Transluminal hypogastric artery occlusion with an Amplatzer vascular plug during endovascular aortic aneurysm repair

Frank Vandy, MD,[a] Enrique Criado, MD,[a] Gilbert R. Upchurch Jr, MD,[a] David M. Williams, MD,[b] John Rectenwald, MD,[a] and **Jonathan Eliason, MD,[a]** *Ann Arbor, Mich*

Objective: **To evaluate our initial experience with hypogastric artery occlusion using a nitinol vascular plug during endovascular aortic aneurysm repair (EVAR).**

Methods: **We reviewed the records and images of 23 consecutive patients who underwent transluminal vessel occlusion of the hypogastric artery with a nitinol plug, as well as a cohort of 19 patients who underwent hypogastric artery embolization with coils in conjunction with EVAR.**

Results: **There were no demographic differences between the two groups of patients. Hypogastric artery occlusion was successful in all cases when a nitinol vascular plug was used. When coils were used, there was one unsuccessful embolization which required a second procedure. The number of embolic devices used in the coil group was 7.53 (range, three to 13) compared with 1.35 (range, one to six) in the plug group ($P < .05$). Only one plug was used in 19 of 23 cases. The average cost to embolize per hypogastric artery was $1,496 compared with $470 when a nitinol plug was used. There were two instances of coil migration. No other intraoperative complications occurred. At one month follow up, seven patients (35%) in the coil group complained of buttock claudication compared with two patients (9%) in the nitinol plug group ($P = .027$).**

Conclusion: **Our experience demonstrates the safety and effectiveness of the nitinol vascular plug for hypogastric artery occlusion during EVAR. When compared with coils for hypogastric embolization during EVAR, nitinol vascular plugs are less expensive, produce less technical complications, and are associated with a significantly lower incidence of gluteal claudication. (J Vasc Surg 2008;48:1121-4.)**

Common iliac artery aneurysms have been reported in 20% to 30% of patients presenting with abdominal aortic aneurysms.[1,2] Endovascular stent-graft repair of such lesions, in many instances, involves extending the distal end of the ipsilateral graft into the external iliac artery covering the hypogastric artery orifice. In most cases, embolizing the ipsilateral hypogastric artery is necessary to prevent a Type II endoleak.

Embolization of the internal iliac artery, either unilaterally or bilaterally, is generally well tolerated.[3-5] However, manifestations of pelvic ischemia are not uncommon; specifically buttock claudication, buttock necrosis, rectosigmoid ischemia, and sexual dysfunction.[2,6,7] A significant association between the position of coils in the hypogastric artery and the development of symptoms has been suggested.[2,6] We present here our experience with the use of a nitinol vascular occlusion plug for precise proximal occlusion of the hypogastric artery.

PATIENTS AND METHODS

Between January 2001 and October 2007, 42 patients with aortoiliac aneurismal disease underwent hypogastric artery embolization prior to or at the time of placing an infrarenal aortic endograft. Embolization of the hypogastric artery was indicated to prevent a Type II endoleak when a common iliac artery aneurysm necessitated extending the endograft limb into the external iliac artery. The indication for hypogastric embolization was uniform among all patients in this group. For unilateral hypogastric artery embolization, the vessel was occluded either one day prior to or at the time an aortic endograft was placed. When bilateral hypogastric artery occlusion was necessary, this was done in a staged fashion to allow time for collateralization, allowing approximately two weeks time between embolizations. Only hypogastric arteries that were subjectively found to be of normal morphology, void of aneurysm, or ectasia were included in our series.

In March 2006, our group began using the nitinol vascular plug for large vessel embolization and rapidly became the preferred method for hypogastric artery embolization. The nitinol plug (Amplatzer Vascular Plug; AGA Medical, Golden Valley, Minn) is a self expanding nitinol mesh embolic device indicated for arterial and venous occlusion of large vessels that produces a rapid thrombosis of the mesh, thereby occluding the vessel lumen. This device is a variation of nitinol occluder devices engineered for closure of septal intracardiac defects and patent ductus arteriosus. A thorough description of the Amplatzer plug is available.[8] The plug is a self-expanding cylindrical mesh made from 144 nitinol wires (Fig 1). The plug is available in diameters of 4 to 16 mm in 2 mm increments. It is secured

From the Cardiovascular Center, Sections of Vascular Surgery[a] and Interventional Radiology,[b] University of Michigan School of Medicine.

Competition of interest: none.

Reprint requests: Enrique Criado, MD, Section of Vascular Surgery, University of Michigan School of Medicine, CVC 5463, 1500 E. Medical Center Dr., SPC 5867, Ann Arbor, MI 48109-5867 (e-mail: ecriado@umich.edu).

0741-5214/$34.00

doi:10.1016/j.jvs.2008.06.002

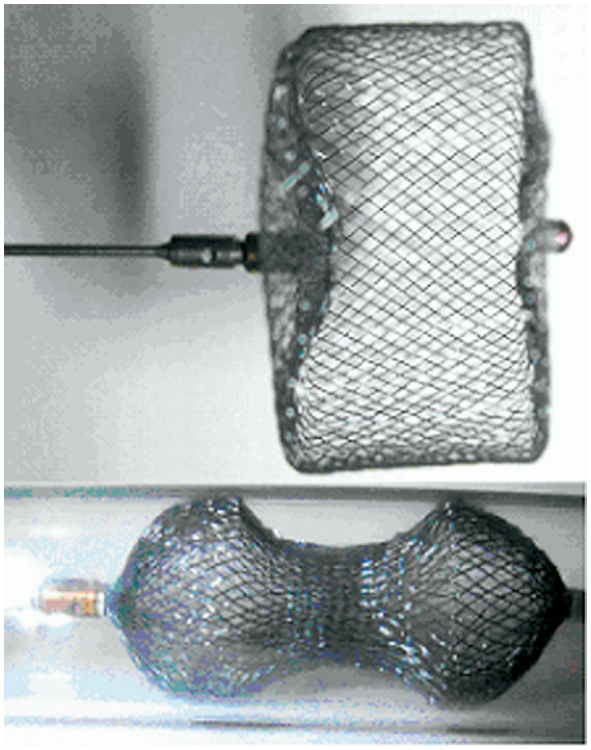

Fig 1. Top: Fully expanded view of the nitinol Amplatzer plug. **Bottom:** The same plug constrained within a transparent plastic tube. Mimics shape of the plug within a vessel after deployment.

Table. Comparison between the nitinol plug and coils for hypogastric artery occlusion during EVAR

	Nitinol plug	*Coils*	P
Patients	23	19	
Age (years)	71.9	69.9	.53
Male (%)	19 (83%)	17 (90%)	.67
Cost (USA dollars)	470.03	1496.82	.16
Buttock claudication	9%	35%	.027
Number of devices used	1.35	7.53	<.05

EVAR, endovascular aortic aneurysm repair.

to the end of a 135 cm long nitinol wire by a microscrew, which is unscrewed for device release purposes. The required sheath size for delivery ranges from 4 French to 6 French depending on the size of the plug chosen.

Prior to March 2006, hypogastric artery embolization was performed using coils. The number and type of coils used were operator dependent (Table I). For either method of embolization, coiling or placing a plug, the size of the plug or coil used was made from an assessment of the intraoperative angiogram findings. Nitinol plugs were oversized using plug diameters 50% greater than the measured luminal diameter of the hypogastric artery.

Patient demographics, number of plugs or coils used, direct manufacturer's cost of each device, and complications at one month's follow up were recorded in a prospective fashion for 23 consecutive patients in whom a hypogastric artery was embolized with a plug. These same data points were collected in a retrospective manner for 19 consecutive patients who underwent hypogastric artery embolization prior to the use of the plug at our institution. Cost analysis was determined using the manufacturer's listed price of the plugs and coils. Hospital cost, physician fees, and additional catheter based interventions and devices (contrast dye, guidewires, sheaths, etc.) were not included in our cost analysis. As all patients additionally underwent placement of an aortic endograft, follow up computed tomography (CT) angiography was obtained in all patients at one month after surgery. During the one-month follow up visit, patients were questioned and examined for complications associated with hypogastric artery embolization including buttock claudication, buttock necrosis, rectosigmoid ischemia, and sexual dysfunction. Chi square and two-tailed Student *t* test was used to compare these two groups of patients. This study was approved by our institutional review board for the study of human subjects (IRB–HUM00016077).

RESULTS

Between January 2001 and February 2006, 19 consecutive patients underwent embolization of the hypogastric artery with coils. Of these 19, one patient had a bilateral hypogastric embolization in a staged fashion. The average age was 70 years and 90% of patients were male. From March 2006 to October 2007, 23 consecutive patients underwent embolization of the hypogastric artery with a nitinol plug. The average age was 72 years and 83% of patients were male. There was no significant difference in age or gender between these two groups. The average number of coils necessary to embolize one hypogastric artery was 7.53 (range, three to 13). In comparison, when occlusion was accomplished with a nitinol plug, the number of embolic devices used was a significantly less 1.35 (range, one to six) ($P < .05$). Only one plug was used in 19 of 23 cases. In three patients, two plugs were used. In one patient, five 8/3 Tornado coils (Cook, Bloomington, Ind) were packed in front of the plug to ensure occlusion. Our average cost of coils used per hypogastric artery was $1496. The average cost to embolize a hypogastric when a plug was used was $470.

When a nitinol plug was used as the initial device for hypogastric artery occlusion, successful embolization of the vessel occurred 100% of the time. When coils were used, there was one instance of failed embolization that required a second procedure to achieve successful hypogastric artery occlusion. Intraoperative complications were limited to two episodes of coil migration. The first case occurred in the coil group when an 8 × 14 mm Nestor coil migrated into the external iliac artery while the operator was attempting to create a nest of coils at the proximal hypogastric artery. Retrieval was successful but complicated by a localized dissection of the mid and proximal external iliac artery. The second case of coil migration occurred in an instance when coils and plugs were used jointly to occlude a hypo-

gastric artery. An 8/3 Tornado coil migrated out of the hypogastric orifice distally into a branch of the profunda femoral artery while the operator was trying to pack a nest of coils proximal to a deployed nitinol plug. The coil could not be retrieved.

The average follow up time for individuals with a nitinol plug was 5.4 months, while in the coil group average follow up time was 35.6 months. A one month post-operative CT angiogram revealed occlusion of the hypogastric artery in all patients. During the first post-operative visit, also at one month, there were no symptoms of buttock necrosis, rectosigmoid ischemia, or new sexual dysfunction in any patients. However, seven patients (35%) in whom a hypogastric artery was embolized with coils complained of buttock claudication. Only two patients (9%) in whom a hypogastric artery was occluded with a nitinol plug complained of buttock claudication. The incidence of buttock claudication was significantly lower in the nitinol plug group ($P = .027$).

Fig 2. Fluroscopic view of the nitinol plug at the time of hypogastric artery implantation. Note the excellent visibility of the device.

DISCUSSION

With favorable anatomy, the endovascular approach to aortoiliac aneurysm repair is widely used. Hypogastric embolization is routinely done with EVAR associated with common iliac aneurysms in our practice. Despite reports of favorable outcomes with both unilateral and bilateral embolization of the hypogastric artery, this is not always an innocuous procedure. Embolization of the hypogastric artery has been associated with complications of buttock claudication in up to 50%, rectosigmoid ischemia in 11%, and sexual dysfunction in 13%.[7] The distal hypogastric artery bifurcates, with the anterior division of the hypogastric artery supplying the rectosigmoid and genital areas while the posterior division supplying the gluteal area. Occlusion of the hypogastric artery distally is significantly associated with an increase in pelvic ischemia.[6] Presumably, proximal occlusion preserves collateral flow from the contralateral hypogastric artery and ipsilateral external iliac artery to perfuse the pelvis.[2]

Prior to the development of the nitinol plug, coil embolization was used for percutaneous vessel occlusion. Even in the hands of an experienced interventionist, the technical complications of coil embolization are not rare.[6-9] In large vessels with pulsatile flow, precise placement of coils can be challenging and coil migration distal to the intended position is not uncommon even when coils are oversized.[6] Furthermore, large coils can cause displacement of the catheter from its selected location. The practice of packing many small coils can be associated with distal or proximal migration causing embolization into unintended vessels. Even detachable coils can be difficult to control during deployment, as the leading edge of the coil can migrate with pulsatile flow and drag the rest of the coil distally. Additionally, the price of detachable coils can be several fold greater than the price of non-detachable coils. Although using coils for vessel embolization can be effective, their use in proximal hypogastric occlusion is unreliable and do not allow precise proximal hypogastric artery occlusion.

In our experience, coil migration occurred two times, while there were no plug migrations. Fortunately, there were no adverse clinical effects in either case. In our series, only two of 23 patients undergoing hypogastric embolization with a plug experienced buttock claudication compared with seven of 19 patients who were embolized with coils. Proximal placement of coils tends to avoid this complication, however, this is not always technically feasible with coils. The nitinol vascular plug eliminates this concern as it delivers radial tension to the vessel wall, allowing for precise deployment in the intended vessel target without migration.

In addition to an increased incidence of buttock claudication, traditional coils are a more expensive method of hypogastric embolization. A nitinol plug costs $400. A single coil can cost between $70 and $1000. While there may be a cost advantage in coils if just one or two are used, this is rarely the case in hypogastric embolization. The average number of coils used to occlude one hypogastric artery was over seven with an average cost of $1496. This is similar to the number of coils used per hypogastric artery published by Ha and Calcagno.[7] When nitinol plugs were used, the average number of devices used to embolize one hypogastric was 1.35, with an average cost of $470. This number is slightly inflated because one patient required one plug followed by five Tornado coils. We have observed, as have earlier published series, that vessel thrombosis does not occur immediately with the nitinol plug, and that it may not occur until 15 minutes or more after deployment.[9] Because of this, in our early experience, additional nitinol

Fig 3. Right: CT scan of pelvic area containing coils in the hypogastric artery following EVAR. Note the massive artifact making difficult the identification of possible leaks in the area or other pelvic pathology. **Left:** Pelvic CT scan with a nitinol plug in the hypogastric artery. Note the lack of image artifact.

plugs or embolic devices might have been used unnecessarily. Thus, we did not consider the use of additional coils in this single instance, a failure of the nitinol plug, as we did not allow adequate time for vessel occlusion. The newer version of the Amplatzer nitinol plug, although more expensive, has a tighter nitinol mesh that thromboses faster and may eliminate this problem.

The nitinol plug is easily identifiable with fluoroscopy, facilitating precise and proximal placement (Fig 2). Furthermore, the nitinol plug produces very little artifact on CT scanning in comparison to coils. Fewer artifacts may decrease the risk of missing an endoleak on follow up imaging or other pelvic pathology (Fig 3).

In summary, our experience suggests that the nitinol plug is safe, cost effective, and associated with a decreased incidence of buttock claudication in comparison with coils for hypogastric artery occlusion during EVAR. Although there is still a role for coils as the primary embolic device in small vessels, our experience suggest that the nitinol plug may be the method of choice for hypogastric artery occlusion.

AUTHOR CONTRIBUTIONS

Conception and design: EC
Analysis and interpretation: FV, EC
Data collection: FV, EC, GRU, JR, JE, KY, ND, DMW
Writing the article: FV, EC
Critical revision of the article: FV, EC, GRU, JR, JE, KY, ND, DMW
Final approval of the article: FV, EC
Statistical analysis: FV, EC
Obtaining funding: EC
Overall responsibility: EC

REFERENCES

1. Henretta JP, Karch LA, Hodgson KJ, Mattos MA, Ramsey DE, McLafferty R, Sumner DS. Special iliac artery considerations during aneurysm endografting. Am J Surg 1999;178:212-8.
2. Kritpracha B, Pigott JP, Price CI, Russell TE, Corbey MJ, Beebe HG. Distal internal iliac artery embolization: a procedure to avoid. J Vasc Surg 2003;37:943-8.
3. Criado FJ, Wilson EP, Velazquez OC, Carpenter JP, Barker C, Wellons E, et al. Safety of coil embolization of the internal iliac artery in endovascular grafting of abdominal aortic aneurysms. J Vasc Surg 2000;32:684-8.
4. Kickuth R, Dick F, Triller J, Ludwig K, Schmidli J, Do DD. Internal iliac artery embolization before endovascular repair of aortoiliac aneurysms with a nitinol vascular occlusion plug. J Vasc Interv Radiol 2007;18:1081-7.
5. Wolpert LM, Dittrich KP, Hallisey MJ, Allmendinger PP, Gallagher JJ, Heydt K, et al. Hypogastric artery embolization in endovascular abdominal aortic aneurysm repair. J Vasc Surg 2001;33:1193-8.
6. Cynamon J, Lerer D, Veith FJ, Taragin BH, Wahl SI, Lautin JL, et al. Hypogastric artery coil embolization prior to endoluminal repair of aneurysms and fistulas: buttock claudication, a recognized but possibly preventable complication. J Vasc Interv Radiol 2000;11:573-7.
7. Ha CD, Calcagno D. Amplatzer Vascular Plug to occlude the internal iliac arteries in patients undergoing aortoiliac aneurysm repair. J Vasc Surg 2005;42:1058-62.
8. Rimon U, Heldenberg E, Golan G, Shinfeld A, Garniek A. Amplatzer vascular plug: expanding the applications spectrum. Cardiovasc Intervent Radiol 2007. [Epub ahead of print.]
9. Tuite DJ, Kessel DO, Nicholson AA, Patel JV, McPherson SJ, Shaw DR. Initial clinical experience using the Amplatzer Vascular Plug. Cardiovasc Intervent Radiol 2007;30:650-4.

Submitted Feb 20, 2008; accepted Jun 1, 2008.