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Review Article

Complications associated to midline- and long peripheral catheters in adults. Systematic review of literature and proposal for a standardized model for data collection

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ABSTRACT

Introduction: Long peripheral catheters (LPCs) and midline catheters (MCs) are indiscriminately labelled with different names, leading to misclassifications both in primary and secondary studies. The available studies used different methods to report the incidence of catheter-related complications, affecting the possibility of properly comparing the catheter outcomes. The aim of this review was to explore the complications related to LPCs and MCs after reclassifying according to their length.

Methods: Systematic literature review based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses, conducted on PubMed, Scopus and CINAHL databases. The study protocol was registered in the International Prospective Register of Systematic Reviews. Data regarding LPCs and MCs were compared. Catheter outcomes were classified into major and minor complications, recomputed and reported as cases/1000 catheter-days.

Results: Fourteen studies were included. Over-half of the devices were correctly labelled by the authors, misclassifications affected particularly LPCs improperly labelled MCs. The cumulative incidence of catheter-related bloodstream infections was 0.3 and 0.4/1000 catheter-days, that of symptomatic catheter-related thrombosis was 0.9 and 1.8/1000 catheter-days for MCs and LPCs, respectively. Minor complications and catheter failure were higher for LPCs.

Conclusions: A misclassification exists in the labelling of MCs and LPCs. A widespread heterogeneity of diagnostic criteria adopted to classify the catheters' outcomes was found, exposing the risk of misestimating the incidence of complications and undermining the possibility of effectively comparing results of the published research. We proposed a list of definitions and relevant variables as a first step toward the development of standardized criteria to be adopted for research purposes.

1. Introduction

In an increasing number of patients with a difficult intravenous access condition or needing a medium-term therapeutic plan (>7 days), the placement of a long peripheral catheter (LPC) or a midline catheter (MC) is performed [1–4]. Different to traditional short peripheral catheters, both LPCs and MCs are always inserted in deep vessels under ultrasound (US) guidance, usually at the Dawson's green zone of the upper arm, through the basilic, brachial or cephalic vein [5].

Many guidewire-equipped catheters of various lengths have been proposed by the industry over the years. Unfortunately, both manufacturers and literature on the topic indiscriminately labelled these devices with many different names (e.g., midline, midline catheter, mini-midline, short-midline, new midline, midclavicular catheter, long peripheral catheter, extended-dwell-catheter, long cannulas, etc.). To bring order, a standardization in the nomenclature has been proposed, based on catheter length, final tip position, material, insertion technique and costs [3,4,6]. However, a clear distinction between LPCs and MCs

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has become increasingly less obvious over time. First, LPCs and MCs can be made of the same biomaterial (e.g., polyurethane). Second, no clear distinction can be made regarding the catheter tip position, which—in addition to a catheter's length—may depend on factors such as the anthropometric characteristics of the patient and the puncture site (e.g., caudal border rather than cranial border of Dawson's green zone) [7]. Third, at present, the cost of the two devices is often similar. Fourth, despite MCs positioning generally requiring a 'modified' Seldinger technique and LPCs requiring a faster procedure based on a 'direct' or 'simplified' Seldinger technique, LPCs that are implantable with direct, simplified or modified techniques and MCs implantable with direct or modified methods are now available. In addition, a possible criterion related to the expected duration of the catheters does not seem adoptable given that the literature reports many examples of LPCs with very long uncomplicated indwelling times [7–10]. Therefore, considering the above-mentioned proposed classification, the only distinguishing feature seems to be related to the catheter length, being 6–15 cm for LPCs and > 15 cm for MCs. However, it should be noted that the proposed thresholds are not completely clear, since both short- and LPCs may belong to '6 cm' category.

Recently, several systematic literature reviews have been performed to investigate the safety and efficacy of LPCs and MCs. However, some reviews aimed at analysing MC-related complications included articles reporting data on both MCs and LPCs, as well as articles in which the catheter characteristics (e.g., length) were not declared by the authors, thus preventing a correct catheter classification [11–15]. On the other hand, reviews designed to investigate LPC-related complications also included MCs (catheters longer than 15 cm) or—not having included terms identifying MCs in their search strings—may have mistakenly overlooked possible articles where the authors misclassified LPCs naming them as midline-catheters [16,17]. To the best of our knowledge, no systematic review exploring the catheter-related complication of LPCs and MCs, after clearly distinguishing the different devices, is available.

Therefore, the aim of this study was to explore the complications related to LPCs and MCs in adults, after reclassifying the devices according to the above-described characteristics, regardless of how the authors catalogued them.

2. Methods

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [18]. The study protocol was registered in the International Prospective Register of Systematic Review (n° CRD42023474247).

2.1. Eligibility criteria

All primary quantitative studies were considered potentially eligible if they focused on either LPCs or MCs in adult populations and reported the catheter-related complications. Articles were accepted if they included the following: 1) the length of catheters was clearly described or, when lacking, the information was retrievable by consulting the catheter manufacturers' technical documentation; 2) the catheters were positioned by ultrasound-guided techniques; and 3) at least one catheter-related complication was documented. Studies were excluded for the following reasons: 1) the criteria used for identifying complications were not described; 2) the number of catheters included in the study was not declared; 3) the catheter dwelling times were not reported or the catheters were electively removed or replaced after a pre-established time interval (e.g., seven days), irrespective of complications or end-of-use. Case reports, letters, abstracts, commentaries, conference proceedings and secondary studies such as reviews were also excluded. Finally, studies were excluded if they were judged to be of poor methodological quality based on the quality screening process described below.

2.2. Search strategy

According to the research question, the electronic search was conducted on PubMed, Scopus and CINAHL databases using Boolean operators to combine the following terms, as appropriate: 'midline catheter', 'midclavicular catheter', 'mini-midline', 'short-midline', 'long peripheral catheter' and 'long peripheral cannula'. The search was limited to articles published in English. The last search was run on 16 November 2023 at 5:00 p.m. The complete search strings used to explore the above databases are reported in Table A1 (appendices).

2.3. Study selection

After removing duplicates, the four authors independently reviewed the potentially eligible titles and abstracts, and the papers were either selected for the next step or excluded based on the eligibility and exclusion criteria. In cases of disagreement, a face-to-face discussion took place to achieve a consensus. Subsequently, the full texts of the selected documents were independently reviewed by two authors (AF and GS). An additional search was also carried out using the bibliographical references of the selected articles and the articles of potential interest were reviewed as well. In the cases of disagreement, the articles were cross-checked to reach a consensus.

2.4. Quality screening of selected studies

The selected studies were assessed for eligibility based on methodological quality and risk of bias, according to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement [19] for observational studies or the Consolidated Standards of Reporting Trials (CONSORT) checklist [20] for randomized clinical trials. According to the above checklists, for each item, the authors independently assigned a score as follows: 0 = not reported/not considered; 1 = partially/weakly reported; or 2 = correctly and exhaustively reported; the items not applicable for a particular study were not considered. Any disagreement was discussed and resolved by consensus. The final score was computed as the ratio between the number of items scored as 2 and the total number of applicable items (range 0 to 100). The study rating was defined as follows: <60 = poor quality (very high risk of bias), 60–79 = low quality (high risk of bias), 80–89 = good quality (moderate risk of bias) and ≥ 90 = high quality (low risk of bias). Only studies with a quality score of ≥60 were included in the final review. Finally, the studies were classified according to their level of evidence (LOE) (Table A2, appendices) according to previously adopted criteria [21].

2.5. Synthesis of results

Data on the study design, research setting, sample size and type of catheters, including their structural characteristics (length and material), placement indication and dwelling time, were extracted. To overcome the above described overlapping in catheter lengths of current classification, LPCs were considered to be those having a minimum length of >6 cm. After their reclassification, data regarding LPCs and MCs were reported separately.

Data on catheter outcomes were classified into major and minor complications and reported together with the respective diagnostic criteria or authors' definition, as appropriate. Only complications supported by clearly defined diagnostic criteria were considered. The unplanned removal of the catheter before the end of the therapy was generically defined as 'catheter failure', irrespective of the causes. Catheter-related bloodstream infections (CR-BSIs) and symptomatic or asymptomatic catheter-related thrombosis (CRTs) were considered as major complications. Based on the definitions used in included studies, minor complications were classified into the following five categories: 1) phlebitis and exit site infections; 2) leaking, extravasation and

infiltration; 3) occlusion, malfunction; and 4) accidental removal or dislodgement.

Since the included studies used different methods to report data on the incidence of catheter-related complications, the possibility of properly comparing the catheter outcomes between studies could have been precluded. The use a standardized methodology has been recommended for documenting the catheters' outcome for both surveillance and research purposes in different settings; therefore, the complication rates were reported as an incidence per 1000 catheter-days [22,23]. For studies reporting the incidence using different ways, the standardized incidence was calculated on the basis of the reported number of events and total number of catheter-days according to the following equation:

$$\text{Incidence} = \frac{\text{n}^{\circ}\ \text{events}}{\text{total catheters days}} \times 1000.$$

When one or more of the required items of information were not reported, the authors of the articles were contacted to obtain additional data.

Finally, a cumulative synthesis of the results was reported by considering the data of each single study as a part of a unique population of LPCs or MCs. In detail, for each major outcome, the sample sizes, the number of events and the total catheter-days of each individual study were added, when available, and the overall standardized incidences of complication per 1000 catheter-days were computed.

3. Results

3.1. Study selection

A total of 3515 records were identified by database searches. After removing duplicates and articles considered non-pertinent, 171 studies underwent the full-text review. Eight additional studies were identified from the reference lists. Among studies screened as potentially eligible, 25 were consistent with the inclusion and exclusion criteria. For example, reasons for exclusion were the lack of information regarding the length of the catheter or having considered LPCs and MCs as belonging to the same midline-catheter category—thus preventing complications from being attributed to MCs or LPCs. In other cases, complications were not reported at all or the criteria used to establish the presence of a certain complication were not described.

Among 25 studies selected for the systematic quality assessment, 11 were excluded because of the high risk of bias (quality score < 60); the identified biases were mostly related to the study design (e.g., undeclared design, randomization methods not described, weakness in defining study variables or outcomes), statistics (e.g., statistical methods not reported, sample size not calculated), and reporting or discussion of the results (e.g., characteristics of the enrolled subjects not described, number of missing data not reported, limitations not analysed, internal/external validity of the study not discussed). Finally, 14 studies reached the expected quality threshold and were included in the review (Fig. 1).

3.2. Study characteristics, methodological quality and level of evidence

The main characteristics of the included study are reported in Table 1. The articles were published between 2018 and 2023. Three randomized clinical trials [10,24,25], as well as three prospective [26–28] and eight retrospective observational studies [7–9,29–33] were included. Five studies were conducted in Italy, two in the United States, two in Australia, two in Denmark, and one in Spain, Czech Republic and Korea, respectively. The enrolled populations considered only hospitalized subjects and included both medical, surgical and critically ill patients. Six studies exclusively reported data on LPCs, five only on MCs, while three studies compared LPCs and MCs.

For five studies the quality was low and six were good, while three studies were classified as high quality (Fig. A1, appendices). Only three studies were considered at the best level of evidence.

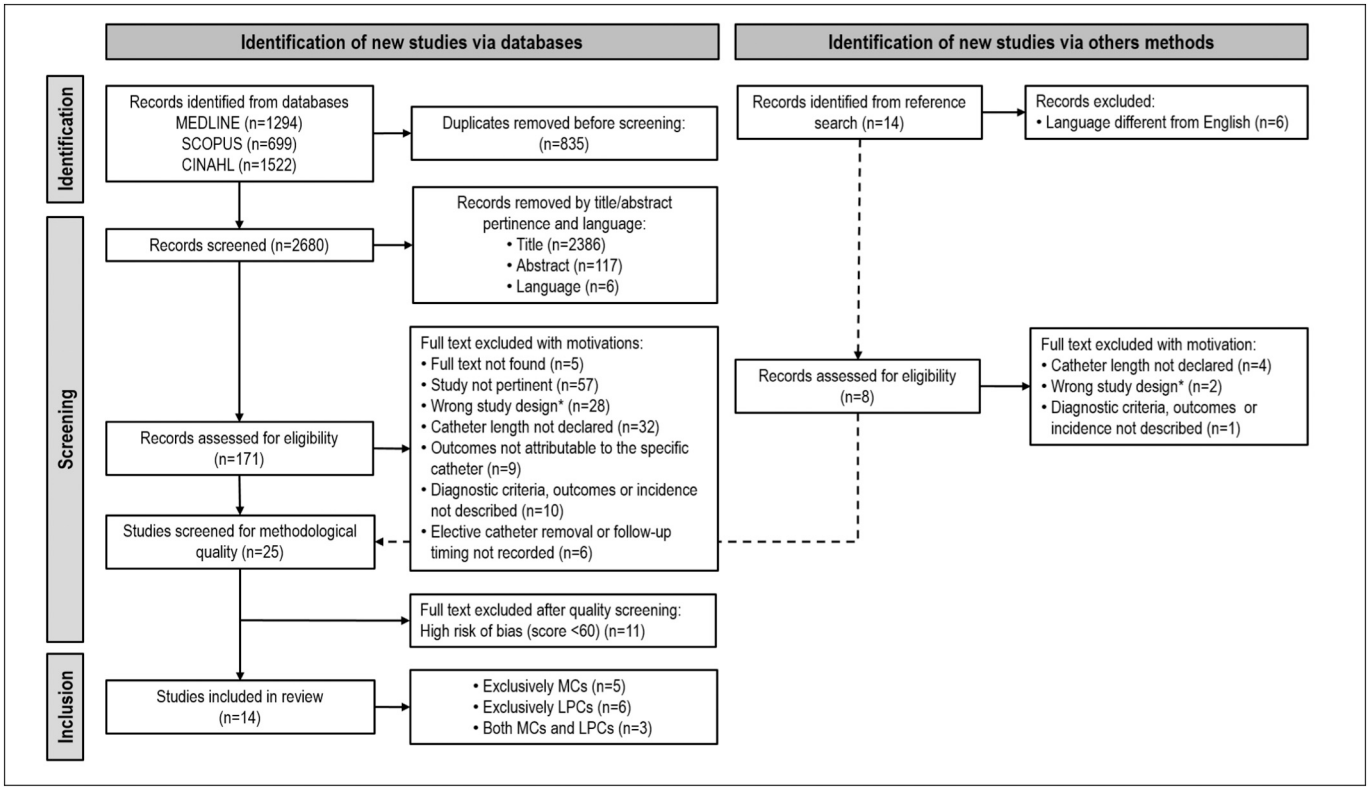

Fig. 1. PRISMA flow chart of the review process. *: case reports, letters, abstracts, commentaries, conference proceedings, secondary studies.

Table 1
Summary of main characteristics of the studies included in the review.

Author, Year	Country	Design	Number of catheters	Quality score (LOE)	Setting	Population
Bahl, 2021	USA	RCT	191	93 (1)	Suburban tertiary care center	DIVA, iv therapy (7–28 days)
Campagna, 2018	Italy	ROS	1538	69 (5)	Two acute care hospitals	n.d.
Fabiani, 2020	Italy	ROS	184	96 (4)	Cardiovascular dpt	DIVA
Fabiani, 2023	Italy	ROS	240	86 (4)	Cardiovascular dpt	Patients with MCs or LPCs insertion.
Frondizi, 2023	Italy	POS	158	79 (4)	COVID-19-non-ICU- hospital	DIVA
Jeon, 2022	Korea	ROS	117	83 (4)	Single center	Patients with MCs insertion
Johnson, 2022	USA	ROS	115	78 (5)	Veterans hospital	DIVA, iv therapy, blood draws
Jones, 2022	Australia	ROS	207	74 (5)	Rural regional hospital	DIVA, iv therapy (5–30 days)
Lisova, 2018	Czech Republic	POS	439	61 (3)	Surgical, medical dpt	DIVA, iv therapy (>5 days)
Locatello, 2022	Italy	ROS	265	80 (4)	Surgical	n.d.
Bundgaard M, 2020	Denmark	ROS	98	80 (4)	Surgical, medical, ICU	DIVA, iv therapy (medium-long term)
Marsh, 2022	Australia	RCT*	61	97 (1)	Surgical, medical, anaesthetic dpt	DIVA, iv therapy (>5 days)
Nielsen, 2021	Denmark	RCT	97	87 (1)	Cardiology, infectious diseases dpt	iv therapy (> 5 days)
Tomàs-Lòpez, 2022	Spain	POS	2275	84 (3)	Surgical, medical	DIVA, iv therapy (6–30 days)

RCT: randomized clinical trial. ROS: Retrospective observational study. POS: Prospective observational study. ICU: intensive care unit. DIVA: difficult intravenous access condition. iv: intravenous. LOE: level of evidence. n.d.: not declared. *: pilot study. dpt: department.

3.3. Characteristics of the catheters

Overall, in the included studies, a total of 962 LPCs and 5023 MCs were considered, with a total dwell time of 11,147 and 129,179 days, respectively.

Data regarding LPCs were presented in nine studies (Table 2). Seven studies misclassified LPCs as MCs. All but one study analysed LPCs made of polyurethane, with 20 or 18 G in diameter and 8 to 15 cm in length. The maximum documented dwell time was 76 days.

Midline catheters' characteristics were extracted from eight studies (Table 3). Only one study misclassified MCs as LPCs. Six studies analysed MCs made of polyurethane; one compared polyurethane and polyethylene catheters, while one study did not report this information. The diameter of catheters was 4 or 5 Fr, with a length ranging from 18 to 30 cm. The maximum documented dwell time was 312 days.

3.4. Major complications

Cumulative rates of major complications, considering the overall data of the included studies, are reported in Table 6.

CR-BSIs were documented in all studies considering LPCs and in seven considering MCs. The reported incidences ranged from 0 to 3.2 cases per 1000 catheter-days in MCs and from 0 to 1 in LPCs. The methods adopted to diagnose this complication were not homogeneous among studies; they included the following: 1) blood cultures differential-time-to-positivity of 120 min or more; 2) catheter-tip culture positive for the same microorganisms of the blood culture, considering, or not considering, the resolution of symptoms after catheter removal; 3) positive blood culture with a still indwelled catheter or within 48 h after catheter removal; and 4) laboratory confirmed bloodstream infection judged not secondary to an infection at another body site. Considering the aggregated data of 3046 MCs (overall dwell time: 61,369 days) and 755 LPCs (overall dwell time: 9562 days), the cumulative incidences of CR-BSIs were 0.3 and 0.4 per 1000 catheter-days for MCs and LPCs, respectively.

Symptomatic CRTs were documented in all studies considering LPCs and MCs. The incidence per 1000 catheter-days ranged from 0.4 to 4.7 and from 0.5 to 5.7 for MCs and LPCs, respectively. In all considered studies, symptomatic CRTs were diagnosed by US scan, mostly as the presence of echogenic material inside an incompressible vein at the US-compression test. Considering the aggregated data of 5023 MCs (overall dwell time: 129,179 days) and 962 LPCs (overall dwell time: 11,147 days), the cumulative incidences per 1000 catheter-days of symptomatic CRTs were 0.9 and 1.8 for MCs and LPCs, respectively.

3.5. Minor complications

Overall, several minor complications were documented in all LPCs and in all but one MCs studies (Tables 4 and 5). For MCs, the reported incidences per 1000 catheter-days ranged from 0 to 3.8 for exit-site infection or phlebitis; from 0 to 10.4 for leak, infiltration or extravasation; from 0 to 5.3 for complete occlusion or catheter malfunction and from 0 to 9.3 for accidental removal or dislodgement. For LPCs, the incidences for 1000 catheter-days ranged from 0 to 16.0 for exit-site infection or phlebitis; from 0 to 9.5 for leak, infiltration or extravasation; from 0 to 13.9 for complete occlusion or catheter malfunction and

Table 2
Long-peripheral-catheters: characteristics of the devices and major complications as reported by studies included in the review.

Author, Year	Catheter characteristics	Author's catheter classification	Dwelling days mean/median [max][a]	Catheter failure[b] (method)	CR-BSI[b] (method)	S-CRT[b] (method)
Bahl, 2021	4.5 Fr/15 cm (PUR-AT-AM)	Midline-catheter	10.1 ± 6.6 [NA]	22.8 (PR-UM/C)	0 (NHSN)	5.7 (US+Co)
Fabiani, 2020	20–18 G/8–10 cm (PET)	Long-peripheral-catheter	11 ± 8.9 [54]	15.9 (PR-C)	0 (DTP/TC)	1.2 (US+Co)
Fabiani, 2023	18 G/10 cm (PUR)	Long-peripheral-catheter	17.1 ± 12.3 [74]	5.1 (PR-C)	1,0 (DTP/TC)	3.1 (US+Co)
Jeon, 2022	20–18 G/8–10 cm (PUR)	Midline-catheter	16.8 ± 13.5 [76]	26 (PR-C/NC)	1,0 (BC/TC + RS)	0.5 (US)
Johnson, 2022	10 cm (PUR)	Midline-catheter	(11; 5.5–19.5) [NA]	12.8 (PR-C)	0 (BC[c] + TC/DTP+ NOI)	0.6 (US/V)
Jones, 2022	20 G/8–10 cm (PUR)	Midline-catheter	8 ± NA [38]	18.3 (PR-C)	NA	0.6 (US)
Bundgaard M, 2020	20–18 G/10 cm (PUR)	Midline-catheter	(8; *0–41*) [41]	71.8 (PR-C)	0 (BC/TC)	2.1 (US)
Marsh, 2022	20–18 G/8–10 cm (PUR)	Midline-catheter	(4.9; 3.2–8) [NA]	69.3 (APIF)	0 (NHSN)	5.3 (US)
Nielsen, 2021	20–18 G/10 cm (PUR)	Midline-catheter	(9; *0–60*) [60]	48.9 (PR)	0 (BC/TC + NOI)	0.8 (US)

CR-BSI: catheter-related bloodstream infection. S-CRT: symptomatic catheter-related thrombosis. PUR: polyurethane. PET: polyethylene. AT: anti-thrombotic. AM: anti-microbic. NA: not assessed. PR: premature removal. C: complications. NC: non complications. UM: unresolvable malfunction. APIF: all causes post-insertion failure. DTP: differential time to positivity. TC: tip culture. NHSN: National Health and Safety Network. BC: blood culture. NOI: no other infections. RS: resolution of symptoms. US+Co: US-scan + US compression test. US: US-scan. V: venogram.

[a] Data presented as "mean ± standard deviation" or "(median; interquartile range)" or "(median; *range*)".

[b] Incidence per 1000 catheter/days. c: up to 48 h after catheter removal.

Table 3
Midline-catheters: characteristics of the devices and major complications as reported by studies included in the review.

Author, Year	Catheter characteristics	Author's catheter classification	Dwelling days mean/median [max][a]	Catheter failure[b] (method)	CR-BSI[b] (method)	S-CRT[b] (method)
Bahl, 2021	4 Fr/20 cm (PUR-AT)	Midline-catheter	11.2 ± 6.6 [nd]	20.8 (PR-UM/C)	0 (NHSN)	4.7 (US+Co)
Campagna, 2018	4–5 Fr/20–25 cm (nd)	Midline-catheter	26 (NA) [273]	2.5 (R-AE)	NA	0.9 (US+Co)
Fabiani, 2020	18 G/18 cm (PET)	Long-peripheral-catheter	16 ± 10.8 [48]	10.6 (PR-C)	1.3 (DTP/TC)	1.3 (US+Co)
Fabiani, 2020	4 Fr/20 cm (PUR)	Midline-catheter	26 ± 22.6 [153]	6.3 (PR-C)	0.5 (DTP/TC)	1.9 (US+Co)
Fabiani, 2023	4 Fr/20 cm (PUR)	Midline-catheter	25.7 ± 20.4 [125]	3.4 (PR-C)	0 (DTP/TC)	0.9 (US+Co)
Frondizi, 2023	4–5 Fr/20–25 cm (PUR)	Midline-catheter	12.4 ± 11.2 [nd]	NA	3.2 (DTP)	1.1 (US)
Lisova, 2018	4 Fr/20 cm (PUR)	Midline-catheter	10 (1−112) [112]	NA	NA	3.4 (US+Co + CD)
Locatello, 2022	4–5 Fr/20–25 cm (PUR)	Midline-catheter	13.1 ± 7.7 [nd]	NA	0.3 (DTP/TC)	0.9 (US+Co)
Tomàs-Lòpez, 2022	4 Fr/30 cm (PUR)	Midclavicular-catheter	21.8 ± 24.3 [312]	6.0 (UR)	0.2 (DTP/TC)	0.4 (US+Co)

CR-BSI: catheter-related bloodstream infection. S-CRT: symptomatic catheter-related thrombosis. PUR: polyurethane. PET: polyethylene. AT: anti-thrombotic. AM: anti-microbic. nd: not declared. NA: not assessed. PR: premature removal. C: complications. NC: non complications. UM: unresolvable malfunction. APIF: all causes post-insertion failure. R-AE: removal for adverse events. UR: unexpected removal. DTP: differential time to positivity. TC: tip culture. NHSN: National Health and Safety Network. US+Co: US-scan + US compression test. US: US-scan. CD: color doppler.

[a] Data presented as "mean ± standard deviation" or "(median; interquartile range)" or "(median; *range*)".

[b] Incidence per 1000 catheter/days. c: up to 48 h after catheter removal.

from 0 to 12.7 for accidental removal or dislodgement.

The cumulative incidences per 1000 catheter-days were computed based on the aggregated data of 4865 MCs and 962 LPCs, with a total dwell time of 127,316 and 11,147 days, respectively. The cumulative incidences were found to be as follows (Table 6): 0.1 in MCs and 4.4 in LPCs for exit-site infection or phlebitis; 0.2 in MCs and 2.5 in LPCs for leaking, infiltration or extravasation and 1.7 in MCs and 5.9 in LPCs for accidental removal or dislodgment. Based on different aggregated data of more studies (MCs: $n = 5023$, total dwell time 129,179 days; LPCs: $n = 962$, total dwell time 11,147 days), the incidence per 1000 catheter-days of complete occlusion and malfunction was 1.3 in MCs and 2.5 in LPCs.

3.6. Catheter failure

Catheter failure was reported in six MCs and in all LPCs studies. All authors generically described catheter-failure as unexpected or premature catheter removal before completion of therapy plan, regardless of whether the cause was attributable to catheter related complications. The incidence per 1000 catheter-days ranged from 2.5 to 20.8 for MCs and from 5.1 to 71.8 for LPCs (Tables 2 and 3). Since the definitions of catheter-failure were extremely heterogeneous in the included studies, an aggregate analysis of this outcome was not performed.

4. Discussion

4.1. Main findings

The main objective of this systematic review was to explore complications associated with MCs and LPCs use. To the best of our knowledge, this is the first systematic review to analyse and compare the catheter outcomes after reclassifying the devices based on literature recommendations, and to report the catheter-related incidence by adopting a standardized methodology (cases per 1000 catheter-days) to overcome different methods used in the included studies to report data about complications.

The majority of studies were carried out in Europe. All included articles were published in the last six years; this result is not surprising, as research in this area is relatively young and, in our opinion, only recently has there been greater attention paid to the methodological quality of research. Indeed, a number of potentially pertinent studies were excluded due to a high risk of bias. The overall methodological quality of the included studies was high, with a few exceptions. However, as most research had observational retrospective designs, a high LOE was assigned to a very few studies.

The standardized incidence of major complications (i.e., catheter-related thrombosis and bloodstream-infections) was similar in both MCs and LPCs and, more importantly, was low overall. Regarding the other explored outcomes, as studies used non-homogeneous modalities of recognition, we grouped the reported complications into consistent categories; on this basis, higher standardized rates of minor complication were documented for LPCs compared to MCs.

An important finding was that all literature included in the present review enrolled hospitalized patients, highlighting an important gap in the field of research regarding MCs or LPCs in out-of-hospital settings (e.g., home care, nursing homes). The use of vascular devices is becoming increasingly widespread, both for patients discharged from hospital who continue treatment in other settings, and for individuals who undergo the whole treatment cycle in primary care contexts. A growth in research interest in out-of-hospital fields is desirable to compare catheter outcomes with those documented in hospital, from which hospital research would also benefit to complete the follow-up of catheters still present in discharged patients.

4.2. Catheter characteristics

After reclassifying MCs and LPCs based on the above-described criteria, we noticed that just over half of the devices (10 out of 18) were correctly labelled by the authors. The attribution was almost always correct for catheters classified as MCs, with a single study [8] labelling a polyethylene 18-cm long catheter as a long-peripheral-catheter, possibly because this research compared two similar (8–10 cm and 18-cm) devices. Conversely, we had to reclassify as LPCs nearly 80 % of catheters improperly labelled as midline catheters by the various studies' authors, since only two studies correctly labelled the devices [7,8]. Therefore, we found that a large misclassification exists in primary studies which prevents a clear distinction between MCs and LPCs, leading to the research risk of attributing indiscriminately the outcomes of interest to non-homogeneous categories of catheters. As highlighted in the Introduction section of the present work, this bias often affects secondary studies, such as literature reviews, increasing the risk of transmitting incorrect information with potential repercussions on clinical practice. A better adherence by the scientific community to the proposed classification of vascular accesses is therefore needed to make the research more rigorous and the results comparable.

The studies included in the present review report a mean dwelling time ranging from 11.2 to 26 (median 10–26) days for MCs and from 8 to 17.1 (median 4.9–11) days for LPCs. This finding seems consistent with a recent European consensus document which, beside difficult intravenous access conditions, recommended using LPCs or MCs for therapeutic plans whose expected length is one-to-four weeks or longer-than-four weeks, respectively [3]. Interestingly, several authors describe both LPCs and MCs as having uncomplicated dwelling times of up to 76 and 312 days, respectively. These results suggest that both catheters are

Table 4
Long-peripheral-catheters: characteristics of the devices and minor complications as reported by studies included in the review.

Author, Year	Catheter characteristics	Author's catheter classification	Exit-site infection or phlebitis[a]	Leak, infiltration or extravasation[a]	Catheter occlusion or malfunction[a]	Accidental removal or dislodgement[a]
Bahl, 2021	4.5 Fr/15 cm (PUR-AT-AM)	Midline-catheter	9.1	8	0	2.3
Fabiani, 2020	20–18 G/8–10 cm (PET)	Long-peripheral-catheter	0	9.5	4.8	6.3
Fabiani, 2023	18 G/10 cm (PUR)	Long-peripheral-catheter	0	0	1.0	0
Jeon, 2022	20–18 G/8–10 cm (PUR)	Midline-catheter	0	0	0	9.7
Johnson, 2022	10 cm (PUR)	Midline-catheter	1.2	2.4	6.7	6.1
Jones, 2022	20 G/8–10 cm (PUR)	Midline-catheter	3.2	1.9	0.6	5.7
Bundgaard M, 2020	20–18 G/10 cm (PUR)	Midline-catheter	10.7	4.3	13.9	5.4
Marsh, 2022	20–18 G/8–10 cm (PUR)	Midline-catheter	16.0	0	2.7	5.3
Nielsen, 2021	20–18 G/10 cm (PUR)	Midline-catheter	15.2	3.4	5.9	12.7

PUR: polyurethane. PET: polyethylene. AT: anti-thrombotic. AM: anti-microbic.
[a] Incidence per 1000 catheter-days.

Table 5
Midline-catheters: characteristics of the devices and minor complications as reported by studies included in the review.

Author, Year	Catheter characteristics	Author's catheter classification	Exit-site infection or phlebitis[a]	Leak, infiltration or extravasation[a]	Catheter occlusion or malfunction[a]	Accidental removal or dislodgement[a]
Bahl, 2021	4 Fr/20 cm (PUR-AT)	Midline-catheter	3.8	10.4	0	2.8
Campagna, 2018	4–5 Fr/20–25 cm (NA)	Midline-catheter	0.1	0	1.4	1
Fabiani, 2020	18 G/18 cm (PET)	Long-peripheral-catheter	0	2.7	5.3	9.3
Fabiani, 2020	4 Fr/20 cm (PUR)	Midline-catheter	0	1.4	2.4	2.9
Fabiani, 2023	4 Fr/20 cm (PUR)	Midline-catheter	0.6	0	1.9	0
Frondizi, 2023	4–5 Fr/20–25 cm (PUR)	Midline-catheter	NA	NA	0	NA
Lisova, 2018	4 Fr/20 cm (PUR)	Midline-catheter	0.3	0,3	0	0
Locatello, 2022	4–5 Fr/20–25 cm (PUR)	Midline-catheter	0.6	3.2	4.3	1.7
Tomàs-Lòpez, 2022	4 Fr/30 cm (PUR)	Midclavicular-catheter	0	0	1.1	2.7

PUR: polyurethane. PET: polyethylene. AT: anti-thrombotic. NA: not assessed.
[a] Incidence per 1000 catheter-days.

Table 6
Cumulative complication rates by considering the overall data of the included studies.

Outcome	Midline-catheters				Long-peripheral-catheters			
	Catheters (n)	Events (n)	Crude rate (%)	Incidence (1000 c/d)	Catheters (n)	Events (n)	Crude rate (%)	Incidence (1000 c/d)
Major complications								
CR-BSI	3046	19	0.6	0.3	755	4	0.5	0.4
S-CRT	5023	114	2.3	0.9	962	20	2.1	1.8
Minor complications								
Exit-site infections/phlebitis	4865	18	0.4	0.1	962	49	5.1	4.4
Leaking/infiltration/extravasation	4865	29	0.6	0.2	962	28	2.9	2.5
Occlusion/malfunction	5023	172	3.4	1.3	962	28	2.9	2.5
Accidental removal/dislodgment	4865	215	4.4	1.7	962	66	6.9	5.9

CR-BSI: catheter-related blood-stream infection. S-CRT: symptomatic catheter-related thrombosis.

suitable for safe and effective medium to long term use, especially considering that in some studies, the observations were interrupted before a catheter removal due to the difficulty in completing the follow-up, for example, after patients were discharge from hospital. Conversely, some research reports extremely short uncomplicated dwelling times, even one day or a few hours. Whether from a clinical point of view these results are unsurprising (e.g., it is not unusual for patients with poor venous pool to require a safe vascular access for a short therapeutic plan), the choice to include these patients in studies documenting catheter-related complications might be questionable: it risks underestimating the incidence of some late complications, particularly catheter-related bloodstream-infections. However, this problem may be overcome by computing each outcome on the basis of the catheter's actual observed dwell times, as per the recommended standardized methodology (incidence per 1000 catheter-days) we adopted in this review and already adopted in recent clinical trials on this topic [34].

4.3. Catheter-related bloodstream infections

CR-BSI is probably the most serious complication associated with the use of vascular devices and has an important impact on patients' outcomes such as longer length of hospital stay, higher mortality, morbidity and hospital costs [35]. Several studies have reported lower rates of CR-BSIs for both MCs and LPCs compared to peripherally or centrally inserted central venous catheters [15,36]. In this systematic review, we found an overall similar very low CR-BSIs incidence for both MCs and LPCs (0.3 to 0.4/1000 catheter-days). Only Frondizi and colleagues [26] found a greater incidence (3.2/1000 catheter-days) in a population of COVID-19 patients, which was very similar to that of peripherally inserted central catheters (4.5/1000 catheter-days) documented in the same investigation. The authors attributed these poor outcomes to an ineffective management of the venous access devices linked to the particular burden of healthcare professionals during the pandemic. These findings seem to confirm that the risk for CR-BSIs can be effectively decreased by strictly observing catheter management bundles during and after the catheter insertion [2,37].

Nevertheless, data on CR-BSIs incidence found in the present review should be considered with caution. Indeed, the diagnostic criteria adopted in the included studies were extremely heterogeneous, exposing some studies to the risk of detection bias, leading to overestimating or underestimating the actual CR-BSIs incidence. For example, a positive blood culture in a patient with an indwelled intravenous device does not allow the infection to be attributed to the catheter with certainty. The use of a differential time to positivity >2 h in comparing cultures of two blood samples—drawn from the vascular catheter and from a peripheral vein—is the recommended method for standardizing the diagnosis of infections related to central catheters [35]. In cases where sampling from the catheter is precluded, the device should be removed and its tip, as well as a peripheral blood sample, undergo a semi-quantitative culture test; if both samples have a positive result, the bloodstream-infection can be attributed to the catheter if a same microorganism (species and antimicrobial susceptibility testing) is isolated from the catheter tip (>15 colony-forming units/catheter segment) and the peripheral blood [35]. Since these methods have been already effectively used both in MCs and LPCs studies [7,8,26,28,31,33], we suggest extending this recommendation to standardize the CR-BSIs diagnosis in these devices.

4.4. Catheter-related thrombosis

Thrombosis represents a very common complication associated with intravenous devices, which can remain asymptomatic or may manifest as an inflammation. Moreover, CRTs may compromise catheter patency (e.g., leakage, infiltration, obstruction) and develop post-thrombotic syndrome or, although rarely, systemic complications such as pulmonary embolism [38]. Different to CR-BSIs, the studies included in this systematic review reported a wider range of symptomatic CRTs standardized rates for both catheters, which seemed slightly higher for LPCs than MCs (1.8 and 0.9/1000 catheter-days, respectively). Moreover, five studies reported definitely higher CRTs incidences in both MCs (3.4 to 4.7/1000 catheter-days) [24,27] and LPCs (3.1 to 5.7/1000 catheter-days) [7,24,25,29]. It is not easy to understand the reason for these very different results. As per CR-BSIs, we could have reason to suspect that these data could be over- or under-estimated in some studies. Indeed, in patients whose catheter was removed due to malfunction, in the absence of a preliminary ultrasound examination to exclude the presence of thrombosis, a CRTs or a different complication (e.g. leakage, infiltration) may have been arbitrarily reported, thus potentially over- or underestimating the CRTs rate.

Furthermore, although all studies' authors declared having documented the presence of symptomatic CRTs using a very similar ultrasound-based method, the presence of a fibroblastic sleeve—a structured connective tissue made of collagen and endothelial cells, usually coating 33 % to 100 % of the external surface of the catheter—may have been confused with venous thrombosis by inexperienced observers [39]; this might lead to incorrectly over-estimating the reported incidence of symptomatic CRTs. Fibroblastic sleeve is a complication completely different from CRTs, as it can be considered a 'foreign body' early reaction (occurring since 24 h after catheter insertion) of the blood tissue toward the catheter [39]. Although fibroblastic sleeve is an expected physiological phenomenon, it could cause a catheter malfunction (typically, difficulty in blood aspiration while maintaining catheter patency during infusion: the so-called persistent withdrawal occlusion) which, considered together with the ultrasound finding of echogenic intravascular material, may have been considered as the presence of a CRTs.

On the other hand, we believe that the real incidence of CRTs has definitely been under-estimated, since no study investigated the incidence of asymptomatic thrombosis. Indeed, CRTs can develop very early and often have a completely asymptomatic clinical course: if CRT is not intentionally and systematically searched for via ultrasound, its presence could be totally ignored until the catheter is removed. For several

Table 7
Definitions and variables to standardize data collection for epidemiological and research purposes.

Catheter nomenclature	
Central venous catheters (CVC)	Intravenous device having its distal tip placed either at the lower third of superior (inferior for femoral devices) vena cava, or at the atrio-caval junction, or in the upper portion of the right atrium. Based on the insertion point, CVCs are classified as: - Centrally inserted CVC (CICC): CVC accessed via cervico-thoracic district veins - Femorally inserted CVC (FICC): CVC accessed via femoral veins - Peripherally inserted CVC (PICC): CVC accessed via deep veins of the arms
Peripheral venous catheters (PVC)	Intravenous device positioning in the upper limbs having its distal tip placed outside the vena cava. Based on their length, PVCs are classified as: - Short PVC (S-PVC): PVC $\leq$ 6 cm - Long PVC (L-PVC): PVC $>$ 6 cm and $\leq$ 15 cm - Midline PVC (M-PVC): PVC $>$ 15 cm
Identification of catheter and vein characteristics	
Catheter	Nomenclature, manufacturer, biomaterial, length, internal/external diameter
Vein	Exit site location. Name, depth, internal diameter of cannulated vein (at insertion and tip levels)
Catheter related complications (CRCs): definitions, diagnostic criteria and metric to report catheter outcomes	
Bloodstream infection	- Catheter patency for withdrawal: differential time to positivity >2 h in comparing cultures blood samples drawn from the catheter and from a peripheral vein - Impossible withdrawal: isolation of the same microorganism (species and antimicrobial susceptibility testing) from the catheter tip (>15 colony-forming units) and a peripheral blood sample
Thrombosis	US visualization of an echogenic intravascular structure involving the vein wall of a US-incompressible vein. Report if: - the thrombus is mural (i.e., not completely occupying the vein lumen) or obstructive (i.e., completely occupying the vein lumen) - the thrombosis is symptomatic (i.e., associated with at least one of the symptoms of inflammation [see Phlebitis] or leakage by the exit site, infiltration or extravasation) or asymptomatic-CRT (no associated symptoms)
Fibroblastic sleeve	Thin layer echogenic material (>1 mm) around the catheter wall, detectable along the entire catheter length, with a regular surface and little ("bridges") or no relationship with the vein wall. Report if the FS is symptomatic (associated with loss catheter usability, extravasation) or asymptomatic (no associated symptoms)
Exit site infection	Infection of the skin at the exit site is usually associated with serous or purulent exudate and signs of inflammation, consider obtaining swab of site for culture.
Phlebitis	Inflammation of the vein as detected by the presence of inflammation (tenderness, swelling, pain, erythema or palpable vein). Use Visual Infusion Phlebitis score (VIP) to monitor and classify severity. To be considered and reported only after excluding symptomatic CRT
Extravasation	Leakage of injected drugs out of the vein, with infiltration the surrounding tissues or leaking from the exit site. To be reported only after excluding symptomatic CRT or FS
Standardized CRC incidence	(total number of CRC / total catheters days) $\times$ 1000
Condition associated with loss of catheter usability[a]	
Total occlusion	Inability to infuse and aspirate
Sub-occlusion	Difficulty in infusing and aspirating
Persistent withdrawal occlusion	Possibility to infuse but not to aspirate
Dwelling time and reason for catheter removal[b]	
Catheter dwelling time	Interval (days) between the dates of placement and removal (whatever the reason). Monitoring stopped before cath. removal: report the information and the last follow-up date
Catheter success	Removal at end of use despite possible complications non precluding catheter usability
Catheter failure	Removal due to loss of catheter usability (any complication) while it was still necessary (e.g., iv therapies, frequent blood sampling), requiring a catheter replacement
Cath. unplanned removal	Removal of an uncomplicated still in-use catheter (e.g., accidental removal, patient death)

References: see Table A3, appendices.
[a] Report in cases of catheter failure or unplanned removal.
[b] Report as a cumulative indicator of catheter safety and reliability.

reasons, fibroblastic sleeve as well as both symptomatic and asymptomatic thrombosis should be documented as separate catheter-related complications based on their respective specific diagnostic criteria. The first aim should be determining what impact they have on clinical practice and patients' outcomes. Moreover, each indwelled catheter is exposed to biofilm development—a colony of micro-organisms embedded in a self-produced matrix adherent to a catheter surface [40]: the development of fibroblastic sleeve, which is intimately related to the presence of biofilm, may lead to the formation of thrombosis and infections [41]. Finally, some manifestations of catheter malfunctioning could be possible symptoms of thrombosis or fibroblastic sleeve. By encouraging research in this area, we may discover that complications such as leakage or infiltrations, as well as phlebitis, are always associated with CRTs or fibroblastic sleeve.

4.5. Catheter failure and other minor complications

In this systematic review, very wide ranges of catheter-failure incidence were found for both MCs (2.5 to 20.8/1000 catheter-days) and LPCs (5.1 to 71.8/1000 catheter-days). This finding could be explained by the heterogeneity of causes attributed to the catheter failure in different studies. Indeed, catheter-failure is a generic definition to classify premature catheter removal before completing the therapeutic plan, resulting in the placement of a new device. As a consequence, some authors describe catheter-failure as removal caused by the onset of any complication, sometimes including accidental catheter slide out or patient death.

On the other hand, regrettably, no standard criteria are available to classify complications different from CRTs and CR-BSIs, so we arbitrarily grouped into four categories complications that the included studies

reported in a non-homogeneous way. On this premise, the present review clearly documented a higher overall incidence of minor complications for LPCs compared to MCs (Table 6), although without revealing clear and definitive risk factors that could explain this trend. As discussed in the previous paragraph, it should be noted that some complications such as leakage, extravasation, infiltration, phlebitis, persistent withdrawal occlusion or other complications generically defined as 'malfunctions' may be attributable to specific unrecognized, and therefore underestimated, complications such as thrombosis or fibroblastic sleeve. Since none of the included studies analysed the possible association between thrombosis/fibroblastic sleeve and their clinical presentation, in some studies the same complications may have been documented twice as independent outcomes (e.g., thrombosis and phlebitis).

4.6. Implications for clinical practice and research

This systematic review noted the lack of standardization in defining and diagnosing catheter-related complications, as well as in methodologies used for data collection. This fact undermined the possibility of effectively comparing results of the published research and, ultimately, of answering our research questions in a satisfactory way. Furthermore, catheter outcomes should be analysed in the light of relevant confounders such as kind and dosages of medications infused through the device or patient's coagulation profile. New risk factors associated with catheter-related complications are emerging in the literature, such as the catheter insertion point at the skin level, the final position of the catheter tip into the vein, or the catheter-to-vein ratio at the tip level [5,7,42]. Unfortunately, only a few studies analysed catheter outcomes by multivariable analyses considering the above covariates.

We think it is extremely urgent that order is brought to this research field. Therefore, we have proposed a list of definitions and relevant variables of interest based on the better available literature (Table 7); this could represent a first step toward the development of standardized criteria to be adopted for epidemiological and research purposes. We hope this topic will be discussed soon in a broad debate, to reach a widely shared and validated interdisciplinary consensus.

4.7. Limitations at the review level

The results of this review should be interpreted taking into account some methodological issues. Despite an in-deep and methodologically rigorous literature search and selection, some relevant articles might have been missed as a result of the limited number of explored databases, the search strategy, the search strings, or the publications' language, which was limited to English. To partially reduce this risk, we did not apply any limitation on the publication year and extended the search to articles' references. Moreover, we adopted a preliminary rigorous analysis of studies' methodological quality to avoid including in the review those studies that are burdened by high risk of bias. As a consequence, only 14 papers underwent our systematic review. Overall, the aim of reporting strong or definitive evidence from the available literature was not reached, since a low level of evidence was attributed to most studies, mainly because of their observational designs.

4.8. Limitations at the outcome level

Some limitations affecting the impact of our results should also be considered. We found a high degree of heterogeneity among the selected studies in terms of catheters' classification and criteria used to classify the catheter-related complications. This prevented, in particular, credibly reporting aggregated data on catheters' outcomes. Significant concerns exist that, although recomputed in a standardized way, the rates of CR-BSIs and CRTs might have been over- or underestimated because of the different diagnostic criteria adopted by the authors. Unfortunately, it was not possible to carry out a meta-analysis since there are not enough homogeneous comparative studies between MCs and LPCs in the literature. Moreover, not all authors we contacted provided data on the overall number of complications and catheters' dwelling times, preventing the inclusion of some studies in standardized complication rates calculation. Finally, the overall data on dwelling times and complication rates are to be considered partial, as the lack of studies conducted in out-of-hospital settings provides only a partial picture of the safety and reliability of LPCs and MCs.

However, it is precisely these limitations that could constitute the main strength of this review, giving the opportunity to develop an interprofessional consensus process aimed at collecting homogeneous and comparable data in future research, laying the groundwork for designing benchmarks that are comparable between clinical settings and patient groups.

5. Conclusions

This systematic review clearly showed that a large misclassification exists in primary and secondary studies, preventing a clear distinction being drawn between MCs and LPCs, leading to the risk of research indiscriminately attributing the outcomes of interest to non-homogeneous categories of catheters. Furthermore, a widespread heterogeneity of diagnostic criteria adopted to classify the catheters' outcomes was found, exposing the risk of misestimating the incidence of complications. Keeping in mind these premises, we found— despite some exceptions—similar, low standardized rates of catheter-related bloodstream-infections and symptomatic catheter-related thrombosis in both MCs and LPCs. Conversely, results regarding catheter-failure and minor complications should be considered with even greater caution since the included studies described and reported them unevenly.

Further studies based in standardized catheter nomenclature, diagnostic criteria and outcome classification are needed to obtain consistent and comparable data regarding LPCs and MCs' safety and reliability.

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Complications associated to Midline- and Long Peripheral Catheters in Adults. Systematic Review of Literature and Proposal for a Standardized Model for Data Collection.

CRediT authorship contribution statement

Adam Fabiani: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Nicola Aversana:** Writing – review & editing, Investigation, Data curation. **Marilena Santoro:** Writing – review & editing, Investigation, Data curation. **Gianfranco Sanson:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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