Preventing Complications: The Biological and Functional Success of Anti-Reflux Needleless Connectors

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BACKGROUND

In a previous quality improvement study with data from nearly 500,000 patient days, it was demonstrated that switching from a non-anti-reflux needleless connector (NC) to an anti-reflux connector produced:

- 48% reduction in tPA usage,
- 66% reduction in ER visits,
- 27% fewer patient encounters for clotted catheters,
- savings of more than $100,000 on tPA, nursing expenses and items related to treating the occlusion[1].

This current research examines the root cause of catheter occlusions and the function of neutral anti-reflux NCs. Blood is often the first body fluid that comes into contact with IV catheters. Interactions between blood and IV catheter material trigger a complex series of events including protein adsorption, platelet adhesion and activation, coagulation, and thrombosis. These biological reactions necessitate using anti-reflux technology that decreases the risk of occlusions and central line-associated bloodstream infections (CLABSI).

PURPOSE

The purpose of this research was to study the clinical, biological and functional differences between anti-reflux needleless connectors and connectors without anti-reflux capabilities. Our hypothesis is that these past results were due to switching to an anti-reflux needleless connector that minimized blood proteins within the inner surface of the IV catheter, thereby preventing biological reactions that led to thrombus formation.

METHODS

Two in-vitro simulation studies examined how anti-reflux and non-anti-reflux NCs performed using IV containers with green and clear water.

- Test #1 simulated pressure changes by observing fluid movement between IV bags. This was accomplished by elevating an IV bag with dyed fluid 2 inches above a clear bag.

- Test #2 used a venous simulation manometer **(figure 1)** measured fluid reflux or displacement upon syringe connection and disconnection. Negative and positive fluid displacement represent reflux into the catheter and aspiration towards the patient.

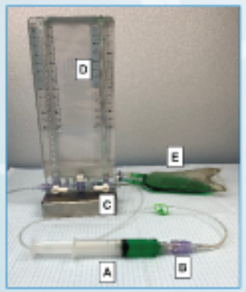

Figure 1: Venous Simulator;
A – 10 mL BD Luer Lock Syringe,
B – NC Unit Under Test,
C – Stopcock,
D – Glass rod beside metric ruler,
E – Output to reservoir bag

RESULTS

These two tests indicate anti-reflux technology can reduce uncontrolled blood reflux into IV catheters upon pressure changes, connection and disconnection.

- Test #1 showed anti-reflux NCs were able to stop blood reflux when pressure changes occurred in the closed IV system, while non-anti-reflux NCs were not able to prevent bi-directional fluid movement.

- Test #2 demonstrated the anti-reflux NCs had the lowest amount of reflux upon both connection and disconnection.

DISCUSSION

The results demonstrate that anti-reflux NCs may significantly reduce the amount of blood reflux upon disconnection of a syringe compared to NCs without anti-reflux technology ($p < 0.0001$). It is reasonable to hypothesize that increased volumes of blood reflux will lead to increased risk of intraluminal thrombotic catheter occlusions and bloodstream infections[2]. This is important for home infusion clinicians because, as demonstrated in the previous study, occlusions decrease nursing efficiency and increase costs associated with the treatment of occlusions and CLABSI1.

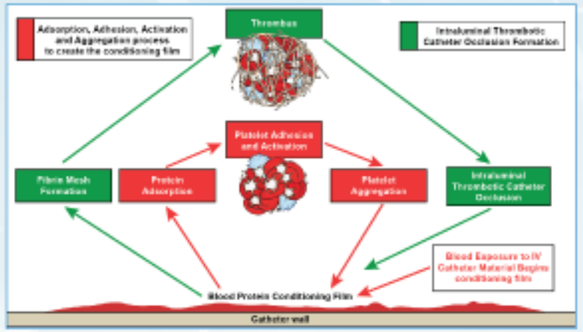

Figure 2: Foreign body response following blood contact to IV catheter material leading to intraluminal thrombotic catheter occlusions

The body's natural biological response to foreign materials is to form a protective layer of plasma proteins. When an IV catheter enters the vein, the layer of plasma proteins instantly adsorbs to the intraluminal surfaces, which forms a biofilm that attracts platelets and clotting factors[3, 4, 5, 6, 7, 8]. **(figure 2)** This biological reaction continues to form a fibrin mesh that traps blood cells and promotes thrombus formation within the catheter[3].

Bacteria can enter and contaminate IV catheters from skin-surface organisms that migrate into the blood stream, contaminated catheter hubs, NCs, infusate, and via an existing distant infection[4, 5, 10, 11]. Bacteria can bind to the protein coated surfaces described above, which then proliferate the highly antibiotic-resistant biofilm[3, 12, 13]. **(Figure 3 & 4)**

DISCUSSION (cont'd)

The biofilm can break away naturally or by the intervention of flushing or use of thrombolytics. Harmful infections can happen once biofilm enters the bloodstream[14, 15, 16, 17]. The infection risk increases by 2.87 to 3.59 times when thrombolytics are used on intraluminal catheter occlusions[14, 15, 18].

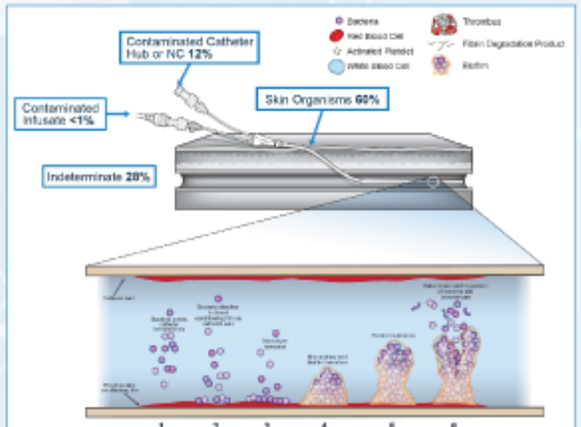

Figure 3: Top: Contrasts in pathways of bacteria entry leading to catheter-related bloodstream infections. Bottom: Schematic of microbial ingress leading to attachment to the blood protein conditioning film, biofilm formation and detachment.

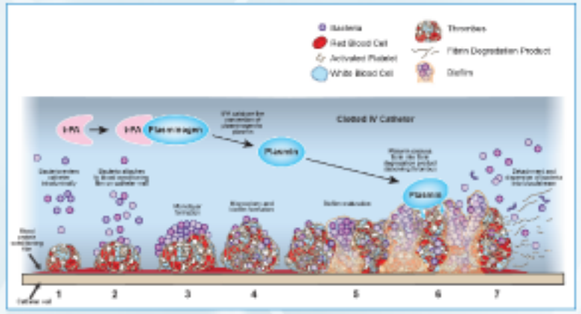

Figure 4: Mechanism of action of tPA causing the intraluminal thrombotic catheter occlusion dissolve and the bacteria to enter the bloodstream.

CONCLUSION

This research demonstrates anti-reflux devices function differently than other commercially available NCs. Anti-reflux NCs control bi-directional fluid movement and greatly inhibit blood reflux which prevented occlusions in the home infusion setting. Reducing occlusions has been shown to also cut down on nursing visits, tPA use, costs associated to provide tPA in the home, delays in treatment, ER visits, treatment of CLABSIs and potentially placement of new IV access. The use of anti-reflux NCs support the treatment of the patient and not a complication from treating the patient.

DISCLOSURES

Bob Buzas: Consultant, Nexus Medical
Nancy Moureau: Consultant, Nexus Medical
S. Matthew Gibson: Consultant, Nexus Medical
Michael Buzas: Consultant, Nexus Medical

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