Literature Summary

GORE EXCLUDER®

ILIAC BRANCH
ENDOPROSTHESIS

PERFORMANCE
through experience

Early Experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis

Schönhofer S, Mansour R, Ghotbi R. **Initial results of the management of aortoiliac aneurysms with GORE® Excluder® Iliac Branched Endoprosthesis.** *Journal of Cardiovascular Surgery* 2015;56(6):883-888.

Objectives
A prospective observation of the outcomes of all patients with an aortoiliac and a common iliac artery aneurysm who were electively treated with the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE).

Summary of Results

15 Patients, Mean follow-up of 9 months
93.3% (14 / 15) Procedural technical success
0% Perioperative mortality
0% Buttock claudication or any sign of pelvic ischemia was reported
0 IBE occlusions, **100%** Patency of internal iliac side branch
0 Type Ia, Ib, or III endoleaks were observed
20% Type II endoleak
0% Reintervention
5 Days mean hospital stay

Summarized Conclusion
The 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 when compared to previous endovascular or hybrid methods, it should be performed in every anatomically suitable case.

Millon A, Schiava ND, de Lambert A, *et al*. **Endovascular treatment of iliac aneurysms: short-term results of a new branched iliac stentgraft.** Presented at the 30th Annual Meeting of the French Society for Vascular Surgery (SCV); June 27-29, 2015; Montpellier, France. *Annals of Vascular Surgery* 2015;29(6):1045.

Objectives
A retrospective monocentric study to evaluate the short-term results of the new GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) for the treatment of common iliac artery (CIA) aneurysms without a distal neck.

Summary of Results

10 Consecutive Patients, 30-day Results Discussed
No technical failures observed
No perioperative complications observed
100% Patency of branches (internal and external) at 30 days
1 Type Ia endoleak identified on GORE® EXCLUDER® Device, treated with aortic extender POD3
0 Type Ib or III endoleaks
4 Days mean hospital stay

Summarized Conclusion
The technical success rate and the results at 30 days of this new stent-graft are very encouraging. A long-term follow-up is necessary.

Ferrer C, De Crescenzo F, Coscarella C, Cao P. **Early experience with the Excluder Iliac Branch Endoprosthesis.** *Journal of Cardiovascular Surgery* 2014;55(5):679-683.

Objectives

To evaluate early results with the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) in the treatment of iliac aneurysms associated or not with abdominal aortic aneurysms.

Summary of Results

7 IBE in 5 Patients, Reported up to 30 Days
100% Technical success
100% Branch patency
No 30-day mortality
In 1 of 2 bilateral cases, endovascular relining with bare stents was required due to compression of the iliac legs (of the GORE® EXCLUDER® AAA Endoprosthesis) at the level of the aortic bifurcation

Summarized Conclusion

Use of the IBE in the treatment of aorto-iliac disease is feasible and safe. Late results are necessary to evaluate the performance of this endograft in the long-term.

Alternative Treatment Methods

Embolization (aka Coil and Cover)

Kalteis M, Gangl O, Huber F, Adelsgruber P, Kastner M, Lugmayr H. **Clinical impact of hypogastric artery occlusion in endovascular aneurysm repair.** *Vascular* 2015;23(6):575-579.

Objectives

Single site, retrospective study to evaluate results of patients who had hypogastric artery (HA) embolization during EVAR (n = 24) with patients who had EVAR without HA involvement (n = 82). The purpose of this study was to determine the impact of HA embolization on long-term clinical and technical outcomes.

Summary of Long-Term Results

- Persistent buttock claudication and erectile dysfunction were more frequent in the HA embolization group with high significance.
- Several patients effected by new onset erectile dysfunction complained about a reduction in their quality of life due to this new symptom.

	EVAR without HA Involvement (n = 82)	HA Embolization (n = 24)
Mean follow-up	46.6 months	41.8 months
Long-term clinical success	87.3%	80%
Reintervention	12.8%	22.7%
Aneurysm growth	9.4%	27.8%
Late rupture	1.2%	12.5%
Complication	2.4%	12.5%
Buttock claudication	8.6%	43.8%
New onset erectile dysfunction	17.3%	42.9%

Summarized Conclusion

EVAR patients with HA embolization have an increased risk of operative complications, late rupture, ongoing buttock claudication, and new onset erectile dysfunction over the long-term. *"Therefore, alternative treatment modalities, such as branched endografts or open repair, should be considered for these patients."*

Lin PH, Chen AY, Vij A. **Hypogastric artery preservation during endovascular aortic aneurysm repair: is it important?** *Seminars in Vascular Surgery* 2009;22(3):193-200.

Objectives

This article examines:

- The natural history of hypogastric artery (HA) embolization and clinical data regarding the safety and complications following this procedure.
- Clinical studies regarding risk factors that might contribute to ischemic complication following HA embolization.
- Treatment strategies to preserve the HA.

Summary of Key Points

- Includes a literature review of papers that compared clinical outcomes and risks associated with HA embolization.
- Summary of the patients who developed buttock claudication and / or erectile dysfunction following HA embolization from the papers reviewed:

First Author (year)	Number of Patients	Claudication		Erectile Dysfunction	
		n	%	n	%
Cynamon (2000)[1]	34	13	40	N / A	
Razavi (2000)[2]	32	9	28	2 / 16	13
Karch (2000)[3]	22	7	32	N / A	
Criado (2000)[4]	39	5	13	N / A	
Lee (2000)[5]	27	5	19	N / A	
Yano (2001)[6]	103	21	20	N / A	
Lee (2001)[7]	23	9	39	N / A	
Mehta (2001)[8]	107	17	16	7 / 73	10
Wolpert (2001)[9]	18	8	44	N / A	
Lyden (2001)[10]	23	7	30	N / A	
Schoder (2001)[11]	46	21	46	5 / 20	25
Lin (2002)[12]	12	6	50	5 / 11	45
Rhee (2002)[13]	49	14	29	N / A	
Wyers (2002)[14]	11	5	45	N / A	
Engelke (2002)[15]	16	4	25	N / A	
Kritpracha (2003)[16]	20	9	45	N / A	
Tefera (2004)[17]	13	4	31	N / A	
Mehta (2004)[18]	32	5	16	2 / 18	11
Arko (2004)[19]	12	6	50	N / A	
Farahmand (2008)[20]	101	51	50	19 / 101	20
Bratby (2008)[21]	39	12	31	2 / 39	5
Ryat (2008)[22]	29	16	55	5 / 29	17

Abbreviations: N / A not available.

Summary of Key Points *(continued)*

- 3.4% overall incidence of colonic ischemia following EVAR with HA embolization based on available literature.
- One reference indicated three risk factors for pelvic ischemia:
  - > 70% stenosis of the origin of the contralateral hypogastric
  - Absence of filling of three or more named hypogastric branches
  - Disease /absence of ascending branches from the femoral artery

Summarized Conclusion
HA embolization during EVAR is not benign and can lead to numerous pelvic ischemic complications. Current literature advocates to avoid bilateral HA embolization if possible. Availability of branch stent-grafts may preclude the need for HA embolization.

Ryer, Evan J., *et al.* **Comparison of outcomes with coils versus vascular plug embolization of the internal iliac artery for endovascular aortoiliac aneurysm repair.** *Journal of Vascular Surgery* 56.5 (2012): 1239-1245.

Objectives
Six-year retrospective study comparing the safety and efficacy of coil embolization to vascular plug embolization to achieve internal iliac artery (IIA) occlusion prior to EVAR.

Summary of Results

- 57 IIAs were embolized between January, 2004 and December, 2010.

	COIL EMBOLIZATION (N = 29 IIAS)	PLUG EMBOLIZATION (N = 28 IIAS)
Number of embolization devices used	5.8 ± 3.8	1.1 ± 0.4
Procedure time	118.4 ± 64.7 minutes	72.6 ± 22.4 minutes
Fluoroscopy time	32.6 ± 14.6 minutes	14.4 ± 8.6 minutes
Patient reported buttock claudication at one month	17.2%	39.3%
Average hospital costs	$44,720 ± 19,153	$37,367 ± 10,915
Mean follow-up	39.3 ± 24.2 months	34.8 ± 14.9 months

Summarized Conclusion
Plugs and coils were both successful at occluding internal iliac arteries prior to EVAR. Claudication occurred in approximately one-third of patients with either embolization modality. More serious complications were not seen in this study.

Alternative Treatment Methods

Parallel Stenting (aka CHIMPs)

DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. **Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoilac endovascular abdominal aortic aneurysm repair.** *Journal of Vascular Surgery* 2012;56(5):1252-1259.

Objectives

Multicenter retrospective study to assess the technical feasibility and short term outcomes of double-barrel (parallel) endograft repair of aortoiliac aneurysms to preserve hypogastric flow.

Summary of Results

	N = 21 Patients
Mean follow-up	7.2 months (range: 1–20 months)
Mean operative time	231 minutes
Mean fluoroscopy time	61 minutes
Number of implanted devices: – Mean for unilateral procedures – Mean for bilateral procedures	 5.6 devices 8 devices
Endoleak Rates	
Type Ib	4.7% (1 / 21)
Type II	14.3% (3 / 21)
Type III between branch components*	9.5% (2 / 21)
Patency rates	
Internal iliac artery	91% at 1 month 88% at 6 months
External iliac artery	95% at 1 month 93% at 6 months
Additional Outcomes	
Buttock claudication or sexual dysfunction with two patent iliac arteries	0
Postoperative buttock claudication**	19% (4 / 21) patients
> 5 mm aneurysm increase	0 at 6 months
Freedom from reintervention	87% at 6 month

* Treated with repeat ballooning without success. Spontaneously resolved by next follow-up scan.

** With unilateral embolization when hypogastric preservation was performed on the contralateral side only.

Summarized Conclusion

Off-label solutions, such as the double-barrel technique, can be utilized to treat aortoiliac aneurysmal disease using commercially available devices without device modification. Limb-patency and endoleak rates appear similar to those in published reports of bifurcated devices designed for hypogasteric preservation. Long-term follow-up will be required to determine the durability of this treatment.

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INDICATIONS FOR USE IN THE US: Iliac Branch and Internal Iliac Components. The GORE® EXCLUDER® Iliac Branch Endoprosthesis is indicated for use with the GORE® EXCLUDER® AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: Adequate iliac / femoral access; minimum common iliac diameter of 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; adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy), and gold. Patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. ℞ Only

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