

A New Treatment Option for Maintenance of Hemodialysis Access Sites

Initial commercial experience with the Hotspur Technologies GPSCath® Balloon Dilatation Catheter.

BY JOHN R. ROSS, MD

Globally, end-stage renal disease (ESRD) continues to increase at a dramatic rate, largely driven by the prevalence of diabetes and hypertension. At the end of 2009, almost 570,000 patients were under treatment for ESRD in the United States with costs reaching \$42.5 billion annually.¹ Nearly 2 million persons worldwide depend on dialysis for filtration of the blood, with 90% of all ESRD patients in the United States and 70% in Canada typically undergoing hemodialysis 3 times per week.²

Despite improvements over the past 40 years since hemodialysis has become available, annual mortality rates for dialysis patients continue to exceed 20%.¹ In addition, hemodialysis access site failure is the single most important factor related to morbidity in this population,³ and the ability to effectively complete hemodialysis treatments is a critical factor in reducing this morbidity and mortality. Furthermore, vascular access dysfunction as defined by low- or no-flow fistulas and grafts accounts for 20% of all hospitalizations in ESRD, with annual costs in the United States exceeding \$1 billion.³

Multiple clinical studies, dating back to 1992,⁴ have demonstrated that high-pressure balloon angioplasty is successful in treating vascular access stenoses, prolonging the patency of the hemodialysis access. The primary patency rate for an arteriovenous (AV) graft is 23% at 1 year, while the primary patency rate for a functioning AV fistula varies based on the study.⁵ Even with endovascular intervention, 1-year patency rates only rise modestly to 50% for AV grafts and 70% for AV fistulas.⁴

With limited patency, regular interventional procedures are required to maintain functionality of the access over time, thereby causing physicians to look for improved methods to maintain patency. With multiple reinterventions typically required over the lifespan of each access site, a cost-conscious approach also becomes an important consideration in today's economic environment.

THE GPSCath® BALLOON DESIGN

The GPSCath Balloon Dilatation Catheter ("GPSCath device" or "GPSCath balloon") (Hotspur® Technologies,



Figure 1. Hotspur GPSCath Balloon Dilatation Catheter.

Mountain View, CA) is an innovative, multifunctional angioplasty balloon catheter, which combines the functionality of an angioplasty balloon with the injection capability of an angiographic catheter while remaining on the guidewire. The GPSCath device (Figure 1) incorporates the VisioValve™ component, a proprietary and innovative microvalve, into the proximal edge of a semicompliant, high-pressure angioplasty balloon, permitting injection of physician-specified fluids and potential use of a single catheter for lesion location, angioplasty, thrombolytic treatment, and postdilatation evaluation of the treatment site. These capabilities provide numerous benefits by reducing catheter exchanges that may prolong procedure times and compromise access, while offering the functionality of multiple catheters into one. The GPSCath balloon is commercially available and has an intended use in percutaneous transluminal angioplasty (PTA) of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic AV dialysis fistulas.

EARLY CASE EXPERIENCE

The current report presents the initial commercial experience with the GPSCath balloon and provides a retrospective analysis of results in the treatment of hemodialysis access sites.

From May 2011 to January 2012, a total of 127 GPSCath balloons were used at 18 US institutions to treat 94 patients with reduced or absent flow of their hemodialysis access sites. Twenty-four physicians participated in the initial experience and, of the 94 patients evaluated, 52% had a native



Figure 2. Contrast injection without removing catheter or guidewire through GPSCath balloon VisioValve injection port.

fistula and 48% had an AV graft. Each patient was referred for the procedure based on clinical symptoms, abnormal physical examination, or changes in blood flow or pressure. All procedures were performed on an outpatient basis. Data were collected to include technical success, complications associated with the GPSCath balloon, and physician satisfaction related to GPSCath balloon's performance. Technical success was defined as achievement of a residual stenosis less than 30%⁶ and achievement of significant hemodynamic improvement, allowing the patient to successfully undergo hemodialysis. Balloon diameters, the number of inflations per catheter, and inflation pressures were also recorded.

PROCEDURE OVERVIEW

Traditional techniques for performing dialysis access interventions were employed. Access was gained using a micropuncture kit and either a 6- or 7-F introducer sheath, and heparin was administered per operator protocol. Preliminary diagnostic angiograms were obtained to identify lesion location and severity.

After angiography, an appropriately sized GPSCath balloon was selected and prepped in the standard fashion according to the manufacturer's instructions. Following the passage of an 0.035-inch guidewire into the hemodialysis access, the balloon was inserted into the sheath and tracked over the wire to the site of the stenosis. Once the GPSCath balloon was positioned correctly, a standard inflation device or injection syringe was used to inflate the balloon to pressures required to fully dilate the stenosis. The GPSCath balloon currently has rated burst pressures (RBP) that range from 17 atmospheres (atm) to 21 atm depending on balloon diameters with performance data provided up to 25% above RBP (Table 1).

Upon successful expansion of the balloon, a final angiogram was obtained either by injecting contrast through the introducer sheath or the VisioValve microvalve of the GPSCath balloon. Contrast was injected through the VisioValve microvalve by activating the switch on the GPSCath balloon handle, which opens the VisioValve microvalve located at the proximal portion of the balloon (Figure 2). Angioplasty was repeated as necessary to fully

TABLE 1. UNITED STATES GPSCath BALLOON COMPLIANCE LABEL

GPSCath Balloon Compliance Data				
Inflation Pressure (atm)	Balloon Diameter by Size (mm)			
8	5.0	6.0	7.0	8.0
9	5.1	6.1	7.1	8.1
10	5.1	6.1	7.2	8.2
11	5.2	6.2	7.3	8.3
12	5.2	6.2	7.3	8.3
13	5.3	6.3	7.4	8.4
14	5.3	6.3	7.5	8.5
15	5.3	6.4	7.5	8.5
16	5.4	6.4	7.5	8.6
17	5.4 ^a	6.4	7.6	8.6
18	5.5	6.5 ^a	7.6	8.7
19	5.5	6.5	7.7	8.7
20	5.6	6.6	7.7 ^a	8.8
21	5.6	6.6	7.8	8.8 ^a
22	-	-	7.8	8.9
23	-	-	7.9	9.0
24	-	-	7.9	9.0
25	-	-	8.0	-
Key	Nominal	Rated Burst Pressure (RBP)		
^a Do not exceed RBP for specified balloon size.				

treat stenoses, and patients were assessed and discharged per hospital standard of care.

GPSCath BALLOON CLINICAL PERFORMANCE

Ninety-four patients undergoing hemodialysis underwent procedures treating stenoses, and, when present, the associated thromboses, in either native fistulas or synthetic grafts. Successful dilatation of stenoses and significant hemodynamic improvement permitting successful hemodialysis occurred in 100% of patients, and there were no adverse events related to the use of the GPSCath balloon occurring through hospital discharge (Table 2). Physician satisfaction with the GPSCath balloon was achieved in 97.9% of patients.

BALLOON PERFORMANCE

Critical to the successful use of the GPSCath device was the performance of its semicompliant balloon, which successfully dilated the challenging stenoses seen in failed access, including focal anastomotic lesions, diffuse venous outflow disease, and central venous obstructions. The GPSCath balloons were inflated an average of 3.83 times per

TABLE 2. GPSCath BALLOON PROCEDURE OUTCOMES

(N = 94 patients)	N	%
Stenosis dilated as intended (< 30% residual stenosis) ^a	94	100
Significant hemodynamic improvement ^a	94	100
Complications related to GPSCath balloon	0	0
Physician satisfaction	92	97.9
^a Flow restored with GPSCath balloon; further improvement obtained through higher pressure balloon use in three patients.		

procedure to an average inflation pressure of 16.10 atm with a maximum of 18 inflations of one balloon. A summary of the GPSCath balloon performance is provided in Table 3.

DISCUSSION

The importance of effectively treating ESRD patients receiving hemodialysis is critical to patients. Unfortunately, vascular access sites are quite susceptible to reduction in blood flow and eventual failure. With low rates of AV graft and fistula patency and the need for frequent intervention to maintain a well-functioning vascular access, a more cost-effective approach is of significant interest, especially considering the projected increase in the number of patients requiring hemodialysis treatment. Treatment effectiveness remains the primary objective, but a clear need to provide a more cost-effective treatment exists.

In the initial commercial experience with the GPSCath device, the balloon proved highly effective in dilating lesions typically associated with dialysis access sites. In treated patients, the GPSCath balloon was used successfully in 100% of cases, restoring flow adequate to facilitate the completion of dialysis with no associated complications. With these results, the GPSCath balloon proved to be a viable primary treatment option for dialysis access interventions, and its attractiveness will increase with the projected expansion of its available size matrix in the near future.

While the GPSCath balloon was highly successful in performing high-pressure angioplasty, there are also several other characteristics of the balloon that proved beneficial and warrant further study and discussion.

Although currently available noncompliant balloons place significant focal pressure upon stenoses, the GPSCath's semicompliant balloon provided pressures adequate to dilate even resistant lesions, while also demonstrating greater treatment flexibility at certain anatomical locations. A semicompliant balloon conforms to the curvature of native vessels, potentially improving treatment effectiveness and reducing potentially traumatic stress on the vessel. Additionally, the semicompliance of the balloon provides an attractive alternative for

TABLE 3. GPSCath BALLOON PERFORMANCE

	Number of Balloons Used	Average Number of Inflations	Average Pressure (atm)
5-mm GPSCath	13	2.85	15.15
6-mm GPSCath	22	3.59	14.79
7-mm GPSCath	31	3.90	14.92
8-mm GPSCath	61	4.08	17.38
All devices	127	3.83	16.10

treating venous disease. The inherent elasticity of veins presents significant recoil potential, and the ability to progressively adjust the diameter of the GPSCath balloon by increasing inflation pressures provides the option of gradually increasing the diameter of the vein without needing a second, larger-diameter angioplasty balloon.

In addition to treatment advances afforded by the balloon, the VisioValve microvalve offers intriguing possibilities for use during interventional dialysis access procedures. Injection of contrast is usually accomplished with infusion through the procedural sheath or by injecting contrast through either an angiographic catheter or a balloon catheter after guidewire removal. With the GPSCath balloon, contrast may be injected through the VisioValve microvalve, reducing volume requirements

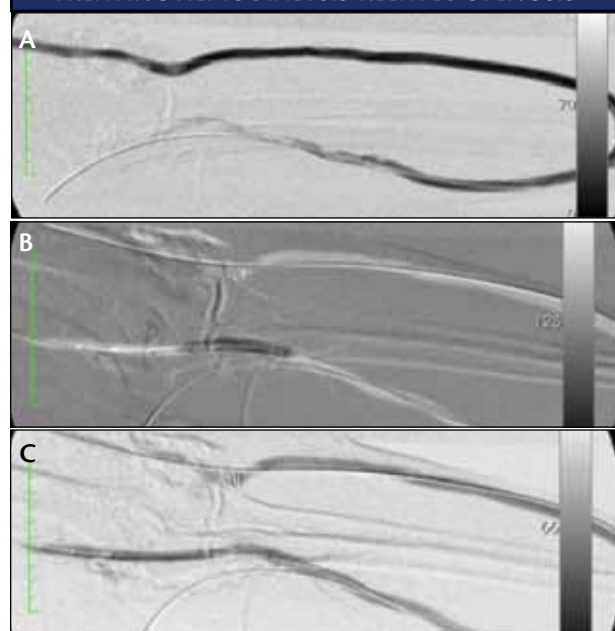
GPSCath BALLOON ANGIOPLASTY FOR TREATING HEMODIALYSIS-RELATED STENOSIS

Figure 3. (A) Preintervention angiogram showing blockage and subsequent thrombus build-up at arterial anastomosis. (B) Angioplasty with 6-mm GPSCath balloon. (C) Postdilatation angiogram utilizing VisioValve without removing balloon or losing guidewire position.

because of the local injection and eliminating the potential of lost access during guidewire removal or catheter exchange. In each case during this initial experience, angiography was successfully performed through the VisioValve microvalve (Figure 3). In addition to contrast delivery, the VisioValve microvalve may also be used to infuse thrombolytic agents, facilitating de clotting procedures and providing visualization on the arterial side of vascular access sites, even in retrograde flow. Permitting injection of contrast media, lytics, and other physician-specified fluids may reduce equipment supplies and procedure times by potentially obviating the need for angiographic catheters and minimizing steps such as catheter exchanges. In total, attributes of the VisioValve microvalve may also support cost reduction measures and demand additional study to validate cost savings.

CONCLUSION

The initial commercial evaluation of the GPSCath balloon's performance confirmed that the semicompliant balloon was effective in dilating all hemodialysis access lesions treated, restoring patency of the vascular access, and permitting hemodialysis treatment. The lack of product complications and high technical success in combination with the enhanced capabilities of the

catheter design resulted in a high degree of physician satisfaction. The initial clinical performance of the GPSCath balloon suggests that its attributes may encourage use as the catheter of choice for improved versatility in the treatment of dialysis access sites as well as to promote and implement a cost-containment strategy. ■

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