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ENDOVASCULAR REPAIR OF NARROW DISTAL AORTAS USING AN IN-SITU FENESTRATION TECHNIQUE

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ABSTRACT

Purpose: The aim of this study was to demonstrate that in situ fenestration (ISF) of an aorto-uni-iliac endograft to treat aortoiliac disease with narrow distal aorta vessels is effective and safe.

Materials and Methods: Data in regard to all patients treated by ISF between August 2014 and December 2019 was retrospectively analyzed. The series included 27 patients, aged 70 ± 11 years. The pathologies treated included aortoiliac occlusive disease ($n=16$), asymptomatic abdominal aortic aneurysm ($n=8$) and ruptured abdominal aortic aneurysm ($n=3$). The technique consisted of deploying an aorto-uni-iliac graft, which was converted into a bifurcated repair through contralateral iliac ISF. The inclusion criteria encompassed: (1) the presence of an abdominal aortic aneurysm (diameter >50 mm, rapid growth, ruptured or symptomatic) associated with a narrow distal aorta (NDA) or (2) the presence of severe aortoiliac occlusive disease with an NDA. An NDA is defined as an aortic diameter less than 16mm.

Results: The average aortic bifurcation diameter was 11.9 ± 1.5 mm. 55% of the fenestrated endografts were performed with a multifilament polyester endograft and 45% with ePTFE endografts. Technical success was 100%. Fluoroscopy time was 28 ± 12 min and 94 ± 43 ml of iodine contrast was used. In the postoperative course, a single benign retroperitoneal hematoma was identified. Mean hospital stay was 5 ± 3 days. After a 26 ± 22 months follow-up, overall primary patency was 94% and no endoleak was observed at the ISF site.

Conclusion: The ISF technique is safe and effective in the treatment of aortoiliac disease with an NDA. Comparison with alternative techniques are needed to determine long-term durability.

INTRODUCTION

At the level of the abdominal aorta, endovascular tools are limited with narrow distal aortas (NDA) in both aneurysmal pathologies and occlusive disease. NDA is defined by an aortic bifurcation diameter of less than 20 mm ¹. The major risks of this anatomic feature are both perioperative rupture of the bifurcation and early limb thrombosis in the postoperative course^{2,3}. Current anatomic companies' instructions for use recommend a minimum diameter of 16 mm at the aortic bifurcation. Despite the technical improvements of the devices, an NDA still represents a limitation for bifurcated endograft and kissing stent techniques ⁴.

In situ fenestration (ISF) is described at the level of the aortic arch and the thoraco-abdominal aorta ⁵. This "off-label" technique presents satisfactory mid-term outcomes in terms of patency and fenestration mechanical behavior. It provides a new endovascular approach for high risk patients and in cases whereby custom-made devices are not available. Experimental evaluations highlighted damage to the perforated endograft but the leakage was limited by textile elastic recoil ⁶. Different techniques (needles, laser and radiofrequency catheters) and different endografts are currently used to perform ISF, however, long-term data is lacking to conclude on a clear fenestration creation protocol ⁵.

ISF allows conversion of an aorto-uni-iliac endograft into a bifurcated endograft, thereby avoiding crossover femoro-femoral bypass and its complications ⁷. A protected oversized kissing stent could be performed without risk of aorta bifurcation rupture.

The aim of this study was to demonstrate that performing in situ fenestration (ISF) of an aorto-uni-iliac endograft to treat aortoiliac disease with narrow distal aorta vessels is effective and safe.

MATERIALS AND METHODS

Patient selection

After preliminary experimental testing including an in vivo and mechanical evaluation ⁶, the Institutional Hospital review board approved the study which was conducted in agreement with the Helsinki II declaration. The consent form was waived by the Institutional Hospital review board. Patient were selected to allow an average follow-up time of 2 years.

Between August 2014 and December 2019, 27 patients were treated by ISF and included in this retrospective study. Patient characteristics and preoperative conditions are presented in **Table 1**. The data was analyzed retrospectively. All patients underwent a preoperative computed tomography angiography (CT) scan to assess the anatomy of the abdominal aorta, and the decision to perform ISF was discussed by an expert multidisciplinary team (4 vascular surgeons and 2 interventional radiologists). The standard CT angiography protocol included 3 phases: unenhanced, arterial phase CT angiography (automatically triggered at 100 Hounsfield units) , and delayed venous phase (performed at 60 seconds). A contrast agent, Iohexol (100ml, Omnipaque 350, GE healthcare, Chicago, Illinois), was injected at a rate of 4mL/second, followed by a 20mL saline flush at 4mL/second via a minimum 20-gauge intravenous, peripherally inserted central catheter. The diameter of the aorta was determined using the centerline of flow. An NDA was defined by an outer-to-outer aortic diameter less than 16 mm measured in any location within the distal 5 cm of the abdominal aorta. Mean aortic bifurcation diameter was 11.9 ± 1.5 mm. The distance was measured by each operator. Apart from emergent cases, all patients were informed of the off-label nature of this technique, of the risk of early fenestration failure and of uncertainties concerning long-term device integrity. All patients received an oral antiplatelet agent (aspirin(75-250 mg/dl)(Bristol Laboratories, Berkhamsted, UK) or clopidogrel in case of contraindication to Aspirin (75

mg/dl)(Mylan, Paris, France) and a statin before the procedure. Preoperative clinical data, including demographics, cardiovascular risk factors and comorbidities, were retrieved. Hypertension was defined by an increase in arterial blood pressure above the normal value of 140/90 mmHg. Renal insufficiency was defined by a glomerular filtration rate less than 60 ml/min/1.73m².

Indication

The inclusion criteria encompassed: (1) the presence of an abdominal aortic aneurysm (diameter>50 mm, rapid growth, ruptured or symptomatic) associated with an NDA and (2) the presence of aortoiliac occlusive disease with an NDA. NDA was defined by an aortic diameter<20 mm¹.

Indications included aortoiliac occlusive disease in 16 patients, asymptomatic abdominal aortic aneurysm in 8 patients, and ruptured abdominal aortic aneurysm in 3 patients. All patients presented an NDA during the preoperative evaluation.

In situ fenestration technique

As previously described ⁷, the procedure was performed under general anesthesia and guided with a mobile C-arm (Cios Alpha, Siemens) **Figure 1**. The less diseased and tortuous iliac artery, selected on the preoperative CT scan, was used to introduce the needle because of the inflexibility of the device. Whenever possible, the procedure was carried out percutaneously with the preclosure technique using Proglide vascular devices (Abbott vascular, CA, USA) for retrograde punctures of the common femoral arteries.

The first step consisted of placing an endograft or a covered stent from a retrograde femoral access. The endograft was positioned down to each distal renal artery in cases of aneurysm

exclusion. Regarding the occlusive disease, the endograft was positioned down to the inferior mesenteric artery. The endograft was placed over a Lunderquist wire (Cook Medical, Bloomington, IN, USA). The endograft and its suprarenal stent were deployed. The distal security wire was not released to maintain control of the distal part of the endograft and to keep the graft straight while performing fenestration. A transjugular intrahepatic access needle (Colapinto Ring, Cook Medical, Bloomington, IN, USA) was inserted in a 9F introducer through contralateral femoral access. When the top of the introducer was at the level of the aortic bifurcation, the dilator of the introducer was removed, and the introducer was pushed up to the proximal part of the endograft. In abdominal aortic aneurysm cases, fenestration was performed into the ipsilateral limb of the endograft. Contact between the introducer and the endograft was ensured by observing a slight deformation of the endograft while pushing the introducer in a front and profile view. Both front and profile views allowed to position the needle at a 90° angle. The needle was then advanced, and the endograft was punctured at the level of the aortic bifurcation. The hole created was secondarily enlarged using cutting (Boston Scientific, Natick, MA, USA) or high pressure balloons (Conquest; Bard Vascular, Tempe, AZ, USA). A long sheath was advanced via fenestration to control the success of the technique. A kissing stent using balloon expandable covered stents was then performed to stabilize the repair. The diameter of the balloon expandable covered stent was oversized by 1 mm with respect to the common iliac artery diameter.

The completion angiography confirmed the patency of the stents and the absence of an early leak at the level of the ISF. If compression of the endograft had been observed at completion angiography, additional stent placement was performed into the endograft.

Outcomes

The primary outcome was the primary patency after in situ fenestration by CT scan or Doppler ultrasound **Figure 2**. Primary patency refers to patency that is obtained without the need for additional or secondary surgical or endovascular procedures as defined by the reporting standards for endoluminal revascularization devices ⁸. During the follow-up, the adverse events were graded using the reporting standards for endoluminal revascularization devices ⁸.

Technical success was measured as a ratio between the number of successful perforations and the number of attempts.

Statistical Analysis

Continuous variables are presented as the mean and standard deviation or median and interquartile range. Categorical variables are presented as counts and percentages. For patients who died before the final follow-up examination or for patients lost to follow-up, the status of the last follow-up examination was recorded.

RESULTS

Procedural data.

Percutaneous access was performed in 26% of femoral arteries (14/54). Multifilament polyester endografts were used in 15 cases (55%): Cook Zenith aorto-uni-iliac (Cook Medical, Baereskov, Denmark) in 9 cases (34%) and Medtronic Endurant II (Medtronic, Santa Rosa, CA, USA) in 6 cases (21%). Expanded polytetrafluoroethylene (ePTFE) endografts were used in 12 cases (45%): Fluency plus (Bard Vascular) endografts in 9 cases (34%) and Gore Excluder limbs (W.L Gore & Associates, Flagstaff, Arizona, USA) in 3 cases (11%). Fenestration was performed via right femoral access in 15 cases (55%). The fenestrated hole was enlarged using the combination of sequential cutting balloon (Boston Scientific, Natick, MA, USA) and high pressure balloon (Conquest; Bard Vascular, Tempe, AZ, USA) in 12 cases (44%), cutting balloon (Boston Scientific, Natick, MA, USA) alone in 9 cases (33%), high pressure balloon (Conquest; Bard Vascular, Tempe, AZ, USA) alone in 5 cases (18%) and a 9 French introducer in 1 case (9%). The average diameter of balloon-expandable covered stents used to perform the kissing were 7.4 ± 0.8 mm on the right side and 7.5 ± 0.8 mm on the left side. Lifestream stents (Bard Vascular) were used in 21 cases, and Advanta V12 stents (Atrium Medical; Hudson, New Hampshire, USA) were used in 33 cases. Distal limb extension was needed in 35% of cases (19/54). An endarterectomy of the femoral bifurcation was performed in 18% of cases (5/27). A proximal aortic cuff (Medtronic, Santa Rosa, CA, USA) was used in 2 cases (7%). No open conversion was needed.

The mean operative time was 193 ± 84 minutes, the fluoroscopy time was 28 ± 12 minutes and 94 ± 43 ml of iodinated contrast medium was used. The mean Air Kerma and dose area product were 218 ± 87 mGy and 42 ± 18 Gy.cm² respectively.

Thirty-day outcomes and postoperative complications.

Mean hospital stay was 5 ± 3 days. None of the patients underwent surgery for aortic or iliac causes during the early postoperative course. The mortality rates from unrelated causes was 7% (2/27). The first patient died on postoperative day 16 from exacerbation of chronic obstructive pulmonary disease. The second patient died on postoperative day 5 from hemorrhagic shock after major amputation. Major amputation was deemed necessary because of a severe critical limb ischemia preexisting the procedure. Hemorrhagic shock was secondary to active bleeding at the amputation site and important blood coagulation disorders occurred after an anticoagulant drug overdose.

The morbidity rate was 11% (3/27). There was no patient overlap in the morbidity and mortality assessments. One patient occluded the left limb (fenestrated side) due to poor femoral artery outflow (Grade 3). The balloon expandable covered stent diameters were of 9 mm on both sides and there was no compression on the control CT scan at 1 month. One patient presented a retroperitoneal hematoma with no need for reintervention (Grade 2). This hematoma was probably caused by a perforation of the iliac artery which was further covered by the repair. Finally, one patient developed a local hematoma at the groin (Grade 1).

Follow-up.

At 26 ± 22 months (1-69), the overall primary patency was 94% (51/54). Imaging follow-up consisted of ultrasonography in 10 patients and in follow-up CT scans in 17 patients. There was no stent compression at the ISF site and no early stent restenosis. One major adverse event (Grade D) occurred during the follow-up. The patient was referred with bilateral occlusion of the repair at 5 months post procedure. A follow-up CT scan at 5 months

highlighted a kink at the distal part of the balloon expandable covered stent at the endograft side. Open conversion consisted of aorto-bifemoral bypass via a laparoscopic approach.

During the last follow-up, one benign type II endoleak was detected on the control CT- scan.

No type III endoleak was detected at the stent-fenestration interface.

DISCUSSION

Mechanical ISF at the level of the abdominal aorta presents satisfactory midterm outcomes in terms of patency and sealing of the stent-fenestration junction. The technique can be performed safely. No open conversion was needed because of aortic or iliac artery injury.

Mechanical ISF is mainly reported for aortic arch branch reconstruction during TEVAR procedures^{5,9}. The needle is the puncture method mostly employed in this setting. Bench studies experimentally concluded that the fabric was preserved with a needle or a guidewire by spacing the textile fibers. The fabrics need to be punctured perpendicularly to obtain the best morphologic quality of the fenestration. Therefore, steerable sheaths and steerable needles are being developed and could be useful to perform ISF. The strategy in NDA anatomies permits positioning the needle against the endograft at a 90° angle thanks to 1) the anatomy of the aortic bifurcation and 2) the curvature of the extremity of the needle.

NDA is a challenging anatomic configuration in aortoiliac endovascular procedures. Major risks are aortic bifurcation rupture and early limb thrombosis secondary to downsizing of the devices. Traditionally, aorto-uni-iliac converters with crossover femoral bypass are performed in this case. Adjunctive maneuvers may be performed in cases of NDA. The “paving-cracking” technique could be an efficient option but has to be used with caution in patients with poor proximal and distal neck anatomy where type I endoleak could lead to bleeding complications¹⁰. However, ISF allowed optimization of the sealing, and made improvements to oversizing particularly at the level of the iliac arteries. A single lumen endograft design AFX endograft (Endologix, Inc., Irvine, CA) provided another substantial advantage in the case of NDA¹¹. However, this endograft is currently no longer available in France. In occlusive aortoiliac disease, covered endovascular repair of the aortic bifurcation (CERAB) technique is currently the standard when the aorta is involved¹². The CERAB procedure

consists of reconstructing the aortic bifurcation with an iliac kissing stent performed into an abdominal aortic stent- graft. This technique does not prevent leakage between the covered stents in cases of aortic bifurcation injury. The use of retrograde laser in situ fenestration has been reported to overcome NDA¹³. Laser and radiofrequency probes could be an alternative to the needle in this setting.

ISF at the level of the abdominal aorta allows satisfactory oversizing of the kissing, avoiding the risk of rupture of the aortic bifurcation. In the NDA configuration, the needle is easily inserted at the bifurcation directly anterior to the aorto uniiliac endograft. Utilization of the Colapinto TIPS needle is infrequent in vascular surgery practice¹⁴. Aside from performing ISF, a TIPS needle was used to re-enter the true lumen in a subintimal angioplasty for iliac occlusion. ISF was useful in cases of shaggy aortas extending to the common iliac artery. The aorta is first covered to minimize embolization and then fenestrated.

Both ePTFE and polyester endografts were used to perform ISF. However, experimental works highlighted that leakage was higher at the stent-fenestration interface using PTFE endografts. Consequently, PTFE grafts were preferred for occlusive disease whereas aneurysms were excluded with multifilament polyester aorto-uni-iliac endografts. The enlargement protocol, once fenestration is created, is still a matter of debate. Experimental testing reported fabric damage with the use of cutting balloons¹⁵. Undersizing the diameter by 1-2 mm, both cutting and high pressure balloons created satisfactory fenestration in clinical practice.

NDA are a frequent anatomic presentation. A paraplegic condition was found in 15% of patients. From a physio-pathological point of view, chronic spinal cord ischemia causes hemodynamic and morphologic adaptation at the aortoiliac level¹⁶. There is a larger aortic diameter with above all reduced diameters of common iliac arteries. Therefore, ISF was particularly fitting for this population¹⁷.

The limitations of this preliminary study included the absence of comparison with CERAB or the paving-cracking technique. Furthermore, the risks of organ injuries with the needle should be considered. However, no duodenal fistula or peritonitis was reported in this series. Both front and profile views allowed positioning of the needle at a 90° angle. The profile view may be used routinely to control fenestration and avoid the risk of perforation of the iliac artery or aortic bifurcation. A noncompliant balloon placed from the contralateral side and inflated at the level of the fenestration site could also be useful. The deflation of the balloon signals the success of the fenestration. Attention must be given to the evolution of the proximal neck with the need for extension with a fenestrated device. The risk of migration of the kissing stents following the placement of the delivery system is a concern.

Finally, it is important to note that ISF remains an “off-label” procedure that should only be performed with IRB approval or in emergency. The long term behavior of fenestrations is unknown.

Improvements can be considered to widen the technique. First, image fusion guidance has shown efficacy for in situ laser fenestration for complex aortic aneurysms ¹⁸. It could be a useful tool to secure the ISF procedure at the level of the abdominal aorta. Second, steerable needles circumvent complex anatomies such as tortuous iliac arteries.

The ISF technique is safe and effective in the treatment of aortoiliac disease. At the level of the abdominal aorta, it provides a bifurcated repair in cases where it is usually considered at risk as an NDA. Comparison with alternative techniques is needed to conclude on the long-term durability.

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FIGURE LEGENDS

FIGURE 1

A: Intraprocedural angiography showing the success of the perforation of an aorto-uni-iliac endograft with the TIPS needle (arrow).

B: A stiff guidewire (arrow) was advanced through the fenestration and advanced into the thoracic aorta.

C: The kissing stent placement was performed to stabilize the repair.

D: Completion angiography (left anterior oblique view) showed the patency of the stents and the absence of early endoleaks.

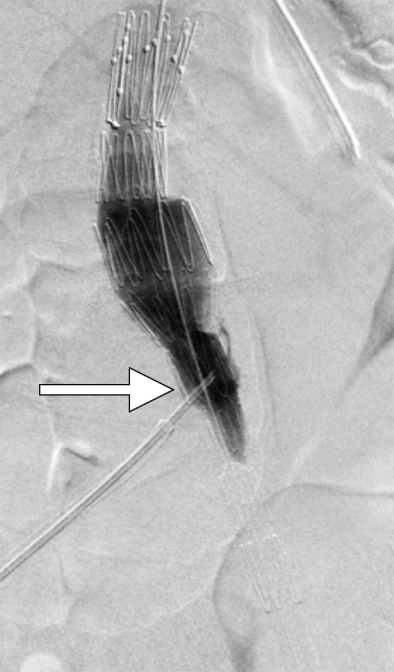
FIGURE 2:

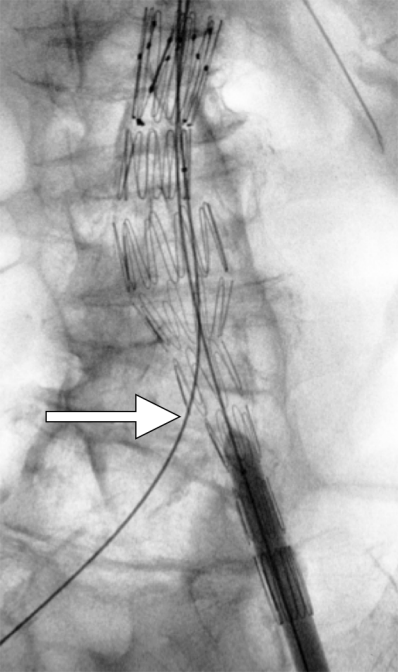
A: Preoperative computed tomography (CT) scan showed a saccular abdominal aortic aneurysm with a narrow distal aorta.

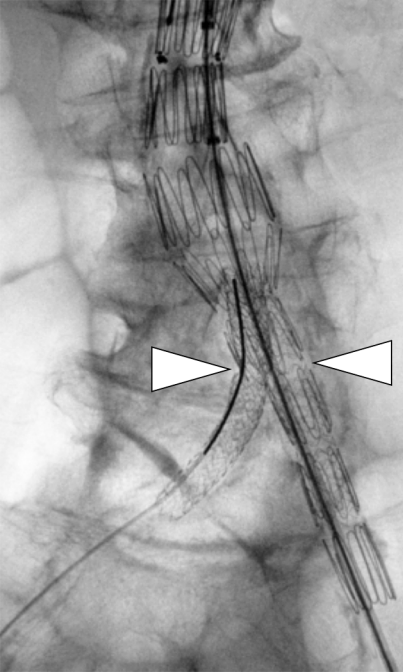
B: Follow-up CT scan at 1 month confirmed the patency of the stent-graft and the absence of endoleaks.

C: Axial view of the follow-up CT scan showed the absence of an endoleak.

D: Coronal reconstruction showed full expansion of the stent at the fenestration (arrow).













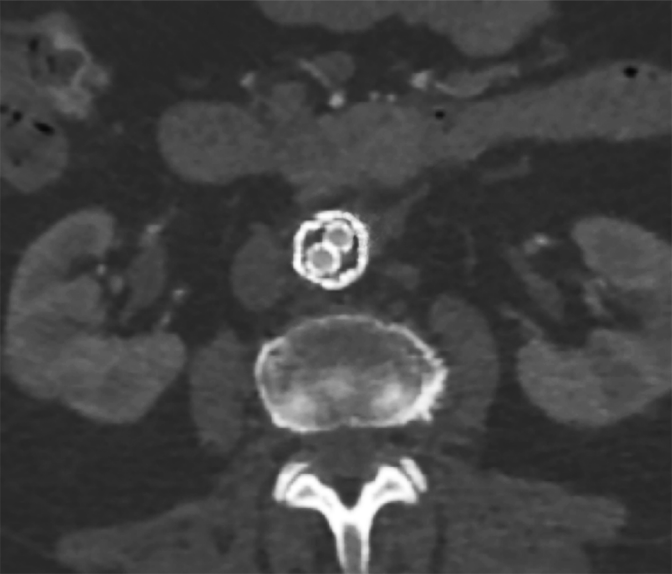




Table 1: Baseline characteristics

Patients	N=27	
Age, years	70±11	
Risk factors	Hypertension	21 (78%)
	Diabetes	5 (18%)
	Hyperlipidemia	17 (63%)
	Smoking	17 (63%)
	Renal insufficiency	4 (15%)
	Coronary artery disease	12 (44%)
	COPD	5 (18%)
ASA	2	12 (44%)
	3	15 (56%)

*Continuous data are expressed as mean+/-standard error of the mean, and categorical data as number or percentage

COPD: Chronic Obstructive Pulmonary Disease