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Long sheath use in femoral artery catheterizations in infants <15 kg is associated with a higher thrombosis rate; proposed protocol for detection and management.

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ABSTRACT

Objectives: To examine the factors contributing to arterial thrombosis after catheterization, particularly the use of long vs short introducer sheaths, and propose a new protocol to address risks.

Background: Post-procedure arterial compromise is an important concern in pediatric cardiac

catheterizations. For certain interventional procedures, the use of a long sheath is necessary, however, the incidence of complications when using such sheaths has not yet been studied.

Methods: This retrospective review includes patients <15 kg who underwent femoral artery catheterization at our institution from Feb 2006 to June 2014. The study examined 29 long sheath and 40 matched interventional short sheath cases. Data collected included age, weight, time to arterial access, total sheath duration, and arterial complications. The long sheath and short sheath groups, and confounding factors, were compared for complication rate.

Results: The incidence of arterial compromise was 38%(11/29) in the long sheath group compared to 15%(6/40) for short sheaths (p=0.029). Arterial thrombosis was documented by ultrasound, CT, or angiography in 71%(12/17) patients. Time to arterial access and total sheath duration were not statistically significant factors. Weight was an independent risk factor, with infants <5kg having a higher complication rate compared to infants >5kg at 38.2%(13/34) and 11.4%(4/35), respectively (p=0.004). Sheath length remained statistically significant after taking weight into account (p=0.046).

Conclusion: The use of a long sheath in infants <15kg is a significant risk factor for arterial compromise compared to short sheaths. Lower patient weight is also a contributing factor to increased incidence of complication, particularly in those <5kg.

INTRODUCTION

Femoral thrombosis at the site of arterial access is an important complication of cardiac catheterization, particularly in pediatric patients in which the complication rate is reported as 8%, of which arterial thromboses contributes a large portion [1,2,3,4,5]. While there have been significant improvements in thrombolytic therapy, it is important to minimize the risk of thrombosis because of the complications involved with thrombolytic therapy [1,5]. If left untreated, arterial thromboses could result in permanently decreased perfusion, leg length discrepancy, and access difficulties during subsequent catheterization procedures. Previous studies have identified age, weight, longer procedure time, need for repeat catheterization, and general technique as risk factors for increased incidence of arterial compromise [6,7,8]. There have been studies on the effect of sheath French on arterial complication rate but no studies on the effect of sheath length [7,8]. Short sheaths (7cm) are standardly used in non-interventional pediatric cases. Longer sheath lengths (45 cm or 75cm) are selectively used in interventional procedures, such as in patent ductus arteriosus stenting, aortic coarctation stenting, and BT shunt procedures because they allow for better catheter manipulation [9]. This study aims to compare the incidences of arterial compromise between long and short introducer sheaths in pediatric patients under 15kg and provide a protocol for management for those <5kg.

MATERIALS AND METHODS

A retrospective review of the Rady Children's Hospital San Diego (RCHSD) PedCath database was used to identify patients for the study. The study group consisted of 69 patients who underwent femoral artery cardiac catheterization between February 2006 and June 2014 at RCHSD. Out of a total of 1155 cases performed on patients <15kg between February 2006 and June 2014, 29 were identified in which an arterial long sheath was used and 40 matched interventional cases were selected in which a short sheath was used. Data collected included

patient age, weight, sheath French size, time to arterial access, total sheath duration, post-cath arterial compromise, and resolution if applicable. Arterial compromise was identified by a documented decreased distal pulse and/or thrombus or fistula identified on arterial Doppler, CT scan, or subsequent angiography. Patients who had a detected arterial thrombosis were either monitored for 24 hours with spontaneous recovery, treated with therapeutic heparin for 24-48 hours (keeping PTT 60-80), or given tPA (0.05mg/kg/hr for 30 minutes, followed by 0.1mg/kg/hr for 4 hours) [10]. The long sheath and short sheath groups, as well as confounding factors, were compared for significant differences in complication rate.

Statistics

Confounding factors were determined by using either an unpaired t-test or Pearson's chi-squared with a cut-off of p=0.10 to suggest possible confounding effect. Logistic regression of the identified factors was performed using R studio to analyze the complication rate.

RESULTS

Between February 2006 and June 2014, 29 cases were identified in which an arterial long sheath was used and 40 matched interventional cases were selected in which a short sheath was used. The total cohort (69) consisted of 59% males and 41% females. Patient's age ranged from 1 day to 4.5 years (mean 11.6 ± 15.1 months), and weight ranged from 2.6 to 14.8 kg (mean 7.0 ± 3.9 kg). Of the patients who received a long sheath, 10 received a 4Fr 75cm sheath (Cook Medical, Bloomington, Indiana), and 19 received a 4Fr 45cm sheath (Cook Medical, Bloomington, Indiana). A total of 17/69 had arterial compromise, 16 of the 17 had decrease pulses and or a confirmed thrombus. One patient had a fistula in one femoral artery and a thrombus in the other, which resulted in severe limb discrepancy (Figures 2A, 2B).

The incidence of arterial compromise was 38% (11/29) in the long sheath group compared to 15% (6/40) in the short sheath group and was statistically significant (p=0.029). Neither time to arterial access nor the sheath implant duration was statistically significant between the groups. Weight was an independent risk factor, with infants <5kg having a higher complication rate compared to infants >5kg at 38.2% (13/34) and 11.4% (4/35) respectively (p=0.004). Sheath length remained statistically significant after performing logistic regression analysis taking weight into account (p=0.046). The odds ratio of long versus short sheaths for arterial compromise was 3.46 (95% CI: 1.10-10.91).

In total, arterial compromise was documented by ultrasound, CT, or angiography in 71% (12/17) of patients with complications, the remaining 29% (5/17) had decreased pulses on exam. 14 patients had early detection of arterial compromise (within 2 weeks of the procedure). Of those, 10 received heparin or tPA therapy with good resolution, 2 recovered spontaneously, and 2 were lost to follow up. 3 patients had late detection of arterial compromise. Of those, 2 developed collateral blood flow, and 1 patient had a leg length and width discrepancy (Figures 2A, 2B). The patient with a fistula and leg discrepancy underwent surgical ligation of the fistula with improved leg length disparity.

DISCUSSION

While long sheaths are the preferred equipment for select pediatric catheterization procedures, there is little evidence comparing the incidence of adverse events, particularly arterial thrombosis, between long and short sheaths. Our analysis shows that there is an increased risk of adverse arterial events when using long sheaths, and particular care should be taken in patients <5kg, who have an overall higher incidence of post-procedure arterial thrombotic events.

There are some caveats of this study to consider. Firstly, there may be an inherent bias in the long sheath cohort in that most patients who needed long sheaths are generally more complicated patients with more complex vessel anatomy and perhaps several serious diagnoses that may affect coagulation. This study used total sheath implant duration as a quantitative surrogate measure of complexity of the procedure, though this may not always be the case. Glat et al recommended taking into account number of sheath and catheter exchanges, contrast volume given, baseline hemoglobin, and baseline and ending activated clotting time as covariates as other possible contributors to arterial compromise [13]. Previous catheterizations in the same vessel were also thought to contribute to increased incidence of thrombosis. In order to address this issue, we examined the patients with and without arterial compromise and compared the percent of patients who had previous access to the vessel and found that there was no statistically significant difference between the two groups (p = 0.45).

In comparing our paper to existing studies looking at arterial compromise, another limitation of this study was that ultrasounds were only performed on patients who showed clinical signs (decreased pulse, decreased temperature, cyanosis) of thrombosis. As shown by Kulkarni et al and Knirsch et al, it is possible that the rate of complications was underestimated without comprehensive ultrasound confirmation of vessel patency [11,12]. In 2 cases within our study population, thrombosis was not discovered until subsequent catheterization several months post-procedure. Because this was a retrospective study, it was not possible to implement a standardized thrombus detection protocol. We subsequently developed a standardized protocol for prevention, early detection, and management of arterial thrombosis. We developed this protocol for the highest risk group, infants <5kg undergoing long sheath femoral artery

catheterization, but would also recommend that it be considered for those <15kg. The protocol emphasizes rigorous monitoring of clinical signs and calls for a low threshold for ultrasound imaging and pharmacologic therapy.

PROTOCOL FOR INFANTS <5kg:

We recommend the routine use of ultrasound for access and the use of a 3.3F sheath (Mongoose, Pedavascular, Ohio) when possible. Intra-operatively, the ACT (activated clotting time) should be checked every half an hour, maintaining it at >200 seconds. In procedures for which a long sheath or a 4F short sheath must be used, prophylactic heparin at 10-15 u/kg/hour should be started immediately after the catheterization, the pressure dressing should be removed from the groin after 1-2 hours and pulses should be checked. If the pulse is present, heparin is maintained at that dose until the next morning. If the pulse is absent, the heparin dose is increased to a more therapeutic range (PTT 60-80). If pulses are still diminished after 6 hours, ultrasound with Doppler is performed. If an occlusive thrombus is present and the foot is cold with capillary refill >2 seconds, a 6 hour course of tPA is started (tPA dose 0.05mg/kg/hr for 30 minutes, followed by 0.1mg/kg/hr for 5 hours) [9]. If a non-occlusive thrombus is observed, Lovenox is initiated and maintained for 10-15 days (Figure 6).

CONCLUSION

Weight and sheath length are both statistically significant contributors to complication rate. Lower weight (<5kg) and longer sheath increase incidences of arterial compromise. There should be an especially high index of suspicion in patients <5kg undergoing arterial access with a long sheath. Early detection by considering routine use of Doppler US in this population would allow for prompt treatment and minimize long-term complications.

TABLES:

Table 1: Demonstrates variables examined between long and short sheath groups

FIGURES:

Figure 1: Chart illustrating the method of detection and resolutions of patients with arterial compromise (AC).

Figures 2: 3D reconstruction of CT imaging of a patient who developed an AV fistula in the left leg (small arrow) and a thrombus in the right leg (large arrow), resulting in clinically significant leg length and leg width discrepancy.

Figure 3: CT imaging of the same patient with an AV fistula and femoral artery thrombus demonstrating leg width discrepancy.

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