

Advances in Research 2(4): 195-206, 2014, Article no. AIR.2014.002



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# The Role of IV Needleless Connectors and IV Complication Management and Prevention

Cynthia Chernecky<sup>1\*</sup> and Denise Macklin<sup>2</sup>

<sup>1</sup>Georgia Regents University, 15<sup>th</sup> Street EC 5440, Augusta GA 30912, United States. <sup>2</sup>Vascular Access Consultant, 355 East Valley Dr. Marietta, GA, 30068, United States.

Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

Mini-review Article

Received 17<sup>th</sup> December 2013 Accepted 20<sup>th</sup> February 2014 Published 3<sup>rd</sup> March 2014

# ABSTRACT

The most common complications associated with vascular access devices are catheter related bloodstream infections (CR-BSI), which occur in acute care patients every minute, and occlusions. This review will address major issues associated with patient care and research associated with vascular access and intravenous (IV) needleless connectors including descriptions of different types of connectors, care and maintenance issues such as septum disinfection and flushing, education of students and practitioners, a new framework for research and relevant questions for healthcare practitioners to ask during patient assessment. Two overall strategies to prevent CR-BSI's and occlusions; 1) prevent the active and passive migration of microorganisms into the fluid pathway and 2) prevent microorganism adhesion to the catheter surface will be discussed. The IV needleless connector, which is placed on the catheter hub is the gatekeeper to the intraluminal fluid pathway and its design directly impacts the success of strategies to prevent complications. Best practice requires that practitioners have specific knowledge of connector technology as well as patient factors for caring for vascular access devices. There is a large gap in the scientific literature and in policies and procedures related to evidenced based decision making associated with care and maintenance of needleless intravenous connectors. Understanding IV needleless IV connectors is necessary to meld research and practice together for best patient practices, so the occurrences of CR-BSI's and occlusions can be mitigated and eliminated.

Keywords: CRBSI; sepsis; IV needleless connector; nursing care; vascular access; occlusion.

#### **1. INTRODUCTION**

Patients with a vascular access device (VAD) experience two major complications - catheter related blood stream infections (CR-BSI) and occlusion either partial or total. This paper discusses how these common intravenous therapy complications are impacted by IV needleless connector design. Methods for article preparation included review of CINHAL and MEDLINE using the key words CR-BSI, occlusion, connector and IV technology. Exclusions included studies not IRB approved. Connector technology included in the paper had to have some published related research. CR-BSI is defined by the Centers for Disease Control & Prevention (CDC) as bacteremia/fungemia in a patient with an intravascular catheter with at least one positive blood culture obtained from a peripheral vein, clinical manifestations of infection (i.e., fever, chills and/or hypotension) and no apparent source for the bloodstream infection except the catheter [1]. A patient obtains a CR-BSI every minute [2]. This can lead to a diagnosis of sepsis which is the most costly hospital acquired infection with up to a 25% mortality rate [2] and higher depending on the causative micro-organism. The second complication is catheter occlusions which can result in loss of vascular access, loss of time for treatments and increased length of stay. Either of these complications causes a poorer quality of life for the patient and can result in death.

The intravenous catheter, whether centrally or peripherally placed, is an extension of the venous system to the outside environment. As a result, a hole in the skin referred to as the insertion site (extraluminal) and the hole in the catheter (intraluminal fluid pathway) are entry points for bacteria, and fungus. Best practices for extraluminal care [3,4] are reported to only prevent 40% of bloodstream infections [5]. Therefore, 60% of CR-BSIs have causes that are intraluminal in nature. It is now well known and accepted that CR-BSIs occur when organisms, in particular bacteria, migrate into either the extraluminal or intraluminal fluid pathway and adhere to the pathway wall. Once attached, the bacteria form a colony and develop a protective cover referred to as biofilm. When biofilm is formed it is difficult to eradicate and the colony can proliferate. Over time bacteria shed into the venous system and can cause an infection. Four major pathogens (*Staphylococcus epidermidis, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli*) are responsible for 60% of CR-BSIs at a total cost of \$225 (£ 143) million per year and 200,000 intensive care unit days/year [6].The cost of CR-BSIs has been calculated to be approximately \$33,000-\$35,000 (£20,915-22,183) per episode making it a relevant cost issue [7,8,9].

Occlusions are common [10] and under reported with about half directly related to thrombus formation [11]. Intraluminal reflux related thrombi rates are reported as 5%-25% [12] of occlusions. Fibrin deposition on the intraluminal surfaces of the intravenous (IV) connector fluid pathway and catheter has been shown to also increase the risk of coagulase-negative staphylococci infection [11]. Therefore, through several mechanisms thrombosis has been shown to enhance the risk of infection [13]. Interestingly, prevention of occlusions may rely heavily on patient assessment and this has not been recognized by healthcare practitioners. The importance of understanding current connector's research and its association with their care, maintenance and educational needs is imperative to professional best care practices.

While the primary responsibility for care and maintenance of a VAD falls on nursing practice, it is extremely important for all healthcare professionals to understand how these complications occur and how they are prevented. It is only when everyone focuses on the

two primary prevention strategies; minimize micro-organism(s) entry into the system, and minimize adhesion that the successful outcome of a VAD remaining safely in place and complication free for the required duration (brief or prolonged) can be accomplished.

This article will focus on the intraluminal fluid pathway and the role needleless IV connector's play in the development of CR-BSIs and occlusions. Best practice requires that practitioners have specific knowledge of connector technology as well as patient factors for caring for VADs in order to provide safe care. There is a large gap in the scientific literature and in policies and procedures related to evidenced based decision making associated with care and maintenance of needleless intravenous connectors. An understanding of needleless IV connectors is necessary to meld research and practice together for best patient practices, so the occurrences of CR-BSI's and occlusions can be mitigated and eliminated.

# 2. NEEDLELESS IV CONNECTOR OVERVIEW

The IV connector is referred to by many different names such as "hep-locks", "male adaptors", "Luer-locks", "split septums", "caps"and "INTs" to name a few. Needleless IV connectors entered the healthcare settinging in the 1990's as a means of preventing needle sticks and decreasing the potential for human immunodeficiency virus transmission. During the last decade research findings have questioned the role of IV connectors by category and as contributors to CR-BSI [14,15]. In 2010, nine design features were outlined as variables that impacted CR-BSI including: septum surface, septum seal, fluid pathway design, presence of dead space, presence of internal mechanism in the fluid pathway, clamping sequence, visibility, blood reflux and flushing solution [16]. All IV connectors available today have four elements in common: an external housing, a septum which is the entry point of the connector, a fluid pathway and a mechanism for returning the septum to its original closed position with disconnection. Dead space, which exists in most connectors, refers to areas within the fluid pathway that cannot be cleared when flushing. Dead space is often required for the closing mechanism. The designs of IV connectors based on these four elements vary greatly from connector to connector.

There are three major types of needleless IV connectors based on reflux known as negative, positive and neutral fluid displacement [7]. Connector designs evolved over a decade with changes made to improve usability and to minimize occlusion associated with use. The first type was negative mechanical valves (NMV). Reflux occurs with disconnection. Total or partial occlusion [11,18] is associated with NMV reflux. In addition NMVs have been associated with CR-BSI [19]. The second type is positive pressure mechanical valves (PPMV) and with this type reflux occurs with connection. PPMVs have been associated with increased bloodstream infections [20,21]. These are under FDA (USA) investigation for possibly causing deaths [22]. The last and most recent type is neutral. With neutral connectors there is no reflux with either connection or disconnection. Several studies reveal that specific connectors are associated with an increased risk of blood stream infections [19,20,23,14] including PPMVs [14,25], while other studies show a lower rate of CR-BSIs [26,27,28,29,30]. It is not one design feature that is important in connector design and their associated outcomes but the combination of all the design features outlined by Dr. Jarvis [16] that will impact complication reductions and eliminations.

# **3. CARE AND MAINTENANCE OF CONNECTORS**

Strategies to prevent intraluminal complications must be two-pronged; 1) prevent the active and passive migration of microorganisms into the intraluminal fluid pathway and 2) prevent catheter wall adhesion. This approach will block bacterial colonization and biofilm formation. Practice has only two actions for intraluminal care, swabbing the connector septum for disinfection and flushing the fluid pathway to remove residue after use to eliminate the primary building block that enables wall adhesion.

# **3.1 Septum Disinfection of Connectors**

Septum disinfection is the first action necessary to prevent bacterial migration. In the US it has been the care giver who has received the attention. The needleless IV connector must be swabbed before each access. 70% alcohol alone or Chlorhexidine (CHG) alcohol are the two most common disinfection agents selected by institutions in the United States. This protocol results in three or four (if using heparin as a final flush) separate swabbing actions with each IV push medication or blood draw. It is common for connectors to be accessed repeatedly during a patient care shift and in many different healthcare areas (eg: xray, nuclear med, OR). In the US, there has been an increase in swabbing times to 15- 30 seconds in an attempt to improve disinfection. This action has placed the entire burden on the care provider and may not be clinically realistic. Even with conventional disinfection with 70% alcohol one study of NMVs revealed 67% transmit microorganisms ranging from 442 to 25,000 colony-forming units [31] and it is known that greater than 15 colony-forming units can lead to sepsis [32]. Another study revealed a range of colony forming units for different connectors, post 70% alcohol swab using downward pressure and 3 rotations, to range from zero to over 13,500 for 4 different bacteria lending data to the knowledge base that connector septum design is a significant variable in the development of infections [33]. Connector design has not been considered even though research has confirmed that complete disinfection of some IV connectors septum's surfaces is difficult and in fact may not be achievable at high rates in the clinical setting [31,34].

To increase septum disinfection success, the septum should be made of hydrophobic material and be smooth without irregularities to prevent bacteria from sticking. The septum seal should be tight when not activated so that there are no areas that lie outside disinfectant contact. When relying on research to set the swabbing practice, it is important to remember that generalization of research findings to connectors not included in the study is problematic. Long, complicated swabbing practices are cumbersome and difficult to consistently perform in the healthcare setting. Selecting a connector that can be swabbed simply with > 99% bacterial kill will improve compliance. The new alcohol caps provide a continuous passive disinfection approach. However, the connector needs to be swabbed prior to applying a new cap. This is not widely understood in the clinical setting. A properly designed connector should not require add-ons to enhance practice outcomes. Ask IV connector manufacturers for independent research in this area and if they have none be weary of using the product. If the manufacturer tells you to follow your hospital policy on swabbing do NOT accept this as valid as it is not research based and is actually an admission that the manufacturers have no research on their product. This lack of research and evidence does not support evidence based nursing practice and can be detrimental to patient outcomes. Research on one neutral fluid displacement connector, validated through an In vitro study by Nelson laboratories (Salt Lake City, UT), that 3-5 twists of swabbing with 70% alcohol pad, like squeezing an orange, removes 100% of bacteria [35]. The connector septum provides an environment that supports simple effective practice.

## 4. CLEARING THE INTRALUMINAL PATHWAY

Flushing is the only mechanism available in the clinical setting to clear the intraluminal fluid pathway. Blood is routinely withdrawn prior to injection to check for patency and confirm venous placement. With withdrawal the entire fluid pathway is filled with blood. In order for flushing to be successful, the fluid pathway must be straight. This is because fluid follows the path of least resistance therefore anything outside this pathway (dead space) will not come in contact with the flushing solution. These areas outside the pathway continue to have blood and medication residue providing an environment for bacterial growth. Fibrin deposition on the intraluminal surfaces of the fluid pathway increases the risk of coagulasenegative staphylococci infection [12] and occlusions. Thrombosis has been shown to enhance the risk of infection [13] Edminston [36] inoculated connector intraluminal fluid pathways and reported that increased intraluminal fluid pathway volume corresponds to higher organism growth rates. With a larger internal volume there was increased area outside the fluid pathway. A small unobstructed, straight fluid pathway provides an area where 100% of the pathway surface comes into contact with the flush solution. An In vitro study showed that a connector designed with a very small priming volume (0.027 mL) and using as little as 1 mL saline flush 99.96% and with 4 mL saline that 100% of microscopic hemoglobin was removed [37].

It is practice in some institutions in the US to use a push-pause flushing method. This practice became very popular because it was hypothesized that fluid turbulence enhances the "scrubbing" action of the flush. No research is available to support this practice. Donlan [38], a leader in biofilm science, reported in 2002 that turbulent flow actually enhances bacterial adhesion and that a steady flush minimizes adhesion. No research exists that focuses flushing on patient diagnosis yet many patients are at high risk for occlusion (Table 1). Performing the identical flushing procedures with all patients may result in uneven outcomes and research is needed in this area.

Negative and positive connectors have reflux associated with usage. Reflux occurs either with disconnection (NNV) or connection (PPV). Mitigating reflux depends on the practitioner's ability to identify the connector by type and then apply the correct clamping sequence [17] either clamping before disconnection (NNV) or disconnecting and then clamping (PPV). There is no clamping sequence with neutral connectors because there is no reflux with either connection or disconnection. However, when using the Y-port on any IV administration tubing a clamping sequence cannot be used and reflux cannot be mitigated. Many institutions use more than one type of connector necessitating the care practitioner to visually identify the connector type and then select the correct clamping sequence. The package label usually does not identify the connector type or which clamping sequence to use. This makes the practitioner's job more difficult. Using the wrong sequence means that occlusion is more prevalent when using a negative pressure system [39,40] with reflux occurring with disconnection. Occlusion incidence is less using one neutral connector [41]. Research shows that flushing ports with the bevel of the needle in an upward position enhances flushing results [42]. Selecting one IV connector to be used exclusively throughout the institution enhances education and ultimately improves procedure compliance [14]. Knowledge about connector design and associated best flushing practices will help in overcoming CR-BSIs and occlusions.

Acute Spinal Cord Injury
Advanced Age
Bone Marrow Transplant
Brain Tumor
Catheters Placed via the Left Subclavian Vein
Catheter Tip Location in Subclavian Vein
Chronic Obstructive Pulmonary Disease
Dehydration
Diabetes
High Platelet Levels
History of Deep Vein Thrombosis
Lung Cancer
Major Trauma Gynecologic Malignancies
Malposition of the Catheter
Oral Contraceptive Use
Pregnancy
Renal Failure
Sickle Cell Anemia
Trauma Patients

#### Table 1. Patients at high risk for vascular access occlusion

#### 5. EDUCATION

The prevention of CR-BSIs and occlusions are possible but requires education of healthcare providers on complication cause, care and maintenance actions related to the specific IV connector and continual current research evaluation with associated implementation of policy and practice changes. Research reveals, for example, that 78% of acute care nurses are uninformed about different connector types and their specific, yet opposing, care [43]. Forty three percent of nurses could not name 2 complications associated with IV connectors (e.g.: infection, occlusion, thrombosis) and 64% are involved with 4 to 5 hours of IV therapy care and maintenance per 12 hour nursing shift, making IV therapy an important clinical issue and educational necessity [43]. There has been no research done looking at similar issues with other care providers who have contact with IVs. However, there are neither courses nor enough lectures in most healthcare provider programs on IV therapy, though information related to science and research has resulted in several books being published in the area of IV therapy.

The ability of healthcare providers to collect cues related to needleless IV connector problems begins with education on information that is basic, understandable, differentiating and complete to aid in clinical reasoning. Patient assessment, knowledge of technology and specific care are required to best protect the intraluminal fluid pathway of VADs [26,44-47]. Without knowledge and appropriate interventions intraluminal protection becomes compromised and there can be an increase in CR-BSI, occlusions, thrombi and potential associated deaths.

#### 5.1 Research Framework

For nursing and medical research associated with VADs the Healthcare and Technology Synergy (HATS) framework (Fig. 1) is appropriate. This framework [48] represents a synergy between three major variables (patient, product, practice) with each one affecting the others and being affected by the others. This framework adds a more holistic and comprehensive approach to comparative effectiveness and evidence based practice research and when translating findings to bedside care. Using connectors as an example the patient variables to be considered, though not an exhaustive list, include age, diagnosis, comorbidities, therapeutic regimens, projected length of stay, physical assessment, mental health status, trans cultural beliefs, finances and length of treatment including current needs and recurring needs. Product variables may include the following; intravenous connectors categorized on the basis of reflux as well as bacterial and biofilm growth as previously discussed, connector septum design including septum seal tightness, fluid pathway design, type of VAD, insertion site and number of catheter lumens. Practice variables may include connector septum disinfection practice, dressing management, clamping sequence, flushing practice including solution(s) and time frequency (eq: 10 mL normal saline every 6 hours), the education and skill levels of the nurse specific to vascular access, availability of specialized vascular access teams and nurse-patient staffing ratios. A multicenter, guasi experimental, 140 month/50,080 catheter days, acute care study compared central line-associated bloodstream infection rates associated with PPMV and NPMV before and after changing only the connector to a neutral connector. There was a statistically significant higher CR-BSI rate when either NNMV (P = .001) or PPMV (P = .032) were used [30]. Product can be a variable and if not specifically studied should be noted as a limitation. Research in some of these areas have already been implemented, presented and/or published [26-29,44,49,50,51,52].



Fig. 1. Healthcare and technology synergy (HATS) framework

#### 6. PATIENT IV CONNECTOR ASSESSMENT

If proper care of a needless IV connector depends on the type of connector, then it may be helpful to answer these questions prior any implementation of care.

- What type of connector does my patient have? Is it negative, positive or neutral?
- Do I have the materials, skills and knowledge to correctly implement scrubbing the hub and flushing?

- Do I have the knowledge to implement appropriate disconnection?
- When should I change the connector? This time frame should be specifically stated by the manufacturer as "follow your usual hospital policy" is meaningless to care.
- Does the patient have a three way stop cock? The use of open stop cocks increased bloodstream infections when compared to using IV connectors to cover entry hubs [50].

#### 7. SUMMARY

- Connector design and category impact occlusion and CR-BSI rates.
- Connector design impacts disinfection and flushing practice success.
- Best practice requires that health care professionals have specific knowledge of connector technology as well as patient factors for caring for vascular access devices.
- The more desirable design features a connector has included in its final product the more users friendly the connector will be and the less complications you will encounter.
- Without specific knowledge regarding connector technology there is an increase in the potential for sepsis, catheter occlusion and death.
- When the connector surface is not properly disinfected, flushed and/or disconnected then bacteria can enter the intraluminal fluid pathway, adhere to the internal surface, colonize and develop biofilm increasing the risk for patient infection and sepsis.
- Healthcare providers should demand that manufactured connector devices be developed with fail-safe engineering advances aimed at further mitigation of risk of infection in the complex hospital environment and devices that include ease of use by the nurse.
- The addition of alcohol caps is another step to implement and one that should not be necessary with a properly designed connector. Additional steps to care also increase human error.
- Instituting the "Healthcare and Technology Synergy (HATS)" framework that includes "Patient, Practice, Product", into intravenous practice settings and within research is paramount to a better understanding of intraluminal vascular access infections.
- The frequent usage and care of connectors in all healthcare settings makes connectors significant variables for practice and comparative effectiveness and outcomes research.
- There are large gaps in the scientific literature, policies and procedures in regards to unbiased evidenced based decision making, care and maintenance related to needleless connectors.

# 8. CONCLUSIONS

An increased understanding of connector design's impact on the intraluminal fluid pathway combined with evidence based practice can prevent CR-BSI's and occlusions through preventing the active and passive migration of microorganisms into the fluid pathway and preventing microorganism adhesion to the catheter surface. The connector, as the gatekeeper to the intraluminal fluid pathway, plays a significant and vital role in the prevention of patient complications, including death. The best designed connector should include all design features outlined by Dr. WR Jarvis [16]. Best practice requires utilization of research in the development and implementation of policy and procedures associated with

needleless intravenous connector care and maintenance. Product should be considered an important variable when designing research. Practice should not be the entire focus for change to improve outcomes. Also, the potential of value enhanced purchasing can best be accomplished through inclusion of evidence. Through a combination of research and education there could be a very significant decrease in 'one every minute' CR-BSI's and vascular access catheter occlusions.

## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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