Successful off-label use of the GORE EXCLUDER Iliac Branch Endoprosthesis to preserve gluteal perfusion during staged endovascular repair of bilateral isolated hypogastric aneurysms

James W. Cornwall, MD, Daniel K. Han, MD, Daniel I. Fremed, MD, Peter L. Faries, MD, *and* Ageliki G. Vouyouka, MD, *New York, NY*

Endovascular repair of iliac artery aneurysms has emerged as an alternative to traditional open surgical repair. Although there is little consensus on indications to preserve hypogastric blood flow during aneurysm repair, it is well understood that complications from bilateral hypogastric occlusion may be significant. The GORE EXCLUDER Iliac Branch Endoprosthesis (W. L. Gore and Associates, Flagstaff, Ariz) received United States Food and Drug Administration approval in March 2016 for treatment of common iliac artery and aortoiliac aneurysms. This case report discusses an off-label use of GORE EXCLUDER Iliac Branch Endoprosthesis to maintain pelvic perfusion during treatment of bilateral internal iliac artery aneurysms without surrounding aortoiliac pathology. (J Vasc Surg Cases and Innovative Techniques 2017;3:37-40.)

Endovascular repair of iliac artery aneurysms is an emerging alternative to open surgical repair. One challenge with endovascular aneurysm repair (EVAR) is the preservation of hypogastric artery perfusion. Complications from bilateral hypogastric occlusion may be significant (buttock claudication and erectile dysfunction) or even devastating (pelvic ischemia, colon ischemia, paralysis).[1]

The GORE EXCLUDER Iliac Branch Endoprosthesis (IBE; W. L. Gore and Associates, Flagstaff, Ariz) received United States Food and Drug Administration approval in March 2016 for endovascular treatment of common iliac aneurysms as an adjunct to EVAR, offering a solution to preserve hypogastric perfusion. The device is a bifurcated stent graft with one branch extending into the hypogastric artery and one branch extending into the external iliac artery.

We present an off-label application of the GORE EXCLUDER IBE to treat an isolated internal iliac artery aneurysm (IIIAA) as part of a two-staged repair of bilateral IIIAAs, one of which was ruptured during the initial presentation. The patient was informed and consented to the writing of this report.

CASE REPORT

Initial presentation. A 70-year-old man presented to the emergency department with sudden right flank and groin pain, tachycardia, and tenderness along right lower quadrant and buttock. His medical history included hypertension, hyperlipidemia, nephrolithiasis, erectile dysfunction, and prior smoking. A computed tomography scan demonstrated a ruptured 5-cm right hypogastric artery aneurysm, free fluid in the pelvis, a 3.5-cm left hypogastric artery aneurysm, and a normal aorta and common iliac arteries (Fig 1).

EVAR of ruptured right hypogastric aneurysm. The anterior and posterior divisions of the hypogastric artery were cannulated and embolized using a microcatheter system. The main hypogastric artery was then embolized back to the iliac bifurcation. A GORE EXCLUDER iliac limb was used to cover the origin of the hypogastric artery and exclude the ruptured aneurysm (Fig 1). The patient was discharged without symptoms.

Follow-up. On follow-up, the patient complained of right buttock claudication, which resolved completely after 2 months. His erectile dysfunction remained unchanged. While discussing elective repair of the left IIIAA and the possibility of hypogastric embolization, the patient was more concerned about lifestyle-limiting buttock claudication during walking or biking. Different endovascular options were discussed, including double-barrel and cross-chimney technique. He opted for the off-label use of the GORE EXCLUDER IBE, which involved extending one limb to the gluteal artery and embolizing the anterior division, ultimately excluding the aneurysm while perfusing the gluteal muscles.

Technical considerations. The GORE EXCLUDER IBE has an iliac branch component and an internal iliac component. The iliac branch component has a proximal diameter of 23 mm, distance to iliac gate of 55 mm, and total length of 100 mm. The internal iliac component has an overall length of 7 cm and variable distal diameters (10, 12, and 14.5 mm) to treat internal iliac vessel diameters of 6.5 to 13.5 mm, respectively. The

From the Division of Vascular Surgery, Department of Surgery, Mount Sinai Medical Center.

Author conflict of interest: none.

Correspondence: Dr Ageliki G. Vouyouka, MD, 1190 Fifth Ave, 1st Flr Guggenheim Pavilion Center, New York, NY 10029 (e-mail: ageliki.vouyouka@mountsinai.org).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2468-4287

http://dx.doi.org/10.1016/j.jvscit.2016.11.001

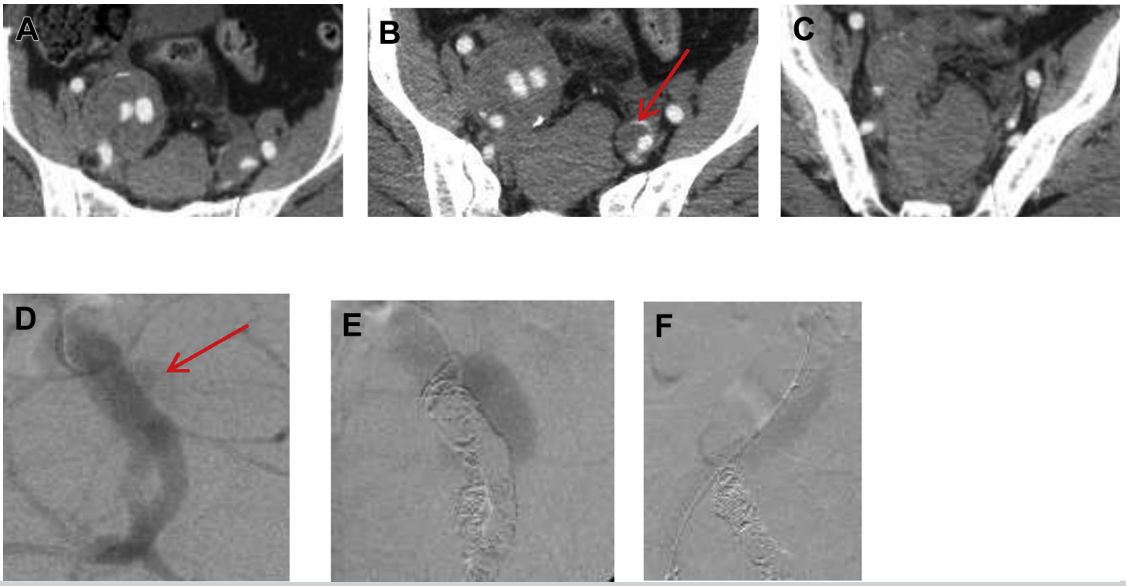

Fig 1. A-C, Computed tomography angiogram and **(D-F)** intraoperative angiogram on the day of initial presentation. **A,** Large 5.5-cm right and 3.5-cm left isolated iliac artery aneurysms are demonstrated. Measurements were infrarenal aorta diameter, 2.0 cm; the right common iliac artery, 1.6 cm; left common iliac artery, 1.6 cm; right external iliac artery, 1.1 cm; left external iliac artery, 1.0 cm; and left gluteal artery, 0.6 cm. **B,** At 2 cm distal to *A*, the left hypogastric artery aneurysm (*red arrow*) is better visualized. **C,** Contained rupture of the right internal iliac artery with free fluid in the retroperitoneum. **D,** Right hypogastric aneurysm with active extravasation after selective catheterization of the right internal iliac. The *red arrow* is pointing to the cavity of the aneurysm with extravasation. **E,** Contained rupture after embolization of the anterior and posterior division of the internal iliac. **F,** Exclusion of right internal iliac aneurysm after further embolization and endograft placement.

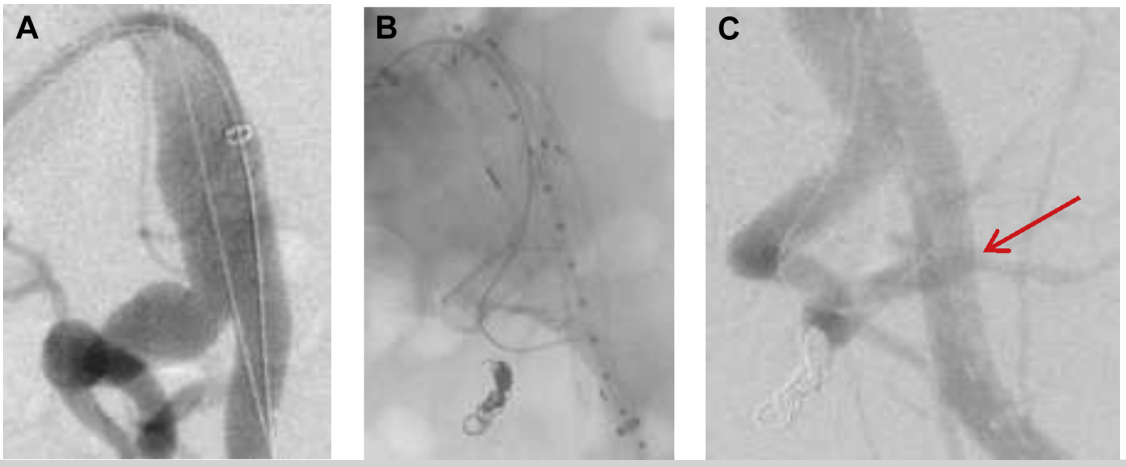

Fig 2. Intraoperative angiogram from elective repair of left hypogastric aneurysms with GORE EXCLUDER Iliac Branch Endoprosthesis (IBE; W. L. Gore and Associates, Flagstaff, Ariz) device. **A,** Intraoperative angiogram demonstrates a left isolated internal iliac aneurysm. **B,** The main body of the IBE is deployed in the common iliac artery with embolization coils in the anterior division and the IBE limb extending into proximal portion of posterior division of hypogastric artery. **C,** Completion angiogram demonstrates flow through the posterior division and collateral perfusion to the buttock. No endoleak is seen. The *red arrow* shows the distal end of a Viabahn covered stent (W. L. Gore and Associates) at the takeoff of gluteal artery.

instructions for use (IFU) specify a minimum of 10 mm of overlap is required at the distal and proximal landing zones.[2]

The patient's common iliac artery was >55 mm long, allowing for deployment of the device within the iliac vessels and not compromising the aortic bifurcation. The left common iliac diameter was 14 mm at the origin and 16 mm at the bifurcation. The distal gluteal artery was 8 mm in diameter. We chose the gluteal artery as a landing zone because it had an adequate diameter, enough length for at least a 10-mm landing zone, lacked tortuosity, and addressed the patient's primary concern

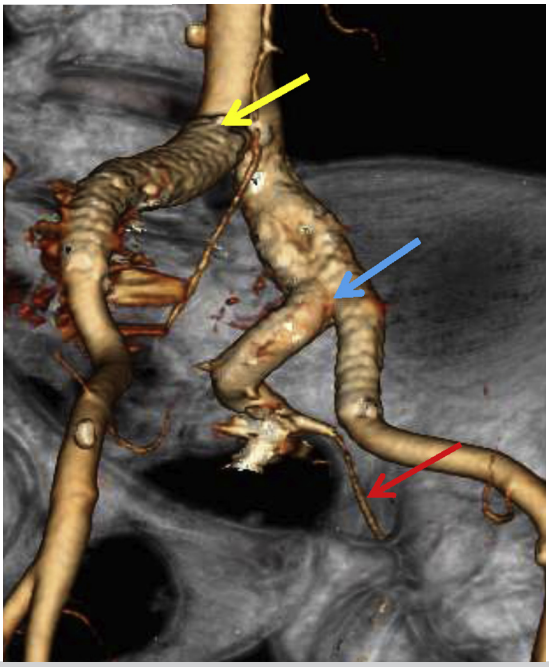

Fig 3. A three-dimensional reconstruction of a computed tomography angiogram at the 1-month follow-up visit after elective repair of left hypogastric iliac artery aneurysm repair shows good positioning of grafts in the right and left iliac arteries. The branched device can be seen on the left side with inclusion of hypogastric and external iliac artery (*red arrow*). The patent gluteal artery on left side can also be seen as well (*blue arrow*). The GORE EXCLUDER (W. L. Gore and Associates, Flagstaff, Ariz) iliac limb (*yellow arrow*) is seen in the right common and external iliac artery.

of buttock claudication. We planned to use the 10-mm-diameter internal iliac component. Although the distal landing zone was adequately sized according to the IFU, we were concerned about the common iliac, which was smaller than the 17 mm required in the IFU. In the event of stent collapse, we planned to use Palmaz stent (Cordis, Miami Lakes, Fla) as bailout. The iliac limb would be extended with 10-mm × 50-mm Viabahn covered stents (W. L. Gore and Associates) to the gluteal artery.

EVAR of the left hypogastric aneurysm. Through bilateral percutaneous access, the left hypogastric artery was accessed in an up-and-over fashion. The anterior branch was coil embolized through a microcatheter using a guidewire. The IBE 23-mm main body was advanced from the left groin to the level of the aortic bifurcation. The gate was opened ~10 mm above the iliac bifurcation. There was no evidence of infolding or collapse at the proximal site. The precannulated gate was accessed with an up-and-over 14F sheath. A 0.035-inch Glidewire (Terumo Medical Corp, Somerset, NJ) was used to enter the aneurysm and left gluteal artery. An iliac limb was deployed into the hypogastric artery and extended with a 10-mm × 50-mm Viabahn covered stent to the gluteal artery. The stents were deployed in a proximal-to-distal manner because there was no size discrepancy.

A completion angiogram demonstrated successful exclusion of the aneurysm with perfusion maintained to the gluteal artery (Fig 2). The patient was discharged home on postoperative day 1. At 1 month after the repair, he was asymptomatic. A computed tomography angiogram (Fig 3) showed aneurysm exclusion and patent gluteal artery.

DISCUSSION

Isolated iliac artery aneurysms are present in ~0.03% of general population. IIIAA are even rarer, comprising <30% of all isolated iliac aneurysms.[3] After compiling all the existing case reports of IIIAAs from 1913 to 2013, Wilhelm et al[4] found only 55 cases, with only 10% of IIIAA being bilateral, whereas Dix et al[3] found 94 cases in a meta-analysis of 82 papers.

Multiple studies define the natural history of abdominal aortic aneurysms and the indications for repair.[5,6] The lower prevalence of IIIAAs precludes such studies. Typically, intervention is warranted on IIIAAs in the case of rupture, symptoms, rapid growth, and asymptomatic aneurysms >3 cm.[7]

Approximately half of iliac artery aneurysms are symptomatic at first presentation[8] and produce symptoms through compression of the colon, ureter, and lumbar plexus.[7] Rarely, common and external iliac aneurysms can present with lower extremity ischemia.[9] Approximately 31% to 40% of all IIIAAs present are already ruptured.[3,4]

In the review by Wilhelm et al,[4] the average diameter of IIIAAs was 7.4 cm, and the overall mortality was 21.8%. The average diameter was 5.1 cm among asymptomatic aneurysms, 7.6 cm among symptomatic aneurysms, and >8 cm among free ruptures, and mortality was 0%, 21.8%, and 52.9%, respectively. Dix et al[3] reported a similar mortality rate among ruptured IIIAAs.

Management of IIIAAs includes ligation, endoaneurysmorrhaphy, arterial reconstruction, and embolization, with or without stent grafting.[4] More recently, endovascular repairs, such as bell-bottom iliac limbs, cross-chimney, and double-barrel technique, have been described. Embolization has been associated with significant buttock claudication rates of 38%.[10]

In the United States pivotal trial of the IBE and Global Registry for Endovascular Aortic Treatment (GREAT), 121 patients were treated for common iliac aneurysms with IBE during EVAR repair of abdominal aortic aneurysms. These registries confirm that IBE is safe and effective in aortoiliac and common iliac artery aneurysms.[11] However, we used the IBE device for the repair of IIIAA in our patient, who did not have aortic or common iliac artery pathology; the procedure was technically feasible and safe. The 30-day follow-up showed successful aneurysm exclusion and gluteal perfusion without endoleak.

In our patient, the emergency treatment of the ruptured right IIIAA did not allow for hypogastric preservation. Therefore, when treating the left IIIAA, preserving hypogastric inflow was of paramount importance.

Previously described endovascular techniques to preserve pelvic perfusion, including cross-chimney and double-barrel technique, were considered; however, we felt that the probability of limb kinking, occlusion or "gutter leak" was significant.[12,13] The use of the GORE EXCLUDER IBE is outside the IFU and may be associated with an increased risk of secondary and other adverse events.[14] However, in a recent report from our group of outcomes in 566 patients, no statistical difference was found in adverse events for patients treated with EVAR outside the IFU.[15] Nevertheless, the long-term durability of our intervention will require close monitoring with clinical evaluation and imaging.

CONCLUSIONS

The GORE EXCLUDER IBE proved valuable in the treatment of IIIAAs, even in the absence of aortic pathology. Although further studies are required to demonstrate the durability of the GORE EXCLUDER IBE, the device widened our endovascular therapeutic options when the importance of preserved hypogastric perfusion is increasingly evident.

REFERENCES

1. Katsargyris A, Oikonomou K, Klonaris C, Bal A, Yanar F, Verhoeven EL. Common iliac and hypogastric aneurysms: open and endovascular repair. J Cardiovasc Surg 2015;56:249-55.
2. W. L. Gore and Associates. Instructions for use for: GORE EXCLUDER Iliac Branch Endoprosthesis Device. Available at: https://www.goremedical.com/assets/MD132829/MD132829.pdf. Accessed June 20, 2016.
3. Dix FP, Titi M, Al-Khaffaf H. The isolated internal iliac aneurysm–a review. Eur J Vasc Endovasc Surg 2005;30:119-29.
4. Wilhelm BJ, Sakharpe A, Ibrahim G, Baccaro LM, Fisher J. The 100-year evolution of the isolated internal iliac artery aneurysm. Ann Vasc Surg 2014;28:1070-7.
5. Powell JT, Brown LC, Forbes JF, Fowkes FG, Greenhalgh RM, Ruckley CV, et al. Final 12-year follow-up of surgery versus surveillance in the UK Small aneurysm Trial. Br J Surg 2007;94:702-8.
6. Lederle FA, Johnson GR, Wilson SE, Chute EP, Hye RJ, Makaroun MS, et al. The aneurysm detection and management study screening program: validation cohort and final results. Aneurysms Detection and Management Veteran Affairs Cooperative Study Investigators. Arch Intern Med 2000;160:1425-30.
7. Richardson JW, Greenfield LJ. Natural history and management of iliac aneurysms. J Vasc Surg 1988;8:165-71.
8. Levi N, Schroeder TV. Isolated iliac artery aneurysms. Eur J Vasc Endovasc Surg 1998;16:342-4.
9. Nachbur BH, Inderbitzi RG, Bär W. Isolated iliac aneurysms. Eur J Vasc Surg 1991;5:375-81.
10. Millon A, Paquet Y, Ben Ahmed S, Pinel G, Rosset E, Lermusiaux P. Midterm outcomes of embolization of internal iliac artery aneurysms. Eur J Vasc Endovasc Surg 2013;45:22-7.
11. Ellozy S, Schneider D, Mastumara J. Outcomes at one year with the Gore excluder iliac branch endoprosthesis. Abstract presented at the 30th Annual Meeting of the Eastern Vascular Society, Philadelphia, PA, September 15-17, 2016.
12. Wu IH, Chou HW, Chang CH, Lin CF, Chi NH, Wang SS. Crossover chimney technique to preserve the internal iliac artery during endovascular repair of iliac or aortoiliac aneurysms: midterm results. J Endovasc Ther 2015;22:388-95.
13. 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 aortoiliac endovascular abdominal aortic aneurysm repair. J Vasc Surg 2012;56:1252-9.
14. Abbruzzese TA, Kwolek CJ, Brewster DC, Chung TK, Kang J, Conrad MF, et al. Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis. J Vasc Surg 2008;48:19-28.
15. Beckerman WE, Tadros RO, Faries PL, Torres M, Wengerter SP, Vouyouka AG, et al. No major difference in outcomes for endovascular aneurysm repair stent grafts placed outside of instructions for use. J Vasc Surg 2016;64:63-74.

Submitted Jul 13, 2016; accepted Nov 30, 2016.