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Editor's Choice — The Impact of Endovascular Aneurysm Repair on Long Term Renal Function Based on Hard Renal Outcomes

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WHAT THIS PAPER ADDS

This study assessed renal decline in patients who have undergone elective endovascular aneurysm repair (EVAR) over the long term (nine years of follow up), based on estimated glomerular filtration rate (eGFR). It appears that patients undergoing EVAR exhibit a significant loss of eGFR over the long term and this is associated with poor survival. This information is important for decision making when selecting patients suitable for EVAR, especially younger patients, and also for guiding follow up in this high risk patient group. Renal function preservation should become part of regular follow up in this setting, especially in male patients with established cardiovascular disease.

Introduction: Over the short term endovascular aneurysm repair (EVAR) is associated with superior outcomes compared with open repair; however, the progression of renal function after EVAR remains unknown because of the use of inconsistent reporting measures. The aim was to define long term renal decline following elective EVAR using estimated glomerular filtration rate (eGFR).

Methods: The prospectively maintained in house database was used to identify consecutive patients having elective EVAR who had been followed up for more than five years. Overall, 275 patients (23 females, 8%; mean age, 75 years) who were not previously on renal replacement therapy (RRT) were included (January 2000 to July 2010). Pre-operative, post-operative, and most recent eGFR values were evaluated using the chronic kidney disease epidemiology collaboration equation. The primary outcome was change in eGFR at latest follow up.

Results: Patients were followed up over a median of 9 years (range 5—17 years). Their mean eGFR dropped from a pre-operative value of 67 mL/min/1.73 m^2 (standard deviation [SD]: 9.4) to 52 mL/min/1.73 m^2 (SD 7.7), which amounts to a yearly loss of 1.7 units; six patients (2%) required RRT (dialysis) during late follow up. Patients requiring RRT and those with an eGFR loss exceeding 20% at latest follow up compared with baseline were more likely to die during late follow up (odds ratio 2.4 and 3.3 respectively, $p < .001$).

Conclusion: This analysis, with some of the longest available follow up to date, suggests that patients undergoing EVAR may experience a significant long term decrease in renal function. This needs to be taken into account when offering EVAR in younger patients; renal follow up and preservation should be optimised in this patient group.

Keywords: Aortic aneurysm, Endovascular aneurysm repair, Chronic kidney disease, Glomerular filtration rate

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INTRODUCTION

Endovascular aneurysm repair (EVAR) has superior short term outcomes than open surgery and has subsequently become the treatment of choice for abdominal aortic aneurysm (AAA) in many patients.[1—3] The latest report from the National Vascular Registry (NVR) in the UK states that 70% of elective infrarenal AAA and 89% of elective complex AAA were treated by EVAR, with a total of 6 208 recorded procedures nationally over a one year period.[4] The implementation of regional and national AAA screening programmes[5] and the development of newer devices with better long term performance are likely to contribute to an even further increase in the number of EVARs being performed globally.

Even though EVAR has been associated with short to mid-term benefits over open AAA repair in terms of mortality,[6—8] it has also been suggested that short and mid-term renal function may suffer following EVAR.[9—11] The

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mechanisms of renal damage during and following EVAR have been described in detail elsewhere[12] and include a series of complex pathophysiological parameters. Contrast induced renal damage is also a potential issue after the EVAR has been completed and the patient has started surveillance, owing to repeated computed tomography angiograms (CTAs) if an endoleak has been detected and frequent re-intervention, encountered in up to 26% of elective EVARs.[13]

A decline in renal function, even if a patient does not require renal replacement therapy (RRT), may have an impact on other organs, as documented in previous animal studies.[14] Also it may be associated with vascular dysfunction leading to worsening atherosclerosis, hypertension, and more cardiovascular events.[15] It is important to try and preserve as much functioning renal mass as possible in this population who are at very high risk of cardiovascular events.

Most of the existing studies reporting renal outcomes in the EVAR literature use serum creatinine (SCr) as a measure of function, which doesn't account for variation in muscle mass and may only detect a deviation from normal values following the loss of one half of the functioning renal mass.[16] It has previously been suggested by this group that EVAR may be associated with increased renal decline compared with a matched population without AAA and a matched group of patients having open aneurysm surgery;[10] however, this evidence does not extend to over five years of follow up. This is due to the number of patients surviving after that time point, patients lost to follow up, and potential selection bias (fittest patients). Knowing the long term natural history of renal function after elective EVAR is paramount in an era when an increasing number of younger patients, some from national AAA screening programmes, are being offered this procedure to treat their AAA. The aim was to assess long term renal outcomes following EVAR using precise outcome measures (namely eGFR), examine potential risk factors, and assess whether renal decline is indeed associated with increased mortality.

METHODS

Patient selection and data collection

The prospectively maintained departmental EVAR database was interrogated to identify patients who underwent elective EVAR for infrarenal AAA between January 2000 and July 2010. The database includes all relevant clinical and biochemical information for patients undergoing endovascular surgery in the unit. The centre is a regional referral centre for patients with aneurysmal disease. A total of 536 patients had an elective infrarenal EVAR in that time period, of which 261 had been lost before completing at least five years of follow up or had died. Clinical data and serum creatinine values were obtained from referring sites where possible. Subsequently, a total of 275 consecutive patients with at least five years of follow up data were included in the final analysis.

Patients who were already receiving or were being considered for RRT before EVAR were excluded. Pre-operative, post-operative, and latest blood tests including SCr were routinely recorded in the database in all cases. Pre-operative blood tests were collected at the point of pre-operative assessment, four weeks before the procedure; the pre-operative CTA (1 mm slices) was performed at least two weeks before the baseline SCr measurement was obtained, as per standard departmental practice. Post-operative blood test results during follow up were recorded electronically and stored indefinitely on the institution's electronic results system. Following EVAR, patients undergo a duplex ultrasound and abdominal radiograph (2 views) before discharge and a further duplex ultrasound at 30 days. They then enter a standardised follow up regime with duplex ultrasound and abdominal radiographs at three, six and 12 months after EVAR and with six monthly duplex ultrasound and annual abdominal radiographs thereafter. Patients who reach five years of follow up without complications are then moved to annual scans for both modalities. Routine blood tests are obtained at the same time. Angiography (CTA) is reserved for suspected endoleak, unless the patient has a type two endoleak on duplex assessment with no evidence of an enlarging aneurysm sac. None of these patients were in a CT based EVAR surveillance programme.

To obtain and validate the latest post-operative SCr reading for each patient, the electronic system to review all available results at latest follow up was used. All post-operative SCr measurements used to calculate eGFR were obtained at least two weeks after performing any procedure requiring administration of contrast. eGFR was calculated using the chronic kidney disease epidemiology collaboration (CKD-EPI) equation, which has been shown to be superior in estimating GFR in populations of this age with incident cardiovascular disease.[16]

Patients had provided written informed consent for their data to be recorded in the database and to be used in future studies as well as the National Vascular Registry (NVR) prior to having EVAR. This project has been registered and approved as a "review of service provision and audit" with the local institution (University of Leicester Hospital NHS Trust, Leicester, UK) and hence ethical review was not deemed necessary as per current Health Research Authority (HRA) NHS-wide guidance.

Outcomes of interest

The primary outcome was change in eGFR at latest available follow up.

Other outcomes of interest included yearly average change in eGFR; loss of eGFR in those with pre-operative chronic kidney disease (CKD) compared with those without CKD; number of patients requiring RRT at end of follow up; associations between post-operative renal decline, defined as a drop in eGFR exceeding 20% compared with baseline[12] or RRT requirement, and mortality during long term follow up. All complications and parameters of interest were defined as per the EVAR reporting criteria of the Society for Vascular Surgery.

Statistical analysis

Continuous data are reported using mean values and standard deviation (SD), where applicable. Comparisons between continuous variables were made using the Student *t* test. Chi-square tests were performed to assess the relationship between loss of eGFR and mortality and progression to RRT and mortality. A multivariable regression was performed to assess the influence of baseline parameters known to influence long term renal function on an eGFR drop exceeding 20% during late follow up, which has previously been proposed as the most appropriate definition of significant renal deterioration.[12,17,18] A Cox multivariable regression adjusted for age, sex, diabetes, and prior history of ischaemic heart disease was performed to assess the influence of a drop in eGFR > 20% as a predictor of late mortality. A p value $< .05$ was considered as statistically significant in all cases.

RESULTS

Some 275 consecutive patients undergoing elective EVAR were included, of which 23 were female, with a mean age of 75 years (range 58—92, SD 7). Table 1 describes baseline characteristics and co-morbidities.

An infrarenal device with suprarenal fixation was used in 234 of the patients; the remaining 41 patients received a device with no suprarenal fixation. The decision as to what device would be used was made pre-operatively during the department multidisciplinary meeting. All devices were used based on the manufacturers' instructions for use.

The mean pre-operative eGFR was 67 mL/min/1.73 m^2 (SD 9.4; median 66, interquartile range 13). Patients were followed up over a median of 9 years (range 5—17 years). The mean post-operative eGFR at latest follow up was 52 mL/min/1.73 m^2 (SD 7.7; median 50, interquartile range 26). This amounts to a yearly loss of 1.7 units (SD 3.3). Those with a pre-operative eGFR > 60 mL/min/1.73 m^2 lost an average of 2.0 mL/min/1.73 m^2 vs.1.4 mL/min/1.73 m^2 for patients with a pre-operative eGFR ≤ 60 mL/min/1.73 m^2 ($p = .43$). Six patients (2%) required RRT (dialysis) and 134 (49%) had suffered a loss in eGFR of > 20% at latest follow up. Four of the six patients requiring RRT had a history of diabetes (all insulin dependent), all were hypertensive but all were prescribed both aspirin and a statin (best medical therapy). There was no evidence of renal artery coverage during their EVAR; based on duplex imaging (all had duplex led follow up), no renal artery occlusion was noted. Four had additional CT angiograms at least one year after the original EVAR and again no renal occlusions were observed. All six had a device with suprarenal fixation.

One hundred and forty-four patients (144) had died at latest follow up (median of nine years), of whom 92 had suffered eGFR loss > 20%. All patients requiring RRT (dialysis) had died by the end of follow up (nine years). On average, patients received a mean of two CTAs (SD 0.2) during the nine year follow up (70 mL of iodinated contrast medium per CTA) and the overall endovascular re-intervention rate was 16% (44/275 patients). There were three conversions to open surgery because of sac expansion secondary to endoleak; none of these patients died peri-operatively (30 days post-surgery). Age, male sex, history of diabetes, and prior history of ischaemic heart disease were independently associated with an eGFR of > 20% in multivariable analysis (Table 2). Re-intervention was also not associated with an eGFR drop > 20% (47% for those having re-intervention vs. 49%, for those not having had re-intervention, $p = .88$); however, patients having re-intervention did have a significantly higher baseline eGFR (71.2 vs. 66.9 mL/min/1.73 m^2, $p < .001$). None of the patients in this series had excessive proximal neck calcification or thrombus load (defined as exceeding 50% of circumference; all were treated per instructions for use). Neck angulation was not independently associated with eGFR drop (Table 2).

Table 1. Baseline characteristics of 275 patients undergoing elective endovascular aneurysm repair studied for estimated glomerular filtration rate

Character	Patients (n = 275)
Age — y	75 (±7)
Female sex	23 (8)
Abdominal aortic aneurysm diameter — cm	6.4 (±0.8)
Diabetes	47 (17)
Previous ischaemic heart disease	92 (33)
Previous stroke	29 (11)
Peripheral arterial disease	31 (11)
Hypertension	249 (91)
Statin therapy	211 (77)
Antiplatelet therapy	247 (90)
Chronic kidney disease stage 3 or above	12 (4)
Angiotensin converting enzyme inhibitors	121 (44)
Proximal neck angulation > 60°	34 (12)

Data are given as n (%) or mean (± standard deviation).

Table 2. Multivariable regression assessing the impact of baseline parameters on an estimated glomerular filtration rate loss of more than 20% at the end of follow up of 275 patients undergoing elective endovascular aneurysm repair

Parameter	Odds ratio (95% CI)	p
Age	2.8 (1.3—4.5)	.02
Male sex	1.1 (1.0—3.8)	.04
Abdominal aortic aneurysm diameter	1.8 (0.7—4.4)	.28
Diabetes	2.7 (1.1—5.6)	.03
Previous ischaemic heart disease	2.5 (1.4—3.9)	.02
Previous stroke	1.7 (0.4—7.8)	.72
Peripheral arterial disease	4.4 (0.2—11.5)	.88
Hypertension	2.3 (0.9—5.2)	.09
Statin therapy	2.1 (0.4—3.7)	.18
Antiplatelet therapy	1.1 (0.2—4.6)	.90
Chronic kidney disease stage 3 or above	2.1 (0.9—3.9)	.08
Angiotensin converting enzyme inhibitors	2.2 (0.9—7.7)	.16
Proximal neck angulation > 60°	1.1 (0.3—8.8)	.87
Number of computed tomography angiograms during follow up	1.7 (0.8—7.3)	.17

No associations between baseline characteristics and subsequent requirement for RRT (dialysis) could be explored given the small number of individuals who developed end stage renal failure requiring dialysis over the nine year follow up.

An eGFR loss exceeding 20% (compared with baseline) at latest follow up was associated with an increased risk of mortality over the study period in a univariable analysis (Odds Ratio [OR] 3.3, $p < .001$). Multivariable analysis (Cox regression) adjusted for age, sex, diabetes, and prior history of ischaemic heart disease disclosed that an eGFR loss $> 20\%$ was an also independent predictor of long term mortality (hazard ratio [HR]: 1.9, $p = .02$).

DISCUSSION

It was demonstrated that patients who undergo EVAR generally display a significant decline in renal function over the long term. This analysis contains the longest reporting of renal outcomes following elective EVAR in the literature to date using precise validated hard renal measures (estimated GFR). The implications of this finding are important regarding decision making when offering EVAR in younger patients and those with pre-existing CKD. Furthermore, follow up should not only consist of imaging to ensure the EVAR device remains intact but should include assessment of renal function, namely repeated estimates of GFR, which should then prompt relevant medical therapy or review by a nephrologist. Older individuals, males, those with existing CKD, and patients with diabetes merit even closer follow up and potentially more aggressive control of risk factors.

Previous research has explored the short and long term mechanisms of renal injury encountered in endovascular aortic surgery.[12,19] Short term injury is mainly attributed to ischaemic tubular damage as a result of contrast exposure, ischaemia—reperfusion phenomena (which may take place both during the original EVAR due to transient exclusion of the limbs from circulation and/or during follow up when undergoing re-intervention), micro-embolisation (both during EVAR and when having re-intervention), and possible coverage of accessory renal arteries. In fact, it was previously shown that this acute renal decline is both common and associated independently with medium term outcomes.[10,18,19]

Over the medium and long term, similar and potentially even more complex mechanisms may contribute to deteriorating renal function in these patients. Repeated exposure to contrast, given that re-intervention rates are still as high as 26%[13] and/or requirement for CTA for diagnostic purposes, is the main nephrotoxic mechanism that comes to mind in this clinical setting. Interestingly, re-intervention (endovascular) was not associated with a drop in eGFR exceeding 20% during late follow up in this series. This may be because of a type 2 error or because patients who had re-intervention had a higher baseline eGFR and were therefore less likely to develop a deterioration of their future renal function in the first place.

It is worth mentioning the effects of suprarenal fixation on renal function, and how individual studies have examined its impact.[20–23] Two meta-analyses, published in 2006[24] and 2008,[25] were unable to detect a significant short to mid-term loss in renal function when using infrarenal EVAR devices with suprarenal fixation modalities. A more recent meta-analysis from the group reported no significant difference in renal outcomes at one year when using hard renal outcomes such as eGFR;[26,27] this was in contrast to another recent literature synthesis, which, however, did not use eGFR as the main outcome of interest.[28,31] In this study the differences in renal outcomes between supra- and infrarenal fixation devices were not reported, given that the majority of the devices used featured suprarenal modalities. As such, no meaningful comparative analyses could be made between the two modes of fixation.

Overall, increased age, male sex, history of diabetes, and prior history of ischaemic heart disease were independently associated with an eGFR of $> 20\%$ in multivariable analysis in this series. None of these factors is modifiable; however, patients with these characteristics do merit closer follow up with repeated measurements of eGFR, early referral to a nephrologist, aggressive control of cardiovascular risk factors, and good diabetic care. It is of interest that patients with an eGFR < 60 mL/min/1.73 m^2 in the series did not have a more pronounced drop in renal function in the long term. This may be due to type 2 error or selection bias (given that patients with at least five years of follow up data were included in this analysis). This finding cannot support a change of practice in terms of offering those with reduced renal function before EVAR aggressive peri- and post-operative reno—protection. Future prospective research should look into risk factors of long term renal decline more closely in this patient group.

Regarding previous research examining the long term impact of EVAR and endovascular aortic intervention on renal function, Karthikesalingam *et al*.[31] reported a clinically significant decline in renal function in 18% of patients who undergo EVAR at one year in a systematic review of all published series.[28] The study highlighted the lack of accurate methods and use of various non-validated reporting standards for renal outcomes in this population, which practically makes the application of meta-analytical methods impossible if concentrating on hard renal endpoints. In the study renal function was evaluated using eGFR based on the CKD-EPI equation, which has been shown to report eGFR with less bias and higher precision than other equations, especially in populations of advanced age and with eGFR levels between 60 and 90 units.[16] Previous research has extended to five years post EVAR and it has been shown that indeed those undergoing EVAR do exhibit a steeper decline in eGFR than populations without AAA or those having open surgery, for at least the first five years post-intervention.[10] A retrospective analysis of the DREAM trial dataset by de Bruin *et al*.,[9] including 94 patients having open aneurysm surgery and 95 having EVAR who survived to five years and had an SCr measurement, showed that patients having EVAR lost almost 1 mL/min/1.73 m^2 per year (no statistically significant between group differences at five years). An in depth multivariable analysis was not possible due to the size of the cohort. This annual loss is 40% less than the decline seen in this series and slightly lower than the decline reported in previous cohorts.[10] These differences are most likely to be because the paper by de Bruin *et al*. reported on patients from a randomised trial, with different follow up pathways compared with the current non-randomised pragmatic cohort series.

It would be interesting to quantify and compare the long term (> 5 years) loss of renal function in EVAR with patients having open surgery or individuals with no AAA. Given the length of follow up and non-uniform follow up procedures for open AAA repairs, a suitable control group of patients could not be identified undergoing open reconstruction with meaningful follow up data beyond five years. Furthermore, this analysis opted to define the "natural history" of renal function in patients having EVAR who survive more than five years, hence a direct comparison with an open surgery control group was beyond the scope of this research and would be methodologically very challenging, if not impossible, to perform. This is because fitter patients are likely to be offered open aneurysm reconstruction, hence matching or adjusting for the plethora of parameters that may influence long term renal decline (i.e., age, sex, diabetes, cardiovascular disease, existing renal dysfunction, intra-operative and post-operative complications, and/or anaesthetic technique) would require a population of many thousands of aneurysm repairs. This could be addressed using the existing EVAR trial(s) data; however, only a very small proportion of patients in these studies have had complete follow up after the fifth year. The National Health and Nutrition Examination Survey (NHANES), however, does provide large scale epidemiological data for the general population, which provide a fairly accurate estimate of renal decline. According to the NHANES reports, in a population aged 70—80 years, an average of 24.6% of individuals would have an eGFR of 30—59 mL/min/1.73 m^2 (CKD stage 3). The average annual loss of eGFR in this group is 1% with a range of 0.3—0.59 mL/min/1.73 m^2 per year.[29] The mean annual loss in the group was 1.67 mL/min/1.73 m^2, which is significantly higher than the values reported in NHANES for this age bracket. In depth comparative or adjusted analyses are not possible given that patient level data are not available from NHANES, which is a limitation and does not allow definitive comparative conclusions to be made or a causative extrapolation of clinical outcomes. In any case, this provides evidence that this EVAR population may exhibit a significant degree of annual loss of eGFR compared with the general population of same age.

This research should be taken into account in the context of existing evidence regarding the management of younger patients with AAA. The existing European guidance relating to AAA states that there remains some uncertainty about the management of small aneurysms in defined subgroups (e.g., young patients) and none of the randomised trials were powered to detect differences in all cause mortality between subgroups by age or gender.[30,32] As such, the decision to offer EVAR or open repair should be judged on a per-patient basis until such data become available. The results of this current analysis may guide clinicians regarding follow up and consent, especially in those with reduced renal function before surgery; however, the choice of therapeutic modality should be based on a risk assessment, clinical evaluation, and discussion with the patient.

Limitations

Although this analysis is based on a prospectively maintained institutional database, this is not a prospective cohort study and outcomes (death and morbidity) were reported retrospectively. Furthermore, comparative analyses were limited, given that an appropriate matched group of patients having open AAA repair or no AAA could not be identified. A significant number of patients from the original cohort were either lost to follow up (e.g., no creatinine or appropriate imaging was available) or died (36 patients) before completing their five year follow up, hence only 275 patients were included in the final analysis. A part of this can be explained by the adoption of a different hospital electronic records system partway through the study period and the fact that this study took place in a tertiary referral centre, hence some patients cannot attend follow up appointments. The local centres were contacted to obtain latest creatinine values where possible. This was predominantly due to the length of follow up and lack of uniform follow up procedures in the open surgery groups. Most importantly, because of obvious limitations relating to the number of patients surviving or being available to follow up exceeding five years, creating groups of case matched individuals having EVAR or open surgery to compare renal outcomes over such long timeframes would add considerable selection bias and be underpowered to detect meaningful clinical differences.

CONCLUSION

Patients undergoing elective EVAR display a significant drop in their renal function over the long term (> 5 years) based on eGFR measurements. This should be taken strongly into account when offering EVAR to younger patients and should guide appropriate follow up and preventive measures with a focus on renal outcomes.

CONFLICT OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ejvs.2019.03.024.

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