In patients stratified by preoperative risk, endovascular repair of ruptured abdominal aortic aneurysms has a lower in-hospital mortality and morbidity than open repair

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Objective: Previous studies have reported that endovascular repair (EVAR) of ruptured abdominal aortic aneurysms (RAAAs) has lower postoperative mortality than open repair (OR). However, comparisons involved heterogeneous populations that lacked adjustment for preoperative risk. We hypothesize that for RAAA patients stratified by a validated measure of preoperative mortality risk, EVAR has a lower in-hospital mortality and morbidity than does OR.

Methods: In-hospital mortality and morbidity after EVAR and OR of RAAA were compared in patients from the Vascular Quality Initiative (2003-2013) stratified by the validated Vascular Study Group of New England RAAA risk score into low-risk (score 0-1), medium-risk (score 2-3), and high-risk (score 4-6) groups.

Results: Among 514 patients who underwent EVAR and 651 patients who underwent OR of RAAA, EVAR had lower in-hospital mortality (25% vs 33%, *P* = .001). In risk-stratified patients, EVAR trended toward a lower mortality in the low-risk group (n = 626; EVAR, 10% vs OR, 15%; *P* = .07), had a significantly lower mortality in the medium-risk group (n = 457; EVAR, 37% vs OR, 48%; *P* = .02), and no advantage in the high-risk group (n = 82; EVAR, 95% vs OR, 79%; *P* = .17). Across all risk groups, cardiac complications (EVAR, 29% vs OR, 38%; *P* = .001), respiratory complications (EVAR, 28% vs OR, 46%; *P* < .0001), renal insufficiency (EVAR, 24% vs OR, 38%; *P* < .0001), lower extremity ischemia (EVAR, 2.7% vs OR, 8.1%; *P* < .0001), and bowel ischemia (EVAR, 3.9% vs OR, 10%; *P* < .0001) were significantly lower after EVAR than after OR. Across all risk groups, median (interquartile range) intensive care unit length of stay (EVAR, 2 [1-5] days vs OR, 6 [3-13] days; *P* < .0001) and hospital length of stay (EVAR, 6 [4-12] days vs OR, 13 [8-22] days; *P* < .0001) were lower after EVAR.

Conclusions: This novel risk-stratified comparison using a national clinical database showed that EVAR of RAAA has a lower mortality and morbidity compared with OR in low-risk and medium-risk patients and that EVAR should be used to treat these patients when anatomically feasible. For RAAA patients at the highest preoperative risk, there is no benefit to using EVAR compared with OR. (J Vasc Surg 2015;61:1399-407.)

Ruptured abdominal aortic aneurysm (RAAA) continues to be a highly fatal condition with an overall mortality rate of 80% to 90%.[1] Despite improvements in perioperative care, open repair (OR), which has long been considered the gold standard, continues to be associated with high mortality of 38% to 50% in recent reports.[2-9] The reason for the high mortality with OR for RAAA is

likely because these patients are critically ill with major multisystem physiologic derangements that are very difficult to adequately treat. In an attempt to reduce mortality, endovascular repair (EVAR) has been used for RAAA. Successful EVAR for RAAA was first described in 1994.[10] Most recent studies suggest that EVAR is superior to OR for RAAA in patients with EVAR-suitable anatomy, reporting that the use of EVAR for RAAA has lowered postoperative mortality to 21% to 32%.[11-15]

However, most comparisons of EVAR and OR for RAAA have been retrospective single-center studies that were limited by selection bias.[16] Furthermore, the comparisons have involved heterogeneous populations that have not been stratified by validated measures of preoperative risk. Significant heterogeneity in patient populations selected for EVAR or OR has raised doubts about the apparent benefit of EVAR reported in most studies. Patients selected for EVAR may have greater hemodynamic stability than those treated with OR.[16,17] Because hemodynamic stability is associated with decreased RAAA operative mortality,[18] comparisons of

EVAR and OR without preoperative risk stratification may not be valid.

The optimal treatment of RAAA has remained controversial and has been the subject of three randomized trials. The randomized trials showed no benefit of EVAR over OR for RAAA. However, these studies were limited by inclusion of relatively stable patients and high crossover rates.[19] The Immediate Management of the Patient with Ruptured Aneurysm: Open Versus Endovascular repair (IMPROVE) trial and the Amsterdam Acute Aneurysm (AJAX) trial showed no benefit to EVAR over OR for RAAA.[20,21] The findings of these trials are in contradistinction to most of the other literature and additional analysis is therefore necessary to determine the optimal RAAA treatment. In addition, in the absence of a randomized trial in the United States, an analysis of the Vascular Quality Initiative (VQI) using a validated method for risk stratification provides valuable information about which patients with RAAA may benefit from EVAR rather than OR. Therefore, whether EVAR offers significant benefit compared with OR for RAAA remains unclear.

In this study, the Vascular Study Group of New England (VSGNE) RAAA risk score was validated in the VQI cohort and was then used to stratify all patients who underwent RAAA repair in the VQI database according to preoperative mortality risk. In patients stratified by preoperative mortality risk, in-hospital mortality, major morbidity, and length of stay (LOS) after EVAR and OR of RAAA were compared. The hypothesis of this risk-stratified analysis was that EVAR would be associated with lower rates of in-hospital mortality and major morbidity and shorter LOS compared with OR, with increasing benefit to EVAR over OR in patients at the highest preoperative mortality risk.

METHODS

This study was reviewed by the University of Massachusetts Medical School Institutional Review Board and received "Not Human Subjects Research" exemption from full Institutional Review Board review.

VQI database. The outcomes of EVAR and OR of RAAA in a contemporary United States cohort were compared using the VQI database, which is the largest available North American vascular surgery database providing detailed clinical information.[22] The VQI is a national collaborative of regional quality groups, incorporating 242 academic and community hospitals, that maintains a North American database in an effort to improve patient care in vascular surgery.[22] All data are self-reported at each participating institution by physicians, nurses, or clinical personnel with use of standardized definitions. The VQI uses rigorous data collection, including patient demographics, comorbidities, and intraoperative and postoperative information, which are collected for the inpatient period from the index case. The VQI has 100% capture rate for 11 major vascular surgery procedures, including EVAR and OR of RAAA.[23]

Patients. The clinical data of patients in the VQI who underwent EVAR and OR for RAAA from years 2003 to 2013 was reviewed. In-hospital mortality, major morbidity, and LOS after EVAR and OR of RAAA were compared in patients from the VQI stratified by the validated VSGNE RAAA risk score into low-risk, medium-risk, and high-risk groups. Patients with missing data or prior aortic surgery were excluded.

Validation of the VSGNE RAAA risk score in the VQI cohort. The accuracy of the VSGNE RAAA risk score model for predicting in-hospital mortality for all patients undergoing EVAR or OR in the VQI cohort was validated. The VSGNE RAAA risk score is the first United States-based validated measure of an in-hospital mortality risk score model after OR of RAAA. The derivation and validation of the VSGNE RAAA risk score has been described previously.[9]

Independent predictors of death in the VSGNE RAAA risk score include age >76 years, preoperative cardiac arrest, loss of consciousness, and suprarenal aortic clamp.[9] The VSGNE RAAA risk score (range 0-6) is tabulated by summing points given to each of the four variables: age >76 years (2 points), preoperative cardiac arrest (2 points), loss of consciousness (1 point), and use of suprarenal aortic clamp (1 point). EVAR patients received no points for suprarenal clamp.

Previous work demonstrated that this model accurately stratified patients in the VSGNE into low-risk (score 0-1), medium-risk (score 2-3), and high-risk (score 4-6) groups with respective expected mortality rates of 8% to 25%, 37% to 60%, and >80%.[9] Logistic regression modeling determined that the VSGNE RAAA risk score had excellent discrimination (C statistic = .78) and good calibration ($P = .1$ by Hosmer-Lemeshow test) in the current cohort.

Outcomes. The primary end point was in-hospital mortality. The secondary end points included major morbidity (cardiac, respiratory, renal insufficiency, leg and bowel ischemia) and LOS in the hospital and intensive care unit (ICU). Cardiac complications included myocardial infarction (determined by clinical findings and electrocardiographic changes), congestive heart failure, and dysrhythmia. Respiratory complications included pneumonia and any need for mechanical ventilation. Renal insufficiency was defined as increase in creatinine by 0.5 mg/dL or any need for hemodialysis. Primary and secondary end points were calculated across all preoperative risk strata and within each stratum of preoperative risk.

Statistical analysis. Dichotomous variables were compared between type of repair (EVAR vs OR) using the χ^2 test or the Fisher exact test (if cell sizes were ≤5). The Wilcoxon rank sum test was used to compare non-normally distributed continuous variables that had a skewed distribution. The Student t-test was used to compare normally distributed continuous variables. Data were analyzed on an intent-to-treat basis. Analyses were performed using SAS 9.2 software (SAS Institute Inc, Cary, NC).

RESULTS

Patients and prehospital characteristics. A total of 1282 patients underwent RAAA repair. EVAR was