Repositionable iliac branch endoprosthesis

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Disclosures

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Common iliac artery aneurysms

- Isolated common iliac artery aneurysms are rare with and incidence of <1%
- Common iliac artery aneurysms are more common in conjunction with AAA and then often bilateral
- Eurostar data:
 - CIA in 28% of 6,286 EVAR patients
 - Patients with CIA had more:
 - Type Ib and II endoleaks
 - Secondary re-interventions
 - Aneurysm ruptures

Sandu RS, et al. Semin Vasc Surg 2005 Dec;18(4):209-15 Hobo et al. J Endovasc Ther 2008 Brunkwall, J., et al. Vasc Surg 1989 Oct;10(4):381-4 Armon MP, et al. Eur J Vasc Endovasc Surg. 1998 Mar;15(3):255-7



Endovascular treatment options

- Coil-and-coverage of the internal iliac artery
- Preservation of the internal iliac artery:
 - Bell-bottom limb
 - Off-label endovascular techniques
 - Sac anchoring techniques
 - Iliac branched devices



Coil and cover internal iliac artery

- Occlude internal iliac artery and cover with endograft with sealing in the external iliac artery
- Buttock claudication:
 - Unilateral
 - Bilateral
- Erectile dysfunction:
 - Unilateral
 - Bilateral
- Colonic ischemia
- Spinal ischemia

27% (range 14-50%) 32% (range 13-80%)

14% (range 11-45%) 18% (range 11-50%) up to 3% <1%





Verzini F, et al. J Vasc Surg 2009;49(5):1154-61 Farahmand et al. Eur J Vasc Endovasc Surg 2008;35(4):429-35 Lin PH, et al. Semin Vasc Surg 2009;22:193 Rayt HS, et al. Cardiovasc Intervent Radiol 2008;31:728–34

Bell bottom iliac limbs

- An adequate sealing zone of at least 1.5 cm proximal of the origin of the IIA
- Does not imply a higher risk of reintervention or endoleak compared to regular EVAR
- Reinterventions and perioperative complications lower compared to coil and coverage strategy
- Maximum CIA diameter of 24-25 mm limited applicability



Outside IFU techniques

- Parallel or chimney grafts
- Trifurcated endograft technique with a second bifurcated endoprosthesis
- AUI with cross-over and 'banana' graft EIA-IIA
- Upside-down Excluder limb



Iliac Branched Devices

Cook[®] Zenith[®] Branch Iliac Endovascular Graft

- First branched endoprosthesis for the treatment of common iliac aneurysm s (CE mark October 2006)
- 20 Fr introducer sheath
- Single component **no dedicated internal iliac component**
- Requires additional covered stent (Other platform , mostly BE)
 - ATRIUM[®] ADVANTA V12 Covered Stent
 - BARD[®] FLUENCY[®] PLUS Stent Graft
- Technical success rate 85-100%
- Initial results included:
 - Endoleak rate 3% 30%
 - Patency

91%-96% at one year

81% at three years

Parlani G, et al. Eur J Vasc Endovasc Surg 2012;43(3):287-292. Malina M, et al. J Endovasc Ther 2006;13(4):496-500. Karthikesalingam A, et al. Eur J Vasc Endovasc Surg 2010;39(3):285-294 Loth AG, et al, J Vasc Surg 2015 Nov;62(5):1168-75. Lebas B, et al. Ann Vasc Surg. 2016 Mar 4. [Epub ahead of print]



Iliac Branched Devices

Gore Excluder Iliac Branch Endoprosthesis

- CE mark November 2013
- Used in conjunction with the Excluder endoprosthesis
- 16 Fr introducer sheath
- Option for repositioning
- SE Iliac component based on the same platform

Instructions for Use:

- Minimum common Iliac diameter 17 mm at the proximal implantation zone of the IBE
- External Iliac artery treatment diameter range of 6.5–25 mm and seal zone length of at least 10 mm
- Internal Iliac artery treatment diameter range of 6.5–13.5 mm and seal zone length of at least 10 mm



Iliac Branched Devices *Gore Excluder Iliac Branch Endoprosthesis*



Retrospective cohort study of patients treated in the Netherlands

- November 2013 December 2014
- 13 sites in the Netherlands
- 51 CIA aneurysms in 46 patients
- Age
- Male gender
- Bilateral treatment
- IBE only
- Treated outside IFU

70.2 ± 8.5 year 45/46 (98%) 5/46 (11%) 7/46 (16%) 7/46 (16%)



van Sterkenburg SM, Heyligers JM, van Bladel M, Verhagen HJ, Eefting D, van Sambeek MR, Zeebregts CJ, Reijnen MM, for the Dutch IBE collaboration. Early experience with the GORE[®] EXCLUDER[®] Iliac Branch Endoprosthesis for common iliac artery aneurysms in the Netherlands. J Vasc Surg, in press.

Retrospective cohort study of patients treated in the Netherlands *Anatomical characteristics*

Maximum diameter right CIA (mm)	38.5 (12.0-90.0)
Maximum diameter left CIA (mm)	31.0 (12.0-73.0)
Length right CIA (mm)	70.0 (44.0-182.0)
Length left CIA (mm)	68.0 (40.0-155.0)
Maximum diameter right IIA (mm)	10.0 (3.0-18.0)
Maximum diameter left IIA (mm)	10.0 (6.0-21.0)
Maximum diameter right EIA (mm)	12.0 (9.0-17.0)
Maximum diameter left EIA (mm)	12.0 (7.0-15.0)
Diameter infrarenal aortic neck (mm)	22.0 (18.0-30.0)
Maximum diameter infrarenal aorta (mm)	44.5 (19.0-80.0)



Retrospective cohort study of patients treated in the Netherlands *Procedural data*

General anesthesia **Contralateral IIA embolized** \bullet **Operation time** ulletImmediate endoleak Type Ib ٠ Type II ۲ Unknown ۲ **Technical success** Hospitalization time \bullet

44/46 (96%) 9/44 (20%) 198 ± 56 min n=6 (13%) n=2 (4%) n=3 (7%) n=1 (2%) 94% (one implant failure) 3.5 ± 1.5 days

Retrospective cohort study of patients treated in the Netherlands *Results*

Follow-up		At 30-days (n=40)	At 6 months (n=28)
Mortality		0 (0%)	1 (4%)
Re-interventions		0 (0%)	2 (7%)
External iliac limb stenosis/occlusion		1 (3%)	1 (4%)
Internal iliac limb stenosis/occlusion		1 (3%)	2 (7%)
Endoleak		6 (15%)	5 (18%)
	Type Ib	0 (0%)	1 (4%)
	Type II	5 (13%)	4 (14%)
	Unknown	1 (3%)	0 (0%)
Intermittent buttock claudication	Contralateral	2 (5%)	0 (0%)
	Ipsilateral	2 (5%)	1 (4%)
Erectile dysfunction		1 (3%)	2 (7%)

Retrospective cohort study of patients treated in the Netherlands Latest follow-up (n=29, 32 IBE devices): mean 5.8 months

- Primary patency IIA limb at six months is 94%
- Significant decrease in CIA aneurysm diameter:
 - Baseline 42.4 ± 7.2 mm
 6 months 38.4 ± 7.5 mm
- Re-interventions preformed in 2 patients (7%):
 - BE stent external iliac limb stenosis
 - Type 1b endoleak

Iliac Branched Devices

Gore Excluder Iliac Branch Endoprosthesis

Lessons learned:

- Use a 0.035 " flexible throughwire in combination with a 12 Fr flexible sheath
- Take care to avoid wrapping of throughwire
- Change for 0.018" guidewire in case of resistance advancing internal component
- Use repositioning option to optimize position
- Device can be used for revision after EVAR
- Combination of the internal component with proximally flaired BE stent in case of diameter discrepancy





Courtesy of Dr. Flett, Ninewells, Dundee

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Revision after EVAR



Combination with tapered BE stentgraft

Overview data on iliac branched devices

Author (Year)	N	Branches	Mortality	Technical success	Mean FU (months)	Branch occlusion	Re- intervention
Haulon (2006)	52	53	0%	94%	14	11%	-
Dias (2008)	22	23	0%	91%	20	13%	18%
Ferreira (2010)	37	54	0%	97%	22	11%	-
Parlani (2012)	100	100	0%	95%	17	7%	9%
Wong (2013)	130	138	0%	94%	20	15%	16%
Bisdas (2014)	18	22	0%	100%	-	0%	10%
Pratesi (2014)	81	85	0%	99%	20	2%	12%
Torsello (2015)	178	188	0.3%	99%	20	8%	23%
GORE Trial (2015)	75	78	0%	99%	6	3%	1%
Cook Trial (2015)	40	40	0%	100%	7	0%	8%
Lebas (2016)	25	26	0%	96%	6	4%	4%
Van Sterkenburg (2016)	40	51	0%	94%	6	6%	5%

Trend towards a lower rate of branch occlusions and re-interventions during time

Iliac Branch Excluder ReGistry – ICEBERG

- Multi-centre, observational, post-market, real world registry
- 10 European sites
- 100 Consecutive patients with follow-up to 5 years

Inclusion criteria

- Age 18 years or older
- Written informed consent
- Elective procedure
- Indication for aorto-iliac endovascular stent graft repair

Exclusion criteria

- Patient's life expectancy <2 years</p>
- Psychiatric or other condition that may interfere with the study
- Allergy to any device component
- Patient with a systemic infection
- Coagulopathy or uncontrolled bleeding disorder
- Acute or mycotic aneurysm
- CVA or MI within the prior three months Pregnancy

Other stents placed in CIA or hypogastric arteries than the Gore[®] EXCLUDER[®] iliac branch Endoprothesis

Iceberg registry





Iceberg registry Endpoints



• Primary endpoints:

- Primary patency of hypogastric side branch at 1 year
- Successful exclusion of the aneurysm without type I endoleak at 1 year

Secondary endpoints:

- 30 day morbidity
- Complications during follow-up including any endoleak, aneurysm sac expansion, migration, conversion to open repair
- Primary-assisted and secondary patency of hypogastric artery
- Secondary endovascular procedures
- Clinical success, defined as freedom from flow-limiting stenosis and from new onset of clinical ischemic symptoms (buttock claudication, erectile dysfunction, bowel ischemia)
- Freedom from buttock claudication; Walking impairment questionnaire (WIQ)
- Freedom from Erectile dysfunction; (International Index of Erectile Function (IIEF-5)

Iceberg registry Design



- Enrollment anticipated in 2016 and 2017
- 19 patients included to date
- Scheduled analysis
 - 30-day outcome after inclusion of the target population
 - After completion of 1 year follow-up
 - After completion of 5 year follow-up
- Analysis on intention to treat base

Conclusions

- Hypogastric artery preservation is indicated when treating common iliac artery aneurysms, especially in young patients
- Iliac branched devices are the treatment of choice for CIA aneurysms with a diameter >25mm
- Initial results with the Gore IBE device are promising:
 - Low complication and re-intervention rates at short-term follow-up
 - Low incidence of ischemic complications
 - 17 % outside Instructions for Use and learning curve
- Results of the ICEBERG registry expected in Q4 2017

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