Internal Iliac Artery Embolization before Endovascular Repair of Aortoiliac Aneurysms with a Nitinol Vascular Occlusion Plug

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PURPOSE: To evaluate the acute and midterm effectiveness of a novel vascular occlusion device for embolization of the internal iliac artery (IIA) before endovascular repair of aortoiliac aneurysms.

MATERIALS AND METHODS: Between March 2005 and April 2006, nine men (mean age, 75 years; range, 66–83) with aortoiliac aneurysms underwent bifurcated endovascular stent-graft procedures. All these patients were referred specifically for embolization. Pre- and perioperatively, eight patients underwent unilateral embolization and one underwent bilateral embolization of the IIA to prevent type II endoleak. Via a contralateral femoral approach with a 6-F or 8-F sheath, the embolization procedure was performed with an Amplatzer Vascular Plug, a self-expandable cylindrical device consisting of a nitinol-based wire mesh. Technical success, clinical outcome, and complications were evaluated. Follow-up at 3, 6, and 12 months was performed with clinical and radiologic examinations.

RESULTS: IIA embolization was technically successful in all cases and no procedure-related complications occurred. Imaging at discharge and at 3-, 6-, or 12-month follow-up was accomplished in all nine patients. Control computed tomography and magnetic resonance angiography did not reveal retrograde perfusion of the aneurysmal sac, ie, type II endoleak. Three of nine patients (33.3%) reported symptoms of buttock claudication that did not resolve completely. Clinical symptoms such as bowel ischemia or sexual dysfunction were not observed.

CONCLUSIONS: The midterm results of this study suggest that preoperative IIA embolization with a nitinol vascular occlusion plug during endovascular treatment of aortoiliac aneurysms is safe and effective.

Since the pioneering study of Parodi et al (1) that initially described endovascular aneurysm repair (EVAR) as an alternative to surgery in the treatment of abdominal aortic aneurysms (AAAs), there has been an increasing interest in this kind of therapy in recent years (2–4). It is a commonly held opinion that EVAR represents a safe and effective procedure, especially in patients at high surgical risk (4–6).

An evident requirement for the insertion of a bifurcated or aortoiliac stent-graft is the presence of an adequate anchoring zone in the aortic neck and the common iliac arteries (CIAs) (4). However, approximately 20% of all AAAs extend into the iliac axis, necessitating a combined treatment of ipsilateral internal iliac artery (IIA) embolization and prolongation of the endograft limb into the external iliac artery (EIA) (4,5). In general, preprocedural embolization of the ipsilateral IIA seems to be mandatory to prevent retrograde perfusion of the aneurysmal sac and potential endoleaks after extension of the aortic stent-graft into the EIA (4,7,8).

With accumulated experience, coil embolization of the proximal IIA has become the standard technique for the induction of thrombosis to provide collateral flow among the distal branches (4,6,8–10). Nevertheless, accurate embolization of the proximal IIA may be complicated by coil migra-
tion or unintentional placement of coils into more distal IIA branches, leading to a compromise of collateral flow, with its inherent clinical symptoms (6). In addition, IIA embolization may be costly and time-consuming because, in most interventions, numerous coils have to be deployed to achieve cessation of blood flow (5).

To date, the role of vascular occlusion plugs for IIA embolization during EVAR in aortoiliac aneurysms is incompletely documented in the literature, and this embolization approach seems to be relatively new to the interventional radiology field (5,11).

Consequently, to address the need for more data, we evaluated our experiences with the new embolization device known as the Amplatzer Vascular Plug (AVP; AGA Medical, Golden Valley, MN) in the setting of EVAR with special focus on midterm radiologic and clinical follow-up. The rationale for embolizing IIA in all our patients was involvement of at least one CIA requiring stent-graft implantation with extension down to the EIA.

MATERIALS AND METHODS
Study Sample

Between March 2005 and April 2006, nine male patients (mean age, 75 years ± 5; range, 66–83 y) were referred for pre- and perioperative IIA embolization in the setting of EVAR with use of the AVP. All patients had involvement of the CIAs necessitating stent-graft placement across the origin of the IIA. Patients were selected on an intent-to-treat basis defined just before initiation of the embolization procedure. Plug embolization was performed in patients with (i) medium-sized IIA (6–12 mm in diameter) or (ii) aneurysmatic IIA with a medium-sized proximal neck (6–12 mm in diameter). All our patients referred for embolization met the criteria. Five patients underwent additional embolization of the lumbar arteries; one patient had supplementary embolization of the inferior mesenteric and lumbar arteries. Microcoils were used for embolization of the inferior mesenteric and lumbar arteries. None of our patients had renal insufficiency. The preference of a pre- or perioperative embolization approach was at the discretion of the vascular surgeon. Preoperative evaluation included computed tomography (CT) angiography or magnetic resonance (MR) angiography examinations. Before the embolization approach, AAAs were graded on a scale of A to E according to the classification system of the European Collaborators on Stent-Graft Techniques for Aortic Aneurysm Repair (Table) as previously described (4,12). All patients were examined and treated as part of routine care and gave informed consent. Our institutional review board did not require its approval or informed consent for this study.

The AVP is a cylindrical device composed of a self-expandable nitinol-based wire mesh with a platinum marker band embedded in its proximal and distal ends to enhance radiopacity for accurate positioning. A microscrew mechanism is fixed to the proximal end of the mesh that connects the AVP with a 135-cm-long delivery cable. Attached on this delivery cable and preloaded in a plug loader, the vascular occlusion plug can be advanced through a long sheath or a guiding catheter. Available plug diameters range from 4 to 16 mm in 2-mm increments, with a length of 7–8 mm. Plugs with diameters of 4, 6, and 8 mm and a length of 7 mm usually require a sheath of at least 5-F in internal diameter; for 10- and 12-mm devices with respective lengths of 7 and 8 mm, 6-F sheaths have to be used. Ocluters with diameters of 14–16 mm and a length of 8 mm necessitate the use of 8-F sheaths. According to the manufacturer’s recommendations, plugs should be selected approximately 30%–50% larger than the diameter of the vessel to be treated. As a consequence, a solid embedding of the occlusion device within the target vessel and a release of the plug from the delivery cable—which is not problematic—is possible. The AVP is MR imaging–compatible at a field strength as high as 1.5 T.

Interventional Technique

With all nine patients under local anesthesia, all embolization procedures were performed via a contralateral femoral artery approach with a long 6-F (Terumo, Japan) or 8-F sheath (Super Arrow-Flex, Arrow International, Reading, Pa). Eight embolizations were carried out in our angiography suite and one was conducted peripherally in an operating theater. Heparin was not administered during the embolization procedure. All patients received antibiotic coverage.

A 5-F calibrated angiographic pigtail catheter (William Cook Europe, Bjaeverskov, Denmark) placed just above the aortic bifurcation was used to obtain a nonselective diagnostic arteriogram to identify the IIA and measure the diameters of the target vessels. Selective catheterization of the main trunk of the intended IIA was performed with a Cobra-shaped catheter (5-F C-2 catheter; William Cook Europe). These diagnostic catheter maneuvers were usually performed with a steerable 0.035-inch guide wire (Radifocus; Terumo). Over the wire, the long sheath was advanced beyond the desired level of the IIA. The diagnostic catheter and the guide wire

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Note.—EUROSTAR = European Collaborators on Stent-Graft Techniques for Aortic Aneurysm Repair.


were removed, and the loader with the adequate AVP inside was passed through the hemostasis valve of the sheath. The AVP was expelled into the sheath and advanced to the target level of the IIA. Exposure of the AVP was achieved by withdrawing the sheath, and angiographic verification of its correct position was performed by injection of contrast medium through the sheath. If the device position was not satisfactory, the vascular plug was adjusted accurately or pulled back into the guiding sheath and positioned in a second step. When an adequate position had been verified angiographically, the AVP was released by rotating the delivery cable in a counterclockwise direction. Plug embolization ended with angiographic documentation of minimal or absent antegrade flow into the IIA. This control angiogram was usually obtained 3–5 minutes after plug placement. After the embolization procedures had been completed, hemostasis at the puncture site was achieved with use of a closure device (StarClose; Abbott Vascular, Redwood City, Calif.). Although none of our patients had undergone anticoagulation, vascular sealing was performed to improve patient throughput and comfort.

Follow-up

All patients were closely monitored after IIA embolization. Peri- and postinterventional complications at the puncture site were documented for 24 hours. Immediately before EVAR, an intraoperative angiogram was obtained in patients who had undergone preoperative IIA occlusion to assess the success of the embolization procedure. After EVAR the patients were followed with clinical visits at 3, 6, and 12 months, as is usually done in our cardiovascular surgery department. Follow-up CT or MR angiography examinations were performed at discharge and at intervals of 3, 6, and 12 months. The images from the follow-up CT or MR angiography examinations were reviewed by three interventional radiologists (R.K., J.T., K.L.). During clinical follow-up examinations, patients were queried regarding the signs and symptoms of buttock claudication, bowel ischemia, and sexual dysfunction. This information was completed by means of telephone interviews with the patients’ referring physicians. Patients were generally advised to contact the outpatient clinic immediately at the onset of new or worsening symptoms.

Endpoint Definition

Primary endpoints of our study were technical success, clinical success, side effects, embolization time, and rates of minor and major complications. Technical success was designated as the absence of antegrade flow into the embolized IIA and was angiographically evaluated just before endovascular aortic graft placement. Clinical success was defined as the absence of endoleaks caused by retrograde IIA perfusion and was documented by postoperative imaging follow-up. Clinical side effects evaluated included symptoms like buttock claudication, bowel ischemia, and sexual dysfunction. Embolization time was defined as the time elapsed between nonselective diagnostic angiography before the release of the plug and control angiography after release of the plug.

Complications of treatment were classified on the basis of outcome according to the reporting standards of the Society of Interventional Radiology (13). Minor complications included those resulting in no therapy and no consequence (class A) or nominal therapy and no consequence including overnight admission for observation only (class B). Major complications included those that required therapy or minor hospitalization less than 48 hours (class C); those that required major therapy, unplanned increase in level of care, or prolonged hospitalization for more than 48 hours (class D); those that resulted in permanent adverse sequelae (class E); and those that resulted in death (class F).

RESULTS

Technical and Clinical Results and Complications

Preinterventional CT angiography examinations of all patients demonstrated two type D AAAs and seven type E AAAs. IIA embolization was left-sided in five patients, right-sided in three patients, and bilateral in one patient. Eight patients underwent staged IIA embolization and one patient underwent embolization in the same operative session as EVAR. The median interval between IIA embolization and EVAR was 28 days, with a range between 0 and 56 days. IIA embolization was successfully performed in all nine patients (100%). Intraoperative angiograms confirmed vessel occlusion in all eight patients who had preoperative embolization.

An example of the embolization technique is provided in the Figure. One AVP was deployed in each of seven patients who received unilateral embolization and two AVPs were deployed in one patient with bilateral embolization. The IIA was occluded with two AVPs in one patient with unilateral embolization; this patient had a short main trunk of the left IIA and an early ramification of the superior gluteal artery, so both vessels were embolized. The mean plug embolization time was 40 minutes ± 16 and ranged between 19 and 71 minutes. Postoperative imaging follow-up (mean, 8 months ± 3; range, 3–12 months) was available in all patients. CT angiography (in eight cases) or MR angiography (in one case) studies did not show retrograde perfusion of the aneurysm sac in any patient. No endoleaks related to plug embolization were detected.

Clinical side effects attributed to APV embolization were documented in three (33.3%). One patient reported severe buttock claudication immediately after embolization with a free walking distance of less than 50 meters; however, this patient reported continuous improvement of symptoms with free walking distance of more than 500 meters at 12-month follow-up. It was his subjective impression that the side effects were not lifestyle-limiting for him at that time. Another patient reported persistent buttock claudication after walking more than 100 meters. A third patient described symptoms of postembolization buttock claudication after walking distances of approximately 100 meters, but this patient also reported relief of symptoms at 6-month follow-up with free walking distance of approximately 500 meters. No patient reported sexual dysfunction. Symptoms associated with bowel ischemia such as abdominal pain, diarrhea, or hematochezia did not occur.
Minor complications like vasovagal reaction, temporary spasm of a catheterized artery, groin hematoma, or pseudoaneurysm of the access artery were not observed. There was no evidence of major complications such as plug migration, nontarget embolization, or sepsis, and no deaths occurred.

DISCUSSION

Treatment Strategies

With the immense increase in the expertise with EVAR during the past decade, several adjunctive techniques have been developed to enable safe anchoring of the distal graft in cases of iliac involvement (5,6,10,14–18). In this context, the most frequently recommended definitive strategy in the past consisted of IIA embolization with coils to prevent potential reflux and endoleak (4,6,19–22). Many authors have demonstrated that coil embolization of the IIA is a safe and efficient approach that can significantly increase the applicability of EVAR (6,8,20,23–28). Nevertheless, it has been reported that unilateral or bilateral IIA exclusion may cause serious symptoms of pelvic ischemia. With regard to pelvic malperfusion, it has been discussed that coil migration into distal IIA branches, atheroembolization as a result of catheter manipulation during embolization, and severe stenosis of the contralateral IIA, ipsilateral deep femoral artery, or ipsilateral EIA may be contributing factors (4–6,8,11,20,22).

Several authors favor intentional IIA coverage with extension of the endograft into the EIA, but without supplemental coil embolization before EVAR (10,29,30). However, this method was regarded as practicable only in cases in which the IIA orifice is small and in close proximity to the EIA orifice so an appropriate sealing of the CIA could be achieved; otherwise, a type II endoleak directly from the IIA could occur. Promising results with the use of the so-called bell-bottom technique were reported by other investigators.

Figure. Digital subtraction angiographic images of right-sided plug embolization in a 75-year-old man who underwent bilateral IIA exclusion before EVAR. (a) Preprocedural right anterior oblique image demonstrates a type E AAA. (b) Preprocedural right anterior oblique image documents placement of the long sheath within the right IIA. (c) Radiograph obtained in a right oblique projection shows advancement of the AVP through the sheath into the target IIA. (d) Right anterior oblique image shows correct positioning of the AVP within the IIA before release from the delivery cable. (e) Right anterior oblique image after the procedure documents successful exclusion of the right IIA.
Plug Embolization

Recently, Ha and Calcagno (5) published a study dealing with the use of AVPs in IIA embolizations before EVAR or CIA aneurysm repair. In this series, a total of five patients underwent plug embolization and 10 patients underwent treatment with conventional coils. The investigators reported successful plug embolization in all five patients with one single AVP. However, two of five patients developed mild buttock claudication that completely resolved over a period of 6–8 weeks. One patient had groin hematoma that did not require further therapy. When the authors compared the expenses of AVPs and conventional coils per IIA embolization, they found that potential cost savings might be realized with the use of plug embolization. In their trial, an average of seven coils were used, versus one AVP. Depending on the size and shape, the cost of each deployed coil varied from $225 to $1000, whereas the cost per AVP regardless of size was $375. Consequently, the mean estimated total cost for AVPs used per IIA was $375, comparing to a total of $3500 for conventional coils. From these results, the investigators inferred that IIA embolization with a vascular plug could be considered as precise, safe, and cost-effective.

Similar to the trial of Ha and Calcagno (5), we found a technical success rate of 100% and no major complications in our series. In all but one patient, a single plug was sufficient to achieve IIA exclusion. Three of nine patients (33.3%) had buttock claudication that improved in two cases, but was not self-limiting at their latest follow-up examination. With regard to plug embolization time, directly comparable information on the average length has not been available in the literature so far. In our series, there was probably a startup or learning factor that prolonged plug deployment because operators had experience with coil embolization only. In general, embolization time is always a result of numerous inherent factors such as level of difficulty, vascular anatomy, number of embolization devices needed, and operators’ technical skill. However, it may be hypothesized that, with improved embolization times and fewer devices used per IIA, decreases in radiation exposure, patient discomfort, and incidence of complications could be observed.

In this study, we did not try to embolize the IIA via the ipsilateral femoral artery to avoid extreme kinking of the sheath when placing it into the target vessel. We believe that such kinking of the sheath may make adequate delivery of the AVP more difficult.

We agree with Ha and Calcagno (5), who considered the application of vascular plugs with available diameters of 4–16 mm to be appropriate only in medium-sized blood vessels. Because of the cylindrical characteristics of the plugs, they recommended use of plugs in vessels with a short portion of constant diameter on a case-by-case basis. They came to the conclusion that coil placement might be more advantageous in tapering and smaller vessels.

All patients with AAA in our trial were chosen for IIA embolization on the basis of the special anatomy of the CIAs. They all showed concomitant aneurysmal CIA affection with extension into the iliac bifurcation that did not allow adequate distal stent-graft sealing. Because these patients’ anatomy required elongation of the stent-graft into the IIA, preprocedural IIA embolization was obligatory to prevent retrograde perfusion and potential endoleak. The particular morphology of the IIA’s of our patients—medium size and at least a short constant segment—lent itself to plug embolization.

In our study, in which the selection of a staged or concomitant embolization approach was at the discretion of the vascular surgeon, a clear trend in favor of preoperative IAA exclusion could be observed. Lee et al (6) emphasized that a staged procedure might help to avoid excessive use of intravenous contrast medium and may decrease operative time. Another striking advantage of a preoperative embolization approach is that additional collateral vessels may evolve before implantation of the endograft; hence, symptoms of buttock claudication are less often evident as with a concomitant procedure. A disadvantage of the AVP seems to be that it does not have an over-the-wire capability. As reflected by our series, a solution to this dilemma might be the use of armed sheaths. A short, powerful saline solution flush might also contribute to improved pushability of the AVP. Although we are aware of only one case published so far (33), unintended re-canalization of the AVP in an IIA might be also problematic. However, it remains speculative if plug positioning too close to the IIA ostium with increased EIA flow could have con-
tributed to lysis of the primary thrombus in this instance.

Study Limitations
There are three main limitations to this study. First, the sample size is small, which prevents us from generalizing on the basis of the results of this study. Second, this series is consecutive and lacks randomization; therefore, patient selection bias may have played a role. A prospective randomized trial would be beneficial to define the exact value and clinical outcome of IIA embolization with vascular occlusion plugs compared with conventional coils. Third, evaluation of plug embolization time in our study is limited by the absence of a control group of patients who also underwent EVAR with staged or concomitant coil embolization.

CONCLUSION
In conclusion, our acute and midterm results suggest that preoperative IIA embolization with the new self-expandable nitinol AVP before EVAR appears to be a promising, safe, and efficacious treatment option with the potential to become established. However, this technique requires further prospective randomized evaluation with larger patient populations to fully assess its therapeutic potential in comparison with coil embolization. Long-term follow-up also remains necessary to examine the efficacy of this procedure.

References


**CME TEST QUESTIONS**

Examination available at [http://directory.sirweb.org/jvircme](http://directory.sirweb.org/jvircme)

1. Nitinol vascular occlusion plugs were placed in this study for prevention of what type of endoleak?
   a. Type 1
   b. Type 2
   c. Type 3
   d. Type 4

2. According to literature on aortic endografting cited by the authors, approximately what percentage of abdominal aortic aneurysms extend sufficiently far into the iliac artery to require ipsilateral internal iliac artery embolization and extension of the endograft limb into the external iliac artery?
   a. 5%
   b. 10%
   c. 20%
   d. 30%

3. In this series of 9 patients undergoing embolization of the internal iliac artery with a nitinol vascular occlusion plug, which of the following complications was observed?
   a. Iliac aneurysm rupture
   b. Symptoms associated with bowel ischemia
   c. Sexual dysfunction
   d. Buttock claudication

4. Procedural aspects of nitinol vascular occlusion plug deployment in this study included all of the following except?
   a. Plug diameter approximately 30–50% larger than diameter of the target vessel
   b. Contralateral femoral artery approach
   c. Prophylactic antibiotic administration
   d. Supplemental fibered coil embolization to achieve flow stasis when necessary