WHITE PAPER

SKYDANCE VASCULAR INC.

Clinical Summary

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06/2020

Version 1.0

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Background

A peripheral intravenous catheter (PIV) is the vehicle that delivers life-saving therapies into the peripheral vascular system. There is a staggering 435MM PIVs sold in the U.S. and an estimated 200MM PIVs placed (based on mean number of device attempts of 2.18). Studies show that PIVs are placed in up to 90% of hospitalized patients.

Though PIVs are indeed commonplace and generally safe, they do come with risk. The PIV associated blood stream infection rate is estimated to be 0.2-0.7 per 1000 catheter days. This rate is seeming low when compared to central line associated bloodstream infection (CLABSI) rate. However, when PIV utilization is so far greater than the central line utilization, the total number of PIV bloodstream infections becomes quite significant. In fact, there is an estimated 200,000 PIV related bloodstream infections per year in the U.S. costing nearly $6B. These estimates are thought to be low because unlike central lines, PIV surveillance and reporting is not yet a part of most United States' hospital infection control program scopes.

In 2015 SHEA/IDSA updated their CLABSI compendium document where they introduced the concept that infections do occur from short peripheral catheters and raise the possibility that surveillance may need to be expanded to include these devices at some point. More recently, The Center for Disease Control (CDC) issued a call for comments regarded extended surveillance that would encompass all hospital onset bacteremia including PIVs. PIVs earned more national recognition making the top 10 patient safety concerns of 2019 by the ECRI institute.

Problem

Staphlococcus Aureus (S.Aureus) is a normally occurring bacteria on and within human skin, within hair follicles, and within sebaceous glands. It has been identified as one of the most common causes of hospital associated bloodborne infections and 23 - 50% of these hospital related S. aureus bloodborne infections are associated to PIVs.

It is well understood percutaneous, non-tunneled vascular access devices (which include PIVs) may be compromised by infectious

bacteria in two 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 infection.

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%.

This circumstance places traditionally configured (over the needle) PIVs at inherent risk because the catheter is in direct contact with remaining skin flora during each insertion. Flora such as S. aureus adheres to the catheter surface, grows and aggregates into microcolonies, ultimately breaking off into the blood stream and a catheter related bloodborne infection is the result. Colonization of vascular access devices passing through the skin during insertion ranges from 17% - 57.6%.

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. This research aligns well with 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."

Evidence for Catheter Protection

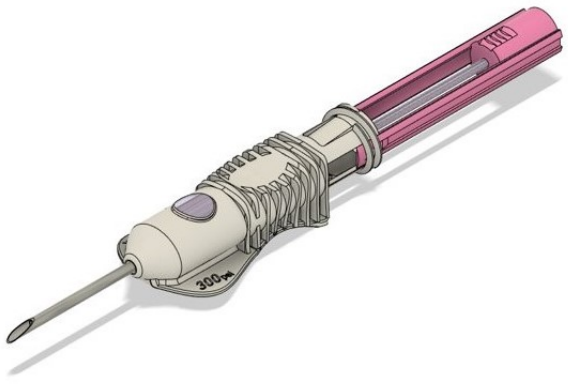
The 1998 Livesley et al. publication studied the presence of microorganisms on the catheter tip 90 minutes after insertion and compared those placed directly through the skin and those inserted through a sterile sheath. They found considerable support that despite adherence to best practices for insertion the results were suggestive that organisms had a greater likelihood (17% vs. 3%, NS) of introduction to the catheter if a sheath was not used.

Expanding on the Livesley work and featured at the 2019 Association for Vascular Access National Convention was the SkyDance Vascular, Inc sponsored NAMSA bench top study entitled **Reducing Extraluminal Skin Flora Attachment During PIV Insertion Using Through-the-Needle Insertion Methods.** This study was designed to demonstrate if microorganisms will or will not be transferred onto a catheter while passing through an inoculated simulated skin environment using a through the needle deployment equal to or less than the traditional over the needle method. Of the 5 samples from the through the needle test, 1 culture resulted in microbial growth. Of the 5 samples from the over the needle test, 3 culture resulted in microbial growth.

The results represent a 66% reduction in microbial attachment when the through the needle catheter deployment method was compared to the over the needle catheter deployment method. when this bench top study is coupled with existing research, the data becomes highly suggestive that physical barriers between catheters and the skin is directly linked to minimizing early catheter colonization.

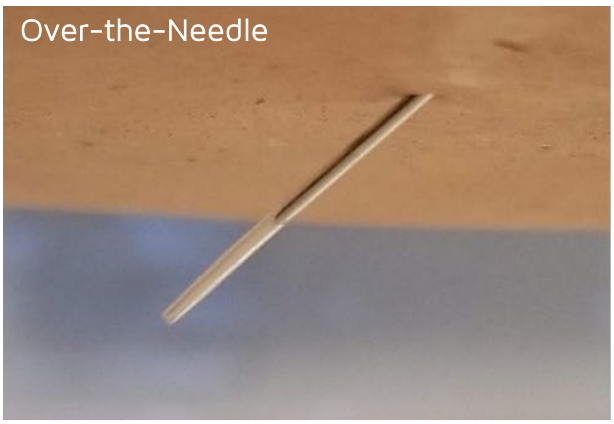
Solution

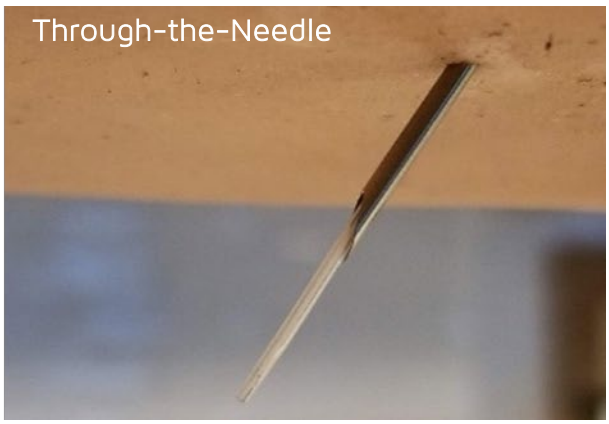
The Osprey from SkyDance Vascular, Inc is the first peripheral vascular access device specifically designed for front-line protection in the growing fight against PIV associated blood stream infections. It offers the only protected catheter delivery system eliminating the risk of skin flora contact by creating a physical barrier between the sterile catheter and the normal flora on and within the skin during insertion.



The sterile catheter is safely housed within the access needle during the insertion process and deployed only when the targeted vein is reached. This barrier between the catheter and skin provides a reliable method to deploy a truly protected vascular access device.

A Visual Representation





Professional's Comments

"A hospital is likely to have nearly as many BSIs associated with peripheral I.V. (PIV) lines as with central lines." Michelle DeVries, MPH, CIC

"Prevention is aimed at diverting access of micro-organisms to the external and internal surfaces of the catheter so that biofilm cannot form." Marcia A. Ryder, PhD, MS, RN

"I believe a through-the-needle design solves many of the challenges facing vascular access today. I believe this proposed design will maximize dwell times, minimize complications, may increase catheter insertion success, and ultimately be adopted as a new clinical standard." S. Matthew Gibson RN CRNI VA-BC

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.

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.