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Disabling Outcomes After Peripheral Vascular Catheter Insertion in a Newborn Patient: A Case of Medical Liability?

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Statistical Analysis C
Data Interpretation D
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Patient: Female, newborn
Final Diagnosis: Loss of falange of the hand
Symptoms: Manual disability • Pain
Medication: Ampicilline
Clinical Procedure: Insert vascular catheter
Specialty: Forensic Medicine

Objective: Rare disease

Background: The positioning of peripheral venous catheters (PVC) is an invasive procedure commonly performed in pediatrics hospital wards to obtain vascular access for the administration of fluids, medications and other intravenous (IV) therapies. Many studies exist about management of peripheral venous access in adults. On the contrary, scientific evidence on the management of this procedure in children and newborns, especially regarding the optimal duration of infusion and the possible related side effects, is still poor.





To minimize the risk of phlebitis, the guidelines of the US Centers for Disease Control and Prevention suggest the replacement of the catheter every 72–96 hours in adult patients, while in pediatric patients the catheter can remain in place for the entire duration of the IV therapy, unless complications arise.

Case Report: In the presented case, after the positioning of a PVC in a newborn, no clear signs/symptoms of phlebitis were registered before the sixth day and, despite the immediate removal of the catheter, the thrombotic process, secondary to phlebitis, was already occurring, causing serious and permanent disabling outcomes, susceptible to legal medical evaluation and financial compensation.

Conclusions: The knowledge of this case is particularly interesting to clinicians working in the field of neonatal care and to clinical risk management services inside hospital structures, since similar cases may be the source of requests for extremely high financial compensations due to medical liability.

MeSH Keywords: Catheterization, Peripheral • Liability, Legal • Malpractice • Risk Management

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Background

Peripheral vascular catheter (PVC) insertion is an invasive procedure commonly performed in pediatric wards to obtain intravenous (IV) access for administration of medication or fluids. Peripheral venous access allows a connection between the cutaneous surface and a peripheral blood vessel. Catheters are medical devices equipped with a thin tube consisting of bio-compatible materials (Teflon®, polyurethane, silicone); they may be assembled in different ways according to specific purposes.

Obtaining a peripheral venous access in newborn patients is often a difficult process, whose related adverse events include phlebitis, thrombosis, catheter dislocation, bleeding, and infiltration. The complexity of this procedure may be attributed to the fact that newborns are noncompliant and have smaller, less visible veins and a higher percentage of adipose tissue. Conditions such as premature birth and chronic illnesses may further complicate the procedure of PVC insertion [1,2].

To minimize damage to venous vessels of the newborns, it is extremely important to carefully choose the vein in which the PVC will be inserted. Vein conditions as well as type and duration of IV infusion therapy should be considered in the decision-making process [3–5].

In infants, a PVC is commonly inserted in the veins of the dorsum of the hand, since the placement in this site does not significantly impair mobility and allows easy detection of the onset of phlebitis.

Despite the great number of studies on the management of IV peripheral access in adults, there is a lack of scientific evidence on this matter in pediatric patients, specifically with regard to the optimal duration of the procedure and to the possible adverse events.

In the presented case, the severe sequelae resulting from the insertion of a PVC in a newborn patient will be discussed.

Case Report

A female infant was born prematurely at 23 weeks and 5 days' gestation through spontaneous vaginal delivery after a normal pregnancy. At birth, the newborn weighed 590 grams. Due to the prematurity of the lungs, she was given surfactant by endotracheal intubation. The procedure resulted in increased oxygenation and a normal Apgar score after a few minutes. Ten days after birth, a 24-G PVC was placed on the volar surface of the right wrist, through which fluids (physiological saline) and antibiotics (ampicillin, gentamicin, vancomycin) were administered, since hemocultures were positive for *Haemophilus*



Figure 1. Severe PVC-related sequelae on the patient's right hand compared to the contralateral limb.

influenzae and *Staphylococcus capitis*. In the following days, blood components (4 units of packed red blood cells and 2 units of fresh frozen plasma) were also transfused through the same venous access. No other agent was administered. After its insertion, the device was neither removed nor replaced. Six days after PVC placement, an ecchymosis appeared on the right index finger and the newborn looked distressed. Paracetamol was administered and the catheter was removed and replaced in the axillary vein. In the following 12 hours, the patient displayed, upon examination, coldness in the distal phalanges; her wrist and forearm appeared cyanotic. Thus, the physicians applied moist heat packs and heparan sulfate lotion to the affected areas. The following day, about 48 hours after removal of the device, an ischemic area and confined areas of necrosis on all distal phalanges of the right hand were observed and brachial artery pulse could not be detected. Blood tests excluded hypercoagulable states. An ultrasound scan of the right upper limb was performed, showing extended venous thrombosis at the site of investigation; thus, the patient was administered Urokinase 4400 U/kg by venous infusion via external jugular vein access. Antithrombotic therapy was protracted for 11 days with administration of fractionated heparin until complete resolution of thrombosis. A vascular ultrasound performed after treatment completion showed an interruption of arterial blood flow in the right hand and common digital arteries near the areas of necrosis. Upon surgical consultation, the plastic surgeon detected "dry gangrene of the tips of all 5 fingers on the right hand, well-contoured in the first and second finger". Since the clinical conditions were deemed stable and unlikely to undergo further changes, surgical treatment was not recommended. The patient was discharged from the hospital 60 days after birth in good condition and was monitored with regular follow-up examinations.

During the legal medicine examination, about 2 years after birth, the girl appeared lively and reactive to stimuli. On inspection, the right hand was swollen and clumsy, with light edema detected during palpation. The distal and most of the

proximal phalanx of the first and second finger and the distal phalanges of the third, fourth and fifth finger were clearly missing (Figure 1). Upon palpation, extremities appeared swollen, flushed, and moderately tender. The child attempted to grab small objects with visible difficulty due to the incomplete finger grip.

Discussion

Phlebitis, defined as the inflammation of the wall of a venous blood vessel, is the most feared PVC-related adverse event and it occurs rather frequently. If the inflammatory state continues for an extended period, it may spread to nearby structures and promote the onset of thrombosis. Phlebitis is classified depending on the underlying cause of the inflammation: mechanical, chemical, or infective. Mechanical phlebitis occurs as the movement of the cannula within the vein causes friction on the vessel wall [6]. Chemical phlebitis is caused by the irritating action on the vessel wall of drugs that are infused through the catheter; antibiotics with low pH and hypertonic solutions increase the likelihood of chemical phlebitis [7]. Infective phlebitis is caused by the bacterial contamination of the catheter. Common symptoms of phlebitis include pain along the venous track; edema, which may spread to the entire limb; erythema and redness at the site of catheter insertion; and local hyperemia. The presence of just one of these symptoms should prompt the physician to suspect that an inflammatory process is occurring [8]. Some of the aforementioned symptoms may present as highly non-specific in newborn patients, making an early identification rather difficult. The initial step for any type of phlebitis is to suspend the infusion and remove the cannula [9]. All types of phlebitis may either completely revert or evolve to thrombosis, determining blood flow obstruction [10], which may cause permanent damage, leading to the request for economic compensation.

In the presented case, the catheter was maintained at the same site of access for about 6 days, a period long enough for the development of thrombophlebitis, which caused severe and permanent damage to the newborn girl.

The final lesion was caused by the consequent deep venous thrombosis. The exclusion of an accidental arterial cannulation was based on reconstruction of clinical events. On the sixth day after the insertion of a PVC, an ecchymosis appeared on the right index finger and the patient was suffering. In the following 12 hours, the patient displayed coldness in the distal phalanges and cyanosis on her wrist and forearm. After other 36 hours, an ischemic area and confined areas of necrosis on all distal phalanges of the right hand were observed; moreover, brachial artery pulse could not be detected. An

ultrasound scan of the right upper limb showed extended venous thrombosis at the site of investigation. The presence of cyanosis at an early stage of the clinical story, together to the findings of the ultrasound scan, indicate the occurrence of a deep venous thrombosis.

If the arterial flow was compromised first, the limb would have been expected to be pale and not cyanotic. The reason for the absence of pulses in correspondence of brachial artery, as subsequently found in the present case, is that arterial thrombosis may sometimes coexist with venous occlusion.

In fact, cases of severe and diffuse deep venous thrombosis, also known as phlegmasia cerulea dolens, clinically present with sudden severe pain in a part of an extremity, which quickly spreads to involve the whole limb. The most striking change is the severe cyanosis that produces an alarming picture. The limb becomes numb and cold and the peripheral pulses may disappear. A generalized hypothesis for the lack of pulses implies a relationship of veins, arteries, and lymph vessels in the extremity during an acute thrombotic process. It was shown that venous irritation by mechanical/inflammatory occlusion resulted not only in venostasis, but also in severe arterial spasm which, in turn, could markedly impede the lymphatic return and cause fluid retention in the limbs of experimental animals. Another hypothesis is connected to the development of edema as a consequence of the obstruction of the venous vessels, with interference in the arterial blood flow.

In our case, the area of ischemia and the absence of brachial artery pulse appeared after 36 hours from the observation of the ecchymosis on the right second finger, indicating the secondary involvement of the arterial vessels.

In the scientific literature, there are ongoing debates on the consequences of keeping a catheter at the same site of access for such an extended period. Center for Disease Control and Prevention (CDC) guidelines [11] recommend replacement of the catheter in adults every 72–96 hours to minimize the risk of phlebitis, whereas in pediatric patients a PVC may be left *in situ* until completion of IV therapy, unless complications arise. If the patient does not exhibit signs of phlebitis and/or infection, a PVC may be left *in situ* for over 96 hours, especially in children [12,13]. A study suggested that a 3-day routine replacement of peripheral venous catheter does not reduce the risk of phlebitis and that the device may remain *in situ* up to 144 hours with no significant increase of PVC-related complications, provided that the patient is adequately monitored [14]. In the reported case, no clear signs of phlebitis were observed before day 6 and, although the device was promptly removed, the underlying thrombosis had already begun to develop. The resulting ischemia-related debilitating sequelae called for professional liability evaluation and economic compensation.

In addition to the aforementioned CDC guidelines, other scientific evidence exists in the literature relating to the optimal management of PVC for extended periods. The site of insertion must be regularly monitored (at least once a day) by inspection and palpation through the medication [4–12]. If the patient reports pain at site of insertion or develops signs of infection/inflammation, the PVC must be removed and a complete examination of the site of insertion must be performed. Some authors recommend the placement of a sterilized transparent medication to allow better visualization of the site of insertion and early detection of the PVC-related complications. Moreover, it is important to verify that the cannula is correctly and firmly placed at the site of insertion to avoid an accidental displacement of the device or its removal by the child. These procedures must always be performed carefully to minimize the risk of mechanical irritation and phlebitis [15,16]. Physicians should consider the insertion of a central venous catheter (CVC) when they treat patients who require long-term IV infusions of fluids and/or medications; if the CVC is placed in the upper limbs, the dominant arm should be avoided as the site of access [17]. Special attention is needed during IV administration of solutions whose pH and osmolarity values differ from those of the blood, as in the case of blood products and insufficiently diluted drugs [18,19].

The presented case, as well as others that illustrate legal medical issues in the matter of professional liability, may be particularly relevant and informative to clinicians who work in

neonatal care units and to clinical risk management services in hospital units, as similar events may persuade the patients to register medical malpractice claims [20].

Conclusions

Although no evidence could be found in the scientific literature that supports the practice of replacing PVC within 72–96 hours in pediatric patients, in the presented case the maintenance of the device in the same site for 6 days caused the onset of thrombophlebitis and subsequent severe permanent sequelae, with significant related economic consequences. It must be noted that no symptoms and/or signs of phlebitis preceded this event. However, strict monitoring of the patient was necessary, as the catheter was going to be used to infuse antibiotics and blood products.

The knowledge of this case is particularly interesting to clinicians working in the field of neonatal care and to clinical risk management services inside hospital organizations, since similar cases may be the source of requests for extremely high financial compensation due to medical liability.

Conflict of interests

None.

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