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Major Article

Prospective observational study on central line–associated bloodstream infections and central venous catheter occlusions using a negative displacement connector with an alcohol disinfecting cap

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Background: Major complications of central venous catheter (CVC) use include bloodstream infection and occlusion. We performed a prospective, observational study to determine the rate of central line–associated bloodstream infection (CLABSI) and CVC occlusion using a negative displacement connector with an alcohol disinfecting cap.

Methods: Patients were followed from the time of CVC insertion through 2 days after removal, at the time of hospital discharge if there was no documentation of removal, or 90 days after the insertion of the CVC if it was not removed. CLABSI was defined using National Healthcare Safety Network criteria. Data for evidence of lumen occlusions were extracted from the electronic health record. Direct observations were performed to assess adherence to hospital policy regarding CVC insertion practice.

Results: A total of 2,512 catheters from 2,264 patients were enrolled for this study. There were 21 CLABSIs (0.84%; 95% confidence interval [CI], 0.48%-1.19%; 0.62 per 1,000 line days) and 378 occlusions (15.05%; 95% CI, 13.65%-16.45%; 11.23 per 1,000 line days). Eighty-five direct observations demonstrated insertion protocol adherence in 881 of 925 (95.24%; 95% CI, 93.87%-96.61%) measured criteria.

Conclusions: Lines placed following a standardized protocol using a negative displacement connector with an alcohol cap have low rates of infection compared with historically published findings. We also established that the occlusion rate is >15-fold the CLABSI rate.

BACKGROUND

Central line–associated bloodstream infection (CLABSI) and catheter occlusion remain an ongoing problem associated with use of central venous catheters (CVCs),[1,2] especially with immunocompromised and critically ill patients.[3] These infections increase the care cost per case episode for the health care system and prolong hospital stay for an affected patient.[1,2] Needle-free connectors for central line access were introduced during the last 2 decades and are widely used to prevent needlestick injuries among health care workers.[4] Although needlestick injury has decreased, there is a remaining concern regarding complications, such as CLABSI and CVC lumen occlusion, associated with the use of these devices.[5,6]

Needle-free connectors have been associated with a number of CLABSI outbreaks in acute care hospitals and home care settings.[7-9] Two common risk factors associated with those outbreaks are poor care practices before use of the devices and device design that allows contamination when not in use.[9,10] Whenever product changes are made and a new device is introduced, it is essential to monitor rates of infection and occlusion because practice changes can be associated with a change in adverse events. We performed a year-long observational study of a negative displacement connector in a setting where disinfection caps containing 70% isopropyl alcohol cover all unused connectors and ports. We also performed direct observation of central line insertions and catheter care at each hospital site. The purpose of this study was to demonstrate how the rate of catheter infection and occlusion can be monitored. We also sought to

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establish a benchmark of CLABSI and lumen occlusion rates when good compliance (>90%) of insertion practices are followed.

MATERIALS AND METHODS

Study population

The study health care system is comprised of 4 hospitals that together are generally representative of U.S. health care. One is a tertiary teaching facility with the full range of academic training programs. The second is a community facility with general internal medicine, emergency medicine, neurology, ophthalmology, and family medicine training programs. The third is a community hospital with internal medicine, anesthesia, and general surgery training programs. The fourth is a community hospital with child psychiatry and family medicine training programs. Combined, there are between 50,000 and 60,000 inpatient admissions, 100,000 emergency department visits, and 3 million outpatient encounters annually. In 2003 our organization adopted an entirely paperless medical record and deployed Epic Systems' Electronic Health Record system (Epic Systems, Verona, WI) across the full range of inpatient and outpatient care. Among the benefits of exclusively electronic documentation is a locally developed, comprehensive enterprise data warehouse with searchable content, including all physiological data, laboratory results, orders, medication prescription, patient satisfaction, administration events, radiology reports, laboratory and pathology data, calculated severity scores (eg, APACHE II scores), and the full text of provider notes.

Subjects enrolled were inpatients of the 4 hospitals from October 2012-October 2013. Throughout the 12-month study period, 2,264 patients underwent CVC placement with a negative displacement CLAVE Needlefree Connector (ICU Medical, San Clemente, CA) used with an alcohol disinfecting cap (SwabCap; Excelsior Medical, Neptune, NJ). All 2,264 patients were enrolled for this study at the time of catheter insertion. Data collection was conducted for all patients with a central line catheter dwell time of >2 days. This study was approved by the organization's institutional review board (protocol no. H11-090).

Data collection

We used Research Electronic Data Capture (REDCap, Nashville, TN) for recording data in this study. REDCap is a Qeb-based, Health Insurance Portability and Accountability Act of 1996–secure application developed by Vanderbilt University and a consortium of institutional partners for electronic collection and management of human subject research and clinical trial data. REDCap provides an intuitive user interface that streamlines project development and improves data entry through real-time validation rules, including automated data type and range checks.[11] REDCap is interfaced with the electronic health record (EHR) and generated a list of new central line placements each night. From that list we evaluated those patients who had new central lines for study enrollment. If a subject was eligible for the study, REDCap automatically assigned a study number for the subject and created a new case report form, electronically adding the required information to the case report form. It also assisted the investigators in following patients who completed intravenous therapy and those no longer in our system after discharge.

Data were collected in a case report form that contained the patient's demographics, diagnosis, catheter insertion and removal information, laboratory results, and vital signs. Data collection for a study subject was considered completed when the follow-up period ended, which was defined as 2 days after central line catheter removal; at the time of hospital discharge if there was no documentation of removal; or 90 days after the insertion of the CVC if it was not removed. CLABSI was defined using National Healthcare Safety Network criteria.[12] Evidence for luminal occlusion was determined by reviewing patient ultrasound reports, reading the medical record progress notes, discussion with vascular access team personnel, and documentation of plasminogen activator administration prescription data extracted from the EHR by the study staff.

In addition to follow-up and data collection, we observed a minimum of 20 central line insertions at each of the 4 hospitals to document compliance with standardized written procedural practices. In each hospital, central lines were primarily inserted by the vascular access team or by interventional radiology. We observed a minimum of 10 central line insertions with each department at all 4 sites. Each observation had a list of 11 criteria that needed to be followed before, during, and after central line placement as follows. Before the procedure, did the operator (1) cleans hands immediately prior to procedure; (2) disinfect the insertion site with chlorhexidine using the correct motion and timing requirements (30 seconds); and (3) drape entire patient in a sterile fashion? During the procedure, did those assisting (4) wear sterile gloves, a hat, a mask, and sterile gown (all must be worn); (5) maintain a sterile field; (6) use a catheter cart or kit; and (7) did all personnel assisting follow these precautions? After the procedure was (8) a sterile technique maintained when applying a dressing; (9) were a biopatch and securement device placed appropriately; (10) was the dressing labeled with the date and operator initials; and (11) was a disinfection alcohol cap placed on all connector hubs? Each of the 11 elements were counted when determining compliance with the standardized insertion practice when calculating percent compliance. Therefore, if 10 of the 11 elements were followed, then the compliance would be 90.9% for a given insertion.

Statistical analysis

Continuous variables were reported as mean ± SD and median (range) and then analyzed by the 2-sample *t* test or Wilcoxon rank-sum test. Categorical variables were reported as the frequency and percentage and analyzed by the χ^2 or Fisher exact test. For the first catheter inserted in each patient, univariate analysis was performed to screen for potential risk factors of infection or occlusion, and then a multivariable logistic regression model was developed with significant univariate risk factors. Akaike information criterion and likelihood ratio tests were adopted for model evaluation and variable selection.[13] Crude and adjusted odds ratios, *P* values, and confidence intervals (CIs) are reported. The goodness-of-fit for the model was assessed through the Hosmer-Lemeshow test with $P < .05$. The event rate for infection or occlusion was defined in 2 ways: (1) events per 100 lines and (2) events per 1,000 line days. The overall event rate per 1,000 line days was compared across hospital locations using Poisson regression. Statistical analysis was performed through proc GENMOD on SAS 9.3 (SAS Institute, Cary, NC) Windows platform. A *P* value ≤.05 was considered statistically significant.[14-16]

RESULTS

A total of 2,512 catheters (lines) from 2,264 patients were enrolled for this study. There were 21 CLABSIs for a rate of 0.84% (asymptotic standard error [ASE], 0.18%; 95% CI, 0.48%-1.19%) of lines and 0.62 per 1,000 line days. A total of 378 occlusions occurred for a rate of 15.05% (ASE, 0.71%; 95% CI, 1.36%-1.64%) of lines and 11.23 per 1,000 line days. Infection and occlusion rates, by hospital, are presented in Table 1.

Table 2 shows the details for the first catheter inserted among the 2,264 patients. Overall, 18 (0.8%; ASE, 0.19%; 95% CI, 0.43%-1.16%) patients developed infection, and 317 (14%; ASE, 0.73%; 95% CI,