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Clinical Case Update

Ambulatory Venous Thrombectomy: Shifting Strategies in the Treatment of Patients with Deep Vein Thombosis

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Case Report

A 48-year-old female presented to the emergency room with an acutely painful swollen leg. The symptoms were present for two days. The patient had recently traveled to England to accompany her daughter to college and had flown there and back within 48 hours. She stated her leg was slightly swollen immediately after the flight back. She felt it had gotten slightly better initially, but then got worse to the point where it was painful to walk. She has no significant medical history and takes no medications other than vitamins and oral contraceptive pills (OCP).

Upon arrival to the emergency room, the patient's work-up consisted of laboratories inclusive of a complete blood count, chemistries, coagulation profile, beta hcg, and d-dimer. The labs were unremarkable except for an elevated d-dimer of 12.9 ug/ml. Imaging studies included a venous duplex, which revealed a large left deep vein thrombosis (DVT). The DVT started from the common femoral extending through the common iliac vein. The emergency room physician started her on low molecular weight heparin and admitted her for pain control and anticoagulation. He consulted vascular surgery for further evaluation.

After the examination, the vascular surgeon determined that the patient had a large iliofemoral DVT likely related to prolonged flight and OCPs. The patient was considered high-risk for developing post-phlebitic syndrome due to her extensive DVT. She was subsequently evaluated for venous thrombectomy and had no major or minor contraindications for lytics. The risks, benefits, and alternatives were discussed with the patient and she chose to proceed with venous thrombectomy and secondary intervention. She was scheduled to have her venous thrombectomy three days from the time she was evaluated and was discharged from the hospital on low molecular weight heparin. The patient was scheduled for a two-part ambulatory venous thrombectomy (AVT). Elective scheduling allowed her to be released from the hospital, allowed her daughter time to travel to be with her mother for the procedure, and provided logistical convenience for the interventionalist and cath lab.

The patient was brought back to the cath lab in an ambulatory fashion and was placed in prone position. Her left popliteal vein was cannulated under ultrasound guidance. A left lower extremity venogram was performed, which identified a large DVT occlusive from the common femoral vein to the common iliac vein (Figure 1). The DVT was crossed with a Bern catheter and glide wire. Once this was done, an AngioJet® Thrombectomy System with a Proxi Catheter was used in power pulse mode to deliver 10 mg of tPA across the length of the DVT. A lytic catheter was then placed across the DVT and the patient was then taken to the cath lab holding area for a lytic infusion. The lytic infusion was planned for approximately two hours.

The two-hour lytic infusion allowed for the pulsed bolus to exert its effect on the thrombus and the patient was brought back to the cath lab and once again placed in prone position. A repeat venogram was performed through the previous catheter, which showed partial resolution of the thrombus (Figure 2). At this point the AngioJet Proxi catheter was used in thrombectomy mode to perform venous thrombectomy of the common femoral vein (CFV), external iliac vein (EIV), and common iliac vein (CIV). After this was done, repeat venography revealed that there was an area of compression at the transition of the EIV and CIV (Figure 3). This area was subsequently angioplastied and stented (Figure 4). After the procedure the patient's leg was wrapped in an ace wrap. She was observed and allowed to recover for two hours and subsequently discharged on low molecular weight with a planned transition to warfarin. Prior to discharge, she was educated on the signs and symptoms of both external and internal bleeding. She was instructed to orally hydrate for the next 24 hours and that the hemoglobinuria would resolve within 24 hours.

The patient was seen in the office at 2 weeks, 3 months, 6 months, 12 months, 18 months, 24 months, and 36 months. Her leg returned to normal size and function within 2 weeks (Figure 5). She was maintained on warfarin and 81 mg of aspirin for 6 months and taken off anticoagulation at 6 months with hypercoagulable work up started prior to stopping anticoagulation and completed within a month after coming off warfarin.

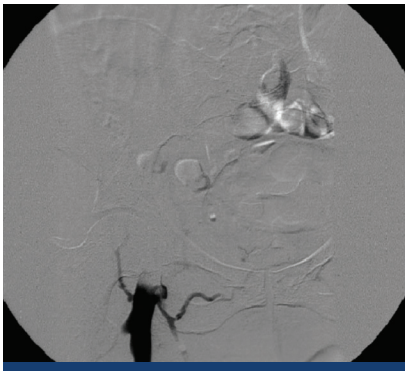

Figure 1. A left lower extremity venogram identified a large DVT occlusive from the common femoral vein to the common iliac vein.

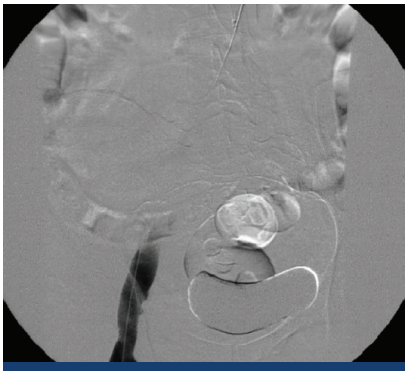

Figure 2. A repeat venogram was performed through the previous catheter, which showed partial resolution of the thrombus.

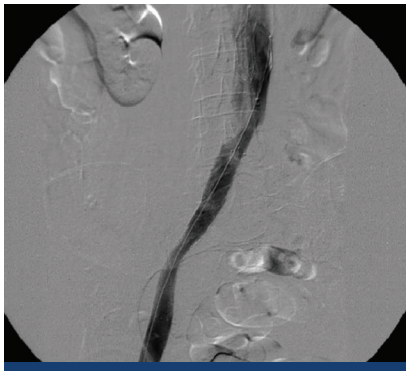

Figure 3. Repeat venography revealed an area of compression at the transition of the EIV and CIV.

She will remain on lifelong low dose aspirin. Her left leg continues to remain free of recurrent thrombus and has returned to normal function and size with no signs of postphlebitis syndrome.

Conclusion

Early thrombectomy of large iliofemoral DVT can provide great benefit both short-term and long-term to the patient. It has been proven to reduce the risk of postphlebitic syndrome and can also shorten the time to return to normal function of the limb. The ACCP recommends the removal of these large DVT if the symptoms are less then 2 weeks old and the patient has a greater than 2-year life expectancy. For this patient, her limb recovered within 2 weeks and for at least 3 years has not shown any sign of postphlebitic syndrome. Ambulatory venous thombectomy (AVT) allows for flexibility in scheduling, reduction in complications, and a more economically feasible pathway for treatment.

Can you describe your ambulatory thrombectomy approach for treating patients with DVT?

Dr. Wang: My approach to ambulatory thrombectomy starts with identifying the appropriate patient, one with a large iliofemoral deep vein thrombosis (DVT) who has had symptoms for less than 2 weeks. The patient should also have a life expectancy of 2 years with no strong contraindications for lytics or anticoagulation. While this is the expected criterion, there are some exceptions.

To begin the procedure, the patient is brought to the lab in the morning and placed on the table in prone position. The ipsilateral side popliteal vein is accessed, the clot is crossed, and a wire is left in the inferior vena cava (IVC). Once the wire is in place, 10 mg of tPA is delivered into the DVT using an AngioJet catheter in power pulse mode. Then a lytic catheter is placed, the sheath and catheter are secured, and the patient is taken to the holding area for a short lytic infusion. Typically I wait 1.5 hours so that the lytic agent can have at least 5 half lives to work on the clot, but realistically it turns into the time it takes to do one or two cases. After 1.5 hours, I bring the patient back into the lab for a second session. The patient is once again in prone position for a venogram to access the effectiveness of the lytic agent. The patient usually needs additional thrombectomy, which I also perform with the AngioJet catheter in thrombectomy mode. Repeat venography is then performed, which determines the need for secondary intervention such as angioplasty and stenting. In many cases, secondary intervention is needed to resolve some underlying issue that may have instigated the clot, such as May-Thurner syndrome.

This technique has evolved over time. I started treating DVT in an inpatient model, simply doing inpatient thrombolysis. It was effective and I was getting good results. To make DVT treatment less costly, using an outpatient ambulatory setting is more viable to the hospital as it converts the patient from a diagnosis-related group (DRG) reimbursement model to a current procedural terminology (CPT) model. I then started treating the patients in the morning and doing a single setting power pulse and subsequent thrombectomy. This was successful in fresh, less extensive clots, but I still used lytic infusions to clear up some of the more extensive clots. I researched different types of lytic agents such as tPA vs. rtPA vs. TNK and I found literature that stated the half-life of tPA is 3-15 minutes and there are active metabolites that continue to work for significantly longer. I decided to let the tPA sit for at least five half lives or 1 hour and 15 minutes to allow it to fully work. The first case I did I almost had a revolt in the cath lab trying to keep a patient on the table for a hour and 15 minutes waiting for the tPA to work. It was difficult enough to slow down and wait for 15-20 minutes doing standard power pulse. In an effort to become more efficient and preserve the desire of the lab staff to do these cases, I decided to leave a lytic catheter and deliver the lytic infusion in the holding area and bring them back later. This allows me to do 1-2 cases between sessions, while keeping the staff satisfied, having appropriate nursing care for a patient on lytic infusion, and maintaining the ambulatory status

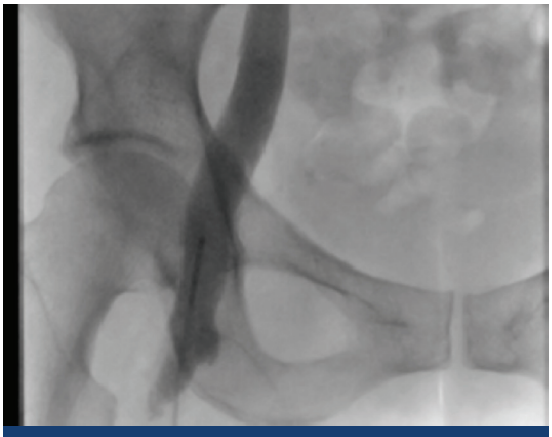

Figure 4. After repeat venography revealed compression at the transition of the EIV and CIV, the area was angioplastied and stented.

of the patient and procedure. The patient is then taken back to the lab where we finish the thrombectomy and secondary intervention, remove the sheath, hold pressure, and discharge him or her 2 hours later.

What benefits do you see in using an endovascular approach versus anticoagulation therapy in treating DVT patients?

Dr. Wang: There are huge benefits to the patients with iliofemoral DVT treated with venous thrombectomy as opposed to just anticoagulation alone. There is a reduction in the risk of developing postphlebitic syndrome and therefore a reduction in the risk of developing chronic pain and swelling as well as possible ulceration. Patients who are placed on anticoagulation alone do not receive these benefits. Also, in the periprocedural time frame, the patient will feel a much more rapid relief of symptoms.

Can you describe your AVT approach utilizing the AngioJet thrombectomy system for thrombus removal?

Dr. Wang: I almost always use an endovascular treatment approach when it comes to acute DVT. The one exception involved a pregnant woman with phlegmasia. The AngioJet thrombectomy system is versatile in having both the power pulse to deliver the bolus of tPA in a fashion to really penetrate the clot and then to subsequently remove the residual thrombus in thrombectomy mode. It really allowed me the tools to evolve my treatment plan into the ambulatory technique I use currently.

How do you work with your hospitalist to establish a treatment paradigm?

Dr. Wang: One very important step to establish a treatment paradigm is to get patients referred and then scheduled and set up for thrombectomy as an outpatient. This requires engaging the emergency room physicians and the hospitalists to refer the patients for venous thrombectomy, but the busiest and most overworked physician in the hospital is the admitting hospitalist. They are overburdened with admissions for acute medical issues and ensuring that patients had a recent colonoscopy and/or breast exam, and offering a pap smear, etc. To then remember to call you as the vascular specialist for patients with acute iliofemoral DVT is challenging. As a result, I developed a DVT protocol, which was constructed as a power plan inclusive of diagnostic laboratories and imaging studies, full admission orders including diet and activity, and anticoagulation therapy with recommendations for renal and liver patients. It also includes best practice recommendations for referral to vascular specialists for venous thrombectomy for large iliofemoral DVT and for procedural therapy for massive and submassive pulmonary embolism. This allows the hospitalist to simplify the diagnosis, admission, and treatment process of thromboembolic events. By providing a useful tool for the hospitalists, it also provided a modality to reinforce best clinical practices of venous thrombectomy on an almost daily basis. The protocol in combination with lectures, and most importantly, providing clinical feedback on the results of the patients once they come back to the office, is the driving force behind creating a successful DVT program.

How much lytic do you use and how long to you let it work before using the AngioJet thrombectomy?

Dr. Wang: I typically use 10 mg tPA injected up front in power pulse mode for a single leg with an additional 1-3 mg given during the infusion. For a bilateral DVT, 15 mg is power pulsed delivered in with an additional 2-6 mg during the bilateral infusions. The power pulse dose is standard across patients, but the infusion dose is variable depending on if I do one or two cases between the two sessions. With acute DVT and arterial thrombosis, I feel that pretreatment with lytic will provide better clearance of thrombus than AngioJet alone.

Do you have any clinical suggestions for your ambulatory thrombectomy approach?

Dr. Wang: I use this technique for both arterial and venous thrombus cases. I think that many of the same principles are applicable. Every case can be broken down into thrombus management and secondary intervention. In the thrombus management portion, the most important suggestion that I can give is to concentrate on more proximal vessels. Also, when there is no flow through the vessel, it is your best chance to get optimal penetration of the tPA during power pulse. Once a flow channel is established the lytic will not penetrate as well. During the secondary intervention I would stress that stent placement in the iliac segments works very well, but in the more distal vessels there is clearly more concern for rethrombosis.

How did this technique change your practice?

Dr. Wang: This technique was instrumental in developing an interventional DVT program. It allowed us to perform these procedures in an elective fashion. It eliminated scheduling issues. There are no longer takebacks in the late evening. There are no longer any calls from the ICU in the middle of the night. It preserved the length of stay of patients with DVT and with no readmissions it became very popular with the hospital and the hospitalists. Also, the conversion from DRG to CPT was advantageous to the institution, which garnered significant support in promoting the program.

Is there an application in an outpatient setting utilizing AVT?

Dr. Wang: Absolutely! As primary care physicians began to see the results of venous thrombectomy and were getting feedback that these procedures were being done in an ambulatory fashion, the application in an outpatient setting became apparent. I am currently seeing the conversion of some of the referrals from the ED and hospitalists to patients referred directly from the primary care doctors to the office. Once that occurred, there were some adjustments made to get those patients in for treatment in an appropriate time frame, but that lent itself to having patients treated in an outpatient-based lab setting.

All images are courtesy of Dr. Jeffrey Wang.

Case studies are not necessarily representative of or predictive of expected clinical experience or results. Actual results may differ.

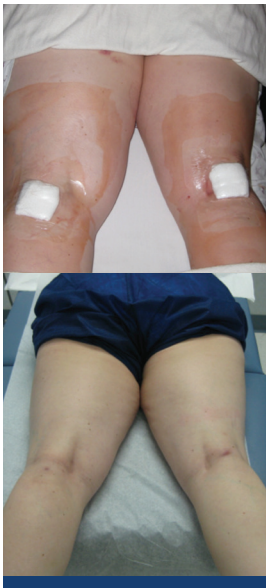

Figure 5. After 2 weeks, the patient's leg returned to normal size and function. Note the difference in the before and after images.

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Solent catheters combined w/console

INDICATIONS AND USAGE

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 IFU).

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

WARNINGS AND PRECAUTIONS

- 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 (unless accompanied by a separate coronary IFU).
- 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 nonhealed 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 IFU); 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.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) 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.
- 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)*
- 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)*
- 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.
- 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.
- 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.

. (Below is 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 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 *Information 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 Instructions 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 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 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 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 IFU.

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 • 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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