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Brief report

Comparison of central line-associated bloodstream infection rates when changing to a zero fluid displacement intravenous needleless connector in acute care settings

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This was a multicenter, quasiexperimental, 140-month, acute care study comparing central line-associated bloodstream infection rates associated with positive or negative intravenous connectors to a zero fluid displacement connector. A decrease in central line-associated bloodstream infections was found after changing from either negative or positive intravenous connectors to the zero fluid displacement connector ($P = .005$) with total cost savings of over $3 million.

The ability to decrease central line-associated bloodstream infection (BSI) (CLA-BSI) has seen some improvement, but more is necessary to prevent negative patient outcomes. One area that has not been researched is the actual technology or connector product and its effect on BSIs. Using the Healthcare and Technology Synergy (HATS) framework,[1] the purpose of this multicenter study was to compare CLA-BSI rates associated with the use of intravenous (IV) positive- or negative (including mechanical valve and split septum devices)-pressure needleless connectors (positive reflux mechanical valve connectors included Smartsite Plus [Carefusion, San Diego, CA], MaxPlus [Carefusion], and UltraSite [B. Braun Medical Inc, Bethlehem, PA], and negative reflux split septum connector Q-Syte [Becton Dickson, Salt Lake City, UT]) and mechanical valves SmartSite (Carefusion) to a zero fluid displacement needleless connector (Invision-Plus; RyMed Technologies, Inc, Franklin, TN). IV needleless connectors have been associated with increased CLA-BSI rates in the past.[2-6]

Infection preventionists have identified the need for the manufacture of devices that involve fail-safe engineering advances aimed at further mitigation of risk of infection in the complex hospital environment.[7] What nursing needs as part of the solution to CLA-BSIs are catheters and connectors that operate in a way that is not going to defeat health care workers if they do not use the device correctly, whether it is disinfecting or flushing the device.[8] The IV connector design including septum surface, septum deal, fluid pathway, dead space, internal mechanism, clamping sequence, visibility, and reflux have been identified as possible design features that may have a negative impact on CLA-BSI rates.[8] If swabbing and flushing procedures are standardized and connector design is overlooked, outcomes may vary, and this variance may not be related to inconsistent nursing adherence to connector practice procedures.

Both positive and negative needleless connectors[5,6] have been associated with increased CLA-BSI,[2-4] and the Centers for Disease Control and Prevention 2011 Intravenous Guidelines[9] recommend either against the use of positive-pressure connectors or mechanical valve needleless connectors (positive, negative, or neutral) in general, respectively. In August 2009, the US Food & Drug Administration alerted all infection control personnel of the increase in CLA-BSI risk and potential death associated with positive-pressure needleless connectors and have asked the manufacturers of these positive-pressure and positive displacement mechanical valve needless connectors to conduct studies to

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RyMed Technologies, Inc (Franklin, TN), personnel were permitted to be contacted for contact information. No data were omitted or modified.

The authors analyzed the complete data set and wrote the manuscript.

Conflicts of interest: D.M. is a consultant and investor in RyMed Technologies. The remaining authors report no conflicts.

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Table 1
CLA-BSI rates by needleless connector type

Site/state	Connector type	Prezero connector numerator (number infections)/denominator (catheter-days)	Prezero connector CLA-BSI rate	Postzero connector numerator (number infections)/denominator (catheter-days)	Postzero connector CLA-BSI rate	*P* value
MICU/CO	Positive: Smartsite Plus	3/722	4.2	1/1,218	0.8	.007
MICU/PA	Positive: MaxPlus	10/2,348	4.3	4/2,608	1.5	
SICU/CO	Positive: Smartsite Plus	8/1,121	7.1	2/1,607	1.2	
ICU/NV	Positive: UltraSite	28/2,458	11.4	12/3,462	3.5	
ICU/TX	Negative: Q-Syte	21/7,251	2.9	1/6,901	0.1	
Acute long-term care/TN	Negative: Q-Syte split septum for 12 months	26/6,277	4.1	N/A	N/A	
	and SmartSite mechanical valve for 8 months	15/4,282	3.5	N/A	N/A	
	and total of both 20 months	41/10,559	7.6	2/9,825	0.2	

prove noninferiority to negative or neutral mechanical valve or split septum needleless connectors within 3 years.[10] Because the needleless connectors were designed with a focus on simple needle-free connection and because intraluminal fluid pathway protection was not considered because its impact was unknown at the time, it is not surprising that the use of needleless connectors increased complications.

METHODS

This was a quasiexperimental study during 2009-2010 over 140 months, 5 states (Colorado, Nevada, Pennsylvania, Tennessee, and Texas), 6 specialty settings (3 intensive care units [ICU], and 1 each of medical ICU, surgical ICU, and long-term acute care) comparing CLA-BSI rates associated with positive (6,649 catheter-days) or negative (17,810 catheter-days) IV needleless connectors to a zero fluid displacement needleless connector. There was a total of 24,459 prezero fluid displacement catheter-days over 70 months compared with 25,621 total postzero displacement connector catheter-days over 70 months. The long-term care unit used 2 types of negative connectors (1 split septum and 1 mechanical valve) prior to changing to the zero fluid displacement connector. CLA-BSIs were defined using Centers for Disease Control and Prevention National Healthcare Safety Network criteria.[9] No changes in catheter insertion or maintenance care were implemented except changing the needleless connector to the zero fluid displacement connector. Insertion and maintenance care bundles remained constant over time without changes and included hand hygiene, all inclusive dressing change kits, chlorhexidine (CHG) containing skin prep, CHG-disc (ie, BioPatch; Ethicon, Johnson and Johnson, New Brunswick, NJ) applied to insertion site, catheter securement devices, swabbing protocols, standard connector change protocols (ie, 72-96 hours), and annual vascular access education programs in all health care facilities. Two facilities included a vascular access education program at the time of hire as well as annually. Alcohol or CHG/alcohol was used for septum swabbing. Swabbing times of a connector hub varied between "no designated time specified" to "20 seconds," with 15 seconds being the most common swabbing time. All settings reported using the saline-administer medication-saline flushing method and using full barrier precautions for central line insertions. Paired *t* tests were used to examine differences between catheter-days and CLA-BSI rates before and after zero fluid displacement connector adoption. Statistical significance was assessed using an α level of .05. The HATS framework, an interaction among the variables patient, product, and practice, was used in this study.

RESULTS

The number of catheter-days was similar both before and after zero fluid displacement connector adoption. There was a statistically significant higher CLA-BSI rate when either negative- ($P = .039$) or positive- ($P = .0158$) pressure mechanical IV connectors were used. Overall, a decrease in CLA-BSIs per 1,000 catheter-days was found after changing from negative or positive IV connectors to the zero fluid displacement connector ($P = .007$).

DISCUSSION

We documented a statistically significant decrease in CLA-BSI rates when either negative or positive IV needleless connectors were changed to a zero fluid displacement connector in multiple acute settings (Table 1). The data reveal that IV needleless connector design impacts CLA-BSI rates, and product is a significant variable in the HATS framework for comparative effectiveness. The study results also call into question the one-size-fits-all approach to needleless connector swabbing and flushing procedures. All connectors may not be equal, and their care and maintenance practices may need to be more product specific. Furthermore, research needs to assess all needless connectors and include clinical validation. Using current cost estimates of each CLA-BSI averaging $35,000 per episode, then the change from positive or negative connectors to a zero displacement connector saved these health care facilities over $3 million. We conservatively estimate that 13 lives were saved, based on a 15% mortality rate from CR-BSI in ICUs.

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