Risk factors for 1-year mortality after thoracic endovascular aortic repair

Asad A. Shah, MD,[a] Damian M. Craig, MA,[b] Nicholas D. Andersen, MD,[a] Judson B. Williams, MD,[a] Syamal D. Bhattacharya, MD,[a] Svati H. Shah, MD, MHS,[b] Richard L. McCann, MD,[a] and G. Chad Hughes, MD[a]

Objective: Thoracic endovascular aortic repair, although physiologically well tolerated, may fail to confer significant survival benefit in some high-risk patients. In an effort to identify patients most likely to benefit from intervention, the present study sought to determine the risk factors for 1-year mortality after thoracic endovascular aortic repair.

Methods: A retrospective review was performed on prospectively collected data from all patients undergoing thoracic endovascular aortic repair from 2002 to 2010 at a single institution. Univariate analysis and multivariate Cox proportional hazards regression analysis were used to identify risk factors associated with mortality within 1 year after thoracic endovascular aortic repair.

Results: During the study period, 282 patients underwent at least 1 thoracic endovascular aortic repair; index procedures included descending aortic repair (n = 189), hybrid arch repair (n = 55), and hybrid thoracoabdominal repair (n = 38). The 30-day/in-hospital mortality was 7.4% (n = 21) and the overall 1-year mortality was 19% (n = 54). Cardiopulmonary pathologies were the most common cause of nonperioperative 1-year mortality (22%, n = 12). Multivariate modeling demonstrated 3 variables independently associated with 1-year mortality: age older than 75 years (hazard ratio, 2.26; $P = .005$), aortic diameter greater than 6.5 cm (hazard ratio, 2.20; $P = .007$), and American Society of Anesthesiologists class 4 (hazard ratio, 1.85; $P = .049$). A baseline creatinine greater than 1.5 mg/dL (hazard ratio, 1.79; $P = .05$) and congestive heart failure (hazard ratio, 1.87; $P = .08$) were also retained in the final model. These 5 variables explained a large proportion of the risk of 1-year mortality (C statistic = 0.74).

Conclusions: Age older than 75 years, aortic diameter greater than 6.5 cm, and American Society of Anesthesiologists class 4 are independently associated with 1-year mortality after thoracic endovascular aortic repair. These clinical characteristics may help risk-stratify patients undergoing thoracic endovascular aortic repair and identify those unlikely to derive a long-term survival benefit from the procedure. (J Thorac Cardiovasc Surg 2013;145:1242-7)

Thoracic endovascular aortic repair (TEVAR) is being increasingly used to treat a variety of thoracic aortic pathologies.[1] The short-term benefits of TEVAR versus open repair have been demonstrated and include decreased operative mortality,[2-5] decreased morbidity,[2,5,6] and decreased hospital length of stay.[6] The low perioperative risk of TEVAR has led to its application to a wider range of patients, including higher risk patients who might not have been offered traditional open repair in the past.[7,8] It has been previously shown in patients undergoing endovascular abdominal aortic aneurysm repair (EVAR) that the early perioperative benefits of an endovascular approach were not sustained in longer term analyses.[9] Therefore, although physiologically well tolerated, some patients offered TEVAR may still experience significant mortality risk beyond the perioperative period[10] and, thus, not obtain an overall survival benefit from the procedure.

The risk factors for death after TEVAR have been partially elucidated, including the predictors of 30-day and long-term mortality.[11,12] However, many patients survive the initial postoperative period, but die after discharge and within 1 year of surgery.[10] The risk factors for death within this period have yet to be specifically defined. The identification of such risk factors might lead to more appropriate application of TEVAR, improved risk stratification, and better patient prognostic information. Therefore, the objective of the present study was to determine the risk factors for 1-year mortality after TEVAR. We hypothesized that specific

From the Departments of Surgery[a] and Medicine,[b] Duke University Medical Center, Durham, NC.

Disclosures: Dr Hughes is a consultant for W.L. Gore and a consultant and speaker for Vascutek Terumo. The other authors have nothing to disclose with regard to commercial support.

This study was presented in part at the Society for Vascular Surgery 2011 Vascular Annual Meeting, June 17, 2011, Chicago, Ill.

Received for publication Jan 3, 2012; revisions received April 13, 2012; accepted for publication May 4, 2012; available ahead of print June 14, 2012.

Address for reprints: G. Chad Hughes, MD, Director, Aortic Surgery Program, Division of Cardiovascular and Thoracic Surgery, Department of Surgery, Duke University Medical Center, Box 3051, Durham, NC 27710 (E-mail: gchad.hughes@duke.edu).

0022-5223/$36.00

doi:10.1016/j.jtcvs.2012.05.005

Abbreviations and Acronyms
ASA = American Society of Anesthesiologists
EVAR = endovascular abdominal aortic aneurysm repair
TEVAR = thoracic endovascular aortic repair

preoperative patient characteristics and intraoperative variables are associated with 1-year mortality after TEVAR.

METHODS

Patients and Data Source

A retrospective review was performed on prospectively collected data from all patients undergoing TEVAR from May 2002 to December 2010 at a single referral institution. Preoperative, intraoperative, and postoperative variables were abstracted from the Duke Thoracic Aortic Surgery Database, a prospectively maintained clinical registry of all patients undergoing thoracic aortic surgery at Duke University Medical Center (Durham, NC). For patients with multiple TEVAR procedures, the first was used as the index procedure for the time-to-event analyses. The institutional review board of Duke University reviewed and approved the study, and the need for individual patient consent was waived. All procedures and management were a part of routine clinical care as determined by the clinical care team.

TEVAR Procedures

TEVAR patient selection, techniques of device delivery and deployment, and postoperative surveillance have been previously described.[13-15] All 5 currently Food and Drug Administration–approved thoracic stent grafts and the investigational Zenith TX2-LP (Cook Medical, Bloomington, Ind) device were used. The indications for each TEVAR procedure were classified as degenerative aneurysm (including penetrating atherosclerotic ulcers), acute and chronic dissection, or acute blunt traumatic aortic injury (transection). The procedures were further classified as descending-only repair,[16] hybrid arch repair (aortic arch debranching with aortic endograft coverage),[13] and hybrid thoracoabdominal repair (visceral abdominal debranching with aortic endograft coverage).[14,17]

Variables and Outcomes

The primary study outcome was 1-year mortality, defined as death occurring between postoperative day 0 and postoperative day 365. The causes of death were classified as perioperative (death within 30 days of TEVAR or within the same hospitalization as the initial TEVAR procedure), aortic-related, cardiopulmonary, cancer, sepsis, failure to thrive, neurologic, other, and unknown. The cause of death was determined by autopsy, medical records, or family interview. The present report included all data collected through the patients' 1-year follow-up visit, a review of outside medical records, or patient/family telephone interview in the case of missing 1-year follow-up information. Deaths from all causes were included in the analysis. In addition, the Social Security Death Index was queried (available from http://ssdi.rootsweb.com/) to confirm all patient deaths.

Those variables previously identified in peer-reviewed literature[11,12,18,19] as potential predictors of outcome in aortic surgery were included as candidate variables for the analysis. The final list of preoperative model variables assessed included age, race, gender, body mass index, left ventricular ejection fraction (from echocardiography, cardiac magnetic resonance imaging, or cardiac catheterization), aortic diameter, preoperative hemoglobin concentration, preoperative serum creatinine level, congestive heart failure, a history of myocardial infarction, gastroesophageal reflux disease, peripheral vascular disease, steroid use, angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker use, a history of alcohol abuse, type 1 or 2 diabetes, hypertension, a history of stroke, chronic obstructive pulmonary disease, restrictive lung disease, a history of previous aortic surgery, the presence of aortic-related symptoms (ie, chest pain, back pain, malperfusion), American Society of Anesthesiologists (ASA) physical status classification system, indication for procedure, urgency of case, and preoperative white blood cell count. The intraoperative variables assessed included procedure performed, number of endografts placed, extent of aortic pavement, endograft type, subclavian artery coverage, and use of cerebrospinal fluid drainage.

Statistical Analysis

The preoperative and intraoperative variables were compared between patients who died within 1 year of TEVAR (event group) and those who survived until at least 1 year after TEVAR (nonevent group) using univariate linear regression analysis and chi-square tests for continuous and discrete variables, respectively. Continuous variables were checked for normality using Kolmogorov-Smirnov tests and are presented as the mean ± standard deviation. Categorical variables are presented as percentages (raw numbers). For the variable "aortic diameter," a threshold of greater than 6.5 cm was chosen because this value represented the 75th percentile within the distribution of aortic diameters in the cohort. We have previously performed this analysis using aortic diameter as a continuous variable and found similar results. We chose to use aortic diameter as a categorical, rather than a continuous, variable to give the reader a more clinically relevant cutoff to use when risk stratifying these patients.

Multivariable Cox proportional hazards regression analysis was then used to determine the risk factors for 1-year mortality. Variables with a nominal $P < .1$ on univariate analysis were entered into the multivariable model. The maximum time-to-event was set at 365 days, and the entire study population was therefore censored at that point. Events were defined as death occurring within 1 year of TEVAR. Statistical analysis was performed by 2 authors (D.M.C. and A.A.S.) using SAS, version 9.1 (SAS Institute, Cary, NC).

RESULTS

A total of 316 procedures were performed on 282 patients. The preoperative and intraoperative characteristics of the study population are listed in Tables 1 and 2, respectively. Indications for the index TEVAR procedure included degenerative aneurysm (n = 183), aortic dissection (n = 82), and blunt aortic injury (n = 17). The procedures performed included descending aortic repair (n = 189), hybrid arch repair (n = 55), and hybrid thoracoabdominal repair (n = 38). Concomitant procedures were performed in 21% (n = 58) and most frequently included carotid-subclavian bypass (n = 26). Aortic-related reintervention was required in 9.6% (n = 27) of the patients in the initial year after TEVAR. Follow-up was 100% complete.

The 30-day/in-hospital mortality was 7.4% (n = 21), and the overall 1-year mortality was 19% (n = 54). Cardiopulmonary pathologies were the most common cause of nonperioperative mortality within 1 year of TEVAR (22% of all 1-year deaths [n = 12]; Table 3). The patient variables associated with 1-year mortality on univariate analysis were age older than 75 years ($P < .001$), congestive heart failure ($P = .03$), peripheral vascular disease ($P = .02$), a history of stroke ($P = .04$), creatinine greater than 1.5