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Safety and efficacy of midline catheters versus peripheral intravenous catheters: A pilot randomized controlled trial

Nicole Marsh RN, MAdvPrac, PhD, Nursing and Midwifery Director, Research[1,2,3,4,5] 🄳 |
Emily N. Larsen RN, GDipHlthRes, PhD(c), Research Fellow, Vascular Access[1,2,3,4] |
Catherine O'Brien RN, Clinical Trial Co-ordinator[1] |
Robert S. Ware BSc, PhD, Professor[4] |
Tricia M. Kleidon RN, MNSc (NursPrac), PhD(c), Nurse Practitioner[1,2,3,6] |
Peter Groom RN, GradCert, Nurse Unit Manager[1] |
Barbara Hewer RN, Clinical Nurse Consultant[1] |
Evan Alexandrou RN, MPH, PhD, Senior Lecturer[7,8] |
Julie Flynn RN, MAdvPrac, PhD, Lecturer[9] |
Kaylene Woollett RN, GradCert, Nursing and Midwifery Director, Surgical and Perioperative Services[1] | **Claire M. Rickard RN, PhD, Professor**[1,2,3]

[1]Nursing and Midwifery Research Centre, Surgical and Perioperative Services; Herston Infectious Diseases Institute, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia

[2]School of Nursing, Midwifery and Social Work, The University of Queensland, UQCCR Herston, Herston, Queensland, Australia

[3]School of Nursing and Midwifery, Griffith University, Brisbane, Queensland, Australia

[4]School of Medicine and Menzies Health Institute Queensland, Griffith University, Brisbane, Australia

[5]School of Nursing, Queensland University of Technology, Kelvin Grove, Queensland, Australia

[6]Queensland Children's Hospital, South Brisbane, Queensland, Australia

[7]Liverpool Hospital, Department of Intensive Care, Liverpool, New South Wales, Australia

[8]School of Nursing and Midwifery, Western Sydney University, New South Wales, Australia

[9]School of Nursing and Midwifery, University of Southern Queensland, Ipswich, Queensland, Australia

Correspondence
Nicole Marsh, Nursing and Midwifery Research Centre, Royal Brisbane and Women's Hospital, Butterfield Street, Herston, QLD 4029, Australia.
Email: Nicole.marsh@griffith.edu.au

Abstract

Background: Despite pervasive need for peripheral intravenous catheters, insertion is often difficult, and approximately two thirds fail prematurely. Midline catheters are an alternative long peripheral catheter, inserted in the upper arm, ideal for patients with difficult access.

Aim: The aim of this study is to test feasibility of the protocol and compare the efficacy and safety of midline catheters to peripheral intravenous catheters.

Design: A parallel-group, pilot randomized controlled trial of adult medical/surgical hospitalized patients, from a single Australian referral hospital.

Methods: Participants with difficult vascular access (≤2 palpable veins) and/or anticipated ≥5 days of peripherally compatible intravenous therapy were recruited between May 2019 and March 2020. Participants were randomized to (1) peripheral intravenous catheter or (2) midline catheter. Primary feasibility outcome measured eligibility, recruitment, protocol adherence, retention and attrition. Primary clinical outcomes measured device insertion failure and post-insertion failure.

Results: In total, $n = 143$ participants (71 peripheral intravenous catheters and 72 midline catheters) were recruited; $n = 139$ were analysed. Most feasibility criteria were met. Peripheral intravenous catheters had shorter functional dwell time, with higher incidence of post-insertion failure compared to midline catheters.

Conclusion: Midline catheters appear to be superior for patients with difficult vascular access or receiving prolonged intravenous therapy; a large, multi-centre trial to confirm findings is feasible.

KEYWORDS
catheterization, peripheral, catheters, nursing, phlebitis, randomized controlled trials

Summary statement

What is already known about this topic?

- Peripheral intravenous catheters have endemically high incidence of complications.
- Midline catheters have been proposed as an alternative peripheral intravenous device, following recent advancements in catheter material and design.
- Few studies have compared safety and efficacy of contemporary midline catheters with peripheral intravenous catheters.

What this paper adds:

- Midline catheters had a longer functional dwell time and lower incidence of post insertion-failure, compared to peripheral intravenous catheters.
- Midline catheters appear safe; however, inserter skill appears to have critical influence on insertion success.

The implications of this paper:

- This study established the feasibility and importance of a large, multicentre, randomized controlled trial to confirm findings.
- Future research should also focus on financial impacts, including cost-efficiency.
- Policy makers should consider training specialist inserters to place midline catheters.

1 | INTRODUCTION

Peripheral intravenous catheters (PIVCs) are placed for short-term administration of intravenous (IV) fluids and medications (Keogh et al., 2016; Marsh, Webster, Larsen, et al., 2018a; Sabri et al., 2012). While patient need for a PIVC is high, one in three fail prematurely from mechanical or infectious complications (Keogh et al., 2020; Maki et al., 2006; Marsh, Webster, et al., 2020; Rickard et al., 2018). Phlebitis (vein irritation), infiltration (IV fluid in tissues) and occlusion (blockage) are the most frequent mechanical complications (Marsh,

Webster, et al., 2020; Ray-Barruel et al., 2014). Although overall infectious complications are rare, with over two billion catheters purchased globally each year, a substantial number of PIVC-related infections occur (Marsh, Webster, et al., 2020; Rickard & Ray-Barruel, 2017). When a PIVC fails, a new catheter is required and each subsequent catheter exponentially increases risk of complications (Hadaway, 2012; Helm et al., 2015). Replacing failed PIVCs places burden on healthcare costs (staff time/equipment) and is distressing for patients (Cooke et al., 2018; Larsen et al., 2017; Marsh, Webster, Larsen, et al., 2018a; Tuffaha et al., 2019). Failed PIVCs further lead to

venous depletion, with some patients requiring insertion of high cost and more risk-prone central vascular access devices (CVADs) (Helm et al., 2015; Kleidon et al., 2021).

An alternative to PIVCs are midline catheters (MC). Although available since the 1950s, hypersensitivity reactions (anaphylaxis and phlebitis) to outdated catheter materials (e.g., Aquavane - elastomeric hydrogel) saw them lose favour in the 1990s (Adams et al., 2016; Alexandrou et al., 2018). Since re-engineering with polyurethane and silicone, they are increasingly used for patients with difficult access (Adams et al., 2016; DeVries et al., 2019). MCs for adults are generally 7.5 to 25 cm long and frequently inserted in upper arm veins such as the cephalic, brachial and basilic (Alexandrou et al., 2018). The catheter tip should lie outside the lateral axillary border of the thoracic cavity, at the level of the axilla, thus potentially avoiding the infectious and thrombotic risks of CVADs (Adams et al., 2016; Gorski et al., 2021). MC placement in the peripheral circulation of the upper arm allows infusion of peripherally compatible IV medication and fluids through a larger diameter vessel than the lower arm, potentially increasing haemodilution and reducing chemical phlebitis compared to PIVCs (Adams et al., 2016). The perceived efficacy of MCs is supported by observational data with average MC dwell times of 7.7–16.4 days (Fabiani et al., 2017; Moureau et al., 2015), starkly superior to average PIVC dwell of 2.3–4.2 days (DeVries et al., 2016; Larsen et al., 2021). Placement in the upper arm may also improve securement and avoid dislodgement and vein irritation that plague PIVCs, often placed over the hand or elbow joints (Marsh, Webster, Larsen, et al., 2018a; Wallis et al., 2014). Hence, MCs could potentially result in patients requiring only one device per treatment, not multiple, sequential PIVCs. Despite initial promising results, there are concerns that the MC tip position may risk severe vessel damage in the event of undetected extravasation (Ryder et al., 2020). Additionally, there is questionable cost-effectiveness due to higher costs associated with MCs (device and ultrasound equipment) and need for advanced staff with ultrasound skills (Bahl et al., 2019).

Regulatory approval for MCs is in the same class as PIVCs (expected use up to 29 days), and international bodies recommend MCs for peripherally compatible IV therapy of between 5 days and 2 weeks (Chopra et al., 2015; Gorski et al., 2021). However, there is a lack of gold-standard evidence from high-quality randomized controlled trials (RCTs) comparing MCs and PIVCs, to guide device selection. The aim of this study was to test the feasibility of an RCT protocol by assessing the rigour of trial methods and to estimate the comparative effectiveness of MCs and PIVCs for device insertion failure and post-insertion failure.

2 | METHODS

2.1 | Study design and ethical considerations

We conducted a single centre, parallel group, pilot RCT. Ethical approval was obtained from the hospital (HREC/2018/QRBW/46295) and Griffith University (2018/962). The study protocol was

published (Marsh, Larsen, et al., 2020) and the trial registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000383167).

2.2 | Participants and setting

Between May 2019 and March 2020 research nurses (ReNs) screened the general medical/surgical wards and anaesthetic department of a large (929 beds) referral teaching hospital in Queensland, Australia. Eligibility criteria included ≥18 years; able to provide informed consent; difficult vascular access (≤2 palpable veins) (Hallam et al., 2016) and/or expected to require ≥5 days of peripherally compatible IV therapy. Patients were excluded if they had a current blood stream infection (within 24 h); a CVAD; were non-English speaking without an interpreter; receiving end-of-life care or had previously been enrolled in the study.

2.3 | Interventions

Patients were randomized to either:

1. Standard care: PIVC (BD Insyte™ Autoguard™ BC, BD Medical, Sandy UT, USA) inserted by an accredited PIVC inserter, at the bedside; using predominately landmark/palpation or
2. Midline Catheter (PowerGlide Pro™, BD, Franklin Lakes NJ, USA) inserted by a nurse with established skills, at the bedside or in a dedicated procedure room, using ultrasound.

2.4 | Outcome measures

2.4.1 | Feasibility outcome

Protocol feasibility was measured against criteria based on previous studies (Marsh, Webster, Larsen, et al., 2018b) (Table S1):

2.4.2 | Primary and secondary outcomes

The primary clinical outcomes were *insertion failure*, proportion of PIVCs/MCs unable to be successfully inserted (within 24 h post-randomisation), and all-cause *post insertion failure*, a composite of pain, infiltration/extravasation (movement of IV fluid/vesicant into surrounding tissue), blockage/occlusion (with or without leakage), phlebitis, thrombosis, dislodgement (complete or partial) or infection (laboratory-confirmed local or blood stream infection [BSI]) (Centers for Disease Control, 2017). This composite measure incorporated the multifocal path to the same endpoint of PIVC/MC failure.

Secondary outcomes included number of insertion attempts (needle puncture to insertion); time taken to insert device (randomisation to successful insertion); device dwell-time (insertion to removal,

in hours); patient reported insertion pain (0–10 verbal rating scale); patient reported satisfaction regarding insertion procedure (0–10 verbal rating scale); serious adverse events (e.g., death); adverse events (e.g., haematoma); cost; infection: laboratory-confirmed local or BSI that is not secondary to an infection at another body site, as per the National Health and Safety Network criteria (NHSN) (Centers for Disease Control, 2017); blockage/occlusion (will not infuse); infiltration/extravasation; dislodgement; phlebitis (two or more of: pain/tenderness; redness; swelling or palpable cord/vein streak from the entry site); thrombosis (suspected or confirmed with ultrasound); pain (0–10 verbal rating scale) and subsequent device required (until discharge, insertion of CVAD or no PIVC/MC in situ for 48 hours).

2.5 | Sample size

The recruitment target was 140 participants, 65 per arm plus five per arm for potential attrition. As a pilot trial, sample size was not determined by a statistical power to test hypotheses, rather to test protocol feasibility and gain initial estimates of effect (Hertzog, 2008; Julious, 2005).

2.6 | Randomization and masking

Clinical areas were screened Monday to Friday for eligible participants. ReNs liaised with treating nurses and medical staff to determine the expected duration of patients' IV treatment. If patients were eligible, the ReN requested written informed consent. Patients were randomized (1:1 ratio) with randomly varying block sizes (4 and 8) using a web-based randomisation service (randomisation.griffith.edu.au/) to ensure allocation concealment. Thrombosis and BSI were assessed by a radiologist and infectious disease expert respectively, who along with the study statistician were masked to group allocation.

2.7 | Device insertion and maintenance

Prior to device insertion hair was clipped (if necessary) and skin decontaminated with 3M (St Paul, MN, USA) Solu-Prep™ Antiseptic Swab (2% chlorhexidine gluconate in 70% isopropyl alcohol). Local anaesthetic (2–3 mg of 1% lignocaine hydrochloride) was offered. Catheter diameter and length were at the inserter's discretion. The device had extension tubing with Smart-Site™ Needle-Free Valves (BD) (Connecta™, BD) applied; the insertion site was covered with a sterile dressing (Sorbaview SHIELDTM -SV233, Centurion Medical Products, Williamston, MI, USA).

Devices were assessed each shift by clinical staff and documented as per usual care. Devices were removed by the patients' treating team as per usual clinical practice, for example, if no longer needed, suspected of infection, painful or the device dysfunctional (leaking or occluded).

2.8 | Data collection

Feasibility outcomes were collected from enrolment screening logs and study data. At recruitment, ReNs collected: baseline patient demographic (e.g., age, gender and weight), clinical (e.g., diagnosis, co-morbidities, current infection/s and vein assessment; Hallam et al., 2016) and device characteristics (e.g., device allocation, insertion site, inserter discipline, technology assisted insertion, number of insertion attempts, size/gauge and side [right/left]). ReNs inspected device sites daily (until device removal) to document the presence and condition of the allocated device and any site complications (e.g., redness and swelling) and assess for primary, secondary and adverse outcomes. At device removal, the ReN collected information including reason for removal, IV treatment received (e.g., intravenous antibiotics) and conducted a site assessment for site complications. Forty-eight hours after device removal, the ReN reviewed microbiology results for positive catheter tip or blood culture reports.

All data were entered into a REDCap database (Research Electronic Data CAPture, Vanderbilt) (Harris et al., 2019). The Trial Co-ordinator undertook quality checks for allocation integrity and monitored 100% of source data for the first five patients; consent forms; primary outcomes and a random 5% of other data for all patients.

2.9 | Statistical analysis

Feasibility outcomes were reported descriptively and analysed against pre-determined acceptability criteria. De-identified data were exported into Stata software v14.0 (StataCorp, College Station, TX, USA) for analysis. An intention-to-treat analysis framework was used with patient the unit of analysis and one device per patient. Frequencies (%) have been reported for categorical data. Means and standard deviations (SD) are reported for normally distributed data; medians and 25th/75th percentiles are reported otherwise. The association between device (PIVC/MC) and device failure was assessed using log-binomial regression. Effect estimates are reported as relative risk (RR) and 95% confidence interval (CI). The association between device and pain outcomes was assessed using linear regression. Effect estimates are reported as mean difference (MD) and 95% CI. The association between device and both insertion and dwell time was assessed using median regression. Effect estimates are reported as median difference (MedD) and 95% CI. The association between device and adverse events was assessed using Fisher's Exact Test. A Kaplan–Meier survival curve was constructed to compare functional dwell times between devices, and between-group difference was assessed using the log rank test. The association between device and time to functional failure was assessed using Cox proportion hazards regression. Costs were estimated by assessing number of products used (whole sample), staff number and length of time required (e.g., minutes) for device insertion (a sub-set of 10 participants per group and convenience sample).

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3 | RESULTS

Of 231 eligible patients, 143 were randomized (Figure 1). At recruitment, participants had similar demographic characteristics (Table 1). The majority of patients were male, overweight/obese, with three or more co-morbidities and admitted to a surgical ward. However initial patient assessment identified more patients in the MC group had poor veins ($n = 31$; 44.9%) compared to patients in the PIVC group ($n = 12$; 26.7%). Furthermore, a higher number of patients with a PIVC received anti-thrombolytic therapy ($n = 64$; 91%) or had no co-morbidities ($n = 10$; 14.5%) compared to the MC group ($n = 56$, 81%, and $n = 2$, 2.9%, respectively). There were 161.1 device days studied in the PIVC group and 374.7 in the MC group.

3.1 | Feasibility outcomes

Of the 231 patients screened for recruitment, 62% ($n = 143$) were eligible for study inclusion (Figure 1), consequently the predetermined feasibility outcomes for eligibility were not met. All remaining feasibility criteria were met with 100% of eligible patients consenting to participate (one patient withdrawing post randomisation due to concerns of receiving an MC that they saw as a new type of vascular access device), meeting the predetermined recruitment target of >80%. Protocol adherence was achieved with 97% of patients in both groups receiving their allocated intervention; no patients were lost to follow up.

3.2 | Efficacy outcomes: Device insertion and post insertion failure

Of the 70 patients randomized to receive an MC, 9 (12.9%) experienced failed device insertion compared to 11/69 (15.9%) failed insertions for those allocated to a PIVC (RR 0.81; 95% CI 0.36 to 1.82; $P = .61$) (Table 2). A total of 19 (31.2%) MCs experienced post insertion failure compared to 34 (58.6%) PIVCs (RR 0.53; 95% CI, 0.34 to 0.82; $P = .004$). The median functional dwell time for MCs (117.4 h) was longer than for PIVCs (61.4 h), with a median difference of 55 hours (95% CI: 22.5 to 87.6; $P = .001$). Figure 2 displays function dwell duration for the two devices. MCs had significantly longer duration (log-rank test, $P < .001$) and were
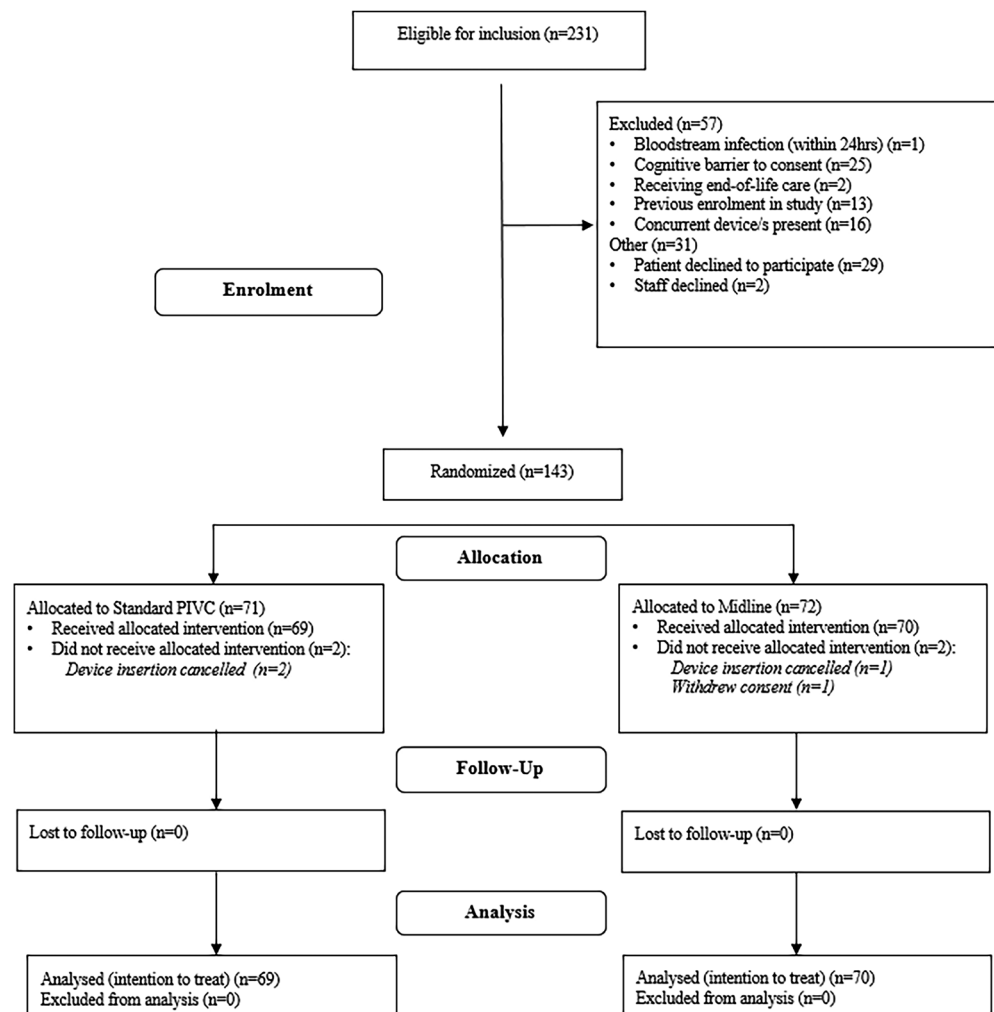

FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) flow chart

TABLE 1 Patient, insertion and device characteristics

	Midline (N = 70) n (%)	PIVC (N = 69) n (%)
Age (in years)	57 (SD 15.17)	58 (SD 15.17)
Gender (female)	28 (40.0)	33 (47.8)
BMI overweight or obese	44 (62.9)	47 (68.1)
Reason for admission		
Planned medical	2 (2.9)	1 (1.5)
Emergency medical	6 (8.6)	11 (15.9)
Planned surgical	18 (25.7)	16 (23.2)
Emergency surgical	44 (62.8)	40 (58.0)
Other	0 (0.0)	1 (1.4)
Number of co-morbidities		
0	2 (2.9)	10 (14.5)
1	8 (11.4)	7 (10.1)
2	14 (20.0)	5 (7.3)
≥3	46 (65.7)	47 (68.1)
Wound at recruitment	31 (44.3)	40 (58.0)
Infection at recruitment	43 (61.4)	37 (53.6)
History of blood clot	13 (23.2)	13 (18.6)
Vein assessment[a]		
Excellent	8 (11.6)	2 (4.4)
Good	14 (20.3)	12 (26.7)
Fair	16 (23.2)	19 (42.2)
Poor	31 (44.9)	12 (26.7)
Receiving anti-thrombolytic medication	56 (81)	64 (91)
Successfully inserted	61 (87)	58 (84)
Department of insertion		
Ward	56 (91.8)	55 (94.9)
Radiology	0 (0.0)	1 (1.7)
Theatre	5 (8.2)	2 (3.4)
Inserting health professional		
Research nurse	61 (100.0)	1 (1.7)
Nurse (vascular access specialist)	0 (0.0)	34 (48.6)
Nurse	0 (0.0)	3 (5.2)
Doctor	0 (0.0)	20 (34.5)
Device (PIVC)		
18 g – 30 mm		1 (1.7)
20 g – 30 mm		31 (53.4)
20 g – 48 mm		7 (12.1)
22 g – 25 mm		18 (13.1)
24 g – 19 mm		1 (1.7)
Device midline		
18 g – 10 cm	52 (85.3)	
20 g – 10 cm	6 (9.8)	
22 g – 8 cm	3 (4.9)	
Vein of insertion		
Basilic	23 (37.7)	6 (10.3)
Brachial	7 (11.5)	4 (6.9)

TABLE 1 (Continued)

	Midline (N = 70) n (%)	PIVC (N = 69) n (%)
Cephalic	31 (50.8)	41 (70.6)
Dorsal venous network/arch		5 (8.6)
Radial		1 (1.7)
Median cubital		1 (1.7)
Insertion site		
Upper arm	61 (100.0)	9 (15.5)
Cubital fossa		4 (6.9)
Upper forearm		16 (27.6)
Lower forearm		12 (20.7)
Wrist		12 (20.7)
Hand		4 (6.9)
Other		1 (1.7)
Ultrasound guidance (inserted devices)	61 (100)	7 (12.1)
No. of insertion attempts for devices that were unable to be placed[b]		
1	3 (33.3)	7 (63.6)
2	5 (55.6)	4 (36.4)
3	1 (11.1)	0 (0)
Local anaesthetic given at insertion	23 (33.0)	3 (4.4)

[a]No participants classified as 'non-identifiable vein quality'.
[b]Not inserted within the 24 h.

less likely to fail (hazard ratio = 0.33; 95% CI = 0.22 to 0.48; $P < .001$).

Of the 119 patients who had a device placed, 12/61 (19.7%) MCs required 2 or more insertion attempts, compared to 17/58 (29.3%) PIVC (RR 0.56; 95%CI, 0.29 to 1.04; $P = .06$). The average insertion pain score on an 11-point scale (0 = no pain; 10 = extreme pain) was similar for MC (2.2) and PIVC placements (2.5) (MD -0.2 [95% CI, −1.1 to 0.6; $P = .58$]).

Device insertion timing and procedural resources were collected for a subset of patients (48 MCs; 14 PIVCs). The individual device cost (AUD; 2020) was $79.00 ($61.20 USD) for the MC compared to $2.03 for the PIVC ($1.57 USD). The mean time from preparation of the sterile field to device insertion was 27 min (95% CI, 23 to 30) in the MC versus 6 min (95% CI, 3 to 8) in the PIVC group. A full cost analysis was not undertaken due to an inability to collect costs associated with treating complications and the timings of insertions for subsequent devices.

3.3 | Device complications

There were no primary bloodstream infections or laboratory-confirmed local infections in either group. A total of three serious adverse events occurred in the MC group and all were unrelated to the study intervention. Pain at the insertion site was the most frequently reported symptom of complication, present in 19 (32.8%) PIVCs and 15 (24.6%) MCs. Infiltration/extravasation was the most common PIVC complication present in 13 (22.4%) devices; however, no episodes of infiltration/extravasation were reported for MCs. PIVC failure from phlebitis (n = 14; 21.1%) and occlusion were higher (n = 5; 8.6%) than for MCs (phlebitis: n = 6; 9.8%, $P = .05$) (occlusion: n = 1; 1.6%). Thrombosis was present in 2 MCs compared to none for PIVCs.

4 | DISCUSSION

This study established the feasibility of a large, multicentre, RCT to compare two peripheral vascular access devices. All feasibility criterion were met except eligibility, which excluded PIVCs needed for < five days. Future trials should target patients with prolonged IV treatment, for example, for chronic lung disease, pneumonia or complicated urinary tract infection, and for patients undergoing treatment for complex medical procedures (Turnidge et al., 2016).

This study observed multiple insertion attempts required to place both devices, but first-time insertion success was more common with MCs (74.3%) than PIVCs (68.7%). This was despite MC inserters, although skilled at ultrasound placement of other devices, being new to MC insertion. MC insertion success was impacted by this, and there were 5 (50%) insertion failures in the first 10 MC patients. As MC inserter skill improved, there were only 4 of 60 (7%) insertion failures.

TABLE 2 Association between device inserted, and device and patient outcomes

	Midline catheter (n = 70) (%)	PIVC (N = 69) (%)	Between group differences (95% CI)
Primary outcomes			
Insertion failure	9 (12.9) (N = 61)	11 (15.9) (N = 58)	RR = 0.8 (0.4 to 1.8) P = .61
	Midline catheter (N = 61)	PIVC (N = 58)	
Device failure	19 (31.2)	34 (58.6)	RR = 0.5 (0.3 to 0.8) = .004
Secondary outcomes			
Insertion attempts			
1	49 (80.3)	41 (70.7)	RR = 0.6 (0.3 to 1.0) P = .06
≥2	12 (19.7)	17 (29.3)	
Time to insert device (minutes), (median; IQR)	40 (33, 45)	18 (11, 27)	MedD = 22 (15.5 to 28.5) P < .001
Dwell time (hours)(median; IQR)	117.4 (76.9, 191.8)	61.4 (27.4, 79.7)	MedD = 55.0 (22.5 to 87.6) P = .001
Total device days	374.7	161.1	MedD = 2.3 (0.9 to 3.6) P = .001
Insertion pain 0–10 NRS(n = 129) (mean; SD)	2.2 (2.3)	2.5 (2.5)	MD = −0.2 (−1.1 to 0.6) P = .58
Patient satisfaction (insertion) 0–10 NRS (n = 128) (mean; SD)	9.6 (0.7)	9.3 (1.8)	MD = 0.4 (−0.1 to 0.8) P = .14
Serious adverse events[a]			
Deceased	1 (1.6)	0 (0)	P > .99
ICU admission	2 (3.3)	0 (0)	0.50
Complications at removal: (n = 119)	(N = 61)	(N = 58)	
Primary bloodstream[b] infection	0 (0.0)	0 (0.0)	
Positive tip culture[b]	0 (0.0)	0 (0.0)	
Positive swab culture[b]	0 (0.0)	0 (0.0)	
Local infection[b]	0 (0.0)	0 (0.0)	
Occlusion (blockage)	1 (1.6)	5 (8.6)	.11
Infiltration/extravasation	0 (0.0)	13 (22.4)	P < .001
Dislodgement	2 (3.3)	4 (6.9)	.43
Phlebitis	6 (9.8)	14 (21.1)	.05
Thrombosis	2 (3.2)	0 (0.0)	.50
Too painful to tolerate	15 (24.6)	19 (32.8)	.42
No. of subsequent PIVCs (mean; SD)	0.5 (1.1)	1.4 (1.5)	MD = −0.9 (−1.4 to −0.4) P < .001

Abbreviations: MedD, median difference; MD, mean difference; RR, relative risk.

[a]Not related to study.

[b]Analyses impossible due to lack of outcome.

Once familiar with MCs these inserters likely drew upon their existing vascular access expertise compared to the generalist inserters (often junior doctors or nurses) who routinely place PIVCs (Carr et al., 2014; Marsh, Webster, Larsen, et al., 2018b). Specialist expertise can overcome difficult vascular access caused by extremes of age (both elderly and neonates), chronic disease or previous vascular damage from multiple devices (Dychter et al., 2012; Gabriel, 2012; Hallam et al., 2016; Moureau et al., 2012; Yalcinli et al., 2019). This study highlights the potential benefit of MCs to reduce insertion failure and highlights a need to further investigate this outcome in a large multi-centre RCT.

All-cause post-insertion failure was substantially (27%) lower for MCs compared to PIVCs, with a longer median complication free dwell of 55 h. Moreover, MC patients required fewer subsequent devices to complete IV treatment compared to PIVC patients (mean difference −0.8 devices). These are important results as one MC placement could potentially avoid multiple PIVCs, preserving patients' vasculature for future IV treatment needs. These results signify potential cost savings for hospitals and health services through less products and staff time to insert and troubleshoot multiple devices. The study identified a substantial cost difference (AUD$77.00) associated with MCs compared to PIVCs. However, this study was unable to undertake the full cost effectiveness analysis needed to incorporate costs associated with reduced insertion attempts, longer dwell time and lower all-cause failure. This should be considered a priority for future research.
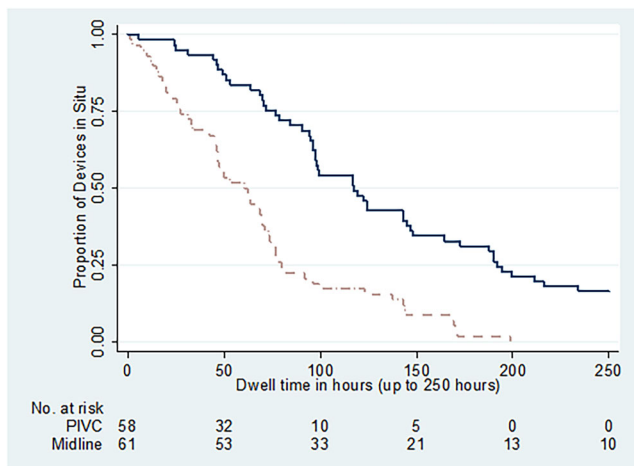
FIGURE 2 Kaplan–Meier survival curve of time to functional failure by device. Figure legend: PIVCs represented by dashed line; MCs represented by solid line

The finding of less post-insertion failure for MCs compared to PIVCs is consistent with an RCT (n = 70) in an emergency department that reported a 21% lower incidence of post-insertion failure, and an additional 2.8 days of functional dwell for MCs compared to long PIVCs (4.7 cm [cms] in length) (Bahl et al., 2019). In addition, a recent prospective observational study (n = 86) of ultrasound inserted long PIVCs found 100% failure when <30% of the PIVC was residing in the vein, and no failure when >65% of catheter was in the vein (Pandurangadu et al., 2018). The longer length of MCs (8–10 cm) than standard PIVCs (2.5–3 cm) in this study allowed more catheter length in the vein, which likely decreased catheter mobility, device complications and failure (Elia et al., 2012; Pandurangadu et al., 2018; Scoppettuolo et al., 2016).

The superior MC complication free dwell also likely reflected placement in the upper arm, minimizing MC movement. More than one third of PIVCs were inserted at points of flexion (hand, wrist, antecubital), which precipitates complications and failure (Cicolini et al., 2009; Kaur et al., 2011; Saini et al., 2011). Insertion over a joint can loosen the dressing or securement and allow movement within the vein. This in turn potentiates tip irritation or piercing of the vessel wall resulting in phlebitis, infiltration or occlusion (Doellman et al., 2009; Helm et al., 2015). Additionally, PIVC placement in small easily visualized surface veins, likely contributed to the frequent phlebitis (21.1%) compared to MCs (9.8%) and PIVC infiltration of 22.4% compared to no MC infiltration. There were also higher rates of occlusion and catheter dislodgement for PIVCs than MCs. Finally, there were two ultrasound confirmed MC thromboses, and no ultrasounds clinically ordered for PIVCs. Thus, thrombosis may be a complication only for MCs or may be an under recognized issue for PIVCs. A recent prospective observational study of 439 MCs reported a 4.5% thrombosis rate (3.3 per 1,000 catheter days) suggesting that the risk of MC thrombosis negates their suitability for all patients (Lisova et al., 2018). The results of our study suggest MC thrombosis should be further explored.

4.1 | Limitations

The main study limitation to this study was the pilot RCT design, as not designed to provide conclusions about the efficacy, although post-insertion failure differences were statistically significant. Moreover, the consistent use of ultrasound and vascular access specialists for the MC group compared to generalist PIVC inserters may have influenced device insertion success. All devices were cared for identically post-insertion so this should not have impacted the post-insertion failure results. An additional limitation was the non-blinding of devices; however, the infection and thrombosis outcome assessments were blinded.

5 | CONCLUSION

MCs are a promising vascular access device for hospitalized patients with difficult vascular access or requiring IV therapy greater than 5 days, with less insertion failure and almost half the post insertion failure of standard PIVCs. Thrombosis was experienced by two participants in the MC group, which highlights a need for further research to understand the risk profile associated with MC use. This study found that it is feasible and clinically important to test MCs in a large multicentre RCT.

CONFLICT OF INTEREST

NM's associated institution, Griffith University, has received on her behalf, speaker fees from 3 M, investigator-initiated research grants from Becton Dickinson, Eloquest and Cardinal Health, and a consultancy payment from Becton Dickinson for clinical feedback related to catheter placement and maintenance (unrelated to the current project). EL reports an educational scholarship (conference attendance) from Angiodynamics (unrelated to the current project) and an investigator-initiated grant from Eloquest, administered by the University of Queensland (unrelated to the current project). TK reports investigator-initiated research grants and speaker fees provided to her employer Griffith University from 3 M Medical, Becton Dickinson, Medical Specialties Australia and Smiths Medical, and a consultancy payment provided to Griffith University from Access Scientific for consultancy work (unrelated to the current project). CMR's current or former employer has received, on her behalf investigator-initiated research or educational grants from Becton Dickinson-Bard, Eloquest, Cardinal Health and consultancy payments for educational lectures/expert advice from 3 M Medical and Becton Dickinson-Bard (unrelated to the current project). Other authors declare no conflict of interest.

ORCID

Nicole Marsh https://orcid.org/0000-0002-5779-1304

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