Anti-Reflux Valves: Can We Afford Not to Use Them?

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OBJECTIVES

- Define the frequency of catheter occlusion as a complication of central venous access devices
- State the association between central venous catheter thrombosis and catheter colonization and infection
- Define the product evaluation process
- Identify the factors which can influence the outcome of a product evaluation
- Recognize the role of each team member involved in the evaluation of new technologies for the maintenance of central venous access devices
- Understand the economic components to be considered when evaluating anti-reflux valve technology

Central Venous Access Devices

- Integral part of care for critically ill and long-term IV therapy patients
- Used to administer treatment modalities and supportive therapies: antibiotics, blood products, and total parenteral nutrition and for withdrawal of blood samples
- 75% of IV device-related bloodstream infections originate from central venous catheters (CVCs) of various types

CVCs and Catheter-Related Bloodstream Infections (CRBSI)

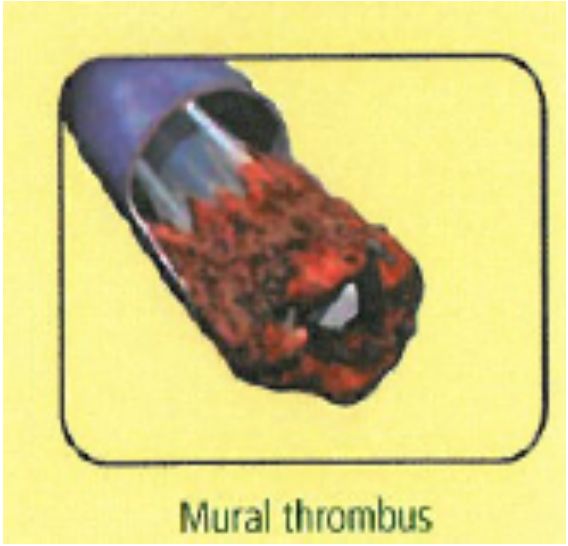
- Estimated 250,000 cases of BSIs occur annually
  - attributable mortality rates of 12-25%[1]
  - mean excess length of stay of 12 days[2]
  - mean attributable cost of $19,000 (range of $3,592-$34,410)[2]
- Predominant mode of pathogenesis for CVCs in place for >10 days: intraluminal (contamination of the catheter hub and lumen)

[1]Pittet D, Tarara D, Wenzel R. Nosocomial Bloodstream Infection in Critically Ill Patients: Excess Length of Stay, Extra Costs and Attributable Mortality. *JAMA* 1994; 271:1598-1601

[2] Perencevich E, Stone PW, Wright SB, Carmeli Y, Fisman DN, Cosgrove SE. Raising Standards While Watching the Bottom Line: Making a Business Case for Infection Control. *Infect Control Hosp Epidemiol* 2007;28(10):

Catheter Occlusion

- Can result from extraluminal or intraluminal complications
  - Thrombi forming along the wall of the vein but exterior to the catheter - mural thrombi – can interfere with fluid flow through the catheter
  - Intraluminal thrombotic occlusions – fibrin deposits can produce a plug residing within the lumen of the catheter – can impair fluid instillation and blood withdrawal
- The type of CVC influences the risk of occlusion
  - Greatest risk with PICCs due to the narrow lumen
  - Certain catheter materials are more thrombogenic



Catheter Occlusion

- Blood can reflux into the catheter tip with changes in intrathoracic pressure
  - Sneezing
  - Coughing
  - Vomiting
- Poor infusion technique
  - Failure to flush lines properly
  - Incorrect procedure when disconnecting a displacement device from the line
- Most frequent non-infectious complication of CVCs
  - Occurs with 25% of catheters

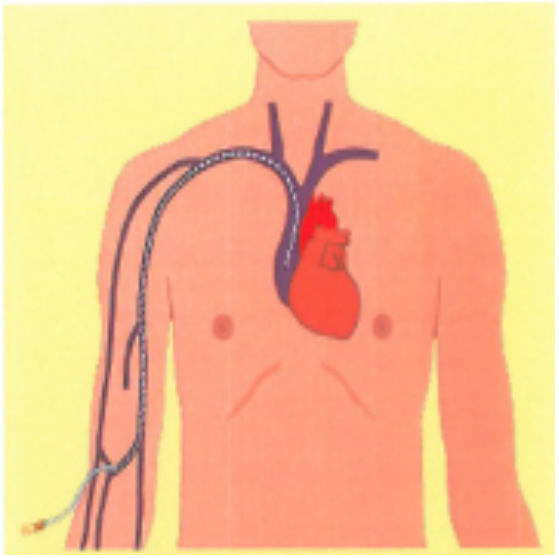
Is there an association between thrombus formation and CRBSI?

- Pathogenic determinant of CRBSI
  - Formation of a sheath around the catheter (due to host factors consisting of protein adhesions, such as fibrin and fibronectin)
- Certain catheter materials are associated with higher risk of catheter infections
  - Silastic catheters have a higher risk than polyurethane catheters
  - Some catheter materials that are more thrombogenic might predispose to catheter colonization and infection. **This association has led to emphasis on preventing catheter-related thrombus as a mechanism for reducing CRBSI.**
- Raad and colleagues examined postmortem catheterized veins and contralateral uncatheterized veins of 72 cancer patients
  - Of 31 patients with mural thrombosis of the catheterized vein, seven developed catheter-related septicemia, whereas none of the 41 patients with normal catheterized veins developed catheter-related septicemia ($p<.01$)
  - They concluded that thrombotic complications are common in catheterized veins and are often associated with catheter sepsis

Raad I, Luna M, Khalil SM, Costerton JW, Lam C, and Bodey GP. The Relationship Between the Thrombotic and Infectious Complications of Central Venous Catheters. *JAMA* 1994;271(13):1014-1016

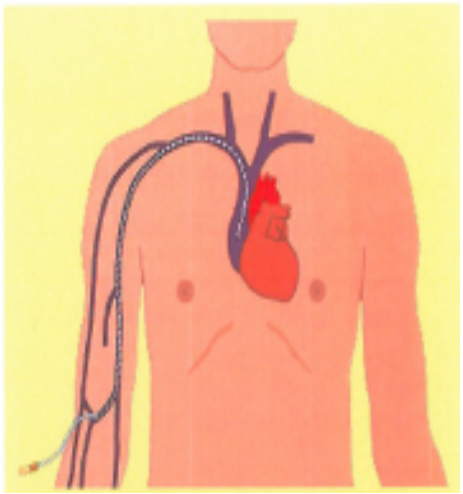
Grady NP, Alexander M, Burns LA, Dellinger P, Garland J, Heard SO, et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections 2011 www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

PICC Catheters: What's New



- Increased use in recent years
  - Factors driving the trend include low reported incidence of infection and ease of insertion
  - Nurse-based IV therapy teams insert and maintain decreasing physician workload and costs

PICC Catheters: What's New



- Safdar and Maki (2005) reported that PICCs used in ICU patients had CRBSI rates comparable to other nontunneled CVCs
- Ajenjo et al (2011) saw the use of PICCs increase throughout the hospital after the discontinuation of a nurse-based IV team
  - 3.13 PICC BSIs per 1000 catheter days
  - PICC use and PICC BSI rates were higher in the ICUs but most of the PICC BSIs occurred in non-ICU patients

Safdar N, Maki DG. Risk of catheter-related bloodstream infection with peripherally inserted central venous catheters used in hospitalized patients. *Chest 2005;128(2):489–495.*
Ajenjo MC, Morley JC, Russo AJ, McMullen KM, Robinson C, et al. Peripherally Inserted Central Venous Catheter-Associated Bloodstream Infections In Hospitalized Adult Patients. *Infect Control Hosp Epidemiol 2011;32(2):125-130*

Case Study

- 2011 -Administration at Hospital X decide to eliminate the nurse-based intravenous therapy team as a cost containment measure
- 2012 – PICC catheter utilization has doubled (200 placements to 400 placements annually).
- Feb 2012 – Meeting of the Vascular Care Committee
  - Interventional radiology notes an increase in patients needing replacement of dysfunctional PICCs in whom patency salvage failed
  - Pharmacy reports an increase in t-PA or alteplase usage
  - Infection Preventionist reports an increase in the CRBSI rate for both ICU and non-ICU patients and expresses concern that 25% of the patients had PICCs in place when the CRBSI was detected. It is noted that the hospital recently transitioned to the ICU Medical MicroClave® needlefree connector and a performance improvement initiative was launched for "scrub the hub"

Introducing Neutron™

Neutron™

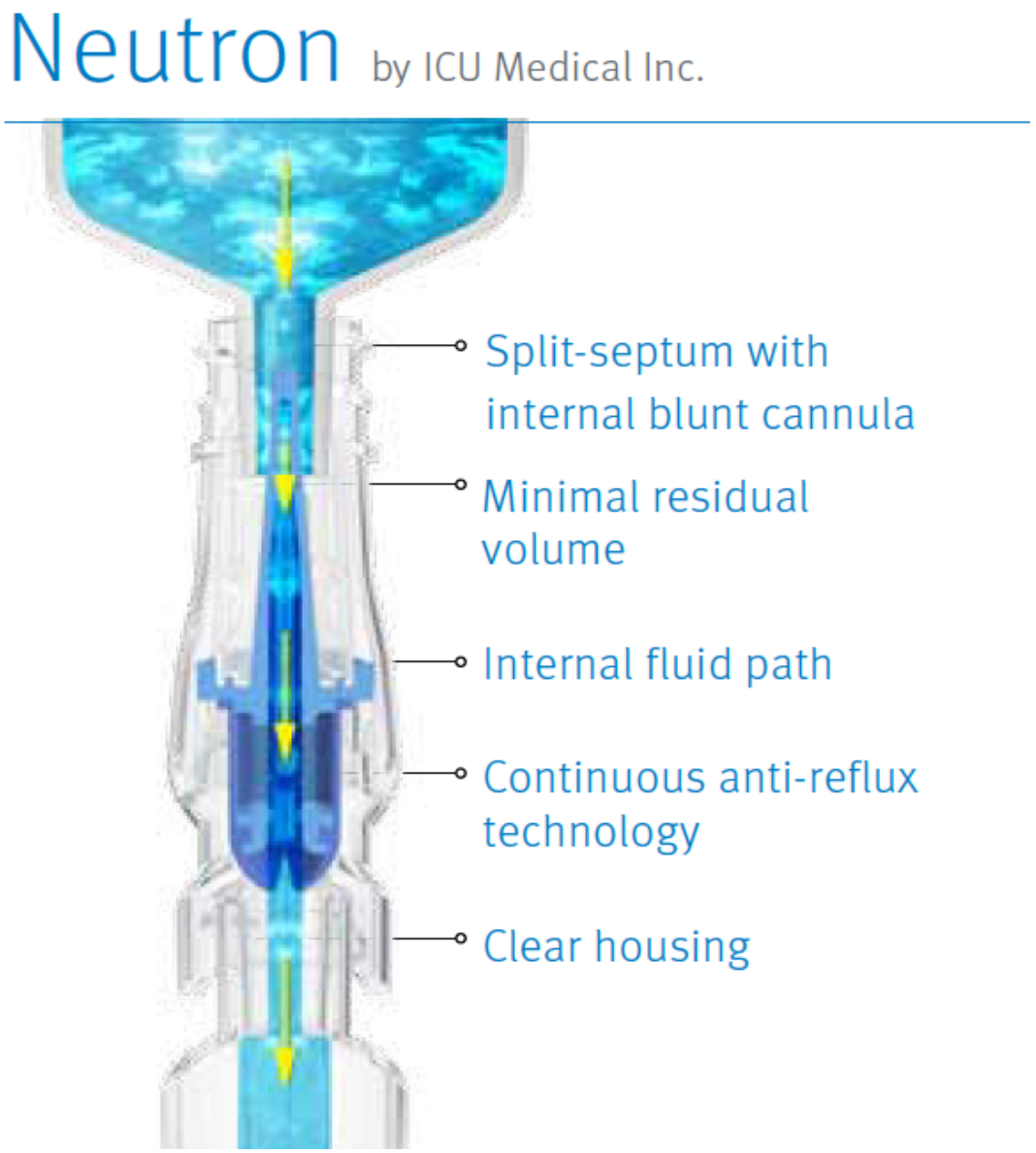
Needlefree Catheter Patency Device

The world's first and only FDA-cleared device that has been shown to significantly reduce *all* types of reflux into a catheter.

Reducing reflux has been clinically proven to help reduce occlusions.

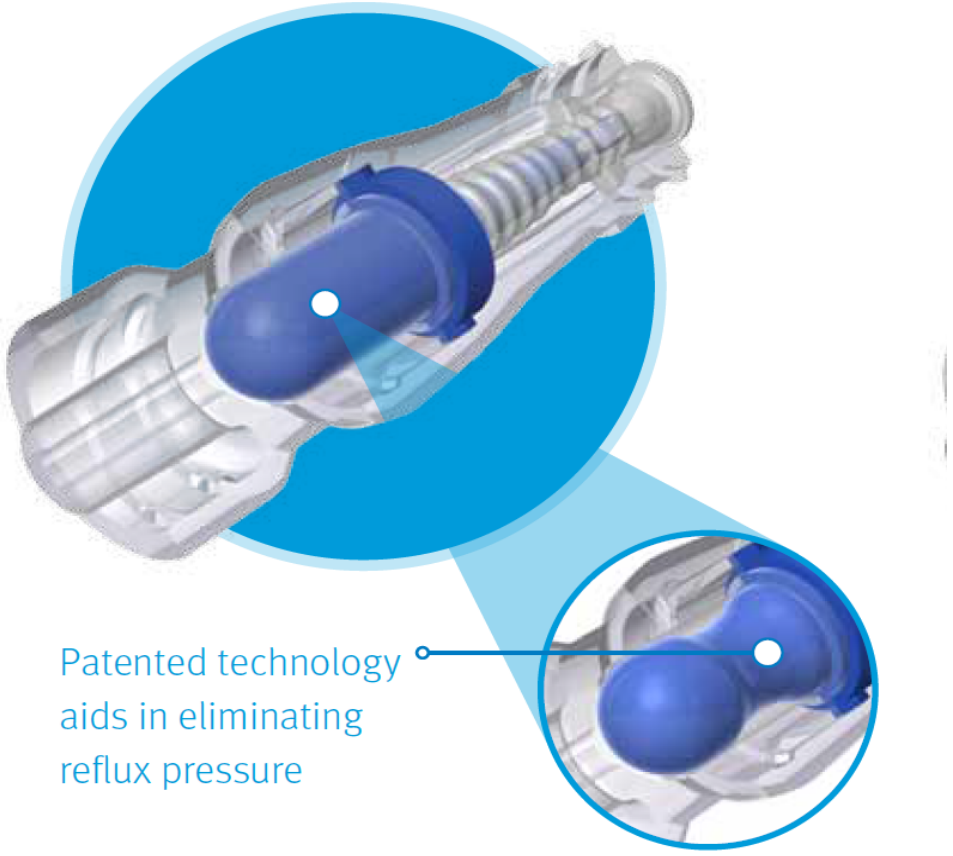
Neutron shares the same design features as the MicroClave® Clear Connector

- Identical housing component
- Neutral displacement
- Split-septum seal
- Blunt cannula geometry



Neutron™ – Anti-Reflux Technology

- Bidirectional silicone valve and bellows design work together to prevent blood reflux at all times
- Valve remains closed unless Neutron is accessed for aspiration or infusion
- Bellows gives Neutron the ability to absorb and physically compensate for pressure variations that typically result in blood reflux into the catheter



Product Evaluation

- A methodology that is scientifically less rigorous than a clinical trial
  - Requires systematic thinking and planning to ensure a valid outcome (Chiarello, 1995)
- Identify the rationale for the evaluation
  - What are the drivers behind the evaluation?
    - Patient safety, employee safety, sustainability, cost containment, product standardization
  - How will this product help us address the drivers of change?
  - How will the success of the change be measured?

CASE STUDY: Neutron™

- Product request initiated as a joint effort between Infection Prevention (IP), Critical Care Intensivist and Nurse Champions, Interventional Radiology (IR) Nurse Manager
- Rationale:
  - FDA-cleared device with the microbial barrier features of the in-use needleless connector with the ability to prevent reflux resulting from internal and external causes. It is recognized that catheter occlusions delay patient treatment, may be associated with catheter-related infection and affect the patient's quality of life.

IP's Position

- The risk of CRBSI from PICCs increased with wider usage among ICU patients
- Neutron™ has the split-septum, neutral pressure features of the MicroClave® needleless connector – lowest bacterial transfer rate [1]
  - Alignment with 2011 CDC Guidelines: When needleless systems are used, a split septum valve may be preferred over some mechanical valves due to increased risk of infection with the mechanical valves (Category II)
- Nursing compliance with disinfection of the needleless connector prior to access varies considerably – interested in standardizing to the Microclave® technology for all needleless connectors. Recent data supports a 5 sec scrub with alcohol[2]

1 Ryder M, Fisher S, Hamilton G, Hamilton M, James G. Bacterial transfer through needlefree connectors: comparison of nine different devices. Presented at SHEA Annual Scientific Meeting, April 2007.

2 Rupp M, Yu S, Huerta T, Cavalieri J, Alter R, Fey P, et al. Adequate Disinfection of a Split-Septum Intravascular Connector with a 5-second Alcohol Scrub. *Infect Control Hosp Epidemiol* 2012;33(7):661-665.

IP's Position

- Alignment with 2011 CDC Guidelines: Minimize contamination risk by scrubbing the access port with an appropriate antiseptic and accessing the port only with sterile devices (Category 1A)

- Work collaboratively with IR and ICU clinical staff to ensure that all areas involved with the evaluation are informed of the trial and trained on its use
- Connect with IPs in other facilities using the product; did implementation go smoothly, how was the company's customer support, any concerns

ICU Champions' Position

- Patient safety focus
  - Unit-based CRBSI reduction target not met
  - Nursing competency validation needed for management of occluded PICCs with thrombolytic treatment (alteplase); restoring of catheter patency less than expected
- ICU bed utilization
  - PICC replacements delay therapy and procedures and increase patient's length of stay

IR's Position

- PICC occlusion occurring too frequently
  - Why ? Poor flushing technique
- PICC replacement rate too high
  - Failure to salvage: is proper protocol in place for use of alteplase?
- Patient safety
  - Clinical risks associated with replacement: infection, bleeding, embolization, etc.
  - Limited vessels to cannulate
- Financial
  - Loss of IR time and resources for other procedures

Product Evaluation

- Collect and analyze data that will be used as outcome metrics
  - rate of PICC occlusions
  - cost of alteplase administration for patency salvage
  - replacement of catheters in IR : success of salvage
  - CRBSI rates
- Product Performance Criteria
  - ✓ ease of use
  - ✓ clinician confidence

Product Evaluation

- Decide the product evaluation methodology
  - GOAL: obtain feedback on how well the product meets its intended purpose and how well it is accepted by the end users
    - Not practical or desirable to involve all potential users
    - Evaluators should represent the universe of users
    - Involvement of both new and experienced staff is ideal: favorable bias from staff attracted to the new product, negative bias from staff resistant to change
  - Determine the duration of evaluation
    - How frequently is the product used
    - Estimated length of the learning curve

Product Evaluation

  - Decision should be made by the multidisciplinary team; suggested range of 2-4 weeks
- Determine how staff feedback will be obtained
  - Survey tool should be easy to complete and score
  - Questions should reflect performance criteria
  - Provide for individual comments
  - Request recommendation for future use of the product
- Staff training by individuals thoroughly familiar with the product
  - Team approach with manufacturer's representative and a facility representative
  - Inform end users why a product change is being considered

Product Evaluation

- Decide how the product will be distributed
  - Replace the existing product with the trial product
- Determine how evaluation data will be collected
  - Passive vs. active
  - Response rates may be affected by the strength of opinions; those that are enthusiastic about or strongly opposed are more motivated to respond
  - Encourage completion of forms

– Data analysis, cost analysis and product selection

- Tabulate and analyze the evaluation data
- Perform the cost analysis

Neutron™ – Cost Analysis

- Economic elements
  - Cost of current needleless connector vs. Neutron™
  - Cost of alteplase administration
  - Cost of catheter replacements
    - Cost of Catheter
    - IR time: staff and room time
    - Diagnostic imaging

Product Evaluation

- Present results of product trial to facility's Product Standardization/Value Analysis Committee with recommendation
  - Ideally performed by the coordinator of the trial and an end user
  - Address each of the drivers initially cited
  - Highlight the economic elements
    - Products that are cost neutral or achieve cost savings without compromising patient or employee safety are generally fast-tracked!
  - Have implementation plan developed
    - Identify all end users, educational strategy, purchasing and distribution

SUMMARY

- The selection and use of anti-reflux valves in healthcare should be guided by FDA clearance and scientific literature
- Optimize partnerships with colleagues who embrace the implementation of new technologies on behalf of patient and employee safety
- The task of product evaluation requires a systematic approach to achieve a valid outcome