CONCISE COMMUNICATION

The Risk of Adverse Events Related to Extended-Dwell Peripheral Intravenous Access

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Midline catheters (MCs) may be useful to avoid repeated venipuncture in patients requiring prolonged intravenous infusions with limited adverse events (AEs). We analyzed 2 Italian hospital databases to ascertain the safety of MCs. Among 1,538 adult patients, 154 MC-related AEs (10%; 2.49 AEs per 1,000 MC days) were reported.

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When selecting the best vascular access device for a patient, the goal is always to choose the one that will best foster vessel health and preservation.[1] To improve efficiency in treatment delivery, healthcare professionals must select the most appropriate device according to the patient's needs: peripheral short catheter (PSC), extended-dwell peripheral catheter, peripherally inserted central catheter (PICC), or central venous access device (CVAD).[2,3]

Compared to PSCs, extended-dwell peripheral intravenous accesses devices, such as midline catheters (MCs) have been associated with increased dwell time and lower first-attempt failure. Moreover, the use of MCs avoids complications related to central lines, such as bloodstream infections (BSIs) and catheter-related thrombosis.[2,3]

With the increasing attention to cost control, MCs (with their longer dwell-times and low complications rates) may be a viable, cost-saving alternative to central catheters that can also ensure patient safety. In this study, we aimed to ascertain the safety of MCs.

METHODS

Midline-catheter data from the databases of 2 acute-care public Italian hospitals were analyzed. All inpatients and outpatients (n = 1,584) who received a MC between September 2007 to December 2014 were eligible for inclusion. We excluded those who still had the MC inserted (n = 5, 0.3%) or for whom no removal date reported (n = 41, 2.6%).

As part of standard practice, the intravenous site was prepared using an aseptic technique. Midline-catheters were inserted by a member of the MC insertion team, a team of registered nurses with a postgraduate specialization in positioning PICCs and MCs. All MCs were inserted using ultrasound-guided puncture and were 4–5 French (Fr) in diameter and 20–25 cm in length. Almost all MCs were single lumen; 4 were bilumen. After the catheter insertion, a sterile 5 × 5-cm gauze dressing was positioned and held in place with a transparent dressing, which was changed the day after insertion. Thereafter, transparent dressings were changed every 7 days. If evidence of hematic or serous leakage was noted, gauze plus transparent dressings were changed every 48 hours. Midline catheters were anchored with an adhesive-based suture-free device. After insertion, MCs were accessed by ward staff, and intravenous sites were inspected once per shift.

Midline catheters were left in situ until the end of therapy or until complications occurred, although MC manufacturers recommend a maximum dwell time of 28 days.[2]

Data Collection

Data on patient characteristics, MC characteristics, and cause of MC removal were collected. The causes of MC removal were distinguished in MC-related adverse events (eg, AEs, occlusion, exit-site infection, or symptomatic thrombosis) or other reasons (eg, accidental removal, termination of therapy, natural device expiration, or death of the patient).

The following definitions were adopted:

- Occlusion: Complete inability to flush, infuse, or aspirate; resistance with flushing and aspiration or sluggish infusion; or ability to flush and infuse but not aspirate.[4]
- Exit-site infection: Presence of tenderness, erythema, and/or purulent discharge at the catheter site.[5]
- Symptomatic thrombosis: Lack of flow or nonpulsatile and nonphasic flow associated with lack of compressibility of the veins, edema, and erythema of the cannulated arm.[6] Symptomatic thrombosis was confirmed by ultrasound.
- Accidental removal: Unplanned removal of the catheter either by the patient or the staff.[7]

Primary Outcome Measure

Midline catheter removal due to MC-related AEs was set as the primary outcome measure. Thus, the primary outcome was a composite measure defined as the number of AEs per MC days (ie, the period an MC was in place) and was presented as per 100 MCs (%) and per 1,000 MC days.

A Posteriori Sample Size Calculation

A power analysis was conducted using AE frequencies from the literature.[8] A sample of 1,538 MCs ensured an estimation of 10% of AEs with a precision of ±1.5% at a confidence level of 0.05. Each patient was included in the study only once.

Data Analysis

The primary outcome measure was MC removal due to AEs and MC removal due to other reasons (categorical variable). As appropriate, the χ^2 test, the Fisher exact test, and the Mann-Whitney U test were used to detect associations between the variables measured and the rate of AEs. The statistical significance level was set at $P < .05$. Analyses were performed using R version 3.3.3 statistical software (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

In total, 1,538 (97.1%) patients had an MC removed during the study period. The removal due to AEs was associated with a shorter dwell time compared to other reasons, when receiving supportive therapy and when a MC with an open system was inserted (Table 1). Most MCs (n = 1,384, 90%) were removed for reasons other than AEs: 719 (52%) for patient death, 586 (42.3%) for termination of therapy, 62 (4.5%) for accidental removal, and 17 for device expiration (1.2%). A significant difference in accidental removals was observed between MCs inserted on the right versus left side (64.9% vs 35.1%; $P = .03$).

The 154 AEs reported accounted for 10% of catheter removal, corresponding to a complication's incidence density of 2.49 AEs per 1,000 MC days. The individual AEs experienced by patients and time elapsed between MC insertion and the onset of each AE are listed in Table 2.

DISCUSSION

Our findings suggest that MC can be a safe device for medium-term therapy, confirming the findings of a previous systematic review that reported that the risk of BSI was lower among patients with MCs (0.2 per 1,000 catheter days) than those with peripherally inserted central catheters (2.1 per 1, 000 catheter days) or short-term central venous catheters (2.7 per 1,000 catheter days).[3]

We found a lower aggregate incidence density of all complications that those of previous reports[3,9]; however, we did not include pain and bleeding in the composite outcome, and we considered accidental removal separately.

The median MC dwell time (26 days) was in line with CDC guidelines, which recommend the use of a MC for intravenous therapy exceeding 6 days.[5] However, our data suggest that this ideal period could be extended up to 273 days without risk of AE occurrence. These findings confirmed a preliminary retrospective analysis of 92 home-care patients with advanced cancer, which reported a median MC dwell time of 85 days, ranging up to 1 year.[10] Thus, MCs may work successfully even beyond their recommended period of use. This consideration may be particularly important for healthcare professionals because they weigh the risk of leaving a MC in place longer than suggested against the sometimes limited benefit of more frequent replacement, especially in patients with limited life expectancy.

This study has some shortcomings. First, as with all retrospective studies, there were problems with incomplete

TABLE 1. Patient and Midline Catheter (MC) Characteristics According to Reason for MC Removal: Bivariate Analysis (n = 1,538)

Variables	All Patients (n = 1,538)	MC Removal Due to AEs[a] (n = 154)	MC Removal for Other Reasons (n = 1,384)	*P* Value
Patient characteristics				
Male gender, no. (%)[b]	155 (38.3)	17 (41.5)	138 (37.9)	.784
Age, median y (IQR)	83 (77–88)	83.5 (80–87)	83 (77–89)	.915
MC characteristics				
MC system, n (%)				.074
Open	829 (53.9)	94 (61)	735 (53.1)	
Valved	709 (46.1)	60 (39)	649 (46.9)	
Insertion location, no. (%)				
Left side	413 (27.5)	39 (26)	374 (27.6)	.745
Accessed vein				
Basilic vein	1,281 (83.3)	130 (85)	1,151 (83.2)	.675
Brachial vein	242 (15.7)	21 (13.7)	221 (16)	
Cephalic vein	14 (1.0)	2 (1.3)	12 (0.9)	
Administered therapy, no. (%)				.147
Supportive therapy	1,370 (89.1)	143 (92.9)	1,227 (88.7)	
Chemotherapy	168 (10.9)	11 (7.1)	157 (11.3)	
Dwell time, median d (IQR)	26 (12–37)	14 (6–28)	27 (13–37.25)	<.001
Chemotherapy	25.5 (15–32)	22 (6–30)	26 (16–32)	.318
Supportive therapies[c]	26 (11–38)	14 (6–28)	27 (13–40)	<.001
Open system	27 (15–36)	13 (6–24)	29 (17–37)	<.001
Valved system	23 (9–39)	19 (6–50)	24 (10–38)	.493

NOTE. AEs, adverse events; IQR, interquartile range.

[a]AEs were defined as ≥1 of the following: occlusion, exit-site infection, or symptomatic thrombosis.

[b]Data on 409 patients: 155 male (38%) and 254 female (62%).

[c]Supportive therapies included peripheral parenteral nutrition with osmolarity <600 mOsm/L and hydration.

TABLE 2. Individual Adverse Events (n = 154)

Adverse Events	No.	No. of Complications per 1,000 MC days	Time Elapsed Between MC Positioning and Onset of AE, median d (IQR; range)
Occlusion[a]	89	1.44	13 (6–28; 1–273)
Symptomatic thrombosis[b]	57	0.92	19 (8–32; 1–307)
Exit-site infection[c]	8	0.13	9 (7.8–39.8; 5–323)
All adverse events[d]	154	2.49	14 (6–28; 1–323)

NOTE. MC, midline catheter; AE, adverse event; IQR, interquartile range.

[a]Defined as the complete inability to flush, infuse, or aspirate (ie, complete occlusion), or resistance with flushing and aspiration or sluggish infusion (ie, partial occlusion), or ability to flush and infuse but not aspirate (ie, persistent withdrawal occlusion).[4]

[b]Defined as the lack of flow or nonpulsatile and nonphasic flow associated with lack of compressibility of the veins, edema, and erythema of the cannulated arm.[6] Symptomatic thrombosis was confirmed by ultrasound examination.

[c]Presence of tenderness, erythema, and/or purulent discharge at the catheter site.[5]

[d]Consisting of a composite of AEs: occlusion, exit-site infection, and symptomatic thrombosis.

documentation. Relevant factors that may contribute to MC-related AEs, such as recent surgery, comorbidities (ie, obesity, diabetes, nephropathies, malnourishment), or administered drugs were not collected. Moreover, we had no information on the reason for inserting a MC or on the postinsertion use and care of the MCs. The setting of AEs (ie, inpatient or outpatient) was not specified; thus, comparisons between inpatient and outpatient AEs were not possible. We may hypothesize that the shorter dwell time in patients with an open MC or receiving supportive therapies was due to flushing practices that may need improvement (ie, positive pressure and pulsating technique), but data on the local flushing practices were not available. On the other hand, the large, heterogeneous sample makes our findings more generalizable.

In conclusion, the MC can be considered a safe device when inserted by trained nurses, with limited complications, even beyond the suggested period of use.

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