Case Report: Significant Removal of Fresh Large-Vessel Thrombus With the New 8-F AngioJet™ ZelanteDVT™ Catheter

By Eric G. Schoch, MD, and Christoph A. Binkert, MD, MBA

A 76-year-old woman was referred by her gynecologist for suspected left deep vein thrombosis (DVT). For 3 days, she suffered from severe left leg swelling and pain. On physical examination, the patient was obese (body mass index, 40.4 kg/m²) and had a painful and swollen left leg with no ulcerations.

Diagnostic Evaluation
CT venography was performed, confirming the patient’s swollen left leg (Figure 1A) with an enlarged unenhanced femoral vein (Figure 1B). In order to secure the diagnosis of DVT, an ultrasound was performed, which showed hyperechoic acute thrombus in the left common femoral vein (Figure 1C). A multidisciplinary group decided to treat with pharmacomechanical thrombolysis for fast symptomatic relief and prevention of sequelae. Because only a small amount of thrombus extended into the inferior vena cava, no filter was implanted.

Treatment Approach
The procedure was performed under conscious sedation, and 5,000 units of heparin were administered intravenously at the beginning of the intervention. The patient was placed in a prone position on the angiographic table. Ultrasound-guided access into the popliteal vein was performed, and an 8-F sheath was inserted. The AngioJet™ ZelanteDVT™ thrombectomy catheter (Boston Scientific Corporation) was advanced into the thrombus, and 200,000 units of urokinase were injected into the thrombus using the Power Pulse™ spray technique. Because of the large vein diameter, the steerable option of the ZelanteDVT catheter was used to deliver the urokinase into the entire thrombus. After a dwell time of 20 minutes, the ZelanteDVT catheter was switched into thrombectomy mode, and the thrombus was aspirated for a total of 180 seconds. The rotation option of the ZelanteDVT catheter tip was used to direct the

Figure 1. Preinterventional workup with CT venography showing substantial left leg swelling (A) and an enlarged iliofemoral vein (B). Ultrasound confirmed the diagnosis of acute DVT (C).
Clearing the Clot

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

thrombus removal power and clean the vein as completely as possible. A follow-up venogram showed successful thrombus removal within the left common femoral and left external iliac vein (Figure 2A); however, at that time, there was no flow because of the obstruction in the left common iliac vein due to May-Thurner syndrome. After stenting the left common iliac vein with a self-expandable nitinol stent and expanded to 14 mm, good venous outflow was observed (Figure 2B).

After the procedure, the leg was wrapped with compression bandages, and rivaroxaban was started the next morning. A control duplex examination the next day showed a widely patent common femoral vein with no residual thrombus and good venous flow with respiratory modulation (Figure 3). Clinically, the pain improved within 24 hours after the procedure, and the leg swelling resolved over the following week.

CONCLUSION

The removal of thrombus in a large vein was successful using the ZelanteDVT catheter with the Power Pulse spray technique followed by the thrombectomy mode using the Venturi-Bernoulli effect. AngioJet offers a variety of catheters for different venous and arterial thrombus applications. The newest addition, the ZelanteDVT catheter, offers the opportunity to remove thrombus from large venous vessels with a directional tip. It will be interesting to see if this new directional catheter will allow for consistent removal of thrombus from large vessels.

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WARNINGs AND PRECAUTIONs

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.

- Do not use the Thrombectomy Set in vessels smaller than the minimum vessel diameter for each specified fluid, including thrombolytic agents, into the peripheral vascular system.
- Abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolyisis • hemorrhage • hypotension/hypertension • infection at the access site • injury to the catheter • perfusion • pulmonary embolism • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage

SOLENT CATHETERS COMBINED W/CONSOLE

Systemic heparinization is advisable to avoid pericatheterization thrombus and acute thrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is recommended.

- Do not pull the catheter against arterial resistance. If increased resistance is felt when removing the catheter, it is possible that the catheter or the lesion has been fractured. 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.

- The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombus.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Console 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 • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolyisis • hemorrhage • hypotension/hypertension • infection at the access site • injury to the catheter • perfusion • pulmonary embolism • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage

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- 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 in contaminated areas.
- Equipment not suitable for use in the presence of flammable anesthetic mixture with air or oxygen or other anesthetics.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protection.
- Where the “Trapping Zone Hazard for Fingers” symbol is displayed on the console, there exists a risk of trap ping or pinching fingers during operation and care must be exercised to avoid injury. Do not push or pull the catheter after the catheter has been advanced any further into the patient. A condition of overbalance or tipping may ensue.
- 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.

AMPLATZ SUPER STIFF GUIDEWIRE

- 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 visualized during console activation, the catheter may be occlusive within the vessel verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may result in risk of vessel injury.
- Do not use the guide wire without understanding and knowing the guide wire into the catheter during the 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. (Direct only)
- Use of a tip-guard wire is not recommended as it is possible for the tip of the guide wire to exit through a diseased vessel. The operator should therefore be prepared to use a guidewire without a tip-guard in this situation.
- Do not pull the catheter against arterial resistance. If increased resistance is felt when removing the catheter, it is possible that the catheter or the lesion has been fractured. 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.
- 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 in patients with a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
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- Use of the catheter may cause a vessel dissection or perforation.
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CONTRAINDICATIONS

Do not use the catheter in patients:
- Who are contraindicated for endovascular procedures
- Who cannot tolerate contrast media
- In whom the lesion cannot be accessed with the guide wire

WASTE LUMEN PATENCY

- 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 specified fluid, including thrombolytic agents, into the peripheral vascular system.
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Vessel perforation/ dissection/tissue trauma, vessel spasm, wire entrapment/entanglement, foreign body/wire

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