Prognostics of outcome of total knee replacement: on patient selection and intraoperative issues

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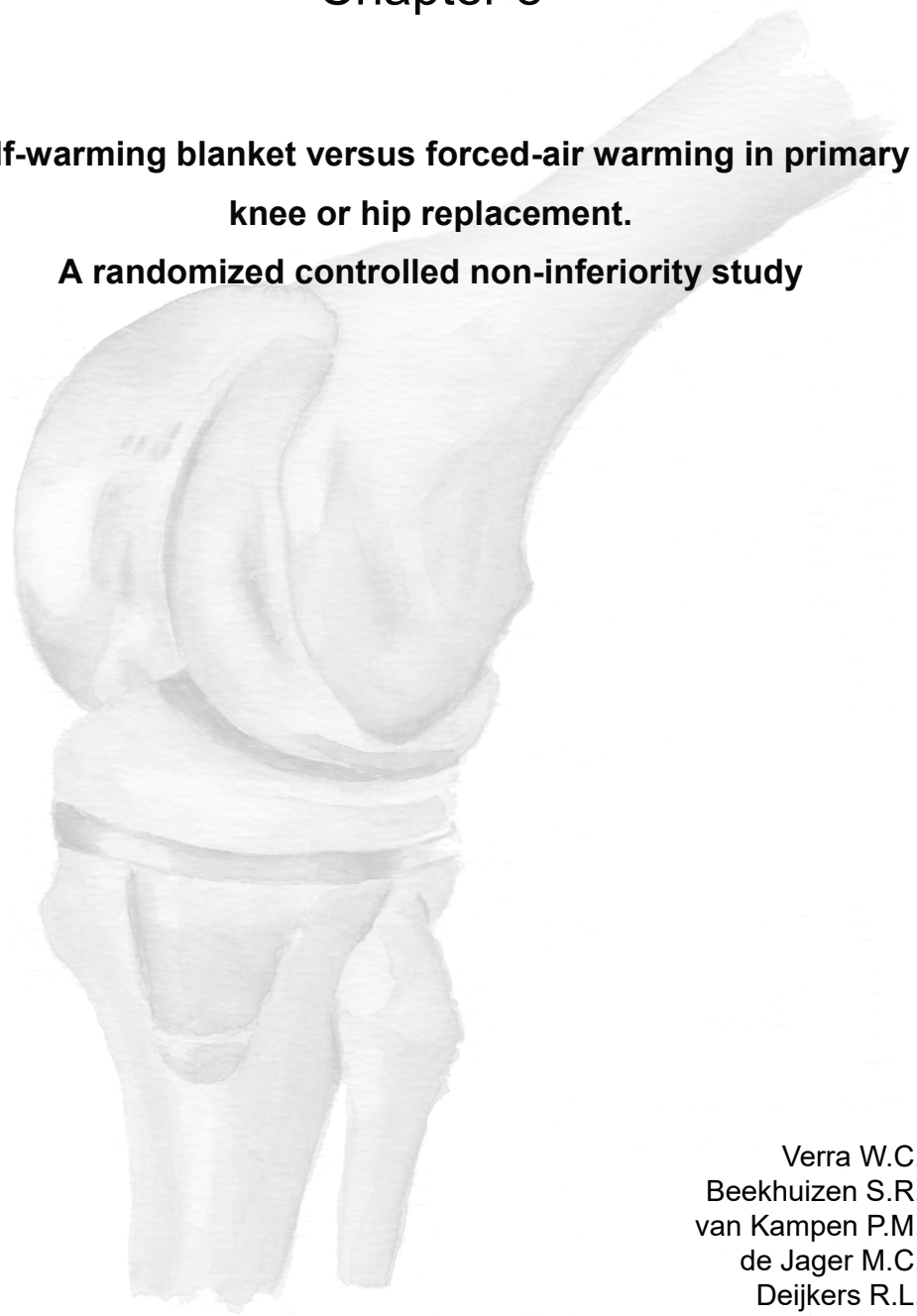
Chapter 8

Self-warming blanket versus forced-air warming in primary knee or hip replacement. A randomized controlled non-inferiority study



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Abstract

Introduction. After primary total knee/hip replacement (TKR or THR respectively) a prosthetic joint infection could develop. Hypothermia could raise the risk of infection. Heating by forced-air can disrupt laminar airflow at the operation room (OR), potentially raising the risk of infection. We aimed to study non-inferiority of an active self-heating blanket (*BARRIER EasyWarm, BE*) compared to a forced-air blanket (*BairHugger, BH)* in preventing hypothermia.

Methods. A randomized controlled non-inferiority trial (N=86 patients) was performed comparing BE versus BH in elective primary TKR/THR patients. Primary outcome was lowest measured temperature during surgery. Secondary outcomes were patients' core temperature before, during and after surgery, thermal comfort visual analogue score (VAS) and complications during hospitalization.

Results. Lowest measured temperature was 35.9°C(±0.6) in BE and 36.1°C(±0.5) in BH group (p=0.05). No significant correlation was found with duration of surgery or temperature of the OR. No significant difference in core temperature was found before surgery (BE 36.8°C±0.4, BH 36.8°C ±0.5, p=0.49), after induction of anesthesia (BE 36.6°C±0.5, BH 36.7°C ±0.5, p=0.22) nor as a mean during surgery (BE 35.8°C±1.6, BH 36.0°C±1.3, p=0.68). BE patients were 'colder' at the recovery bay, 35.8°C(±0.6) compared to BH patients, 36.1°C(±0.5) (p=0.04). Mean VAS thermal comfort was 53.3(±15.7) in BE and 52.9(±12.3) in BH patients. No difference in complication rate was found.

Conclusion. In this study both warming blankets did not prevent perioperative hypothermia. Although a difference of 0.2^{o}C was found between both groups at the end of TKR/THR surgery, this is most probably not clinical relevant. Complication rate in both groups was the same.

Introduction

Most general anesthetics impair thermoregulatory responses resulting in mild hypothermia.[1] Mild hypothermia, defined as a body temperature between 34.0 and 36.0 degrees Celsius (^{o}C), during primary total knee or hip replacement surgery (TKR or THR respectively) is associated with adverse events.[2] Studies showed that mild hypothermia might result in more postoperative discomfort, prolonged length of hospital stay, higher risk of myocardial infarction and a higher risk of surgical site infection.[3-5] This is why warming of joint replacement patients has become routine practice. Several strategies can be used to warm patients during surgery; two commonly used techniques are active warming by forced-air devices or warming using self-warming blankets.[6,7]

Clean laminar airflow in operating rooms is considered to reduce the risk of infection in TKR or THR surgery.[8] This downward directed airflow has shown to be disrupted by forced-air warming devices when hot air moves upwards against this downward air current.[8,9] Furthermore, this upwards directed air current has could potentially induce prosthetic joint infection (PJI) by creating air currents with a downward directed flow on the operating field.[10]

In an effort to further reduce the risk of developing prosthetic joint infection we hypothesized that using a self-warming blanket would keep the core temperature of the patient at the end of surgery at the same level as the forced-air devices, but with the advantage that no air currents were present or disturbed. So we aimed to study the non-inferiority of the self-warming blanket compared to the, more frequently used, forced-air warming.

Methods

This prospective, randomized controlled, single-center non-inferiority trial was approved by the Medical Ethics Committee (METC ZWH, no.17-049). The trial was registered in the Dutch Trial Registry (NTR6495).

Participants

Inclusion took place between June and August 2017. All consecutive patients who were planned for primary TKR or THR surgery, older than 18 years of age and able to speak and understand the Dutch language were considered eligible and were asked to participate in the study. They were included after signing informed consent. Patients with severe peripheral arterial disease were excluded from the study. All surgeries were performed in one large general training hospital in the Netherlands.

Intervention

Participants were randomized to one of two treatment groups;

1. Forced-air warming using the Bair Hugger™ device (3M Co. St.Paul, MN, USA)
2. Self-warming blanket BARRIER EasyWarm™ (Mölnlycke Health Care AB, Götenborg, Sweden)

At the ward all participants received the self-warming blanket to pre-heat before going to the operating room (which is standard protocol of care at our institution). At the anesthesiology bay patients received the SpotOn™ (3M Co. St.Paul, MN, USA) thermometer.[11] This is a non-invasive device continuously measuring and recording core body temperature.[11] All data were directly saved into the electronic patient-care system. At the end of the surgery tympanic temperature was recorded as well. Patients in both groups were operated on according to the standard protocol for TKR or THR. In case of THR the patient was supine and the direct anterior approach was used in all cases. In case of TKR patients were also supine and the median incision, medial parapatellar approach was used in all cases. Both warming systems were applied on the upper part of the body of the patient in a way that most of the skin was covered by the blanket. Temperature of the operating room during all procedures was recorded continuously. Upon return of the patient at the postoperative recovery bay a visual analogue scale (VAS) regarding temperature comfort experience was recorded. The scale on this VAS ranged from extreme cold (0) to extreme hot (100).

Outcomes

Primary outcome was the lowest temperature measured during surgery.

Secondary outcomes measures were core temperature preoperatively at the holding, after induction of anesthesia, intraoperatively and postoperatively at the recovery ward. Also tympanic temperature at the end of surgery, the total number of measurements <36.0°C, thermal comfort VAS and complications during hospitalization were recorded.

Randomization

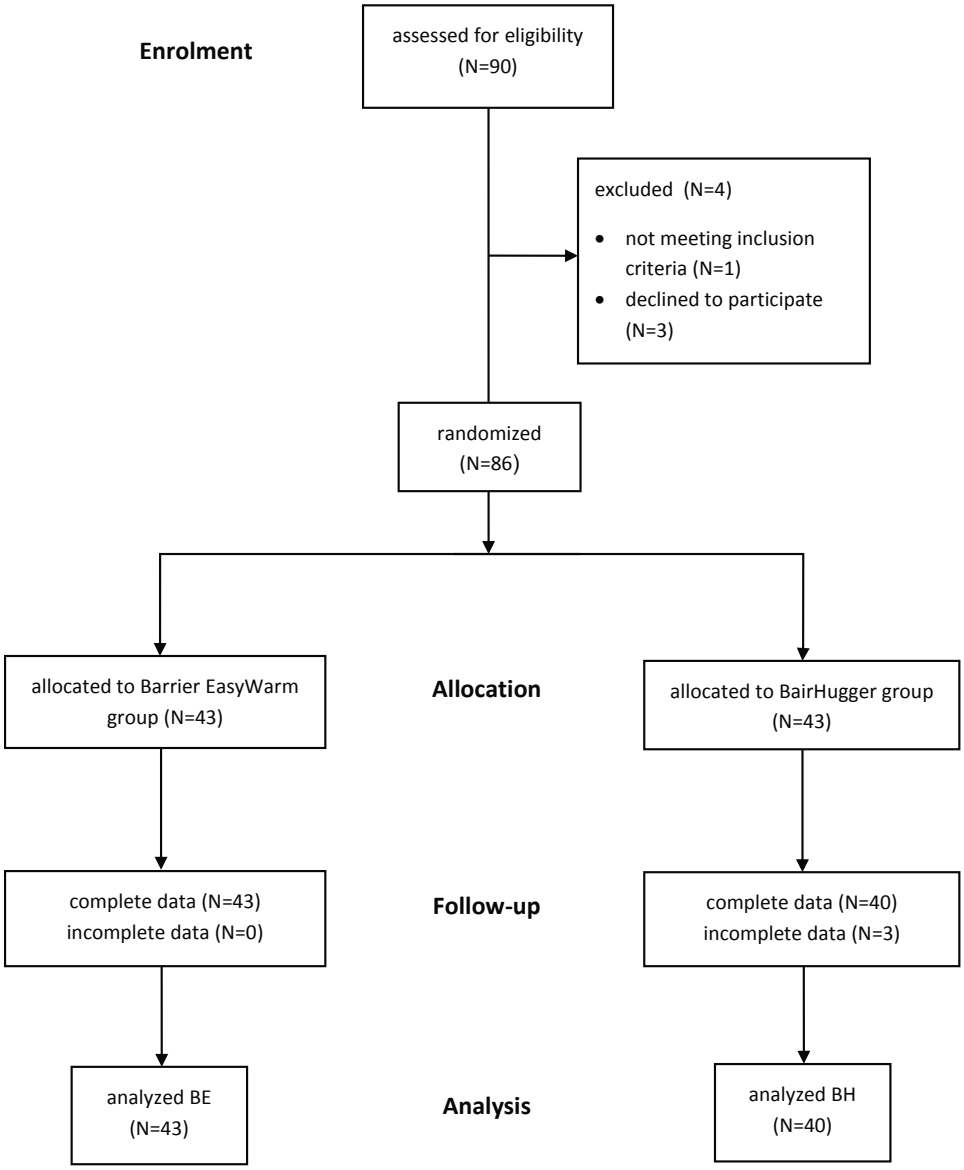
Allocation of treatment sequence was generated by a computer using Castor EDC data management software (Castor EDC, Amsterdam, the Netherlands). Variable block randomization was used with block sizes of 2, 3 or 4. Before entering the OR-center the bed of the patient was tagged with the allocated treatment. Blinding during surgery was not possible due to the obvious differences between the two warming systems. Investigators assessing outcomes were blinded for treatment allocation.

Statistical analysis

Statistical analyses were performed using SPSS Statistics for Windows, version 24.0. (Armonk, NY: IBM Corp.) To calculate sample size, a power analysis for equivalence (unpaired test) was performed. Based on Brandt et al. (2010) lower and upper equivalence bounds were ±0.5°C, with a standard deviation of 0.6°C. To achieve a power of 90% to detect equivalence within the equivalence bounds of ±0.5°C, a total sample size of 40 patients per group (80 patients) was estimated, including loss of follow-up. The primary outcome was analyzed by a TOST (two-one sided test), a test of equivalence that is based on the classical t-test used to test the hypothesis of equality between two means, as well as an independent sample t-test.[12]

Demographic variables, secondary outcomes regarding to core temperatures and thermal comfort (VAS) were calculated with independent samples t-test. To determine correlations between the lowest mean preoperative core temperature and OR temperature or duration of surgery a logistic regression analysis was performed. Dichotomous variables were calculated by chi-squared test. Results are expressed in means ± standard deviation or 95% confidence intervals (95%-CI). Differences were considered statistically significant at $p<0.05$.

Figure 8.1: Flowchart of patient inclusion



Results

From 90 consecutive patients 86 were randomized to receive one of the two warming systems (Figure 8.1). All patients were treated according to allocation. Table 8.1 shows baseline characteristics per treatment group. Groups were comparable in terms of demographic and clinical characteristics.

Table 8.1: Baseline characteristics

	BARRIER EasyWarm (N=43)	**Bair Hugger** (N=42)
Age years (SD)	71.2 (10.1)	72.1 (10.9)
Gender (male/female)	15/28	15/27
Body Mass Index kg/m^2 (SD)	27.7 (3.8)	28.3 (4.5)
Diabetes Mellitus (type1/type2/none)	0/3/40	0/3/39
Cardiovascular diseases N (%)	26 (60)	11 (26)
Anesthesia		
General (N)	8	11
Spinal (N)	35	31
Procedure		
Total hip replacement (N)	27	23
Operated side (left/right)	13/14	7/16
Total knee replacement (N)	16	19
Operated side (left/right)	5/11	7/12
Tourniquet (yes/no)	5/11	5/18
Tourniquet time min(SD)	18.8 (17.8)	19.0 (12.4)
Duration of surgery min (SD)	69.9 (18.6)	65.8 (16.0)
Duration of anesthesia min (SD)	89.8 (21.8)	88.8 (18.7)
Blood loss (mL)	199 (253)	164 (228)
OR temperature start °C (SD)	18.6 (0.4)	18.6 (0.4)
OR temperature end °C (SD)	18.6 (0.4)	18.6 (0.4)

SD: Standard deviation

Table 8.2 shows outcome measures. For the primary outcome; the mean lowest measured core temperatures were respectively 35.9(±0.6)°C for the BARRIER EasyWarm (BE) group and 36.1(±0.5)°C for the Bair Hugger (BH) group.

A secondary non-inferiority test (TOST) showed non-inferiority of the BE in relation to the predetermined delta of 0.5°C. In relation to the zero-point (i.e. no difference between BE and BH) the BE is just inferior by 0.2°C.

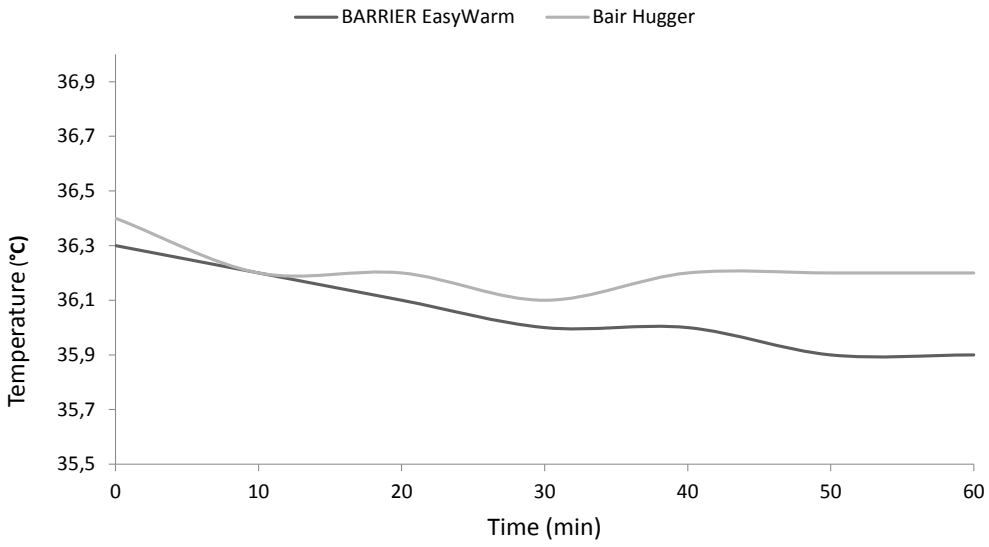
No correlation was shown between the mean lowest measured core temperature during surgery and the duration of surgery (p=0.12), nor with the temperature in the operation room (OR) at the start or end of the operation (p=0.11 and p=0.06 respectively). Mean core temperature before surgery did not differ significantly between the two groups (p=0.49), nor did mean core temperature after induction of anesthesia (p=0.22), at the start of surgery or mean core temperature during surgery (p=0.68). A significant difference (p=0.02) in core temperature was found at the end of surgery, 35.9°C ±0.6 for the BARRIER EasyWarm group and 36.2°C ±0.5 for the Bair Hugger group. After surgery, at the recovery bay, the BE group was 'colder' compared to the BH group, 35.8°C ±0.6 and 36.1°C ±0.5 respectively (p=0.04). Figure 8.2 shows mean core temperature during surgery.

Table 8.2: Outcome measures

	BARRIER EasyWarm (N=43)	**Bair Hugger** N=40)	p-value
Mean core temperature holding °C (SD)	36.8 (0.4)	36.8 (0.5)	0.49
Mean core temperature after induction of anesthesia °C (SD)	36.6 (0.5)	36.7 (0.5)	0.22
Core temperature start °C (SD)	36.3 (0.5)	36.4 (0.5)	0.56
Mean intraoperative core temperature °C (SD)	35.8 (1.6)	36.0 (1.3)	0.68
Mean lowest peroperative core temp °C (SD)	35.9 (0.6)	36.1 (0.5)	0.05
Core temperature end °C (SD)	35.9 (0.6)	36.2 (0.5)	0.02
Mean core temperature recovery °C (SD)	35.8 (0.6)	36.1 (0.5)	0.04
Measurements <36°C N (%)	26 (60)	15 (38)	0.24
Measurements <36°C (n)	2.6 ± 2.5	2.0 ± 2.7	0.32
Complication during hospitalization (yes/no)	2/41	2/41	1.0
Thermal comfort VAS mean (SD)	53.3 (15.7)	52.9 (12.3)	0.90

All temperatures are in ^{0}C. SD = standard deviation, VAS = visual analogue scale, rang from 0 (extreme cold) to 100 (extreme hot).

Figure 8.2: Mean perioperative core temperature



Measurements below 36.0°C were seen in both groups (BE: 26/43 (60%), BH: 15/40 (38%) p=0.24) and the number of measurements below 36.0°C was comparable; 2.6 ±2.5 for the BE group and 2.0 ±2.7 for the BH group (p=0.32). Tympanic temperature measurement showed a mean difference of approximately 0.1°C (range -1 – 1.1) compared to the SpotOn core thermometer. Evaluation of patients' experienced thermal comfort, using a Visual Analogue Scale (VAS), showed no differences between both groups (p=0.90). The mean VAS was 53.3 ±15.7 in the BE group and 52.9 ±12.3 in the BH group. The number of complications was equal between both groups. In each group two complications during hospital stay occurred. In the BE group one THR treatment was complicated by persistent wound leakage postoperatively. CRP (44) and BSE (31) were elevated. This resulted in surgical debridement and microbial cultures were taken two weeks after the primary surgery. Cultures showed growth of enterococcus faecalis and staphylococcus lugdunensis. The patient was treated with intravenous vancomycin and rifampicin and subsequent oral antibiotics (Augmentin/rifampicin) during three months. The second complication

in the BE group had a history of hemorrhagic stroke. Postoperative clinical signs of aphasia, which was a result of a cerebral infarction, was seen. Acetylsalicylic acid and dipyridamole were started for secondary prophylaxes.
In the BH group one THR patient had persistent wound leakage postoperatively. Lab results, showed elevated infection parameters (CRP44, BSE93), which gradually decreased during the postoperative period in several days. The patient was discharged without antibiotics or other intervention. Follow-up showed no infection. The other complication in the BH group had also THR. Several days after surgery, the patient was evaluated for tachypnea and hypotension. High infection parameters (CRP222, BSE56) and fever were present, the patient was diagnosed with a urinary bladder infection. Antibiotics were started. The patient improved clinically and was discharged to a temporary rehabilitation clinic.

Discussion

Both intraoperative patient warming methods failed to prevent hypothermia from occurring during the perioperative phase in our study. Measurements below 36.0^{o}C were seen in 60% of the patients in de BE group as well as in 38% in the BH group. The results show that the self-warming blanket (BE) is less effective compared to the forced air blanket (BH) at the end of surgery and postoperatively at the recovery bay. It is important to consider whether the differences between both systems are clinically relevant because apparently both methods failed to prevent hypothermia.
The complications, that occurred in both groups, might be related to hypothermia. Hypothermia affects the immune system. Decreased cell-mediated immunity and NK-cell activity, suppression of B lymphocytes and defective function of T lymphocytes is seen due to hypothermia.[13,14] There is also an association with suppressed phagocytic activity and reduced bacterial killing. It could be possible that hypothermia contributes to the immune alterations perioperatively and thereby increase the risk of postoperative complications.[13,14]
Comparing both groups, no differences in complications related to the surgery were seen during hospital stay. Hypothermia, which could be a result of temperature redistribution due to induction of anesthesia, fluid loss and reinfusion during surgery,

is difficult to manage with passive methods, making active warming necessary. High incidences of postoperative hypothermia are seen in THR and TKR.[5,15] Because hypothermia could result in several complications it should be managed properly.[2] There are different active warming methods, but for each of them their safety and efficacy should be questioned.

The Bair Hugger system has widely been used in studies on perioperative warming.[16] In contrast to the Bair-Hugger, the BARRIER EasyWarm system is quite new. A randomized study showed that the BE system was superior to passive thermal insulation.[17] However, another randomized study reported that a thermal reflective blanket was not able to prevent hypothermia during surgery.[16] This finding is consistent with our study. Fanelli et al. randomized 56 patients undergoing elective THR to be warmed either by a forced-air system or by a resistive heating blanket.[6] Primary outcome was temperature as measured by tympanic thermometer. No significant differences were found, mild hypothermia was found in both groups at the end of surgery.[6] A Cochrane systematic review and meta-analysis comparing forced-air with active resistive heating was unable to show differences in terms of thermal comfort and also in terms of postoperative blood loss.[16]

This study has several strengths and limitations. In this single-center randomized controlled non-inferiority trial we were able to randomize 86 of 90 consecutive TKR and THR patients without any loss to follow-up. Core temperature from all patients was measured in a uniform way. The reliability of tympanic temperature measurement is questioned with regard to accuracy compared to core temperature.[18] A relevant difference between both recording methods was not found. One factor that might compromise generalizability is that all THR patients were operated in a supine position via the direct anterior approach while the lateral decubitus position is still more frequently used in hip replacement surgery.

Another possible limitation of our study is that a considerable amount of patients dropped below a temperature of 36.0 ^{o}C. The inability to prevent hypothermia in the BE group could be the result of a deviating use of the blanket; the BE was not directly placed on the patient as instructed by the manufacturer; a cotton blanket was placed in between and could have limited the penetration of warmth towards the patient, the

warmth has to penetrate this cotton blanket before reaching patient's skin. Possibly prevention of hypothermia could have be better without placing this cotton blanket in between, as instructed by the manufacturer. The reason to use this interposing cotton blanket was prevention of burn lesions to the skin. To optimize the use of the BH, the operators' manual cites to use a cotton blanket on top of it, in our study the Bair Hugger was used without blanket. Another factor, applicable for both groups, is that the patient could not be fully covered by the BE nor the BH due to the sterile field, with a larger uncovered field during THR compared to TKR.

One of the potential advantages of the BE self-warming blanket is the possibility to use it continuously; before, during and after surgery, there is a constant active warming of the patient possible without interruption. The BH was turned on as soon as the sterile draping procedure was finished, the time during which the patient was moved from the bed to the operating table until finishing the sterile draping procedure of the surgical site no active warming was used for the patient.

An advantage for the surgical team of a self-warming blanket over a forced-air blanket is the comfort of the operating team during surgery. A forced-air device has continuous flow of warm air affecting the surrounding air, if it is close to the operating staff it could feel quite 'hot'. The warmth that a self-warming blanket generates remains close to the patient, possibly less affecting the surrounding air and thereby operating staffs' comfort. Another factor affecting the staff's comfort is the amount of noise in the OR; it goes without saying that a blanket is quiet while forced-air devices contribute to noise pollution in the OR.[16]

Conclusion

In this study both warming blankets did not prevent hypothermia from occurring in both the self-warming blanket group as well as in the forced-air blanket group. A statistical significant difference between both groups was found in core temperature at the end of TKR or THR surgery. Whether the difference of 0.2 ^{o}C is clinically relevant remains to be evaluated, it was nevertheless less than the hypothesized difference of 0.5 ^{o}C for our non-inferiority study. For that matter the self-warming

blanket was non-inferior to the forced-air blanket. But since many patients in both groups showed hypothermia, this should be addressed better.

At the end of surgery and at the recovery room the BE group had significant, although little, lower core temperatures, whether such a small difference is clinically relevant remains to be discussed.

We should ask ourselves the question if it is more important to keep the patient normothermic by using the BH with slightly better results, but with the risk of an infection due to interruption of the laminar flow and thereby affecting the sterile field. Perhaps it would be better to optimize the BE protocol, without interrupting the air flow and thereby reducing the risk of infection. However, hypothermia is also associated with infections. Both aspects, managing normothermia and avoiding interruption of laminar air flow, should be optimized to reduce the risk of infection and therefore further research is needed.

References

1. Gessler DI, Olofsson CI, Rubinstein EH, Beebe JJ. The thermoregulatory threshold in humans during halothane anesthesia. Anesthesiology 1988;68:836-42.
2. Brandt S, Oguz R, Huttner H, et al. Resistive-polymer versus forced-air warming: comparable efficacy in orthopedic patients. Anesth Analg 2010 1;110(3):834-8.
3. Koëter M, Leijtens B, Koëter S. Effect of thermal reflective blanket placement on hypothermia in primary unilateral total hip or knee arthroplasty. J Perianesth Nurs 2013 28(6): 347-52.
4. Kurz A, Sessler DI, Lenhardt R, et al. Perioperative normothermia to reduce the incidence of surgical wound infection and shorten hospitalization. N Eng J Med 1996 9;334(19):1209-15.
5. Reina N, Fennema P, Hourlier H. The impact of mild peri-operative hypothermia on the effectiveness of tranexamic acid in total hip arthroplasty. Int Orthop 2017 41(1):55-60.
6. Fanelli A, Danelli G, Ghisi D, Ortu A, Moschini E, Fanelli G. The efficacy of a resistive heating under-patient blanket versus a forced-air warming system: a randomized controlled trial. Anesth Analg 2009;108(1):199-201.
7. Tjoakarfa C, David V, Ko A, Hau R. Reflective blankets are as effective forced air warmers in maintaining patient normothermia during hip and knee arthroplasty surgery. J Arthroplasty 2017 32:624-7.
8. Legg AJ, Hamer AJ. Forced-air patient warming blankets disrupt unidirectional airflow. Bone Joint J 2013 95-B(3):407-10.
9. Dasari KB, Albrecht M, Harper M. Effect of forced-air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012 67:244-9.
10. Kellam MD, Dieckmann LS, Austin PN. Forced-air warming devices and the risk of surgical site infections. AORN J 2013 98:356-66.
11. Eshraghi Y, Sessler DI. Exploratory method-comparison evaluation of a disposable non-invasive zero heat flow thermometry system. 2012 American Society of Anesthesiologists Annual Meeting. A63.
12. Piaggio G, Elbourne DR, Altman DG, et al. Reporting of non-inferiority and equivalence randomized controlled trials. An extension of the CONSORT statement. 2006 JAMA 295(10):1152-60.
13. Beilin B, Shavit Y, Razumovsky J, Wolloch Y, Zeidel A, Bessler H. Effects of mild perioperative hypothermia on cellular immune responses. Anesthesiology 1998 89;1133-40.

14. Brand JM, Frohn C, Luhm J, Kirchner H, Schmucker P. Early alterations in the number of circulating lymphocyte subpopulations and enhanced proinflammatory immune response during opioid-based general anesthesia. Shock 2003 20;3:213-7.

15. Leijtens B, Koeter M, Kremers K, Koeter S. Hihj incidence of postoperative hypothermia in total knee and total hip arthroplasty. J Arthroplasty 2013 28;895-8.

16. Madrid E, Urrutia G, Roqué i Figuis M, et al. Active body surface warming systems for preventing complications caused by inadvertent perioperative hypothermia in adults. Cochrane Database Syst Rev 2016 21:4:CD009016.

17. Torossian A, van Gerven E, Geertsen K, van de Velde M, Raeder J. Active perioperative patient warming using a self-warming blanket (BARRIER EasyWarm) is superior to passive thermal insulation: a multinational, multicenter, randomized trial. J Clin Anesth 2016 34:547-54.

18. Hooper VD, Andrews JO. Accuracy of noninvasive core temperature measurement in acutely ill adults: the state of the science. Biol Res Nurs 2006 8(1):24-34.