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Safety concerns related to use of unapproved needles for accessing implantable venous access devices

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Implantable venous access devices (IVADs) are commonly used in patients who require frequent apheresis procedures, such as patients with sickle cell disorders undergoing serial red blood cell (RBC) exchange and patients requiring prolonged photopheresis therapy. In such subjects, IVADs are used to facilitate repeated vascular access over extended periods of time.¹ Access of these devices is typically performed using a specialized “noncoring” or Huber needle. The noncoring adaptation of a Huber needle is a slight inward curve of the needle tip designed to prevent the needle from “coring” the plastic septum or roof of a vascular port. Huber needles are recommended by IVAD manufacturers for use with their ports, both to prolong the life of the port and to protect the catheter from occlusion by a septum core.

One such needle in common use was the high-flow noncoring Arrow Huber 16 gauge needle (Arrow International, Reading, PA), approved by the FDA for use with the Arrow IVAD device but widely used off-label with other IVAD devices. This needle was specifically designed to reduce the risk of disruption of the integrity of the Arrow IVAD membrane and thus prevent premature device failure and device complications such as plastic emboli or blood extravasation. In late 2008, production of the Arrow Huber 16-gauge needle was discontinued. Within a short time, production was restarted as a result of intense customer pressure, until apheresis services could identify and become familiar with suitable alternative needles. Two replacement 16-gauge needles were proposed during discussions among apheresis centers, the Medisystems apheresis needle with Masterguard (straight needle, Medisystems, Lawrence, MA) and the Two-Fer noncoring Huber needle (Baxa,

CONFLICT OF INTEREST

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Englewood, CO; Fig. 1). However, when compared with the Arrow needle, there were differences in the design of these two needles that might be problematic. The Arrow Huber needle is a stylet inside a catheter, whereas both of the alternative needles were nonstylet in nature, with sharp needle bevels surrounding a hollow core. The Medisystems needle further differs in that it does not have a noncoring design. The Baxa Huber needle is intended for use in transferring liquids among closed vials; the manufacturer's product insert designates it "for pharmacy use only."

Although both replacement needles were in use in apheresis facilities for accessing IVADs, no definitive testing in humans undergoing apheresis had been performed. In addition, no data were available regarding the safety or efficacy of either needle in accessing IVADs. Neither manufacturer stated that its needle was intended or acceptable for use in accessing IVADs.

Before implementing a new IVAD needle at our institution, we performed comparative in vitro testing of the following three 16-gauge needles: Arrow Huber (Arrow), Two-Fer Huber (Baxa), and Masterguard (Medisystems) needles for accessing the IVADs. The IVAD membrane was punctured with each needle five times on two separate occasions (10 punctures per needle). We found that repeated puncturing of the IVAD membrane by the Arrow Huber needle (Fig. 1) did not damage the IVAD membrane. Since the Arrow needle has a stylet, no membrane fragments were generated upon penetration of the septum. In contrast, puncturing the IVAD membrane with either the Baxa Huber or the Medisystems needle resulted in fragmentation of the membrane and creation of multiple plastic chips ranging from 0.1 to 0.5 cm in length (Fig. 2). This coring of plastic occurred four to five times per insertion series for each of these two needles.

The iatrogenic "coring out" of plastic fragments in IVAD membranes by access needles is problematic. Occlusion of the IVAD orifice and resultant device failure by these plastic fragments, and blood extravasation or hematoma formation due to membrane perforation, may occur. More ominously, the high input flow rates of 60 to 80 mL/min often seen during apheresis procedures² raise the risk of embolization of plastic membrane fragments into the patient's bloodstream. Large fragmented pieces of plastic traveling at high velocity in the circulation places patients at risk for embolization via right heart (pulmonary emboli) or left heart (coronary or cerebrovascular occlusion).

The application of IVADs for use in patients requiring serial, frequent apheresis procedures was appealing both cosmetically and medically. They could potentially reduce the risk of adverse outcomes associated with repeated needle access of externalized central venous catheters.¹ Given our findings of plastic coring and fragmentation induced by IVAD septum perforation using either the Medisystems or the Baxa Huber needle, use of these needles should be reconsidered, particularly if they are not approved for human use. If used in therapeutic apheresis procedures, patients must be informed of the potential risks associated with use of these needles to access an IVAD device. Alternatives to the use of an IVAD in patients requiring serial RBC exchange are suboptimal, but include insertion of either temporary or long-term central venous catheters with externalized access ports, with their known increased risk of infection, or simple transfusion, although it carries the risk of iron overload with long-term use.

At present, there is no best practice to guide the apheresis practitioner in identifying an acceptable apheresis needle in patients who already have IVADs. Our findings suggest that clinicians should reconsider off-label use of either the Medisystems or the Baxa Huber needles since use of these non-approved needles damages IVAD devices and may compromise patient safety. We urge the current manufacturer of the Arrow Huber needle to

continue to manufacture and make their needle available for clinical use. In addition, we encourage alternative manufacturers to develop and study stylet-type access needles appropriate for this purpose.

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Fig. 1. (Left panel) Needles tested from top to bottom: Arrow needle with blunt stylet below, Baxa Two-Fer needle, and Medisystems needle. (Right panel) Closeup of needle tips. (Top left) Arrow needle (right) and blunt stylet (left). (Bottom right) Baxa Two-Fer needle (vertical) and Medisystems needle (horizontal).

Fig. 2. (Left) Punctured IVAD device with membrane fragment protruding vertically. (Right) Plastic fragments induced from puncturing IVAD utilizing nonapproved needles.