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ORIGINAL ARTICLE

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An open-label, randomised controlled trial on the effectiveness of the Orve + wrap® versus Forced Air Warming in restoring normothermia in the postanaesthetic care unit

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Abstract

Aims and objectives: To determine the clinical effectiveness and safety of the Orve + wrap® thermal blanket.

Background: Inadvertent perioperative hypothermia is a common problem in postanaesthetic care units and can have significant effects on patients' postoperative morbidity. Despite its commercial availability, there is no clinical evidence on the effectiveness of Orve + wrap®.

Design: A single centre prospective, open-label, noninferiority randomised controlled trial.

Methods: Postoperative hypothermic (35.0–35.9°C) patients who had undergone elective surgery were randomised to receive either Orve + wrap® or Forced Air Warming during their PACU stay. Patient temperatures were recorded every 10 min using zero-heat-flux thermometry. This study is reported using CONSORT Extension checklist for noninferiority and equivalence trials.

Results: Between December 2016–October 2018, 129 patients were randomised to receive either Orve + wrap® blanket (n = 65, 50.3%) or Forced Air Warming (n = 64, 49.7%). The mean 60-min postoperative temperature of patients receiving Orve + wrap® blanket was 36.2 and 36.3°C for the patients receiving Forced Air Warming. The predefined noninferiority margin of a mean difference in temperature of 0.3°C was not reached between the groups at 60 min. Additionally, there were no statistical differences between adverse event rates across these groups.

Conclusions: In the context of this study, warming patients with the Orve + wrap® was noninferior to Forced Air Warming. There were comparable rates of associated postoperative consequences of warming (shivering, hypotension, arrhythmias or surgical site infections), between the groups.

Relevance to clinical practice: The Orve + wrap® potentially provides an alternative warming method to Forced Air Warming for patients requiring short-term

This study was prospectively registered on the ISCRTN database (ISRCTN11563874).

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postoperative warming. However, there are still a number of unknowns regarding the Orve + wrap® performance and further exploration is required.

KEYWORDS

body temperature, orthopaedics, PostOperative Care, postoperative sequelae, randomised controlled trials, temperature measurement

1 | INTRODUCTION

Inadvertent perioperative hypothermia, core temperature below 36°C, remains a common occurrence in clinical practice (Karalapillai et al., 2013; National Institute for Health & Care Excellence [NICE], 2016). In addition, NICE guidance (2016) recommends targeting a normal temperature range of between 36.5–37.5°C for adult patients, except when otherwise clinically indicated.

The risk of developing inadvertent perioperative hypothermia varies widely (Alderson et al., 2014; Al-Qahtani & Messahel, 2014; Harper, Andrzejowski, & Alexander, 2008) but has been found to be as high as 73.5% in a cohort of orthopaedic patients (Kiekkas, Poulopoulou, Papahatzi, & Souleles, 2005). It is precipitated by exposure of the skin and internal organs, ambient use of fluids and gases, combined with the use of sedatives and anaesthetic agents inhibiting the physiological response to cold (Alderson et al., 2014). Those most susceptible include the older people, patients with cancer and chronic conditions, burn victims and patients with thyroid dysfunction (Warttig, Alderson, Campbell, & Smith, 2014).

The sequelae of perioperative hypothermia can result in an increased morbidity (Billeter, Hohmann, Druen, Cannon, & Polk, 2014), including cardiac complications (Sessler, 2001), higher blood transfusion rates (Rajagopalan, Mascha, Na, & Sessler, 2008) and the delaying of wound healing leading to increased risk of surgical site infections (Melling, Ali, Scott, & Leaper, 2001).

Whilst avoidance of hypothermia is desirable, it is often difficult to achieve. Therefore, the institution of techniques to rewarm the patient promptly is essential to minimise potential complications, whilst at the same time ensuring interventions are well tolerated and effective.

1.1 | Background

There are two different approaches to rewarming. Active warming, comprising of the application of an external heat source, that is Forced Air Warming (FAW) and underbody resistive heating. Alternatively, passive rewarming consists of thermal insulation, whereby the heat generated from the patient is conserved to enable rewarming to occur, that is additional cotton blankets or reflective blankets. Currently, two Cochrane systematic reviews (Alderson et al., 2014; Warttig et al., 2014) found no clear evidence of the warming effects of thermal insulation on core temperature during surgery or in the postoperative period, resulting in advocating the use of Forced Air Warming.

What does this paper contribute to the wider global community?

- This study provides the first insight into the clinical effectiveness of the Orve + wrap® blanket.
- The Orve + wrap® could be used as an alternative intervention to Forced Air Warming in postoperative warming.
- The Orve + wrap® has a comparable safety profile to Forced Air Warming.

One new passive warming device is the Orve + wrap® thermal insulation blanket (Orvecare®) (Figure 1). The Orve + wrap® is a Class I medical device, comprised of a foil blanket in combination with a fleece lining. Under laboratory conditions, it has demonstrated the ability to absorb and retain heat providing effective insulation [Data on file]. The Orve + wrap® blanket can be used from ambient temperature or prewarmed in a blanket warmer, and the manufacturers currently advocate its use in prehospital, hospital, survival and veterinary applications. There are currently no randomised controlled trials on the effectiveness of the Orve + wrap® in a clinical environment or direct comparisons against other warming devices.

With a paucity of evidence of the Orve + wrap's® clinical performance, an assessment of the Orve + wrap's® predicted performance is based on the balance of laboratory data supplied by the manufacturer [Data on file] and the results of a Cochrane review (Alderson et al.,

FIGURE 1 Orve + wrap® blanket [Colour figure can be viewed at wileyonlinelibrary.com]

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2014), which highlighted 0.5–1.0°C higher mean temperatures in patient who received Forced Air Warming compared with passive warming devices. As a result, we hypothesise that there will be no clinically important difference between patient's temperatures at 60 min for patients receiving either the Orve + wrap® or Forced Air Warming.

2 | METHODS

We conducted a single centre, parallel design, stratified, open-label, noninferiority, randomised controlled trial. The protocol was reviewed by the National Research and Ethics Service, Leeds West committee (16/YH/0097) and registered on the ISCRTN database (ISRCTN11563874). In addition, patient and public review of the protocol was undertaken by the Trans Humber Consumer Research Panel.

The study was performed at Castle Hill Hospital, East Yorkshire, UK between December 2016–October 2018. Adult patients (≥16 years) planned for major (>90 min) surgery were screened from elective theatre lists, initially from eight orthopaedic and latterly three cardiothoracic surgeons. Patients were excluded if they were unable to provide informed consent, had known thyroid dysfunction, already participating in a conflicting research study or unable to understand English language.

Postsurgery, immediately on admission to a postanaesthetic care unit (PACU), a noninvasive zero-heat-flux (ZHF) temperature sensor (SpotOn™, 3M) was used to measure the patients' temperature (after a period of sensor stabilisation), with placement on the patient's lateral forehead. The patient's corresponding tympanic temperature (Genius 3, Cardinal Health, Dublin) was also taken as part of standard care.

Patients were randomised to receive either a warmed Orve + wrap® blanket or a Forced Air Warming blanket, if their temperature was between 35.0–35.9°C. Patients outside of this temperature range were managed as per normal local practice and not randomised into the study.

Randomisation occurred on a 1:1 basis, using permuted blocks of 4, 6 and 8 with stratification for age (16–64 years and ≥65 years) and anaesthesia type (General and Spinal ± sedation) via a web-based generation software (Sealed Envelope™) and was performed by a Research Nurse at the bedside.

Postrandomisation, patients in the intervention group received an Orve + wrap® blanket directly to the skin that had been warmed in a blanket warmer (Kingfisher, LTE Scientific) set at 50°C, and this was then covered with a single cotton sheet.

Patients in the control arm were warmed using either a Warm Touch™ WT 6000 or Warm Touch™ 5300 warming unit (Covidien) with a Warm Touch™ full body warming blanket (Covidien) and covered with a single cotton sheet.

Patients then had their temperature recorded every 10 min with the ZHF thermometry and tympanic probe, up to and including discharge from PACU. Any evidence of shivering, clinically significant hypotension and bradycardia, new arrhythmias and bleeding were identified and recorded as adverse events.

Ambient PACU temperature was recorded for the duration of the PACU stay for all randomised patients using a calibrated LogTag® TRID30-7 (LogTag®). All temperature measurement devices were regularly maintained and calibrated throughout the course of the study in line with existing organisational procedures.

At discharge from PACU to ward-based care, all subsequent treatments were at the discretion of the ward-based team. Patients were followed up until 7 days postsurgery or discharge from hospital, whichever occurred first.

The primary objective of this study was to determine whether the Orve + wrap® was noninferior to Forced Air Warming when warming hypothermic patients. The primary outcome measure was mean temperature difference at 60-min post-PACU admission. Secondary outcomes included PACU and hospital length of stay and the prevalence of all the adverse events including the severity of any postoperative shivering, which was graded 0–4 using Crossley and Mahajan's shivering assessment tool (1994).

There are limited contemporaneous studies exploring thermal insulation blankets against a Forced Air Warming device. In calculating the sample size, we used local unpublished temperature audit data indicating a standard deviation of 0.5, a noninferiority limit of 0.3°C was set based on what was deemed to be clinically relevant. A power analysis was conducted which determined that 102 patients (51 per group) were required to ensure that the lower limit of the confidence interval about the mean difference between the two groups fell within the 95% confidence interval of zero. In addition, we accounted for a potential 25% dropout of randomised patients who fail to reach the 60-min primary outcome point in PACU due to, return to theatre, subsequent admission to critical care, refusal to use the blanket or withdrawal of consent. In total, we aimed to randomise 128 patients into the study.

The primary outcome was patient body temperature which was measured at 10-min intervals post-PACU admission. It was planned that the key dependent variable would be patients' temperature at 60 min. However, it was recognised that temperature on admission to PACU could influence the temperature at 60 min; therefore, admission temperature was treated as a covariate. Accordingly, analysis using ANCOVA was used to account for this admission temperature covariate, when comparing Orve + wrap® with Forced Air Warming.

Chi-squared tests were used to compare the categorical data between groups for the adverse events. A p-value <.05 was used to indicate statistical significance. Statistical analyses were performed using SPSS (Version 22, IBM). This study is reported using the Consolidated Standards of Reporting Trials (CONSORT) Extension checklist for noninferiority and equivalence trials (See Appendix S1).

3 | RESULTS

Five hundred and three patients were assessed for suitability for the study from which 281 consented to participate (see Figure 2),

One hundred and twenty-nine patients were randomised into the two groups. However, one patient was excluded from analysis

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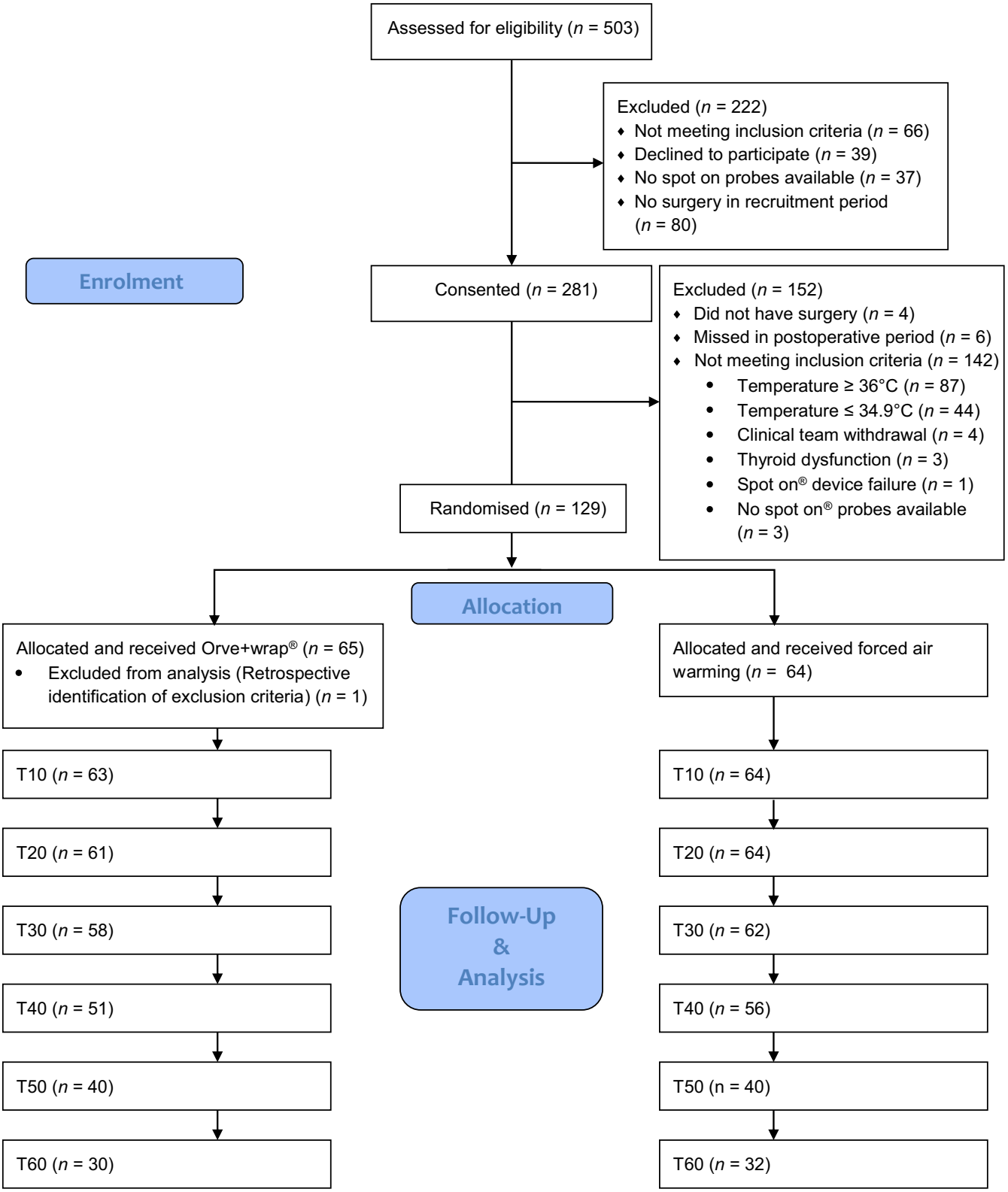

FIGURE 2 CONSORT diagram of patient recruitment [Colour figure can be viewed at wileyonlinelibrary.com]

due to the retrospective identification of pre-existing thyroid dysfunction. The split between surgical specialties was 96% (*n* = 123) orthopaedic and 4% (*n* = 5) cardiothoracic. The patients' baseline characteristics are displayed in Table 1.

The crude mean difference in temperature at each of the 10-min intervals for the first 60 min is shown is Figure 3, with this difference between the groups remaining within 0.1°C, throughout the first hour of observations.

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TABLE 1 Characteristics and intraoperative data of patients receiving Orve + wrap® or Forced Air Warming. Values are mean or number with *SD* or proportion in parentheses

	Orve + wrap® (*n* = 64)	Forced Air Warming (*n* = 64)
Age (years)	62.6 (14.3)	63.3 (14.2)
Sex; male	38 (59%)	28 (44%)
Body surface area (m^2)	1.97 (0.24)	1.96 (0.21)
ASA physical status		
I	14 (22%)	12 (19%)
II	33 (52%)	33 (51%)
III	16 (25%)	19 (30%)
Missing	1 (1%)	
General anaesthesia (yes)	35 (55%)	34(53%)
Spinal (yes)	31 (48%)	32 (50%)
Vasopressors (yes)	22(34%)	31(48%)
Ambient temperature on PACU arrival (°C)	23.7 (1.4)	23.6 (1.3)
First Spot On™ temperature (°C)	35.4 (0.3)	35.5 (0.3)
First tympanic temperature (°C)	35.5 (0.6)	35.5 (0.5)
Surgery length (mins)	112.9 (68.0)	119.7 (56.7)
Anaesthesia length (mins)	150.4 (77.7)	163.8 (66.7)
Orthopaedic surgery	62 (97%)	61 (95%)
Cardiothoracic surgery	2 (3%)	3 (5%)

Patient mean temperatures at 60-min postwarming device placement between Orve + wrap® (n = 30) with Forced Air Warming (n = 32), when adjusted for patients' temperature on arrival to PACU, showed no statistical difference (p = .748) between the mean differences (Table 2). Furthermore, Figure 4 demonstrates the mean difference of 0.040°C and the associated 95% confidence intervals (CI: 0.206,0.286) in relation to the predefined noninferiority margin.

Regarding the safety aspects of the devices during patients' PACU stay, there was a low instance of issues observed, with postoperative shivering the most common. There was no statistical difference between groups noted in any of the adverse event (Table 3). Patient stay data (Table 4) demonstrated a statistically shorter length of PACU stay for those patients who received Orve + wrap® postoperatively, 67.3 min (22.59) versus 80.2 (44.36). This however did not translate to a shorter postsurgery length of hospital stay. The application of the warming device was slower in the Forced Air Warming group, with the time taken to place the Forced Air Warming device being significantly longer from the point at which the baseline Spot On™ temperature demonstrated hypothermia (Table 5). This translated into a statistically significant ($p \leq .001$) overall longer duration for Forced Air Warming device placement from admission into PACU.

4 | DISCUSSION

This study represents the first direct comparison of the Orve + wrap® in a randomised controlled trial against any other warming device. The study is unique in that it compares a new passive warming blanket with Forced Air Warming, which Alderson et al. (2014) describe as the current advocated "gold standard" treatment for postoperative hypothermia.

For the primary outcome, the predefined noninferiority criteria, of a temperature difference of <0.3°C at 60 min, were observed. However, due to the insufficient number of patients who had evaluable data at the 60-min timepoint and based on our power calculator, there is a clear risk that these results are underpowered to determine any difference at the 60-min warming timepoint. This is despite accounting for a 25% dropout rate prior to 60 min. Failure to achieve this threshold is attributed partially to the period of time taken for the ZHF thermometry to calibrate

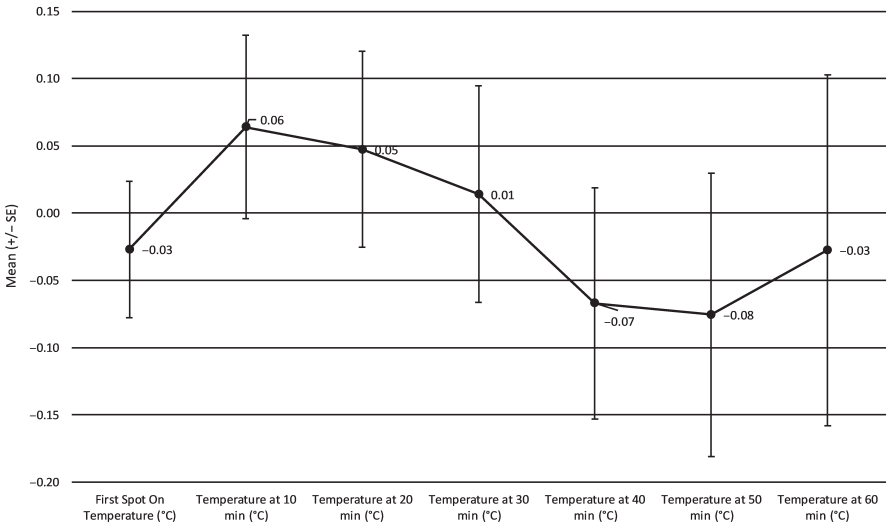

FIGURE 3 Mean Temperature at 10-min intervals from warming device placement with standard error bars

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TABLE 2 Mean temperature at 10-min intervals from device placement. Values are displayed as mean (*SD*) and number

	Orve + wrap®	Forced Air Warming	
	Mean (*SD*), *n*	Mean (*SD*), *n*	ANCOVA, *p*-value
First Spot On™ temperature (°C)	35.4 (0.3), 64	35.5 (0.3), 64	–
Temperature at 10 min (°C)	35.9 (0.4), 63	35.8 (0.4), 64	.18
Temperature at 20 min (°C)	35.9 (0.4), 61	35.9 (0.4), 64	.34
Temperature at 30 min (°C)	36.0 (0.4), 58	36.0 (0.5). 62	.76
Temperature at 40 min (°C)	36.0 (0.5), 51	36.1 (0.4), 56	.57
Temperature at 50 min (°C)	36.1 (0.5), 40	36.2 (0.5), 40	.32
Temperature at 60 min (°C)	36.2 (0.6), 30	36.3 (0.5), 32	.75

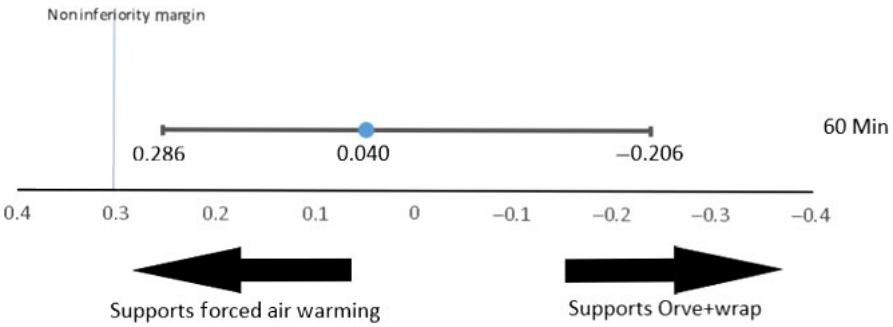

FIGURE 4 Mean temperature (°C) differences at 60 min, with error bars for two-sided 95% confidence intervals. The noninferiority margin is represented by a solid line set at 0.3°C [Colour figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Postoperative adverse events in between Orve + wrap® and Forced Air Warming patients (0.5 level of significance)

	Orve + wrap®	Forced Air Warming	*p*-value
Arrhythmia	1	0	.32
Hypotension	1	2	.56
Shivering	6	4	.51
Surgical site infections	0	0	–

after being placed on the participant and the subsequent delay in the placement of warming devices.

In this study, only 60% of participants spent 60 min or more in PACU, in hindsight examination of the primary endpoint at an earlier timepoint may have been more clinically appropriate. Supporting this is the evidence from the planned secondary outcomes analysis of the 10-min warming intervals which indicate no statistical difference throughout the first 60 min. In the initial stages after warming begins, there appears to be a small nonstatistically significant trend towards improved warming with the Orve + wrap® (Table 2, Figure 3). We believe this is as result of stored heat in the blanket acquired from the blanket warmer being transferred to the patient, as this improvement appears to plateau at 20 min, potentially reflecting when the point at which the Orve + wrap® has lost all its stored heat and then primarily working through insulation.

The selection of a mean difference of 0.3°C as the noninferiority was chosen based on the accuracy of the available thermometry techniques (±0.25°c) alongside what was felt would be clinically relevant for practitioners to change clinical practice. This is supported by existing data demonstrating a 0.5–1.0°C higher mean temperature in Forced Air Warming compared with other passive warming devices (Alderson et al., 2014). In practice, however, absolute thresholds, alongside patients' clinical or sensorial status, are used to initiate warming measures (i.e. temperature <36°C or patients feeling cold). In the absence of data on practitioners' perspectives of clinically relevant warming differences and the evidence presented by Alderson et al. (2014), it may be that a larger inferiority margin would have provided both clinically and statistically convincing findings.

These results are consistent with historic data using this outcome measure which also showed minimal impact of Forced Air Warming after 60 min of warming (Ereth, Lennon, & Sessler, 1992; Summers, Dudgeon, Byram, & Zingsheim, 1990). In the absence of a core outcome set for this group of patients, the use of this measure as a primary outcome may be flawed and alternative measures such as time to normothermia may provide more patient-focused indicators of blanket performance. In hindsight, on this basis we believe that a study with adequate power at 60 min, and an appropriate a primary outcome measure or noninferiority margin, it would be likely to demonstrate the Orve + wrap® noninferiority to Forced Air Warming.

Whilst this study was not powered to identify any changes between the groups with regard to the postoperative adverse events, it is reassuring to see comparable incidence in this study. Of note is the

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TABLE 4 Length of stay for patient receiving Orve + wrap® and Forced Air Warming. Values are mean with *SD* in parentheses

	Orve + wrap®	Forced Air Warming	Mean difference (95% CI)	*p*-value
PACU LOS (mins)	67.3 (22.6)	80.2 (44.4)	12.5 (0.1, 25.0)	.05
PostSurgery length of stay (days)	3.1 (2.6)	3.3 (2.4)	0.1 (−0.8, 1.0)	.64

TABLE 5 Time taken in minutes to place warming devices for patient receiving Orve + wrap® and Forced Air Warming. Values are mean and *SD* in parentheses

	Orve + wrap®	Forced Air Warming	Mean difference (95% CI)	*p*-value
PACU Admission to Spot On™ reading	5:28 (2:02)	06:26 (3:42)	00:48 (00:17, 01:19)	.71
PACU Admission to device placement	7:16 (2:36)	10:16 (4:04)	02:46 (02:12, 03:20)	<.001
Spot On™ reading to device placement	1:48 (1:33)	3:50 (2:18)	05:58 (01:32, 02:23)	<.001

incidence of surgical site infections (SSI); we used a pragmatic definition to determine the presence of SSI, "any nonprophylactic antibiotic use for suspected wound infection prior to hospital discharge." In both arms, there were no surgical site infections during the initial hospital stay. Data for England identify around a 0.6% incidence of SSI for comparable orthopaedic procedures to those undertaken in this study, with a median onset date of around 17–20 days (Public Health England, 2018). In our study, the intraoperative warming methods were not protocolised and a mixture of methods were used including Forced Air Warming. With mixed opinions and evidence (Kellam, Dieckmann, & Austin, 2013) on the use and impact of Forced Air Warming during surgery, the decision for its use was at the discretion of the surgeon and anaesthetist. The absence of SSI infections in the study is promising, but not surprising based on current SSI rates and an observed shorter mean length of stay in this study than the observed median days for onset of SSI in England.

The prevalence of postoperative hypothermia in this study was 62% which corresponds well with previous data (Alderson et al., 2014; Al-Qahtani & Messahel, 2014; Harper et al., 2008). Highlighting that despite recent efforts and techniques for pre- and intraoperative warming, temperature management in the postoperative phase remains as important. In view of current guidance for managing inadvertent perioperative hypothermia and the lack of clinical data on the efficacy of the Orve + wrap®, this study focuses on a narrow but clinically relevant temperature window (35.0–35.9°C). Accordingly, these data only reflect patients in the postoperative period, and it is unknown how the device would perform on patients presenting with temperatures outside this range or in different contexts.

NICE guidance (NICE, 2016) recommends direct measurement of temperature in the perioperative phase, which include distal oesophagus, rectum, urinary bladder and ZHF. To generate the primary outcome data for this study, ZHF was used to measure temperature in this study. Whilst not widely adopted in the UK, the use of the 3m Spot On™ probes, ZHF thermometry was based on a growing body of evidence describing increased accuracy and reduced variability, compared with other means of thermometry, whilst also being an acceptable and risk-free approach in awake patients (Arunachalam, Akehurst, & Eitel, 2015; Eshraghi et al., 2014; Boisson et al., 2018; NICE, 2017). We found close agreement between the mean first Spot On™ and tympanic temperature measurements but a higher degree of variation in the tympanic measurements. The possibility of a larger variance between the two thermometry methods is possible through different temperature ranges and the influence of the thermometry equipment on these outcomes should not be underestimated.

There are several limitations to this study; firstly, we observed a statistically significant longer PACU length of stay for the Forced Air Warming group; this may have been due to the extended time taken to remove the warming equipment in the Forced Air Warming; however, this it is unlikely to explain the entire delay. Alternatively, despite randomisation, there may have been nonclinical reasons that contributed to delays in PACU discharge that were not controlled for in this study, such as a lack of surgical ward beds for patients to be transferred to. This increased mean length of stay may be also be related to a number of outliers in the Forced Air Warming group, as the seven longest PACU stays were all in patients who had Forced Air Warming.

Secondly, the nature of the interventions resulted in the inability to blind PACU staff to the randomisation; for this reason, we are unable to unequivocally determine that specific outcomes have not been influenced by bias, such as the earlier discharge of patients. The novel and open usage of the Orve + wrap® could have led to the possibility of performance bias on the part of the nurses caring for patients, where they either consciously or subconsciously were more proactive in discharging these patients earlier. This bias may be attributed to the steeper warming trajectory of the Orve + wrap® group which primed the PACU nurses for the potential discharge.

Finally, it also took longer to commence the Forced Air Warming placing the Orve + wrap® on the patients. It is conceivable that this setup delay for Forced Air Warming was exclusively

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related to the practicality of delivering Forced Air Warming, that is locating a warming unit, accessing a suitable power source and connecting hoses to blankets, rather than any deliberate delay to start therapy. This is reinforced by the higher variability in the mean duration of Forced Air Warming placement, suggesting that the Orve + wrap® warming was more straightforward to initiate. The impact of this real-world delay of instigating Forced Air Warming is unclear in this study but may have resulted in underperformance of the Forced Air Warming. The incorporation of User Acceptability Testing with the healthcare professionals in this study for both devices would have helped highlight the Orve + wraps'® clinical utility.

In summary, when evaluating against mean patient temperature at 60 min, this study demonstrates the Orve + wraps'® noninferiority to Forced Air Warming in the postoperative phase in conditions described here. Alongside this during the patients' PACU stay, the adverse event rates were low and were statistically not significantly different, demonstrating the safety of the Orve + wrap® in the postoperative period. The advantages of the Orve + wrap® blankets are that they appear to be quick to apply to the patient and that numerous blankets only require a single heat source to "charge" with heat. However, their effectiveness without preheating still requires further exploration.

4.1 | Relevance to clinical practice

This study adds useful clinical data to the use of the Orve + wrap® blanket. It provides healthcare practitioners with information on its utility in a postoperative setting, and whilst efforts to reduce the incidence of intraoperative and subsequent postoperative hypothermia should be prioritised, the availability of the Orve + wrap® increases the options available to practitioners in warming and keeping patients warm.

However, recommendations for future explorations of the Orve + wrap® blanket should include the efficacy for the whole duration of the perioperative period, efficacy in different patient populations, alongside health economic evaluations, ensuring the device is cost effective compared to other patient warming interventions. Additionally, due to its low-tech design, explorations into its use in low-income countries and those with limited access to reliable electricity sources may provide far-reaching opportunities for Orve + wrap's® clinical utility.

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CONFLICT OF INTEREST

All authors declare no conflict of interest.

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