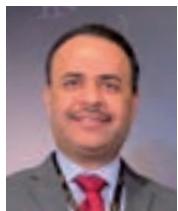


REVASCULARIZATION OF CHRONIC TOTAL OCCLUSION OF SFA IN DIALYSIS PATIENT



Bander Aldhafery, MD
Endovascular & Interventional Radiologist
College of Medicine
Imam Abdulrahman Bin Faisal University
Dammam, Saudi Arabia

PATIENT PRESENTATION:

A 72 year-old male patient with diabetes mellitus, end-stage renal disease on hemodialysis presented at our department. He had a Rutherford class-5 symptoms with gangrene in the left forefoot and rest pain. The patient had a palpable pulse in the left femoral artery, non-palpable left-popliteal and distal pulses, showing signs of chronic ischemia of the left leg, and had monophasic signal over the dorsalis pedis and posterial tibial arteries.

Doppler US showed heavy calcification of the aortoiliac axis, patent bilateral iliac and common femoral arteries, total occlusion of the left SFA with extensive calcification, and diseased but patent left popliteal and tibial arteries.

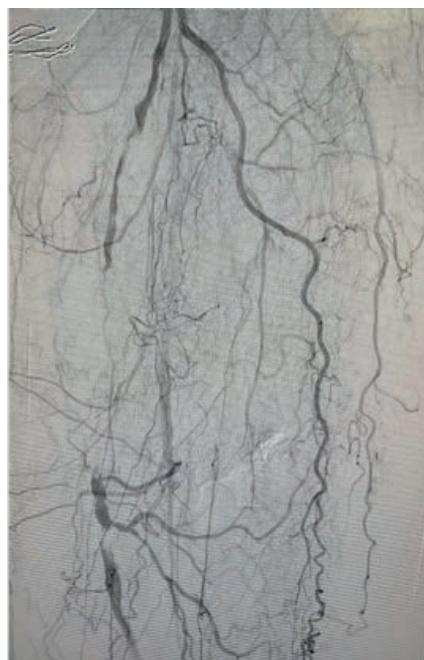
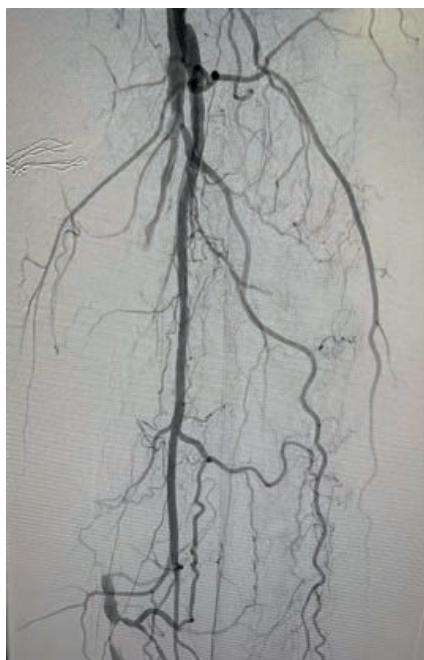


Fig. 1: DSA of left lower limb showed long segment complex total occlusion of the left SFA few centimeters from its take off to the level of adductor canal with heavy calcifications and irregular plaques all over the occlusion.

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INTERVENTIONAL PROCEDURE:

Ipsilateral antegrade access under US guidance with placement of 6F BRITE TIP™ Sheath (Cordis) and antegrade crossing of the occlusion was attempted using multiple CTO wires (0.14 inch COMMAND™ - Abbott and V14™ - Boston Scientific, as well as an 0.035" Glidewire from Terumo), but failed due to heavy calcification. Retrograde access through the posterolateral tibial artery was then obtained using an .014" COMMAND™ Guidewire (Abbott), it was possible to cross the occlusion from retrograde approach. We then recanalized after wire snaring from the antegrade sheath followed by balloon angioplasty using SABER™ .035 PTA Dilatation Catheter 6mm x 15cm and stented with the S.M.A.R.T.™ Flex Vascular Stent System 6mm x 15 cm.

In those difficult chronic occlusions with heavy calcifications, it's important to choose the right tools that can help to shorten procedure time and increase the chance of success. A great advantage of the SABER™ .035 PTA Balloon is that it has a great crossability even in severely calcified occlusions and can track and navigate easily through difficult anatomy. The S.M.A.R.T.™ Flex Vascular Stent System has an excellent radial force and precise deployment with almost minimum if any jumping as well as easy mechanism of deployment, the fracture rate of those stents even in heavy calcification is rare in addition to their excellent long-term primary patency in long occlusion¹.

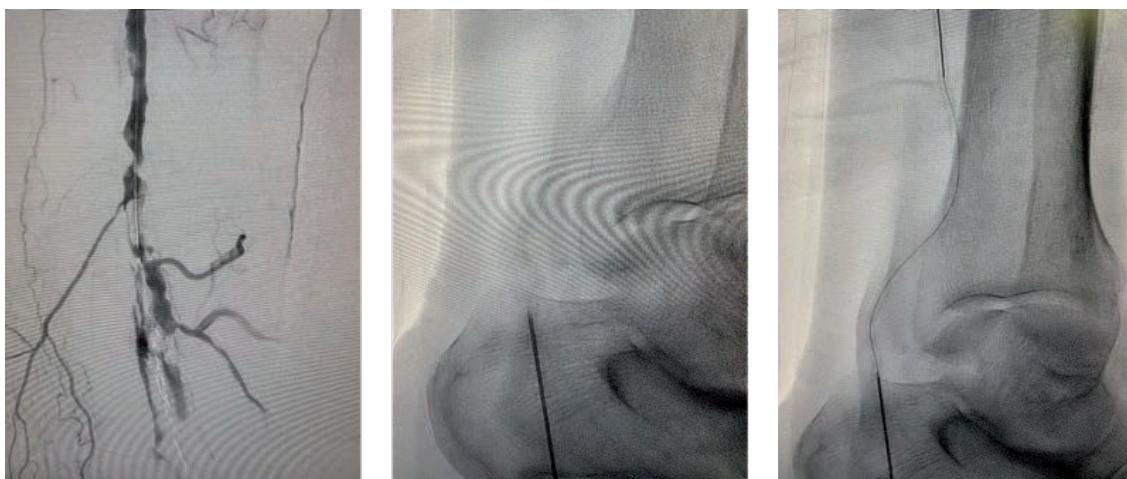


Fig. 2: DSA during intervention showing failure of wire to cross the occlusion from antegrade approach, 2nd image showed needle stick of posterior tibial artery at the foot with 21g micropuncture needle, 3rd image showed passing of .014" COMMAND™ Guidewire through posterior tibial artery.

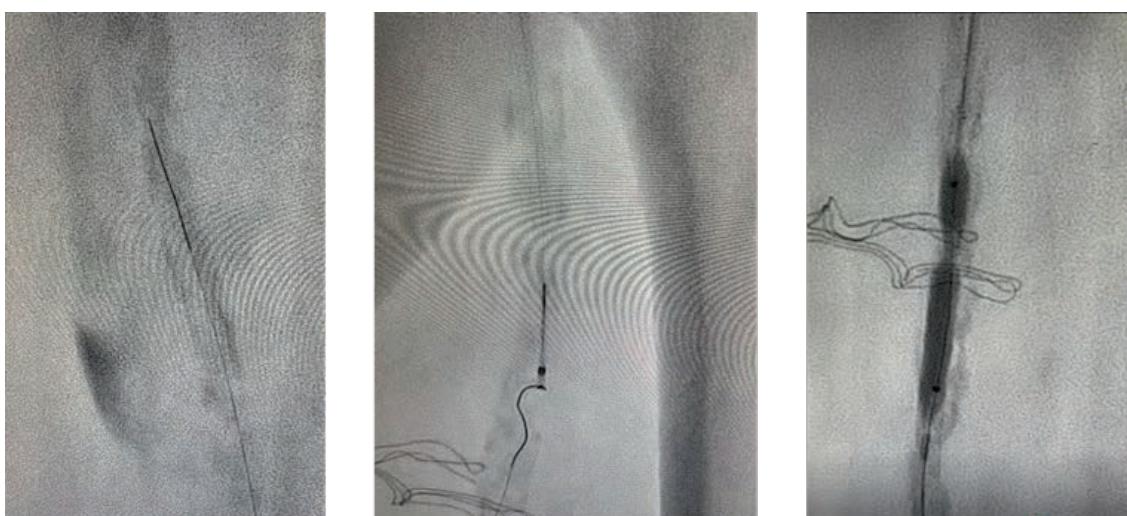


Fig. 3: 1st image showed passing of the wire through the occlusion at the thigh, 2nd image showed snaring of the wire from the antegrade sheath, 3rd image showed balloon dilatation of the occlusion with obvious waist through the balloon due to heavily calcified occlusion.

1. <https://onlinelibrary.wiley.com/doi/10.1002/ccd.26718>
Long-term outcomes of S.M.A.R.T. Stent implantation in patients with femoro-popliteal disease
Junya Matsumi M

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RESULTS

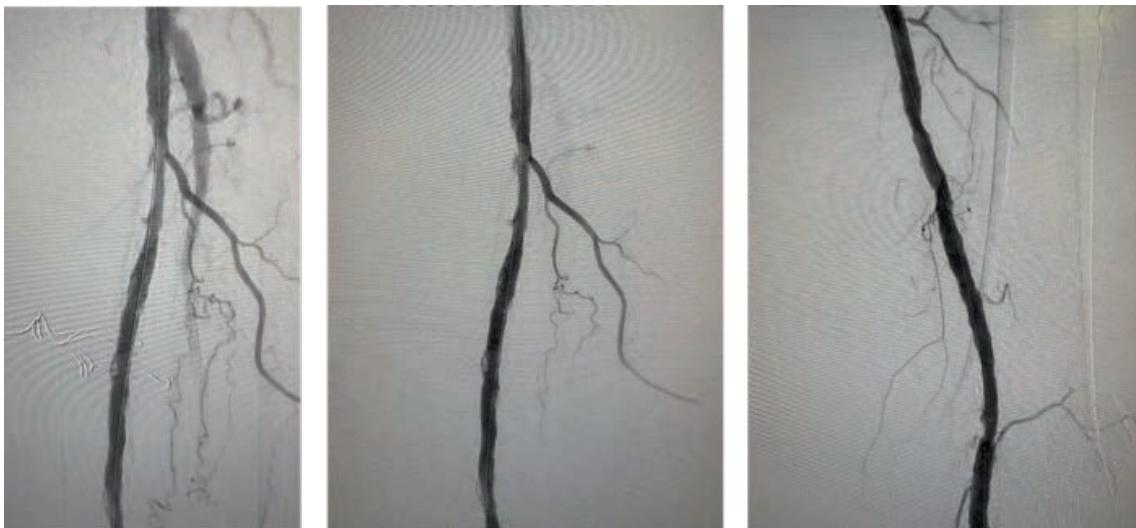


Fig 4: DSA showed widely patent left SFA after pre dilatation with balloon and placement of stent with no residual stenosis or dissection.

Patient was discharged home on dual antiplatelet therapy and he was followed up in the clinic with optimum wound care.

According to our experience, treating long vascular occlusions with heavy calcification can be challenging. PTA alone has a high rate of recurrence and can lead to dissection, while atherectomy devices carry the risk of distal showering and worsening ischemia. Although drug-coated balloons are typically less effective in heavy calcium, they can be beneficial when vessel preparation is thorough and effective. Stenting is our preferred treatment method in these cases. It is important to choose a stent with excellent radial force, good flexibility (especially at the distal and proximal SFA), ease of deployment, and, most importantly, good long-term patency. We believe the S.M.A.R.T.™ Flex Stent meets these criteria.

For Healthcare Professionals Only.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, suggested procedure, warnings and precautions. As part of its continuous product development policy, Cordis reserves the right to change product specifications without prior notification.

Please contact your Cordis representative for additional product availability information.

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