With more than 1000 Gore Excluder Iliac Branch Endoprosthesis patients treated

Is preservation the new standard of care?

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Director, Maimonides Aortic Center
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Brooklyn, New York
AAA DISEASE
extends into the common iliac arteries

~ 25% OF ALL AAA CASES
Iliac Artery Aneurysms

• Complicated challenge for surgeons and interventionalists!

• Multiple surgical and endovascular options
The issue: Can we sacrifice the IIA?
Complications of intentional hypogastric artery occlusion

• claudication
• bowel ischemia
• sexual dysfunction
• spinal cord ischemia
• buttock necrosis
• death
Options

- Open repair
- Hybrid repair
- Endovascular
  - Sacrifice the IIA
  - Save the IIA
  - One or Both?
Open Direct Repair
the gold standard vs “old school”
Endovascular Treatment Options

Hypogastric Embolization
a.k.a. “Coil and Cover”

Chimney / Snorkel
a.k.a. “CHIMPS”
RYR sandwich experience

- 18 patients
- 24 “sandwiches”
- Transaxillary approach
- 75% patency (18/24) at 1 year (Viabahn)
- EVAR systems
  - Excluder (14)
  - Zenith (2)
  - Endurant (2)
How safe is it really to sacrifice the hypogastric artery?
Embolization and IIAA
Clinical outcomes after internal iliac artery embolization prior to endovascular aortic aneurysm repair.

Park KM, Yang SS, Kim YW, Park KB, Park HS, Do YS, Kim DI.
Division of Vascular Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, 50 Irwon-dong, Kangnam-gu, Seoul, 135-710, Korea.

Abstract

PURPOSE: The success of endovascular aortic aneurysm repair (EVAR) is highly dependent on the anatomical features of the aneurysm. In order to prevent type II endoleaks from the internal iliac artery (IIA), embolization of one or both IIAs may be required.

METHODS: A total of 150 patients were enrolled, and patients were divided into two groups: those who underwent IIA embolization and those who did not. The outcomes were compared between the two groups.

RESULTS: The rate of type II endoleaks was significantly lower in the group that underwent IIA embolization. The incidence of buttock claudication and sexual dysfunction was also significantly lower in this group.

CONCLUSION: Based on our experience, IIA embolization prior to EVAR is not a benign procedure. It can lead to numerous effects associated with pelvic ischemia, such as buttock claudication and sexual dysfunction. It is necessary to preserve both internal iliac arteries if possible, especially in young patients.
Safety of IIA sacrifice?

Can the internal iliac artery be safely covered during endovascular repair of abdominal aortic and iliac artery aneurysms?

Rhee RY, Muluk SC, Tzeng E, Missig-Carroll N, Makroun MS.
Division of Vascular Surgery, Department of Surgery, University of Pittsburgh Medical Center, PA 15213, USA. rheery@msx.upmc.edu

Abstract
Aneurysmal involvement of the common iliac (CIA) or the internal iliac arteries (IIA) have been relative contraindications for safe endovascular aortic aneurysm (AAA) repair. Our goal was to review our experience in dealing with this problem by performing permanent coverage of one or both IIA during endoluminal repair of aneurysms of the aortoiliac region and to develop a safe, durable strategy. Of the 228 consecutive patients who had endoluminal repair of abdominal aortic (AAA) and iliac artery (IAA) aneurysms between 4/1999 and 4/2001, 141 patients (62.5%) had aneurysms that involved the IIA. Of these, 112 patients had one or both IIA embolized with minimum adverse consequences in patients.

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Heart & Vascular Center
MAIMONIDES MEDICAL CENTER
IJA coiling during EVAR at UPMC in N=49 patients

Unilateral N=37

Bilateral N=12

## Complications of IIA occlusion

<table>
<thead>
<tr>
<th></th>
<th>Unilateral N=43</th>
<th>Bilateral N=6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Claudication</td>
<td>12 (28%)</td>
<td>2 (33%)</td>
</tr>
<tr>
<td>Persistent Claudication</td>
<td>3 (7%)</td>
<td>1 (17%)</td>
</tr>
<tr>
<td>Colon Ischemia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sexual Dysfunction</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Neurologic (spinal cord) Dysfunction</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Endoleak</td>
<td>2 (5%)</td>
<td>1 (17%)</td>
</tr>
<tr>
<td>Buttock Tissue Necrosis</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
</tbody>
</table>

### Reference

Philosophy of IIA coverage

Preserve at least one!
Clinical Value of Preservation

Society Clinical Practice Guidelines support the value of preservation

USA (SVS, 2009): recommended that blood flow be preserved to at least one hypogastric artery in the course of OSR or EVAR.

Europe (ESVS, 2011): Preservation of flow to at least one hypogastric artery is recommended in standard risk patients.
Endovascular Aneurysm Repair Treatment of Aortoiliac Aneurysms: Can Iliac Branched Devices Prevent Gluteal Claudication?

Taudorf M¹, Grønvall J², Schroeder TV³, Lönn L⁴.

Abstract

PURPOSE: To compare the risk of gluteal claudication after endovascular aneurysm repair (EVAR) of aortoiliac aneurysms by interventional exclusion of the internal iliac artery (IIA) with plugs or coils versus a branch iliac device to maintain pelvic blood supply and to identify risk factors for postoperative gluteal claudication.

MATERIALS AND METHODS: A retrospective analysis of a prospectively collected data set included patients with aortoiliac aneurysms treated with EVAR from January 2007 to December 2013 at a tertiary referral vascular unit. Descriptive and procedural data were obtained from a database of prospectively enrolled patients. Medical records of 112 consecutive patients treated with EVAR were scrutinized for graft-related adverse events and pelvic ischemia. The occurrence of gluteal claudication was determined from medical records.

RESULTS: Iliac occlusion was performed in 115 limbs, and a branch iliac device was placed in 25 limbs. Gluteal claudication developed in 38% of limbs treated with IIA exclusion but in none of the limbs treated with branch iliac devices (P < .001). Procedure time, fluoroscopy time, and use of iodine contrast material did not differ between the two groups. The incidence of gluteal claudication was higher when coils rather than plugs were used. The use of a branch iliac device significantly reduces the risk of gluteal claudication after EVAR.
Branched Iliac artery EVAR
• 64 M with hypertension.
• PShx: None FamHx: None
• 6.8X6.2 cm AAA
• 5.6 cm R CIA
• 6.3 cm L CIA
OR time 3.5 hrs
Contrast: 30 cc
Fluoro time: 20 min
US IBE 12-04 Trial

- Prospective, nonrandomized, multicenter, single-arm evaluation study
- COMPLETED ENROLLMENT
- 50 Investigational sites
- 60 subjects IDE trial plus 34 CA
- Subjects will be followed for 5 years
US IDE Preliminary Site Reported Data (n=88)

6 month follow up, N=70
- 0 migrations
- 1 claudication (location not reported by site)
- 1 reintervention (embolized Type II endoleak)

1 year follow up, N=53
No reinterventions, migrations, claudications
No new occlusions or endoleaks (Type I or III)
Iliac Branch Endoprosthesis provides a more durable solution to maintain perfusion

- Higher patency rates
- Lower rate of claudication and sexual dysfunction
- Lower procedure time, fluoro time, and amount of contrast used
- Lower reintervention rates

<table>
<thead>
<tr>
<th>Metric</th>
<th>CHIMPs⁸</th>
<th>Iliac Branch Endoprosthesis Clinical Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success*</td>
<td>88%</td>
<td>95.2%</td>
</tr>
<tr>
<td>Patency—External Iliac Artery</td>
<td>1 Month–95% 6 Months–93%</td>
<td>1 Month–100% 6 Months–100%</td>
</tr>
<tr>
<td>Patency—Internal Iliac Artery</td>
<td>1 Month–91% 6 Months–88%</td>
<td>1 Month–95% 6 Months–95%</td>
</tr>
<tr>
<td>Buttock Claudication</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Sexual Dysfunction</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Procedure Time (minutes)</td>
<td>231</td>
<td>151.8</td>
</tr>
<tr>
<td>Fluoro Time (minutes)</td>
<td>61</td>
<td>40</td>
</tr>
<tr>
<td>Contrast Used (mL)</td>
<td>130</td>
<td>114</td>
</tr>
<tr>
<td>Aneurysm Increase (&gt; 5 mm)</td>
<td>1 Month–0% 6 Months–0%</td>
<td>6 Months–0%</td>
</tr>
<tr>
<td>Aneurysm Decrease (&gt; 5 mm)</td>
<td>1 Month–0% 6 Months–0%</td>
<td>6 Months–0%</td>
</tr>
<tr>
<td>Freedom from Reintervention</td>
<td>6 Months–87%</td>
<td>6 Months–96%</td>
</tr>
</tbody>
</table>

IBE Comparison to Chimneys and Snorkels
Recently Received CE Mark

October, 2013

1000+ cases
ICEBERG REGISTRY

Retrospective

51 CIA treated in 46 patients
11% bilateral
16% IBE only
16% out of IFU

Operational time: 198 min
Fluoro Time: 41 min
Hospital Stay: 3.5 days
13% endoleaks: 4% type Ib, 7% type II and 2% unknown
ICEBERG REGISTRY

Retrospective

30 days results:
- 0 ruptures
- 1 external iliac artery stenosis
- 1 internal iliac artery occlusion
- 3 pt developed claudication (2 on the IBE side)
- 1 pt out of 21 have erectile dysfunction

6 months results (N = 29):
- Primary patency of 94%
- 7% reinterventions (treating type Ib endoleaks and external iliac artery stenosis)
Initial results of the management of aortoiliac aneurysms with GORE® Excluder® Iliac Branched Endoprosthesis.

Schönhofen S, Mansour R, Ghotbi R.

Abstract

AIM: We prospectively observed the outcomes of all patients (N=15) with an aortoiliac and a common iliac artery aneurysm who were electively treated with the GORE® Excluder® Iliac Branched Endoprosthesis (IBE) with regard to clinical, anatomical and radiological results.

METHODS: We evaluated operative mortality, aneurysm rupture rate and aneurysm related mortality as well as conversion to open surgery, incidence of endoleak, rate of aneurysm migration, aneurysm enlargement, graft patency, reintervention rate and the clinical outcome. Postoperative follow-up included a computed tomography angiography (CTA) before discharge, clinical evaluation and Duplex ultrasound or CTA 3 weeks after the intervention and Duplex ultrasound every 3 months afterwards.

RESULTS: Mean patient age was 79 years (range 61-83 years); f/m: 1/2; mean follow-up was 9 months; 80% of the patients presented 2 or more iliac side branches remained patent. Reintervention rate, buttock claudication rate and pelvic complication rate were 0%.

CONCLUSION: The GORE® IBE provides a new and safe alternative for the management of complete endovascular repair of an extensive aortoiliac or common iliac aneurysm while maintaining pelvic blood flow in iliac branched devices. Due to the lower complexity if compared to previous endovascular or hybrid methods, it should be performed in every anatomically suitable case.
Ongoing IBE Clinical Registries

Iliac Branch Excluder ReGistry (ICEBERG) in Netherlands (prospective)

Comparison of Aortoiliac Repair with Iliac Branch Endoprosthesis versus hypogastric occlusion in aorto-iliac aneurysms (CARIBE) in Italy
Conclusion

• Unilateral hypogastric artery disruption is relatively well tolerated but can have significant consequences such as bowel ischemia.
• Patients are rarely completely asymptomatic
• Claudication symptoms are usually temporary but real
• Bilateral IIA coverage should be avoided if possible.....complications can be severe!
Conclusion

• Sandwich techniques are OK in certain anatomic situations but not ideal, IIA graft patency is questionable

• Branch graft systems have excellent IIA patency

• **NO REASON TO SACRIFICE AN IIA IN 2016** with currently available branched systems
QUESTION

Is preservation of IIA the new standard of care?

YES!
Thank you!
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