An Economic Analysis of Stent Grafts for Treatment of Vascular Access Stenosis: Point-of-Care and Medicare Perspectives in the United States

Bart Dolmatch, MD, Andrew Hogan, BSc, and Nicole Ferko, MSc

ABSTRACT

Purpose: To conduct an economic analysis on the impact of increased stent graft (SG) use for treatment of arteriovenous graft (AVG) anastomotic stenosis or arteriovenous fistula (AVF)/AVG in-stent restenosis (ISR) from United States point-of-care (POC) and Medicare perspectives.

Materials and Methods: The analyses compared initial device and reintervention costs over 2 years between current and projected treatment mixes, including percutaneous transluminal angioplasty (PTA), bare metal stents (BMSs), and SGs. In projected scenarios, the absolute increase in SG use was approximately 3%. Costs included procedure reimbursement rates (Medicare) and device list prices (POC) for index procedures and reinterventions. Reintervention rates and types were informed by the RENOVA and RESCUE randomized trials. Reinterventions were primarily PTA only; however, stent use occurred a proportion of the time. BMS reintervention rates were assumed to be identical to PTA based on observational data. A population size of 1,000 patients was assumed.

Results: To the POC (n = 1,000), increased SG use was predicted to result in cost savings ranging from $4,106 to $34,420 for AVG anastomotic stenosis. For AVF/AVG ISR, increased SG use was predicted to result in either a cost increase of $17,187 or a cost savings of $13,159. To Medicare (n = 1,000), increased SG use was predicted to save costs for both populations, with savings ranging from $57,401 to $169,544.

Conclusions: The use of SG for treatment of AVG anastomotic stenosis and AVF/AVG ISR appears to be economically favorable for POC providers and Medicare. Further data on reintervention rates are required from other SG trials to validate findings.

ABBREVIATIONS

ASC = ambulatory surgery center, AVG = arteriovenous graft, AVF = arteriovenous fistula, BMS = bare metal stent, FDA = US Food and Drug Administration, HOC = hospital outpatient center, ISR = in-stent restenosis, OBL = physician office based lab, POC = point-of-care, PTA = percutaneous transluminal angioplasty, RCT = randomized controlled trial, SG = stent graft

Over 670,000 prevalent patients in the United States have end-stage renal disease, with approximately 63% managed with hemodialysis using a central venous catheter, arteriovenous fistula (AVF), or arteriovenous graft (AVG) (1). The leading cause of AVF or AVG dysfunction is the development of stenosis that leads to reduced blood flow, which may interfere with hemodialysis (2,3). If left untreated, stenosis may progress to thrombosis and possible access circuit abandonment, with high associated economic burden (1,4,5).

Management of vascular access stenosis commonly includes percutaneous transluminal angioplasty (PTA)

From the Department of Interventional Radiology (B.D.), The Palo Alto Medical Foundation, Mountain View, California; and Cornerstone Research Group Inc. (A.H., N.F.), 3228 S Service Rd, Burlington, ON L7N 3H8, Canada. Received July 10, 2017; final revision received January 16, 2018; accepted January 17, 2018. Address correspondence to N.F.; E-mail: nferko@cornerstone-research.com

From the SIR 2017 Annual Meeting

B.D. is a paid consultant and advisor for Bard Peripheral Vascular, Inc. (Tempe, Arizona). A.H. and N.F. are paid employees of Cornerstone Research Group, Inc. (Burlington, Ontario) and received funding from Bard Peripheral Vascular, Inc. to conduct the study.

Figure E1, Tables E1 and E2, and Appendix A are available online at *www.jvir.org*.

J Vasc Interv Radiol 2018; 29:765–773

https://doi.org/10.1016/j.jvir.2018.01.777

EDITORS' RESEARCH HIGHLIGHTS

- This manuscript creates a theoretical construct based on randomized trials to answer the question of whether the increased device cost of stent grafts is offset by long term savings given the improved patency of these devices compared to angioplasty or bare metal stents in venous anastomotic stenosis or in-stent restenosis.
- From a Medicare perspective, it appears that stent graft use result in overall savings.
- From a point-of-care perspective, the use of stent grafts may or may not result in cost savings depending on device costs of reinterventions.
- The article highlights the need for cost-effectiveness analysis and clinical trials for these very questions.

with or without stenting (6). The standard of care for stenosis is largely considered to be PTA; however, long-term patency is limited (7–9). Recent randomized controlled trials (RCTs) of AVG stenosis have reported PTA access-circuit primary patency rates ranging from 20% to 41% after 6 months (10–12). As an alternative to PTA, bare metal stents (BMSs) have been used to treat AVG stenosis despite their lack of US Food and Drug Administration (FDA) approval in the hemodialysis setting, absence of RCTs, and inconsistent results in observational studies (13–17). In-stent restenosis (ISR) with BMS can also limit long-term patency (18,19).

To overcome limitations associated with PTA and BMS, stent grafts (SGs) have been used to treat access stenosis. These devices are currently FDA approved for the treatment of AVG anastomotic stenosis and/or ISR associated with AVF/AVG, with RCT evidence supporting their use (10,12,19,20). To date, 4 RCTs have compared SGs with PTA in these populations. The Flair Endovascular Stent Graft and Viabahn Endoprosthesis significantly improved primary patency from 6- to 24-months compared with PTA alone for treatment of AVG anastomotic stenosis (10,12,20). The Fluency Plus Endovascular Stent Graft also demonstrated significantly improved primary patency compared with PTA alone for the treatment of ISR related to AVF/AVG (19).

However, the added benefits of SGs come at a higher cost. Thus, the purpose of our study was to conduct a cost analysis of SG compared with BMS and PTA for the treatment of AVG anastomotic stenosis or in-stent (BMS) restenosis of AVF/AVG from Medicare and point-of-care (POC) cost perspectives in the United States.

MATERIALS AND METHODS

An economic model, developed using Microsoft Excel 2010, evaluated the impact of increasing the adoption of SG in clinical practice for treatment of anastomotic stenosis (AVG) and ISR (AVF/AVG) related to hemodialysis over 2 years. A current treatment mix of PTA, BMS, and SG use was compared with 2 projected treatment mixes. The analyses were conducted from both a POC (ie, provider) and Medicare (ie, payer) perspective. The model was developed in accordance with budget impact analysis recommendations from the International Society for Pharmacoeconomics and Outcomes Research (21). A schematic of the model is provided in **Figure 1**.

Populations

Two patient populations were evaluated based on the approved FDA indications for SG in hemodialysis patients: (*i*) AVG anastomotic stenosis and (*ii*) ISR related to AVF/AVG. Each population was modeled as 1,000 patients. This population size was chosen so that projections could be easily made for alternative settings by scaling the results upwards or downwards for the population size of interest. Data informed a distribution of patients across physician office-based lab (OBL; 66.5%), ambulatory surgical center (ASC; 0.9%), and hospital outpatient center (HOC; 32.5%) settings (22).

Perspectives

Costs were evaluated from a POC (provider) and Medicare (payer) perspective. For POC, device-related costs (ie, list prices) were used in the analysis for index and reintervention procedures, since such costs impact provider bottomline/net profits. The total device costs were also expressed as a proportion of procedure reimbursement. For the Medicare perspective, reimbursement amounts (ie, 2017 Medicare payments) for index and reintervention procedures were used because these represent their actual costs. Specific device costs were not considered from the Medicare perspective given that they are indirectly integrated into their payment rates.

Treatment Mix Scenarios

Costs for a mix of treatments in current and projected scenarios were compared for both populations over 2 years. The current treatment mix included PTA, BMS, and SG for the index procedure. The breakdown of each treatment type was based on real-world physician claims data according to Braid-Forbes Health Research (22). Since future treatment adoption is uncertain, the authors made assumptions for the model using 2 projected scenarios, each involving increased SG use. The breakdown for current and projected treatment mixes is reported in **Table 1**.

The first projected scenario assumed that the increased adoption of SG would result from decreased BMS use, with the proportion of PTA use remaining constant (ie, an assumption that there would be less need for off-label BMS use with the availability of SG). The second projected scenario similarly assumed that increased adoption of SG would result from decreased BMS use; however, PTA use would also slightly increase. This is supported by clinical trial data that found that use of SG resulted in reduced stenting relative to PTA reinterventions (19,20).