CONCISE COMMUNICATIONS

Increased Catheter-Related Bloodstream Infection Rates After the Introduction of a New Mechanical Valve Intravenous Access Port

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The technology of intravenous catheter access ports has evolved from open ports covered by removable caps to more-sophisticated, closed versions containing mechanical valves. We report a significant increase in catheter-related bloodstream infections after the introduction of a new needle-free positive-pressure mechanical valve intravenous access port at our institution.

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Central venous catheters (CVCs) are frequently used to obtain intravenous access for the administration of fluids and medications in inpatients and outpatients, especially in intensive care units (ICUs). In most cases, intravenous administration sets include 1 or more access ports that can be used to inject medication or to draw blood samples through the catheter. The technology of these infusion access devices has evolved from open ports with removable caps to more-sophisticated, closed versions containing mechanical valves (MVs). Closed ports are less likely to become contaminated or to have organisms migrate into the lumen of the catheter than are open ports with removable caps.[1-3] The simplest closed-access ports have diaphragms that are pierced by needles to inject medication. To decrease accidental needlestick injuries, needleless systems were developed. One type of needleless device, the split-septum connector, has a slit in the access surface diaphragm that is accessed using a compatible blunt cannula injector. Intravenous access ports with MVs allow the use of syringe tips to directly access the port without needles or special injectors (Figure 1). More recently, positive-pressure MV (PPMV) ports were designed to keep catheters patent without the use of heparin flushes, by preventing back flow and reducing the clotting of blood in the catheter.

Three recent studies report that MV intravenous ports reduce colonization of the catheter tip,[1] passage of microorganisms into the catheter lumen,[2] and rates of catheter-related bloodstream infections (CR-BSIs).[3] However, all 3 of these studies compared the MV devices with conventional open systems that include caps, rather than comparing them with earlier versions of closed systems. Two of the studies applied a disinfectant to only the MV device and not to the cap before accessing the port. In addition, none of these studies included pediatric patients, and none of them evaluated PPMV devices.

The Johns Hopkins Hospital used an MV intravenous access port (CLAVE NeedleFree Connector, ICU Medical) for approximately 10 years before switching to a new PPMV device in 2004 (SmartSite Plus Needle-Free Valve, Alaris Medical Systems) (Figure 1). The change was made to decrease the use of heparin flushes in CVCs. We detected a 60% increase in the rate of CR-BSIs in our ICUs that was temporally associated with the introduction of the new access port. The effect was most apparent in pediatric patients in the Children's Center. To our knowledge, this is the first report of increased CR-BSI rates after a change from one type of MV device to a PPMV device.

METHODS

Setting. The Johns Hopkins Hospital is a 946-bed tertiary-care academic medical center in Baltimore, MD, that houses 6 adult ICUs and a Children's Center, which includes a pediatric ICU and a neonatal ICU. Active surveillance for CR-BSIs in each ICU and among pediatric oncology patients is performed using Centers for Disease Control and Prevention criteria and National Nosocomial Infection Surveillance definitions.

Introduction of the new MV. The new PPMV access port was introduced in early April 2004 in the Children's Center and in mid-October 2004 in the neurology critical care unit. Although exact start dates for the other adult ICUs are not available, all units introduced the new PPMV device between April and December 2004.

Vascular access device policy. There were no changes to the vascular access device policy during the period of this study. Along with the entire intravenous administration set, both the MV and the PPMV were changed every 96 hours. Intravenous administration sets used for infusion of blood products, parenteral nutrition, or lipids were changed more frequently. The protocol for cleaning both intravenous access devices was disinfection with a 70% alcohol swab before accessing the port. The protocol for sampling blood from a CVC was to discard the first 6 mL of blood before drawing the blood sample.

The major difference in the use of the 2 devices is that the MV is clamped before the syringe is disconnected, whereas the PPMV is not clamped until after the syringe is disconnected. The open clamp allows the positive-pressure feature to prevent reflux of blood into the catheter lumen. Before introduction of the new PPMV and reintroduction of the MV, education on proper use of the devices was provided to healthcare personnel by nurse educators on the units and by representatives of the device manufacturers.

Discontinuation of use of the new MV. Because of dramatically increased CR-BSI rates, use of the PPMV device was discontinued at the Johns Hopkins Children's Center on December 6, 2004, and the previous MV port was reintrod-

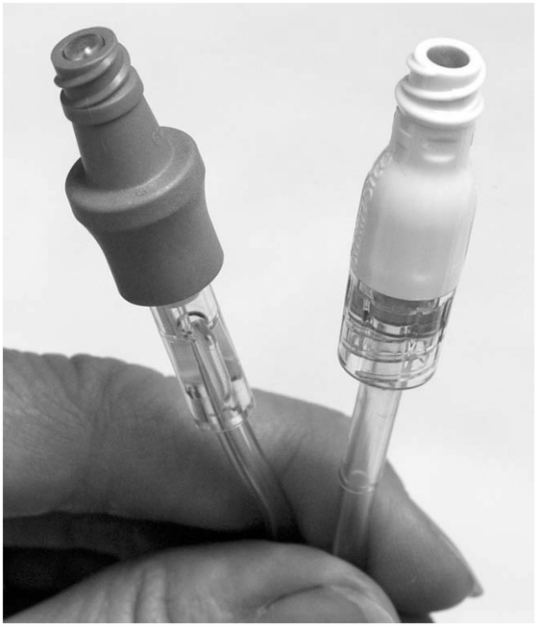

FIGURE 1. Two intravenous access ports used at the Johns Hopkins Hospital. The mechanical valve device used for more than 10 years is shown on the left, and the new, positive-pressure mechanical-valve device is shown on the right.

uced. Use of the PPMV was subsequently discontinued in the rest of the institution.

Statistical analysis. CR-BSIs before and after introduction of the new device were compared by calculating an incidence rate ratio (IRR). A start date for use of the new devices of April 1, 2004, was used for all analyses, and data for the Children's Center were included through December 6, 2004, the date that use of the devices was discontinued in those units. Point estimates, 95% confidence intervals (CIs), and *P* values for the IRRs were calculated (Stata, version 8.0, StataCorp).

RESULTS

All ICUs. The low baseline rates of CR-BSI in our ICUs make it difficult to detect a statistically significant increase in a single unit. When data from all ICUs are pooled, however, the numbers of CR-BSIs are adequate to allow for comparisons. When a date of introduction of the new device on April 1, 2004, was used, the CR-BSI rate for all ICUs was found to have increased significantly (by 60%), from 1.5 per 1,000 catheter-days in the period of June 2003 through March 2004, before the new PPMV device was introduced, to 2.4 per 1,000 catheter-days in the period of April 2004 through January 2005, after the PPMV device was introduced (IRR, 1.60 [95% CI, 1.04-2.48]; $P = .03$). Overall, the majority of CR-BSIs were due to coagulase-negative staphylococcus and other skin flora, with smaller proportions caused by gram-negative bacilli, enterococci, or yeast. After introduction of the PPMV, the percentage of CR-BSIs that were polymicrobial increased from approximately 6.5% to 14% ($P = .17$). The polymicrobial BSIs were caused by a variety of gram-negative bacilli, gram-positive cocci, and yeast. After introduction of the PPMV, the percentage of CR-BSIs caused by gram-negative bacilli increased from approximately 17.7% to 28.1% ($P = .18$), with a compensatory decrease in the proportion of CR-BSIs caused by skin flora.

The Children's Center. The CR-BSI rate in the Children's Center, including the pediatric ICU, neonatal ICU, and pediatric oncology service, increased significantly (by 79%), from 1.55 per 1,000 catheter-days in the period of January 2003 through March 2004, before the new PPMV device was introduced, to 2.79 per 1,000 catheter-days in the period of April 2004 to December 6, 2004, when the PPMV was in use (IRR, 1.79 [95% CI, 1.1-2.9]; $P = .01$). The pediatric ICU CR-BSI rate was the first noted to have increased significantly, from 5.4 per 1,000 catheter-days to 17.3 per 1,000 catheter-days (IRR, 3.22 [95% CI, 1.1-9.6]; $P = .02$). The percentage of pediatric ICU CR-BSIs that were polymicrobial increased from approximately 8% to 26% ($P = .19$) after the new PPMV device was introduced. In the Children's Center, the CR-BSI pathogens and their proportions and trends were very similar to those reported above for all ICUs. An investigation failed to reveal any infection-control violations of CVC insertion or maintenance practices. However, the new PPMV access port was introduced in April 2004, just before the CR-BSI rate increase. The neonatal ICU CR-BSI rate increased from 0.51 per 1,000 catheter-days to 1.34 per 1,000 catheter-days (IRR, 2.63 [95% CI, 0.52-12.2]; $P = .17$), and the pediatric oncology CR-BSI rate increased from 2.61 per 1,000 catheter-days to 4.71 per 1,000 catheter-days (IRR, 1.81 [95% CI, 0.64-4.8]; $P = .21$), although these increases were not statistically significant. After December 6, 2004, when use of the new devices was discontinued and the previous MV port was reintroduced, the CR-BSI rate in the Children's Center decreased (by 49%), from 2.79 per 1,000 catheter-days in the period of April 2004 to December 6, 2004, when the PPMV was in use, to 1.43 per 1,000 catheter-days in the period of December 6, 2004, to March 31, 2005 (IRR, 0.51 [95% CI, 0.22-1.08]; $P = .06$) (Figure 2).

DISCUSSION

In the present study, we report a temporal association between the introduction of a new PPMV intravenous access port and increased CR-BSI rates in our ICUs. Concern about an association between MV access ports and increased rates of CR-BSIs was first raised in April 2004, when Hall et al.[4] reported a 61% increase in the nosocomial BSI rate after introduction of a new MV intravenous port at the University of Virginia. Thirteen additional institutions, including 1 large infusion company, reported similar findings in peer discussion groups at national meetings. Multiple devices and manufacturers

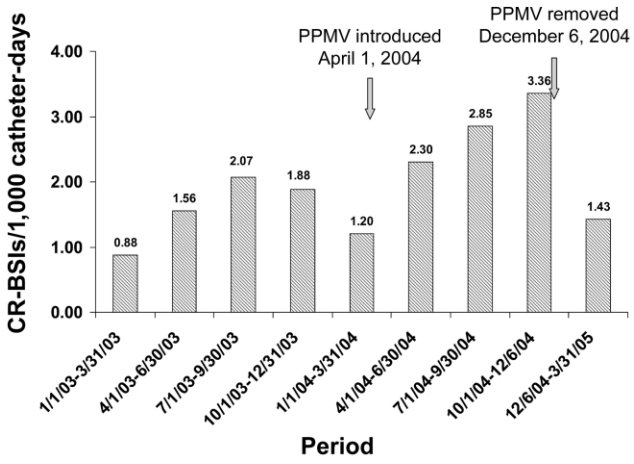

FIGURE 2. Nosocomial catheter-related bloodstream infection (CR-BSI) rates for the Johns Hopkins Children's Center from January 2003 through March 2005. The Children's Center data include rates for the pediatric and neonatal intensive care units and the pediatric oncology service. PPMV = positive-pressure mechanical valve intravenous access port.

were implicated at these meetings (W. Jarvis, MD, oral communication, March 2005).

Given the increasing anecdotal evidence from peer-review groups and our experience, the need for formal assessment of the situation is critical. Reportedly, many different models and manufacturers of MV and PPMV devices are implicated, although most report the association with switching from split-septum technology. Our experience is unique, because one type of MV device was already in long-term use at our institution before the change to a PPMV port.

In must be noted that the data in this study are limited because they are observational, uncontrolled, and from a single study site. Exact dates of the implementation of use of the PPMV device were not available for some ICUs. In addition, there is variation in CR-BSI rates over time, and many factors, such as catheter care, can affect these rates. Despite these limitations, however, the temporal relationship between the introduction of the new PPMV device and increased rates of CR-BSIs is striking, especially in the Children's Center, where follow-up data show a decrease that was temporally associated with discontinuation of use of the device.

On the basis of the data presented, the Hospital Epidemiology and Infection Control Committee voted to discontinue use of the new PPMV access port in our institution. The previous MV device has now been reintroduced throughout the institution. Because of the potential public-health implications, we reported our observations to the Food and Drug Administration, the Maryland Department of Health and Mental Hygiene, and the Centers for Disease Control and Prevention.

Further study is needed to determine whether access ports with MVs and/or the relatively new positive-pressure design are associated with microbiological contamination and CR-BSIs. One theory is that the MV devices have intricate access surfaces that are more difficult to disinfect than the simpler split-septum models. The fluid path in the MV devices has moving parts, and at least 1 of the MV devices has internal corrugations that may serve as reservoirs and foster the growth of microbial contaminants. Our finding of increased rates of polymicrobial CR-BSIs during the time that the PPMV was in use suggests that such a reservoir of microbial contamination exists in or on these devices. Some of the devices have been noted by healthcare personnel to have incomplete flushing of blood from the fluid channel, and some are opaque, so that this would not be readily apparent to the user. It is unclear why the effect seems to be greater in pediatric patients, although we postulate that it may be a result of smaller volumes being infused to flush the catheter or more-frequent use of CVCs to obtain blood samples in this population.

Healthcare facilities need to be aware of this possible association between the new technology and increases in healthcare-associated infections. Increased focus on infectious outcomes, with public reporting and public campaigns such as the Save 100,000 Lives,[5] will require attention to all potential factors that could increase or alter BSI rates. We recommend that infection-control programs carefully evaluate their CR-BSI rates after any such change in infusion technology. Important differences may be difficult to detect in smaller hospitals, especially if there is no housewide surveillance for CR-BSIs, or in institutions with targeted surveillance strategies. Facilities should aggressively report any perceived problem to the Food and Drug Administration and to public-health authorities. Given the empirical, anecdotal nature of the data so far, more study is needed to compare the effects that MV technology (with and without the positive-pressure feature) and other closed-system technology (such as the split-septum devices) have on patient outcomes.

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Determining the Significance of Coagulase-Negative Staphylococci Identified in Cultures of Paired Blood Specimens from Neonates by Species Identification and Strain Clonality

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Of 13 paired coagulase-negative staphylococci (CoNS) isolates recovered from cultures of paired blood specimens obtained simultaneously from peripheral sites from neonates with clinical sepsis, 12 were identical species with identical genotypes. Isolation of CoNS in cultures of 2 blood samples obtained simultaneously from separate sites in neonates usually represents true infection.

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Coagulase-negative staphylococci (CoNS) have become the major cause of nosocomial bacteremia in neonatal intensive care units (NICUs) during the past 2 decades.[1-3] Because CoNS are ubiquitous skin commensals, they are also frequent contaminants of blood cultures. Distinguishing true infection from culture contamination is very important but remains a difficult clinical challenge. Numerous clinical and laboratory findings, such as isolation of CoNS from multiple blood cultures, results of quantitative blood cultures, and detection of clinical surrogate markers, have been described as predictors of true infection.[4-9] The first of these 3 criteria is based on the assumption that the isolates represent a single clone of CoNS.[10-13] Several studies involving species identification and strain clonality have been conducted to assess whether this assumption is true, but the results were inconsistent.[14-16] Blood samples for culture were obtained sequentially but not simultaneously in these studies. In this prospective study, we cultured paired blood samples obtained simultaneously from 2 different sites in infants in our NICU who had clinical symptoms and signs of sepsis.

METHODS

Between July 1999 and November 2000, paired blood samples for culture were simultaneously collected from different peripheral sites during the daytime from infants who had been in the NICU at Chang Gung Children's Hospital (Kweishan, Taiwan) for at least 48 hours and had developed clinical symptoms and signs of sepsis (intent-to-treat population). Attending neonatologists determined both the antibiotic therapy and whether additional blood samples were obtained for culture. Blood samples were cultured during the study period with the Bactec 9240 system (Beckton Dickinson). Samples from infants for whom both blood cultures were positive for CoNS were saved and frozen for further analysis. CoNS were defined as gram-positive cocci that were catalase positive and coagulase negative. Species identification was performed with the ID 32-Staph gallery (bioMérieux). All saved strain pairs were genotyped by pulsed-field gel electrophoresis (PFGE) of genomic DNA digested with *Sma*I and by infrequent-restriction-site polymerase chain reaction (IRS-PCR). Both methods were performed in accordance with procedures described elsewhere, with a few modifications.[17,18]

RESULTS

During the 17-month study period, 2 blood cultures were performed for 130 infants who had a total 142 episodes of sepsis. Culture results are shown in the Figure. Isolation of any bacterium from 1 of 2 blood cultures was noted in 14 episodes (10%), with CoNS detected in 7 (50%). Two different bacterial species were isolated from blood cultures in 3 episodes, with CoNS detected in each episode. The same bacterial species were isolated from both blood cultures in 52 episodes (37%), with CoNS found in 26 episodes (50%) (24 infants).

Of the 26 episodes in which both blood cultures were positive for CoNS, there were only 13 in which isolates from each culture were saved and available for strain identification. The paired CoNS isolates were the same species in all 13 episodes. A total of 11 genotypes were identified by means of PFGE, whereas 12 genotypes were identified by means of IRS-PCR. Both genotyping methods showed concordant re-