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

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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 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. 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 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 left hypogastric artery aneurysm 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.
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/C2 50-mm Viabahn covered stents (W. L. Gore and Associates) to the gluteal artery.

**DISCUSSION**

Isolated iliac artery aneurysms are present in ~0.03% of general population. IIIA are even rarer, comprising <30% of all isolated iliac aneurysms. After compiling all the existing case reports of IIIAAs from 1913 to 2013, Wilhelm et al found only 55 cases, with only 10% of IIIAAs being bilateral, whereas Dix et al 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. 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. Approximately half of iliac artery aneurysms are symptomatic at first presentation and produce symptoms through compression of the colon, ureter, and lumbar plexus. Rarely, common and external iliac aneurysms can present with lower extremity ischemia. Approximately 31% to 40% of all IIIAAs present are already ruptured.

In the review by Wilhelm et al, 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 reported a similar mortality rate among ruptured IIIAAs.

Management of IIIAAs includes ligation, endoaneurysmorrhaphy, arterial reconstruction, and embolization, with or without stent grafting. 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%.

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. However, we used the IBE device for the repair of IIIA 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 IIIA, 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.\(^\text{12,13}\) 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.\(^\text{14}\) 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.\(^\text{15}\) 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.

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