IMPORTANCE Because of the restrictions applied to the conduct of randomized clinical trials, the risks reported in their comparison of open and endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAA) may not be applicable to real-world vascular surgical practice. The magnitude of this deviation is indeterminate.

OBJECTIVES To compare 30-day mortality from the recent Open Vs Endovascular Repair (OVER) Veterans Affairs Cooperative trial with results obtained from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) and to assess temporal trends in perioperative mortality.

DESIGN, SETTING, AND PARTICIPANTS We analyzed data from 21 115 patients who received elective EVAR or open repair for asymptomatic infrarenal AAA between January 1, 2005, and December 31, 2011, in the NSQIP database. We used χ² and t tests to compare perioperative mortality between groups. Logistic regression was used to analyze perioperative mortality, adjusting for age, sex, race, and comorbidities. The outcomes of the OVER trial were then compared with the national estimates obtained from the NSQIP.

MAIN OUTCOMES AND MEASURES Death within 30 days of surgery.

RESULTS Perioperative mortality was 3.7% (95% CI, 3.2%-4.3%) after open repair and 1.3% (95% CI, 1.2%-1.5%) after EVAR. There was a 70% reduction in operative mortality after EVAR compared with open repair (adjusted odds ratio [aOR], 0.30; 95% CI, 0.25-0.38; P < .001). Mortality was significantly lower in men compared with women (aOR, 0.73; 95% CI, 0.57-0.92; P = .009). Thirty-day mortality in the NSQIP cohort was higher than that reported in the OVER trial for both EVAR and open repair (EVAR, 1.3% vs 0.2%; open, 3.7% vs 2.3%). There was an increase in the proportion of patients who received EVAR during the 7 years studied (65% in 2005 and 80% in 2011). There has been no significant decrease in perioperative mortality during these years (P > .05).

CONCLUSIONS AND RELEVANCE Perioperative mortality reported by the OVER trial is significantly lower than outcomes from practices outside the restriction of randomized clinical trials. We attribute this difference to the fact that the OVER trial excluded high-risk patients deemed unfit for open repair. This finding supports the need for individualized assessment of risk and treatment selection for patients with infrarenal AAA. There has been no change in perioperative mortality after EVAR in recent years despite improvements in techniques, devices, and proficiency.
Since its introduction, open repair was the exclusive approach in the repair of abdominal aortic aneurysms (AAA) for 4 decades. In the advent of endovascular aneurysm repair (EVAR), significant research efforts have been directed toward evaluating the approaches to aneurysm repair, with the goal of establishing superiority in varying patient conditions.

By minimizing the influence of confounders, randomized clinical trials (RCTs) play an important role in identifying differences between treatment groups. The Open Vs Endovascular Repair (OVER) Veterans Affairs Cooperative trial is the most recent RCT that examined the differences between open repair and EVAR for AAA. This study was conducted in the United States and recruited 881 patients between October 15, 2002, and October 15, 2008. The OVER trial and other RCTs have shown better perioperative survival rates with EVAR compared with open repair.2,4

The conditions, such as strict patient selection schemes and large volume centers, in which RCTs are conducted constitute a significant deviation from routine practice. Thus, the applicability of the perioperative risk reported by the OVER trial to clinical scenarios outside of an RCT is uncertain. The primary aim of this study is to ascertain the extent to which 30-day mortality rates reported by the OVER trial correlate with outcomes from practice outside of RCTs. This real-world outcome will be obtained from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) data set. The NSQIP is a nationally validated sample that is more broadly representative of real-world practice because it contains prospectively collected, risk-adjusted data from more than 400 academic and community hospitals in the United States.

Our focus on perioperative mortality is imperative because it has been identified as the key contributor of the differences in long-term survival rates between EVAR and open repair.5,7 Furthermore, evolving technology and increasingly widespread skill and availability of EVAR warrants the continuous assessment of the absolute and relative outcomes after aneurysm repair. Second, we will examine temporal trends in perioperative mortality because it has been suggested that the outcomes after EVAR will improve over time.6

Methods
The Johns Hopkins Medicine Institutional Review Board determined that this study qualified for an exemption under the Department of Health and Human Studies regulations.

Database and Patient Selection
The study cohort was derived from the NSQIP Participant Use Data File from January 1, 2005, to December 31, 2011. These data are collected by surgical clinical reviewers from each site and contain preoperative risk factors, intraoperative variables, and mortality and morbidity outcomes for inpatients and outpatients who receive major clinical procedures.

Patients who received surgery for the repair of AAA were identified and selected using the Current Procedural Terminology codes for EVAR (34800, 34802, 34803, 34804, and 34805) and open repair (35081 and 35102) of isolated infrarenal aortic aneurysms and aortoiliac aneurysms. The etiology and presentation of AAA in patients younger than 50 years is atypical; they account for 0.9% of the entire data set and were excluded from the analyses. The repair of ruptured or symptomatic aneurysms is also a clinical scenario distinct from elective repair of asymptomatic aneurysms. This distinction warrants separate analyses, so these cases were excluded.

Covariates and Outcome
The demographic variables of age, sex, and race were identified from the NSQIP participant user files. Race was categorized as white or not white because most of the observed participants were white. Comorbidities included in the analyses were history of myocardial infarction 6 months before surgery, diabetes mellitus requiring medication, hypertension requiring medication, chronic obstructive pulmonary disease, and congestive heart failure. A history of smoking in the year before surgery, angina 1 month before surgery, cardiac surgery, percutaneous coronary intervention, disseminated malignant neoplasms, acute or chronic renal failure requiring treatment, and the American Society of Anesthesiologists (ASA) classification of physical status were also included. The primary outcome was mortality within 30 days of surgery.

Statistical Analysis
Comorbidities were analyzed as binary variables and defined as the presence or absence of the risk factor. The ASA classification of physical status was included as a categorical variable. Comparison of covariates was conducted using the χ² statistic and t test. Logistic regression models were built to identify predictors of the outcome. Likelihood ratio tests were used to test the predictive value of each covariate in the buildup of the final model. Predictive covariates and clinically relevant risk factors were included in the final model. Sensitivity analyses were carried out for variables with missing data, and only observations with complete values were used. Data query and analyses were carried out using Stata Statistical Software, release 12 (StataCorp), and statistical significance was defined as P < .05.

Results
Of the 21,115 patients aged 50 years and older who received elective repair of infrarenal AAA between 2005 and 2011 in the NSQIP, 5308 (25.1%) received open repair while 15,807 (74.9%) received EVAR. Data on sex were unavailable for 46 patients. Data on race and ASA class were missing for 7559 and 18 patients, respectively. Data on history of myocardial infarction, percutaneous coronary intervention, cardiac surgery, and angina were missing for 2048 patients. All other variables were complete. Data were missing in a nonsystematic manner, and sensitivity analyses showed that results were consistent with the complete case analyses.

Patient Characteristics
Patients who received repair of AAA were more likely to be male (open repair, 74.4%; EVAR, 82.0%; P < .001) and white (open repair, 73.6% and EVAR, 80.0%; P < .001) than female (open repair, 25.6%; EVAR, 18.0%) and black (open repair, 16.4%; EVAR, 10.0%).
repair, 91.5%; EVAR, 93.4%; \( P < .001 \) (Table 1). The patients who received open repair were, on average, 3 years younger than those who received EVAR (mean [SD] age of open repair group, 71 [8] years; EVAR group, 74 [8] years; \( P < .001 \)).

A history of smoking in the year before surgery was more common in patients who received open repair (open repair, 42.8%; EVAR, 29.5%; \( P < .001 \)). Other patient characteristics in the OVER trial that have the same definitions in the NSQIP are reported in Table 1.

### Outcome

Thirty-day mortality in the OVER cohort was 2.3% for open repair and 0.2% for EVAR.\(^1\) In the NSQIP cohort, there were 199 deaths (3.7%; 95% CI, 3.2%-4.3%) in the open repair group and 210 deaths (1.3%; 95% CI, 1.2%-1.5%) in the EVAR group (\( P < .001 \)) within 30 days of surgery. The predictors of mortality in the univariate analyses were age, sex, history of smoking within a year, chronic obstructive pulmonary disease, congestive heart failure, myocardial infarction, renal failure, history of percutaneous coronary intervention, cardiac surgery, disseminated malignant neoplasm, and patients’ ASA class. After excluding all female patients from the NSQIP cohort, 30-day mortality was 3.3% (95% CI, 2.6%-4.0%) for open repair and 1.2% (95% CI, 1.0%-1.4%) for EVAR (\( P < .001 \)).

### Multivariable Logistic Regression

There was a 65% reduction in the unadjusted odds of death following EVAR compared with open repair (odds ratio [OR], 0.35; 95% CI, 0.28-0.42; \( P < .001 \)) (Table 2). After adjusting for risk factors, ASA class, and year of operation, the odds of death comparing EVAR with open repair remained relatively unchanged (OR, 0.30; 95% CI, 0.25-0.38; \( P < .001 \)). The lower odds of death in men compared with women (adjusted OR [aOR], 0.73; 95% CI, 0.57-0.92; \( P = .009 \)) also persisted. Patients with renal failure had a 4-fold increase in the risk of operative mortality (aOR, 4.00; 95% CI, 2.31-6.92; \( P < .001 \)). Patients with significant morbidities (ASA class 5) had an almost 8-fold increase in the risk of operative mortality (aOR, 7.81; 95% CI, 1.44-42.31; \( P = .02 \)).

### Trends in Mortality Rate

In 2005, there were more EVARs of AAA compared with open repairs (EVAR, 65%; open repair, 35%) (Figure 1). These proportions remained the same in 2006. However, since 2007, the proportion of patients who received EVAR has increased yearly, with a steady decline in open repair. By 2011, these proportions reached 80% for EVAR and 20% for open repair. This amounts to a 23% increase in the proportion of patients who received EVAR and a 43% decrease in the proportion of patients who received open repair between 2005 and 2011.
In each of the 7 years studied, the mortality rate following open repair was consistently higher than the mortality rate associated with EVAR (Figure 2). For both treatments, there was no significant difference in the odds of death in each year compared with 2005 (P > .05).

**Discussion**

This study presents the analyses of a cohort of patients from across the United States in the NSQIP who had elective repair of their infrarenal AAA in real-world settings, devoid of RCT restrictions. We showed a significant 3-fold increase in perioperative mortality with open repair compared with EVAR (OR, 3.3; 95% CI, 2.6-4.0); this difference was independent of risk status and changes over time. The goal of the OVER trial was to provide evidence to guide clinical decisions relating to the choice of approach for the repair of AAA. The controlled method of this RCT enabled the unconfounded comparison of the approaches to aneurysm repair. When the need to prognosticate arises in clinical practice, caution might be warranted in applying the event rates reported from this RCT to one’s patients because the strict criteria applied to the RCT exclude factors that affect everyday practice. This factor raises the need to assess outcomes from practice outside of RCTs. Our evaluation of the outcomes in real practice exposes a deviation from the event rates reported from the OVER trial. This difference iterates the need for patient-specific risk assessment and treatment.

Although both studies were conducted in the same source population, the United States, the OVER trial was conducted in Veteran Affairs centers where the population is predominantly male (99.5%). We find a significantly higher operative mortality rate in women compared with men, and this finding is consistent with prior studies. It may be argued that the male predominance in the OVER trial is responsible for the difference in results between the OVER trial and NSQIP data. However, analyses of the NSQIP data set restricted only to men yielded results that were similar to the overall NSQIP results and still different from those of the OVER trial. The difference in results between both studies is greater for EVAR. The increasingly disseminated endovascular skills, device improvement, and availability, as well as scenarios in which surgeons are pushing conventional limits and executing EVAR in high-risk patients, might also contribute to the

### Table 2. Multivariable Logistic Regression

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Unadjusted Odds Ratio (95% CI)</th>
<th>P Value</th>
<th>Adjusted Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR</td>
<td>0.35 (0.28-0.42)</td>
<td>&lt;.001</td>
<td>0.30 (0.25-0.38)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Male sex</td>
<td>0.56 (0.46-0.70)</td>
<td>&lt;.001</td>
<td>0.73 (0.57-0.92)</td>
<td>.009</td>
</tr>
<tr>
<td>White race</td>
<td>0.71 (0.47-1.07)</td>
<td>.10</td>
<td>0.73 (0.47-1.13)</td>
<td>.16</td>
</tr>
<tr>
<td>MI</td>
<td>1.71 (0.80-1.67)</td>
<td>.17</td>
<td>1.05 (0.45-2.42)</td>
<td>.90</td>
</tr>
<tr>
<td>CHF</td>
<td>1.86 (0.95-1.64)</td>
<td>.07</td>
<td>1.07 (0.52-2.18)</td>
<td>.86</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.68 (1.25-2.25)</td>
<td>.001</td>
<td>1.43 (1.04-1.96)</td>
<td>.03</td>
</tr>
<tr>
<td>Angina</td>
<td>1.62 (0.88-2.98)</td>
<td>.12</td>
<td>1.37 (0.72-2.59)</td>
<td>.34</td>
</tr>
<tr>
<td>COPD</td>
<td>1.60 (1.28-1.99)</td>
<td>&lt;.001</td>
<td>1.50 (1.17-1.91)</td>
<td>.001</td>
</tr>
<tr>
<td>Smoking</td>
<td>0.82 (0.66-1.01)</td>
<td>.04</td>
<td>0.94 (0.73-1.21)</td>
<td>.64</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.16 (0.89-1.51)</td>
<td>.26</td>
<td>1.20 (0.90-1.59)</td>
<td>.22</td>
</tr>
<tr>
<td>PCI</td>
<td>0.93 (0.71-1.20)</td>
<td>.56</td>
<td>0.87 (0.66-1.13)</td>
<td>.30</td>
</tr>
<tr>
<td>PCS</td>
<td>1.62 (1.29-2.01)</td>
<td>&lt;.001</td>
<td>1.47 (1.17-1.86)</td>
<td>.001</td>
</tr>
<tr>
<td>Renal failure</td>
<td>2.47 (1.70-3.58)</td>
<td>&lt;.001</td>
<td>4.00 (2.31-6.92)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Malignant neoplasm</td>
<td>1.84 (1.02-3.34)</td>
<td>.04</td>
<td>3.10 (1.11-8.65)</td>
<td>.03</td>
</tr>
<tr>
<td>2</td>
<td>0.11 (0.02-0.51)</td>
<td>.01</td>
<td>0.10 (0.02-0.52)</td>
<td>.01</td>
</tr>
<tr>
<td>3</td>
<td>0.20 (0.05-0.84)</td>
<td>.03</td>
<td>0.14 (0.03-0.62)</td>
<td>.01</td>
</tr>
<tr>
<td>4</td>
<td>0.55 (0.13-2.35)</td>
<td>.42</td>
<td>0.30 (0.07-1.37)</td>
<td>.12</td>
</tr>
<tr>
<td>5</td>
<td>10.89 (2.2-53.69)</td>
<td>.003</td>
<td>7.81 (1.44-42.31)</td>
<td>.02</td>
</tr>
</tbody>
</table>

Abbreviations: ASA, American Society of Anesthesiologists Classification of Functional Status; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; EVAR, endovascular aneurysm repair; MI, myocardial infarction; PCI, percutaneous coronary intervention; PCS, previous cardiac surgery.

There was a consistent increase in the proportion of patients who received endovascular aneurysm repair (EVAR) and a converse decrease for open repair.
higher operative mortality rate in our study. These are patients who are excluded from clinical trials because of advanced age or significant comorbidities. Furthermore, these trials are conducted in high-volume referral institutions, thus creating further deviation from actual practice. These real-world cases are included in our analyses, making them more generalizable. Our results are also derived from the analyses of a significantly larger sample of patients.

The increase in the proportion of patients who received EVAR confirms the increasing preference for this minimally invasive approach by patients and their surgeons. There has been no significant change in the mortality rate associated with EVAR and open repair in 7 years. It can be argued that the mortality rate associated with the traditional approach may have plateaued over the decades. We believe that, in clinical practice today, EVAR is being increasingly offered to high-risk patients previously deemed unable to tolerate surgery. These patients have been shown to contribute inherently poorer outcomes, thus negating any benefits in outcomes anticipated as a result of improvements in techniques, devices, and surgical proficiency.

There is an overlap in the study periods for the OVER trial (2002-2008) and NSQIP (2005-2011). We believe this overlap (>50%) is sufficient to make a comparison between the 2 studies. To assess for the potential effect of this overlap, we analyzed the time-restricted NSQIP data (2005-2008), and the primary event rates were the same as for the entire NSQIP data set (open repair, 3.9%; 95% CI, 0.03%-0.05%; EVAR, 1.3%; 95% CI, 0.01%-0.02%; P < .001). The NSQIP data might also not be precisely representative of national practice; however, the larger number and wide range of hospitals that contribute to this data set provides a reliable estimate of actual practice. The validity and reliability of the NSQIP as a superior data source has also been established. We recognize that our findings are not representative of patients younger than 50 years or applicable to patients with suprarenal, symptomatic, or ruptured AAA.

The data set used in these analyses contains missing data; however, this fact does not impair the validity of our findings because the data set is large, and sensitivity analyses of observations with and without the missing values showed no deviation from these results. While our report of the mortality rate within 30 days of surgery is a valid measure of perioperative mortality, it limits comparisons of long-term survival between EVAR and open repair. Last, the NSQIP data set does not contain details on the anatomy of aneurysms repaired or details of the repair procedure, such as the volume of radiographic dye and incidence of iliac artery coiling. These details are important to consider and present areas deserving of further study.

Conclusions

We have shown that perioperative mortality determined by the OVER trial underestimates the findings after repair of AAA from vascular practice outside the restriction of RCTs. This outcome was more pronounced for EVAR. While the OVER trial is useful in identifying differences between EVAR and open repair, results from our real-world analyses pose a better reference for prognosis, with emphasis on the need for patient-specific risk assessment and treatment. Open repair is associated with a 3-fold increase in the rate of mortality within 30 days of surgery compared with EVAR of asymptomatic infrarenal AAA.

There has been an increase in the proportion of patients who receive EVAR. However, perioperative mortality after EVAR remained the same in the study period despite improvements in techniques, devices, and proficiency. We believe that, in current practice, more patients with prohibitive risks for surgery are being offered EVAR. These patients contribute inherently poorer outcomes to the postoperative results, thus negating the benefit of this approach.
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REFERENCES