Vicor says PD2i could help detect internal blood loss

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When emergency medical responders arrive at a trauma scene their most important job is to quickly sort patients by the urgency of their injury and then to allocate treatment accordingly.

The problem, as Jerry Anchin, PhD, of **Vicor Technologies** (Boca Raton, Florida) tells *Medical Device Daily*, is that "the most obviously wounded are not necessarily the most critically wounded."

A prime example is when an IED explodes in Afghanistan or Iraq underneath a vehicle carrying, say, five to eight soldiers. When the medics arrive, a soldier with a missing limb will most likely be treated before another soldier who might be suffering from internal bleeding – a very critical, but much less obvious, injury.

Anchin, VP and director of development at Vicor, said the company believes its PD2i nonlinear algorithm could be used in trauma situations – both on and off the battlefield – to detect acute hypovolemia. The company recently set out to prove that hypothesis with a small pivotal study using blood donors. The study was conducted in cooperation with the **University of Mississippi Medical Center** (UMMC; Jackson) and **Mississippi Blood Services** (MBS; Jackson) on Dec. 12, in Smithdale, Mississippi.

As with any clinical trial, Anchin said it's usually best to do a pilot study before jumping into a full blown, large scale trial. The challenge for Vicor, he said, was to figure out a way to test this theory in a controlled manner to show that its PD2i would reflect, in very short time frames, very small amounts of blood loss. So, using its connections at the UMMC and MBS, the company decided to test out the hypothesis on blood donors.

During the pilot study, Vicor tested all 18 participants prior to donation to determine a baseline PD2i value, and re-tested them during and after collection. The average PD2i value of participants prior to donation was 2.60, the company noted; the average PD2i value following donation was 1.80. With a P value of 0.001, Vicor says the study results are highly statistically significant and indicate a better than 99% probability that the results were not achieved randomly.

"These results are not due to chance, the hypothesis is proven to be true," Anchin said. Still, the company knows this was a very small scale study and plans to use it as a stepping stone for a larger study, perhaps in multiple centers, to convince others that the algorithm is capable of detecting acute hypovolemia.

"You can't just walk in with this new metric and tell people, 'well, we have this new metric, but you have to just believe us it that it works," Anchin told *MDD*.

Vicor describes its PD2i algorithm as a "deterministic, nonlinear measure of electrophysiological potentials that predicts future pathological events with a high degree of accuracy in target populations." The idea behind the technology is to try to decode the interaction between our brain and our heart.

The company's PD2i Analyzer already has FDA 510(k) clearance as a measure of heart rate variability. The PD2i CA (cardiac analyzer), which is designed to identify patients at risk of sudden cardiac death, is currently being studied and the company expects to receive marketing clearance for that indication sometime this year. Vicor also is studying the use of its PD2i-VS (vital sign), in collaboration with the U.S. Army Institute for Surgical Research, in identifying combat and civilian trauma victims at risk of "crashing," (*Medical Device Daily*, Sept. 25, 2009). The company says it plans to submit these findings to the FDA to obtain an amendment to its existing 510(k).

Vicor CEO David Fater said the company is "very encouraged" by the results achieved in this small pilot study. "However, as this pilot study measures internal blood loss resulting from external blood donation, we anticipate further studies as part of our progress in commercializing a noninvasive diagnostic to detect acute hypovolemia," Fater said.

Vicor also says it anticipates additional applications employing the PD2i nonlinear algorithm to enable early detection and risk stratification for a variety of other disorders and diseases.

"What we're doing is being very deliberate," Anchin said. "We want to do pilot studies, we want to generate attention and show people that this . . . is not just some fly-by-night metric."

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