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Major article

A comparative evaluation of antimicrobial coated versus nonantimicrobial coated peripherally inserted central catheters on associated outcomes: A randomized controlled trial

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Background: Central line–associated bloodstream infections (CLABSIs) are a common life-threatening risk factor associated with central venous catheters (CVCs). Research has demonstrated benefit in reducing CLABSIs when CVCs coated with antimicrobials are inserted. The impact of chlorhexidine (CHG)-impregnated versus non-CHG peripherally inserted central catheters (PICCs) on risk of CLABSI is unknown. Venous thromboembolism (VTE) is also a complication associated with CVCs. This study compares the impact of both PICC lines on these outcomes.

Methods: Patients in 3 high-risk units were randomly assigned to receive either a CHG-impregnated or non-CHG PICC line. Laboratory data were collected and reviewed daily on all study patients. The PICC dressing site was assessed daily. Medical record documentation was reviewed to determine presence of CLABSI or VTE.

Results: There were 167 patients who completed the study. Three patients developed CLABSI (2 in the CHG group, and 1 in the non-CHG group), and 3 patients developed VTE (2 in the non-CHG group, and 1 in the CHG group). No significant relationship was noted between the type of PICC line on development of a CLABSI ($P = .61$) or VTE ($P > .99$). A significant difference was noted in moderate bleeding ($P \leq .001$) requiring thrombogenic dressing in the patients who had the CHG PICC line.

Conclusions: No differences were noted in the development of CLABSI and VTE between the CHG and non-CHG groups.

Central venous catheters (CVCs) are important in the medical management of acutely ill patients. The most common and life-threatening complication of CVCs is the risk for a central line–associated bloodstream infection (CLABSI). CLABSIs are preventable, and when they occur during hospitalization, they are considered to be a hospital-acquired infection (HAI). Subsequently, they impact patient outcomes and reimbursement of hospitalization costs from the Centers for Medicare and Medicaid Services and private insurance companies. It is estimated in the United States that 1 of 20 hospitalized patients will develop an HAI.[1] CLABSIs are the third leading cause of HAIs, after catheter-associated urinary tract infections and surgical site infections.[2]

According to the Joint Commission in 2012, 3 million central lines are used each year.[3] It is estimated that 41,000 CLABSIs occur in U.S. hospitals each year, with approximately 18,000 occurring in the intensive care unit and 23,000 occurring in nonintensive care unit populations.[4] CLABSIs are costly and associated with poor patient outcomes, such as increased length of stay, hospital costs, and mortality.[5,6] It is estimated that CLABSIs cost the health care system approximately $16,550 per episode[7] and are associated with a mortality rate of 15%-25%.[8] Reducing CLABSIs is a priority for improving patient safety and reducing health care costs.

Peripherally inserted central catheters (PICCs) are CVCs inserted via ultrasonographic technique into the upper veins of the arm, with the

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tip advanced to the superior vena cava. PICC lines provide intravenous access for the administration of parenteral fluids, medications, blood products, and nutrition and provide venous access for phlebotomy. PICC lines are a commonly used CVC, especially for patients requiring longer-term intravenous access. As with all CVCs, CLABSI is a potential risk in patients with PICC lines. Risk factors for the development of CLABSI include the number of times the line is manipulated, location of insertion,[9] prolonged dwell time,[10,11] and development of thrombus.[12] Trauma and critical care patients and those admitted with immune suppression are at an increased risk for CLABSI.[13,14]

In addition to the risk of CLABSI associated with PICC lines, upper-extremity venous thromboembolism (VTE) is another potential complication.[15,16] One study found 5% of hospitalized patients develop a symptomatic upper-extremity VTE post–PICC line insertion.[17] VTEs related to PICC lines present a challenge in clinical practice because they may interrupt or delay the patient's medical treatment plan. Factors associated with the development of VTE include catheter size, vein selection,[15] and number of insertion attempts.[18] In addition, researchers acknowledge there may be a reciprocal relationship where infection promotes thrombus formation or the presence of thrombus may facilitate the development of an infection.[16,19] Increased morbidity, hospital costs, and length of stay have been associated with PICC-related CLABSI and VTE.[5,6]

One of the most important aspects in the prevention of CLABSIs is the care and maintenance of the line. Evidence-based bundles for insertion and maintenance care have been developed to prevent CLABSIs. These include insertion techniques such as maximum sterile barriers, site preparation and disinfection using chlorhexidine (CHG), sterile insertion procedures (mask, gown, and gloves) and avoidance of femoral site selection.[3] In addition to these interventions, the use of antimicrobial or antimicrobial-impregnated catheters has been recommended if there is no change in CLABSI rate after the implementation of evidence-based bundles.[14] Research has demonstrated significant benefit in reducing CLABSIs when antimicrobial (CHG–silver sulfadiazine) or antibiotic (minocycline/rifampin) CVCs are inserted. A meta-analysis of randomized controlled trials (RCTs) demonstrated antimicrobial-impregnated CVCs were associated with a decrease in bacterial colonization and CLABSI.[20] However, most of the studies included in the meta-analysis focused on CVCs located in the femoral, subclavian, and jugular veins. There is a paucity of research related to the impact of antimicrobial-impregnated PICC lines on the development of CLABSIs or VTE.

In 2011, a PICC line impregnated with CHG and with clearance as a device with a minimum 30 day antimicrobial and antithrombogenic protection was approved the U.S. Food and Drug Administration.[21] Although this device does not contain heparin, it has been shown to have antithrombogenic properties.[21] Two publications[22,23] noted decreases in CLABSI rates when the CHG-impregnated antimicrobial PICC lines were used, but they did not examine their impact on the development of VTE. One of the publications described the findings from a quasi-experimental study, whereas the other was a 2-year product evaluation.[22,23] To our knowledge, no RCTs have been conducted to examine the impact of CHG PICC lines. Therefore, the purpose of this study was to compare an antimicrobial PICC line impregnated with CHG with a non–CHG-impregnated PICC line on the development of CLABSI or VTE among high-risk hospitalized patients in the cardiovascular thoracic, medical intensive care (MICU), and oncology units.

METHODS

Study setting and design

This study was conducted over 18 months at a large, 800-bed tertiary community hospital in the Midwest. The study was approved by the hospital's institutional review board. To reduce the potential for bias, both the CHG and non-CHG PICC lines were purchased by the institution. Three units were chosen for study recruitment because of higher CLABSI rates than other units in the hospital. Patients were enrolled in the study if they met the following inclusion criteria: (1) PICC line insertion on the cardiovascular thoracic, cardiovascular thoracic, MICU, or oncology units; (2) inpatient ≥18 years of age; (3) no allergy to CHG; (4) insertion of a single- or double-lumen PICC line (the study PICC did not have a triple-lumen option); and (5) anticipated hospital length of stay >48 hours. Patients were excluded from the study for pregnancy and difficult PICC insertion requiring placement in vascular laboratory. Patients were notified on consent that if their hospital length of stay or duration of the PICC line was in <48 hours they would be excluded from the study.

Sample

Convenience sampling was used along with stratified sampling to ensure an equal number of participants came from each of the 3 designated study units. Target enrollment was set at 60 subjects (30 subjects in the control group, and 30 subjects in the standard of care group) from each of the 3 units for a total of 180 subjects. To reduce bias, randomization was conducted by a third party who randomly mixed and selected envelopes containing study assignment group for each unit. Sixty envelopes per unit were divided evenly (30 in each group) and randomly assigned to either group A (CHG PICC) or B (non-CHG). The randomized envelope(s) were selected and placed in the enrollment folder.

Procedures

After informed consent was obtained, patients were randomly assigned to receive either the CHG-impregnated antimicrobial PICC or the non-CHG PICC. The non-CHG PICC was the standard of care at the facility at the time of the study. Both PICC lines were power injectable.

The PICC lines were inserted by the hospital's specially trained PICC team. There are specific differences in the insertion technique between the 2 types of PICC lines. To ensure competency and consistency in placement, all PICC team members completed training on the insertion of the CHG-impregnated antimicrobial PICC prior to study initiation. Standard procedures were followed for insertion of both types of PICC lines. Postinsertion, the PICC team documented type of PICC placed (CHG or non-CHG), catheter size, number of lumens, insertion date, time, and initials of PICC team member responsible for insertion. The PICC team also documented postinsertion location, amount and extent of postinsertion bleeding, and if application of thrombogenic dressing or pressure dressing was required.

Data collection

Demographic information was collected at the time of enrollment and included sex, age, unit location, and duration of PICC line. The type of PICC line (CHG or non-CHG), insertion location, and number of catheter lumens were also collected. Daily inspection of the PICC dressing and site was conducted by a study investigator to assess for signs and symptoms of infection and VTE. The assessment for infection included daily observation and documentation of dressing integrity and appearance of insertion site for presence of redness, warmth, edema, purulent drainage, and bleeding. To control for variations in technique, patients in the study had PICC dressing changes completed by the PICC team nurses or study investigators. PICC team nurses and study investigators attended a