PIC and Midline Catheter Occlusion Rates:

A Prospective Study Comparing the Interlink Split Septum Device versus Nexus TKO Split Septum Pressure Activated Anti-Reflux Valve

Sarah Mitch, RN, CRNI & Brent Brandmeyer, RN, BSN

PURPOSE: To evaluate whether the Nexus TKO® split septum "pressure activated anti-reflux valve" will have an impact in tPA utilization compared to the current Interlink split septum device on peripherally inserted central and midline catheters placed in a hospital by the IV access team members.

METHODS: A prospective study with retrospective data was utilized for comparison between the current hospital split septum devices versus the implementation of the Nexus TKO® valve. Data collected from the PICC team in a 545 bed hospital on PIC & Midline catheters placed per ultrasound or without ultrasound. 30 weeks of data collected on current hospital IV connection system; PICCs (n=636) & Midlines (n=128) placed by IV team were flushed using the SASH technique. Nexus TKO® valves were implemented for 10 weeks; PICCs (n=154) & Midlines (n=32) placed by IV team were flushed with saline only. This technique documented in patient chart for clinical staff. During the 30 and 10 week periods, tPA usage was collected; 30 week period (n=58) & 10 week period (n=3). Catheters during the trial were either open-ended or valved at the distal tip.

RESULTS: There was an 85% decrease in tPA usage during the 10 week implementation of the Nexus TKO® valve on all PICC & Midlines placed by the IV access team. Heparinized saline flush was not utilized as a directive by the IV access team on PICC & Midlines during the Prospective 10 week period.

CONCLUSION: Using the Nexus TKO® split septum "pressure activated anti-reflux valve" resulted in decrease in tPA usage during the 10 week period versus the current hospital system over a 30 week period. The results demonstrated fewer occlusions and a potential economic savings to the facility in patients requiring PICC & Midlines.

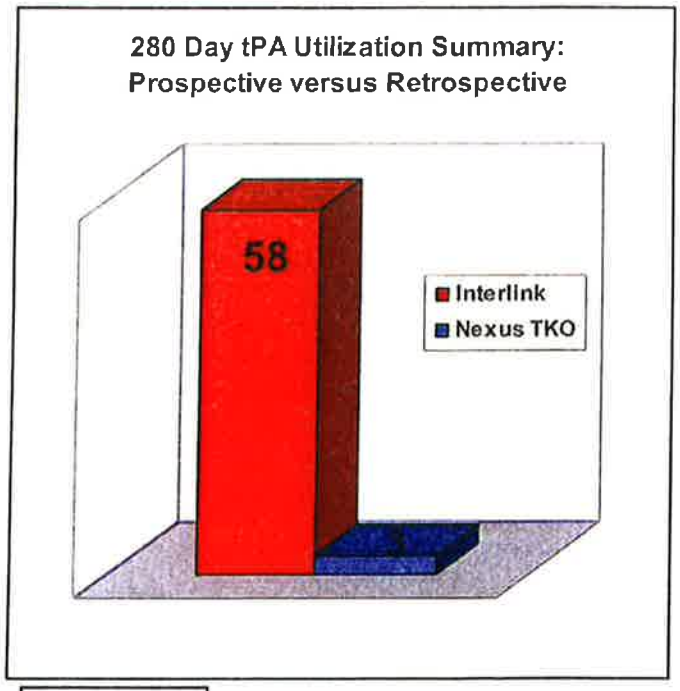

Table 1.0

Introduction

It is estimated that over 5 million Central Vascular Access Devices (CVAD's) are placed in this country annually and that up to 25% of catheters will develop problems with occlusion (*Stephens, Haire, & Kotulak, 1995*). Specific to home care, in an analysis of over 50,000 vascular access devices used in home care patients, *Moureau (2002)* found that approximately 5% of devices experienced a loss of patency. This author (*Gorski, 2000*) found occlusion rates of 6.5% in PICCs and 1.8% in non-PICC central venous access devices in a 4-year analysis of CVAD-related outcomes for one home care agency.

Definition of Catheter Occlusion: Catheter occlusion is defined as a partial or complete obstruction of the CVAD that limits or prevents the ability to withdraw blood, flush the catheter, and/or administer parenteral solutions or medications. Catheter occlusions are a significant complication because infusion therapy may be delayed or interrupted. Thrombotic catheter occlusions account for approximately 60% of occlusions (*Stephens et al., 1995*). They occur when deposits of fibrin and blood components within and around the CVAD slow or stop flow. Thrombotic occlusions may contribute to the development of CVAD related infection because the blood clot serves as a rich culture medium for bacterial growth. Therefore, it is clinically important to recognize and treat CVAD occlusion. Keep in mind that when the patient has a multilumen CVAD, it is not acceptable practice to leave an occluded lumen alone just because another lumen is functional.

5 Ways Blood Can Reflux into an IV Catheter or Central Venous Access Devices

There are five (5) ways blood will enter the catheter:

1. Blood is intentionally aspirated during a blood draw.
2. Changes in patient venous pressure resulting from movement, coughing, sneezing and vomiting can cause blood to move in and out of the catheter tip.
3. When an IV bag runs dry – the reduced head pressure will allow blood to reflux into the catheter and eventually into the IV administration set.
4. During the flushing procedure the syringe plunger compresses into the end of the syringe barrel and as it springs back into its resting position this plunger tip movement will actually suction blood back into the catheter.
5. When a syringe or IV administration set is disconnected from negative pressure injection site or connected to positive pressure devices – blood will reflux into the catheter.

I.V. Bag Run Dry:

I.V. bag run dry is a very common and frequent occurrence in I.V. therapy. I.V. infusions of medication and fluid are commonly administered using gravity pressure regulated I.V.'s. When an I.V. bag runs dry on an uncontrolled or gravity pressure regulated I.V. administration, blood will quickly reflux back into the Peripheral I.V. catheters (PIV) or CVAD and then into the I.V. administration set. This rapid reflux of blood occurs due to the decrease and subsequent loss in gravity pressure of the hanging I.V. container. As soon as the pressure level drops below 6 inches of water column (.216 psig, 11.22 mm Hg, 15.24 CmH2O). Blood from the patient's vascular system will quickly mix with the I.V. fluid. Any patient movement shortly after the loss of gravity pressure will accelerate the reflux of blood and can increase the blood return further into the I.V. administration set. This reflux of blood into the PIV or CVAD if not corrected can quickly coagulate and cause an intraluminal trombotic catheter occlusion.

Syringe Plunger Reflux:

Syringe plunger reflux is the resulting phenomenon that occurs during the final sequence of operation of a standard I.V. catheter flushing procedure. Nurses have been trained to fully compress the syringe plunger to administer all contents of the syringe. This simple commonly practiced procedure can cause reflux of blood into the patient's catheter. The physics and fluid dynamics of this situation occurs when thumb pressure is applied to the rubber syringe plunger tip and compressed against the end of the syringe barrel. Once the thumb pressure is released the rubber syringe plunger tip rebounds or expands back into place. This rebounding or expansion creates negative pressure which causes blood to reflux back into the PIV or CVAD.

It should be note that the force required to move the plunger of most pre-filled syringes is about 3.5 pounds per square inch (psig). This author found (*Hadaway*) that approximately 29 psig is produced at the syringe tip when 3.5 psig is applied to the plunger of a 3 mL syringe. For a 10mL syringe, 11 psig is produced at the syringe tip when 3.5 psig is applied to the plunger. Excessive force applied to the plunger of the syringe to overcome resistance inside the catheter lumen can lead to catheter damage, regardless of the syringe size. Until recently, very little attention has been paid to the interaction between the syringe and the fluid flow dynamics inside the catheter. (*Hadaway Med, RNc, CRNI "Technology of Flushing Vascular Access Devices"*)

Increased venous pressure:

Increased venous pressure due to sneezing, coughing, vomiting and patient movement can cause blood to move into the patient's catheter. This increase in venous pressure can cause blood to transfer into the catheter can create fibrin and cause clots to begin to form. Mechanical devices such as ventilators can also cause increased levels of venous pressure that can create partial or total catheter occlusions.

Disconnection of I.V. Luer:

The disconnection of flushing syringe or I.V. administration sets can cause blood to reflux into the patient's catheter. Blood refluxes into the patient's catheter due to the negative pressure that is created during the removal of the luer on the tip of the syringe or I.V. administration sets. The physics and fluid dynamics of the situation are created due to the negative volumetric displacement area of the luer tip. The negative volumetric displacement of the

luer tip will in turn reflux an equal volume of blood back into the PVC or CVAD where the un-oxygenated blood if not corrected will quickly clot.

Nexus TKO® Split Septum Valve

Unlike traditional IV connections, the NexusTKO® technology incorporates into the design a 3-position Pressure Activated Anti-Reflux Safety Valve technology that is normally closed.

This very small, crystal clear, silicone valve is placed in the fluid pathway of the Nexus needle free injection site. The 3-position NexusTKO® valve is designed to operate like an "automatic" IV clamp.

This simple, reliable, highly engineered silicone valve automatically "opens outward" into the patient vascular system and allows IV fluid to flow through the valve at normal gravity infusion pressures (low cracking pressure of 8 to 10 inches of water).

This normally closed Pressure Activated "Anti-Reflux" Valve automatically "closes" when IV fluid pressures are interrupted and not flowing. The NexusTKO® valve will automatically "close" and prevent blood from entering the catheter when 1.) I.V. Bags run dry, 2.) Syringe plunger reflux 3.) Increase in venous pressure from patient movement. 4.) Deactivation/activation of flushing syringes and I.V. luer connectors.

The NexusTKO® valve opens inward away from the patient when blood withdrawals are desired by the doctor or nurse. This unique patented feature occurs at higher pressures (6-7 psig) that are created when the doctor or nurse aspirates and draws a blood sample with a standard syringe. The NexusTKO® technology is the only "swabable" product in the market that reduces the incidence of costly tissue plasminogen activator (t-PA) treatments (est. $100-$200 per occlusion) to dissolve the intraluminal thrombotic catheter occlusion; or the expensive central venous catheter exchange for those unresponsive occlusions (est. $1,500.00/incedent) while improving patient care with overall improved clinical outcomes.

The Nexus TKO® (Firgure 1.0) is the only injection device in the market with an integrated Bi-Directional Pressure Activated Anti-Reflux Valve (PAV). The PAV technology has a crystal clear construction so clinicians can visually confirm that blood has been properly flushed from the injection device.

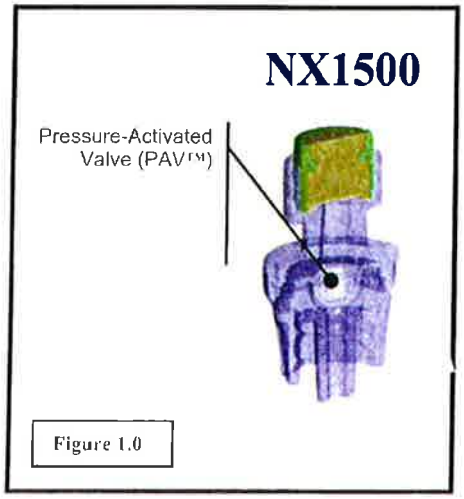

Figure 1.0

Nexus TKO® *Valve.. Anti-reflux valve prevents blood reflux which can significantly reduce intraluminal thrombotic catheter occlusions.*

- *I.V. Bag Run Dries*
- *Syringe plunger reflux*
- *Patient movement & manipulation*
- *Increased vascular pressure from ventilator, etc.*
- *Some hospitals have chosen to not use heparin with this system.*

Materials and Methods

A prospective study with retrospective data for comparison was implemented on patients in a 545 bed hospital. During a 70 day period the Nexus TKO® split septum "pressure activated anti-reflux valve" was placed on each lumen of all new peripherally inserted central and midline catheters by the IV access team. Nexus TKO® valve is compatible with the blunt tip cannula. These PIC and Midline Catheters were flushed with 5 ml of normal saline every 12 hours and after each use using the positive flush technique. The tracking of tPA to regain patency of the access device was documented on a form (Table 2.0) utilized by IV access team members.

During the 210 day period the Interlink needleless device with compatible blunt tip cannula was placed on all new peripherally inserted central and midline catheters by the IV access team. These PIC and Midline Catheters were flushed with 5 ml of normal saline followed by 5 ml of heparinized (10un/ml) saline every 12 hours and after each use. The tracking of tPA utilization was documented on form utilized by IV access team. The document did not include whether the device was single, dual or triple lumen. If the catheter had greater than a single lumen then a tPA agent was utilized for each lumen. This was not documented by the IV access team. In conversation with the IV access team members, the actual tPA usage would possibly be greater.

The study period totaled 40 weeks, from January to October 2006. The inclusion criteria for patients were all new peripherally inserted central and midline catheters by the IV access team. The PIC and Midline Catheters were predominately open-ended PICC & Midlines with a few PICCs have a valve at the distal tip.

Retrospective Sampling:

A total of 636 PICCs and 128 Midlines were placed by the IV access team members during the 210 day period. Interlink needleless device placed on each lumen of catheter during that period. The PICCs were placed by the IV team members with/without ultrasound. Current flushing protocol and procedure established and followed by nursing staff on the units using the SASH technique. IV team paged to the unit to regain patency of PIC or Midline Catheter using tPA per hospital policy and procedure. The complication later documented in "*IV TEAM STAT*" form. The number of tPA vials during the 210 day time period was 58. (Document 1.0)

Date	Sun.	Mon.	Tues.	Wed.	Thurs.	Fri.	Sat.
PICC/Ultrasound							
PICC w/o Ultrasound							
Midline Inserted							
Regain line patency							

Document 1.0

Prospective Sampling:

A total of 154 PICCs and 32 Midlines were placed by the IV access team during the 70 day period. No change in flushing procedure or training needed to educate nursing staff on the units during the time period the Nexus TKO® valve was implemented. The only change to the flushing protocols implemented by the IV access team was to eliminate the heparinized saline flush from the care and maintenance of the PIC or Midline Catheters once successfully placed. The Nexus TKO® valves were still flushed with 5 ml of normal saline every 12 hours and after each use. IV team paged to the unit to regain patency of PIC or Midline Catheter using tPA if necessary. Complication of catheter later documented in *"IV TEAM STAT"* form. The number of tPA vials during the 70 day time period was 3.

Results

The reduction of tPA usage on PIC and Midline Catheters was dramatic post implementation of the Nexus TKO® valve. tPA was reduced by 85% during the 70 day period Nexus TKO® split septum "pressure activate anti-reflux valve" was implemented.

Total tPA utilization summary prospective versus retrospective is reviewed in Table 2.0. The elimination of heparinized saline from the care and maintenance of PIC and Midline Catheters can have a significant economic savings to the hospital.

Conclusion

The change from the hospitals current needleless split septum device to the Nexus split septum "pressure activated anti-reflux valve" was to evaluate the safety device as an improved design through innovative technology with better valve properties. This next generation in needless devices helps reduce the high costs of tPA usage within the hospital setting and possible costly exchange rates from restarting or inserting a new access device.

Patient PICC & Midlines using the Nexus TKO® valve had significantly fewer complications related to occlusive rates as evidenced by a dramatic decrease in tPA usage. Data suggests that the "pressure activated anti-reflux valve" technology will further enhance the way clinicians are providing IV therapy.

The innovative technology designed by Nexus can also help with decreasing the high level costs associated with tPA usage, heparin utilization, catheter exchanges, and potential high risk complications that can occur with vascular access devices.

The implementation of the Nexus TKO® valve can greatly contribute to reducing the high costs associated with intraluminal occlusion rates and provide a solution to the way IV access devices are being cared for today and into the future.

Economic Impact

Resolution of catheter occlusion can result in a costly procedure. A fibrinolytic agent such as tPA is utilized to lyse the fibrin sheath and clear the catheter of clotted blood. This procedure can take from 5 minutes to 24 hours, and the cost can be extensive. The most significant impact is the delay of the patient's infusion therapy. Successful antibiotic regimens require consistent drug levels in the blood stream. When delays in dosing occur, treatment efficacy can be impacted significantly, ultimately leading to higher costs. See table 2.0 for the potential economic impact in the hospital setting as it relates to tPA and heparin usage. Results can vary depending on the hospitals current flushing policy.

Estimated Impact with 85% decrease in tPA Utilization		Monthly Savings	Annual Savings
Estimated Savings tPA utilization with Nexus TKO		$ 1,254	$ 15,052
Heparinized Saline savings with Nexus TKO		$ 2,520	$ 30,240
Total Hospital tPA and Heparin savings with Nexus TKO		$ 3,774	$ 45,292
Heparinized Saline flush syringes utilized on PICCs per month	6300 syringes		
Current cost of Heparinized Saline Flush Syringe	$0.40/syringe		

Table 2.0

Research
Medical Center
Your HCA Midwest Hospital

To Whom It May Concern: July 16, 2007

I am a CRNI in the practice of IV therapy for over 35 years and find the development of the Nexus TKO safety injection cap one of the most significant contributions to IV therapy in years. I firmly believe that this technology will change the way IV therapy is delivered in the hospital setting.

Our IV team has been using the Nexus TKO-5 injection cap for approximately 1 year. The hospital system has been able to completely eliminate the use of Heparin to flush PICCs and central line catheters. Our occlusion rate and tPA use has significantly decreased by greater than 90% since implementing the TKO-5 cap. During the initial evaluation of the TKO-5 product, the nursing staff required little if any education/training when switching to the TKO-5 cap. We have had no difficulties during this transition to the new device when it came to care and maintenance of PICCs or Central Lines. The only issues that occurred were that some nurses had removed the TKO-5 device off the catheter and began placing the Interlink cap on the end of the PICC. Not surprising to me was that we had to perform a declotting procedure on those particular PICCs that the Interlink cap was placed. We also had an issue of product not being ordered by the hospital. During the first month an a half of being on the TKO-5 cap, we had no occlusions. We were not using the TKO-5 cap for almost three weeks because product had not been ordered. Our occlusion rate spiked to 7 occlusions the first week and then 5 the following week.

The decrease need for extra flushes and declotting procedures is significantly more cost effective and safer for the patient. Also, by decreasing the use of extra flushes and one less entry into the IV catheter is far more valuable in decreasing the possibility of infection and is less time consuming for the busy RN today.

I have seen several competitive products in my lifetime as an RN practicing IV therapy and none compare to the clinical and economic benefits of the Nexus TKO injection cap.

Sincerely,

Sarah Mitch RN CRNI

Sarah Mitch, RN, CRNI
Vascular Access Nurse
Research Medical Center