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Clinical Evidence Summary

3M™ Bair Hugger™ Temperature Monitoring System

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The 3M™ Bair Hugger™ Temperature Monitoring System can non-invasively measure core temperature

Eshraghi Y, Nasr V, Parra Sanchez I, et al. An evaluation of a zero heat flux cutaneous thermometer in cardiac surgical patients. *Anesth Analg*. 2014;119(3):543 549.

Background

Current methods to monitor core temperature are invasive. This study compared a new zero-heat-flux thermometer to a pulmonary artery catheter.

Design

Observational study

Population

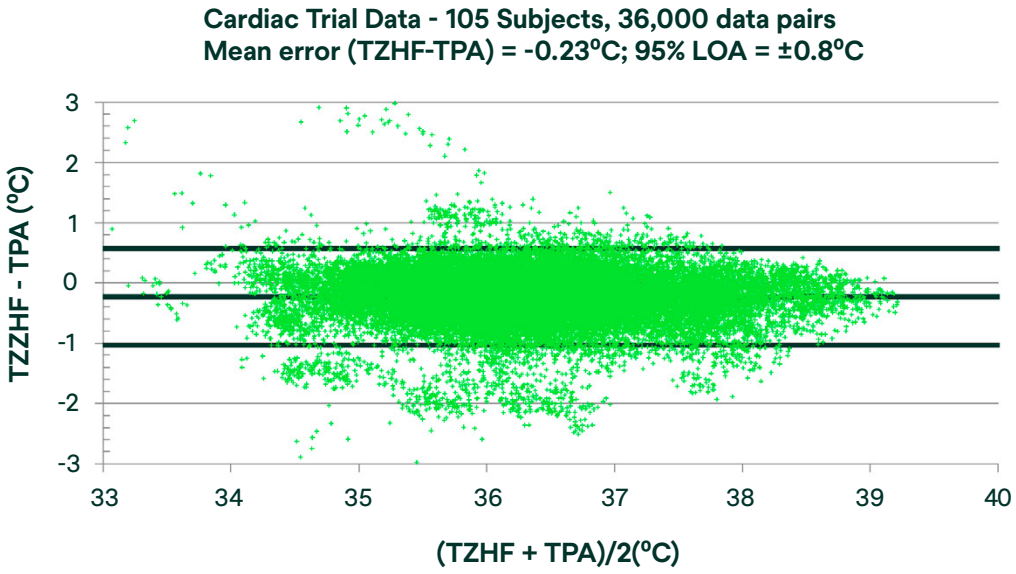
105 patients undergoing nonemergent cardiac surgery, excluding the period of cardio pulmonary bypass (CPB).

Methods

Core temperature was measured with both a pulmonary artery catheter and a non-invasive zero-heat-flux sensor. Patient core temperature was recorded every minute following anesthesia induction, and for four-hours postoperatively. A bias analysis was used to compare the two devices. Temperature differences of >0.5°C were considered clinically significant.

Conclusion

Core temperature can be measured non-invasively with zero-heat-flux technology. The Bair Hugger temperature monitoring system's core temperature readings were in agreement with pulmonary artery temperature, with a mean bias of -0.23°C.



The 3M™ Bair Hugger™ Temperature Monitoring System* was in good agreement of monitoring temperature compared to conventional methods

Mäkinen M, Pesonen A, Jousela I, et al. Novel Zero Heat Flux Deep Body Temperature Measurement in Lower Extremity Vascular and Cardiac Surgery. *J Cardiothorac Vasc Anesth*. 2016;30:973 978.

Background

The goal of this study was to compare core body temperature using a new non-invasive method compared to conventional methods.

Design

Prospective, observational study

Population

30 total patients: 15 patients undergoing vascular surgery for lower extremities and 15 patients undergoing cardiac heart surgery on cardiopulmonary bypass

Methods

Patient temperatures were simultaneously measured with a non-invasive zero-heat-flux (ZHF) temperature sensor (Bair Hugger temperature monitoring system) on the forehead and esophageal during vascular surgery, and nasopharyngeal and pulmonary artery during cardiac surgery.

Conclusion

This study demonstrated agreement with core body temperatures measured using the non-invasive Bair Hugger temperature monitoring system comparable to esophageal, nasopharyngeal and pulmonary artery with temperatures ≥34°C.

The Bair Hugger temperature monitoring system is a reliable, non-invasive method to measure deep body temperature.

Mean difference (°C)

ZHF vs. Esophageal	ZHF vs. Pulmonary Artery	ZHF vs. Nasopharyngeal
+0.08°C Vascular Surgery	-0.05 °C Cardiac Surgery (Off CBP)	-0.12 °C Cardiac Surgery (On & Off CBP)
(95% limits of agreement -0.25 to +0.40°C)	(95% limits of agreement -0.56 to +0.47°C)	(95% limits of agreement -0.94 to +0.71°C)

*Formerly known as the 3M™ SpotOn™ system.

The 3M™ Bair Hugger™ Temperature Monitoring System* was found to provide clinically sufficient accuracy

Kato H, Kawashima S, Mimuro S, Obata Y, Doi M, Nakajima Y. An evaluation of deep-forehead temperature (spoton©) in ICU patients after cardiac surgery. *Intensive Care Medicine Experimental*. 2015;3(Suppl 1):

Background

Pulmonary artery blood temperature is considered the gold standard in core temperature monitoring. This study aims to evaluate pulmonary artery blood temperature compared to a non-invasive zero-heat-flux (ZHF) thermometry method.

Design

Prospective, observational

Population

20 postoperative cardiac surgical patients in the ICU.

Methods

Each patient was connected to both a pulmonary artery thermistor catheter, urinary catheter thermistor and the 3M™ Bair Hugger™ sensor*. Temperatures were recorded at one one-minute intervals following admission to the ICU. The mean duration of temperature measurement was 865 minutes (range, 251-2,283 min), and a total of 16,407 data points were collected for analysis.

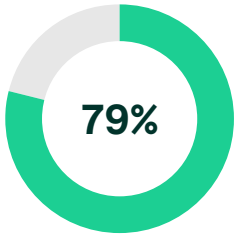
Conclusion

The authors in this study found that the Bair Hugger temperature monitoring system, which uses zero-heat-flux thermometry, provides clinically sufficient accuracy for measuring core body temperature. However, the accuracy is inferior to that of pulmonary artery catheter.

Mean average difference of temperature

ZHF vs. Pulmonary Artery Thermistor Catheter

Mean average difference of **-0.28°C**



of the differences were ≤0.5°C

*Formerly known as the 3M™ SpotOn™ system.

Zero-heat-flux thermometry is an effective, non-invasive alternative to accurately measure core temperature

Christensen J, Eddy G, Rawlins N, et al. Core temperature measurement using a non-invasive zero heat flux thermometer. Mayo Clinic Rochester, Minnesota 2015.

Background

Core temperature should be measured throughout the perioperative process. However, not all non-invasive devices accurately measure core temperature. The study aimed to determine reliability of core temperature in the OR with the 3M™ Bair Hugger™ Temperature Monitoring System* using zero-heat-flux (ZHF) technology and an esophageal temperature probe, and to compare agreement to oral thermometry in pre- and post-op.

Design

Prospective, observational

Population

369 patients undergoing general anesthesia for general, orthopedic, plastic or urology surgery

Methods

Temperatures were measured with both oral and zero-heat-flux thermometry (Bair Hugger temperature monitoring system*) starting in pre-op and continuing through post-op. In the OR, temperatures were measured with both esophageal and zero-heat-flux thermometry.

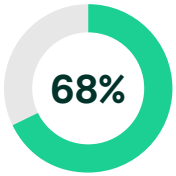
*Formerly known as the 3M™ SpotOn™ system.

Conclusion

This study demonstrated that the non-invasive Bair Hugger temperature monitoring system, which uses zero-heat-flux (ZHF) thermometry, is an effective method to accurately measure core temperature comparable to esophageal and oral temperature.

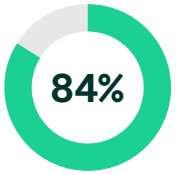
Absolute difference of temperature pairs ≤ 0.5°C (% [95% CI])

Pre-Op
ZHF vs. Oral
-0.25°C



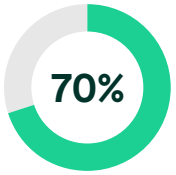
of the differences were +/-0.5°C

Intra-Op
ZHF vs. Esophageal
+0.15°C



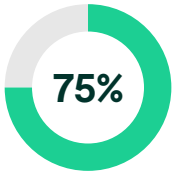
of the differences were +/-0.5°C

PACU Admit
ZHF vs. Oral
-0.22°C



of the differences were +/-0.5°C

PACU D/C
ZHF vs. Oral
-0.09°C



of the differences were +/-0.5°C

The 3M™ Bair Hugger™ Temperature Monitoring System* is a clinically acceptable temperature monitoring method

Zaballos JM, Salinas U, Guipuzcoa P. Clinical Evaluation of Spot On®, a New Non-invasive and Continuous Temperature Monitoring System. *ASA Abstracts*. 2014;A4270.

Background

There is a clinical need for an accurate and consistent temperature monitoring method for surgical patients under general or regional anesthesia. This study aimed to evaluate zero-heat-flux (ZHF) thermometry to an esophageal temperature probe.

Design

Prospective, observational study

Population

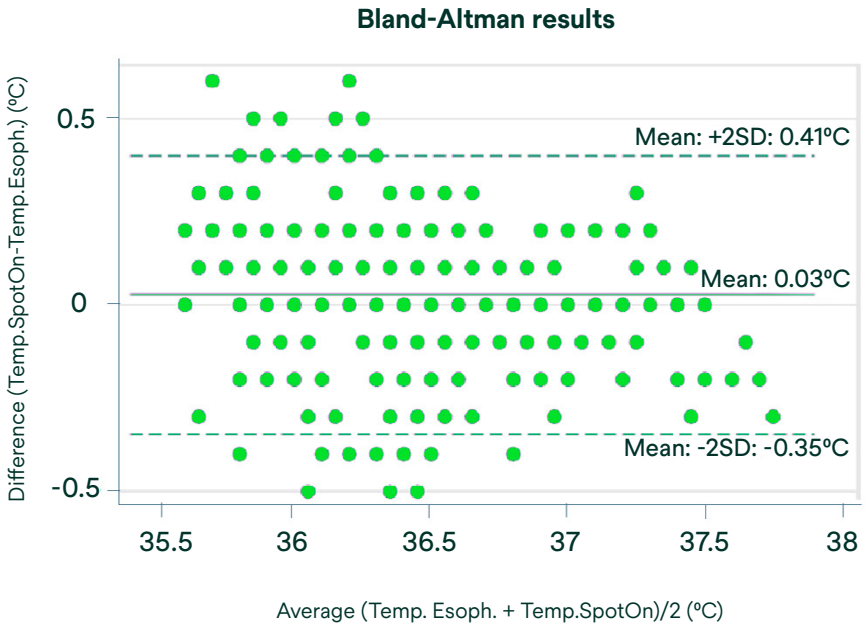
34 patients undergoing general, thoracic, orthopedic, ear nose and throat (ENT), urology and neurosurgical procedures

Methods

Temperatures were recorded at 10 minute intervals from anesthesia induction until the end of surgery. The esophageal probe was placed after induction of anesthesia and served as the reference for core body temperature. The ZHF sensor (Bair Hugger temperature monitoring system*) was placed on the forehead and allowed to equilibrate for 10 minutes.

Conclusion

Overall, the average difference between Bair Hugger temperature monitoring system temperatures and esophageal temperatures was 0.03 C (95% limits of agreement of -0.35/+0.41). These results demonstrated that the Bair Hugger system is a clinically acceptable way to non-invasively measure perioperative core temperature.



*Formerly known as the 3M™ SpotOn™ system.

The core temperature measured by the ZHF method is comparably reliable to esophageal and arterial temperatures measured by a femoral artery catheter

Dahyot Fizelier C, Lamarche S, Kerforne T, et al. Accuracy of Zero Heat Flux Cutaneous Temperature in Intensive Care Adults. *Critical Care Medicine*. 2017;45:e715 e717.

Background

Esophageal or arterial temperature monitoring methods are considered reliable, but these devices are invasive. The study aimed to compare accuracy of zero-heat-flux (ZHF) thermometry to esophageal and arterial temperature using a femoral artery catheter in ICU patients.

Design

Prospective study

Population

52 ICU and Neuro ICU patients over a 4-month period

Methods

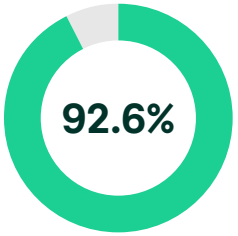
Patient temperatures were simultaneously measured with both an esophageal probe and a non-invasive temperature sensor using ZHF technology. Temperatures were recorded from one to five days, and a total of >62,000 pairs of temperature were collected.

Conclusion

The investigators analyzed >62,000 pairs of temperature to determine that the ZHF method of core temperature monitoring with the 3M™ Bair Hugger™ Temperature Monitoring System* offers comparable reliability to esophageal or arterial temperatures in ICU patients.

Absolute difference of temperature pairs ≤ 0.5°C (% [95% CI])

ZHF vs. Esophageal



(95% CI, 91.9-93.4)

ZHF vs. Arterial

(95% CI, 95.3-100.0)

*Formerly known as the 3M™ SpotOn™ system.

The 3M™ Bair Hugger™ Temperature Monitoring System* provides an accurate, non-invasive way to measure core body temperature

Iden T, Horn E, Bein B, Böhm R, Beese J, Höcker J. Intraoperative temperature monitoring with zero heat flux technology in comparison with sublingual and nasopharyngeal temperature. *Eur J Anaesthesiol.* 2015;32:387 391.

Background

Measuring core body temperature during surgery is an important way to ensure unintended hypothermia is prevented. Accurate and invasive measurements are not suitable for all patients. The study aimed to evaluated the accuracy of zero-heat-flux (ZHF) thermometry to sublingual and nasopharyngeal methods.

Design

Observational study

Population

83 patients undergoing elective gynecological or trauma surgeries under general anesthesia

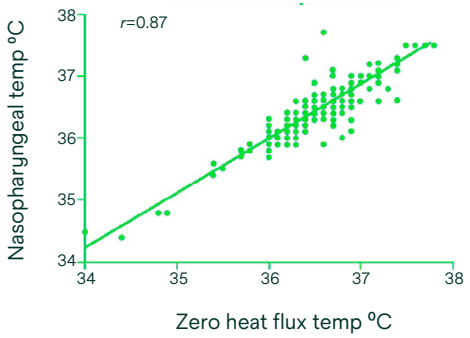
Methods

Patient temperature was monitored following anesthesia induction, and measured at 15, 45, and 75 minutes using a sublingual probe, nasopharyngeal probe and a 3M™ Bair Hugger™ Temperature Sensor.

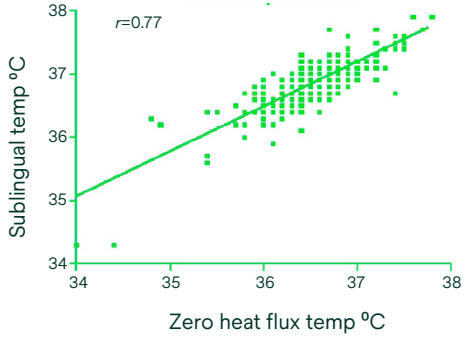
Conclusion

The Bair Hugger temperature monitoring system is an acceptable clinical method to monitor core temperature compared to nasopharyngeal and sublingual thermometers. Temperatures for the Bair Hugger sensor were nearly identical to nasopharyngeal temperatures (mean difference 0.07°C; P =0.1424), and slightly lower than sublingual temperatures (mean difference -0.35°C; P <0. 0001).

Nasopharyngeal and zero health flux temperatures



Sublingual and zero health flux temperatures



*Formerly known as the 3M™ SpotOn™ system.

The 3M™ Bair Hugger™ Temperature Monitoring System* can help reduce or eliminate the disadvantages associated with invasive methods

Evans M, Davis P, McCarthy D, Van Duren A, Morse DJ, Strom C. 3M™ SpotOn™ Temperature Monitoring System versus Nasopharyngeal Temperature Monitoring in Pediatric Surgical Patients. Presented at the 2014 PostGraduate Assembly of Anesthesiology (New York).

Background

Current methods of temperature monitoring are invasive and offers disadvantages including placement technique, patient discomfort, risk of injury and inconsistent methodologies used in the OR, PACU, or ICU. The Bair Hugger temperature monitoring system was studied to demonstrate accuracy compared to nasopharyngeal.

Design

Non-blinded, non-randomized, comparative research study

Population

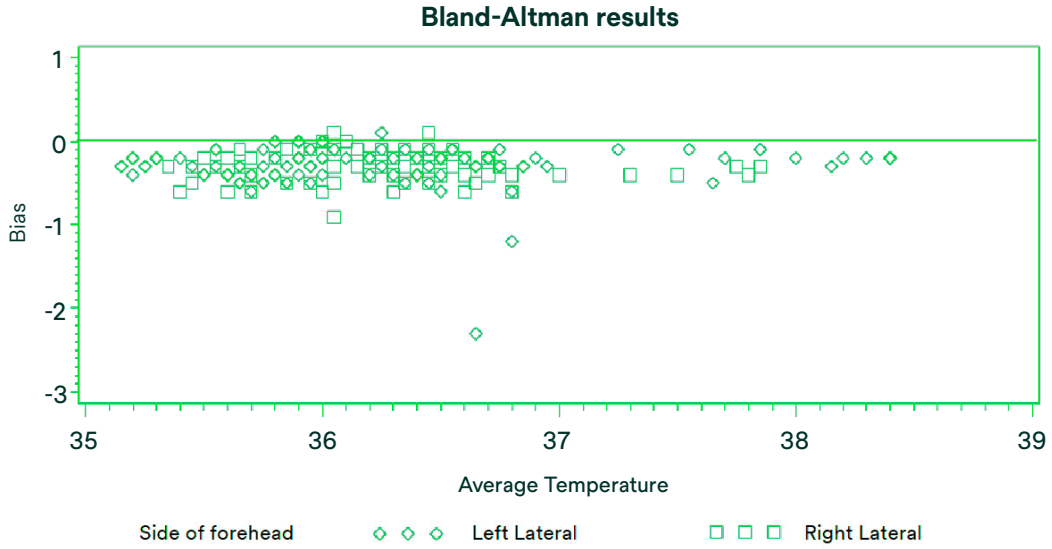
20 pediatric patients undergoing non-emergent urology, orthopedic or general abdominal surgery

Methods

Temperatures were simultaneously measured using both nasopharyngeal and the Bair Hugger temperature monitoring system*. Temperatures were recorded from anesthesia induction, and every 5-10 minutes in the OR.

Conclusion

Overall, the average bias between the Bair Hugger temperature monitoring system and nasopharyngeal temperatures was small at 0.28 C. In addition, the non-invasive method helps to reduce or eliminate the disadvantages associated with nasopharyngeal temperature monitoring including placement technique, patient discomfort, risk of injury, cross-contamination and inconsistent methodologies across departments.



*Formerly known as the 3M™ SpotOn™ system.

3M™ Bair Hugger™ Temperature Monitoring System* is an accurate way to demonstrate early and accurate recognition of hypothermia

Searle J, Fawcett E, Gove R, Mandour Y, Mackinnon J. Effect of thermometry method on recognition of peri-operative hypothermia and patient throughput: Traditional infra red tympanic vs non-invasive zero heat flux thermometry. *Abstracts of AAGBI WSM London 2014*. 2014:41.

Background

Accurate and reliable temperature monitoring methods are important in order to detect unintended hypothermia which is associated with negative outcomes.

Design

Prospective single-center trial

Population

100 patients undergoing surgery for >30 minutes

Methods

Patient temperatures were simultaneously measured using infra-red tympanic thermometry and the Bair Hugger temperature monitoring system for a total of 509 paired readings. The mean operative time was 64 minutes and the mean recovery time was 29 minutes.

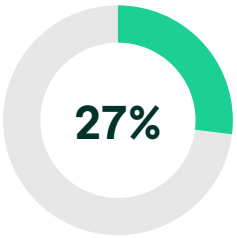
Conclusion

The Bair Hugger temperature monitoring system demonstrated significant correlation to tympanic readings in the OR (P 0.02), and in recovery (P<0.001).

Mean difference (ºC)
0.1 ºC
(95% limits of agreement -1.2 to +1.1ºC)

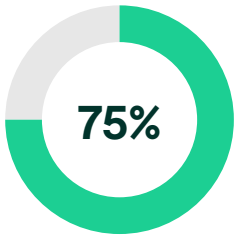
The Bair Hugger temperature monitoring system also demonstrated early and accurate recognition of hypothermia compared to tympanic. The ability to provide early detection of hypothermia may help improve patient throughput and reduce costs.

Operating room



27% of patients listed as normothermic with tympanic were hypothermic when measured with the Bair Hugger system.

Recovery room



75% of patients listed as hypothermic with tympanic were normothermic when measured with the Bair Hugger system.

*Formerly known as the 3M™ SpotOn™ system.

The 3M™ Bair Hugger™ Temperature Monitoring System* has good agreement with invasive temperature thermometry methods used in the ICU

Schell Chaple H, Matthay M, Puntillo K, Liu K. 434: Evaluation of non-invasive core thermometry with zero heat flux technology in febrile ICU patients. *Critical Care Medicine*. 2015;43:110 110.

Background

Maintaining normal body temperature of patients in the ICU is important. However, common methods of continuous temperature monitoring are invasive. A recently available non-invasive temperature monitoring system using zero-heat-flux (ZHF) technology was tested for agreement and precision compared to other thermometry methods.

Design

Method comparison design

Population

36 febrile (≥38.3°C) patients in the ICU

Methods

Patient temperatures were simultaneously measured over four hours with a ZHF sensor (Bair Hugger temperature monitoring system*) and either rectal (n=28) or urinary bladder (n=8) thermometry methods.

Conclusion

The results of this study indicate that the Bair Hugger temperature monitoring system has good agreement and precision and can be considered as an alternative to invasive methods, i.e. rectal, urinary bladder, as a way to non-invasively measure core temperature in febrile ICU patients.

	ZHF and Rectal	ZHF and Bladder
Bias	-0.24 +/- 0.29°C	-0.02 +/- 0.20°C
95% Limits of Agreement	-0.81 to 0.33°C	-0.41 to 0.37°C

*Formerly known as the 3M™ SpotOn™ system.

Zero-Heat-Flux presents the advantage of being noninvasive allowing its use early before anesthesia induction

Atallah F, Arnaud E, Game X, Cerea G, Mazerolles M and Fourcade O. Comparison between three temperature monitors during laparoscopic surgery. EuroAnaesthesia London 2016.

Background

This study was designed to compare the differences between esophageal, tympanic, and a new non-invasive zero-heat-flux (ZHF) thermometry method.

Design

Prospective, observational

Population

50 patients undergoing laparoscopic urologic surgery

Methods

Temperatures were simultaneously recorded eight times per patient with a ZHF sensor (3M™ Bair Hugger™ Temperature Monitoring System*), an esophageal probe (Philips 21090A) and a tympanic probe (Welch Allyn Braun Thermoscan® PRO 4000). The investigators statistically analyzed temperatures for both correlation and accuracy.

Conclusion

The new, non-invasive ZHF method offered by the Bair Hugger temperature monitoring system is a reliable and accurate method for temperature monitoring. In addition, the non-invasive method offers an additional advantage over the esophageal probe. The sensor can be placed in advance of anesthesia induction.

There was a high correlation with esophageal thermometry, but a weak to moderate correlation with tympanic. The authors observed low accuracy with tympanic which they suggest may be biased by external surface warming that increases ear temperature but does not accurately reflect core temperature.

Thermoscan® is a registered trademark of Welch Allyn®
*Formerly known as the 3M™ SpotOn™ system.

Degrees matter, beginning with the degree of care you provide before, during, and after surgery

At Solventum, we use science to help you influence the most important aspects of a patient's experience - the outcomes with clinically proven solutions that help safeguard them during surgery.

The 3M™ Bair Hugger™ Temperature Monitoring System is an accurate, noninvasive, easy to use temperature monitoring system that continuously measures patients' core body temperature and provides standardization throughout the perioperative journey.

For additional information, please contact your Solventum representative, call 800 228 3957, or visit **bairhugger.com**.

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