Neurocrit Care (2020) 32:400–406
https://doi.org/10.1007/s12028-019-00843-z

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ORIGINAL WORK

A Randomized Trial of Complications of Peripherally and Centrally Inserted Central Lines in the Neuro-Intensive Care Unit: Results of the NSPVC Trial

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Abstract

Objective: The objective of this study was to compare the relative number of complications from peripherally inserted central venous catheters (PICC) and centrally inserted central venous catheters (CVC) in the neuroscience intensive care unit (NSICU).

Methods: This study was carried out in a 32-bed NSICU in a large academic hospital in the USA from July 2015 until January 2017. Patients admitted requiring central venous access were randomly assigned to have a PICC or CVC inserted. Complications were recorded and compared. The primary outcome was all complications as well as combined numbers of large vein thrombosis, central-line-associated blood stream infections, and insertional trauma. Outcomes were compared using the Fisher's exact test, logistic regression, or unpaired *T* tests, as appropriate.

Results: One hundred and fifty-two patients were enrolled; 72 were randomized to the PICC arm and 80 to the CVC arm. There were no crossovers, withdrawals, nor losses to follow-up. The study was stopped at the second pre-planned interim analysis for futility. The combined number of large vein thrombosis, central-line-associated blood stream infection, and insertional trauma was 4/72 in the PICC arm and 1/80 in the CVC group (OR 4.6 (95% CI 0.5–42.6) $p = 0.14$). The number of all complications in the PICC arm was 14/72 compared to 10/80 in the CVC arm (OR 1.7 (95% CI 0.7–4.1) $p = 0.24$).

Conclusions: PICCs and CVCs have similar numbers of complications when placed in patients admitted to the NSICU.

Keywords: PICC, CVC, Central line, Peripherally inserted central catheter, Neuro ICU, ICU

Introduction

Central lines provide needed vascular access in critically ill patients and their use is common [1]. Central lines are available as both peripherally inserted central venous catheters (PICC) and centrally inserted central venous catheters (CVC). The use of both types of lines is common in the intensive care (ICU) setting [1].

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This study was carried out in accordance with the CONSORT standards and a checklist is provided.

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These two types of central lines provide similar vascular access, but the risk profile between them may be different [2–5]. When debating the relative merits of the different catheter choices, some have focused on the increased risk of large vein thrombosis (LVT) associated with PICCs [4, 6, 7]. Others have focused on the insertion-related complications of CVCs that can be entirely avoided by placing PICCs [5, 8–10]. Previous comparisons of central line types have been mixed: some studies indicate that PICCs and CVCs are equivalent whereas others suggest one may be superior to the other [2, 11–13]. The differences in these results may be due to patient selection; the patient population being studied, as well as the endpoints selected by the authors.

The Neurosciences Intensive Care Unit (NSICU) represents a unique patient population [14]. Patients in the NSICU often suffer from decreased mobility, decreased mental status and hemiplegia. This provides a unique set of risk factors for central-line-associated complications in both PICCs and CVCs. Previous studies have attempted to address these issues in a retrospective fashion or by focusing on one specific complication of central lines [4, 11]. These studies do not account for the relative increase in other types of complications that may occur in CVCs vs. PICCs or vice versa. Further, these studies relied on a dedicated vascular access team for the placement of PICCs, potentially leading to a strong bias for only the healthiest patients or those needing lines during normal business hours to be enrolled. Studies that focus on only a single complication associated with central access (i.e., pneumothorax or deep vein thrombosis) offer limited guidance as to the appropriate choice of vascular access, since intensivists must weigh all the complications of a given procedure when choosing an intervention.

Objective

The objective of this study was to determine the relative number of complications between PICCs and CVCs placed in patients in the NSICU. The primary outcomes were the number of all complications as well as the number of more classical complications associated with central line placement (LVT, central-line-associated blood stream infection [CLABSI] and insertion-related trauma).

Materials and Methods

Design

This study was a prospective randomized controlled trial. Patients were considered eligible if they were admitted to the NSICU and required central venous access. Exclusion criteria included inability to speak English, renal failure, emergent situation requiring central venous access that would preclude time for informed consent, preexisting LVT anywhere in the body, existing central venous access, and preexisting bacteremia.

Randomization was carried out by means of a computer-generated randomized sequence with equal allocation to each arm and no blocking scheme. Allocation was concealed to the patients and researchers prior to enrollment. Study endpoints were failure to insert the catheter, removal of the device, discharge from the hospital, or death. Assessments of complications were completed by the attending NSICU intensivist caring for the patient and documented in the chart. Assessments were not masked because of the obvious clinical differences between a PICC and a CVC. Workup and evaluation of complications (i.e. cultures to identify CLABSI or venous Doppler studies to identify LVT) were performed at the treating physician's discretion based on clinical findings. This was done to focus trial data on clinically relevant complications rather than those identified on screening tests in patients without symptoms that are more likely to represent a false positive or finding of no clinical significance [15, 16]. PICCs were placed by study authors after a requisite online course as well as attending a training course with a Bard Access representative. Individuals were then proctored until competency placing PICCs was achieved. All study authors had placed greater than 50 central venous catheters prior to randomization. Study members were available 24 h per day, 7 days per week, including holidays, to place lines for patients eligible for the study to maximize enrollment.

This study was carried out with the approval and under the supervision of the institutional review board and departmental data safety monitoring board (DSMB) in accordance with accepted ethical standards. It was registered prior to enrollment with ClinicalTrials.gov (NCT02314520). All participants, or their legally authorized representatives, signed informed consent prior to enrolling in the study.

Based on a previous observational report, the difference expected between PICCs and CVCs for the primary outcome was 11% versus 4% [4]. Using this as well as an alpha of 0.05 and a power of 0.8, the number of patients needed in each arm to find that difference was 181. Interim analyses were pre-planned when the study reached enrolment of 50 and 150. At these points, the DSMB would decide on the continued safety and feasibility of the study. Analysis of the data outside of the prespecified interim analyses was not permitted.

Technique

Insertion of PICCs (Bard Access Systems, Inc. Salt Lake City, UT) was performed using a Bard Site Rite

ultrasound with the Sherlock tip confirmation system. The largest vein above the elbow was chosen as the insertion site. If the patient was hemiparetic, the non-paretic side was chosen for insertion unless there were other factors to guide placement (traumatic injuries, etc.). Guidance of the catheter toward the superior vena cava was aided by magnetic tip guidance. Final tip position was confirmed by bedside chest X-ray. Insertion was carried out by study authors (NB, JD, RP) utilizing the institutional sterile bundle for line placement. Line maintenance was carried out by nurses with specialized training in line maintenance according to institutional protocols. Dressings were changed under sterile conditions. Insertion failure was determined by the inserting physician at their discretion without prespecified guidelines.

Insertion of CVCs (Teleflex, Inc., Reading, PA) was done with ultrasound assistance for internal jugular placement and based on anatomic landmarks for subclavian placement. Side and site of line placement were at the placing physician's discretion, and no specific attention was given to the side of hemiparesis. Final tip position was confirmed with portable chest X-ray. Insertion was carried out with sterile technique using the hospital's sterile bundle and line maintenance was identical to the PICC lines.

Physicians could change sites of insertion or add adjuncts to improve odds of success after an insertion attempt had begun. For example, during PICC placement the brachial vein could be accessed whether the cephalic had been attempted unsuccessfully, or the other arm could be tried. Likewise, in placing CVCs, the internal jugular approach could be used if the subclavian proved unsuccessful.

Lines were assessed daily by the treating intensivist for necessity, and when no longer needed, they were removed. The treating intensivist also assessed lines for complications and if suspected, an appropriate workup was carried out (for instance, blood cultures and venous duplex studies would be ordered for fever workup). No surveillance cultures or ultrasound studies were performed. If the patient was discharged from the NSICU with the line still in place, the study team continued to follow the patient and discuss the need for central access with the primary team and when the line was no longer needed it was discontinued. In rare circumstances, a patient was discharged to a rehabilitation hospital with a PICC in place, but never with a CVC.

Variables and Statistical Analysis

The primary outcome variables were all combined complications. Classical complications of central line insertion were also examined in isolation (CLABSI, LVT, insertional trauma). Traumatic complications related to insertion were pneumothorax, hemothorax, arterial dilation, and venous laceration. Secondary outcomes included NSICU days, and mortality. Secondary analyses were based on other independent variables recorded. These included the presence of hemiparesis, Glasgow Coma Scale (GCS), the use of ultrasound for CVCs, and primary diagnosis. Basic demographic data were also collected. When contingency tables contained 0 values, estimations (such as the Haldane–Anscombe) were not used because the small numbers of events introduced too much error.

Categorical variables were compared with contingency tables and Fisher's exact test. Ordinal variables were compared using logistical regression. Continuous variables were compared with unpaired *t* tests. Microsoft Xcel (Microsoft Inc., Redmond, WA) and XLSTAT (Addinsoft Inc., New York, NY).

Results

Patients and Enrollment

Five hundred and eighty patients were admitted to the NSICU during the study period, of those, 152 were enrolled. Seventy-two were randomized to the PICC arm and 80 to the CVC arm. There were no crossovers or losses to follow-up so an intention to treat analysis was unnecessary. The demographic details of the patient cohort are summarized in Table 1. The enrollment of the patients is summarized in Fig. 1.

Primary Outcomes

At the second interim analysis, the DSMB determined that the study was unlikely to achieve its prespecified endpoint, and it was terminated early. The reason was the very low number of complications. The total number of complications across both groups was similar (Table 2). When only classical complications were examined, the number of complications was again similar between cohorts (Table 2). The PICC cohort suffered four LVTs. All LVTs were detected while the patients were admitted to the NSICU. The CVC suffered one insertional trauma (a pneumothorax that was treated with a chest tube for 24 h and resolved completely). This CVC was inserted with ultrasound guidance. The details of the other complications are listed in Table 2.

Secondary Outcomes

Randomization to PICC or CVC did not affect patient mortality, NSICU days or the risk of a failure of insertion (Table 2) Although NSICU days and NSICU days with a line were not different between groups, patients with PICCs were significantly more likely to be

Table 1 Baseline and demographic data of patient cohort

Variable	PICC	CVC	Overall
N	72	80	152
Males	35	45	80:72
Age	59.7 ± (18)	63.3 ± (13.6)	61.4 ± (15.9)
GCS	9.5 ± (4)	10 ± (3.6)	10 ± (3.8)
Hemiparetic	38	38	76
Ultrasound used	72	25	97
Diagnosis			
Ischemic	28	29	57
SAH	14	18	32
TBI	11	8	19
IPH	10	12	22
MG	0	1	1
IVH	0	1	1
Other	9	11	20

Age is reported in years. GCS is reported as a point value. Other values are reported as patient numbers. Values are reported as number ± (standard deviation)

GCS Glasgow Coma Scale, *IPH* intraparenchymal hemorrhage, *Ischemic* ischemic stroke, *IVH* intraventricular hemorrhage, *MG* myasthenia gravis, *other* diagnoses not prespecified during study design, *SAH* subarachnoid hemorrhage, *TBI* traumatic brain injury

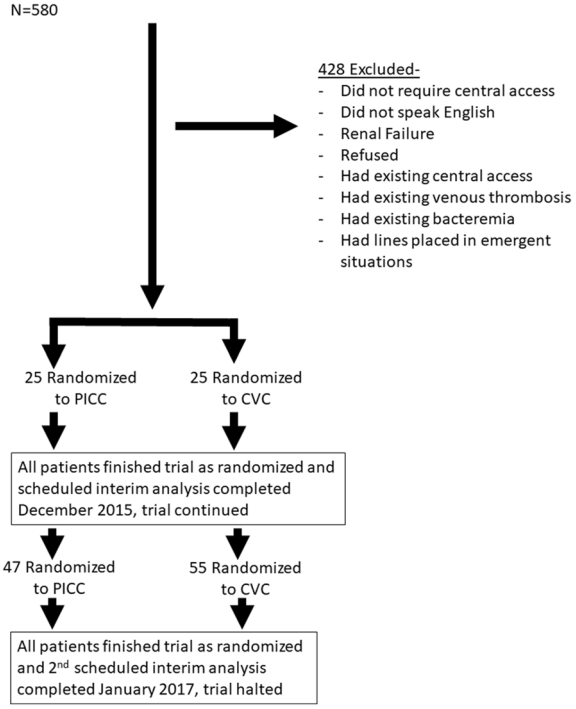

Fig. 1 Patient enrollment. Diagram demonstrating patient flow and enrollment. *CVC* centrally inserted central venous catheter, *NSICU* neuroscience intensive care unit, *PICC* peripherally inserted central venous catheter

discharged with the line in place than those with CVCs (Table 2).

Other independent variables were examined to determine if they affected complications or mortality. Admitting diagnosis was not correlated with any either (Table 3). The study number of the patient (at what point in the trial the patient was enrolled), did not correlate with failure to insert PICCs or CVCs or with complications (Supplementary Tables 1, 2). Hemiparesis on the same side as the catheter was not correlated with LVT in PICC ($p = 0.30$). There were no LVTs in the CVC cohort.

A lower admission GCS did not correlate with catheter-related complications (Supplementary Table 3).

Discussion

A previous study published by Fletcher et al., comparing PICCs and CVCs had difficulty recruiting an adequate number of patients and was focused primarily on LVT rather than all complications [11]. That report showed a higher number of LVTs in PICCs using a screening protocol to assess LVT rather than clinical symptoms.

Our study, which is the largest randomized study to investigate the relative number of complications between PICCs and CVCs in the NSICU, focused on comparing all complications and classical complications as a combined outcome with the goal of providing direct decision-making data to NSICU intensivists. Our study found that when patients were randomized to receive either PICC or CVC from the same group of practitioners that the risk of all complications and classical complications were not significantly different. This is different from some previous reports [3, 11] and in accordance with others [2, 12].

There are several strengths to our study that increase confidence in our results. We used a masked, randomized design and had no treatment crossovers. Our study also had one team responsible for placing all lines (PICCs and CVCs). This eliminated the bias inherent in having separate groups of providers responsible for interventions in different treatment arms. In such cases, the confounder of the inserting provider cannot be separated from the intervention in question. Our design allowed us to evaluate the intervention as an isolated variable as much as is reasonably possible. A separate strength of our study is that team members were available 24-hours per day. This allowed inclusion of patients who needed urgent placement of central access, even during odd hours, which allowed a better reflection of the actual population in the NSICU. While this design allowed optimal comparison of PICCs and CVCs, it does limit the external validity of our results. It is important to note that our results relied on having highly motivated, expert proceduralists available 24 h per day to obtain central access according to a

Table 2 Comparison of PICC to CVC

Variable	PICC	CVC	OR	*p*
N	72	80		
Classic complications*	4 (5.5%)	1 (1.3%)	4.6 (0.5–42.6)	0.14
LVT	4	0		0.07
CLABSI	0	0		NA
Insertional trauma	0	1		0.64
All complications*	14 (19.4%)	10 (12.5%)	1.7 (0.7–4.1)	0.24
Failure to insert	8	5	1.9 (0.6–6.0)	0.28
Mechanical failure	0	2		
Tip malposition	0	1		
Early removal	2	1	2.3 (0.2–25.4)	0.49
NSICU days	9 (7.5)	6.4 (5.1)		0.01
NSICU days with line	6 (4.7)	7.3 (5.2)		0.11
Patients discharged with line	30 (37%)	10 (12.3%)	5.0 (2.2–11.3)	< 0.0001**
Mortality	13 (18%)	9 (11%)	1.7 (0.7–4.4)	0.23

All data are presented as patient number (percentage). NSICU days are presented as average days (standard deviation). Prespecified alpha for Classic complications (LVT, CLABSI, and Insertional Trauma) and All Complications was 0.05. For all other comparisons, it was 0.01. Insertional trauma included pneumothorax, hemothorax, arterial dilation, and venous laceration. Categorical data are compared with Fisher's exact test. Continuous data was compared with an unpaired *T* test

CLABSI central line associated blood stream infection, *LVT* large vein thrombosis, *NSICU* neuroscience intensive care unit, *OR* odds ratio, presented with 95% confidence intervals, *primary outcome, **statistically significant

Table 3 Correlation of primary diagnosis with complications and mortality

Diagnosis	*N*	Classic complication	All complication	Mortality
Ischemic	57	1 (1.7%)	7 (12%)	7 (12%)
SAH	32	0	5 (16%)	5 (16%)
TBI	19	1 (5.3%)	3 (16%)	4 (21%)
IPH	22	1 (4.5%)	5 (23%)	4 (18%)
Other/MG/IVH	22	4 (18%)	4 (18%)	2 (9%)
p		0.28	0.65	0.77

Table shows the relationship between the patient's admitting diagnosis and the likelihood of having a line-related complication. Data are presented as number of patients (percentage of patients). Fisher's exact test was used to calculate *p* values

Ischemic ischemic stroke, *IPH* intraparenchymal hemorrhage, *IVH* intraventricular hemorrhage, *MG* myasthenia gravis, *Other* diagnosis unspecified in the trial design, *SAH* subarachnoid hemorrhage, *TBI* traumatic brain injury

prespecified protocol. This does not reflect the reality of many ICUs and our absolute number of complications may not be generalizable to individual ICUs.

The practice for detecting complications also increases the generalizability of the study. Other studies relied on routine surveillance with ultrasound and cultures to detect LVTs and CLABSIs, respectively [3, 11, 17]. It is the usual practice in our NSICU to only workup symptomatic patients for LVTs or CLABSIs. By preserving this practice in the execution of the clinical trial, it gives a more generalizable report of clinically important disease states, rather than imaging findings of questionable clinical significance [15, 16].

Another strength of this study is not narrowly focusing on the more classic complications of LVT, CLABSI, and insertional trauma, but including line maintenance problems, failure of insertion and other issues. Including these outcomes allowed us to assess the reliability of a given technique in successfully achieving central access. A catheter with a low complication rate that is exceedingly difficult to place is not a helpful intervention and this should be accounted for in a surgical trial of the catheter's usefulness. This is the first study to include these issues as a primary outcome along with the more classic complications.

This study was stopped early by the DSMB. The number of events observed in our data was much lower than in the most relevant literature available during the planning states of the study. Wilson et al. had reported a total complication rate of ~ 11% for PICCs and ~ 4% for CVCs [4]. Our results showed a combined LVT, CLABSI, and insertional trauma risk for PICCs of 5.5% and for CVCs of 1.2% (Table 2). These values were significantly lower than anticipated. When all complications were considered the percentages were larger, but the difference was even smaller. The DSMB also considered that the rate of complications seemed to be falling over time. While the comparison of study number to complication risk showed no statistically significant relationship (Supplementary Tables 1, 2), the DSMB noted that the number of complications was the same from patient 0 to 50, as from patient 51-152. As a result, the committee concluded that an increase

in complications in one arm was not likely enough to merit continued enrollment.

The low number of events observed in this trial could be due to our different diagnostic criteria (discussed above) or, possibly that observational trials do not control for the procedural skill of the practitioner nor line maintenance. In the case of the current study, only providers with experience and demonstrated skill in placing both PICCs and CVCs were inserting lines and strict adherence to best line maintenance was ensured. This demonstrates that with prespecified protocols and tight controls for procedural skill, complications can be lowered, even in a high-risk population and lines inserted under urgent conditions. This lends support to the development of highly skilled teams for line placement in ICUs. Further, lines were followed by the study team after patients were transferred out of the NSICU and discontinued when no longer necessary. This does not reflect the most common practices and may have prevented complications that occur when patients are not in the NSICU. This limits the generalizability of our results to PICCs and CVCs actively managed by the NSICU team. There are some inherent differences in the care of CVCs and PICCs that cannot be overcome by our design. Although NSICU days and NSICU days with a line did not differ between groups, patients with PICCs were more likely to be discharged with the line in place than those with CVCs. This reflects the reality and general practice pattern that PICCs may be continued after discharge for IV access, while CVCs cannot and are usually discontinued and replaced with some type of tunneled catheter (including a PICC) prior to discharge.

Our complication risk is specific to the devices placed in this study. Other devices may have benefits that raise or lower certain complications, especially CLABSI and LVT with special coatings, catheter design, etc.

Overall numbers of LVT in hemiparetic patients were low, with only 1 LVT total. Secondary outcome analyses showed that placing a PICC on a hemiparetic side did not significantly increase the risk of LVT. There are potential benefits to placing a PICC opposite of the paretic side other than avoidance of LVT. These include easier maintenance of the line and patient comfort. Also, the increased LVT risk conferred by the paresis alone would indicate that placement of a PICC in the paretic side should still be avoided when possible. Our data does support that if the clinical scenario demands it, placement of a PICC in the paretic side is safe.

We found that admission diagnosis did not affect mortality or complication risk (Table 3). This is interesting, but hypothesis generating only since this study was not designed to look primarily at the effect of diagnosis on mortality and was not designed as a prognostic study.

The major limitation of this study is that outcomes were not blinded. It is easy to tell the difference between PICC and CVC placement on both ultrasound and X-ray interpretation and clinical exam. Outcome assessment was symptom based and followed the long-standing practice of our NSICU for the workup of fever and elevated white blood cell count. Limb swelling was evaluated based on clinical suspicion and clinician judgment. This increases the generalizability of our results but is a fundamental and unalterable source of bias in the design of surgical trials like this one, where blinding is impossible.

Another limitation is that the central lines in our trial were placed by experienced physician providers. In most NSICUs, PICCs are placed by dedicated vascular access teams that may have different experiences, training, and skill sets than those in this study. The same can be said about physicians and/or physician extenders placing CVCs. The number of complications reported here reflects the experience of the study team and may not be reflective of centers at large. While this is ideal for directly comparing PICCs to CVCs, the relative complications associated with each line type at individual centers must be known before this data can be generalized to an individual NSICU. Similarly, this is important regarding our use of ultrasound guidance in placing CVCs. While all practitioners in our study are very experienced with landmark-guided subclavian CVC approach, this is becoming less common and our results should not be taken support deviation from the generalized practice of ultrasound guidance.

Conclusions

This study provides [18] evidence that PICCs and CVCs have similar risks of complications in the NSICU when compared in a randomized controlled clinical trial.

Electronic supplementary material

The online version of this article (https://doi.org/10.1007/s12028-019-00843-z) contains supplementary material, which is available to authorized users.

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Author Contributions

NJB was involved in Protocol/Project Development, Data collection/management, Data analysis, Manuscript writing; JRD contributed to Project Development, data collection/management, manuscript editing; RP took part in Data collection, data analysis, manuscript editing; EPS was involved in Data collection, data analysis, manuscript editing; AH was involved in Data

collection/management; AT was involved in Data collection/management; JW was involved in Data collection/management; SWH was involved in Data collection/management, protocol/project development, data analysis, manuscript editing/writing; JCZ was involved in Protocol/project development, data analysis, manuscript editing, project supervisor/Primary investigator.

Source of Support
Database software was funded by NIH/NCRR Grant Number UL1RR033184, the remainder of the study was departmentally/institutionally funded.

Conflict of interest
The authors declare that they have no conflict of interest to disclose.

Ethical approval/informed consent
This study was carried out with the approval of the institutional review board and in accordance with the 1964 Declaration of Helsinki. Informed consent was obtained for all participants in the research.

Publisher's Note

Published online: 25 September 2019

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