CONQUEST™ PTA DILATATION CATHETER

BARD PERIPHERAL VASCULAR

PERCUTANEOUS SALVAGE OF A HEMODIALYSIS GRAFT

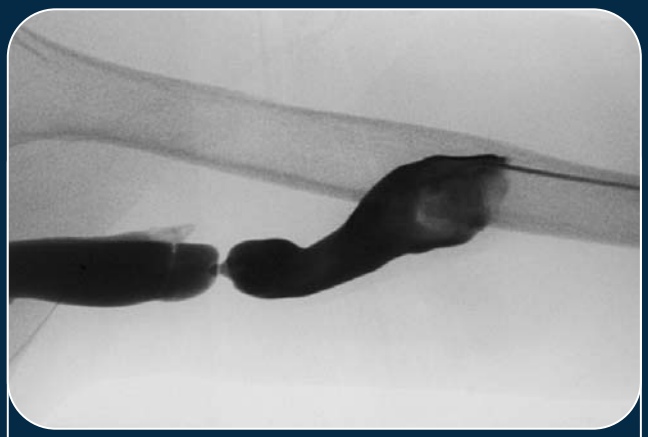

FIGURE 1 Stenosis of the venous outflow tract following thrombolysis and prior to angioplasty.

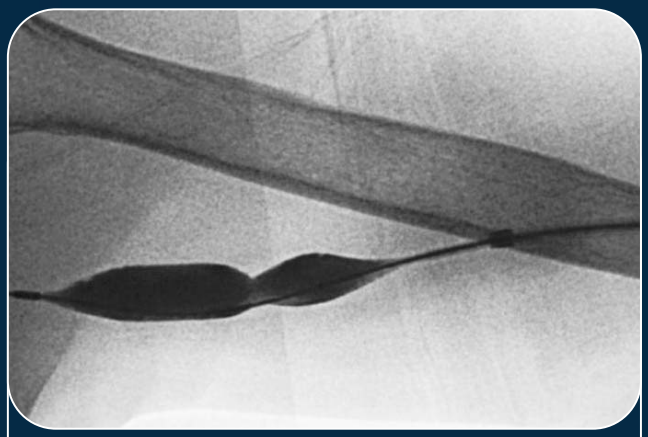

FIGURE 2 Partial inflation (16 atm) of a 10 mm diameter Conquest™ PTA Balloon Dilatation Catheter; the waist on the PTA balloon indicates that the lesion is very rigid, requiring high-pressure angioplasty.

Background

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Despite efforts to optimize hemodialysis vascular access in recent years, prosthetic bridge grafts are still necessary in about half of all hemodialysis patients, although graft patency results are inferior to arteriovenous fistulae results.[1] The most common cause of graft failure is thrombosis, usually secondary to stenosis at the venous anastomosis.[2] Stenosis is caused by neointimal hyperplasia. Maintaining graft patency requires frequent salvage procedures, including, perhaps most importantly, percutaneous transluminal angioplasty (PTA).

Venous stenoses can be very rigid and resistant to standard balloon dilatation. High-pressure angioplasty is often needed to resolve such lesions.[3,4] High-pressure PTA balloons can be used after failure of a low- or intermediate-pressure PTA balloon or as the initial primary balloon for angioplasty of the venous anastomosis. Previous generations of high-pressure PTA balloons necessitated the use of a larger access sheath: either a 7 or an 8 French sheath for a 6 mm diameter PTA balloon. The Conquest™ PTA Balloon Dilatation Catheter is unique with its low profile – a 6 French sheath may be used for Conquest™ PTA balloons of up to 8 mm in diameter, which is equivalent to most intermediate-pressure balloons.

Failure to fully efface the waist of an angioplasty balloon indicates incomplete resolution of the stenotic lesion, requiring additional efforts. Exchange of a low-pressure balloon for a high-pressure balloon is not uncommon.[5] While high-pressure PTA balloons are more expensive, one should consider the hidden costs of the added time in the procedure room needed for the balloon exchange, as well as the cost of the initial, ineffective low-pressure balloon. Consider also the added radiation to the operator and patient that is administrated during that balloon exchange.

Many operators routinely inflate low-pressure angioplasty balloons above their rated burst pressure in attempts to treat particularly resistant lesions.[5, 6] This leads to bursting of the balloon in some instances, often resulting in the rupture of the vein itself and subsequent loss of the graft.[6] Thus, this practice may have both negative clinical and cost implications.

The following case study illustrates successful salvage of a thrombosed hemodialysis graft using a high-pressure Conquest™ PTA Balloon Dilatation Catheter as the primary angioplasty balloon.

Clinical Experience

The patient is a 57-year-old African-American female with end-stage renal disease secondary to diabetes. The patient has a synthetic, 18-month-old hemodialysis bridge graft in the upper arm. She had had one intervention, 4 months prior, in which a venous outflow stenosis was seen and dilated to 9 mm.

Her graft was patent and working fine until her last hemodialysis attempt. She had recently noticed prolonged post-treatment bleeding. There was no report of exceptionally high pressures during dialysis, nor was there evidence of swelling of the arm. Upon arrival to the dialysis unit, the nurse noticed the lack of a thrill, indicating graft thrombosis. No attempt to puncture the graft was made. The patient was referred for percutaneous graft salvage.

Pharmacological thrombolysis was performed by conventional techniques using pulse spray thrombolysis with 6 mg of tissue plasminogen activator. Subsequent imaging revealed a tight stenosis in the venous outflow tract (Figure 1); high-pressure angioplasty (30 atm) was performed with a 10 mm diameter Conquest™ PTA Balloon Dilatation Catheter (Figures 2-3) to fully resolve the stenosis (Figure 4).

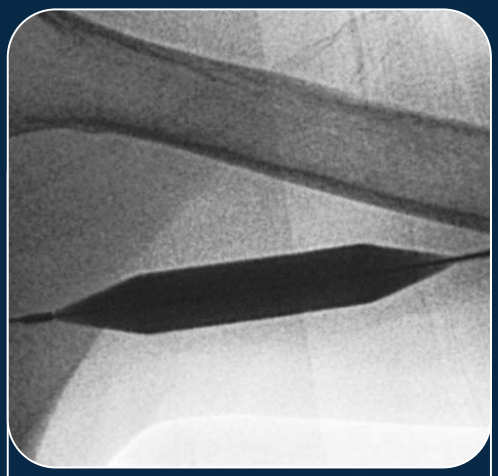

FIGURE 3 Full inflation (30 atm) of the same high-pressure Conquest™ PTA Balloon Dilatation Catheter resulting in effacement of the waist and complete resolution of the rigid lesion.

Conclusion

Following thrombolysis and angioplasty with a Conquest™ PTA Balloon, the patient experienced good flow, allowing for thrice-weekly hemodialysis; her graft has remained intervention-free for three months. The high-pressure Conquest™ PTA Balloon Dilatation Catheter for angioplasty of dialysis access venous stenosis is effective and safe and should be considered as the initial balloon for treatment of these tight stenosis.

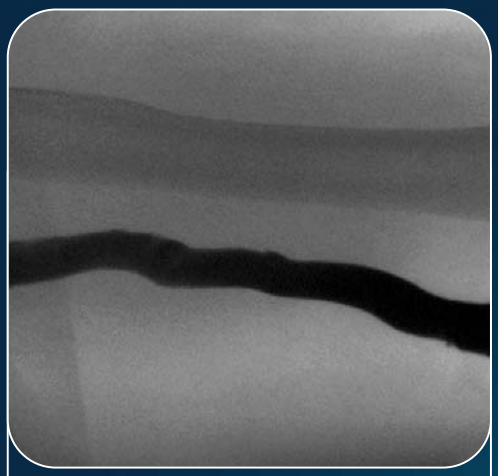

FIGURE 4 Successful restoration of flow and graft salvage following thrombolysis and high-pressure angioplasty with the Conquest™ PTA Balloon Dilatation Catheter.

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