

ORIGINAL ARTICLE

Increased Rate of Catheter-Related Bloodstream Infection Associated With Use of a Needleless Mechanical Valve Device at a Long-Term Acute Care Hospital

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OBJECTIVE. To determine whether introduction of a needleless mechanical valve device (NMVD) at a long-term acute care hospital was associated with an increased frequency of catheter-related bloodstream infection (BSI).

DESIGN. For patients with a central venous catheter in place, the catheter-related BSI rate during the 24-month period before introduction of the NMVD, a period in which a needleless split-septum device (NSSD) was being used (hereafter, the NSSD period), was compared with the catheter-related BSI rate during the 24-month period after introduction of the NMVD (hereafter, the NMVD period). The microbiological characteristics of catheter-related BSIs during each period were also compared. Comparisons and calculations of relative risks (RRs) with 95% confidence intervals (CIs) were performed using χ^2 analysis.

RESULTS. Eighty-six catheter-related BSIs (3.86 infections per 1,000 catheter-days) occurred during the study period. The rate of catheter-related BSI during the NMVD period was significantly higher than that during the NSSD period (5.95 vs 1.79 infections per 1,000 catheter-days; RR, 3.32 [95% CI, 2.88-3.83]; $P < .001$). A significantly greater percentage of catheter-related BSIs during the NMVD period were caused by gram-negative organisms, compared with the percentage recorded during the NSSD period (39.5% vs 8%; $P = .007$). Among catheter-related BSIs due to gram-positive organisms, the percentage caused by enterococci was significantly greater during the NMVD period, compared with the NSSD period (54.8% vs 13.6%; $P = .004$). The catheter-related BSI rate remained high during the NMVD period despite several educational sessions regarding proper use of the NMVD.

CONCLUSIONS. An increased catheter-related BSI rate was temporally associated with use of a NMVD at the study hospital, despite several educational sessions regarding proper NMVD use. The current design of the NMVD may be unsafe for use in certain patient populations.

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Prevention of percutaneous sharps injuries is important in preventing transmission of bloodborne pathogens to health-care personnel. The Centers for Disease Control and Prevention (CDC) estimates that 385,000 needlesticks and other sharps-related injuries each year are sustained by hospital-based healthcare workers¹; however, the true magnitude of the problem is difficult to assess because the frequency of injuries may be underreported by up to 50%.²⁻⁵ Although seroconversion after an occupational exposure to hepatitis A, B, and C viruses and human immunodeficiency virus is rare, there are costs associated with such exposure. For example, direct financial costs associated with the treatment of exposed healthcare workers are estimated to be \$500-\$3,000, depending on the treatment provided.⁶ Harder to describe in objective terms are the emotional costs associated with occupational bloodborne exposures and the adverse effects of potentially toxic treatment regimens.

The risk of percutaneous injury depends on the responsibilities of the healthcare worker and the devices used during patient care. Most of the healthcare workers injured by needles and other sharps are nurses, likely because they comprise the largest proportion of the healthcare workforce.⁷ Devices that require manipulation or disassembly after use (such as needles attached to tubes used for intravenous [IV] access) have been associated with a rate of injury that is 5.3 times that for conventional disposable syringes.⁸ To prevent percutaneous injuries, healthcare organizations have adopted various policies, such as eliminating or reducing the frequency of use of needles and other sharps when possible. The majority of US hospitals have eliminated unnecessary use of needles through implementation of an IV delivery system that does not require (or permit) needle access.⁹ Such systems have been successful in reducing IV access-related sharps injuries.¹⁰⁻¹³

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The technology associated with the needleless system has evolved over time. The needleless split-septum device (NSSD) has a surface that can be accessed with a compatible blunt-cannula injector. Problems associated with NSSDs have included frequent occlusion at the connection site and backflow into the device. Also, bloodstream infection (BSI) outbreaks temporally associated with their use have been reported among patients receiving infusion therapy at home and patients hospitalized in intensive care units.¹⁴⁻¹⁶ Development and use of needleless luer-activated systems or needleless mechanical valve devices (NMVDs) with or without positive pressure displacement followed, which allowed use of a syringe tip for port access. NMVDs may reduce occlusion rates and backflow into the device; however, BSI outbreaks temporally associated with their use have recently been reported in acute care hospitals.¹⁷⁻²⁰

Central venous catheters are often used to sustain IV access for patients who require hemodynamic monitoring or IV fluids, nutrition, or medication, and it has been estimated that more than 250,000 catheter-related BSIs occur in the United States each year.²¹ The risk of infection depends on the type of catheter used and the site of insertion. Peripherally inserted central catheters, the most common type of catheter used for central IV access in the facility discussed in the present study, have been associated with a rate of 0.4 catheter-related BSIs per 1,000 catheter-days.²² Catheter-related BSI has an estimated attributable mortality rate of 12%-25% and is associated with excess hospital stay and additional health-care costs of approximately \$33,000-\$35,000 per infection.²² The study facility, a long-term acute care hospital in Charleston, South Carolina, switched from a NSSD to a luer-activated NMVD (SmartSite Needle-Free Valve; Alaris Medical Systems) in the first quarter of 2004. Education on proper use and disinfection of the NMVD was provided to healthcare personnel by nurse educators from the hospital and representatives from the manufacturer. The objective of this study was to compare the rate and microbiological characteristics of catheter-related BSIs in the period before the NMVD was introduced (hereafter, the NSSD period) with the rate and characteristics of catheter-related BSIs in the period after the NMVD was introduced (hereafter, the NMVD period). We found a significantly increased rate of catheter-related BSI temporally associated with use of the NMVD.

METHODS

Study Hospital

The study hospital is a 59-bed freestanding facility for patients with complex medical needs that prevent them from being cared for in a traditional long-term care facility, such as a rehabilitation center, a subacute care facility, or a skilled-nursing facility. Common reasons for admission include pulmonary rehabilitation, weaning from long-term mechanical ventilation, receipt of long-term antibiotic therapy or parenteral nutrition, and long-term treatment of wounds. In this

facility, approximately three quarters of patients have central venous catheters, almost all of which are peripherally inserted central catheters that were placed before admission. During the study period, there were no changes in the hospital policy regarding the care of central venous catheters. The IV tubing (including the needleless device) was routinely changed every 96 hours unless blood (or blood products) or parental nutrition was administered, in which case the tubing was changed each day. The surface of each NMVD was disinfected with a 70% isopropyl alcohol swab (vigorously rubbed for 3-5 seconds) prior to access. When blood was obtained for culture from the catheter, the initial 6 mL of the specimen was discarded. During the period in which the rate of catheter-related BSI was increased, several additional educational sessions were held among healthcare personnel to ensure that there was proper training regarding NMVD manipulation. Healthcare workers demonstrated their line care techniques during these sessions.

Surveillance Characteristics and Data Collection and Analysis

Active surveillance for catheter-related BSI was conducted and data collected and maintained by the infection control practitioners at the study hospital. Catheter-related BSI was defined using CDC and National Nosocomial Infection Surveillance system criteria, and the rate of catheter-related BSI was calculated as the number of catheter-related BSIs per 1,000 catheter-days. This surveillance method did not change throughout the study period. A sustained increase in the catheter-related BSI rate was perceived after the start of the NMVD period in January 2004, and this rate was compared with the rate during the preceding 24-month period of NSSD use (January 2002 through December 2003) to determine whether the perceived increased rate was statistically significant. Use of the NMVD continued through December 2005, and the rate of catheter-related BSI during the entire 24-month NMVD period was compared with the baseline rate during the NSSD period.

The causative organism(s) for each catheter-related BSI was also recorded, and the percentage of catheter-related BSIs with a polymicrobial etiology, as well as the percentages due to gram-positive organisms, gram-negative organisms, or fungal organisms, were compared between the 2 periods. Comparisons and calculations of relative risks (RRs) with 95% confidence intervals (CIs) were performed using χ^2 analysis (Epi Info, version 3.3; CDC). A *P* value of .05 or less was considered statistically significant.

RESULTS

Eighty-six catheter-related BSIs occurred during the study period (20 during the NSSD period and 66 during the NMVD period), with a median of 18 days (mean, 30 days) between admission to the study hospital and onset of BSI. The catheter-related BSI rate during the NMVD period (5.95 infec-

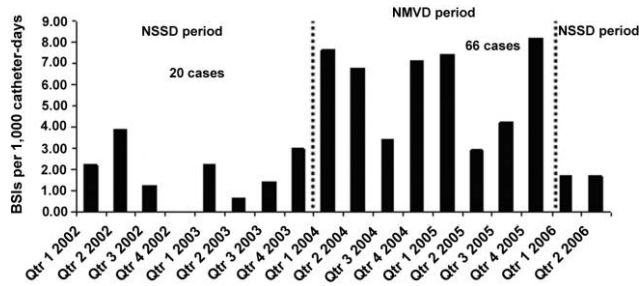


FIGURE 1. Rates of catheter-related bloodstream infection, by quarter (Qtr), during use of a needleless split-septum device (NSSD) and use of a needleless mechanical valve device (NMVD) at a long-term acute care hospital in Charleston, South Carolina.

tions per 1,000 catheter-days) was significantly higher than that during the NSSD period (1.79 infections per 1,000 catheter-days), with an associated RR of 3.32 (95% CI, 2.88-3.83; $P < .001$) (Figure 1). Additionally, there was a 65% relative increase in the percentage of BSIs that were polymicrobial between the NSSD and NMVD periods (25% vs 41.2%; RR, 1.65 [95% CI, 0.72-3.77]; $P = .32$); however, this difference was not statistically significant. The percentage of catheter-related BSIs due to fungal organisms was not significantly different between the NSSD and NMVD periods (4% vs 5.3%; RR, 1.32 [95% CI, 0.15-11.23]; $P > .99$).

The percentage of catheter-related BSIs due to gram-negative organisms increased significantly between the NSSD and NMVD periods (8% vs 39.5%; RR, 4.93 [95% CI, 1.27-19.19]; $P = .007$) (Figure 2). Among catheter-related BSIs due to gram-positive organisms, the percentage caused by enterococci increased significantly (13.6% vs 54.8%; RR, 4.02 [95% CI, 1.35-11.91]; $P = .004$) and the percentage caused by staphylococci decreased significantly (86.4% vs 38.1%; RR, 0.44 [95% CI, 0.29-0.67]; $P < .001$) between the NSSD and NMVD periods (Figure 2). During the NMVD period, of the catheter-related BSIs due to gram-positive organisms, the majority caused by enterococci involved vancomycin-susceptible isolates, and of the catheter-related BSIs due to gram-negative organisms, a variety of gram-negative organisms were identified as the cause (Figure 2).

Multiple educational sessions regarding proper use of the NMVD were held with nursing staff, but the catheter-related BSI rate remained high. According to published estimates on the burden of catheter-related BSI,²² the 46 excess infections during the NMVD period may have been associated with 5-12 excess deaths and \$1.5-1.6 million in excess healthcare costs.

The long-term acute care hospital stopped using the NMVD in January 2006, switching back to a NSSD. During the 6-month period after use of the NSSD resumed, there were 8 catheter-related BSIs, for a rate of 1.70 infections per 1,000 catheter-days. This rate was significantly lower than that during the NMVD period, with an associated RR of 0.29

(95% CI, 0.25-0.33; $P < .001$); however, additional study is needed to determine how long the decreased rate was sustained. Notably, 2 of the catheter-related BSIs that occurred during this 6-month follow-up period involved patients for whom a needleless luer valve was used with the IV tubing, instead of a NSSD.

DISCUSSION

This study describes a sustained, significantly increased rate of catheter-related BSI associated with use of a NMVD among patients in a long-term acute care hospital. It is important to note that the protocol for management of central venous catheters did not change in this facility over the study period.

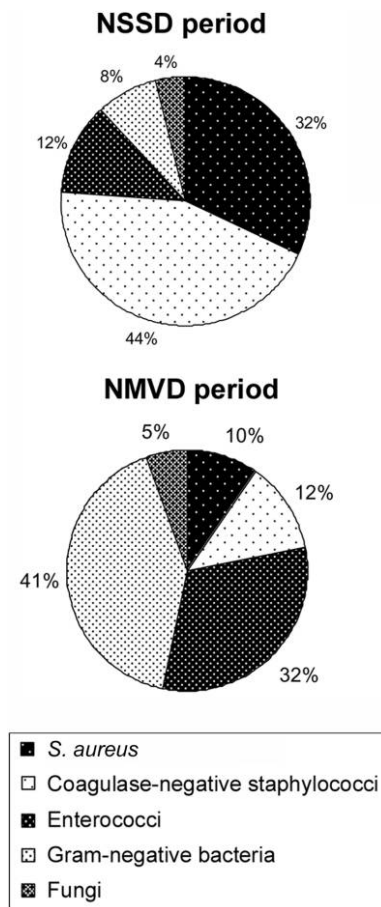


FIGURE 2. Organisms associated with use of a needleless split-septum device (NSSD) or a needleless mechanical valve device (NMVD). NSSD period: *Staphylococcus aureus*, 7 resistant and 1 susceptible to methicillin; enterococci, 2 resistant and 1 susceptible to vancomycin; gram-negative organisms, 1 *Klebsiella* isolate. NMVD period: *S. aureus*, 3 resistant and 4 susceptible to methicillin; enterococci, 2 resistant and 21 susceptible to vancomycin; gram-negative organisms, 11 *Klebsiella* isolates, 5 *Serratia* isolates, 4 *Enterobacter* isolates, 3 *Pseudomonas* isolates, 2 *Escherichia coli*, 2 *Citrobacter* isolates, 2 *Proteus* isolates, 1 *Stenotrophomonas* isolate.

One confounding variable that could have influenced the catheter-related BSI rate was a high rate of nursing turnover at the facility; however, this was a problem over the entire study period, not just during the NMVD period.

To our knowledge, an outbreak of catheter-related BSI among patients hospitalized in a long-term acute care facility has not been previously described; however, similar outbreaks temporally associated with use of NMVDs have been reported, including 3 abstracts from national scientific meetings^{17,19,20} and 1 article from a peer-reviewed journal.¹⁸ An abstract by Hall et al.¹⁷ described a 61% overall increase in the rate of catheter-related BSI at an academic hospital in 2002 that was temporally associated with hospital-wide implementation of NMVDs. They performed a retrospective investigation comparing the rates of false-positive and true-positive results of cultures of blood samples drawn from central venous catheters before and during implementation of the NMVD. Their analysis revealed a 3.74-fold increase in the rate of false-positive results and a 1.90-fold increase in the rate of true-positive results after use of the NMVD began.¹⁷ Maragakis et al.¹⁸ also described a catheter-related BSI outbreak among intensive care unit patients at an academic hospital in 2004 that was temporally associated with use of a positive pressure NMVD (SmartSite Plus Needle-Free Valve; Alaris Medical Systems). Implementation of the positive pressure NMVD was associated with a 60% overall increase in the rate of catheter-related BSI (1.5 vs 2.4 infections per 1,000 catheter-days), with an associated incidence rate ratio of 1.60 (95% CI, 1.04-2.48; $P = .03$). Similar to our findings, the percentage of catheter-related BSIs with a polymicrobial etiology was greater during the period of NMVD use, compared with the period before the device was used (14% vs 6.5%; $P = .17$), as was the percentage of catheter-related BSIs caused by gram-negative organisms (28.1% vs 17.7%; $P = .18$).¹⁸ An abstract by Karchmer et al.¹⁹ also described a significant increase in the rate of catheter-related BSI temporally associated with use of a NMVD (Clearlink IV Delivery System; Baxter) in an intensive care unit of an academic hospital. Among patients being cared for in the intensive care unit, use of the NMVD was associated with a significantly increased catheter-related BSI rate of 8.5 infections per 1,000 catheter-days, compared with a rate of 6.3 infections per 1,000 catheter-days before introduction of the device (95% CI, 1.03-1.74; $P = .02$).¹⁹ Rupp et al.²⁰ described significant facility-wide increases in catheter-related BSI rates associated with a switch from a split-septum device to a NMVD with positive pressure displacement. The rate of catheter-related BSI in critical care and transplantation units increased from 3.87 infections per 1,000 catheter-days during the period of split-septum device use to 10.43 infections per 1,000 catheter-days during the period of NMVD use ($P < .001$). Similarly, the rate of catheter-related BSI increased from 3.47 to 7.51 infections per 1,000 catheter-days in other inpatient areas ($P < .001$) and from 5.8 to 15.18 infections per 1,000 catheter-days in the

outpatient transplantation unit ($P < .001$) after the switch to the NMVD.²⁰ Others have shared similar findings in peer discussion groups at national scientific meetings, implicating many devices from different manufacturers.^{18,23} The findings from our study and these 4 reports suggest that an increased rate of catheter-associated BSI is an emerging problem associated with the use of NMVDs.

The exact reason for the increased catheter-related BSI rates associated with use of these devices is not known; however, our findings, along with the findings of other investigators, suggest that the mechanical valve system could be more difficult to disinfect because of the complicated nature of the multipart device. The most common method of disinfection of the injection port is to vigorously wipe it with a 70% isopropyl alcohol swab before access. A simulation study of the efficacy of this method was conducted by Menhay et al.²⁴ A total of 105 NMVDs were purchased from various manufacturers, and the membranous septum of each was heavily contaminated with *Enterococcus faecalis* and allowed to dry for 24 hours. A group of control catheters were then accessed with a sterile syringe and injected with 3 mL of nutrient broth media without disinfection of the injector port. The broth was then captured on the downstream side of the intraluminal fluid pathway and quantitatively cultured. Fifteen (100%) of 15 of the control catheters showed transmission of microorganisms at a magnitude of 4,500-10,000 colony forming units (cfu). Similarly, another group of catheters underwent disinfection of the injector port with a 70% isopropyl alcohol swab prior to access, and 20 (67%) of 30 still showed transmission of microorganisms at a magnitude of 442-25,000 cfu.²⁴

In conclusion, a sustained, significantly increased rate of catheter-related BSI was associated with use of a NMVD in a long-term acute care hospital, despite numerous educational sessions regarding proper use of the device. During the NMVD period, a significantly greater percentage of catheter-related BSIs was caused by gram-negative organisms, and among catheter-related BSIs due to gram-positive organisms, a greater percentage was caused by enterococci. Given the increasing evidence of temporal associations between increased catheter-related BSI rates and use of NMVDs, formal assessment of these devices is warranted.

We agree with Maragakis et al.¹⁸ that healthcare facilities should be aware that infection control-related problems could be associated with the use of these needleless IV infusion systems and that facilities should actively analyze catheter-related BSI rates among patients with these devices. Our data, added to those from other reports, suggest that the current design and/or recommended protocol for disinfection of these devices may not be safe or adequate for patient use.

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