Interventional Cardiology

Ruptured abdominal aortic aneurysm: open vs. endovascular repair: literature review

Ruptured abdominal aortic aneurysm is a surgical emergency, invariably leading to death without urgent intervention. The emergence of endovascular repair has challenged open repair as the treatment of choice and has featured as the focus of numerous observational and randomised trials across the globe. At present, there is no formal consensus upon the gold standard approach in managing patients with ruptured abdominal aortic aneurysms in the emergency environment, despite the formation of protocols and evidence-based guidance within the elective setting. This literature review examines the current evidence underpinning the use of endovascular repair, and evaluates its efficacy compared to open repair. In summary of the literature, there is no conclusive body of evidence to support the claim that endovascular repair is superior to open repair, particularly from a mortality, complication and cost-utility viewpoint. There are significant conflictions within the evidence-base, often between observational studies, but also between the randomised trials, which themselves are limited in number. It would be appropriate to conclude that endovascular repair is as efficacious as open repair but would be invalid in light of the scientific literature to claim it superior.

Keywords: Abdominal aortic aneurysm ▪ open repair ▪ endovascular repair ▪ ruptured aorta

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Introduction

Rupture of an abdominal aortic aneurysm (rAAA) is often a catastrophic event, responsible for over 8,000 deaths in the United Kingdom each year [1,2]. The incidence of underlying abdominal aortic aneurysmal disease in the UK varies widely based on age and gender, affecting 6% of men aged 65-69, and 17% of males aged 70-74 [3]. The risk of abdominal aortic aneurysmal rupture is related to size, with <5% of AAA's with a diameter of 4-5cm rupturing per year, compared to a 20-40% rupture rate in those with an aneurysmal diameter of 6-7 cm [4].

Rupture of an abdominal aortic aneurysm (rAAA) is often the first clinical presentation of disease; with overall mortality rates exceeding 80% [5], making it one of the most commonly fatal surgical emergencies, and an important public health problem in most countries [6]. One-third of patients with a rAAA do not reach hospital alive, and a further third do not receive an intervention [7]. The only substansive treatments for rAAAs are open surgical repair (OR) or endovascular aneurysm repair (EVAR) [8]. The literature reports that patients with a rAAA have the highest chance of survival if they receive prompt treatment, delivered by a specialised team with high caseloads of surgical interventions [9,10].

For nearly four decades, open repair was widely accepted as the treatment of choice for ruptured abdominal aortic aneurysms [11]. This complex operation often carried a significant level of morbidity and mortality as a result of haemodynamic instability, the co-morbid state of patients, surgical exposure and aortic clamping with associated lower body ischaemic injuries [12–14]. However, significant work surrounding patient selection and optimising perioperative care has allowed open repair to demonstrate excellent outcomes in managing these critically ill patients with rAAAs [15,16]. Since its inception in the early 1990's, the arrival of endovascular repair has challenged the supremacy of open repair [8], by offering a number of theoretical benefits associated with minimally-invasive techniques, such as avoidance of laparotomy, reduction in tissue damage and haemorrhage, reduced risk of hypothermia, and a diminished requirement for deep anaesthesia [17,18]. Over recent years, EVAR has become the first-choice technique in the management of elective repairs, where it has been shown to reduce early complications and mortality [19,20], and its efficacy profile in the management of ruptured abdominal aortic aneurysms is being developed at a rapid rate [14]. It is important to recognise that at present, open repair will remain a major component in rAAA management, due to the fact that only 46-64% of patients with a ruptured AAA have anatomy considered suitable for endovascular repair [21]. Over the last 10-15 years, there has been a widespread and rapid uptake of EVAR for rAAAs, with nearly 40% of cases being treated endovascularly in 2010, compared to<1% in the year 2000 [22,23].

Development of the evidence-base

The IDEAL (Idea, Development, Exploration, Assessment and Long-term study) recommendations providing a statement outlining the evaluation of surgical innovations is followed and applied to endovascular repair for rAAAs [24]. The 'innovation' was first reported in 1993, and 'developed' at a number of centres across the globe with efforts to produce protocols and address associated problems [24–27]. Currently, the tendency to only report on EVAR case-series with successful outcomes is common, with a lack of reporting on significant unfavourable results which creates an extensive publication bias and limits the globalisation of reported results [28]. Additionally, cohort studies are plagued by selection bias, with some studies failing to discriminate between rAAAs, and high risk non-ruptured AAAs [29]. Authors participating in 'cherry picking' of cases contributes to the apparent impressive results achieved at individual centres, in which study methodology should incorporate reporting of sequential cases of both EVAR and OR. In doing so, the bias attributed to case-selection may become apparent and would reinforce the need to develop standardised protocols for reporting, which would be in line with the recommendation as outlined in the STROBE statement [30]. The 'exploratory' phase of IDEAL relating to EVAR was performed via a pilot randomised trial in the UK [31], which demonstrated the feasibility of randomising patients within high-intensity emergency situations, but did, however, highlight many organisational difficulties. Randomised controlled trials are established as the gold standard in the 'assessment' of surgical innovations. The AJAX (Amsterdam Acute Aneurysm Trial) and ECAR (Endovasculaire ou Chirugie dans les Anévrysmes aorto-iliaques Rompus) trials for rAAAs are examples of exploratory trials [32,33], with the multi-centre IMPROVE trial (The Immediate Management of the Patient with Ruptured Aneurysm: Open Versus Endovascular repair) providing evaluations informing clinical policy decision making [34]. The other sources of literature evaluating EVAR for rAAAs comes in the form of systematic reviews and associated meta-analyses of cohort studies, which suffer from heterogeneity, under-reporting of unfavourable results, and incomplete/inadequate adjustment for confounding variables [28]. Often these limitations are recognised by authors, but should still be considered as low-level evidence [29]. The rest of this paper is devoted to providing a commentary and summary of the current evidence-based comparing the use of EVAR against OR for rAAA. It is crucial for the field going forward to push for high-quality, robust, and intricately designed studies, with the ability to perform long-term follow-up on participants, and to build on the conflicted literature, allowing the profession to guarantee the best outcomes for future patients with aneurysmal rupture. It is only such knowledge that will drive change in the provision of vascular services to benefit populations over time [29].

Mortality rate differences between endovascular repair and open repair

One pilot and three major RCTs have published data comparing EVAR with OR for patients presenting with rAAA [21,31–33]. The three large multi-centre trials concluded that early mortality rates (30-day mortality or in-hospital mortality) following treatment for rAAAs are no better with EVAR than with OR (Table 1) [21,33,35]. A Cochrane systematic review and meta-analysis involving two of the major RCTs and the one pilot trial found no difference in early mortality between EVAR and OR (pooled odds ratio 0.91, 95% CI: 0.67–1.22; P=0.52) [15]. A further meta-analysis incorporating the data from the three multi-centre RCTs corroborated these findings (pooled odds ratio 0.88, 95% CI: 0.66-1.18; P=0.84) [36]. Conversely, a further meta-analysis including two RCTs and 39 observational studies, revealed a statistically significant early mortality benefit of EVAR compared to OR (odds ratio 0.56, 95% CI: 0.50-0.65; P<0.01) [37]. Numerous other observational studies also report in favour of EVAR [12,38,39], with authors commonly acknowledging the significant limitations of their work; citing variable management protocols, selection bias, sub-optimal methodological considerations and

Table 1: Comparison between the three multi-centre RCTs: AJAX, ECAR and IMPROVE [21,32,33,47,48].

	AJAX	ECAR	IMPROVE
Number of study sites	3	14	30
Total number of patients with rAAA	520	372	1275
Number randomised	116	107	613
Randomised before or after CT	After	After	Before
Primary end-point	30-day composite of death and severe complications	30-day mortality	30-day mortality
Secondary end-point	Length of hospital and ITU stay, duration of intubation/ ventilation, use of productions	30-day cardiovascular, pulmonary, gastrointestinal, renal, and neurological morbidity; time spent in ITU and volume of blood transfusion	Reintervention, hospital discharge, health-related quality of life, cost, quality-adjusted life years, cost-effectiveness
Number allocated to EVAR and OR	EVAR: n=57 OR: n=59	EVAR: n=56 OR: n = 51	EVAR: n=316 OR: n = 297
30-day mortality: n, (%)	EVAR: 12/57 (21.1) OR: 15/59 (25.4) (odds ratio 0.78, 95% CI: 0.33–1.86)	EVAR: 10/55 (18.2) OR: 12/50 (24.0) (odds ratio 0.70, 95% CI: 0.27–1.81; P=0.239)	EVAR: 112/316 (35.4) OR: 111/297 (37.4) (odds ratio 0.92, 95% CI: 0.66 – 1.28; P=0.62)
90-day mortality: n (%)	EVAR: 15/57 (26.3) OR: 17/59 (28.8) (odds ratio: 0.88, 95% CI: 0.39-1.99)	EVAR 22/53 (41.5) OR: 17/45 (37.8) (odds ratio: 0.43, 95% CI: 0.18 – 1.06)	EVAR: 120/316 (38.0) OR: 118/296 (39.9) [odds ratio: 0.85, 95% CI 0.67 – 1.28]
6-month mortality: n. (%)	EVAR: 16 (28) OR: 18 (31) (odds ratio 0.89, 95% CI: 0.40 – 1.98, P=0.62)	No data.	No data.
1-year mortality: n, (%)	EVAR: 16 (28) OR: 18 (31) (odds ratio 0.89, 95% CI: 0.40 – 1.98, P = 0.62)	EVAR:17 (30.3) OR: 18 (35) P=0.296	EVAR: 130 (41.4) OR: 133 (45.1) (odds ratio 0.85, 95% CI: 0.62–1.17; P=0.33)
3-year mortality: n, (%)	No data.	No data.	EVAR: 47 (42) OR: 60 (54) (odds ratio, 0.73, 95% CI: 0.53–1.00, P=0.053)

inconsistent reporting of clinical parameters as reasons for cautiously interpreting results [40,41]. More specifically, participants who are haemodynamically stable are often assigned to EVAR, introducing a well-defined selection bias [42]. While there is an accompanying body of observational research failing to reveal any early-mortality benefit in utilising an endovascular approach [15,31,36,40,43–45], there are virtually no literature items reporting EVAR as a more morbid curative approach [37]. So while there is no high-level evidence from randomised trials supporting EVAR over OR from an early mortality perspective [15,36], the trends within observational research favour the former. In considering the quality and apparent bias within the evidence base investigating early mortality, it would be fair to conclude that EVAR is not inferior to OR in the emergency management of rAAAs, but further research, ideally through randomised trials, are required to validate claims of superiority with endovascular approaches.

The consensus relating to long-term mortality is equally unclear, with significant heterogeneity between studies [46]. Time intervals in the reporting of late mortality are variable, ranging from three months to over seven years [46,47]. The majority of observational studies report that there are no late mortality benefits using an endovascular approach when compared to open repair in managing rAAAs [46]; a finding corroborated by the three multi-centre RCTs investigating outcomes at three-months, six-months and one-year post-intervention (pooled odds ratio 0.84, 95% CI: 0.63-1.11; P=0.209) (Table 1) [36]. Only the IMPROVE trial provides data at three-years post-intervention, demonstrating a statistically significant improvement in mortality compared to OR (odds ratio 0.73, 95% CI: 0.53-1.00; P=0.053) [47]. However, this is circumvented by the fact that by seven years, there is no clear difference in mortality between the two approaches (hazard ratio: 0.86, 0.68-1.08) [47]. Interestingly, there is a growing body of observational research reporting that EVAR is associated with a statistically significant lower late mortality incidence compared to OR [40,46], however, this has yet to be demonstrated in randomised trials, and thus needs to be scientifically validated. Mirroring the short-term mortality conclusions, no randomised trial suggests that EVAR confers any long-term mortality advantages when compared to OR. It is possible that superiority with EVAR may be demonstrated with further trials, but for now, EVAR is equivalent to OR from a long-term mortality perspective.

Complications incidence between endovascular repair and open repair

The majority of observational studies report complication incidence in a narrative, with the remaining studies reporting statistical significance split between no difference and EVAR superiority [46]. The Cochrane systematic review and meta-analysis by Badger et al. involving two of the major RCTs and the one pilot trial reports on 30-day complication incidence rates between EVAR and OR for rAAA[15]. The review was unable to provide statistical conclusions on the following complications due to poor reporting and low incidence rates: myocardial infarction, stroke, moderate/severe cardiac complications, severe bowel ischaemia, spinal cord ischaemia, amputation and respiratory failure. Furthermore, there was no clear evidence at the 30-day mark to support a difference in reoperation rates between the interventions (odds ratio 0.89, 95% CI: 0.39-2.01; P=0.78) [15]. The meta-analysis by Sweeting et al. [36], which incorporates the data from the three multi-centre RCTs, found a lower incidence of mesenteric and/or colonic ischaemia in EVAR when compared to OR (pooled odds ratio 0.57, 95% CI 0.32-1.01), narrowly failing to achieve statistical significance [36].

A literature review by Patelis et al. reports that two-thirds of studies support the notion that length of hospital stay is shorter in EVAR compared to OR [46]. Of these studies, the IMPROVE trial reports a statistically significant reduction in total admission length in favour of EVAR (total admission length: 17 days vs 26 days, P<0.001) [48], a finding not corroborated by ECAR (14.3 days vs 17.1 days, P=0.208) or AJAX (9 days vs 13 days, P=0.57) [32,33]. Overall, for those patients discharged alive from the vascular surgical centre, the duration of hospital admission was statistically significantly shorter in EVAR groups versus OR (pooled hazard ratio 1.24, 95% CI: 1.04-1.47; P=0.717) [36]. Interestingly, the ECAR trial demonstrates shorter intensive care unit (ICU) admission length in the EVAR group compared to the OR group (total ICU length: 7 days vs 11.9 days, P=0.012) [33], whilst the AJAX found no significant difference in ICU length between EVAR and OR (28 days vs 48 days, P=0.14) [32].

The majority of the evidence-base supports EVAR as the approach associated with less blood loss and requirements for blood product transfusion compared to OR, including the AJAX and ECAR trials [32,33,36,46]. The ECAR trial demonstrates a significantly lower number of blood product units in the EVAR group compared to OR (6.8 units *vs* 10.8 units, P=0.024) [33], with similar results found within the AJAX trial (4 units *vs* 9 units, P=0.02) [32].

It is clear that EVAR is associated with less blood loss than OR and is likely to reduce total admission length, but there is no evidence to support EVAR from a complication and reoperation perspective. It would be valid to conclude that EVAR is at least equal to OR from a complication perspective, but further trials are required to demonstrate superiority.

Cost-utility between endovascular repair and open repair

Calculating the true costs associated with endovascular repair or open repair for rAAA is a challenge. The cost associated with each intervention is not purely limited to the life-saving procedure and should include the financial assessment of surgical equipment, intensive care admissions, radiological imaging, laboratory tests, outpatient clinics and treatment of complications [47]. Unfortunately, observational cohort studies reporting on such information are not usual, and when performed, the analysis often lacks detail, with a collective failure to evaluate the cost associated with long-term follow up [49]. RCTs on the other hand, provide a vast quantity of information related to many of the costs associated with the intervention, and often provide excellent information pertaining to long-term costs [50]. The two main reports on the cost-effectiveness of EVAR and OR are provided by the investigators of the AJAX trial and the IMPROVE trial [47,51].

The AJAX trial provides detailed information regarding the financial implications of choosing EVAR over OR for rAAAs [51]. The headline costs at 30-days post procedure is €41,350 for EVAR compared to €31,161 for open repair (Table 2) [51]. The main differences in cost can be attributed to the price of the endovascular stent used in EVAR, which is partly mitigated against by a reduced stay in ITU when compared to OR (4.7 days *vs.* 6.6 days) [51]. Conversely, the IMPROVE trial reports cheaper 30-day costs in the EVAR group compared to OR, which is likely to be the result of incomplete cost reporting (Table 2) [47].

The IMPROVE trial reported on cost-effectiveness and QALY's up to three years post-intervention, the only study to date to have done so [47]. Due to the higher average quality of life in the EVAR strategy versus OR, coupled with the lower mortality at three years; this resulted in an average gain of 0.17 QALYs at three years [47]. Importantly, the probability of the endovascular strategy being cost-effective within the IMPROVE trial is greater than 90 percent across all levels of willingness to pay for a QALY gain [47]. This contrasts markedly with the cost-utility analysis within the AJAX trial, which reported willingness-to-pay per life saved of €80,000, with the probability of EVAR being cost-effective being less than 25 percent [51].

A selection of observational cohort studies report on the differences in cost and cost-effectiveness between EVAR and OR for rAAA. A retrospective cost-analysis in a non-randomized cohort study by Visser et al. [52] found that the 30-day costs were lower for patients undergoing EVAR compared to OR (€20,767 *vs.* €35,470, P=0.004) [52], however, there is a high chance of selection bias within this study [52]. A study by Hayes et al. [53] utilising a 2-stage cost-utility model assessing the lifetime costs and quality-adjusted life years (QALYs) of EVAR versus OR was performed. The investigators found the mean QALY per patient were 3.09 for EVAR and 2.45 for OR [53]. Interestingly, EVAR was considered cost-effective compared with OR at a threshold value of £20,000-£30,000 per QALY gained [53]. A prospective cohort study by Kapma et al. [54] utilising a preferential protocol favouring EVAR was compared to a historical group of patients treated with OR. It was found that treatment with EVAR was not more expensive than OR, however, the conclusions drawn are limited by the study design and small sample size [54].

Table 2: Cost-utility of EVAR and OR as reported within the AJAX and IMPROVE trials [15,47,51]

	AJAX	IMPROVE
Total 30-day cost (average) (€)	EVAR: 32,743 OR: 27,437	EVAR: 13,433 OR: 14,619
Surgery costs (average) (€)	EVAR: 16,589 OR: 7,599	No data.
Cost of endovascular stent (EVAR) & aortic prosthesis (OR) (€)	EVAR: 7,895 OR: 727	No data.
ITU cost (average) (€)	EVAR: 4.7 days – 10,264 OR: 6.6 days – 14,504	No data.
Additional costs at six-month post-procedure (average) (€)	*Total:* EVAR: 8,607 OR: 3,724 *Hospital re-admission:* EVAR: 6,969 OR: 3,450	No data.
Total cost per patient up to 6 months (average) (€)	EVAR: 41,350 OR: 31,161	No data.
Mean Quality-Adjusted Life-Years (QALY)	EVAR: 0.324 (95% CI 0.198 – 0.445) OR: 0.298 (95% CI 0.164 – 0.433)	EVAR: 1.14 OR: 0.97 (95% CI 0.002 – 0.331; P = 0.048)

The evidence supporting EVAR as a more cost-effective treatment for rAAA is largely incomplete, with large proportions of the literature limited through poor methodological design and reporting of cost. At present, it is unlikely EVAR offers acceptable returns on investment from a societal willingness-to-pay for health gains.

Quality of life between endovascular repair and open repair

The success of a surgical intervention is more than rates of mortality, major complications and reintervention rates. It is essential to investigate the impact of surgical work on the quality of life, as this should be a significant consideration in the acceptability of interventions [55]. Every patient with a ruptured abdominal aortic aneurysm would die if they are not treated with either EVAR or OR, thus, either operation if successful, would appeal to the victims of this highly morbid condition [31]. A study by Hinterseher et al. [56] using the WHO-QOL-BREF questionnaire to assess quality of life showed there was no significant difference in quality of life between patients with previous RAAA and a normal age and sex-matched population [55,56]. Similar findings have been reported in other studies [57–59].

The AJAX trial provides some useful insights into the differences in quality of life between rAAA survivors receiving either OR or EVAR [51]. Using two of the commonly used survey forms: Medical Outcomes Short-Form 36 health survey (SF-36) and the EQ-5D [60,61], quality of life was measured at 30-days, three months and six months after receiving either EVAR or OR for repair of rAAA. The investigators found there was no difference in the quality of life (QALY) in patients undergoing EVAR versus OR at six months (Table 2) [51]. The IMPROVE trial also used the EQ-5D tool in assessing quality of life, with its results favouring EVAR over OR (mean difference 0.087, 95% CI: -0.004-0.140) [47]. The IMPROVE trial investigators found that patients undergoing endovascular repair had a shorter hospital admission overall (P<0.001), were more likely to be discharged to their home (P<0.001), and to also have a superior quality of life in the short-term when compared to open repair (Table 2) [47].

Anatomical suitability for endovascular repair and open repair

It has been suggested that aortic morphology is an important factor guiding mortality post-intervention for rAAAs [62]. When considering suitability for endovascular stent-graft placement, having an adequate 'neck' is important, otherwise defined as the normal portion of the aorta between the origin of the renal arteries and start of the aneurysm sac [62]. Barnes et al. [63] performed retrospective analysis of computed tomography scans in patients with a rAAA to correlate aortic morphology with mortality. The authors found that the one-year mortality for patients deemed suitable for EVAR was lower than in those not anatomically suitable for EVAR (1-year mortality: 20% *vs.* 59%, P=0.020) [63]. A further study performed by Dick et al. [62] quantified mortality rates in patients with anatomy suitable for endovascular repair (neck length≥10 mm, neck diameter<32, and neck angle<60 degrees) and in participants with anatomy not suitable for endovascular repair [62]. Interestingly, it was found that the 30-day mortality for open repair in patients outside the above definition 'unsuitable for EVAR' was 8-9 times higher than those patients considered 'suitable for EVAR' (odds ratio 9.21, 95% CI: 2.16-39.23, P=0.003) [62]. Furthermore, those participants with anatomy considered 'borderline for EVAR', found their mortality rates to be 6-7 times higher than those considered 'suitable for EVAR' (odds ratio 6.80, 95% CI: 1.47-31.49, P=0.014) [62].

The effect of six morphological parameters (maximum aortic diameter, aneurysm neck diameter, length and conicality, proximal neck angle, and maximum common iliac diameter) was studied within the IMPROVE trial to evaluate the impact on 30-day mortality rates and reintervention [64]. Analysis showed that the greatest predictor of mortality across both groups was aneurysm neck length, to the extent that every 16 mm increase in neck length equated to a reduction in 30-day mortality of approximately 20% (odds ratio 0.72, 95% CI: 0.57-0.92) [64]. The systematic review and meta-analysis performed by Sweeting et al. [36] showed that aneurysmal neck length, but not AAA diameter, neck diameter or proximal neck angle, appeared to be a predictor of mortality, particularly in the OR group [36]. For open repair, every 15 mm increase in neck length resulted in a decrease in the 30-day mortality rate (odds ratio 0.69, 95% CI: 0.53-0.89) [36]. The relationship between sequential increases in neck length and mortality within the EVAR cohort was not statistically significant (odds ratio 0.99, 95% CI: 0.72-1.36) [36].

The principal factor-influencing outcome in rAAA appears to be aortic anatomy. EVAR confers no mortality benefit over open repair in those patients with anatomy considered amenable to endovascular repair.

Conclusion

Endovascular repair or open repair? It is a debate that has been raging for years, and no doubt will continue for many more. At present there is no conclusive body of evidence to support the claim that EVAR is superior to OR in the management of rAAA, particularly from a mortality, complication and cost-utility perspective. There are significant conflictions within the evidence-base, often between observational studies, but also between the major multi-centre randomised trials. Currently, it would be appropriate to conclude that endovascular repair is as efficacious as open repair but would be invalid in light of the scientific literature to claim it superior.

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