CLINICAL RESEARCH STUDIES

From the Eastern Vascular Society

Outcome of elective endovascular abdominal aortic aneurysm repair in nonagenarians

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Objective: **Compared with open repair of abdominal aortic aneurysms (AAA), endovascular repair (EVAR) is associated with decreased perioperative morbidity and mortality in a standard patient population. This study sought to determine if the advantage of EVAR extends to patients aged ≥90 years.**

Methods: **This was a retrospective review from a prospectively maintained computerized database. Of the 322 patients aged ≥80 treated with EVAR from January 1997 to November 2007, 24 (1.9%) were aged ≥90. Mean age was 91.5 ± 1.5 years (range, 90-95 years), and 83.3% were men. Mean aneurysm size was 6.8 cm (range, 5.2-8.7 cm).**

Results: **Mean procedural blood loss was 490 mL (range, 100-4150 mL), and 20.8% required an intraoperative transfusion. Mean postoperative length of stay was 6.0 days, (median, 4 days; mode, 1 day; range, 1-42 days), with 33.3% of patients discharged on the first postoperative day. Amongst the 24 patients, there were 6 (25.0%) perioperative major adverse events, and 2 patients died, for a perioperative mortality rate of 8.3%. Mean follow-up was 20.5 months (range, 1-49 months). Overall, three patients (12.5%) required a secondary intervention, comprising thrombectomy, angioplasty, and proximal cuff extension. No patients required conversion to open repair. Two patients (8.3%) died of AAA rupture at 507 and 1254 days. Freedom from all-cause mortality was 83.3% at 1 year and 19.3% at 5 years. Freedom from aneurysm-related mortality was 87.5% at 1 year and 73.2% at 5 years. Endoleak occurred in five patients (20.8%), with three type I and two of indeterminate type; of these, two patients with type I endoleak underwent secondary intervention at 153 and 489 days after EVAR, of which one case was successful.**

Conclusion: **Our study supports that EVAR in nonagenarians is associated with acceptable procedural success and perioperative morbidity and mortality. The medium-term results suggest that EVAR may be of limited benefit in very carefully selected patients who are aged ≥90 years. (J Vasc Surg 2011;54:287-94.)**

As life expectancy continues to increase, the number of nonagenarians is now greater than ever. In the United States, individuals aged >85 years currently represent the fastest growing demographic of the population and are expected to nearly double in number from 4 to 7 million from 2000 to 2020.[1] Furthermore, the average life expectancy of those reaching 90 in the general population is nearly 4 years.[2] As an age-related disease, abdominal aortic aneurysms (AAA) are increasing in prevalence in this demographic.

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Nonagenarians are uniformly considered to be a "high risk" population by virtue of both age and high rates of comorbidities, and are often not considered candidates for open repair.[3] Although endovascular repair of AAAs (EVAR) has become an increasingly used approach, EVAR in older patients has been independently associated with higher perioperative and long-term morbidity and mortality compared with younger patients.[3-5] Many recent studies have focused on the benefits of EVAR in the high-risk patient, but age is only one of several criteria used to define high risk.[6-10] Studies looking at outcomes specifically in the oldest of patients undergoing EVAR are largely lacking. The purpose of this study was to determine if the advantage of EVAR extends to nonagenarians.

METHODS

This study was a subset analysis of a previously published retrospective review of a prospectively collected database from our institution. The study was approved by the institution's Internal Review Board. The study included patients who underwent elective EVAR between January 1997 and November 2007 and were aged

≥90 years at the time of the procedure. All EVAR procedures were performed at the Mount Sinai Hospital, New York, NY. Patients were excluded if they had undergone a previous EVAR at age <90. Primary and secondary end points were reported according to previously published guidelines.[11]

Preoperative aneurysm size and anatomic characteristics were determined with computed tomography (CT) angiography. Postoperatively, patients were followed-up at 1, 6, and 12 months, and annually thereafter. The standardized follow-up protocol included physical examination, helical CT angiography, and plain abdominal radiographs. Postoperative surveillance was not modified in patients with documented renal insufficiency (serum creatinine >1.5 mg/dL). At time of EVAR, patients with renal insufficiency were given *N*-acetylcysteine before and after the procedures, as well as pretreatment with intravenous hydration.

Endoleaks were detected by CT scan and were considered primary if they occurred within the perioperative period (<30 days), and otherwise, as secondary endoleaks. Given that this series dates back to the late 1990s, the quality of CT imaging did vary considerably during this 10-year period. In freedom from endoleak analysis, events were considered to be present at time of the initial endoleak detection, regardless of subsequent change in endoleak size.

Technical success and clinical success were also reported according to previously published Society for Vascular Surgery guidelines. Technical success was defined as successful intravascular access to the aneurysm site, deployment of the stent graft with secure fixation and patency, and absence of type I and III endoleaks within the first 24 hours. Clinical success required technical success as well as absence of death, type I and III endoleaks, graft infection, graft thrombosis, rupture, or conversion to open repair ≤30 days.[11]

Analysis of data was based on the intention-to-treat principle. Results are reported as mean and standard deviation. All freedom from event analyses were estimated with the Kaplan-Meier method. The Social Security Death Registry was used to confirm date of death for patients lost to follow-up. Patients who were not listed in the registry were assumed to be alive for the purpose of calculating death rate. However, all patients were removed from Kaplan-Meier analysis at the time of the last follow-up. All statistical analyses were conducted using SPSS software (SPSS Inc, Chicago, Ill).

RESULTS

From a group of 322 patients aged ≥80 years who underwent elective EVAR, a subgroup of 24 patients (83.3% men) who were ≥90 years were included in this study. Patients were a mean age of 91 ± 1.5 years (range, 90-95 years). The mean follow-up time was 20.5 months (range, 1-49 months). The mean maximum AAA diameter was 68 ± 10 mm (range, 52-87 mm). Only one AAA <5.5 cm underwent intervention (5.2 cm). The two most frequent comorbidities, hypertension and arrhythmia, affected 58.3% and 37.5% of the patients, respectively (Table I).

Table I. Preprocedural characteristics

Characteristic	*Outcome*
Patients, No.	24
Demographics	
Age, mean ± SD, y	91.5 ± 1.5
Male gender, %	83.3
Risks, %	
Hypertension	58.3
Coronary artery disease	33.3
Angina	0.0
Arrhythmia	37.5
Myocardial infarction	20.8
Congestive heart failure	12.5
COPD	25.0
Hyperlipidemia	25.0
Creatinine, >1.5 mg/dL	25.0
Peripheral vascular disease	8.3
Diabetes	4.2
Stroke	4.2
Smoking	54.2
Cancer	8.3
ASA 3	83.3
ASA 4	16.7

ASA, American Society of Anesthesiologists physical status classification; *COPD,* chronic obstructive pulmonary disease; *SD,* standard deviation.

Table II. Procedural details

Variables[a]	*Outcome*
Procedural characteristic, No.	24
Aneurysm diameter, mm	68.3 ± 10.0 (52-87)
Duration of procedure, min	230 ± 73 (105-353)
Anesthesia	
Regional	24/24 (100.0)
Procedural blood loss, mL	490.63 ± 997.92 (100-4150)
Volume contrast, mL	252.50 ± 112.03 (150-520)
Time until discharge, d	6.00 ± 9.46 (1-42)
Time in intensive care unit	2/24 (8.3)[b]
Follow-up, mo	20.5 (1-49)

[a]Continuous data are presented as the mean ± standard deviation (range) or as mean (range), and categoric data are presented as No. (%).
[b]Number of patients who spent any time in an ICU setting.

Regional anesthesia was used in all cases. The average duration of the procedure was 230 ± 73 minutes (range, 105-353 minutes). During the procedure, an average of 252 ± 112 mL (range, 150-520 mL) of contrast was used. The mean estimated blood loss was 491 ± 998 mL (range, 100-4150 mL) and was <800 mL in all but one patient (Table II). Five patients (20.8%) required an intraoperative transfusion.

A bifurcated device was used in 87.5% of the cases and 12.5% were treated with an aortouniiliac device: 58.3% received Talent grafts (Medtronic, Minneapolis, Minn), 33.3% received Gore (W. L. Gore and Assoc, Flagstaff, Ariz), and 8.3% received AneuRx (Medtronic). Graft types and endovascular approaches both varied throughout the 10 years of this study, reflecting changes in surgeon expe-

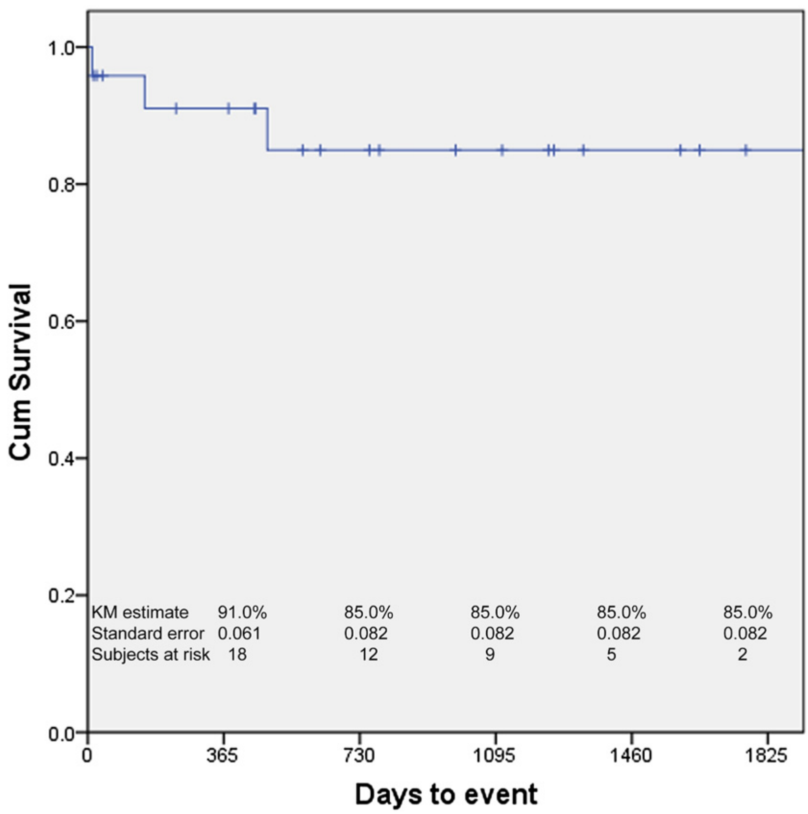

Fig 1. Kaplan-Meier (*KM*) graph documents freedom from secondary intervention, including coil embolization, cuff extension, conversion to open repair, and femoral-femoral bypass.

rience. Mean postoperative length of stay was 6 ± 9 days (median, 4 days; range, 1-42 days), with 33.3% of patients discharged on the first postoperative day. Two patients required a postoperative stay in the intensive care unit. In one patient, complications related to operative blood loss led to colonic ischemia requiring a colostomy and mechanical ventilation, and the patient ultimately died of sepsis 42 days after EVAR. A second patient required an intensive care unit stay for myocardial infarction and ultimately died of ventricular arrhythmia 15 days after EVAR.

The technical success rate was 91.6%. The two technical failures included a type I endoleak that failed to resolve despite proximal cuff extension. The second technical failure was the result of aortic perforation near the aortic bifurcation from a bifurcated device at the time of stent dilatation. Although open conversion was considered, favorable anatomy and stabilization with an 8-unit transfusion led to continuation of the endovascular approach. The patient was not thought to be a candidate for open repair.

No deaths occurred in the first 24 hours. The perioperative mortality rate was 8.3% (2 events). The first death previously mentioned occurred in a 92-year-old man who developed a myocardial infarction 2 days after surgery and died 15 days after EVAR. The second death occurred in a 90-year-old man who developed respiratory failure after elective right hip hemiarthroplasty and died 24 days after EVAR.

Table III. Perioperative adverse events

Complications	*No.*	*%*
Lower limb ischemia[a]	1	4.2
Bleeding[b]	1	4.2
Vascular injury[c]	1	4.2
Respiratory failure	2	8.3
Cerebral[d]	1	4.2

[a]Lower limb ischemia includes graft thrombosis.
[b]Bleeding includes a groin hematoma.
[c]Vascular injury includes a perforated aorta.
[d]Cerebral includes a postoperative transient ischemic attack.

Clinical success rate at 30 days was 79.2%, with perioperative death responsible for the greatest number of clinical failures (2 of 5). The overall freedom from secondary reintervention, including coil embolization, conversion to open repair, distal extension, and femoral-femoral bypass, was 91.0% at 1 year and 85.0% at 5 years (Fig 1). Three secondary interventions included an angioplasty and a cuff extension for the repair of type I endoleaks and an iliofemoral thrombectomy in a patient readmitted 11 days after

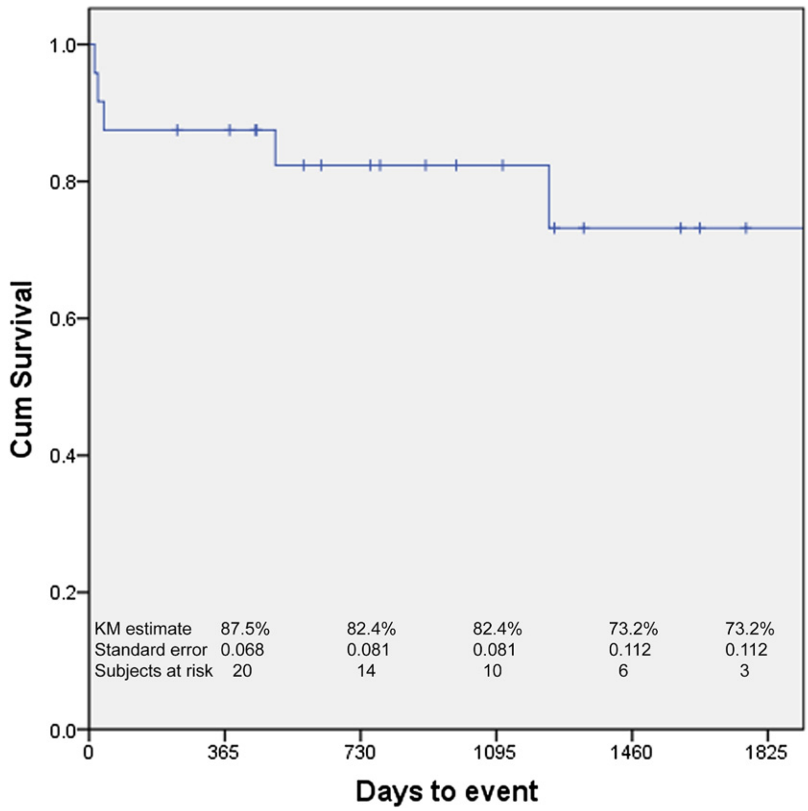

Fig 2. Kaplan-Meier (*KM*) graph represents freedom from abdominal aortic aneurysm (AAA)-related mortality, including all perioperative deaths, deaths from AAA rupture, and death due to secondary intervention.

EVAR with lower limb ischemia secondary to graft limb occlusion.

Six independent major adverse events occurred within the 30-day perioperative period. Previously mentioned adverse events include two patients with respiratory failure, vascular injury necessitating multiple transfusions, and lower limb ischemia necessitating iliofemoral thrombectomy. Other events included transient ischemic attack and groin hematoma 3 weeks postoperatively that required evacuation under general anesthesia (Table III). Overall, 12 patients (50%) had no AAA-related complications, met technical and clinical success, and had no endoleak or AAA-related death during the follow-up.

Freedom from AAA-related mortality was 87.5% at 1 year and 73.2% at 5 years (Fig 2). Freedom from overall mortality was 83.3% at 1 year and 19.3% at 5 years (Fig 3). Overall, there were five AAA-related deaths. By definition, these included the two perioperative deaths; the other causes of death included one patient with complications related to aortic perforation previously mentioned, and two ruptures that occurred at 507 and 1254 days after EVAR. The first of two ruptures occurred in a patient with routine surveillance and known type I endoleak who underwent previous angioplasty and then had endoleak recurrence that was elected not to be treated. The second patient had no routine surveillance. At the time of analysis, three nonagenarians were still alive at an average of 5.2 years after EVAR.

The rate of freedom from endoleak was 79.7% at 1 year and 74.0% at 2 years (Fig 4). Endoleak occurred in five patients (20.8%), with three cases of type I and two cases of indeterminate type. Two patients with type I endoleak underwent secondary intervention: one required cuff extension, and the other was repaired with angioplasty. The final type I endoleak was monitored regularly; the aneurysm size remained stable and no further intervention was taken (Table IV). There were no conversions to open repair in the 24 patients in this study.

DISCUSSION

With the number of nonagenarians in this country rising dramatically, the approach to treatment of AAA in this unique population is of increasing importance. Nonagenarians are of particular interest because both their age and numerous medical comorbidities make them almost uniformly unfit for open repair. Although watchful waiting may be a desirable option in this population, several studies have elucidated the natural history of untreated large AAAs. In 2002, Lederle et al[12] found 1-year rupture rates in patients deemed unfit for surgery were 19% for AAA between 6.5 and 6.9 cm and 32.5% for AAA >7.0 cm, and

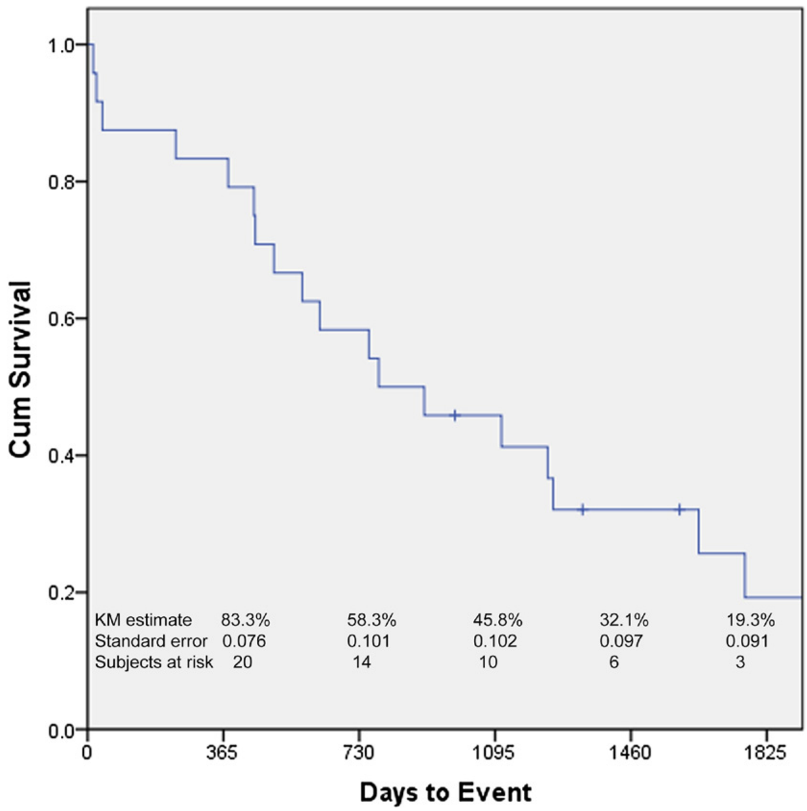

Fig 3. Kaplan-Meier (*KM*) graph represents freedom from all-cause mortality.

these figures are likely underestimates due to the low autopsy rate in their study. Conway et al[13] monitored 106 patients deemed unfit for open repair. The rate of death from AAA rupture over the 3 years of follow-up was 50% in patients with aneurysms of 6.0 to 7.0 cm and 55% in patients with larger aneurysms.

As a result, recent studies have sought to determine if EVAR offers a survival advantage compared with no intervention in patients unfit for open repair. The United Kingdom Endovascular Aneurysm Repair 2 (EVAR2) trial randomized high-risk patients to EVAR or no intervention and found no significant difference between EVAR and no intervention in all-cause mortality or aneurysm-related mortality to 4 years. The study concluded that EVAR does not improve survival in high-risk patients. The study had several limitations, most notably the 14 patients who were randomized to surgery and died before intervention that were included in the mortality estimates for the treatment group.[6] Iannelli et al[14] found similar results in a 2005 study in which high-risk patients were randomized to EVAR or open repair. Despite differences in the perioperative death rate between EVAR and open repair (0% and 14.3%, respectively), there was no significant difference in late mortality.

Despite these initial suggestions that EVAR offers no long-term survival benefit to high-risk patients compared with no intervention or open repair, subsequent studies looking at high-risk populations have found favorable results with EVAR. EVAR has been associated with low operative mortality of 0% to 4.3% and better long-term outcomes, with a 4-year survival of 56% to 79%, compared with open repair or watchful waiting in this population.[7-10,15] However, these subsequent studies were all nonrandomized EVAR and thus represent an inferior level of evidence.

The intraoperative mortality in our study was 0%, similar to previous studies of EVAR in high-risk populations. Although the perioperative mortality rose to 8.3%, one of the two perioperative deaths occurred from complications related to a right hip hemiarthroplasty the patient underwent 3 weeks after EVAR. We report low long-term survival at 5 years of 19.3%, much lower than that of previous studies of high-risk patients. These long-term data suggest that EVAR may not be of a mortality benefit in this subset population. However, it also underscores the age difference between the nonagenarians in this study (average age, 91 years) and participants in all previous studies on high risk patients, whose ages ranged from 72.6 to 77 years, nearly 14 years younger that the population in this study.

There has been no accepted standard to define "high risk." In a recent prospective cohort study, Mastracci et al[16] identified several independent predictors of mortality in patients undergoing EVAR, including age, aneurysm diameter, peripheral arterial disease, chronic obstructive pulmonary disease, congestive heart failure, use of home oxygen,

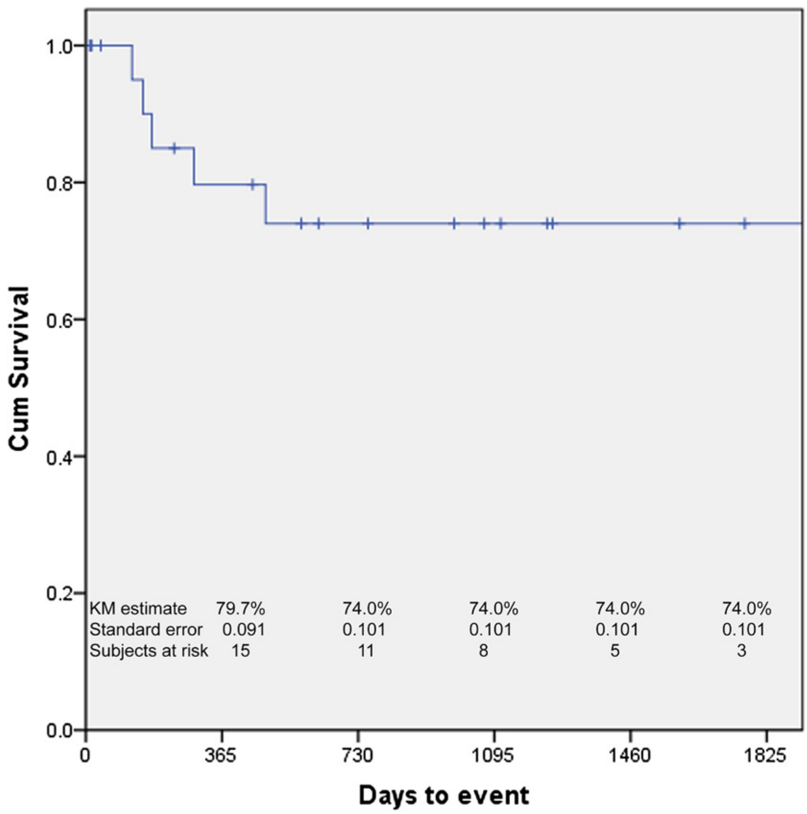

Fig 4. Kaplan-Meier (*KM*) graph represents freedom from type I and type II endoleaks, as well as freedom from those of indeterminate type.

Table IV. Late outcomes at 4 years

Events	*No.*	*%*
Freedom from mortality		
Overall	2	11.4
AAA-related	2	58.1
Overall conversion	0	0.0
Overall rupture	2	8.3
Endoleaks		
Type I	3	12.5
Type II	0	0.0
Indeterminate type	2	8.3

AAA, Abdominal aortic aneurysm.

and use of salicylates. The inclusion criteria for studies on high risk similarly often include absolute age criteria (range, 60-80 years) as well as the presence of one or more comorbidities that place the patient at risk for general anesthesia.[7-10,15] Although the patients in this study are similar to those in EVAR2 and other studies, the discrepancy in long-term outcomes suggests that much of the medium-term and long-term risk in nonagenarians may result solely from reduced life expectancy.

A recent report documented a higher incidence of aneurysmatic degeneration of the iliac vessels, increased tortuosity, larger aneurysm necks, and greater neck angulation in older patients compared with younger cohorts.[3] Indeed, in this study, the high rates of type I endoleak (12.5%) and rupture (8.3%) may be related to the more complicated anatomy seen in nonagenarians. Additionally, this study dates back to the early days of EVAR and includes many first-generation devices that were not as effective at aneurysm exclusion compared with newer stents. Many of these early stents did not accommodate femoral access as easily, also partially explaining the high rates of blood loss in this study compared with other studies of EVAR. Nonagenarians are nearly uniformly not fit for open repair; thus, despite more hostile anatomy, the decision was made to attempt EVAR in the selected patients in this study.

Although EVAR is associated with decreased initial morbidity and mortality compared with open repair, this is balanced and may be outweighed by increased morbidity in the long-term related largely to secondary procedures. Previous studies of EVAR have suggested that up to 27% to 35% of patients eventually required a secondary procedure.[17,18] In this study, three patients underwent reintervention (12.5%). Some have suggested that this tradeoff may be worthwhile, particularly in older patients who are less likely to tolerate the prolonged recovery and intensive care unit stay associated with open repair.[19] Unfortunately, secondary procedures may also be less well tolerated in this population. In this study, one of the two ruptures occurred in a patient with previous secondary intervention with angioplasty and known recurrent endoleak who decided not to pursue an additional reintervention. The patient died 1 month later.

Finally, as a retrospective review, this study is subject to selection bias because patients deemed unfit for EVAR were not included in the analysis. Although it is not possible to determine how many nonagenarians sought EVAR, the 24 patients in this study certainly represent a small minority of all nonagenarians presenting as surgical candidates. Recent analysis has estimated the cost of EVAR for the first year to be roughly $35,000. Thus, cost-effectiveness estimates largely depend on the quality of life gained by the patient, data that were not obtained in this study.[20] In one recent report, compared with open repair, patients aged ≥80 who underwent EVAR had a statistically significant more rapid return to baseline despite a lower quality of life at 6 months.[21] Preoperative and anticipated postoperative quality of life are essential in the consideration of which nonagenarians to intervene on.

Freedom from all-cause mortality at 5 years was only 19.3%, highlighting the natural history of this demographic. However, at the time of publication, three nonagenarians from this study were still alive, on average 5.2 years after EVAR. Although the risk of rupture of a large AAA is certainly substantial, studies comparing long-term outcomes in nonagenarians undergoing EVAR with those treated medically are lacking and are necessary to more accurately determine if any survival benefit is conferred from EVAR. Additionally, because the number of nonagenarians is only increasing, analysis of which nonagenarians are most likely to benefit from EVAR is of paramount importance.

CONCLUSION

Our study supports that EVAR in nonagenarians is associated with acceptable procedural success and perioperative morbidity and mortality. However, life expectancy and quality of life of these individuals are both of significant concern. EVAR prevented death from AAA rupture in most individuals with low rates of reintervention. Regional anesthesia and reduced hospital stay may be of significant benefit to this population. The medium-term results suggest that EVAR may be of limited benefit in very carefully selected patients who are aged ≥90 years. Additional studies are necessary to further delineate which nonagenarians will benefit from EVAR and to determine if any survival benefit is gained compared with conservative management.

AUTHOR CONTRIBUTIONS

Conception and design: SP, IT, GS, EF, SE, AV, MM, PF
Analysis and interpretation: SP, IT
Data collection: SP
Writing the article: SP, IT
Critical revision of the article: SP, IT, GS, EF, SE, AV, MM, PF
Final approval of the article: SP, IT, GS, EF, SE, AV, MM, PF
Statistical analysis: SP, IT
Obtained funding: MM, PF
Overall responsibility: PF

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INVITED COMMENTARY

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As the population continues to age, vascular surgeons will continue to be confronted with the difficult problem of treating increasingly elderly patients. In this article, the authors address the issue of endovascular abdominal aortic aneurysm repair (EVAR) in nonagenarians, a population of patients clearly expected to increase in the coming decades. The data from their report can be used to both support and refute the wisdom of performing EVAR in patients in their ninth decade.

Although procedural results were "acceptable," to use the authors' word, perioperative morbidity (25%) and mortality (8.3%) were much higher than what we have come to expect from EVAR in the general population. Ultimately, >20% of the patients died as a direct result of the aneurysm or the repair, so it is not clear that EVAR in this patient group has improved the natural history of the disease. Furthermore, one has to question the wisdom of extending expensive health care resources to patients with limited life expectancy, only 19% at 5 years in this study. It must always be kept in mind that elective EVAR is a prophylactic operation for an asymptomatic condition. From a public health standpoint, it is questionable whether the cost/benefit ratio pencils out in this scenario.

On the other hand, all vascular surgeons have seen and treated the "vigorous" nonagenarian whose health and quality of life defy their chronologic age. Although, as one of my mentors once told me, they may not look 90 before their operation, they always look 90 afterward. Clearly, though, there exists a subset of nonagenarians for whom EVAR is appropriate. Unfortunately, the numbers treated in this study were not large enough to stratify patients to determine factors predicting good and poor outcomes. Given the rarity of this procedure in nonagenarians, it is unlikely that a single center would be able to do so, and pooled data from multiple centers may be necessary to answer this question and identify nonagenarians for whom this procedure is most appropriate.

The authors are to be congratulated for critically analyzing and presenting their results in this difficult group of patients. The conclusions are open to debate, and this article does not provide a definitive answer; however, it does serve as a point of comparison for future studies that address this issue.