Performance of endovascular aortic aneurysm repair in high-risk patients: Results from the Veterans Affairs National Surgical Quality Improvement Program

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Objective: Recent results after endovascular abdominal aortic aneurysm repair (EVAR) have brought into question its value in patients deemed at high-risk for surgical intervention. The Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP) is the largest prospectively collected and validated United States surgical database representing current clinical practice. The purpose of our study was to evaluate outcomes after elective EVAR performed in high-risk veterans.

Methods: Using NSQIP data from 123 participating VA hospitals, we retrospectively evaluated patients who underwent elective aneurysm repair from May 2001 to December 2004. High-risk criteria were used to identify a cohort for analysis (EVAR, n = 788; open, n = 1580). High-risk criteria analyzed included age ≥60 years, American Society of Anesthesiology (ASA) classification 3 or 4, and the comorbidity variables of history of cardiac, respiratory, or hepatic disease, cardiac revascularization, renal insufficiency, and low serum albumin level. Our primary end points were 30-day and 1-year all-cause mortality, and we evaluated a secondary end point of perioperative complications. Statistical analysis included univariate analysis and multivariate modeling.

Results: Veterans who were classified as high-risk underwent elective EVAR with significantly lower 30-day (3.4% vs 5.2%, P = .047) and 1-year all-cause mortality (9.5% vs 12.4%, P = .038) than patients having open repair. EVAR was associated with a decrease in 30-day postoperative mortality (adjusted odds ratio [OR], 0.65; 95% confidence interval [CI], 0.42 to 1.03; P = .067) as well as 1-year mortality (adjusted OR, 0.68; 95% CI, 0.51 to 0.91; P = .0094) despite the presence of severe comorbid conditions. The risk of perioperative complications was significantly lower after EVAR (16.2% vs 31.0%; P < .0001; adjusted OR, 0.41; 95% CI, 0.33 to 0.52; P < .0001). A subset analysis of higher-risk patients (ASA 4 and the above comorbidity variables) still demonstrated an acceptable 30-day mortality rate.

Conclusion: In veterans deemed high-risk for surgical therapy, outcomes after elective EVAR are excellent, and the procedure is relatively safe in this special patient population. Our retrospective data demonstrate that patients with considerable medical comorbidities and infrarenal abdominal aortic aneurysms benefit from and should be considered for primary EVAR. (J Vasc Surg 2007;45:227-34.)

Endovascular abdominal aortic aneurysm (AAA) repair (EVAR) is a major advance in minimally invasive surgical technology because of the potential for reducing perioperative morbidity and mortality as well as recovery time, especially in patients deemed at high surgical risk by conventional open standards. The rapid evolution of endoluminal devices and surgical and anesthetic techniques during the past decade has allowed higher-risk patients, including octogenarians and others considered medically unfit for conventional open repair, to be offered EVAR as an alternative to observation alone.

Many retrospective, single institution studies documenting acceptable morbidity and mortality rates following EVAR in special high-risk patient populations are available.
in the literature. Furthermore, a recent analysis of high-risk patients using the Society of Vascular Surgery database for EVAR (registry established in 1998) concluded that endovascular repair is safe and effective in preventing aneurysm rupture.

Conversely, in prospective, randomized trials comparing EVAR with open surgical repair, patients who were considered to be at excessive surgical risk and medically unfit for conventional open repair were excluded from participation. In the recently published EVAR Trial 2 performed in the United Kingdom, this subset of excluded patients were further studied by being randomized to either EVAR or no intervention. The 30-day mortality rate of 9% and the 4-year mortality of 64% are both much higher than has been previously reported in high-risk patient cohorts. Furthermore, the investigators found no survival advantage after repair compared with those who had observation alone.

This prospective and randomized trial, with its level I evidence, has thus challenged the promising outcomes considered to be associated with EVAR in high-risk individuals. These data have resulted in suggestions that perhaps EVAR should not be performed in select high-risk individuals owing to the possibility of poor outcomes and lack of improvement in survival, both at excessive financial expenditure.

In the United States, no prospective, randomized trial similar to EVAR Trial 2 has been completed to date. The availability of data that demonstrate positive outcomes with EVAR in high-risk patients, who represent those treated in routine surgical practices, is paramount to physician, patient, and policy-makers alike. The National Surgical Quality Improvement Program (NSQIP) represents a large, validated, prospective data set that is organized and implemented through the Department of Veteran Affairs (VA). The purpose of our study was to compare postoperative mortality and complications as well as survival in high-risk patients undergoing elective EVAR vs open repair within a national publicly funded health care system using a large prospective cohort.

PATIENTS AND METHODS

Data sources and sample. All patients who underwent either EVAR or open abdominal aortic aneurysm repair between May 1, 2001, and December 31, 2004, were identified through the VA NSQIP database of surgical procedures performed at 123 participating VA hospitals. We chose this time frame because before May 2001, no suitable current procedural terminology (CPT) codes existed in the database for EVAR, although endovascular grafting systems were approved by the US Food and Drug Administration and became commercially available in September 1999.

Patients undergoing elective repair were defined by the primary International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnostic code 441.4 (intact, nonruptured abdominal aortic aneurysm). Open AAA repairs were defined by CPT codes 35081 and 35102. EVAR was defined by codes 34800, 34802, and 34804. Patients with secondary diagnostic codes for ruptured AAA or thoracic or thoracoabdominal aortic aneurysm were excluded from the analysis. CPT codes representing open repair after EVAR (34830, 34831, 34832) were also excluded from primary analysis.

The NSQIP database contains very detailed, prospectively collected clinical data on all patients undergoing major surgical procedures within the VA. At the time of surgery, patients are enrolled in NSQIP, and baseline demographic, preoperative laboratory, and clinical information is collected by dedicated trained nurse reviewers. Additional perioperative data are prospectively collected by the nurses, including 30-day morbidity and mortality information.

To supplement the information in the NSQIP records with longer-term utilization and vital statistics data, we used encrypted Social Security numbers, date of admission, date of discharge, and primary operative date to link the NSQIP database with the VA Patient Treatment File (PTF), which contains abstracts of all patients discharged from all VA hospitals. To obtain additional information, we similarly linked the VA Outpatient Clinic File (OPC), which contains records for every outpatient visit to a VA facility. Linkage to the VA Beneficiary Identification Record Locator System (BIRLS) was performed to assess mortality data. The sensitivity of the BIRLS to estimate death rates of inpatients has been demonstrated in several studies to be approximately 87% to 95%. Approval for the study was obtained from the Baylor College of Medicine Institutional Review Board and the Michael E. DeBakey VA Medical Center Research and Development Review Committee.

Definition of independent variables. Patient demographic data are recorded prospectively in the NSQIP database, including age, gender, race, and hospital location. Comorbid conditions known to have an influence on the risk of cardiovascular morbidity and mortality were chosen for analysis. These independent variables were defined using NSQIP definitions and the ICD-9-CM codes. Within NSQIP, nurse reviewers recorded diabetes (persons using insulin or oral hypoglycemic agent), renal dysfunction or dialysis dependence, hepatic dysfunction, history of malignancy, history of congestive heart failure during the month preceding surgery, history of stroke or transient ischemic attacks, functional status, and tobacco use within the year preceding AAA repair.

We additionally identified 24 individual comorbid conditions and included a separate variable for elevated creatinine (≥2.0 mg/dL) that was based on the Revised Cardiac Risk Index. American Society of Anesthesiology (ASA) classification was included as a subjective estimation of a patient’s preoperative risk and baseline comorbid status. Both the inpatient (PTF) and outpatient (OPC) files were searched for matching ICD-9-CM codes 1 year before the operation date to ensure accuracy of comorbidity status.

Definition of a high-risk cohort. High-risk criteria were used to identify a cohort for analysis. Minimum criteria for entry into our study included age ≥60 years and ASA
classifications 3 or 4. We further classified patients according to the comorbidity variables of history of cardiac, respiratory, or hepatic disease, cardiac revascularization, renal insufficiency, and low serum albumin. Because hypoalbuminemia has been shown to be associated with adverse surgical outcomes, preoperative serum albumin concentration was analyzed as an independent variable. We defined a low albumin level of <3.4 g/L, which represents the 10th percentile in this cohort.

**Outcome measures.** The outcomes of interest included 30-day and 1-year mortality and any perioperative (30-day) complications. The 30-day mortality was obtained from the NSQIP database, and 1-year mortality was calculated using death dates obtained from BIRLS and the PTF.

Perioperative complications from the NSQIP (see Appendix, online only) were aggregated into categories, including adverse cardiac events, renal dysfunction, pulmonary complications, wound complications, neurologic complications, postoperative bleeding requiring transfusion, and graft failure. Unfortunately, the original NSQIP guideline does not have a strict definition for what constitutes a “graft failure” except for a return to the operating room. This term is not specific to endovascular devices; thus, this variable may be misleading and difficult to analyze in a meaningful way. Within the data sets used, specific analysis of secondary interventions was not possible.

Postoperative length of stay and intensive care unit length of stay were calculated by using the date of surgical repair as the index date. Complete vital status information (either via death or follow-up records) was available on all patients at 30 days and at 1 year.

**Statistical analysis.** All clinical outcomes of interest were tested for association with type of AAA repair and with the presence of the six additional high-risk comorbidities as defined. The effect of type of operation performed was then tested for its unique association with the morbidity and mortality outcomes (30-day, 365-day, any complication), after adjusting for the number of high-risk comorbidities and 20 additional demographic and clinical covariates in multivariable logistic regression models. A significance level of 0.10 was required to stay in the final model. This model was selected arbitrarily to capture as many possible confounding factors that might be strongly associated with both the selection of EVAR and postoperative outcomes. Models were assessed for goodness of fit by the Hosmer-Lemeshow statistic and for discrimination by the c-index.

Additional assessment of time to death was made using Kaplan-Meier estimators and log-rank tests. All P values reported are two-sided.

**RESULTS**

**Patient population.** From the NSQIP database, we initially identified 2966 elective repairs of nonruptured aneurysms that occurred between the time period of interest and that met the minimum criteria of age ≥60 and ASA class 3 or 4. Further classification with our high-risk criteria narrowed the cohort for analysis to 788 patients who underwent EVAR and 1580 patients who underwent open repair.

Basic demographic characteristics of the sample and prevalence of high-risk comorbid conditions are summarized in Table I. EVAR patients were on average age about 1 year older (P < .001). Less than 1% of all patients were women. Racial/ethnicity distribution did not vary by type of surgery; more than three quarters of all patients were white, with at least 7% black and 2% Hispanic. Approximately 58% of the patients had respiratory disease, 20% had prior revascularization, about 75% had cardiac disease, 4% to 5% had hepatic disease, and 16% had a low serum albumin level. With the exception of renal disease, which was more frequent among open repair patients (P = .014), the prevalence of high-risk conditions was similar for patients receiving both types of surgery.

**Outcome measures.** The crude, unadjusted association of type of surgery with clinical outcomes, and the risk associated with increasing number of high-risk comorbidities are presented in Table II. The 30-day mortality rates were 5.2% for patients undergoing open repair compared with 3.4% for patients receiving EVAR (P = .047). One-year mortality and perioperative complications were similarly reduced in EVAR patients (P = .038 and P < .0001, respectively). About 20% of patients undergoing each type of surgery had none of the additional high-risk comorbidities when the NSQIP data were cross-linked to the PTF and PTF data sets, indicating that four fifths had at least one or the high-risk conditions. Our final analysis included only patients identified from the NSQIP that had at least one of the high-risk conditions in addition to age ≥60 years and ASA class 3 or 4.

Table II also presents the adjusted odds ratios (OR) and 95% confidence intervals (CI) for the association of
type of surgery with outcomes, after adjusting for the number of high-risk conditions and additional covariates. Risk of all clinical outcomes was reduced in patients undergoing EVAR compared with patients receiving open repair: the ORs for EVAR were 0.65 for 30-day mortality (95% CI, 0.42 to 1.03), 0.68 for 1-year mortality (95% CI, 0.51 to 0.91), and 0.41 for any complication (95% CI, 0.33 to 0.52). Among patients receiving open repair, this converts to a relative increased risk of 1.56 for 30-day mortality, 1.47 for 1-year mortality, and 2.33 for complications.

In stratified analyses (Fig 1, 2, and 3), the risk of all clinical outcomes increased dramatically as the number of these conditions increased and was generally lower among patients receiving EVAR across strata. We were able to obtain 2-year data on patients in the cohort via linkage with the BIRLS database. Fig 4 shows the survival advantage in EVAR patients compared with open repair for 2-year follow-up (log-rank test \[ \chi^2 = 5.23, P = .0222 \]). In addition, postoperative length of stay averaged 5.6 days for patients receiving EVAR compared with 12.6 days for patients receiving open repair (data not shown, \( P < .0001 \)).

Highest-risk cohort. A separate analysis of only the 721 patients with ASA class 4 showed a crude 30-day mortality rate of 5.6% (14/249) in EVAR patients and 7.0% (33/472) in open repair patients (\( P = .48 \)). The 1-year crude mortality rates were 12.8% in EVAR patients and 16.7% in open patients (\( P = .17 \)). Although neither the 30-day nor 1-year rates were statistically different, a beneficial trend was seen with EVAR. Furthermore, the proportion of patients with complications was significantly reduced in the EVAR patients (22.1%) compared with open repair patients (35.8%; \( P = .0002 \)).

DISCUSSION

In this unique cohort of US veterans, representing routine surgical practice, high-risk patients presenting for elective AAA repair who underwent EVAR had statistically significantly lower risk-adjusted perioperative mortality rates, lower complication rates, improved survival, and shorter lengths of stay compared to patients having open repair. Furthermore, even the highest risk patients, those with the ASA 4 classification, were found to benefit from EVAR with lower mortality and morbidity rates compared to open surgical counterparts. Our findings with regard to outcomes following EVAR and open AAA repair are consistent with several other published observational studies, with additional survival information via database linkage.2-5,9,25,26 The results herein are also similar to a previous study we published on a smaller, veteran cohort which included all elective aneurysm repairs. The similarities in findings are not surprising as others have suggested that patients presenting for treatment in the VA system may have more comorbidities and a greater illness burden than non-VA patients.27 Thus, a greater percentage of patients will match a “high-risk” definition. The fact that our study

Table II. Outcomes, adjusted odds ratios, and 95% confidence intervals for the association of type of surgery with outcomes*

<table>
<thead>
<tr>
<th></th>
<th>EVAR n = 788 (%)</th>
<th>Open n = 1580 (%)</th>
<th>OR* (EVAR)</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day mortality</td>
<td>27 (3.4)</td>
<td>83 (5.2)</td>
<td>0.65</td>
<td>0.42, 1.03</td>
<td>0.067</td>
</tr>
<tr>
<td>1-year mortality</td>
<td>75 (9.5)</td>
<td>196 (12.4)</td>
<td>0.68</td>
<td>0.51, 0.91</td>
<td>.0094</td>
</tr>
<tr>
<td>Any complication</td>
<td>128 (16.2)</td>
<td>490 (31.0)</td>
<td>0.41</td>
<td>0.33, 0.52</td>
<td>&lt;.0001</td>
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EVAR, Endovascular aneurysm repair; OR, odds ratio; CI, confidence interval.

*Adjusted for count of high-risk conditions and 20 additional demographic and clinical covariables.

Fig 1. Bar graph shows the unadjusted association between types of surgery, either endovascular aneurysm repair (EVAR) or open repair, and 30-day mortality rates stratified by number of surgical risk factors. The \( P \) value reflects comparison between Open (clear bars) and EVAR (shaded bars) within the level of risk factors.

Fig 2. Bar graph shows the unadjusted association between types of surgery, either endovascular aneurysm repair (EVAR) or open repair, and 1-year mortality rates stratified by number of surgical risk factors. The \( P \) value reflects comparison between Open (clear bars) and EVAR (shaded bars) within the level of risk factors.
The NSQIP was prompted in 1986 by a congressional mandate and officially established in 1994 by the Veterans Health Administration. Though there are inherent deficiencies within retrospective data analyses, the NSQIP meticulous data collection methods and their effectiveness have been validated in multiple studies.28-30 We used the NSQIP database to identify our cohort based upon set criteria as outlined herein. With data from 123 institutions, the information contained within the NSQIP is robust with respect to variability in surgical techniques and skills as well as in cohort size, albeit procedure (and device) specific variables are not included. Moreover, data entry into NSQIP does not have the patient or aneurysm morphology exclusion criteria that randomized trials contain, increasing the generalizability of our findings beyond VA patients. Furthermore, we cross-referenced the NSQIP data with both the inpatient and outpatient VA files to ensure accuracy of comorbidity and ICD-9 code reporting and thus, the actual presence of discrete co-morbidities of interest.

The criteria used for defining what constitutes a “high-risk” patient differ among clinical reports. Whether the patient is considered at “high-risk” or medically unfit for a specific operation, such as open AAA repair, may depend upon either specific criterion or upon guidelines established by the trial designers. In prospective, randomized trials comparing open to endovascular AAA repair, such as the Dutch and United Kingdom (UK) trials,11,31 patients who were medically unfit for open surgical repair were essentially excluded from the randomization process. In the UK trial, the determination of fitness for surgery was left to the discretion of the local physicians participating in the trial.32 Guidelines for high-risk criteria, such as poor cardiac or respiratory status, were suggested but the presence or absence did not definitively determine trial eligibility. In many retrospective analyses, investigators establish inclusion/exclusion criteria based upon advanced age and coexisting medical conditions, for which the database of choice may be queried. There is now much information regarding successful operations in high-risk individuals due to improvements in anesthetic options, surgical techniques, and intensive care management.

Data from recent prospective, randomized trials evaluating elective AAA repair provides compelling Level One evidence for performing EVAR in patients “judged fit for open repair”.11,31 Patients who were not deemed “medically fit for open repair” were then placed into EVAR Trial 2 in which patients were randomized to EVAR or no intervention. Within the high-risk cohort, twenty-five percent of the patients randomized to observation ultimately underwent aneurysm repair at the request of the patients or treating physician. These post-randomization crossovers may lead to bias if the crossover occurred in order to potentially avoid a worse outcome. Thus, the inability to evaluate the true effect of the “intervention”, EVAR or surveillance, may have resulted. However, the EVAR Trial 2 authors do state that an per protocol analysis demonstrated similar results. Many reasons may exist for the reported mortality rates in either group: time interval between randomization and repair leading to ruptures prior to repair, complex patient care secondary to coexisting medical conditions, or lack of preoperative medical treatments (statins and β-blocker medication use). At 4 years of follow-up, there was no difference in all-cause mortality between the EVAR and no intervention patients. This is not surprising as aneurysm-related events are not common beyond the perioperative period and patients generally succumb from causes unrelated to their AAA. Furthermore, aneurysm-related deaths can only be accurately determined by a post-mortem examination or rupture seen on an imaging study prior to death. However, obtaining an autopsy is generally not a common occurrence especially if a patient dies outside of a hospital setting.
Several studies have performed cost analyses and have determined that EVAR is a more expensive treatment than open aneurysm repair\textsuperscript{13,36} and no intervention.\textsuperscript{12} The main difference in the two types of surgical repair is due to the increased costs of endovascular grafts and the lifelong surveillance and follow-up costs after EVAR none of which were available to us through the NSQIP. In an analysis of specific prospective studies, a recent Belgium document has concluded that EVAR is not cost-effective, and thus, there is no validation for widespread use.\textsuperscript{57} A full discussion on health care reimbursement, and whether or not certain costly procedures such as EVAR should be restricted, is beyond the scope of this manuscript.

Equal opportunities for good surgical outcomes do not exist among all persons. Circumstances transpire where a person’s illness or disability significantly reduce their opportunity to respond to a therapy, such as any of the criteria that we used in our definition of a high-risk surgical patient. Society is not obligated to spend whatever it must to provide them with such a therapy. However, society is obligated to provide persons with the chance to optimize their enjoyment of life, within the constraints of their disease or disability. In some, the presence of a large or expanding aneurysm, may contribute significantly to their psychological ability to enjoy life, as well as knowing that the outcomes following ruptured AAA repair remain dismal. Quality of life is not reported to the NSQIP but most recent studies have shown that though quality of life is improved in the perioperative period following EVAR compared to open repair, there is no difference when patients are surveyed at remote time points.\textsuperscript{12,39,39} It is clear from these published studies that EVAR is associated with early improvements in physical mobility and pain as well as a likelihood for a patient to be discharged to home rather than an institution.\textsuperscript{40,41} Rationing parameters for health care resources are admittedly controversial and generate ethical dilemmas. It has been suggested that perhaps EVAR should be restricted to those patients who are “fit” for surgery, by whatever definition deemed appropriate, as the procedure, the endovascular devices, the continuing need for surveillance imaging, and possible secondary reinterventions are costly.

Decidedly, there are several limitations to our analysis in addition to the deficiencies inherent in a retrospective design. Furthermore, direct comparisons to currently published literature are impossible due to dissimilarities in study design and content of data collected. Our comparison was between EVAR and open repair as we do not have a surveillance arm for control comparison. As previously stated, the NSQIP does not contain aneurysm size which has been shown to correlate with outcomes. Additionally, we do not have cause of death and hence, use the term “all-cause mortality” in stating our results. The use of the BIRLS database, which contains death dates regardless whether or not the death occurs in a VA facility, has been demonstrated to miss approximately 5% to 10% of veteran decedents.\textsuperscript{42} Nonetheless, we have no reason to believe that more EVAR deaths than open deaths were overlooked in our study. Lastly, patients served at VA hospitals are predominantly men. One might suggest that our results could be positively biased as women may have worse results after elective AAA repair (either open or EVAR). However, the proportion of men is the same for both cohorts.

**CONCLUSIONS**

In the absence of a prospective, randomized trial, this large patient cohort, representing routine clinical practice, demonstrated the superiority of endovascular repair over open repair in veterans deemed high risk for surgical therapy. Our outcomes after elective EVAR are excellent, although we compared EVAR with open repair and did not have a surveillance arm\textsuperscript{10} for comparison. Our data demonstrate that patients with considerable medical comorbidities and abdominal aortic aneurysms benefit from and should be considered for primary EVAR.

We are grateful for the advice and support given by Drs Robert B. Rutherford and Ralph G. DePalma.

**AUTHOR CONTRIBUTIONS**

Conception and design: RB, MJ, ABL.

Analysis and interpretation: RB, MJ, WH.

Data collection: RB, MJ.

Writing the article: RB, MJ, NH, ABL, WH.

Critical revision of the article: PHL.

Final approval of the article: RB, MJ, WH.

Statistical analysis: MJ.

Obtained funding: RB.

Overall responsibility: RB.

**REFERENCES**


DISCUSSION

Dr Gregorio Sicard (St. Louis, Mo). I really congratulate Dr Bush for this excellent paper. The NSQIP database is serving as a model for outcomes assessment. It has the uniqueness of risk adjustment, which is one of the issues that has always haunted outcomes assessment. I would like to state that I am really glad to see that the results of Dr Bush’s evaluation were not that dissimilar to the results we found when we looked at the high-risk cohort of patients in the IDE trials, (ie, the 29% mortality in the EVAR arm of the high-risk surgical group).

I do have a question for Dr Bush. When you looked at the EVAR versus open at one year, were you able to determine if this was all-cause mortality or aneurysm-related mortality?

Dr Ruth L. Bush. The death data in the BIRLS database, the veterans’ beneficiary database, only answers the question, to the results we found when we looked at the high-risk cohort of patients with abdominal aortic aneurysm in “high-risk” surgical patients: comparison of open and endovascular repair. Ann Surg 2003;237:623-9, discussion 629-30.


“Is the veteran alive or deceased?” The database does not contain any information on what caused the death. We have proposed looking at the National Death Index, which is available via linkage with Social Security numbers to determine cause of death. However, the problem even with this data set is that, for determining aneurysm-related death, autopsy rates are so low that a lot of assumptions are made and speculations on what is the cause of death, so we decided to only analyze all-cause mortality.

Dr Sicard. And since this is a data set that is very robust in risk adjustments, did you do any univariate or multivariate analysis to identify what those risk factors that could predict or that have an association with mortality?

Dr Bush. In this particular study, we did not. In our first study, now published in the Journal of the American College of Surgeons, we looked at the endovascular versus open repair in all elective cases listed in the NSQIP database. In this study we looked at factors that may be independent predictors of outcome. We found that advanced age, especially over 80, was associated with mortality as was a history of stroke, smoking, and liver disease. And we created a separate variable for hospital volume. In this study, low-volume hospitals, in univariate analysis, were predictive of mortality. However, in our multivariate analyses, this variable was not significant.

Dr Sicard. Again, congratulations, and I hope all the members that are here will attend this Saturday’s session because we will be looking at different levels of evidence exactly on this issue of high-risk patients.

Dr Robert Cambria (Bangor, Me). I had a simple question about the definition of high risk. Looking at your slides, I don’t think I see any low-risk patients based on those criteria. How many procedures were excluded, both in the EVAR and open category, for not being high risk, if you have that information?

Dr Bush. I do. During the time frame we looked at, from May 2001 through December 2004, there were about 3400 elective aneurysm repairs performed at that time in VA hospitals. Of these, 2400 patients fit our high-risk criteria. We found that in our first study, again, when we looked at the whole cohort together, probably 75% of our patients in that original cohort could be identified as a high risk, so we made the definition fairly strict for this study. VA patients have been suggested to have more comorbidities and this may account for our relatively high-risk population overall.

Dr George Geroulakos (London, United Kingdom). I wonder whether you considered that perhaps the population of high-risk, as you defined it, is not entirely comparable to the EVAR 2; therefore, you cannot draw the conclusion that is written in the abstract that high-risk patients could be considered safely, or relatively safely, for intervention. To give you an example, you said that a history of coronary artery bypass graft was considered as one of the risk factors that makes patients to belong to the high-risk group; while, in fact, what we’re trying to do is to convert these high-risk factors to low-risk factors. So if a patient had coronary artery bypass grafts and remained asymptomatic, he would not be considered anymore, as far as risk factor is concerned, to a high-risk group.

Dr Bush. You are absolutely right. One of the problems with looking at administrative databases is, indeed, what is the definition of the variables being entered into the database as well as the consistency of data entry? Furthermore, the data entry relies on the people that are putting in the data. For example, a patient who is undergoing coronary revascularization, or has had this procedure, may or may not be completely now symptom-free or free from coronary disease after their bypass.

The NSQIP database, it is a robust validated database. The data are being entered by trained nurse abstractors who are continuously audited by the Department of Veteran Affairs, and they have strict definitions of actually what goes into the database. So it’s more than just ICD-9 codes within that database.

But you are correct, I do not know if the patients are symptom-free or still symptomatic following their coronary revascularization.

Dr Michel Makaroun (Pittsburgh, Pa). To my knowledge, this is probably the first time I see a long-term survival curve from all-cause mortality with a significant advantage of the endovascular group over the open group long term. And I did not even see the early separation in the first year that is very typical of these curves.

Do you have an explanation why your results are so different than the usual analysis of one versus the other?

Dr Bush. That’s a very good point, and we did see our patients demonstrating a benefit of endovascular repair and we also saw that in all the patients as well, not just those that fit our high-risk criteria. With the BIRLS database, we had death information on almost every patient. We found that very few patients had unavailable information. So our number of patients at risk at the beginning is the same as the number of patients at the end of the 2 years who are at risk. So it may be part of the lack of data censorship in our survival curves that makes this difference.

INVITED COMMENTARY

Gregorio A. Sicard, MD, St. Louis, Mo

The treatment of infrarenal aortic aneurysm (AAA) in the high-risk patient remains a challenge. The clinical introduction of endovascular aneurysm repair (EVAR) offers the benefits of a less invasive technique that was originally intended to expand treatment to patients previously deemed not surgical candidates.

During the last decade, many single-center and registry series have consistently demonstrated a perioperative mortality and morbidity benefit of EVAR compared with conventional open repair (COR). Subgroup analyses of the high-risk patient cohorts have shown a similar benefit of EVAR over COR. What have been missing from the literature are uniformity, objectivity, and a precise definition of what constitutes a high-risk patient. Scoring systems have been proposed for COR, but in general, they do not apply to high-risk patients. Furthermore, none of the scoring systems for high-risk patients treated with EVAR have been validated.

A recently published randomized clinical trial of high-risk patients (EVAR 2) comparing EVAR with medical follow-up showed a high perioperative mortality (9%) in the treatment arm and no survival advantage at 4 years between EVAR and the medical follow-up arm. Some concerns have been raised about whether the results of this randomized clinical trial should be extrapolated to all “unfit-for-surgery” AAA patients. A high mortality in the EVAR randomized group and a low mortality of EVAR in the no-treatment group who crossed over to EVAR has raised questions about the validity of the conclusions in this trial.

Bush and colleagues evaluate the results of EVAR versus COR in the high-risk patients in the National Surgical Quality Improvement Program, a large, national, validated, highly audited database. The lower 30-day and 1-year all-cause mortality in the EVAR compared with the COR group concurs with the recently published Society for Vascular Surgery Outcomes Committee’s analysis of the high-risk patients in the investigational device exemption United States Food and Drug Administration EVAR trials. Bush and colleagues attempt to further stratify the results of the high-risk population by separately analyzing the American Society of Anesthesiologists class 4
subgroup. Although not statistically significant, EVAR also demonstrated a perioperative and 1-year survival benefit over open repair.

Most investigators agree that some high-risk patients do not benefit from either COR or EVAR. The objective identification of those patients remains a great challenge, primarily because of the many variables to consider. The international vascular community should come together to establish and validate a scoring system with objective definitions that reproducibly predict outcomes in high-risk patients with AAA.

REFERENCES
APPENDIX (online only). Categories of aggregated National Surgical Quality Improvement Program complication variables and definitions

1. Cardiac
   Cardiac arrest requiring CPR
   - Absence of cardiac rhythm or presence of chaotic cardiac rhythm (ie., ventricular fibrillation) requiring CPR
   Myocardial infarction
   - New transmural acute myocardial infarction occurring within 30 days of surgery

2. Neurologic
   Cerebrovascular accident/stroke
   - New stroke
   Coma
   - Impaired level of consciousness for >24 hours
   Peripheral nerve injury
   - As stated (either sensory or motor)

3. Pulmonary
   Failure to wean >48 hours
   - On ventilator >48 hours postoperative
   Pneumonia
   - CDC definition
   Pulmonary embolism
   - Either high probability VQ scan, positive pulmonary angiogram, or a positive CT scan
   Reintubation for respiratory/cardiac failure
   - Unplanned intubation after surgery

4. Renal
   Acute renal failure
   - Worsening renal function requiring hemodialysis, ultrafiltration, or peritoneal dialysis
   Progressive renal insufficiency
   - Rise of creatinine of >2 mg/dL from preoperative value
   Urinary tract infection
   - CDC definition

5. Wound
   Deep wound surgical site infection
   - CDC definition
   Superficial surgical site infection
   - CDC definition
   Wound disruption or dehiscence
   - Disruption of the fascia

6. Bleeding requiring >4 units RBC
   - Any transfusion of packed RBCs given from the time the patient leaves the operating room

7. Graft failure
   - Mechanical failure of a vascular graft or prosthesis

CPR, cardiopulmonary resuscitation; CDC, Centers for Disease Control and Prevention; VQ, ventilation perfusion; CT, computed tomography; RBC, red blood cells.