Central Venous Catheter (CVC)–Related Bloodstream Infections in Pediatric Cancer

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ABSTRACT

Background: Treatment for most children with cancer includes the use of a central venous catheter (CVC). CVCs provide reliable venous access for delivery of chemotherapy and supportive care. This advantage is mitigated by an increased risk of bloodstream infections (BSIs). Despite the ubiquitous use of CVCs, few prospective studies have been conducted to address infection prevention strategies in pediatric oncology patients.

Design: Prospective, randomized, pilot study of a CVC team intervention vs. standard care

Setting: Two inpatient oncology units in an urban, tertiary care children's hospital

Patients: Initial 6 months, a total of 26 pediatric oncology patients (95 admissions) on the experimental unit (EU) and 21 (60 admissions) on the control unit (CU) with a CVC

Methods: The primary aim was to evaluate the feasibility of implementing a CVC nurse team and to determine if there was a significant difference in CVC-related BSIs between the team intervention versus standard care. Secondary aims included the investigation of the association of selected risk factors utilizing both categorical and continuous variables in the development of CVC-related BSIs.

Results: There were two CVC-related BSIs/682 catheter days in the EU group (2.94/1000 catheter days) versus three CVC-related BSIs/900 catheter days in the CU group (3.33/1000 catheter days; P = 0.63). Selected risk factors were not significantly associated with the development of a CVC-related BSI.

Conclusions: These interim results indicate that a CVC team in the care of pediatric oncology patients is feasible; however, a larger cohort will be required to adequately investigate the CVC team's effectiveness in reducing CVC-related BSIs.

Key Words: CVC-related BSIs, pediatric oncology, CVC team intervention

The majority of the 12,400 children diagnosed with cancer each year in the United States (US) will benefit throughout their treatments from the placement of a central venous catheter (CVC) for venous access.[1] However, the use of CVCs, which increases the risk of infection, has been reported predominantly in critically ill adult and pediatric patients.[2,3,4,5,6,7,8,9,10] An estimated 250,000 CVC-related blood stream infections (BSIs) occur annually in US hospitals, with associated mortality rates ranging between 12 and 25%.[11] Mean CVC-related BSI rates from the National Nosocomial Infection Surveillance System (NNIS) range from 3.4 to 11.3 per 1000 catheter days in critically ill pediatric and neonatal patients.[11]

Central venous catheter evidence-based practice guidelines and educational programs in pediatric patients have been developed.[4,9,12,13,14] Trends in reduction of CVC-related BSIs have been identified with the implementation of CVC practice guidelines and education programs.[3,15,16,17,18,19,20,21] Several investigators have reported specific risk factors (age, CVC type, diagnosis, treatment regimen) thought to be related to an increased incidence of CVC BSIs in children with cancer.[22, 23, 24] Currently, there are no published studies regarding the efficacy of a CVC registered nurse (RN) team for reduction of CVC-related BSIs in pediatric oncology patients.

This report describes the preliminary results of the first 6 months of a randomized, crossover, single-site, pilot study testing the use of a CVC RN team compared to standard care for the reduction of CVC-related BSIs in pediatric oncology patients. The primary aims of this pilot study were to evaluate 1) the feasibility of implementing a CVC RN team and 2) its effectiveness in reducing CVC-related BSIs compared to standard care. The secondary aims were to examine risk factors related to the development of CVC-related BSIs and to determine the required sample size for a future multi-site, randomized, prospective study using current rather than historical data.

Methods

After institutional review board approvals, a randomized, crossover trial of a CVC RN team versus standard care was initiated. This report summarizes data from the first 6-month arm of the single-site pilot study. The experimental intervention included daily application of the CVC blood draw bundle procedure (proper hand hygiene, use of clean gloves, gather appropriate supplies, alcohol 20-second scrub/10-second dry, stopcock method for blood discard, specimen and normal saline (NS) flush, maintain sterility, and proper disposal and handling) according to institutional policy and national standards performed by a CVC RN team member (EU).[4,11,12,13] Standard CVC care included daily performance of the same procedure by the assigned bedside RN (CU). The numbers of CVC-related BSIs were reported as the number of infections per 1000 catheter days. The relationship of patient acuity along with other selected risk factors (gender, age, CVC types, lengths of stay (LOS), reasons for admissions, and number of blood draws) potentially associated with BSI rates were also determined.

Subjects

The study subjects included pediatric oncology patients with a CVC. Subjects met al the following eligibility criteria: 1) a diagnosis of cancer with a CVC; 2) 2-16 years; and 3) admitted with a new oncology diagnosis, routine chemotherapy/radiation therapy treatment, or a non-infectious surgical or radiological procedure. Patients were excluded if they were 1) <2 or >16 years; 2) admitted with a defined infection; 3) under evaluation for a probable infection; and/or 4) receiving active end of life care.

Instruments

Gender, diagnosis, age, date of admissions, lengths of stay (LOS), patient acuity, CVC types, and reasons for admissions were abstracted from a general demographic data form and a daily patient status form that were completed during each admission. Patient acuity was measured by the Optilink Healthcare Management© patient acuity system (The Advisory Board Company, Washington, DC, USA, 2010) utilized at our children's hospital. The Optilink electronic management tool collected

in real time, and reasons for definition of acuity were recorded daily by the charge nurses. The principal investigator (PI) verified that the patient acuity recorded by the RNs on the daily patient status form was congruent with the Optilink management data. Individual patient data regarding BSIs were abstracted from the monthly laboratory confirmed BSI report generated by the hospital senior infection control coordinator. A CVC-related BSI was defined as a BSI occurring in study patients who had an indwelling CVC for at least 48 hours prior to the onset of the BSI.

A CVC blood draw bundle procedural checklist was used to record the number of blood draws performed and to document adherence to CVC evidence-based blood draw bundle procedures. The CVC RN team and/or bedside RN was required to complete this checklist for each blood draw procedure performed. Reliability of treatment and measures was ensured by providing staff education, confirming CVC care competencies and establishing validity and reliability of the checklist prior to study implementation.

Procedures

The PI provided education regarding the experimental study to both units prior to patient enrollment. The PI met with the parent/primary caregiver of each patient to explain the research study and obtain informed consent. For the EU, the consent process included permission for the CVC RN team to perform the blood draw procedures. In both units, which are spatially separated, identical nurse staffing patterns were employed according to institutional policy and California nurse:patient ratio requirements. Tunneled and non-tunneled CVCs were available for placement in pediatric oncology patients on both units. The decision regarding what types of CVC were placed in patients, however, was determined jointly by the primary physician and family.

All RNs on the study units had identical training, education, and competencies on institutional CVC procedures. Additionally, the 10-member RN team for the EU regularly participated as CVC skills

lab instructors and members of the unit-based CVC task force. The PI directly observed the team members performance on the EU and the bedside RNs on the CU for a total of 120 observations.

Statistical Analysis

A priori estimates from historical hospital data regarding patients meeting eligibility requirements indicated that approximately 140 admissions per month would be available for analysis. Power computations were based on a one-sided test with 10% ($p = .10$) type I error and 80% power to detect a halving of the estimated BSI incidence rate of 5/1000 catheter days. These admissions were projected to represent a total of 5600 catheter days, or approximately 7 catheter days per admission. The sample size was divided equally between units (EU and CU). A priori power computations were based on that of a two-sample log rank test with an underlying exponential failure process.

Comparison of patient and admission characteristics by unit was conducted by two-sided X^2 or Fisher's exact test for categorical variables and t-test or Wilcoxon test for continuous variables. Monthly rates of CVC-related BSIs per 1000 catheter days were recorded by unit. For analysis, each admission was considered an independent analytic case. Multiple admissions for the same patient were assigned the same study ID number and distinguished by admit date. The primary endpoint, the incidence rate of BSIs, was estimated for each unit by dividing the number of new infections by the total number of catheter days on the unit and reported as BSIs per 1000 days with 95% CIs. A one-sided Fisher's exact test was performed to determine whether the CVC RN team (EU) resulted in a 50% reduction, believed to indicate a clinically important change by the Institute for Healthcare Improvement in CVC-related BSIs compared to standard care (CU).[3,25]

The selected risk factors were examined for association with developing a BSI by calculating rates as described above for levels of categorical variables and dichotomized strata of continuous variables and comparing between groups with two-sided Fisher's exact tests for each unit separately, as well as for the entire combined sample.

Finally, power computations based on a one-sided test with 5% (p = .05) type I error and 80% power to detect a halving of the CU BSI incidence rate were performed to estimate the sample size needed for a future multi-site, prospective, randomized study to determine the efficacy of CVC RN team in reducing the risk by of developing a BSI compared to standard care.

Results

In the 6-month study period, there were a total of 47 patients/155 admissions with a total of 1582 catheter days and 1169 blood draws. There were 21 patients/60 admissions on the CU and 26 patients/95 admissions on the EU. The majority of the patients were diagnosed with acute lymphocytic leukemia (ALL) (n=10, 47.6%) on the CU compared to central nervous system tumors (n=6, 23.1 %) and osteosarcoma (n=6, 23.1%) on the EU. There was no overlap in diagnoses between the two units, so no comparisons were made between units on diagnoses.

Despite a similar number of admissions per patient, there was a significant increase in the length of stay (LOS; 15.0 + 11.2; p = 0.0066), on the CU compared to the EU. In contrast, there was a significant increase in the patient acuity (1.97 + 0.41 vs. 1.72 + 0.36; p = 0.0004) and number of blood draws per CVC days (0.96 + 0.75 vs. 0.61 + 0.36; p = 0.0046) on the EU versus the CU. Most importantly, there was a significance difference in the CVC types utilized on the units, with a significantly greater percent of tunneled versus non-tunneled CVCs on the EU compared to the CU (81% vs. 10%; p =<0.0001).

Over the 6-month study period, the 10-member CVC RN team covered successfully all blood draw procedures on the EU. During the 40 random observations of the CVC team's performance, the PI observed 100% procedural adherence to the evidence-based and unit guidelines. In 80 random observations of the RN staff on the CU, adherence was 83.6%. The mean time for completion of the procedure did not differ between the two units.

Rates of BSI in the CU and EU were 3.33/1000 and 2.94/1000 catheter days, respectively. There were five CVC-related BSIs: three on the CU and two on the EU. The selected risk factors in the five patients that developed BSIs are depicted in Table 3. The CVC RN team intervention (EU) did not significantly reduce the BSI rate compared to the bedside RN (CU) (2.94/1000 vs. 3.33/1000 catheter days; $p = 0.63$) (Table 4). The observed event rate in this initial study was 0.3%. Power computations for an adequately powered, larger, randomized, multi-site study revealed that a total of 24,700 catheter days would be required to determine a CVC team's effectiveness in reducing the risk of the current CU BSI rate of 3.33/1000 catheter days by 50%.

The BSI rates/1000 catheter days for selected risk factors in each unit and for the combined sample were determined. Univariate analysis of risk factors did not reveal any associations with later occurrence of a BSI.

Discussion

This is the first CVC RN team intervention trial for CVC-related BSI reduction in pediatric oncology patients. The concept of implementing a CVC RN team on a pediatric oncology unit was deemed feasible, and the team adhered to all policies and procedures 100% of the time. In the 15 months preceding the study, the institutional incidence of CVC-related BSIs for all patients admitted to the CU and EU ranged from 0 to 5.2 and 0 to 3.9 per 1000 catheter days, respectively. Although these preliminary 6-month results did not demonstrate a significant reduction in CVC-related BSIs in the EU compared to the CU, combined results from both units showed an overall reduction in the number of CVC-related BSIs compared to institutional historical data.

The current single-site pilot study accrued 72% less total catheter days than planned. The historical admission estimates for subject eligibility included all patients admitted to our two oncology units, compared to the selected and finite group of pediatric oncology patients enrolled in the pilot study, which led to lower power than anticipated.

Future studies utilizing larger sample sizes in a multi-site trial will be necessary to determine whether a CVC RN team will be effective in significantly reducing CVC-related BSIs.

Several factors may have accounted for these preliminary results. First, targeted CVC nursing education may have heightened staff awareness of the problem, resulting in a positive "bystander effect" on the bedside nurses on the CU. Second, ongoing and active participation in this research effort of all nurses may have contributed to the overall improved clinical outcome. Importantly, implementation of a CVC bundle blood draw checklist, an approach highly recommended by professional organizations,[12,13] may have served as an unanticipated intervention on the CU. The likelihood of this possibility is supported by previous reports of the advantages of checklists.[3, 4,12,13]

Other investigators in adult acute care facilities have studied the effect of specialty intravenous (IV) teams on IV complications, quality of care and hospital costs.[26, 27, 28, 29, 30, 31] These studies reported that the overall benefits with the implementation of a specialty IV team included reductions in BSI and phlebitis rates, hospital costs, bedside RN workload, and hospital LOS. In a randomized trial of 60 pediatric patients with CVCs, Nelson et al reported a significant reduction in CVC-related BSI rates with a team of RN experts performing CVC care compared to non-RN experts.[32]

In this study, three of the five patients who developed BSIs were diagnosed with acute myelogeous leukemia (AML). In a nonrandomized study of pediatric oncology patients with 418 CVCs, Fratino et al reported higher BSI rates in those with hematological disease versus those with solid tumors.[24] Additionally, the LOS on the CU was double compared to the EU. Although the LOS was not associated with risk of developing infection ($p = 0.19$), all five study patients who developed a BSI had LOSs greater than 7 days. Though these preliminary results further support that children with hematological malignancies and/or increased LOS with CVCs may be at greater risk for CVC-related BSIs, a larger cohort will be required to determine if these are independent risk factors.

This is one of the first studies to investigate patient acuity in the context of CVC-related BSIs in the pediatric oncology population. Patient acuity in the EU was higher than that of the CU. However, acuity levels were not significantly associated with risk of developing a BSI. Patient acuity is recognized as an important quality and safety indicator because, as patient acuity rises, more nursing resources are needed to provide care.[33] It is likely that the small number of observed BSIs and the limited distribution of acuity may have reduced the power of our CVC RN intervention to detect this relationship.

The current study patients who developed BSIs all had external CVCs. Four of the five infections were in patients with non-tunneled peripherally inserted catheters, which may also be associated with increase infection risk compared to tunneled catheters.[34] There are inconclusive reports that suggest that tunneled, externalized, double-lumen catheters are significantly associated with increased rates of BSIs.[15,22] In a prospective study of 286 CVCs in 264 pediatric oncology patients, Mirro et al demonstrated a trend toward lower rates of BSIs with implanted ports compared to external CVCs.[22] Abbas et al reported no significant difference in BSIs in children with cancer with 199 external CVCs compared to 87 implanted ports.[23] Further studies with a larger cohort will be required to determine whether CVC type is a significant risk factor in the development of CVC-related BSIs in pediatric oncology patients.

Each CVC blood draw procedure increases a patient's vulnerability for risk of BSI. In each unit separately and in both units combined, the BSI rate did not differ between in the groups of children who had <5 vs. >5 blood draws per 1000 catheter days. However, all the patients who developed a BSI during their admission had greater than five blood draws. These findings suggest that frequent CVC hub access blood draw procedures may increase the risk of BSI. Thus, to reduce CVC-related BSIs, it may be important to limit the number of blood draws by batching specimen collections whenever possible.

There were several limitations to our study. Generalizability of the study results from a single institution may not hold true for all pediatric oncology patients.

Additionally, historical data, which included all patients admitted to our two oncology units, were utilized for estimation of sample size. However, fewer eligible pediatric oncology patients were available during the study period, which yielded a lower power than anticipated. This insufficiently powered study may have incorrectly concluded that the relationship between the team intervention and rate of BSIs was not significant. Additionally, due to small sample size and an overall low BSI rate, multivariate regression analyses regarding risk factors for BSI were not possible.

Heterogeneity of the patients on the two units may have limited the effectiveness of the CVC RN team intervention, because patients on the EU and CU had different diagnoses and treatment regimens which could have influenced their risk of BSI. To minimize this risk, patients were enrolled if they were admitted for routine chemotherapy and were excluded if a pre-existing infection was suspected. Other heterogeneities of the patients on the two units, including variables such as CVC type, patient acuity or age, were not equally stratified on both units. Last, an additional limitation may have included the possibility of experimenter expectancies, if RNs perceived the investigator's desired responses ("Hawthorne effect"). To control for this limitation, the investigator included in the staff education a discussion of the importance of documenting behaviors accurately, with emphasis on the anonymity of data collection.

In summary, these preliminary results demonstrated the feasibility of implementing a CVC RN team for CVC blood draw procedures in pediatric oncology patients. The results of this pilot study from both units suggest in part that essential CVC BSI prevention interventions should include targeted CVC nursing education, ongoing and active staff nurse participation in CVC BSI prevention research, and implementation of a CVC care bundle checklist. Furthermore, a larger cohort in a multi-site study will be required in the future to determine the effectiveness of a CVC RN team intervention in reducing BSIs and to determine if the previously mentioned risk factors are significantly associated with the development of CVC-related BSIs in pediatric oncology patients.

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Planned Publications:

1. The Feasibility of a Central Venous Catheter (CVC) Blood Draw Bundle Checklist in a Randomized Intervention Study

2. Results from a Randomized Prospective Pilot Study Evaluating a Central Venous Catheter Team in Reducing Catheter-Related Bloodstream Infections In Pediatric Oncology Patients