Randomized non-inferiority trial of the vitalHEAT™ Temperature Management System vs the Bair Hugger® warmer during total knee arthroplasty

Étude randomisée de non-infériorité du Système de gestion de la température vitalHEAT™ par rapport au système de réchauffement Bair Hugger® pendant une arthroplastie totale du genou

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Abstract

Purpose Intraoperative and postoperative hypothermia occur commonly; mild hypothermia (34–36°C) is associated with adverse events. The use of perioperative warming devices has become routine, but currently available active warming devices may be limited in certain circumstances. The vitalHEAT™ Temperature Management System provides conductive warming (circulating warm water) around a single extremity together with a vacuum that is applied to the limb. In this randomized trial, we tested the hypothesis that the vitalHEAT™ system is non-inferior to the Bair Hugger® during unilateral total knee arthroplasty.

Methods Physical status I–III patients who were ≥18 yr-old were eligible to participate. The patients were randomly assigned to the vitalHEAT™ system (n = 30) or to Bair Hugger® (n = 25) warming. Intraoperative and first recovery room temperatures were recorded in both groups.

Results The baseline characteristics of the groups were similar. In terms of the primary outcome measure, i.e.,

sublingual temperature measured within 10 min of recovery room arrival, the vitalHEAT™ system did not meet the criterion for non-inferiority. Specifically, the confidence interval for the difference between means included the non-inferiority margin (−0.5°C). In terms of the secondary measures, i.e., intraoperative esophageal temperatures, the vitalHEAT™ system also underperformed compared with the Bair Hugger®.

Conclusions The vitalHEAT™ system may have advantages over convective warming systems because it requires a much smaller body surface area; however, in this study of warming during total knee arthroplasty, it underperformed when compared with the Bair Hugger®, especially around and after the time of tourniquet release.

Clinical trial registration number: NCT00711867.

Résumé

Objectif L'hypothermie peropératoire et postopératoire est courante; l'hypothermie légère (34–36°C) est associée à des événements indésirables. Le recours à des appareils de réchauffement périopératoires est entré dans la pratique courante, mais les appareils de réchauffement actif actuellement disponibles sur le marché pourraient avoir des limites dans certaines circonstances. Le Système de gestion de la température vitalHEAT™ procure un réchauffement par conduction (circulation d'eau chaude) autour d'un seul membre avec un vide et est appliqué au membre. Dans cette étude randomisée, nous avons testé

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l'hypothèse que le système vitalHEAT™ est non inférieur au Bair Hugger® pendant une arthroplastie totale du genou unilatérale.

Méthode Les patients de statut physique I-III de ≥ 18 ans étaient admissibles à l'étude. Les patients ont été randomisés à être réchauffés soit avec le système vitalHEAT™ ($n = 30$) ou avec le Bair Hugger® ($n = 25$). Les températures ambiantes peropératoire et de la première salle de réveil ont été enregistrées dans les deux groupes.

Résultats Les caractéristiques de base des groupes étaient semblables. En termes de mesure du critère d'évaluation principal, soit la température sublinguale mesurée dans les 10 premières minutes suivant l'arrivée en salle de réveil, le système vitalHEAT™ n'a pas répondu au critère de non-infériorité. Plus spécifiquement, l'intervalle de confiance pour la différence entre les moyennes comprenait une marge de non-infériorité ($-0,5^{\circ}\text{C}$). Du point de vue des mesures secondaires, soit les températures oesophagiennes peropératoires, le système vitalHEAT™ a également été sous-performant par rapport au Bair Hugger®.

Conclusion Le système vitalHEAT™ pourrait avoir des avantages par rapport aux systèmes de réchauffement par convection étant donné qu'il nécessite une surface corporelle bien plus petite; toutefois, dans cette étude du réchauffement pendant une arthroplastie totale du genou, ce système a été sous-performant comparativement au Bair Hugger®, particulièrement au moment du dégonflement du garrot et après.

Numéro d'enregistrement de l'étude clinique: NCT00711867.

Intraoperative and postoperative hypothermia occur commonly¹; mild hypothermia (core temperature $34\text{--}36^{\circ}\text{C}$) is associated with many adverse events, including shivering (and thereby increased cardiac oxygen demand), prolonged postanesthetic recovery, impaired wound healing, platelet inhibition, and cardiac morbidity.^{2–5} The use of perioperative warming devices has become routine, e.g., forced-air (convective) devices such as the Bair Hugger® (Arizant Medical, Inc., Eden Prairie, MN, USA) and circulating water pads.

Currently available active warming devices may be limited in certain circumstances.⁶ For instance, in surgery where limited space for warming is available, a convective (forced-air) or water pad based system may not access sufficient skin surface area to adequately warm the patient or prevent hypothermia from developing. This situation may apply to some orthopedic, thoracic, plastic reconstructive, or laparotomy surgery.

The vitalHEAT™ (vH²™) Temperature Management System (Dynatherm Medical Inc., Fremont, CA, USA)

Fig. 1 The vitalHEAT™ (vH²™) Temperature Management System (Dynatherm Medical Inc., Fremont, CA, USA) with control unit, umbilical tubing, and warming sleeve

provides conductive warming (circulating warm water) around a single extremity together with a vacuum that is applied to the limb (Fig. 1). The negative pressure combined with a thermal load is intended to produce a thermal conduit to the central core by opening the arteriovenous anastomoses (AVAs) in the extremity. Simultaneously, the mild negative pressure causes the circulating fluid pads to adhere to the extremity. Tight adherence of the pads efficiently delivers a thermal load to the extremity as air pockets and their insulating effects are eliminated.

In this randomized controlled trial, we tested the hypothesis that the vH²™ system is non-inferior to a forced-air warming system during total knee arthroplasty surgery (TKA). The vH²™ was compared with an active warming system rather than a placebo, as patients in the placebo group potentially could become hypothermic. The primary outcome measure was sublingual temperature measured within 10 min of arrival in the postanesthesia care unit (PACU). Secondary measures included intraoperative esophageal temperatures and the use of alternative warming.

Methods

After Institutional Review Board approval of the study protocol and with the patients' written informed consent, ASA physical status I–III patients who were ≥ 18 yr-old and scheduled for unilateral TKA were recruited for the study. The duration of the cases was expected to be 2–3 hr under a planned general endotracheal anesthetic. During the screening process, patients were excluded in the event of their refusal to participate, skin abrasions, trauma, allergic skin conditions of the upper extremities, or a history of

peripheral vascular disease, malignant hyperthermia, or methicillin-resistant *Staphylococcus aureus* (MRSA) infection. After randomization, patients were excluded who received a laryngeal mask airway device (LMA North America, Inc., San Diego, CA, USA) instead of an endotracheal tube or patients who specifically requested or required regional anesthesia (spinal or epidural block) for the procedure. Peripheral nerve blocks in addition to general anesthesia were acceptable. The participants were recruited and underwent surgery during June 2008 to December 2008.

The patients were recruited sequentially and assigned at random in a one-to-one ratio to either the vH^{2TM} system or the Bair Hugger® warming. All participants were enrolled by a research study coordinator (K.J.) and signed informed consent. The study statistician (J.H.) created the randomized treatment allocation schedule by using a computerized random number generator. Randomization was not restricted. Allocation was concealed by storing the schedule on a randomization website hosted by the Mayo Clinic Research Computing Facility. The patient and clinical staff did not know the treatment assignment until after the patient signed informed consent to participate and the coordinator had entered the patient's identifier into the randomization website.

Core temperature was measured in both groups with a Nova Plus 400 Series Thermistor Esophageal Stethoscope Temperature Sensor, 18 French (Smiths Medical, Watford, UK) inserted to a depth of at least 24 cm from the dental plate.

The vH^{2TM} system was managed as follows: When the patient was transferred to the operating room (OR) table but before induction of anesthesia, the vH^{2TM} warming sleeve was applied to one of the patient's hands/forearms and secured in place with a Velcro closure mechanism. The hand/forearm that was selected for the application of the warming sleeve was free of identification bracelets as well as any therapeutic and/or diagnostic devices, such as arterial lines, pulse oximeter probes, and/or intravenous sites. A non-invasive blood pressure cuff could be applied above the elbow on the side of the warming sleeve. The vH^{2TM} system was then activated at a "high" setting, which was $\leq 42^{\circ}\text{C}$ fluid temperature at the skin surface, with a vacuum at approximately 10 mmHg negative pressure. Anesthesia induction and surgery then proceeded in the usual manner. A large (17 in. $\times$ 23 in.) clear plastic drape was placed over the patient's head and neck in a manner similar to the placement of the Bair Hugger® blanket's head wrap. A single cotton blanket was also placed over the patient's arms and upper chest. In addition to documenting ambient room temperature every 15 min, the patient's temperature was recorded every 15 min while the vH^{2TM} system was turned on. Key events, such as

administering warmed or non-warmed fluids or initiating conventional warming (Bair Hugger®) were also noted. A forced-air warmer was provided to patients assigned to vitalHEAT^{TM} warming who reached a core temperature $< 35^{\circ}\text{C}$. At the end of the procedure, the vH^{2TM} system was discontinued, and the patient's initial temperature in the recovery room was recorded.

The control (Bair Hugger®) group was managed as follows: When the patient was transferred to the OR table, the Bair Hugger® system upper body blanket was applied to the patient's body and covered with one cotton blanket. Anesthesia induction and surgery proceeded in the usual manner. The Bair Hugger® was set on "high" (43°C) per usual practice, and the patient's head was covered with the clear head drape that is an integral part of the Bair Hugger® blanket. Temperature recording was as above.

In an early Bair Hugger® study conducted on orthopedic (total hip arthroplasty) surgery patients, Bennett *et al.* compared the Bair Hugger® with reflective insulation and no intraoperative warming.⁷ Core temperatures and body heat content decreased significantly in the reflective insulation and control groups, while the Bair Hugger® patients maintained thermal homeostasis. In the Bennett study, the patient population and use of the Bair Hugger® were similar to ours in that general anesthesia was administered, an upper body Bair Hugger® was used (set at 43°C), ambient temperature fluids were infused, and the patients were placed in the supine position.

The primary outcome measure, primary method of comparison, non-inferiority margin, and sample size were determined prior to analyzing the data. The primary outcome measure was the sublingual temperature measured within 10 min of the patient's arrival in the PACU. The mean temperature of the vH^{2TM} group was compared with that of the Bair Hugger® group, and the statistical significance was calculated by using the two-sample *t* test. The primary comparison was a test of non-inferiority. The non-inferiority margin was defined as -0.5°C . ($H_0: \mu_{\text{vH}} - \mu_{\text{BH}} \leq -0.5; \alpha = .05$). The choice of the non-inferiority margin was based on clinical judgment. The primary method of comparison was based on the per-protocol set according to Food and Drug Administration guidance,¹ because it was a test of non-inferiority rather than a test of superiority. Patients were included in the per-protocol set if the primary outcome measure was available and if they did not receive other methods of warming in addition to the assigned study device. The result for the full set was also reported.

¹ United States Food and Drug Administration. International conference on harmonization; guidance on statistical principles for clinical trials; availability—FDA. Notice. Federal Register 1998; 63: 49583–98.

A sample of 25 patients per group was planned in order to achieve 80% power if the population difference between mean temperatures was 0.0°C and the standard deviation was 0.7°C. The standard deviation was estimated from Kabarra.⁸ Simple unrestricted randomization was used, and patients were recruited until the 25th patient was enrolled in the smaller group.

For measures other than the sublingual temperature in the PACU, the full set and per-protocol set were the same. Statistical significance of the secondary comparisons was calculated by using the two-sample *t* test (60-min esophageal temperature, minimum esophageal temperature, and maximum esophageal temperature) or Pearson's Chi square test (proportion of patients with mild hypothermia during the operation, incidence of mild hypothermia in the PACU, and incidence of alternative warming). Equality of variances was tested by using the folded form *F* test.

Results

Seventy-five patients met the study criteria and agreed to participate. Nine of these were not randomized due to surgery cancellation or change in surgery schedule. Eleven of the remaining 66 patients were excluded after randomization. Thirty-six patients were allocated to vH²^{TM} warming. Two patients were excluded from the vH²^{TM} group because a vacuum could not be established with the device; two were excluded because research staff were not available, and two were excluded due to use of an arterial line. Thirty patients were allocated to Bair Hugger® warming. Four patients were excluded from the Bair Hugger® group due to use of a laryngeal mask airway, and one patient was excluded due to epidural anesthesia. Additional warming was used for two patients in the vH²^{TM} group (Bair Hugger® added once, fluid warmer added once) and three patients in the Bair Hugger® group (fluid warmer). The primary measure (sublingual temperature within 10 min of arrival in

the PACU) was not available for three patients in the vH² group and one patient in the Bair Hugger® group. Therefore, the per-protocol set for the primary comparison included 25 patients in the vH²^{TM} system group and 21 patients in the Bair Hugger® group.

The two groups were similar at baseline (Table 1). The mean duration of warming in the vH² group was 13 min less than the Bair Hugger® group, potentially providing a slight advantage to the study intervention. Mean ambient operating room temperature differed by less than 0.5°C at all time points (data not shown).

In the per-protocol set, the mean sublingual temperature within 10 min of arrival in the PACU was 36.4°C (range 34.8–36.8°C) for the vH²^{TM} group vs 36.7°C (range 36.3–37.2°C) for the Bair Hugger® group (Fig. 2 and Table 2). The primary comparison did not meet the criterion for non-inferiority, i.e., the lower confidence limit for the difference between groups did not exclude the non-inferiority margin (95% CI = −0.55 to −0.14°C). However, the upper confidence limit was <0°C. The result for the full set was similar to that of the per-protocol set (95% CI = −0.52 to −0.15°C).

Beginning with the 60-min time point, the mean esophageal temperature in the vH²^{TM} group was at least

Fig. 2 Sublingual temperature among 25 patients treated with vitalHEAT^{TM} warming and 21 patients treated with Bair Hugger® warming during general anesthesia for total knee arthroplasty

Table 1 Baseline and operative characteristics among patients with general anesthesia for total knee arthroplasty

	vitalHEAT ^{TM}	Bair Hugger ®
Female	18/30 (60%)	13/25 (52%)
Age (yr)	68.9 (11.4), 30	67.0 (9.4), 25
BMI (kg · m ⁻²)	31.1 (5.2), 30	32.1 (5.5), 25
Preoperative sublingual temperature (°C)	36.73 (0.24), 30	36.66 (0.32), 25
Esophageal temperature at 0 min (°C)	36.00 (0.52), 30	35.97 (0.34), 25
Duration of warming with study device (min)	135 (46), 30	148 (45), 25
Duration from beginning of warming with study device to tourniquet deflation (min)	100 (41), 30	106 (36), 25
Duration from anesthesia induction to beginning of warming with study device (min)	−3.6 (5.0), 30	7.7 (5.1), 25

Prevalence or mean ± SD (*n*)

BMI body mass index

Table 2 Body temperature (°C) among patients with general anesthesia for total knee arthroplasty

	vitalHEAT™	Bair Hugger®	Δ	95% CI
PACU—per-protocol set ^a	36.38 (0.38), 25	36.73 (0.29), 21	−0.34	−0.55 to −0.14
PACU—full set	36.39 (0.36), 27	36.72 (0.28), 24	−0.34	−0.52 to −0.15
60-min esophageal	36.00 (0.52), 29	36.28 (0.32), 25	−0.28	−0.52 to −0.04
Minimum esophageal	35.74 (0.50), 30	35.84 (0.42), 25	−0.10	−0.35 to 0.16
Maximum esophageal	36.17 (0.55), 30	36.68 (0.31), 25	−0.51	−0.73 to −0.27

Mean $\pm$ SD (*n*)

PACU post-anesthesia care unit; CI confidence interval

^a Primary comparison

Fig. 3 Mean esophageal temperature during general anesthesia for total knee arthroplasty. *Solid circles* indicate vitalHEAT™ warming, *open circles* indicate Bair Hugger® warming, and vertical lines indicate standard deviations. *n* number of patients at each time point; *VH* vitalHEAT™, *BH* Bair Hugger®

0.25°C lower than in the Bair Hugger® group (Table 2 and Fig. 3). The mean of the maximum esophageal temperatures in the vH²™ group was 0.5°C lower than in the Bair Hugger® group. In the vH²™ group, the variation in esophageal temperature from one patient to the next was also higher than in the Bair Hugger® group at all time points.

Beginning with the 60-min time point, the proportion of patients with mild hypothermia (34–36°C) was more than 30 percentage points higher in the vH²™ group than in the Bair Hugger® group. On average there was more than one extra occurrence of mild hypothermia for every three patients treated with vH²™ warming instead of Bair Hugger® warming. The incidence of mild hypothermia at any point during the operation was 7 percentage points higher in the vH²™ group (19/30) than in the Bair Hugger® group (14/25). The incidence of mild hypothermia within 10 min of arrival in the PACU was 4 percentage points higher in the vH²™ group (1/27) than in the Bair Hugger® group (0/24). Additional warming was used for two patients (7%) in the vH²™ group and three patients

(12%) in the Bair Hugger® group (95% CI = −0.21 to 0.10). No adverse events were noted in either the vH²™ group (95% CI = 0–12%) or the Bair Hugger® group (95% CI = 0–14%).

Discussion

Perioperative temperature management continues to challenge anesthesia providers despite widespread recognition of adverse events associated with hypothermia. A substantial body of literature exists on this topic, including recent reviews on the physiology of thermoregulation,⁸ perioperative temperature monitoring,⁹ the effects of mild hypothermia on blood loss and transfusion requirements,¹⁰ and complications of hypothermia.¹¹ The vitalHEAT™ (vH²™) Temperature Management System is one of several commercially available warming devices that seek to prevent and treat intraoperative hypothermia.

In order to meet the predefined definition of non-inferiority, the lower bound of the 95% confidence interval

(CI) for the magnitude of the difference in sublingual temperature within 10 min of arrival in the PACU had to be no less than -0.5°C . Non-inferiority was not established, as the lower bound for both the per-protocol and full analyses exceeded this margin. In terms of the secondary measures, i.e., the intraoperative esophageal temperatures, the vH²™ system also underperformed compared with the Bair Hugger®.

Although the vH²™ did not meet the test of non-inferiority, the mean PACU temperature difference was only 0.34°C , and the difference in mean temperatures was never more than 0.69°C . While the mean recovery room temperatures were higher for the Bair Hugger® group, the vitalHEAT™ group had all but one patient at or above 36°C upon entrance to the PACU. Since the vH²™ only involves one extremity compared with the surface area required by the Bair Hugger®, it may have advantages in surgeries where a forced-air or circulating water pad has limited access to body surfaces, such as orthopedic, multi-site plastic, or thoracic surgery performed in the lateral decubitus position. The vH²™ was tested here on the hand/forearm, but the foot/lower leg can be used as well.

With its limited surface area, it is possible that the vH²™ system is at a particular disadvantage during a surgery where tourniquet use contributes to hypothermia. Tourniquet release results in delivery of cold blood to the central circulation that can rapidly decrease core temperature.¹² After tourniquet release, the vH²™ may not recover from the drop in core temperature as effectively as the Bair Hugger®. Our data points were not specifically gathered around the time of tourniquet release, so we cannot definitively support or refute this hypothesis. However, Fig. 3 demonstrates an unfavourable pattern regarding the vH²™ system. At time zero, the groups had essentially identical mean temperatures with a drop of about 0.7°C compared with their pre-operative temperature. The Bair Hugger® group then recovered from the initial drop in temperature after induction of anesthesia, while the vH²™ system group maintained temperature with a much smaller recovery. During the time period when tourniquet release would be occurring in most patients (60–140 min after warming initiation), both groups' mean temperatures plateaued. The Bair Hugger® group was subsequently able to recover and increase core temperature, while the vH²™ system group did not.

Although it has been claimed that the vH²™ negative pressure feature opens arteriovenous anastomoses and thereby “shunts” warm blood directly to the core, it is more likely that the vacuum simply eliminates air pockets around the patient's skin in anesthetized patients. Air pockets can function as insulation and inhibit the transfer of the thermal load. Anesthetic agents are well-known

vasodilators, so it seems unlikely that the vH²™ would further vasodilate the periphery and thereby shunt heat to the central core. Smith *et al.* showed that a negative pressure rewarming device was not effective in accelerating rewarming in postoperative hypothermic patients,¹³ and Taguchi *et al.* showed that heat did not flow to the central core although a negative pressure rewarming device delivered calories to the forearm in hypothermic postanesthetic volunteers.¹⁴ These results suggest that elimination of the air pockets is the greatest contribution of the vH²™ vacuum for patients under general anesthesia. In these studies, it should be noted that the thermal load was delivered utilizing a hard plastic shell, chemical heat, and a very high vacuum (-40 mmHg). The device tested by Smith *et al.* and Taguchi *et al.* (ThermaStat, Aquarius Medical, Scottsdale, AZ, USA) is a forerunner of the vH²™ system that we studied.

There are several limitations to our study. As noted above, we do not have specific data on the effects of tourniquet release on body temperature. Our patient population was small, and several patients were excluded from analysis of the primary outcome because either PACU data was not collected in time or the patients received additional warming. Fluid temperature management was not strictly controlled, i.e., fluid warmers were not used on all patients as this was left to the discretion of the anesthesiologist. However, the analysis with and without the excluded patients was not favourable to the vH²™ in this study population, and there was no significant difference between groups in the use of additional warming methods. Further studies of the vH²™ system, perhaps with increased surface area exposure, may demonstrate improved performance. For instance, larger sleeves could be used or sleeves on bilateral upper or lower extremities. The vH²™ vacuum applied to the patient's extremity resulted in indentations (“sleep marks”), but these were noted to resolve within a few hours without sequel.

In summary, we found that the vH²™ system did not meet the test of non-inferiority compared with the Bair Hugger® during total knee arthroplasty surgery. Both the primary and secondary outcome measures were favourable to the forced-air system. Further studies may clarify whether the vH²™ system has advantages over the currently available patient warming systems and during which surgeries.

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Conflicts of interest None declared.

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