Embolic Protection using the WIRION Embolic Protection System with JetStream Atherectomy in a Patient with Superficial Femoral Artery Chronic total Occlusion

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Abstract

Keywords

- WIRION embolic protection system
- embolic filter protection
- atherectomy
- JetStream

Distal embolization is a common occurrence with peripheral arterial interventions and is more frequent with the use of atherectomy devices. We report the first case of JetStream atherectomy (Boston Scientific, Maple Grove, MN) with the use of the novel WIRION embolic protection system filter. The procedure was performed successfully with no distal embolizations beyond the filter and with no complications in the delivery or retrieval of the filter. The pros and cons of the off label use of this filter with JetStream atherectomy are discussed.

Distal embolization (DE) remains a problem with endovascular infrainguinal interventions and is more frequently encountered with the use of atherectomy devices.^{1–4} JetStream, a rotating atherectomy system with aspiration capacity is designed to reduce DE but several reports continue to indicate its occurrence with this device.^{5,6} Here, we report the first case of JetStream atherectomy with the use of the WIRION embolic protection system (EPS) filter device (Allium Medical, Caesarea, Israel).

Case Report

The patient is a 62-year-old male with claudication Rutherford Becker III in his left leg for several months. Claudication occurs within two to three blocks of walking and relieved with rest. He has no skin ulcerations, dependent rubor, or elevation pallor. Risk factors include a history of hypertension, hyperlipidemia, diet-controlled adult-onset diabetes mellitus, and history of smoking. His examination was remarkable for severely diminished left posterior and anterior tibialis pulses and bilateral chronic venous insufficiency CEAP class IVa. After informed consent and explaining the pros and cons of various treatment options, patient elected to proceed with peripheral angiography and endo-

vascular revascularization. Right common femoral access was obtained using a 6F sheath. Following the completion of peripheral angiography, a total occlusion of the left mid and distal superficial artery was noted (►Fig. 1). Collaterals were seen from the profunda femoris artery to the popliteal and distal runoff. He had moderate diffuse disease in the peroneal and moderate-to-severe disease in the anterior tibialis and posterior tibialis. A 7F Pinnacle destination sheath (Terumo, Somerset, NJ) was placed in the contralateral left external iliac vessel. Using a 5.0 mm × 4 cm Ultraverse balloon (Bard, Tempe, AZ) and an extra stiff 0.035 angled glide wire (Terumo), the chronic total occlusion was crossed successfully. Unfractionated heparin was administered to keep the activated clotting time at approximately 240 seconds. Using a Spartacore wire (Abbott Vascular, Abbott Park, IL) placed in the distal third of the posterior tibialis, the Gardia WIRION EPS filter (►Fig. 2) was loaded on the wire and locked into position at the mid left popliteal level. JetStream expandable cutter (XC) atherectomy (Boston Scientific, Maple Grove, MN) was then performed using the JetStream XC 2.4 mm/3.4 mm cutter. Only blades down mode was used as there was some resistance to advancing the cutter at the distal end of the left superficial femoral artery

Fig. 1 Chronic total occlusion treated with the JetStream (Boston Scientific, Maple Grove, MN) device under embolic filter protection using the WIRION EPS (Allium Medical, Caesarea, Israel). (A) Chronic total occlusion, (B) filter deployed in the popliteal, (C) post-JetStream atherectomy (arrows) and drug-coated balloon, (D) final results after spot stenting of the distal superficial femoral artery and balloon dilation. EPS, embolic protection system.

raising suspicion for a possible short segment subintimal wire entry at the end of this vessel. Following the atherectomy, predilation of the lesion was carried on with a 5.0 mm × 22 cm Ultraverse balloon at 10 atm for 60 seconds. This was followed by balloon dilation with 2 IN.PACT drug-coated balloons (Medtronic, Minneapolis, MN) (6.0 mm × 12 cm and 6.0 mm × 8.0 cm). These were inflated for 3 minutes each at 10 atm. Angiography showed that a focal distal segment continued to show recoil and this was stented with an Everflex 7.0 mm × 8 cm self-expanding stent (Medtronic), postdilated with the 6-mm Ultraverse balloon. The residual stenosis was less than 20% and the WIRION EPS system was successfully retrieved with no complications. Microdebris was noted coating the filter (► Fig. 3). As a routine in our laboratory, the sheath is flushed backward by disconnecting the hemostatic valve of the Pinnacle destination sheath. A large macrodebris was noted

that was stuck in the sheath upon the removal of the filter (► Fig. 4). Angiography then confirmed excellent flow in the distal tibial with no distal embolization. On 30-day follow-up patient experienced resolution of his claudication.

Discussion

To our knowledge this is the first case of the WIRION EPS application in peripheral arterial intervention to be done with the JetStream device. The WIRION EPS has received CE mark in Europe and has been used in peripheral arterial interventions with the laser (Spectranetics, Colorado Springs, CO), Turbohawk (Medtronic), and Rotarex (Straub Medical, Switzerland). The WIRION EPS device is approved in the United States for carotid applications,⁷ but it is off label for peripheral interventions and to our knowledge has not yet been used for peripheral applications. This embolic

Fig. 2 WIRION EPS filter (Allium Medical, Caesarea, Israel) (A) and JetStream XC (Boston Scientific, Maple Grove, MN) cutters (B). EPS, embolic protection system; XC, expandable cutter.

Fig. 3 WIRION EPS filter (Allium Medical, Caesarea, Israel) retrieved successfully. Filter is coated with microdebris. EPS, embolic protection system.

protection system consists of an independent filter unit precrimped on the distal end of a rapid exchange delivery catheter. The system is compatible with 0.014 guidewire, 6 to 8F guiding catheters and has a 1.1 mm crossing profile. The filter unit consists of a filter basket and a locking mechanism. The filter basket is made of self-expanding nitinol frame, compatible with a vessel diameter of 3.5 to 6.0 mm and a nylon filter mesh with 120 μ m pores ($n \sim 1,000$ /filter). The locking mechanism allows deployment of the independent filter unit on any 0.014 guidewire at any location along the wire. An activating handle at the proximal end of the delivery catheter activates the locking mechanism by turning it clockwise until a clicking noise is heard.

JetStream atherectomy is a rotating atherectomy catheter with aspiration capacity. Despite the strong aspiration power on the device, distal embolization continues to be seen.^{5,6} Embolic filter protection has been used with the JetStream and this practice varies with operators. The most common filter used in our laboratory with this device is the off label Nav-6 filter

Fig. 4 Macrodebris trapped in the lumen of the Pinnacle destination sheath (Terumo, Somerset, NJ) noted with flushing back of the sheath after removal of hemostatic valve.

(Abbott Vascular, Abbott Park, IL) because it is not attached to its BareWire (Abbott Vascular), therefore, allowing wire motion with no filter motion and a more flexible placement of the wire in the distal vascular bed. The latter is an important step when using the JetStream device to provide more stability to the rotating cutter on the wire. The WIRION EPS offers an alternative option to the Nav-6 wire as shown in our case. The advantage over the WIRION EPS is that it can be used on any wire that the operator prefers rather than be limited to the BareWire. Also, the ability of the filter to be crimped anywhere on the wire allows the operator to position the wire distally in the tibialis or peroneal then lock the filter on the wire more proximally such as in the popliteal or a distal superficial femoral artery. The disadvantage, however, is that the wire and filter are locked as one system and wire motion during the JetStream may lead to filter motion during atherectomy. We did not observe this in our case as the filter remained very stable. This could be due to the design of the filter which allows it to “grab” on the vessel wall in three different points along the mid basket providing more stability to the filter. This however needs to be proven in a larger cohort of patients treated with JetStream and the WIRION EPS filter. Furthermore, since the wire and the filter are one unit, wire rotation with the JetStream, if it occurs, can potentially lead to filter spinning and potential vessel disruption. We believe this theoretical disadvantage can be mitigated with the use of rotaglide (Boston Scientific) with the JetStream that will prevent wire sticking on the device. In our case, rotaglide was used and we did not observe any rotational movement of the filter during atherectomy. This also needs to be confirmed in a larger study.

Finally, the filter mesh with 120 μ m is effective in capturing microdebris which can lead to slow flow during the treatment with the JetStream. The flow normalizes immediately after filter removal. We have observed the same in several cases with the use of the Nav-6 filter. The latter has a filter mesh with 100 μ m and also very effective in microdebris capture. We normally continue the procedure and do not remove the filter until the end of the case. Of interest, the filters can capture macrodebris on their proximal nitinol wire holding the basket. When retrieved in the sheath, these macrodebris are generally stuck inside the lumen of the sheath. We have used routinely the Pinnacle sheath with a removable hemostatic valve⁸ to be able to flush blood back before reinjecting dye after filter retrieval. Also on some occasions, the basket is filled with debris and may not be able to exit the hemostatic valve at the end of the sheath requiring a detachable valve. On several occasions, including this case, large macrodebris flushes out of the sheath when removing the hemostatic valve. This practice is critical to avoid reinjecting debris down the vessel following filter retrieval.

Conclusion

To our knowledge this is the first published case with JetStream atherectomy with the WIRION EPS filter. This case illustrates the ability to use the JetStream with the WIRION EPS filter effectively. The ability to deploy the filter anywhere on the wire and maintain wire choice is a clear advantage to this filter. Further studies are needed however to determine

whether the filter longitudinal motion would be an issue with the JetStream. Also more research is needed to ensure that rotational motion of the filter will not be a problem with this device and the role of rotaglide in preventing this.

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