Real-world evidence of superiority of endovascular repair in treating ruptured abdominal aortic aneurysm

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ABSTRACT

Objective: The majority of previous studies, including randomized controlled trials, have failed to provide sufficient evidence of superiority of endovascular aneurysm repair (EVAR) over open aortic repair (OAR) of ruptured abdominal aortic aneurysm (rAAA) while comparing mortality and complications. This is in part due to small study size, patient selection bias, scarce adjustment for essential variables, single insurance type, or selection of only older patients. This study aimed to provide real-world, contemporary, comprehensive, and robust evidence on mortality of EVAR vs OAR of rAAA.

Methods: A retrospective observational cohort study was performed of rAAA patients registered in the Premier Healthcare Database between July 2009 and March 2015. A multivariate logistic regression model was operated to estimate the association between procedure types (OAR vs EVAR) and in-hospital mortality. The final model was adjusted for demographics (age, sex, race, marital status, and geographic region), hospital characteristics (urban or rural, teaching or not), and potential confounders (hypertension, diabetes, hypercholesterolemia, obesity, ischemic heart disease, chronic kidney disease, symptoms of critical limb ischemia, chronic obstructive pulmonary disease, smoking, and alcoholism). Furthermore, coarsened exact matching was applied to substantiate the result in the matched cohort.

Results: There were a total of 3164 patients with rAAA (1550 [49.0%] OAR and 1614 [51.0%] EVAR). Mortality was 23.79% in the EVAR group compared with 36.26% in the OAR group (P < .001). The adjusted odds ratios of mortality (1.9; 95% confidence interval [CI], 1.62-2.25; P < .001), cardiac complication (1.54; 95% CI, 1.22-1.96; P < .001), pulmonary failure (1.90; 95% CI, 1.60-2.24; P < .001), renal failure (1.90; 95% CI, 1.61-2.23; P < .001), and bowel ischemia (2.40; 95% CI, 1.70-3.35; P < .001) were significantly higher after OAR compared with EVAR. We further applied coarsened exact matching, which followed the same pattern of mortality (odds ratio, 1.68; 95% CI 1.41-1.99; P < .001) and all major complications.

Conclusions: Although the choice of repair of rAAA is highly dependent on the experience of the operating team and the anatomic suitability of the patient, this contemporary analysis of a large cohort of rAAA showed significantly higher adjusted risk of mortality in OAR compared with EVAR and substantially higher complications. (J Vasc Surg 2018;[••]:1-8.)

After the introduction of endovascular aneurysm repair (EVAR) in 1991, more than two decades have passed since vascular surgeons first used this novel approach to treat complex and critical cases of ruptured abdominal aortic aneurysm (rAAA). Initial studies including one randomized controlled trial (RCT) showed no difference in perioperative mortality and morbidity or any survival advantage of EVAR over open aortic repair (OAR) in rAAA patients. Newer studies showed lower mortality in selected rAAA patients but remained cautious in interpreting the results in view of patient characteristics, hospital volume, and surgical expertise. During the last 10 years, many studies have shown the advantage of EVAR over OAR in terms of mortality and complications because of growing expertise of vascular surgeons in dealing with this complex clinical scenario. At the same time, however, several newer studies including RCTs failed to provide sufficient evidence of superiority of EVAR over OAR in rAAA while comparing mortality and complications. This fact is highlighted by various systematic reviews periodically. The rationale for this ambiguity is in part due to methodologic limitations (small population size, patient selection bias in defining inclusion and exclusion criteria, improper adjustment for existing comorbidities, studies based on Medicare data having single insurance and only older patients, and inadequate reporting or definition of postoperative complications). Clinical factors are more complex to define because these are associated...
with hospital rAAA volume, availability of resources, feasibility of preoperative imaging (computed tomography), personal judgment of the operating team in choosing between two procedures, physiologic condition of the patient at presentation (low, intermediate, or high surgical risk), and suitable aortic anatomy.

In this study, we aimed to provide real-world, comprehensive, and robust evidence of mortality and morbidities of EVAR compared with OAR of rAAA in a contemporary national database with matched analysis.

METHODS
A retrospective observational cohort study was performed in the Premier Healthcare Database (PHD). The study was approved by the Johns Hopkins Institutional Review Board. PHD is a nationwide, weekly updated, dynamic database representative of >700 hospitals and institutions from geographically diverse nonprofit, nongovernmental, community and teaching hospitals and health systems from rural and urban areas. PHD provides deidentified, Health Insurance Portability and Accountability Act-compliant data from standard hospital discharge billing files, which includes demographics, disease states, admission and discharge diagnoses, patient disposition, and discharge health status. The information on billed services includes charges at the departmental level (medications and devices), laboratory tests, microbiology tests, and diagnostic and therapeutic services. Patients can be tracked in the same hospital across the inpatient and hospital-based outpatient settings, with the ability to assess hospital length of stay and readmissions to the same hospital. Less than 1% of patient records have missing information for most data elements and <0.01% have missing data for key elements such as demographics and diagnostic information. The details of data collection strategies, inclusion criteria, outcomes measured, and quality management in the PHD have been reported elsewhere. We analyzed the PHD from July 2009 to March 2015 (more contemporary).

PHD generates the unique identifier for each patient diagnosed with rAAA as well as the patient’s comorbidities, operative procedures (OAR vs EVAR), and complications by respective International Classification of Diseases, Ninth Revision (ICD-9) codes. We identified our study cohort by using ICD-9 codes for rAAA (441.3 and 441.5). Patients who had undergone both OAR and EVAR procedures (54 patients, 0.02% of the total population), patients with a history of connective tissue disorder, and patients with any nonatherosclerotic kind of aortic aneurysm were excluded to keep the procedure groups as comparable as possible.

Postoperative complications explored in the secondary analysis included cardiac complications (acute or subacute myocardial infarction, acute coronary occlusion without myocardial infarction, angina), cerebrovascular ischemic complications (thrombosis, embolism, unspecified occlusion of precerebral and cerebral arteries), pulmonary failure (embolism, atelectasis, collapse, acute respiratory failure, acute pulmonary insufficiency), acute renal failure (postoperative acute and due to vascular insufficiency with different presentations, such as tubular necrosis, cortical necrosis, or medullary necrosis), and acute bowel ischemia.

**Statistical analysis.** Student t-test was used to compare continuous variables, and χ² test was used for dichotomous variables. The nonparametric test for trend was used to see trends in use of EVAR for rAAA by successive years. Multivariate logistic regression was operated to identify predictors of all-cause in-hospital mortality and complications. Based on a priori literature, clinically relevant potential confounders were included in the final adjusted model, including age, sex, race, marital status, insurance, urban-rural location, geographic area, teaching-nonteaching institute, hypertension, smoking, alcoholism, diabetes mellitus, hypercholesterolemia, obesity, atherosclerosis, ischemic heart disease, cerebrovascular ischemic disease, chronic kidney disease, peripheral vascular disease, critical limb ischemia, dialysis, and chronic obstructive pulmonary disease. Models were checked for multicollinearity using the variance inflation factors. The significance level was decided with P < .05.

Coarsened exact matching (CEM) was performed on the basis of demographics (age, sex, race, marital status, and geographic region), insurance type, year of admission, and hospital characteristics (urban or rural, teaching or not). Similar to other studies, age categories of 10 years were used for matching and control units within each stratum are weighted to equal number of treated units in that stratum. This matching method is proven superior to propensity matching as it
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