Clinical summary

Study to assess the safety and efficacy of an active self-warming blanket used to prevent hypothermia

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Key points

- With BARRIER® EasyWarm® active self-warming blanket, intraoperative temperature was maintained at a stable level for 2.5 hours.
- With BARRIER EasyWarm, the typical temperature drop of 1–1.5°C on induction of anaesthesia did not occur in patients. A temperature drop of only 0.6°C was recorded.
- No serious adverse events were reported when using BARRIER EasyWarm.
- BARRIER EasyWarm was well received in terms of comfort and warmth by the patients.

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Background

Patients undergoing general and major conduction anaesthesia will experience varying degrees of hypothermia with a typical core temperature loss of up to three degrees centigrade in the first three hours.[1] This is most pronounced during the first hour of anaesthesia, with a loss occurring of around 1.5ºC.[2] Inadvertent anaesthetic-induced mild hypothermia (34-36°C) has documented ill effects, including a three-fold increase in surgical wound infections, a tripling of cardiac morbidity, coagulopathy, and prolonged emergence and recovery, all translating into longer hospital stays and increased costs.[2-6]

Hypothermia also appears to have a significant effect on patient satisfaction and anxiety. Nurses at the 2003 Congress of Association of periOperative Registered Nurses (AORN) and the American Society of PeriAnesthesia Nurses (ASPAN) convention cited patient warmth as the top comfort concern.[7]

Strategies for maintenance of peri-operative normothermia include passive insulation and active warming. Several studies indicate that active methods are more efficient than passive insulation in maintaining peri-operative normothermia.[7-12]

Objectives

The objective with the study was to collect safety and efficacy data for the active self-warming blanket used in the peri-operative setting with the aim to investigate prevention of change in core body temperature.

Methodology

- Prospective, open label, one-armed, multicenter, trial.
- Two study centers:
  - University General Hospital, Houston, Texas, USA. Dr Joseph Varon, MD.
  - Physicians Surgical Care Center, Winter Park, Florida, USA. Dr Sean McFadden, MD.
- Adult patients with a rating of 1-3 (according to American Society of Anesthesiologists) scheduled to undergo general anaesthesia during a surgical procedure scheduled for a minimum of 60 minutes and maximum of 180 minutes, where the schedule must allow the subjects to be warmed with a fully activated blanket at least 30 minutes prior to anaesthesia.
- Medical history, concomitant medication and other factors pertaining to thermoregulation and skin integrity were assessed.
- Assessments, including subjects' temperature, room temperature and vital signs were recorded pre-operatively.
- Administration of fluid, additional warming devices, type and length of procedure were also recorded together with concomitant medication.
- Blanket coverage and skin status under the heating pads were assessed every 30 minutes, and continued, every 15 minutes during surgery and general anaesthesia.
- Postoperatively, assessments of temperature, skin status, blanket coverage and vital signs continued until the blanket was removed.
- A follow up visit was performed 24 (+/- 6) hours after blanket removal, where skin status was assessed.
- The subjects were asked to reply to two questions relating to comfort and warmth.
- Adverse events were recorded throughout the study period.

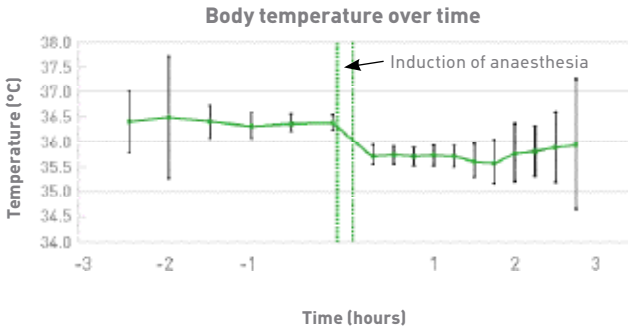
Results

- A total of 112 patients were enrolled and evaluated for safety; 63% males, 37% females.

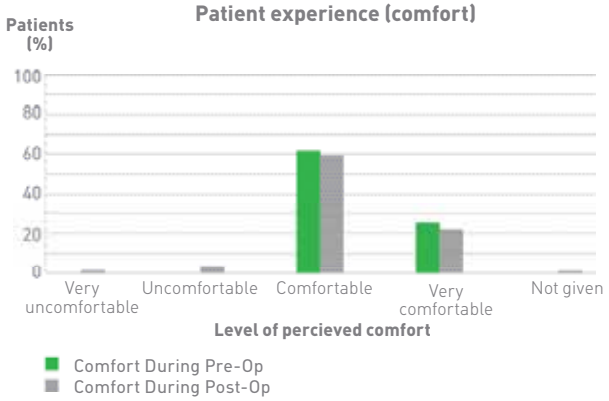
  23 were excluded due to lack of data, 18 due to wrong temperature recordings used (skin and nasal) and 3 had additional warming devices (inadvertently applied as standard of cure).

- 68 patients were evaluated for efficacy.
- No serious adverse events were reported. One device-related adverse event was reported, in which one patient had red spots where the warmers had been. The redness vanished within 20 minutes after the blanket was removed. No further follow up was required.
- Mean inclusion temperature was 36.5°C.
- After pre-warming of 30 minutes or more with the active self-warming blanket, the typical temperature drop of 1–1.5°C upon induction of anaesthesia was not seen in patients. The temperature drop was only 0.6°C.

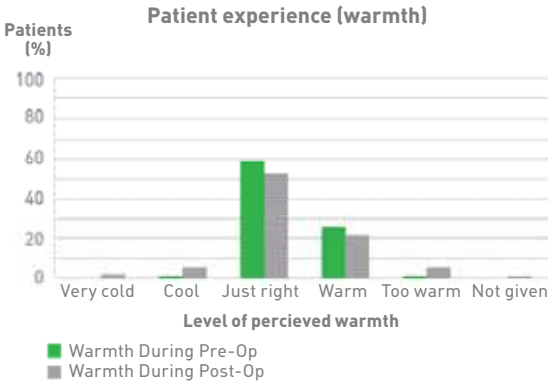
During the surgery, there were no significant changes to the mean core body temperature for 2.5 hours.



The majority of the patients rated the blanket's comfort as "very comfortable" or "comfortable" both before and after surgery.



The majority of the patients rated the blankets temperature as "warm" or "just right" both before and after surgery.



Conclusion

This study to assess the safety and efficacy of BARRIER EasyWarm, an active self-warming blanket, shows that the use the blanket helps to prevent hypothermia.

The typical temperature drop of 1–1.5°C on induction of anaesthesia did not happen. Only a drop of 0.6°C was recorded in this trial. It was concluded that temperature was maintained at a stable level for 2.5 hours during the period of surgery.

Only one device related non-serious adverse event was reported and required no further follow up hence the active self-warming blanket was safe to use for the patients included in this study.

Patient experience with regard to comfort and warmth was highly rated.

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Mölnlycke Health Care AB, Box 13080, SE-402 52 Göteborg, Sweden.
T +46 31 722 30 00. F +46 31 722 34 00. www.molnlycke.com

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