

Peripherally Inserted Central Catheter (PICC) Insertion Success and Optimal Placement with New Technology: A Pre-Post Cohort Study

Megan Nicholas, RN, BN

Royal Brisbane and Women's Hospital, Queensland, Australia

Emily N. Larsen, BN, BHLthSci, GDip(HlthRes)

Royal Brisbane and Women's Hospital, Queensland, Australia

Alliance for Vascular Access Teaching and Research Group, Menzies Health Institute Queensland, Australia

Claire M. Rickard, RN, PhD

Royal Brisbane and Women's Hospital, Queensland, Australia

Alliance for Vascular Access Teaching and Research Group, Menzies Health Institute Queensland, Australia

School of Nursing and Midwifery, Griffith University, Queensland, Australia

Gabor Mihala, MEng(Mech), GCert(Biostat)

Alliance for Vascular Access Teaching and Research Group, Menzies Health Institute Queensland, Australia

School of Medicine, Griffith University, Queensland, Australia

Centre for Applied Health Economics, Menzies Health Institute, Queensland, Australia

Peter Groom, RN, BN

Royal Brisbane and Women's Hospital, Queensland, Australia

Nicole Marsh, RN, BN, MAdvPrac(HealthRes), PhD

Royal Brisbane and Women's Hospital, Queensland, Australia

Alliance for Vascular Access Teaching and Research Group, Menzies Health Institute Queensland, Australia

School of Nursing and Midwifery, Griffith University, Queensland, Australia

School of Nursing, Midwifery and Social Work, The University of Queensland, Queensland, Australia

Highlights

- Advanced tip-confirmation systems enable catheter-to-vein ratio assessment which may result in improved clinical decision making.
- We did not find significant improvement in patient outcomes with this technology.
- Future high-quality RCTs are needed to explore the impacts of technology on PICC failure.

Abstract

Background: Peripherally inserted central catheters (PICCs) are commonly placed with the assistance of fluoroscopy or medical imaging, ultrasound, electrocardiogram guidance, or all the above. Innovative ultrasound technologies continue to emerge; however, the impact upon clinical outcomes is not well understood. In this study, we aimed to compare outcomes of an existing ultrasound system with SHERLOCK 3CG™ Tip Confirmation (preintervention) to an updated SHERLOCK 3CG Diamond Tip Confirmation system, incorporating catheter-to-vein ratio measurement capabilities and an advanced magnetic-based tip navigation system (postintervention). **Methods:** In this prospective pre-post cohort study, we recruited adult patients requiring a new PICC. The study was conducted at a quaternary hospital in Queensland, Australia. Data were collected between May 2017 (4 months before equipment introduction) and January 2018 (4 months after equipment introduction), with a 1-month exclusion (education or learning) period in between. Patient, PICC, and device removal details were collected. The primary outcome was first-time insertion success, defined as successful PICC insertion after a

Correspondence concerning this article should be addressed to e.larsen@griffith.edu.au

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single attempt (skin puncture), with the tip confirmed in an optimal location by the navigation system and a subsequent chest x-ray (as per hospital policy).

Results: There were 503 participants with patient demographics and PICC characteristics balanced between the preintervention (n = 266) and postintervention (n = 237) groups. First-time insertion success was higher in the preintervention group (203/255, 80%) than the postintervention group (166/226, 73%), but this was not statistically significant (risk ratio = 0.92, 95% confidence interval = 0.83–1.02).

Conclusions: There was no change in clinical outcomes with the use of next-generation ultrasound technology. These results justify future large studies and subsequent review into the efficacy of tip-confirmation systems and processes to maintain patient safety.

Keywords: vascular, quality improvement, ultrasound

Background

Peripherally inserted central catheters (PICCs) are a common vascular access device for patients requiring high-volume, vesicant, or both treatments and those with severely limited peripheral vasculature.¹ Their popularity has increased over the last decade² due to suitability for medium- to long-term treatment duration (14 days to 3 months and longer),¹ capacity for outpatient use,^{3,4} and overall cost effectiveness (compared with other central venous catheters).⁵

New technology, developed and refined over time, has seen an improvement in PICC insertion procedures from a blind (auscultation) insertion (into the antecubital fossa vein) to the use of ultrasound, electrocardiogram (ECG), and real-time x-ray imaging (fluoroscopy) guidance.^{6,7} These technologies have helped reduce the frequency of multiple insertion attempts and unintentional vein damage and increase the ease of insertion and the ability to achieve optimal tip placement^{8,9} (lower third of the superior vena cava [SVC], cavoatrial junction, or the upper right atrium),^{6,10} all of which decrease the risk of patients developing a venous thromboembolism (VTE).¹¹

Early ultrasound technology guided PICC insertions allowed for ease of vein cannulation but lacked a magnetic guidance system for visualization of the PICC tip, and thus, tip placement required x-ray confirmation. X-rays are costly, involve time delays, and expose patients to radiation.¹² Recent advancements in ultrasound technology with tip-confirmation systems (TCSs) with electromagnetic navigation enable inserters to monitor in real time the PICC tip as it is threaded via the vein in the upper arm into the central venous system using ECG waveform rhythms to identify optimal positioning.¹³ This technology is aimed at reducing PICC tip malpositioning, thereby reducing complications such as catheter migration and malfunction, cardiac arrhythmias, pulmonary embolism, and deep vein thrombosis (DVT).¹⁴ Advanced ultrasound imaging has also enabled catheter-to-vein ratio (CVR) measurements. High CVRs have recently been identified as likely risks for DVT, with 1 study identifying eightfold more VTE where the CVR was $\geq 50\%$ ¹⁵; however, these results are yet to be confirmed by high-level clinical research.

The impact of advanced ultrasound modalities, however, is not limited to improved tip positioning and complication prevention; it has also enabled PICC insertions by proceduralists

such as nurses outside of the radiology setting.⁶ Nurse-led PICC insertion teams and specialists are now a convenient, reliable, and cost-effective service for the ever-expanding population in need of central vascular access.^{5,16}

Aims

This comparative study aimed to evaluate the impact of an updated ultrasound technology which incorporated new features including both CVR measurement capability and an advanced magnetic-based tip navigation system upon first-time insertion success (1 attempt made, correct placement in optimal position).

Methods

A prospective pre-post cohort study was conducted within a nurse-led PICC insertion service of a quaternary hospital in Queensland, Australia, between 1 May 2017 (4 months before ultrasound equipment introduction) and 31 January 2018 (4 months postintervention). There was a 4-week washout when the new technology was introduced, during which time patients who had PICCs inserted were not studied. The manufacturer of the technology had no influence on the methods of the study or interpretation of the findings, nor did they provide any financial support.

Technologies

- Preintervention: SiteRite® 5 Ultrasound System with SHERLOCK 3CG™ TCS (Bard Access Devices, Salt Lake City, UT) allows clear vessel visualization and has a proportional reference chart to guide catheter size selection. It enables the clinician to compare the nominated PICC size with vessel size. The TCS allows visualization of the PICC tip pathway and emits an audible cue as the inserter nears optimal position.
- Intervention: SiteRite 8 with integrated SHERLOCK 3CG Diamond TCS (Bard Access Devices) features a catheter size selection and measurement tool that calculates CVR based on the nominated catheter size (4 Fr single-lumen or 5 Fr dual-lumen) by the clinician and a magnetic-based tip navigation system that visualizes the PICC tip pathway and identifies optimal tip placement with a green diamond visual cue in addition to an audible

cue. This technology is argued to improve the ease, accuracy, and frequency of optimal tip location.¹³

Participants

All adult patients requiring a PICC were eligible for inclusion. There were no exclusion criteria. Patients were referred by treating clinical (medical) staff to the nurse-led PICC insertion service from clinical units including Infectious Diseases, Cancer Care Services, Hospital in the Home, Respiratory, Gastroenterology, Surgical, Orthopaedic, Maternity and Obstetrics, and General Medical units. The Intensive Care Unit and Emergency Department do not refer patients to this service.

Setting

PICC insertions were conducted in a procedure room between 7:30 am and 4:00 pm (weekdays). Eight registered nurses (RNs) undertook device insertion; their training included a learning module and competency assessment package and a minimum of 35 successful supervised insertions. Currency of practice was maintained, with a minimum of 2 PICC insertions per month. Education during the introduction of the new technology (wash-in) period (September 2017) was provided by industry representatives and experienced staff superusers.

Standard Operating Procedures

Standard hospital PICC insertion policies and procedures were maintained throughout the project (including preintervention and postintervention phases). These included 2% chlorhexidine gluconate (CHG) in alcohol 70% for skin preparation (SoluPrep™; 3M, St Paul, MN), using a surgical sterile technique and sterile ultrasound probe covers (SiteRite Probe Cover Kit, Bard Access Systems). All study insertion attempts were limited to 2 by a single clinician. A second clinician attempted insertion only where an appropriate vessel was clearly identifiable, the patient provided verbal consent to continue, and the CVR was <40% (postphase only). All patients received a standard polyurethane valved catheter (PowerPICC Solo®2, Bard Access Systems). Devices were 55 cm in length and trimmed as required at time of insertion to the external measurement. Device gauge (4 Fr single-lumen or 5 Fr dual-lumen catheter) was selected based on the patient's clinical needs and a vascular assessment. In the postintervention group, patients were referred to the clinical team for reassessment and the PICC insertion if CVR exceeded 40%.

Standard dressing and securement methods (unless contra-indicated) included a simple polyurethane dressing (IV3000* Standard 10 × 14 cm, Smith & Nephew, Hull, UK), a sutureless securement device (StatLock® PICC Plus, Becton Dickinson/Bard Access Systems), and a CHG impregnated disc (Biopatch®, Johnson & Johnson, Somerville, MA). Needleless connectors (applied to each lumen) were MaxPlus™ (BD, Rolle, Switzerland). In both the preintervention and postintervention groups, tip position was confirmed immediately postprocedure by chest x-ray in a separate department. Medical staff from the patient's specialist team and the radiologist confirmed tip position and documented appropriateness for use in the medical chart. Postinsertion care was by ward clinical staff. PICC

insertion staff prospectively used a database (purpose-built Microsoft® Excel, Redmond, WA) to record insertion, device, and outcome details for quality improvement purposes, which provided the dataset for the study.

Data Collection

Variables included patient demographics (gender, discipline) and device insertion data (indication, insertion date and time, gauge, side of insertion, length, insertion attempts, tip location [determined by x-ray], and CVR). Due to the function of the equipment, CVR measurements were only available in the postintervention group. Patients were monitored remotely (electronic medical records at least weekly) until the PICC was removed, at which time the reason for device removal was documented. Missing or unlikely data values were identified by a research nurse after data exportation and corrected using the patient's clinical notes and imaging reports. Missing data were not imputed.

Outcomes

Primary Outcome

First-time insertion success is defined as the successful insertion of a PICC after a single attempt (i.e., the first skin puncture) with the device tip located in the lower third of the SVC, cavoatrial junction, or the upper right atrium, as per study site standards (no adjustment required after x-ray).^{6,10}

Secondary Outcomes

1. Number of insertion attempts (skin punctures) made during the PICC insertion procedure.
2. *Insertion failure* is defined as
 - a) the inability to insert the PICC after 1 or more attempts (skin punctures), or
 - b) the incorrect placement (which could not be corrected with device adjustment), requiring removal within 24 hours or retraction of the PICC, as per radiology report (x-ray) of tip position.
3. *Device failure* is a composite measure of colonized central venous access device (CVAD) tip, suspected bloodstream infection, occlusion, thrombosis, or dislodgement.
 - a) *Colonized PICC tip* (local unit definition) is defined as the growth (any) of a microorganism on the tip after PICC removal in a patient with signs or symptoms of infection, with clinical improvement after PICC removal. Blood cultures were collected as standard practice but were not entered into the database as required data.
 - b) *Suspected CVAD bloodstream infection* (local unit definition) is defined as PICC removed for clinical signs or symptoms of infection, with no tip growth, or no clinical improvement after PICC removal. Blood cultures were collected as standard practice but were not entered into the database as required data.
 - c) *Occlusion* is defined as the inability to flush or aspirate blood from 1 or both catheter lumens, prompting removal.¹⁷

Table 1. Patient Characteristics (N = 503)

	Preintervention (n = 266), No. (%)	Postintervention (n = 237), No. (%)	Total, No. (%)
Sex: males	146 (55)	157 (66)	303 (60)
Diagnostic group			
Surgical	121 (45)	106 (45)	227 (45)
Medical	84 (32)	69 (29)	153 (30)
Cancer care	48 (18)	55 (23)	103 (20)
Other	13 (5)	7 (3)	20 (4)

- d) *Thrombosis* is clinically diagnosed with the use of ultrasound, with accompanying clinical signs (e.g., oedema, redness), symptoms (e.g., pain), or both at the PICC insertion site or the upper arm.¹⁸
- e) *Dislodgement*¹⁷ is defined as partial or complete dislodgement, where
 - *partial dislodgement* is defined as the external migration of the PICC resulting in suboptimal tip position determined by x-ray, and
 - *complete dislodgement* is defined as PICC removal from the site of insertion.

ues were deemed significant at $P < 0.05$ level. Stata Release 16 (StataCorp, College Station, TX) was used.

Ethics

An exemption from full ethical review was provided by the Royal Brisbane and Women’s Hospital Human Research Ethics Committee (HREC/18/QRBW/87) as per the National Statement on Ethical Conduct in Human Research (2007).¹⁹ Additional consent above and beyond that required for the PICC insertion procedure was not required.

Results

Patient and Device Characteristics

In total, 503 participants were included in the study (266 in the preintervention group [53%] and 237 in the postintervention group [47%]). Participant demographics including gender and diagnostic group were similar between groups (Table 1).

Of the 503 participants referred for PICC insertion, 481 PICC insertion procedures were commenced (Figure 1, Table 2), with 451 (94%) subsequently placed. Patient and device characteris-

Analysis

Patient and device characteristics were presented qualitatively to allow descriptive comparison of the 2 groups. Continuous data were presented as medians and interquartile ranges (IQRs) or means and standard deviations, as appropriate; categorical data were presented as rates and percentages. Primary and secondary outcomes was compared between the exposed (postintervention) and unexposed (preintervention) groups by calculating the risk differences and relative risks. Here, P val-

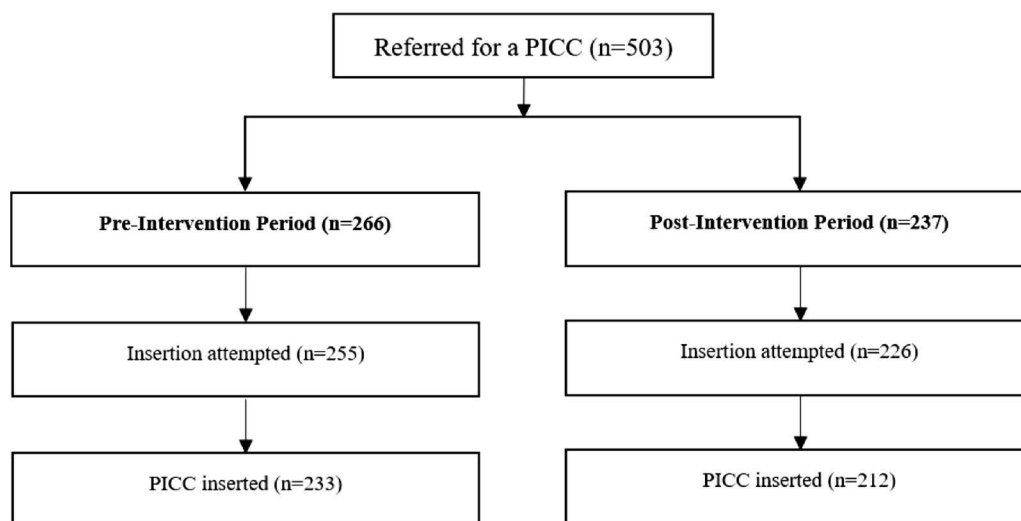


Figure 1. Flowchart.

Table 2. Insertion Characteristics (Inserted Devices Only; N = 451)

	Preintervention (n = 239)	Postintervention (n = 212)
Trimmed preinsertion ^a	221 (92)	196 (92)
Catheter size ^a		
4 Fr	137 (57)	125 (59)
5 Fr	102 (43)	87 (41)
Side of insertion ^a		
Right	179 (75)	151 (71)
Left	60 (25)	61 (29)
Catheter-to-vein ratio ^b (N = 170)		
33% or less	— ^c	99 (58)
34% to 40%	—	71 (42)
Catheter length ^b (cm)	46.5 (4.5)	47.8 (4.0)
Exposed line length ^b (cm)	4.6 (3.2)	4.6 (3.2)

^aFrequencies (%).^bMean (SD).^cDashes indicate data not collected.

tics were similar between groups (Table 1, Table 2), with slight imbalance in gender (55% versus 66% in the preintervention and postintervention groups, respectively).

Primary Outcome

Overall, first-time insertion success (1 attempt, correct placement) was less frequent in the postintervention group (73%) than the preintervention group (80%), although this difference was not statistically significant (risk ratio [RR] = 0.92, 95% confidence interval [CI] = 0.83–1.02; Table 3).

Secondary Outcomes

Most PICCs were placed on the first attempt (single needle-stick) at 91% and 88% in the preintervention and postintervention groups, respectively. However, malposition of the PICC tip (on x-ray tip confirmation) was common (13% preintervention, 18% postintervention). Of these, n = 22 were too low in the right atrium and were retracted in the preintervention group, as were n = 31 in the postintervention group. Total insertion failure, after 1 or multiple insertion attempts (or in the following 24 hours) was the same (6%) in both the preintervention and the postintervention groups.

In total, 451 PICCs accounted for 10,445 catheter-days. Subsequent device failure was not significantly different between the preintervention (18%) and postintervention (22%) groups (RR = 1.18, 95% CI = 0.81–1.71; Figure 2), with incidence

rate ratio (failure per 1,000 catheter-days) also not significant (preintervention: 7.87; postintervention: 9.48; rate ratio = 1.21, 95% CI = 0.78–1.87).

Discussion

The results from this prospective cohort observational study provide valuable insight into the impact of various technology changes influencing outcomes for patient with PICCs. Theoretically, the newer ECG tip-guidance technology would improve outcomes due to the advanced magnetic-based tip navigation and the added green diamond visual cue intended to find optimal tip location. Our findings, however, indicated no significant differences after the introduction of new technology, even though we included a relatively large number of patients and did not analyze the immediate postintroduction period, and so the learning curve should have been achieved. We found first-time insertion success (determined by x-ray confirmation) was 80% and 73%, in the preintervention and postintervention groups, respectively. The finding was consistent with other studies which recorded first-time insertion success rates among inserters using 3CG technology between 79.5%^{10,20} and 84%.²¹ As this study was not powered to detect significant outcome differences nor conducted in a manner which would account for confounding (such as a randomized controlled trial), results should be considered with caution. Further high-level research including blinded randomized controlled trials are urgently needed in this area to inform practice change.

Table 3. Outcomes by Attempted (N = 481) and Successful (N = 451) Insertions

	Preintervention	Postintervention	Total	Risk difference ^a	Rate ratio ^a
Insertion attempted ^b (N = 481)	255 (53)	226 (47)	481 (100)		
PICC inserted ^b (N = 481)	239 (94)	212 (94)	451 (94)		
Incorrect tip location ^b (N = 450)	31 (13)	37 (18)	68 (15)		
Device retracted ^b (N = 450)	22 (9)	31 (15)	53 (12)		
Device-days (N = 451)	5594	4851	10,445		
Primary outcome ^b					
First-time insertion success (N = 481)	203 (80)	166 (73)	369 (77)	-6% (-14-1)	0.92 (0.83-1.02)
Secondary outcomes ^b					
No. of attempts					
1 (sole)	241 (91)	209 (88)	450 (89)		
2	12 (5)	17 (7)	29 (6)		
3	2 (1)	0 (0)	2 (<1)		
Insertion failure ^b (N = 481)	16 (6)	14 (6)	30 (6)		
Device failure ^b (N = 451)	44 (18)	46 (22)	90 (20)	3% (-4-11)	1.18 (0.81-1.71)
Suspected CVAD BSI or colonized PICC tip	19 (8)	18 (8)	37 (8)		
Dislodgement	15 (6)	18 (8)	33 (7)		
Occlusion	2 (<1)	6 (3)	8 (2)		
Thrombosis	2 (<1)	1 (<1)	3 (<1)		
Other	6 (3)	3 (1)	9 (2)		
Incidence rate (device failure) ^{a,c} N = 451	7.87 (5.85-10.6)	9.48 (7.10-12.7)			1.21 (0.78-1.87)

BSI = bloodstream infection; CVAD = central venous access device; PICC = peripherally inserted central catheter.

^a95% confidence interval also shown.

^bFrequencies (%).

^cPer 1000 device-days.

The most frequently recorded reason for insertion failure was incorrect tip location; while this was common (15%, overall), most (78%) were easily corrected by retracting the device from the skin and redressing. This supports previous literature which found 20% of PICCs had incorrect tip positioning with 3CG TCS technology.²⁰ While x-ray confirmation is still local standard practice and continues to be recommended to ensure pa-

tient safety,²² it has been suggested that, after the introduction of 3CG TCS, routine x-ray may only be required when ECG tip confirmation cannot be achieved as a result of obesity, cardiac anomalies (atrial fibrillation), or the presence of a permanent pacemaker.^{12,22,23} Our results question this assertion, as incorrect tip position was common. Despite this, the verification of PICC tip position by chest x-ray is an imperfect solution, as tip

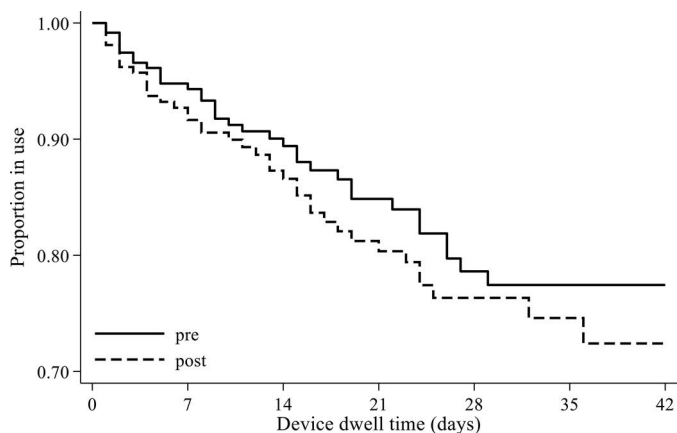


Figure 2. Kaplan-Meier survival of PICC failure over dwell time (log-rank $P = 0.312$).

location may be inaccurately identified due to factors such as perspective error and patient positioning.²⁴

Notably, the newer technology anecdotally improved clinicians' ability to assess and make clinical decisions based on CVR measurements not previously available using the SiteRite5. Our study found that the majority of PICCs inserted were 4 Fr (single lumen) catheters (57% preintervention, 59% postintervention). Despite this, a large percentage of PICCs (in the postintervention group, when CVR measurements were taken) continued to occupy more than 34% of the vein (42%). A recent study found a CVR of >45% increased the risk of PICC-related DVT by a factor of 13 compared with PICCs occupying less than 45% of the vein.¹⁵ Due to these risks, PICCs which were to occupy >40% of the vein were not placed and instead referred to the treating team for reconsideration or placement at a later time. While the risk profiles of >35% compared with <35% have not been sufficiently explored, the low rate of thrombosis found in the postintervention group (<1%) suggests this risk may be low.

The results also highlighted the functionality of nurse-led PICC insertion services, which have been increasing in popularity due to cost effectiveness, the ability to provide a bedside service,⁵ and the role in advocating for alternative vascular devices in place of PICCs. The mean catheter dwell time for both the preintervention and postintervention groups was 23 days. However, of the 289 PICCs removed after the completion of therapy, an astonishing 13% (almost 1 in 6) were required for 7 days or less. Short-dwell PICCs are discouraged in current recommendations, as they suggest a lower-risk device may have been indicated¹; however, this practice is common with 2 recent large multicenter studies reporting median PICC dwells of 10 (range = 1–60) and 11 days (IQR = 5–23 days), respectively.^{25,26} Within the facility studied, alternative devices such as midline catheters considered most suitable for treatments of up to 14 days¹ were not available. This finding supports the need for the facility to explore these and other alternative devices more suited for short durations of treatment. It is expected this will help preserve

vessel health, reduce costs, and potentially reduce the risks of central line associated blood stream infection and its affiliated costs to patients and health care facilities.²⁷

This study had several limitations. First, as a study of data from an existing database, the 2 groups were not randomized, and thus, potential confounders including patient risk factors (e.g., age, acuity, vein quality) and device characteristics (e.g., number of lumens, trimming) may be inadequately controlled, and the pre-post design means temporal-based differences may have existed between the periods. Second, the sample size was not calculated to determine statistical significance. Rather it was a convenient sample of a predetermined time. Third, this was a study in a single referral hospital in Queensland, Australia, and findings may not be representative of a wider population. Fourth, the chest x-ray report and medical knowledge of correct tip position varied. Finally, proficiency of PICC-inserter skill and knowledge of technology varied, and data was collected and entered by a range of clinicians. Despite this, standard operating procedures, such as annual staff competency maintenance and continuity of data collection, ensure reliability of general findings.

Conclusions

The findings demonstrated no initial differences before and after the introduction of new technology incorporating an advanced TCS upon PICC insertion success or device failure. Further high-level research is needed to definitively compare the efficacy of advanced tip confirmation technologies.

Disclosure

EL's employer has received, on her behalf, an investigator-initiated research grant from Cardinal Health (formerly Medtronic) and an educational (conference) scholarship from Angiodynamics.

CR's employer has received, on her behalf, investigator-initiated research grants from Cardinal Health and BD/Bard and consultancy payments from 3M and BD/Bard.

NM's former employer has received, on her behalf, investigator-initiated research grants from BD and Cardinal Health and a consultancy payment from BD/Bard.

MN, GM, and PG declare no relevant competing interests.

Acknowledgments

All authors report substantial input for the conception and design of the study. MN and EL were responsible for data acquisition. GM conducted the analysis. All authors made substantial contributions to the interpretation of data as well as drafting and revising the manuscript. All authors provided final approval for the submitted manuscript.

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