances if a leak within the coaxial tubing occurs. Such faults, although rare, have been reported with the Hotline device [35] and the Level 1 fluid warmer [36], although neither of the patients concerned suffered any significant ill effects.

A potential problem with heating blood before administration to the patient is the risk of red cell thermal damage and haemolysis, resulting in a reduced transfusate oxygen carrying capacity and electrolyte disturbances. One study using immersion-warming techniques found biochemical markers of haemolysis when blood was warmed at 45 °C [37]. A later study utilising microwave blood warming concluded that the safe upper limit to heat blood was 49 °C [38]. The British Committee for Standards in Haematology have recommended a maximum operating temperature of 43 °C for blood warmers, and have not advocated the use of water baths or microwave technology [39].

Body warming devices

As a means of preventing accidental peri-operative hypothermia, a growing number of body warming devices have been developed (Table 1) utilising either convective warming or direct-contact thermal conduction. Forced-air convective warming systems are commonly used in the UK and have been recommended by NICE in targeted peri-operative patients [1].

Forced-air warmers

Forced-air warmers operate by distributing heated air generated by a power unit through a specially designed downstream blanket resulting in heat transfer to the covered body surface [40]. This is the most commonly tested body warming modality and is unsurprisingly associated with significantly higher postoperative core temperatures when compared with patient control groups where no warming was used [41–43]. The dual benefit of transferring heat to the body and reducing heat losses [44] from the skin under the air warmer accounts for this finding.

Table 1 Classification of warming devices.

Intravenous fluid warmers	Insulated intravenous tubing
	Convective warming system
	Heated cylinder warming system
	Heated block warming system
	Heated element warming system
	Steel foil exchanger
	Water bath warming system
	Counter-current heated water system
Body warming devices	Forced-air warmer
	Water filled mattress
	Circulating water garments
	Electric warming blankets
	Radiant warmer
	Carbon fibre
	Resistive polymer blanket
	Electric heating pad
	Plastic garment
	Thermal exchange chamber
	Circulating sleeve

Forced-air warmers have also been evaluated against certain types of passive insulation including the use of cotton blankets, reflective blankets and sleeping bags [45–50]. These studies have shown superiority of forced-air warming both to prevent postoperative hypothermia and to rewarm already hypothermic individuals (Table 2).

The rewarming rate of hypothermic individuals did not differ significantly in favour of forced warming in only one crossover study comparing forced-air warming with a passive system (polyester filled blanket) [51]. However, the sample size was low and consisted of healthy non-anaesthetised volunteers. The authors concluded that endogenous heat production was the major contributor to rewarming; however, as it is widely accepted that basal metabolic rate and heat generation fall during anaesthesia [52], results from awake volunteer studies should not be extrapolated to patients undergoing anaesthesia.

The necessity of using active warming as opposed to passive insulation (pre-operative and intra-operative) in moderate duration non-body-cavity surgery has been questioned by certain observers [46] on the basis that passively insulated patients have shown no significant differences in postoperative oxygen consumption, shivering, thermal comfort and pain when compared with the warmer forced-air warmed patients.

Table 2 Randomised trials comparing forced-air warming with passive- and no warming.

References	n	Groups	Temperature measured	Main findings
Borms et al. [48]	20	FAW = 10 INS = 10	Intra-operative	FAW superior to INS (p < 0.01)
Zhao et al. [50]	40	FAW = 20 CB = 20	Postoperative	FAW superior to CB (p < 0.01)
Wongprasartsuk et al. [46]	26	FAW = 14 CB = 12	Recovery room	Significant difference favouring FAW only for immediate RR temperature (p = 0.017)
Lennon et al. [45]	30	FAW = 15 CB = 15	Postoperative (rewarming)	FAW superior to CB (p < 0.05)
Patel et al. [47]	37	FAW = 19 TB = 18	Intra- and postoperative	Significantly higher intra-operative and postoperative temperatures in FAW group (p < 0.05)
Bennett et al. [42]	45	None = 15 INS = 15 FAW = 15	Intra-operative	Intra-operative temperature drop significantly less in FAW group (p = 0.0001)
Camus et al. [41]*	33	None = 11 FAW = 11 FAWi = 11	End of surgery	Significantly higher end of surgery temperatures in FAW and FAWi groups (p < 0.01)

FAW, forced-air warming; INS, thermo-lite reflective insulation; CB, cotton blanket; TB, thermodrape reflective blanket, FAWi, insulated forced-air warming.
*Second trial of study.

Nonetheless, current guidance advocates the use of active forced-air warming as opposed to passive insulation methods for operations with an anticipated operating time of ≥ 30 min [1].

It is important to note that many studies that show a benefit in the use of forced-air warming devices to reduce the risk of peri-operative hypothermia also use warmed intravenous fluids [46, 48, 50, 53–58]. Warmed fluids do not actively warm patients, but infusions below body temperature can be regarded as a form of active cooling. It is therefore unsurprising that the studies where convective and fluid warming were combined show less accidental peri-operative hypothermia than convective warming alone [59].

Types of forced-air warming systems
There are numerous forced-air convection warmer systems available to prevent peri-operative hypothermia, although few studies have directly compared these different types against one another. An early study showed that the total heat transfer from the Bair Hugger system (power unit and blanket) was significantly greater than the Warmtouch® (Mallinckrodt Medical Inc, St. Louis, MO, USA), Thermacare® (Gaymar Industries, Orchard

Park, NY, USA) and WarmAir® (Cincinnati Sub-Zero Products, Cincinnati, OH, USA) systems when used to warm non-anaesthetised healthy volunteers with full body blankets [60]. However, these results were not reproduced in a more recent randomised crossover trial involving awake upper body warming, which showed the WarmTouch superior to the Bair Hugger with regard to heat flux capacity [61]. The suggested explanations for this disparity included that an older device series was studied in the original trial, and that upper and full body blankets might have performed differently.

When assessed using sophisticated temperature sensing manikins, the WarmTouch forced-air warming system was associated with the highest heat transfer when upper body blankets were used [62] and the Bair Hugger during full body warming [63]. Interestingly, no significant difference between forced-air warming devices was found when lower body blankets were used [64].

It is important to note, however, that forced-air warmers prevent hypothermia not only through heat transfer but also by stopping convective and radiant heat loss from exposed skin. When this is taken into account, the clinical relevance of significant differences in heat transfer between forced-air warming devices is

small [61]. In the only clinical trial to our knowledge comparing different forced-air warming systems, both the Bair Hugger and WarmAir systems were equally as effective in ensuring normothermia postoperatively [65], despite previous studies showing significant differences in heat transfer capacity [60].

It has also been argued that the efficacy of forced-air warming systems is primarily determined by the associated blanket properties as opposed to the power unit [66]. In contrast to the nozzle temperature and airflow generated by the power unit, the blanket's ability to optimise the patient-blanket temperature gradient, and its capacity to distribute heat evenly correlates well with the heat transfer ability of the forced-air system according to manikin studies.

The surface area covered by the warming blanket also has a significant influence on forced-air warming performance as greater coverage both reduces exposure and offers a larger interface for heat transfer. This is particularly important for forced-air warming because air has a very low specific heat capacity. Increased coverage can explain the superior heat transfer ability of lower body blankets in comparison with smaller upper body blankets [64], and why surgical access blankets have significantly improved intra-operative temperature profiles when compared with upper body blankets [67].

The effect of blanket design on forced-air warming performance has also been studied. During simulated operating conditions, the use of hospital bed sheets in conjunction with forced-air units heat thermal bodies twice as effectively as commercial blankets [68]. Clinical studies involving neonates during major non-cardiac surgery have also shown that re-usable blankets made of water resistant canvas were equally efficacious in preventing intra-operative hypothermia compared with a standard Bair Hugger blanket model [69]. Furthermore, parity between bed sheets and commercial blankets in terms of postoperative core temperatures and thermal comfort has also been shown in adult patients undergoing major surgery [70], although the authors warned that this experimental technique should be avoided until further safety evaluation has been undertaken.

Forced-air warming device safety
It has been shown that forced-air warming systems can create significant temperature gradients within the oper-

ating room that have the potential to disrupt laminar airflow patterns [71] and contaminate the surgical site with floor-level air mobilised by convection currents [72]. However, contesting the notion that these devices disrupt operating room ultra-clean airflow patterns, a recent study using smoke as a visual tracer demonstrated effective laminar airflow in the presence of a working forced-air warming system [73]. Furthermore, two trials involving colorectal and clean-site surgery have also shown that the use of forced-air warming significantly reduces surgical site infection risk [6, 74], although neither study stipulated whether or not laminar flow theatres were used. An interesting study sampling air in the operative field of laminar flow theatres showed small increases in colony-forming units when forced-air warmers were turned on, although the authors deemed these unlikely to have clinical significance [75]. In fact, the effectiveness of laminar flow at reducing infections has recently been called into question [76].

Evidence suggests that forced-air warmers may also harbour microbial pathogens that have the potential to be emitted into the operating theatre environment via the air warmer hose [77–79]. However, the correct use of microbial filters and the recommended perforated blankets has been shown to prevent their transmission [77]. Moreover, analysis of theatre air samples in positive pressure theatres has shown a significant decrease in bacterial counts when forced-air warming was used correctly [80].

Although rare, forced-air warmer use has been associated with thermal injuries in both adults [81–83] and children [84–86], some of which have required surgical intervention and prolonged wound care [82, 83]. The underlying causes in the majority of cases involve incorrect assembly of the warmer hose to the blanket or accidental disconnections allowing hot air to be blown directly on to the patient's skin for a prolonged period of time ('hosing'). In cases where the warming device has been assembled correctly, uneven temperature distribution under the blanket [81] and incorrect positioning of the exit vents [84] have been postulated as potential causes. A novel underbody forced-air warming blanket has also been implicated with the development of full thickness pressure ulcers following its prolonged use in a patient with vascular disease [87].

Resistive heating

Resistive heating is a warming modality that utilises a low-voltage electric current that passes through semi-conductive polymer or carbon fibre systems to generate heat. Heat transfer occurs primarily by conduction, and skin contact is achieved through either a mattress or blanket. As it is re-usable, energy efficient [88], easily cleaned and relatively silent, it has been promoted as a more cost-effective and practical alternative to forced-air warming [89]. Studies evaluating resistive heating performance in preventing and treating hypothermia have shown mixed results in comparison with alternative warming approaches.

Unsurprisingly, when compared against passive insulation [90] or no warming [41, 91], resistive heating achieves significantly higher patient core temperatures. Furthermore, when evaluated against forced-air warming, an early non-clinical investigation with healthy volunteers showed that the heat transfer achieved from resistive heating was significantly greater [92]. However, the superiority of resistive heating over forced-air warming in this non-clinical study has not been reproduced in clinical trials, with the majority showing equivalence [54, 55, 93–96] between devices and three favouring forced-air warming (Tables 3 and 4) [56, 57, 97].

In patients undergoing laparotomies [56], underbody resistive heating is associated with significantly lower final operative temperatures when compared with forced-air warming. This is surprising, as the posterior surface area available for resistive heating is greater than the limited upper body area during open abdominal surgery. To explain the clinical findings, the authors suggested that posterior heat transfer is limited by reduced perfusion of dependent areas. However, a recent study that compared posterior forced-air warming against posterior resistive heating on the rewarming rates of patients during on-pump cardiac surgery still showed a significant difference in favour of forced-air warming [97].

The benefit of forced-air warming over resistive heating (blankets) with regard to rewarming hypothermic patients has also been shown in maxillofacial surgery cases [57]. In this study, the rewarming rate of the resistive heating blanket group was half that of the forced-air warming group. Suboptimal contact between the heating blanket and the lower body may have contributed to the observations.

Assessing the rate of rewarming, as opposed to the ability to maintain normothermia, is deemed a more rigorous test of warming ability as greater heat transfer is required. It is therefore interesting that an earlier crossover study that assessed core rewarming rates in volunteers showed, in contrast, equivalent performance between forced-air warming and resistive heating [89]. In this study, however, the subjects were young, healthy, not anaesthetised and were exposed to full body warming as opposed to lower body warming.

Six studies assessing the ability of forced-air warming and resistive heating to maintain intra-operative normothermia have shown parity between devices.

Table 3 Randomised trials comparing resistive heating with passive and no warming.

References	n	Groups	Temperature measured	Main findings
Camus et al. [41]*	22	RHB = 11 None = 11	End of surgery	RHB superior to no warming (p < 0.001)
Kober et al. [90]	100	RHB = 50 WB = 50	Arrival (warmed pre-hospital)	Significantly higher hospital arrival temperatures in RHB group (p < 0.001)
Camus et al. [91]	18	RHB = 10 None = 8	Intra-operative	Intra-operative temperature decrease significantly less in RHB group (p < 0.01)
Engelen et al. [97]	129	RHM = 43 FAW = 41 PI = 41	Intra-operative (CPB rewarming)	No significant difference in rewarming rates (p = 0.14)

RHB, resistive heating blanket; WB, wool blanket + resistive heating blanket turned off; RHM, resistive heating mattress; FAW, forced-air warming; PI, passive insulation; CPB, cardiopulmonary bypass.
*First trial of study.

Table 4 Randomised trials comparing resistive heating with forced-air warming.

References	n	Groups	Temperature measured	Main findings
Negishi et al. [55]	24	RHB = 8 FAW = 8 (CWM = 8)	Intra-operative	No significant difference in intra-operative temperature change between RHB and FAW (p > 0.05)
Matsuzaki et al. [54]	24	RHB = 8 FAW = 8 (CWM = 8)	Intra-operative	No significant difference in intra-operative temperatures between RHB and FAW (p < 0.05)
Egan et al. [93]	36	RHM = 18 FAW = 18	Intra-operative; end of surgery	No significant differences in intra-operative or end of surgery temperatures (p = 0.018, non-inferiority)
Brandt et al. [94]	80	RHB = 40 FAW = 40	Intra-operative	No significant difference in intra-operative temperature changes
Fanelli et al. [95]	56	RHM = 28 FAW = 28	Intra-operative; end of surgery	No significantly differences in intra-operative and end of surgery temperatures between RHM and FAW (p > 0.05)
Ng et al. [96]	60	RHM = 30 FAW = 30	Intra-operative	No significant difference in intra-operative temperatures between RHM and FAW (p > 0.05)
Engelen et al. [97]	129	RHM = 43 FAW = 41 PI = 41	Intra-operative (CPB rewarming)	Significantly greater rewarming rate in the FAW group (p < 0.001)
Röder et al. [57]	28	RHB = 14 FAW = 14	Intra-operative (rewarming)	Significantly greater rewarming rate in the FAW group (p < 0.001)
Leung et al. [56]	60	RHM = 30 FAW = 30	Intra-operative; end of surgery	Significant difference in intra-operative and end of surgery temperatures favouring FAW (p < 0.01)

RHB, resistive heating blanket; FAW, forced-air warming, CWM, circulating water mattress; RHM, resistive heating mattress; PI, passive insulation; CPB, cardiopulmonary bypass.

This includes patients undergoing general anaesthesia [54, 55, 93–95] and neuraxial blockade [96].

As heat transfer from resistive warming devices occurs primarily via conduction, the surface area available for warming plays an important role in devices' performance. In accordance with this, resistive heating blankets and underbody systems that have the capacity to warm limbs as well as the torso feature prominently in the studies showing parity between forced-air and resistive heating [54, 55, 93, 95].

In contrast to forced-air warming, underbody resistive heating does not interfere with surgical draping or skin preparation, so it can therefore be commenced immediately upon transfer to the operating table. The practical ease in its operation also allows the resistive heating mattress to be turned on in anticipation of patient transfer to ensure that the mattress target temperature is attained before patient contact. This method was used in two [93, 96] of the three studies showing parity between underbody resistive heating and forced-air warming. The resistive heating mattress is also straightforward to use in conjunction with forced-air warming, and the combined warming power has been proven to achieve significantly higher peri-operative core body temperatures in off-pump coronary bypass surgery to reverse induced hypothermia [98].

During general anaesthesia, patients predictably undergo an initial decrease in core temperature as a consequence of redistribution of blood and therefore body heat from the core to the periphery [99]. Pre-warming before induction of anaesthesia is the only technique that has been shown to attenuate redistributive heat loss. The maximal effect takes 2 h to achieve [100], although periods as short as 10 min have a significant effect [101]. The optimal combination of practicality and effectiveness has yet to be determined. In terms of practicality and ease of use, resistive heating may offer a better and cheaper alternative to forced-air warming. Adding weight to the argument, recent studies have shown favourable significant differences in

peri-operative core temperatures between patients pre-warmed through resistive heating [102] but not forced-air warming when compared with controls [103, 104]. Furthermore, an earlier study assessing the clinical impact of extending peri-operative conductive warming during abdominal surgery has also shown that the mattresses are well tolerated and that pre- and postoperative conductive warming significantly reduces blood loss and complication rates [105].

In the light of the majority of clinical evidence suggesting that resistive heating is as effective as forced-air warming in maintaining patient peri-operative core temperatures above 36 °C, NICE has recently supported the use of the Inditherm® mattress (Inditherm plc, Rotherham, UK) for patients at risk of hypothermia [106].

To our knowledge, there have been no trials directly assessing the different types of resistive heating systems available and caution needs to be observed when extrapolating results from one system to another. As heat transfer via resistive heating is critically dependent on skin contact, the variable designs and types of blanket or mattress are likely to significantly influence performance.

Resistive heating device safety

Resistive heating relies on direct skin contact to warm patients and, as a consequence, can cause significant burns if the mattress or blanket temperatures become inappropriately elevated. Full thickness burns requiring split skin grafting and scar therapy have occurred in two paediatric patients on the same list as a result of a single fault causing a localised hotspot in a Klimamed® Thermal Mat System (Klimamed Technology, Herrenberg, Germany) resistive heating mattress [107].

Circulating water devices

Circulating water devices operate by passing heated water within mattresses, blankets or garments in contact with patients. Due to the greater specific heat capacity [108] and thermal conductivity [109] of water, it is, in theory, a more effective medium to transfer heat when compared with air. This theoretical advantage is not translated into a clinical one as all of the trials comparing the two different warming modalities favoured forced-air warming [53–55, 67].

The interface between patient and circulating water mattress has an important impact on device performance and to achieve optimum heat transfer, the mattress ideally needs unimpeded high thermal contact with well-perfused skin. Therein lies the problem as the posterior surface is poorly perfused from the weight of the body compressing cutaneous capillaries and water mattresses operate at relatively lower water temperatures to prevent pressure-heat necrosis [110]. Heat flux studies on posterior circulating water mattresses have confirmed their modest effect on body heat balance [111]. A further limitation of water mattress heating is that the device does not prevent the high anterior heat losses from radiation and convection.

Water blankets providing anterior heat transfer have been trialled [112, 113], but these devices are still not as effective in maintaining core temperatures when compared with forced-air warming (Table 5).

Circulating water garments, however, have shown greater promise, achieving significantly higher core temperature profiles when compared with forced-air warming [108, 114–117] during liver transplant operations, open abdominal surgery and in volunteer studies. Water garment heating provides both anterior and posterior patient access from one unit, which greatly increases the surface area available for warming. One study estimated that water garments were able to warm up to 80% of the total patient body surface area compared with only 20–40% using upper body forced-air warming during open abdominal surgery [117]. Although equivalence has been shown between water garments and the combination of posterior water mattress heating with anterior forced-air warming [118], the former is arguably a more practical warming strategy. Newer temperature management systems incorporating energy transfer pads containing circulating water also offer flexibility in patient warming sites and have been shown to be more effective than forced-air warming (Table 6) [119, 120]. These are, however, more expensive than other warming methods [108]. Only a handful of studies have tested the use of water mattresses or garments in paediatric cases [121–123]. The authors of one paper described water mattresses as reasonably effective in rewarming hypothermic infants, although this study was only observational with no other active treatment group for comparison

Table 5 Randomised trials comparing forced-air warming with circulating water mattresses/blankets.

References	n	Groups	Temperature measured	Main findings
Negishi et al. [55]	24	CWM = 8 FAW = 8 (RHB = 8)	Intra-operative	Significant difference in intra-operative temperature change favouring FAW (p > 0.05)
Matsuzaki et al. [54]	24	CWM = 8 FAW = 8 (RHB = 8)	Intra-operative	Intra-operative temperatures significantly lower in CWM group after 30 min (p < 0.05)
Ihn et al. [67]	90	CWM = 30 FAWu = 30 FAWs = 30	Intra-operative	Intra-operative temperatures significantly lower in CWM group (p < 0.05)
Kurz et al. [53]	99	CWM = 51 FAW = 48	Intra-operative	Intra-operative temperature significantly greater in FAW group (p < 0.01)
Hynson et al. [113]	20	CWB = 5 FAW = 5 (HH = 5) (None = 5)	Intra-operative	FAW was more effective than CWB in transferring heat and preventing hypothermia (p < 0.05)

CWM, circulating water mattress; FAW, forced-air warming; RHB, resistive heating blanket; FAWu, upper body forced-air warming; FAWs, surgical access forced-air warming; CWB, circulating water blanket; HH, heated humidifier.

Table 6 Randomised trials comparing forced-air warming with circulating water garments

References	n	Groups	Temperature measured	Main findings
Hasegawa et al. [115]	36	CWW = 12 FAW = 12 (RHB = 12)	Intra-operative; end of surgery	Intra-operative and end of surgery temperatures significantly higher in the CWW group (p < 0.05)
Janicki et al. [116]	24	CWG = 12 FAW = 12	Intra-operative	Significantly higher intra-operative temperatures in the CWG group (p < 0.05)
Janicki et al. [117]	53	CWG = 25 FAW = 28	Intra-operative; end of surgery	Significantly higher intra-operative temperatures in the CWG group (p < 0.05)
Calcaterra et al. [120]	50	CWP = 25 FAW = 25	End of surgery	End of surgery temperatures significantly higher in the CWP group (p < 0.01)
Grocott et al. [119]	29	CWP = 14 FAW = 15	Intra-operative	Significantly less intra-operative hypothermia in the CWP group (p = 0.0008)

CWW, circulating water wrap + mattress; FAW, forced-air warming; RHB, resistive heating blanket; CWG, circulating water garment; CWP, circulating water pad.

[121]. Most comparative studies in children have shown inferior performance of water mattress warming against forced-air warming [122] and water garments [123], which accords with studies in adults.

Negative pressure warming systems
Effective heat transfer is not just dependent on the features of the warming device, but also the ability of tissues to receive and distribute heat. These properties are intimately linked to tissue perfusion and early pioneers attempted to optimise this by applying subatmospheric pressures to limbs [124]. The aim of negative pressure warming systems is to apply a subatmospheric pressure with a thermal load that would improve subcutaneous perfusion and open arteriovenous shunts, thus promoting peripheral to core heat transfer. Negative pressure warming devices come in the form of a mitt covering the hand and forearm. When applied to hypothermic vasoconstricted postoperative patients, the early studies showed a remarkable

ten-fold increase in rewarming core temperature rates of up to 13.6 °C.h^{-1} [124]. However, later studies were unable to reproduce these high rates, instead showing that negative pressure warming systems were no better than warmed blankets [125] and worse than full body forced-air warming in postoperative patients [126]. The negative pressure warming system used in the later studies, vitalHEAT® (Aquarius Medical Corp, Phoenix, AZ, USA) [125, 126], contained a cooler sodium acetate chemical heat source rather than water; this may account in part for its worse performance.

As anaesthetic agents are well-known vasodilators, the benefit of negative pressure warming systems to dilate peripheral vessels further in the intra-operative setting is questionable. In a recent study, the vitalHEAT system was found to be statistically inferior to forced-air warming during orthopaedic surgery in preventing postoperative hypothermia (Table 7) [127]. The reduced ability of this negative pressure warming system to cope with the drop in temperature following tourniquet release compared with forced-air warming may also have contributed to the poor result.

The vitalHEAT has, however, been found in one study to be statistically non-inferior to forced-air warming during open abdominal surgery [58]. Although mean core temperatures were lower in the negative pressure warming group, they were not > 0.5 °C less, the set threshold to judge inferiority. The authors suggested that removal of insulating air pockets between skin and warmer by the negative pressure improved warming. Interestingly, a novel form of water warming device has been developed that aims to combine enhanced thermal contact (via negative pressure) and improved skin perfusion (by applying the negative

pressure in a pulsed form) [109]. Initial results have been encouraging, with the pulsed negative warming device outperforming forced-air warming during laparotomy.

Water warming device safety
Every warming device has the potential to cause burns and there have been numerous documented cases involving water warming devices [58, 128, 129]. Two burns developed during the same trial as a consequence of incorrect assembly of a negative pressure water warming device [59], whilst others have been associated with full body water garments [128] and circulating water mattresses [129]. Posterior surface skin damage is challenging to manage as this surface is vulnerable to pressure-heat necrosis from reduced perfusion when supine, and cannot easily be observed during the operation. Furthermore, some burns can present late and even a lack of skin damage during the operation does not rule out a burn. Some burns can be severe enough to require corrective surgery; as aggressive warming is more likely to be undertaken during long operations in frail patients, vigilance is advised.

Future developments
Increased awareness of the adverse effects of accidental peri-operative hypothermia and the recognition that pre-warming may be required to prevent it in many cases will spur on more innovation. Already on the market, although as yet without clinical data to support its use, is the Easywarm™ blanket (Mölnlycke Health Care, Gothenburg, Sweden) with pockets that contain substances that heat up when exposed to air. This kind of technology, which does not require a

Table 7 Randomised trials comparing forced-air warming with negative pressure (NP) warming.

References	n	Groups	Temperature measured	Main findings
Trentman et al. [127]	55	NP = 30 FAW = 25	Intra-operative; recovery room temperatures	Recovery room temperatures in the NP group were inferior to FAW
Ruetzler et al. [58]	71	NP = 37 FAW = 34	Intra-operative temperatures	Intra-operative temperatures in the NP group were not inferior to FAW
Rein et al. [109]	20	NPP = 10 FAW = 10	Intra-operative temperatures	Significantly faster intra-operative temperature rewarming rate in NPP group (p < 0.05)

FAW, forced-air warming; NPP, negative pulsed pressure warming.

power supply, may gain widespread use for pre-warming and even pre-hospital care if shown to be effective.

Conclusions

It is acknowledged that accidental peri-operative hypothermia is associated with numerous adverse outcomes, and there are many types of warming device available to avoid this. Like all aspects of peri-operative management, the warming method needs to be tailored to the individual patient; frequently, different modalities are needed in combination to prevent peri-operative hypothermia. Surgical access, ease of use, bulkiness, patient positioning, intravenous access sites and device performance are all important considerations to take in to account when deciding which device is appropriate.

Forced-air warming is commonly used in the UK and the most tested warming modality in the published literature; this is reflected in the NICE guidelines. This method outperforms passive insulation and water mattresses, and is at least as effective as resistive heating. Correct assembly and the use of recommended microbial filters will minimise recent concerns about the risk of burns and infections.

Resistive heating is a newer warming modality with favourable characteristics such as silent running, energy efficiency and re-usable components. Recent clinical trials have shown, at best, equivalence in device performance when compared against forced-air warming. However, it is potentially cheaper [106] and may also offer advantages in terms of practicality and ease of use with regard to pre-warming.

Circulating water mattresses have been used for decades for intra-operative warming, but the evidence suggests that they are not as effective as forced-air warming. Water garments, on the other hand, are able to cover larger body surface areas and outperform forced-air warming, although they may interfere with surgical and anaesthetic access and remain expensive.

An interesting recent development is the use of negative pressure water warming devices, believed to remove insulating air pockets and improve subcutaneous perfusion available for warming. Recent studies have shown promising results particularly when the negative pressure is delivered in a pulsed form, but there may be practical problems with their use and safety information is lacking.

The peri-operative warming management plan should not only be restricted to choosing the appropriate body warming device, but also involve limiting exposed body surfaces, ensuring that the ambient temperature is above 21 °C and using warmed fluids. It is important to note that fluid warmer performance is dependent on the flow rate at which the fluid is delivered, with Hotline systems being the most effective at low flow rates in contrast to the Level 1 series that is more suited to high flow warming. The Fluido system appears to be the most effective over the whole range of fluid flows.

It should also be noted that for major cases, a single warming modality does not completely eliminate the occurrence of accidental peri-operative hypothermia and so combinations may be appropriate either intra-operatively or for pre-warming.

With an ageing population and advances in surgery often requiring greater body surface exposure and duration of surgery, the challenge to prevent peri-operative hypothermia is as great as ever. This challenge can only be overcome by an awareness of warming device performance.

Acknowledgements

Competing interests

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Annex 9: Harper CM, McNicholas T, Gowrie-Mohan S. Maintaining perioperative normothermia. Brit Med J. 2003;326(7392):721-2.

BMJ

Maintaining perioperative normothermia

A simple, safe, and effective way of reducing complications of surgery

Perioperative hypothermia can have a wide range of underappreciated, detrimental effects. These include increased rates of wound infection, morbid cardiac events, blood loss, and length of stay in both recovery and hospital. Maintaining core temperature at or above 36°C can be beneficial for the patient and cost effective.

Frank et al studied high risk cardiac patients undergoing thoracic, abdominal, and vascular surgery.[1] Patients randomised to routine thermal care were, on average, 1.3°C cooler than patients warmed more aggressively. Despite this small difference the incidence of perioperative morbid cardiac events, assessed in a double blind fashion, was 300% higher in the cooler group. Frank et al thought that this may be the a consequence of the dramatic increase in noradrenaline release seen in even mild hypothermia.

It has also been said that the increase in noradrenaline may contribute to the higher number of wound infections seen in hypothermic patients. A randomised study of patients undergoing colorectal surgery showed that 1.9°C hypothermia resulted in an infection rate of 19% compared with 6% in the normothermic group.[2]

The same study also showed that postoperatively the hypothermic group remained, on average, 2.6 days longer in hospital. Interestingly, even those hypothermic patients who did not have wound infections were discharged two days later. The surgeons participating in discharging the patients and assessing their wounds were unaware of the thermal management.

Efficiency of the operating theatre and costs can be affected adversely by delayed discharge of patients from recovery. In a blinded, randomised study of 150 patients undergoing major elective abdominal surgery it was found that the hypothermic patients (34.8 ±0.6°C) were fit to be discharged an average of 40 minutes later than the normothermic group (36.7 ±0.6°C).[3] This decision was made on the basis of a validated scoring. The delay would have been 90 minutes had a temperature of equal to or more than 36°C been part of the criteria for discharging patients.

The clinical effect of hypothermia on blood loss was shown in a randomised, controlled study of 60 patients undergoing primary total hip replacement. The hypothermic group, whose mean postoperative temperature was 1.6°C lower than that of the normothermic group, lost on average 500 ml or 30% more blood.[4] When using predetermined targets for packed cell volumes, this translated into seven of the hypothermic group receiving transfusions, as against one out of 30 in the normothermic group. Although not a primary end point, the increased blood loss was also noted in the study by Kurz et al.[2]

Such an outcome is unsurprising given that hypothermia produces a multifactorial coagulopathy involving defective thromboxane A2 release, alterations in platelet function, and inhibition of the coagulation cascade. These effects can often be overlooked as most widely available tests of coagulation are compensated by temperature. When prothrombin times are measured at different temperatures a 3°C drop can increase the value by approximately 10%.[5]

A recent editorial in the *BMJ* said that a haemovigilance programme is overdue in the United Kingdom, with mandatory local participation; new funds to pay for training, innovation, and audit; removal of incentives to supply and use blood; and an independent body to administer the programme.[6] On this evidence it seems that aggressive perioperative warming policies should be considered as a means of reducing the need for allogenic blood transfusion.

Urology patients, particularly those presenting for transurethral prostatectomy, are at a relatively high risk of hypothermia and its consequences. They tend to be elderly and as such at higher risk of perioperative complications.[7][w1] The use of irrigation fluids can cause significant fluid shifts[w2] and the development of the transurethral prostatectomy syndrome,[8] which may aggravate any problems secondary to hypothermia. If inadequately warmed the fluids can exacerbate drops in temperature.[9][w3] Furthermore, many of these operations are carried out under regional anaesthesia, which has been shown to attenuate the thermogenic response to hypothermia,[10] thereby prolonging the adverse effects.

In 1984 Carpenter noted that hypothermia during transurethral prostatectomy has received relatively little attention in the urology literature, and this is still the case.[11] One study, which looked at the consequences of hypothermia in these patients, showed a clinically significant, adverse, haemodynamic response in those patients who were not warmed aggressively.[12]

Hypothermia can be reduced by the use of forced air warming blankets, irrigation fluid that has been warmed in a heating cabinet, and by warming intravenous fluid.[12] Blankets and fluid warmers are likely to present the largest ongoing costs; they currently cost approximately £11 ($18; €16) each. In our institution operating theatres cost £750 an hour to run, and a unit of packed red blood cells costs £120. A

saving of one hour and three units of blood could perhaps cover the cost of warming 50 patients.

Perioperative warming can be cost effective and reduce a patient's discomfort by cutting the incidence of wound infections, length of stay in hospital, and shivering. It may also reduce the rate of allogenic blood transfusions and its associated risks. Given these end points it should now be possible to set up a randomised controlled trial to encompass all the possible benefits of maintaining perioperative normothermia.

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Setting global health research priorities

Burden of disease and inherently global health issues should both be considered

When the G8 countries met in Canada in 2002 the topics of security, health, and Africa figured prominently. The three issues are related. Africa's human health is reeling from HIV/AIDS and other infectious diseases, posing national and regional security risks. The continent's economic health is stagnant or eroding, the result of structural adjustment programmes,[1] domestic conflicts, corruption, and deteriorating human health. Recognising the complexities of these entwined relations, the G8 Africa action plan included a commitment to support health research on diseases prevalent in Africa. How well G8 member nations—Canada, the United States, England, France, Germany, Italy, Japan, and Russia—abide by this commitment is a matter of time and lobbying efforts. But what form should this new health research investment take? Should it emphasise specific diseases affecting poor people most, as favoured by the Commission on Macroeconomics and Health of the World Health Organization?[2] Should it heed the call of biotechnology researchers, who have tabled their list of "top 10" research investments for global health, which range from better diagnostic devices and recombinant vaccines against HIV/AIDS to simpler vaccine devices replacing needle injections?[3]

Both lists are consistent with the "burden of disease" approach to research priorities. This approach has become an important vehicle for exposing the imbalance between research investment and disease burden, the "10/90 gap"—less than 10% of worldwide health research is devoted to diseases that account for 90% of the global burden of disease.[4] The burden of disease approach has helped efforts to create and finance new programmes for treatment and prevention of disease (for example, the Global Fund to Fight Aids, Tuberculosis and Malaria) or for vaccine research (for example, the Global Alliance for Vaccines and Immunisation), however inadequate these commitments are at present. But is the burden of disease approach sufficient to sustain improvements in human health? We think not and propose its integration with a different conceptualisation of global health that emphasises the social, environmental, and economic contexts in which health, disease, and healthcare interventions are embedded.

The social and environmental contexts that determine disease are no longer simply domestic but increasingly global. The box lists what we consider the main inherently global health issues, a term describing health determining phenomena that transcend national borders and political jurisdictions. Considerable research exists on each of these issues, although not always with health as a principal outcome. Greater attention in research is required to the linkages between these issues and to their economic and political drivers that are, like the issues, increasingly global in scope. Such drivers include macroeconomic policies associated with international finance institutions, liberalisation of trade and investment, global trade agreements, and technological innovations, all of which are creating greater interdependence between people and places.[5] Assessing how these inherently global health issues affect health is a complex task. Recent work on locating these inherently global health issues in comprehensive health frameworks,[5 6] however, will prove useful in identifying specific research questions that are useful to policy makers and civil society.

Annex 10: Harper CM, Andrzejowski JC, Alexander R. NICE and warm. Br J Anaesth. 2008;101(3):293-5.

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Editorial II

NICE and warm

Inadvertent perioperative hypothermia, defined as core body temperature ≤36.0°C, is a common consequence of anaesthesia. Its adverse effects are well known to anaesthetists and include greater intraoperative blood loss and consequent blood transfusion.[1] After operation, inadvertent perioperative hypothermia can lead to an increased rate of wound infection,[2] morbid cardiac events,[3] and pressure sores,[4] and also a longer stay in both recovery and hospital.[5] These are apart from the subjective discomfort and wound pain which cold and shivering may cause the patient. Significantly, maintaining normothermia perioperatively can modify these adverse effects.

Despite this knowledge, implementation of warming strategies remains patchy. An audit in the hospital of one of the authors (C.M.H.) indicated that there is an incidence of inadvertent perioperative hypothermia in the region of 20% and that there is inconsistency in the methods of warming used. There are no active temperature management protocols and, as with anything that may cost money, there is resistance to more aggressive prevention of inadvertent perioperative hypothermia on economic grounds. In the USA, where there are guidelines,[6] compliance remains poor. It has been suggested that there are a number of factors contributing to this: a misguided belief that forced-air warming can increase the rates of infection,[7] surgeons' complaints of discomfort, inconsistent monitoring (hindered by the inconsistency between different thermometers and sites of measurement), and a simple lack of appreciation of the causes and consequences of inadvertent perioperative hypothermia.[8] Additionally, even where there are standards such as those of the American Society of Anesthesiologists (ASA),[9] they are criticized for being vague and giving flexibility at the expense of clear guidance.[8]

Recognizing the significance of inadvertent perioperative hypothermia and the deficiencies in current practice in the UK, the National Institute for Clinical Excellence (NICE) convened a guideline development group to address the issue. This culmination of the group's work came with the publication of the 'Management of inadvertent perioperative hypothermia in adults' guideline.[10]

The guidance is divided into the pre-, intra-, and post-operative phases. Before operation, the key recommendations are that a formal assessment of the risk of hypothermia should be undertaken for each patient and that patients themselves should be empowered by being given information that will help them minimize that risk. Another important element is that the temperature should be measured in the hour before surgery. Should it be <36.0°C, unless the operation is life or limb saving, active warming should be initiated until such time as the patient is normothermic.

Intraoperatively, the recommendations are that forced-air warming is commenced as early as possible, preferably in the anaesthetic room, for any patient having surgery with an anaesthetic time (i.e. from first anaesthetic intervention to arrival in recovery) of >30 min, or who has two or more risk factors for inadvertent perioperative hypothermia. I.V. fluids should be warmed when >500 ml is to be given.[11] [12] These recommendations therefore encompass the majority of operations and infusions.

Monitoring is an integral part of perioperative thermal management and one that remains neglected.[13] The guide recommends that core temperature should be recorded at

least every 30 min intraoperatively to ensure that heat delivery is titrated optimally so that the patient does not become too cold or too hot. There are limitations to all currently available methods of perioperative temperature monitoring but, unfortunately, this area was deemed to be outside of the scope of the guidelines.

After operation, patients should not be discharged from the recovery area before their temperature reaches 36.0°C. Their temperature should be measured with the same frequency as pulse, arterial pressure, and other standard postoperative observations for the first 24 h for in-patients. For ambulatory surgery, normothermia should be a prerequisite for discharge. This should focus attention on the issue.

The guidance is clear and the recommendations are logical. The implementation of forced-air warming for all operations over 30 min and the warming of all i.v. infusions of 500 ml or more may seem controversial at first. Although clinicians are unlikely to object to this advice on medical grounds, it will have significant cost implications.

A broad-ranging analysis was carried out in setting these guidelines, but the analysis can only be as good as the available evidence. One weakness of the analysis is that, because of the lack of direct evidence, much of the data on the benefits of forced-air warming for short procedures have been extrapolated from studies in longer operations. Despite this, even if the estimated economic effects of the complications are diluted quite significantly, the cost-effectiveness analysis results in overall savings. The cost implications of implementing the guidelines could be mitigated through the use of warming equipment that requires the use of fewer or no disposables. This again exposes another weakness in that there are papers suggesting that new technology has rendered older warming techniques more effective. Both circulating-water[14] and electric mattresses[15][16] are reusable so have the potential to substantially reduce the cost of implementing optimal thermal perioperative care. However, because evidence for a reduction in complications comes from publications using forced-air warming, this is what the guideline has to reflect. The situation is similar with regard to fluid warming. No technological assessment was carried out, but there is evidence to suggest that not all warmers are the same.[17] It may be that for short cases where 500–1000 ml is given i.v. that fluid taken from a warming cabinet may be effective.

In recognition of the gaps in the evidence-base, the guideline makes certain research recommendations. Of particular note are those for research into alternative (i.e. to forced-air warming) warming technologies, the incidence and effects of inadvertent perioperative hypothermia on patients undergoing short (i.e. anaesthetic duration of <1 h) operations, and the effectiveness of prewarming.

It is unusual for NICE to produce a guideline that relies so heavily on anaesthetists for its implementation. The nearest it has come in the past is its technological assessment on the use of ultrasound for central venous catheter (CVC) placement.[18] That guideline had a significant impact on the provision of ultrasound machines in operating theatres.[19] The inadvertent perioperative hypothermia guideline gives anaesthetists significant leverage to obtain adequate funding for warming equipment. To assist in this process, a new version of the inadvertent perioperative hypothermia audit that takes into account the NICE recommendations will shortly be available. The combination of audit information along with the NICE guideline should make it possible to significantly reduce the incidence of inadvertent perioperative hypothermia. This guidance provides anaesthetists with an unprecedented opportunity to have a positive effect on the outcome of surgery.

Declaration of interest

C.M.H. has received support for a study (ref. 15) from Inditherm, the manufacturer of electric warming mattresses. Arizant provided temperature monitoring devices for research. The Surgical Company (manufacturers of Fluido fluid warmers) sponsored a speaking engagement at ESA 2007. R.A. was on the TEMMP (Thermoregulation in Europe Monitoring and Managing Patient Temperature) Task force that was financially supported by Augustine Medical. J.C.A. has been loaned equipment and received support for research from Arizant Healthcare UK. R.A. was the chairman, C.M.H. was the RCA, and J.A. the AAGBI, representative on the NICE IPH Guideline development group.

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Annex 11: John M, Harper M. Inadvertent peri-operative hypothermia: guidance and protecting patients. British Journal of Healthcare Management. 2014;20(5):206-11

Inadvertent peri-operative hypothermia: guidance and protecting patients

Martin John, Mark Harper

ABSTRACT

Inadvertent peri-operative hypothermia is a complication of surgery which is associated with significant patient morbidity, with indirect consequences to hospital efficiency and resource burden. Despite increased awareness and the expansion of new warming equipment, peri-operative hypothermia remains a persistent problem. This review aims to provide a brief overview of the mechanisms and consequences of inadvertent peri-operative hypothermia as well as the salient features of recent guidelines that aim to protect patients.

Key Words: Inadvertent perioperative hypothermia • patient warming • clinical guidance • warming equipment • patient safety

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Inadvertent peri-operative hypothermia (IPH) is a well-recognised complication of surgery which causes an increase in patient morbidity and resource demand post-operatively. Despite awareness, it is surprising that the rates of IPH are still high and it is now becoming clear that the challenge of maintaining peri-operative normothermia also represents an opportunity to improve hospital efficiency and resource burden. This article will attempt to provide an overview of IPH and relevant guidance as to how it can be prevented and managed.

Normal thermoregulation

The human body is highly sensitive to small fluctuations in core temperature and possesses an advanced thermoregulatory system equipped to maintain this near 37 °C (Sessler, 1997). The normal thermoregulatory response against cold can broadly be divided into behavioural and autonomic components. The behavioural changes are very powerful and include searching for a warmer environment and dressing warmly in response to thermal discomfort. The autonomic defences against cold stress are not under conscious control and include arteriovenous shunt vasoconstriction (which reduces peripheral blood flow and heat loss), and shivering (which generates heat as a by-product of involuntary skeletal muscular activity) (Sessler, 2009).

General anaesthesia

IPH is defined as a core temperature of < 36 °C by the National Institute for Health and Care Excellence (NICE) (2008), and is by far the most common peri-operative thermal disturbance. It arises as a consequence of patient exposure to the cold operating room environment and the negative effects of anaesthetic agents on the

> *...it is clear that surgical list management, recovery room throughput, as well as hospital bed availability and critical care demand, will indirectly benefit from improved peri-operative temperature management.*

aforementioned thermoregulatory response. General anaesthesia not only eliminates the patient's ability to make appropriate behavioural changes to regulate body temperature, but also reduces both the shivering and vasoconstrictor temperature thresholds, thus blunting these defences (Kurz, 2008). As a consequence, most surgical patients will become hypothermic if counter-measures are not instituted.

Under general anaesthesia, hypothermia develops in a characteristic pattern. During the first hour, there is a rapid reduction in core temperature by up to 1.5°C. This is followed by a less rapid (linear) decrease in temperature before a plateau is finally reached after 3–4 hours as described by Sessler (1993). To understand this temperature profile, it is important to appreciate that body heat is not evenly distributed. In fact, temperatures at the peripheries are normally 2 °C cooler than the core and this gradient is maintained by tonic thermoregulatory vasoconstriction. General anaesthetics however, reduce the threshold for vasoconstriction, and, as a consequence, cause redistributive heat loss from the core to the periphery as described by Matsukawa et al (1995). After an hour, the decline in core temperature is usually less rapid and is attributed to heat loss exceeding metabolic heat production. A temperature plateau is eventually reached after 3–4 hours under anaesthesia when heat loss equals production.

Neuroaxial anaesthesia (spinal and epidural) is a known risk factor for developing inadvertent peri-operative hypothermia due to the associated direct blockade of sympathetic nerves and subsequent vasodilatation (Buggy and Crossley, 2000). Neuroaxial anaesthesia also appears to affect thermoregulation through the alteration of afferent thermal inputs as suggested by Hynson et al (1991).

Adverse effects

Inadvertent peri-operative hypothermia is associated with a number of adverse events which can cause significant patient harm. There is evidence that hypothermic patients are at an increased risk of bleeding, and are more likely to require allogenic blood transfusions (Schmied et al, 1996, Rajagopalan et al, 2008). Hypothermia is also associated with a higher incidence of surgical wound infections and a more prolonged hospital stay (Kurz et al, 1996). Post-operative shivering (Just et al, 1992) and thermal discomfort (Kurz et al, 1995) are also more prevalent in patients who experience hypothermia, as are more serious complications such as unstable angina, cardiac arrest and myocardial infarction (Frank et al, 1997). From this evidence, it is clear that surgical list management, recovery room throughput, as well as hospital bed availability and critical care demand, will indirectly benefit from improved peri-operative temperature management.

NICE guidance

In light of the associated poor outcomes, NICE issued guidance on the prevention and management of inadvertent peri-operative hypothermia in 2008. The guidance is applicable to adults undergoing both elective and emergency surgery under general anaesthesia—with or without central neuroaxial blockade.

Temperature control should be managed throughout the patient's operative pathway and is divided into pre-operative, intra-operative, and post-operative phases.

Pre-operative phase

This stage is frequently overlooked by healthcare professionals but plays an integral part in preventing IPH, particularly the early redistributive heat loss seen following anaesthetic induction. The phase is defined as the hour before induction of anaesthesia, and within this time, patients need to be risk assessed, monitored and pre-warmed if necessary.

Risk assessment prior to anaesthesia identifies which patients are at a higher risk of developing IPH (*Table 1*). This is important since these patients have a lower threshold for intervention and should always receive active warming regardless of operative time.

While waiting for surgery, it is recommended that patient's should be kept 'comfortably warm' (36.5–37.5°C) by the provision of suitable bedding, and that vigilance should be observed in patients taking pre-medication known to increase IPH risk (such as midazolam or opioids).

If the patient's pre-operative temperature is below 36°C, active warming should be started before induction of anaesthesia (unless there is an urgent need to expedite surgery). Warming before the start of anaesthesia is termed pre-warming, and it is the only effective way of attenuating the early redistributive hypothermia commonly seen after anaesthetic induction (Sessler et al, 1995). By reducing the core to peripheral tissue temperature gradient, pre-warming limits the amount of heat that gets redistributed away from the core following anaesthetic induced vasodilatation.

Intra-operative phase

The intra-operative phase is defined as the total anaesthetic time from induction to arrival in recovery. NICE guidance for this phase stresses the importance of regular temperature monitoring (every half an hour), and provides clear criteria for when to induce anaesthesia, and which patients need intra-operative cutaneous warming.

Essentially, anaesthesia should only be started when the patients' temperature is above 36°C unless surgery is urgently needed. If their core temperature is below 36°C, the patient is by definition already hypothermic, and the thermal insult associated with anaesthesia will only exacerbate the situation and increase patient morbidity. Patients should receive active warming during induction of anaesthesia if they are high-risk patients (identified pre-operatively), already being warmed, or when operative duration of greater than 30 minutes is anticipated.

Table 1. When a patient is considered high-risk

Patients are considered high-risk if any two of the following apply:

- American Society of Anesthesiologists (ASA) grade above 1
- Pre-operative temperature <36°C
- Combined general and regional anaesthesia
- Major or intermediate surgery
- Risk of cardiovascular complications

In order to limit heat loss to the environment, the theatre temperature needs to be at 21.0°C or above, and the patient should be covered adequately, only being exposed during the surgical operation. Furthermore, since the administration of fluid at room temperature is effectively a form of cooling, NICE have also advised that all fluids (500 ml or more) and blood products be warmed to 37°C.

Post-operative phase

The post-operative phase refers to the first 24 hours after the patient arrives in the recovery room, and encompasses temperature management on the ward as well as in recovery. The management is in principal the same although the monitoring intensity differs between areas. The temperature should be checked every 15 minutes in the recovery room (compared to every 4 hours on the ward) and transfer between areas should only be made when patient temperature is 36°C or above. If this drops below 36°C, forced-air warming should be used to achieve normothermia.

'*NICE issued guidance on the prevention and management of inadvertent peri-operative hypothermia in 2008…applicable to adults undergoing both elective and emergency surgery under general anaesthesia*'

KEY POINTS

- The human body is highly sensitive to small fluctuations in temperature and has an efficient regulatory system to maintain tight control
- .General and neuroaxial anaesthesia impairs this regulatory system and puts surgical patients at risk of inadvertent peri-operative hypothermia
- Inadvertent peri-operative hypothermia can lead to serious patient harm
- The National Institute for Health and Care Excellence (NICE) have published a comprehensive guideline to allow healthcare staff to protect against inadvertent peri-operative hypothermia
- Preventing IPH represents an opportunity to improve hospital efficiency and reduce resource burden

Equipment

There is an abundance of warming equipment available on the UK market, although only forced-air warming and resistive heating have been recommended by NICE.

Forced-air warming works by blowing heated air through a specialised blanket which covers the patient. This warming method has been extensively studied and outperforms passive insulation (Zhao J et al, 2005), water mattresses (Ihn et al, 2008) and is at least as effective resistive heating (Brandt et al, 2010, Engelen et al, 2011). There have been reports of burns and recent concerns regarding the spread of infections from the apparatus, however correct assembly and use of recommended microbial filters minimises this risk.

Since forced-air warming uses non-reusable blankets, this warming modality is associated with a cumulative expense. Resistive heating however, is re-usable and represents a potentially

'Improving the peri-operative temperature management of patients can therefore indirectly benefit surgical list management, recovery room efficiency and hospital resource burden'

cheaper alternative. Resistive heating operates by passing an electric current through a polymer or carbon fibre blanket or mattress which generates heat to warm the patient. In light of the majority of clinical evidence suggesting that resistive heating is as effective as forced-air warming (Ng et al, 2006; Fanelli et al, 2009; Brandt et al, 2010; Egan et al, 2011), NICE has supported their use in preventing IPH (NICE, 2011).

Circulating water devices operate by passing heated water within blankets, mattresses and garments that are in contact with patients. Evidence from water mattress and blanket studies show these devices inferior to forced-air warming (Negishi C et al, 2003). Water garments which are able to cover a larger body surface area do however outperform forced-air warming (Taguchi et al, 2004), although they may interfere with surgical and anaesthetic access.

There are numerous fluid warming devices, and their heating methods include: passing intravenous tubing through heating blocks; counter-current systems; convective-air systems; and insulators. NICE concluded that if any amount of intravenous fluid is given, it is more cost effective to warm this. No individual fluid warming device was recommended and choice of device should dependent on anticipated fluid flow rate needed.

Conclusion

IPH is a common and preventable complication of surgery which can lead to serious patient harm. Improving the peri-operative temperature management of patients can therefore indirectly benefit surgical list management, recovery room efficiency and hospital resource burden. NICE have published clear guidelines to help identify patients at risk of IPH and how to prevent it. The guidance is broad, with recommendations affecting numerous hospital disciplines, and starting from one hour before surgery and lasting until 24 hours post-operatively. By successfully implementing these guidelines to protect patients from hypothermia throughout their operative pathway, the hospital will become efficient, safer and more rewarding for healthcare staff. BJHCM

Conflict of interest

Martin John: No conflict of interest declared
Mark Harper: Has received loans of equipment
from various manufacturers of warming
devices including Inditherm, Augustine
Biomedical, Arizant and Mölnlycke. He has also
received expenses and an honorarium for sitting
on an advisory board for Mölnlycke.

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Annex 12: Theron P, Harper C. Inadvertent Perioperative Hypothermia Mini-topic Review. NHS library for health 2009

Inadvertent Perioperative Hypothermia – mini topic review

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Introduction

Inadvertent periopertive hypothermia is known to negatively influence patient outcome [1,2,3,4,5,6] but unfortunately remains a common occurrence in present day practice. The aim of this review is to discuss the definition of inadvertent perioperative hypothermia, the considerations when measuring temperature, the effect of hypothermia on patient outcome, the methods of preventing inadvertent hypothermia and the cost implications.

Definition

The 2008 NICE guidelines define inadvertent perioperative hypothermia as a *core* temperature below 36 ºC at any time from 1 hour before the start of anaesthesia to 24 hours after entry into recovery.[7] This gives us a clear standard to adhere to which should be audited regularly to ensure that patient outcome is improved.

Considerations when measuring temperature

NICE guidelines refer to core body temperature as this is the best indicator of the thermal status of the body. Obtaining a reliable measurement of core temperature can be difficult when non-invasive monitoring is used and there are particulars of core temperature measurement sites to consider.

Reliable sites for core temperature measurement are the lower oesphagus, nasopharynx, tympanic membrane and pulmonary artery.[8] Lower oesophageal monitoring can be unreliable if the probe is just posterior to the trachea, therefore blind insertion of a probe is not adequate. An oesphageal stethescope is a reliable way of positioning such a probe. Nasopharyngeal monitoring is only reliable when no cool air is passing near the probe and is therefore best used in patients with a supraglotic airway or endotracheal tube in situ.

The tympanic membrane does give reliable measurement of core temperature when actually measured, however current infrared "tympanic" monitors have been shown to be inadequate for clinical use.[9,10] Thermocouple tympanic monitors are reliable but they need to be inserted to touch the tympanic membrane which may be difficult. Pulmonary artery monitoring is accurate but is unlikely to be inserted solely for core temperature measurement.

The temporal artery infrared scanner has shown some promise and appears to be more reliable than infrared tympanic monitors.[11,12] It is however considered by some to be too inaccurate for clinical use.[8]

Further sites that can be used are the bladder, rectum, mouth and the axilla but these are all subject to artifact.[8] Bladder temperature is dependant on urine flow, which makes interpretation difficult while rectal temperature has a significant lag period before equalising with core temperature. Oral temperature is considered by some to be the standard by which to compare other non-invasive thermometers but it may be affected by recent hot/cold drinks or breathing. Accurate axillary measurement is reliant on good technique with placement over the axillary artery. These thermometers are not measuring core temperature. The MRHA in 2005 stated in its review of intermittent-use thermometers that: rectal temperature is on average 1.25°C below core temperature; axillary temperature 1.1°C below; ear temperature 0.85°C below, forehead temperature 0.7°C below and oral temperature 0.55°C below.[7] To complicate matters further, many of the

newer methods of temperature measurement devices use an algorithm to output a core temperature but this is not always entirely clear to the user.

NICE recognises the wide variety of devices and sites used with in the NHS and states that staff should be trained in the use of the thermometers and must be "aware of adjustments …needed to estimate core temperature" or whether these adjustments are made automatically.[7]

NICE does not advise on best methods or device but rather states that "Choice of body site and selection of instrumentation for monitoring and detection are equally important, and local decisions within NHS Trusts should form local policy in this area".[7]

Effect of Hypothermia

It is well documented that hypothermia negatively influences patient outcome. There is published evidence that inadvertent perioperative hypothermia results in increased rate of morbid cardiac events (6.3% vs 1.4%)[1], increased blood loss (16%)[2], increased relative risk for blood transfusion (22%)[2]. Evidence shows increased rate of wound infection (19% vs 6%)[3], prolonged hospital stay (by 2.6 days)[3] and recovery stay (94 vs 53 min)[4]. Patient satisfaction is reduced due to increased shivering, subjective discomfort and wound pain.

The temperature differences that result in these different outcomes are in the region of 0.85°C.[2] The smallest difference to influence outcome was 0.4°C.[6] This strongly supports NICE guidance to keep core temperature above 36°C.

Prevention of perioperative hypothermia

The 2008 NICE guideline considers the patient pathway in 3 stages: pre-, intra- and post-anaesthetic. Before surgery the patient should be informed that keeping warm preoperatively can lower their risk of complications and that should they feel cold to inform staff.

In the preoperative phase, formal risk assessment should be conducted to determine those at a higher risk:

Any two of:
-ASA II-V
-Preoperative temperature <36°C
-Combined General and regional anaesthesia
-Major or intermediate surgery
-at risk of cardiovascular complications

Forced air warming should commence if the temperature is below 36°C and non-life-or-limb-saving surgery should be postponed until the patient's temperature is greater than 36°C.

Intraoperative guidance states that if >500ml of fluid is to be given it must be warmed to 37°C. On this note, Sessler considers it clinically negligent not to warm intravenous fluid. For procedures >30min or for those at

higher risk of hypothermia forced-air warming devices should be used. Core temperature should be measured every 30 min aiming to maintain a temperature of at least 36.5°C. Ambient temperature should be kept at 21°C, patient exposure should be kept to a minimum and irrigation fluids should be warmed

Postoperatively patients should not be discharged from recovery if their temperature is less than 36°C and temperature should be measured every 4 hours on the ward and acted upon if less than 36°C.

Financial implications

Warmed fluid and forced-air warming for a majority of patients is unlikely to be opposed on clinical grounds but naturally comes at a cost that needs to be weighed against the cost of increased complications.

There is no direct evidence of the cost-effectiveness of forced-air warming for short procedures. However economic benefits remain even if they are significantly less than the extrapolated data would suggest. Furthemore, although not cited in the guideline due to lack of evidence, there are other methods of warming, such as electric mattresses[13,14] and circulating water devices[15] that appear to be similarly effective yet may prove to be cheaper due to the fact that they are re-usable.

NICE's analysis of cost effectiveness also concluded that warming IV fluids (if more than 500ml is to be given) was cost effective and therefore should be implemented throughout the NHS.

There is no doubt that inadvertent hypothermia is bad for patients. NICE has completed an extensive review on the subject and published a clear guideline indicating the expected standard of care. The aim of this mini topic review is to increase awareness of the guideline and the considerable benefits to be gained from adhering to its advice. To help with its effective implementation, an audit 'recipe' based on the guideline has been produced by the Royal College of Anaesthetists.

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Annex 13: Chakladar A, Harper CM. Keeping the right temperature during surgery - anaesthetists are warming to advice on inadvertent hypothermia. Hospital Healthcare Europe 2009/10 [Internet]. 2010 1st February 2011.

Keeping the right temperature during surgery – anaesthetists are warming to advice on inadvertent hypothermia

The UK's clinical watchdog – NICE – has produced guidance on perioperative hypothermia, and following it need not involve too much expense or effort, as it represents flexible advice. But accurate thermometers remain a trickier issue

The National Institute for Health and Clinical Excellence's (NICE) guidance on the management of inadvertent perioperative hypothermia (IPH) in the UK is now more than a year old and has a significant impact on the day-to-day workings of anaesthetists and theatre staff. It amalgamated international research spanning more than a decade and provided succinct guidance to the clinical practitioner.[1] Its guidance is by no means exclusive and serves as a primer for reducing hypothermia.

The significance of IPH and its role in perioperative morbidity has been known for some time and it is a common consequence of hospital admission, anaesthesia and surgical exposure. Prevention of IPH or reducing operative heat loss has been shown to decrease bleeding during operations and postoperatively reduce recovery time from general anaesthesia,[2-4] reduce length of hospital stay, improve wound healing and reduce wound infection.[5]

There have been discussions in the anaesthesia press about impending capital investments and financial implications,[6] and the inappropriate applications of the NICE guidance.[7] Guidelines are suggestions toward better practice and capital investments may not be required to fulfil their aims. As such, NICE issues a disclaimer;[1] it says it is just common-sense advice, giving clinicians the opportunity to audit their own practice, apply only guidelines that are appropriate to their patient populations and reduce target-based political pressures. For instance, an audit

at a specialist ear nose and throat (ENT) hospital showed that its patients are not at high risk from IPH, with low rates of hypothermia.[6] It is therefore not appropriate to warm this patient group routinely, as simple warming methods are effective, thus not requiring the purchase of additional warming equipment.

Much of the focus is given to intra-operative warming, but prevention is better and often less resource-intensive than cure, and this is emphasized in the pre-operative phase of the NICE guidance which recommends temperature monitoring and management on the ward.

The guideline also suggests that, should a patient's temperature be less than 36.0°C, unless the operation is life- or limb-saving, active warming should be initiated until such time as the patient is normothermic. The potential effect of this on theatre efficiency has been noted,[7] but clinicians must evaluate each case individually as to whether to proceed or not. Nevertheless, there is an argument for active warming prior to anaesthesia. Much of the heat lost after induction of anaesthesia is from the body's core to its peripheries, caused by vasodilatation after general and neuroaxial anaesthesia, and active skin warming may prevent this.[8]

As guidelines mature, discussions about their efficacy move from ones of applicability and cost to what the guidelines have left out. Much of the concern surrounded increased cost relating to the purchase of disposable forced-air warming blankets (FAWB) and associated devices. The

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Reducing heat loss has been shown to decrease bleeding during operations and reduce recovery time from anaesthesia, reduce length of hospital stay and reduce wound infection

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clinicians involved in creating the NICE guidelines understand that they were limited by a lack of direct evidence and the need to extrapolate data on the effectiveness of warming devices.[9] Forced-air warmers are the only devices used in published studies where complications have been reduced with warming, and so were the only devices that could be recommended by NICE at that time.

Small studies have shown that warmed intravenous fluids are effective in reducing temperature decreases,[10] and warming mattresses using carbon polymer technology and air-free blankets employing resistive polymer semi-conductive fabrics are just as efficacious as forced-air warming blankets.[11,12] Simpler methods such as warmer ambient temperatures and extra blankets may prove equally effective, and the NICE guidance does not preclude their use. The warming method used must fit the clinical situation and be palatable to the patient and clinical teams.

Obstetric procedures

Obstetric procedures were not covered by the NICE guidance. There is a paucity of research in obstetric perioperative warming and what research has occurred has involved small numbers of patients. Some studies have shown important trends after neuro-axial anaesthesia, prior to elective Caesarean section, such as reduced hypothermia and shivering with forced-air pre- and perioperative warming.[13]

More recently, reduced maternal temperature decrease with pre-warmed and actively warmed intravenous fluids has been demonstrated.[10] However, a national survey has shown that the majority of obstetric units in the UK do not routinely warm patients undergoing elective section.[14] Our own (unpublished) audit has shown that 10% of patients undergoing elective Caesarean section become hypothermic and 25% suffer from shivering.

A recent audit at another institution showed that 42% of patients undergoing elective Caesarean section were hypothermic (as defined by NICE) on admission to the recovery room after their operation (additional data obtained from authors),[15] and analysis of previous audits has suggested that all patients undergoing Caesarean section with spinal or epidural anaesthesia should receive intra-operative warming.[16]

Alternative warming methods and their relation to maternal and foetal outcomes must be researched, as although FAWBs reduce maternal heat loss and are useful in general anaesthesia,

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The prevention of hypothermia and subsequent beneficial outcomes to patients is the key message; the means employed are secondary

they may be obstructive to the awake mother holding her baby.

The guidance did not consider technologies used to measure core temperature, perhaps due to a lack of good evidence. Thermometers in use range from glass-alcohol to infrared tympanic and temporal to thermistor or thermocouple-based tympanic, naso-pharyngeal, oesophageal, urinary catheter-bladder and pulmonary artery catheter (PAC) thermometers. For the NICE guidance to be appropriately applied, tools used to measure temperature must be reliable and accurate.

Pros and cons of different thermometers

All thermometers have advantages and disadvantages. PAC thermometers may be seen as the gold-standard method of measuring core temperatures, but their associated complications precluded routine use.[17] Alcohol thermometers are cheap and reliable, but are prone to breakage and have a response time too slow for efficient intra-operative use. Though accurate when proximal to the tympanic membrane, most available infrared tympanic devices are too large to fit far enough into the external auditory meatus to retain this accuracy,[18] and a local study found that, on average, these thermometers under-read by 0.74°C.[19]

Naso-pharyngeal and oesophageal probes are useful when the patient is anaesthetised, but they are limited to intra-operative use, require careful positioning and cannot be comfortably used in awake patients. The accuracy of bladder thermometers with respect to PAC temperature measurements has been demonstrated and can be used throughout the operative period,[20] but specialised urinary catheters and monitoring equipment are required. Although most patients undergoing operations with a neuro-axial block have urinary catheters inserted, this is not essential and infection risks preclude their use in every patient.

Temporal artery infrared thermometers may be a good alternative, as they are non-invasive, give reproducible results with simple training and are comfortable for awake patients. A recent pilot study has shown that infrared tympanic thermometers can give an accurate peripheral representation of core temperature measured via a urinary catheter,[17] and may prove to be a more useful device. However, larger trials comparing the various monitoring methods are required.

The level of allowable inaccuracy from peripheral estimation of core temperature has not been formally defined, but it has been suggested that it should not vary from the true core temperature by more than 0.5°C.[18] The limitations of current thermometer technologies must be appreciated by the anaesthetist and these limitations must be factored into decisions surrounding perioperative temperature management. There is a clear need to 'establish the least inaccurate' non-invasive thermometer.[19]

New guidelines often lead to reviews of current practice and good guidance aimed at interested professionals generates much debate, and the NICE guidance has done just that. National guidance can only be successful if its applicability to local populations is established through audit and then only applied where it is appropriate. An audit recipe, incorporating the NICE guidelines, can be found on the UK's Royal College of Anaesthetists' website with a data-collection form and spreadsheet tool to facilitate anaesthetic departments in auditing, interpreting and presenting their current performance in managing IPH.[21]

We must continue to monitor and audit the prevalence of IPH, institute appropriate measures and actively research new methods to prevent it. The NICE guidance on IPH offers perioperative physicians unprecedented evidenced-based influence in perioperative patient care and the ability to introduce positive, effective and patient-orientated changes. The prevention of hypothermia and subsequent beneficial outcomes to patients is the key message; the means employed are secondary. ■

Competing Interests

C.M.H. has received support for research and loans of equipment from Inditherm, Arizant, The Surgical Company, and Augustine Medical. A.C. has no competing interests.

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The Royal College of Anaesthetists

Raising the Standard:
a compendium of audit recipes
for continuous quality improvement in anaesthesia

3rd edition
2012

Editors
Dr John R Colvin
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of Anaesthetists**

2.7

Peri-operative temperature management

Dr M Harper

Why do this audit?	Temperature monitoring is essential during induction and maintenance of anaesthesia and should be available during recovery from surgery.[1] Both hypothermia and hyperthermia (including malignant hyperthermia) can complicate anaesthesia.[2,3]

There are a number of reviews of the adverse effects of inadvertent peri-operative hypothermia (IPH) in the literature. Research has shown that IPH can lead to morbidity including prolonged recovery and hospital stay,[4] increased blood loss and transfusion and an increased incidence of pressure sores,[5] wound infections[6] and morbid cardiac events.[7] Reducing the incidence of IPH through appropriate peri-operative care can reduce the incidence of these complications.

In hyperthermia the margin between temperatures for normal cellular processes and cell damage from high temperature is very small compared with hypothermia. Hyperthermia can be corrected by cooling.

This audit reflects the recommendations of the NICE guideline 'Perioperative hypothermia (inadvertent): the management of inadvertent perioperative hypothermia in adults'.[8]

Best practice: research evidence or authoritative opinion

It has been shown that when mildly hypothermic volunteers shiver post-anaesthesia, they can regain heat with simple passive re-warming.[9] However, the anaesthetised patient is unable to shiver and it is unpleasant for the patient in recovery where it can increase oxygen demand and worsen pain. This makes the provision of active warming essential in at-risk patients peri-operatively.

Patients are at higher risk of hypothermia and its consequences if any two of the following apply:

▷ ASA grade 2–5 (the risk at 5 is greater than the risk at 2)
▷ pre-operative temperature below 36.0°C
▷ combined regional and general anaesthesia
▷ intermediate or major surgery
▷ at risk of cardiac complications
▷ extremes of age.

Care should be taken to ensure that patients are adequately covered on the ward and during transfer to the operating theatres. Unless surgery is life or limb saving, patients should be actively warmed to a temperature 36.0°C or above before being anaesthetised. Otherwise, active warming should be initiated in the anaesthetic room for all procedures where the total operative time (from first anaesthetic intervention to arrival in recovery) is greater than 30 minutes. For total operative times less than 30 minutes, only higher risk patients should be actively warmed. All intravenous infusions of greater than 500 ml (and all blood products and irrigation fluids) should be warmed.

Body temperature is as vital a clinical sign as the pulse or blood pressure and should be recorded in the hour prior to the patient coming to theatre. It should be measured throughout the operation and in recovery until such time as it reaches 36.0°C. It should be recorded at the same frequency as other vital sign measurements for the first 24 post-operative hours.

NICE have recently published a guideline on the management of IPH which details appropriate peri-operative thermal management.[8] Although it recommends the use of forced-air warming, there is some preliminary evidence that other forms of active warming may be equally effective[10,11] and that combining two methods can improve outcome.[12] In fact NICE have now produced an additional new technology guidance on the use of the Inditherm warming mattress.[13]

The ultimate aim is for all patients to have a core temperature of 36.0 °C or above on arrival in the recovery room.

Suggested indicators

▷ Frequency of temperature measurement.
▷ Temperature < 36.0°C at any time.
▷ Use of body and fluid warming techniques.

Proposed standard or target for best practice

Pre-operative phase

▷ 100% patients should have received written information regarding IPH pre-operatively.
▷ 100% patients should have had their risk of IPH and its consequences assessed and documented pre-operatively.
▷ 100% patients should have their temperature recorded in the hour prior to their arrival in theatres.

ᗞ 100% patients should have a sheet and two blankets or a duvet for their transfer to theatres and be comfortably warm throughout.

ᗞ 100% patients not scheduled for emergency surgery should have a temperature of 36.0°C or above before the start of anaesthesia.

Intra-operative phase

ᗞ 100% of 'at-risk' patients should have active warming from the first anaesthetic intervention unless febrile.

ᗞ 100% ambient theatre temperature at or above 21°C whilst active warming is being established.

ᗞ 100% intravenous infusions greater than 500 ml and all blood products and irrigation fluids should be warmed.

ᗞ 100% patients should have their temperature recorded every half-hour during anaesthesia.

Post-operative phase

ᗞ **Key outcome: All patients admitted to recovery should have core body temperature of 36.0°C or above.**

ᗞ 100% patients should have their temperature recorded every 15 minutes in recovery until they are ready for discharge to the ward.

ᗞ 100% patients should have their temperature recorded on the ward at same frequency as other vital signs.

ᗞ 100% patients should not be discharged from recovery until their temperature is above 36.0°C.

ᗞ 100% patients whose temperature drops below 36.0°C in recovery or on the ward should receive active warming until this is rectified.

Suggested data to be collected	Refer to NICE Clinical Guideline 65.[8] (see audit data collection form available on the RCoA website)
Common reasons for failure to meet standard	Failure to follow NICE guidelines in terms of warming patients. This stems in particular from patients not receiving warming from the first anaesthetic intervention to the start of surgery and failure to monitor patients' temperatures in the peri-operative period.
CPD and Curriculum mapping	Training curriculum: **PB_IK_36**

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Warming devices

C Mark Harper

BACKGROUND

Inadvertent perioperative hypothermia (IPH), defined as core body temperature ≤36.0°C, is a common consequence of anaesthesia. It has a number of adverse effects, including greater intraoperative blood loss and consequent blood transfusion,[1] an increased rate of wound infection,[2] morbid cardiac events[3] and pressure sores,[4] as well as a longer stay in both recovery and hospital.[5] It also causes subjective discomfort.

Maintaining normothermia perioperatively can reduce the incidence of these adverse effects. There are a number of devices that can be used to this end. They may be devices that attempt to conserve the patient's own heat (*passive*) or devices that transfer heat from an external source to the patient (*active*). The latter may warm the patient externally or via warmed intravenous and irrigation fluids.

In 2008, the United Kingdom's National Institute for Clinical Excellence (NICE) produced the 'Management of inadvertent perioperative hypothermia in adults' guideline.[6] Its strength is in the fact that it is a clear endorsement of the clinical and cost benefits of perioperative warming, but its weakness is that it does not cover the full range of technology available due to a sparse research base.

The recommendations can be succinctly summarized as:

- all patients having operations lasting more than half-an-hour, or
- at high-risk of perioperative hypothermia

should receive warming. In addition, all fluid infusions of 500 ml or more should be warmed.[7,8] Together, these recommendations, therefore, encompass the majority of operations and most intravenous infusions, and highlight the need for a wide knowledge of the available warming technologies.

Temperature monitoring is covered elsewhere in this book. However, it should not be forgotten that this is an integral part of perioperative thermal management. Unfortunately, there are limitations to all currently available methods of perioperative temperature monitoring and it should be remembered that accuracy in the laboratory does not necessarily imply accuracy in the clinical setting.

PHYSICAL PRINCIPLES

These are important in understanding how warming devices work, how heat is lost and gained by the body, how warming devices work and, consequently, the best way to go about maintaining normothermia.

Heat generation

In the human body, the generation of energy is by chemical reaction and its quantity determined by the substrates and products of the reaction. Combustion of glucose and protein produces 4.1 kcal/kg, whereas fat provides 9.3 kcal/kg. Although heat generated in this way

depends on the level of activity/metabolism, which is reduced under anaesthesia by 15–40%, most core hypothermia is the result of altered distribution of body heat rather than alterations in the balance of heat production and dissipation.

Heat transfer

Heat transfer can only take place down a temperature gradient. Within the body there is a gradient between core and peripheral 'compartments'. Peripheral tissues are usually 2– 4°C cooler than the core. There is then the much more variable gradient between the peripheral tissues and the environment. This simplistic model is, however, somewhat modified by the body's control over heat distribution via the circulation. The importance of this is demonstrated by the fact that even during warming, the peripheral compartment remains about 1°C less than the core temperature.

Conduction

This is defined as the transmission or conveying of energy through a medium without perceptible motion of the medium itself. In terms of heat, this is the transfer of thermal energy through a substance from a higher- to a lower-temperature region. Heat conduction occurs by atomic or molecular interaction. Core cooling occurs through conduction loss to the cooler peripheral tissues. In the same way, temperature loss through the infusion of cold intravenous fluids may, for practical purposes, be considered a conductive loss.

Convection

This is defined as the transfer of heat through a fluid medium (liquid or gas) caused by molecular motion. This is an important route of heat loss, wherein heating of air in contact with the body causes it to expand and rise resulting in the formation of convective currents that carry away heat. These losses are greatly exaggerated wherever external air currents remove this warmed air more rapidly. It is is the dominant source of heat loss in environments such as laminar flow operating theatres.

Radiation

This is defined as the transfer of heat from one surface to another via photons. It is not, therefore, dependent on the temperature of the intervening air. It is dependent upon the emissivity of two surfaces and the difference between the fourth power of their temperatures in degrees Kelvin. A black body absorbs and emits heat perfectly and has an emissivity of one (the opposite is a perfect mirror). Human skin acts more like a black body having an emissivity of

0.95 for infrared light. This is a significant source of perioperative heat loss.

Evaporation

This is the process whereby heat energy is used to change water from a liquid state into a vapour. This phenomenon which causes an observed heat loss, is governed by the latent heat of vaporization of water and consumes 0.58 kcal for each gram of sweat evaporated. Under normal circumstances and in the absence of sweating evaporation contributes only 10% of heat loss, mainly due to losses from the respiratory tract. However, its contribution becomes quite substantial during operations in which there is significant visceral exposure. It has also been suggested that alcoholic skin preparations may decrease the temperature of a 70 kg person by up to 0.7°C.

Thermal capacity

This is defined as the amount of heat energy required to increase the temperature of a unit quantity of a substance by a specific temperature interval and is significant in both the loss of heat and its prevention. All alterations in body temperature are the result of changes in the heat content of the tissues.

The specific heat capacity of body tissue is 0.83 kcal/kg/°C. In terms of perioperative thermal balance, of additional importance are the specific heat capacities of (dry) air, which is 0.24 kcal/kg/°C, and water, which is 1.0 kcal/kg/°C.

Insulation

Within the body this affects the conductive component of heat loss insofar as fat insulates almost three times as well as muscle. It is also the principle behind passive means of preventing IPH.

DEVICES USED TO PREVENT PERIOPERATIVE HYPOTHERMIA

Passive devices

Although ordinary blankets, bedding and clothes prevent heat loss to some extent, they are not appropriate in the setting of the operating theatre where higher standards of cleanliness are required. The first products specifically designed for this setting were called 'space' blankets. These are made from a lightweight non-permeable material incorporating a reflective layer that reduces the patient's radiant heat losses. The non-permeable element provides insulation from the operating theatre environment and

reduces the convective heat losses. Their effectiveness is partly based on the high emissivity of heat from the human body. They also have the advantage that they meet the safety standards of 'Flammable Fabrics' Acts. However, for the majority of procedures, insulation alone is insufficient in preventing heat losses during anaesthesia, surgical pre-paration and subsequent surgery. There is, therefore, the need to provide heat from an external source.

Active devices

Circulating water devices

Initially, prior to the advent of forced-air warming, patients were placed on circulating hot water mattresses in an attempt to counteract heat loss and maintain normother-mia. In theory the high specific heat capacity of water in the mattress should be very effective at providing heat. In practice, however, these devices only effectively deliver heat to those areas in direct contact with the mattress, which constitutes a relatively small proportion of the body. Furthermore, those small areas in direct contact are under pressure and so have a compromised blood supply that reduces the amount of heat transfer even further. Additionally, in this situation the relatively high thermal capacity of the water is a disadvantage as it increases the likelihood of thermal damage, which has been described at settings of 39°C.

   Newer devices overcome these problems by circulating the water through special garments or pads. They include the Kimberly-Clark Patient Warming System (Figs 30.1A and B), which uses adhesive 'energy transfer' pads with micro-channels for circulating water that can be applied to the back, thighs, chest, or any combination of the three, depending on the site of surgery. Another modern system is the Allon circulating-water garment. This conductive heating garment is divided into separate segments for arms and thighs, which allows clinicians to cover different body surfaces depending on the site of surgery. Perhaps unsurprisingly, given the different thermal characteristics of water and air, both the above have both been shown to be more efficient at warming volunteers than forced-air devices (see below).

Carbon fibre and polymer devices

Carbon fibre heating mattresses consist of electrically con-ductive bundles of this material that criss-cross the device in much the same way as the wire element in electric blankets. When an electric current is passed through the device the resistance of the material causes the mattress to heat up. However, the biggest problem with these is that it is difficult for such systems to deliver uniform heating characteristics, with the consequent risk of burns to a patient. This is because the area of heating surface may be inadequate and the hardness of the bundles means that

Figure 30.1 Kimberly-Clark Patient Warming System. **A**. back pad with warm water microcirculation channels. **B**. warm water delivery and control unit. *Images courtesy of Kimberley-Clark Healthcare.*

these require some form of pressure relief material on top which attenuates the warming performance.

In contrast to carbon fibre, *carbon polymer* theoretically benefits from a higher thermal transfer capacity, more uniform heating characteristics and better elasticity (see below).

The heat generated in the polymer is caused by excitation of the carbon atoms within the polymer due to the passage of an electric current. This is produced by a low-voltage source applied across the edges of the sheet. The polymer increases the electrical resistance by holding the pattern of the carbon particles. The variation in temperature across a sheet the size of an operating table is less than 1°C, thereby delivering heat in a uniform manner over a large surface area. The properties of the polymer also allow a viscoelastic foam to be placed under the warming surface which provides pressure relief superior to a standard operating table mattress or gel pad. The moulding of the foam improves the efficiency of the mattress as the heat is transferred through conduction rather than convection. It also prevents one of the problems with other warming mattresses in that there is less pressure to occlude the skin circulation, which in turn reduces the incidence of thermal damage and pressure sores.

A full-length mattress takes approximately 65W at full power (i.e. during warming up phase). The power needed to maintain temperature varies depending on patient characteristics and ambient conditions. A thermistor on the rear face of the polymer sheet is connected to a microprocessor control unit that regulates the power to the mattress to maintain the selected temperature. This can usually be set at between 37 and 40°C.

The working components are encapsulated in a latex-free cover, with welded seams, which means that the mattress can be cleaned in the same way as an operating table (Fig. 30.2).

The logistical advantages of carbon technologies include that the warming area can be maintained largely irrespective of the surgical access required and the operating theatre is quieter due to the absence of circulating air and complaints from the surgical staff that they are too warm. On the other hand, in circumstances where there is reduced patient contact with the mattress (e.g. lithotomy position) equivalence with the variety of shaped ('specialist') forced-air warming blankets has yet to be established. Recent advances incorporating carbon polymer into blankets may serve to overcome problems of inadequate mattress contact area.

Forced-air warming blankets

These have revolutionized patient warming. Broadly speaking a large volume of air is blown over a 450–1400 W electrical element which warms it to 35–46°C. This is then passed through a 'quilted' blanket that covers the patient (Fig. 30.3). The power consumption is around 850 W for the lower powered devices and up to 1500 W for the more powerful ones (i.e. a factor of 10–20 greater than the carbon polymer mattresses). There is a significant variability in the performance of the different types of forced air heating devices (Table 30.1).

Various different blankets have been developed in order to maximize the surface area covered during different surgical procedures and exposures; including now forced warm air mattresses for positioning underneath the patient. With improving technology, the heating devices themselves can be much smaller and so it has been possible to develop special jackets with portable heaters

Figure 30.2 Inditherm carbon polymer warming mattress. *Images courtesy of Inditherm Medical.*

Figure 30.3 Bair Hugger forced air warming blanket. *Image courtesy of Arizant UK.*

Table 30.1 Efficacy of forced air warming systems with full body blankets in a laboratory simulation. Heat exchange coefficients (h), mean temperature gradients at a calculated surface temperature of 32°C (ΔT at 32°C), 34°C (ΔT at 34°C), 36°C (ΔT at 36°C) and 38°C (ΔT at 38°C) and the resulting heat exchange between the full body blanket and the manikin

SYSTEM	H	Δ (°C) AT				HEAT EXCHANGE (W) AT			
	(WM^{-2} °C^{-2})	32 °C	34°C	36°C	38°C	32 °C	34°C	36°C	38°C
Bair Hugger 505 and full body blanket	21.9	1.40	0.91	0.43	−0.06	30.7	19.9	11.4	−1.6
Bair Hugger 750 and full body blanket	28.0	2.76	2.09	1.31	0.53	77.3	58.5	44.4	18.0
Life Air 1000 S and full body blanket	26.4	1.76	1.17	0.58	−0.02	46.5	30.9	18.5	−0.6
Snuggle Warm SW-3000 and full body blanket	32.2	1.93	1.42	0.91	0.40	62.1	45.7	35.5	15.6
Thermacare and full body blanket	23.6	1.97	1.40	0.83	0.26	46.5	33.0	23.70	7.4
Thermacare and Optisan full body blanket	17.1	2.79	2.00	1.22	0.43	47.7	34.2	25.2	8.9
WarmAir and full body FiltredFlo blanket	13.4	2.61	1.83	1.05	0.27	35.00	24.5	17.0	4.4
Warm-Gard and full body blanket	15.4	3.18	2.65	2.12	1.59	49.0	40.8	39.5	29.6
Warm-Gard and reusable full body blanket	15.3	2.50	1.83	1.16	0.49	38.3	28.0	21.5	9.1
WarmTouch and full body blanket	28.1	1.24	0.74	0.24	−0.26	34.8	20.8	8.2	−8.8
WarmTouch and MultiCover full body blanket	14.5	3.18	2.46	1.74	1.02	46.1	35.7	30.5	17.9

(From Brauer A, English MJ, Steinmetz N, et al. Efficacy of forced-air warming systems with full body blankets. *Can J Anesth* 2007;**54**:34–41, with permission.)

that can be used to keep patients warm throughout the perioperative period.

There are both disposable and reusable products. What is gained in terms of reduced consumables with the latter may be partly lost by the environmental and financial costs of laundering.

Of the single-use types, there are two versions which differ in that one is a closed system whereas the other forces air out through small holes on the side of the blanket facing the patient. There is the unproven possibility that the latter may introduce pathogens into the surgical field. They both have filters on the air intake; although these are not small enough to exclude all pathogens that may also exist on and within the warming unit, there is nothing in the NICE literature review to suggest an increase in infection rates.

Radiant heaters

Radiant heaters are electric heaters that generate heat using infrared radiation in the same way that the sun heats the Earth (Fig. 30.4). The infrared spectrum has a wavelength of 0.7–10 μm. Non-industrial heaters use the medium part of the spectrum (approx. 1.5–5.6 μm), typically utilizing the range 2–4 μm. Radiant heat transfer, unlike conduction and convection, requires no intermediate conductor or convector, as infrared energy, like light, passes directly from the source to the receiver. The rate of heat transfer depends on the emissivity of the source, the absorptivity of the receiver, the difference between their absolute temperatures (raised to the fourth power), and the distance between them.

Figure 30.4 An infrared radiant warmer for infants.

The element on a typical neonatal unit typically consumes 600 W power. They can either generate heat to a set air temperature or, via a feedback mechanism, to a set skin temperature. The danger with the latter is that if the sensor falls off it will read air temperature, which will run the risk of overheating of the patient.

Radiant heaters have the advantage that they provide efficient, uniform and immediate heat, and they are unaffected by air currents, such as those in laminar flow operating theatres. In addition, they do not generate air-currents, which might facilitate the spread of pathogens.

The disadvantages are that they warm the operating staff even more than forced-air warmers, that they may be impractical for patients much larger than 8 kg and that they will only warm exposed surfaces (which can increase evaporative losses). Thus, their use is largely restricted to paediatrics.
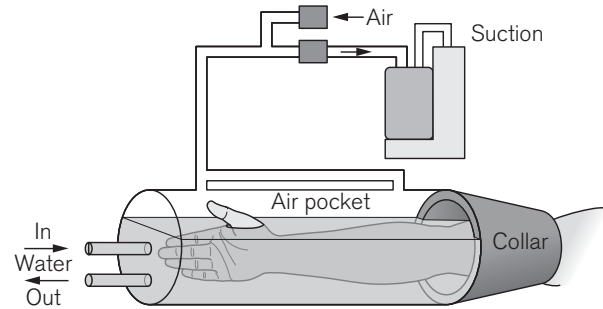
Figure 30.5 Cylindrical transparent plexiglass cylinder. *Redrawn with permission from Rein EB, Filtvedt M, Walloe L, Raeder JC. Hypothermia during laparotomy can be prevented by locally applied warm water and pulsating negative pressure.* Br J Anaesth 2007 Mar;98(3):331–6.

Other devices

A number of alternative surface warming devices have also been developed but which have not yet entered the mainstream of clinical practice. One such device is described below.

Locally applied warm water and pulsating negative pressure

With appropriate methodology it is feasible to warm the whole patient with very localized heat application. One study has shown the device illustrated in Fig. 30.5 to be more effective than forced-air warming used during laparotomy[10].

It consists of a custom-built, tube-shaped, transparent Plexiglass chamber, which is sealed to the proximal part of the arm by a neoprene collar. Warm water at 42.58°C is circulated between the cylinder and a thermostat-regulated water bath, which is circulated at 3.5 l min⁻¹. Prior to commencing warming, the chamber is three-quarters filled, leaving an air pocket from which the air could be evacuated to give negative pressure, which is pulsated between 0 and 240 mmHg.

Devices used to warm intravenous fluids

NICE (2008, see above) in the UK has identified the risk of infusion of cold intravenous fluids as a potential cause of IPH and has issued guidance on the warming of volumes of 500 ml or more in adults. Extrapolating from the thermal capacities of water and body tissues, the infusion of 1 L of fluid intravenously at room temperature will theoretically lead to a decrease in core temperature of >0.2°C in a 70 kg person.

Fluid warmers can be broadly classified into forced air, metal plate, circulating water and infrared devices. There are also high-flow and low-flow versions with large variations in performance especially at higher flow rates (Tables 30.2 and 30.3).

Table 30.2 Simulated clinical evaluation of four standard fluid warming devices to measure output temperature and flow rates (mean and range)*

	NO WARMING DEVICE	BAIRE HUGGER	HOTLINE	STANDARD RANGER	FLUIDO
Output temperature, °C	22.9	26.3	31.1	35.2	35.3
Flow					
Measured (ml min^{-1})	185 (184–185)	68 (68–73)	152 (152–154)	153(152–154)	141 (140–142)
Recommended**	–	≤17	≤83	≤150	15–800
% change in flow from no warmer	–	−63	−16	−16	−23

*When subject to gravity flow with 1 m head of fluid compared to no warming device (all through a standard IV set and 14 G cannula).
**Manufacturer's recommended maximum flow rates are given for delivery of fluid at 37°C.[11]
(From Turner M, Hodzovic I, Mapleson WW. Simulated clinical evaluation of four fluid warming devices. *Anaesthesia*. 2006;**61**:571–5, with permission.)

Table 30.3 Simulated clinical evaluation of four standard fluid warming devices to measure output temperature and flow rates (mean and range)*

	GRAVITY FLOW	PRESSURE-DRIVEN FLOW			
	NO WARMING DEVICE	BAIRE HUGGER	HOTLINE	STANDARD RANGER	FLUIDO
Output temperature, °C	22.9	23.9	26.3	31.2	35.5
Flow (ml min^{-1})	185 (184–185)	225 (224–228)	375 (372–380)	407(404–410)	446 (442–448)
% change in flow from gravity flow with no warmer	–	+22	+103	+120	+141

*With giving set pressurised to 300 mmHg compared to no warming device with gravity flow (all through a standard IV set and 14 G cannula).[11]
(From Turner M, Hodzovic I, Mapleson WW. Simulated clinical evaluation of four fluid warming devices. *Anaesthesia*. 2006;**61**:571–5, with permission.)

Forced-air/coil warmers

As can be seen from the entry for the Baire Hugger (Fig. 30.6) device in Table 30.2, these are the least effective and consist simply of a coil placed inside the hose of a forced air warming mattress. Their poor performance can be explained by the different thermal capacities of air and water (see above). In this case air, which has a low capacity, is being used to heat fluid which has a high capacity.

Plate warmers

In these devices the fluid passes through a special cartridge that brings it into indirect contact with an electrically heated metal plate. The temperature of the plate is set to 40°C (rather than 37°C) to compensate for the loss of heat over the length of line between the warmer and the patient. Small warmer units are also available that can be placed close to the patient's infusion site (Fig. 30.7). The water channel of the cartridge is made from plastic with one side bonded to an aluminium-serrated plate. The latter is placed in direct contact with the heater element and is responsible for the transfer of heat to fluid passing through the plastic channels in the cartridge.

Counter-current warmers

These attempts to offset the losses between a warming device and the patient by placing a circulating warm water jacket around the intravenous line along its whole length. Although the warmed water does not come into direct contact with intravenous fluids, bacteria can proliferate in the reservoir and so the possibility of cross-infection remains.
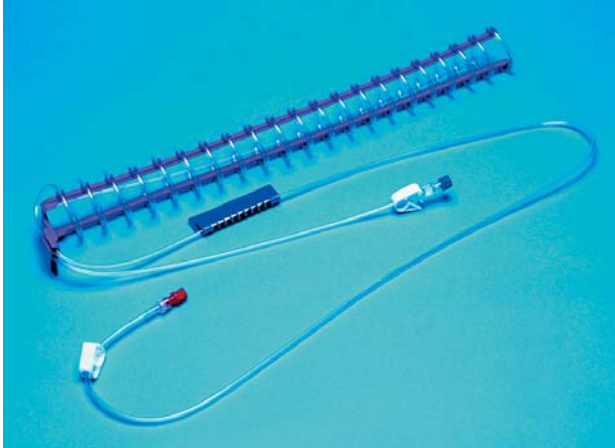
Figure 30.6 Dry air fluid warming coil.

Figure 30.7 The Vital Signs enFlow dry plate warmer. The small IV casette is shown inserted into the warming plate. *Image courtesy of GE Healthcare.*

Connect to IV bag

De-aeration chamber

Upper channel IR temp probe measure points

Transparent frontside with windowed metal non-conductive layer

Lower channel IR temp probe measure points

Arrow indicate fluid flow in channels

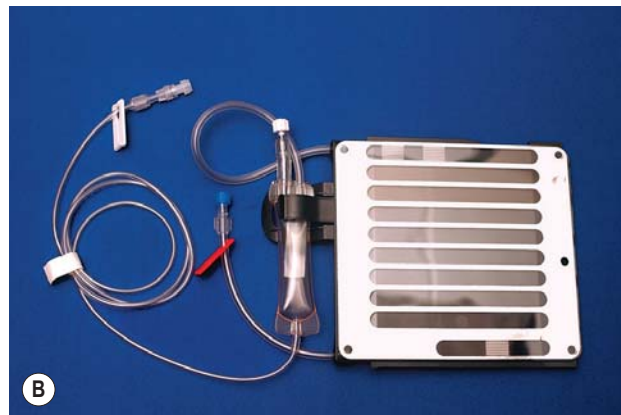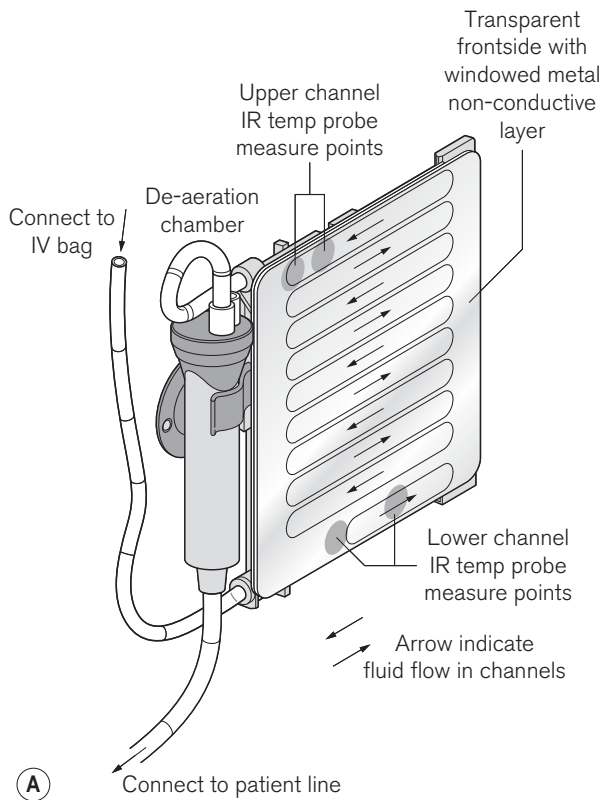(A) Connect to patient line

(B)

(C)

Figure 30.8 Fluido dry fluid warmer. **A.** Stucture. **B.** Insert. **C.** External appearance.
Image of Fluido device (C) courtesy of TSCI International, BV.

Infrared flow compensated fluid warmers

The Fluido system (Fig. 30.8) is a dry fluid warming system. Fluid channelled through a rigid cassette is heated by four infrared lamps with a maximum output of 1200 W.

By calculating fluid flow rate from the temperature change across two set points the device is able to alter the output temperature of the fluid to compensate for the expected heat loss along the fluid administration set to the patient. Flow rates up to 800 ml min^{-1} are claimed at temperatures of up to 39°C at the patient.

High-flow fluid warmers

Devices designed for infusing fluids at high flow rates require both lower resistance 'cartridges' and some form of pressurization.

The 'Level One' (Fig. 30.9) system from Smiths Medical uses heated water at 42°C and an aluminium counter current heat exchanger to deliver flow rates up to a claimed 1400 ml min^{-1}. Two rigid housings for the bags of infusate are pressurised to 300 mmHg by an in built compressor to deliver an uninterrupted flow. The maximum effective flow rate for fluids at 10°C is approximately half of that for fluids stored at 20°C. These devices have been inadvertently charged with bags partly containing air and have delivered fatal air emboli into patients. Although newer versions have an air detector, this can be bypassed. There is also an upgrade available for the older machines, but the risk of air embolus remains significant with any system that uses a pressurised infusion bag.

The Fluido infra red warmer (see above) can also be used as a high flow device. The casette can be fitted with two infusion lines that are inserted into IV fluid bags pressurised by pneumatic chambers fed by a compressor. The AirGuard component (Fig. 30.10) protects against air embolism. If the fluid in the chamber falls below a fixed level a valve will close the supply tubing, to prevent the infusion of air. In addition, an infrared tube sensor continuously monitors the presence of this tubing to ensure that it is fixed correctly into the shut-off valve. The complete system is mounted on a drip stand (Fig. 30.11).

Figure 30.9 Level 1, high flow fluid warming system. *Image courtesy of Smiths Medical, UK.*

(A)

Figure 30.11 Fluido High flow system.
Image courtesy of TSCI International BV.
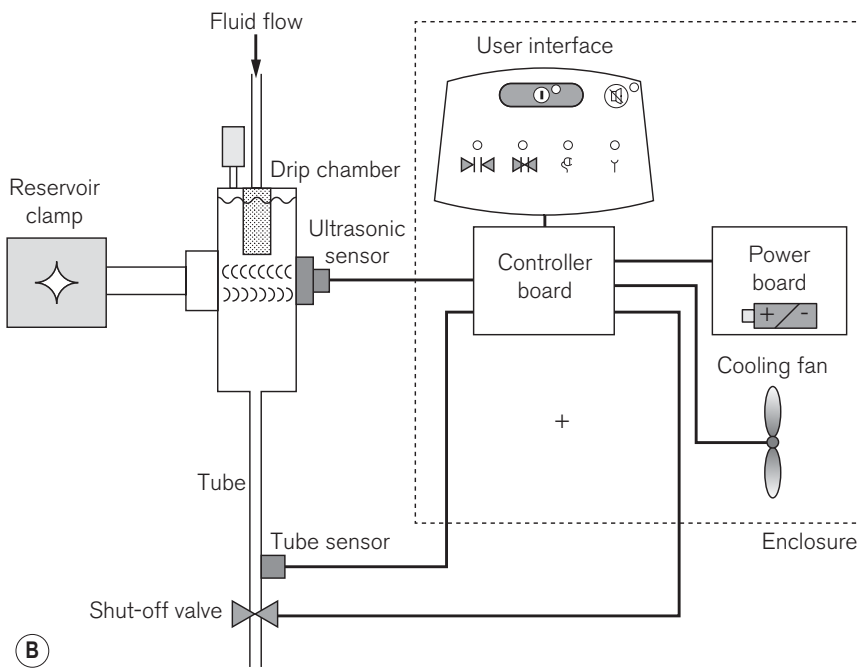
(B)

Figure 30.10 (**A**) The Fluido AirGuard. (**B**) A schematic of the Fluido AirGuard system.
Images courtesy of TSCI International BV.

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FURTHER READING

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