Impact of the Use of the HeRO Vascular Access Graft vs. Tunneled Dialysis Catheters on Dialysis Provider Economics in an Era of Bundling

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INTRODUCTION

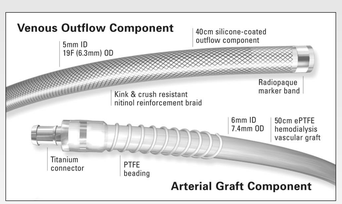
CMS will institute a new prospective payment system (PPS) for facilities that provide dialysis services to Medicare ESRD beneficiaries beginning on January 1, 2011. This PPS will provide a single bundled payment to dialysis facilities that covers the majority of items and services used in providing outpatient dialysis services.

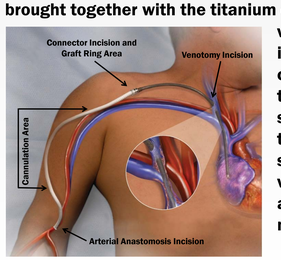
Since the use of chronic catheters for hemodialysis access have a well documented association with increased morbidity, mortality, and costs compared to AV fistulas and grafts, reducing the utilization of tunneled dialysis catheters represents a significant opportunity for dialysis providers to improve dialysis delivery, reduce complications, decrease patient care costs, and increase dialysis center revenue in a bundled payment environment.

Based on the reported differences in clinical outcomes associated with use of the HeRO® vascular access graft (Hemosphere, Inc., Eden Prairie, MN) versus tunneled dialysis catheters in catheter-dependent patients[1], we developed a model to assess the potential economic impact associated with the conversion of catheter access to the HeRO graft (in suitable patients) as a part of a catheter reduction algorithm in a bundled payment environment.

THE HeRO VASCULAR ACCESS GRAFT

The HeRO graft is a conventional ePTFE graft connected to a subcutaneous, nitinol - reinforced silicone venous outflow component, designed to traverse central venous stenosis routing blood flow to the right atrium via a major central vein. The graft is surgically placed in the upper arm over the biceps muscle and the venous outflow component is placed via an incision at the deltopectoral groove. The two components are brought together with the titanium connector. The radiopaque tip of the venous outflow component is placed in the right atrium. The graft provides continuous arterial blood flow into the central venous system, forming a subcutaneous arteriovenous access that bypasses central venous stenosis and the need for a graft-to-vein anastomosis. The graft is accessed for dialysis in the same manner as a conventional graft.





METHODS

A quantitative model with multiple input parameters was developed to calculate the potential per annum differences in economic outcomes associated with the use of tunneled hemodialysis catheters and the HeRO graft for dialysis providers under Medicare's new bundled payment system. Baseline assumptions utilized to create the model were obtained from the USRDS 2010 Annual Data Report,[2] the 2008 Annual Report for ESRD CPM Project,[3] and from published results of relevant clinical studies.

The first step of our analysis focused on the projection of differences in hospitalization, missed dialysis sessions, and associated loss of dialysis provider revenue resulting from the diagnosis/treatment of bacteremic episodes. Subsequently we expanded the analysis to identify potential cost differences resulting from differing patterns of I.V. medication usage and need for blood cultures between the two groups.

Clinical and Economic Parameters Included in Model

- Inpatient and outpatient bacteremic episodes
- Days hospitalized for bacteremic episodes
- Number of missed dialysis sessions resulting from hospitalization for bacteremia
- Lost revenue due to hospitalization for bacteremia
- Cost of blood cultures for suspected bacterial infections
- Cost for managing outpatient bacteremic episodes
- Use of thrombolytics for catheter thrombosis
- Difference in ESA utilization

The patient population utilized for the model was based on an estimate of the total number of catheter-dependent hemodialysis patients in the U.S. in 2011 who are projected to be dialyzing via a tunneled catheter as a result of having exhausted all fistula and graft sites.

- The number of prevalent hemodialysis patients for 2011 was projected by assuming a 4.05% compounded annual growth rate in the hemodialysis patient population from 2008 through 2011
- This rate is equivalent to the average growth in the hemodialysis patient population between 2004 and 2008.[2]

Using data from the ESRD CPM Project[3]:

- The model assumed that 5.1% of the total hemodialysis patient population would be catheter dependent in 2011.
- This is based on the assumption that 27% of prevalent hemodialysis population will be dialyzing via a catheter in 2011 and that 19% of these catheter patients will have exhausted all fistula and graft options.

Total patient population included in model = 399,352 projected HD patients in 2011 × 27% × 19% which is equivalent to 20,492 patients.

The model utilized the CMS base bundled rate of $229.63 per dialysis treatment[4] and is not adjusted to reflect patient- and facility-specific differences in case-mix and other adjustments.

RESULTS

Based on the calculations we utilized for our model, we estimate that there will be 20,492 catheter-dependent hemodialysis patients in the U.S. in 2011 who have exhausted all AV fistula and graft options. Our model projects that the use of hemodialysis catheters in this patient population would result in an increase in the number of bacteremias, hospital days for catheter-related bacteremias, and missed dialysis sessions annually compared to the use of the HeRO graft.

Projected differences in infectious disease-related outcomes

	Dialysis Catheter	HeRO® graft
Bacteremic episodes[a]	17,203	5,236
Number of patients hospitalized for bacteremic episodes[b]	12,833	3,906
Days hospitalized for bacteremia[c]	218,168	66,399
Missed dialysis sessions[d]	94,539	28,773
Lost revenue due to missed dialysis sessions[e]	$21,709,066	$6,607,107
Outpatient bacteremic episodes[f]	23,566	7,172
Dialysis provider cost of IV antibiotics for management of outpatient bacteremia[g]	$8,789,995	$2,675,216
Cost of blood cultures[h,i]	$1,014,973	$308,905

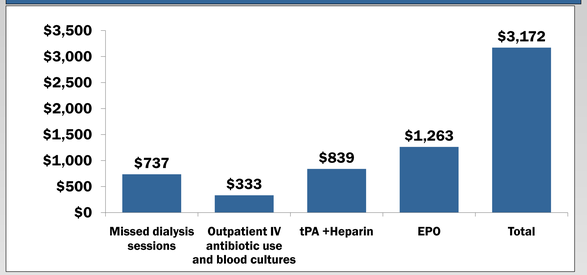
[a] Infection rate of 2.3 /1,000 patient days for catheters and 0.7/1,000 patient days for the HeRO graft[1]
[b] Based on a hospitalization rate of 74.6% for access-related bacteremic episodes[5]
[c] Based on an average length of stay of 17 days for catheter-related bacteremias[5]
[d] Assumes 13 dialysis sessions per month
[e] Proposed bundled rate multiplied by number of missed dialysis sessions[4]
[f] Assumes 1.15 outpatient bacteremic episodes per year[5]
[g] Assumes average cost of outpatient IV antibiotics of $373 per patient[6]
[h] Assumes 2 blood cultures per bacteremia episode[7]
[i] Assumes average cost of $29.70 per blood culture[8]

Economic modeling projects that dialysis providers would generate total incremental revenue of $15,101,959 or $737 per patient, per year when using the HeRO graft versus catheters as a result of reductions in hospitalizations for catheter-related bacteremias leading to fewer missed dialysis sessions. Our model also projects that dialysis providers would realize a cost savings of $6,114,779, or $298 per patient, per year as a result of a reduction in use of IV antibiotics for the outpatient management of bacteremic episodes and a cost savings of $706,068 associated with a decrease in need for blood cultures when using the HeRO graft instead of hemodialysis catheters in this patient population.

Based on recently published data on the utilization and cost of tPA and heparin locks for catheter patients[9], our modeling projects that 28,422 doses of tPA would be required to manage occluded catheters in this patient population in 2011 with an associated cost to dialysis providers of an estimated $4,092,803 or $199 per patient. Our model also projects that the cost of heparin to lock catheters in these patients would be estimated additional $13,114,808 or $640 per patient. These costs are not applicable to patients implanted with the HeRO graft since it has continuous AV flow and managing HeRO related occlusions will not be covered as a part of the bundled payment.

The use of the HeRO graft compared to hemodialysis catheters in this patient population would result in substantial cost savings for dialysis providers relative to the use of erythropoietin stimulating agents (ESA) based on our modeling. Using results from a published report indicating an increase in average weekly EPO dose of 35.6 units/kg/week for catheter patients versus patients dialyzing via an AV graft,[10] we calculated an averaged estimated increase in EPO requirements of 2,483 units per week for catheter patients with an associated annual cost of $1,263 per patient. This equates to a potential total annual cost savings of $25,871,032 across the entire catheter-dependent population.

Projected Per Patient Annual Cost Savings Associated with the HeRO Graft



Modeled results indicate that the use of the HeRO vascular access graft instead of tunneled dialysis catheters in this patient population would produce a per patient economic benefit of $3,172 to dialysis providers on an annual basis as a result of increased dialysis provider revenue and decreased costs. This equates to a total dialysis provider financial benefit of $65,001,750 when projected across the entire catheter-dependent, hemodialysis patient population. Additional savings would also be incurred by dialysis providers as a result of the reduced need for catheter care related supplies which have not been calculated or included in this model.

CONCLUSION

Implementation of catheter reduction strategies will enable dialysis providers to decrease costs and increase revenues by reducing the rate of catheter-related complications and reductions in medications that are included in Medicare's new bundle payment for dialysis services. Incorporation of the HeRO graft into a vascular access algorithm and its preferential use over a catheter in patients who have exhausted their AV access options will likely be associated with improved dialysis provider economics under a bundled payment system.

REFERENCES

1. Katzman HE, et al. *J Vasc Surg* 2009; 50:600-7.
2. U.S. Renal Data System, USRDS 2010 Annual Data Report.
3. Centers for Medicare & Medicaid Services. 2008 Annual Report, End Stage Renal Disease Clinical Performance Measures Project.
4. Centers for Medicare & Medicaid Services. *Fed Regist.* 2010; 75(155):18466.
5. Ramanathan V, et al. *Infect Control Hosp Epidemiol.* 2007; 28:606-9.
6. Li Y, et al. *Clin J Am Soc Nephrol* 2009; 4:428-34.
7. K/DOQI Clinical Practice Guidelines and Clinical Practice Recommendations 2006 Updates. *Am J Kidney Dis* 2006; 48(Suppl 1):S1.
8. Hermson ED, et al. *J Clin Microbiol*, 2008; 46:2924-29.
9. Maya IV, et al. Clin J Am Soc Nephrol 2010; 5:1458–1462
10. Chand DH, et al. *Nephron Clin Pract* 2008;108:c91-8.