SFA and BTK Interventions With the Chocolate® PTA Balloon Catheter

This device allows operators to achieve excellent results with low rates of dissection, as demonstrated in these cases of high-grade stenosis.

BY BRANDON OLIVIERI, MD, AND ROBERT BEASLEY, MS, MD

Percutaneous balloon angioplasty has been the backbone of endovascular peripheral arterial disease therapy since it was first pioneered by Charles Dotter in 1964.[1] However, the sequelae of percutaneous angioplasty are inherent in its mechanism of action. Balloon inflation results in longitudinal and radial plaque redistribution, plaque extrusion, arterial expansion, and plaque rupture for its effect on luminal gain. Uneven application of this shear stress results in significant radial, longitudinal, and torsional vessel trauma.[2-5] This injury to the vessel wall may present itself acutely as a flow-limiting dissection or elastic recoil, often necessitating stent placement. Vessel wall trauma also results in the release of a significant amount of thrombogenic, mitogenic, and vasoactive factors, which likely contribute to late lumen loss via neointimal hyperplasia and vascular remodeling.[4,5]

The Chocolate® PTA Balloon Catheter (manufactured by TriReme Medical, LLC., distributed by Cordis Corporation) seeks to minimize vessel wall trauma, thereby theoretically decreasing both early and late lumen loss.[6] Composed of a nitinol pressure shield* over a semicompliant balloon, inflation results in the formation of multiple alternating grooves and modules, or balloon pillows, allowing for a more controlled distribution of shear force despite variability in lesion morphology.[6] The Chocolate BAR registry demonstrated markedly reduced rates of dissection and bailout stenting compared to trials using normal percutaneous angioplasty alone in both above- and below-the-knee applications.[7-10]

The authors have found similar results and regularly use the Chocolate® PTA Balloon Catheter to achieve excellent angioplasty results, particularly in eccentric or heavily calcified lesions. In our experience, combining this technology with plaque-debulking atherectomy is particularly useful for achieving dissection-free maximum luminal gain, as demonstrated in the following cases.

CASE STUDY ONE

A 79-year-old woman with a past medical history of hypertension, diabetes mellitus, and 65 pack-years of cigarette smoking presented with a chief complaint of progressively worsening severe right lower extremity claudication after ambulating approximately 1 block. The patient's symptoms were refractory to an exercise regimen started by her primary care physician. Her medications included lisinopril, aspirin, metformin, atorvastatin, and hydralazine. Physical examination of the lower extremities revealed hairlessness and nail hypertrophy. There was no carotid bruit or palpable abdominal aortic aneurysm, and pulses were palpable in the bilateral upper extremities. The bilateral femoral, left

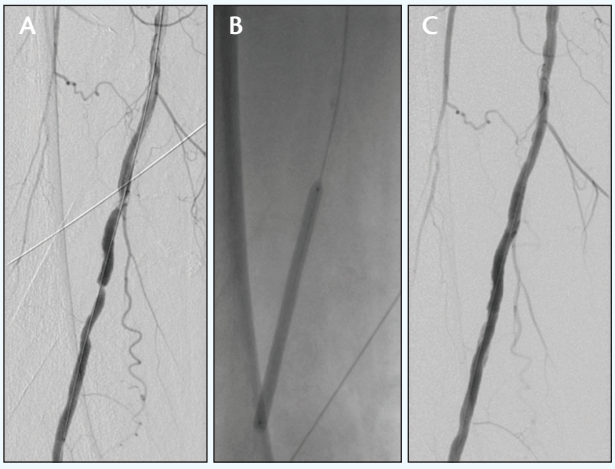

Figure 1. Diagnostic angiography of the right superficial femoral artery revealed multiple tandem high-grade stenoses of the right superficial femoral artery (A). Images obtained during plaque-modifying balloon angioplasty with the Chocolate® Balloon, applied with standard prolonged inflation times (B). Repeat angiography of the right superficial femoral artery revealed significantly improved vessel patency with no signs of dissection (C).

*Nitinol constraining structure.

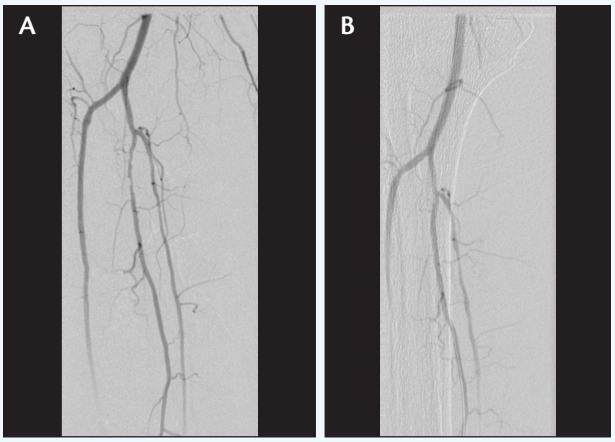

Figure 2. Diagnostic angiography of the right infrapopliteal arterial vasculature high-grade stenosis in both the distal right tibioperoneal trunk and proximal right peroneal arteries (A). Repeat angiography demonstrates dissection-free improved vessel patency with brisk flow down to the ankle (B).

popliteal, and left dorsalis pedis artery pulses were present. The right femoral pulse was palpable, but the right popliteal artery could not be detected on manual examination. The right dorsalis pedis and posterior tibials were not detected on evaluation with portable Doppler.

Lower extremity arterial Doppler ultrasound revealed high-grade stenosis of the right superficial femoral artery and right tibioperoneal trunk. The patient then underwent diagnostic lower extremity angiography for further evaluation, revealing two heavily calcified high-grade stenoses in the mid-right superficial femoral artery (Figure 1A) with additional high-grade stenosis in both the distal right tibioperoneal trunk and proximal right peroneal arteries (Figure 2A).

With this clinical scenario of lifestyle-limiting claudication refractory to medical management and an exercise regimen, the decision was made to perform endovascular revascularization.

Revascularization

Contralateral access was achieved using a combination of manual palpation and fluoroscopic guidance. A 6-F short sheath was placed across the iliac bifurcation, and the patient was systemically anticoagulated with unfractionated heparin. A microcatheter and a hydrophilic guidewire were used to navigate the severe right superficial femoral artery stenoses. Atherectomy was then performed using a 1.25-mm Diamondback 360 orbital atherectomy device (Cardiovascular Systems, Inc.). Balloon angioplasty was performed using a 6-mm outer-diameter over-the-wire Chocolate® PTA Balloon Catheter, inflating slowly to reach half nominal by 30 seconds, nominal by 1 minute, and holding at nominal for 2 minutes (Figure 1B). Follow-up angiography revealed widely improved vessel patency (Figure 1C).

Attention was then focused to the right infrapopliteal vasculature. A microcatheter and a 0.014-inch hydrophilic guidewire was used to negotiate the severe stenoses in the tibioperoneal trunk and proximal aspect of the peroneal artery. Next, atherectomy was performed using a 1.25-mm Diamondback 360 orbital atherectomy device. Balloon angioplasty was then performed using a 3-mm outer-diameter over-the-wire Chocolate® PTA Balloon Catheter. The inflation technique was used as described. A follow-up angiogram demonstrated wide patency and luminal gain with brisk flow down to the ankle (Figure 2B).

Follow-Up

At 1-, 3-, and 6-month follow-up, the patient noted continued significant improvement in her lower extremity claudication and notes that she is now able to participate in activities with her grandchildren.

CASE STUDY TWO

A 64-year-old woman with a history of hypertension, diabetes mellitus, and coronary artery disease presented to our clinic with progressively worsening two-block left lower extremity claudication that had begun to severely affect her ability to work. Her medications included lisinopril, aspirin, atorvastatin, metformin, and metoprolol. Physical examination of the lower extremities revealed hairlessness, nail hypertrophy, and mild coolness to the touch. There were no carotid bruits or palpable abdominal aortic aneurysms, and pulses were palpable in the bilateral upper extremities. The bilateral femoral, right popliteal, right dorsalis pedis, and posterior tibialis pulses were present. The left popliteal artery pulse was not palpable by manual examination. The left dorsalis pedis and posterior tibial pulses were 1+ on portable Doppler examination.

A lower extremity arterial ultrasound performed in

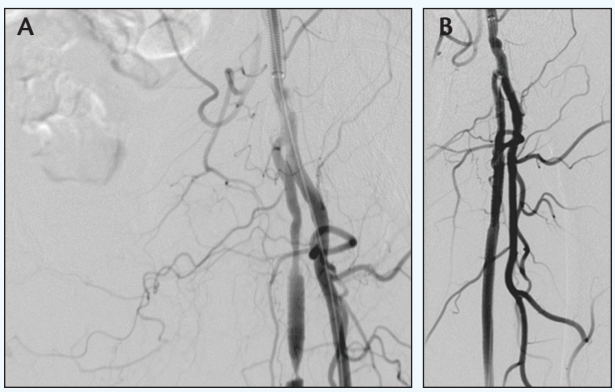

Figure 3. Diagnostic angiography of the proximal left superficial femoral artery revealed multiple tandem high-grade stenoses of the left superficial femoral artery with areas of subtotal occlusion (A). Repeat angiography after atherectomy and plaque-modifying balloon angioplasty demonstrated significantly improved vessel patency (B).

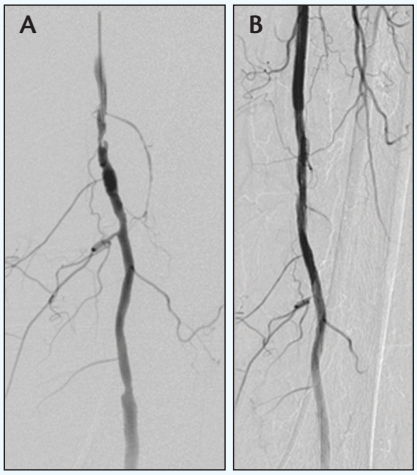

Figure 4. Diagnostic angiography of the mid-left superficial femoral artery revealed multiple tandem high-grade stenoses of the left superficial femoral artery with heavily calcified plaque (A). Repeat angiography after atherectomy and plaque-modifying balloon angioplasty again demonstrated significantly improved vessel patency (B).

Figure 5. Diagnostic angiography of the mid-distal left superficial femoral artery revealed multiple heavily calcified severe stenosis with areas of subtotal occlusion (A). Repeat angiography postintervention revealed a widely patent vessel with no evidence of dissection (B). Three-vessel runoff was noted to the ankle.

our office demonstrated high-grade stenosis of the left superficial femoral artery. Diagnostic lower extremity angiography revealed multiple tandem, highly calcified, high-grade stenoses with areas of subtotal occlusion extending along the length of the left superficial femoral artery (Figures 3A, 4A, and 5A).

Considering the patient's clinical scenario of lifestyle-limiting claudication, as well as her desire for intervention to attempt to improve her symptoms, the decision was made to perform endovascular revascularization.

Revascularization

Contralateral right femoral arterial access was achieved using a combination of manual palpation and fluoroscopic guidance. A 6-F sheath was introduced and advanced across the iliac bifurcation, and the patient was systemically anticoagulated with unfractionated heparin. A microcatheter and a hydrophilic guidewire were used to navigate the severe left superficial femoral artery stenoses. Next, atherectomy was performed using a 1.25-mm Diamondback 360º orbital atherectomy device. Balloon angioplasty was then performed using a 6-mm outer diameter over-the-wire Chocolate® PTA Balloon Catheter. A repeat angiogram demonstrated significantly improved vessel patency with no evidence of dissection (Figures 3B, 4B, and 5B). The process was then repeated, using the same Chocolate® PTA Balloon Catheter, to treat multiple other high-grade SFA stenoses, retracting the device through the sheath and reprepping it after treating each lesion. In the authors' experience, the device profile is slightly worsened after its initial use; however, the balloon retains total effectiveness after multiple uses.

Follow-Up

At 1-, 3-, and 6-month follow-up, the patient noted significant improvement in her lower extremity claudication, allowing her to continue her work.

CONCLUSION

Designed to reduce angioplasty-induced vascular trauma, the Chocolate® PTA Balloon Catheter has proven to be a useful tool in our peripheral arterial armamentarium. As demonstrated in these cases, the Chocolate® PTA Balloon Catheter enables the achievement of dissection-free maximum luminal gain in difficult lesions. We look forward to new technological developments on the horizon, particularly with regard to the results of the ENDURE trial, which will examine infrainguinal revascularization outcomes using a drug-coated Chocolate® PTA Balloon Catheter.[11] ■

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