

Catheter-Directed Thrombolysis and Percutaneous Thrombectomy for Acute Arterial Ischemia in Children

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Introduction

Acute arterial ischemia is defined as the sudden decrease in blood flow to a tissue bed due to an embolism or thrombosis, resulting in a potential threat to the viability of the area.¹ The intravascular administration of thrombolytic agents originated in the 1960s for the treatment of pulmonary embolism. Thrombolysis by selective catheter infusion for vascular occlusion entered the mainstream during the 1970s.² Thrombolytic agents have been successfully employed to dissolve the occluding thrombus, reconstitute blood flow and improve the status of the tissue bed supplied by the involved vascular segment, especially in patients in whom no outflow vessels are present at the time of the initial presentation with acute arterial occlusion. These agents also may open target vessels and allow for a surgical limb salvage procedure when it was not possible before.

Catheter-directed administration of thrombolytic agents offers practical and theoretical advantages to the traditional surgical approach first introduced by Fogarty.² Percutaneous thrombectomy (PT) was developed to treat intravascular thrombosis, allowing percutaneous recanalization of thrombosed vessels and thus providing an additional therapeutic option for the treatment of acute arterial ischemia. PT and catheter-directed thrombolysis (CDT) used in conjunction are associated with shorter treatment duration, lower lytic agent doses and lower cost than thrombolysis alone.³ These techniques have been studied in adults, but their benefits and risks have not been established in the pediatric population. We present 5 cases where PT (aspiration or mechanical) and CDT were used concomitantly to improve ischemic limb outcomes in children.

Case Reports

Case 1. A 2-year-old male patient with no history of systemic illness (Table 1) was taken to an area hospital by his parents due to vomiting and poor oral intake of over the previous 3 days. Upon arrival to the hospital, the patient

was severely dehydrated and lethargic. Fluid resuscitation was started when he was found to be hypotensive. Laboratory reports demonstrated a glucose level of 1,200 mg/dl, large ketones, low CO₂ at 5 mEq/L and a pH of 6.9. Fluids were adjusted, but the patient became obtunded and was intubated.

Arterial and venous femoral catheters were inserted in the left side. Less than 12 hours later, the left leg became pulseless and pale, therefore, both catheters were removed and heparinization was initiated. Twelve hours later, cyanotic changes up to the mid-thigh were observed, without improvement of his pulse in the distal aspect of the extremity. During our evaluation approximately 26 hours later, the patient's leg had obvious necrotic changes up to the femoral area, with cyanosis, ecchymoses and bullas. The leg also did not respond to pain stimulation and remained pulseless, even with Doppler evaluation.

The patient was taken to the catheterization laboratory where arteriography via a contralateral femoral approach revealed total obstruction of the left iliofemoral arterial system (Figure 1).

Case 2. A 20-hour-old baby boy was born by cesarean-section at another facility after an uncomplicated first pregnancy. Upon birth, the baby was found to have a bulla in the right anterolateral aspect of the forearm and deep cyanotic changes of the right hand (glove-like). A Doppler exam revealed no arterial flow to the hand from the mid-forearm. A repeat Doppler exam was performed approximately 16 hours later due to worsening cyanosis all the way up to the shoulder. The patient's obstruction progressed and there was no flow from the right subclavian artery to the entire arm. The patient was transferred to our institution, but just before the transfer, he had a seizure. He was given benzodiazepines and was started on phenobarbital intravenously. This situation gave us more concern, since, with the progression of the thrombosis and a seizure, there was a good chance that the disease had continued up to the carotid arteries. The patient had no radial or axillary pulses and no motion of the arm, even with deep stimulation.

At approximately 20 hours of age, the patient was taken to the catheterization laboratory where thoracic aortography revealed total occlusion of a trifurcate brachiocephalic trunk (Figure 2). His right common carotid and subclavian arteries were totally occluded, however, the left carotid artery was spared from the obstruction.

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Disclosure: The authors report no financial relationships or conflicts of interest regarding the content therein.



Figure 1. Contralateral injection showing total occlusion of the arterial supply to the left lower extremity (arrow).

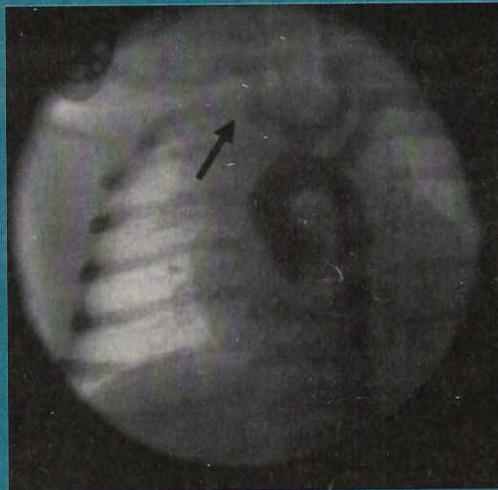


Figure 2. Aortogram showing complete occlusion of flow (arrow) to the right subclavian and carotid arteries. Note that there is a trifurcated brachiocephalic branch with good flow to the left carotid artery.

Nevertheless, angiography showed no contralateral flow across the Circle of Willis to the right side of the brain. Percutaneous aspiration thrombectomy (PAT) of the arm and head vessels with the infusion of intra-arterial urokinase was performed.

Case 3. A 6-month-old baby boy with a history of Ebstein's anomaly had a right-to-left shunt across a large atrial septal defect. While in the intensive care unit, he presented with sudden-onset of diminished pulses in the right hand. The hand became pale and the patient was in obvious discomfort. However, after over 24 hours of intravenous heparin sulfate, there was no improvement of the hand. His hand color changed from pale to cyanotic and digital ulcerations were already apparent. Angiography revealed total occlusion of the right ulnar and radial arteries. We felt that the reason for this occlusion was an embolism. Tissue-plasminogen activator (t-PA) was administered, however, there was no improvement in blood flow after sufficient monitoring, thus PAT was performed.

Case 4. A 13-year-old male was admitted due to fever and uncontrolled diarrhea and was then transferred to our institution after presenting with no pulse in both of his legs. His past medical history included having nephrotic syndrome. He was acidotic and lethargic; he did not move his legs and had no sensation. After an Allen's test was performed via a right radial approach, emergency thoracic and abdominal arteriograms revealed total bilateral iliofemoral occlusions. A 6 Fr Oasis catheter (Boston Scientific/Medi-tech, Natick, Massachusetts) was inserted, and percutaneous mechanical thrombectomy (PMT) followed by PAT in the smallest vessels were performed bilaterally all the way down to the popliteal and tibial

arteries. Intra-arterial urokinase drip via a 2.3 Fr Rapid Transit Catheter (Cordis Corp., Miami Lakes, Florida) placed in the abdominal aorta from a right radial artery approach was commenced, and heparin was continued intravenously. After 24 hours, some improvement in both legs was observed. However, the acidosis continued and the patient went into renal failure requiring dialysis, followed by multiorgan failure. Unfortunately, the patient died 4 days after the treatment. No autopsy was performed.

Case 5. A 1-year-old with a neuromuscular disorder presented with a diminished pulse in the left hand and bluish discoloration of the 3rd, 4th, 5th fingertips. Arteriography was performed approximately 20 hours after the initial presentation and revealed occlusion of the left ulnar artery and obvious emboli to the digital arteries. The patient was treated with PT and t-PA. After 48 hours, the patient was brought back to the catheterization laboratory where a repeat arteriogram revealed stenosis of the ulnar artery at the level of the elbow and some residual thrombus in the 5th finger. The clot was removed and angioplasty was carried out. Excellent flow was observed upon completion of the procedure.

Materials and Methods

Patients. The cases are presented here in the order in which they were referred. All the patients were transferred from another institution to ours after the initial diagnosis of acute arterial occlusion was established by Doppler evaluation. The timeframe of diagnosis-to-arrival was from 16–30 hours. All of the patients were already treated with heparin sulfate drips and their partial thromboplastin times (aPTT) were monitored. The procedural risks and possible outcomes were discussed with the parents and proper consent was obtained.

Catheterization technique. The procedures were performed under general endotracheal anesthesia or sedation. After arterial access was established, an additional bolus of heparin sulfate (50–100 IU/kg) was given, and the intravenous (IV) drip was adjusted if the aPTT was not adequate. All patients were maintained on IV heparin sulfate during the acute phase and were later changed to enoxaparin subcutaneously for the duration

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Table 1.
Demographics and Treatment

Case	Age	Affected Area	Obstructed Arteries	Thrombolysis and Anticoagulation	Complications
1	2 yrs/old	Left leg	Total obstruction of left common iliac artery	Urokinase - IA Heparin - IV	Hematoma in left femoral area
2	1 day/old	Right arm	Total obstruction of brachiocephalic trunk. No contralateral flow across the Circle of Willis	Urokinase - IA Heparin - IV	Bleeding from umbilical vessels requiring transfusion
3	6 mos/old	Right hand	Total mid forearm-right ulnar and radial arteries	t-PA - IA Heparin - IV*	None
4	13 yrs/old	Both legs	Total obstruction bilateral common iliac arteries	Urokinase - IA Heparin - IV	Renal failure Died
5	1 yr/old	Left hand	Left ulnar artery and palmar arches	t-PA - IA Heparin - IV*	None

IA = intra-arterial; IV = intravenous; *patient received nitroglycerin intra-arterially; yr(s) = year(s); mos = months

of their hospitalization. Initial angiograms of the affected areas were performed using a 4 Fr pig-tail catheter (Cordis) by power injection, or using a 4 Fr Benson-Hanafee-Wilson-1 (JB-1) (Terumo Corp., Natick, Massachusetts) by hand-injection of contrast.

After localization of the affected vessel, an initial bolus of urokinase 4400 U/Kg or t-PA 0.9 mg/kg over 10 minutes was administered intra-arterially to all of the patients (Table 1). The thrombolytic was chosen arbitrarily based on its availability at our institution at the time of presentation. After giving the medication, PAT was performed in all patients, as described by others.⁴ However, variations from the previously-described technique were employed based on the location and the catheter's ability to reach the clot. A 6 Fr Oasis catheter (Boston Scientific/Medi-tech) was used, and thrombectomy was performed bilaterally all the way down to the popliteal arteries only in Case 4 due to the advantage of his size. Nitroglycerin boluses at 1–2 µg/kg were given intermittently every 5–10 minutes throughout the procedures if vasoconstriction occurred due to catheter manipulation and if no hypotension followed. The total duration of treatment (days) with urokinase or t-PA was based on the patients' arteriograms and clinical improvement. At the same time, complications with the urokinase were kept at a minimum by monitoring fibrinogen levels and other clotting factors, which needed to be stopped in 1 case.

In areas the catheters were unable to reach, a 0.014 inch guidewire (Guidant Corp., Santa Clara, California) was advanced in an attempt to break the clot and allow more thrombolytic agent to reach the distal aspects of the obstruction.

When the removal of the clot was considered adequate, a 2.3 Fr Rapid Transit catheter (Cordis) was placed in a proximal aspect of the main arterial supply of the affected extremity, and the rest of the thrombolytic medication was given. In those who received urokinase, the medication was continued for 48–72 hours as a continued intra-arterial infusion at a rate of 4400 U/Kg/hour. Fibrinogen levels were monitored and maintained at approximately 100–150 mg/dl, with adjustments in the urokinase drip as needed. Results were analyzed by arteriography, and PAT was performed at that time if deemed necessary. In Cases 1 and 2, the urokinase drip was restarted after the second procedure and PTA was continued for an additional 48–72 hours (Table 1). In Cases 3 and 4, after completing the total dose of t-PA, an intra-arterial infusion of nitroglycerin at a dose of 0.25 µg/kg/minute was continued for 48 hours. Nitroglycerin paste (1 to 3 inches, depending of the area) was rubbed over the affected limb of all the patients. Blood pressure was strictly monitored. The patients' aPTT was monitored and maintained at approximately 2–2.5 times their initial level. The patient in Case 1 underwent a third arteriogram along with PTA and urokinase was continued for another 24 hours.

Results and Observations

All of the patients tolerated the procedures without problems (Tables 1 and 2). One patient underwent 3 arteriograms and interventions (PAT) with concomitant administration of urokinase for a total of 7 days of intra-arterial treatment. Three underwent 2 interventions, 1 was treated with urokinase for 4.5 days, and the other 2 were given 2 doses of t-PA 2 days apart (Cases 3 and 5). In Case 3, intra-arterial nitroglycerin was restarted after the second

Table 2.
Interventions and Results

Case	Total Number of Interventions	Days Treated with Thrombolytic	Anatomical Loss	Follow Up	Current Medications	Other Medical History
1	3	7	Toes and distal metatarsal bones left foot	Active, growing well	Insulin	Diabetes mellitus
2	2	4.5	4 fingers (2nd to 5th) - right hand	Active, growing well	Aspirin	Coarctation of the aorta
3	2	2 doses	None	Active, growing well	None	Ebstein's anomaly
4	1	3	Died	--	--	Unknown
5	2	2 doses	None	Active, growing well	Anticonvulsives	Neuromuscular disorder

treatment with t-PA and maintained for 72 hours more before discontinuing it. Case 4 underwent only 1 procedure and was given urokinase.

In all the patients, repeat angiography revealed that the occlusions were not totally resolved after their previous interventions (Figures 3 and 4). For that reason, repeat PAT was performed on these patients. In the distal areas the catheters were unable to reach, we advanced a 0.014 inch guidewire to create a track for the medication. We noticed that the medication was able to clean the areas up to where the catheters or wires were advanced, but not further than that. All surviving patients were continued on enoxaparin sodium 1.5 mg/kg subcutaneously every 12 hours for 6 months.

Complications

In Case 1, a hematoma formed in the left groin area where the initial central-line catheters for monitoring and blood sampling were placed (Table 1). In Case 2, the urokinase drip was stopped after 48 hours when the patient started to bleed through his umbilical vessels, requiring fresh-frozen plasma, blood and platelet transfusions. At that time, the urokinase and heparin sulfate infusions were stopped for approximately 18 hours. The heparin was then restarted until the patient underwent a second intervention 24 hours later. Case 4 experienced improved blood flow to both legs by 24 hours, however, he developed renal failure and became too unstable, requiring hemodialysis. He died 4 days after the initial presentation, and no autopsy was performed. Case 5 had no complications.

Anatomical Losses and Follow Up

The patient in Case 1 developed gangrene of his toes, requiring amputation approximately 4 weeks after presentation (Table 2). He then developed an infection of the surgical incision and had osteomyelitis of the distal metatarsal

bones requiring their partial amputation. The patient is now 3 years post event and living a normal and active life using a prosthetic shoe. He is being monitored by endocrinology for the treatment of his diabetes.

Patient 2 lost 4 of his right-hand fingers (2nd to 5th), but preserved his thumb (Table 2). He needed skin grafts for his hand and forearm. In regards to his neurological development, he has thus far reached all of his milestones on time. He has not had any more seizures and is currently on 81 mg of baby aspirin once a day. His mother was evaluated and found to have protein C and S deficiencies. The patient presented no abnormal laboratory values at 6 months of life.

Cases 3 and 5 had no anatomical losses whatsoever and are doing well 2 years and 1 year after the procedure, respectively. The fourth patient died 4 days after the initial event.

Discussion

In the 1960s, Fogarty described the use of a balloon embolectomy catheter that facilitated the removal of a thrombus and embolus from a distal site. In the 1970s, with the predominance of patients with atherosclerotic disease, it became clear that embolectomy alone was not sufficient for the reconstitution of limb blood flow.² Although open-surgical procedures are reliable, they subject the patient to significant perioperative risks including wound infection and myocardial infarction, among others.⁵ Thrombolysis was then introduced in the overall management of thrombotic events, thus buying time for the endangered limb and minimizing the necessity of future reconstructive limb surgery.⁶ The use of CDT with a thrombolytic such as urokinase proved to cause a reduction in the need for open-surgical procedures, with no significant increase in the risk of amputation or death.⁷ Despite its advantages, the use of CDT has been associated with



Figure 3. On the second intervention (Case 2), the patient still had a large thrombus in the axillary artery (arrow).

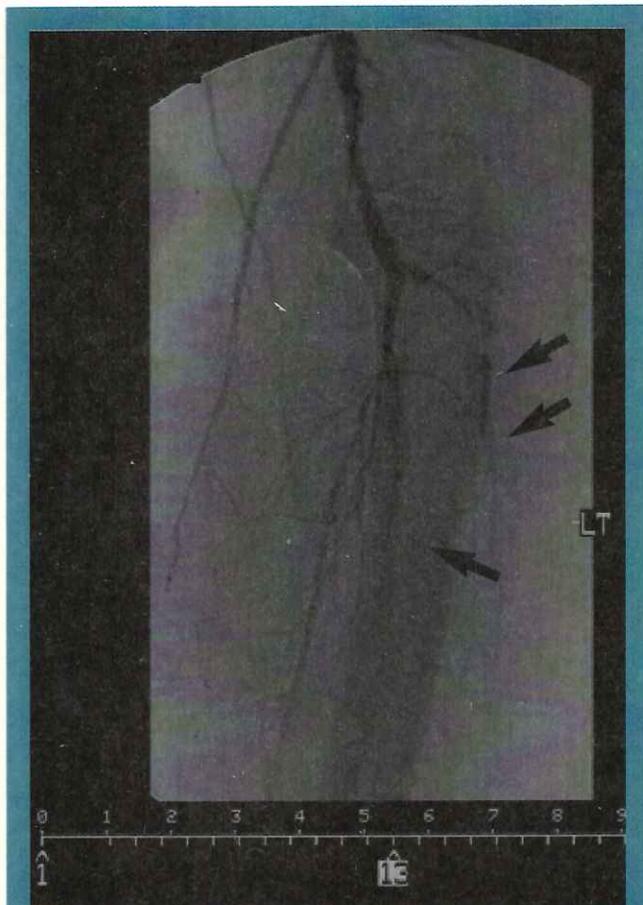


Figure 4. Lateral view. Observe the trifurcation of the left popliteal artery (Case 1). There are several areas of occlusion at different levels 48 hours after the first intervention had been on an intra-arterial urokinase drip.

greater hemorrhagic risks, long exposure to lytic agents, lengthy hospital stays and high medication and hospitalization costs.³⁻⁷

With the introduction of PAT and mechanical thrombectomy (PMT) as an adjunctive treatment for the removal of acute thrombus in vessels, the outlook for patients with vascular occlusions has changed. It has now been clearly proven that the use of CDT and PMT is an effective treatment combination. Kim et al³ found that CDT with PMT was associated with a 46% reduction in treatment duration, a 56% reduction in total lytic agent dose and a reduction in interventional material costs compared to CDT alone in the treatment of lower-extremity deep venous thrombosis. Furthermore, a 100% survival rate has been demonstrated at 30 days with improved renal function in acute renal thrombosis patients who were treated with CDT and PMT.⁸

In patients > 40 years of age, the leading cause of occlusive arterial disease of the extremities is atherosclerosis.⁹ In the pediatric population, a thrombotic or embolic phenomenon could be devastating and requires immediate intervention since no collateral circulation is present.

Currently, there are no studies relating to the management of acute limb ischemia in the pediatric population, even though catheters are known to be responsible for more than 80% of venous- and 90% of arterial-acquired thrombotic complications.¹⁰ Approximately 2.4 per 1000 patients admitted to the neonatal intensive care unit develop symptomatic secondary thromboembolic complications, although asymptomatic catheter-related thrombi occur more frequently, as evidenced by postmortem (3-59% of cases) and angiographic studies (10-90% of cases).¹⁰

The use of CDT and PT has not been studied in children, although the use and efficacy of both techniques are well documented in the adult population.^{1,2,5,6,11-18} In our cases, due to the absence of protocols for the management of acute limb ischemia secondary to arterial catheterization in pediatric patients, we decided to adapt the use of CDT and PT to treat peripheral vascular occlusions in adults to the needs of our pediatric patients. In our pediatric patients, arteriography revealed extensive arterial occlusions. The infusion of IV anticoagulants and intra-arterial thrombolytics did not yield rapid improvement, however. In fact, in repeated interventions, arteriography showed that the thrombolytic agents only treated the manually-opened vessels and did not affect the rest of the distal obstruction. PAT was repeated with the idea that after additional cleaning of the affected areas, and even by passing a wire through the clotted vessels, the medication could reach more distal tissue. These decisions appeared to be favorable for our patients.

Of particular concern in these cases was our ability to determine the window of time available for intervention before irreversible damage occurred. If we applied

the classification by Rutherford et al¹⁸ for acute limb ischemia to determine when to intervene in these patients, we would not have been able to perform the procedures since the patients were in the irreversible stage (Category III). However, this report shows that each case must be evaluated on its own merits and, in children, a more aggressive approach may be beneficial since collateral vessels have not yet developed.

Today, the success rate for surgical bypass in adults using a saphenous vein is approximately 66% at 5 years.⁶ Increasingly complex procedures are being undertaken, but the problem of extensive calcification found in adults remains. In the pediatric population, it is not the calcification, but the size of the vessels and the lack of trained personnel in the areas of peripherovascular and microsurgery in many centers that place this subset of patients at a disadvantage and limit the physician's ability to offer the children a good chance of limb survival.

Other than surgery, newer devices for percutaneous interventions have been developed over the last decade that will help physicians to treat their patients. Examples of these are: the Oasis Catheter (*Boston Scientific/Mediatech*),¹² the AngioJet system (*Possis Medical, Minneapolis, Minnesota*),¹³ and the Hydrolyser Percutaneous Thrombectomy Catheter (*Cordis*).¹⁴ All of these use the Venturi effect as their principal cleaning action.

The X-Sizer Thrombectomy System (*ev3, Inc., Plymouth, Minnesota, EndiCOR Medical, Inc., San Clemente, California*) combines vacuum technology with a helical cutter housed in the tip of a small catheter. Once engaged, the vacuum captures the thrombus.¹⁹

The Pronto Catheter (*Vascular Solutions, Inc., Minneapolis, Minnesota*) is an extraction catheter that is specifically designed for manual percutaneous aspiration thrombectomy. It is indicated for the removal of fresh, soft emboli and thrombi from vessels of the arterial system, and is contraindicated in vessels < 2 mm in diameter.²⁰

The Crosser catheter (*Flowcardia, Inc., Sunnyvale, California*) is an ultra high-frequency catheter designed to disintegrate calcified lesions. It is an experimental device, but appears to have a future in the thrombectomy arena. However, this device may be more useful for those with chronic occlusions since it is most effective on hard surfaces.²¹

Conclusion

Acute arterial insufficiency is most frequently the result of the obstruction of major arteries by clot and emboli. On occasion, it occurs abruptly and without warning. Its features include rest pain, reduced sensation or movement and tissue necrosis.

The use of thrombectomy catheters, thrombolytics and combinations of these have been extensively reported in the adult literature. In the pediatric population, although rare reported cases exist, there are no studies supporting the use of either of them. However, the authors believe that by

combining CDT and percutaneous aspiration and/or mechanical thrombectomy, when possible, we can achieve better results in the treatment of acute limb ischemia in children. Also, repeated interventions may be needed to improve success, since in our cases, the medications given showed that they can break small proximal clots, but may not be able to reach distal clots if complete occlusions are present, especially in the absence of collateral circulation. More data and experience will be needed to establish protocols of treatment for these patients. However, in children, aggressive management is warranted, since in our limited experience, tissue salvage can be achieved, even when initial gangrenous changes are present, and the risks of amputation and death may be higher.

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