Endovascular repair for abdominal aortic aneurysms

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Received 2 December 2020
Revised 9 February 2021
Accepted 15 February 2021
Published Online First 4 March 2021

To cite: Debono S, Nash J, Tambyraja AL, *et al*. *Heart* 2021;**107**:1783–1789.

ABSTRACT

Management of abdominal aortic aneurysms has been the subject of rigorous scientific scrutiny. Prevalence studies have directed the formation of screening programmes, and observational studies and randomised controlled trials have defined aneurysm growth and treatment thresholds. Pre-emptive intervention with traditional open surgical repair has been the bedrock of improving long-term outcome and survival in patients with abdominal aortic aneurysms but it is associated with a significant procedural morbidity and mortality. Endovascular aneurysm repair (EVAR) has substantially reduced these early complications and has been associated with promising results in both elective and emergency aneurysm repair. However, the technique has brought its own unique complications, endoleaks. An endoleak is the presence of blood flow within the aneurysm sac but outside the EVAR graft. Although in randomised control trials EVAR was associated with a reduced early mortality compared with open repair, its longer-term morbidity and mortality was higher because endoleak development is associated with a higher risk of rupture. These endoleak complications have necessitated the development of postoperative imaging surveillance and re-intervention. These contrasting benefits and risks inform the selection of the mode of repair and are heavily influenced by individual patient factors. An improved strategy to predict endoleak development could further help direct treatment choice for patients and improve both early and late outcomes. This article reviews current EVAR practice, recent updates in clinical practice guidelines and the potential future developments to facilitate the selection of mode of aneurysm repair.

Trial registration number: ClinicalTrials.gov NCT04577716.

INTRODUCTION

Endovascular aneurysm repair (EVAR) has evolved rapidly since being performed in the early 1990s. In these pioneering early stages, a tailor-made Dacron graft was manually sutured onto a stainless steel balloon-expandable stent. This was then deployed through 22-French sheaths and femoral arteriotomies under fluoroscopic guidance.[1] Following this early demonstration of proof of concept, EVAR technology developed quickly. It can now be performed percutaneously under local anaesthesia using an off-the-shelf stent graft and same day discharge is not uncommon.[2] Indeed, third generation stent grafts have now been developed, and the long-term outcomes of several randomised controlled trials comparing open surgical repair and EVAR are known. Clinical practice guidelines by the European Society for Vascular Surgery[3] and the Society for Vascular Surgery[4] have been produced and subsequently revised. The National Institute for Health and Care Excellence[5] in the UK has also made its own recommendations.

The aim of this review is to define current knowledge on abdominal aortic aneurysms, describe EVAR practice, assess the growing body of evidence behind it and highlight some of the problems that continue to challenge endovascular surgery.

ABDOMINAL AORTIC ANEURYSM

The abdominal aorta is defined as being aneurysmal when its diameter is at least one and a half times the normal aortic diameter at the level of the renal arteries. For men, this would be ≥30 mm.[6]

Pathophysiology

The pathophysiology of abdominal aortic aneurysms is incompletely understood. It appears to result from medial wall atrophy and degeneration[7] that may be triggered by an initial inflammatory response, and neutrophil infiltration at the junction between the media and adventitia. This leads to a reduction in elastin, collagen, glycosaminoglycans, and an imbalance of matrix metalloproteinases, reducing the amount of connective tissue protein content and aortic wall strength.[8]

Risk factors, prevalence and screening

The strongest modifiable risk factor is cigarette smoking. In a screening and validation study of US veterans, smoking habit increased the odds of having an abdominal aortic aneurysm fivefold[9] whereas a healthier lifestyle (weekly exercise, and consumption of fruit and vegetables) reduced the risk.[10] Hypertension and atherosclerosis are also associated, but patients with diabetes mellitus appear to be less likely to develop an aneurysm.[9 11] This underscores some important differences between the pathophysiology of atherosclerotic and aneurysmal disease. Non-modifiable risk factors include male sex, increasing age, family history, concomitant peripheral artery aneurysms and white ethnicity.[11]

Prevalence of abdominal aortic aneurysms is extremely low before the age of 55 years but increases thereafter: up to 2.3% in the 75–79 years age group (2275 per 100 000 population).[12] Prevalence data in 65-year-old men suggest aneurysms are present in 1.5% of the Swedish (2006–2014)[13] and 1.34% of the English (2009–2013) screening programmes.[14]

In Sweden and the UK, screening programmes only cover men who are invited for an abdominal ultrasound scan at the age of 65 years. In the USA, screening is recommended for men aged 65–74 years with a past or current smoking habit. Screening programmes reduce all-cause mortality and disease-specific mortality due to early detection and treatment.[15]

Diagnostic imaging

Ultrasound scan is the clinical standard for diagnostic imaging. Its high sensitivity and specificity, and lack of radiation, make it ideal for screening and surveillance.[16] CT angiography has a central role in management and intervention planning by visualising the whole aorta to allow accurate anatomical measurements that can be fused with real-time angiography for intraoperative use. CT angiography also defines arterial tributaries, renal vein anatomy and neck morphology, crucial information for planning of either open or endovascular repairs. Ultrasound is not sensitive enough to detect retroperitoneal haemorrhage in an emergency setting and CT angiography is required.

Growth and repair thresholds

Individual patient data meta-analysis of 15 475 individuals with a small aneurysm (30–54 mm diameter)[17] showed a growth rate of 2.2 mm/year. This is higher in current smokers (2.6 mm/year) and lower in patients with diabetes (1.7 mm/year). Rupture rate is strongly associated with smoking and female sex. The use of common cardiovascular drugs (beta-blocker, calcium channel blocker, antiplatelet or antihypertensive therapies) does not correlate with growth rates except for statin therapy which is associated with lower growth rates.[18] In randomised controlled trials, ACE inhibitor therapy[19] and doxycycline[20] have no effect on aneurysm growth. Studies exploring the effect of metformin therapy are ongoing (ClinicalTrials.gov numbers NCT04224051 and NCT04500756). Since patients with abdominal aneurysms are also at high risk of all cardiovascular events, 5-year survival rates are higher in those taking antiplatelet, statin or antihypertensive therapies.[21]

Most aneurysms are considered for repair after a diameter of 55 mm is reached, or when rapid growth occurs (more than 10 mm per year).[3–5] A Cochrane review summarised the four trials on which size threshold recommendations are based. The annual risk of rupture comparing surveillance versus repair was found to be less than 1% below 50 mm, 10% between 50–60 mm and 20% above 60 mm. Furthermore, treatment using EVAR for a diameter of 40–55 mm showed no survival advantage.[22]

ELECTIVE REPAIR

Abdominal aortic aneurysms can be repaired by open surgical repair or by endovascular means. Use of EVAR has increased, as its technology and technique developed. In the USA, EVAR was performed in 76% of all aneurysm repairs in 2013.[23] This proportion was 58% in Sweden in repairs performed between 2010 to 2014.[24] The National Vascular Registry 2020 Annual Report in the UK reported this to be 61%.[25]

Endovascular aneurysm repair

The EVAR stent graft works by excluding the aneurysm from the circulation from the inside of the artery. The proximal and distal aspects of the stent need to provide an adequate seal with the native arterial wall so that blood cannot leak around the endograft and enter the aneurysm sac; this could lead to ongoing expansion and secondary aneurysm rupture. The stent is made of a nitinol (a nickel-titanium alloy) stent covered with polytetrafluoroethylene. It has its own delivery system and is self-expanding. The proximal part of the graft is held in place by barbs or anchors at its proximal end to ensure adequate fixation. The complete endograft is comprised of modular parts of at least two or three separate components including a bifurcate main body and limb components. The modular parts provide a degree of flexibility in size selection, although the overlap between each component must be sufficient to ensure no intervening leaks occur.

The effectiveness of EVAR is dependent on achieving a good seal with the native arteries at the proximal and distal sealing zones, that is, the infrarenal aortic neck and (usually) the common iliac arteries. Manufacturers' 'Instructions for Use' refer to the endograft-specific anatomical requirements which aneurysm anatomy must adhere to, in order to reduce the risk of stent migration, endoleak formation and late aneurysm rupture. Instructions for use give recommended morphological features at the sealing zones and outline the hostile neck features that are incompatible with the use of a specific endograft (box 1). Additionally, there must be adequate femoral access, and no substantial or circumferential calcification or thrombus in the landing zones.[3] When one of the iliac seal zones is of insufficient quality, an aorto-uni-iliac stent graft can be used. Here, the iliac artery is occluded with a plug and a surgical femorofemoral cross-over graft is fashioned to perfuse the leg in question. If one of the common iliac arteries is also aneurysmal, an iliac branch device may be used. This involves inserting a further bifurcated endograft into the common iliac artery, with limbs into the internal and external iliac arteries.

The stent graft is delivered into the aneurysm under fluoroscopic guidance through sheaths inserted into the femoral arteries (figure 1). Open cutdown onto the femoral arteries may be required, although percutaneous EVAR with sheath insertion using ultrasound and fluoroscopic guidance is increasingly performed. This requires predeploying closure devices into the common femoral artery before sheath insertion and fully deploying them on sheath removal to close the arterial puncture site. This approach is less invasive and allows EVAR to be performed under local anaesthesia. A systematic review found that percutaneous access is associated with a lower frequency of postoperative groin infection and lymphocoele formation, and a reduction in procedure time and hospital stay. There was no additional risk of haematoma formation, pseudoaneurysm or arterial thrombosis.[26]

Endoleak and long-term EVAR outcomes

Long-term EVAR durability is compromised by endoleak formation. Endoleak is the presence of persistent blood flow within the aneurysm sac but outside of the stent graft. It can be observed either immediately following stent graft delivery (early) or it can develop months or years after the procedure (late). There are five types of endoleaks, classified by their origin (figure 2).

Box 1 Features of a hostile neck which can preclude use of a 'standard' stent graft (these measurements can vary between different manufacturers)[30]

- Short neck of less than 10 mm
- Infrarenal angulation of more than 60°
- Conical or reverse tapered
- Infrarenal diameter of more than 28 mm
- Circumferential mural thrombus or calcification

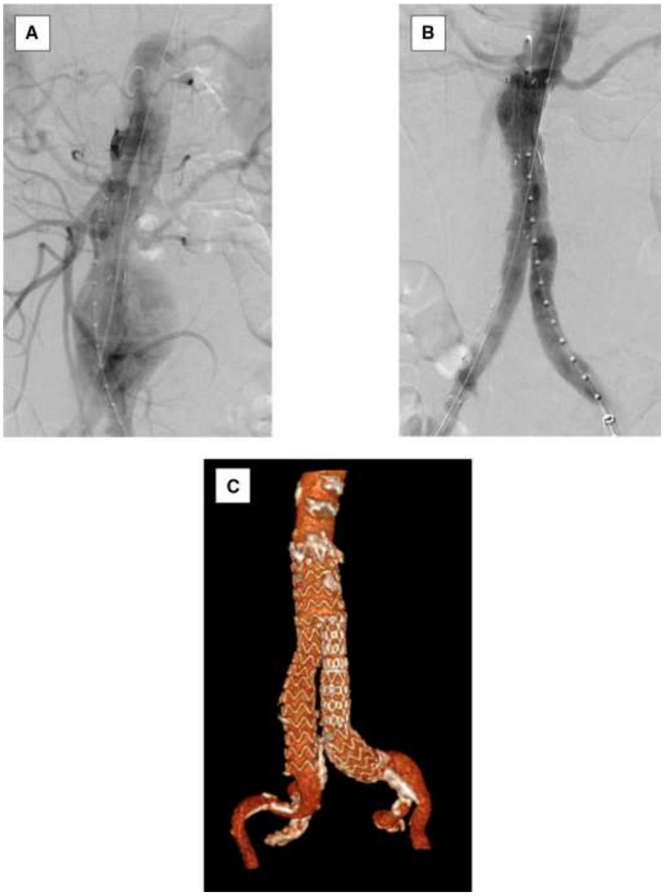

Figure 1 (A) Intraoperative fluoroscopy showing digital subtraction angiography of the non-deployed stent graft within the abdominal aorta and aneurysm. Contrast can be seen within the aortic branches and the aneurysm sac. (B) Digital subtraction angiography after the stent graft was deployed demonstrating correct position and absence of endoleaks. (C) Three-dimensional reconstruction of a postoperative CT angiography showing a stent graft in place.

Inflow of blood around the stent graft can result in a pressurised aneurysm sac which may lead to rupture.[27] Therefore, types Ia and type III endoleaks noted either on completion angiography or follow-up imaging require urgent management. Type Ia endoleak occurs more frequently when hostile neck features are present (box 1).[4] In contrast, around half of early type II endoleaks appear to follow a more benign course and tend to be managed conservatively unless there is aneurysm sac growth. Surveillance of type II endoleaks without intervention is rarely associated with an increased risk of aneurysm-related mortality, all-cause mortality, sac expansion or type I endoleak development.[28]

Stent graft migration is defined as a >10 mm movement of the graft or stent resulting in symptoms or the need for re-intervention.[29] Stent migration can result in a type I endoleak, separation of modular components or graft occlusion. Similar to type Ia endoleak, stent migration is more likely to occur when hostile neck features are present.[30] Device adjuncts have been developed with the aim of reducing the risk of type I endoleak and migration, especially in short necks. These include circumferentially deploying helically shaped anchors to tack the endograft to the wall of the aortic neck.[31]

Most endoleaks are asymptomatic, mandating lifelong surveillance in order to detect and prevent subsequent complications. Cost, and the risks of contrast nephropathy and ionising radiation from serial CT scans preclude the use of just CT angiography for EVAR surveillance. Duplex ultrasound or contrast-enhanced duplex ultrasound also form part of current surveillance strategies. Duplex ultrasound-based surveillance may be used if CT angiography performed within the first postoperative year is reassuring. However, while duplex ultrasound reliably detects the presence of type I endoleaks, it is less sensitive in detecting type II endoleaks. A surveillance programme could therefore take the form of a CT angiogram at 30 days postoperatively proceeding to annual ultrasound surveillance. An increase in aneurysm sac diameter or an endoleak would trigger early cross-sectional imaging, otherwise a CT angiogram could be repeated after 5 years (figure 3).[3]

Surgical repair

Open surgical repair is performed through either a midline vertical or a transverse abdominal incision. A textile polyester graft such as Dacron is used to replace the diseased aorta. The

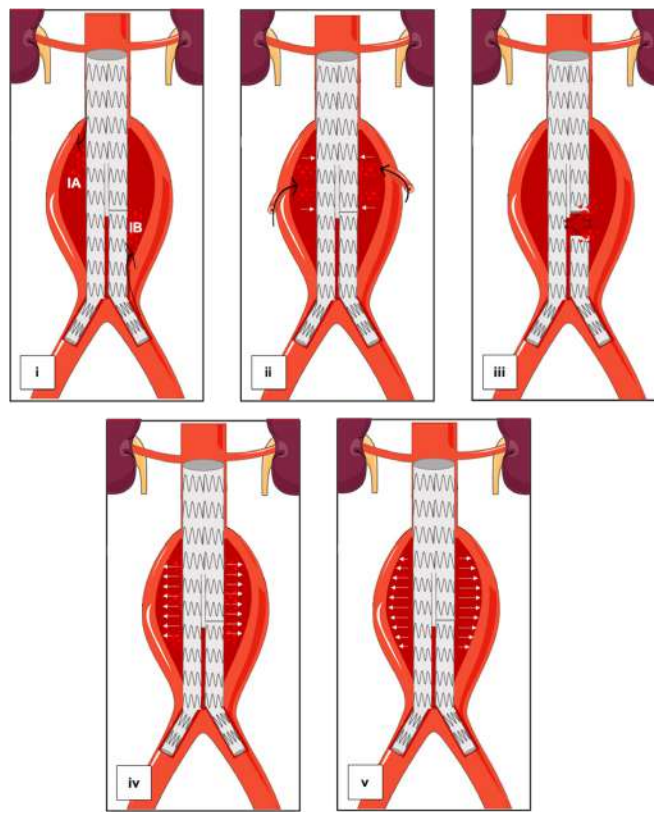

Figure 2 (A) Type I endoleak: This results from loss of seal at the proximal or distal sealing zones. It is further categorised depending on the location of seal loss. IA, proximal seal loss; IB, distal seal loss; IC, an iliac plug (not shown). (B) Type II endoleak: Blood flow within the sac from the patent collateral arteries arising from the aneurysm itself, such as the inferior mesenteric artery (type IIA) or lumbar arteries (type IIB). (C) Type III endoleak: Loss of seal arising either from around the junctions of the different modular parts (type IIIA) or due to holes in the graft fabric (type IIIB). (D) Type IV endoleak: This occurs due to graft porosity, and used to be more common with older generation stent grafts. (E) Type V endoleak: Sometimes described as endotension, this refers to sac enlargement on serial imaging, in the absence of a visualised endoleak. Other types of endoleaks should be completely excluded first. Black arrows indicate direction of blood and white arrows indicate pressure within the sac.

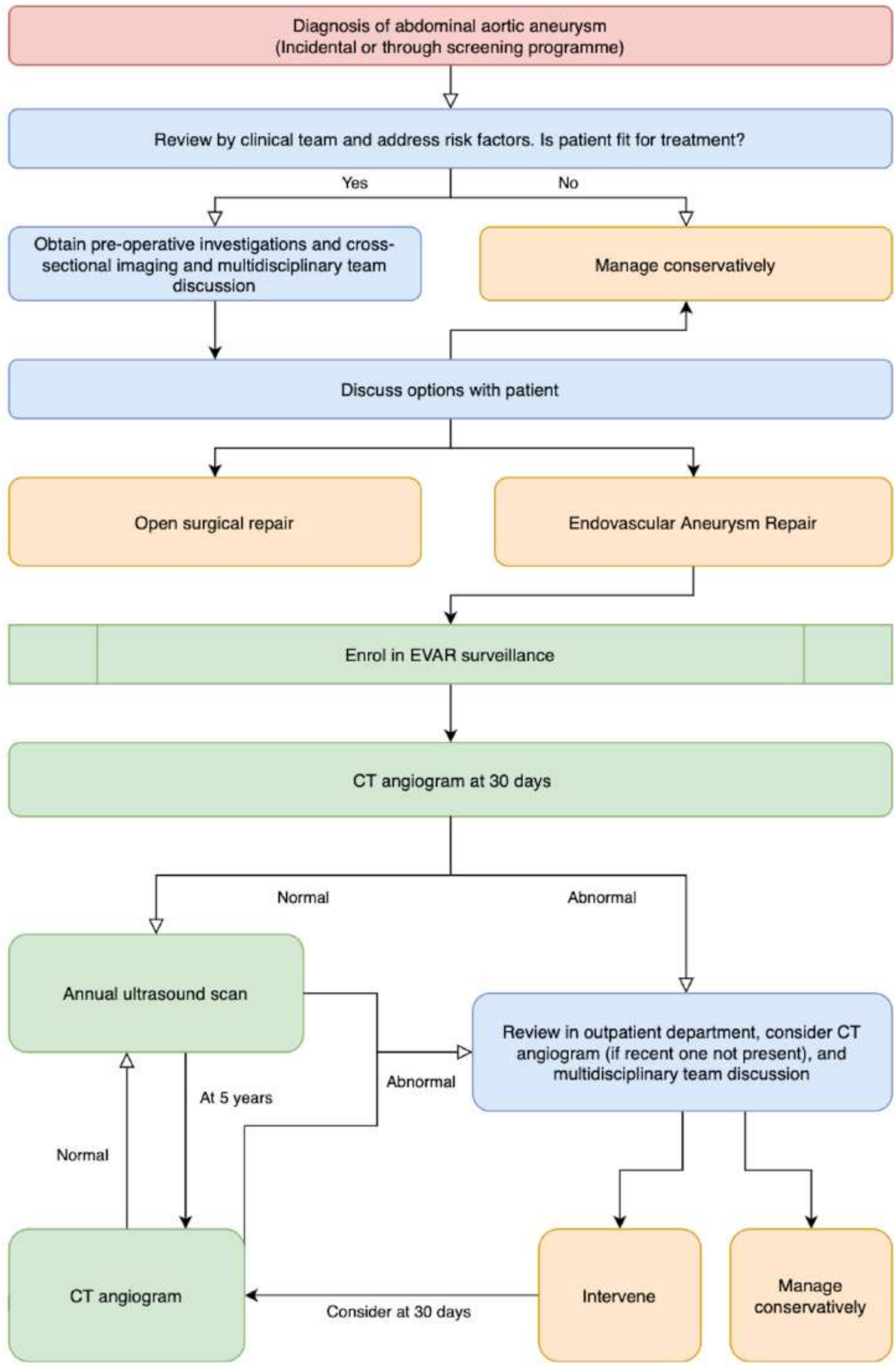

Figure 3 An approach to elective management of patients with abdominal aortic aneurysm. Following diagnosis, the patient should be reviewed by a member of the clinical team. If obvious contraindications to treatment are present, for example, active malignancy with a reduced life expectancy, it may be more prudent for the patient to be managed conservatively from the outset. If not, cross-sectional imaging in the form of a CT angiogram should be sought to provide anatomical details on the aneurysm morphology. Preoperative investigations which assess the patient's aerobic capacity may be performed at this point. The case should be discussed at a multidisciplinary team (MDT) level, this is usually comprised of vascular surgeons, interventional radiologists and vascular anaesthetists. The outcome of the meeting would then be discussed with the patient and a treatment decision reached. If conventional endovascular aneurysm repair (EVAR) is performed, a normal postoperative CT angiogram would lead to enrolment within an EVAR surveillance programme. While not yet standard practice, one example of an EVAR surveillance programme would be an ultrasound scan annually and a CT angiogram at 5 years. An abnormal ultrasound scan would trigger more detailed and earlier imaging (CT angiogram) which would also be discussed at an MDT. Interventions can then be planned depending on what abnormality is identified.

proximal anastomosis is sutured as close to the renal arteries as possible to prevent later aneurysm formation in the remaining infrarenal aortic neck. Aneurysm anatomy dictates whether the graft is a simple tube or bifurcated 'trouser' graft. The distal anastomoses are completed at either the common iliac, external iliac or femoral arteries as necessary.

Abdominal aortic aneurysm repairs are high-risk interventions. Mortality with open repair has been reported as high

Table 1 Long-term complications common to both endovascular and open aneurysm repair

Complication	Estimated incidence[3] EVAR	Open	Details
Limb kinking and/or occlusion	1.4%–8%	1%–5%	While kinks within the graft limbs can be asymptomatic, occlusions may present with symptoms of new-onset (acute) or worsening limb ischaemia. These should be imaged and treated as clinically necessary. In EVAR, the biggest risk for limb occlusion is landing the limb in the external iliac artery and its diameter.[42 43]
Graft infection	0.2%–1%	0.3%–6%	Graft infection is more likely to occur if prosthetic material is present in the groin. Treatment includes surgical excision of the graft and debridement of the operative field. It has high morbidity, with a 25% risk of re-infection and a 54% 5-year mortality.[44]
Secondary aortoenteric fistula	0.3%–0.5%	0.3%–0.5%	Rare but serious. This usually presents with significant gastrointestinal bleeding. Removal of all infected material with concurrent surgical reconstruction is necessary for definite treatment but bridging endovascular therapy is sometimes performed in the immediate setting to prevent catastrophic haemorrhage and death.
Secondary aortic rupture	1%–5%	<1%	Rupture secondary to clinical failure of the stent graft, for example, due to untreated endoleak. In open repair this may be secondary to aneurysm formation in the infrarenal aortic segment or infection.
Sexual dysfunction	16%	27%	Sexual dysfunction can occur in both types of repairs and although risk factors and therapeutic options are as yet undefined, it should be discussed at the consent process as certain operative factors may play a role, for example, dissection close to the pelvic nerve plexus in tube graft open repair or bilateral occlusion of internal iliac arteries in EVAR.

EVAR, endovascular aneurysm repair.

as 10%,[32] but it is greatly reduced (2.3%) in higher-volume centres.[25] Morbidity with both types of interventions can also be serious and certain long-term complications can occur in both open repair and EVAR (table 1).

EVAR trials and clinical practice guidelines

Four major randomised controlled trials have compared EVAR and open surgical repair (table 2). A meta-analysis of the individual patient data (2783 patients) at 5 years confirmed the original trial findings. The early (0–6 months) reduction in EVAR group mortality (pooled HR 0.61; 95% CI 0.42 to 0.89; p=0.010) changed within 3 years and the survival rates converged. Beyond this, aneurysm-related mortality was higher in the EVAR group (pooled HR 5.16; 95% CI 1.49 to 17.89; p=0.010). There was no early survival advantage with EVAR in patients with moderate renal dysfunction or coronary artery disease.[33] Long-term follow-up of these trials has shown that EVAR is not associated with a higher risk of death due to cancer, but a greater need for re-intervention (HR 2.13; 95% CI 1.69 to 2.68; p=<0.001).[34] The increasing re-interventions with EVAR highlight concerns over endograft durability and the need for ongoing postoperative surveillance. These contrasting findings of early benefit with endovascular treatments but later benefits from open surgery strike a chord with the experience of coronary revascularisation where percutaneous coronary intervention is associated with better short-term outcomes but coronary artery bypass surgery reduces longer-term mortality.[35]

These EVAR trials have informed the recommendations in clinical practice guidelines published by the Society for Vascular Surgery, the European Society for Vascular Surgery and the National Institute for Health and Care Excellence. However, each has come to different conclusions. The Society for Vascular Surgery recommends an assessment of operative risk and life expectancy when contemplating repair, arguing that a patient who is at high risk for open surgery may be at lower risk for EVAR. The European Society for Vascular Surgery recommends EVAR as the preferred treatment modality where anatomically suitable, but open repair in patients with longer life expectancies (more than 10–15 years). The National Institute for Health and Care Excellence recommends open surgical repair unless contraindicated due to a hostile abdomen, anaesthetic risks or comorbidities when EVAR is recommended but notes that this needs balancing with the uncertainty benefit of EVAR in these patients.

There are many critics of the differences in the recommendations. Some argue that the quoted trials were performed with either older generation endografts or ones which are not commercially available anymore. Newer generation grafts appear to have fewer re-intervention rates than their older counterparts in more recent studies.[36] Endovascular experience among clinicians has also continued to increase and imaging

Table 2 Summary of randomised controlled trials comparing open surgical repair and endovascular aneurysm repair (EVAR) for unruptured abdominal aortic aneurysm

Study	Recruitment period	Aneurysm size	Patients	Follow-up	Main findings
Endovascular Aneurysm Repair 1 Trial (EVAR-1)[45]	1999–2004	>55 mm	1252 626 EVAR 626 Open	15 years	No all-cause mortality difference between the two groups Beyond 8 years, higher all-cause mortality and aneurysm-related mortality in the EVAR group Higher re-intervention rate in the EVAR group
Open vs Endovascular Repair (OVER)[46]	2002–2008	>50 mm	881 444 EVAR 437 Open	13 years	No significant difference in all-cause mortality between the two groups A higher number of secondary therapeutic interventions in the EVAR group
Dutch Randomised Endovascular Aneurysm Management (DREAM)[47]	2000–2003	>50 mm	351 173 EVAR 178 Open	12 years	No survival difference was observed between the two groups, this despite an increasing number of re-interventions within the EVAR group
Anevrysme de l'aorte abdominale: Chirurgie vs Endoprothese (ACE)[48]	2003–2008	>50 mm	316 150 EVAR 149 Open	5 years	No difference in the cumulative survival free of death and major adverse event rates Higher re-intervention rates in the EVAR group at 3 years

technology and devices have continued to develop. In contrast, the surgical technique for open repair has remained more or less unchanged since the 1950s. Similar arguments have previously been advanced for percutaneous and open surgical approaches for coronary revascularisation and yet open surgery continues to have the best long-term outcomes.[35]

The European Society for Vascular Surgery took into consideration more contemporary population-based registries, some of which reported improved short-term outcomes that are sustained for at least 5 years.[24] Others would argue that the conclusions by the National Institute for Health and Care Excellence are more valid since they only considered higher quality evidence (in the form of randomised controlled trials). They also looked at cost-effectiveness in more detail and used UK-specific economic modelling. It concluded that despite the short-term benefit, the higher net costs and lower net benefits of EVAR than open repair, put it above the range normally considered to be a cost-effective use of National Health Service resources. This lack of consensus has even led some to suggest that new randomised controlled trials are required.[37]

EMERGENCY REPAIR

A ruptured abdominal aortic aneurysm refers to acute haemorrhage from the aneurysm beyond the true aortic wall. It is a surgical emergency which invariably results in death if left untreated. While the National Institute for Health and Care Excellence guidelines suggest that EVAR *should be considered*, both the Society and European Society for Vascular Surgery suggest that when anatomically suitable, a ruptured abdominal aortic aneurysm *should be* repaired by EVAR. The largest randomised trial comparing open aneurysm repair versus EVAR in ruptured abdominal aortic aneurysms (the IMPROVE Trial—Immediate Management of Patients with Ruptured Aneurysm: Open vs Endovascular repair) recruited 613 patients with a clinical diagnosis of rupture in the UK and Canada. There were no mortality differences at 30 days (37.4% vs 35.4%)[38] or 1 year (45.1% vs 41.1%) between the two groups.[39] Three-year outcomes however suggest that the endovascular strategy was associated with a survival advantage, a gain in quality-adjusted life years, similar levels of re-intervention and reduced costs.[36]

FUTURE DIRECTION

The future of aneurysm treatment cannot solely depend on the continuing development of the endovascular clinician's skill set, and of stent graft devices and their adjuncts. It must take place alongside better patient selection, and our increasing understanding of the underlying disease.

Along with adherence to instructions for use, the recognised aneurysm morphological features associated with the risk of EVAR complications (box 1) can guide treatment choice for individual patients. Surveillance programmes to diagnose and to trigger treatment of endoleaks are also essential. However, aneurysm disease occurs in the aortic wall, and while excluding the wall from the circulation protects the aneurysm from rupture on account of luminal pressure, the disease process remains ongoing and could underlie the occurrence of subsequent endoleaks.

The development of novel imaging techniques which can detect ongoing aneurysm disease activity within the wall could provide an approach for better patient selection. Some emerging MRI techniques can detect cellular inflammation within the aneurysm wall,[40] and positron emission tomography-CT approaches can predict aneurysm growth.[41] If successful, such approaches could enable the delivery of more personalised medicine by identifying which patients would benefit from EVAR, and which patients are at risk of endoleak development and if able, should undergo open repair.

CONCLUSION

Over the last 30 years, our understanding of aneurysm disease has matured, treatment has developed and clinical practices have changed. The lower early mortality risk associated with elective EVAR may be attractive for patients and healthcare providers in the first instance, particularly within an increasingly elderly population. But this is mitigated by a well-documented increase in late mortality, re-interventions and cost when compared with open repair. There remain gaps in our understanding of the factors contributing to reduced durability and re-interventions and this appears to affect long-term results and increase mortality. Better understanding of aneurysm biology, particularly the ongoing disease activity in the aorta following aneurysm repair may permit an individualised treatment strategy. This will improve patient selection for EVAR and identify those whose long-term outcomes will be superior to open repair.

Acknowledgements The authors thank Mark Thomas Macmillan, Centre for Regenerative Medicine, the University of Edinburgh, for the reconstruction image in figure 1.

Contributors SD wrote the manuscript with support from DEN. JN, AT, ROF contributed to the final version of the manuscript.

Funding All funding support is from the UK. SD is supported by the British Heart Foundation Research Excellence Award (RE/18/5/34216). DEN is supported by the British Heart Foundation (CH/09/002, RE/18/5/34216, RG/16/10/32375) and is the recipient of a Wellcome Trust Senior Investigator Award (WT103782AIA).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Commissioned; externally peer reviewed.

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