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**Clinical data, guidelines and real-world
outcomes of endovascular iliac aneurysm
repair with the GORE® EXCLUDER®
Iliac Branch Endoprosthesis**

**REPORT OF SATELLITE SYMPOSIUM SPONSORED BY GORE
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Introduction

Isolated aneurysms of the iliac arteries are extremely rare. They most frequently occur in the common iliac artery (CIA) and are least frequent in the external iliac artery (EIA).¹ Most (95%) affected patients are male and the median age of diagnosis is in the seventh decade of life.²

The underlying pathology of isolated iliac artery aneurysms is similar to that of abdominal aortic aneurysms. This includes degenerative aneurysm, pseudoaneurysm, penetrating ulcer, post-dissection aneurysm mycotic aneurysm, and traumatic aneurysm.³ Unlike patients with abdominal aortic aneurysms, those with iliac artery aneurysms present with symptoms of compression of other structures, particularly the ureter, sacral plexus and iliac veins.

Reported growth rate of isolated iliac artery aneurysms is similar to that of abdominal aortic aneurysms. Ruptured isolated iliac artery aneurysms are associated with significant mortality,⁴ which is higher when treatment is undertaken as an emergency rather than an elective surgical procedure. Effective and timely intervention is therefore essential to improve survival.

The aim of surgical treatment is to exclude the aneurysm from the circulation to prevent further growth and rupture. Traditional open surgical repair (OSR) was the mainstay of treatment but is technically challenging due to the location of the aneurysms in the pelvis and a frequent prior history of abdominal aortic aneurysms.¹

Endovascular repair (EVAR) of isolated iliac artery aneurysms is a less invasive alternative to OSR. It is performed by a combination of branch-vessel coil embolisation and stent grafting, and has potential advantages over OSR in reducing perioperative morbidity and mortality.⁵

This supplement is a report of a satellite symposium held during the Vascular Societies' Annual Scientific Meeting in November 2022. It reviews clinical data, guidelines and real-world outcomes of endovascular iliac aneurysm repair with the GORE® EXCLUDER® Iliac Branch Endoprosthesis.

Registry data on iliac branching techniques

Dr Jan Heyligers

Consultant Vascular Surgeon, Elisabeth TweeSteden Hospital Tilburg, The Netherlands

Dr Heyligers began by reminding delegates that isolated common iliac artery (CIA) aneurysms are rare, comprising less than 2% of all aneurysms. In more than 20% of cases, CIA aneurysms occur in conjunction with abdominal aneurysms, and often occur bilaterally.^{6,8} It is possible to occlude the internal iliac artery (IIA) and cover it with endograft, at the same time sealing the external iliac artery (EIA). This is not, however, without risk of complications. Buttock claudication is the most common, reported as unilateral in 27% and bilateral in 32% of patients. Other complications include erectile dysfunction (up to 18%) colonic ischemia (up to 3%) and spinal ischaemia (<1%).⁹⁻¹²

Several iliac branched devices are available. Cook have a 20Fr delivery system and the internal component is used with either the GETINGE® ADVANTA V12® Balloon Expandable Covered Stent or the BD® FLUENCY® PLUS Endovascular Stent Graft. Artivon has a 18Fr delivery system and is used with the JOTEC E-VENTUS BX Stent Graft. At 16Fr the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is the smallest currently available delivery system. It has its own dedicated internal iliac component, and is also the only iliac branching device to be approved by the US Food and Drug Administration (FDA) since 2016.

Reviewing the current clinical guidelines, Dr Heyligers reported that both the European and US guidelines recommend preserving at least one iliac artery, the European guidelines stating that this is mandatory to avoid early complications. The US guideline also strongly recommends the use of an FDA-approved iliac branched endograft to maintain perfusion of the internal iliac artery.^{5,13}

Dr Heyligers then presented clinical studies of the use of the IBE. He noted that all these studies were published in peer-reviewed journals, and that most were retrospective.

Dutch Retrospective Cohort¹⁴

The retrospective cohort analysis by the Dutch IBE Collaboration included 51 CIA aneurysms in 46 patients recruited from 13 sites in The Netherlands. The patients were aged 70.2 (±8.5) years and 45 of the 46 (98%) were male.

Dr Heyligers reported that at six months, the primary patency of the internal iliac limb was 94%, and there was a significant decrease in the diameter of the CIA aneurysm: from 42.4(±7.2)mm at baseline to 38.4(±7.5)mm. Reinterventions were performed in two patients (7%). These interventions comprised repair of a type 1b endoleak.

Global Retrospective Study on Bilateral IBE¹⁵

This international retrospective review of multicentre experience of bilateral IBE included 24 centres (16 in the USA, 8 in Europe) and 47 patients (45 male). Dr Heyligers highlighted that the patients were younger than those in the Dutch IBE Collaboration, having a mean age of 68 (41-84) years.

Technical success was achieved in 46 of 47 patients (98%), with no type I or III endoleaks detected. IIA adjunctive stenting was needed in four patients. Follow-up imaging was available in 40 patients (85%). After mean follow-up of 6.5 (1-36) months there were no type I or III endoleaks. Two of 80 (2.5%) branches were occluded and one patient suffered buttock claudication.

Dr Heyligers concluded that in this retrospective review, bilateral preservation could be performed safely using the IBE, with excellent technical success and short-term patency rates. Limb and branch occlusions were rare, usually due to kinking, and could almost always be treated successfully with stenting.

US IDE trial versus GREAT registry data¹⁶

The Gore IBE® investigational device exemption (IDE) trial was a prospective, multicentre single-arm study designed to assess the safety and effectiveness of the IBE as concomitant treatment in patients with CIA aneurysms or aortoiliac aneurysms. Pivotal enrolment was completed in 2015 and the continued access arm was completed in 2016. Bilateral treatment was allowed only in the continued access arm.

The Global Registry for Endovascular Aortic Treatment (GREAT) registry is Gore initiated and designed to obtain real-world data on the performance of Gore aortic devices for a variety of aortic diseases. GREAT does not include US IDE trial patients. GREAT

completed enrolment in 2016 with >5000 patients and follow-up of up to 10 years is ongoing.

At baseline the numbers of patients in the IDE trial and the GREAT registry were comparable with 99 (98 male) in the IDE trial and 92 (85 male) in the GREAT registry. Dr Heyligers noted that there were more male patients in the IDE trial and the GREAT registry patients were more diseased, with a greater prevalence of hypertension, hypercholesterolaemia and peripheral vascular disease (Figure 1).

In the IDE cohort, 35 patients had bilateral disease and 26 had a staged procedure: first, occlusion of one side followed by an IBE contralaterally. Patients who had bilateral treatment were allowed only in the continued access arm and four patients of 35 had bilateral IBE placement.

Internal iliac limb patency was 93.6% (86.4%-97.1%) at 12 and 24 months in the IDE study. In the total IDE cohort there were eight cases of buttock claudication. In one case buttock claudication was ipsilateral with the patient endograft. Seven cases (27%) were contralateral to the IBE in 26 staged procedures – according to Dr Heyligers a similar proportion to that seen in the literature.

Three IDE patients and three GREAT patients underwent reintervention at one month; two IDE reinterventions (2.1%) and one GREAT reintervention (1.6%) were for thrombotic events. In each study five additional patients underwent reintervention at up to months (5% versus 5%), all for non-thrombotic events.

Dr Heyligers concluded that at up to two years in the IDE trial there are continued excellent outcomes for iliac aneurysm treatment using the IBE. No patient experienced CIA aneurysm sac expansion and in 45% there was CIA aneurysm sac regression of ≥5mm.

Figure 1 Baseline demographic characteristics for 99 pivotal phase and continued access patients enrolled in the investigational device exemption (IDE) trial of the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) and 92 patients treated with the IBE in the Gore Global Registry for Endovascular Aortic Treatment (GREAT)

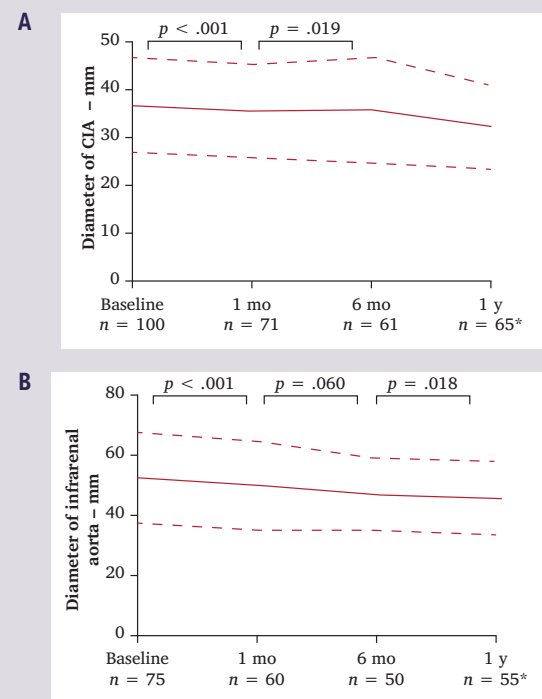
Variable	IDE (n = 99)	GREAT (n = 92)	P value
Male	98/99 (99)	85/92 (92)	.02
Age, years	69.0 ± 9.3	72.2 ± 7.7	.01
Weight, kg	99.9 ± 20.1	89.2 ± 19.0	<.001
BMI >30 kg/m ²	53 (54)	34 (37)	.02
Height, cm	179.5 ± 6.7	174.7 ± 7.2	<.001
CHF	16/99 (16)	6/92 (7)	.04
CABG	12/99 (12)	7/92 (8)	.30
Hypercholesterolemia	69/99 (70)	46/91 (51)	.007
Hypertension	82/99 (83)	66/92 (72)	.07
COPD	20/98 (20)	19/92 (21)	.97
Diabetes	24/98 (24)	18/92 (20)	.41
Renal insufficiency	7/99 (7)	10/92 (11)	.36
PVD	37/99 (37)	13/91 (14)	<.001
ED	12/71 (17)	8/47 (17)	.99
Smoking (current or prior history)	57/99 (58)	38/84 (45)	.10
Cancer	26/97 (27)	23/92 (25)	.78
Myocardial infarction	18/98 (18)	—	—

BMI, Body mass index; CABG, coronary artery bypass graft; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disorder; ED, erectile dysfunction; PVD, peripheral vascular disease. Continuous data are expressed as mean ± standard deviation. Categorical data are expressed as numerator/denominator (%). P values are derived from unpaired t-test and χ^2 test.

ICEBERG registry¹⁷

The ICEBERG registry was a physician-initiated, prospective, multicentre, observational, post-marketing registry on the IBE for aorto-iliac aneurysms. It recruited 100 patients (97 male; median age 70.0 [IQR 64.50-75.5]) years from eight international sites. Scheduled follow-up was up to five years and the registry was

Figure 2 Change in mean diameters during follow up of the (A) iliac branch endoprosthesis treated common iliac artery (CIA), and (B) infrarenal aorta of patients with an aneurysmal infrarenal aorta before implant of the device. * $p < 0.001$ between baseline and one year. Dashed lines indicate standard deviation.



closed in 2018. Twenty-two patients received bilateral treatment and seven had an isolated IBE.

At one year follow-up, Dr Heyligers regarded erectile dysfunction as unique in this patient population. Survival was 95%, with no abdominal aortic aneurysm-related mortality. Four reinterventions were performed for endoleaks. There were 15 type II endoleaks that were not clinically significant. At one year, aortic diameter and treated CIA diameter had declined significantly ($p < 0.001$) (Figure 2).

There were no changes to patients' scores on the Walking Impairment Questionnaire (WIQ) total score before and after surgery. The patients also reported no changes on the domains of the EQ5D questionnaire (mobility, self-care, usual activities, pain/discomfort, anxiety/depression).

Of 100 patients, 43 completed a questionnaire about their erectile function. At baseline, the patients reported moderate erectile dysfunction on the International Index of Erectile Function (IIEF). IIEF scores remained stable during the first year after treatment. The presence of a contralateral hypogastric occlusion was associated with a greater likelihood of worsening erectile dysfunction – according to Dr Heyligers, a reminder to salvage as much blood flow as possible.

Dr Heyligers concluded that the ICEBERG registry shows a favourable one-year outcome of the IBE device, with good clinical results. He added that erectile dysfunction is prevalent, underestimated and related to contralateral occlusions.

Conclusions

In conclusion, iliac branched technology is a feasible technique and offers endovascular specialists a tool to preserve the IIA with good clinical results. Bilateral iliac aneurysms can also be safely treated with this technique. Guidelines recommend preserving at least one IIA, but sacrificing the contralateral IIA leads to buttock claudication and erectile dysfunction. Dr Heyligers concluded that it is well worth preserving what it is possible to preserve.

European Society for Vascular Surgery guidelines and their impact on practice

Mr Gregory McMahon

Consultant Vascular Surgeon, University Hospitals of Leicester, NHS Trust

The European Society for Vascular Surgery (ESVS) first published clinical practice guidelines for the care of patients with aneurysms of the abdominal aorta and iliac arteries in 2011.¹⁹ Mr McMahon reported that these first guidelines were the most cited article in the *European Journal of Vascular and Endovascular Surgery*, being downloaded more than 3000 times and having a major impact on clinical practice. Work on the second, updated version began in 2015, culminating with publication of the revised guidelines in 2019.⁵

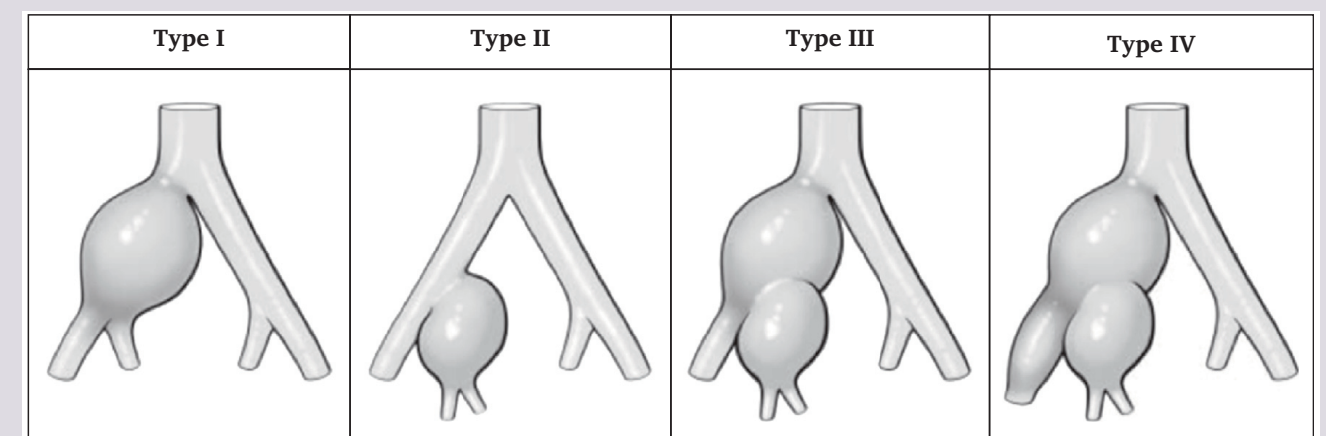
The new guidelines have a broader scope than the 2011 version

and include several new topics that were previously not addressed. These include a plain English section of patient information, pathologies such as isolated iliac aneurysm, and treatment concepts such as endovascular aneurysm repair (EVAR).

Definition

The term iliac artery aneurysm describes aneurysms of the common iliac artery (CIA), the internal iliac artery (IIA) and the external iliac artery (EIA). An isolated aneurysm of the IIA is an aneurysm without

Figure 3 Isolated iliac aneurysm classification by Reber



an aneurysm of the infrarenal abdominal aorta. While the ESVS guidelines focus on isolated IIA, most of the recommendations also apply to patients with abdominal aortic aneurysms (AAA) and concomitant involvement of the iliac segments.

Mr McMahon explained that the ESVS defines an aneurysm of the CIA as dilatation to ≥ 1.5 times the normal diameter. In men the CIA is aneurysmal if the diameter is ≥ 18 mm. A diameter of ≥ 15 mm is aneurysmal in women since they have smaller CIA. In both men and women, aneurysms of the IIA are aneurysmal if they are ≥ 8 mm. There are no criteria to define an aneurysm of the EIA, but these are far less common, probably as a result of the different embryological origin of that vessel. Several systems are used to classify isolated iliac artery aneurysms, but the ESVS has chosen Reber's classification, which categorises these aneurysms into four types based on anatomical configuration and the position of the aneurysmal portions (Figure 3).²⁰

Surveillance

The growth rate of isolated iliac artery aneurysms is similar to that of AAA at about 1–4 mm/year depending on their diameter.²¹ Mr McMahon reported that, in contrast to AAA where the threshold for intervention is 5.5 cm, there is little consensus on when to intervene for an iliac artery aneurysm, especially when a patient presents with an isolated iliac artery aneurysm.

Similarly, there is little evidence to guide the decision to treat, but according to the literature it is usual for ruptured iliac artery aneurysms to be > 5 cm and rarely < 4 cm.⁵ According to the ESVS, conservative management appears to be safe for any aneurysm below maximum of 3.5 cm diameter, though the patient's operative risk and suitability for open versus endovascular repair should be taken into account.⁵

Based on extrapolation from AAA, surveillance may be every three years for iliac artery aneurysms/IIA aneurysms with a diameter 2.0–2.9 cm and annual for a diameter 3.0–3.4 cm. Surveillance may be feasible with ultrasound, but Mr McMahon considered that, given the challenges of visualising the iliac arterial system, the most reliable technique is likely to be cross-sectional computed tomography (CT) imaging.⁵

Open surgery

Before the introduction of EVAR, the mainstay of treatment of isolated iliac artery aneurysms was, as for other intra-abdominal aneurysms, open surgery. This is technically challenging, especially when a large IIA aneurysm is occupying most of the space in a narrow male pelvis — and 90% of iliac artery aneurysms occur in men.¹ There are also many important structures within the pelvis that increase the risk of iatrogenic injury to the ureter, veins or nerves during open surgery.

Open repair may be limited to an isolated iliac artery segment or may, of necessity, involve more proximal reconstruction of the abdominal aorta and contralateral iliac artery. This applies if there is not enough healthy CIA neck for anastomosis or if the patient also has an AAA.

Depending on the extent of the aneurysm, reconstruction in open surgery is by iliac tube graft repair or by bifurcated graft repair including the infrarenal aorta, with or without revascularisation of the IIA. Where access to the pelvis is limited, another option to exclude an iliac artery aneurysm is to ligate CIA inflow and outflow via the EIA and IIA circulation. This is followed by reperfusion of the ipsilateral leg with an extra-anatomic bypass, usually a femoro-femoral crossover from the contralateral side.²²

Endovascular aneurysm repair (EVAR)

Endovascular stenting is the alternative to open surgical repair. Mr McMahon commented that in the early years of EVAR, sealing iliac artery aneurysms involved embolisation of the IIA and extension from the CIA to EIA. Endovascular stenting is more likely than open repair to require coverage of both the infra-renal aorta and the contralateral CIA, to enable a seal from healthy vessel to healthy vessel. As a result, lumbar arteries and the inferior mesenteric artery are more frequently excluded from the circulation. This is relevant in the presence of more extensive aortic coverage that might jeopardise spinal cord perfusion, or co-existing mesenteric circulation disease.

When it is necessary to embolise an IIA, there is usually cross-filling from the contralateral IIA. Although pelvic circulation is usually well compensated by collateralisation from the contralateral internal

iliac circulation, interruption can nonetheless lead to complications. These include buttock claudication, colonic ischaemia, pelvic necrosis and erectile dysfunction, which are far more likely if both internal iliac arterial systems are interrupted.¹¹

Mr McMahon described the introduction of iliac branched endoprostheses as leading to a revolution in the preservation of IIA perfusion, and the 2019 European guidelines recommend that EVAR be considered as first-line therapy for patients with iliac artery aneurysms.⁵ There is a high rate of technical success and high mid-term patency of the target vessel, while avoiding the potential complications of sacrificing circulation in the IIA.

When iliac branching is not possible and embolisation is necessary, the guidelines recommend that embolisation material should be placed as proximally in the IIA as possible in order to maintain as much collateralisation in the distal arterial tree. In cases where there is no option apart from bilateral IIA exclusion, the

guidelines advise that this should be staged with a view to maximising the prospects for the development of contralateral perfusion.⁵

Conclusion

In Mr McMahon's view, it is not unreasonable to consider EVAR as first-line therapy for patients with an iliac artery aneurysm. In addition, maintaining blood flow to at least one internal iliac artery is recommended during either open surgery or endovascular stenting.

The criteria for suitability for iliac branching varies slightly according to the prosthesis. In general, however, if the EIA diameters are 6.5-25mm, the internal iliac artery diameters are 6.5-13.5mm and if there are sealing zones of at least 10mm in those two target vessels, Mr McMahon commented that it is difficult to justify internal iliac artery sacrifice and branching should be routine. There really is no reason not to, he concluded.

Iliac branch endoprosthesis: case study

Dr Martin Hennessy

Interventional Radiologist, Queen Elizabeth University Hospital, Glasgow

Dr Hennessy's case history concerned Mr B, who is 82 years old and lives in a rural area on the west coast of Scotland. Mr B has a five-year history of right intermittent claudication, hypertension, stable angina and chronic obstructive pulmonary disease (COPD). He is otherwise well and is living independently.

Mr B visits his general practitioner (GP) because of a history of intermittent diarrhoea as well as constipation. On examination, the GP finds a large pulsatile mass in Mr B's abdomen and, suspecting an aneurysm, arranges an urgent ultrasound with the local district general hospital.

Investigation

Thursday 15 September - The ultrasound shows that Mr B has a 9cm diameter abdominal aneurysm. Mr B needs an urgent computed tomography (CT) scan and lives more than an hour's drive from the hospital, so the ultrasonographer and radiologist arrange a same-day scan. The CT scan confirms an aneurysm with an almost identical 9cm-diameter measurement (Figure 4).

On the CT scan, the neck of Mr B's aneurysm is highly angulated and the iliac arteries below the aneurysm on both sides are almost aneurysms in themselves. There is also an 89° bend in the neck of

the aneurysm—according to Dr Hennessy, an important influence on the choice of endoprosthesis device (Figure 5).

The CT scan shows that only the right internal iliac artery (IIA) is suitable for sealing, whereas the left internal iliac artery looks diseased and unsuitable for seal.

Figure 4 Ultrasound (left) and CT scan (right) showing 9cm diameter aneurysm

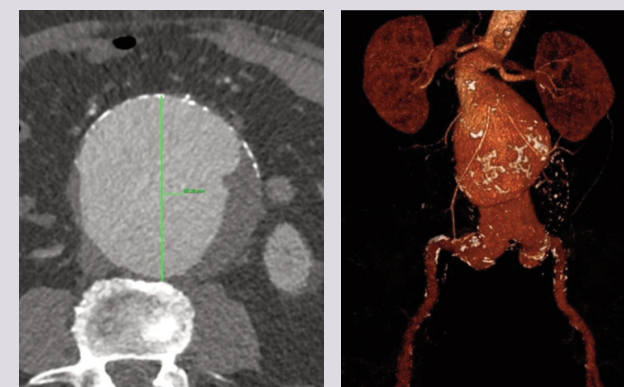
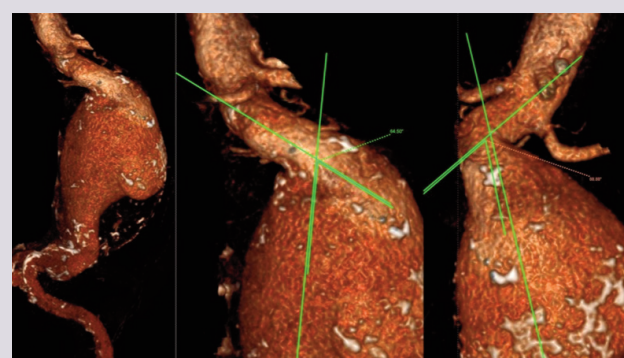


Figure 5 CT scan showing 88.88° bend above the aneurysm



Sunday 18 September - The results of the CT scan are reported to Mr B's GP.

Wednesday 21 September - Seeing that Mr B has a large, life-threatening aneurysm, Mr B's GP refers him by telephone to the Vascular Team at the Queen Elizabeth University Hospital (QEUE) in Glasgow. Dr Hennessy added that this tertiary centre is a nearly two and half hour journey by road from Mr B's home, underlining his risk of mortality should he require emergency aneurysm repair.

Friday 23 September - After discussing Mr B's case, the Vascular MDT agrees that his aneurysm is treatable using the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE). Mr B's scans together with the plan for the surgery are sent to Gore for sizing up via dedicated file transfer from the NHS radiology system. After further discussion between Dr Hennessy and Gore, the IBE is despatched by courier to the QEUE.

Intervention

Monday 26 September - Mr B is admitted by the Vascular Team to QEUE and the next day undergoes the two standard pre-procedure tests mandated by the Vascular Team: an echocardiogram to check his cardiac function and pulmonary function tests to check his lung function.

Wednesday 28th September: Repair procedure - The first step is to inject contrast and insert a catheter into Mr B's left IIA, which is blocked as the first stage of the procedure (Figure 6).

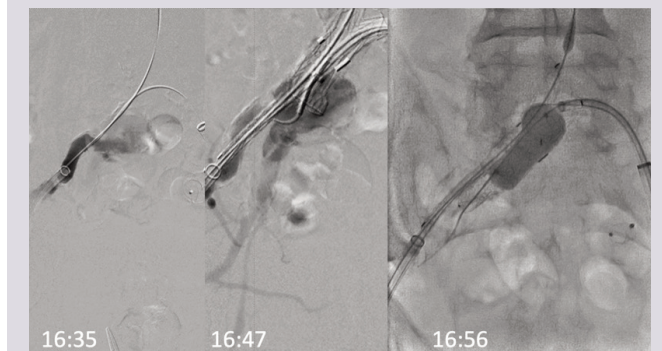
16:35-16:56: The team then turn to the right IIA, beginning with an angiogram to ensure correct positioning followed by deployment of the iliac branch endoprosthesis and then internal iliac component (Figure 6).

16:57-17:03: There is a very tight bend in Mr B's aneurysm and Dr Hennessy drew attention to how the angulation control mechanism of the GORE® EXCLUDER® AAA Conformable Endoprosthesis enables optimal positioning in Mr B's aneurysm (Figure 8). Once the device is in position, contrast is injected to confirm the patency of the seal of the aneurysm.

Conclusion

After three days in hospital, Mr B is discharged back to his home and has recovered well, attending his local hospital for regular follow-up. Mr Hennessy concluded by highlighting that the total time of 1 hour 20 minutes for Mr B's procedure shows how the combination of choice of the right device for each patient and an experienced team can ensure efficient use of operating room time.

Figure 6 Angiograms showing the deployment of the right iliac branch endoprosthesis and internal iliac component



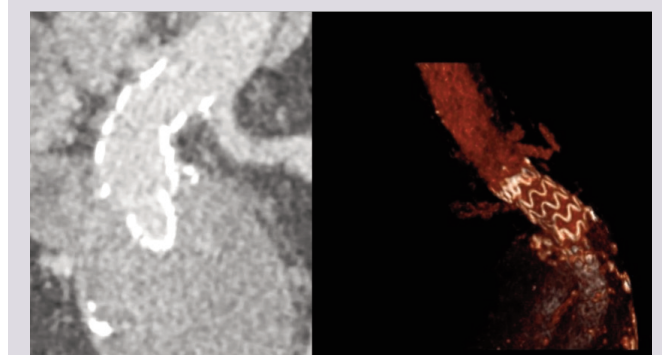
These images show the right sided GORE® EXCLUDER® Iliac Branch Endoprosthesis being deployed. Numerals show the time that the image was taken during the procedure.

Figure 7 These images show the deployment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis at the angulated neck



Numerals show the time that the image was taken during the procedure

Figure 8 These are surveillance images showing the position of the EVAR three months after insertion



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