

Iliac artery recanalization of chronic occlusions to facilitate endovascular aneurysm repair

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Introduction: Concurrent iliac occlusion and abdominal aortic aneurysm is rare. Traditionally, the endovascular approach to these patients has consisted of aortoiliac devices combined with femoral–femoral bypass. With improved facility of endovascular techniques, standard bifurcated endografts represent an alternative option in these patients. This study examined outcomes of patients undergoing iliac recanalization and traditional bifurcated endovascular aneurysm repair in the face of access vessel occlusion.

Methods: Outcomes of patients at three academic tertiary referral centers who underwent attempted iliac recanalization of chronic iliac occlusions and concurrent endovascular aneurysm repair of an infrarenal aortic aneurysm were retrospectively reviewed. Patients with acute iliac thrombosis and those with severely stenotic (but patent) iliac vessels were excluded.

Results: During a 6-year period, 15 occluded iliac arteries were treated in 14 patients (13 men). Mean age was 67.8 years (range, 52–80 years). Primary indication for intervention was disabling claudication in four patients, size of abdominal aortic aneurysm in nine, and symptomatic aneurysm in one. Seven patients presented with a unilateral common iliac artery (CIA) occlusion, four with a unilateral external iliac artery (EIA) occlusion, three with a unilateral combined CIA and EIA occlusion, and one with bilateral CIA occlusions. Stents had been placed previously in two of the occluded CIAs and in one of the occluded EIAs. Average length of the occluded segment was 7.5 cm (range, 2–17 cm). The occluded CIAs and EIAs had mean diameters of 8.6 and 5.7 mm, respectively. Successful recanalization was achieved in 14 of the 15 vessels (93.3%). One EIA ruptured during recanalization but was easily controlled with a covered stent. A re-entry device was used in two cases. Overall, 13 bifurcated devices were successfully implanted. Bilateral iliac occlusions in one patient were recanalized. One Talent (Medtronic, Santa Rosa, Calif), eight Excluder (W. L. Gore and Associates, Flagstaff, Ariz), and four Zenith (Cook Medical, Bloomington, Ind) devices were used. Mean length of stay was 2.3 days (range, 1–6 days). No major perioperative complications or deaths occurred. During a mean follow-up of 28.2 months (range, 1–86 months), there was 100% primary patency of successfully recanalized iliac arteries. Aneurysm sac size decreased from a mean of 5.1 cm (range, 3.1–7.6 cm) preoperatively to 4.4 cm (range, 2.8–7.1 cm) at follow-up. No aneurysms grew or ruptured. Three type II endoleaks occurred, one of which required coiling at 15 months. Two late deaths occurred: one at 36 months secondary to complications from a coronary artery bypass graft/mitral valve replacement and one at 34 months from a myocardial infarction.

Conclusions: The use of bifurcated endovascular devices after recanalization of an occluded iliac system is technically feasible and durable at midterm follow-up. This technique re-establishes aortoiliac inflow to both lower extremities, obviates the need for extra-anatomic bypass, and may preserve hypogastric perfusion in some patients. (*J Vasc Surg* 2012;56:1549–54.)

Since the first description of endovascular aortic aneurysm repair (EVAR) by Parodi et al¹ in 1991, there have been many advances in the technology and ability to treat abdominal aortic aneurysms (AAA) by endovascular means. Concomitant aortoiliac occlusive disease (AIOD) still remains a challenge to endograft implantation and may pre-

clude placement of EVAR in 6% to 15.4% of patients.^{2,3} Patients with aortic aneurysm and significant iliac artery stenosis or occlusion precluding placement of an endovascular graft are considered to have TransAtlantic Inter-Society Consensus (TASC) D lesions, for which the TASC II criteria recommend open repair.⁴ These patients often experience severe claudication and have significant comorbidities that are associated with their peripheral arterial disease, making them higher-risk candidates for open operations.

Open surgical repair has been the traditional therapy in patients with concomitant aneurysmal disease and AIOD. However, open surgical repair has been associated with higher rates of perioperative morbidity and mortality. Hybrid strategies using iliac conduits have been used to provide patients with poor access an endovascular repair of their aneurysms.⁵ Conduit construction subjects the patient to a retroperitoneal incision and has been associated with higher complication rates and length of stay than in patients whose repair is solely through femoral access.⁵ In

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patients with unilateral iliac occlusive disease and an AAA, aortouniliac (AUI) stent graft repair of the aneurysm with crossover femorofemoral bypass graft (CFFB) is an alternative therapy. However, the results of these repairs are worse compared with the outcomes of bifurcated stent grafts, with decreased patency,⁶ added risk of femoral graft infection and occlusion, and a small risk for hemodynamically significant steal of blood flow in the donor leg.⁷

Iliac recanalization of occlusive disease is common in treatment of AIOD; however, this technique has never been evaluated in patients with aneurysmal disease receiving a bifurcated EVAR. The aim of this study was to evaluate short-term and midterm outcomes of bifurcated EVAR in patients with aortic aneurysms and concomitant chronic iliac occlusions requiring recanalization.

METHODS

Patients. A retrospective review of all patients who underwent attempted iliac recanalization of chronic iliac occlusions and concurrent EVAR of an infrarenal AAA was performed at three academic tertiary referral centers between January 2004 and December 2010. Institutional Review Board approval was obtained at each of the participating institutions. Inclusion criteria included all patients with iliac occlusions as well as aortic aneurysms in which an EVAR with a bifurcated stent graft was attempted. The analysis excluded patients with acute iliac thrombosis and those with severely stenotic (but patent) iliac vessels.

We identified 14 patients with 15 occluded iliac arteries in whom repair had been attempted. All patients were evaluated preoperatively with computed tomography (CT) imaging. Indications for repair included one of the following: asymptomatic aneurysmal diameter; symptoms associated with the aortic aneurysm; or disabling claudication with a concomitant aneurysm. Postoperative imaging surveillance was CT angiograms at 1, 6, and 12 months during the first year and annually every year thereafter.

Anatomic and intraoperative variables recorded included length of occlusion, size of iliac arteries, size of aorta, adjunct procedures used, device used, and use of a re-entry device. Variables recorded included perioperative length of stay, perioperative complications, technical success, death, and adjunct procedures. Length of follow-up, secondary interventions, patency, and follow-up mortality were also recorded.

Technique. All patients underwent a diagnostic angiogram of the occluded side. Iliac occlusions were crossed by subintimal angioplasty or intraluminal recanalization when possible. Re-entry devices were used according to the surgeon's preference. After angioplasty, the bifurcated stent graft or additional stent was placed at the discretion of the interventionalist. Devices approved by the U.S. Food and Drug Administration were used in all procedures.

Statistical analysis. Statistical analysis was performed using SigmaStat software (Systat Software Inc, Chicago, Ill). Mean values are presented with ranges.

Table I. Primary indication for operation

| <i>Indication</i> | <i>No.</i> |
|----------------------|------------|
| Size of aneurysm | 9 |
| Claudication | 4 |
| Symptomatic aneurysm | 1 |
| Total | 14 |

RESULTS

During a 6-year period, 15 recanalizations of occluded iliac arteries were attempted for placement of bifurcated aortic stent grafts in 14 patients (13 men; Table I). The mean age was 67.8 years (range, 52-80 years). Primary indication for intervention was disabling claudication in four patients, size of AAA in nine, and symptomatic aneurysm in one. Seven patients (50%) presented with a unilateral common iliac artery (CIA) occlusion, four (28.9%) with a unilateral external iliac artery (EIA) occlusion, three (21.4%) with a unilateral combined CIA and EIA occlusion, and one (7.1%) with bilateral CIA occlusions. In two of the occluded CIAs and one of the occluded EIAs, stents had been placed previously that had subsequently occluded. Average length of the occluded iliac segment was 7.5 cm (range, 2-17 cm). The mean diameters of the occluded CIAs and EIAs were 8.6 and 5.7 mm, respectively (Table II).

Successful recanalization was achieved in 14 of the 15 vessels (93.3%; Fig). An Outback re-entry device (Cordis Corp, Warren, NJ) was used in two iliac arteries (13.3%). Overall, 13 bifurcated devices were implanted: eight Excluder (W. L. Gore and Associates, Flagstaff, Ariz), four Zenith (Cook Medical, Bloomington, Ind), and one Talent (Medtronic, Santa Rosa, Calif). One technical failure occurred in a patient with an occluded EIA stent, in which recanalization and re-entry into the true lumen could not be accomplished. Subsequent treatment required the implantation of a Cook Renu graft and CFFB.

Several adjunct procedures were performed during these cases to assist in completion (Table III). One EIA ruptured during recanalization but was controlled with a Viabahn (W. L. Gore & Associates) covered stent. One patient had a severely calcified small but patent right external iliac artery and an occluded right hypogastric and left external iliac artery. This patient received a right common iliac conduit for deployment of the main body given the small patent external iliac size on the right and a right-to-left iliofemoral bypass. His left EIA was crossed using subintimal angioplasty for deployment of the contralateral leg to maintain pelvic perfusion through antegrade perfusion of the patent left hypogastric artery.

The mean length of stay was 2.3 days (range, 1-6 days). No deaths or major perioperative complications occurred related to recanalization of the iliac vessels. One patient had evidence of distal embolization on postoperative day 5 on the contralateral side to which his CIA was recanalized. This was treated with an embolectomy.

During a mean follow-up of 28.2 months (range, 1-86 months), there was 100% primary patency of successfully recanalized iliac arteries. Aneurysm sac size decreased from a preoperative mean of 5.1 cm (range, 3.1-7.6 cm) to 4.4 cm (range, 2.8-7.1 cm) at follow-up. No aneurysmal growth or rupture occurred. All patients treated because of severe claudication showed subjective improvement in their symptoms at follow-up. Preoperative and postoperative ankle-brachial indexes were obtained in two of the four patients whose main indication was claudication. These were 0.8 and 0.5 on the limb ipsilateral to the occlusion preoperatively and improved to >1 on the recanalized side in both patients at follow-up. The claudication in the other two patients improved, and they were asymptomatic postoperatively.

Three patients received secondary interventions during the follow-up period. One balloon angioplasty of a contralateral Excluder limb for asymptomatic graft infolding was performed at 3 months, and one patient received subsequent renal and subclavian stent placement, which were unrelated to their aneurysm. There were three type II endoleaks, one of which required coiling at 15 months. There was no evidence of graft occlusion. There were two late deaths: one at 36 months secondary to complications from a combined coronary artery bypass grafting and mitral valve replacement operation and one at 34 months from a myocardial infarction.

DISCUSSION

EVAR with a bifurcated device has largely replaced open aortic aneurysm repair in patients due to lower perioperative morbidity and mortality as well as patient preference. In 2007, up to 67% of all aortic aneurysms were repaired by endovascular techniques.⁸ Some patients do not have ideal anatomy for an EVAR, and up to 15.4% of patients may undergo open aneurysm repair because of access vessel size that is inadequate for delivery of a stent graft.³

Options to open surgical repair in patients with aneurysms and AIOD include placement of bifurcated endografts after recanalization of the occlusion, AUI devices with CFFB, or hybrid procedures with iliac conduits. In our study, we evaluated patients with AAAs and chronic total occlusions who underwent attempted treatment with an endovascular modular bifurcated device at three tertiary referral centers. We were successful in recanalizing all of the lesions except for one (93.3%) in a woman who had undergone previous stent placement in her EIA. It is difficult to determine if her previously occluded stent was a risk factor for technical failure, especially because recanalization was possible in two other patients with occluded stents.

In our midterm follow-up of 28.2 months, we showed 100% iliac primary patency in patients receiving a bifurcated EVAR and a recanalized iliac artery. This correlates with studies showing good midterm to long-term outcomes of bifurcated aortic stent grafts in off-label treatment of patients with TASC C and D AIOD and no aneurysmal disease with favorable midterm outcomes.^{9,10} The use of a

bifurcated device may prove to be more durable compared with traditional iliac stents in select patients with significant AIOD and TASC C and D lesions who are unable to tolerate open surgical repair.

AUI with CFFB has been shown to have decreased primary and secondary patency rates in patients with bifurcated aortic endografts.⁶ This has mostly been related to significance of AIOD, with TASC C and D lesions being the largest predictor of poor outcomes and increased morbidity.⁶

Crossover femorofemoral bypass has been shown to be effective, with higher patency rates when combined with AUI in aneurysmal disease than in occlusive disease, with 3-year patency rates of >90% touted in several studies.¹¹⁻¹³ These studies, however, included very few patients with total chronic occlusions, and many of the patients included in these reports had undergone AUI graft placement before bifurcated EVAR was available at their institution, thus including patients who did not necessarily have significant peripheral vascular disease. In this study, we looked only at patients with occluded iliac arteries and AAAs. These patients would likely not have as high a patency rate as the previous studies of AUI and CFFB and would likely have patency rates closer to 60% at 3 years, as shown in AIOD studies.^{14,15}

There is also a decreased risk of graft infection from not having the extra-anatomic bypass in the groins and using a bifurcated device. Graft infection develops in 2.6% to 5% of patients undergoing CFFB¹¹ and has been reported to lead to death in some patients.¹¹ The ability to repair the patient's aneurysm and restore inflow to a leg with a lower risk of infection, as well as the higher patency, is an appealing argument for using recanalization of occluded iliac arteries in bifurcated EVAR.

There are patients with aortic aneurysms, patent hypogastric arteries, and occluded ipsilateral external iliac arteries who would benefit from recanalization and placement of a bifurcated endograft. If these patients received an AUI device with CFFB, they would lose perfusion of the hypogastric artery on the recipient side of the CFFB proximal to the external iliac occlusion. Recanalization helps maintain perfusion in these patients with patent hypogastric arteries that would otherwise be occluded. In four patients in our study with isolated EIA occlusions, antegrade hypogastric perfusion was maintained by recanalization of the occlusion. The hypogastric artery may provide important collateral blood supply to the intestines, spinal cord, and pelvic organs. Loss of important collaterals, especially in the face of previous surgery, may increase the risk of mesenteric ischemia,¹⁶ paraplegia,¹⁷ thigh and buttock claudication, and pelvic ischemia.¹¹ This may also be important if future thoracic aortic interventions are necessary to decrease the risk of paraplegia from spinal ischemia by maintenance of collateral circulation.¹⁷

The two main issues that prevent patients with an infrarenal AAA from receiving EVAR are anatomy of the proximal landing zone and vascular access.¹⁸ Significant progress has been made with respect to unfavorable infra-

Table II. Patient perioperative characteristics

| Variable | Patients | | | | | | |
|-------------------------|-------------------|-----------------|-------------------|----------|----------|----------|----------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| AAA size, cm | 4 | 4.6 | 4.5 | 5.7 | 7.3 | 5 | 5 |
| Operative indication | Severe claudicant | Symptomatic AAA | Severe claudicant | AAA size | AAA size | AAA size | AAA size |
| Device | Excluder | Excluder | Excluder | Excluder | Excluder | Zenith | Talent |
| Iliacs recanalized, No. | 1 | 1 | 1 | 1 | 2 | 1 | 1 |
| Occluded vessels | R CIA | L CIA, L EIA | L CIA, L EIA | L EIA | B/L CIA | L EIA | R CIA |
| Previous stent | No | No | No | No | No | No | No |
| Occlusion length, cm | 4 | 13 | 17 | 9 | 6/2 | 10 | 2 |
| LOS, days | 2 | 4 | 2 | 2 | 2 | 2 | 2 |
| Technical success | Yes | Yes | Yes | Yes | Yes | Yes | Yes |

AAA, Abdominal aortic aneurysm; B/L, bilateral; CIA, common iliac artery; EIA, external iliac artery; L, left; LOS, length of stay; R, right.

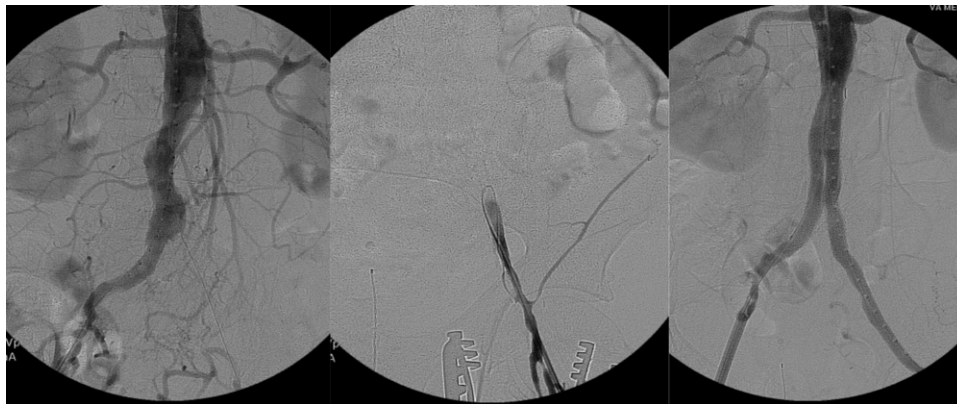


Fig. Patient with symptomatic 4.6-cm symptomatic abdominal aortic aneurysm (AAA) and disabling claudication in lower left extremity. **Left**, Patient had occluded left common iliac, left external iliac and left hypogastric arteries. **Middle**, Patient received a Gore Excluder device after subintimal angioplasty and recanalization of the left iliac system with extension of a Viabahn stent graft into the left external iliac artery. **Right**, Completion angiogram demonstrates widely patent left iliac system. This remains patent at 22 months of follow-up.

renal necks, including the development of fenestrated and branched endovascular devices. However, access issues still remain quite a problem. Placement of a device may be difficult in patients with small access vessels. Lower-profile and more hydrophilic devices are being developed and are undergoing trials to help with this problem and allow easier passage of devices through difficult anatomy.

These devices, however, do not address the issue of occluded iliac arteries. Iliac conduits are the most common way that small blood vessels are bypassed for EVAR. Conduits may confer up to a 59% complication rate to the case, mostly from the effect on the patient of the retroperitoneal incision.⁵ It is commonly only used for delivery of the main body of the bifurcated device. Recanalizing an occluded vessel may allow placement of the bifurcated endografts without a conduit.

One patient in our series needed a conduit because of a small EIA that would not accommodate a device and had an iliofemoral bypass to the side that was recanalized. This was done because the patient had a small but patent EIA on the side of the conduit and an occluded hypogastric artery on that side as well. On the side contralateral to the conduit,

there was a very diseased EIA that was occluded extending to the femoral artery. Because the patient had already received the conduit, we used it to help maintain hypogastric perfusion after recanalization of the occluded EIA and delivery of the device.

One of the potential complications of recanalizing small, calcified tortuous vessels is the possibility of rupture of the iliac artery. Angioplasty of stenotic calcified arteries has been reported to have a <1% risk of rupture in large series.¹⁹ Covered stent graft insertion to treat this complication has met with good success but can prove fatal if wire access is lost. Recanalization of chronic total iliac occlusions has been reported, with a risk of rupture in 1.4% of cases.²⁰ Only one rupture occurred in our series, and we were able to treat this with a covered stent graft, with minimal added morbidity.

Preoperative planning is very important in these complex cases. Three-dimensional imaging with centerline of flow measurements of vessel diameters is important to determine if the size of the native iliac arteries can accommodate a bifurcated device. Typically, the more diseased iliac artery with the occlusion is used to deliver the con-

Table II. Continued.

| 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|-------------------------------|-------------------------------|----------------------|------------------|--------------------|--------------------|--------------------|
| 4 | 3.1 | 5.1 | 5.8 | 5.8 | 5.7 | 6.1 |
| Severe claudicant Excluder | Severe claudicant Excluder | AAA size Excluder | AAA size Renu | AAA size Zenith | AAA size Zenith | AAA size Zenith |
| 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| L CIA | R CIA | L CIA | L EIA | L CIA L EIA | L EIA | L CIA |
| Yes | Yes | No | Yes | No | No | No |
| 4 | 4 | 6 | 13 | 12.6 | 5.6 | 4.7 |
| 1 | 2 | 1 | 2 | 6 | 2 | 5 |
| Yes | Yes | Yes | No | Yes | Yes | Yes |

Table III. Adjunct procedures

| Procedure | No. |
|---|-----|
| Covered stent graft in EIA | 2 |
| Iliofemoral endarterectomy | 2 |
| Bare stent in EIA | 1 |
| Extension to EIA | 1 |
| Re-entry device used | 2 |
| Right iliac conduit iliofemoral bypass contralateral side | 1 |

EIA, External iliac artery.

tralateral limb because of the smaller sheath size needed to deliver the device. The smallest diameter device should be used to effectively exclude the aneurysm.

These patients typically also have severe comorbidities and may not be good candidates for open repair. Preoperative counseling with the patients should describe potential alternative procedures if there is a technical failure, including AUI CFFB as well as possible conversion to open surgical repair. A full range of adjunctive equipment should be available for the case, including AUI devices, a full range of balloons, and bare-metal and covered stent grafts in case of iliac rupture. Re-entry devices may be useful if the true lumen cannot be re-entered during recanalization.

This study has several limitations. This retrospective nonrandomized study looked at patients who were operated on with intent to perform endovascular recanalization of these occlusions. Patients with aortoiliac occlusions that were not anatomically suitable for this procedure were potentially seen at the three institutions, so there was a potential for selection bias. We did not evaluate patients with aneurysms and iliac artery occlusions that were treated by more traditional means such as open aortic surgery or AUI and CFFB. We also did not include patients with severe stenosis, although these patients may potentially also be treated with adjunctive angioplasty, sequential dilation or stenting of the arteries, or both.

This was also a relatively small study, with only 14 patients garnered from three tertiary referral centers during a 6-year period. Larger studies with longer follow-up assessments of this method would be needed to determine the long-term outcomes of these patients.

CONCLUSIONS

Use of a bifurcated EVAR to treat patients with concomitant infrarenal aortic aneurysms and chronic total occlusions of the iliac arteries is feasible, with a high rate of technical success, and is effective, with good midterm patency and aneurysm sac regression in selected patients. Larger long-term studies are needed to prove that this is an effective and durable treatment strategy for patients with aneurysmal and occlusive disease.

AUTHOR CONTRIBUTIONS

Conception and design: RV, ES, WJ, DM, MF

Analysis and interpretation: RV, WJ, DM, MF

Data collection: RV, ES, WJ, DM, MF

Writing the article: RV, MF

Critical revision of the article: RV, WJ, MF

Final approval of the article: RV, ES, WJ, DM, MF

Statistical analysis: RV

Obtained funding: Not applicable

Overall responsibility: MF

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DISCUSSION

Dr Samuel Money (*Scottsdale, Ariz*). I thank the authors for sending me a copy of their manuscript well before this meeting. The manuscript by Vallabhaneni and coauthors describes recanalizing chronic occlusions of the iliac system to facilitate placement of devices for endovascular aneurysm repair (EVAR). It is quite an interesting paper and quite an interesting concept. I have numerous questions. My first question regards the actual incidence of this occurring. You describe 14 patients at three very busy tertiary care institutions over a 7-year period. How many total EVARs were performed at these institutions, and how many were turned down? You talk about 14 patients. Are we talking 1% of the total population with abdominal aortic aneurysm (AAA) population, 2%, or 10%? It seems to me that this is a very, very small percentage of patients; however, I would ask you to just sort of share with us what percentage you really think this would be.

Another question: What was the mean size of your AAAs? You describe a range from 3.1 to 7.6 with a mean of 5.1 cm. Clearly, these are smaller aneurysms than one would expect; however, I believe some patients were treated because of their occlusive disease. Can you please delineate on the fact that your average aneurysm size was 5.1 cm?

You discuss one patient who had a ruptured external iliac. As salvage for the bleeding you placed a covered stent. Did you then have enough diameter to pass the endograft up with the Viabahn in place? Or, did you place the endograft while there was still some oozing and then place the Viabahn? My guess is you probably used this as the contralateral limb, is this so?

My next question involves the use of additional bare-metal stents. Did you use these? Frequently, when we place an endograft, it lays in an area of unusual tortuosity or in an area of such severe calcification that ballooning just does not help. We found that we have probably reduced our iliac limb occlusions by placing a self-expanding stent and sort of smoothing out the abrupt angulation. I was wondering if you used any bare-metal stents in these cases?

My final question complements you on this superb paper and I just ask you to hypothesize about the long-term results. Do you think that this will be as successful long-term or will more patients

need what we call "touch-up procedures?" Thank you very much. I appreciate discussing this paper.

Dr Ehab E. Sorial. Thank you. In reference to the first question, the actual incidence or the occurrence of this iliac occlusion in the setting of aortic aneurysm is based on our institution, the University of Kentucky. I would say we do approximately 70 EVARs a year. It is hard to basically say how many of them had occluded iliacs. One of the flaws of the study is that we did not identify all patients who had iliac occlusions receiving open or endovascular repair. It was not a randomized trial. All that we looked at were patients who had iliac occlusions and aneurysms who underwent EVAR placement. So I would guess the range is about 2% to 5% to have the iliac occlusion and the aneurysm at the same time, but that is a guess.

In reference to the second question, most of these patients underwent EVAR placement for an aneurysm size >5 cm. The few patients that underwent aneurysm repair <5 cm are because of claudication symptoms or because of their aneurysm being symptomatic.

The third question was regarding the iliac rupture that required placement of an external iliac Viabahn stent. The ruptured iliac in this patient happened after recanalizing his left side and after placement of main body of the aortic graft from the right side. Basically, trying to dilate the left external iliac with a bigger balloon is when it ruptured. So the Viabahn stent was placed and extended to the contralateral gate so at that time we already had the main body of the aortic graft placed from the contralateral side.

Regarding the use of bare-metal stents, we use them occasionally for the distal part of the iliac limb at the tortuosity area just to tack the graft down so that it does not begin "bird's beaking" or just does not lift up, but in those patients, we used them just because of the occlusive disease the patient had.

Successful long-term results? I speculate that possibly it will be a good option for a lot of patients, especially if we can recanalize the iliacs. We have just a few years of follow-up on those patients, but I expect it is going to be a successful long-term outcome for these patients. Thank you.