The system used in our study. The cooling helmet and conditioning unit used in their study is not the system used in our study. The cooling helmet and conditioning unit used by us were designed specifically for our research purposes, requiring FDA exemption. Our experimental system is not commercially available.

There are many significant differences in the two systems. For example, our conditioning unit has a constant air pressure of 26 mm Hg, more than 73% higher than the 15 mm Hg air pressure in the commercially available CoolSystem conditioning unit used in the authors’ study. The fact that the head was unshaven, combined with the much lower counter-pressure, would significantly reduce the heat transfer efficiency of the system. Due to the lower counter-pressure, the hair would maintain an air barrier between the cooling panel in the cap and the head-neck skin surface.

Further, the CoolSystem unit uses water circulated through a bath of ice cubes. This has several disadvantages. For example, the water flow seeks the path of least resistance and will therefore find open channels, most commonly occurring at the bottom of the bath where the temperature will be 3.8°C. Our conditioning unit used an antiseptic mix of propylene glycol and water, circulated through heat exchangers immersed vertically in the ice bath, resulting in a more evenly distributed pattern of heat exchange. The result temperature of the cooling cap used by the authors would therefore be higher than temperatures maintained by our system.

In addition, our conditioning system used approximately twice the volume of ice and water. This increases the ratio of ice to water, maintaining a constant bath temperature for a much longer period of use.

Such significant differences between the conditioning units alone would result in significant performance difference in achieving selective cerebral hypothermia.

The sequence of questions proposed at each stage of the investigation requires further discussion and clarifications. The strategic planning of a scientific evaluation of an externally applied selective cerebral hypothermia system should occur categorically in the following sequence:

Stage I: Proof of Concept

Questions Proposed: 1) Is it possible to have significant selective cerebral hypothermia using a head-neck surface cooling system in a realistic clinical setting yet with all conditions optimized, such as in patients with heads shaved and monitored in the intensive care unit? 2) Does it result in any local cold injuries to the skin and does it impede the standard care of such patients in the intensive care unit? 3) Does it result in delayed systemic hypothermia, thereby creating a safe therapeutic window for ultra-early delivery of head-neck regional hypothermia by emergency medical services personnel in the field?

The above questions were answered conclusively in our published study using a head-neck cooling helmet and conditioning unit that was specifically designed for the research purpose.

Stage II: Field Testing for Ultra-Early Delivery of Regional Hypothermia

Questions Proposed: 1) Could we further design a head-neck cooling system that would have enhanced heat extraction capacity to achieve sufficient intracranial cooling in field patients with heads unshaved? 2) Could we further design a head-neck cooling system to secure the cervical spine without compromising the heat extraction capacity? 3) Would the application of this newly designed system impede standard field medical evaluation and introduce other complicating factors?

We have recently secured funding to investigate the above questions.

Stage III: Outcome Study for Ultra-Early Delivery of Regional Hypothermia—A Multicenter Randomized Study

Many steps would have to occur within each stage to allow for further progress. Each study is designed to address the primary questions suitable for that stage only. Attempts to prematurely answer questions more suitable for advanced stages may introduce confusion and misinformation.

We would like to congratulate the authors on their work. As we proceed to the field testing phase of our investigation with a newly designed head-neck cooling system, we look forward to future scientific collaboration.

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Disclosure

William Elkins is the former chief technical officer of bio-COOL Technologies.

Reference


RESPONSE: We thank Dr. Wang and colleagues for their thoughtful comments regarding our manuscript. We would like to acknowledge our agreement with Wang et al., in that there remains a continued need for further investigation of technologies associated with selective hypothermia. The article by Wang et al., titled “Rapid and selective hypothermia achieved using a cooling helmet,” in the February 2004 edition of the Journal of Neurosurgery, introduced this technology and further informed the debate regarding the potential for benefits of cerebral hypothermia.

We would like to address the concerns of Dr. Wang and his associates regarding our recent clinical trial and article. Firstly, we agree that the system utilized in our trial is distinct from that of Dr. Wang. The manuscript does not state, nor do the authors wish to represent, that these systems are the same, only similar. The points of distinction raised are noted.

The questions posed in the letter indicate that a goal of Dr. Wang’s initial project was to determine whether it was “possible to have significant selective cerebral hypothermia using a head-neck surface cooling system in a realistic clinical setting yet with all conditions optimized....” We too felt this was an important objective in assessing a potential device. In evaluating both effectiveness and applicability, we made the decision to not shave the patients’ heads, as this best represented the true clinical setting. Our article details our associated results and our observations regarding the relevance and implications this posed.

The other issues raised by Wang and associates in their letter are not applicable to our manuscript. Specifically, our trial did not focus on field assessment of ultra-early delivery of hypothermia. The goal of our trial was to “determine the effectiveness of the Discrete Cerebral Hypothermia System” in patients with traumatic brain injury (TBI), with primary outcomes described as “the effectiveness of the cooling cap in reducing the patient’s internal brain temperature and establishing a gradient between patients’ core and brain temperatures following TBI.” The secondary objective was an outcome analysis of “mortality, GOS, and FIM scores following severe TBI.”

We would like to thank Dr. Wang and his associates for their initial work related to regional cerebral cooling, and we wish them success in their planned investigations.

Reference