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Intraoperative temperature monitoring with zero heat flux technology (3M SpotOn sensor) in comparison with tympanic and oesophageal temperature and hypothermia risk factors: an observational study

Submission date
25/06/2018

Recruitment status
No longer recruiting

Registration date
12/07/2018

Overall study status
Completed

Last Edited
18/05/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Inadvertent hypothermia (body temperature below 35oC) is a common and avoidable challenge during surgery under anesthesia. It is related to coagulation (clotting) disorders, an increase in blood loss, and a higher rate of wound infection. One of the methods for non-invasive monitoring of the core body temperature is the 3M SpotOn zero heat flux method. In this approach, sensors placed at the frontal region of the patient measure the temperature of the skin by creating an isothermic channel. The aims of this study are to determine the risk factors for hypothermia and to compare the 3M SpotOn zero heat flux method with the tympanic membrane (eardrum) and esophageal (food pipe) temperature measurement methods.

Who can participate?
Patients undergoing major abdominal cancer surgery and recording of body temperature with the SpotOn zero flux, tympanic and esophageal measurements

What does the study involve?
The patients' data are collected, including age, gender, weight, body mass index, other illnesses, smoking history, type of anesthesia, duration of the operation, operating room temperature, pulse rate, blood pressure, blood loss and transfusions. Body temperatures measured by the tympanic membrane method before and after surgery, esophageal temperatures during surgery, and SpotOn measurements throughout all three periods are recorded.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Dokuz Eylül University (Turkey)

When is the study starting and how long is it expected to run for?
June 2015 to October 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Hale Aksu Erdost
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015/16-15 2168-GOA

Study information

Scientific Title
Intraoperative temperature monitoring with zero heat flux technology (3M SpotOn sensor) in comparison with tympanic and oesophageal temperature and hypothermia risk factors: an observational study

Study objectives
The aims of this study were to determine the risk factors in hypothermia and to compare the 3M SpotOn zero heat flux method with the tympanic membrane and esophageal temperature measurement methods.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Dokuz eylul university school of medicine Local Institutional Ethics Committee, 18/06/2015, ref: 2015/16-15 2168-GOA

Study design
Observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Comparison of three temperature measurements and detection of hypothermia risk factors

Interventions
The hospital records and anesthesia cards of patients who had undergone major abdominal cancer surgery in the trialists' institution, in whom the SpotOn zero heat flux method, tympanic membrane measurement method and esophageal temperature measurement method had all been used were investigated retrospectively. The inclusion criteria of the study were defined as being previously operated and data of all measurements recorded; the exclusion criterion was defined as the absence of recorded data.

In the intervention group, patients were warmed up according to a standard protocol. According to this protocol, when the patient is in the preoperative waiting room in the OR all parts of the anterior body are covered by these blankets; patients were warmed up with FAW systems (3M Bair Hugger™ Temperature Management Blanket, Arizant Healthcare Inc., a 3M company. MN, USA) actively adjusted to 43°C for 30. Then patients transferred to OR. After the anesthesia induction and skin preparation, the patients were covered with an operation specific blanket which was placed on the patient and forced warm air was started. If the patient’s body temperature was higher than 38 °C, active warming was discontinued either in preoperative room or OR. Active warming was also continued in the PACU or ICU if necessary as admitted in the preoperative period only if the temperature of the patients was < 38 °C.

In the control group, no standardized warming protocol was used. Patients were warmed up with the traditional methods of our institution. So these patients were not prewarmed preoperatively. There were not any specific blankets for these patients used in the OR. These patients’ upper extremities and upper bodies were covered up with a simple cotton cover by

rolling these cotton covers around the replacement hose of the device, at the end by making an air hole. A Warm Touch Nellcor System® (Operational Headquarters: 710 Medtronic Parkway, MN 55432-5604 Minneapolis, USA) was inserted between their layers also during the PACU or ICU period if only necessary (if the body temperature was <36, not routinely) and during the entire surgery intraoperatively. Hypothermia was defined as < 36 °C measured by SpotOn zero heat flux at any time (preoperative, intraoperative or postoperative).

Once, preoperative core temperature of patients was measured indirectly with SpotOn zero heat flux and tympanic membrane probe. Then, indirect core temperature measurement via SpotOn zero heat flux was repeated before induction of general anaesthesia. All patients had a temperature probe inserted approximately 1/3 oesophagus distal part under direct vision, after induction of anaesthesia. Body temperatures measured by the tympanic membrane method only in the preoperative and postoperative periods, esophageal temperatures in the intraoperative period at intervals of 60 minutes and SpotOn measurements throughout all three periods were recorded. The standard for maintenance of the operating room temperature was 21 °C.

Temperature monitoring was established in the preoperative period with tympanic probe and the SpotOn sensor. After anesthesia induction, all patients had a temperature probe inserted approximately 1/3 oesophagus distal part under direct vision, after induction of anaesthesia. The data concerning the age, gender, weight, body mass index, comorbidities, smoking history, preoperative Hemoglobin and albumin levels, the amount of perioperatively administered colloids and colloids, American Society of Anesthesiologist (ASA) physical status classifications of patients type of anesthesia, central catheter usage, patient warming, duration of the operation, operating room temperature, pulse rate, arterial blood pressure, amount of blood loss, transfused red blood cells (RBS) (units) and fresh frozen plasma (FFP) (units), and postoperative hemoglobin and albumin levels were recorded.

Intervention Type
Device

Primary outcome measure
Body temperature measured preoperative, before anesthesia induction, following intubation, 60 min, and every one hour until the surgery, after surgery, in the entry to the recovery room and before discharge to the ward

Secondary outcome measures
Demographic and preoperative/postoperative measurements (age, gender, weight, body mass index, comorbidities, smoking history, preoperative hemoglobin and albumin levels, the amount of perioperatively administered colloids and colloids, American Society of Anesthesiologist (ASA) physical status classifications of patients type of anesthesia, central catheter usage, patient warming, duration of the operation, operating room temperature, pulse rate, arterial blood pressure, amount of blood loss, transfused red blood cells (RBS) (units) and fresh frozen plasma (FFP) (units), and postoperative hemoglobin and albumin levels)

Overall study start date
18/06/2015

Completion date
25/10/2015

Eligibility

Key inclusion criteria
Patients who had undergone major abdominal cancer surgery in the trialists' institution, in whom the SpotOn zero heat flux method, tympanic membrane measurement method and esophageal temperature measurement method had all been used

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Absence of recorded data

Date of first enrolment
01/10/2015

Date of final enrolment
25/10/2015

Locations

Countries of recruitment
Türkiye

Study participating centre
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ROR
https://ror.org/00dbd8b73

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The trialists are considering publishing in the European Journal of Anesthesiology.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Hale Aksu Erdost (haleaksu78@yahoo.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		28/06/2018	25/04/2019	No	No
Results article		01/04/2021	18/05/2021	Yes	No