



Fluid warming with parylene-coated enFlow™ cartridge: bench and pilot animal study of aluminum extraction due to prolonged use

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Objectives

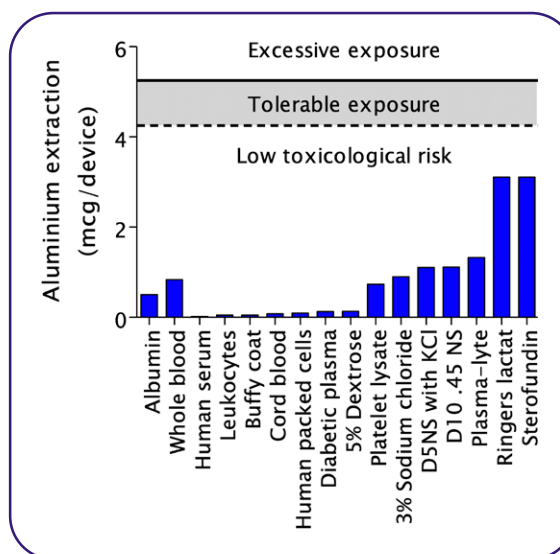
Intravenous fluids administered during surgery are warmed to near body temperature to prevent hypothermia. A commonly used method of warming involves passing the fluid over warming plates just prior to infusion into the patient. Historically because the fluids came into direct contact with the aluminium warming plates, there was potential for the warming plate to leach aluminium into the infusate. This study evaluated the leaching of aluminium from the enFlow™ cartridge aluminium warming plates when they were coated with Parylene.

Study methods

The authors performed three experiments. In the first study, three different fluids were pumped continuously through coated enFlow cartridges for 5 hours and extracted aluminium was measured. In the second study parylene-coated enFlow cartridges were soaked for 72 hours in 16 different fluids to simulate fourteen 5-hour surgeries. Finally, an in vivo animal study was performed using mice injected with fluids warmed for 72 hours by the coated enFlow cartridge.

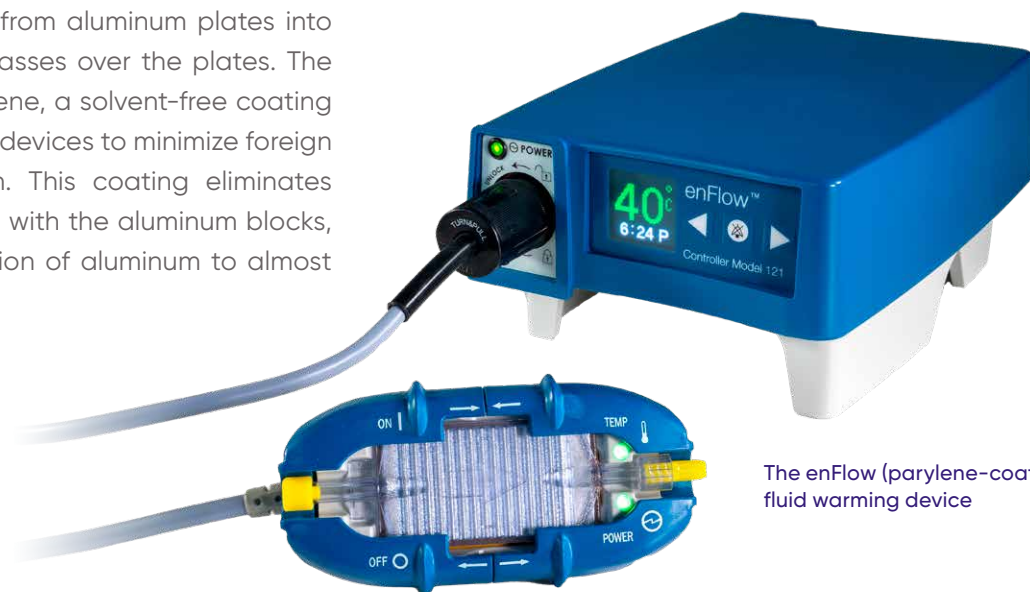
Results

The enFlow cartridge (parylene coated) demonstrated low toxicological risks in all tests. One fluid, Sterofundin ISO, resulted in the highest aluminum concentration after simulated prolonged use of the enFlow cartridge (parylene coated), and aluminum in all fluids were well below Tolerable Exposure (see Figure). Dynamic tests at two different flow rates with three challenge solutions resulted in aluminum concentrations that were below the limits of detection. The animals in the in vivo study showed no evidence of toxicity.



What is unique about the enFlow (polyethylene coated) fluid warmer?

The enFlow (polyethylene coated) fluid warmer works by direct transfer of heat from aluminum plates into the infusate as the fluid passes over the plates. The plates are coated in polyethylene, a solvent-free coating often used on implantable devices to minimize foreign body reactions or elution. This coating eliminates direct contact of the fluids with the aluminum blocks, dramatically reducing elution of aluminum to almost undetectable levels.



The enFlow (polyethylene-coated) fluid warming device

Take home message

Observed toxicological risk levels associated with the enFlow cartridge (polyethylene coated) intravenous fluid warmer were below those set by the FDA with some even below the level of detection. This demonstrates that the use of enFlow cartridge (polyethylene coated) is safe with a variety of IV solution types and in different therapeutic scenarios. The design of this study was unique in that it tested 16 fluids, most of which are clinically relevant (blood products, electrolyte solutions, lipophilic, hydrophilic). In addition, one of the experiments evaluated the possibility of an extreme number of surgeries, simulating 14 five-hour surgeries. As a result use of the enFlow (polyethylene coated fluid warmer for the most vulnerable patients can be considered safe from aluminium toxicity.

GLOBAL HEADQUARTERS

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