



ORIGINALS

Complications of midline catheters in pediatric patients: a prospective observational study

Complicaciones asociadas a los catéteres midline en pacientes pediátricos: estudio observacional prospectivo

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ABSTRACT:

Introduction: The use of midline catheters (MCs) in pediatrics is increasing; however, evidence in the literature is scarce.

Objective: To describe the complications associated with MCs in pediatric patients and to identify related factors.

Material and Methods: A prospective observational study was conducted between 2022 and 2024, involving pediatric patients aged 0 to 16 years who had an MC inserted by nursing staff. Variables included: age, sex, length of hospital stay before catheter insertion, date of insertion, reason for MC insertion, MC size, and length, vein used, tip position, use for blood draws, continuous infusion to maintain patency, date of removal, and reason for removal. Potential associations between the complications documented and the other studied variables were analyzed.

Results: A total of 69 MCs were inserted in patients ranging from 7 days to 16 years of age. In over two-thirds (69.6%) of cases, no complications were observed, and the scheduled treatment was completed. The mean catheter dwell time was 12 days, and the complication rate was 25.6 cases per 1000 catheter-days. Thrombosis occurred in 8.7% of cases. An association was found between difficult venous access as the reason for MC insertion and premature device removal for any reason. None of the studied variables were found to be linked to thrombosis.

Conclusions: The complication rate found is similar to that reported in other studies in the pediatric population. Thrombosis was the leading complication and the most frequent reason for catheter removal.

Keywords: Catheterization, Peripheral; Vascular Access Devices; Pediatrics; Nurses.

RESUMEN:

Introducción: El uso de catéteres midline (MC) en pediatría se está incrementando, sin embargo, la evidencia en la literatura es escasa.

Objetivo: Describir las complicaciones ocurridas en MC en pacientes pediátricos e identificar factores que pudieran asociarse a su aparición.

Material y Métodos: Estudio observacional prospectivo entre 2022 y 2024, en pacientes de 0 a 16 años a los que se canalizó un MC por parte de enfermería. Variables: edad, sexo, días de ingreso previos a inserción, fecha de inserción, motivo, diámetro y longitud del MC, vena canalizada, localización de la punta, uso para extracciones, mantenimiento con suero, fecha de retirada y motivo de retirada. Se evaluó la asociación entre la aparición de complicaciones y las variables recogidas.

Resultados: Se registraron 69 MC en pacientes de 7 días de vida a 16 años. El 69.6% de MC no presentaron complicaciones y permitieron finalizar el tratamiento. El tiempo medio de permanencia fue 12 días. Se obtuvo una tasa de complicaciones de 25.6 casos por 1000 días de catéter. Presentaron trombosis el 8.7% de los catéteres. Se halló asociación entre el mal acceso venoso como motivo de canalización y que el dispositivo fuera retirado antes de lo previsto por cualquier causa. Las variables estudiadas no se pudieron relacionar con la aparición de trombosis.

Conclusiones: La tasa de complicaciones hallada es similar a estudios publicados llevados a cabo en pediatría. La aparición de trombosis supuso la complicación más importante y el motivo de retirada más frecuente.

Palabras clave: Cateterismo Venoso Periférico; Dispositivos de Acceso Vascular; Pediatría; Enfermería.

INTRODUCTION

Most hospitalized children require placement of a vascular access device to receive intravenous (IV) medications or facilitate blood sampling⁽¹⁾. Midline catheters (MCs) are longer than conventional short peripheral intravenous catheters (PIVCs), with the tip positioned outside the central venous system, usually in the axillary or subclavian vein. In pediatrics, these devices range from 4 to 15 cm in length, and the most widely used sizes are 2 and 3 Fr. They are commonly inserted using either the direct or the modified Seldinger technique.^(2,3)

The most common indications for the placement of an MC are: IV therapy expected to last more than 6 days that can be delivered peripherally and difficult venous access or vascular exhaustion^(4,5). MCs play a key role in intermediate-duration IV therapy. They may also be a good option in shorter treatments for delivering drugs considered “moderate risk”, that is, medications with a relatively high osmolarity and/or non-physiological pH⁽⁶⁾. In pediatrics, there is insufficient evidence regarding the appropriate use of these devices. However, they are considered appropriate for treatments lasting up to 14 days that are compatible with peripheral IV administration^(7,8).

These devices have gained popularity and are preferred over PIVCs due to their longer survival time, sometimes exceeding 2 weeks⁽⁹⁾. Nonetheless, they have certain complications, such as leakage, accidental dislodgement, extravasation, occlusion, and thrombophlebitis⁽¹⁰⁾. In pediatrics, MCs have been associated with complication rates of up to 51%, mainly related to leakage and accidental dislodgment. Despite this, the evidence available indicates that these devices are a valid option for administering antibiotics and other IV therapies to young patients^(3,11-14). Additionally, it has been suggested that their use, as it reduces the need for PIVCs, helps to preserve venous capital and minimize the distress and anxiety associated with repeated attempts at cannulation^(11,12).

A literature review found limited data on the use of MCs in children⁽¹⁵⁾. It is nonetheless considered that they may be very useful in children on IV therapy lasting several days, who have difficult venous access, or experience unexpectedly frequent catheter failure. In this context, the primary objective of this study was to describe the complications associated with the use of MCs in children. The secondary objective was to identify potential risk factors for these complications.

MATERIAL AND METHODS

Study design and population

We carried out a prospective observational cohort study between July 2022 and March 2024 in the Department of Pediatrics at Donostia University Hospital. All inpatients between 0 and 16 years of age were eligible to participate. The inclusion criteria were the need for an MC and placement of this type of device by a pediatric intensive care unit nurse. Infants hospitalized in the neonatal intensive care unit were excluded.

Variables

The primary outcome was non-elective catheter removal for any reason, defining non-elective as removal before completion of the intended IV therapy, and this was considered 'MC failure'. Failure was attributable to complications, such as thrombosis, infection, or obstruction, as well as other events, including catheter dislodgement or rupture. The following data were recorded:

- Sociodemographic and clinical data: age, sex, reason for admission, and length of hospital stay before device insertion.
- Device insertion-related data: date of insertion and reason: IV treatments of more than 6 days of duration, moderate-risk drugs (an osmolarity of 450–600 mOsm/L or a pH of 4–5 or 7.5–9), and/or a difficult venous access (history of more than six unsuccessful attempts at inserting a PIVC or failure of two PIVCs within 24 hours of insertion)
- MC-related data: size and length, vein cannulated, and catheter tip position
- Catheter management: use for blood draws, saline continuous infusion to maintain patency, and lastly, date of removal and whether the removal was elective (yes/no).

Data sampling

When patients met the inclusion criteria, their parents or legal guardians were asked to consent to their child participating in the study. When they agreed, an MC was placed in accordance with usual practice. The catheter size and length were selected considering the patient's size and the vein to be cannulated at the discretion of the nurse. After catheter insertion, data related to the cannulation, the catheter itself, and the patient were entered into a case report form. Subsequently, a designated nurse recorded data concerning catheter maintenance on the hospital ward or unit where the patient was staying until device removal.

Statistical analysis

Data were analyzed using free open-source statistical software, R, version 4.4.3. For the descriptive analysis, means and standard deviations were calculated for quantitative variables, and frequencies and percentages for qualitative variables. Inferential analysis was performed to evaluate potential associations of complications with patient- and catheter-related characteristics. The level of significance was set at 0.05. Comparisons were made using the Mann-Whitney U test for quantitative variables and the χ^2 test for categorical variables, except when expected frequencies were <5 , in which case Fisher's exact test was used.

Ethical considerations

The study was approved by the Ethics Committee of the Gipuzkoa Integrated Healthcare Organization in June 2022. Before participation, parents and/or legal guardians were asked to provide written informed consent, and assent was requested from patients older than 12 years of age.

RESULTS

A total of 69 MC placements were documented in children aged between 17 days and 16 years, with a mean age of 4.8 years. Infection was the most common reason for admission. Table 1 summarizes the study patients' characteristics.

Table 1: Characteristics of study patients. Quantitative data are expressed as mean $\pm$ standard deviation, and qualitative data as frequency (percentage).

Variable	Cases (N = 69)
Age (in years; range: 17 days – 16 years):	4.8 $\pm$ 4.5
Sex:	
Male	35 (50.7%)
Female	34 (49.3%)
Reason for admission:	
Cardiovascular	1 (1.5%)
Infectious	52 (75.4%)
Metabolic	1 (1.5%)
Neurological	2 (2.9%)
Surgical	7 (10.1%)
Respiratory	1 (1.4%)
Other	5 (7.2%)
Length of stay before catheter insertion (days):	6.8 $\pm$ 8.4
Reason for midline catheter insertion:	
Difficult venous access	35 (50.7%)
Treatment lasting >6 days	61 (88.4%)
Moderate-risk drug	61 (88.4%)

Variable	Cases (N = 69)
Size (Fr):	
2	33 (47.8%)
3	35 (50.7%)
4	1 (1.5%)
Length of catheter (8-30 cm):	13.4 ± 6.7
Vein cannulated:	
Basilic	53 (76.8%)
Cephalic	5 (7.2%)
Brachial	3 (4.4%)
Forearm	3 (4.4%)
Great saphenous	4 (5.8%)
External jugular	1 (1.4%)
Catheter tip position:	
Forearm vein	4 (5.8%)
Axillary vein	30 (43.5%)
Leg vein	4 (5.8%)
Subclavian vein	24 (34.8%)
Upper arm vein	6 (8.7%)
Brachiocephalic vein	1 (1.4%)
Use for blood draws:	
Yes	42 (60.9%)
Continuous infusion to maintain patency:	
Yes	55 (79.7%)
Catheter dwell time (2-42 days):	11.9 ± 8
Non-elective removal (failure):	
Yes	21 (30.4%)
No	48 (69.6%)

Generally, the reason for inserting an MC was the need for long IV therapy and/or drugs that carry a risk of tissue damage. In half of our cases, patients also had difficult venous access. The preferred insertion vein was the basilic vein. The catheters were variable in length and generally 2 or 3 Fr in size, a 4 Fr catheter being used in just one case. The most common tip position was the axillary vein, followed by the subclavian. The mean catheter dwell time was 11.9 days. A total of 21 MCs were removed prematurely. The complication rate observed was 25.6 per 1000 catheter-days.

Regarding premature MC removal, the most common reason was thrombosis (formation of a clot between the vein wall and the catheter), accounting for six cases, followed by catheter obstruction (defined as the inability to infuse fluid through the catheter). The other causes of premature removal were accidental dislodgement or pulling, suspected infection, leakage of the infused fluid at the insertion site, mechanical phlebitis without thrombosis, and catheter rupture. Two devices were removed on medical order before treatment completion with no documented cause. Among the MCs studied, the rate of thrombosis was 8.7%, with 7.3 cases per 1000 catheter-days.

We analyzed the potential relationship of non-elective MC removal for any cause and for thrombosis with other variables assessed (see Tables 2 and 3, respectively). Non-elective removal was found to be significantly associated with difficult venous access and an MC being used to administer moderate-risk drugs. We did not find significant associations with any of the other variables examined that might be related to the development of complications.

Table 2: Comparison of patients by removal category: elective vs non-elective for any cause (failure). Quantitative data are expressed as mean $\pm$ standard deviation, and qualitative data as frequency (percentage). P values are from the Mann-Whitney U test for quantitative variables and the χ^2 test or Fisher's exact test for qualitative variables.

	Elective catheter removal (N = 48)	Non-elective removal (failure) (N = 21)	P value
Age (years):	4.7 $\pm$ 4.2	5.1 $\pm$ 4.4	0.676
Sex:			1.000
Male	24 (50%)	11 (52.4%)	
Female	24 (50%)	10 (47.6%)	
Length of stay before insertion (days):	6.2 $\pm$ 7.8	8 $\pm$ 9.8	0.728
Reason for midline catheter insertion:			
Difficult venous access:			0.044
Yes	20 (41.7%)	15 (71.4%)	
No	28 (58.3%)	6 (28.6%)	
IV therapy >6 days:			0.692
Yes	43 (89.6%)	18 (85.7%)	
No	5 (10.4%)	3 (14.3%)	
Moderate-risk drug:			0.050
Yes	45 (93.8%)	16 (76.2%)	
No	3 (6.2%)	5 (23.8%)	
Size (Fr):			0.314
2	22 (45.8%)	11 (52.4%)	
3	26 (54.2%)	9 (42.9%)	
4	0 (0%)	1 (4.76%)	
Length (cm):	13.2 $\pm$ 6.6	13.8 $\pm$ 7	0.768
Catheter tip position:			0.795
Forearm vein	3 (6.3%)	1 (4.76%)	
Axillary vein	22 (45.8%)	8 (38.1%)	
Leg vein	2 (4.2%)	2 (9.5%)	
Subclavian vein	17 (35.4%)	7 (33.3%)	
Upper arm vein	3 (6.3%)	3 (14.3%)	
Brachiocephalic vein	1 (2.1%)	0 (0%)	
Blood sampling:			1.000
Yes	29 (60.4%)	13 (61.9%)	
No	19 (39.6%)	8 (38.1%)	
Continuous infusion to maintain patency:			1.000
Yes	38 (79.2%)	17 (81.0%)	
No	10 (20.8%)	4 (19%)	
Catheter dwell time (days):	12.3 $\pm$ 8.4	10.9 $\pm$ 6.8	0.615

Among the cases of premature MC removal, the most common reason was thrombosis. None of the variables studied (including age, reason for MC insertion, catheter characteristics, tip position, device management, and catheter dwell time) were found to be associated with the development of thrombosis.

Table 3: Comparison of patients by removal category: elective vs non-elective for thrombosis. Quantitative data are expressed as mean $\pm$ standard deviation, and qualitative data as frequency (percentage). P values are from the Mann-Whitney U test for quantitative variables and the χ^2 test or Fisher's exact test for qualitative variables.

	Elective removal (N = 48)	Non-elective removal due to thrombosis (N = 6)	P value
Age (years):	4.7 $\pm$ 4.2	6.7 $\pm$ 4.6	0.270
Sex:			1.000
Male	24 (50%)	3 (50%)	
Female	24 (50%)	3 (50%)	
Length of stay before insertion (days):	6.2 $\pm$ 7.8	14.5 $\pm$ 12.7	0.084
Reason for midline catheter insertion:			
Difficult venous access:			0.085
Yes	20 (41.7%)	5 (83.3%)	
No	28 (58.3%)	1 (16.7%)	
IV therapy >6 days:			1.00
Yes	43 (89.6%)	6 (100%)	
No	5 (10.4%)	0 (0%)	
Moderate-risk drug:			1.00
Yes	45 (93.8%)	6 (100%)	
No	3 (6.2%)	0 (0%)	
Size (Fr):			0.682
2	22 (45.8%)	2 (33.3%)	
3	26 (54.2%)	4 (66.7%)	
4	0 (0%)	0 (0%)	
Length (cm):	13.2 $\pm$ 6.6	14.3 $\pm$ 6.3	0.525
Catheter tip position:			0.296
Forearm vein	3 (6.3%)	1 (16.7%)	
Axillary vein	22 (45.8%)	1 (16.7%)	
Leg vein	2 (4.2%)	1 (16.7%)	
Subclavian vein	17 (35.4%)	3 (50%)	
Upper arm vein	3 (6.2%)	0 (0%)	
Brachiocephalic vein	1 (2.1%)	0 (0%)	
Blood sampling:			1.000
Yes	29 (60.4%)	4 (66.7%)	
No	19 (39.6%)	2 (33.3%)	
Flushing for maintenance:			1.000
Yes	38 (79.2%)	5 (83.3%)	
No	10 (20.8%)	1 (16.7%)	
Catheter dwell time (days):	12.3 $\pm$ 8.4	12.5 $\pm$ 8.5	0.847

DISCUSSION

This observational study describes the complications associated with MCs inserted by nurses in pediatric inpatients. We identified some variables associated with these complications that might be risk factors. Our main conclusion is that there were no catheter-related complications, and hence, it was possible to complete the prescribed treatment in more than two-thirds (69.6%) of cases. This may have contributed to improved patient care and experience, with no need for further catheterization in 48 cases. In this way, the number of venipunctures children underwent during admission was reduced.

Our findings are similar to those of an observational study in pediatric patients in which 70% of catheters were removed electively⁽¹³⁾. In a study comparing peripherally inserted central catheters (PICCs) and MCs, Anderson et al. found complications associated with more than half of the MCs⁽¹¹⁾. A clinical trial by Kleidon et al. and a retrospective study in children receiving hospital-at-home care both reported better results, with no failures in 84% and 76% of catheters throughout their use^(12,14). A systematic review that included 31 studies, mainly in adults, found a high rate of complications for MCs in general, with higher rates in pediatric and neonatal care⁽¹⁵⁾.

In our study, catheter dwell time was 12 days, longer than in previous studies in children, which have reported times of 134 hours to 10 days⁽¹¹⁻¹⁴⁾. As noted by Qin et al., failure rates cannot be compared between studies unless catheter dwell times are similar⁽³⁾. Consequently, these rates should be expressed in terms of relative incidence, that is, per 1000 catheter-days, using the equation: $(\text{number of events} / \text{total catheter-days}) \times 1000$. In our study, the complication rate was 25.6 cases per 1000 catheter-days. This is not notably different from figures in pediatric studies that report their data in a similar format, with the lowest rate being that of 22.4 cases per 1,000 catheter-days reported by Kleidon et al. ⁽¹²⁻¹⁴⁾. Regarding results for adults, in whom catheter dwell times ranged from 1.1 to 14.7 days, only 2 of the studies reported failure rates in catheter-days, and the findings were comparable⁽³⁾.

Thrombosis was the most important complication from a clinical point of view and the main reason for non-elective catheter removal (failure). It had major clinical implications, with children developing thrombosis requiring anticoagulation therapy and follow-up over 2 to 3 months after catheter removal. We observed a thrombosis rate of 8.7% and 7.3 cases per 1000 catheter-days. The aforementioned studies indicated rates of 4.8% to 30%⁽¹¹⁻¹⁴⁾. In this context, our findings indicate rates similar to those of previous studies. Other authors have indicated that the risk of catheter-related thrombosis is high in both adults and children^(16,17). The available evidence regarding MC in paediatrics is limited. However, based on existing data on PICC lines, which are also inserted via a peripheral vein, it has been observed that they carry a higher risk of thrombosis than centrally inserted central catheters ^(18, 19). In our case, radiologists performed Doppler ultrasound examinations on all patients suspected of thrombosis, that is, those with edema, erythema, pain in the catheterized limb, and/or a palpable cord that followed the course of the cannulated vein. Additionally, ultrasound examinations were performed in all cases of malfunctioning catheters, including those that did not show adequate blood reflux or showed leakage at the insertion site. These factors might explain our relatively high rates, as asymptomatic thrombosis may have been underdiagnosed elsewhere if such procedures had not been followed⁽²⁰⁾.

The length of hospital stay before catheter insertion was more than twice as long in patients who developed thrombosis (14 days) as in those whose catheters were removed electively (6 days), with a near-significant association between these factors ($p=0.084$). We also observed a near-significant association between difficult venous access as the reason for MC insertion and the development of thrombosis, in line with previous studies, in which repeated cannulation attempts were associated with thrombosis⁽²¹⁾. It is reasonable to suppose that these two variables are correlated, given that patients admitted for a few weeks are likely to have required IV medication and may have had repeated PIVC failures and undergone multiple venipuncture procedures. The risk of developing thrombosis is multifactorial, including patient, treatment and device-related factors. Therefore, no universal preventive strategy can be recommended⁽²²⁾. Nevertheless, the ratio between catheter size and vein diameter has been shown to be protective against thrombosis: to reduce the risk of thrombosis, the catheter-to-vein ratio should not exceed 45%⁽²³⁾. In our study, we did not measure vein diameter.

Notably, however, after observing that three of the four occluded catheters were of the smallest size (2 Fr), we did compare outcomes with catheters removed for occlusion and other cases, but our results did not show an association between the MC size and occlusion. Fläring et al. reported a potential increase in the risk of failure when shorter and smaller-sized catheters were used⁽¹⁴⁾. In pediatric patients, blood sampling through vascular access devices is a common practice seeking to minimize the number of venipunctures required, despite not being recommended by some manufacturers. Nonetheless, in our study, occlusion was not associated with this practice, nor with catheter length, continuous infusion to maintain patency, or dwell time. Accidental dislodgement, a common event in children, was another complication observed, except among those receiving hospital-at-home care, in whom no accidental removals were reported^(13,14,24).

There were no cases of catheter-related infection in our patients. Two catheters were removed for suspected infection, but infections were not microbiologically confirmed in either case. Our results are in line with previous research: most studies find very low rates of MC-associated infections, and many report no cases of catheter-related bacteremia^(13,14).

On the other hand, our results do indicate an association between difficult venous access as the reason for MC insertion and non-elective device removal for any reason. This may be related to children being inherently more susceptible to PIVC failure, due to factors such as difficult venous access, capillary fragility, developmental or physiological factors, and a high level of activity, as stated by other authors⁽²⁵⁾.

Regarding IV administration of moderate-risk drugs, we found a close-to-significant association with non-elective catheter removal for any cause ($p=0.05$), but no association with thrombosis. In our opinion, these data are insufficient to warrant the assertion that this type of medication can be safely administered through an MC. It should be noted that in most cases documented in our study, the catheter tip was positioned in relatively large veins: the axillary, subclavian, or brachiocephalic. At these levels, blood flow is higher than in distal limb vessels. This may result in greater drug dilution, and consequently, less irritation of the vascular endothelium (which is a triggering factor for thrombosis)⁽²⁶⁾.

This study has several limitations. First, it was conducted in a single center, and hence, results may not be generalizable to other settings or populations. Secondly, it was not a

clinical trial but rather an observational study focused on MCs, with no control or comparison groups. Efforts were made to record all possible cases of MC placement during the study period, yielding a total of 69 cases. Nonetheless, studies with larger sample sizes are needed to confirm our findings. Further, the results might have been influenced by factors we did not assess, such as catheter-to-vein ratio, comorbidities, or other patient-related factors, and nurse experience. In particular, specialized vascular access nursing teams for the selection and placement of these devices have been shown to reduce complications^(26,27).

CONCLUSIONS

In this study, we found a high MC success rate, with 70% of catheters being removed electively at the end of treatment. These devices were a good option for medium-term therapies (up to 1 month) in our patients. The complication rate was similar to that in other studies in children.

In terms of frequency and severity, the leading complication was thrombosis.

Children with difficult or limited venous access need individualized assessment considering their venous capital, the medication prescribed, and the expected treatment duration, as early placement of an MC may be beneficial.

Given the limited evidence, further studies on children are needed to explore factors that may influence the onset of complications, such as indication for use, insertion site, and drug administered, as well as the catheter-to-vein ratio, nurse experience, and care provided during catheter dwell time.

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