WHITE PAPER

SKYDANCE VASCULAR INC.

Extraluminal vs. Intraluminal Colonization

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Extraluminal vs. Intraluminal

It is well understood percutaneous, non-tunneled vascular access devices (which include PIVs) may be compromised by infection in 2 specific ways. First, is during insertion by the catheter's external surface being exposed to the normal flora of the skin which then adheres to the catheter, forms microcolonies, and ultimately detaches into the blood stream to cause sepsis. Second, is through the intraluminal pathway. This is generally care and maintenance related – poor hand hygiene, poor disinfection of needleless adaptors, etc. In a major study by Safdar& Maki, 45% of infections in percutaneous non-tunneled vascular access devices were extraluminally acquired, 26% were intraluminally derived, and the mechanism of infection was indeterminate in 29% (6).

Published research indicates CRBSIs associated with percutaneously placed non-tunneled catheters that occur within the first 10 days of insertion are most often correlated with extraluminal biofilm formation and subsequent colonization (1, 2, 3). This research aligns well multiple other papers such as Helm, et al 2015 Accepted but Unacceptable: Peripheral IV Catheter Failure in which it is clearly stated Extraluminal and intraluminal contamination have different pathogenic mechanisms and temporal characteristics, with extraluminal colonization and infection occurring early and intraluminal contamination appearing later in the catheter's dwell time (4). Mermel also echoes this sentiment in his 2010 paper in which he writes "Most of the evidence suggests that, in general, an extraluminal source of infection predominates in catheters placed for a shorter duration of time, whereas an intraluminal source predominates with more prolonged dwell times.".(7). Furthermore, Elliot et al. in a paper entitled "A Novel approach to investigate a source of microbial contamination of central venous catheters" cultured the tips of percutaneous, non-tunneled vascular access devices during cardiac surgery and discovered 16% of the catheter tips were colonized within 90 min of catheter placement (5).

Summary

The evidence is clear that the first extraluminal contamination of the catheter is with skin organisms, occurring during insertion and this is the most common infection route for short-term catheters.

About the Author

Michael Anstett is an accomplished clinician, corporate executive, armed services veteran, and entrepreneur. Michael's clinical career started in 1987 as a US Army Combat Medic. He went on to receive his nursing degree and became a board-certified Registered Nurse in 1994, followed by two additional registrations in 1997 and 2011 respectfully: Certified Registered Nurse Infusion (CRNI) and Vascular Access Board Certification (VA-BC). Michael excelled in clinical practice and eventually accepted the responsibility of establishing and managing a vascular access team of ten staff nurses in a 1000 bed level-one trauma center in Tampa, FL. Michael then founded his private practice known as Professional Infusion Consultants, Inc., which contracted with vascular access nurses from around the state of Florida to provide outsourced vascular access throughout the state, an endeavor that Michael successfully exited from in 2012. Michael accepted the newly created position of Director of Clinical Operations at Medical Components, Inc. in 2013. Michael supported all aspects of the company's business including R&D of new products, business development, clinical education, regulatory and is named on multiple medical device patents. Michael is a member and strong supporter of the Association for Vascular Access (AVA). He has been invited to lecture at national AVA conventions as well as local AVA meetings. Michael is published in JAVA 2003 and won clinical manuscript for that year. He is the Founder and Chief Clinical Officer of SkyDance Vascular, Inc. – inventor of the Osprey vascular access device.

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About SkyDance Vascular

SkyDance Vascular, founded in 2017, is working to redesign the Peripheral Intravenous Catheter (PIV). The new product called Osprey, to be launched in 2021, is expected to provide a positive impact on PIV bloodstream infections utilizing a uniquely designed process called Skin Avoidance Technology. Its goal will be to deliver greater first attempt success and lower complication rates, improve dwell times, greater completion of therapy rates, and improve patient satisfaction. The company has assembled an executive leadership group comprised of individuals with decades of executive, clinical, regulatory, and engineering experience, and who together have built and successfully exited other companies in the vascular access space.

FDA Disclaimer

No statement in this document has been evaluated by the FDA. At the current time, and until 501(k) clearance is obtained from the FDA, all expressed claims made and/or indicated are exclusively the belief of SkyDance Vascular, Inc. (Company).

The Company intends to proceed with obtaining FDA 510(k) clearance to support what it believes to be appropriate claims, but until such time as FDA 510(k) clearance is achieved all information in this, and other Company documents is for informational purposes only.

Resources and Footnotes

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6. Safdar, Maki, The pathogenesis of catheter-related bloodstream infection with noncuffed short-term central venous catheters. 2004
7. Mermel et al. What Is the Predominant Source of Intravascular Catheter Infections?2010

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