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Dear Mr. Bar-Sela:

We had the opportunity to trial the microprocessor based, water-circulating garment (The Allon 2001, MTRE, Caesarea, Israel) at the Department of Congenital Cardiac Surgery of the Cleveland Clinic Foundation.

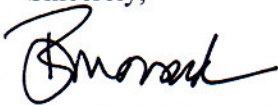
Our active congenital surgical center manages over 500 operations every year with almost 40% of these patients under one year of age, and over 70% done using hypothermic cardiopulmonary bypass. One of the complications that often occurs following separation from bypass, especially in small children, is a continued drop in temperature despite all the routine efforts of maintaining normothermia. Hypothermia following bypass can contribute to coagulopathy and increased bleeding, myocardial dysfunction, increased vascular resistance and oxygen consumption, delaying recovery and extubation.

We used the Allon 2001 garment on 12 patients less than one year of age in the congenital cardiac operating rooms. The garment was able to significantly maintain the children's temperature for over an hour following bypass, compared to the continuous drift in temperature of the control group of patients. The garment proved to be easy to use, reliable and we saw no complications on any of the children. Interestingly, the effect of the garment was more pronounced, the smaller the child (< 5 kg) and the more complicated the surgery.

The use of the Allon 2001 garment did not lead to a decrease in blood loss or transfusion requirements, or an improvement in hemodynamics. However, I believe that normothermia is just a small piece in a big puzzle of post-cardiac surgical care. For anyone device, drug or technique to show a significant effect we will need a large number of patients, which we did not have in our trial.

Children are known to be more vulnerable to hypothermia due to their body surface area, and their inability to shiver. All effort should be done to try to maintain their temperature following bypass, and the Allon 2001 appears to be very efficient in doing that.

Sincerely,



Emad B. Mossad, MD

EBM/glb