



## Endovascular abdominal aortic aneurysm repair in the geriatric population

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### Abstract

Abdominal aortic aneurysm (AAA) is a relatively common pathology among the elderly. More people above the age of 80 will have to undergo treatment of an AAA in the future. This review aims to summarize the literature focusing on endovascular repair of AAA in the geriatric population. A systematic review of the literature was performed, including results from endovascular abdominal aortic aneurysm repair (EVAR) registries and studies comparing open repair and EVAR in those above the age of 80. A total of 15 studies were identified. EVAR in this population is efficient with a success rate exceeding 90% in all cases, and safe, with early mortality and morbidity being superior among patients undergoing EVAR against open repair. Late survival can be as high as 95% after 5 years. Aneurysm-related death over long-term follow-up was low after EVAR, ranging from 0 to 3.4%. Endovascular repair can be offered safely in the geriatric population and seems to compare favourably with open repair in all studies in the literature to date.

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**Keywords:** Abdominal aortic aneurysm; Octogenarians; Geriatric population

### 1 Introduction

Abdominal aortic aneurysm (AAA) is diagnosed in 5%–10% of men above the age of 65.<sup>[1]</sup> Endovascular abdominal aortic aneurysm repair (EVAR) constitutes a minimally invasive alternative to open repair associated with significantly less operating time and blood loss and superior peri-operative results according to data from large EVAR registries and randomized controlled trials.<sup>[2]</sup> As a result, EVAR is an appealing alternative to open repair for the elderly, who have significantly more co-morbidity and would be at increased risk for post-operative complications. There is mounting evidence that the population aged above 80 years will significantly increase over the next 20 years.<sup>[3]</sup> As a result, the elderly population undergoing vascular interventions will most definitely increase in the years to come. Several reports have suggested that EVAR is safe in octogenarians and it is superior over open repair across various age spectrums in terms of post-operative early and medium term morbidity.<sup>[4–7]</sup> Additionally, contemporary

evidence suggests that EVAR is comparable to open repair even in the long term and it may be preferable in older and frailer patients.<sup>[8–10]</sup> The aim of this report is to summarize evidence that confirms the feasibility, efficacy, and superiority of EVAR compared to open repair in octogenarians and nonagenarians.

### 2 Search strategy

A systematic review of the published literature (not limited to English literature) was performed to identify studies relevant to the topic. The MEDLINE (From January 1966 to October 2011) and EMBASE (From January 1980 to October 2011) electronic databases were searched using the NHS evidence online search engine (available at: <http://www.library.nhs.uk>). The following keywords and phrases were used: “endovascular abdominal aortic aneurysm repair” AND “octogenarians” OR “nonagenarians”. An additional search was sequentially performed using the following keywords and phrases: “open” vs. “endovascular aneurysm repair” AND “octogenarians” OR “nonagenarians”. This strategy identified 1,122 articles potentially relevant to the topic. The titles of the articles were screened to identify 512 articles. The abstracts of these articles were screened to eventually identify 16 articles,<sup>[11,26]</sup> specifically reporting outcomes for octogenarians or nonagenarians (age  $\geq$  80) undergoing repair of a non-ruptured AAA, eight of which were directly comparing EVAR and open repair; one study was not eventually included as no mortality or morbidity data were

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given the authors only provided quality of life data.<sup>[13]</sup> The references of these 15 articles were also screened to identify further relevant literature. None of the studies identified was a randomised controlled trial. Figure 1 summarises the search strategy. Given the lack of randomised studies in this specific population group with regards to EVAR, all types of studies were included in this report as long as they reported mortality and morbidity data in an elderly population (age  $\geq 80$ ) undergoing non-ruptured EVAR. Meta-analysis was not in the scope of this article, given the heterogeneity of the currently available evidence.

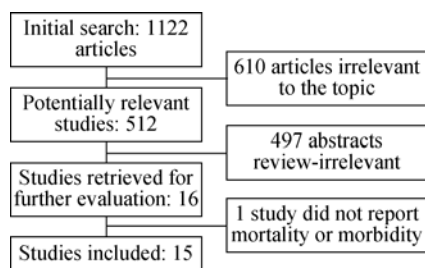


Figure 1. Search strategy.

### 3 Mortality and morbidity data from the EVAR randomised controlled studies

Following the introduction of EVAR, a series of randomised controlled trials compared it with traditional open aneurysm repair. These have largely suggested superior early results, in terms of morbidity and mortality, which means that EVAR is most likely to be the preferable choice in the geriatric population.

Cuypers *et al.*<sup>[27]</sup> randomised 76 patients to undergo EVAR (57 patients, mean age 69 years, range 52–82) or open repair (17 patients, mean age 68 years, range 52–81) of an AAA assessing cardiac response and the incidence of adverse cardiac events peri-operatively. There was a lower incidence of myocardial ischaemia in the EVAR group ( $P = 0.05$ ) and there were more pronounced haemodynamic changes in the open repair group.

The Dutch Randomised Endovascular Aneurysm Management (DREAM) trial had 345 participants of which 174 were allocated to open repair (mean age  $69.5 \pm 6.8$  years) and 171 in the EVAR group (mean age  $70.7 \pm 6.6$  years).<sup>[7,28]</sup> The trial demonstrated significantly favourable results for EVAR in terms of peri-operative morbidity. EVAR resulted in shorter duration of surgery, less blood loss and blood replacement, a lower rate of mechanical ventilation in the post-operative period, a shorter duration of stay in the high-dependency unit/intensive care unit and a shorter hospital stay.

There have been two randomised trials in the United Kingdom, the EVAR-1 and EVAR-2 comparing EVAR to open repair and EVAR to no intervention for patients at high risk for open repair, respectively.<sup>[4,29,30]</sup> Patients enrolled in EVAR-1 were older than 60 years and had an AAA of at least 5.5 cm in diameter. The patients had to be good candidates for EVAR and open repair. If patients were believed unfit for open repair, they were included in the EVAR-2 trial, comparing EVAR with no intervention. A total 1,082 were randomised to undergo open repair (539) or EVAR (543). Overall, EVAR was associated with a better 30-day mortality rate ( $P = 0.0001$ ) and improved aneurysm-related survival at 4 years ( $P = 0.04$ ). The EVAR-2 trial focused on “unfit” patients diagnosed with an AAA. The “unfit” definition was based on a subjective determination made at baseline by the clinician who evaluated the patient. A total of 338 patients (166 EVARs vs. 172 undergoing no intervention) were included. There was no statistical difference in survival at 4 years (34% for no intervention vs. 38% for EVAR) or aneurysm-related mortality at 4 years (19% for no intervention vs. 14% for EVAR). There was also no difference in health-related quality of life; cost was substantially increased in the EVAR group. However, there is a series of significant drawbacks with regards to the design and analysis of the study. There was a large number of deaths (19%) in patients who were randomised to undergo EVAR but never made it to the intervention; in fact, 12% of patients randomised to undergo EVAR never underwent EVAR. Additionally, 20% of patients crossed over from no intervention to EVAR or open repair but the study design meant that all patients had to be analysed on an intent-to-treat basis. As a result, we cannot safely conclude that EVAR conferred no benefit in this population.

Brown *et al.*<sup>[31]</sup> analysed 404 patients from the EVAR-2 population (197 EVARs vs. 207 undergoing no intervention, mean age  $77 \pm 6$  years) to determine whether EVAR alters the rate of cardiovascular events in those “unfit” patients. A large proportion of patients had a history of previous cardiac disease with a non-significantly higher percentage in the no intervention group (74% vs. 67% in the EVAR group,  $P = 0.128$ ). Patients were followed for an average of 6.8 years after their recruitment. A total of 70 cardiovascular events occurred during an average of 2.8 years in 67 patients; the crude overall rate was 6.1 [95% confidence interval (95% CI)] events per 100 person years. In the EVAR group, 10 events occurred within 30 days of the EVAR, with the remaining 23 occurring more than 30 days after EVAR. In the no intervention group, nine events occurred after AAA repair in the 63 patients having aneurysm repair against protocol (none within 30 days). For the 319 patients complying with their randomised allocation, 33 (19%) patients in the

EVAR group and 22 (15%) patients in the no intervention group experienced a cardiovascular event during follow-up; adjusted Cox hazard ratio 1.07 (95% CI: 0.60–1.91).

The ACE trial<sup>[32]</sup> is a multi-centre randomised controlled trial comparing EVAR with open repair in patients with a low to moderate surgical risk. The geriatric population is unlikely to fit in this category, therefore, results from this trial will not be analysed.

The Open vs. Endovascular Repair (OVER) is a multi-centre randomised controlled trial comparing EVAR with open repair in 881 veterans (USA) aged above 49 years over a mean follow-up of 1.8 years.<sup>[33]</sup> The study demonstrated that the EVAR group had significantly reduced procedure time, length of mechanical ventilation, blood loss and transfusion requirement.

There is a clear trend among all the aforementioned studies, confirming the superiority of EVAR in terms of early and medium term mortality and morbidity. This makes EVAR very appealing for the elderly population, who have increased co-morbidity at baseline.

## 4 Results following EVAR in the geriatric population

### 4.1 Studies from EVAR registries reporting results in the elderly–early follow-up

A total of seven retrospective studies analysing non-ruptured EVAR results in an elderly population, based on prospectively collected data from EVAR registries were identified. One of these studies did not specifically report mortality and morbidity rates and was excluded.<sup>[13]</sup>

Three studies reported results from EVAR registries without a direct comparison to open repair.<sup>[11,12,14]</sup> Overall, 378 octogenarians were included in these three analyses, with a cumulative mortality rate of 3.4% and an adverse event rate of 8.5% peri-operatively (Table 1).

Another three studies compared results between young and old patients undergoing EVAR. Biebl *et al.*<sup>[15]</sup> reported data for 182 consecutive patients undergoing elective EVAR. Forty-nine patients (27%) were > 80 years for age (mean 84 years, range 80–89 years), and 133 patients (73%) were younger (mean 72 years; range 53–79 years). Thirty-day mortality was 0.5% among the geriatric population. Systemic complications

occurred in 22% (> 80 year) vs. 11% (< 80 years) of patients ( $P = 0.035$ ). The most common major adverse events in the elderly were renal dysfunction (14%) and groin lymphoceles (12%). Fonseca *et al.*<sup>[16]</sup> analysed 117 patients above the age of 80 against 205 younger subjects. The elderly population had a higher peri-operative rate of pulmonary complications (5.1% vs. 1%,  $P = 0.003$ ) and access-site haematomas (12% vs. 2.4%,  $P = 0.001$ ) with no difference in stroke, myocardial infarction, death, or ischaemic complications. Pol *et al.*<sup>[17]</sup> analysed 274 patients from the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) vs. 926 younger patients using the EuroQoL-5 Dimensions Quality of Life (QoL) questionnaire. All-cause mortality and major adverse event rate peri-operatively was similar among groups ( $P = 0.835$  and  $P = 0.186$ , respectively).

### 4.2 Studies comparing open repair and EVAR in the elderly–early follow-up

Our search strategy identified a total of 8 studies directly comparing EVAR and open repairs in patients with an age exceeding 80 years for a non-ruptured aneurysm (Table 2 summarizes early outcome data from these studies). Three investigators have retrospectively reported outcomes from large multicentre registries. Raval & Eskandari,<sup>[18]</sup> in one of the largest studies reporting results for EVAR in octogenarians to date, analysed 2,034 above the age of 80 from the American College of Surgeons National Quality Improvement Programme. Elderly patients undergoing open repair, against EVAR, had a greater likelihood of infectious, pulmonary, cardiac, and renal adverse events, greater requirements for blood transfusion, and longer duration of stay. Schermerhorn *et al.*<sup>[19]</sup> studied all Medicare beneficiaries who had undergone elective repair of an AAA during 2001–2004, totalling 45,660 patients, documenting a lower peri-operative mortality rate for EVAR in those above the age of 80 (Table 2). Similar findings with regards to early mortality and morbidity have been reported by other investigators in smaller series. The EVAR mortality rate ranged from 0 to 5%, morbidity (major adverse events) ranged from 6.4 to 25% (Table 2).

In all papers EVAR compared favourably with open repair, with regards to early (30 days) mortality and morbidity.

**Table 1. Registries reporting results of endovascular abdominal aortic aneurysm repair in octogenarians.**

Reference	Year	<i>n</i>	Age, mean ± SD	Early morbidity	Early mortality	Mean follow-up (months)	Late aneurysm-related mortality
Brinkman, <i>et al.</i> <sup>[11]</sup>	2004	31	83 ± 3.0	6%	6%	16	3.20%
Botsios, <i>et al.</i> <sup>[12]</sup>	2009	25	83 ± 2.6	20%	4%	25.7	1.20%
Prenner, <i>et al.</i> <sup>[14]</sup>	2010	322	84 ± 3.4	7.80%	3.10%	18.70	0

**Table 2. Early morbidity and mortality data from studies comparing endovascular to open aneurysm repair.**

Reference	Year	n(EVAR)	n(open)	30-day mortality	30-day morbidity
Sicard, <i>et al</i> <sup>[22]</sup>	2001	52	38	EVAR: 1.9%, open: 5.2%	EVAR: 11.5%, open: 37%
Patel, <i>et al</i> <sup>[23]</sup>	2003	16	30	EVAR: 0, open: 3.3%	EVAR: 25%, open: 68.6%
Leon, <i>et al</i> <sup>[24]</sup>	2005	351	1604	EVAR: 3.7%, open: 9.9%	NR
DeDonato, <i>et al</i> <sup>[26]</sup>	2007	32	12	EVAR: 3.1%, open: 8.3%	EVAR: 6.4%, open: 48.4%
Paolini, <i>et al</i> <sup>[25]</sup>	2008	81	69	EVAR: 5%, open: 8.5%	NR
Schermerhorn, <i>et al</i> <sup>[19]</sup>	2008	4589	4566	EVAR: 1.9%, open: 8.4%	NR
Schwarze, <i>et al</i> <sup>[20]</sup>	2009	NR	NR	EVAR: 1.5%, open: 9.5%	NR
Raval & Eskandari <sup>[18]</sup>	2012	1634	391	EVAR: 1.8%, open: 6.1%	EVAR: 13.6%, open: 33.2%

EVAR: endovascular aneurysm repair; NR: not reported. Schwarze *et al.* did not report the cumulative number of patients in each arm (EVAR vs. open) but reported number for each year separately (2001-2006).

A recent meta-analysis by Biancari *et al.*<sup>[21]</sup> included six of these studies.<sup>[18,19,22,24-26]</sup> Their analysis disclosed significantly higher peri-operative mortality after open repair (pooled mortality rates: 8.6% vs. 2.3%; risk ratio: 3.87; 95% CI: 3.19-4.68).

## 5 Long term outcome for the elderly population

Table 1 summarizes results from the three small registries reporting long-term outcomes for octogenarians undergoing EVAR. In addition to these three studies, Biebl *et al.*<sup>[15]</sup> also reported a mean follow-up of 16 months (range: 1-43 months). Patient survival in the octogenarian group was 84.9% at one year, 78.3% at 2 years, and 59.8% at 3 years. Aneurysm-related mortality was zero in the old population. The estimated risk for all-cause related death in octogenarians was 1.8 times higher (95% CI: 0.8-4.0) that in younger patients ( $P = 0.131$ ). Fonseca *et al.*<sup>[16]</sup> reported a 95% 5-year survival rate for octogenarians, compared with 96% for younger patients (Kaplan-Meier analysis), without any difference in aneurysm-related deaths which were 1% at five years for both groups. Overall, survival at one year from the aforementioned Registries for the octogenarians undergoing non-ruptured EVAR ranges from 75% to 84.9% based on Kaplan-Meier analyses.

Two studies<sup>[22,25]</sup> comparing EVAR and open repair reported long-term outcomes for patients above the age of 80 and one study for patients above the age of 85.<sup>[19]</sup> Biancari *et al.*<sup>[21]</sup> performed a meta-analysis of these findings, which disclosed a similar overall survival at 3 years between EVAR and open repair (risk ratio: 1.10, 95% CI: 0.77-1.57). Schermerhorn *et al.*<sup>[19]</sup> in their large study of Medicare beneficiaries found that the peri-operative EVAR survival benefit was strongly related to age, with those above the age of 85 having an absolute reduction in mortality of 8.5% when undergoing EVAR as opposed to open repair, which was maintained at three years.

## 6 Discussion

EVAR is now employed as a first line procedure for the treatment of a non-ruptured AAA in anatomically suitable candidates. Randomised controlled trials and large prospective registries have disclosed a clear early mortality and morbidity benefit over open repair and similar medium and long term results for the general population; however, there is a higher need for re-intervention following EVAR.<sup>[4-7,19,34]</sup> The aim of this article was to investigate whether EVAR can be offered safely to octogenarians and nonagenarians and whether it did compare favourably with open repair in this population, by reviewing the currently available literature. This was not limited to studies directly comparing EVAR and open-repair. Overall, a total of 15 studies were found in the literature, comparing EVAR to open repair in the elderly or reporting outcomes from EVAR registries, again focusing on the elderly. None of these were randomized studies and outcomes were not reported in a consistent manner. The majority of these reports did not include long-term data. However, results from all registry-based analyses do suggest that EVAR is indeed safe in these patients and may be associated with a survival benefit beyond the peri-operative period, with Brinkman *et al.*<sup>[11]</sup> reporting a 68% survival (Kaplan-Meier analysis) three years after EVAR in octogenarians and Fonseca *et al.*<sup>[16]</sup> reporting a 95% survival rate after 5 years. It is important to note that the EVAR-2 trial<sup>[31]</sup> in 2005 failed to disclose any survival benefit in surgically unfit patients undergoing EVAR and most patients above the age of 80 are very likely to be deemed as "unfit". However, EVAR-2 does not allow for safe conclusions to be made for the reasons stated above, namely the large number of deaths (19%) in patients who were randomised to undergo EVAR but never made it to the intervention and the fact that 20% of patients crossed over from no intervention to EVAR or open repair.

Peri-operative morbidity in the registry studies and the reports comparing EVAR and open repair mentioned in this article ranged from 4% to 25%. The majority of adverse events in this elderly population included access site complications, such as lymphoceles and haematomas, renal dysfunction, and cardiovascular morbidity.<sup>[11,15]</sup> Two studies based on EVAR registries in our review reported a 12% access-related major adverse event rate (lymphoceles and access site haematomas). Meticulous surgical technique in terms of arteriotomy and subcutaneous tissue closure and approximation and routine use of drains, where indicated, are necessary to avoid such complications. Meticulous fascial closure is necessary in this population as it has been shown to decrease access site complications.<sup>[35]</sup> Other interventions such as the use of platelet derived products have also been advocated, but cost remains a significant issue. A study from our team showed a benefit following the use of such products in those undergoing femoral cut-downs for EVAR.<sup>[36]</sup> Percutaneous arterial puncture is also being employed more frequently over the last years. This technique has been associated with less access site complications and operating time.<sup>[37]</sup> But, unfortunately, the size of the sheaths of most endovascular devices does not allow percutaneous EVAR in most cases. Another significant issue in the geriatric population is renal dysfunction following EVAR. Acute renal failure after EVAR has clearly been documented in the literature both in randomized trials comparing EVAR and open repair as well as several EVAR registries.<sup>[7,38-41]</sup> The incidence ranges from 1% to 23% for non-ruptured EVAR.<sup>[7,38-41]</sup> Renal dysfunction has been shown to correlate with prolonged hospital stay, morbidity and even mortality following a number of interventions, including EVAR. Biebl *et al.*<sup>[15]</sup> reported a 14% rate of renal dysfunction (creatinine rise exceeding 30% from baseline) among octogenarians undergoing EVAR. Renal adverse events were also more prevalent among the elderly in the study by Raval & Eskandari.<sup>[18]</sup> Various interventions have been proposed in order to prevent renal dysfunction following EVAR, including the administration of *N*-acetylcysteine (NAC), targeted renal therapy using fenoldopam infused into the renal arteries,<sup>[42]</sup> remote ischaemic preconditioning,<sup>[43]</sup> carbon dioxide angiography,<sup>[44]</sup> and EVAR under local anaesthetic.<sup>[45]</sup> Only two randomised controlled study have been performed to evaluate these modalities, comparing NAC to sodium chloride<sup>[46]</sup> and evaluating remote ischaemic preconditioning,<sup>[43]</sup> which did not disclose any benefit in terms of post-operative creatinine rise. Aggressive hydration and stopping nephrotoxic medication are the most important measures to prevent renal dysfunction after EVAR at the moment, as there is no level I evidence to support the use of any other modality.<sup>[47]</sup>

Re-intervention is the main drawback of EVAR, as evidenced in randomized studies and other multicentre reports. Even using the latest generation ACE devices in a relatively healthy population, such as in the ACE trial, re-intervention among those undergoing EVAR remains as high as 16% over a period of 3 years (2.4% vs. 16%,  $P < 0.0001$ ).<sup>[32]</sup> A large retrospective study investigating the Medicare beneficiaries undergoing EVAR or open repair, documented a 7.6/100 person-year re-intervention rate for EVAR vs. 7.0/100 person-years for open repair (relative risk: 1.1,  $P < 0.001$ ).<sup>[48]</sup> Re-intervention was higher for elderly patients (> 80 years) undergoing EVAR at 12.0/100 person-years. However, Kieffer *et al.*<sup>[49]</sup> reported that re-intervention after open-repair can also be as high as 14.4% over a 10 year period, with the majority of re-interventions (63.5%) occurring in the peri-operative period for small bowel obstruction or incisional hernias and 54% of re-interventions requiring a laparotomy. These results need to be taken seriously into account before offering EVAR or open aneurysm repair in those aged above 80, given the highly likelihood of re-intervention. Their life expectancy and quality of life at baseline should be the ultimate guide in offering the primary intervention. An interesting observation is the fact that EVAR seems to benefit this old population the most, in terms of preventing morbidity and mortality, at least over the short term. In the large analysis by Schwarze *et al.*<sup>[20]</sup> including all hospital discharges for EVAR and open aneurysm repair over a five year period, patients above the age of 85 had the greatest benefit in terms of early mortality, cardiovascular complications, pulmonary complications, hospital stay and acute renal failure compared to the younger cohorts. Additionally, Schermerhorn *et al.*<sup>[19]</sup> in their large study of Medicare beneficiaries found that the peri-operative EVAR survival benefit was strongly related to age, with those above the age of 85 having an absolute reduction in mortality of 8.5% which was maintained at three years. Finally, in terms of long term follow-up, aneurysm-related death among the octogenarians undergoing EVAR in the studies included in this review was very low, ranging from 0 to 3.2%.

Overall, this review suggests that EVAR is the preferred method of treating an AAA in the elderly. The currently available data confirm its superiority in terms of early morbidity and mortality among the general population, and the fact that it performs similar to open repair in the medium term. All registries and studies comparing EVAR and open repair in those above the age of 80 have disclosed superior performance in the early term (Table 1) and five year survival rates can be as high as 95%. This practically means that EVAR should be the procedure of choice in the geriatric population, when anatomical criteria are met.

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