Informed Decision Making for Catheter Selection in Hemodialysis Patients

A Prospective Evaluation to Determine the Effectiveness of a Novel Thrombus-Reducing Catheter for Long-term Vascular Access in Hemodialysis Patients

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ABSTRACT

Purpose: To evaluate the role a novel catheter technology may have in reducing thrombotic catheter dysfunction incidence and infectious complications.

Material and Methods: 21 patients were enrolled and performance criteria evaluated prospectively for up to 10 weeks following BioFlo DuraMax implants. Data regarding flow rates, venous and arterial pressures, catheter-related infection, catheter exchanges and tissue plasminogen activator usage was recorded. Additionally, as a limited retrospective comparative, catheter exchange rate data for the incumbent device Palindrome (n=48) and BioFlo DuraMax (n=50) was collected for a total of 3 months during equivalent time periods

Results: During the prospective evaluation of BioFlo DuraMax, zero catheter-related infections were reported. One catheter required a single dose of tPA. Flow rates averaged 397 mL/min. Venous and arterial pressures averaged 139 mmHg and 151 mmHg, respectively.

A retrospective evaluation of catheter exchanges from January 1 through March 31, 2014 and the same period in 2015 after implementation of the BioFlo dialysis catheter yielded 15 exchanges in the Palindrome arm as compared to 8 in the BioFlo DuraMax arm. The resultant reduction of catheter exchanges was 48%.

Conclusions: The early data in terms of flow rates, catheter-related infection, thrombotic complications and exchange rates is compelling for continued improvement in long term outcomes using BioFlo DuraMax HD catheters as compared with incidences documented in the literature. Future studies are needed to validate our observational data and to evaluate the long-term efficacy of the catheter as compared with traditional catheters.

INTRODUCTION

The use of tunneled hemodialysis (HD) catheters is an essential, but complex component in the management of patients with chronic kidney disease. While the Fistula First national movement has increased the use of AV (arteriovenous) fistulas, 82% of US patients still initiate dialysis via a catheter.[1] It is estimated that of the 400,000 hemodialysis patients in the US, 25% are dialyzing with catheters.[2] Management and prevention of complications associated with these vascular access devices remains one of the most challenging aspects of caring for hemodialysis patients. Given the association between these complications and increased morbidity, mortality, length of hospitalization, treatment time and overall cost to the healthcare system, it is essential to focus on improved outcomes across the continuum of care.

The purpose of this evaluation was to understand the role catheter technology may have in preventing thrombotic catheter dysfunction and infectious complications.

Pathophysiology of Dialysis Catheter Dysfunction

Injury to the vessel endothelium begins with insertion of the catheter and is augmented by turbulent flow around the catheter. "Line" reversal or catheter "manipulation" as attempts to improve blood flow promote even more disruption in the fibrinolytic system, initiating the coagulation and inflammatory cascade. Minute irregularities on the catheter polymer surface permit platelet adhesion and activation of the intrinsic coagulation pathway.[3]

Thrombotic Occlusions

Thrombotic occlusions, of which there are four major types (Table 1), are a serious cause of access dysfunction. They occur in 30 to 40% of patients, can occur within 24 hours after insertion or after prolonged continuous successful usage, and can provide a substrate for bacterial growth.[3] A study of 721 HD patients revealed that clot formation was one of four parameters significantly (P< 0.001) and independently related to inadequate dialysis dose delivery.[4] In light of the Center for Medicare and Medicaid Services (CMS) Bundled Payment System that went into effect January 2011, the economic consequences of thrombotic occlusions have a far-reaching effect in the management of End-stage Renal Disease (ESRD) patients. Under this payment structure, CMS pays one amount per person, per treatment for all dialysis, labs, and medications. In 2011, this amount was established at $251.00 per treatment. Applying this payment model, the following scenario demonstrates the potential financial implications of catheter dysfunction:

TABLE 1. TYPES OF THROMBOTIC OCCLUSIONS

Type	Features	Symptoms
Fibrin tail or flap	Fibrin extends from the end of the catheter causing partial occlusion (fibrin tail acts as one way valve)	Ability to infuse but not withdraw blood
Fibrin sheath	Fibrin adheres to the external surface encasing the catheter, possibly extending the length of the catheter; thrombi trapped between sheath and catheter tip	Inability to infuse and/or withdraw blood
Mural thrombus	Fibrin from vessel wall injury binds to fibrin-covered catheter; increased risk of venous thrombosis	Leakage of infusate from the insertion site, swelling, pain, tenderness, engorged vessels
Intraluminal thrombus	Fibrin forms inside catheter lumen causing partial or complete inclusion	Inability to infusate and/or withdraw blood

TABLE 2. FINANCIAL IMPLICATIONS OF CATHETER DYSFUNCTION

Cost of Alteplase per 2 mg vial	$120.80
Number of lumens	2
Average number of doses to treat each lumen	1.5
Total cost of catheter dysfunction	$362.40
Estimated cost to institution	**$110.90**

Infection

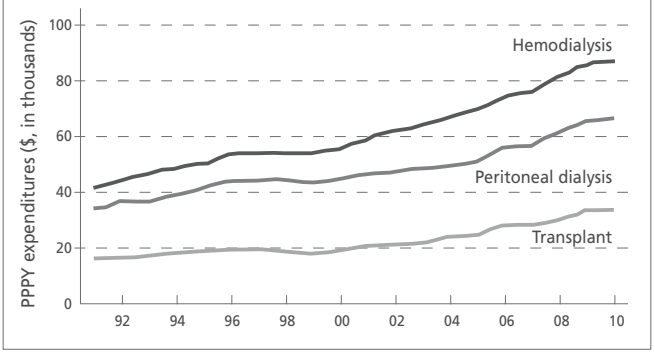
Catheter-related bacteremia often leads to hospitalizations, serious complications and substantial cost to the healthcare system; infectious hospitalization rates in the first months of dialysis are now almost equal to rates of cardiovascular hospitalization, a finding that is new over the past decade.[2] Infection is a major cause of death in ESRD patients, with central vascular access devices being the most important independent risk factors for infection in HD patients.[5]

The economic magnitude of catheter-related bacteremia is staggering. The cumulative risk of bacteremia in catheter-dependent patients is nearly 50% at 6 months with each hospitalization for catheter-related bacteremia costing an average of $23,000. In one study, the cost of treating 33 patients, with 40 hospitalizations for catheter-related bacteremia was close to $1 million dollars.[7] According to Allon et al., there were approximately 110,000 incident hemodialysis patients in the United States in 2007, 80% (88,000) of which initiated hemodialysis with a catheter. Assuming these patients average one hospitalization or treatment of catheter-related bacteremia, the cumulative cost is 88,000 x $23,000 = $2.0 billion. If measures were successful in reducing catheter use among incident patients by 50%, this would translate into a $1 billion savings annually for CMS.[2]

Background and Discission

Caring for ESRD patients has become more complex in recent years. There is even more emphasis on delivering quality care in an efficient manner with the escalating costs of hemodialysis, the growth of the Fistula First initiative and changes in dialysis reimbursement. The cost of hemodialysis continues to increase at a rapid rate (Figure 1.)

FIGURE 1. COST OF HEMODIALYSIS



Due to high utilization of catheters, and associated costs, it is critical to appropriately evaluate the performance of these devices. Within this institution and others, clinicians are under tremendous pressure to provide not only high quality care to patients under the Quality Incentive Program, but also efficient care under the ESRD Prospective Payment System.

An ideal hemodialysis catheter should provide high flow rates, good pressures, low infection rates, minimal exchanges and minimal need for thrombolytic agents to maintain patency.

Catheter technology may play a role in improving outcomes and reducing catheter complications. However, traditional catheter "coatings" lack permanence, expose the patients to additional risks and have not demonstrated improved clinical outcomes in long-term use. [8-10]

The BioFlo Duramax chronic hemodialysis catheter (AngioDynamics, Inc. Latham, NY) was introduced on the market in June, 2014. This catheter is comprised of a novel material with a permanent, non-eluting polymer called Endexo, shown to be more resistant to platelet aggregation compared to non-coated conventional dialysis catheters tested. The in-vitro data for reduction of thrombus formation as compared to conventional polyurethane and heparin-coated catheters† was compelling for a clinical evaluation of the catheter.

The project was initiated as a 90-day product evaluation of BioFlo Duramax dialysis catheters to determine effectiveness within our institution. Our initial goal was to make an informed product decision based on economic and clinical benefits.

Methods

Performance criteria were identified and endpoints were established (Table 3).

TABLE 3. DATA ENDPOINTS

Flow rate	Catheter-related infections
Venous pressure	Catheter exchanges
Arterial pressure	tPA usage

Twenty-one patients were followed for a period of 10 weeks. Data was captured at weeks 1, 2, 3, 4, 6, 8, and 10 using a Microsoft Excel spreadsheet. At each of the planned time points, data regarding flow rates, venous pressures and arterial pressures were recorded. Additionally, any infections, catheter exchanges and the reason for the exchange, as well as any usage of tissue plasminogen activator (tPA) on occluded catheters were recorded.

Patients were treated at 5 different dialysis centers. All clinicians were notified of the project and trained on the data points to be collected. Centers were contacted weekly and all data was reviewed with the principal investigator of the study and entered into the database.

Results

Over the 90-day period we observed flow rates averaging 397 mL/min. Venous pressures and arterial pressures averaged 139 and -151 respectively. There were no reported infections among the 21 patients over the course of 10 weeks. One catheter required a single dose of tPA during week 2, day 1 of a patient's treatment due to a poor flow rate. Following administration of tPA, a flow rate of 364 mL/min was achieved during the dialysis session. One catheter exchange was performed due to fibrin sheath formation. Of note, there were 4 patients in the study that did not make the full 10 week trial—2 patients deceased after 8 weeks and 2 catheters were removed because of working fistulas.

TABLE 4. PROSPECTIVE BIOFLO DURAMAX PERFORMANCE SUMMARY

Duration	10 weeks follow-up post implant
Patients	21
Catheter-related infections	0
tPA utilization	1 single dose
Exchanges due to thrombotic catheter occlusion	**1**

As a limited comparative, we retrospectively evaluated the number of catheter exchanges during January 1, 2014 through March 31, 2014 and the same time period in 2015 after the implementation of BioFlo DuraMax dialysis catheters. There were 15 exchanges in the 2014 3-month period as compared to 8 exchanges during the 3-month period using BioFlo DuraMax catheters. There were 48 and 50 catheters placed in each time period, respectively. This represented a 48% reduction in catheter exchanges.

TABLE 5. RETROSPECTIVE COMPARISON OF EXCHANGE RATES: BIOFLO DURAMAX AND PALIDROME CHRONIC DIALYSIS CATHETERS (3 MOS EACH ARM)

	Palindrome	BioFlo DuraMax
Exchanges	15	8
Number of implants	48	50
Exchange rate	31%	16%
Total reduction of exchanges		**48%**

Limitations in this retrospective review included difficulty in determining the cause of catheter exchange or removal.

Discussion and Conclusions:

We further sought to understand complication rates in the literature associated with the incumbent catheter, a symmetrical tip design (Palindrome - Covidien, Mansfield, MA). Infection rates of 3.3-13.9% have been described[11-13] as well as catheter malfunction rates of 7.3%-17.4% requiring exchange.[12,13] In terms of catheter-related thrombosis (CRT), an incidence of 30.6% was reported in one study although clinical significance or need for catheter exchange was not reported.[11]

In consideration of the scope of this project, the early data in terms of flow rates, infectious and thrombotic complications is compelling for continued improvement in long-term outcomes using BioFlo Duramax HD catheters as compared with the incidence documented in the literature. Future scientific studies are needed to validate our institution's observational data and to evaluate the long-term efficacy of the BioFlo DuraMax hemodialysis catheter as compared to traditional polyurethane catheters.

CONFLICT OF INTEREST

None to disclose.

ABOUT THE AUTHORS

Kyle Nestler—Kyle has worked at Memorial Medical Center, a 470 bed hospital in Springfield, IL, for over 20 years. "When I started my career at Memorial Medical," Kyles states, "the healthcare environment was vastly different than the one in which we operate today. In the current healthcare environment we are all under a tremendous amount of pressure to make evidence-based treatment decisions that are efficient, economical and provide better outcomes for our patients." After recently being promoted to Interventional Radiology Supervisor, Kyle has become even more focused on providing patients with the best care which includes evaluating new, cutting edge treatments and devices.

Syam Vasireddy, MD, MS—Dr. Vasireddy attended Medical School at the University of Illinois, Chicago. He completed residency at Southern Illinois University and a fellowship in Vascular and Interventional Radiology at the University of Chicago. For the past four years, he has worked with Clinical Radiologists, S.C. (based in Springfield, IL) and has a clinical appointment with Southern Illinois University as a Clinical Assistant Professor. Dr. Vasireddy is Board Certified by the American Board of Radiology and Diagnostic Radiology.

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†The reduction in thrombotic accumulation (based on platelet count) is supported by acute in-vitro testing. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation. Results from one institutions' experience may not be indicative of clinical experience with other institutions.

IMPORTANT RISK INFORMATION

BIOFLO DURAMAX DIALYSIS CATHETER WITH ENDEXO TECHNOLOGY

INDICATIONS FOR USE: The BioFlo DuraMax Dialysis Catheter with Endexo Technology is indicated for use in attaining long-term vascular access for hemodialysis and apheresis in adults. Catheters greater than 40 cm are intended for femoral vein insertion.

Indications, contraindications, warnings and instructions for use can be found in the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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