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Management of Acute DVT Extending From the Tibial Veins to the Common Iliac Vein Using the AngioJet Thrombectomy System

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CASE PRESENTATION

A 30-year-old woman with Down syndrome presented to the emergency department with a 4-day history of right lower extremity swelling and pain, which worsened with ambulation. Evaluation in the emergency department revealed severe edema of the right calf and thigh with moderate inflammation and redness. The calf was painful to passive dorsiflexion of the foot.

DIAGNOSTIC EVALUATION

Venous duplex ultrasound of the bilateral lower extremities demonstrated acute nonocclusive deep vein thrombosis (DVT) in the right common and external iliac veins. Acute occlusive DVT extended from the right common femoral vein to the peripheral posterior tibial and peroneal veins. The left lower extremity was unremarkable with no evidence of DVT.

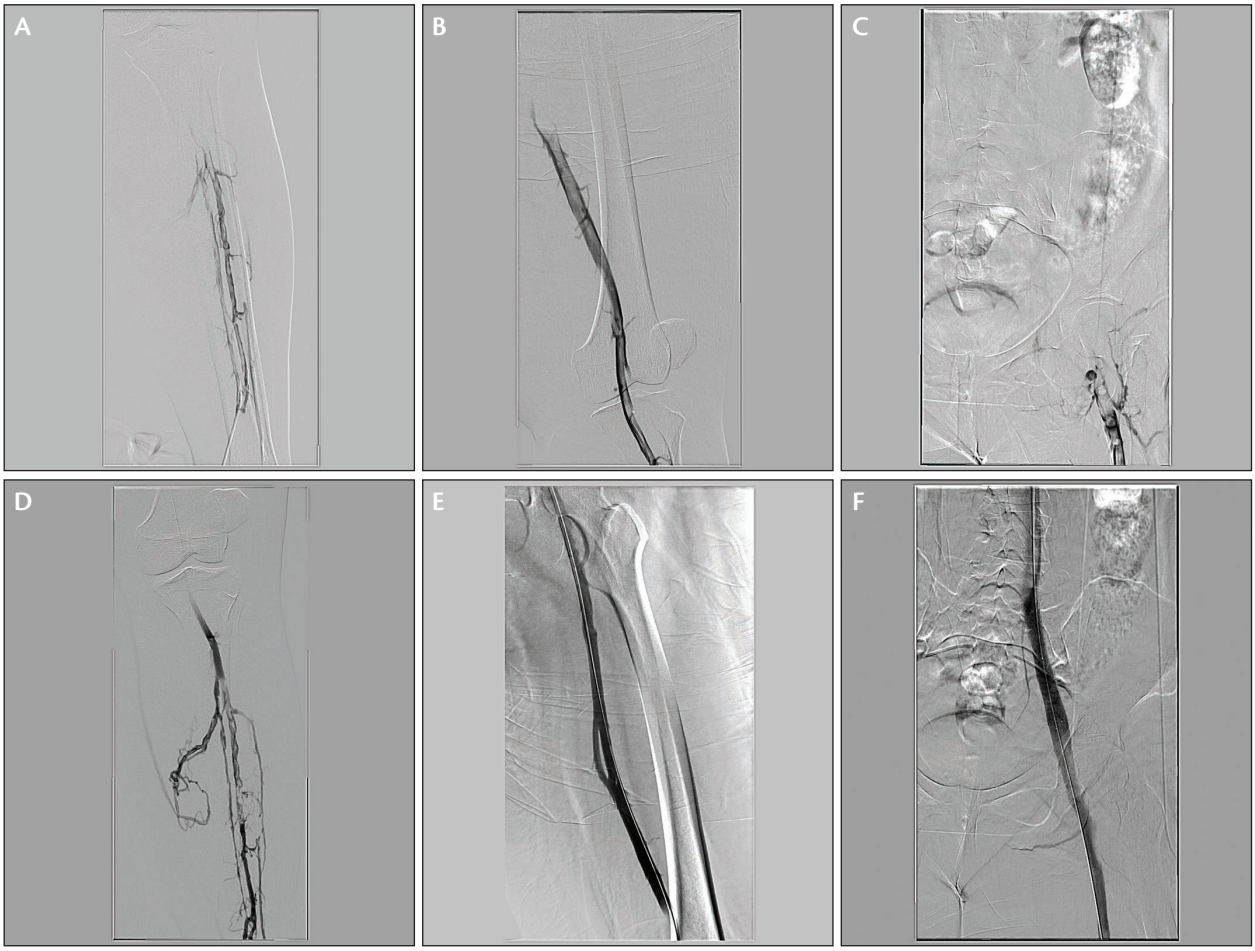

Figure 1. Initial venogram via right posterior tibial vein access demonstrates acute nonocclusive thrombus in the posterior tibial veins and occlusive thrombus at the level of the popliteal vein (A). After initial PMT via posterior tibial vein access, there is complete resolution of thrombus within the popliteal vein. A degree of spasm can be seen in the treated posterior tibial vein (B). Acute thrombus can be seen extending throughout the femoral vein (C) into the external and common iliac veins (D). The completion venogram after femoral and iliac PMT demonstrates an excellent result with complete resolution of thrombus throughout the femoral (E) and iliac veins (F). A patent right common iliac vein stent is also noted (F).

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TREATMENT APPROACH

The options of conservative therapy with compression and anticoagulation versus endovascular management were discussed in consultation with the patient and her family. Given the severity of the patient's symptoms, the decision was made to proceed with endovascular intervention. The patient was transported to the endovascular suite and placed in the prone position. A therapeutic dose of Lovenox (Sanofi US) and moderate sedation was administered. The patient's right leg was prepped from the popliteal fossa to the ankle. Under ultrasound guidance, the right posterior tibial vein was accessed with a micropuncture set, and a 4-F introducer sheath was placed. Initial venography demonstrated acute, partially occlusive thrombus within the paired posterior tibial veins with occlusive thrombus in the popliteal vein (Figure 1A). Over a 0.014-inch guidewire, a 4-F Solent™ Dista AngioJet catheter (Boston Scientific Corporation) was employed for pharmacomechanical thrombectomy (PMT) of the posterior tibial and popliteal veins using an eluent consisting of 10 mg tissue plasminogen activator (tPA) in 500 mL normal saline solution; 145 mL of the lytic solution was used for rheolytic PMT in thrombectomy mode. Completion venography demonstrated resolution of thrombus within the posterior tibial and popliteal veins (Figure 1B). Subsequently, under ultrasound guidance, the right popliteal vein was accessed with a micropuncture set, and an 8-F sheath was placed. Venography via the sheath demonstrated acute thrombus extending from the femoral vein to the common iliac vein (Figure 1C and 1D). A guidewire and catheter were negotiated into the inferior vena cava (IVC), where contrast was injected to exclude IVC involvement. Subsequently, an 8-F ZelanteDVT™ AngioJet catheter (Boston Scientific Corporation) was advanced for PMT of the femoral through common iliac veins using the same eluent in thrombectomy mode. After 470 mL of 10 mg tPA in 500 mL normal saline solution with the ZelanteDVT catheter, completion venography demonstrated complete resolution of acute thrombus (Figure 1E and 1F). Moderate chronic stenosis of the common iliac was noted and treated with a single 14-mm nitinol self-expanding stent (Figure 1F). Total fluoroscopy time for the procedure was 17 minutes.

The patient was discharged the same day on a therapeutic dose of Lovenox. At 1-month follow-up, she reported complete resolution of symptoms. A duplex ultrasound was obtained, demonstrating a widely patent deep venous system with excellent flow. The patient has remained symptom-free since the procedure. Repeat duplex ultrasound obtained at 3 and 6 months postprocedure showed no recurrent thrombosis. On examination, there was no evidence of postthrombotic syndrome (PTS) or chronic venous insufficiency. Villalta scores at the 1-, 3-, and 6-month follow-up remained at 0.

DISCUSSION

This case study describes the endovascular management of acute DVT extending from the tibial veins to the common iliac vein utilizing the AngioJet Thrombectomy System and a dual-access approach via the posterior tibial and popliteal veins. As patients and the medical community have learned more about DVT and PTS, there has been an increasing need for treatment beyond that of standard anticoagulation and compression. The AngioJet catheter is a powerful tool for reliable thrombus removal. The new ZelanteDVT 8-F catheter has the benefit of a larger inflow window as well as rotational directionality, increasing the likelihood of complete thrombus removal without the need for prolonged catheter-directed thrombolysis. Another feature seen in this case study is the value of the ankle access site, which, combined with the 4-F Solent Dista AngioJet catheter, allows for small-bore thrombus removal from the popliteal vein prior to popliteal access and ensures good inflow after subsequent iliofemoral PMT, thus minimizing the chance of future PTS. ■

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SOLENT CATHETERS COMBINED W/ CONSOLE

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

The AngioJet SOLENT Proxi & Omni Thrombectomy Sets are intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

• upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
• upper extremity peripheral veins ≥ 3.0mm in diameter,
• ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
• A-V access conduits ≥ 3.0mm in diameter and
• for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

The AngioJet SOLENT Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

• upper and lower extremity peripheral arteries and
• for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

The minimum vessel diameter for each Thrombectomy Set model is listed in Table 1 (in the DFU).

CONTRAINDICATIONS

Do not use the catheter/Thrombectomy set in patients:

• Who are contraindicated for endovascular procedures
• In whom the lesion cannot be accessed with the guide wire
• Who cannot tolerate contrast media

WARNINGS

• The Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where the catheter was used in treatment of pulmonary embolism.
• The Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
• The Thrombectomy Set has not been evaluated for use in the coronary vasculature.
• Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
• Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
• Use of the catheter may cause a vessel dissection or perforation.
• Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
• Do not use the Thrombectomy Set in vessels smaller than minimum vessel diameter for each Thrombectomy Set model as listed in Table 1 (in the DFU); such use may increase risk of vessel injury.
• Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
• Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the DFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Evaluate the patient's risk tolerance for hemoglobinemia and related sequelae prior to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's overall medical condition.
• Large thrombus burdens in peripheral veins and other vessels may result in significant hemoglobinemia which should be monitored to manage possible renal, pancreatic, or other adverse events.
• Monitor thrombotic debris/fluid flow exiting the Thrombectomy Set via the waste tubing during use. If blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel; verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.
• Obstructing lesions that are difficult to cross with the catheter to access thrombus may be balloon dilated with low pressure (≤ 2 atm). Failure to pre-dilate difficult-to-cross lesions prior to catheter operation may result in vessel injury.
• The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Sets are used to break up and remove peripheral venous thrombus.

PRECAUTIONS

• If resistance is felt during the advancement of the Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
• Do not exchange the guide wire. Do not retract the guide wire into the catheter during operation. The guide wire should extend at least 3 cm past the catheter tip at all times. If retraction of the guide wire into the Thrombectomy Set occurs, it may be necessary to remove both the Thrombectomy Set and the guide wire from the patient in order to re-load the catheter over the guide wire. *(Dista only)*
• Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath or guide catheter as a unit to prevent possible tip separation.
. (Below is Omni, Proxi only)
• Use of a J-tip guide wire is not recommended as it is possible for the tip of the guide wire to exit through a side window on the

distal end of the catheter. *(Omni, Proxi only)*
• Hand injection of standard contrast medium may be delivered through the thrombectomy catheter via the manifold port stopcock. Follow the steps to remove air from the catheter when delivering fluid through the catheter stopcock.
• Fluids should be injected only under the direction of a physician and all solutions prepared according the manufacturer instructions.
• The Thrombectomy Set waste lumen is rated for 50psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
• Do not use a power injector to deliver contrast medium through the catheter stopcock. Power injectors can deliver pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
• Some fluids, such as contrast agents, can thicken in the catheter lumen and block proper catheter operation if left static too long. The catheter should be operated to clear the fluid within 15 minutes of injection.

CONSOLE WARNINGS AND PRECAUTIONS:
• Use the AngioJet Ultra 5000A Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with a previous model pump set and catheter.
• Do not attempt to bypass any of the Console safety features.
• If the catheter is removed from the patient and/or is inoperative, the waste tubing lumen, guide catheter, and sheath should be flushed with sterile, heparinized solution to avoid thrombus formation and maintain lumen patency. Reprime the catheter by submerging the tip in sterile, heparinized solution and operating it for at least 20 seconds before reintroduction to the patient.
• Refer to the individual AngioJet Ultra Thrombectomy Set *Directions for Use* manual for specific warnings and precautions.
• Do not move the collection bag during catheter operation as this may cause a collection bag error.
• Monitor thrombotic debris/fluid flow exiting the catheter through the waste tubing during use. If blood is not visible during console activation, the catheter may be occlusive within the vessel or the outflow lumen may be blocked.
• Ensure adequate patient anticoagulation to prevent thrombus formation in outflow lumen.
• Refer to individual Thrombectomy Set *Directions for Use* manual for specific instructions regarding heparinization of the Thrombectomy Set.
• The Console contains no user-serviceable parts. Refer service to qualified personnel.
• Removal of outer covers may result in electrical shock.
• This device may cause electromagnetic interference with other devices when in use. Do not place Console near sensitive equipment when operating.
• Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
• To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
• Where the *"Trapping Zone Hazard for Fingers"* symbol is displayed on the console, there exists a risk of trapping or pinching fingers during operation and care must be exercised to avoid injury.
• Do not reposition or push the console from any point other than the handle designed for that purpose. A condition of overbalance or tipping may ensue.
• The AngioJet Ultra 5000A Console should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the AngioJet Ultra Console should be observed to verify normal operation in the configuration in which it will be used.
• Portable and mobile radio frequency (RF) communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
• The use of accessories and cables other than those specified, with the exception of accessories and cables sold by Bayer HealthCare as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Ultra 5000A Console.
• MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding Electro-Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables provided in the Operator's Manual.

ADVERSE EVENTS
Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:
• abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • arrhythmia • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolysis • hemorrhage, requiring transfusion • hypotension/hypertension • infection at the access site • pain • pancreatitis • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage

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ZELANTEDVT THROMBECTOMY SET

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INTENDED USE/INDICATIONS FOR USE
The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from:
• Iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and
• Upper extremity peripheral veins ≥ 6.0 mm in diameter.
The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse® technique for the controlled and

selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

CONTRAINDICATIONS

Do not use the catheter in patients:

- Who are contraindicated for endovascular procedures
- In whom the lesion cannot be accessed with the guidewire
- Who cannot tolerate contrast media

WARNINGS

The ZelanteDVT Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where other thrombectomy catheters were used during treatment of pulmonary embolism.

- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary vasculature.
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
- Use of the catheter may cause a vessel dissection or perforation.
- Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the ZelanteDVT Thrombectomy Set in vessels smaller than minimum vessel diameter as listed in Table 1 of the DFU; such use may increase risk of vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombus

PRECAUTIONS

- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- If resistance is felt during the advancement of the ZelanteDVT Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath as a unit to prevent possible tip separation.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

• abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • arrhythmia • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolysis • hemorrhage, requiring transfusion • hypotension/hypertension • infection at the access site • pain • pancreatitis • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage