ORIGINAL RESEARCH

Risk Factors for Midline Catheter Failure: A Secondary Analysis of an Existing Trial

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Objective: While midline catheters (MCs) are considered to be a reliable form of vascular access, up to 25% of the placements culminate in failure. We aimed to explore risk factors for MC failure.

Methods: We performed an analysis of existing randomized controlled trial data involving a comparison of two midline catheters. The study aimed to assess risk factors related to MC failure, including patient, procedure, catheter, and vein characteristics. Cox regression was used for univariable and multivariable analyses to evaluate the association between characteristics and MC failure.

Results: Among 191 patients that were included in this secondary analysis, more patients were female (114/191 [59.7%]) and average age was 60.2 (SD = 16.7) years. Clinical indications for MC placement included antibiotics (60.7%), difficult venous access (32.5%), or both (6.8%). In a univariable Cox regression analysis, the increase in pulse rate (HR 1.02; 95% CI, 1.00–1.04; *P*=0.02), temperature ≥38°C (HR 5.59; 95% CI, 1.96–15.94; *P*=0.001), oxygen saturation <93% (HR 2.91; 95% CI, 1.03–8.24; *P*=0.04), norepinephrine in dextrose infusion (HR 2.41; 95% CI, 1.17–4.97; *P*=0.02) and cephalic vein insertion (HR, 2.47; 95% CI, 1.09–5.57; *P*=0.03) were all associated with higher risk of MC failure. In a multivariable Cox model, difficult venous access (aHR 2.05; 95% CI, 1.04–4.05; *P*=0.04) and norepinephrine in dextrose (aHR 2.29; 95% CI, 1.09–4.82; *P*=0.03) was associated with catheter failure.

Conclusion: Elevated pulse rate, decreased oxygen saturation level, temperature ≥38°C, and norepinephrine use were each associated with an increased risk of MC failure. These factors should be considered when selecting the most appropriate vascular access device for individual patients. Additionally, the cephalic vein insertion has the highest risk for MC failure and other access points could be preferentially considered.

Keywords: midline catheter, complications, risk factors, midline catheter failure, vesicants, vascular access

Introduction

With over 850,000 midline catheters (MCs) sold in the United States in 2019, establishing peripheral venous access with these devices is steadily gaining popularity.[1] MCs are designed for intermediate duration intravenous therapies, generally ranging from 5 to 14 days and in some instances, greater than 15 days.[2,3] They are typically inserted in the upper extremity, with the tip of the catheter located proximal to the axilla, but one study demonstrated successful placement in the femoral vein in the groin.[4] MCs have been shown to be reliable across numerous investigations; however, a minority of these catheters do fail prior to completion of therapy, and risk factors for catheter failure are currently unknown.[2,5–8] Nonetheless, there is some limited data on the premature removal rate of MCs. One systematic review, that included 31 individual manuscripts, reported a incidence range for MC failure of 2.6–57%, with an overall adjusted rate of 12.5%.[5] Patients who experience MC failure have a multitude of downstream sequela as a result, including the need for repeat invasive procedures, venous depletion from repeated IV needlesticks, escalation to more invasive central venous access devices with associated higher risk profiles, extravasation with skin necrosis, catheter-associated bloodstream infections, interruption of medical therapies, and longer hospital stays.[7,9,10]

To date, there are limited data describing outcomes after MC failure and even less literature evaluating potential risk factors that may predict MC failure. In order to select the most effective and safest vascular access device for any given

patient, it is imperative that we understand what potential risk factors may preclude MC use. Additionally, identifying a patient population that is low risk for premature MC failure would be just as beneficial. We believe that several variables including demographics, clinical, procedural, and line/vein characteristics may influence survival and help us better understand catheter failure. Thus, the goal of this analysis is to identify risk factors that are predictive of premature MC failure in order to help identify when and among which patients, a different vascular access device may be a more appropriate solution.

Materials and Methods
Study Sample
This was a secondary analysis of a previous randomized control trial at an 1100 bed tertiary care center with an annual emergency department census of approximately 120,000 visits that compared two midline catheters: a 4 French antithrombotic single-lumen 20 cm MC (MC-AT) from AngioDynamics (BioFlo 4F) and a 4.5 French antithrombotic and antimicrobial single-lumen 15 cm MC (MC-AT-AM) from Teleflex Inc (Arrowg+rd Blue Advance 4.5F). (ClinicalTrials.gov Identifier: NCT03725293)

In short, the primary study was approved for participants over 18 years who required MC placement for difficult vascular access, intermediate duration antibiotics (7–28 days), or both. Patients were excluded if they were previously enrolled in the study, required a catheter with multiple lumens, required alternative catheter diameter, or if they were receiving treatment dose anticoagulation (prophylactic dosages were permitted). Ultimately, 191 participants were included in the dataset. The primary outcome of the trial was catheter-related thrombosis. All participants in the trial provided informed consent and the trial was conducted in accordance with the Declaration of Helsinki. This secondary exploration of predictors of MC failure independent of catheter type was approved by the Institutional Review Board of Beaumont Health.

Outcome Measure
The study outcome was midline catheter failure. Catheter failure was defined as unresolvable malfunction or complication that resulted in catheter removal before completion of therapy. Potential causes of catheter removal included leaking, pain, dislodgement, complete occlusion, persistent withdrawal occlusion, and infiltration. Research staff abstracted the cause of failure from the medical record as this was not a prespecified aim of the original trial. Daily MC site and catheter evaluations performed by the research staff were used to identify functionality and premature catheter failure. A catheter was functional if clinical staff were able to withdraw 3–5 mL of blood and/or if the VAD flushed without resistance using 5 mL of normal saline.

Independent Variables
To identify the potential predictors of MC failure, we included the following variable categories: demographic, clinical, insertion/catheter, and line/vein factors. Demographic and clinical variables included age, gender, body mass index, vital signs immediately preceding catheter insertion, relevant medical history (venous thromboembolism, hypercoagulable state, major surgery, immobilization), indication of MC, and use of irritants or vesicants (Appendix with list of irritants/vesicants used in this study). MC-insertion-related data included location/side of vein of placement, vein depth/diameter, catheter-to-vein ratio, and distance from antecubital fossa (cm).

Primary Data Analysis
Continuous and categorical variables were expressed as means (standard deviations; SD) and frequencies (percentages), respectively. To explore the association between risk factors and premature MC failure, Cox regression was used for univariable and multivariable analyses. Following the univariable analysis, variables with a p-value <0.05 or variables determined by clinicians based on clinical rationale were subjected to a multivariable modeling strategy. There was no violation of proportional hazards assumption. The corresponding c-statistic and a bootstrap cross-validation were used to

evaluate the performance of modeling in multivariable analysis. All tests with a p-value <0.05 were considered to indicate statistical significance. All statistical analyses were performed with SAS v9.4 (SAS Institute, Inc., Cary, NC).

Results

In total, 191 patients were included in this secondary analysis of existing data; 114 (59.7%) of 191 patients were female and the average age was 60.2 (SD = 16.7) years. Clinical indications for MC placement included antibiotics (60.7%), difficult venous access (32.5%), or both (6.8%). Premature MC failure occurred in 42 (22.0%) patients (Table 1).

Of the 42 failures, the most common reason for removal was leaking which occurred in 14 (33%) cases. This was followed closely by pain which occurred in 8 (19%) cases. While persistent withdrawal occlusion was the most frequent complication occurring in 18 (43%) cases, it was the primary cause of removal in only 7 cases (Table 2).

Table 1 Patient and Catheter-Related Characteristics

Variables*	
n	191
Patient Characteristics	
Age, years	60.2 (16.7)
Sex	
Male	77 (40.3%)
Female	114 (59.7%)
BMI, kg/m^2	
<30	92 (48.2%)
≥30	99 (51.8%)
Systolic blood pressure, mmHg	128.5 (20.0)
Pulse, beats per minute	81.9 (16.1)
Blood oxygen saturation, %	
<93	10 (5.2%)
≥93	181 (94.8%)
Body temperature, °C	
<38	185 (96.9%)
≥38	6 (3.1%)
Venous thromboembolism (VTE)	
No	182 (95.3%)
Yes	9 (4.7%)
Hypercoagulable condition	
No	186 (97.4%)
Yes	5 (2.6%)
Major surgery	
No	154 (80.6%)
Yes	37 (19.4%)
Immobilization	
No	147 (77.0%)
Yes	44 (23.0%)
Reason for catheter placement	
Antibiotics	116 (60.7%)
Difficult venous access	62 (32.5%)
Both	13 (6.8%)
Infusates (irritants/vesicants)	
No use	119 (62.3%)
Use	72 (37.7%)

(Continued)

Table 1 (Continued).

Variables*	
Calcium gluconate in dextrose	
No	170 (89.0%)
Yes	21 (11.0%)
Norepinephrine in dextrose	
No	173 (90.6%)
Yes	18 (9.4%)
Vancomycin	
No	178 (93.2%)
Yes	13 (6.8%)
Total dose of infusates (irritants/vesicants)	
0	119 (62.3%)
1–2	28 (14.7%)
≥3	44 (23.0%)
PIVC characteristics	
Location	
Basilic	120 (62.8%)
Brachial	47 (24.6%)
Cephalic	24 (12.6%)
Side	
Left	51 (26.7%)
Right	140 (73.3%)
Depth of vein, cm	
≤1.2	108 (56.5%)
>1.2	83 (43.5%)
Catheter-to-vein ratio	
≤0.40	147 (77.0%)
>0.40	44 (23.0%)
Distance from antecubital fossa, cm	
≤7.0	113 (59.2%)
>7.0	78 (40.8%)
Outcome	
Line failure	
Yes	42 (22.0%)
No	149 (78.0%)

Note: *Data are mean (SD) or n (%) in 191 patients.
Abbreviations: BMI, body mass index; PIVC, peripheral intravenous catheter.

Table 2 Primary Causes of Catheter Removal Among Failed Catheters

Variables	
n	42
Cause of Failure	
Leaking	14 (33.3%)
Pain	8 (19.0%)
Persistent withdrawal occlusion	7 (16.7%)
Dislodgement	5 (11.9%)
Complete occlusion	4 (9.5%)
Infiltration	4 (9.5%)

In the univariable Cox regression analysis, the increase in pulse rate (unadjusted hazard ratio [HR], 1.02; 95% confidence interval [CI], 1.00–1.04; *P* = 0.02), oxygen saturation <93% (HR, 2.91; 95% CI, 1.03–8.24; *P* = 0.04), body temperature ≥38°C (HR, 5.59; 95% CI, 1.96–15.94; *P* = 0.001), catheter placement indication of both antibiotics and difficult venous access (HR, 4.17; 95% CI 1.67–14.41; *P* = 0.002), norepinephrine in dextrose use (HR, 2.41; 95% CI, 1.17–4.97; *P* = 0.02) and placement in the cephalic vein (HR, 2.47; 95% CI, 1.09–5.57; *P* = 0.03) were each associated with higher risk of catheter failure. The multivariable Cox model with an internal bootstrap validation (c-statistic 0.66, 95% CI 0.56–0.77) shows that indication of difficult venous access (aHR, 2.05; 95% CI, 1.04–4.05; *P* = 0.04) and norepinephrine in dextrose use (aHR, 2.29; 95% CI, 1.09–4.82; *P* = 0.03) were each associated with catheter failure (Table 3).

Table 3 Univariable and Multivariable Analyses for Midline Catheter Failure

Variables	Univariable Model		Multivariable Model[‡]	
	HR (95% CI)	p value	aHR (95% CI)	p value
Patient haracteristics				
Age, years	1.01 (0.99–1.03)	0.33		
Sex				
Male	1 [Reference]			
Female	1.15 (0.62–2.12)	0.66		
BMI, kg/m^2				
<30	1 [Reference]			
≥30	1.13 (0.62–2.07)	0.70		
Systolic blood pressure, mmHg	1.00 (0.98–1.02)	0.91		
Pulse, beats per minute	1.02 (1.00–1.04)	0.02	1.01 (0.99–1.03)	0.19
Blood oxygen saturation, %				
<93	2.91 (1.03–8.24)	0.04	2.38 (0.79–7.21)	0.13
≥93	1 [Reference]		1 [Reference]	
Body temperature, °C				
<38	1 [Reference]		1 [Reference]	
≥38	5.59 (1.96–15.94)	0.001	2.04 (0.46–9.12)	0.35
Venous thromboembolism (VTE)				
No	1 [Reference]			
Yes	1.17 (0.28–4.86)	0.83		
Hypercoagulable condition				
No	NA			
Yes	NA	–		
Major surgery				
No	1 [Reference]			
Yes	0.76 (0.32–1.81)	0.54		
Immobilization				
No	1 [Reference]			
Yes	1.68 (0.87–3.23)	0.12		
Reason for catheter placement				
Antibiotics	1 [Reference]		1 [Reference]	
Difficult venous access	1.88 (0.97–3.66)	0.06	2.05 (1.04–4.05)	0.04
Both	4.17 (1.67–10.41)	0.002	2.76 (0.78–9.79)	0.12
Infusates (irritants/vesicants)				
No use	1 [Reference]			
Use	1.43 (0.78–2.65)	0.25		
Calcium gluconate in dextrose				
No	1 [Reference]			
Yes	0.60 (0.18–1.94)	0.39		

(*Continued*)

Table 3 (Continued).

Variables	Univariable Model		Multivariable Model‡	
	HR (95% CI)	p value	aHR (95% CI)	p value
Norepinephrine in dextrose				
No	1 [Reference]		1 [Reference]	
Yes	2.41 (1.17–4.97)	0.02	2.29 (1.09–4.82)	0.03
Vancomycin				
No	1 [Reference]			
Yes	1.15 (0.40–3.33)	0.80		
Total dose of infusates (irritants/vesicants)				
0	1 [Reference]			
1–2	1.22 (0.49–3.04)	0.67		
≥3	1.54 (0.79–3.02)	0.21		
PIVC Characteristics				
Location				
Basilic	1 [Reference]			
Brachial	1.35 (0.66–2.72)	0.41		
Cephalic	2.47 (1.09–5.57)	0.03		
Side				
Left	1 [Reference]			
Right	1.24 (0.59–2.60)	0.57		
Depth of vein, cm				
≤1.2	1 [Reference]			
>1.2	0.90 (0.49–1.66)	0.74		
Catheter-to-vein ratio				
≤0.40	1 [Reference]			
>0.40	1.52 (0.78–2.97)	0.22		
Distance from antecubital fossa, cm				
≤7.0	1 [Reference]			
>7.0	0.95 (0.51–1.75)	0.86		

Notes: ‡The model assessment indicated the predictive ability (c-statistic) on the occurrence of midline catheter failure was 0.64. Using the bootstrap cross-validation with 1000 bootstrap samples, the estimate of c-statistic was 0.66 (95% CI, 0.56–0.77).
Abbreviations: BMI, body mass index; PIVC, peripheral intravenous catheter; HR, hazard ratio; aHR, adjusted hazard ratio; CI, confidence interval; NA, not available.

Discussion

In our cohort, we observed a relatively high rate of premature MC failure (22%). As we have previously described, existing literature suggests that the true MC failure rate is somewhere between 2.6% and 57%, which is consistent with our findings here.[5] Our univariable analysis uncovered several variables associated with an increased risk of MC failure prior to completion of therapy, including body temperature ≥38°C, elevated pulse rate, decreased blood oxygen saturation, and norepinephrine in dextrose use. It is notable, however, that most of these variables were not statistically significant in a multivariable analysis. Given the overall small to moderate sample size of our population, it is plausible that these variables would reach statistical significance in a larger cohort. Regardless, our findings in the univariable analysis do suggest a population of patients where MCs may be a higher risk device and alternative vascular access devices could be considered.

Previous literature has described that critical illness and systemic inflammation (including sepsis) are associated with higher rates of catheter-related complications, specifically thrombosis.[11–13] However, what is less well known is whether a patient with critical illness has an increased risk of catheter-associated complications or if catheter complications increase the duration and/or severity of critical illness. Our findings suggest the former. Patients in our analysis who presented with systemic inflammatory response syndrome (elevated pulse, fever, decreased oxygen saturation) had an

increased risk of MC failure when compared to individuals without these vital sign abnormalities. These findings suggest that patients who meet systemic inflammatory response criteria upon arrival to the hospital, or prior to vascular access device insertion, may experience higher rates of MC failure than other populations. Therefore, among these patients, another vascular access device, such as a centrally inserted central catheter (CICC), may be more appropriate for their acute care needs. However, our findings must be replicated in a larger cohort and specifically evaluate if a diagnosis of sepsis vs another inflammatory disorder portrays a higher risk of catheter failure.

Another significant finding in our analysis was that cephalic vein placement was associated with a higher risk of MC failure prior to completion of therapy. More specifically, cephalic vein placements experienced a nearly two-fold increase in the risk of premature MC failure compared to devices placed in the basilic or brachial vein. This finding aligns with previous literature, which highlighted that MC placement in the cephalic vein is a high-risk venous access site that specifically increases the risk of catheter-related thrombosis.[14] Given the high risk of complications with MC cephalic vein placement, clinicians should preferentially choose another location for MC placement when possible. Based on the findings of this analysis as well as prior literature, we suggest that in scenarios where the cephalic vein is the solely accessible option, clinicians should consider alternative venous access devices such as central venous catheters as a potentially more durable solution.[15] It is also notable that shifting to a central line does not necessarily translate to an elevated safety risk. One recent publication found that when compared to MCs, PICCs did not increase the risk of thrombosis or infection across the study population as well as in a sub-analysis of sepsis and septic shock.[16]

After the implementation of widespread mandatory monitoring and reporting of central line associated blood stream infections since the early 2000s, many institutions have greatly reduced their utilization of CICCs in favor of other options. These regulations likely spurred some of the popularity of MCs which remain unregulated. Given the lack of surveillance, there has also been expanded use of MCs to include the delivery of caustic therapies that traditionally have been infused via CICCs. Minimal existing evidence has shown that infusion of vasoactive medications via MCs does not increase risk to the patient.[17] In this investigation, while the use of vesicants/irritants as a general class did not confer risk of line failure, in univariable and multivariable analyses, use of norepinephrine in dextrose specifically was associated with an increased risk of line failure. As norepinephrine is a commonly used first-line vasopressor and was the second most frequently used caustic medication in this study, clinicians should consider the negative impact on MC survival when considering norepinephrine infusion via MCs. While other caustic substances did not clearly show an increased hazard of MC failure, it is plausible that there are likely several scenarios where a CICC may be preferred over MCs despite recent unchecked widespread adoption of MCs. However, additional larger trials are needed that account for type, dose, duration, and frequency of administration of these medications to determine the precise impact of vesicants on MC survival.

Limitations

This study had some limitations. First, this investigation was performed at a single, large academic suburban tertiary care center with a patient population that may not be generalizable to other sites. Second, as this was a secondary analysis of an existing trial dataset, the potential actionable strategies need to be further substantiated through a larger well-designed evidence-based experimental or observational study. Third, there was a small-to-moderate sample size which limits our conclusions. Fourth, the results are limited to the catheters analyzed in this trial and other factors such as multiple lumens or varying catheter diameters were not evaluated. Finally, details regarding etiology of failure were captured from the medical record based on observations and documentation of the clinical staff. As ultrasound was not used to evaluate all catheters with complications, the exact cause of failure, possibly multifactorial, was unknown.[18,19]

Conclusions

Patients with elevated pulse rates, decreased oxygen saturation levels, and temperatures ≥38°C, all had increased risk of MC failure prior to completion of therapy. Additionally, lines placed in the cephalic vein were at higher risk of failure compared to lines in the basilic or brachial veins. Our findings suggest that among patients who have clinical instability prior to vascular access device placement, MCs may have higher risk of failure and another device could be considered for their acute care needs. Additionally, if only the cephalic vein is available for MC placement, it may be prudent to consider another device as more appropriate.

Data Sharing Statement

The data that support the findings of this study are available via a data access agreement. Please contact the corresponding author for this request.

Ethics Committee Approval

This study was approved by the Beaumont Health Institutional Review Board. All trial participants provided informed consent and the trial was conducted in accordance with the Declaration of Helsinki.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

Disclosure

Amit Bahl has research grant support from B. Braun Medical, Becton-Dickinson, Teleflex, Adhezion, Medline Industries, and Access Vascular. Amit Bahl is a paid consultant for B. Braun Medical, Teleflex, and Interad Medical. All other authors have no disclosures to report for this study.

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