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Editor's Choice – Renal complications after EVAR with suprarenal versus infrarenal fixation among all users and routine users

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WHAT THIS PAPER ADDS?
This study compares outcomes following use of suprarenal versus infrarenal fixation devices during EVAR, including among surgeons who routinely use one or the other.

Background: Previous studies comparing endografts with suprarenal and infrarenal fixation for endovascular abdominal aortic aneurysm repair (EVAR) have found conflicting results and did not account for differences in patient selection. This study aims to evaluate the differences in outcomes among surgeons who routinely use either suprarenal or infrarenal fixation, as well as all surgeons in the Vascular Study Group of New England (VSGNE).
Methods: All patients undergoing EVAR in the VSGNE from 2003 to 2014 were identified. All ruptured aneurysms, repairs with concomitant procedures, and infrequently used stent grafts (<50) were excluded. Suprarenal endografts included Talent, Zenith, and Endurant; infrarenal endografts included AneuRx and Excluder. Grafts were compared among surgeons who used only one type of endograft (suprarenal or infrarenal) for >80% of cases, as well as all surgeons. Multivariate regression and Cox hazard models were utilised to account for patient demographics, comorbidities, operative differences, and procedure year.
Results: This study identified 2574 patients (suprarenal, 1264; infrarenal, 1310) with 888 endografts placed by routine users (suprarenal, 409; infrarenal, 479). There were no differences in baseline comorbidities, including the estimated glomerular filtration rate, between suprarenal and infrarenal fixation, or between patients with endografts placed by routine and non-routine users. Patients treated with suprarenal endografts received more contrast than all users (102 mL vs. 100 mL, $p = .01$) and routine users (110 mL vs. 88 mL, $p < .01$), but other vascular and operative details were similar. Among all users, patients treated with suprarenal grafts had higher rates of creatinine increase >.5 mg/dL (3.7% vs. 2.0%, $p = .01$), length of stay >2 days (27% vs. 19%, $p < .01$), and discharge to a skilled nursing facility (9.2% vs. 6.7%, $p = .02$). There were no differences in 30 day or 1 year mortality. Following adjustment, suprarenal stent grafts remained associated with an increased risk of renal deterioration (OR 2.0; 95% CI 1.2–3.4) and prolonged length of stay (OR 1.8; 95% CI 1.4–2.2). Among routine users, suprarenal fixation was also associated with higher rates of renal dysfunction (3.7% vs. 1.3%, $p = .02$; OR 2.9; 95% CI 1.1–7.8).
Conclusion: Despite potential differences in patient selection, endografts with suprarenal fixation among all users and routine users were associated with higher rates of renal deterioration and longer length of hospital stay. Longer-term data are needed to determine the duration and severity of renal function decline and to identify potential benefits of decreased migration or endoleak.

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INTRODUCTION

Endovascular repair (EVAR) is now the most common treatment for infrarenal abdominal aortic aneurysms (AAAs) with reduced morbidity and mortality compared with open repair.[1–3] Today, multiple endografts are available for surgeon selection in the endovascular treatment of AAA. These

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include a wide variety of grafts including those with suprarenal and infrarenal fixation. Despite both being widely used and recognised as safe and effective, few large studies have compared patient outcomes between suprarenal and infrarenal endografts.[4–7] Among those studies comparing grafts currently available, results are mixed and limited by single institution design from the early era of EVAR, with several finding no differences in patient outcomes between endografts with suprarenal and infrarenal fixation.[8–11] Alternatively, other studies found increased risk of renal impairment including renal infarctions among grafts with suprarenal fixation.[12–15] However, it is unclear if these outcome disparities are due to differences in patient selection. Patients with more complex pararenal anatomy, including shorter neck or increased thrombus burden, are perhaps more likely to receive a graft with suprarenal fixation and also more likely to have post-operative renal complications. A recent Cochrane review, due in part to the limitations of studies in the literature, concluded that insufficient data exist regarding direct comparisons of the performance of different stent graft types.[16] Moreover, the Society for Vascular Surgery noted the need for research to evaluate the long-term safety of suprarenal endografts.[17] Given this significant gap in knowledge, this study aimed to compare the effect of suprarenal and infrarenal fixation among all surgeons, as well as those who routinely use endografts with either suprarenal or infrarenal fixation. By performing a subgroup analysis of only the routine users, confounding by indication can be partially accounted for. Furthermore, routine users to all users can be compared to determine if the results are generalisable across users.

METHODS

Patient selection

The Vascular Study Group of New England (VSGNE) was used to identify all patients undergoing EVAR for an intact AAA from 2003 to 2014. Patients undergoing concomitant procedures ($n = 515$) were excluded from analysis. Only endografts that had been used more than 50 times during the study period were assessed. Grafts with suprarenal fixation included Zenith (Cook Medical, USA) ($n = 789$), Endurant (Medtronic, USA) ($n = 305$), and Talent (Medtronic, USA) ($n = 170$), and grafts with infrarenal fixation included AneuRx (Medtronic, USA) ($n = 271$) and Excluder (W. L Gore and Associates, USA) ($n = 1039$). Powerlink (Endologix Inc, USA) ($n = 342$) was excluded because it has both suprarenal and infrarenal fixation configurations, and this study cannot distinguish between the two. While an analysis comparing suprarenal with infrarenal fixation was conducted among all users, a subgroup analysis was also performed of only those endografts placed by surgeons who routinely used either suprarenal or infrarenal endografts and completed 10 or more EVARs annually in an effort to limit the effects of patient selection. Routine use was defined by use of a single type of graft (infrarenal or suprarenal) for greater than 80% of that surgeon's cases over the study period. The outcomes following suprarenal and infrarenal fixation were compared for all patients (routine and non-routine users) as well as for the subgroup of patients with routine users.

Variables

Demographics, comorbid conditions, operative details, and outcomes were compared for patients receiving endografts with suprarenal versus infrarenal fixation. The glomerular filtration rate (GFR, in mL per minute per 1.7 m^2) was calculated in accordance with the Modification of Diet in Renal Disease (MDRD) equation.[18] Staging of chronic kidney disease was derived from GFR in accordance with the National Kidney Foundation and Kidney Disease: Improving Global Outcomes (KDGIO) clinical practice guidelines.[19,20]

Mortality data were recorded from the Social Security Death Index and evaluated at 30 days and 1 year. A renal complication, as defined by the VSGNE, included an increase in creatinine of $>$.5 mg/dL or new haemodialysis in the peri-operative period. Those patients on dialysis pre-operatively were excluded from analysis of renal complications. A respiratory complication was defined as pneumonia or reintubation. Prolonged length of stay was defined as more than 2 days following EVAR.[21] When the patient discharge location was evaluated, those patients living in a nursing facility pre-operatively were excluded from analysis. Discharge to a nursing home, rehabilitation centre, or other hospital after admission from home was considered discharge to a skilled nursing facility (SNF). The composite variable of any complication included myocardial infarction, heart failure, dysrhythmia, respiratory complication, renal complication, leg ischaemia, wound complication, bowel ischaemia, return to the operating room, or transfusion of more than three units of red blood cells.

Statistical analysis

Univariate analysis was performed using the chi-square test, Fisher exact test, Student *t* test, and Mann–Whitney U test as appropriate. All variables assessed had less than 3% missing data. Cox regression analysis and multivariate logistic regression were used to account for patient demographics, comorbidities, and operative characteristics, including intra-operative contrast volume. Purposeful selection was used to select variables for inclusion into each model.[22] This included all variables with $p < .1$ on univariate screening and those variables shown to be predictive of each evaluated endpoint in previous studies. Each logistic regression model was evaluated for goodness of fit using Hosmer–Lemeshow testing. A p value $<$.05 was considered significant. Statistical analysis was performed using the SPSS statistical package (version 21.0 IBM, Armonk, NY, USA). The institutional review board of Beth Israel Deaconess Medical Center approved this study and waived consent because of the de-identified nature of the data.

RESULTS

All users

Baseline characteristics: all users. This study identified 2574 patients undergoing EVAR by any surgeon in the VSGNE

Table 1. Baseline demographics of infrarenal and suprarenal endografts among all and routine users.

	Patients of all users			Patients of routine users		
	Suprarenal grafts ($N = 1264$) Number (%)	Infrarenal grafts ($N = 1310$) Number (%)	p	Suprarenal grafts ($N = 409$) Number (%)	Infrarenal grafts ($N = 479$) Number (%)	p
Male gender	1047 (83)	1047 (80)	.06	73 (18)	92 (19)	.60
White race	1235 (98)	1271 (97)	.28	397 (97)	463 (97)	.73
Age, mean (SD)	74 (9)	74 (9)	.42	75 (9)	74 (9)	.29
Smoking	1102 (87)	1099 (84)	.02	346 (85)	379 (79)	.04
Hypertension	1075 (85)	1082 (83)	.11	352 (86)	401 (84)	.37
Diabetes	239 (19)	245 (19)	.90	74 (18)	75 (16)	.34
CAD	415 (33)	412 (32)	.45	116 (28)	143 (30)	.64
CHF	122 (10)	123 (9)	.83	46 (11)	43 (9)	.27
COPD	414 (33)	428 (33)	.98	114 (28)	142 (30)	.55
GFR, median (IQR)	69 (54–83)	68 (54–83)	.75	68 (55–83)	69 (55–83)	.80

SD = standard deviation; CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; GFR = glomerular filtration rate; IQR = interquartile range.

Table 2. Operative details among all and routine users.

	Patients of all users			Patients of routine users		
	Suprarenal grafts ($N = 1264$) Number (%)	Infrarenal grafts ($N = 1310$) Number (%)	p	Suprarenal grafts ($N = 409$) Number (%)	Infrarenal grafts ($N = 479$) Number (%)	p
Diameter cm, median (IQR)	5.5 (5.2–6.0)	5.5 (5.2–6.0)	.33	5.5 (5.2–6.0)	5.5 (5.2–6)	.89
Iliac aneurysm	302 (24)	265 (20)	.03	89 (22)	79 (12)	.05
Symptomatic	84 (6.6)	100 (7.6)	.33	23 (6)	29 (6)	.79
Hypogastric covering	16 (1.3)	18 (1.4)	.79	5 (1.2)	6 (1.3)	.94
Contrast mL, median (IQR)	102 (70–145)	100 (64–140)	.01	110 (80–143)	88 (58–120)	<.01
Completion Type I endoleak	38 (3.0)	21 (1.6)	.02	17 (4.0)	12 (3.0)	.17

(suprarenal, 1264; infrarenal, 1310). There were no differences in baseline demographics or comorbidities including GFR (69 vs. 68 mL/min/1.73 m^2, $p = .75$) (Table 1). There were also no intra-operative differences except that patients with suprarenal fixation had more contrast use; however, the difference was less than 5 mL (102 vs. 100, $p = .01$) and is only statistically significant given the large number of patients in this cohort (Table 2). Importantly, intra-operative type I endoleaks were more common in patients with suprarenal grafts (3.0% vs. 1.6%, $p = .02$), which may suggest more challenging neck anatomy and differences in patient selection.

Outcomes: all users. When outcomes were compared, use of suprarenal endografts was associated with the same adverse outcomes seen among routine users. These included increased renal complications (3.7% vs. 2.0%, $p = .01$), prolonged length of stay (27% vs. 18%, $p < .01$), and any complication (11% vs. 7.5%, $p < .01$) (Table 3). The median follow-up was 31 months (IQR 14–53 months). On univariate analysis, there was no difference in 30 day mortality; however, 1 year mortality was higher among suprarenal grafts (6% vs. 4%, $p = .04$). Following multivariate analysis, suprarenal endografts remained associated with an increased risk of renal complications (OR 2.0; 95%

Table 3. Outcomes among all and routine users.

	Patients of all users			Patients of routine users		
	Suprarenal grafts ($N = 1264$) Number (%)	Infrarenal grafts ($N = 1310$) Number (%)	p	Suprarenal grafts ($N = 409$) Number (%)	Infrarenal grafts ($N = 479$) Number (%)	p
30 day mortality	13 (1.0)	10 (.8)	.48	3 (.7)	1 (.2)	.34
Any complication	136 (11)	93 (7.5)	<.01	47 (12)	28 (6)	<.01
Renal complication	46 (3.7)	26 (2.0)	.01	15 (3.7)	6 (1.3)	.02
Bowel ischaemia	10 (.8)	5 (.4)	.17	4 (1)	1 (.2)	.19
Wound infection	11 (.9)	6 (.5)	.20	2 (.5)	3 (.6)	1.0
Myocardial infarction	13 (1.0)	20 (1.5)	.26	4 (1.0)	3 (.6)	.56
Return to operating room	17 (1.3)	13 (1)	.41	6 (1.5)	4 (.8)	.53
Heart failure	12 (.9)	12 (.9)	.93	4 (1.0)	1 (.2)	.19
Respiratory complication	25 (2.0)	22 (1.7)	.58	5 (1.2)	6 (1.3)	.97
Length of stay >2 Days	339 (27)	239 (18)	<.01	136 (33)	89 (19)	<.01
Discharge to SNF	116 (9.2)	88 (6.7)	.02	43 (11)	31 (6.5)	.03

SNF = skilled nursing facility.

Table 4. Multivariate analysis among all and routine users.

	Patients of all users Suprarenal grafts odds/hazard ratio (95% CI)	Patients of routine users Suprarenal grafts odds/hazard ratio (95% CI)
1 year mortality[a]	1.3 (.9—1.9)	1.3 (.7—2.5)
Renal complication[b]	2.0 (1.2—3.4)	2.9 (1.1—7.8)
Any complication[c]	1.7 (1.3—2.3)	2.4 (1.4—4.1)
Length of stay >2 days[c]	1.8 (1.4—2.2)	2.5 (1.8—3.5)
Discharge to skilled nursing facility[c]	1.3 (.95—1.8)	1.8 (.99—3.2)

[a] Cox regression adjusted for age, sex, congestive heart failure, COPD, diameter, symptoms, CKD stage, iliac aneurysm, year.
[b] Logistic regression adjusted for age, symptoms, CKD stage, contrast volume.
[c] Logistic regression adjusted for age, sex, congestive heart failure, COPD, diameter, symptoms, CKD stage, iliac aneurysm, year.

CI 1.2—3.4), prolonged length of stay (OR 1.8; 95% CI 1.4—2.2), and any complication (OR 1.7; 95% CI 1.3—2.3) (Table 4). One year mortality and risk of being discharged to a SNF did not differ after adjustment. The volume of contrast used and outcomes were similar comparing routine and non-routine users for both suprarenal and infrarenal endografts.

Routine users

Baseline characteristics: routine users. Surgeons who were routine users of endografts with either suprarenal or infrarenal fixation performed 888 EVARs. These included 409 (46%) patients with suprarenal fixation grafts and 479 (54%) patients with infrarenal fixation grafts placed by 34 of the 132 surgeons in the VSGNE during the study period. There were no differences in demographics between patients treated with suprarenal and infrarenal grafts (Table 1). The frequency of comorbidities was also similar, including rates of hypertension, diabetes, congestive heart failure, and chronic obstructive pulmonary disease. Only a history of smoking differed with higher rates among patients treated with suprarenal grafts (85% vs. 79%, $p = .04$). The median baseline GFR was similar between patients with suprarenal and infrarenal grafts (68 vs. 69 mL/min/1.73 m^2, $p = .08$).

When operative details were compared, the contrast volume was greater among patients treated with suprarenal grafts (110 vs. 88 mL, $p < .01$) (Table 2). There were no differences in the frequency of symptomatic aneurysms, concurrent iliac aneurysms, hypogastric coiling, or aneurysm diameter. Importantly, there was also no difference in the frequency of type I endoleak at the end of the case (suprarenal 4.0% vs. infrarenal 3.0%, $p = .17$).

Outcomes: routine users. Renal complications were more common among patients with suprarenal fixation grafts (4% vs. 1%, $p = .02$), as were prolonged length of stay (33% vs. 19%, $p < .01$) and discharge to SNF (11% vs. 7%, $p = .03$) (Table 3). Two patients underwent new post-operative dialysis, both of whom were treated with suprarenal grafts. Patients treated with suprarenal grafts also had a higher rate of any complication (12% vs. 6%, $p < .01$). There were no differences in 30 day or 1 year survival. Other complications including bowel ischaemia, myocardial infarction, heart failure, respiratory complications, wound infections, and return to the operating room were similar. There were no differences in time spent in the ICU (median 0 vs. 0 days, $p = .36$).

After adjustment for demographics, operative details, and comorbidities, including chronic kidney disease stage and importantly contrast volume, patients receiving grafts with suprarenal fixation were at increased risk of renal complications (OR 2.9; 95% CI 1.1—7.8), prolonged length of stay (OR 2.5; 95% CI 1.8—3.5), and any complication (OR 2.4; 95% CI 1.4—4.1) (Table 4). One year mortality and discharge to a SNF did not differ after adjustment.

DISCUSSION

Patients receiving endografts with suprarenal fixation have increased rates of renal complications and prolonged length of stay compared with patients receiving endografts with infrarenal fixation. These findings were similar for routine users and non-routine users.

Previous studies have found conflicting results on the effect of fixation on patient outcomes, although they have been limited by small sample size and an inability to account for patient selection. In one of the few studies to include multiple institutions, Saratzis et al.[13] found that patients treated with suprarenal endografts had increased rates of renal complications compared with infrarenal endografts. Alternatively, studies by Pisimisis et al.[10] and Alsac et al.[8] found no difference in renal complications. In an effort to address the effect of small sample sizes, Walsh et al.[23] performed the first meta-analysis, which included 11 studies on endografts used from 1998—2006. This analysis found increased renal impairment following suprarenal fixation; however, the complex heterogeneity of studies led to this effect being lost after adjustment. As a result, the authors concluded that the data were insufficient to determine the precise effect of the level of fixation. A second meta-analysis was published in 2015, which included 21 studies of endografts placed between 1994 and 2011 and found that, despite higher rates of renal infarction (6.4% vs. 2.5%, $p = .09$), suprarenal fixation was not associated with an increased risk of renal dysfunction.[11] In both meta-analyses, authors acknowledged their data were limited by the available literature that included patients from the early endovascular era only with no inclusion of patients treated after 2011 and, despite numerous studies, only one paper included analysis from more than one institution. The small sample size of most studies is particularly problematic

given the low rates of renal complications identified in the current study, which suggest that previous studies may have been underpowered to adequately identify differences in renal complications. As further support to this, one of the largest studies, which included more than 660 patients, did in fact identify increased rates of renal infarction among patients with suprarenal grafts.[12] Finally, it should be noted that the majority of studies on suprarenal fixation were performed outside the United States, and many endografts were included which were never available in the United States making the results difficult to generalise to contemporary US practice.

An additional challenge to interpreting previous data, including the meta-analyses, is the definition of renal complications. In the current study the definition established by the VSGNE that labelled renal complications by an increase in creatinine greater than .5 mg/dL or new dialysis was used. Using this definition, this study found rates of renal complications of 1–4%, similar to what has been previously reported following elective EVAR.[24,25] Importantly, however, previous studies comparing suprarenal and infrarenal fixation have higher rates of renal dysfunction including those reported by Pisimisis et al.[10] (suprarenal 19% vs. infrarenal 15%), Alsac et al.[8] (suprarenal 26% vs. infrarenal 30%), Parmer and Carpenter[9] (suprarenal 8% vs. infrarenal 10%), and Miller et al.[11] (suprarenal 12% vs. infrarenal 12%). There are likely to be multiple explanations for these variable rates including different definitions of renal complications (increase in GFR of >20%, increase in creatinine >30%, or increase by >1.5 mg/dL have all been used).[8–11] Additionally, it should be noted that these studies included endografts from the early era of EVAR, and with significant improvements in patient outcomes seen in the last decade as a result of surgeon experience and device evolution.[26]

There are multiple potential explanations for the increased rates of adverse outcomes identified among endografts with suprarenal fixation. It has been suggested that the increased rate of renal complications may be the result of disruption and embolisation of thrombus into the renal arteries. This hypothesis is supported by previous studies that identified an increased incidence of renal infarctions among suprarenal endografts.[12,27] It is also possible that the bare metal stent sitting across the renal arteries in endografts with suprarenal fixation may stimulate hyperplasia or provide a nidus for future thrombi. However, it should be noted that the current study was unable to assess long-term patency and renal dysfunction.

This study attempted to limit the effect of patient selection by including only those surgeons who routinely used endografts with either suprarenal or infrarenal fixation. By stratifying the analysis on the presumed confounding variable, this study hoped to mitigate the effect of selection bias. However, it is possible that routine users of infrarenal endografts still chose infrarenal grafts for straightforward anatomy and refer complex cases to those with experience with suprarenal fixation, while those who routinely use suprarenal grafts do not need to make that selection, thus some bias may remain. Anatomical characteristics such as shorter neck length, larger diameter, and increased angulation probably lead surgeons to select an endograft with suprarenal fixation, and all of these factors may also predispose patients to an increased risk of renal complications due to hostile anatomy. The larger volume of contrast use, at least among the routine users, probably reflects the more complicated anatomy and may in some cases include an additional angiogram to evaluate the fixation, and may be a contributing factor to the disparity in post-operative renal dysfunction, although, notably, adjusting for contrast volume use in the multivariate models did not mitigate the association between suprarenal fixation and renal complications. However, there may be other variables that are not adjusted for contributing to this disparity, so one should remain critical in considering these results in light of these limitations. The higher risk of renal complications among patients with complicated necks has been reported previously in a study of patients treated with the Talent stent graft.[28] Additionally, studies have shown higher rates of re-intervention and endoleaks in patients with hostile anatomy.[29–32] Despite these findings, other research has found no difference in adverse outcomes among patients with hostile anatomy.[33,34] Importantly, in the current analysis, no difference was seen in the frequency of type I endoleaks or aneurysm size. This finding is supported by the work of Hager et al.,[33] who evaluated nearly 1400 EVARs, and found that more patients with short necks (<1.5 cm) were treated with infrarenal fixation ($n = 60$) compared with suprarenal fixation ($n = 24$). Furthermore, no differences were found in proximal neck length, aneurysm size, re-interventions, or migration between endografts with suprarenal or infrarenal fixation. Despite this, additional research is warranted to better define appropriate patient selection for, and to explain the difference in renal dysfunction following, the placement of suprarenal endografts.

There are important limitations to this study that must be noted. First, this research is bound by the limitations of the VSGNE database, including coding errors, missing data, and variables defined by the registry, including the definition of post-operative renal insufficiency. This study was also unable to assess long-term outcomes including late renal complications, endograft migration, endoleak, and re-intervention due to limitations of the dataset. Additionally, this study was unable to assess all anatomical characteristics including neck length, diameter, and angulation, or the use of proximal extenders which probably impact surgeon endograft choice, and no patients are known to have received additional post-operative imaging with additional contrast exposure prior to their renal complications. Additionally, this study was unable to compare the individual endografts due to limitations in sample size. Despite these limitations, it is believed that the results provide valuable information to improve awareness of potential complications and guide future research. Hopefully, this study will encourage the VSGNE and VQI, NSQIP, and other vascular registries to add these important variables to their data collection instruments in

the future. While surgeons should not change their practices with regard to selecting suprarenal versus infrarenal fixation endografts, it is felt that further comparative research is not warranted.

CONCLUSION

The study suggests that patients receiving suprarenal endografts, even from surgeons who routinely use these grafts, are at higher risk of peri-operative renal complications as well as prolonged length of stay. Some of these differences are probably from patient selection; however, the risk of suprarenal fixation merits further investigation that accounts for anatomical differences to confirm these short-term differences and to determine whether long-term differences exist in renal function, graft migration, endoleak, and re-intervention. Furthermore, vascular registries should be encouraged to include detailed anatomical data in the future in order to be able to better compare outcomes by endograft.

CONFLICT OF INTEREST

None.

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