



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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Flaws in the Study:

- A. The data are observational data collected from one facility which introduced one specific product from one specific manufacturer.
- B. The study hospital is a 59 bed freestanding long term care facility for patients with complex medical needs. The “recommendation” statement is for acute care hospitals thus evidence utilized to make the recommendation should be from data collected in acute care facilities.
- C. The study discusses that almost all the central venous catheters studied were placed before admission to the hospital leading to a conclusion that these catheters were placed elsewhere under uncontrolled conditions. Due to the close link between insertion practices and infections, the lack of control of catheter insertions technique alone makes this data reported in this study inconclusive.
- D. The study mentions that ¾ of patients have central venous catheters, almost all are peripherally inserted central catheters; however, the breakdown of catheter types per study groups is not identified. It is well known that CVC’s and Hickman catheters are associated with a higher CLABSI rate than PICC’s; a breakdown of the types and numbers of catheters utilized in each group is necessary. The fact that catheter homogeneity may not be the same in both groups also influences the data reported.
- E. The hospital did not use the MV device according to the manufacturers’ instructions for use. The study reports the device was changed every 96 hours, yet the manufacturers’ instructions for use suggests changing the device according to number of accesses not number of hours. This misuse of the product may have influenced the data.
- F. The numbers in the text do not agree with the numbers reported in Fig. 2
- G. The authors themselves suggest that “additional study is needed to determine how long the decrease in rate was sustained.”
- H. In addition a third device (needleless luer valve) was introduced during the second NSSD period further complicating the data interpretation.
- I. The authors also suggest that “one confounding variable that could have been 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.” Once again the study lacks control as evidenced by consistent nursing turnover through out the periods studied.
- J. The study also reports the percentage of catheter related BSI’s due to gram negative organisms increased significantly between the NSSD and NMVD periods. The association of gram-negative CRBSI with decubitus ulcers is also noteworthy and should have been discussed considering this study involved long term care patients.

What was studied/reported:

1. *“To determine whether the 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).”*

Conclusions:

2. *“An increased catheter-related BSI rate was temporally associated with the use of an 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”*

Connectors Studied: Interlink (Before) to Smartsite (After)

Limitations to Study:

3. *“One confounding variable that could have influenced the catheter related BSI rate was a high rate of nursing turnover at the facility...”*
4. Patient population consists of patients undergoing long term catheterization, mechanical ventilation, long term parenteral nutrition, antibiotic therapy and long term treatment for wounds. According SHEA/IDSA these groups of patients are associated with increased risk of CLABSI. This study does not discuss differences or similarities in the patient populations between the two groups. All the patients were grouped together therefore the results are inconclusive because no evidence was presented related to the homogeneity of the patient populations in the two study groups.

Product deficits identified by Author:

5. *“The exact reason for the increased catheter related BSI rates associated with the use of these devices is not known, however our findings, along with the findings of other investigations, suggest that the mechanical valve system could be more difficult to disinfect because of the complicated nature of the multi part device.”*

References Cited:

6. Hall et al. *“An abstract by Hall et al. 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.”* (Interlink to Ultrasite)
7. Maragakis et al. *“Maragakis et al. 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.”* (Clave to Smartsite Plus)
8. Karchmer et al. *“An abstract by Karchmer et al. also describes a significant increase in the rate of catheter-related BSI temporally associated with use of a NMVD.”* (Interlink to Clearlink)
9. Rupp et al. *“Rupp et al. described significant facility-wide increases in catheter-related BSI rates associated with a switch from a split-septum device to an NMVD with positive pressure displacement.”* (Interlink to Smartsite Plus)