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REVIEW ARTICLE

Aortic stenting

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Abstract

The approach to aortic pathology is nowadays more and more endovascular at both thoracic and abdominal levels. Thoracic stenting has gained worldwide acceptance as first intention to treat pathologies of the descending thoracic aorta. Indications have been extended to aortic arch aneurysms and also to diseases of the ascending aorta. The current devices in use for thoracic endovascular repair (TEVAR) are Medtronic Valiant, Gore TAG, Cook Tx2 and Jotec. The choice of the endograft depends on the thoracic aortic pathology and the anatomical suitability. The technological evolution of the abdominal aortic endografts was very rapid, arriving now at the fourth generation. We report the results of 55 elective cases of endovascular abdominal aortic repair (EVAR) performed in two vascular surgical centers in Romania and Germany. The prostheses used were 16 E-vita Abdominal XT, 12 Excluder, eight Talent, seven PowerLink, three Endurant and nine custom-made, fenestrated or branched from Jotec. The mean follow-up was 18 months with CT-scan, duplex ultrasound and contrast-enhanced ultrasound. The mortality was 2%. EVAR tends to become the gold standard for abdominal aortic aneurysm repair. Technological development of the devices with lowest profile introduction systems will permit to extend the anatomical indications to new frontiers.

Key words: *Endovascular therapy, aortic stent graft, minimally invasive surgery*

Introduction

In the past decades the approach to aortic pathology has become increasingly endovascular. The minimally invasive techniques designed at first for high-risk patients are taken into account for almost every patient in various aortic pathologies.

Open surgical treatment of thoracic aortic aneurysms is associated with high mortality and morbidity including paraplegia as a consequence of spinal cord ischemia. Today, physicians are more likely to adopt the endovascular techniques.

Open surgical treatment requires highly skilled teams of well-trained vascular or cardiac surgeons and the technical possibilities of extracorporeal circulation and neuro-monitoring. Endovascular techniques are an alternative to surgical procedures, but they also need an interdisciplinary team and well-trained physicians, involving interventional cardiologists, surgeons and anesthetists (1,2). The characteristics of an ideal stent graft for the aorta are

- low overall cost
- stent graft size range
- durability (metallic ultrastructure and graft material)
- a good biocompatibility
- sealing capacity
- lowest delivery device size and flexibility
- radial force stability
- customization.

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Thoracic endovascular aortic repair (TEVAR)

TEVAR technology is used nowadays in treating thoracic aortic aneurysms, aortic dissection, intramural hematoma, penetrating aortic ulcer or aortic coarctation (3). TEVAR has gained worldwide acceptance as first intention to treat pathologies of the descending thoracic aorta. Indications have been extended to aortic arch aneurysms and also to diseases of the ascending aorta.

The indications of TEVAR in the treatment of acute type B dissection are: unstable or complicated dissection (with malperfusion), rapid expansion (>1 cm/year), critical diameter (>6 cm) or refractory pain. About 30–42% of acute type B aortic dissections are complicated (4,5). The indication of TEVAR in aneurysmal pathology is when the diameter of the descending aorta reaches 6.5 cm or more. However, because the risk of endovascular surgery is less than the risk of rupture or dissection, the indication is now at 5.5 cm in diameter. Other indications for TEVAR are penetrating aortic atherosclerotic ulcer, intramural hematoma and traumatic aortic transection or rupture. The mortality of TEVAR in comparison with open surgery is 2.1% vs. 11%. In complicated acute type B dissections the mortality is higher (10.6%), but less than in open surgery (33.9%). The only absolute contraindication is an allergy to the materials of the endografts. Relative contraindications are unsuitable vascular access, bad landing zones or systemic infections (6,7). Endovascular procedures are increasing as open surgery decreases, because of demonstrated lower intraoperative blood loss, shorter hospital stay and recovery period and decreased overall morbidity.

After the implantation of the first devices by the Stanford group in 1994, TEVAR devices have undergone multiple modifications. The current devices in use for TEVAR are Medtronic Valiant and Talent Gore TAG, Cook Zenith Tx2, Relay and Jotec E-vita Thoracic (Table I).

The Talent endoprosthesis (Medtronic, Minneapolis, MN, USA) approved by FDA in 2008 is a preloaded stent graft on a catheter delivery system. The graft is made of polyester (Dacron) sewn to a self-expanding nitinol stent. The Valiant device represents the new generation from Medtronic. The length of the graft has been increased to 212 mm and the improvement of the stent is due to the increase in circumferential force and distribution along the aortic wall. It has a new delivery system called the Captivia delivery system (8).

The TAG thoracic endoprosthesis (W.L. Gore Inc., Flagstaff, AZ, USA) has been used in the US from 2005. The graft is made of polytetrafluoroethylene (ePTFE). Release of the endograft goes from central to peripheral sites, making the deployment sometimes difficult (9).

The Zenith TX2 (Cook Inc., Bloomington, IN, USA) is a modular system with specific proximal and distal configurations (barbs and bare springs to prevent migration and endoleak) (10).

The Relay (Bolton Medical, Sunrise, FL, USA) thoracic, MRI-compatible stentgraft with the new Plus delivery system allows forward and backward repositioning in the semi-deployed state. Proximal sealing is also improved by multiple fixation points. The Dual Sheath System assures better pushability and self-alignment (11).

The E-vita Thoracic 3G (Jotec GmbH, Hechingen, Germany) is an endoprosthesis whose delivery system offers the smallest catheter profile.

TEVAR clinical trials have shown better results than surgery in the treatment of descending thoracic aneurysms. The best-known trials are:

- Pivotal trial, prospective non-randomized controlled multicenter trial comparing TAG

Table I. Current thoracic stent grafts in use.

Type of device	Graft material	Stent material	Deployment	Aortic graft diam (mm)	Length (mm)	Remarks
Valiant (Medtronic, Minneapolis MN)	Polyester	Nitinol	Self-expanding	22–46	100–212	Captivia delivery system Straight and tapered configuration
TAG (W.L. Gore Inc., Flagstaff AZ)	ePTFE	Nitinol	Self-expanding	21–45	100–200	Straight and tapered configuration
Zenith TX2 (Cook Inc. Bloomington, IN)	Polyester	Nitinol	Self-expanding	28–42	120–216	Straight and tapered configuration
E-vita Thoracic 3G (Jotec GmbH)	Polyester	Nitinol	Self-expanding	24–44	130–230	Straight and tapered configuration, also custom-made grafts
Relay Plus (Bolton Medical, Sunrise, FL)	Polyester	Nitinol	Self-expanding	22–46	100–250	Straight and tapered configuration Custom-made up to 50 mm aortic diameter

endoprosthesis to open repair of thoracic aortic aneurysm (TAA) (12)
- VALOR (Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms) trial, prospective non-randomized multicenter trial comparing the TALENT device with surgery
- STARZ (Study of Thoracic Aortic Aneurysm Repair with the Zenith TX2 Thoracic TAA Endovascular Graft) trial, prospective, non-randomized multicenter trial comparing the Zenith TX2 endograft with patients anatomically unfit for TEVAR.

In all studies the 30-day mortality was <3%, favoring TEVAR procedures: 1.5% in Pivotal, 2.1% in VALOR and 1.9% in STARZ (13).

The choice of the endograft depends on the thoracic aortic pathology: aneurysms or chronic dissections and acute aortic syndromes. Anatomical and pathophysiological characteristics of each of these diseases will determine the choice of the graft, as will the experience of the team. The location and extent of the aneurysm will determine the landing zones proximally and distally in the aorta. A 15–20 mm length of aorta with minimal calcification, angulation or tapered is needed. Covering the origin of the left subclavian artery (LSCA) is not recommended in order to avoid vertebrobasilar artery insufficiency, stroke, or left arm ischemia in patients with inadequate circulation through the Willis circle prior to LSCA coverage. If necessary, a carotid–subclavian bypass should be performed prior to the procedure.

TEVAR has its own complications: Vascular complications at the entrance site, neurological complications, endoleaks as well as infections. One of the most redoubtable complications is retrograde dissection of the crossa or ascending aorta, but with very low incidence (1, 3 %) (14).

Multilevel aortic disease (thoracic and abdominal aortic disease)

In patients with thoracic aneurysms the incidence of abdominal involvement is between 13% and 29%. Inverse, in AAA patients, an aneurysm of the thoracic descending aorta can develop in 5% of cases (15). The treatment of these patients with multilevel aortic disease was advocated by Crawford in the early 1980s, by simultaneous open surgery. If the operation is staged, the order is dictated by the clinical status and the surgical risk. Two-stage TEVAR yields lower mortality and more protection against spinal cord injury.

There are few data on the combined repair of thoracic and abdominal aneurysms. Among them Moon (16) reported a mortality of 6% with simultaneous endovascular repair of thoracic and abdominal aneurysm in a series of 18 patients. Szmidt (17) reported 16.6% mortality with TEVAR associated with open abdominal aortic aneurysm repair on a six-patient series during one year. Lucas (15) reported a 6% overall mortality in similar cases. Open or endovascular AAA repair in combination with TEVAR is feasible and safe.

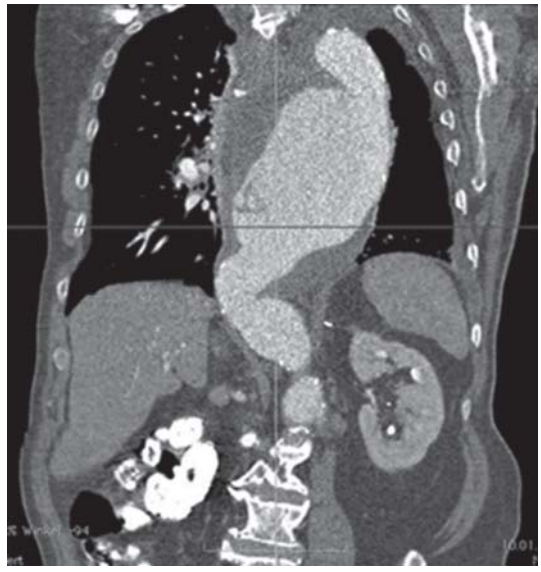

Figure 1. Preoperative multi-slice CT.

Figures 1 and 2 show an example of a giant thoracic descending aneurysm witch compresses the

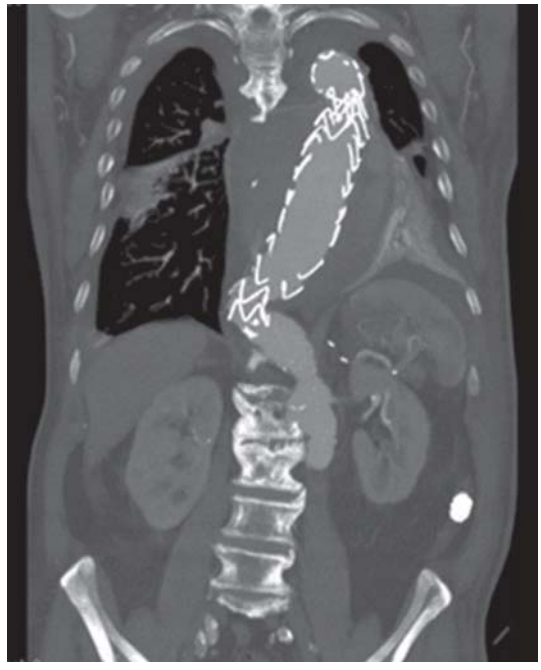

Figure 2. Postoperative multi-slice CT showing the endoprosthesis in place.

esophagus and the bifurcation of the trachea in a young patient who had already been treated surgically for an abdominal aneurysm six years previously. The patient was treated endovascularly with a Valiant stent graft from Medtronic.

Endovascular repair of abdominal aortic aneurysm (EVAR)

A study published in November 2011 identifies the rate of endovascular treatment for AAA in different countries during 2005–2009, whose prospective data were included in the VASCUNET (Vascular Surgery Database on behalf of the European Society for Vascular Surgery) database (18). The study shows a rapid and extensive implementation of the endovascular treatment, with the advent of studies with favorable results in this direction. On the other hand, in less developed countries such as Romania, the endovascular treatment rate in 2009 was 8% (19,20). The 2014 EVAR rates show a clear shift toward the endovascular treatment in developed countries, and a significant increase in the less developed ones (up to 85% in developed EU countries and between 20–30% in Romania and Bulgaria).

The pace of technological evolution of EVAR has been rapid in comparison with the development of successful open aneurysm repair. However, as any other intervention or technique, besides advantages EVAR also has limitations. The outcome of EVAR is highly dependent on the morphological suitability of the AAA. The morphological criteria of the AAA could establish or exclude the indication of EVAR. The failure to comply with these criteria may lead to the increase of the peri- and postoperative complications, reinterventions, and increase the post-EVAR mortality rate. The minimum requirements in terms of AAA morphology are listed below (21):

Proximal aortic neck

- Neck diameter >17 mm, <32 mm
- Angle between the suprarenal aorta and the juxtarenal aorta <60°
- Neck length >10 mm
- Neck thrombus covering <50% of the proximal neck circumference
- Neck calcification <50% of the proximal neck circumference

Aortic bifurcation

- Aortic bifurcation diameter >20 mm (in case of a bifurcated graft)

Iliac arteries

- Iliac luminal diameter >7 mm
- Iliac neck length >15 mm
- Iliac neck diameter <22 mm

Although early problems with commercial endografts resulted in several devices being withdrawn from the market, the technology for currently used stent grafts has improved outcomes. EVAR performed with second- and third generation endografts has good medium- and long-term results with a technical success rate of 98.4% and a clinical success rate of 71.5 % at a mean follow-up of 40 months (22,23).

Stent grafts of the 4th generation are now available on the market, pushing the limits of anatomic suitability even further (24–26) (Table II).

The *Zenith Flex AAA endovascular graft (Cook Medical Bloomington, IN, USA)* presents one of the most desirable features of the delivery system. The hydrophilic kink-resistant Flexor introducer sheath (Cook Medical) works well in very challenging iliac anatomy. The flexible sheath design, combined with the lubricious surface, facilitates device insertion and tracking while allowing a controlled deployment. Familiarity with the three-piece modular Zenith endograft has expedited access to more advanced endograft devices, which include the custom-made and off-the-shelf fenestrated and branched devices.

The *Ovation PRIME abdominal stent graft system (TriVascular, Inc., Santa Rosa, CA, USA)* is the most recently launched device. It has a clinical indication for a 1-cm neck and it tolerates neck angulation of ≤60° if the proximal neck is ≥10 mm and ≤45° if the proximal neck is <10 mm. This minimally invasive, easy-to-use system expands the pool of patients eligible for EVAR.

The *E-vita ABDOMINAL XT Stent Graft System (Jotec Gmbh, Germany)* offers a newly designed multifunctional wire-reinforced catheter with high flexibility in the proximal part and outstanding pushability in the distal portion without any risk of kinking. The hydrophilic coating significantly reduces friction during insertion and passage of the arterial vessel system. The delivery system offers a small crossing catheter profile starting at 16 F for the extensions and 20 F for the main body. The system continues with the patented Squeeze-to-Release deployment mechanism for stepwise or continuous release of the stent graft while focusing on precise positioning and safe handling.

The *AFX endovascular system (Endologix, Inc., Irvine, CA, USA)* handles irregular neck anatomy well with its tolerance to oversizing. The 34-mm-

Table II. Current abdominal aortic stent grafts in use.

Type of device	Graft material	Stent material	Deployment	Diameter (mm)	Length (mm)	Remarks
Talent AAA device (Medtronic, Inc. Minneapolis, MN)	Polyester	Nitinol	Self -expanding	22–36	155–185	Xcelerant® delivery system
Endurant II (Medtronic, Inc. Minneapolis, MN)	Polyester	nitinol	Self -expanding	23–36	124–166	"tip capture" mechanism
Excluder (Gore & Associates, Flagstaff, AZ),	ePTFE	Nitinol	Self -expanding	23–35	120–180	C3 delivery system
Zenith Flex AAA endovascular graft (Cook Medical Bloomington, IN)	Polyester	Nitinol	Self -expanding	22–36	82–149	Hydrophilic kink-resistant Flexor introducer sheath
AFX endovascular system (Endologix, Inc., Irvine, CA)	ePTFE	Nitinol	Self -expanding	25–34	75–120	Unibody Lowest profile system I7F
Ovation PRIME abdominal stent graft system (TriVascular, Inc., Santa Rosa, CA)	ePTFE	Nitinol	Self-Expanding	20–34	80–140	Most recently approved 5th generation endoprosthesis
E-vita ABDOMINAL XT Stent Graft System (Jotec Gmbh, Germany)	Polyester	Nitinol	Self -expanding	24–36	150–170	Squeeze-to-Release deployment mechanism
E-tegra AAA Stent Graft System (Jotec Gmbh, Germany)	Polyester	Nitinol	Self -expanding	23–36	Limb length 10–27 mm	Most recently approved 5th generation endoprosthesis
InCraft AAA Stent Graft System **(**Cordis, Diegem, Belgium)	Polyester	Nitinol	Self -expanding	22–34	Limb length 8–14 mm	Most recently approved 5th generation endoprosthesis Lowest delivery profile 14 Fr

diameter aortic extension is approved for a ≥23-mm neck diameter, so the surgeon can be aggressive with oversizing in cases of reverse-tapered or ectatic, irregular neck morphology. The main body device and aortic or iliac extensions are delivered through a single 17-F ID hydrophilic access sheath without the need for exchanges. The contralateral side is managed through a 9-F sheath that is approved for standard percutaneous access and makes AFX the lowest profile system currently available.

The *ENDURANT II (Medtronic, Inc. Minneapolis, MN, USA)* is a lower-profile delivery system compared to ENDURANT, with an extended hydrophilic coating improves access. The 28 mm-diameter stent graft (the most commonly used size) now fits inside an 18-French OD (outer diameter) catheter (down from 20 French in the original device).Two new contralateral limb lengths (156 mm and 199 mm) provide more options in sizing and can reduce the number of pieces required for an EVAR case.

Report on a study

In the following we report on a study conducted by the authors at centers in Romania and Germany.

Introduction

One-hundred and eighty-seven patients with unruptured AAA and 47 patients with TAA and thoracic aortic dissection were treated endovascularly in the Army's Emergency Clinical Center for Cardiovascular Diseases, Bucharest, Romania and Praxis für Gefäß und Thoraxchirurgie Rolf Dammrau, Duren, Germany between October 2009 and August 2014. In this period we conducted a prospective, comparative study for the evaluation of diagnostic accuracy between Color- Duplex Ultrasound (DUS), Contrast-enhanced Ultrasound (CEUS) and Contrast-enhanced Computed Tomography

(Contrast-enhanced CT) in detecting changes in the AAA size and endoleaks during follow-up after EVAR.

Our aim was to evaluate the clinical safety of CEUS and its utility in the detection of post-EVAR complications, thus contributing to the development of a safe, cost-efficient EVAR follow-up protocol with minimal radiation and contrast administration.

We report the short- and medium-term clinical outcomes of the 55 electively performed EVAR procedures.

Material and methods

One-hundred and fifty-four paired CEUS, DUS and Contrast-enhanced CT images were analyzed from 55 patients with AAA treated by elective EVAR. Measures of CEUS and DUS accuracy (sensitivity, specificity, positive and negative predictive value) relating to endoleak detection were calculated using 2×2 contingency tables. Pearson's correlation was used to compare AAA maximal transverse diameter measured by DUS/CEUS and CTA.

Patients who were treated for a ruptured abdominal aortic aneurysm (AAA), who were unable to follow as an outpatient, who did not comply with the follow-up protocol or did not sign the informed consent were excluded.

The selection criteria for the endovascular approach were based on good aortic anatomy, high-risk co-morbidities and patient preference.

Data from all patients were recorded prospectively in a vascular database that contains patient characteristics, graft characteristics, procedural characteristics, data concerning hospital stay and follow-up data such as readmissions, complications, occurrence of endoleaks and all-cause mortality.

Surveillance of patients after EVAR occurred at the outpatient department by regular clinical examination, Contrast CT-scanning (CTA), Duplex Ultrasound (DUS) and Contrast-enhanced ultrasound (CEUS) using microbubbles filled with sulfur hexafluoride (Sonovue®, Bracco Diagnostics Inc., Milan, Italy) at regular time intervals, at 30 days, six months, 12 months, and then annually after EVAR. The mean follow-up interval was 18 months.

Initial outcome measures included primary-assisted technical success rates, 30-day re-intervention, limb occlusion, morbidity and mortality rates, occurrence of all types of endoleak, aneurysm sac growth, limb occlusion and patient survival. Deaths and morbidity occurring within 30 days of the operative procedure were considered procedure-related. Deaths occurring after 30 days were defined as late deaths.

Results and discussion

Patient demographics and preoperative AAA morphology are described in Table III.

Device selection was based on preoperative CT scan and pre- or intra-operative catheter-calibrated

Table III. Preoperative data.

		N (or mean)	% (or range)
Sex	Male	50	90%
Age (years)		70.6	61–81
Co-morbidities	Diabetes Mellitus	7	13%
	Hypertension	24	44%
	Hypercholesterolemia	31	56%
	Coronary artery disease	14	25%
	Cerebrovascular disease	9	16%
	Obesity	6	11%
	COPD	1	2%
	Previous laparotomy	11	20%
Clinical presentation	Asymptomatic	38	69%
	Symptomatic	17	31%
	Ruptured	0	0
AAA morphology	Maximum aortic diameter	66.9	4.8–9.1
	Infrarenal neck length	24.2	12–31

Table IV. Abdominal devices used.

Type	Manufacturer	N
E-vita Abdominal XT	JOTEC GmbH, Germany	16
Excluder	Gore & Associates, Flagstaff, AZ	12
Talent	Medtronic, Inc. Minneapolis, MN	8
PowerLink	Endologix, Inc., Irvine, CA	7
Endurant	Medtronic, Inc. Minneapolis, MN	3
Custom made fenestrated or branched	JOTEC GmbH, Germany	9

angiography measures. The types of endografts used are presented in Table IV.

Primary-assisted technical success rate was 100%. There was one non AAA-related late death.

Nine endoleaks (16.36%) were documented. Seven cases of type II endoleak, one case of type III endoleak and one case of type I endoleak. None of the patients with type II endoleak required reintervention.

Sensitivity and specificity of CEUS were 98% and 100%, respectively. The Pearson Coefficient correlation indicated a large degree of correlation between DUS/CEUS and CTA when measuring residual aneurysm size following EVAR ($r = 0.968$; $p \leq 0.0001$).

Conversion to open repair was performed in one case, as a late conversion for the type III endoleak (at 15 months after EVAR) with aneurysm sac enlargement >8 mm.

Complications and re-interventions are described in Table V.

All type II endoleaks sealed spontaneously ≤2 years when observed without intervention. The aneurysm size decreased significantly during the first year (≥5 mm) and then remained stable, results that are consistent with the published literature (27,28). The source of the type II endoleak was the lumbar arteries in four cases, the inferior mesenteric artery in two cases and an accessory renal artery in one case. All were low-flow endoleaks as depicted by DUS and CEUS. In one case CTA diagnosed the endoleak, but failed to specify its origin. It could not differentiate whether it was a type I or type II endoleak. CEUS accurately diagnosed it as a low flow type I endoleak (Figure 3).

Muhs et al. (24) reported an incidence of 2.5% type I endoleak at mid-term follow-up of EVAR with fenestrated and branched endografts performed in case of short aortic necks <15 mm. AbuRahma et al. (29) analyzed the correlation of aortic neck length to early and late outcomes. Their results showed that proximal type I endoleaks occurred in 12% of cases with aortic neck length (NL) ≥15 mm, in 42% of cases with NL from 10 to <15 mm and at 53% with NL <10 mm.

Table V. Complications, re-interventions and mortality during follow-up.

	N (or mean)	% (or range)
Complications	**15**	30%
Kinking or stenosis	0	0
Body migration	0	0
Leg migration	0	0
Endoleak		
I	1	2%
II	7	13%
III	1	2%
IV	0	0
AAA rupture	0	0
Infection (access site)	4	7%
Haemorrhage (access site)	2	3%
Systemic complications	0	0
Additional or re-interventions	**14**	25%
Endovascular (at the time of intervention)		
Proximal extension	6	11%
Leg extension	3	5%
Coil embolisation of side branches	4	7%
Conversion to open repair	**1**	2%
Mortality		
AAA –related	0	0
Non AAA-related	**1**	2%

The low, 2% incidence of type I endoleaks in our medium-term EVAR follow-up correlates with the results of these studies, concluding that the proximal extension of the endograft fixation by the use of fenestrations and side branches yields superior results

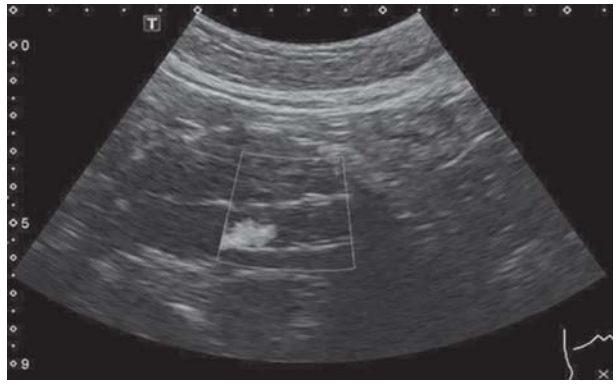

Figure 3. CEUS examination + Power Doppler clearly showing the origin of the endoleak, the right iliac attachment site.

compared to EVARs performed in AAAs with poor neck anatomy. Fenestrations do not appear to result in increased incidences of endoleaks.

Conclusions

Endovascular aortic repair has demonstrated good results in both acute and chronic aortic pathology. Branched or fenestrated graft technology will develop and allow complete endovascular aortic procedures which can compare with open or hybrid technique. Randomized trials are needed to confirm long-term results.

In order to improve outcomes, the indication for TEVAR or EVAR should be decided on an individual basis, according to the anatomy, pathology, comorbidity and durability of the stent grafts, as a result of a multidisciplinary approach (14).

Technological development of the devices, with lowest profile introduction systems, will permit to extend the anatomical indications to new frontiers.

Our prospective comparative study results showed that the diagnostic accuracy of CEUS in detecting complications during EVAR follow-up is equal if not superior to that of CTA. Based on these results we recommend a safe, less harmful EVAR surveillance protocol consisting of CTA and plain abdominal X-ray at 30 days after EVAR followed by CEUS and plain abdominal X-ray at six months, 12 months and yearly thereafter.

Author contribution

Conception and design: ID, FBC, GD, CB, RD. Analysis and interpretation: FBC, GD. Data collection: FBC, CB, RD. Writing the article: ID, FBC, GD. Critical revision: ID, RD, FBC. Final approval: ID, FBC, GD, CB, RD. Overall responsibility: ID, FBC.

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