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POSTINTERVENTIONAL SURVEILLANCE OF ENDOVASCULAR REPAIR OF ABDOMINAL AORTIC ANEURYSMS

Francisca Blanca Călinescu[1], Ionel Droc[2], Aurel Mironiuc[3], Carmen Neamțu[1*], Totolici Bogdan[1]

[1]„Vasile Goldiş" Western University of Arad – Faculty of Medicine, Pharmacy and Dental Medicine, Arad, Romania

[2] Army's Clinic Center for Cardiovascular Diseases, Bucharest, Romania

[3] "Iuliu Haţieganu" university of Medicine and Pharmacy, Surgical Clinic No.II, Cluj-Napoca, Romania

ABSTRACT. The present paper proposed to gather and underline the new developments and evidence at hand in the management of abdominal aortic aneurysms (AAA), focusing especially on the endovascular treatment (EVAR) and the surveillance of EVAR performed for AAA. The intention was to identify the existing controversies, identify a problem and give way to new research possibilities in this direction.

KEYWORDS: abdominal aortic aneurysm, EVAR, postinterventional surveillance, contrast-enhanced ultrasound, contrast CT, endoproshtesis

INTRODUCTION

The management of infrarenal abdominal aortic aneurysms (AAA) has changed radically over the last decades since the introduction of the endovascular treatment by Juan Parodi in 1992. Applied with caution and scepticism in the past, due to the lack of long-term results, today is gaining ground given the new solid evidence at hand.

A study published in November 2011 identifies the rate of endovascular treatment for AAA in different countries during 2005-2009 **(Figure 1)**, whose prospective data were included in the VASCUNET database (K.Mani et al.,2011). The study shows a rapid and extensive implementation of the endovascular treatment, with the advent of studies with favourable results in this direction. The endovascular treatment rate in Romania was illustrated for comparative purposes.

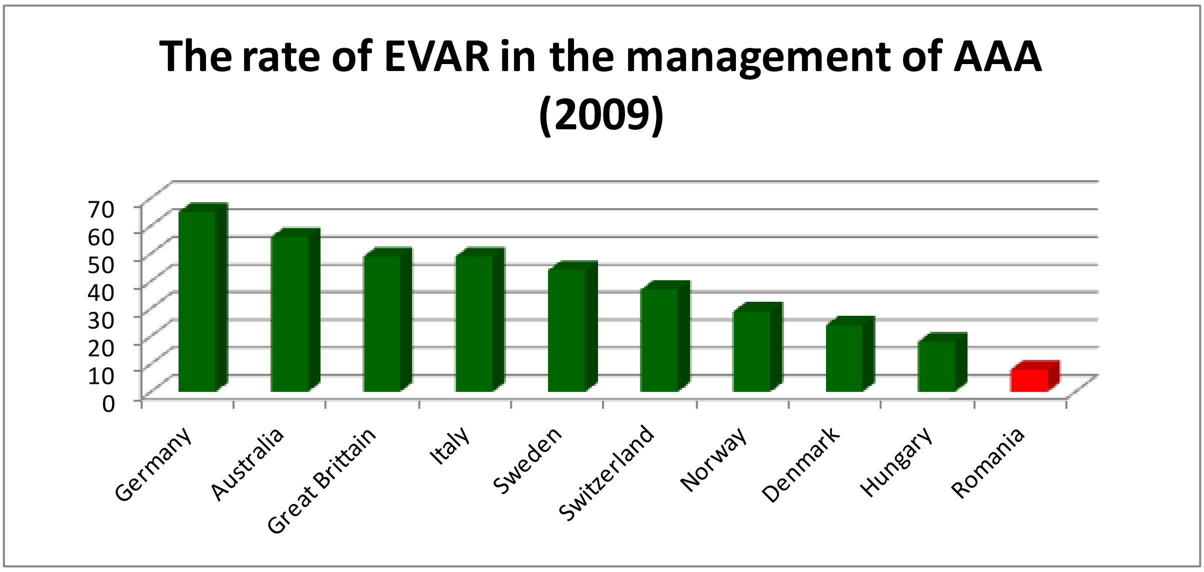

Figure 1: The rate of EVAR in the management of AAA in different counties, between 2005 and 2009 (K.Mani et al.,2011)

EVAR in addition to the advantage of being a minimally invasive method and as such preferred by the patients, has many proven benefits compared with traditional open surgery: low rate of peri- and postoperative mortality and morbidity, shorter hospital stay, significantly reduced intraoperative blood loss and faster recovery. (EVAR Trial Participants, 2005; Prinssen M et al., 2004; Aljabri B et al.,2006)

Results of several controlled, randomized studies are published today, which highlight the many benefits of this minimally invasive treatment, stressing also its shortcomings and controversies.

The first short-term results of the endovascular treatment appeared after EVAR1 (England), EVAR 2 (England) and DREAM (Netherland) trials, randomising patients diagnosed with infrarenal abdominal aortic aneurysm ≥5.5 cm for endovascular (EVAR) or open surgical treatment consisting of an aorto-bifemoral by-pass (EVAR Trial Participants, 2005; Blankensteijn JD et al.,2005) EVAR 1 and DREAM trial showed a 2.5 fold reduction in postoperative mortality in the favour of EVAR: 4.6% for open surgery and 1.2% for EVAR (DREAM trial), 4.7% vs. 1.7% (EVAR 1 trial). A recently published trial, the OVER trial (Open versus Endovascular Repair) reported a perioperative mortality of 0.5% for EVAR (Lederle FA et al.,2009). The higher peri- and postoperative mortality in older studies might be explained by the use of first-generation endoprostheses, prostheses that have undergone many changes until present, being constantly improved. Currently IV-th generation endoprostheses are available on the market.

The above mentioned studies included infrarenal abdominal aortic aneurysms ≥ 5.5 cm in diameter with a well established reason. The Clinical Practice Guidelines of the European Society for Vascular Surgery on the management of AAA, published in April 2011 sets out a series of recommendations in all aspects of diagnosis and management strategies of AAA **(Figure 2, 3)** (F.L. Moll et al., 2011)

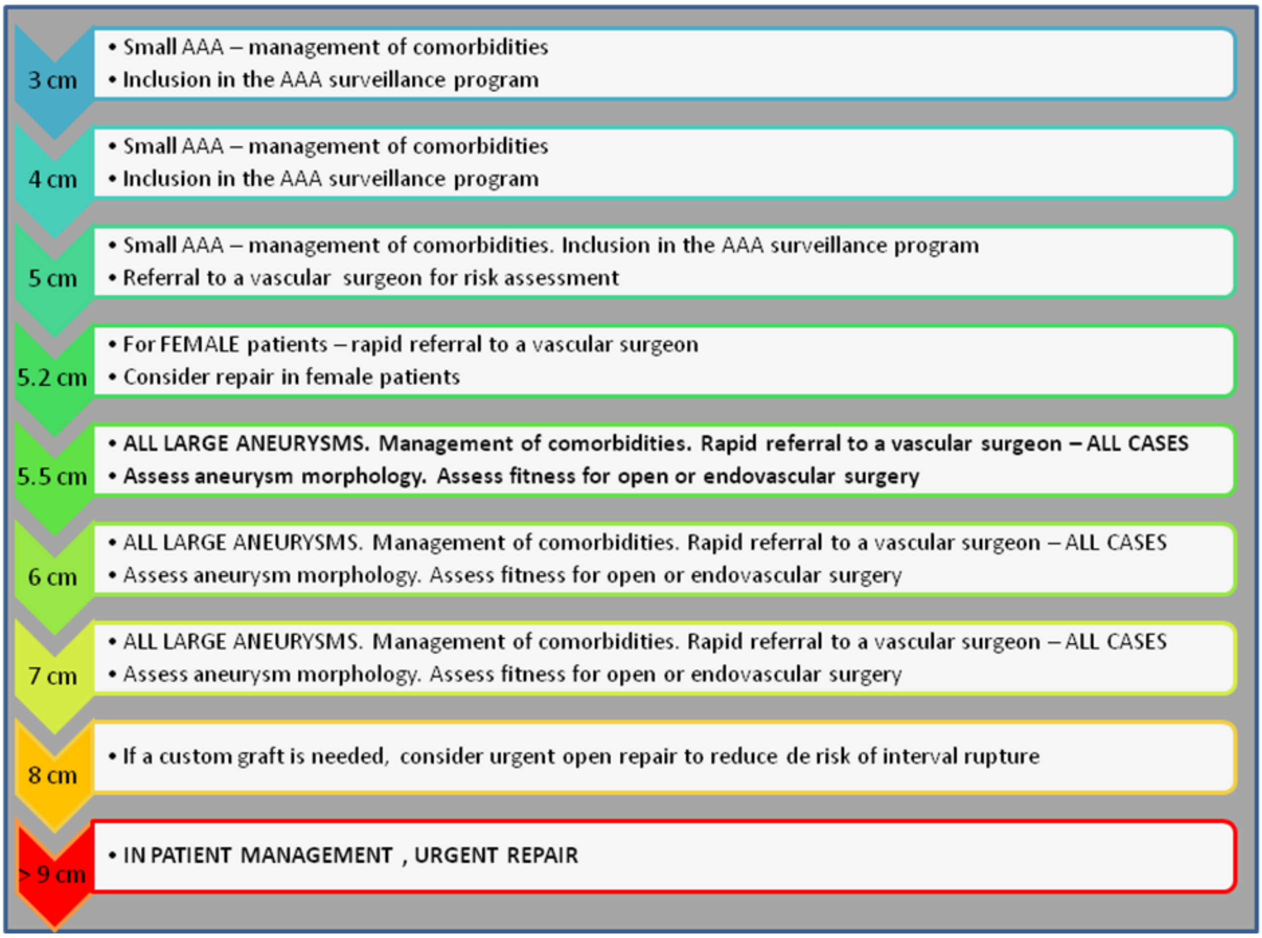

Figure 2: Management strategy of AAA according to the size of the aneurysm (modified after F.L. Moll et al., 2011)

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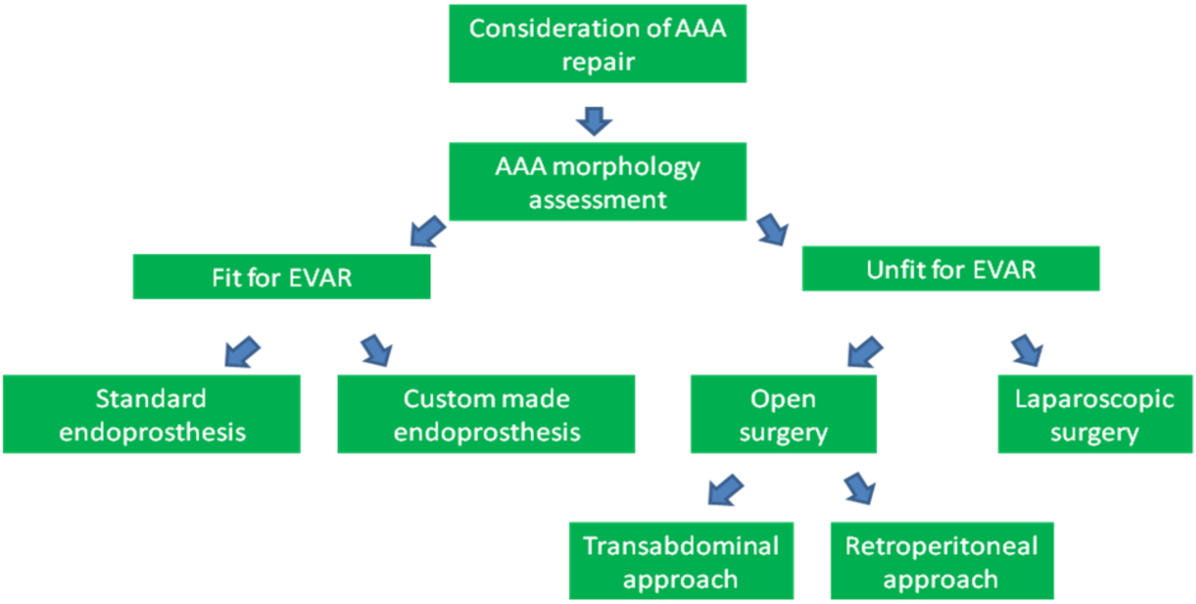

Figure 3: Management of large aneurysms, with a diameter ≥5,5 cm (modified after F.L. Moll et al., 2011)

There is a consensus that in the case of small aneurysms, with a diameter between 3.0-3.9 cm, the risk of rupture in negligible. Therefore, these aneurysms do not require surgery, supervision by Doppler Ultrasound at regular intervals being sufficient. The management of the AAA with a diameter between 4.0-5.5 was determined by two multicenter, randomised, controlled studies, that compared the natural evolution of these aneurysms versus early intervention: UK Small Aneurysm Trial (UKSAT) and American Aneurysm Detection and Management Study (ADAM) respectively (The UK Small Aneurysm Trial Participants, 1998; Lederle FA et al., 2002) and a smaller study, that compared endovascular treatment versus surveillance, the CAESAR study (Cao P et al., 2005). The PIVOTAL study including aneurysms with diameters between 4.0-5.0 cm compared the endovascular treatment versus Doppler Ultrasound surveillance (Ouriel K. et al. 2009)

Medium-term results of these studies did not indicate a statistically significant difference in terms of overall mortality at 5 years, the results being similar in the long-term, at 12 years (The UK Small Aneurysm Trial Participants, 1998; Powell JT et al., 2007).The rupture rate of the aneurysms was 1% in the surveillance group and the overall mortality rate was 5,6% in the early intervention group.

The results of the above mentioned large studies, UKSAT and ADAM were recently included in the COCHRANE study, that underlines the safety and through this the benefits of the Doppler ultrasound surveillance of the AAA with a diameter between 4.0 and 5.5 cm (Ballard DJ et al., 2008)

A conduct of Doppler Ultrasound surveillance of small aneurysms (4.0-5.5 cm) is safe and recommended for asymptomatic aneurysms. If the aneurysm reaches the 5.5 cm diameter limit, measured by Doppler ultrasound (in male patients), it becomes symptomatic or there is an annual diameter increase of >1cm/year, the patient must be immediately referred for further investigation to the specialized vascular surgery department.

As highlighted, the diameter of the AAA establishes the moment for intervention, but this criteria alone is not enough to establish the indication for the endovascular treatment of the AAA. With new treatment methods new complications occur, requiring further investigations in order to assess the feasibility of the AAA for EVAR. The morphological criteria of the AAA are the ones that can establish or exclude the indication of EVAR. The failure to comply with these criteria, requested also in the instruction manuals of the endoprostheses currently on the market may lead to the increase of the peri- and postoperative complication, reintervention and post-EVAR mortality rate (Ionel Droc et al. 2012). The minimum requirements in terms of AAA morphology are listed in Table1.

Table 1. Minimal morphological requirements of the AAA for EVAR (modified after F.L. Moll et al., 2011)

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

THE POSTOPERATIVE SURVEILLANCE OF PATIENTS WITH AAA TREATED BY EVAR

There is no controversy about the short-term benefit of EVAR to open surgery, opinions being divided and reserved as the long-term benefits are concerned.

The real benefit of the AAA treatment depends on the impact on the long-term survival of the patients.

The absence of complications such as aneurysm rupture (due to the emergence of endoleaks), infection, aorto-enteric fistula formation or migration of the endoprosthesis should be considered as an indicator of sustainability and long-term therapeutic success of EVAR.

Despite careful selection of patients with AAA considering and respecting the morphological suitability criteria, the choice of appropriate endoprosthesis, operator experience, specific complications can still occur, underlining the necessity of life-long surveillance of the treated patients.

The results of several randomised, controlled studies show a significant post procedural complication rate up to 8 years post EVAR (De Bruin JL et al., 2010; Greenhalgh RM et al., 2010). A recent study considered mandatory a life-long surveillance after EVAR, in order to identify the complications and to plan a possible reintervention (A. Karthikesalingam et al., 2011).

The most common complication of EVAR, occurring in 10-45% of cases (Van Marrewijk et al., 2002) is represented by the incomplete exclusion of the aneurysm with persistent periprosthetic blood flow in the aneurysm sac. White et al. was the first to define this complication as “endoleak” (White GH et al., 1998). Is considered a serious complication because different types of endoleaks can lead to the repressurisation of the aneurysm sac with consequent sac enlargement and aneurysm rupture.

Incomplete aneurysm exclusion with the persistence of blood flow in the aneurysm sac outside the endoprosthesis, defined and described under the term “endoleak” in 1998 by White et al. is the most common complication of EVAR occurring in 10-45% of cases. It is a severe complication because it leads to the repressurization of the aneurysm sac and consequent aneurysm rupture. White differentiated early endoleaks, occurring within 30 days post-EVAR and late endoleaks occurring later than 30 days in the surveillance period. (Schlosser FJ et al., 2009) showed that endoleaks are the main cause of postinterventional aneurysm rupture, being responsible for 160 out of a total of 235 ruptures of the AAA after EVAR. This result reinforces the need of long term surveillance with an imaging method that can effectively and safely identify this complication. Four types of endoleak were described Table 2 (White GH et al., 1998; Veith FJ et al., 2002).

Table 2. Classification of endoleaks (modified after F.L. Moll et al., 2011)

Endoleak (Type)	Source of perigraft flow
I.	**Attachment site defects of the endoprosthesis**
A	Proximal end of the stentgraft
B	Distal end of the stentgraft
C	Iliac extension
Endoleak (Type)	**Source of perigraft flow**
II.	**Persistent backflow from patent aortic branches**
A	Simple: from one patent branch
B	Complex: two or more patent branches
III.	**Stentgraft defect – junctional leak, modular disconnect or fabric holes**
IV.	**Stentgraft fabric porosity <30 days after placement**
Endotension	**AAA enlargement with increased intrasac pressure after EVAR without visualised endoleak on delayed contrast CTA**

The most common and discussed is the type 2 endoleak, caused by retrograde flow from aortic side branches into the aneurysm sac, outside the endoprosthesis, such as the inferior mesenteric artery, lumbar arteries or accessory renal arteries. The identification and treatment of this type of endoleak is currently the subject of numerous debates. They may have a benign evolution, with gradual decrease of the aneurysmal sac or may also lead in some cases to pressurization and rupture. Their identification with the currently used imaging methods is frequently hampered by a small retrograde blood flow that is below detection (Veith FJ et al., 2002)

Another complication of the endovascular treatment is the migration of the endoprosthesis. It is identified as a dislocation of the endoprosthesis with > 10 mm considering the anatomic landmarks established at the time of the intervention. This complication was

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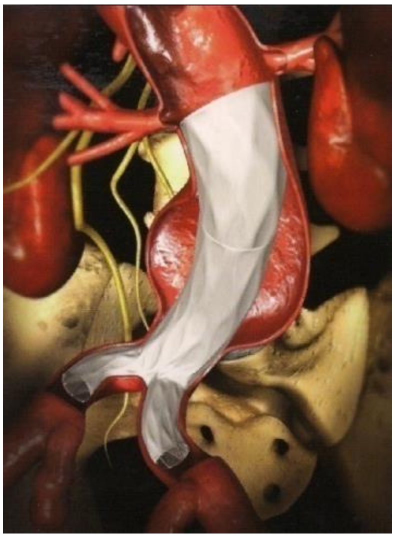
observed using most of the endoprosthesis types available on the market. Studies that examined the incidence of endoprosthesis migration defined it as a late complication occurring more than 24 months after surgery (Tonnessen BH et al., 2005). The complication may be asymptomatic, being identified at the regular follow-up intervals with different imaging modalities, but it represents a significant risk of late rupture. Several predisposing factors have been identified that can be responsible for the migration: inadequate aneurysm and aneurysm neck morphology (short, <15 mm, angulated neck), faulty technique in the initial fixation of the endoprosthesis, late aneurysm neck dilatation.

In order to avoid this complication new endoprostheses were developed, such as the PowerLink (Endologix, CA, USA) endoprosthesis **(Figure 4),** accomplished on the principle of "anatomic fixation". Unibody endoprosthesis with two iliac extensions, that when positioned and deployed rests on the iliac bifurcation thus preventing the caudal migration of the device.



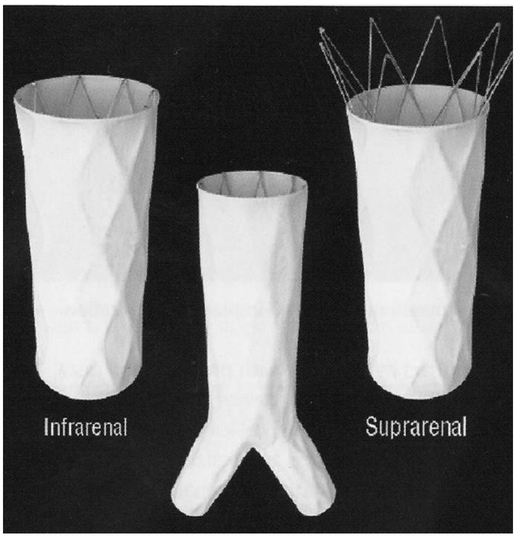


Figure 4: PowerLink Endoprosthesis (Endologix, CA, USA)

POSTINTERVENTIONAL IMAGING METHODS FOR THE FOLLOW-UP OF EVAR FOR AAA

During the last years, multiple studies have focused on establishing a protocol of postoperative surveillance of patients with AAA treated by EVAR, without reaching a consensus in this regard (Dill-Macky M et al., 2007; Thurnher S et al., 2002; V. Cantisiani et al., 2011; T.A Mirza et al., 2010).

The ideal imaging method should meet several requirements: to be cheap, repeatable, widely available, safe, non-invasive and accurate.

Several imaging methods are available in the current practice for the follow-up of EVAR: Native and Contrast Enhanced Computer Tomography (CT), Colour Doppler Ultrasound (US), Contrast Enhanced Ultrasound, Plain radiography, Angiography and Nuclear Magnetic Resonance (NMR). All have their benefits and limitations.

IODINE CONTRAST ENHANCED CT

The "Gold Standard" imaging method used in current practice for the follow-up of patients with AAA treated by EVAR is Contrast Enhanced CT. The high resolution images and data obtained with this method make it possible to measure with great accuracy the dimensions of the excluded aneurysm sac.

Some studies show that CT with contrast can detect endoleaks with a higher sensitivity (Se) and specificity (Sp) that conventional angiography.

Identification of all type endoleaks:

- Contrast-enhanced CT examination: Se 92%, Sp 90%
- Angiography: Se 63%, Sp 77%

Given the fact, that in the case of endoleaks the blood flow intensity varies, they can be detected at different time intervals after the injection of the iodine contrast. For this reason a multiphase CT protocol was recommended, with image acquisition prior to contrast administration, immediately after contrast administration in the arterial phase and in the delayed postcontrast phase. The recorded precontrast images can be useful in differentiating the aortic wall calcifications from intraluminal thrombus or endoleak, thereby reducing the number of false positive results.

Concerns regarding this protocol refer to the high dose of radiation involved, the nephrotoxicity of the administrated iodinated contrast (Walsh SR et al., 2008) and the high cost of the method.

The radiation dose calculated for one examination is around 15 mSv, although this value may change depending on the device used. The patients included in the follow-up program, assessed at 30 days, 3 months, 6 months and then annually have an accumulated exposure of 50-100 mSv, a dose that has been identified as presenting high risk for cancer (Brenner DJ et al., 2003). Limiting the exposure to ionizing radiation by reducing the examination numbers or by replacing the CT examination with other imaging modalities would decrease this risk.

Another study evaluated the risk of developing nephropathy due to the repeatedly administered contrast agent. The results showed an incidence of 11% for renal injury and a mortality of 0.6% after repeated CT examinations.

Another disadvantage of the CT examination is that although the examination may reveal the presence of the endoleak, it often fails to specify its type and exact source of the persistent blood flow. For this reason Contrast-enhanced CT cannot be applied as an unique method of surveillance of patients with AAA treated by EVAR.

COLOR DOPPLER ULTRASOUND

Ultrasound imaging is a method commonly used in the screening of abdominal aortic aneurysms. Some investigators have stressed the importance and usefulness of this method in the postinterventional surveillance of patients with AAA treated by EVAR. It has the advantage of being widely available, safe, cost effective and well tolerated by the patients. The disadvantages of the method include the low quality of the obtained images in obese patients and investigator dependence. Another drawback is that the follow-up protocols vary from one institution to another and from one examiner to the other influencing the reported global results. Numerous studies concluded that there is an urgent need to standardise the US examination technique in order to reduce the variability in the quality of the examination.

Colour Doppler US failed to demonstrate superiority over CT, but in some cases proved equal to it. It is able to detect all known complications of EVAR, particularly the controversial endoleaks. Of course there remains the problem of variations between examination protocols, techniques and diagnostic criteria used. The reported sensitivity of the US examination in the literature varies between 25% and 100%. For the detected endoleaks, Doppler US examination can provide a far better level of characterization than other imaging techniques using spectral Doppler analysis. The type II endoleaks with bidirectional flow, low flow and speed are of interest in this respect. Most of these endoleaks are detected by US examination but not by CT or angiography.

A recent meta-analysis of Mirza et Al. (T.A Mirza et al., 2010) including 21 studies that compared Contrast CT examination with Colour Doppler Ultrasound (DUS) and Contrast-enhanced Ultrasound (CEUS) reported for DUS a sensitivity and specificity in detecting all type endoleaks of 77% and 94% respectively.

Another limitation of the US examination is the inability to provide information about the status and the position of the endoprosthesis. For this reason neither DUS can be considered as a unique method for postinterventional surveillance of patients with AAA treated by EVAR.

CONTRAST-ENHANCED ULTRASOUND

The introduction of Contrast-enhanced Ultrasound examination in the EVAR surveillance raised once again the hope for the possibility to replace the Contrast CT, but there is not enough evidence available in order to establish a clear surveillance protocol. The advantage over the Contrast CT is that the contrast agent used for the US examination is not nephrotoxic and its repeated use does not pose a risk to the patient.

In some cases the accuracy of CEUS in detecting endoleaks proved to be superior to CT examination and NMR examination also.

The results of the meta-analysis of Mirza et al. (T.A Mirza et al., 2010) showed a sensitivity and specificity in the detection of endoleaks of 98% and 88% respectively.

The limitation of CEUS are the same as for DUS.

NUCLEAR MAGNETIC RESONANCE IMAGING (NMR)

NMR is a non-invasive imaging method based on intravenous injection of gadolinium chelates (0.1 mmol/kg). The imaging performance of this method depends largely on the metallic composition of the stent-graft used. Several studies, including patients with nitinol or elgiloy stent-grafts, resulted a sensitivity and specificity of NMR at least equal to that of Contrast CT examination. The identification of type II endoleaks with NMR has a Se of 100% and a Sp of 82% according to recent studies (Ayuso JR et al., 2004)

Regarding the disadvantages, beyond the limitations presented by the metallic composition of the stent-graft, we have to mention the absolute contraindications of the NMR examination, such as the presence of previously implanted metal devices: Pace-makers, mechanical heart valves, intraocular ferromagnetic foreign bodies, vascular clips placed at different levels (ex. Aorto-coronary by-pass with the great saphenous vein or internal mammary artery).

There are also a few technical limitations such as poor visualization of the calcified aortic wall and difficulty in the exact measuring of the aneurysm diameter due to the surrounding fat.

PLAIN RADIOGRAPHY

Even with so many advanced imaging modalities at hand, plain radiography remains a useful technique for postinterventional surveillance of EVAR. X-ray is considered by some authors to be superior to CT in providing information about the conformation and possible migration or deformation of the endoprosthesis (Fearn S et al., 2003)

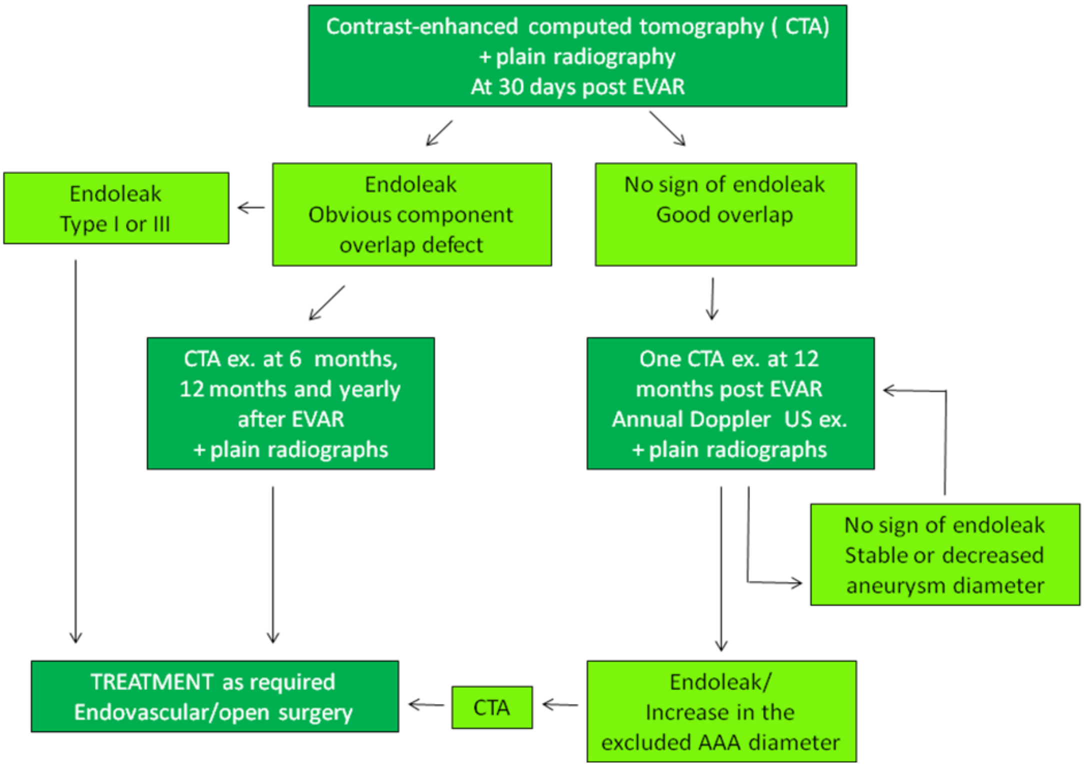


Figure 5. Simplified surveillance protocol of patients with AAA treated by EVAR (modified after F.L. Moll et Al. [7])

The antero-posterior and latero-lateral incidence can accurately detect migration and component separation and the oblique incidence is useful in detecting wire fractures of the stent-graft.

The disadvantage of the X-ray is that it provides no information regarding the excluded aneurysm sac size, failing also to identify the possible endoleaks.

Based on the evidence currently available the European Society for Vascular Surgery issued a guideline, consisting of a set of recommendations for the management of AAA, along with postinterventional follow-up recommendations for patients with AAA treated by EVAR [7].

The final conclusion of this guideline is that there is still a need for further research in this direction, a need to optimise the use of DUS, CEUS and CT by establishing a safe and effective, standardized surveillance protocol of patients with AAA treated by EVAR.

AUTHOR CONTRIBUTION

All authors have contributed equally to the present work.

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***Correspondence**
Carmen Neamtu
Str. Gradinarilor Nr.43
Arad, Romania
Mobile: 0723225793
Mail: carmen.neamtu@gmail.com