Achieving Peak Catheter Performance Through Reflux Valve Protection: Reducing Catheter Occlusions and Failure

Nancy Moureau, RN, PhD, PICC Excellence, Inc.
Lisa Jasinsky, RN, BSN, Ohio Health

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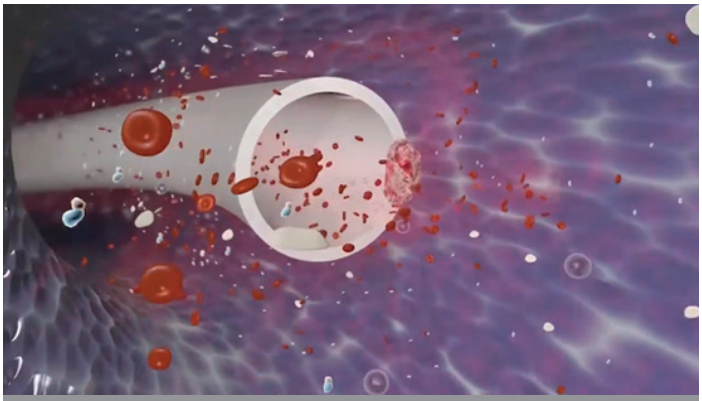
PURPOSE

The aim of this investigation was to answer the question:

"What is the best method to reduce unintentional blood reflux that can cause occlusions and other related complications in peripheral (PIV), midline, peripherally inserted central catheters (PICC), and central venous access devices (CVAD)?"



"Blood is the first body fluid which comes into contact with vascular access catheter materials, such as urethanes and teflons. When the synthetic catheter material comes into contact with blood, a layer of plasma proteins absorbs onto the catheter surface and triggers a complex series of biological responses including protein absorption, platelet adhesion, coagulation and thrombosis. Blood coagulation and platelet adhesion to intraluminal catheter surfaces remain one of the largest contributors to vascular access catheter dysfunction by producing partial and total IV catheter occlusion. Other complications include vein thrombosis, venous inflammation, and catheter-related bloodstream infections (CRBSIs)."

THE PROBLEM

Catheter occlusion and related complications are estimated to affect nearly 80% of peripheral and central vascular access catheters (Steere 2018). The thrombotic deposits that develop within catheters are the result of a natural process as noted above and can impact catheters at any time during treatment. Such occlusions can lead to patency loss and device replacement or removal, all of which can negatively impact therapeutic outcomes.

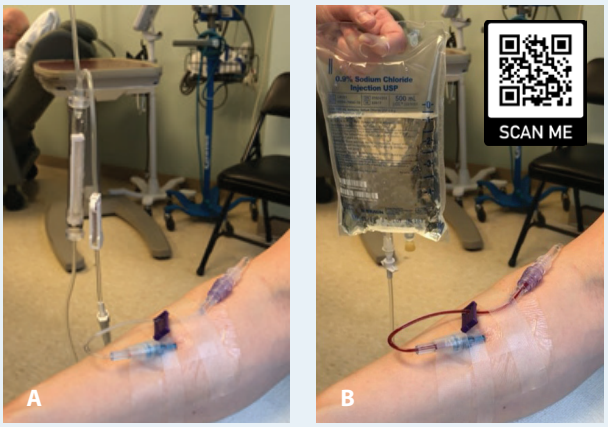
Preventing occlusions, then, becomes a chain of events that present an opportunity for improving both patient outcomes and facilities' bottom lines. The literature contains studies that have examined various methods to reduce catheter failure including the use of thrombolytics. Other studies have sought to evaluate the impact of blood reflux-controlling valves on occlusions and infiltrate complications. Still others have examined the various design features of how valves function to limit or eliminate blood reflux into catheters. Our study sought to find the best method for reducing catheter occlusions.

REFLUX CONTROLLING VALVES

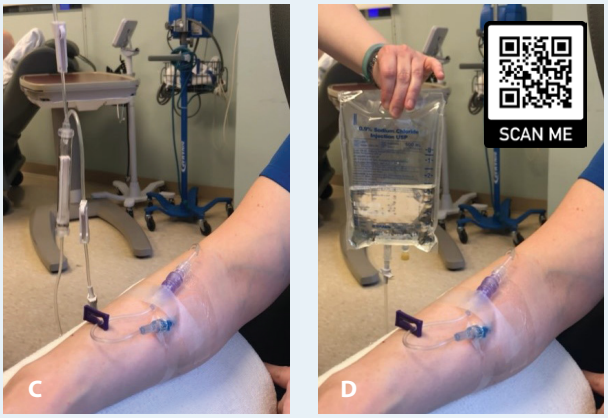
A reflux-controlling valve is an internal mechanism engineered into catheters and/or needleless connectors; these valves are designed to control fluid movement, most notably to prevent backwards flow. Design and performance vary by device type. For example, some devices have bi-directional flow control, while others do not.

Needleless connector without /with a pressure-activated anti-reflux valve

Effect of needleless connector WITHOUT a pressure-activated reflux-controlling valve. A) When IV bag is above arm, there is no reflux visible. B) With bag dropped below arm, full blood reflux is easily visible. To watch the video, scan the QR code in B, or visit https://youtu.be/5BkX6l_Z6U8



Effect of needleless connector WITH a pressure-activated reflux-controlling valve. C) When IV bag is above arm, there is no reflux visible. D) With bag dropped below arm, no blood reflux is visible. To watch the video, scan the QR code in D, or visit https://youtu.be/Mbjonj3cj0I

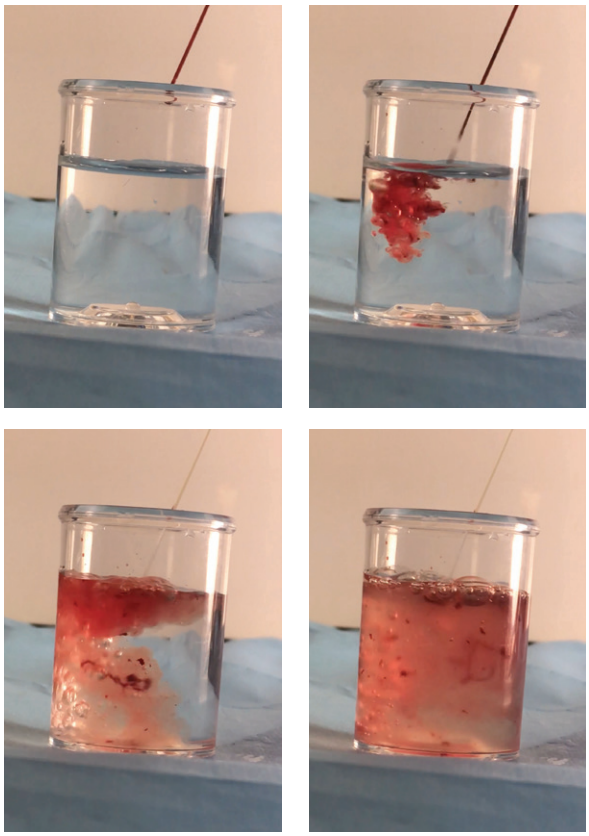


BACKGROUND

Occlusions: Catheter occlusions, which affect nearly 1/3 of all vascular access catheters, are responsible for the highest incidence of complications. Reflux of blood into the catheter, especially small diameter catheters, contributes to partial and complete occlusions. When blood is pulled back into the catheter during syringe connection/disconnection, patient movement, or pressure changes, red blood cells adhere to the inside of the catheter creating suboptimal flow. Methods to reduce catheter failure and evaluate the impact of blood reflux and reflux- controlling valves on occlusion and infiltration complications are discussed elsewhere. A Cochrane Protocol, published in 2019, established reflux-controlling valve function by outlining a systematic review process for validating catheter materials and reduced complications (Schults et al 2019).

Complications of obstruction: These complications are estimated to range from 25% - 44% and include loss of patency, phlebitis, and infiltration in PIV catheters.

Laboratory Experiment Demonstrating Pressures Required for Flushing an Occluded Catheter Leading to IV Infiltrates



"As many as one-third of all catheter failures are caused by occlusions. Instead of treating occlusions once they occur, prevent them from happening in the first place. Thrombotic occlusions are caused by blood reflux, a build-up of platelets and fibrin mesh that eventually blocks or occludes the peripheral catheter lumen. In a laboratory experiment designed to demonstrate the impact of an occluded catheter, blood was allowed to clot in a 22-gauge catheter for 4 hours. When a clot is dislodged due to unknowingly over-pressurizing the flushing syringe, a popping sensation is felt by the clinician. This pressurized clot damages the endothelial layer, causing the fluid to leak into the subcutaneous tissue, presenting later as an IV infiltrate. This infiltration can lead to pain, redness, swelling, leaking at the catheter insertion site, and phlebitis. Why does the seemingly routine flushing practice of an occluded catheter produce a painful IV infiltration? Keep in mind it takes approximately 16.4 pounds per square inch of pressure to dislodge a clot from the 22-gauge catheter—that's almost twice the pounds per square inch of pressure in a basketball. It's worth noting a standard 10mL flushing syringe creates 26 pounds per square inch of pressure when the syringe plunger is advanced 1 cc. By preventing blood reflux into the catheter lumen, you prevent the likelihood of over-pressurizing a clot. As we've learned, dislodgement of the clot formed due to blood reflux can later present as an IV infiltration. Instead of treating occlusions once they occur, prevent them from happening in the first place."

To view the video, scan the QR code or visit https://youtu.be/vi0y9dWJGbI

SCAN ME

Premature catheter failure rates reported in the literature range from 50% – 81% with PIV catheters and 26% – 78% with CVC catheters (Helm 2015, Ernst 2014).

Flushing: Flushing can help mitigate the impact of reflux into the catheter. However, once a clot has formed, seemingly routine flushing can create pressure in the IV catheter causing the clot to dislodge, leading to other complications.

Following the steps of evidence-based practice for an integrative review, we studied the impact of valves and blood reflux in relation to the reduction of complications.

RESULTS

A literature review was performed from 1985 to 2020 using MEDLINE, Google Scholar, and Scopus database; 72 published studies were identified describing and comparing the use of valve technology in catheters (ie. BD Groshong®, AngioDynamics PASV®) and valve designs of needleless connectors with neutral, negative, positive pressure, and pressure-activated anti-reflux (i.e. ICU Neutron™ and Nexus TKO®).

Search criteria of the catheter-related valve, reflux, or occlusion identified 71 peer-reviewed publications with 14 additional study reports from gray literature. A valve was defined as a device for controlling the passage of fluid through a conduit. The pressure-activated safety valve PASV®, a catheter with a proximal hub valve, was a direction-specific valve. The Groshong® silicone catheter with a closed rounded distal tip integrated a three-position valve that allowed liquids to flow in or out, closed when not in use. Other silicone diaphragm valves located within needleless connectors had similar pressure activations.

Literature evaluation and data extraction revealed a meaningful difference in moderate- to low-level evidence grade publications demonstrating the positive effect of catheters protected by blood reflux-controlling valves, versus those that were unprotected. These data indicated a pressure-activated

valve as an effective solution for reflux management to reduce peripheral, midline, PICC, and CVAD catheter occlusions.

CONCLUSIONS

Intravenous device occlusions, both peripheral and central, occur frequently and represent an important cause of catheter failure, loss of patency, and cost associated with management or replacement. Evidence from the publications suggests valve technology will aid in the prevention of unintentional blood reflux to minimize or prevent the occurrence of occlusion and complications associated with occlusion.

Whether the valve technology is integrated into the catheter, or integrated into the needleless connector technology, these devices help reduce clinician dependency on proper clamping sequence and greatly reduce the blood movement from physiological pressure changes that occur inside the patient's vasculature. More research is needed to establish more substantial conclusions on occlusion causation, the impact of reflux on occlusion, and the prevention of reflux-related occlusion.

Limitations

The results of the literature review are not yet quantified by a systematic graded process of meta-analysis. Conclusions are suggestive based on the level of research performed to date.

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