CLINICAL RESEARCH STUDIES

From the Midwestern Vascular Surgical Society

Outcome-based anatomic criteria for defining the hostile aortic neck

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Objective: **There is abundant evidence linking hostile proximal aortic neck anatomy to poor outcome after endovascular aortic aneurysm repair (EVAR), yet the definition of hostile anatomy varies from study to study. This current analysis was undertaken to identify anatomic criteria that are most predictive of success or failure at the aortic neck after EVAR.**
Methods: **The study group comprised 221 patients in the Aneurysm Treatment using the Heli-FX Aortic Securement System Global Registry (ANCHOR) clinical trial, a population enriched with patients with challenging aortic neck anatomy and failure of sealing. Imaging protocols were not protocol specified but were performed according to the institution's standard of care. Core laboratory analysis assessed the three-dimensional centerline-reformatted computed tomography scans. Failure at the aortic neck was defined by type Ia endoleak occurring at the time of the initial endograft implantation or during follow-up. Receiver operating characteristic curve analysis was used to assess the value of each anatomic measure in the classification of aortic neck success and failure and to identify optimal thresholds of discrimination. Binary logistic regression was performed after excluding highly intercorrelated variables, creating a final model with significant predictors of outcome after EVAR.**
Results: **Among the 221 patients, 121 (54.8%) remained free of type Ia endoleak and 100 (45.2%) did not. Type Ia endoleaks presented immediately after endograft deployment in 58 (58.0%) or during follow-up in 42 (42.0%). Receiver operating characteristic curve analysis identified 12 variables where the classification of patients with type Ia endoleak was significantly more accurate than chance alone. Increased aortic neck diameter at the lowest renal artery ($P = .013$) and at 5 mm ($P = .008$), 10 mm ($P = .008$), and 15 mm ($P = .010$) distally; aneurysm sac diameter ($P = .001$), common iliac artery diameters (right, $P = .012$; left, $P = .032$), and a conical ($P = .049$) neck configuration were predictive of endoleak. By contrast, increased aortic neck length ($P = .050$), a funnel-shaped aortic neck ($P = .036$), and neck mural thrombus content, as measured by average thickness ($P = .044$) or degrees of circumferential coverage ($P = .029$), were protective against endoleak. Binary logistic regression identified three variables independently predictive of type Ia endoleak. Neck diameter at the lowest renal artery ($P = .002$, cutpoint 26 mm) and neck length ($P = .017$, cutpoint 17 mm) were associated with endoleak, whereas some mural neck thrombus content was protective ($P = .001$, cutpoint 11° of circumferential coverage).**
Conclusions: **A limited number of independent anatomic variables are predictive of type Ia endoleak after EVAR, including aortic neck diameter and aortic neck length, whereas mural thrombus in the neck is protective. This study suggests that anatomic measures with identifiable threshold cutpoints should be considered when defining the hostile aortic neck and assessing the risk of complications after EVAR. (J Vasc Surg 2015;61:1383-90.)**

Endovascular aneurysm repair (EVAR) surpassed open surgery as the most frequently performed treatment option for patients with abdominal aortic aneurysms (AAAs) within a decade after the first endografts were marketed.[1] EVAR, as a less invasive technique, has many advantages over open surgical repair, principally related to early morbidity and

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mortality.[2,3] The procedure, however, lacks the flexibility and durability of open surgical graft insertion, primarily a result of the interdependence of endograft sealing and the anatomic aspects of the proximal aortic neck.[4,5] Outcome after EVAR is inferior when aortic neck anatomic irregularities are encountered, including a short neck length, large neck diameter, extreme neck angulation, and abundant mural thrombus or calcium within the neck.[4,6,7] Although an open surgical anastomosis can be more difficult to perform in the presence of such anatomic issues, an open procedure depends less on neck anatomy than EVAR.

The term "hostile neck" was first used by Dillavou[7] in 2003 to characterize EVAR outcome in patients with unfavorable aortic neck anatomy. Currently, the term is often used when the aortic neck anatomy falls outside the eligibility criteria for a manufacturer's regulatory clinical trial. Recognition of hostile neck characteristics creates some concern for endograft performance at the aortic neck. Endograft trials are limited to patients with anatomy well suited for a particular endograft, and regulatory approval is granted before the device is used in the general population. Once approved for marketing, however, a broad range of anatomies are encountered, anatomies that were not evaluated in regulatory trials and thus have undefined clinical outcomes.

Despite widespread reliance on anatomic criteria for clinical decision making, there has been little work on characterizing the relative importance of different anatomic measures and on identifying optimal thresholds for each. In part, the paucity of data is a result of the infrequency of aortic neck complications. The reported frequency of type Ia endoleak is <3% in most series, precluding a rigorous multivariate analysis of the factors related to the event.[8,9] By contrast, the Aneurysm Treatment using the Heli-FX Aortic Securement System Global Registry (ANCHOR) data set provides a study population enriched with challenging aortic anatomy and aortic neck complications.[10] As such, the data set enables robust statistical comparisons of each anatomic measure across multiple endografts and operators. In tandem with receiver operating characteristic (ROC) analysis, optimal thresholds for classifying neck complications can be formulated from anatomic criteria. In this report we describe an analysis of hostile neck criteria and their comparative effect on outcome after EVAR.

METHODS

The ANCHOR study is a prospective, nonrandomized, multicenter, multinational study of the real-world use of the Heli-FX EndoAnchor System (Aptus Endosystems, Sunnyvale, Calif) in patients undergoing EVAR or who have undergone EVAR for AAA in the past. The ANCHOR study is registered on ClinicalTrials.gov (NCT01534819). Institutional Review Board or Ethics Committee approval was obtained at each site. Each patient provided written informed consent. Details of the study methodology and the device have been previously described.[11] The investigators are listed in the Appendix (online only).

Briefly, the study eligibility criteria included patients with infrarenal AAA who had adequate iliofemoral access to accommodate a 16F sheath and a life expectancy of at least 1 year. Commercially available endografts that underwent successful testing for EndoAnchor compatibility included the Zenith (Cook, Bloomington, Ind), the Excluder (W. L. Gore and Associates, Flagstaff, Ariz), and the AneuRx, Talent, and Endurant devices (Medtronic Vascular, Santa Rosa, Calif).

The study cohort comprised 221 patients enrolled in ANCHOR at 26 United States and 9 European centers between April 2012 and January 2014. The study population included 66.6% of 332 patients enrolled in the full study over the same timeframe, selected by availability of adequate baseline (before the EndoAnchor implantation procedure) and postoperative computed tomography (CT) imaging for core laboratory analysis. The 221 patients were subdivided into 121 EVAR patients without type Ia endoleak (54.3%) and 100 with aortic neck failure (54.8%) evidenced by type Ia endoleak alone in 86 patients (38.4%) or endoleak in conjunction with endograft migration in 14 (6.3%). Patients with immediate type Ia endoleaks evident on intraoperative angiography performed at the time of the initial EVAR (58 patients [26.2%]) were included in the failure group when EndoAnchors (with or without extension cuffs or bare metal stents) were implanted to address the endoleak, irrespective of whether the additional interventions remediated the endoleak (52 patients [23.5%]) or did not (six patients [2.7%]). The remaining 42 patients (19.0%) were treated with EndoAnchors for type Ia endoleaks a median of 35 months (range, 0.2-168 months) after the initial EVAR procedure. Once enrolled in ANCHOR, patients were monitored clinically for a median of 19 months (range, 0-30 months), with CT imaging studies performed through a median of 7 months (range, 0-23 months).

Imaging studies and definitions. Imaging protocols were not protocol-specified but were performed according to the institution's standard of care. Independent core laboratory analyses (Syntactx, New York, NY) were performed on noncontrast and contrast CT imaging studies. Centerline reformatting and segmentation of CT data sets was performed using iNtuition imaging software (TeraRecon, Foster City, Calif). Imaging end points were measured and reported using the methodology from the Society for Vascular Surgery reporting standards guideline documents where end point definitions were specificed.[12-15]

Aortic diameters were measured as the average diameter of the centerline reformatted aortic adventitia-to-adventitia contour. Circularity was not assumed; rather, any deviation from perfect circularity was taken into account with an electronically traced aortic contour on a plane orthogonal to the aortic centerline. Aortic neck calcium and thrombus content was measured and expressed in degrees of circumference where thickness was ≥2 mm, as evaluated on the CT image 5 mm distal to the lowest main renal artery.

The aortic neck length was calculated using two methods. The first method corresponds to what has been