Reducing Extraluminal Skin Flora Attachment During PIV Insertion Using Through-the-Needle Insertion Methods

Association of Vascular Access Poster Winner

In Association with

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Original interactive report can be found at

https://ava2019-ava.ipostersessions.com/default.aspx?s=FD-E9-97-7C-BA-29-C7-6B-7F-88-1E-48-BE-38-38-D4

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 the mean number of device attempts of 2.18). Studies show that PIVs are established in up to 90% of acutely hospitalized patients.

Though PIVs are indeed commonplace, they do come with risk. Staphylococcus Aureus (S. aureus) is a normally occurring bacteria on human skin. If this skin bacteria invades the bloodstream, the consequences can be catastrophic. S. aureus has been identified as one of the most common causes of hospital-associated bloodborne infections. Studies have shown 23 – 50% of these hospital-related S. aureus bloodborne infections are related to PIVs. The PIV bloodborne infection rate is documented to be 0.2-0.7 per 1000 catheter days with a median duration of catheterization of less than 3 days. 30-day mortality is as high as 20.4% in those with a PIV bloodborne infection and 1-year mortality of 36.4%. There is an estimated 200,000 PIV related bloodborne infections per year in the U.S. costing nearly $6B.

Problem

The problem is the skin. Healthcare professionals disinfect the skin surface prior to each PIV insertion; this unfortunately is inadequate since disinfection merely reduces the number of bacteria on the skin surface. Simply put, the skin surface cannot be fully sterilized in preparation for catheter insertion. Furthermore, 20% of the normal skin flora resides below the skin surface, in hair follicles and sweat glands.

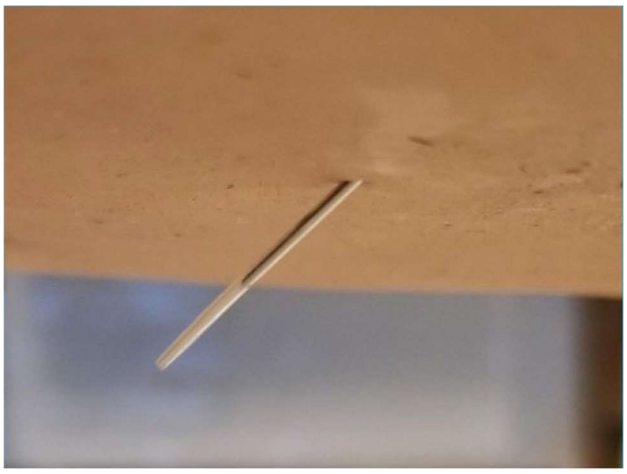
Traditional PIVs are configured with the catheter over the needle. Therefore, the extraluminal surface of these PIVs is at an inherent risk of colonization because they are in direct contact with residual skin flora during each insertion.

Flora such as S. aureus adheres to the catheter surface, grows and aggregates into microcolonies, then ultimately breaks off into the bloodstream and a catheter-related bloodborne infection is a result. In published studies, colonization of vascular access devices passing through the skin during insertion ranged from 16% - 57.6%.

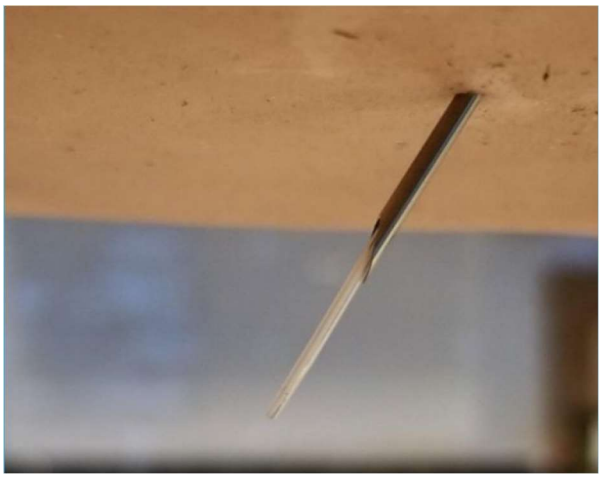
The Study

An alternative catheter introducer design known as through the needle deployment passes the sterile catheter through the inner lumen of the introducer needle. This unique design creates a physical barrier between the sterile catheter and harmful skin pathogens during insertion.

Over the Needle Deployment



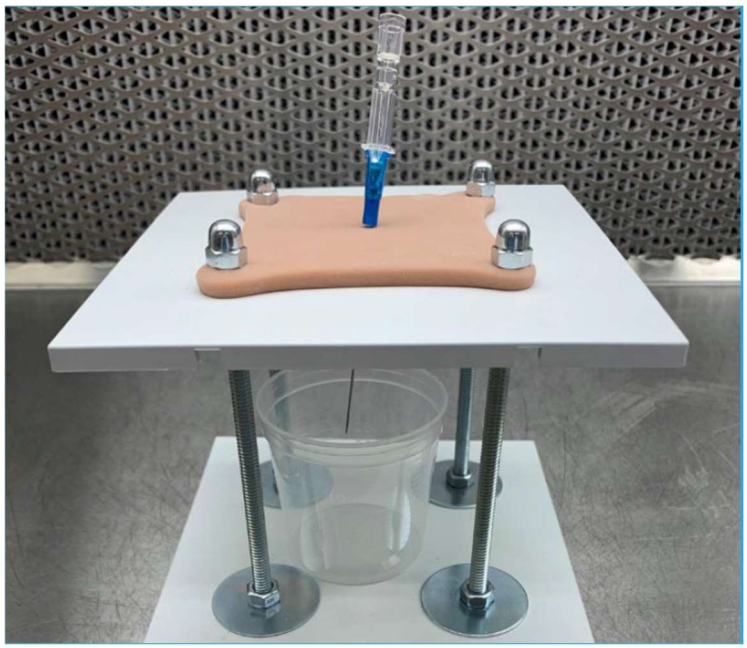
Through the Needle Deployment



The purpose of this bench study was to demonstrate that 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.

Test Method

Aseptically attached a section of disinfected synthetic skin, inside the ISO Class 5 or BSC environment, onto the holding fixture.



S. aureus in tryptic soy broth (TSB) was prepared to yield a population of 1-5 x 105 CFU/mL. This allowed for the intended final population on the surface of the synthetic skin to be 1-5 x 104 CFU. The synthetic skin upper surface was then inoculated using 0.1 mL of the organism.

Through The Needle Test:

Using a sterile 16g x 1" hypodermic needle pierced the needle through the full skin thickness until the needle tip was exposed to the underside of the skin sample. Aseptically, introduced the BBraun 22g x 2.5" catheter (removed from introducer needle) through the lumen of the needle until 1-1.5 cm of catheter was exposed past the needle tip.

The exposed section of the catheter tip was then aseptically cut into a sterile tube or appropriately sized sterile container.

Over the Needle Test:

Using a sterile 20g x 1.5" commercially available peripheral intravanousintravenous catheter, pierced the needle through the full skin thickness until the needle tip was exposed to the underside of the skin sample. Aseptically, advanced the catheter over the needle until 1-1.5 cm of catheter was exposed past the needle tip. Aseptically cut the exposed section of the catheter tip into a sterile tube or appropriately sized sterile container.

The above steps were repeated 5 times for the through the needle and over the needle groups.

A standard plate count was performed using Tryptic Soy Agar (TSA) as the plating medium to verify the population of the inoculum. Incubated the plates at 37 ± 2°C for 72 hours.

Positive Control Test:

Inoculated the positive control device (without piercing the synthetic skin) by dipping the tip of a catheter into the inoculum suspension.

Results

Through the Needle

Sample Number	Confirmed Inoculum Population (Average CFU/ mL)	Average CFU	CFU/ Strike
1	1.54×10^5	0	0
2		0	0
3		0	0
4		0	0
5		0.5	<1

Over the Needle

Sample Number	Confirmed Inoculum Population (Average CFU/ mL)	Average CFU	CFU/ Strike
1	1.54×10^5	1	1
2		0.5	<1
3		0	0
4		1	1
5		0	0

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.

These 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.

Discussion

Although this bench top study demonstrated a 66% reduction in microbial attachment when the through the needle method was compared to the over the needle method, it is understood more research on the topic of catheter protection is required.

This study was limited in Sample Size – 5 samples in each test article and in Methods – the use of a synthetic skin which falls short of representing true living tissue and its tendency to store microbes throughout its multiple layers as well as in sebaceous glands and hair follicles.

Regardless of these limitations, when this bench top study is coupled with existing research on colonization of vascular access devices passing through the skin during insertion ranged from 16% - 57.6% as well as the 1998 Livesley, et al. paper describing a microbial contamination reduction from 17% of catheters passing through the skin to 3% of catheters passing through a sheath the data becomes highly suggestive that physical barriers between catheters and the skin is crucial to minimizing early catheter colonization.

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, Inc., founded in 2017, is working to re-imagine the Peripheral Intravenous Catheter (PIV). The new product called Osprey, to be launched in 2021, is expected to reduce the number of known complications that result from the traditional catheter design. Our patent-pending re-imaging brings with it four major improvements, including:

- Skin Avoidance Technology™ as the catheter never touches the skin to minimize the risk of becoming infected.
- Bevel Only Technique™ so that the needle does not penetrate past the initial entry reducing the risk of Phlebitis and Infiltration.
- Contoured Directional Flow™ designed to deliver fluids more efficiently while lowering the risk of both chemical and mechanical damage and providing more efficient medication delivery.
- Passive Needle Retraction™ as the needle retracts back into the housing automatically so a clinician cannot get stuck.

SkyDance is comprised of industry veterans with the required expertise to develop, commercialize, and scale the business. The executive team has successful prior experience in selling startup businesses in the vascular access space, yielding large returns for the investors. Collective backgrounds span leading medical devices, enterprise software, and vascular access organizations including St. Jude, C.R. Bard, Med- Comp, Medibuy.com, BBraun, Vascular Pathways, Covidien, and Kimberly Clark

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