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Defining Risk and Identifying Predictors of Mortality for Open Conversion after Endovascular Aortic Aneurysm Repair in the Vascular Quality Initiative

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Abstract

Objective—Risk of open conversion after endovascular aortic aneurysm repair(EVAR-c) is poorly defined. The purpose of this analysis was to determine outcomes of elective EVAR-c compared to elective primary open abdominal aortic aneurysm repair(PAR) in the Vascular Quality Initiative(VQI).

Methods—VQI patients undergoing elective EVAR-c and PAR(2002–2014) were reviewed. Candidate predictors of major adverse cardiac events(MACE) and/or 30-day mortality were entered into a multivariable model, and stepwise elimination was used to reduce the number of covariates to a best subset of predictors. To estimate the additive risk of EVAR-c for MACE or 30-day mortality over PAR, this variable was added along with the best subset of predictors into generalized estimating equations logistic regression models.

Results—159 EVAR-c and 3,741 PAR patients were identified. EVAR-c patients were older (73.5±8.1 vs. 69.5±8.4 years;P<.0001), more likely to have diabetes(21% vs. 15%;P=.03) and prior history of lower extremity bypass(9% vs. 4%;P=.0006). EVAR-c was associated with a higher incidence of retroperitoneal aortic exposure(41%;N=64 vs. PAR, 26%, N=976;P<.0001), use of a bifurcated graft(65%;N=101 vs. PAR, 52%;N=1923;P=.001), greater blood loss (median, IQR: 2000mL[1010,3500] vs. PAR, 1200mL[750,2000];P<.0001) and longer procedure times (EVAR-c, 275±122min vs. PAR, 232±9min;P<.0001). However, PAR more frequently was completed with a suprarenal/mesenteric cross-clamp(74%, N=2749 vs. EVAR-c, 53%, N=83;P<.

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0001) and had a higher incidence of concomitant procedures(26%;N=972 vs. EVAR-c, 18%, N=28;P=.03).

Non-risk adjusted 30-day mortality was higher after EVAR-c: EVAR-c, 8%(N=10) vs. PAR, 3% (N=105);P=.009. There was no difference in complication rates: EVAR-c, 33%(N=52) vs. PAR, 28%(N=1056);P=.3. Preoperative 30-day mortality predictors included age(OR 1.06/year, 95% C.I: 1.04–1.1;P<.0001), COPD (OR 2.4, 1.6–3.5;P<.0001), history of prior leg bypass (OR 2.3, 1.2–4.4;P=.01), suprarenal cross-clamp (OR 2.2, 1.2–4.1;P=.01), prior carotid revascularization (OR 2.2, 1.3–3.8;P=.0004), congestive heart failure (OR 1.8, .9–3.5;P=.08) and female gender (OR 1.6, 1.1–2.3;P=.02) (AUC=.75). When controlling for covariates, EVAR-c was not significantly associated with MACE (OR 1.2 95% CI 0.7–2.0;P=.4) or 30-day mortality (OR 2.0, . 9–4.2;P=.08).

Conclusions—EVAR-c patients are typically older, have more comorbidities and experience greater blood loss and longer procedure times compared to PAR patients. However, postoperative morbidity and mortality are primarily driven by patient covariates and intraoperative factors, rather than the need for endograft explantation. Several preoperative variables were identified as predictors of 30-day mortality after elective EVAR-c and should be considered during the decision making process for remedial treatment of failed EVAR.

Introduction

Endovascular aortic repair(EVAR) has become the most common method of infrarenal abdominal aortic aneurysm(AAA) repair[1, 2]. In appropriately selected patients, acceptable long-term durability has been established[2, 3]; however EVAR is associated with the need for ongoing surveillance and risk of aortic-related reintervention[1, 4]. The optimal remedial treatment for failing EVAR is unclear but is dictated by anatomic factors, available technology, surgeon experience, patient preference, surgical risk, rupture risk and life expectancy. These same factors influenced the initial decision to perform the index AAA repair and remain relevant when considering elective reintervention for EVAR.

Open conversion has been increasingly reported and is appropriate for a subset of patients presenting with failed EVAR[5–9]. While this is the definitive strategy for dealing with aortic related complications after EVAR, the morbidity and mortality rates are poorly defined. The presence of the endograft is thought to confer greater risk with open repair and this is highlighted by historical series documenting up to a 22% mortality rate after EVAR-c[10, 11], while modern series have reported elective mortality rates of 3.3% to 10%[12–15] compared to 1–4% for primary open aortic aneurysm repairs(PAR)[16, 17]. Notably, the EVAR-c literature is characterized predominantly by single institution series with mixed populations of elective and non-elective patients. Therefore, the reported results provide little insight about what factors are most important in determining outcomes after EVAR-c.

As an alternative to EVAR-c, there are a variety of endovascular therapies that can be utilized which is potentially justified based upon the presumed higher risk of EVAR-c. Providers can employ creative endovascular solutions for failed EVAR including cuff/limb extensions[18], endostaples (HeliFx, Aptus Endosystems Inc., Sunnyvale, Calif)[19], balloon-expandable stents[20], and various methods of embolization[21, 22]. There are even descriptions

of ‘off-label’ procedures such as parallel stent and fenestrated/branched techniques for salvage of failed EVAR[23, 24]. These techniques have significant merit particularly in high risk patients although longer-term outcomes are not well established. Moreover, the results remain inconclusive due to small patient numbers and the tremendous selection bias that exists in these series.

Therefore, the purpose of this analysis was to determine outcomes of elective EVAR-c and benchmark them to elective PAR in the Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) as well as identify predictors of 30-day mortality to facilitate clinical decision-making.

Methods

This study was approved by the SVS VQI Research Advisory Committee and includes national data from all VQI regional quality groups. Details regarding this multi-center collaboration have been published and are available at www.vascularqualityinitiative.org/components/svs-pso[25, 26]. This study was also approved by the Institutional Review Board at the University of Florida and the requirement for patient consent was waived.

Study cohort

All Vascular Quality Initiative(VQI) patients undergoing elective conversion after EVAR(EVAR-c; N = 159) and elective primary open AAA repair(PAR; N = 3741) from January 2002 to June 2014 were reviewed. Urgent or emergent presentations were intentionally excluded(non-elective EVAR-c, N = 118; non-elective PAR, N = 1388). Patients undergoing open aneurysm repair for traumatic, mycotic and/or anastomotic pseudoaneurysm indications are not captured in the VQI. Similarly, aortic aneurysms that involve a major renal artery such that the proximal aortic anastomosis is above at least one major renal artery and reimplantation or bypass of a main renal artery is required are not recorded in the VQI. However, infrarenal AAA repairs with concomitant renal bypass that is performed to treat renal artery occlusive disease is recorded in the registry. Additionally, open AAA repair that occurs below the main renal arteries and require ligation, re-implantation and/or bypass of accessory renal arteries is included. Notably, isolated open iliac aneurysm repair that does not involve anastomosis to the aorta and revisions of previous open AAA repairs are not included in the registry.

Definitions and end-points

More than 100 patient demographic and clinical variables are prospectively collected in the VQI registry[27]. Specific definitions regarding comorbidities, procedure related parameters and complications are available on-line: www.svsqi.org. EVAR conversion is specifically defined by either partial and/or total endograft explantation. The VQI does not however record if partial or total endograft removal occurred during the conduct of the operation. Similarly, the reason for the EVAR conversion is not recorded. For the purposes of this analysis, all reported non-mortality related complications are in-hospital events. Concomitant procedures during open aortic aneurysm surgery in the VQI are defined as thromboembolectomy, lower extremity bypass, bypass/reimplantation of an accessory renal

artery, and/or ‘other abdominal procedure’. Other abdominal procedure is not further defined in the registry and data capture of these ancillary procedures in the VQI is left to the operative surgeon’s discretion.

Primary end-points included: 1) 30-day death and 2) any in-hospital, postoperative major adverse cardiac event [MACE; clinically significant arrhythmia, congestive heart failure (CHF) or myocardial infarction (MI)]. Secondary end-points included in-hospital complications and long-term mortality. MI was defined as new ST and/or T wave ECG changes, troponin elevation, or documentation by echocardiogram or other imaging modality. Clinically significant arrhythmias included any new atrial or ventricular rhythm disturbance requiring treatment with medication or cardioversion. CHF included new pulmonary edema documented by chest radiograph and requiring treatment or monitoring in the intensive care unit. All mortality events were verified using the Social Security Death Masterfile.

Statistics

The primary goal of the analysis was to estimate the effect of elective EVAR conversion relative to elective primary open repair on the likelihood of death within 30 days. Because there were a relatively small number of 30-day death events (N=115) in the dataset, inclusion of all possible covariates in a multivariable model was not feasible. Instead, we entered all covariates significantly confounded with EVARc at the 0.1 level (Table I), along with EVARc itself, into a logistic regression model with 30-day death as outcome. To account for the clustering of observations on medical center, we used generalized estimating equations to evaluate the effects in this model. We used an identical procedure to evaluate the effect of EVAR conversion on MACE while controlling for important covariates.

To stratify patients by risk, we entered all covariates (excluding EVARc) into a logistic regression model with 30-day as outcome and used a stepwise elimination algorithm based on the Akaike Information Criterion[28] to reduce the number of covariates to a best subset of predictors. To account for the clustering of observations on medical center, we used generalized estimating equations to evaluate the effects in this model.

Each patient was assigned his or her model-estimated probability as a risk score, and we categorized patients as High, Medium or Low risk according to the tertiles of these scores.

We used the Kaplan-Meier method to estimate and compare long-term survival across the entire dataset between patients receiving EVAR-c and PAR, and also to compare survival between these groups within each risk classification. All statistical analyses were performed using the software package R (Vienna, V. 3.1.3). A P-value < .05 was considered statistically significant.

Results

Demographics and comorbidities

In total**,** 14 regions, 151 centers and 676 surgeons contributed data to the initial VQI cohort consisting of 3741 elective PAR and 159 elective EVAR-c procedures. The details regarding

the demographics and comorbidities of elective EVAR-c and PAR patients are summarized in Table I. EVAR-c patients were significantly older(73.5±8.1 vs. 69.5±8.4 years; P < .0001), less likely to be a current smoker(21% vs. 43%; P < .0001), more frequently had a preoperative history of diabetes(21% vs. 15%; P = .03) and more often had a history of lower extremity bypass(9% vs. 4%; P = .006). Notably, a trend toward a higher prevalence of prior coronary artery bypass/percutaneous coronary intervention and congestive heart failure was also present in the EVAR-c subjects when compared to PAR patients.

Operative details

There were several significant differences in operative variables between EVAR-c and PAR patients. VQI patients undergoing elective EVAR-c were more likely to undergo retroperitoneal aortic approach(41% vs. 26%; P < .0001), be repaired with a bifurcated graft(65% vs. 52%; P = .001), experience greater blood loss(median [interquartile range]: EVAR-c, 2000mL [101, 3500] vs. PAR, 1200 mL[750, 200]; P < .0001) and had longer procedure times(EVAR-c, 275±122 min vs. PAR, 232±99 min; P < .0001). However, PAR patients were more likely to undergo a concomitant intraoperative procedures(26% vs 18%; P = .03) and receive supra-mesenteric aortic cross-clamp placement(61% vs. 43%; P < .0001). Additional information regarding intraoperative features is displayed in Table II.

Non-risk adjusted outcomes

Postoperative outcomes after elective EVAR-c and PAR are depicted in Table III. The non-risk adjusted 30-day mortality was significantly higher after EVAR-c compared to PAR(8%, N = 12 vs. 3%, N = 112; P = .01). No difference in the rate of experiencing *any* postoperative complication was present between the two groups(EVAR-c, 33% vs. PAR, 28%; P = .3). However, patients undergoing EVAR-c were more likely to experience in-hospital pulmonary complications(16% vs. 11%; P = .04), postoperative creatinine increase > 0.5 mg/dL(21% vs. 12%; P = .002), or a return trip to the operating room for bleeding(7% vs. 2%; P < .0001).

Outcome predictors

Table IV provides a list of the preoperative predictors of 30-day mortality(AUC 0.75). Notably, the variable EVAR-c was not found to be an independent predictor of 30-day mortality or postoperative in-hospital MACE(Supplementary Table). A model for 30-day death with EVARc and its potential confounders as covariates - age, BMI, CABG/PCI, CHF, smoking status, diabetes, prior bypass/PVI and stress test – yielded a P-value for EVARc of 0.61 (OR=1.3, 95% CI= [0.483, 3.45]), suggesting that even when compared to all primary OAAA patients, there is little evidence that EVAR conversion is associated with increased risk. An identical model for MACE yielded a P-value for EVARc of 0.97 (OR=1.0, 95% CI= [.575, 1.79]).

Further, to understand the additive relative risk of EVAR-c compared to PAR, generalized estimating equations logistic regression was completed. The risk of postoperative MACE for EVAR-c was 1.2 times that of PAR patients(OR 1.2, 95% CI 0.7–2.0; P = .4). The EVAR-c patients had 2-fold higher risk(OR 2.0, 0.9–4.2) of 30-day mortality, however this was not significantly different than PAR subjects(P = .08). Examples of various combinations of

patient and procedure related factors across the low, intermediate and high mortality risk strata with the associated predicted postoperative 30-day mortality rates for EVAR-c and PAR patients are represented in Figure 1.

Risk-adjusted outcomes

There were 159 elective EVAR-c patients and of these, 109 (69%) had complete data to be eligible for both prediction of preoperative 30-day mortality risk and comparison of postoperative outcomes. Of the 109 EVAR-c patients, the proportions of low, medium and high 30-day mortality risk patients are: low- 5%(N=5), medium- 23%(N=25) and high- 72% (N=79). Similarly, in the elective PAR cohort(N=3099 of 3147[98%] were eligible for stratification), the respective low, medium and high risk strata were: low- 34%(N=1057), medium- 33%(N=1032) and high- 33%(N=1010). Notably, a significantly higher proportion of EVAR-c patients were deemed high risk compared to the PAR patients(72% vs. 33%; P<. 0001).

Due to the exceedingly low number of events in each of the low and intermediate risk subgroups, meaningful statistical comparisons could not be made. Figure 2 provides a description of the rates of 30-day mortality, any MACE, and/or any postoperative complication between high risk EVAR-c and PAR patients. No significant differences in any of these composite outcomes are noted. More specifically, high risk EVAR-c patients are estimated to have 0.83 times the odds of 30-day death(95% CI 0.3–1.9; P = .7) compared to elective PAR patients. Similarly, no differences in risk of any MACE([OR .8, 0.4–1.4; P=.4 [15/79 EVAR-c (18.9%); 241/1010 PAR (23.9%)]) or any postoperative complication(OR 1.0, .5–2.1; P=.9 [23/79 EVAR-c (29.4%); 291/1010 PAR (28.8%)] is present. Specific details for individual types of complications in the high risk cohort are listed in Table V. With the exception of a higher rate of return to the OR for bleeding among the EVAR-c high risk cohort(EVAR-c, 6% vs. PAR, 3%; P = .03), no differences in any of the other outcome parameters is observed.

Survival

Overall, non-risk adjusted survival for EVAR-c patients compared to PAR patients at 1 and 5 years, respectively is: 87±3% vs. 93±1% and 82±5% vs. 79±1%(log-rank P<.001)(Figure 3). However, when examining estimated long-term survival among the highest risk patients, no significant differences are noted between EVAR-c and PAR patients: 1-year- EVAR-c, 89±4% vs. PAR, 86±1%; 5-year- EVAR-c, 82±5% vs. PAR, 66±2%; log-rank P =.4 (Kaplan Meier estimates of long-term mortality were not performed for the low and intermediate mortality risk EVAR-c and PAR patients due to limited numbers and follow-up time)(Figure 4).

Discussion

This study provides the first description of national outcomes after elective EVAR-c compared to native open AAA repair. Patients undergoing EVAR-c in the VQI are frequently older and have a higher incidence of cardiovascular comorbidities. EVAR-c is a complex procedure as reflected by longer operative times and greater blood loss compared

to native AAA repair. However, EVAR-c is completed more frequently with a more distal aortic cross-clamp and decreased need for concomitant procedures compared to PAR. Importantly, EVAR-c patients with risk profiles similar to PAR subjects have comparable postoperative complication and mortality rates.

When patients present with a failed EVAR, the ability to determine the probability of a successful outcome with elective EVAR-c is critical in deciding what remedial treatment plan to pursue. Prior studies of EVAR-c outcomes have lacked the unique patient and procedure-specific details that the VQI registry possesses. Moreover, this analysis of EVAR-c benchmarked to open juxtarenal AAA repair provides comparative outcomes that are unavailable in many single center, clinical trial and administrative data sets. The most important predictors of mortality after elective EVAR-c and PAR are related to patient related factors and aortic cross-clamp position, but not the need for endograft explantation. These findings can help identify patients who may be best served with timely open conversion for failed EVAR.

EVAR has largely supplanted open AAA repair over the last decade due to patient preferences, increasingly widespread availability of devices and the minimally invasive nature of the procedure that results in early morbidity and mortality benefits compared to PAR[29, 30]. As experience with EVAR has matured, the technology is being extended to more anatomically and physiologically complex patients, such as ruptured aneurysms, marginal iliac access/landing zones, or those with short angulated proximal seal zones[31, 32]. An important consequence of older generation devices accruing follow-up time and treatment of more difficult anatomies with modern devices may be higher rates of failure[33, 34]. Indeed, the rationale for pursuing this analysis is related to an increasing number of referrals to our own institution for failed EVAR[7].

In an effort to understand the risk of EVAR conversion, we recently performed a study at the University of Florida where we demonstrated that in an anatomically and physiologically analogous group of elective EVAR-c and PAR patients, similar rates of postoperative morbidity and mortality can be anticipated[7]. While EVAR-c was associated with increased operative complexity, short-term outcomes did not significantly differ when compared to a similar risk group of elective open AAA patients which reflects the results of this analysis.

At the core of every patient-physician discussion regarding elective prophylactic AAA repair is a thorough risk assessment. The risk of the natural history of the disease is compared to the operative risk and placed into the context of the overall patient life-expectancy. Contemporary results of elective native open AAA repair are uniformly excellent with 30-day mortality risk of 1–4%[16, 17, 35] while perioperative complication rates can be 25–50%[35, 36]. These results are consistent with the elective PAR outcomes in the VQI from this study, which represents a “real world” analysis of prospectively collected data from multiple institutions, regions and surgeons .

In contrast, reported outcomes of EVAR-c are heterogeneous and reflect the pooled data of patients presenting with various emergency, elective, and infectious indications[5, 9]. This is underscored in the EUROSTAR registry where conversion rates were 7.1%[37], which in

modern series is exceptionally high. Operative mortality in these patients exceeded 10%[37], however this data reflects an early look at first generation infrarenal devices and the inherent care disparities that occur with introduction of new disruptive technologies. A recent systematic review by Kouvelos et. al.[5] highlighted a 3.7% 30-day mortality risk for elective EVAR explantation which compares favorably to results of PAR and further supports a role for timely conversion of failed EVAR.

The decision to explant an endograft is influenced by a myriad of factors. Depending on the etiology of the underlying failure mechanism, simple endovascular remediation is often appropriate. This is supported by multiple reports endorsing the efficacy of endovascular salvage of failed EVAR, particularly as surgeons gain familiarity with more advanced endovascular techniques[23, 38]. These interventions can be relatively straightforward, such as infrarenal extension cuffs, device relining, and/or embolization[23, 24, 39]. All of these techniques have merit and should be viewed as complementary since they may afford advantages in specific cases. However, the frequent rationale for persisting with multiple endovascular re-interventions or attempting complex, off-label parallel stent and/or fenestrated salvage is the concern that EVAR explantation is associated with prohibitive risks[23, 24].

The perceived elevated risk of EVAR-c can often be attributed to the complexity of the operation; however several decisions can be made in the *elective* setting to mitigate the physiologic impact of the operation. For example, Marone et. al.[6] documented a 1.9% 30-day mortality and 31% composite morbidity rate for 54 patients who underwent EVAR-c. A device-specific surgical approach was advocated with a preference for placing an infrarenal cross-clamp, if anatomically feasible to safely complete the repair. Similarly, Nabi and colleagues[8] argue for partial endograft removal when possible to minimize aortic dissection, operative time, risk of aortic/iliac vessel injury and need for visceral/renal ischemia. Unfortunately, we do not have the level of detail in the VQI AAA registry that allows determination of the exact conduct of the EVAR explantation, the type of device explanted, or whether any endograft was left *in situ*, to corroborate these authors.

However, it is our hypothesis that this analysis supports the notion that surgeons are likely altering the surgical plan to simplify a technically demanding procedure and mitigate patient risk with EVAR-c. This is evidenced by the fact that the aortic cross-clamp position was more often distal to PAR patients, as well as the fact that fewer concomitant procedures occurred. EVAR-c subjects are generally older with more comorbidities compared to the PAR patients so it is expected that the non-risk adjusted perioperative outcomes and long-term survival analysis would demonstrate significant differences. However, when the patients at highest risk of developing postoperative mortality are compared, similar rates of complications and long-term survival occurred(Table V & Figure 4).

This finding is significant since if the need to explant the endograft was inherently more risky compared to PAR, this effect should be observed in the most vulnerable subset of patients. We performed several different types of analyses to explore the risk of EVAR-c and this variable was not independently associated with worse outcomes. It appears that EVAR-c is more likely a marker for a patient subgroup that has higher prevalence of

multiple risk factors known to impact postoperative outcomes after elective AAA repair. The predictors that most influenced outcomes were patient and procedure related factors all of which have been reported previously[40].

Limitations

The findings in this study must be considered within the context of its limitations. We concede the presence of selection bias in the dataset and the fact that patients who are potentially at highest risk for complications after EVAR-c may be undergoing endovascular remediation or left untreated. Similar bias would be expected to exist in the PAR group. We also cannot comment on the actual rate of EVAR-c in VQI registry patients due to the potential for VQI patients to undergo EVAR remediation or conversion at non-VQI institutions. As mentioned, this study lacks information regarding the specific reason for conversion or the type of graft that was explanted. Both of these variables can significantly impact perioperative planning. Also as mentioned previously, no information is available in the registry to describe whether partial or total endograft removal occurred. Although this is the largest single series describing EVAR-c outcomes in the current literature, there are still relatively few observations which limit the ability to perform robust statistical analyses of different patient subsets.

While the mortality risk adjustment model derived in this study allowed for the most accurate 30-day mortality prediction and risk stratification in order to determine the true additive risk of EVAR-c over PAR, it has not been validated on other open aortic aneurysm repair populations. Twenty-three percent of the EVAR-c patients had missing information on the 30-day mortality outcome variable due to limitations in updates of Social Security Death Index Masterfile. We cannot account for this missingness for an outcome variable and this may add further uncertainty about the results of the analysis. No reintervention, readmission, and/or cost data is available within the registry to provide more context of the risk of EVAR conversion benchmarked to PAR. Importantly, there is no comparison to a cohort who underwent endovascular remediation of failed EVAR. Finally, no specific insight about regional and center-specific outcomes can be provided due to a lack of sufficient ‘high-volume’ centers to make meaningful comparisons (only 15 of 162 centers (9.3%) in the VQI perform > 20 open AAA repairs/year). Despite these shortcomings, the data provided should provide a means for further identifying patients who would be best served with timely EVAR-c and improve quality of open AAA care nationally.

Conclusions

Elective EVAR-c patients are older with more comorbidities compared to elective PAR patients. EVAR-c is a more complex operation compared to PAR; however postoperative complication and mortality rates are similar when controlling for patient factors and cross-clamp position. Endograft explantation does not appear to be an important driver of outcomes as patient covariates and other intraoperative factors are more predictive. Several preoperative factors are identified that can reliably predict 30-day mortality after elective EVAR-c and/or PAR. These data should be considered during patient/family discussions and prior to endovascular salvage procedures and/or open conversion of failed EVAR.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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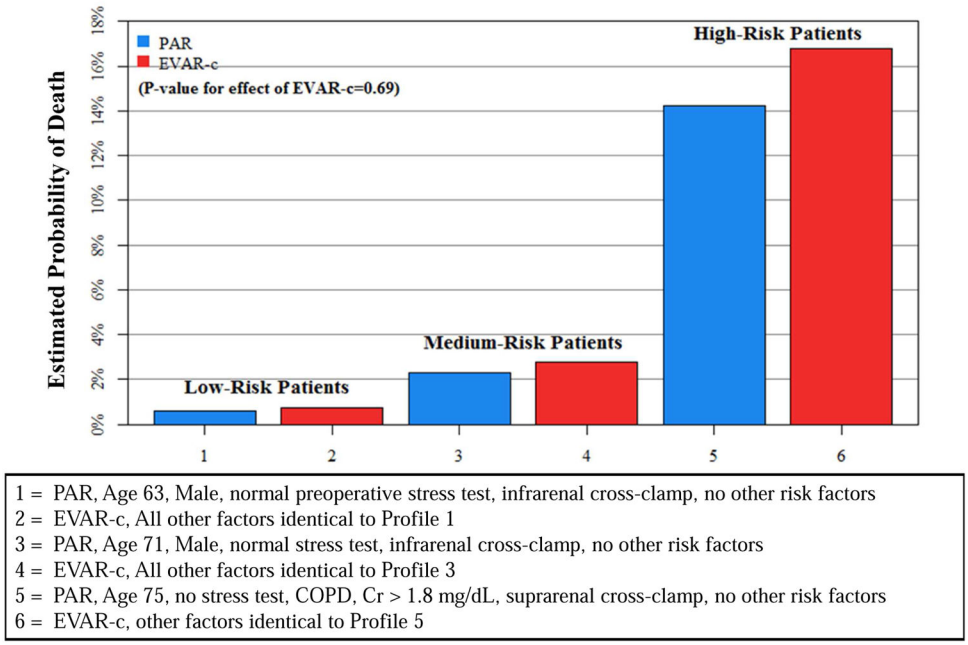

Figure 1. Estimated Probability of Death within 30-days after EVAR Conversion or Primary Aortic Repair for 6 Different Patient Risk Profiles

The figure depicts 6 theoretical patients with combinations of different preoperative risk factors that result in different predicted 30-day mortality risk. Notably, EVAR conversion is not a factor in our risk model. Based on the prediction model derived from the dataset, these patients are representative of low, intermediate and high risk based on the assigned tertile of risk. The graphic reflects estimated probabilities from a model that includes EVAR conversion, as well as all the factors in the original risk model. While the graphic may seem to imply that conversion is a risk factor, the EVAR conversion variable was discarded from the original multivariable 30-day mortality model because it was not associated with mortality. The graphic shows a slight increase in risk for EVAR conversion compared to Primary Aortic Repair however, the P-value for the effect of conversion is .69, indicating that there is no statistical reason to believe that the true ‘additive risk’ of the EVAR conversion variable is not 0 or going in the opposite direction (which would potentially mean higher risk for Primary Aortic Repair compared to EVAR conversion).

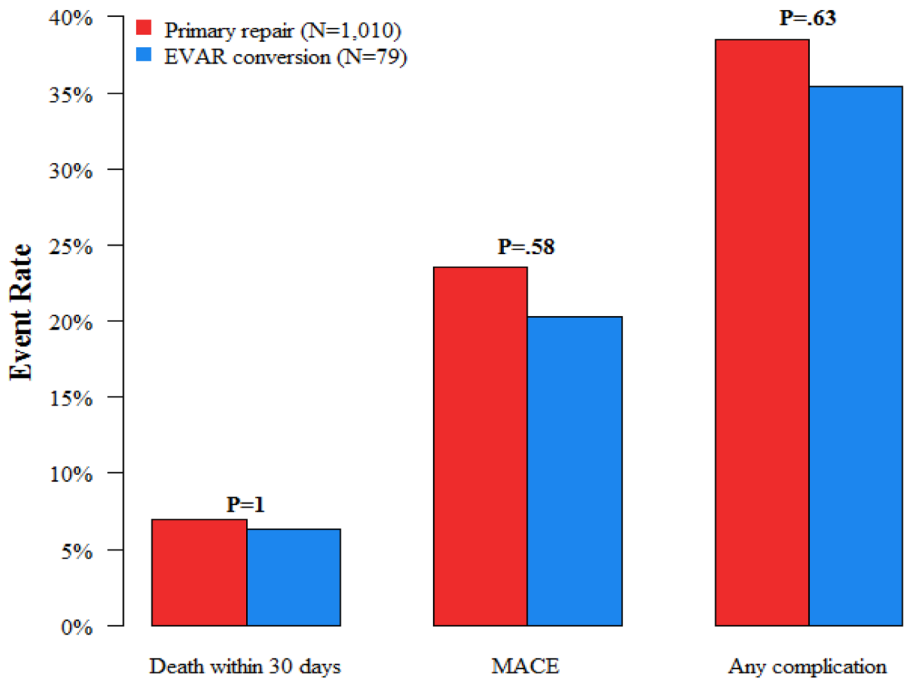

Figure 2. Comparison of the Rate of Postoperative Complications for High Risk Patients undergoing EVAR-c and PAR in the VQI

This figure demonstrates that among the highest tertile of 30-day mortality risk that there is no significant difference in the rate of any major postoperative complications, major adverse cardiac events or 30-day death among Primary Aortic Repair and EVAR conversion patients. Note that 72% of the EVAR conversion patients fall into the highest risk tertile for postoperative 30-day mortality reflecting a subset of patients with a higher prevalence of significant demographic and cardiovascular covariates that independently predict likelihood of postoperative death.

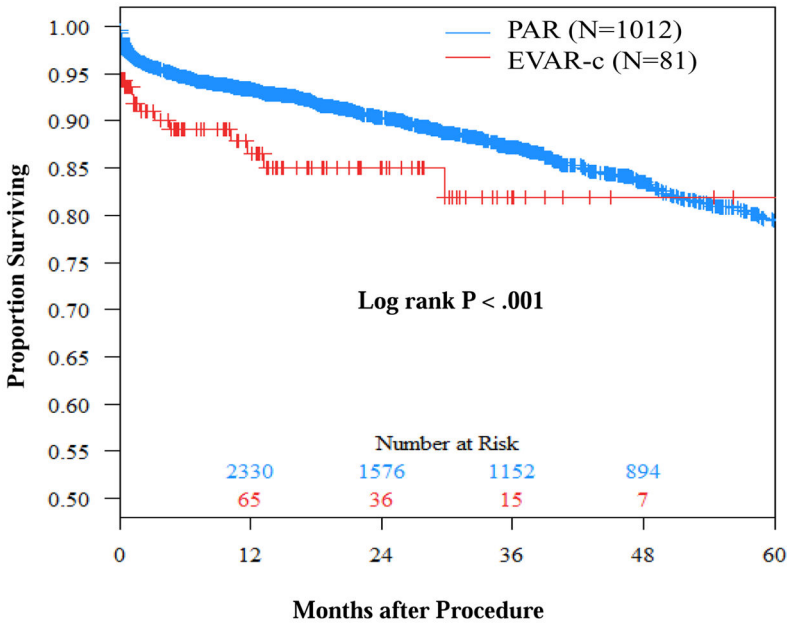

Figure 3. Non-risk Adjusted Survival after Elective EVAR-c and PAR in the VQI

This *Non-risk adjusted* Kaplan-Meier curve provides the estimated survival for all patients in the analysis. As expected, the EVAR conversion patients have worse overall survival compared to the Primary Aortic Repair patients (Log rank P < .001) due to the fact that they have a higher incidence of important mortality predictors. All displayed intervals have less than 10% standard error of the mean.

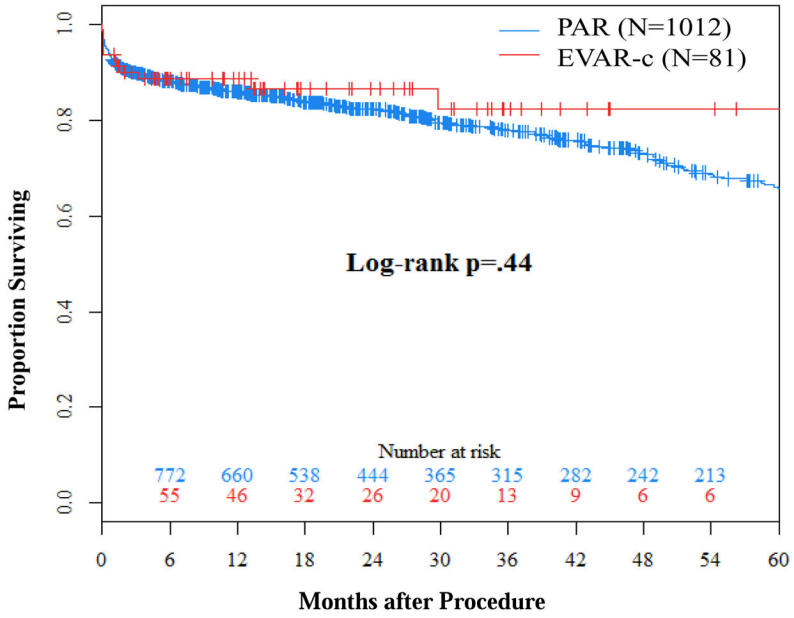

Figure 4. Risk Adjusted Survival after Elective EVAR-c and PAR in the VQI

Survival analysis among high risk patients demonstrates no difference (Log-rank P = .44) in outcome among EVAR conversion and Primary Aortic Repair patients. This further supports the concept that when controlling for patient and procedure related predictors of postoperative mortality that the need for endograft explantation in and of itself is not an important driver of this outcome. All displayed intervals have less than 10% standard error of the mean.

Table I

Demographics and comorbidities of elective EVAR-c and PAR

Feature, %(No.)	EVAR-c (N = 159)	PAR (N = 3,741)	P-value[a]
Age, years±SD	73.5 (8.1)	69.5 (8.4)	<.0001
Male gender	74%(117)	73%(2741)	.9
BMI	28±5	27±5	.07
Comorbidities			
Hypertension	84%(134)	84%(3138)	1
Coronary disease	28%(44)	27%(1020)	.9
Abnormal stress test	13%(20)	14%(530)	.8
Prior CABG/PCI	38%(60)	31%(1146)	.07
Congestive heart failure	11%(17)	7%(252)	.08
Current smoker	21%(33)	43%(1622)	<.0001
Chronic obstructive pulmonary disease	30%(47)	33%(1226)	.4
Creatinine > 1.8 mg/dL	8%(12)	6%(223)	.5
Diabetes mellitus	21%(34)	15%(553)	.03
Prior leg bypass	9%(14)	4%(149)	.006
Prior carotid revascularization	7%(11)	7%(248)	1

[a]Chi-square or Fisher's exact tests to compare the groups on nominal categorical variables and Mann-Whitney tests to compare them on continuous and ordered categorical variables when appropriate. SD, standard deviation; BMI, body mass index; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; Prior carotid revascularization includes preoperative history of carotid endarterectomy and/or angioplasty/stent placement

Table II

Operative variables for elective EVAR-c and PAR

Feature, %(No.)	EVAR-c (N = 159)	PAR (N = 3,741)	P-value[a]
Retroperitoneal aortic exposure	41%(65)	26%(972)	<.0001
Any concomitant procedure	18%(28)	26%(972)	.03
Thromboembolectomy	3%(4)	6%(165)	
Renal bypass	7%(11)	9%(247)	
Infrainguinal bypass	2%(3)	3%(80)	
Other abdominal	10%(15)	12%(345)	
Non-tube graft repair	65%(101)	52%(1923)	.001
Crystalloid (mL)[b]	4500 [3000, 6500]	4300 [3000, 5800]	.4
Estimated blood loss (mL) [b]	2000 [1010, 3500]	1200 [750, 2000]	<.0001
Transfused red blood cells (units) [b]	2 [0, 4]	0 [0, 1]	<.0001
Autotransfusion (mL) [b]	787 [482, 1440]	504 [255, 974]	<.0001
Cross-clamp level			
Supra-celiac	13%(20)	8%(262)	
Supra-superior mesenteric	43%(68)	61%(2282)	
Supra/Intrarenal	44%(70)	31%(1159)	<.0001
Renal/Visceral ischemia time (min) [b]	10 [0, 25]	0 [0, 24]	.0001
Total procedure time (min±SD)	275±122	232±99	<.0001

[a] Chi-square or Fisher's exact tests to compare the groups on nominal categorical variables and Mann-Whitney tests to compare them on continuous and ordered categorical variables when appropriate. mL, milliliters; min, minutes;

[b] Median[interquartile range]; SD, standard deviation

Table III

Non-risk adjusted postoperative outcomes after elective EVAR-c and PAR

Outcome, %(No.)	EVAR-c (N = 159)	PAR (N = 3,741)	P-value[a]
30-day mortality	8%(12)	3%(112)	.01
Length of stay (days)[b]	6 [6, 12]	7 [5, 9]	.01
Total ICU stay (days)[b]	3 [2, 5]	2 [1, 4]	<.0001
Any postoperative complication	33%(52)	28%(1056)	.3
MACE	20%(32)	16%(611)	.4
Pulmonary	16%(25)	11%(418)	.04
Renal			
Creatinine increase > 0.5 mg/dL	21%(33)	12%(448)	
Permanent dialysis	1%(1)	1%(37)	.002
Any return to the OR	9%(14)	7%(261)	.4
Return to OR for bleeding	7%(11)	2%(74)	<.0001
Bowel ischemia	3%(5)	3%(112)	1
Leg ischemia	1%(1)	2%(74)	.6

[a] Chi-square or Fisher's exact tests to compare the groups on nominal categorical variables and Mann-Whitney tests to compare them on continuous and ordered categorical variables when appropriate.

[b] Median[interquartile rage]; MACE, major adverse cardiac event includes in-hospital myocardial infarction, arrhythmia and/or congestive heart failure; OR, operating room

Table IV

Preoperative predictors of 30-day mortality after elective EVAR-c and/or PAR

Covariate	Odds ratio	95% C.I.	P-values
Age	multiplies 1.06/yr	1.04–1.1	<.0001
Chronic obstructive pulmonary disease	2.4	1.6–3.5	<.0001
Prior leg bypass	2.3	1.2–4.4	.01
Suprarenal cross-clamp	2.2	1.2–4.1	.01
Prior carotid revascularization	2.2	1.3–3.8	.004
Current smoker	2.2	.9–5.5	.1
Congestive heart failure	1.8	.9–3.5	.08
Creatinine > 1.8 mg/dL	1.7	.9–3.1	.06
Female gender	1.6	1.1–2.3	.02
Abnormal stress test	1.3	.7–2.4	.3

Table V

Postoperative outcomes among high risk patients after elective EVAR-c and PAR

Outcome, %(No.)	EVAR-c (N = 79)	PAR (N = 1010)	P-value[a]
30-day mortality	6%(5)	7%(70)	1
Length of stay (days)[b]	8 [6, 14]	8 [6, 11]	.6
Total ICU stay (days)[b]	3 [2, 6]	3 [1, 5]	.8
Any postoperative complication	35%(28)	39%(389)	.3
MACE	20%(16)	24%(238)	.6
Pulmonary	20%(196)	20%(202)	1
Renal			
Creatinine increase > 0.5 mg/dL	18%(14)	20%(202)	.8
Permanent dialysis	1%(1)	1%(10)	1
Any return to the OR	9%(7)	11%(108)	.7
Return to OR for bleeding	6%(5)	3%(26)	.03
Bowel ischemia and/or ileus	5%(4)	6%(60)	1
Leg ischemia	1%(1)	3%(33)	.5

[a] Chi-square or Fisher's exact tests to compare the groups on nominal categorical variables and Mann-Whitney tests to compare them on continuous and ordered categorical variables when appropriate.

[b] Median[interquartile range]; MACE, major adverse cardiac event includes in-hospital myocardial infarction, arrhythmia and/or congestive heart failure