optiTHERMM

Study Protocol

Optimising Thermoregulation in Major burn surgery (optiTHERMM): an international survey of clinicians

Protocol authors:
Dr Guy Stanley
Dr Majid Al-Khalil
Mr Jonathon Pleat

Contact
info@optiTHERMM.org

optiTHERMM protocol v3. October 2021

Contents

1. Study Steering Committee

Mr Jonathon Pleat (Principal Investigator), Consultant Burns, Plastic and Reconstructive Surgeon at North Bristol NHS Trust and Honorary Senior Clinical Lecturer, University of Bristol
Jonathon.Pleat@nbt.nhs.uk

Dr Majid Al-Khalil, Core Surgical Trainee, Welsh Centre for Burns and Plastic Surgery
majid.al-khalil@wales.nhs.uk

Dr Guy Stanley, Registrar in Plastic Surgery, University of Western Australia
guy.stanley@uwa.edu.au

Dr Lorna Burrows, Consultant Anaesthetist and Intensivist, North Bristol NHS Trust

2. Introduction and Background

It has long been recognised that patients who receive major burn injuries are at risk of developing a dangerously low body temperature (hypothermia). The reasons for this are multifactorial but include the loss of the thermoregulatory capacity of the skin when it is damaged by heat and the circulatory shunting of blood away from the peripheries to the core as part of the stress response. Burns often require surgery and the tendency to develop hypothermia can be exacerbated by the effects of anaesthetic drugs and other factors around the time of the operation[1]. Perioperative hypothermia has been associated with the development of multiple deleterious consequences[2], from coagulopathy to sudden death. Conversely, burn patients also can develop high body temperatures (hyperthermia) in the intermediate term due to inflammatory modulation of the hypothalamic thermoregulation and the susceptibility to septicaemia due to relative immunosuppression and loss of the skin barrier.

Globally, the measurement of body temperature, and interventions to avoid it becoming dangerously low or high, are critical to safe care for t the patient with a major burn

Methods to increase body temperature in burns patients can be grouped into three main categories:[3]

1) Warming the room indirectly by elevation of the ambient temperature.
2) directly heating the patient's external body surfaces *e.g.* by heated blankets.
3) directly heating the patient's internal body surfaces *e.g.* by heated intravenous fluids or more invasive methods.

A comprehensive literature search was conducted to identify all studies about the perioperative temperature management of burns patients published before 30th July 2020 (search strategy available upon request). Many studies were assessing the efficacy of novel methods of warming patients or comparing different methods of warming [3–5]. Pertinently, it has been noted within the literature that there is no standardised method for recording and reporting body temperature in patients undergoing burn surgery [6].

One study was identified which aimed to assess patient body temperature goals and methods used to achieve them in American and Canadian burn centres [7]. Their main findings were:

- 59% of responding centres reported a target minimum core body temperature between 36 to 37°C and 54% reported a maximum target core body temperature between 37-38°C.
- There were a range of common warming methods used in theatres, including increased room ambient temperature (98%); forced air devices (85%); warmed intravenous fluids (87%); conductive heating pads (62%); and intravascular temperature regulating devices (20%)

No studies were identified relating current practice in perioperative temperature monitoring and management for burns patients in the United Kingdom or Europe.

In addition, there are also guidelines from UK national bodies (*British Burns Association* and *Royal College of Anaesthetists*) which relate to the management of perioperative hypothermia in burns patients, but these do not go into detail regarding which temperature control methods to use or which patient body temperature threshold should trigger a management intervention [8,9].

3. Study aims

This study aims to establish current practice in managing patient body temperature for burns patients undergoing surgery in burn centres across Europe and Australasia.

We are not setting out to compare the efficacy of different temperature control methods. Rather, we aim to identify the consensus of current working infrastructure and attitudes regarding burn patient body temperature control. As part of this aim, we seek to answer a few limited, but vital questions including:

- Are local protocols/guidelines in widespread use concerning burn patient body temperature management?
- What are the patient body temperatures which relevant healthcare professionals consider safe during, and around the time of, surgery?
- What are the methods burn centres are currently using in order to monitor and influence patient body temperature?

It is hoped that by gathering this evidence and presenting the results, we will stimulate debate within the burns healthcare community. In the absence of level I evidence regarding thermoregulation and temperature assessment, understanding current practice is an essential step towards stimulating debate and normalising care across the burns community.

3.1 Primary Outcome

The **primary outcome** is the consensus concerning the major burn patient body temperature which is deemed to be safe during surgery and in the perioperative period.

3.2 Secondary Outcomes

- To establish the techniques used to monitor and alter the body temperature of a patient with a major burn injury.
- To determine whether protocols or guidelines are in widespread use concerning patient body-temperature management in the context of major burns
- To determine whether bigger centres are more likely to have a larger range of relevant equipment and facilities

4. Study Design

This study will be a survey of current practice informed by the standards recommended by The Royal College of Anaesthetists and British Burns Association concerning the thermoregulation around the time of burns surgery[9].

The survey will be conducted online through the use of a university REDCap server.

4.1 Inclusion Criteria

Consultant surgeons, anaesthetists and critical care doctors working in hospitals within Europe and Australasia which offer burns surgery.

4.2 Exclusion criteria

Doctors who are not involved involved in the surgery, anaesthesia or intensive care support of patients undergoing burn surgery.

4.3 Dissemination of the survey

The steering committee will seek to engage relevant organisations involved in burn care such as the European Burns Association (EBA), British Burn Association (BBA) and the Australia & New Zealand Burn Association (ANZBA) to assist with the dissemination of the survey

4.4. Data Collection Period

Participants will be recruited over a 6 month period from 1st October 2021.

4.5 Variables

See the data dictionary for details on the variables to be recorded (www.optiTHERMM.org).

4.6 Analysis plan

We plan to use descriptive statistics to show the variation in practice between hospital, country and speciality of doctors. We will use Cohen's Kappa to estimate the interrater reliability, where applicable.

5. Anonymity and confidentiality

Participants will be asked to choose their professional role, the name of their hospital and the city or town which it is located in. Participants will not be linked to any of their question responses in any resulting presentations or publications. No other confidential data will be collected. All data will be held securely in a university research server.

No patient information will be collected.

The study steering committee will not disclose or use for any purpose other than performance of the study, any data, record, or other information submitted in the survey responses.

6. Ethics & governance

The study will be conducted in accordance with the internationally established principles of good clinical practice (GCP). This study has been submitted for review by an ethical authority.

This is a survey, which will be conducted to establish current practice against the standards outlined by the Royal College of Anaesthetists[9]. No patient data is being collected. Participants will be asked for their email if they wish to have further involvement with the study.

The study has undergone peer-review in the UK and Australia with formal approval from WA Health's Governance, Evidence, Knowledge, Outcomes (GEKO) to proceed, with permission to publish the results

6.1 Potential risks to subjects

Participation in this study poses no potential risks to participants. We will report the range of responses from a variety of hospitals but no individual hospital or individual's responses will be identifiable. We will analyse the data by country or by complexity of burn but will not name any hospital.

6.2 Conflict of interest statement

The researchers have no affiliation to any companies or products relevant to this study. The two senior authors work in a national burns centre (JP and LB).

No financial support has been sought for this project.

7. Acknowledgement of collaborators

Any trainee who recruits at least five consultants to the survey will be listed as a collaborator on any resulting publication.

8. Reporting of Results

The results of this study will be disseminated to the burn care community via presentation at relevant national/international meetings and publication in peer-reviewed journals.

9. References

1. Woodson, L. C. *et al.* Anesthesia for burned patients. *Total Burn Care* 196–228 (2007) doi:10.1016/b978-1-4160-3274-8.50017-9.

2. Rizzo, J. A., Rowan, M. P., Driscoll, I. R., Chan, R. K. & Chung, K. K. Perioperative Temperature Management During Burn Care. *J. Burn Care Res.* **38**, e277–e283 (2017).

3. Kjellman, B.-M., Fredrikson, M., Glad-Mattsson, G., Sjöberg, F. & Huss, F. R. Comparing ambient, air-convection, and fluid-convection heating techniques in treating hypothermic burn patients, a clinical RCT. *Ann. Surg. Innov. Res.* **5**, 4 (2011).

4. Williams, D. *et al.* Use of an Esophageal Heat Exchanger to Maintain Core Temperature during Burn Excisions and to Attenuate Pyrexia on the Burns Intensive Care Unit. *Case Rep. Anesthesiol.* **2016**, 7306341 (2016).

5. Davis, J. S. *et al.* Use of a warming catheter to achieve normothermia in large burns. *J. Burn Care Res.* **34**, 191–195 (2013).

6. Owen, K., Litton, E., Raby, E. & Wood, F. Perioperative Temperature Management During Burn Care. *J. Burn Care Res.* **39**, 172 (2018).

7. Pruskowski, K. A. *et al.* A Survey of Temperature Management Practices Among Burn Centers in North America. *J. Burn Care Res.* **39**, 612–617 (2018).

8. Association, B. B. & Others. National Standards for Provision and Outcomes in Adult and Paediatric Burn Care. (2018).

9. Bowes, J., Yarwood, J., Emerson, B. & Young, A. Guidelines for the Provision of Anaesthesia Services for Burn and Plastics Surgery 2020. in *Guidelines for the Provision of Anaesthetic Services* (ed. Royal College of Anaesthetists) (Royal College of Anaesthetists, 2020).

10. International Committee of Medical Journal Editors. *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*. http://www.icmje.org/icmje-recommendations.pdf (2019).