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Open and endovascular repair of the nontraumatic isolated aortic arch aneurysm

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Objective: **Repair of isolated aortic arch aneurysms (nontraumatic) by either open (OAR) or endovascular (TEVAR) methods is associated with need for hypothermic circulatory arrest, complex debranching procedures, or use of marginal proximal landing zones. This study evaluates outcomes for treatment of this cohort.**

Methods: **Of 2153 patients undergoing arch repair (1993-2013), 137 (mean age, 60 years) were treated with isolated arch resection for nontraumatic aneurysms. Treatment was by open (n = 93), hybrid (n = 11), or TEVAR (n = 33) methods, with the last two approaches reserved for poor OAR candidates. Treatment was predominantly for saccular (n = 53) or fusiform (n = 30) aneurysms or dissection (n = 15). Rupture was present in 15%. Prior aortic repair was performed in the ascending (n = 30), arch (n = 40), descending (n = 24), or abdominal (n = 9) aorta. Propensity score adjustment was performed for multivariable analysis to account for baseline differences in patient groups as well as treatment selection bias.**

Results: **Early mortality was seen in nine patients (7%). Morbidity included stroke (n = 9), paraplegia (n = 1), and need for dialysis (n = 5) or tracheostomy (n = 10). A composite outcome of death and stroke was independently predicted by advancing age ($P = .055$) and performance of a hybrid procedure ($P = .012$). The 15-year survival was 59%, with late mortality predicted by increasing age, presence of peripheral vascular disease, and perioperative stroke (all $P < .05$). The 10-year freedom from aortic rupture or reintervention was 75% and was higher after OAR (2-year OAR, 94% vs TEVAR or hybrid, 78%; $P = .018$). After propensity-adjusted Cox regression analysis, both prior abdominal aortic aneurysmectomy ($P = .017$) and an endovascular or hybrid procedure ($P = .001$) independently predicted late aortic rupture or need for reintervention.**

Conclusions: **Isolated arch repair remains a high-risk procedure occurring frequently in the reoperative setting. Despite being performed in a higher risk group, endovascular strategies yielded similar outcomes but with an increased risk for aorta-related complications. These data support ongoing efforts to develop branched endografts specifically tailored for arch disease to potentially reduce morbidity related to currently available approaches. (J Vasc Surg 2014;60:57-63.)**

Since the first reported attempts at arch aneurysm repair by Michael DeBakey, morbidity rates have improved dramatically.[1-3] Whereas the majority of arch aneurysms exist as distal extensions of more proximal aortic disease or proximal extensions of descending aortic disease, the isolated nontraumatic arch aortic aneurysm represents a unique entity with its associated challenges. Exposure for traditional open aortic repair (OAR) of this pathologic process is through a median sternotomy or a thoracotomy, depending on the relative location of the arch to the midline of the chest. OAR also frequently requires adjunctive use of hypothermic circulatory arrest with its attendant increased morbidity, particularly if it is performed from a thoracotomy.[4] The associated pathologic process often either is a saccular aneurysm arising from a penetrating ulcer with its high associated atherosclerotic burden (Fig 1) or occurs in the reoperative setting of prior incomplete proximal or distal aneurysm resection, both of which contribute to increased morbidity.

In the last decade, endovascular options have been used to reduce the morbidity of thoracic aortic repair.[5] Thoracic endovascular aortic repair (TEVAR) has several limitations when it is extended to the arch aorta. These include the higher risk of stroke and the presence of inadequate landing zones due to arch branch vessel proximity or arch curvature.[6,7] In an effort to overcome these anatomic constraints, complex extra-anatomic arch vessel bypasses are constructed to extend proximal landing zones. These hybrid procedures have been evaluated in prior studies and have also been associated with significant morbidity.[8-14] However, these reports have often included large numbers of patients in whom the arch is modified to facilitate a repair of a predominantly descending thoracic aneurysm rather than solely focusing on an isolated arch aortic aneurysm. With the advent of these newer approaches, we undertook this 20-year study to evaluate both early and late outcomes associated with treatment of isolated arch aortic disease.

METHODS

This study was approved by the Institutional Review Board of the University of Michigan Hospitals (IRB HUM00044262; informed consent waived). Data from

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Fig 1. This three-dimensional reconstruction is an example of the typical saccular aneurysm evaluated in this study and probably arose from a penetrating ulcer in a 79-year-old ex-smoker who had associated coronary artery disease. This patient underwent subsequent total arch debranching with thoracic endovascular aortic repair (TEVAR) and concomitant left internal mammary artery bypass grafting to the left anterior descending coronary artery.

all patients who underwent operative therapy for nontraumatic, isolated aortic arch aneurysms at the University of Michigan from 1993 to 2013 were retrospectively collected and analyzed.

Of 2153 patients undergoing arch repair from 1993 to 2013, 137 (mean age, 60 years) were treated with isolated arch resection for nontraumatic aneurysms. Patients with ascending aneurysms extending into the arch or descending aneurysms that began in the arch and extended distally beyond the level of the left pulmonary artery were excluded. Indications for treatment were predominantly saccular aneurysm (n = 53), fusiform aneurysm (n = 30), or type B dissection (n = 15). Rupture was present in 15% of patients (n = 21), and a prior aortic repair had been performed in the ascending (n = 30; 22%), arch (n = 40; 29%), descending (n = 24; 18%), or abdominal (n = 9; 7%) aorta.

Determination of type of aortic repair was at the discretion of a surgeon experienced in aortic reconstruction. In general, evaluation for TEVAR or hybrid strategies was performed in a multidisciplinary fashion and reserved for poor OAR candidates who had complex aortic arch aneurysms.

OAR was performed in 93 patients. All open repairs were performed with extracorporeal perfusion support (mean perfusion times, 177 ± 59 minutes). Left-sided heart bypass was used in 13 patients. The remaining 80 patients had adjunctive use of deep hypothermic circulatory arrest (mean, 47 minutes), as previously described.[3,4]

For those patients undergoing an endovascular strategy, stent graft sizing and procedural technique were performed as previously described.[5] Our institutional preference employed a "bypass all" strategy of left subclavian artery revascularization unless a patient presented with frank rupture and hemodynamic instability. Forty-four patients were treated with an endovascular strategy classified according to Ishimaru.[15] Treatment into Ishimaru zone 2 (ie, proximal extent of therapy to distal origin of left carotid artery but not including it) was performed in 33 patients. Of this group, 25 patients underwent adjunctive left carotid to left subclavian arterial bypass; eight were treated without branch vessel revascularization because of marginal hemodynamic presentation. Finally, 11 patients underwent a hybrid endovascular procedure with arch vessel debranching, followed by TEVAR, with extension into zone 0 (treatment to include innominate artery and proximally). One patient had repair that extended only into zone 1. The arch vessel debranching usually consisted of initial left carotid to left subclavian arterial bypass, followed by median sternotomy and construction of ascending aorta to innominate artery and left carotid artery bypasses with a prefabricated Dacron prosthesis in nine patients. In two patients, replacement of the ascending aorta was needed to construct an appropriate proximal landing zone. This two-stage process was completed in the same hospitalization for seven patients and in a more delayed fashion in two patients. Ten patients had concomitant antegrade stent graft delivery; the remaining patient underwent delayed transfemoral delivery. Concomitant procedures included coronary artery bypass grafting and aortic valve replacement in four patients and in one patient, respectively.

In patients who were treated with an endovascular strategy, devices included TAG (W. L. Gore, Flagstaff, Ariz [n = 31]), TX2 (Cook, Bloomington, Ind [n = 12]), and Relay (Bolton Medical, Sunrise, Fla [n = 1]).

Preoperative lumbar drains were placed in hemodynamically stable patients at the discretion of the surgeon. Drains were placed in 52 patients (OAR 60% vs TEVAR or hybrid 11%; $P < .001$). Postoperative prevention of spinal cord ischemia was undertaken for patients whose aneurysms were of the distal arch and in whom the extent of treatment involved a component of the proximal descending aorta. In these patients, for all modalities of treatment, postoperative management was conducted as previously described.[4,5]

The primary outcome of this study was all-cause late mortality. Important additional outcomes included composite outcomes of death and stroke as well as death and major morbidity (stroke, spinal cord ischemia, dialysis requirement, and need for tracheostomy) and, finally, an evaluation of treatment efficacy. Data were collected from clinic visit notes, hospital charts, and imaging studies, and mortality was verified by interrogation of the Social Security Death Index.[2] Follow-up was 100% complete for the primary outcome as of September 2013 (mean follow-up, 66 ± 52 months).

Statistical analysis. Data were analyzed with SPSS software (SPSS, Chicago, Ill). All data are expressed as mean ± standard deviation where applicable. Dichotomous variables were evaluated by χ^2 analysis, continuous variables by one-way analysis of variance. A propensity score for type of treatment was constructed from a binary logistic regression with age, tobacco use, preoperative creatinine concentration, prior history of stroke or ascending or arch repair, presentation with rupture or saccular aneurysm, and era of procedure as covariates. The era of procedure was divided into three time periods: 1993-April 2005 (pre-TEVAR commercialization), May 2005-2008 (early commercial TEVAR experience), and 2009-2013 (late commercial TEVAR experience). Multivariate models (binary logistic regression or Cox proportional hazards analysis) were constructed by a forward conditional process to identify factors that were independently associated with each of the outcomes of interest. The factors used in multivariate analysis included those with $P \leq .05$ on univariate analysis. This analysis was then performed again for each of the outcome variables, with inclusion of the propensity score as a covariate to account for treatment selection bias. Survival analysis was analyzed by Kaplan-Meier methods, with log-rank testing where applicable. All results with $P < .05$ were considered statistically significant.

RESULTS

The mean age of the cohort was 59 ± 14 years (70% male). Demographic data and comorbidities are listed in Table I. This comparative analysis identifies the endovascular strategy group as older, with a higher frequency of tobacco use and saccular aneurysm aortic disease but less frequent history of prior ascending or arch repair (all $P < .05$). Procedural details are also listed in Table I. Mean duration of hospitalization was 14 ± 13 days and was significantly shorter after endovascular repair (mean, 9 ± 7 days vs OAR, 16 ± 14 days; $P < .001$). In addition, intubation time was significantly shorter after endovascular repair (mean, 25 ± 36 hours vs OAR, 69 ± 138 hours; $P = .005$).

Early results. Early mortality (defined as in-hospital or 30-day mortality) was seen in nine patients (7%) and was not significantly different between the treatment groups (OAR, n = 6 [8%] vs endovascular strategy, n = 3 [7%]; $P = .936$). After OAR, causes of early mortality included perioperative stroke (n = 4), intraoperative myocardial infarction (n = 1), and rupture of the proximal aortic anastomosis in a patient who presented emergently with a contained arch rupture (n = 1). Causes of early mortality after the endovascular strategy included aortic dissection and rupture after zone 0 debranching and TEVAR for saccular aneurysm (n = 1); cardiogenic shock from right coronary artery occlusion after zone 0 arch debranching, TEVAR, and aortic valve replacement for saccular aneurysm and moderate to severe aortic stenosis (n = 1); and perioperative stroke after emergent zone 2 TEVAR for acute type B dissection (n = 1).

Attesting to the morbidity of repair for this disease, the frequency of neurologic events in this population was high. Permanent stroke was seen in nine patients (7%) but with no significant difference among the treatment groups (OAR, n = 7 [8%] vs TEVAR or hybrid, n = 2 [5%]; $P = .511$). Of the endovascular strategy patients who suffered strokes, both had undergone off-pump coronary artery bypass along with zone 0 debranching and TEVAR. Transient stroke was seen in three patients, all from the TEVAR or hybrid group (hybrid, n = 1; TEVAR, n = 2). Importantly, neither temporary nor permanent stroke was associated with lack of left subclavian arterial revascularization ($P > .38$). Spinal cord ischemia was seen in just one patient who underwent zone 2 TEVAR and did not undergo preoperative lumbar drain placement or left subclavian artery bypass because of emergent need for intervention. Renal failure requiring dialysis was identified in five patients (4%) and equally divided between the treatment groups (OAR, n = 4 vs TEVAR or hybrid, n = 1; $P = .554$). Finally, prolonged ventilation as defined by the need for tracheostomy was identified in 10 patients, all from the OAR group (OAR, n = 10 vs TEVAR or hybrid, n = 0; $P = .024$).

A composite outcome consisting of early mortality and significant morbidity (operative death, 30-day death, continuous coma, permanent stroke, transient stroke, need for dialysis, and tracheostomy) was constructed for multivariable analysis. The composite outcome of these morbidities was independently predicted by presentation

Table I. Demographics, comorbidities, and procedural details with univariate analysis of the study cohort

Study cohort characteristics	*Open repair (n = 93)*	*TEVAR or hybrid (n = 44)*	P *value*
Demographics			
Mean age ± SD, years	57 ± 13	66 ± 15	<.001
Male	65 (70)	31 (71)	.947
Comorbidities			
History of tobacco abuse	78 (84)	5 (11)	<.001
Diabetes mellitus	8 (9)	3 (11)	.607
Hypertension	72 (77)	33 (75)	.755
Prior CVA	7 (8)	6 (14)	.255
COPD	17 (18.3)	8 (18.2)	.989
Connective tissue disease	8 (9)	2 (5)	.386
Prior AAA repair	4 (4)	5 (11)	.119
Prior ascending repair	25 (27)	5 (11)	.04
Prior arch repair	33 (36)	7 (16)	.019
Prior descending repair	19 (20)	5 (11)	.192
Other cardiac intervention	12 (13)	5 (11)	.799
Prior MI	7 (8)	5 (11)	.458
History of CHF	6 (7)	2 (5)	.6567
Mean creatinine concentration ± SD, mg/dL	1.1 ± 0.4	1.2 ± 1.0	.801
Underlying aortic disease			
Saccular aneurysm	28 (30)	25 (57)	.003
Fusiform, prior descending	16 (17)	2 (5)	.041
Fusiform, prior ascending	1 (1)	0 (0)	.49
Anomalous right subclavian	5 (5)	3 (7)	.737
Type B dissection	10 (11)	5 (11)	.915
Procedural details			
Hemodynamic instability on presentation	1 (1)	2 (5)	.195
Emergent or urgent status	22 (24)	15 (34)	.199
Aortic rupture	15 (16)	6 (14)	.803
Preoperative lumbar drain	47 (60)	5 (11)	<.001

AAA, Abdominal aortic aneurysm; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *CVA,* cerebrovascular accident; *MI,* myocardial infarction; *SD,* standard deviation.
Data are presented as number (%) unless otherwise indicated.

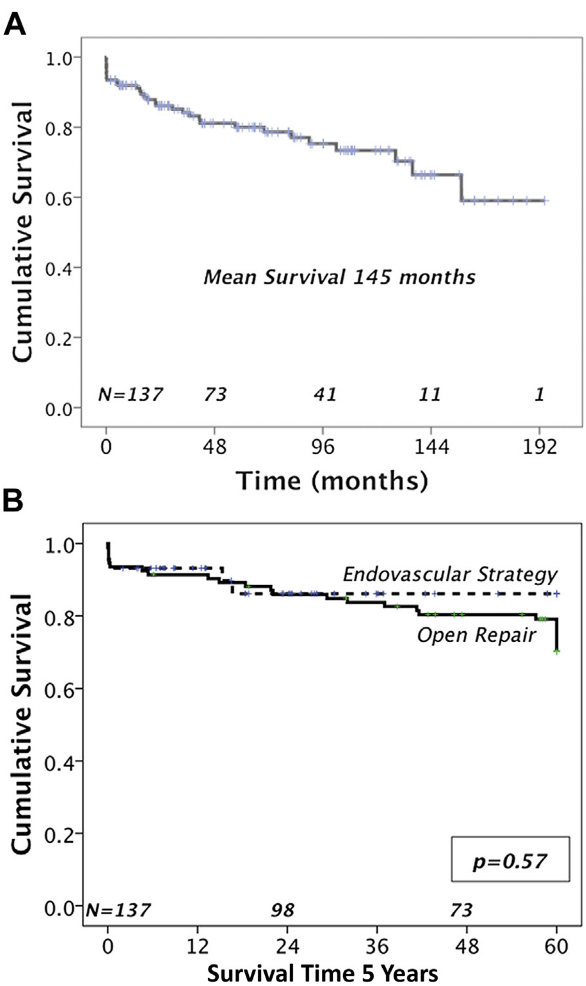

Fig 2. Kaplan-Meier analysis of the entire cohort **(A)** reveals that the 15-year survival is 59% ± 9% (mean ± standard error). Stratified by treatment approach **(B)**, there is no survival difference at 5 years between the open repair (70% ± 5%) and endovascular strategy (86% ± 6%) groups (log-rank, *P* = .57).

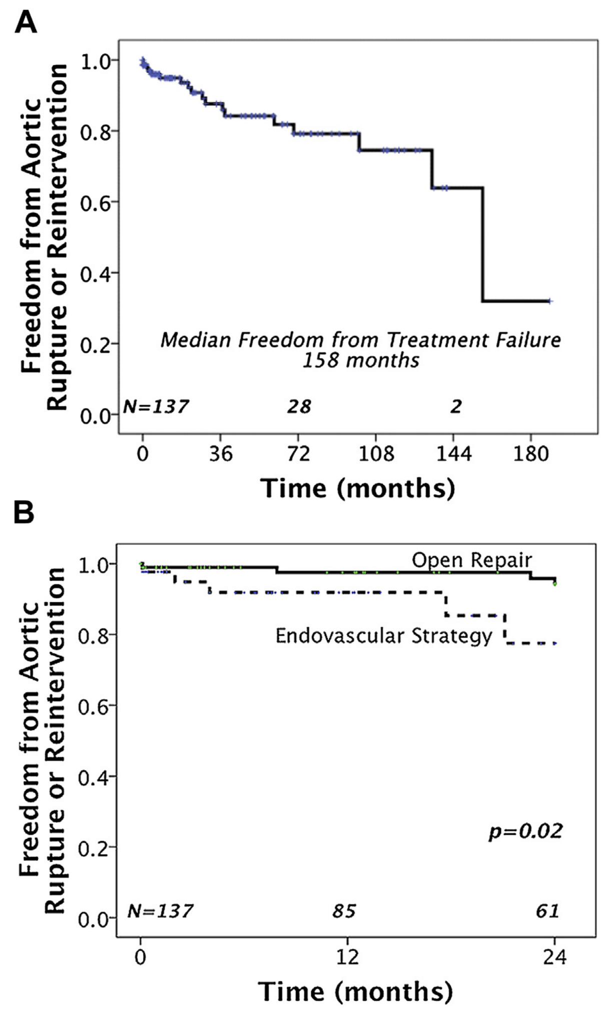

Fig 3. Actuarial analysis examining efficacy of treatment suggests that the 10-year freedom from aortic rupture or need for reintervention (ie, treatment failure) is 75% ± 7% (**A,** mean ± standard error). A comparative analysis **(B)** shows that at 2 years, the endovascular group has a treatment failure rate of 78% ± 10% compared with 94% ± 3% for the open repair group (log-rank, *P* = .02). Cox regression analysis also revealed that endovascular treatment strategy independently predicted late treatment failure.

with rupture (odds ratio [OR], 4.68; *P* = .003) and was unchanged when treatment type and propensity score were added as covariates. In construction of a multivariable model for a composite outcome of early mortality and stroke, both age (OR, 1.05; *P* = .055) and performance of a hybrid procedure alone (OR, 6.36; *P* = .012) emerged as important predictors. Again, adjustment with treatment propensity score did not affect results.

Late results. The crude mortality of the entire cohort was 22.6% (n = 31). By Kaplan-Meier analysis, the 15-year survival was estimated at 59.0% (Fig 2, *A*). Stratified by treatment algorithm, 5-year survival was similar (*P* = .57; Fig 2, *B*). Cox regression analysis revealed that important predictors of late mortality for the entire cohort included advancing age (hazard ratio [HR], 1.05; *P* = .003), peripheral vascular disease (HR, 2.23; *P* = .035), and perioperative stroke (HR, 5.65; *P* < .001) but not treatment strategy (*P* = .16), even with adjustment for propensity score.

An analysis was also performed evaluating the efficacy of treatment strategy. On univariate analysis, a history of hyperlipidemia and prior abdominal aortic aneurysm repair was associated with an increased risk of aortic rupture or aortic reintervention (all *P* < .05). For the entire cohort, survival analysis suggested that the 10-year freedom from aortic rupture or reintervention was 75% (Fig 3, *A*). Stratified by therapeutic strategy, the performance of an endovascular repair was associated with a higher 2-year risk for treatment failure (*P* = .018; Fig 3, *B*). With use of a Cox regression analysis adjusted for treatment propensity score, both prior abdominal aortic aneurysm repair (HR, 4.38; *P* = .017) and endovascular treatment strategy (HR, 7.67; *P* = .001) were independent predictors of aortic

Table II. Aortic events, treatments, and outcomes

Original operation	*Event*	*Time to event*	*Reintervention*	*Outcome*
1. Hybrid intervention	Pseudoaneurysm formation in the descending thoracic aorta	30 months	Reoperation of adjacent aorta (TEVAR)	Alive
2. Hybrid intervention	Aortic rupture	3 days	None	Deceased
3. Hybrid intervention	Type III junctional endoleak between two overlapping stents	18 months	Reoperation of adjacent aorta (TEVAR)	Alive
4. OAR	Aortobronchial fistula secondary to infected graft	70 months	Reoperation of adjacent aorta (TEVAR)	Deceased
5. TEVAR	Acute type A dissection, involving the arch	1 month	Reoperation of adjacent aorta (OAR)	Alive
6. TEVAR	Type I endoleak	29 months	Reoperation of adjacent aorta (OAR)	Alive
7. OAR	New aneurysm formation, contained rupture in the distal arch	28 months	Reoperation of adjacent aorta (OAR)	Alive
8. OAR	New aneurysm formation of the root, ascending, and distal aortic arch	158 months	Reoperation of adjacent aorta (OAR)	Alive
9. OAR	Acute type A dissection, involving the arch	36 months	Reoperation of adjacent aorta (OAR)	Alive
10. OAR	Aortobronchial fistula, saccular aneurysm of the distal arch	81 months	Reoperation of adjacent aorta (TEVAR)	Alive
11. OAR	Type B dissection with aneurysm formation involving the arch	8 months	Reoperation of adjacent aorta (TEVAR)	Alive
12. OAR	Aortic rupture	0 days	None	Deceased
13. OAR	New aneurysm formation in the descending thoracic aorta	61 months	Reoperation of adjacent aorta (TEVAR)	Alive
14. OAR	Aortobronchial fistula secondary to infected graft	18 months	Reoperation of adjacent aorta (TEVAR and OAR)	Alive
15. TEVAR	Chronic type B dissection, enlarging distal arch aneurysm	2 months	Reoperation of adjacent aorta (OAR)	Alive
16. TEVAR	New aneurysm formation in the descending thoracic aorta	38 months	Reoperation of adjacent aorta (TEVAR)	Alive
17. TEVAR	Type I and III endoleak	4 months	Reoperation of adjacent aorta (TEVAR)	Alive
18. TEVAR	Infected carotid-subclavian graft	1 month	Reoperation for carotid-subclavian graft débridement	Alive

OAR, Open aortic repair; *TEVAR,* thoracic endovascular aortic repair.

rupture or reintervention. Table II outlines the late failures in the entire cohort.

DISCUSSION

Isolated (nontraumatic) aortic arch aneurysms are uncommon configurations of thoracic aneurysms that present unique challenges for successful repair. The pathologic process associated with this lesion represents one of several configurations. A frequently seen morphologic type is a saccular configuration with its associated penetrating ulcer and concomitant generalized high atherosclerotic burden (Fig 1). Isolated arch aneurysms can also occur with a prior history of ascending or descending aortic repair, in which the respective inadequately resected adjacent arch segment has enlarged and requires reoperation. Finally, other unique pathologic changes, such as aberrant arch vessel anatomy, can also be manifested with isolated arch disease. With thoracic aneurysm repair evolving toward a more endovascular-based strategy, we analyzed outcomes associated with both open and endovascular repair of isolated arch aneurysms during 20 years.

Our data suggest that the isolated arch aortic repair is associated with a relatively high risk of perioperative stroke and death.[3] The primary outcome of late mortality was also affected by the occurrence of perioperative stroke. Finally, although the risk for late aortic treatment failure was higher for the endovascular group (HR, 7.67; $P = .001$), this did not portend a higher risk for late mortality ($P = .97$), suggesting that strategies to minimize the occurrence of perioperative stroke may improve overall results. It is also noteworthy that lack of left subclavian artery revascularization was not correlated with an increased risk for stroke. Whereas advancing age and intervention on the arch itself are expected to have an increased risk for these early deaths and stroke for both open and endovascular repair, the unique finding in this study was that their occurrence was also independently associated with the performance of a hybrid arch procedure.

In the absence of commercially available arch branched grafts, this procedure has been suggested as a potentially less invasive option for treatment of arch aneurysms by avoiding the use of extracorporeal perfusion and deep hypothermic circulatory arrest (100% and 86% of our open cohort, respectively).[8-14] Recent single-center studies evaluating hybrid arch repair have shown mixed results with this approach.[8-11] In these studies, early mortality and stroke rates have varied from 0% to 20.8% and 0.8% to 18.8%, respectively, but the procedures described have often variably included frozen elephant trunk procedures (which require hypothermic arrest) or extensive descending aortic repair. Czerny et al,[12] in a transcontinental registry evaluation of 66 zone 0 hybrid arch debranching procedures, observed an early mortality rate of 9% and stroke rate of 5%. Similarly, Cao et al,[13] in a systematic review of 27 studies describing 642 patients undergoing hybrid arch debranching, also suggested that the rates of perioperative death and stroke averaged 11.9% and 7.3%. Finally, a meta-analysis of four studies comparing open total arch replacement with hybrid arch repair showed no survival advantage of arch debranching and a trend toward increased neurologic events (OR, 1.93; $P = .1$), again attesting to the morbidity of this approach.[14]

Although it is unknown whether branched or fenestrated arch graft technology may improve early and late outcomes compared with conventional open repair, early reports of total endovascular arch repair appear promising.[16,17] In a recent review of the chimney graft technique to preserve arch vessels during endograft repair in 124 patients, the risks of early stroke and death were 4% and 4.8%, respectively.[16] At a median of 11.4 months, there was an 18% endoleak rate and a 100% patency rate for the chimney grafts, suggesting at least midterm efficacy. Similarly, Yokoi et al,[17] evaluating a precurved fenestrated endograft specifically designed for the aortic arch in 35 Japanese centers, reported death and stroke rates of less than 2%. These data suggest that a totally endovascular approach for isolated arch disease even extending to zone 0 not only is feasible but can be accomplished with excellent early results, particularly with regard to the risks for stroke and perioperative mortality. However, our results showing diminished late treatment efficacy for an endovascular-based approach should provide caution even with arch-specific endografts, and a rigorous assessment of these devices compared with conventional open surgery should be considered before broader application.

There are limitations to our study. First, this is a retrospective study limited by sampling bias and size. The second and most important limitation of this study remains the baseline patient differences between groups. There is an obvious selection bias with respect to treatment strategy, with those generally undergoing TEVAR considered unsuitable for conventional open repair. We attempted to account for this with use of multivariable analysis adjusted by a treatment strategy propensity score derived from multiple preoperative variables thought to be either clinically important in treatment allocation or significantly different between treatment groups as well as time period of the procedure. Despite this limitation, we believe that this study provides a unique comparative evaluation in which the results were similar between treatment strategies for the primary outcome of late mortality. Given the frequency of this disease process, a true randomized evaluation would likely require multiple sites and many years to complete and will likely not occur.

CONCLUSIONS

Understanding the patient population at hand, we conclude that repair of an isolated arch aortic aneurysm can be performed with acceptable early and late results. Cerebrovascular accidents remain an important predictor for both early and late mortality. Although the risk for late rupture or reintervention remains higher, an endovascular strategy may yield a shorter duration of hospitalization and similar early and late survival, particularly in the absence of need for concomitant hybrid arch debranching. These data support the ongoing efforts to develop branched endografts specifically tailored for arch disease to potentially reduce morbidity related to currently available approaches.

AUTHOR CONTRIBUTIONS

Conception and design: HP, VS, DW, ND, BY, GD
Analysis and interpretation: HP, VS
Data collection: HP, VS
Writing the article: HP, VS
Critical revision of the article: HP, VS, DW, ND, BY, GD
Final approval of the article: HP, VS, DW, ND, BY, GD
Statistical analysis: HP
Obtained funding: Not applicable
Overall responsibility: HP

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