“Providing Long-Term Value In The Treatment Of The Thrombosed Dialysis Access Circuit”

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Disclosure
John E. Aruny, M.D:

I have the following potential conflicts of interest to report:

- W.L. Gore: Institutional PI (Yale University) for Revise Trial, Consultant & Speaker
- Bard-BD: Speaker, Investigator, Consultant
- Boston Scientific Corp. Advisory Board (Vascular)


The number of ESRD patients continues to rise each year.

ESRD Expenditures, 2004-2015

ESRD spending is also increasing, but plateauing due to recent focus to control costs.

Value Like Beauty Is In The Eye Of The Beholder

- Payer
- Patient
- Nephrologist
- Hospital
- Private Practice
Value Based Healthcare: Better Outcomes at Same or Lower Cost

Key challenge to health systems:
Increasing value of health care delivery

Health Outcomes that matter to patients
Cost for delivering outcomes


Multiple Dialysis Access Treatments Exist: How to decide which one delivers the most value?

There are a # of treatments when a dialysis circuit goes down.
- PTA
- Bare metal stents
- Covered stents
- Drug Coated Balloons

Is There Long Term Value stent-grafting?

Stent Grafts Have Conceptual, Clinical & Economic Benefits

- Conceptually
  - Physically exclude disease
  - Correct flow disturbances

These Points Were Addressed in the REVISE Trial and Several Other Randomized Trials and Now Presented in REVISE-2 Data

- Considerations for stent-graft selection.

Stent Graft versus Balloon Angioplasty for Failing Dialysis-Access Grafts
Ziv J. Hadad, M.D., Scott Trento, M.D., Paul Dolmatch, M.D., Earl Schuman, M.D., Sanford Altman, M.D., Samuel Melding, M.D., Scott Berman, M.D., Gordon McLennan, M.D., Clayton Trimmer, D.O., John Ross, M.D., and Thomas Vassal, M.D.


RENOVA-Bard Flair at 24 Months

Prospective, Randomized, Concurrently-Controlled Study of a Stent Graft versus Balloon Angioplasty for Treatment of Arteriovenous Access Graft Stenosis. 2-Year Results of the RENOVA Study
Zvi J. Hadad, MD, FBR, Theodore F. Sadowski, MD, Jeffrey G. Haggard, MD, Randy J. Cooper, MD, George S. Lipshutz, MD, Amnon Grigoris, MD, John R. Ross, MD, Timothy A. Phillips, MD, and Samuel W. Melding, MD

JVIR 2013
The predicted reduction in total Medicare Payments ranged from 0.3% to 1.0%, depending on the projected treatment mix and population type.

The reduction in device costs was anticipated to range from 0.1% to 0.6% depending on the projected treatment mix. In the AVF/AVG ISR population, the incremental costs with the projected treatment mixes ranged from a small cost increase (ie, by 0.3%) to cost savings (ie, by 0.2%).

Bart Concludes

- The use of SG for treatment of AVG anastomotic stenosis and AVF/AVG ISR appears to be economically favorable.
REVISE TRIAL

Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts

Thomas Young, MD, William DeFrancis, MD, Scott Redmond, MBBS, Anna DePuy, MD, and John Anaya, MBBS, New Costs, Inc., San Diego, Calif; Louisville, Ky, and San Antonio, Texas

Objective: To evaluate the results of stent graft placement in patients requiring revision for the treatment of failure or thrombosis of prosthetic hemodialysis grafts. Statistical analysis was performed using the log-rank test, and the chi-square test was used for categorical variables. Kaplan-Meier estimates were used to determine target lesion primary patency rates.

Results: The 6-month target lesion primary patency rate was statistically greater in the stent group compared to the balloon angioplasty group (69.3% vs. 56.2%, adjusted HR 1.41, 95% CI 1.01 to 1.96, p = 0.040). Compared with the balloon angioplasty group, the stent group had a trend toward improved patency at 1 year (80.7% vs. 66.8%, adjusted HR 1.50, 95% CI 0.98 to 2.29, p = 0.061). Compared with the balloon angioplasty group, the stent group had similar patency at 2 years (79.5% vs. 77.8%, adjusted HR 0.99, 95% CI 0.70 to 1.42, p = 0.950).

Conclusion: When compared with balloon angioplasty, a stent graft provided superior target lesion primary patency at 6 months. These results support the long-term safety and effectiveness of the Gore REVISE Clinical Study.

VIABAHN HAD BETTER TARGET LESION PRIMARY PATENCY AT 6 MOS. & OUT TO 2 YEARS

Primary Effectiveness Endpoint:

- The GORE® VIABAHN® Device group demonstrated statistical superiority over the PTA group in target lesion primary patency as determined by Kaplan-Meier estimates (p = 0.008).

REVISE-2

REDUCTION IN INTERVENTIONS OVER 24 MONTHS- STUDY POPULATION

Increased time between AV access interventions compared to PTA alone.**

- **Median Time to Target Lesion Reintervention**:
  - GORE® VIABAHN®: 203 Days
  - PTA: 108 Days
Clinical & Economic Analysis of Four Subgroups

<table>
<thead>
<tr>
<th>Reintervention Type</th>
<th>PTA</th>
<th>Thrombectomy</th>
<th>Any Stent Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stenosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Thrombosis</strong></td>
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</tr>
</tbody>
</table>

Within each treatment group, AVG-T circuits required significantly more reinterventions for repeat thrombotic events than AVG-S (P<.001)

Thrombosed circuits treated with PTA required 40% more reinterventions than PTA + Viabahn over a 2-year period

Data on file

<table>
<thead>
<tr>
<th>Reinterventions Subject</th>
<th>Time (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA-Thrombosed</td>
<td>44%</td>
</tr>
<tr>
<td>PTA-Stenosed</td>
<td></td>
</tr>
<tr>
<td>VSG-Thrombosed</td>
<td></td>
</tr>
<tr>
<td>VSG-Stenosed</td>
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</tbody>
</table>

Within each treatment group, AVG-T circuits required significantly more reinterventions for repeat thrombotic events than AVG-S (P<.001)

FEWER FOLLOW-UP BARE METAL/COVERED STENTS PERFORMED IN VSG SUBJECTS THAN PTBA SUBJECTS

Time to First Intervention

<table>
<thead>
<tr>
<th>Stent Reinterventions Subject</th>
<th>Time (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA-Thrombosed</td>
<td>36%</td>
</tr>
<tr>
<td>PTA-Stenosed</td>
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<tr>
<td>VSG-Thrombosed</td>
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Data on file

Within each treatment group, AVG-T circuits required significantly more reinterventions for repeat thrombotic events than AVG-S (P<.001)
Time to First Re-Intervention of Any Type - Longer in the Stent Graft Arm of Each Group But Did Not Reach Significance.

Longer Time Before First Intervention When Stent Graft Used For Index Procedure

Longer Time Before First Thrombosis When Stent Graft Used For Index Procedure

Time to First Occlusion - Longer in the Stent Graft Arm Regardless of Presentation.

Costs

Reintervention Costs Were Lower For Stent Grafts

38% lower reintervention costs when using Viabahn at index for thrombosed grafts
Primary Economic Outcome Measures

- Costs for index procedure & Follow-up interventions through 24 months.
- Costs derived from 2015 Medicare Hospital Outpatient Prospective Payment System (OPPS) claims filed by Braid-Forbes Health Research (Silver Spring, MD), and from publicly available Medicare files (2017 Final Rule OPPS-ASC Addendum J and CPT Cost Statistics file).
- Using cost-to-charge ratios specific to the hospital, the national geometric mean costs by Current Procedural Terminology® (CPT®) procedure codes, with and without devices included, were estimated from claims files. These costs represent the average costs to a hospital, not the payment, to perform the service in the hospital outpatient setting.

Index Costs Were Higher For Stent Grafts

Assumptions Regarding Costs

- Repeat Procedures: Trial collected # balloons only in the VSG arm not PTA arm. Estimate the same average # balloons in both arms 1.2
- CRFs did not specify thrombectomy type. Therefore, we assumed percutaneous thrombectomy performed instead of open thrombectomy.
- Estimated that percutaneous thrombectomy, not thrombolysis was performed during the index procedure.

Total Costs For Stent Grafts Less Than PTA >18 Months Across All Subjects

A. Costs by Index Treatment

Total Costs For Stent Grafts Less Than PTA >15 Months When Treating Thrombosed Grafts

Treating a thrombosed graft with PTA was the most expensive treatment pathway.

Dramatic reduction in re-intervention costs drives total costs: $19,322 vs $31,265 (p<.001)

Gore® VIABAHN® Value-Thrombosed Presentation

General Equation

<table>
<thead>
<tr>
<th>Health Outcomes that matter to patients</th>
<th>Value =</th>
<th>Cost for delivering outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Fewer Reinterventions</td>
<td>Value  =</td>
<td>• Improved patency</td>
</tr>
<tr>
<td>• Improved patency</td>
<td></td>
<td>• Lower cost After 15 months</td>
</tr>
</tbody>
</table>
Gore® VIABAHN® Value - Dysfunctional Access

GORE® VIABAHN® Endoprosthesis reduces reinterventions and is lower cost at 24 months vs. PTA, driving increased value

General Equation

\[
\text{Value} = \frac{\text{Health Outcomes that matter to patients}}{\text{Cost for delivering outcomes}}
\]

\[
\text{GORE® VIABAHN® Endoprosthesis Value} = \frac{\text{Fewer Reinterventions}}{\text{Cost Parity}} - \text{Improved Patency}
\]

Summary

• The data analysis of trials that included thrombosed and failing grafts and other recent economic studies strongly suggest that there is clinical and economic VALUE obtained by treating thrombosed AVGs with stent grafts.

• The REVISE Trial allows a unique opportunity to compare costs since it included thrombosed accesses.

• With thrombosed circuits the VALUE was even larger, with stent grafting reducing all reinterventions by 40% (angioplasties by 44% and thrombectomies/thrombolyses by 36%).

• Thrombosed circuits also tended to have shorter median times to first reintervention and to thrombotic occlusion than stenotic circuits regardless of allocated treatment.