

# Highlights and Key Updates to the ESVS AAA Guidelines

Reviewing important revisions to the guidelines and their impact on practice.

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The European Society for Vascular Surgery's (ESVS) 2019 clinical practice guidelines on the management of abdominal aortic aneurysms (AAAs) were published in January 2019 in *European Journal of Vascular and Endovascular Surgery*<sup>1</sup> and contain a total of 125 recommendations graded according to the European Society of Cardiology grading system (Table 1). The guidelines cover all aspects of AAA management, including treatment of standard AAA, juxtarenal AAA, isolated iliac aneurysms, mycotic and inflammatory aneurysms, and management of AAA patients with concomitant malignant disease. New treatment concepts, such as modern endovascular techniques including fenestrated endovascular aneurysm repair (EVAR) and chimney EVAR, as well as requirements for service standards and surgical volume are also addressed. Several updated recommendations based on new evidence and considerations are included, such as recommendations on a less frequent surveillance protocol for small AAAs, an EVAR-first strategy in most scenarios, and a stratified, less frequent follow-up regimen after EVAR.

The work is the result of a joint effort by 16 European aortic experts, 13 external international reviewers, and the 10 members of the ESVS Guidelines Committee. The extensive review process ensures that the recommendations are up to date and reflect current practice and knowledge worldwide as well as confirms broad support.

This article summarizes key changes in the ESVS 2019 AAA guidelines and discusses its practical implications. Guideline highlights and key changes are summarized in Table 2.

TABLE 1. EUROPEAN SOCIETY OF CARDIOLOGY GRADING SYSTEM

Level of evidence	Definition
A	Data derived from multiple randomized clinical trials or meta-analyses
B	Data derived from a single randomized clinical trial or large nonrandomized studies
C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries
Classes of recommendations	Definition
I (is recommended)	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective
II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure
IIa (should be considered)	Weight of evidence/opinion is in favor of usefulness/efficacy
IIb (may be considered)	Usefulness/efficacy is less well established by evidence/opinion
III (is not recommended)	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful

Adapted from Wanhainen A, Verzini F, Van Herzele I, et al. Editor's choice—European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg*. 2019;57:8-93.

## SERVICE STANDARD

The introduction of endovascular techniques has fundamentally changed the management of AAA. There is convincing evidence of the benefit of EVAR in elective and emergency AAA repair in most patients with suitable anatomy. However, not all patients are suitable for standard EVAR or more complex endovascular treatment options; thus, open surgical repair (OSR) remains the preferred treatment option for some patients. As a result, endovascular techniques cannot entirely replace OSR. Centers performing AAA interventions should have the ability to offer open and endovascular surgical technologies 24-7 (Table 2, Recommendation 2).

The evident volume-outcome relationship in AAA repair makes it necessary to make a recommendation on minimal surgical volume. Various cutoff levels have been suggested in the literature. However, other aspects affecting the possibility of centralization of aortic services have to be taken into account, including population density and geographic distance. Based on the current evidence, the ESVS Guideline Writing Committee concluded that there is enough evidence for a rather weak recommendation on a desired minimum hospital volume of at least 30 cases annually (Table 2, Recommendation 3), while a stronger recommendation is issued on a minimum yearly caseload of at least 20 repairs to perform aortic surgery at all (Table 2, Recommendation 4).

Although the literature suggests that the volume-outcome relationship is primarily applicable to OSR, the writing committee has chosen not to specify the volumes for respective surgical methods but refers to the total surgical volume regardless of surgical technique. Studies of the volume-outcome relationship for AAA repair have so far mainly focused on short-term outcomes, which is most relevant for the more invasive open technology. However, it is reasonable to assume that experience also plays a role in EVAR, which mainly presents with late failures such as endoleaks, migration, and kinking. Defining a clear volume requirement will make it difficult for smaller centers to justify continued activity, and centralization to larger AAA centers is to be expected.

## SCREENING AND SURVEILLANCE

Randomized controlled trials (RCTs) conducted in the 1990s showed that screening elderly men for AAA cost-effectively reduced AAA-specific mortality. Recent data from nationwide screening programs in Sweden and the United Kingdom that targeted 65-year-old men confirmed the benefit of screening in a contemporary setting with a much lower prevalence of the disease. Consequently, the ESVS guidelines issue a strong recommendation that all men aged 65 years should be offered an ultrasound screening

for AAA (Table 2, Recommendation 12). There is currently no evidence to support general screening for AAA in women; therefore, it is not recommended in the guidelines (Table 2, Recommendation 14). Selective AAA screening may be considered in women (and men) with a first-degree relative with an AAA (Table 2, Recommendation 15) as well as in women (and men) with concomitant peripheral arterial aneurysm (Table 2, Recommendation 16).

Based on data from the RESCAN meta-analysis, which showed a relatively low growth rate of small AAAs,<sup>2</sup> less frequent follow-up intervals are recommended in the new AAA guidelines. The revised interval for AAA follow-up is every 3 years for aneurysms 3 to 3.9 cm in diameter, annually for aneurysms 4 to 4.9 cm, and every 3 to 6 months for aneurysms  $\geq 5$  cm (Table 2, Recommendation 17).

Recent screening-based cohort follow-up studies suggest that subaneurysmal aortic dilatation (25–29 mm) has a high tendency to develop into AAAs. There is still limited evidence regarding the clinical effectiveness and cost-effectiveness of surveillance for people with subaneurysmal aortic dilatation. Therefore, a weak recommendation is given that men with subaneurysmal aortic dilatation with a reasonable life expectancy may be considered for rescreening after 5 to 10 years (Table 2, Recommendation 13). The fact that this group constitutes a small cohort (< 5% of all men screened) means that rescreening does not require large resources.

## AAA REPAIR

Based on convincing data from four RCTs—two trials comparing early OSR and two trials comparing EVAR to surveillance of small AAA (< 5.5 cm)<sup>3</sup>—the recommended threshold for elective AAA repair remains  $\geq 5.5$  cm in men (Table 2, Recommendation 22). Despite fewer data available on women, the reported severalfold-higher rupture rate among women justifies a weak recommendation to consider repair of lower-diameter AAAs (5 cm) in women (Table 2, Recommendation 23).

Due to rapid technologic and medical development, the existing RCTs comparing elective OSR and EVAR are not entirely relevant to today's practice. Additionally, several RCTs are limited by the fact that they mainly included patients aged < 80 years, whereas today the greatest increases in AAA repair are among those aged > 80 years. The latter group of patients has also seen the most noticeable improvement in outcome after AAA repair, likely related to the preferential use of EVAR. Therefore, more recent cohort data were also included in the overall evaluation of the evidence base when comparing OSR to EVAR. Overall, the current evidence suggests a significant short-term survival benefit of EVAR over OSR, with similar long-term outcomes at up to 10 to 15 years of follow-up. Thus, in patients with suitable anatomy and reasonable life expectancy, EVAR

TABLE 2. ESVS GUIDELINE HIGHLIGHTS AND KEY CHANGES

<b>Recommendation 2:</b> It is recommended that centers or networks of collaborating centers treating patients with AAA can offer both endovascular and open aortic surgery at all times (class I, level B)
<b>Recommendation 3 and 4:</b> AAA repair should only be considered in centers with a minimum yearly caseload of 30 repairs (class IIa, level C) and should not be performed in centers with a yearly caseload < 20 (class III, level B)
<b>Recommendation 12, 14, 15, and 16:</b> Population screening for AAA with a single ultrasound scan is recommended for all men at age 65 years (class I, level A) but not for women (class III, level B); all men and women aged ≥ 50 years with a first-degree relative with an AAA (class IIb, level C) and/or with a true peripheral arterial aneurysm may be considered for AAA screening (class IIb, level C)
<b>Recommendation 17 and 13:</b> Ultrasonography is recommended for AAA surveillance; every 3 years for aneurysms 3 to 3.9 cm in diameter, annually for aneurysms 4 to 4.9 cm, and every 3 to 6 months for aneurysms ≥ 5 cm (class I, level B); men with an aorta 2.5 to 2.9 cm in diameter at initial screening may be considered for rescreeing after 5 to 10 years (class IIb, level C)
<b>Recommendation 22 and 23:</b> In men, the threshold of ≥ 5.5 cm is recommended for considering elective AAA repair (class I, level A); in women with acceptable surgical risk, the threshold may be considered to be ≥ 5 cm in diameter (class IIb, level C)
<b>Recommendation 57, 58, and 98:</b> For newer-generation stent grafts based on existing platforms such as low-profile devices, long-term follow-up and evaluation of durability in prospective registries is recommended (class I, level C); new techniques/concepts (such as EVAS with endobags, endostaples, and laser in situ fenestration) are not recommended in clinical practice and should only be used with caution, preferably within the framework of studies approved by research ethics committees, until adequately evaluated (class III, level C)
<b>Recommendation 60, 61, and 74:</b> In most patients with suitable anatomy and reasonable life expectancy, EVAR should be considered as the preferred treatment modality (class IIa, level B); in patients with long life expectancy, open AAA repair should be considered as the preferred treatment modality (class IIa, level B); in patients with ruptured AAA and suitable anatomy, EVAR is recommended as a first option (class I, level B)
<b>Recommendation 91 and 92:</b> Early (within 30 days) postoperative follow-up after EVAR, including imaging of the stent graft to assess presence of endoleak, component overlap, and sealing zone length, is recommended (class I, level B), and patients considered at low risk of EVAR failure after their first postoperative CTA may be considered for stratification to less frequent imaging follow-up (class IIb, level C)
<b>Recommendation 94, 95, 96, 97, and 99:</b> Centralization to specialized high-volume centers that can offer both complex open repair and complex EVAR for treatment of JRAAA is recommended (class I, level C); in patients with JRAAA, open repair or complex EVAR should be considered based on patient status, anatomy, local routines, team experience, and patient preference (class IIa, level C); in complex EVAR of JRAAA, fenestrated stent grafts should be considered the preferred treatment option when feasible (class IIa, level C); in complex EVAR for JRAAA, using parallel graft techniques may be considered as an alternative in the emergency setting, when fenestrated stent grafts are not indicated or available, or as a bailout, ideally restricted to ≤ 2 chimneys (class IIb, level C); in patients with ruptured juxta/pararenal AAA, open repair or complex EVAR (with a physician-modified fenestrated stent graft, off-the-shelf branched stent graft, or parallel graft) may be considered based on patient status, anatomy, local routines, team experience, and patient preference (class IIb, level C)
<b>Recommendation 102 and 103:</b> The threshold for elective repair of isolated IAA (common iliac artery, internal iliac artery, and external iliac artery, or a combination thereof) may be considered at a minimum of 3.5 cm in diameter (class IIb, level C); in patients with IAA, EVAR may be considered as first-line therapy (class IIb, level B)
<b>Recommendation 109, 112, and 117:</b> Surgical techniques used in mycotic aneurysm repair should be considered based on patient status, local routines, and team experience, with EVAR being an acceptable alternative to open repair (class IIa, level C); in patients with inflammatory AAA with a threshold diameter of 5.5 cm and suitable anatomy, EVAR should be considered as a first option (class IIa, level C); in patients with complicated penetrating aortic ulcer, dissection, intramural hematoma, or pseudoaneurysm of the abdominal aorta, EVAR should be considered as a first option (class IIa, level C)
Abbreviations: AAA, abdominal aortic aneurysm; ESVS, European Society for Vascular Surgery; EVAR, endovascular aneurysm repair; EVAS, endovascular aneurysm sealing; IAA, iliac artery aneurysm; JRAAA, juxtarenal abdominal aortic aneurysm. Adapted from Wanhainen A, Verzini F, Van Herzele I, et al. Editor's choice—European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. Eur J Vasc Endovasc Surg. 2019;57:8-93.

should be considered as the preferred treatment modality (Table 2, Recommendation 60). Yet, reports indicate an increased rate of complications after 8 to 10 years with earlier-generation EVAR devices, and there is uncertain durability of current devices, particularly low-profile

devices. Although EVAR should be considered the preferred treatment modality in most patients, it is reasonable to suggest an OSR-first strategy in younger, fit patients with long life expectancy, (ie, > 10–15 years; Table 2, Recommendation 61).

The rapid technologic development is an inherent challenge within the endovascular field. The constant modifications and the several devices involved make it extremely difficult to get reliable data about durability, which is of utmost importance. Device-related complications or problems are rare and difficult to detect in single-center environments. RCTs, although representing the highest level of evidence, will eventually become outdated under these circumstances, and cohort and registry data will be the main means of continuously updating our knowledge.

The IMPROVE trial, an RCT comparing OSR and EVAR for ruptured AAA, showed that an endovascular-first strategy for suspected ruptured AAA was associated with a survival advantage, a gain in quality-adjusted life-years, reduced costs, and cost-effectiveness.<sup>4</sup> Together with observational studies and registry data, these data support a strong recommendation of an EVAR-first strategy for ruptured AAA repair (Table 2, Recommendation 74). This places high demands on around-the-clock EVAR availability at all centers that want to engage in AAA surgery, which is in line with other recommendations on availability and centralization.

### FOLLOW-UP AFTER EVAR

Regular follow-up after EVAR is an established routine. However, the true value of these prophylactic images is unclear. Routine surveillance seldom identifies significant findings requiring reintervention, while many patients who require reintervention after EVAR present with symptoms outside of their surveillance programs. Furthermore, compliance with annual prophylactic imaging programs is reportedly suboptimal, and the lack of adherence to follow-up does not seem to affect long-term mortality or postimplantation rupture rate. Annual imaging after EVAR for all patients is neither evidence-based nor feasible. Yet, an early postoperative clinical and imaging follow-up after EVAR is required to assess the success of the performed intervention (Table 2, Recommendation 91). Recent observational data suggest that patients considered at low risk for EVAR failure based on their first postoperative CTA (ie, anatomy within instructions for use with adequate proximal and distal seal and no visible endoleak) may be considered to be stratified to less frequent follow-up. Patients who fulfill the criteria described at early follow-up imaging may be considered for delayed imaging up to 5 years after repair (Table 2, Recommendation 92). Patients who do not meet these requirements should be assessed for the need for reintervention or continued frequent monitoring. This change in practice will save resources but needs to be carefully monitored and evaluated, preferably in prospective cohort and registry studies.

### JUXTARENAL AAA

Given the rarity and complexity of juxtarenal AAA treatment, it is recommended that these patients are treated at specialized high-volume centers that can offer both open and complex endovascular repair (Table 2, Recommendation 94). As a result, continued centralization of juxtarenal AAA surgery should be encouraged.

There are currently no reliable comparative and health economic studies comparing OSR with complex EVAR in patients with juxtarenal AAA. With today's rather extensive experience of complex EVAR (especially fenestrated EVAR), showing generally good results and the ability to offer treatment to many patients less suitable for major open surgery, it is difficult to motivate a strong preference for OSR over complex EVAR for juxtarenal AAA. Instead, the ESVS Guideline Writing Committee suggests a more pragmatic approach with OSR and EVAR being complementary techniques for the treatment of these patients. Decision-making should be tailored to each patient based on anatomy and surgical risk (Table 2, Recommendation 95). For example, OSR with an anastomosis just below the renal arteries and short renal clamping time may be preferable as well as a more durable option for fit patients with a short aortic neck. With more complex anatomy or high surgical risk due to comorbidities, an endovascular solution with a suprarenal proximal landing zone may be better. Despite limited data, the ESVS Guideline Writing Committee believes that fenestrated technology has a small advantage over parallel graft technique when it comes to proven feasibility and durability. There are more multicenter reports and longer follow-up data available supporting fenestrated technology, and it should be the preferable endovascular technique for elective juxtarenal AAA repair (Table 2, Recommendation 96). However, parallel graft techniques may be considered as an alternative technique in the emergency setting or as a bailout (Table 2, Recommendation 97).

Data are scarce for ruptured juxtarenal AAA, but the risk aversion is low in such an immediate life-threatening and complex situation. Therefore, in patients with ruptured juxtarenal AAA, OSR or complex EVAR (with physician-modified fenestrated stent grafts, off-the-shelf branched stent grafts, or parallel grafts) may be considered based on patient status, anatomy, local routines, team experience, and patient preference (Table 2, Recommendation 99).

### NEW DEVICES

New stent grafts and delivery systems with lower profiles to allow an endovascular approach even in



patients with small access vessels have emerged on the market. Although there are some series reporting favorable midterm outcomes for latest-generation low-profile stent grafts compared with standard profile stent grafts, more experience and longer-term outcome data about the durability of these new devices are needed to confirm those findings. It is strongly recommended that the long-term performances of modified devices used in routine clinical practice are evaluated in prospective registries (Table 2, Recommendation 57).

The role of several innovative CE Marked technologies on the market is still unclear, and further data are needed before these can be recommended for routine use in clinical practice. Importantly, CE Mark (or approval) has little to do with efficacy or safety, and there are many unproven, ineffective, or even inappropriate medical devices that are CE Marked. The ESVS guidelines issue a strong negative recommendation against the use of new, unproven devices or concepts in clinical practice outside of studies approved by research ethics committees and with informed consent from the patients, until adequately evaluated (Table 2, Recommendation 58).

This approach is supported by recent alarming reports on endovascular aneurysm sealing (EVAS) with polymer-filled endobags, with higher than expected rates of leaks around the implant, device movement, and aneurysm enlargement after EVAS. This recommendation is also valid for unproven concepts such as the use of standard EVAR with endostaples, laser-generated in situ fenestration, and multilayer stents for treatment of juxtarenal AAA (Table 2, Recommendation 98). A more responsible introduction of new products is important, for ethical reasons as well as for the credibility of our vascular surgery discipline. Hopefully, this recommendation can contribute to that.

## MISCELLANEOUS

The epidemiology of iliac artery aneurysms (IAAs) is not as well established as for AAAs. Most reported ruptured IAAs in the literature are > 5 cm, and rupture rarely occurs at < 4 cm. Based on this, a weak recommendation on conservative treatment in most patients with a maximum iliac aneurysm diameter < 3.5 cm was issued (Table 2, Recommendation 102). This is an increase of the diameter threshold for elective repair of IAAs compared with previous recommendations. Based on favorable outcomes reported for endovascular repair of IAA, including the optional use of iliac side branch devices, EVAR may be considered as first-line therapy for patients with IAA (Table 2, Recommendation 103).

In the past decade, mycotic aortic aneurysms (MAAs) have been increasingly treated successfully by endovascular means. A recent comparative study of OSR and EVAR for MAA showed a significant early survival benefit for EVAR (up to 4 years) with no late disadvantages in terms of rates of late infection, aneurysm-related complications, or survival,<sup>5</sup> suggesting that endovascular repair is an acceptable alternative to OSR (Table 2, Recommendation 109). With lower 30-day mortality rates and fewer major complications, EVAR (as compared with OSR) is recommended as the preferred treatment modality for inflammatory AAA (Table 2, Recommendation 112) as well as in patients with complicated penetrating aortic ulcer, dissection, intramural hematoma, or pseudoaneurysm of the abdominal aorta (Table 2, Recommendation 117).

## CONCLUSION

The new ESVS AAA guidelines are an extensive document offering many other recommendations of clinical importance on the management of AAA. Each recommendation is accompanied by a comprehensive supporting text that summarizes the literature and motivates the positions made. Hopefully, it will guide clinicians in everyday work as well as researchers and decision-makers and contribute to the care and understanding of patients with AAAs. ■

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