PROFILER
BALLOON DILATATION CATHETER

Bilateral Iliac PTA

Chronic lower extremity ischemia is a common cause of morbidity and disability in the United States. Intermittent claudication, defined as pain in the leg musculature following activity, is the earliest and most frequent presentation of chronic lower extremity ischemia. Aorto-iliac occlusive disease is characterized by hip, thigh or buttock claudication and relieved by rest. Treatment of atherosclerotic aorto-iliac disease has evolved from surgical endarterectomy to aortobifemoral bypass grafting to endovascular balloon angioplasty with stenting. Percutaneous transluminal angioplasty (PTA) has remained the cornerstone of percutaneous revascularization. Short focal iliac lesions respond favorably to PTA with primary patency rates reported up to 87% at 5 years.

CASE PRESENTATION

Patient is a 59 year old obese male with history of peripheral arterial disease, hypertension and coronary artery disease. He had lifestyle limiting claudication associated with a decreased ankle brachial index. Abdominal duplex shows elevated peak systolic velocity involving proximal bilateral iliac arteries. Patient also had an abnormal stress test and needed cardiac catheterization. Plan was to perform both procedures in the same setting.

Abdominal aortogram with Omni™ Flush catheter showed high grade stenosis of the proximal common iliac arteries (Figure 1). Using the radiopaque marker band on the catheter, the iliac measured approximately 8 mm. Bilateral kissing angioplasty was performed using two 8 X 4 Profiler angioplasty balloons (Figure 2). The balloons were easily navigated through the area of high grade stenosis using a 5F sheath. The balloons were inflated to nominal pressure for one minute and completion angiogram showed no significant residual stenosis (Figure 3). Pull through pressure gradient showed no significant gradient across the lesion bilaterally.

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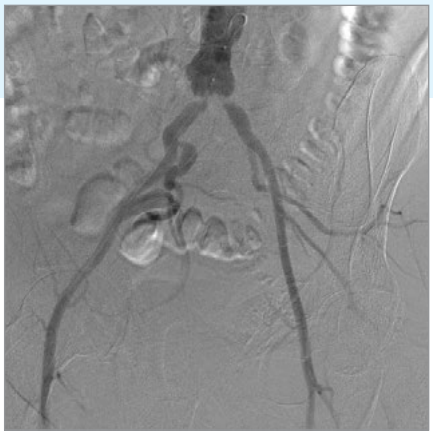
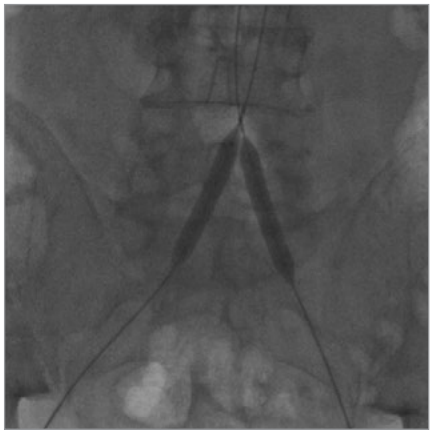
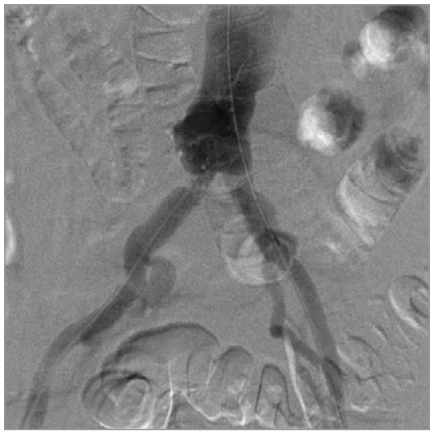


(Figure 1) Abdominal aortogram showing stenosis of proximal common iliac arteries.



(Figure 2) Bilateral kissing angioplasty technique.



(Figure 3) Completion angiography showing no significance residual stenosis.

Profiler Balloon Dilatation Catheter

AngioDynamics' Profiler* balloon dilatation catheter offers a broad range of low profile PTA balloons, with configurations of up to 8 mm x 4 cm balloons compatible with 5F sheaths, as well as 9 mm and 10 mm balloons compatible with 6F sheaths, which provide access to small vessels, tortuous anatomy and tight stenotic lesions.

- Rated burst pressures up to 16 ATM
- Non-compliant PET balloon material
- Highly radiopaque, tapered tip design for enhanced visibility and tracking

PROFILER
BALLOON DILATATION CATHETER

IMPORTANT RISK INFORMATION

INDICATION FOR USE: The PROFILER Catheter is a coaxial designed catheter with a balloon mounted on its distal tip and is indicated for general Percutaneous Transluminal Angioplasty (PTA) of the iliac, femoral, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. These catheters are not designed for use in coronary arteries. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNINGS AND PRECAUTIONS: Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the device and/or lead to device failure. Contents sterile in unopened, undamaged package. Sterilized by ethylene oxide.

Caution: Exceeding the rated burst pressure can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath. A syringe with pressure gauge is recommended to monitor pressure. In PTA, the dilated balloon should not markedly exceed the diameter of the vessel lying just proximal to the stenosis. Do not use air or any gaseous substance as a balloon inflation medium in PTA. Do not advance the guidewire, balloon dilation catheter, or any other component if resistance is met, without first determining the cause and taking remedial action. This catheter is not recommended for pressure measurement or fluid injection. This catheter is not intended for the expansion or delivery of stents. Please see package insert for complete list of warnings and precautions. Observe all instructions prior to use.

POTENTIAL COMPLICATIONS: Procedure-related complications may include, but are not limited to vascular thrombosis; vessel spasm or perforation/dissection; hematoma or hemorrhage; hypotension; drug reactions or allergic reaction to contrast medium; pyrogenic reaction; pain and tenderness; arrhythmias; sepsis/infection; systemic embolization; endocarditis; short-term hemodynamic deterioration; death; arteriovenous fistula; and thromboembolic episodes. Potential balloon separation following rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces. Note: There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to combination of tight focal strictures in large vessels.

angiodynamics

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