Peer-Reviewed Publications


- Prospective interventional trial evaluating performance of the ensoETM in 12 TBI patients.
- A total of 480 temperature measurements were recorded; 85% of the total measurements were within ±1°C of target temperature and 75% were within ±0.5°C of target temperature.
- The ensoETM offered comparable or superior performance to other commercially available TTM modalities, and the low adverse event rate may offer advantages over more invasive methods.


- Prospective study evaluating the performance, shivering burden, and costs of the EnsoETM, compared to patients treated with other devices (Gaymar wraps, Arctic Sun pads, and Zoll catheters).
- Time to get to target and total fever burden were similar in both groups (32 patients total).
- Cost of antishivering medications was $660 less per patient with the EnsoETM than for controls.
- Currently the "Most-Read" article in the journal *Ther Hypothermia Temp Manag*.


- Prospective study of 19 patients undergoing elective non-cardiac surgery, measuring total heat transfer in both cooling and warming modes.
- The authors conclude that the EnsoETM can be used to provide warming in cases not amenable to surface warming and can supplement or replace catheter-based cooling.


- Evaluation of the EnsoETM performance across 3 clinical sites.
- In all active cooling protocols, the average time-to-target was 2.37 h and the average maintenance phase was 22.4 h. Patients spent 94.9% of the maintenance phase within ±1.0°C and 67.2% within ±0.5°C (574 and 407 measurements, respectively, out of 605 total).
- For warming protocols, all of the patient temperature readings remained above 36°C throughout the surgical procedure (average 4.66 h).
- The EnsoETM met performance expectations across a range of temperature management applications in intensive care and burn units, and patients met and maintained temperature goals without any reported adverse events.


- Prospective study of 17 out-of-hospital cardiac arrest (OHCA) patients.
- 100% of patients reached the 32-34°C range, as compared with 97% for the endovascular group and 91% for the external cooling group in the 400 patient ICEREA study. Cooling rates (°C/hr) were likewise similar (surface = 0.27, endovascular = 0.39, EnsoETM = 0.26).
- The EnsoETM demonstrated high accuracy in maintenance of goal temperature, with a percentage of time out of the 32 to 34°C target of 0% [0-0]. Endoscopy revealed no unexpected findings.

- Prospective study of 10 patients sustaining traumatic brain injury with central fever treated with the EnsoETM; patients were compared to historical controls using standard of care (ice packs).
- Patients treated with the EnsoETM showed a significant improvement in outcome, with CPC 1-2 found in 50% versus 20% in usual care cohort at ICU discharge, and 80% versus 30% at hospital discharge.

- Case report showing capability of the EnsoETM to warm from an extreme cold of 23.3°C.

- Review of 18 patients treated with the EnsoETM for at least 72h.
- The longest treatment duration was 452 hours.
- Patients were within ±1°C of target during the protocol 83.3% of the time.
- A reduced shivering burden, resulting in reduced sedation requirements, was reported by clinicians caring for patients.

- Overview of device use in a population of 30 patients, where devices were placed by ER, ICU, and STAT nurses.
- Site observed a rapid initiation to cooling with stable maintenance temperatures throughout treatment.
- Nurses were pleased with the flexibility the EnsoETM offered, and cardiologists saw almost no limitations in the catheterization laboratory.

- Prospective study of the EnsoETM used as sole modality for hypothermia induction, maintenance and rewarming in a series of four postcardiac arrest patients.
- Nursing staff were consistently positive with respect to ease-of-use, observed ease-of-insertion, and handling, and rated the device’s efficacy and overall performance as excellent.

- Report of a 36-year-old woman who was treated with the EnsoETM to reduce fever and elevated ICP due to severe Streptococcus pyogenes meningitis.
- No additional temperature management methods were used simultaneously with the EnsoETM, and the device was removed on day 7, with gastroscopy revealing no significant findings.

- Prospective study of the EnsoETM in 14 patients suffering from post-cardiac arrest.
- Mean time to target temperature was 60 (range 41-195) minutes and the percentage of time outside target temperature range during the maintenance phase was 6.5%.
• Insertion of the device was successful in all patients, nurses noted that the device enabled good access to the patients while the workload for temperature management was decreased.

• Report of the EnsoETM used to warm patients during burn surgery to avoid inadvertent peri-operative hypothermia. Patient perioperative core temperature was maintained for all patients successfully, despite extensive burns, even while reducing ambient operating room temperature to 26°C (from the usual 30°C or more).

• Report of temperature control using the EnsoETM to control refractory fever or induce therapeutic hypothermia.
• Device placement occurred in under 3 minutes, ease-of-use was reported as excellent by nursing staff and physicians, and the authors concluded that the EnsoETM was an effective temperature control modality.

• Report of patients treated with the EnsoETM after cardiac arrest.
• Temperature was kept between 32 and 33.9°C without excessive fluctuations, and rebound hyperthermia was avoided.
• The authors conclude that the device demonstrates performance comparable to intravascular devices and superior to most studies of surface devices.

Conference Presentations


• Recommends esophageal warming for patients with burns >20 % body surface area or an anticipated operating time of greater than 3 hours.

• Comparison of esophageal warming to historical controls, finding that patients treated with the EnsoETM demonstrated better maintenance of normothermia, and that esophageal warming offers a safe and very effective means of reducing the occurrence of inadvertent perioperative hypothermia during major burn surgical procedures.
- Case series showing successful use of esophageal warming during spinal surgery.

- Animal model describing protective effects of esophageal cooling against radiofrequency ablation, with a mathematical model of the system providing guidance for ongoing clinical investigations.

- Description of 5-day treatment of severe exertional heat stroke with complete neurologic and functional recovery.

- Description of first use of esophageal warming for protection from cryoablation thermal injury.

- Full model showing impact of esophageal warming during cryoablation.

- Full model showing impact of esophageal cooling during RF ablation.

- Report of first cohort of patients provided esophageal protection via cooling during RF ablation.

- A retrospective study of 3 patients in which the EnsoETM was used for >120 hours.
- Temperature was in target range for 81% of time, ±0.5°C outside target range for 11.6% of time, and ≥0.6°C outside of target range for 7.4%.

- Prospective study of 22 patients comparing endovascular, surface, and esophageal temperature management.
- Variation of temperature during the maintenance phase, expressed as mean hourly standard deviation, was 0.26 °C in endovascular, 0.42°C in esophageal and 0.76 °C in surface groups.
The percentage of patients with post-rewarming hyperthermia (>38 °C) at any measurement was 43% in endovascular group, 20% in the esophageal group and 50% in surface group.

**Pre-clinical publications**


- Faster hypothermia successfully induced by esophageal cooling was significantly better than conventional cooling in improving early markers of postresuscitation cardiac and neurological injury.


- Cooling performance did not differ between esophageal and intravascular in maintaining target temperature and in active rewarming.
- The authors note that given that intravascular device placement requires capabilities for preparation and application, immediate onset of esophageal cooling may achieve a target temperature of 33°C in the same time or even faster.


- Prospective study in animal model of two different sizes of esophageal heat exchange device.
- Devices with diameters of 11 mm and 14.7 mm achieved effective cooling rates and did not cause any relevant esophageal tissue damage. Both diameters demonstrated acceptable deviations from target temperature and allowed for an intended rewarming rate of 0.25°C/h.


- Prospective study of the EnsoETM esophageal heat transfer device in a pediatric swine model.
- The device successfully modulated temperature, suggesting that this approach to temperature modulation may offer a useful modality to control temperature in conditions warranting temperature management, such as maintenance of normothermia, induction of hypothermia, fever control, or malignant hyperthermia.
- Histopathologic analysis of esophageal tissue showed no adverse effects.


- Prospective large-animal model study of the EnsoETM esophageal heat transfer device.
- The device successfully and safely induced, maintained, and reversed therapeutic hypothermia.
- Goal temperature was maintained within a narrow range, and thermogenic shivering did not occur.
- Histopathology of esophageal tissue showed no adverse effects from the device.


- A prototype of the EnsoETM esophageal cooling device induced hypothermia effectively in a large single-swine model.
- Histopathology of the esophagus showed normal tissue without evidence of injury.
   - Mathematical modeling demonstrating feasibility of temperature modulation via the esophagus.

Recent Reviews or Mentions of the EnsoETM

   - Discusses various options for performing targeted temperature management.

   - Mentions current methods utilized at burn centers to maintain normothermia, including use of the esophageal temperature management device.

   - Provides comprehensive recommendations and a standardized shivering protocol.

   - Discusses various options for performing targeted temperature management.

   - Overview of the EnsoETM esophageal temperature management device, with video demonstration and description of published results in cooling and warming.

   - Highlights esophageal warming as a means to avoid hypothermia in trauma.

   - Overview of the esophageal cooling and warming device and data on its use.

   - Discusses various options for performing targeted temperature management

   - Discusses various options for performing targeted temperature management

Clinical Trials pending, recruiting, or completed on Clinicaltrials.gov

- Temperature Control With an Esophageal Cooling Device in Post Cardiac Arrest Patients (E-Chill) - NCT02387775
- Prospective, Interventional Study Evaluating the Feasibility and Safety of the Esophageal Cooling Device in Traumatic Brain Injury - NCT02420639
- Esophageal Temperature Management After Cardiac Arrest (THE-COOL study) - NCT02327871
• Evaluating Heat Transfer with the Esophageal Cooling Device - NCT02743884
• Mild Hypothermia and Acute Kidney Injury in Liver Transplantation (MHALT) - NCT03534141
• Esophageal Cooling in Radiofrequency Cardiac Ablation - NCT03481023
• Intraoperative Warming During Major Surgical Procedures Using the Esophageal Temperature Management System (EnsoETM) - NCT03790683
• Improving Desophageal Protection During AF Ablation (IMPACT) - NCT03819946
• Protection of the Cardiothoracic ESOphagus with an Esophageal Device for COOLing During RadioFrequency Ablation of the Left Atrium (ESO-COOL-RF): A Prospective, Interventional, Single Blinded, Single Center Pilot Study – Pending listing on Clinicaltrials.gov

Online Publications and Protocols

Latest EBM Guidelines – Orlando Health Surgical Critical Care Fellowship (provides evidence-based medicine guidelines that are used in intensive care units and hospitals around the world):

  • Perioperative Hypothermia Prevention in Burn Patients

Radiopaedia – Radiopaedia.org is a rapidly growing, open-edit radiology resource, compiled by radiologists and other health professionals from across the globe.

  • Esophageal cooling device

References


