Title page

Thermal suit in preventing unintentional intraoperative hypothermia during general anaesthesia. A randomized controlled trial.

Sirkka-Liisa Lauronen[1], Maija-Liisa Kalliomäki[1], Antti J. Aho[2,3], Jarkko Kalliovalkama[2,3], Jarno M. Riikonen[4], Marja-Tellervo Mäkinen[5], Heli M. Leppikangas[1], Arvi M. Yli-Hankala[1,3]

[1] Department of Anaesthesia, Tampere University Hospital, Tampere, Finland

[2] Coxa Ltd., Hospital for Joint Replacement, Tampere, Finland

[3] University of Tampere, Faculty of Medicine and Life Sciences, Tampere, Finland

[4] Department of Urology, Tampere University Hospital, Tampere, Finland

[5] Department of Anaesthesiology, Intensive Care and Pain Medicine, University of Helsinki and Helsinki University Hospital

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Correspondence: Sirkka-Liisa Lauronen, Department of Anaesthesia, Tampere University Hospital, Teiskontie 35, PB2000, 33521 Tampere, Finland tel. +358 3 311 66027, fax. +358 3 311 65444 , E-mail: sirkka-liisa.lauronen@pshp.fi

Footnote:

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Abstract

Background: Unintentional perioperative hypothermia causes serious adverse effects to surgical patients. Thermal suit (T-Balance®) is an option for passive warming perioperatively. We hypothesized that the thermal suit will not maintain normothermia more efficiently than conventional cotton clothes when also other preventive procedures against unintentional hypothermia are used.

Methods: One hundred patients were recruited to this prospective, randomized trial. They were allocated to the Thermal Suit group or a Control group wearing conventional hospital cotton clothes. All patients received our institution`s standard treatment against unintentional hypothermia including a warming mattress, a forced-air upper body warming blanket and a warming device for intravenous fluids. Eardrum temperature was measured preoperatively. In the operating room and post anaesthesia care unit temperatures were measured from four locations: oesophagus, left axilla, dorsal surface of the left middle finger and dorsum of the left foot. The primary outcome measure was temperature change during robotic-assisted laparoscopic radical prostatectomy.

Results*:* The temperatures of ninety-six patients were analyzed. There was no difference in mean core temperatures, axillary temperatures or skin temperatures on the finger between the groups. Only foot dorsum temperatures were significantly lower in the Thermal Suit group. Intraoperative temperature changes were similar in both groups. In the post anaesthesia care unit temperature changes were minimal and they did not differ between the groups.

Conclusion: Provided that standard preventive procedures in maintaining normothermia are effective the thermal suit does not provide any additional benefit over conventional cotton clothes during robotic-assisted laparoscopic radical prostatectomy.

Trial registration*:* Clinicaltrials.gov identifier: NCT01571544.

Introduction

Unintentional perioperative hypothermia causes well-known adverse effects: increased incidence of wound infections,[1] increased blood loss,[2] increased risk for myocardial ischemia[3] and prolonged recovery postoperatively[4]. In addition to these shivering and the feeling of cold in the post anaesthesia care unit are uncomfortable and distressing for the patient.

Laparoscopic surgery exposes the patients to heat loss by rather a large area of exposed skin in a comparable manner to open abdominal surgery[5,6]. Pre-heating the insufflating gas has little effect on body thermoregulation during laparoscopy[7]. Similarly, prewarming the ambient temperature does not prevent intraoperative hypothermia[8] but the temperature of the operation room has a direct effect on the heat balance of the patients.

There are several methods to reduce heat loss in the perioperative setting. Active heating methods consist of warming of intravenous and irrigation fluids[9], using forced-air warming devices and thermoadjustable mattresses. Passive warming methods such as space blankets, cotton and microfiber blankets, as well as low-flow anaesthesia are used during surgery.

Thermal suit (T-Balance®, TelesPro Finland Ltd., Kuopio, Finland) is an option for passive warming perioperatively. In a previous study body temperature was maintained 0.5°C higher in patients wearing the T-Balance® thermal suit compared to patients wearing conventional hospital clothes during transurethral resection of the prostate under spinal anaesthesia[10].

The aim of this prospective, randomized, controlled study was to investigate if using the T-Balance® thermal suit in addition to our institution's standard preventive procedure against unintentional perioperative hypothermia is beneficial during robotic-assisted laparoscopic radical prostatectomy (RALP) under general anaesthesia. Our null hypothesis was that the T-Balance® thermal suit will not maintain normothermia more efficiently than conventional cotton clothes during RALP. Primary aim was difference in core temperature during anaesthesia. Secondary aims were differences in peripheral temperatures and relevant surgical outcomes.

Methods

After approval from the Ethical Committee of Tampere University Hospital, Tampere, Finland (R12038) (Chairperson Prof. Amos Pasternack) on 21st February 2012 the study was registered with ClinicalTrials.gov (Code NCT01571544). The study was carried out at Tampere University Hospital, Tampere, Finland, during the period of November 2012 to April 2013. Written informed consent was obtained from all patients. The study was conducted according to rules and regulations of the Declaration of Helsinki.

Inclusion criteria were: age 18-90 years, American Society of Anesthesiologists ASA physical status I-III and scheduled for RALP. Exclusion criteria were: decreased mental status, neuromuscular disorders, Raynaud's phenomenon and unstable coronary artery disease.

Study design and trial protocol

One hundred patients were recruited to the study: 50 patients wearing conventional hospital cotton clothes (Control group) and 50 patients wearing the T-Balance® thermal suit (Thermal Suit group). Randomization was accomplished using a computerized random number generator. Blocked randomization was used including ten patients in each block. During the preoperative visit the patients were randomized to treatment groups. The randomization was kept blinded for the patient and the staff until the day of the surgery. The first patient of the day arrived from home to the hospital at seven o`clock and the second patient was scheduled to arrive at 11 o'clock. The attending nurse at the preoperative holding area opened the sealed randomization envelope and instructed the patients to switch to study clothes accordingly.

All patients received standard methods against unintentional intraoperative hypothermia. At our institution the following are in use for RALP patients: warming mattress (Astopad®, Armstrong Medical, Coleraine, Northern Ireland) set to 38.5°C, warming of intravenous fluids to approximately 41°C (Hotline®, Smiths Medical, Ashford, United Kingdom) and upper body forced-air warming blanket set to 38°C (Bair Hugger®, Arizant Heathcare, Eden Prairie, MN, USA). According to the routine care the patients in the Control group were administered single-use nonwoven leg

stockings (Barrier®, Mölnlycke Health Care, French Forest, NSW, Australia) before induction of anesthesia whereas the patients in the Thermal Suit group were barefoot.

Thermal suit

T-Balance® thermal suit has been developed to prevent inadvertent hypothermia perioperatively. It is dressed on the ward or in the preoperative holding area before surgery. The T-Balance® thermal suit can be worn throughout all kinds of surgeries and perioperative care. The thermal suit has multiple zippers that can be opened and closed as required for anaesthesia, surgery and postoperative care. The fabric of the thermal suit is three-layer laminate: the outermost layer is woven from smooth microfibers, the middle layer is made of waterproof, breathable fabric, and the innermost layer is made of microfleece. The reusable thermal suit can be washed in normal hospital laundry at 70-72°C. The thermal suit should be washed maximum of 80 times or maximal using time is 180 weeks if washing times cannot be calculated. New thermal suits were taken into use in the beginning of this study.

Temperature measurement

Baseline body temperature was measured with an eardrum thermometer (Covidien Genius 2, Tympanic Thermometer and Base, Covidien llc, Mansfield, MA, USA) before patient changed to study clothes. The temperature measurement points in the operating room were oesophagus (core temperature, T1), left axilla (T2), dorsal surface of the middle phalanx of the left middle finger (T3) and the dorsum of the left foot (T4). As soon as the patient had moved onto the operating table the measurement of the skin temperatures (T2, T3 and T4) were started using disposable probes (Skin Temperature Probe®, GE Healthcare Finland, Helsinki, Finland). The disposable oesophageal thermometer (General Purpose Temperature Probe®, GE Healthcare Finland, Helsinki, Finland) was placed immediately after endotracheal intubation. All temperature data were collected at 10-second intervals on a laptop computer with S5 Collect software (GE Healthcare Finland, Helsinki, Finland) for offline analysis. Ambient temperature at one-meter distance from the patient (Prologue® Digital Thermometer, Model No

RS3010, Clas Ohlson, Insjön, Sweden) and humidity (from the digital display on the operating room wall) of the operating room were also measured and recorded every 15 minutes. In the post anaesthesia care unit the measuring and recording of all temperatures continued until the patient was transferred to the ward or up to three hours.

If core temperature (T1) rose over 38°C the anaesthesiologist was instructed to: turn off the forced-air warming blanket, turn off the warming device for intravenous fluids, and turn off the warming mattress. If core temperature (T1) fell below 35°C the following steps were instructed: temperature of the warming mattress would be set to 40°C, and temperature of the forced-air warming blanket would be set to 43°C. It was also instructed to warm up the patient until the core temperature was over 35°C at tracheal extubation.

Anaesthesia

Patients received per os paracetamol 1000 mg and if needed also midazolam 7.5 mg per os 0.5-1 hour before surgery. All patients were anaesthetized with target controlled infusions (TCI, Asena™ PK, Alaris Medical Systems, Basingstoke, UK) of propofol and remifentanil. Pharmacokinetic models of Schnider and Minto were used for administration of propofol and remifentanil, respectively.[11,12] Total amounts of anaesthetics were recorded at the end of anaesthesia. The administration of anaesthetics was targeted to keep State Entropy (GE Healthcare, Helsinki, Finland) values between 30 and 60. Rocuronium 0.6 mg/kg was used to facilitate endotracheal intubation and additional doses were given according to clinical needs. Neuromuscular transmission was monitored with the M-NMT Mechanosensor™ (Datex-Ohmeda, Helsinki, Finland) and assessed using the train of four stimulation mode.

Positive end-expiratory pressure was set to 5 cmH_2O and maintained throughout the anaesthesia. The end-tidal oxygen concentration of 45 % and fresh gas flow of 1.2 l/min were used during surgery. To avoid anaesthetic-induced relative hypovolemia the study protocol permitted infusing 1000 ml of Ringer's acetate (Ringer-Acetat Baxter Viaflo®, Baxter Healthcare Ltd, Thetford, Norfolk, Great Britain) and 500 ml of hydroxyethyl starch (Tetraspan® 60 mg/ml, B. Braun Melsungen AG, Melsungen, Germany) intraoperatively via Hotline® fluid warmer. The noninvasive mean arterial pressure was

maintained over 65 mmHg; additional intravenous fluids and/or infusion of noradrenaline were used if needed.

Surgery

RALP was carried out with the aid of a four-arm da Vinci S robot (Intuitive Surgical, Sunnyvale, CA, USA). Pneumoperitoneum was established by the Hasson technique 2 cm above the umbilicus and maintained by unheated CO_2 insufflation. A transperitoneal six-port approach was used. During the operation the patient was in the 30 degree Trendelenburg position, hips were abducted and knees flexed. Intra-abdominal pressure was 12 mmHg, excluding division of the deep venous complex when pressure was raised up to 18-20 mmHg. The prostate specimen was removed via periumbilical incision.

At our institution two RALP surgeries are performed daily (in the text referred to as order of the patient, 1 or 2). The planned discharge from hospital is the first day after surgery. The removal of the urinary catheter is planned from six to nine days postoperatively. The postoperative complications from surgery to catheter removal are collected using Clavien-Dindo classification.[13]

Statistical analysis

We aimed to detect a difference of 0.5°C in core temperature between the study groups as this is considered clinically significant. Based on the previous study[10] standard deviation of 0.7°C in the core temperature was assumed. The study was designed to have a power of 0.80, assuming alpha error of 0.05. To meet the criteria of power calculation 42 patients per group were needed. To allow for dropouts we enrolled 50 patients per study group.

Statistical analyses were performed using SPSS 21.0 (IBM, Chicago, Ill, USA). T-test was used for parametrical continuous independent data and Mann-Whitney for non-parametrical data. ANOVA was performed for the comparison of several groups. Paired t-test was used for analyzing statistical difference in paired samples. P value < 0.05 was considered statistically significant.

Results

One hundred patients were enrolled. Four patients, all from the Control group, were left out of the final analyses (Figure 1). The patient characteristics and the relevant intraoperative data are presented in Table 1. All patients except one in the Control group received paracetamol 1000 mg for premedication. Seven patients in the Control group and eleven patients in the Thermal Suit group received also midazolam 7.5 mg per os. Before surgery the mean time spent at the preoperative holding area was 55 min (median 45 min) in the Control group and 70 min (median 80 min) in the Thermal Suit group (P=0.015). Altogether mean preoperative waiting time was 63 minutes and median 47 minutes. To maintain mean arterial pressure > 65 mmHg the infusion of noradrenaline was used in 20 and 13 patients in Control and Thermal Suit groups, respectively. Additionally 13 controls and 10 patients wearing the thermal suit needed noradrenaline boluses (total dose 8-24 µg, no statistical difference). Ambient temperature (Control 21.3°C ± 0.38, Thermal Suit 21.4°C ± 0.39) and humidity (Control 47.4% ± 1.0, Thermal Suit 47.4% ± 1.0) were similar in both groups. Mean volume of gas delivered was 267 liters ± 130 (median 245) in the Control group and 253 liters ± 121 (median 216) in the Thermal Suit group. The warming devices were not regulated during the anaesthesia. Four patients in the Control group and five patients wearing the thermal suit needed additional warming in the post anaesthesia care unit.

Core temperature

No over 0.5°C differences were found in the mean core temperatures between the two groups. Neither did the minimal core temperatures differ significantly. There was, however, a 0.6°C difference in the maximal core temperature for the benefit of the Control group at time point 120 min (Figure 2, Table 2). Sixteen patients in the Control group and nineteen patients in the Thermal Suit group had a temperature below 36.0°C during surgery. Time spent at the temperature below 36.0°C was not different between the groups (Table 2). The core temperature at the time of tracheal extubation was below 36°C in two and five patients in Control and Thermal Suit groups, respectively. The differences in the core temperatures between Control and Thermal Suit –groups were not dependent on the order of the patient (data not shown). In addition the core

temperature of both groups rose significantly during anaesthesia, more prominently in the Control group (Figure 2).

The difference between the groups in the post anaesthesia care unit was not significant, and in both groups the temperature rose to a similar extent (Figure 3).

Skin temperatures

The axillary temperatures followed the oesophageal temperatures (Figure 4). The skin temperatures in the finger and foot dorsum rose significantly in the both groups during the first hour of anaesthesia. The finger temperatures (T3) did not differ significantly between the study groups. The minimal and maximal foot dorsum temperatures (T4) were statistically significantly lower in the patients wearing the thermal suit (Table 3).

The skin temperatures in the post anaesthesia care unit were similar in both groups. The axillary temperatures rose in both groups. The finger temperatures decreased first and then rose. The foot temperatures did not change. There were no differences in thermal distribution between the Control and the Thermal suit groups.

Relevant surgical outcomes

Eighty-four percent (81/96) of the patients were discharged from the hospital on the first postoperative day. Clavien-Dindo classification was available for 73 patients, 23 patients went for postoperative control in their local hospitals. In 53 (73%) patients no complications were observed. One patient from each group required cystoscopy. One patient in the Thermal Suit group needed antibiotics for urinary tract infection and another one analgesics for pain in the perineum. No differences in discharge time or complication rates were found between the Control and Thermal Suit groups.

Discussion

In this randomized controlled trial no difference was found in the core temperature between groups wearing conventional hospital cotton clothes or the T-Balance® thermal suit. To our knowledge this is the first study comparing the conventional hospital cotton clothes and the T-Balance® thermal suit during laparoscopy under general anaesthesia. A statistically but not clinically significant difference (0.6°C) of the maximal core temperature for the benefit of the Control group was seen at 120 minutes after intubation. The patients in the Control group were more prone to be warmed up during anaesthesia. The thermal suit most probably acts as an insulator, i.e. external warming devices do not reach the patient through the thermal suit, but on the other hand these patients do not loose thermal energy through convection, evaporation and conduction in comparison with control patients. The lack of benefit of the suit cannot be explained by excessive washing of the reusable suits since all thermal suits were brand new in this study.

It can be argued that there was a statistically significant difference in the temperature of the foot between the study groups but, in our opinion, it is justifiable to claim that this difference is not clinically relevant. Patients wearing the thermal suit had lower foot temperatures already at the induction of anaesthesia. This may be a sum effect of longer waiting time and lack of leg stockings in the Thermal Suit group compared to the Control group. This discrepancy may be considered as a limitation of the study. A method for equalizing the waiting times could have been randomizing the days first and second patients separately into hospital clothes and thermal suits. We recommend this to be considered in further studies.

The manufacturer claims that the longer the thermal suit is on the patient the better the benefit from it. In our study population the waiting time at the preoperative holding area was significantly longer in the Thermal Suit group. Even so we did not find any significant changes of body temperatures in favor of the thermal suit. The manufacturer recommends the thermal suit to be worn for several hours before entering the operating room. This however is not possible in the era of day- and short-term surgery when the patients come to the hospital in the morning of their surgery. In order to find out the benefit of wearing the thermal suit for a longer time patients should be able to wear the

thermal suit from the previous evening of surgery.

Thermal redistribution after the induction of anaesthesia happens due to the disturbance of central thermoregulation and the peripheral vasodilatation.[14] In our study the thermal distribution during anaesthesia was similarly affected in both clothing groups – the difference between core and skin temperatures diminished with time from the beginning of anaesthesia. We hypothesize that because the thermal suit acts as an insulator it does not prevent or change the pattern of thermal redistribution. It would be of interest to investigate the efficacy of thermal suit in preserving body`s thermal energy. This should be done in a separate, well planned setting with a long enough preoperative period.

Hypothermia during surgery is a sum effect of radiation, convection, evaporation and conduction of the body surfaces and the respiratory tract. Factors affecting these are: type of surgery, exposed area of skin, volume and temperature of irrigation and intravenous fluids, ventilation with cold gases and the length of anaesthesia. Two earlier studies have compared the open surgical technique with a laparoscopic technique for cholecystectomy[5] and gastric bypass surgery[6].Neither of the studies detected difference in the core temperature[5,6] nor the thermal balance[5] between the open and laparoscopic surgical groups. It is thus unlikely that the thermal suit could provide any benefit in other types of surgery under general anaesthesia.

One of the limitations in our study is that we aimed for a 0.5°C difference but according to our analysis the 0.2°C difference in the mean core temperature between Thermal Suit and Control groups was statistically significant. However, at this time point there was a larger (0.6C) temperature difference in the maximal temperatures, which explains the statistical difference. This discrepancy occurred because the variation of temperatures was smaller in our study sample than in the reference[10] study sample. It may be considered yet as another limitation that neither the patients nor the nurses were asked for the convenience of the thermal suit. Patient-related features of importance for thermoregulation during laparoscopy are the radius of abdomen, the thickness of the distended abdominal wall, initial blood mass flow rate and body metabolic heat ratio[15] which were not calculated in our study.

In conclusion in a setting where routine procedures against unintentional perioperative hypothermia are effective, as in our hospital, the thermal suit does not bring additional

value to maintaining normothermia during general anaesthesia in major laparoscopic surgery.

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Conflicts of interest: S-LL has received speaker fees (Finland 3M); M-TM was a member of the 3M Patient Temperature Management Advisory Board until 31st December 2016.

Presentation: none.

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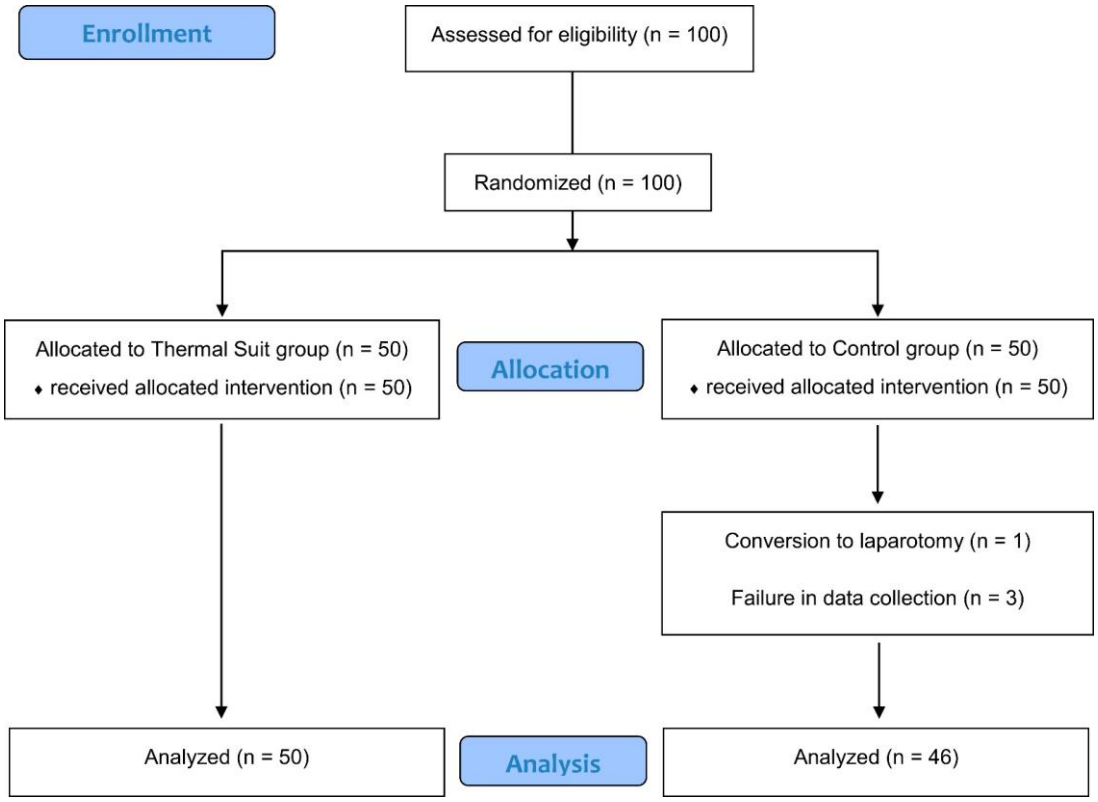

Figure 1.

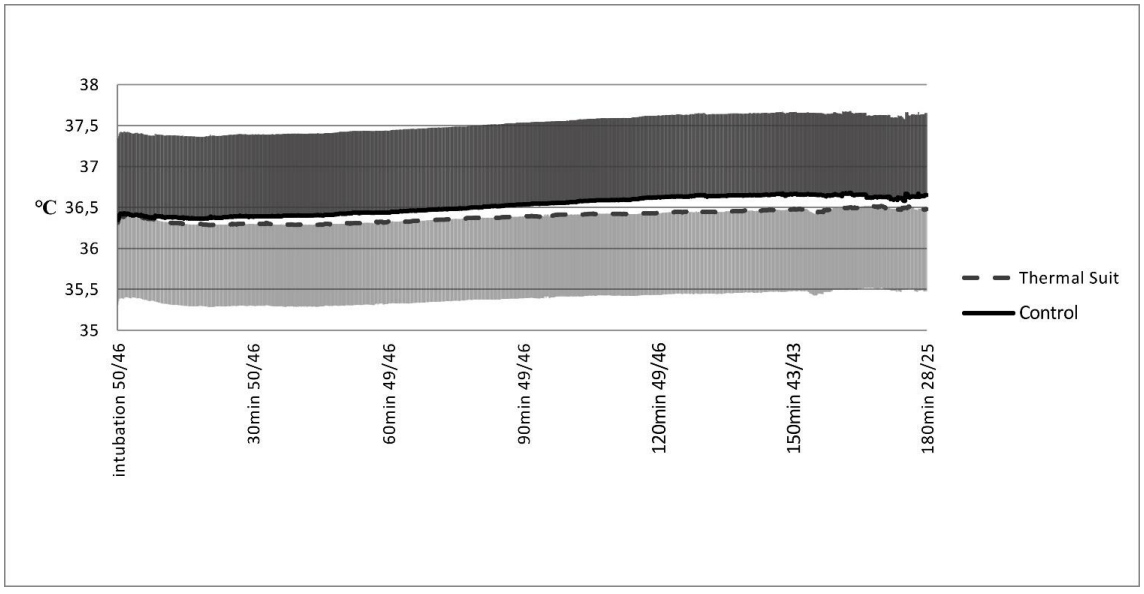

Figure 2. Diagram showing the core temperature change within groups Control and Thermal Suit in the operating room. There is no significant difference between the groups during the anaesthesia. The X-axis shows time in minutes and number of patients in each group (Thermal Suit/Control).

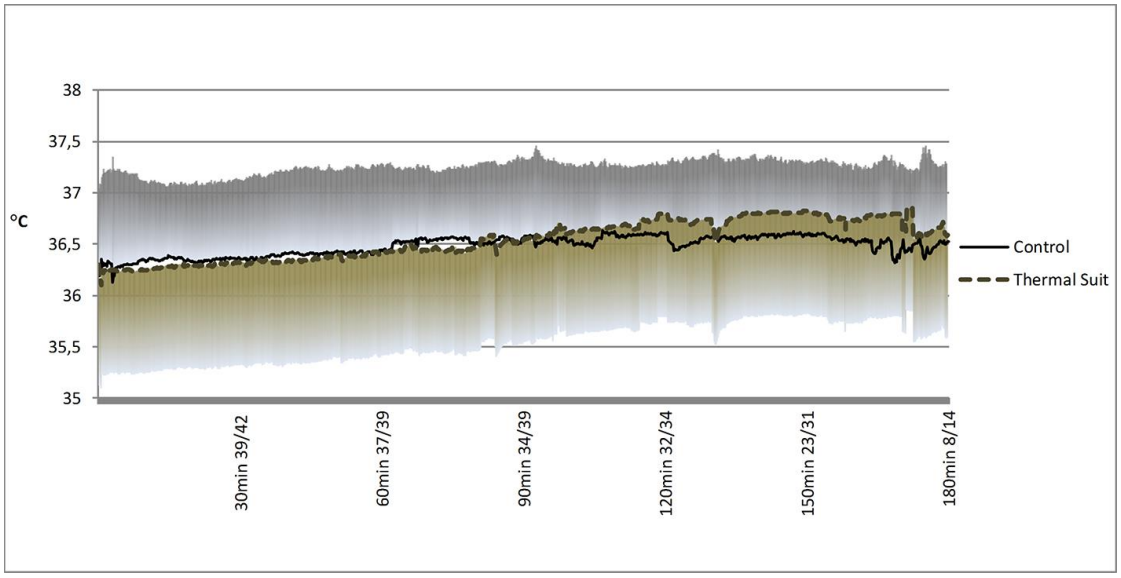

Figure 3. Diagram showing the core temperature change within groups Control and Thermal Suit in the postanaesthesia care unit. The difference in between the groups is not significant (P=0.08). The temperature rises significantly in both groups, P=0.000 (Lower Bound), and the difference is more pronounced in the Control group, P=0.036 (Lower Bound). Black line=Control group, Grey line=Thermal Suit group. The X-axis shows time in minutes and number of patients in each group (Thermal Suit/Control).

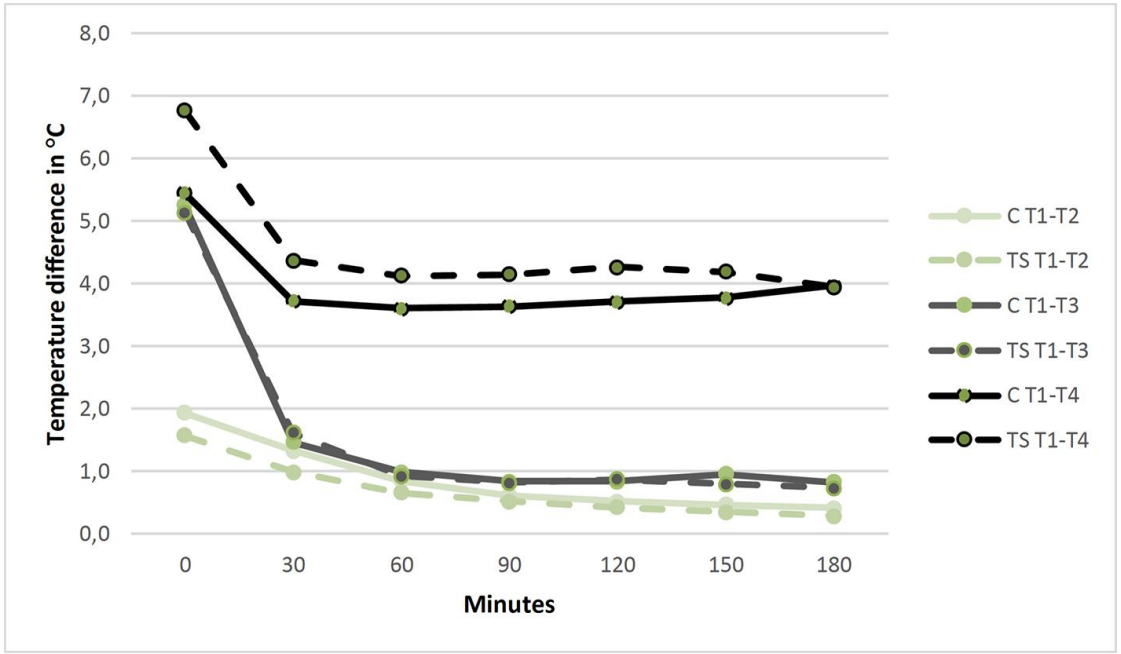

Figure 4. Thermal distribution during anaesthesia. There was no difference in the oesophagial (T1) and axillary temperatures (T2). The temperature difference between oesophagial (T1) and peripheral (T3, finger and T4, foot dorsum) is largest at the beginning and diminishes during the first 30 minutes after the induction of anaesthesia whereafter it stays stabile. C= Control, TS= Thermal Suit.

Table 1. Demographic data

	Thermal Suit (N=50)	Control (N=46)	p value
Age years	60.38 (6.76)	62.04 (5.54)	0.193
Body Mass Index kg/m^2	27.76 (3.51)	27.85 (4.15)	0.903
Pre-operative eardrum temperature °C	36.55 (0.39)	36.61 (0.36)	0.404
Blood loss ml	172,45 (163.54)	161.52 (122.13)	0.714
Hydroxyethyl starch ml	340.00 (194.83)	370.65 (162.47)	0.407
Remifentanil µg	2149.43 (669.00)	2292.13 (670.85)	0.305
Propofol mg	2287.61 (591.05)	2288.64 (509.20)	0.986
Preoperative waiting time h	1:10:02 (0:32:35)	0:55:04 (0:25:18)	0.015
Order of the patient (N1) / (N2)	23 / 27	29 / 17	0.105
Duration of surgery h	2:41:46 (0:36:20)	2:41:56 (0:32:32)	0.983
Duration of anaesthesia h	3:18:09 (0:37:13)	3:19:43 (0:34:28)	0.832
ASA class I / II / III (number of patients)	10 / 28 / 12	6 / 24 / 16	

Footnote: otherwise values mean (SD). Order of the patient: (N1) is amount of the patients being the first patient in the operating room, (N2) is amount of the patients being the second patient in the operating room. ASA American Society for Anesthesiologists.

Table 2. Core temperature parameters

	Group	N	Mean	SD	lowest-highest	p
min	Control	46	36.15	0.52	34.90-37.40	0.57
	Thermal Suit	50	36.07	0.51	34.90-37.00	
max	Control	46	36.82	0.44	35.80-37.90	0.19
	Thermal Suit	50	36.71	0.37	35.90-37.40	
mean	Control	46	36.54	0.41	35.61-37.53	0.09
	Thermal Suit	50	36.40	0.41	35.54-37.16	
mean120	Control	46	36.62	0.47	35.60-37.90	0.04
	Thermal Suit	49	36.43	0.45	35.60-37.30	
extubation	Control	46	36.69	0.49	35.70-37.90	0.06
	Thermal Suit	50	36.51	0.45	35.60-37.60	
time spent at	Control	16	17.02	41.81	0.3-198	0.32
<36°C (minutes)	Thermal Suit	19	27.55	58.75	0.5-200	

Table 3. Peripheral temperatures

	Group	Mean TC	SD	Range	P
Mean	T2 Control	35.82	0.46	34.7-37.1	0.47
	Thermal Suit	35.75	0.49	34.6-36.6	
	T3 Control	35.10	0.69	33.4-36.5	0.28
	Thermal Suit	34.93	0.75	32.8-36.2	
	T4 Control	32.73	1.68	28.1-35.2	0.01
	Thermal Suit	31.90	1.53	26.8-33.9	
TC at 120min	T2 Control	36.12	0.48	34.7-37.5	0.24
	Thermal Suit	36.00	0.50	34.7-36.8	
	T3 Control	35.78	0.64	34.0-36.8	0.13
	Thermal Suit	35.56	0.77	32.4-36.5	
	T4 Control	32.92	1.78	28.0-35.3	0.05
	Thermal Suit	32.16	1.87	26.4-34.6	

Footnote: T2 axilla, T3 finger and T4 foot dorsum. Means of temperatures in degrees Celsius (TC) and mean of temperatures at 120min from the induction of anaesthesia, when the temperature differences were largest. SD= stardard deviation.