CONQUEST™ PTA DILATATION CATHETER

BARD PERIPHERAL VASCULAR

FOR THE RESOLUTION OF SEVERE, FIBROTIC STENOSIS IN THE VENOUS OUTFLOW TRACT

FIGURE 1 Diagnostic fistulogram demonstrating severe stenosis (2 cm; >90% occlusion) in the venous outflow tract adjacent to the vein-PTFE graft anastomosis at the level of the elbow in a chronic hemodialysis patient.

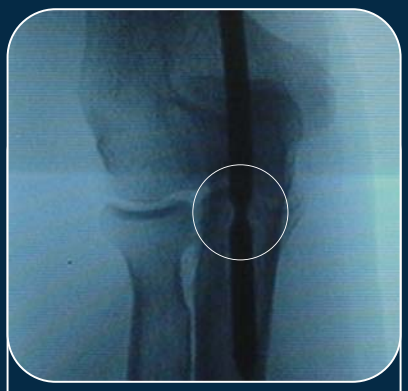

FIGURE 2 Routine angioplasty with a conventional 7 mm x 10 cm PTA balloon catheter inflated to 20 atm for 2 minutes failed to fully open the severe, fibrotic lesion as demonstrated by the "waist" in the PTA Balloon.

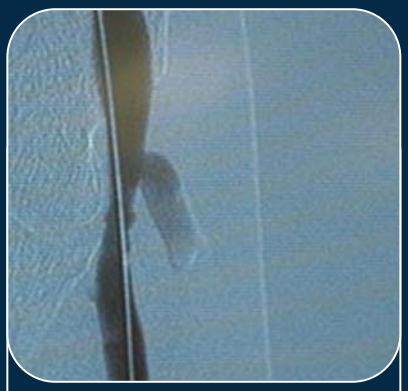

FIGURE 3 Full resolution of the resistant lesion with ultrahigh-pressure PTA using a 7 mm x 4 cm Conquest™ PTA Balloon Dilatation Catheter inflated to 30 atm for 2 minutes.

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Clinical Experience

John R. Ross, MD
Bamberg County Hospital and Access Connections, LLC; Bamberg, South Carolina, April 2004

Maintaining functional vascular access is essential for successful chronic hemodialysis. Indeed, preservation of hemodialysis access can significantly reduce patient morbidity and mortality. Stenosis and subsequent thrombosis of the hemodialysis access are often the "Achilles' heel" of long-term hemodialysis. Accordingly, clinical practice guidelines recommend the treatment of hemodynamically significant stenosis to maintain vascular access patency.[1] In contrast to surgical revision of an obstructed hemodialysis access, percutaneous transluminal angioplasty (PTA) offers the advantage of conserving native veins – a precious resource in hemodialysis patients whose long-term survival is dependent on the availability of adequate vessels for future hemodialysis access.

Polytetrafluoroethylene (PTFE) grafts remain the most common form of hemodialysis vascular access in the United States. Synthetic hemodialysis grafts, however, are susceptible to the development of progressive intimal hyperplasia, stenosis, and consequently thrombosis. Stenotic lesions commonly occur in venous outflow tract at the vein-graft anastomosis; as many as 60% of the access stenoses occur at or very near to the vein-graft anastomosis.[2] Severe lesions in the outflow tract can be fibrotic and sometimes resistant to successful treatment by PTA at conventional pressures (15-20 atm).[3] Attempts to treat such lesions by routine angioplasty are often characterized by rupture of the PTA balloon at pressures between 22 and 25 atm – pressures incompatible with conventional angioplasty balloons.[3-5]

At our facility, we have successfully resolved more than 85 cases of severe stenosis through ultrahigh-pressure PTA using the Conquest™ PTA Balloon Dilatation Catheter at pressures up to 30 atm. In our experience, severe stenoses normally resistant to conventional PTA can be treated successfully by ultrahigh-pressure PTA using the non-compliant, low-profile Conquest™ PTA Balloon on an out-patient, same-day basis. The patient is typically returned immediately to the dialysis clinic following the procedure to continue hemodialysis. The following case is representative of our experience with the Conquest™ PTA Balloon for the resolution of a severe, fibrotic lesion in the venous outflow tract of a hemodialysis patient with a conventional PTFE graft.

The patient was a 48-year-old female hemodialysis patient with a conventional forearm PTFE loop graft involving the brachial artery and the cephalic vein. The graft had been patent for 28 months with two

percutaneous thrombectomies performed in the previous 8 months. The patient was referred by the dialysis clinic and the procedure was conducted on the same day.

A diagnostic fistulogram was performed to locate and assess the stenotic lesion. The severe lesion in the venous outflow tract was noted at the vein-graft anastomosis at the level of the elbow (Figure 1). The lesion extended 2 cm and resulted in >90% occlusion of the vein lumen. Routine angioplasty with a 7 mm x 10 cm PTA balloon was performed using the Seldinger technique with conventional pressures up to 20 atm. As seen in Figure 2, these conventional pressures were unable to fully open the fibrotic lesion, as indicated by the "waist" in the PTA balloon. As full effacement was not achieved with this approach, the conventional balloon catheter was removed and replaced with a 7 mm x 4 cm Conquest™ PTA Balloon Dilatation Catheter. Using the Conquest™ PTA Balloon inflated to 30 atm for 2 minutes, the recalcitrant, fibrotic lesion was fully resolved (Figure 3). The patient was returned immediately to the dialysis clinic to continue treatment. The graft remained patent after >6 months following this intervention. If this stenosis had not been alleviated, subsequent clotting may have occurred, potentially resulting in access loss or the need for additional interventional or surgical procedures.

In our clinical experience, the Conquest™ PTA Balloon Dilatation Catheter has sufficient strength to resolve highly resistant, fibrotic stenosis and allows us to extend vascular access longevity by endovascular rather than surgical techniques, even in challenging patients. In over 85 cases in which we have successfully used the Conquest™ PTA Balloon for ultrahigh-pressure PTA at up to 30 atm, we have had no balloon ruptures. The potential for ultrahigh-PTA with this device has allowed us to reduce our inventory of different types of angioplasty balloons, while improving the maintenance of vascular access in our hemodialysis patients.

Step-by-Step Procedure

- Conduct physical exam and identify optimal insertion site
- Use local anesthetic at puncture site
- Insert introducer 7F or 6F*
- Assess lesion by fistulogram
- Select appropriately sized balloon
- Prepare balloon catheter per manufacturer's instructions
- Under fluoroscopy, pass guidewire into the graft or fistula
- Pass balloon over the guidewire up to the site of the stenosis
- Use syringe or inflator to inflate the balloon
- Monitor dilatation procedure using a pressure gauge
- When inflation is complete and the waist of the balloon disappears, hold inflated balloon for ~2 minutes
- Deflate balloon
- Conduct final fistulogram to confirm full resolution of the stenosis

*Note: an 8 mm Conquest™ Balloon passes easily through a 6F introducer and may be easily removed for dye injection and reinserted.

References:

1. National Kidney Foundation. NKF / DOQI Clinical Practice Guidelines for Vascular Access: Update 2000. *Am J Kidney Dis.* 2001;37:S137-181.
2. Kanterman R, Vesely T, Pilgram T, et al. Dialysis access grafts: anatomic location of venous stenosis and results of angioplasty. *Radiology* 1995;195:135-139.
3. Bittl J. Percutaneous therapy of dialysis access failure. *Cathet Cardiovasc Intervent.* 2002;56:157-161.
4. Bittl JA, Feldman RL. Cutting balloon angioplasty for undilatable venous stenoses causing dialysis graft failure. *Catheter Cardiovasc Interv.* 2003;58:524-6.
5. Ross JR. Ultrahigh-pressure PTA for hemodialysis. *Endovasc Today.* 2003;2:61-4.

For more information, contact:

Bard Peripheral Vascular, Inc.
1625 West 3rd Street
P. O. Box 1740
Tempe, AZ 85280-1740
USA
Tel: 1-480-894-9515
1-800-321-4254
Fax: 1-480-966-7062
1-800-440-5376
www.bardpv.com

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