Development and Validation of an Induced Hypothermia Thermoregulation Model for Assessing Patient Warming Devices

Steven Bernal-Diaz, Andre van Grieken, & Meredith McQuerry, Ph.D., Florida State University

Keywords: Manikin, modeling, hypothermia, anesthesia, medical device

Background: Medical warming devices used during anesthesia help prevent unintended perioperative hypothermia, which can lead to serious postoperative complications (Sessler, 2000). To accurately assess new warming technologies, an advanced thermoregulation model is needed, as clinical assessments are invasive and highly limited. Instead, utilization of a unique dynamic thermal manikin model that can simulate induced hypothermia under anesthesia conditions should be developed. Thermal manikins have evolved from basic tools measuring heat transfer to sophisticated devices simulating human thermal responses. In the 21st century, thermal manikin technology has advanced significantly, enabling simulations of a broader range of conditions (Rugh, Farrington, Bharathan, Vlahinos, Burke, Huizenga, & Zhang, 2004). Ongoing research focuses on enhancing their accuracy and versatility through emerging technologies (Yang et al., 2020). Such work is needed to simulate induced hypothermia such that warming devices can be thoroughly tested pre-clinic to refine protocols and settings. This benefits patient safety by optimizing medical device technologies before they reach human patients. Therefore, the purpose of this research was to develop and validate an induced hypothermia thermoregulation model using a dynamic sweating thermal manikin to assess patient warming devices for preventing perioperative hypothermia. This model development and validation will allow for quantification of the efficacy of new devices in regard to preventing unintended perioperative hypothermia and maintaining normothermia compared to existing solutions to improve surgical patient outcomes.

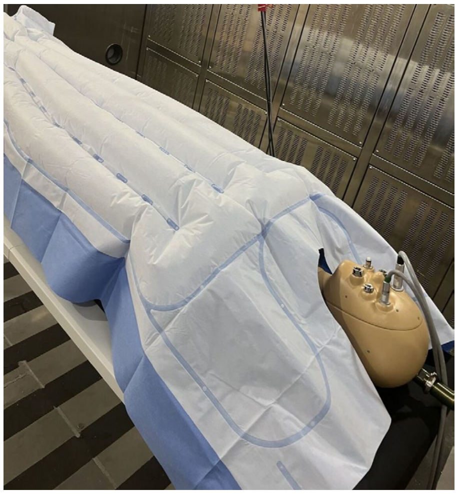

Figure 1. Patient warming device on ANDI dynamic thermal

Methods: Using an ANDI dynamic sweating thermal manikin (Figure 1; Thermetrics, Seattle, WA) with simulated active thermoregulation modeling (ManikinPC, ThermoAnalytics, Calumet, MI) allows researchers to model human physiological responses under controlled, repeatable conditions not possible with human subject testing. In this study, the researchers developed an adapted induced hypothermia (IH) model within ManikinPC that neutralized vasoconstriction, perspiration, and shivering to reflect more accurate real-world physiological responses under anesthesia. Vasodilation was not restricted. The IH model was adapted from the established ManikinPC active thermoregulation (AT) model which is based on the Fiala et al. and Berkeley comfort models (McQuerry, 2018). Predicted responses (core temperature, skin temperature, skin blood flow, comfort, and sensation perceptions) were assessed between the AT and IH models both with and without the warming device powered on to determine how the two models varied in the accuracy of their physiological response predictions. Three test replicates were performed in each of the four test conditions (two models x blower on/off). A test duration of 70 minutes was selected based on previous research (Horn et al., 2012) such that the transient and steady state periods of heat transfer between the warming device and manikin were captured. Environmental conditions were precisely controlled at 15°C and 50% relative humidity to simulate an operating theatre. Data was analyzed using one-way ANOVAs and individual two-sample T-tests.

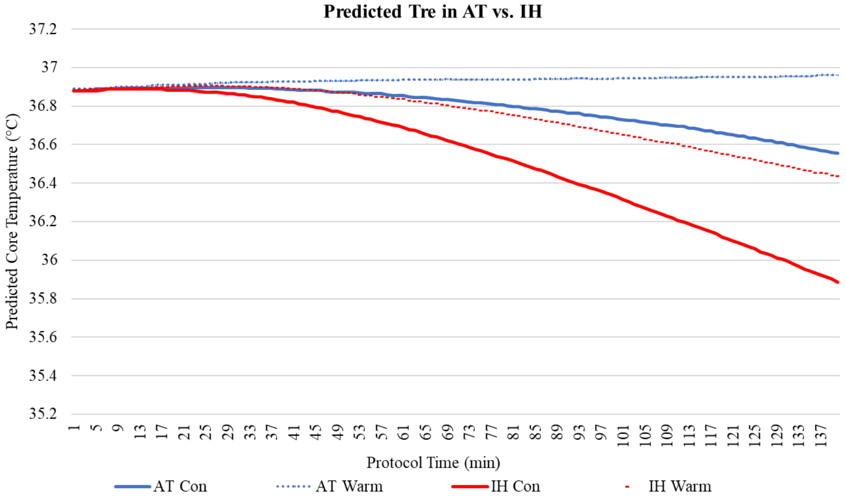

Figure 2. Predicted Tre in AT vs IH

***Results*:** The induced hypothermia (IH) model demonstrated significant differences (*p <0.05*) in predicted physiological responses compared to the active thermoregulation (AT) model when testing the patient warming device. Without the device powered on, the IH model predicted a significant steady decline in core temperature (Figure 2), while the AT model-maintained core temperature through shivering and vasoconstriction. With the warming device activated, the IH model showed the device was able to maintain core temperature above 36°C, whereas the AT model predicted a significant increase above normothermic levels due to the lack of thermoregulatory control. Skin temperature predictions followed similar significant trends, with the IH model showing greater declines without the device and more moderate increases with it compared to the AT model. The IH model also predicted lower overall skin blood flow *(p<0.05),* and no shivering response compared to the notable vasoconstriction and shivering predicted by the AT model. Thermal comfort and sensation predictions were less favorable for the IH model without the device. Both models predicted improved comfort and sensation with the warming device on, with the AT model predicting slightly higher comfort due to additional heat gain.

***Conclusions*:** The newly developed induced hypothermia (IH) thermoregulation model successfully predicted the unique physiological responses of anesthetized surgical patients at risk for inadvertent perioperative hypothermia. Unlike the standard active thermoregulation (AT) model, the IH model demonstrated the critical need for effective patient warming to maintain normothermia when anesthesia impairs shivering and vasoconstriction. The IH model provides a new tool for evaluating patient warming devices under realistic physiological conditions not captured by existing thermal manikin models. This research validates the IH model's use in optimizing warming device design and clinical protocols based on key parameters like core temperature, skin blood flow, and thermal comfort. By offering a more clinically relevant simulation platform, the IH model can accelerate the development of superior patient warming solutions to reduce the incidence and complications of perioperative hypothermia. This study was limited in scope to one medical device therefore, future research should be performed to further assess and hone the IH model development and validation.

References

Havenith G, Holmér I, den Hartog EA, Parsons KC. (1999). Clothing evaporative heat resistance--proposal for improved representation in standards and models. Annals of Occupational Hygiene, 43(5), 339-46.

Ho, C. F., Chow, W. K., Yang, W. F., & Lin, C. I. (2005). An artificial sweat system using thermal feedback control for sweating manikin applications. Measurement Science and Technology, 16(11), 2222–2229.

Horn, E.-P., Bein, B., Böhm, R., Steinfath, M., Sahili, N., & Höcker, J. (2012). The effect of short time periods of pre-operative warming in the prevention of peri-operative hypothermia.

International Organization for Standardization. (2004). ISO 15831:2004. Clothing—Physiological effects—Measurement of thermal insulation by means of a thermal manikin. Geneva, Switzerland: Author.

McQuerry, M. (2018). Validation of a clothing heat transfer model in nonisothermal test conditions. Journal of Testing and Evaluation, 46(1), 1-7.

Psikuta, A., Frackiewicz-Kaczmarek, J., Frydrych, I., & Rossi, R. M. (2018). Quantitative evaluation of three calibration methods for a sweating thermal manikin. International Journal of Industrial Ergonomics, 67, 230-240.

Rugh, J & Farrington, R & Bharathan, Desikan & Vlahinos, Andreas & Burke, R & Huizenga, Charlie & Zhang, Hanren. (2004). Predicting human thermal comfort in a transient nonuniform thermal environment. European journal of applied physiology. 92. 721-7. 10.1007/s00421-004-1125-2.

Sessler, D. I. (2000). Perioperative heat balance. Anesthesiology, 92(2), 578-596.

Yang, H., Choi, J. S., Park, J. Y., Du, Z. M., Loftness, V., & Lee, K. W. (2020). Evaluation of the capabilities and limitations of the human body model of an articulated thermal manikin in simulating human thermoregulatory responses. Building and Environment, 178.