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ORIGINAL ARTICLE

Infective and thrombotic complications of central venous catheters in patients with hematological malignancy: prospective evaluation of nontunneled devices

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Abstract
Goals Central venous catheter (CVC)-related bloodstream infection (CR-BSI) is a significant complication in hematology patients. A range of CVC devices may be used, and risks for the development of complications are not uniform. The objectives of this study were to determine the natural history and rate of CVC-related complications and risk factors for CR-BSI and to compare device-specific complications in a hematology population.
Patients and methods An observational cohort of patients with hematologic malignancy was prospectively studied following CVC insertion. Participants were reviewed until a CVC-related complication necessitated device removal, completion of therapy, death, or defined end-of-study date. The National Nosocomial Infection Surveillance definition for CR-BSI was used. Overall and device-specific rates of infective and noninfective complications were calculated and potential risk factors were captured.
Main results One hundred six CVCs (75 peripherally inserted central venous catheters [PICCs], 31 nontunneled CVCs) were evaluated in 66 patients, over 2,399 CVC days. Thrombosis occurred in 16 cases (15.1%), exit-site infection in two (1.9%), and CR-BSI in 18 (7.5 per 1,000 CVC days). No significant differences were found when complication rates in PICC and nontunneled devices were compared. An underlying diagnosis of acute myeloid leukemia was negatively associated with CR-BSI (odds ratio (OR) 0.14, $p=0.046$), and a previous diagnosis of fungal infection was associated with infection (OR 22.82, $p=0.031$).
Conclusions CR-BSI rates in our hematology population are comparable to prior reports. A low rate of exit-site infection and high proportion of thrombotic complications were observed. No significant differences in thrombotic or infective complications were evident when PICC and nontunneled devices were compared. PICC devices are a practical and safe option for management of hematology patients.

Keywords CVC-related bloodstream infection · Thrombosis · Peripherally inserted CVC · Nontunneled CVC · Hematology · Surveillance

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Introduction

Patients with hematologic disorders frequently require the insertion of medium or long-term central venous catheters (CVCs) for stem-cell transplantation, the administration of chemotherapy, or transfusion of blood products. This patient population is also at increased risk of infection, including CVC-related bloodstream infection (CR-BSI) [2, 23]. CR-BSI is associated with prolonged hospitalization,

increased healthcare costs, and increased mortality [20]. However, robust and reproducible surveillance strategies are not frequently employed in this population [21, 22].

Diagnosis of CVC-related mechanical and infective complications in hematology patients is difficult [3], and few studies have prospectively used standardized and comparable methodology to monitor infective and noninfective complications in this population. The objectives of this study were to:

1. Determine the natural history of CVC insertion and complications, including the timing of onset of infections with regard to catheter placement in patients with hematologic malignancy
2. Establish risk factors for CR-BSI in patients with hematologic malignancy
3. Compare infective and mechanical complications according to type of CVC used

Materials and methods

Study population and setting

The Peter MacCallum Cancer Centre (PMCC) is a tertiary cancer center, including a large hematology unit. Autologous, but not allogeneic, stem-cell transplantation is performed. For new CVC placement, elective or semi-elective insertion is performed under radiological guidance or in the operating theater, rather than in emergency or uncontrolled environments. During the study period, antibiotic prophylaxis was not routinely administered at the time of CVC insertion.

The study population was defined as adult patients with hematologic malignancy who were expected to become neutropenic (absolute neutrophil count $<0.5\times10^9$/L for ≥7 days) following insertion of a medium- or long-term CVC. The studied cohort of catheters was defined as each consecutive CVC inserted over a 6-month period (May–November 2005). Where an individual patient had more than one catheter inserted during the study period, each was regarded as a separate event. Identification of potential study participants was facilitated by daily review of recorded bookings made within the PMCC radiology department for new catheter insertions under radiological guidance.

Following catheter insertion, a standardized clinical care plan for catheter care was followed. Twenty-four hours after CVC insertion, the primary dressing was replaced with a sterile occlusive film dressing. This was changed weekly or more frequently if not completely intact, dry, and clean. When not in use, a heparin lock (heparinized saline, 50 U in 5 mL) was instilled weekly into each CVC. The policy for management of febrile neutropenia included the collection of three sets of blood cultures after the onset of fever in neutropenic patients (one peripheral and one drawn from each lumen of a double-lumen central venous catheter). Repeat septic workup (including further three sets of blood cultures) was recommended if a new fever developed within 48–72 h of the first febrile episode.

The study was approved by the institutional human ethics review committee. Consent for study participation, use of microbiology and hematology results, and regular review throughout study period was obtained from each patient by the study investigator or infection-control nurse. At the time of CVC insertion, participants nominated a preferred mode and time for telephone contact to be made, in the event of hospital discharge with CVC in situ. Patients were reviewed weekly until completion of study period (6 months), a complication necessitated catheter removal (infection, thrombosis/occlusion), treatment was completed, or death.

Definitions

The following definitions were used:

(a) CVC: A CVC was defined as any of the following: peripherally inserted central venous catheter (PICC), nontunneled central venous catheter (e.g., Arrowcath™), or tunneled venous access device (e.g., Hickmans). Single, double, or triple lumen devices were eligible. Patients with peripheral venous catheters, Swan-Ganz catheters, or hemodialysis catheters alone were excluded.

(b) Catheter event: All complications related to catheter placement: infective (exit-site infection, tunnel infection, CR-BSI, suspected CR-BSI, clinical sepsis) and noninfective (thrombosis, thrombophlebitis).

(c) CR-BSI: The National Nosocomial Infection Surveillance (NNIS) definition [10] was used, requiring that either: (1) the patient had a recognized pathogen cultured from one or more blood cultures and the pathogen cultured from blood was not related to an infection at another site or (2) the patient had at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension, and at least one of the following:

- Common skin contaminant (e.g., diphtheroids, *Bacillus* spp., *Propionibacterium* spp., coagulase-negative staphylococcus, or micrococci) cultured from two or more blood cultures drawn on separate occasions.
- Common skin contaminant (e.g., diphtheroids, *Bacillus* spp., *Propionibacterium* spp., coagulase-negative staphylococcus, or micrococci) cultured

from at least one blood culture from a patient with an intravenous line, and the physician instituted appropriate antimicrobial therapy.

Signs and symptoms with positive laboratory results were not to be related to an infection at another site. Antigen testing on blood as a means of microbiological confirmation (e.g., *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Neisseria meningitidis*, or group B streptococcus) was not performed.

(d) Suspected CR-BSI: Suspected CR-BSI was defined as removal of a CVC because CR-BSI was suspected by the treating clinician. These events were classified as "suspected CR-BSI: microbiologic" if the decision to remove the CVC was based upon exit swab or blood culture result (central or peripheral), where criteria for the NNIS definition were not fulfilled, and classified as "suspected CR-BSI: clinical" if the decision to remove the CVC was based upon clinical factors only (cause of fever not identified by septic workup, or fever persisting despite empiric antimicrobial therapy).

(e) Exit-site infection: According to Infectious Diseases Society of America recommendations [14], exit-site infection was defined as the presence of erythema, induration, and/or tenderness within 2 cm of the catheter exit site and may have been associated with other signs and symptoms of infection, such as fever or pus emerging from the exit site, with or without concomitant bloodstream infection.

(f) Thrombosis and septic thrombophlebitis: Thrombosis was defined as clinically identified occlusion of ≥1 lumen of CVC. Septic thrombophlebitis was defined as continued positive blood cultures after catheter removal, with radiological confirmation of venous thrombosis.

Data collection

A range of reported risk factors for CVC-related bloodstream infection in patients with hematologic malignancy were collected at specified times throughout the entire period for which each catheter remained in situ for each patient. Table 1 lists all potential risk factors and the timing of data capture. In brief, data were captured at study entry, weekly review, and study exit. Date of catheter insertion was recorded at study entry and the following baseline data were also collected: demographics, underlying malignancy, most recently administered chemotherapy, hematopoietic stem cell transplantation during previous 12 months, type of catheter, location of catheter insertion, and number of previous episodes of CR-BSI.

Weekly review, performed by the study investigator or an infection-control nurse, was direct (chart review and clinical examination if patient was hospitalized with CVC in situ) or indirect (telephone contact with patients in the community who had CVC in situ). Symptoms of catheter events were obtained (fever, pain, or exudate at exit site), and assessment for possible risk factors was made (receipt of antibiotic therapy or total parenteral nutrition, staff member responsible for accessing device; Table 1). Neutropenic episodes and severity of mucositis were recorded at time of weekly review and by review of hospital pathology results.

Specific data were captured for all infective and noninfective complications. One or more catheter events were permitted for each study participant and each CVC during the study period, with each recorded separately. The dates of study completion, CVC removal, or death were used to calculate the total number of observed catheter days per patient.

Statistical analysis

Data were entered into an Access database, before importing to Stata 8 for analysis. The rate of CR-BSI was calculated using the denominator of "per 1,000 CVC days" [15]. Potential risk factors for catheter outcomes were determined by univariate and multivariate logistic regression, using a forward stepwise model with exclusion of variables with $p>0.2$. Fisher's exact test was used to compare proportional outcomes according to device.

Duration of cannulation prior to development of CR-BSI was modeled using the technique of survival analysis. The effect of prognostic variables was expressed in terms of hazard ratios, with data censored at time of study end-date. This method enabled the inclusion of multiple episodes of cannulation in an individual patient, with "previous infection" as a covariate. The analysis included an assessment of proportional hazards assumptions.

Results

Patient and catheter characteristics

In total, 106 catheters were studied in 66 patients: Forty-one patients had a single catheter, 16 had two catheters, eight had three catheters, and one had nine catheters inserted during the study period. Thirty-eight patients were male and 28 patients were female, with a median age of 56.2 years (range 17.2–77.8 years). Underlying hematologic disorders are listed in Table 2, with lymphoma and acute myeloid leukemia (AML) comprising the majority. "Other" conditions included one each of mycosis fungoides, testicular teratoma, neuroblastoma, myelomonocytosis, essential thrombocythemia, osteosarcoma, Burkitts lymphoma, and myelodysplasia.

Table 1 Potential risk factors and timing of surveillance data capture

Risk factor category	Potential risk factor	Timing of data collection
Comorbid conditions	Diabetes mellitus	Study entry
	Obesity	
	Previous number of catheter insertions	
	Previous catheter events (complications)	
Malignancy-related factors	Underlying disease	Study entry
	Chemotherapy	
	Transplantation	
Catheter insertion factors	Type of device used	Catheter insertion
	Location of device	
	Neutropenia at time of insertion	
	Antibiotics at time of insertion	
Catheter care and host susceptibility	Antibiotic therapy	Weekly review
	Number of times device accessed	
	Individual accessing the device	
	Receipt of TPN	
	Number of neutropenic days	
	Mucositis grade	
	G-CSF administration	
	Occlusion or thrombosis	
	Other events, e.g., exit site infection	
Denominator	CVC days	Study exit

TPN total parenteral nutrition, *G-CSF* granulocyte colony-stimulating factor, *CVC* central venous catheter

Seventy-five of the studied catheters (70.8%) were PICC devices, and 31 (29.2%) were nontunneled CVCs. No tunneled devices were inserted. Of the nontunneled CVCs, six were inserted into the femoral vein and eight into the internal jugular vein. The remaining 17 were inserted into a subclavian vein. Of the PICC devices, two were inserted into a femoral vein, and the remaining 73 were inserted into upper limb veins.

Table 2 Composition of study cohort, by underlying disease

Underlying hematologic disorder	Number of patients studied
Lymphoma	30
Acute myeloid leukemia	13
Myeloma	9
Transformed MDS	4
ALL	1
CLL	1
Other	8
Total	66

MDS myelodysplastic syndrome, *ALL* acute lymphoblastic leukemia, *CLL* chronic lymphocytic leukemia

Natural history of CVC insertion and complications

The mean duration that catheters remained in situ was 22.6 days (standard deviation (SD) 22.84), with a range of 1–114 days. Figure 1 shows the distribution of catheters according to number of days in situ. For PICC devices, the mean duration the catheters remained in situ was 24.2 days (SD 24.3); for nontunneled CVCs, the mean duration of catheterization was 18.8 days (SD 18.7; $p=0.27$).

Catheter outcomes

Exit-site infection occurred in just two cases (1.9%). In one, a PICC device developed intraluminal thrombosis, and *Bacillus* spp. was isolated in blood culture, leading to catheter removal. In the other, a nontunneled CVC was removed following the clinical diagnosis of exit-site

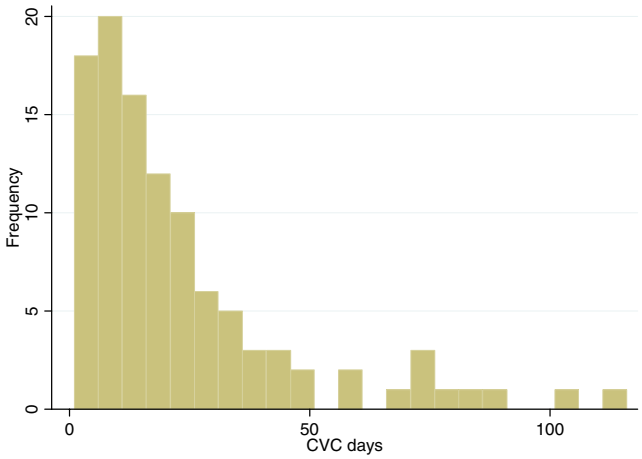

Fig. 1 Frequency distribution: in situ catheter days

infection. The rate of exit site infection was therefore 0.83 per 1,000 CVC days (95% confidence interval (CI), 0.10–3.01 per 1,000 CVC days).

Sixteen of the 106 catheters (15.1%) developed thrombosis (two also developed CR-BSI), necessitating catheter removal in 15 cases. The time to event plot for thrombosis is shown in Fig. 2a.

Overall, 33 catheters (31.1%) were suspected to be associated with bloodstream infection. In 23 cases (21.7%), microbiological results (blood culture ± catheter tip culture) provided the basis for the treating clinician to commence directed antibiotic therapy or remove the device. In ten cases, a clinical diagnosis only was made (persisting fever, despite antibiotic therapy, without confirmatory microbiological test results). Eighteen cases fulfilled NNIS criteria for CR-BSI, resulting in an overall rate of CR-BSI of 7.50 per 1,000 CVC days (95% CI, 4.45–11.86 per 1,000 CVC days).

Comparison according to device

Table 3 summarizes catheter outcomes according to device. One exit-site infection occurred in association with a PICC device and the other with a nontunneled device (p=0.501).

Fourteen of the 16 episodes of thrombosis occurred in association with a PICC device, with only two episodes of thrombosis observed in nontunneled CVCs. For PICC devices, the rate of thrombosis was therefore 18.7%, or 7.71 per 1,000 CVC days, and for nontunneled CVCs, the rate of thrombosis was 6.5%, or 3.42 per 1,000 CVC days (p=0.142). Time to onset of thrombosis was not significantly different for PICC devices compared to nontunneled CVCs (p=0.285; Fig. 2b).

Twelve of the 18 CR-BSIs occurred in association with PICC devices. The rate of infection in this group was therefore 6.61 per 1,000 CVC days, compared to a rate of infection of 10.27 per 1,000 CVC days for nontunneled catheters (p=0.777).

Risk factors

Results of univariate and multivariate analysis are summarized in Table 4. After adjustment for other variables, an underlying diagnosis of AML was negatively associated (protective effect) with CR-BSI (odds ratio (OR) 0.14, p=0.046), and a previous diagnosis of fungal infection was associated with infection (OR 22.82, p=0.031). No other factors examined were significantly associated with this outcome.

Time to infection

For all devices, the median time to development of CR-BSI was 14 days (range 6–82 days). Using CR-BSI as the failure event, the log-rank test for equality of survival functions was applied for each studied risk factor. Of the variables studied, the presence of exit-site infection showed a significant difference in time to development of CR-BSI (p=0.02). Cox regression analysis, however, did not demonstrate a significant association between the presence of exit-site infection and time to developing CR-BSI (p=0.052).

Discussion

This study is the first to apply standardized surveillance methodology for CR-BSI in an Australian hematology unit. Furthermore, noninfective complications of CVC use in this population are reported. Such monitoring is important for benchmarking, for quantifying the impact of interventions for risk reduction, and for accountable resource allocation for preventive strategies.

Predominantly, patients had lymphoma or AML, many likely to have received previous therapies prior to the onset of CR-BSI. Institutional preference and clinician behavior were in favor of using PICC devices (approximately 70% of all CVCs inserted during the study period), with an overall mean duration of catheterization of 22 days. These observations may reflect an increasing preference for use of medium-duration CVCs and to facilitate venous access in ambulatory-care settings. The studied population did not include allogeneic stem cell transplant recipients, and this may be relevant if findings are to be applied elsewhere, as previous studies have suggested a higher rate of infection in this group when compared to autologous stem cell transplant recipients or hematology patients receiving conventional chemotherapy [4–6].

No statistical difference was demonstrated in the rate of thrombosis for PICC devices, compared to nontunneled devices. Previous reports have suggested that thrombogenicity of PICC devices is greater, related to endothelial injury

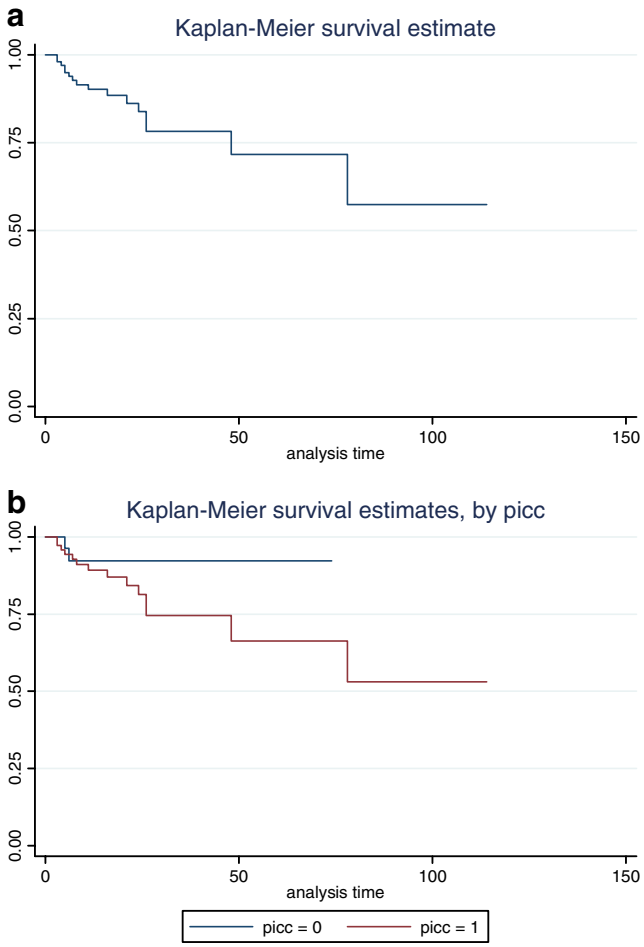

Fig. 2 **a** Kaplan–Meier curve for time to thrombosis, all CVCs. **b** Kaplan–Meier curve for time to thrombosis, by device (*blue* = nontunneled CVC, *red* = peripherally inserted CVC; p=0.285)

and phlebitis following device insertion [1]. One retrospective study of heterogeneous patient populations estimated the rate of thrombosis to be 38% for PICC devices [1]. However, asymptomatic radiologically defined events were included as outcomes. This is in contrast to studies of clinically relevant or symptomatic episodes of thrombosis [8, 11], estimated to occur at a rate of 3.9–12% when PICC devices are used, with highest rates seen with wider-bore catheters (e.g., 9F) [8]. The rate observed in the current study (18.7%) is higher than previous reports and may be related to factors specific to the studied hematology population. For example, phlebitis induced by particular chemotherapeutic agents administered via the studied PICC devices, or the frequency of accessing CVCs for administration of blood products or antibiotics may play a contributory role. As a comparison with tunneled devices, the rate of thrombosis in Hickman catheters at our center has previously been estimated to be 14% [19].

Very few exit-site infections were observed (n=2), this possibly related to devices remaining in situ for medium-term, rather than long-term, duration (mean number of days=22). The low rate of exit-site infections observed with PICC devices (0.55 per 1,000 CVC days) is consistent with a large retrospective study of hospitalized patients (0.24 per 1,000 CVC days) [16]. However, this study did not specifically include immunocompromised or hematology patients. In the current study, although log-rank survival analysis suggested a significant association between presence of exit-site infection and time to onset of CR-BSI, statistical significance was not demonstrated after adjustment for other variables, likely related to the small number of observed events.

The rate of CR-BSI was higher than previous reports, although published rates vary considerably according to study population and definitions employed. For example, lower rates of CR-BSI (2.2 per 1,000 CVC days) were reported in an ICU population where duration of catheterization was considerably shorter (mean 11.3 days), and risks for infection related to neutropenia and underlying malignancy were not likely to be comparable to the current study [18]. The observed overall rate of 7.5 per 1,000 CVC days (and for PICC devices, 6.6 per 1,000 CVC days) was approximately threefold higher than Harter et al., who prospectively evaluated the use of PICC devices in adult hematology patients, with an observed rate of 2.2 CR-BSIs per 1,000 CVC days [9]. One explanation for this is the fact that a clinical definition was employed in that study, whereas the higher rate observed in the current study was based upon a surveillance definition. When a clinical definition is used, the rate of CR-BSI in the current study (3.3 per 1,000 CVC days) is comparable to the previous report. A prior Australian study of hematology–oncology

Table 3 Catheter outcomes, by device

Outcome	PICC (N=75)			Nontunneled CVC (N=31)			p value	Overall (N=106)		
	n	Per 1,000 CVC days	95% CI	n	Per 1,000 CVC days	95% CI		n	Per 1,000 CVC days	95% CI
Exit site infection	1	0.55	0.01–3.07	1	1.71	0.04–9.54	0.50	2	0.83	0.10–3.01
Thrombosis	14	7.71	4.22–12.94	2	3.42	0.41–12.37	0.14	16	6.67	3.81–10.83
CR-BSI	12	6.61	3.42–11.55	6	10.27	3.77–22.36	0.78	18	7.50	4.45–11.86

PICC peripherally inserted CVC, *CVC* central venous catheter, *CR-BSI* catheter-related bloodstream infection

Table 4 Crude and adjusted odds ratios for factors associated with catheter-related bloodstream infection

Variable[a]	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p* value	OR	95% CI	*p* value
Sex	1.369	0.494–3.794	0.55			
Weight	0.999	0.964–1.035	0.94			
Diabetes	1.235	0.130–11.749	0.85			
Underlying disease = AML	0.429	0.115–1.602	0.21	0.144	0.021–0.970	0.046
Underlying disease = lymphoma	2.293	0.790–6.656	0.13			
Previous transplantation	0.522	0.109–2.490	0.42	0.046	0.001–1.699	0.095
Indication = chemotherapy	1.800	0.590–5.492	0.30			
Indication = HSCT	1.267	0.318–5.040	0.73			
Indication = antimicrobial	0.807	0.241–2.704	0.73			
Device = PICC	0.794	0.268–2.346	0.68			
Internal jugular insertion site	1.800	0.331–9.779	0.50			
Neutrophil count	0.951	0.819–1.104	0.51			
Neutropenia	0.661	0.136–3.198	0.61	5.551	0.576–53.496	0.14
Antibiotics received at insertion	0.500	0.152–1.649	0.26	0.136	0.018–1.046	0.055
Previous thrombosis	1.120	0.658–1.905	0.68			
Previous suspected BSI	0.956	0.557–1.639	0.87			
Previous confirmed BSI	0.571	0.078–4.202	0.58			
No. of previous device insertions	1.065	0.804–1.411	0.66			
Previous fungal infection	2.733	0.615–12.143	0.19	22.824	1.339–388.953	0.031
Neutropenic episodes	1.560	0.510–4.772	0.44			
Thrombosis	0.875	0.177–4.334	0.87			
Exit-site infection	5.118	0.305–85.868	0.26			
No. of CVC days	1.003	0.981–1.025	0.78			

AML acute myeloid leukemia, *HSCT* hematopoietic stem cell transplantation, *PICC* peripherally inserted CVC, *BSI* bloodstream infection, *CVC* central venous catheter

[a] Variables "indication = blood product", "indication = TPN", "indication = inotropes", "insertion site = femoral", and "previous exit site infection" dropped because absence of variable predicted CR-BSI perfectly; variable "previous tunnel/pocket infection" dropped because of collinearity

patients with tunneled CVCs has reported the rate of CR-BSI to be 2.6 per 1,000 CVC days [7], consistent with reports of higher rates of CR-BSI when nontunneled CVCs are compared to tunneled devices [12].

Of all collected variables, we demonstrated that underlying disease and previous fungal infection were associated with CR-BSI, and this may be relevant for the planning of ongoing targeted surveillance strategies in this population. A negative association was observed between CR-BSI and an underlying diagnosis of AML. Reasons for this remain unclear but may include the frequent use of empiric antibiotic therapy in this group, leading to reduced risk for infection. Previous fungal infection was found to be associated with infection. This may be an indication of the degree of previous immunosuppression (disease- or treatment-related) contributing to contemporary risk for developing bloodstream infection.

Nonimplanted devices may have a higher rate of accidental loss [13], and this may be expected to be the case for noncuffed devices inserted into upper limb veins, such as those in the current study. However, we did not observe CVC dislodgement in any of the studied CVCs, and these findings are consistent with a large study of oncology patients where durability was demonstrated when a similar device and insertion site were used [17].

A limitation of the study includes the fact that device selection was not randomized, and choice was dependent upon the practice of the treating clinician. Potential bias related to past history, disease- or treatment-related factors was not examined. In addition, tunneled devices were not evaluated. Larger and multicenter evaluation would facilitate comparison of tunneled CVCs with PICC devices and potentially capture a broader range of patient groups (e.g., allogeneic transplant recipients). Future agendas must also address effective and easily implemented preventive measures. For example, CVC locks with novel agents (ethanol, trisodium citrate) may prevent CR-BSI. Findings of the current study support ongoing use of PICC devices in the studied hematology population. However, together with safety and clinical outcome data, economic evaluation of PICC devices in the hematology population is now required to enable responsible product selection by individual units and healthcare facilities.

In summary, rates of CR-BSI in an Australian hematology population were comparable to previous international reports, with a low rate of exit-site infections. Although high rates of CVC thrombosis were observed, there was no significant difference in thrombotic or infective complications when nontunneled and PICC devices were compared. Our findings suggest, therefore, that PICC devices are a viable and safe option for management of the hematology patient.

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