Configuration Affect Parallel Graft Results

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Configuration Affects Parallel Graft Results:

Conflict of Interest

- **Speaker:** Gore, Medtronic, Cook
- **Consultant:** Gore
- **Medical Advisory Board:** Medtronic
- **Educational program support:** Cook, Gore, Medtronic
- **Research Study Investigator:** Gore, Medtronic, Cook
- **Off-label use of endovascular products**
Introduction – Parallel Grafts

- Widely used as an adjunct to expand indications for EVAR and TEVAR
- 94-100 % technical success
- 84-100 % 1 year-parallel stent patency
- 0-38% early Type Ia (gutter) endoleak
- No standard configuration, sizing
- Variable combinations of grafts, stents, PG orientation
Introduction – Background

Collected World Experience About the Performance of the Snorkel/Chimney Endovascular Technique in the Treatment of Complex Aortic Pathologies: The PERICLES Registry

Donas KP, Lee JT, Lachat M, Torsello G, Veith FJ; PERICLES Investigators
Ann Surg 2015, Sept

- 517 Snorkel EVAR (US 119, 398 Europe)
- 898 Chimney grafts -692 RA, 156 SMA, 50 CA (49.2% BE, 39.6% SE)
- 17.1 months FU
- Primary patency 94%
- Type 1a Endoleak 7.9%
- 79% survival
Configuration Affects Parallel Graft Results: 
Introduction – Background

The PROTAGORAS Study to Evaluate the Performance of the Endurant Stent Graft for Patients With Pararenal Pathologies Treated by the Chimney/Snorkel Endovascular Technique

Konstantinos P. Donas¹, Giovanni Torsello¹, Gianluca Piccoli², Georgios A. Pitoulia³, Giovanni Federico Torsello¹, Theodosios Bisdas¹, Martin J. Austermann¹, Daniele Gasparini⁴. ¹St. Franziskus Hospital Munster, St. Franziskus Hospital Munster, Munster, Germany; ²University Hospital Udine, Italy; ³Aristotle University of Thessaloniki, Thessaloniki, Greece; ⁴SIRM, Udine, Italy

128 pts, 178 CG’s
Medtronic Endurant and iCAst stents
100% technical success
95.7% CG patency
1.6% Type Ia endoleak
The Best Conditions for Parallel Stenting During EVAR: An *In Vitro* Study

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cDepartment of Radiology, Clínica Creu Blanca, Barcelona, Spain

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All endgrafts were tested in silicon aortic models following three oversizing conditions:

1) *Normal oversizing*: recommended oversizing for infrarenal aortic aneurysms following the instructions for use of each endograft manufacturer (usually around 15%).

2) *Excessive oversizing*: off-label conditions, one endograft size over recommended oversizing (around 30%).

3) *Over-excessive oversizing*: two endograft sizes over recommended oversizing (around 40%).
Configuration Affects Parallel Graft Results: Introduction – Optimal Configuration

• Conclusions
  – 30% oversizing demonstrated better apposition to aortic wall and stent surface with decreased gutter area without excessive stent compression (single parallel graft)
  – 40% oversizing increased risk of graft infolding
  – Self expanding stents higher compression (23% vs. 9%)
  – More compression on Viabahn with Endurant graft
  – Suggest use BE stents with Endurant, either SE or BE with Excluder
Configuration Affects Parallel Graft Results:

Introduction – Optimal Configuration

- “Stent graft diameter for a two-chimney procedure should be equal to the circumference of an ellipse with major diameter (A) equal to the sum of the aortic diameter plus the CGs diameters and minor diameter (B) equal to the aortic diameter [ie, \(0.72\pi \left((A^2 + B^2)^{1/2}\right)\) or simplified \((A + B)/2\)].” Lachat, M. Multiple chimneys: technique, results and limitations. (33rd CX Symposium, April 9–12, 2011)

\[A = a + b + c = 26 + 7 + 6 = 39\]
\[B = b = 26\]
Stent graft = \(39 + 26/2 = 32.5\)
\(26 + 7.8 \text{ (30\%)} = 33.8\)

For 3 snorkels use 1.5X the CG diameter
From the Society for Vascular Surgery

Configuration affects parallel stent grafting results

Adam Tanious, MD, MMSc, Mathew Wooster, MD, Paul A. Armstrong, DO, Bruce Zwiebel, MD, Shane Grundy, MD, Martin R. Back, MD, and Murray L. Shames, MD, Tampa, Fla

ABSTRACT

Objective: A number of adjunctive “off-the-shelf” procedures have been described to treat complex aortic diseases. Our goal was to evaluate parallel stent graft configurations and to determine an optimal formula for these procedures.

Methods: This is a retrospective review of all patients at a single medical center treated with parallel stent grafts from January 2010 to September 2015. Outcomes were evaluated on the basis of parallel graft orientation, type, and main body device. Primary end points included parallel stent graft compromise and overall endovascular aneurysm repair (EVAR) compromise.

Results: There were 78 patients treated with a total of 144 parallel stents for a variety of pathologic processes. There was a significant correlation between main body oversizing and snorkel compromise (P = .0195) and overall procedural complication (P = .0019) but not with endoleak rates. Patients were organized into the following oversizing groups for further analysis: 0% to 10%, 10% to 20%, and >20%. Those oversized into the 0% to 10% group had the highest rate of overall EVAR complication (73%; P = .0003). There were no significant correlations between any one particular configuration and overall procedural complication. There was also no significant correlation between total number of parallel stents employed and overall complication. Composite EVAR configuration had no significant correlation with individual snorkel compromise, endoleak, or overall EVAR or procedural complication. The configuration most prone to individual snorkel compromise and overall EVAR complication was a four-stent configuration with two stents in an antegrade position and two stents in a retrograde position (60% complication rate). The configuration most prone to endoleak was one or two stents in retrograde position (33% endoleak rate), followed by three stents in an all-antegrade position (25%). There was a significant correlation between individual stent configuration and stent compromise (P = .0385), with 31.25% of retrograde stents having any complication.

Conclusions: Parallel stent grafting offers an off-the-shelf option to treat a variety of aortic diseases. There is an increased risk of parallel stent and overall EVAR compromise with >10% main body oversizing. Thirty-day mortality is increased when more than one parallel stent is placed. Antegrade configurations are preferred in any retrograde configuration, with optimal oversizing >20%. (J Vasc Surg 2017;.)

Division of Vascular Surgery
Parallel graft, EVAR configuration plays an important role in determining results for Ch-EVAR procedures.
Configuration Affects Parallel Graft Results: Methods

- Institutional review board approval
- Retrospective review of prospectively collected database
- Jan 2010- Sep 2015
- Datasheet
  - Device type
  - PG type
  - PG Configuration
  - Oversizing %
Configuration Affects Parallel Graft Results: Methods

• Endpoints
  – PG compromise
    • Stenosis
    • Occlusion
  – Type Ia endoleak
  – AAA growth
  – Any MAE

• Statistical analysis
  – Chi square
  – Fisher exact test
  – Logistic regression
## Configuration Affects Parallel Graft Results: Results - Demographics

<table>
<thead>
<tr>
<th>Demographic Data</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>78</td>
</tr>
<tr>
<td>Number of Parallel grafts</td>
<td>145</td>
</tr>
<tr>
<td>Average Aneurysm Size</td>
<td>6.3cm (+/- 1.2)</td>
</tr>
<tr>
<td>Previous EVAR</td>
<td>19 (24%)</td>
</tr>
<tr>
<td>Ruptured AAA</td>
<td>5 (6.4%)</td>
</tr>
<tr>
<td>Average Number of PG’s</td>
<td>1.8 (+/- 0.9)</td>
</tr>
<tr>
<td>Average Follow up</td>
<td>311 days (+/- 347 days)</td>
</tr>
</tbody>
</table>
Configuration Affects Parallel Graft Results: Results - Type of PG

<table>
<thead>
<tr>
<th>PG Type</th>
<th>Number</th>
<th>PG complication</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viabahn (Gore)</td>
<td>61 (42.1%)</td>
<td>18.0%</td>
<td>NS</td>
</tr>
<tr>
<td>iCast (Atrium)</td>
<td>76 (52.4%)</td>
<td>14.5%</td>
<td>NS</td>
</tr>
<tr>
<td>Bare metal</td>
<td>8 (5.5%)</td>
<td>0</td>
<td>NS</td>
</tr>
</tbody>
</table>
Configuration Affects Parallel Graft Results:

Results – Type of EVAR/PG

<table>
<thead>
<tr>
<th>Repair Data</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic Endurant + iCast</td>
<td>16 (20.5%)</td>
</tr>
<tr>
<td>Medtronic Endurant + Viabahn</td>
<td>3 (3.8%)</td>
</tr>
<tr>
<td>Medtronic Endurant + Other</td>
<td>5 (6.4%)</td>
</tr>
<tr>
<td>Gore Excluder + iCast</td>
<td>6 (7.7%)</td>
</tr>
<tr>
<td>Gore Excluder + Viabahn</td>
<td>5 (6.4%)</td>
</tr>
<tr>
<td>Gore Excluder + Other</td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td>Cook Zenith + iCast</td>
<td>5 (6.4%)</td>
</tr>
<tr>
<td>Cook Zenith + Viabahn</td>
<td>3 (3.8%)</td>
</tr>
<tr>
<td>Cook Zenith + Other</td>
<td>2 (2.6%)</td>
</tr>
<tr>
<td>Other + iCast</td>
<td>10 (12.8%)</td>
</tr>
<tr>
<td>Other + Viabahn</td>
<td>8 (10.3%)</td>
</tr>
<tr>
<td>Other + Other</td>
<td>14 (17.9%)</td>
</tr>
</tbody>
</table>

*Device Type, combination NS With respect to Endoleak, PG compromise, AAA growth or MAE*
### Configuration Affects Parallel Graft Results: Results - Complications

<table>
<thead>
<tr>
<th>MAE</th>
<th>Rate n = 78</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a Endoleak</td>
<td>17.95%</td>
</tr>
<tr>
<td>Snorkel Compromise</td>
<td>18%</td>
</tr>
<tr>
<td>AAA growth</td>
<td>22.06%</td>
</tr>
<tr>
<td>30 d Mortality</td>
<td>6%</td>
</tr>
<tr>
<td>Secondary Intervention</td>
<td>5.13%</td>
</tr>
</tbody>
</table>
### Configuration Affects Parallel Graft Results:

**Results – PG Number/Orientation**

<table>
<thead>
<tr>
<th>Repair Data</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 or 2 Antegrade Parallel Stent</td>
<td>58 (74.4%)</td>
</tr>
<tr>
<td>1 or 2 Retrograde Parallel Stent</td>
<td>3 (3.8%)</td>
</tr>
<tr>
<td>1 Antegrade, 1 Retrograde Parallel Stent</td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td>2 Antegrade, 1 Retrograde Parallel Stent</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>2 Antegrade + 2 Retrograde Snorkel</td>
<td>5 (6.4%)</td>
</tr>
<tr>
<td>3 Antegrade Snorkel</td>
<td>8 (10.3%)</td>
</tr>
<tr>
<td>4 Antegrade Snorkel</td>
<td>1 (1.3%)</td>
</tr>
</tbody>
</table>

89% PG antegrade orientation
16 patients with 3 or 4 PG’s
Configuration Affects Parallel Graft Results: Results - % Oversizing

<table>
<thead>
<tr>
<th>EVAR Oversize (n)</th>
<th>Endoleak</th>
<th>PG Compromise</th>
<th>AAA growth</th>
<th>AAA MAE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-15% (15)</td>
<td>33.3%</td>
<td>40% * (p &lt; 0.05)</td>
<td>33.3%</td>
<td>73.3%*</td>
</tr>
<tr>
<td>15-20% (24)</td>
<td>20.59%</td>
<td>17.65%</td>
<td>20.59%</td>
<td>26.5%</td>
</tr>
<tr>
<td>&gt; 20% (34)</td>
<td>8.33%</td>
<td>8.3%</td>
<td>16.67%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>
Configuration Affects Parallel Graft Results:
Results – Logistic Regression

- 1 PG vs. all others associated with decreased MAE, OR 0.2, P = 0.0336
- Oversizing < 20% increased MAE’s, OR 24.6, p = 0.019
- PG compromise
  - Oversizing < 15%, OR 6.3, P = 0.0268
  - Orientation, NS
  - PG stent type, NS
Configuration Affects Parallel Graft Results:

Conclusions

- While Ch-EVAR provides an option for complex AAA repair, MAE’s not uncommon after Ch-EVAR procedures
- Oversizing < 20% significantly increases the risk of Type Ia endoleak, PG compromise, MAE’s
- Using more than 1 PG is associated with worse results
- Type of EVAR device, PG orientation or combination of EVAR and PG does not adversely influence PG results
Identification of optimal device combinations for the chimney endovascular aneurysm repair technique within the PERICLES registry

Salvatore T. Scali, MD, Adam W. Beck, MD, Giovanni Torsello, MD, Mario Lachat, MD, Paul Kubilis, MS, Frank J. Veith, MD, Jason T. Lee, MD, and Konstantinos P. Donas, MD, on behalf of the PERICLES investigators, Gainesville, Fla; Birmingham, Ala; Münster, Germany; Zurich, Switzerland; New York, NY; and Palo Alto, Calif

(J Vasc Surg 2018;:1-12.)
PERICLES Registry Results

Fig 1. Inclusion and exclusion criteria. This diagram highlights the inclusion and exclusion criteria that were employed to define the study population within the PERformance of chimney technique for the treatment of Complex aortic pathoLogiES (PERICLES) registry. There were 398 patients for analysis who had the selected indications and data on chimney/aortic stent graft type as well as the end points of chimney occlusion, type 1a endoleak, and survival. The information on the number of chimney stents implanted (one vs two or more) for each aortic stent graft category is also included. AAA, Abdominal aortic aneurysm; IMH, intramural hematoma; TAAA, thoracoabdominal aortic aneurysm.
Conclusions:
• Use of nitinol/polyester stent graft devices with BECS during chimney endovascular aneurysm repair is associated with improved survival compared with other aortic endografts.
• Repairs incorporating multiple chimney subtypes were also associated with increased mortality risk.
• Increasing chimney stent number and bare-metal endolining stents increase chimney occlusion risk.
• Patients treated at low-volume centers have higher risk of type Ia endoleak.
Medtronic Launches ENCHANT Study to Evaluate ChEVAR Parallel Graft Technique with the Endurant(TM) II/IIs Stent Graft System

January 24, 2018 7:00 AM CT

Medtronic

Clinical Study to Investigate the Performance of the ChEVAR Technique in AAA Patients with Short Aortic Necks

DUBLIN - January 24, 2018 - Medtronic plc (NYSE: MDT) today announced the launch of the ENCHANT (ENdurant CHEVAR New Indication Trial) study. The post-market, non-interventional, multi-center, non-randomized, single-arm study will enroll approximately 150 patients across 25 sites in Europe and Russia, and will evaluate the safety and performance of a ChEVAR procedure using the Endurant(TM) II/IIs stent graft system in a real-world setting. The first enrollment at St. Franziskus Hospital in Munster, Germany, was led by Professor Giovanni B. Torsello, M.D., chief of Vascular Surgery and principal investigator for the ENCHANT study.