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ORIGINAL ARTICLE

Intra-operative cutaneous temperature monitoring with zero-heat-flux technique (3M SpotOn) in comparison with oesophageal and arterial temperature

A prospective observational study

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BACKGROUND Continuous monitoring of core temperature is essential during major surgery as a way of improving patient safety. Oesophageal probes or specific arterial catheters are invasive methods used in this setting. A new noninvasive device based on zero-heat-flux (ZHF) technique (SpotOn) seems promising but has been poorly investigated during rapid core temperature changes (RCTC).

OBJECTIVE To assess the accuracy of a SpotOn sensor vs. an oesophageal probe or specific arterial catheter during a slow change in core temperature of less than 1 °C within 30 min and RCTC $\geq$ 1 °C within 30 min.

DESIGN Prospective observational study.

SETTING Operating rooms at the University Hospital of Poitiers, France.

PATIENTS Fifty patients scheduled for major abdominal surgery under general anaesthesia were enrolled from June 2015 to March 2016. Data from 49 patients were finally analysed. Among these, 15 patients were treated with hyperthermic intraperitoneal chemotherapy.

INTERVENTION Each patient had a ZHF sensor placed on the skin surface of the forehead ($Temp_{ZHF}$) and an oesophageal probe ($Temp_{Eso}$) used as a reference method. Twenty-two patients also had a thermodilution arterial catheter ($Temp_{Art}$) placed in the axillary artery.

MAIN OUTCOME MEASURES Core temperature was continuously recorded from the three devices after induction of anaesthesia. Comparison of temperature measurements between methods was made using the Bland and Altman method during two separate periods according to the speed of core temperature changes.

RESULTS Compared with $Temp_{Eso}$, bias and limits of agreement for $Temp_{ZHF}$ were 0.1 ± 0.5 °C during slow core temperature changes periods and 0.6 ± 1.8 °C during RCTC periods ($P = 0.0002$). Compared with $Temp_{Art}$, these values were -0.1 ± 0.4 and 0.5 ± 1.7 °C, respectively ($P = 0.0039$). The ZHF sensor was well tolerated.

CONCLUSION A SpotOn sensor using the ZHF method seems reliable for core temperature monitoring during abdominal surgery when variations in core temperature are slow rather than rapid.

TRIAL REGISTRATION ClinicalTrials.gov identifier: NCT02869828.

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Introduction

Hypothermia during surgery is common due to inhibition of thermoregulation by anaesthetic drugs, reduction in thermogenesis, reduced insulation from clothes and the effect of a cold environment.[1] It is responsible for increased peri-operative complications such as myocardial ischaemia,[2] peroperative bleeding[3,4] and surgical site infections.[5] As a result, it is recommended that patients are kept warm, with measures that are started before

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induction of anaesthesia[6] and that temperature monitoring is continued throughout the peri-operative period.

The gold standard for core temperature monitoring is the pulmonary arterial catheter, but other less invasive devices such as oesophageal probes[7–9] have good accuracy and are widely used in clinical practice. In patients requiring haemodynamic monitoring, peripheral arterial catheters can be used as an alternative with good accuracy.[7] Nevertheless, these devices remain somewhat invasive and seldom enable monitoring of core temperature before induction of anaesthesia. Other noninvasive techniques – tympanic membrane[10] or sublingual[10,11] temperature – have quite good accuracy and can be used in awake patients, although they do not allow continuous monitoring. As an alternative, the zero-heat-flux (ZHF) – a noninvasive method of core temperature monitoring from the skin surface – was developed several decades ago[12] and has been compared with different devices.[13–18] More recently, a new sensor, the 3M SpotOn (3M, St Paul, Minnesota, USA) based on ZHF technology, has shown accuracy in continuous noninvasive core temperature monitoring during lower extremity vascular and cardiac surgery.[19,20] High accuracy should be the primary selection criterion for the choice of temperature measurement device in those patients at high risk of fever or hypothermia. Clinicians are frequently confronted with rapid changes in core temperature, such as those occurring in the first hour of anaesthesia, hyperthermic intraperitoneal chemotherapy (HIPEC), cardiopulmonary bypass (CPB) and bacteraemia, but few studies have been conducted using the ZHF technique in these conditions.

The aim of this study was to assess the accuracy of the 3M SpotOn device compared with two reliable techniques, an arterial thermodilution catheter or an oesophageal probe, for core temperature monitoring during slow and rapid periods of core temperature changes in patients requiring major abdominal surgery.

Methods

Ethics

The current prospective clinical study was conducted at the University Hospital of Poitiers, France, after obtaining ethics committee approval (Comité de Protection des Personnes Ouest III; EudraCT ID 2015-A001462-47) and registration at ClinicalTrials.gov (number NCT02869828). Informed consent was obtained from all patients prior to their inclusion in the study.

Patients

Adult patients anaesthetised for elective major abdominal surgery were enrolled. Patients with any contra-indication to oesophageal probe insertion or undergoing emergency surgery were excluded.

Study protocol

In all patients, a ZHF sensor (3M SpotOn) was placed on the skin surface of the forehead ($Temp_{ZHF}$), and an oesophageal probe (MON-A-THERM, 12Fr; Covidien, Dublin, Republic of Ireland) was inserted through a nostril ($Temp_{Eso}$) and fed in to a depth based on standing height according to Mekjavić and Rempel[21] formula after induction of anaesthesia. For patients requiring haemodynamic monitoring, a peripheral arterial catheter (Pulsiocath Arterial Thermodilution Catheter 5F; Pulsion Medical Systems AG, Munich, Germany) was inserted in an axillary artery ($Temp_{Art}$). $Temp_{ZHF}$, $Temp_{Eso}$ and $Temp_{Art}$ were recorded automatically at a 5-min interval throughout surgery. General anaesthesia was induced with sufentanil, propofol and atracurium or rocuronium, and maintained with desflurane, supplemented with increments of sufentanil and muscle relaxants as needed. Respiratory and anaesthetic gas concentrations, spirometry, SpO2, ECG, invasive blood pressures and body temperatures were displayed on the patient monitor (IntelliVue MX550; Phillips, Boeblingen, Germany) and recorded in the anaesthesia recording system (Diane, Version 4.4.5, Bow Medical, Boves, France).

All patients received continuous active warming, starting before induction of anaesthesia, with forced-air warming (Bair Hugger, 3M) through an upper body warming blanket (Mistral-air, The 37Company, Amersfoort, The Netherlands). Operating room temperature (RT) was set at 19 to 21 °C.

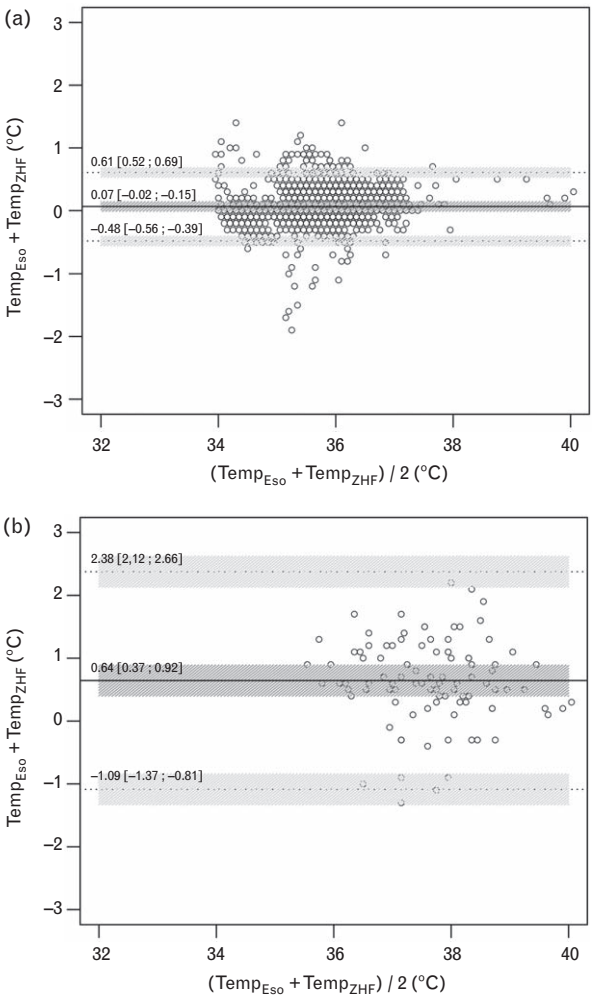
For patients undergoing HIPEC during surgery, two periods were identified according to the speed of changes in core temperature: slow core temperature changes (SCTC) with a change in core temperature less than 1 °C within 30 min and rapid core temperature changes (RCTC) with change in core temperature equal to or more than 1 °C within 30 min. HIPEC was administered through an open approach with two inflow and two outflow catheters connected to a perfusion device (SunCHIP; Gamida, Eaubonne, France). The perfusion device heated the solution quickly (about 10 min) to between 42 to 45 °C. Perfusion was performed for 30 min from the time of temperature achievement in the abdominal cavity. At the end of procedure, the abdominal cavity was washed out with saline (Sodium chloride 0.9%, Aguettant, Lyon, France) at RT.

Statistical analysis

Categorical data are expressed as number (n) and percentage (%). Quantitative data are reported as median [25 to 75th] percentiles.

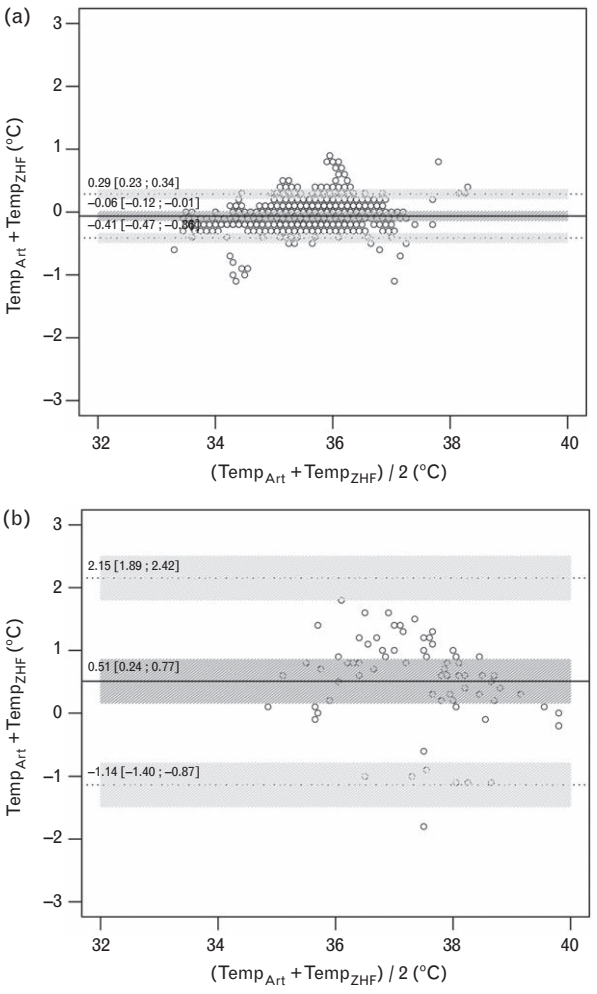
Agreement between $Temp_{Eso}$ (considered as the reference method), $Temp_{Art}$ and $Temp_{ZHF}$ was assessed using Bland and Altman[22] plots with determination of bias and adjusted limits of agreement for an unequal number of multiple measurements. Mean values with 95% confidence interval (95% CI) are presented in Figs. 1 and 2. The standard error of the 95% limit of agreement is approximately $\sqrt{(3s^2/n)}$, in which s is the SD of the

Fig. 1



Bland–Altman plots of temperatures obtained concomitantly with the zero-heat-flux sensor or oesophageal probe for a) slow core temperature changes b) and rapid core temperature changes. Solid line represents the bias between the two methods of temperature assessment and short-dash lines the limits of agreement adjusted for repeated measures (95% confidence intervals are presented in grey area).

Fig. 2



Bland–Altman plots of temperatures obtained concomitantly with the zero-heat-flux sensor or arterial catheter for a) slow core temperature changes and b) rapid core temperature changes. Solid line represents the bias between the two methods of temperature assessment and short-dash lines the limits of agreement adjusted for repeated measures (95% confidence intervals are presented in grey area).

differences between measurements by the two methods and n is the sample size. The number of measurement was estimated so as to obtain a 95% CI of adjusted limits of agreement ±0.107 s, which is a very good level of accuracy.

Accuracy of Temp$_{ZHF}$ during SCTC or RCTC was compared with using the paired Student's t test corrected for multiple testing, with a P value equal to or lower than 0.05 considered as statistically significant.

The number and percentage (with 95% CI) of absolute difference of temperature pairs between reference and tested methods equal to or lower than 0.3, 0.5 and 0.8 °C were also determined.

Data were entered into Excel 2007 (Microsoft Office Excel 2007; Microsoft Corp., Redmond, Washington, USA) and statistical analysis using R software version 3.2.2 (R Development Core Team: R: A Language and Environment for Statistical Computing, Vienna, Austria, R Foundation for Statistical Computing, 2008. Available at: http://www.R-project.org).

Results

Patient characteristics

Between June 2015 and March 2016, 50 patients were enrolled in the study; 22 were monitored with a thermodilution peripheral arterial catheter. One patient was excluded due to data recording problems. Consequently,

Table 1 Patients characteristics

	All population, *n*=49	Population with arterial catheter monitoring, *n*=22
General		
Sex, male	33 (67)	13 (59)
Age (year)	64 [55 to 69]	55 [47 to 69]
BMI (kg m^{-2})	26 [34 to 30]	25 [23 to 27]
ASA physical status		
ASA 1	7 (14)	3 (14)
ASA 2	21 (43)	11 (50)
ASA 3	21 (43)	8 (36)
Type of surgery		
Hyperthermic intraperitoneal chemotherapy	15 (31)	11 (50)
Gastric	6 (12)	8 (36)
Colo-rectal	14 (29)	2 (9)
Liver and pancreas	7 (14)	1 (4)
Others	7 (14)	
Peroperative period		
Duration of surgery (min)	405 [247 to 475]	405 [258 to 460]
Blood loss (ml)	200 [100 to 400]	100 [100 to 300]
Ephedrine use	39 (80)	18 (82)
Norepinephrine use	26 (53)	15 (68)

Categorical data are expressed as number and percentage *n* (%), quantitative data are reported as median values and [25 to 75th] percentiles.

the data from 49 patients were analysed, including fifteen treated with HIPEC. Their characteristics are summarised in Table 1.

Comparison between peripheral arterial catheter and oesophageal probe

A total of 1358 pairs of $Temp_{Art}$ and $Temp_{Eso}$ (1281 during the SCTC period and 77 during the RCTC period) were collected, ranging from 33.4 to 38.8 °C. Compared with $Temp_{Art}$, bias and limits of agreement for $Temp_{Eso}$ were 0.1 ± 0.3 °C during the SCTC period and 0.0 ± 0.8 °C during the RCTC period ($P = 0.725$).

Comparison between zero-heat-flux and oesophageal probe

A total of 2446 pairs of $Temp_{ZHF}$ and $Temp_{Eso}$ (2345 during the SCTC period and 101 during the RCTC period) were collected, ranging from 34.0 to 40.2 °C. Compared with $Temp_{Eso}$, bias and limits of agreement for $Temp_{ZHF}$ were 0.1 ± 0.5 °C during the SCTC period and 0.6 ± 1.8 °C during the RCTC period ($P = 0.0002$, Fig. 1). The number of temperature pairs with an absolute difference of 0.3, 0.5 and 0.8 °C or less is presented in Table 2.

Comparison between zero-heat-flux and peripheral arterial catheter

A total of 1780 pairs of $Temp_{ZHF}$ and $Temp_{Art}$ (1708 during the SCTC period and 72 during the RCTC period) were collected, ranging from 33.0 to 39.8 °C. Compared with $Temp_{Art}$, bias and limits of agreement for $Temp_{ZHF}$ were -0.1 ± 0.4 °C during the SCTC period and 0.5 ± 1.7 °C during the RCTC period ($P = 0.0039$, Fig. 2). The number of temperature pairs with absolute difference of 0.3, 0.5 and 0.8 °C or less is presented in Table 2.

Safety

The ZHF sensors were well tolerated in all patients and no manifestation of burn or anaphylaxis was observed during the study period.

Discussion

The current study performed in patients under anaesthesia during abdominal surgery showed that the ZHF device has good accuracy compared with an oesophageal probe or arterial catheter only during periods of slow core temperature changes. The ZHF sensors were well tolerated with no safety issue reported.

Thus, during periods of slow core temperature changes – which involve the majority of patients undergoing surgery – biases and limits of agreement of the ZHF method were equal to 0.1 ± 0.5 and -0.1 ± 0.4 °C compared with the oesophageal probe and the arterial catheter, respectively. Furthermore, in 94% (oesophageal probe) and 99% (arterial catheter) of measurements, absolute differences of temperature pairs were equal to or lower than 0.5 °C. Studies performed in cardiac surgical patients,[19,20] gynaecological or trauma surgical patients[23] and intensive care adults[24] comparing the ZHF method to invasive methods (pulmonary artery catheter, oesophageal probe or femoral artery catheter) have reported comparable results. Eshraghi *et al.* compared a prototype 3M SpotOn sensor and a pulmonary artery catheter intra-operatively and for the first 4 postoperative hours. During surgery, they observed a limited bias at -0.1 ± 0.9 °C with absolute differences of temperature pairs equal to or lower than 0.5 °C in 84% of cases. Significantly, due to limited or absent blood flow in the pulmonary artery during cross-clamp, they excluded the CPB period from their analysis.[19] In elective gynaecological and trauma surgery, Iden *et al.*[23]

Table 2 Percentage of absolute difference of temperature pairs between zero-heat-flux and oesophageal probe or arterial catheter equal to or lower than 0.3, 0.5 and 0.8 °C according to the speed of change in core temperature

	Comparison ZHF vs. oesophagal probe		Comparison ZHF vs. arterial catheter	
	SCTC, *n*=2345	RCTC, *n*=101	SCTC, *n*=1708	RCTC, *n*=72
≤±0.3 °C	79% (1843) (75 to 82)	17% (17) (10 to 27)	93% (1581) (88 to 97)	22% (16) (13 to 36)
≤±0.5 °C	94% (2211) (90 to 98)	39% (39) (28 to 53)	99% (1685) (94 to 100)	31% (22) (19 to 46)
≤±0.8 °C	98% (2299) (94 to 102)	56% (56) (42 to 72)	100% (1699) (95 to 100)	53% (38) (37 to 72)

Values are expressed as percentage, number of temperature pairs and 95% confidence interval: % (*n*) [95% CI]. RCTC, rapid core temperature changes equal to or more than 1 °C within 30 min; SCTC, slow core temperature changes less than 1 °C within 30 min; ZHF, zero-heat-flux.

compared temperature monitoring noncontinuously using a SpotOn sensor and a nasopharyngeal probe and found a mean bias at 0.1 ± 0.4 °C.

Our study highlighted some limitations on the reliability of the ZHF method during periods of rapid change in core temperature such as those caused by HIPEC. During periods of core temperature changes equal to or more than 1 °C within 30 min, biases and limits of agreement increased substantially and reached 0.6 ± 1.8 and 0.5 ± 1.7 °C compared with oesophageal probe and arterial catheter, respectively, with absolute differences of temperature pairs equal to or lower than 0.5 °C in less than 40% of cases. Few studies focussed on the reliability of the ZHF method during rapid changes in core temperature and, to the best of our knowledge, SpotOn has not been tested yet during HIPEC. Even so, rapid change in core temperature is not an uncommon phenomenon. In fact, during the first hour of general anaesthesia without warming manoeuvres, core temperature rapidly decreases by 1 to 1.5 °C.[25] In rare but feared malignant hyperthermia, core temperature rapidly increases by around 2 °C per hour.[26] In cardiac surgery, Akata *et al.* compared another ZHF device with jugular bulb temperature and pulmonary arterial catheters during deep hypothermic CPB. With a mean bias of 4.7 °C in comparison with jugular bulb temperature during induction of deep hypothermia, they concluded that the ZHF method was not reliable for brain temperature measurement.[17] In a recent study, Mäkinen *et al.*[20] compared the 3M SpotOn with nasopharyngeal temperature in 15 patients undergoing cardiac surgery with hypothermic CPB. Before and after CPB, bias and limits of agreement were close to our results (-0.10 ± 0.59 °C). During CPB, which corresponds to a phase of rapid changes in core temperature, agreement was weaker (-0.14 ± 1.09 °C), but the difference was not as big as in our study. The researchers did not report the range of absolute differences in temperature pairs. Eshraghi *et al.*[19] excluded CPB from their analyses and explained their only slightly elevated limits of agreement of 0.82 °C – compared with pulmonary arterial catheter – by the many rapid thermal perturbations occurring during cardiac surgery. In critically ill patients, Dahyot-Fizelier *et al.*[24] reported stable bias and precision of the ZHF method over temperatures ranging from 33.0 to 39.7 °C. Consequently, increased agreement during the rapid phase does not generally appear to be linked with extreme temperatures. Our results were not consistent with those of a previous study on healthy volunteers conducted by Teunissen *et al.*[18] using a prototype ZHF sensor. In an experimental study performed in ambient conditions of 35 °C, the authors compared the accuracy of the ZHF method with an oesophageal probe during stable (at rest) and rapid changes in core temperature (during exercise, with an increase in core temperature of 1.5 °C within 30 min). They reported a comparable bias and limits of agreement (0.17 ± 0.19 °C at rest and -0.05 ± 0.18 °C during exercise). This difference could be explained by different experimental conditions and by the use of a different ZHF sensor.

A ZHF sensor insulates the skin locally, thereby creating a region of zero heat flow from the body core to the skin.[12] Limitations on the reliability of the ZHF method during RCTC could be due to equilibration duration between core temperature and the insulated skin under the sensor. During HIPEC, rapid changes in core temperature are due to warming of the abdominal cavity which could explain differences between the oesophageal probe and the forehead ZHF sensor. But due to similar differences between ZHF and axillary arterial catheter, sensor location did not appear as the only explanation.

As previously reported, the ZHF sensor is well tolerated,[24] but we were not able to effectively evaluate safety. More studies are warranted to address this issue.

Our study has some limitations. First, we did not check the position of the oesophageal probe with a chest radiograph, even though its position in the oesophagus could affect its accuracy.[27] To limit this bias, the oesophageal probe was inserted through a nostril into the oesophagus under direct vision during laryngoscopy and the length of insertion was determined according to Mekjavić and Rempel[21] formula. Second, as regards rapid temperature changes, the number of temperature measurement pairs was rather low (around 4% of total pairs recorded), due to our having preferred to observe a 5-min interval between temperature measurements to ensure that potential changes of core temperatures had sufficient time to occur. Third, we used a thermodilution arterial catheter inserted in the axillary artery as our method of reference, but the accuracy of PICCO (Pulsion Medical Systems AG, Munich, Germany) in temperature monitoring has been evaluated only in femoro-iliac artery.[7]

The major strengths of our study were continuous temperature recording and the participation of a substantial number of patients, which ensured a reliable comparison between the different devices.

To conclude, our study confirmed that for monitoring core temperature during abdominal surgery during periods of slow core temperature changes the SpotOn sensor using the ZHF method has good reliability in comparison with an oesophageal probe or a specific arterial catheter. However, SpotOn sensor accuracy is questionable during RCTC.

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sponsor and 3M were not involved in study design, collection, analysis and interpretation of data, writing of article or in the decision to submit the article for publication.

Conflicts of interest: MB received travel expenses from Pulsion. OM has received honoraria to present work at a symposium and to attend an international conference supported by 3M and has also received honoraria for attendance at advisory board meetings.

Presentation: preliminary data were presented at the European Society of Anaesthesiology congress (Euroanaesthesia), 28 to 30 May 2016 and at the French Society of Anaesthesiology and Intensive Care (SFAR), 22 to 24 September 2016.

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