

ARTICLE TITLE

Resistant Fabric Warming is a viable alternative to Forced Air Warming to Prevent Inadvertent Perioperative Hypothermia during Hemiarthroplasty in the elderly

RUNNING TITLE

RFW is a viable alternative to FAW

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STRUCTURED SUMMARY

Background:

Surgical site infection (SSI) is associated with inadvertent perioperative hypothermia (IPH). This can be prevented by active patient warming. However, results from comparisons of warming techniques are conflicting. They are based mostly on elective surgery, are from small numbers of patients, and are dominated by the market leader, Forced Air Warming (FAW). Furthermore, the definition of hypothermia is debatable and systematic reviews of warming systems conclude that a stricter control of temperature is required to study the benefits of warming.

Aim:

To analyse core temperatures in detail in a large subset of elderly patients who took part in a randomised trial of patient warming following hemiarthroplasty who had received constant zero-flux thermometry to record their temperature.

Methods:

Regression models with a fixed effect for warming group and covariates related to temperature were compared for 257 participants randomised to FAW or Resistant Fabric Warming (RFW) from a prior clinical trial.

Findings:

Those in the RFW group were -0.08°C cooler and had a cumulative hypothermia score -1.87 lower than those in the FAW group. There was no difference in the proportion of hypothermic patients at either $<36.5^{\circ}\text{C}$ or $<36.0^{\circ}\text{C}$.

Conclusions:

This is the first study to provide accurate temperature measurements in patients undergoing a procedure predominantly under regional rather than general anaesthetic. It shows that RFW is a viable alternative to FAW for preventing IPH during hemiarthroplasty. Further studies are needed to measure the benefits of patient warming in terms of clinically important outcomes.

KEYWORDS

1. Forced air warming
2. Resistive fabric warming
3. Inadvertent perioperative hypothermia
4. Surgical site infection
5. Hemiarthroplasty
6. Zero-flux thermometry

ABBREVIATIONS

IPH	Inadvertent Perioperative Hypothermia
SSI	Surgical Site Infection
FAW	Forced Air Warming
RFW	Resistant Fabric Warming

INTRODUCTION

Inadvertent perioperative hypothermia (IPH) during surgery is associated with poorer clinical outcomes, including increased morbidity ^[1], cardiac complications ^[2] and delay in recovery ^[3], and numerous studies have linked IPH with an increased risk of surgical site infection (SSI) ^[4-7]. Furthermore, whilst a reduction in core temperature of as little as 0.5°C has been shown to increase the amount of blood loss and requirement for transfusion in both general ^[8] and arthroplasty ^[9-11] patients, transfusion is positively correlated in a dose-dependent fashion with increased risk of infection following arthroplasty surgery ^[12].

Early intervention to maintain normothermia reduces (SSI), cardiovascular events, perioperative pain, postoperative pressure ulcers and bleeding, as well as the duration of surgery, length of stay in intensive care and total hospital stay ^[13]. Consequently, active

warming, recommended by the National Institute for Health and Care Excellence (NICE) ^[14] and the World Health Organization ^[15], has become routine unless induced hypothermia is required. The incidence of IPH in orthopedic procedures, however, remains high ^[16, 17] and results from comparisons of the different warming techniques available are conflicting.

Several intraoperative warming methods exist to maintain normothermia ^[18]. FAW has traditionally been considered the most effective, non-invasive method of transferring heat to the patient and is still the dominant technique in use ^[19, 20]. RFW is an alternative air-free method that uses conduction rather than convection; it is included as an option for perioperative warming in recent NICE guidelines when FAW is not possible ^[14]. There have been numerous studies comparing patient warming techniques, but all have included low numbers of patients, lacked continuous, standardised temperature measurement and have been primarily for elective surgery. Some studies have found FAW to be superior ^[21-24] with RFW achieving lower core temperatures ^[21, 23-25], whereas other studies have either demonstrated non-inferiority ^[26-31] or equivalence ^[29; 31-36] of RFW compared to FAW. Consequently, systematic reviews of warming systems have not been able to identify which technique is better for warming the patient or reducing post-operative complications. Previous studies conclude that a stricter control of temperature is required to assess the benefits of warming in relation to the risk of SSI ^[20, 37].

Accurate continuous perioperative core temperature measurement is integral to preventing IPH ^[14], and, therefore, to preventing SSI, but there is continued debate over the definitions of normal temperature and hypothermia ^[38]. Currently, IPH is defined as a core temperature of less than 36.0°C ^[14]. This is a figure determined by consensus rather than

being derived from direct evidence. Some studies suggest that aggressive warming maintain a temperature above 36.5°C reduces the incidence of SSI ^[4] and reduces the incidence of intraoperative blood loss ^[10]. It is of clinical importance, therefore, to determine the optimal threshold for hypothermia in terms of clinical outcome but this requires a gold standard technique for temperature measurement.

Conventional, reliable core body temperature monitors are invasive whereas traditional, non-invasive methods are less suitable for continuous monitoring ^[39]. Zero-flux thermometry, which estimates core body temperature from the intact skin at the forehead, first demonstrated by Fox and Solman in 1971 ^[40], has comparable accuracy to conventional core temperature measurements used in trauma, gynaecological and vascular surgery ^[41, 42], and equal accuracy to an oesophageal probe ^[43]. It can be used to provide continuous temperature readings throughout the perioperative period.

This analysis looks at continuous, standardised temperature measurements, obtained using Zero-flux thermometry, in a large subset of patients (n=257) who participated in the RIIIO pilot study ^[44, 45] in which patients had been randomly allocated to warming with either RFW or FAW during non-elective hemiarthroplasty for hip fracture surgery. We have compared the incidence of hypothermia and the time spent hypothermic at <36.0°C and <36.5°C. This is the first study to provide accurate, continuous temperature measurements in patients undergoing a procedure predominantly under regional rather than general anaesthetic.

METHODS

Patient Population

This analysis uses data collected during a parallel group, open label randomised pilot study comparing post-operative infection rates following orthopaedic implant surgery using RFW or FAW (the RIII Pilot Study), in which participants were randomised by 1:1 allocation to RFW or FAW (www.isrctn.com/ISRCTN74612906) [44, 45]. A subset of the participants involved in that study had temperature measurements by zero-flux thermometry. Temperatures were recorded at 5-minute intervals during surgery with the beginning and end of surgery defined as the first and last zero-flux thermometry readings respectively. In all cases, BairHugger (Arizant Healthcare, Inc., Eden Prairie, MN, USA) was the method of FAW used. Either UniqueTemp® (Geratherm, Geschwenda, Germany) or the Alpha Patient Warming System (Inditherm Medical, Wath-upon-Deane, UK or Inspiration Healthcare, Leicester, UK) was used for the method of RFW.

Sample Size

The sample size for this analysis was pre-defined in a statistical analysis plan such that with 125 participants in each group, there would be 80% power for 5% significance to detect a difference in the proportion hypothermic of approximately 16% between groups (12% for 0.05 vs 0.17, 16% for 0.15 vs 0.31, 18% for 0.32 vs 0.5). The analyses here used a superiority testing framework – the null hypotheses tested were those of equality between the intervention groups.

Statistical Analyses

The primary objectives were comparisons of (a) the incidence of hypothermia at any time during surgery and at the end of surgery for temperature below 36.5°C and 36.0°C, (b) average temperature during surgery, and (c) cumulative analyses of the time spent hypothermic at <36.5°C and <36.0°C between the intervention groups. A secondary objective was comparison of the time from the end of surgery until discharge from hospital between the intervention groups. Baseline participant characteristics are summarised by trial group: normally distributed variables by means and standard deviations, skewed variables by the medians and interquartile ranges, and categorical variables by frequencies and percentages in each category.

Each model used for analysis of the primary outcomes compared the intervention groups, adjusted for participant temperature at the start of surgery (mean-centred), site (compared to Heart of England NHS Foundation Trust, the site recruiting the largest number of participants with temperatures measured by zero-flux thermometry), age (mean-centred), sex (males compared to the larger female group) and ASA grade (ASA I and III compared to the larger ASA II group). 252 out of 257 participants had complete data for these variables and were included in the models. BMI was not included in the models due to missing data (only 191 participants had BMI recorded). Covariates were checked for collinearity before being included in the final regression models. Linear, logistic, tobit or Cox regression models were used depending on distribution of the relevant outcome variable (as described below) but each contained the same set of covariates. All analyses were performed in Stata 16.0 (StataCorp. 2019. *Stata Statistical Software: Release 16*. College Station, TX: StataCorp LLC.). Histograms and line plots were produced in GraphPad Prism 8.

Average temperature during surgery

A mixed effects linear regression model was fitted for average temperature during surgery. A random effect for patient was included to account for correlation within individuals. Residuals at both levels were checked to assess if the assumptions of linear regression were appropriate - robust standard errors were used as the model residuals at the participant level were not normally distributed. The estimated effects trial group and for each covariate are reported with 95% confidence intervals (95% CI) and *P*-values.

Hypothermia

A logistic regression model was fitted to compare the odds of hypothermia during surgery and at the end of surgery in each intervention group. The estimated odds ratio (OR) for the trial group effect and for each covariate are reported with 95% CI and *P*-values. The final models fitted had at least 5 cases of hypothermia (or cases of no hypothermia, whichever was lower) per covariate in the model ^[46], except for the hypothermia <36.0°C at end of surgery model, which had 4.1 cases per variable, but was not refitted with fewer covariates to maintain consistency with other models.

Cumulative hypothermia score

Cumulative hypothermia scores, for the time spent hypothermic at <36.5°C and <36.0°C, were calculated as the sum of the temperature at each time point minus 36.5 or 36.0 respectively. The further below 36.5°C or 36.0°C, the greater the contribution of that time point to the overall score, for which a lower value would indicate more time/lower

temperature. The scores, which did not take into account length of surgery, represent the actual time spent hypothermic rather than the time spent hypothermic relative to the length of the operation. A tobit regression model was chosen and fitted for each of the cumulative hypothermia scores because it allows for censoring of a normally distributed variable at an upper or lower limit. In this case, the censoring was at 0, as the cumulative hypothermia variables did not take into account values above 36.5°C/36.0°C.

Time from surgery to discharge

A Cox proportional hazards regression model was used to compare the time from surgery to discharge between the intervention groups. The proportional hazards assumption was tested, and no evidence was found to suggest that it was inappropriate. The hazard ratio is reported with its 95% CI and *P*-value.

Missing data

For data that were missing for a zero-flux measurement but where readings were available before and after the missing data point, the missing data point was replaced with the mean of the preceding and following points. 174 missing data points were imputed for 118 participants (45.1% of 257). No imputation of missing data was performed for any other variables.

RESULTS

Figure 1 shows how participants were selected from the RIIIO Pilot Study to form the population analysed here (257/515; 50%). Baseline and surgical characteristics are shown in Tables I and II respectively, with the full data set compared to the participants without zero-flux thermometry in the supplementary file (Table S1). The length of surgery was similar for FAW and RFW, as shown in Table II. The final two zero-flux thermometry readings for two participants fell outside the range 33-40°C and were removed from the analysis; neither of these participants died during surgery. Following imputation of data, only 5 participants (2%) had fewer than 5 temperature recordings. A total of 3884 readings were analysed. The median (IQR) number of data points per participant was 15 (11-19). A summary of the primary outcomes is shown in Table III with the full model output in Tables S2 – S5.

Temperature during surgery

Line plots of the individual and median temperatures during surgery are shown in Figure 2. Temperature readings for those in the RFW group were -0.08°C (95% CI, -0.15 to -0.01) cooler than those in the FAW group on average ($P=0.030$). The intraclass correlation coefficient estimated from this model was 0.77 (95% CI, 0.71-0.81), indicating high correlation between the repeated measurements within participants, as expected.

Hypothermia

There was no evidence of a difference in the proportion of participants that experienced hypothermia at <36.5°C either during surgery (FAW 59.2%, RFW 58.3%; OR, 1.04, 95% CI, 0.50-2.17; $P=0.910$) or at the end of surgery (FAW 45.6%, RFW 49.2%; OR, 1.60, 95%

CI, 0.84-3.04; $P=0.152$) between the RFW and FAW groups. Likewise, there was no evidence of a difference in the proportion of participants that experienced hypothermia at $<36.0^{\circ}\text{C}$ either during surgery (FAW 30.4%, RFW 26.5%; OR, 1.61, 95% CI, 0.60-4.33; $P=0.345$) or at the end of surgery (FAW 19.2%, RFW 18.2%; OR, 2.12, 95% CI, 0.81-5.54; $P=0.126$).

Cumulative hypothermia scores

There was evidence of differences in cumulative hypothermia scores between the RFW and FAW groups for both $<36.5^{\circ}\text{C}$ and $<36.0^{\circ}\text{C}$. On average, those in the RFW group had a cumulative hypothermia score -1.87 lower than the FAW group for $<36.5^{\circ}\text{C}$ (95% CI, -3.31 to -0.42; $P=0.012$). Similarly, those in the RFW group had a cumulative hypothermia score -2.02 lower than the FAW group for $<36.0^{\circ}\text{C}$ (95% CI, -3.58 to -0.46; $P=0.011$). The distributions of the cumulative hypothermia scores for time spent hypothermic at $<36.5^{\circ}\text{C}$ and $<36.0^{\circ}\text{C}$ were left skew. 106 participants did not have any temperature recordings $<36.5^{\circ}\text{C}$ and 184 participants did not have any $<36.0^{\circ}\text{C}$. The distribution of the 151 participants with recordings $<36.5^{\circ}\text{C}$ and 73 participants with recordings $<36.0^{\circ}\text{C}$ is shown in Figure 3.

Time from surgery to discharge

The time from surgery to discharge was calculated for 223 participants (109 in the FAW group and 114 in the RFW group). The overall median time to discharge was 14 days in both the FAW group (IQR, 8-22) and the RFW group (IQR, 9-26). There was no evidence of a difference in time from surgery to discharge between FAW and RFW (hazard ratio, 0.88, 95% CI, 0.67-1.16; $P=0.367$). The full model output is shown in Table S6.

Death within 30 days of surgery

Fourteen participants died within 30 days of surgery, 8 (6.4%) in the FAW group and 6 (4.5%) in the RFW group, but no statistical modelling was performed for this outcome due to the small number of events.

DISCUSSION

FAW is the patient warming system endorsed by NICE as the preferred method with RFW included in the guidelines as an alternative when FAW is not possible ^[14]. Systematic reviews a decade apart confirm that FAW is still the dominant warming technology in use, no doubt as a result of the NICE guidelines, and yet it remains unclear if FAW is the optimal method for warming the patient and reducing post-operative complications ^[19, 20, 47]. In this analysis, there was no difference in the proportion of participants that experienced hypothermia either during surgery or at the end of surgery between the RFW and FAW groups, whether hypothermia was defined as $<36.5^{\circ}\text{C}$ or $<36.0^{\circ}\text{C}$. Although participants in the RFW group were found to be -0.08°C cooler on average than those in the FAW group, while statistically significant, a difference of just 0.08°C has not been shown to be of clinical importance.

The overall observed rate for hypothermia was 28.4% during surgery and 18.7% at end of surgery. Frisch and colleagues ^[17] reported a lower IPH rate of 17% in similar patients and showed that lower BMI and increased age were positively associated with hypothermia. This analysis showed equal effectiveness of FAW and RFW in a cohort of patients that were elderly (mean age 85.4 years; SD 6.9), generally frail, had significant comorbidities (72% had 1 or

more co-morbidity) and low BMI (mean BMI 23.9kg/m²; SD 4.8). Likewise, no difference was observed between the groups in terms of length of hospital stay.

The main strengths of this analysis are firstly, that it is based on prospectively collected data from a large cohort of randomised patients, and secondly, that the temperature measurements were continuous and standardised via the use of zero-flux thermometry which generated 3,710 readings. This analysis shows conclusively that FAW and RFW are equally effective at preventing IPH in the elderly, a cohort that is particularly vulnerable to infection, and is the first study to provide accurate, continuous temperature measurements in patients undergoing a procedure predominantly under general anaesthetic. The main limitation of this analysis was the inability to compare clinical outcomes meaningfully due to the lack of data for blood loss and the low numbers of deaths and surgical site infections. A clinical trial comparing FAW and RFW involving more than 9,000 participants would be necessary to fully investigate the potential benefits of aggressive warming on clinical outcomes.

Studying the time spent hypothermic may be a more accurate way of determining which warming method is most effective ^[48]. A small effect was observed in this analysis, with cumulative hypothermia scores (a quantification of the time and magnitude of hypothermia) in the RFW group slightly lower at both <36.5°C and <36.0°C than the FAW group. The implication of this small difference in cumulative hypothermia score is uncertain in terms of long-term clinical outcome, however, which warrants further investigation.

CONCLUSIONS

Preventing IPH is an important and effective way of managing the vulnerability to infection. This detailed analysis of continuous, standardised temperature measurements during non-elective hemiarthroplasty for fractured neck of femur, in patients randomised to

FAW or RFW, shows that RFW is similarly effective as FAW in preventing IPH in the elderly. This is significant in terms of the current NICE guidelines recommending FAW over RFW for the prevention of IPH. A larger clinical trial is required to determine the optimal method of patient warming for preventing SSI. Likewise, further study of aggressive patient warming in relation to clinical outcomes is needed to ascertain if hypothermia should be defined as <36.5°C rather than <36.0°C.

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TABLES

Table I: Baseline participant characteristics recorded by allocated intervention

	Forced Air Warming			Resistive Fabric Warming			Overall		
	Mean	SD	n	Mean	SD	n	Mean	SD	n
Age (years)	86.0	6.8	124	85.0	7.0	132	85.4	6.9	256
Height (m)	1.64	0.12	93	1.64	0.10	103	1.64	0.11	196
Weight (kg)	64.4	16.6	92	63.6	14.6	106	64.0	15.5	198
BMI (kg/m ²)	24.1	4.9	90	23.7	4.7	101	23.9	4.8	191

Table II: Variable participant characteristics by allocated intervention

	Forced Air Warming		Resistive Fabric Warming		Overall	
	No.	%	No.	%	No.	%
Sex						
Female	78	62.9	89	67.4	167	65.2
Male	46	37.1	43	32.6	89	34.8
ASA Physical Status						
ASA II	16	13.0	18	14.0	34	13.5
ASA III	85	69.1	92	71.3	177	70.2
ASA IV	22	17.9	19	14.7	41	16.3
ASA V	0	0.0	0	0.0	0	0.0
Laminar flow during surgery	122	98.4	129	97.7	251	98.0
Surgical procedure						
Cemented Prothesis	85	68.5	99	75.0	184	71.9
Uncemented Prothesis	39	31.5	33	25.0	72	28.1
Length of surgery ^a (minutes)	Median 80.0	IQR 60.0 to 100.0	Median 75.0	IQR 62.5 to 100.0	Median 80.0	IQR 60.0.to 100.0

ASA, American Society of Anaesthesiologists

^a Length of surgery was calculated from the number of 5minute readings plus 5

Table III: Primary Outcomes

	Forced Air Warming		Resistant Fabric Warming		Overall	
	Mean	SD	Mean	SD	Mean	SD
Average temperature during surgery ^a	36.6	0.61	36.5	0.59	36.6	0.60
	No.	%	No.	%	No.	%
Number participants experiencing hypothermia						
<u>During surgery</u>						
<36.5°C	74	59.2	77	58.3	151	58.8
<36.0°C	38	30.4	35	26.5	73	28.4
<u>At end of surgery</u>						
<36.5°C	57	45.6	65	49.2	122	47.5
<36.0°C	24	19.2	24	18.2	48	18.7
	Median	IQR	Median	IQR	Median	IQR
Cumulative hypothermia score ^b						
<36.5°C	-0.7	-4.2 to 0.0	-0.4	-4.9 to 0.0	-0.6	-4.4 to 0.0
<36.0°C	0.0	-0.6 to 0.0	0.0	-0.2 to 0.0	0.0	-0.4 to 0.0

^a Average temperature during surgery was calculated as the mean of the participants' average temperature during surgery

^b Cumulative hypothermia score is a quantification of the time and magnitude of hypothermia at <36.5°C and <36.0°C

LEGENDS TO FIGURES

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing the sub-population of participants from the RIIiO Pilot Study ^[44, 45] that formed the temperature analysis population. FAW, forced air warming; RFW, resistive fabric warming.

Figure 2: Line graphs of overall temperatures in the FAW group (A) and RFW group (B).

Figure 3: Histograms showing the distribution of cumulative hypothermia scores under 36.5°C (A and B) and under 36.0°C (C and D) by intervention group.