Cordis®

saber® .035 PTA DILATATION CATHETER

CASE REPORT

Successful Treatment of Arteriovenous Fistula Inflow Stenosis with SABER® .035 PTA Dilatatation Catheter

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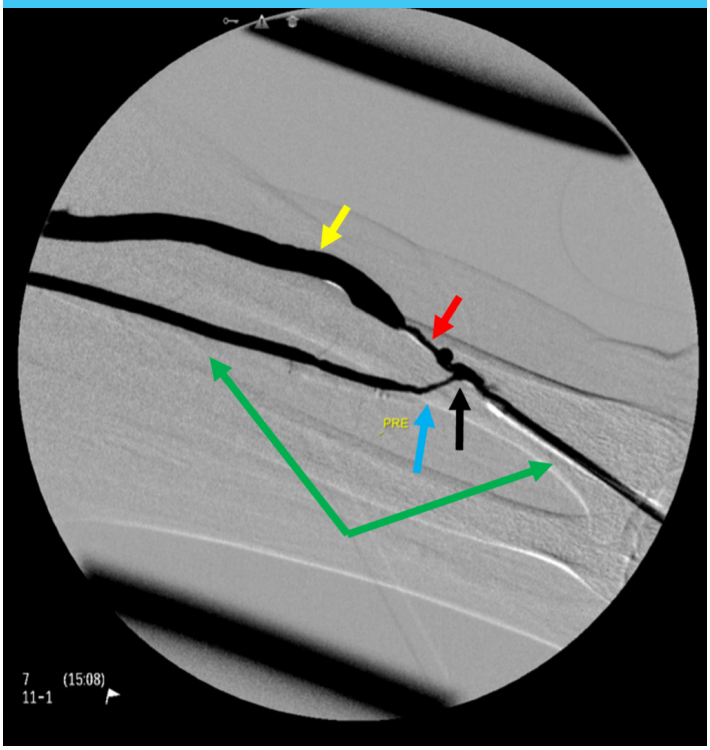
PATIENT PRESENTATION

Patient is a 65-year-old diabetic female with end stage renal disease who required hemodialysis 6 months after creation of a radiocephalic arteriovenous fistula (AVF). The fistula had never matured and was never used for cannulation. On exam, the fistula had no bruit, but a faint thrill. It had very little flow across the anastomosis **(Figure 1)** on ultrasound doppler. She had been using her tunneled hemodialysis catheter as access since the start of dialysis. Patient was referred for endovascular repair of the AVF so it can mature enough for use on dialysis.

Figure 1

Pre-Intervention Angiogram of the Radiocephalic AVF Inflow Stenosis



Yellow Arrow – Radiocephalic Arteriovenous Fistula
Red Arrow – Juxtaarterial Anastomosis Stenosis
Black Arrow – Arterial Anastomosis Stenosis
Blue Arrow – Distal Radial Arterial Stenosis

PROCEDURE OVERVIEW

The patient had almost no flow coming in to the radiocephalic fistula, therefore the cephalic forearm vein was completely collapsed and thin walled, so a decision was made to enter the artery under ultrasound guidance from the distal radial arterial access point. The 5Fr sheath (Merit Medical MAK™ Mini Access Kit) was successfully advanced through the radial artery over an .018" guidewire (Merit Medical SPLASHwire™ Hydrophilic Guide Wire) past the point of anastomosis. An arteriogram was performed that revealed distal radial artery stenosis and plaque typical of diabetic arteries. It also showed an arterial anastomosis stenosis and juxtaarterial stenosis with hardly any flow in the cephalic vein (or radiocephalic AVF).

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A decision was made to dilate these stenotic lesions with the hope of restoring flow to the fistula. Earlier in the arteriogram, brachial bifurcation was confirmed and ulnar flow to the palmar arch was also confirmed to be adequate. The guidewire was then upsized to a stiff hydrophilic .035" guidewire (Merit Medical Laureate™ Hydrophilic Guidewire) into the radial artery over a catheter. With careful roadmap guidance, a 3mm x 100mm Cordis SABER® .035" PTA Catheter was slowly advanced through the radial artery **(Figure 2)** across the distal stenosis and inflated slowly to nominal pressures. The balloon was kept inflated for 3 minutes while full balloon effacement was achieved **(Figure 3)**.

Figure 2

SABER® .035 Balloon advanced through the distal radial artery

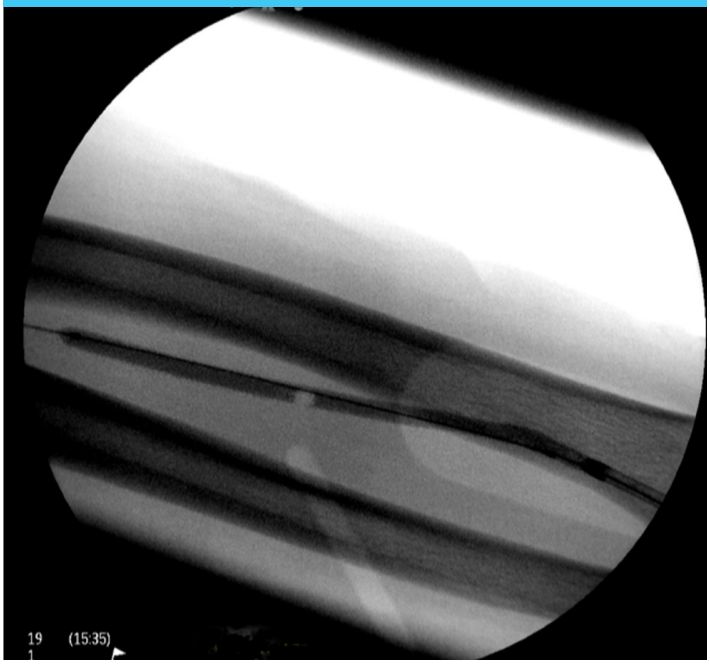

Figure 3

SABER® .035 3mm x 100mm Balloon through AVF into distal radial artery

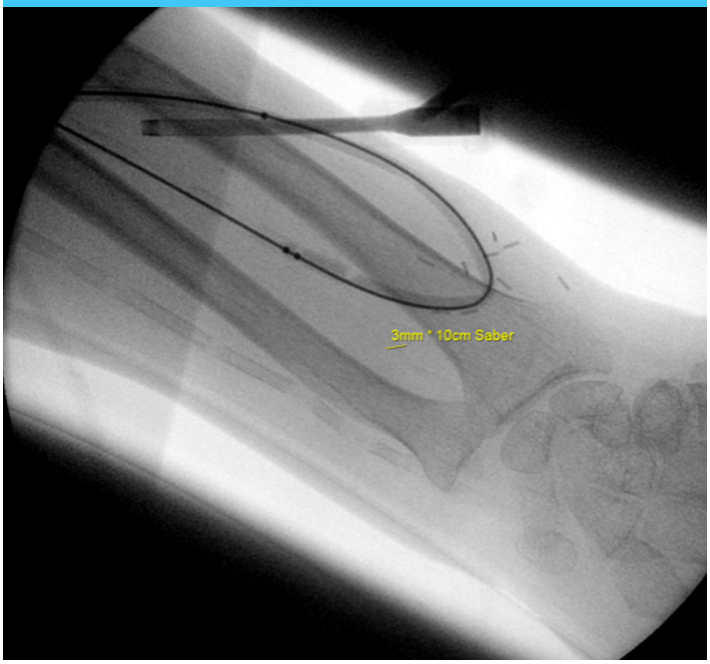

Figure 4

SABER® .035 3mm x 100mm Balloon through AVF, across stenosed arterial anastamosis and into radial artery

The balloon was then deflated and replaced over the wire with a 5F guiding catheter for post angioplasty arteriogram that revealed resolution of the critical arterial stenosis and some flow restoration to the fistula with no post angioplasty spasm. The guide catheter and wire (.018") were then advanced to the cephalic vein through the stenosed anastomosis. The .018" wire was then upsized to .035" and the 3mm x 100mm balloon was inflated across the arterial stenosis and juxta arterial anastomosis stenosis **(Figure 4)** from the same distal radial artery access point. The balloon was kept inflated for 3 minutes.

Post angioplasty, the arteriogram showed improved flow through the radial artery to the radiocephalic fistula and a thrill could be observed at this point. The radiocephalic AVF now had flow. The forearm cephalic vein was now larger in caliber and could be cannulated in the retrograde direction. An .018" wire was successfully advanced across to the radial artery and a sheath was laid over the wire. The arteriogram revealed flow through the radial artery and into the AVF, but residual stenosis was still present. Hence, a decision was made to dilate the anastomosis stenosis with the same 3mm x 100mm SABER® .035" Balloon from the AVF to the proximal radial artery (Angioplasty performed in same location as **Figure 3**). The wire was up sized to .035" and prolonged angioplasty was performed. Post angioplasty arteriogram **(Figure 5)** revealed less than 20% residual stenosis and flow was excellent from radial artery to AVF.

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Despite the angiographic appearance of residual stenoses, the physical exam of the fistula was significantly improved, and therefore, no further angioplasty was attempted. The sheaths located at the distal radial artery and cephalic AVF were both removed and manual pressure was held to achieve hemostasis.

Figure 5

Post-Treatment Arterial Angiogram of AVF Anastomosis artery

DISCUSSION

This case describes a classic primary failure observed with fistulas. Addressing the arterial anastomosis stenosis, with a long low-profile balloon that is gradually dilated at low pressures, helped to salvage this fistula without causing any arterial spasm or dissection of the vessel. It is very common in practice for clinicians to reach for a high-pressure balloon to purposely fracture the intimal hyperplasia often observed with this type of stenosis. However, we have found that this often leads to further progression of arterial plaque or spasm and accelerates restenosis of the venous juxtaarterial stenosis. The fractured intimal hyperplasia sets off a chain reaction that is the root cause of the progression of restenosis / rethrombosis. Thus, instead of breaking the plaque and promoting restenosis at a more accelerated pace, we are using a low profile semi-compliant balloon dilated at low pressures to direct blood flow through the sharp bend of the anastomosis. This method also greatly reduces the instances where it was found necessary to place a covered stent. With high pressure balloon dilatations in this region, there is a risk of restenosis or rethrombosis happening at the arterial anastomosis, thereby necessitating the placement of a covered stent to maintain blood flow through the fistula.

When crossing tight anastomosis stenoses with PTA balloons, there is often a risk of triggering arterial spasm or causing plaque rupture. However, the SABER® .035 PTA Catheter exhibited good trackability and flexibility to navigate through the sharp bend of the anastomosis very smoothly. The dual-hydrophilic coating on the surface of the balloon seemed to help minimize friction as it was advanced. It was also very durable and achieved full effacement of the lesion at a low nominal atmospheric pressure. I also found it ideal to use a longer length balloon of at least 10 cm to treat the entire anatomical lesion at once. This may have helped to prevent spasm at both ends of the lesion.

CONCLUSION

Due to the high prevalence of diabetes and end stage renal disease, primary fistula failures lead to high incidence of morbidity and mortality. Primary fistula failures are often the root consequence of arterial anastomosis stenosis and juxtaarterial stenosis and lead to the abandonment of these access pathways. Also, as a result, patients can suffer added morbidity with the need for repeat surgeries. The traditional high-pressure balloon, when used in these primary fistula failures, may not be the most effective approach because they tend to cause accelerated restenosis or rethrombosis by subjecting the vessel to fracture of the new intimal hyperplasia. The SABER® .035 PTA Balloons have been very effective when I used long length sizes dilated at low pressures to reestablish blood flow across the arterial anastomosis. Consequently, while using this approach, I successfully repaired multiple primary fistula failures without a need for the subsequent placement of a stent.

This Case Report represents independent evaluations and opinions of the author and contributors independently from Cordis.