### ACQUIRED CARDIOVASCULAR DISEASE: AORTIC ARCH

# Total aortic arch replacement: A comparative study of zone 0 hybrid arch exclusion versus traditional open repair

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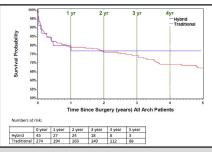
#### **ABSTRACT**

**Objective:** We attempted to identify predictors of adverse outcomes after traditional open and hybrid zone 0 total aortic arch replacement.

**Methods:** We performed multivariable analysis using 16 variables to identify predictors of adverse outcomes (mortality, permanent neurologic events, and permanent renal failure necessitating hemodialysis) in 319 consecutive patients who underwent total aortic arch replacement in the past 8.5 years and a subgroup analysis in 25 propensity-matched pairs. A total of 274 patients (85.9%) had traditional open repair, and 45 patients (14.1%) had hybrid zone 0 total arch exclusion.

**Results:** Operative mortality was 10.3% (n = 33): 11.1% (n = 5) in the hybrid group and 10.2% (n = 28) in the traditional group (P = .79). A total of 19 patients (5.9%) had permanent stroke (15 traditional [5.5%] vs 4 hybrid [8.9%]; P = .32), and 2 patients (both traditional) had permanent paraplegia (P = 1.00). The hybrid group had more total neurologic events (P = .051) but not more permanent strokes (P = .32). Prior cardiac disease unrelated to the aorta (P = .0033) and congestive heart failure (P = .0053) independently predicted permanent adverse outcome (operative mortality, permanent neurologic event, or permanent renal failure). Concomitant coronary artery bypass grafting independently predicted permanent stroke (P = .032), as did previous cerebrovascular disease (P = .032). In multivariable analysis, procedure type (hybrid or traditional) was not an independent predictor of stroke (P = .09). During a median follow-up of 4.5 years (95% confidence interval, 3.9-4.9), survival was 78.7%, with no intergroup difference (P = .14).

**Conclusions:** Among contemporary cases, both traditional and hybrid total aortic arch replacement had acceptable results. Comparing these 2 different surgical treatment options is challenging, and an individualized approach offers the best results. Permanent adverse outcome was not significantly different between the 2 groups. Procedure type is not an independent predictor of permanent stroke. Prior cardiac disease, past or current smoking, and congestive heart failure predict adverse outcomes for total aortic arch replacement. (J Thorac Cardiovasc Surg 2015;150:1591-600)



Survival was similar after traditional versus hybrid TAAR.

#### Central Message

In TAAR, open surgical versus hybrid (zone 0) repair does not seem to affect the risk of a permanent adverse outcome on the basis of our multivariable analysis of all patients.

#### Perspective

Surgical TAAR has improved through new methods and ACP. Hybrid (combined surgical/endovascular) TAAR was developed for use in high-risk patients. The choice of technique did not significantly affect permanent adverse outcome rates, but the higher stroke rate associated with hybrid TAAR makes wire manipulation and catheter skills mandatory for operators.

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Read at the 95th Annual Meeting of The American Association for Thoracic Surgery, Seattle, Washington, April 25-29, 2015.

Received for publication May 15, 2015; revisions received Aug 11, 2015; accepted for publication Aug 22, 2015.

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0022-5223/\$36.00

Copyright © 2015 by The American Association for Thoracic Surgery http://dx.doi.org/10.1016/j.jtcvs.2015.08.117 Total aortic arch replacement (TAAR) is one of the most challenging procedures in cardiovascular surgery. Since 1975, when Griepp and colleagues<sup>1</sup> reported 4 patients who underwent replacement of the aortic arch and different portions of the ascending and descending aorta under total hypothermic circulatory arrest, surgical advancements have introduced different tools to facilitate this complex operation. Today, selective antegrade cerebral perfusion (ACP) and different surgical arch reconstruction techniques offer respectable results.<sup>2-10</sup>

#### **Abbreviations and Acronyms**

ACP = antegrade cerebral perfusion CABG = coronary artery bypass grafting

CHF = congestive heart failure
CI = confidence interval
CPB = cardiopulmonary bypass
CSF = cerebrospinal fluid
CT = computed tomography

ET = elephant trunk FET = frozen elephant trunk

LCCA = left common carotid artery
MAP = mean arterial pressure

POD = postoperative day

TAAR = total aortic arch replacement
TIA = transient ischemic attack

Emerging endovascular technology offers alternative techniques for TAAR. 11-13 "Hybrid" repair, in which both open surgical and endovascular techniques are used in an effort to limit operative time or avoid circulatory arrest, is performed in patients with multiple comorbidities to minimize their morbidity and mortality. 14-16 We attempted to determine predictors of adverse outcomes in contemporary patients who underwent traditional open and hybrid zone 0 TAAR, both in the full cohort and in a propensity-matched subgroup.

#### MATERIALS AND METHODS Study Design, Variables, and Definitions of Adverse Outcomes

During the last 8.5 years, data from 319 patients who underwent TAAR (Table 1) were collected from a prospectively maintained database. Institutional review board approval was obtained from Baylor College of Medicine. The Social Security Death Index, clinic visits, and telephone calls with patients or patients' families were used for follow-up.

Of these patients, 274 (85.9%) had open total arch replacement with or without elephant trunk (ET) repair, and 45 (14.1%) had hybrid total arch exclusion, with the landing zone of the endograft exclusively in the ascending aorta (zone 0). Both groups were treated during the same period. The patient's preoperative status, frailty, the extent of the aortic pathology treated, and the presence of dissection determined the choice of replacement technique (hybrid vs traditional open). In addition, 25 propensity-matched pairs were identified between the 2 groups. Definitions of the variables used in this study, including preoperative pulmonary disease, renal disease, short-term outcomes, and operative times, have been described.<sup>17</sup> Briefly, congestive heart failure (CHF) was defined as a New York Heart Association functional class of III or IV at presentation. Operative mortality was defined as death before the current hospital discharge or within 30 days, and postoperative stroke was defined as new brain injury that was clinically or radiographically evident after the procedure. Permanent neurologic event was defined as stroke or spinal cord injury with persistent deficit at hospital discharge. Postoperative renal injury was defined as the need to start dialysis or a doubling of the patient's baseline serum creatinine level, and permanent renal injury referred to the need for hemodialysis at the time of hospital discharge. Permanent adverse outcome was defined as operative mortality, permanent neurologic event, or permanent renal failure.

The ACP time was defined as the period during circulatory arrest during which the patient was receiving ACP. The circulatory arrest time was the total time of circulatory arrest with and without ACP. The pure circulatory arrest time was the total circulatory arrest time minus the ACP time. The cardiopulmonary bypass (CPB) time was the period of CPB, not including the ACP time or the circulatory arrest time. Finally, the myocardial ischemia time was the time from the initiation of circulatory arrest or crossclamp placement until clamp removal.

# **Intraoperative Techniques and Postoperative Follow-up**

Traditional open arch repair. Different cannulation sites (right axillary, innominate, right common carotid, and femoral arteries) were used for arterial inflow for CPB, depending on the individual case. In cases of redo sternotomy with proximity of the ascending aorta and aortic arch to the sternum, right axillary artery cannulation was our first choice. The target nasopharyngeal temperature used was approximately 21°C to 25°C, and the near-infrared spectroscopy signals were monitored during the procedure. Reconstruction techniques included island patch configuration with 2 or all 3 head vessels implanted, and the Y-graft aortic arch repair with a prefabricated or custom-made bifurcated (Y), trifurcated (double-Y), or single graft (Vascutek, Terumo, Renfrewshire, Scotland). The Y-graft technique has been previously described.<sup>4</sup> An ET procedure was added when the need for a second operation in the descending or the thoracoabdominal aorta was anticipated. The skirted ET graft with a side arm is our preference (Vascutek). The side arm allows us to initiate full flow and perfuse the body distally during the aortic reconstruction. It also facilitates the initiation of the rewarming process. In 26 patients, our technique was performed concomitantly with antegrade stent delivery (frozen ET [FET]) during the open aortic arch repair in preparation for the endovascular, second-stage repair of the descending thoracic aorta or with the intent to treat the entire "mega-aorta." 18

Regardless of the repair, ACP was first administered unilaterally via the right common carotid artery and then bilaterally via the left common carotid artery (LCCA) at a flow of 10 mL/kg/min. In cases in which the regional cerebral oxygen saturation reading from near-infrared spectroscopy decreased to less than 10% of the patient's baseline measurement, we increased the flow to 13 mL/kg/min or more. Bilateral ACP was easily administered via the branches of the Y graft or directly into the LCCA via a 9F Pruitt balloon-tip catheter (LeMaitre Vascular, Burlington, Mass) in cases of island arch repair.

**Hybrid aortic arch repair.** In the hybrid group (n=45), brachiocephalic debranching with endovascular exclusion of the arch was performed, with the landing zone of the stent in zone 0 of the ascending aorta as described previously. <sup>15</sup> CPB was used in cases in which the aortic root, aortic valve, or ascending aorta needed to be replaced (n=3).

Briefly, after median sternotomy (in all but 2 cases), the brachiocephalic vessels were mobilized. Near-infrared spectroscopy was used during the supra-aortic vessel debranching, and the systemic mean aortic pressure was kept at 80 to 100 mm Hg during the head-vessel reconstruction. The head-vessel reconstruction involved the use of a prefabricated Y graft (Vascutek) or a custom-made version prepared at the operating table. Our reconstruction started by attaching the main body of the graft to the right anterolateral aspect of the ascending aorta. During this anastomosis, we kept the mean arterial pressure (MAP) low (50-60 mm Hg). The head-vessel debranching was performed distally to proximally by revascularizing the left subclavian artery first (end-to-end anastomosis) and then the LCCA and innominate artery. If the left subclavian artery was not accessible through the median sternotomy, a left carotid-to-subclavian bypass was done via a left supraclavicular incision during the same operation or a subsequent one. If the left vertebral artery

TABLE 1. Preoperative characteristics of total and propensity-matched cohorts

	Total cohort (n = 319)			Propensity-matched cohort $(n = 50)$			
Characteristic	Traditional $(n = 274)$	Hybrid (n = 45)	P value	$\begin{aligned} & Traditional \\ & (n=25) \end{aligned}$	Hybrid (n = 25)	P value	
Median age (y)	63 (53-70)	68 (62-72)	.0098	67 (56-71)	68 (58-72)	.46	
Age >70 y	83 (30.3)	17 (37.8)	.32	9 (36.0)	10 (40.0)	.77	
Male gender	178 (65.0)	16 (35.6)	.0002	12 (48.0)	11 (44.0)	.78	
Smoking	120 (43.8)	11 (24.4)	.015	9 (36.0)	9 (36.0)	1.00	
Hypertension	223 (81.4)	42 (93.3)	.048	24 (96.0)	22 (88.0)	.61	
Chronic obstructive pulmonary disease	99 (36.1)	31 (68.9)	<.0001	15 (60.0)	14 (56.0)	.77	
Preoperative cardiac disease unrelated to aorta (MI, CABG, PTCA, CAD, pacemaker)	72 (26.3)	26 (57.8)	<.0001	11 (44.0)	12 (48.0)	.78	
Acute/subacute aortic dissection	18 (6.6)	3 (6.7)	1.00	3 (12.0)	2 (8.0)	1.00	
Prior proximal aortic dissection*	99 (73.9)	3 (6.7)	<.0001	2 (40.0)	2 (8.0)	.12	
CHF	94 (34.3)	5 (11.1)	.0018	3 (12.0)	4 (16.0)	1.00	
Renal dysfunction	41 (15.0)	14 (31.1)	.0079	6 (24.0)	7 (28.0)	.75	
History of stroke, TIA	32 (11.7)	8 (17.8)	.25	1 (4.0)	5 (20.0)	.19	
Diabetes mellitus	15 (5.5)	5 (11.1)	.18	1 (4.0)	3 (12.0)	.61	

Data are reported as median (25%-75% IQR) for continuous variables and number (percentage) for categoric variables. MI, Myocardial infarction; CABG, coronary artery bypass grafting; PTCA, percutaneous transluminal coronary angioplasty; CAD, coronary artery disease; CHF, congestive heart failure; TIA, transient ischemic attack. \*Prior proximal aortic dissection only for patients who underwent redo and hybrid (not primary surgical) procedures; n = 179 for full cohort, n = 30 for propensity-matched cohort.

originated from the arch, it was directly reattached to the side of the Y graft, the LCCA, or the left subclavian artery. Different anatomic variations resulted in different debranching configurations. The endovascular exclusion of the arch was performed by antegrade or retrograde stent delivery. The choice of delivery method was based on the surgeon's preference and the quality and size of the iliofemoral vessels. Antegrade delivery was performed through a sheath inserted directly into the ascending aorta or via a 10-mm Dacron graft sutured to the main trunk of the debranching graft or directly to the aorta. The endograft was ballooned if necessary, and the stent graft was oversized by 10% to 20%. If the coverage of the descending aorta was more than 15 cm, a cerebrospinal fluid (CSF) catheter was inserted and CSF was drained intraoperatively and postoperatively. In addition, we protected the spinal cord by increasing the MAP to 90 to 100 mm Hg after stent deployment. Postoperatively, if paraplegia was encountered and the patient did not have a CSF drain, a drain was placed immediately by the anesthesia team, and the MAP was increased. The patients' operative data are presented in Table 2.

**Postoperative monitoring and follow-up.** Before a patient's discharge, a contrast-enhanced computed tomography (CT) scan of the chest was performed. An abdominal and pelvic CT was also performed if the thoracic pathology extended into the iliac bifurcation. For the hybrid group, follow-up CT was performed 3 to 6 months postoperatively and then yearly thereafter. For the traditional open group, in patients for whom the ET or the FET technique was used, we allowed a period of recovery—ranging from a few weeks to a few months or years, depending on the urgency of treating the remaining pathology—before performing the second-stage procedure.

#### **Statistical Analysis**

Univariate analysis of categoric data was performed with the chi-square test or, when necessary, the Fisher exact test. For continuous variables, the Wilcoxon 2-sample test was used. Significance was defined as P < .05. Multivariable analysis consisted of both nominal and exact logistic regression. The following 16 preoperative and intraoperative variables were used in the logistic regression analysis: type of surgery (hybrid vs traditional), age, gender, emergency/urgent need for operation, past or current smoking, hypertension, chronic obstructive pulmonary disease, cardiac disease unrelated to aorta, CHF, acute/subacute aortic dissection, renal dysfunction,

history of stroke or transient ischemic attack (TIA), diabetes mellitus, redo sternotomy, concomitant coronary artery bypass grafting (CABG), and concomitant aortic root replacement. Three additional variables—the CPB, myocardial ischemia, and ACP times—were used in the mortality model for the traditional patients alone (only 3 patients in the hybrid group required CPB). The models were run as a logistic regression with all the variables. Those variables that were significant at a *P* value of <.05 were then used in an exact logistic regression, which was done to add rigor to the results because of the relatively small number of outcomes.

To reduce the effects of any observable differences between the hybrid and traditional groups, we matched traditional and hybrid patients by using propensity scores, which were calculated for each patient by multivariable logistic regression. In the model, type of surgery was used as the dependent variable, and 17 other preoperative and intraoperative variables were included as covariates. The resulting model had a c index of 0.94. We then used an SAS macro (SAS Institute Inc, Cary, NC) to match each hybrid patient to a traditional patient with a similar propensity score, resulting in a matched cohort of 25 hybrid and 25 traditional patients. We compared these 2 groups' preoperative and intraoperative patient characteristics, as well as outcomes. The Kaplan-Meier method was used to estimate the survival functions for those patients who survived the operative period. Survival curves for the hybrid versus the traditional patients were compared by using both Wilcoxon and log-rank P values. The time to death from the date of the surgery was computed for patients who died before May 31, 2014. All statistical analyses were conducted with SAS version 9.1 (SAS Institute, Inc).

# RESULTS Operative Mortality

The overall operative mortality was 10.3% (n = 33): Five patients (11.1%) in the hybrid group died versus 28 patients (10.2%) in the traditional group (P=.79) (Table 3). Ten of the 65 urgent/emergency patients died (15.4%), and 23 among the 254 elective patients died (9.1%) (P=.13). Among the patients in the traditional group who died, 10 (35.7%) were septuagenarians, 6 (21.4%) underwent emergency procedures, and 3

TABLE 2. Operative variables for total and propensity-matched cohorts

	Total cohort (n = 319)			Propensity-matched cohort (n = 50)		
Variable	Traditional $(n = 274)$	$Hybrid\ (n=45)$	P value	Traditional (n = 25)	$Hybrid\ (n=25)$	P value
Redo sternotomy	146 (53.3)	6 (13.3)	<.0001	6 (24.0)	5 (20.0)	.73
Urgency of operation			<.0001			1.00
Elective	230 (83.9)	24 (53.3)		18 (72.0)	18 (72.0)	
Emergency/urgent	44 (16.1)	21 (46.7)		7 (28.0)	7 (28.0)	
Concomitant procedures						
Aortic root replacement	27 (9.9)	2 (4.4)	.40	1 (4.0)	2 (8.0)	1.00
Aortic valve repair	34 (12.4)	_	_	4 (16.0)	_	_
Aortic valve replacement	28 (10.2)	_	_	3 (12.0)	_	_
Coronary artery bypass	37 (13.5)	3 (6.7)	.20	1 (4.0)	0 (0.0)	1.00
Tricuspid, mitral, PFO repair	9 (3.3)	_	_	1 (4.0)	_	_
Ascending aortic replacement	_	2 (4.4)	_	_	2 (8.0)	_
Operative times (min)						
CPB time	134 (106-174) (n = 273)	118 (71-276) (n = 3)	_	138 (93-175) (n = 25)	_	_
Myocardial ischemia time	90 (72-124) ( $n = 266$ )	94 (86-166) (n = 3)	_	82 (70.5-102) (n = 24)	_	_
ACP time	59 (44-82) (n = 248)	_	_	72 (56-83) (n = 23)	_	_
Pure circulatory arrest time	21 (9-52) (n = 65)	_	_	36.5 (33-40) (n = 2)	_	_

Data are reported as median (25%-75% IQR) for continuous variables and number (percentage) for categoric variables. PFO, Patent foramen ovale; CPB, cardiopulmonary bypass; ACP, antegrade cerebral perfusion.

(10.7%) had preexisting aortic root or ascending grafts. Causes of operative mortality included multiorgan failure (n = 11, 39.3%), heart failure and inability to separate from mechanical support (n = 5, 17.9%), and fatal arrhythmia in the intensive care unit (n = 5, 17.9%). In addition, 2 patients underwent unsuccessful cardiopulmonary resuscitation for hypotension and unresponsiveness on postoperative days (PODs) 12 and 44; 1 patient became profoundly coagulopathic in the early postoperative period,

and the family agreed to withdrawal of support; 1 patient had a fatal stroke; and 1 patient died at home on POD 27 after aortic arch replacement. In 2 patients who were awaiting a stage II ET procedure, the thoracoabdominal aneurysm ruptured; 1 patient died immediately, and the other had a fatal stroke after undergoing emergency extent I repair of the aneurysm.

Of the 5 operative deaths in the hybrid group, the main cause was fatal stroke in 3 patients; 1 patient had

TABLE 3. Early outcomes for total and propensity-matched cohorts

	Total cohort (n = 319)			Propensity-matched cohort $(n = 50)$			
Outcome	Traditional (n = 274)	$Hybrid\ (n=45)$	P value	$\hline \textbf{Traditional} \ (n=25)$	$Hybrid\ (n=25)$	P value	
Permanent adverse outcome*	39 (14.2)	6 (13.3)	.87	2 (8.0)	5 (20.0)	.42	
Operative mortality	28 (10.2)	5 (11.1)	.79	2 (8.0)	4 (16.0)	.67	
30-d mortality	23 (8.4)	5 (11.1)	.57	1 (4.0)	4 (16.0)	.35	
In-hospital mortality	26 (9.5)	5 (11.1)	.79	2 (8.0)	4 (16.0)	.67	
Stroke	21 (7.7)	7 (15.6)	.091	0 (0.0)	5 (20.0)	.050	
Permanent stroke	15 (5.5)	4 (8.9)	.32	0 (0.0)	3 (12.0)	.23	
Paraplegia	2 (0.7)	1 (2.2)	.37	1 (4.0)	1 (4.0)	1.00	
Permanent paraplegia	2 (0.7)	0 (0.0)	1.00	1 (4.0)	0 (0.0)	1.00	
Total neurologic event (stroke/paraplegia)	22 (8.0)	8 (17.8)	.051	1 (4.0)	6 (24.0)	.098	
Total permanent neurologic event	16 (5.8)	4 (8.9)	.50	1 (4.0)	3 (12.0)	.61	
(stroke/paraplegia)							
Ventilation >48 h	112 (40.9)	17 (37.8)	.69	10 (40.0)	10 (40.0)	1.00	
Tracheostomy	47 (17.2)	7 (15.6)	.79	4 (16.0)	4 (16.0)	1.00	
Acute renal insufficiency	55 (20.3)	4 (8.9)	.073	7 (28.0)	3 (12.0)	.16	
Permanent hemodialysis at discharge	3 (1.1)	0 (0.00)	1.00	1 (4.0)	0 (0.0)	1.00	
Reoperation for bleeding	34 (12.4)	0 (0.00)	.0074	3 (12.0)	0 (0.0)	.23	
Pericardial window	8 (2.9)	0 (0.00)	.61	2 (8.0)	0 (0.0)	.49	
Intensive care unit stay (d)	5 (3-13)	6 (3-13)	.43	4 (3-10)	8 (4-21)	.092	
Length of stay (d)	12 (9-23)	13 (9-21)	.88	12 (10-17)	15 (10-27)	.43	

Data are reported as median (25%-75% interquartile range) for continuous variables and number (percentage) for categoric variables. \*Permanent adverse outcome = operative mortality or permanent stroke, permanent paraplegia, or permanent hemodialysis at discharge. P values: chi-square/Fisher for categoric and Wilcoxon for continuous.

TABLE 4. Multivariable analysis for outcomes for all 319 patients

Outcome	Significant predictors	P value exact regression
Mortality – all patients	Past or current smoking	.049
	Preoperative cardiac disease unrelated to the aorta	.0012
	CHF	.0022
Mortality – traditional only $(n = 241)^*$	CPB time	.0002
	Preoperative cardiac disease unrelated to the aorta	.0058
	CHF	.011
Stroke	Concomitant CABG	.0043
Permanent stroke	Concomitant CABG	.032
	Previous cerebrovascular events (stroke or TIA)	.032
Permanent neurologic event	Concomitant CABG	.043
	Previous cerebrovascular events (stroke or TIA)	.043
Permanent adverse outcome	Preoperative cardiac disease unrelated to the aorta	.0033
	CHF	.0053
	Smoking	.037

The following 16 variables were analyzed: hybrid versus traditional, age, male gender, emergency/urgent need for operation, past or current smoking, hypertension, chronic obstructive pulmonary disease, preoperative cardiac disease unrelated to aorta, congestive heart failure, acute/subacute aortic dissection, previous renal dysfunction, previous cerebrovascular disease (stroke or TIA), diabetes mellitus, concomitant CABG, concomitant aortic root replacement, redo sternotomy. *CHF*, Congestive heart failure; *CPB*, cardiopulmonary bypass; *CABG*, coronary artery bypass grafting; *TIA*, transient ischemic attack. \*P values from nominal logistic regression. Exact regression unable to run because of memory limitations.

extensive myocardial infarction on POD 3; and 1 patient died of respiratory distress on POD 28 after undergoing extensive aortic arch and abdominal aortic debranching in 1 stage.

In the propensity-matched cohort, operative mortality did not differ between the hybrid and traditional patients (n = 25 for each) (P = .67) (Table 3). Multivariable analysis using exact regression showed that past or current smoking (P = .049), preoperative cardiac disease unrelated to the aorta (P = .0012), and CHF (P = .0022) were independent predictors of mortality for the entire group. Cardiac disease unrelated to aorta, CPB time, and CHF were independent predictors of mortality for the traditional group (P = .0058, .0002, and .011, respectively) (Table 4).

Of note, in a subgroup analysis from which we excluded from the traditional group the patients who underwent FET repair (n = 26), no difference in operative mortality was identified (n = 25/248 [10.1%] traditional group, n = 5/45 [11.1%] hybrid group; P = .79).

#### **Neurologic Events**

Nineteen patients (5.9%) had permanent stroke at discharge: 4 in the hybrid group (8.9%) and 15 (5.5%) in the traditional group (P=.32). Permanent spinal cord ischemia was observed in 2 patients (traditional group); 1 of these patients had undergone an FET procedure intended to treat the entire descending thoracic aortic pathology. In the hybrid group, 1 patient had paralysis with substantial recovery. In the univariate analysis, the hybrid group had more total neurologic events (n=8, 17.8%) than the traditional group (n=22, 8.0%; P=.051) (Table 3). This difference persisted when we excluded patients who underwent an FET procedure from the traditional group

(P = .040). In the propensity-matched cohort, the hybrid group had more strokes overall (P = .050) but not more permanent strokes (P = .23) (Table 3).

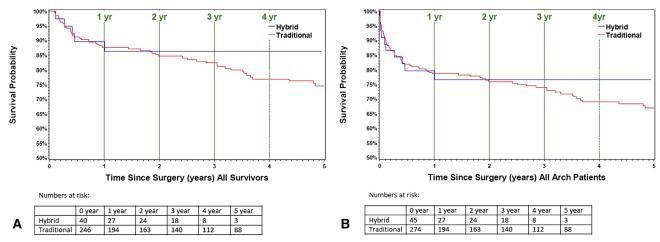
The multivariable analysis for all 319 patients (Table 4) did not identify procedure type (hybrid vs traditional) as an independent predictor of stroke (P = .090). Concomitant CABG and previous cerebrovascular events (stroke or TIA) were independent predictors of permanent stroke (P = .032 and .032) and permanent neurologic events (P = .043 and .043).

#### **Permanent Adverse Outcome**

Among all 319 patients, 45 (14.1%) had a permanent adverse outcome (mortality, permanent neurologic event, or permanent renal failure necessitating hemodialysis at discharge): 39 (14.2%) in the traditional group and 6 (13.3%) in the hybrid group (P = .87). In the propensity-matched cohort, the rate of permanent adverse outcome did not differ between the traditional (n = 2, 8%) and hybrid groups (n = 5, 20%; P = .42).

In the multivariable analysis, preoperative cardiac disease unrelated to the aorta (P=.0033), CHF (P=.0053), and current or remote smoking history (P=.037) independently predicted permanent adverse outcomes for the entire series. The elective status versus the emergency status did not play a role with regard to the overall adverse outcome.

The survival for the entire TAAR group was 78.7%, with no intergroup difference (hybrid 87.5%, traditional 77.2%; P=.14). The median follow-up period was 4.5 years (95% confidence interval [CI], 3.9-4.9) (Figure 1, A and B). Kaplan–Meier survival curves computed for the propensity-matched subgroups also were not significantly different (Figure 2, A and B).



**FIGURE 1.** A, Kaplan–Meier survival curves for the patients who underwent traditional and hybrid replacement of the total aortic arch and survived the operative period. Median follow-up was 4.5 years (95% CI, 3.9-4.9). Survival was 78.7% (225/286) overall and did not differ significantly between the hybrid group (35/40; 87.5%) and the traditional group (190/246; 77.2%) (P = .14). Wilcoxon P value comparing hybrid versus traditional survival curves = .58. Log-rank P value comparing hybrid versus traditional survival curves = .39. B, Kaplan–Meier survival curves for all the patients who underwent traditional and hybrid replacement of the total aortic arch (includes the operative deaths). Median follow-up was 4.5 years (95% CI, 3.9-4.9). Survival was 70.5% (225/319) overall and did not differ significantly between the hybrid group (35/45; 77.8%) and the traditional group (190/274; 69.3%) (P = .25). Wilcoxon P value comparing hybrid versus traditional survival curves = .83. Log-rank P value comparing hybrid versus traditional survival curves = .58.

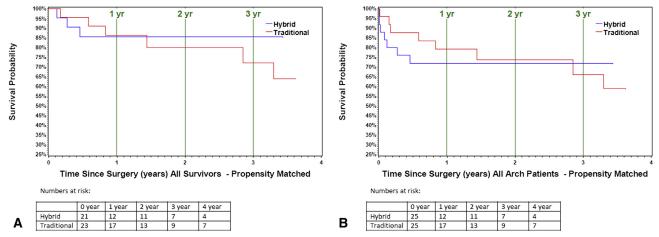
#### **DISCUSSION**

The technical and clinical challenges involved in traditional open replacement of the aortic arch inspired the development of alternative treatments for aortic arch disease. Advancements in endovascular technology and the increasing knowledge and catheter-based wire skills of cardiothoracic and cardiovascular surgeons led to increasing frequency of hybrid aortic arch operations, which are still used in high-risk patients with multiple comorbidities. <sup>14,15</sup>

A hybrid agric arch operation does not necessitate CPB or circulatory arrest. A fair comparison between hybrid and traditional TAARs should include only those hybrid procedures that involve open supra-aortic arch vessel debranching via median sternotomy 14-16,19 or, in type I and II repairs, <sup>11</sup> a series of extra-anatomic bypasses of the head vessels with arterial inflow from the descending thoracic aorta or the iliac artery in combination with the endovascular exclusion of the aortic arch with proximal landing of the endograft in zone 0 of the ascending aorta. 15 ET repairs, whether "frozen," "stented," or nonstented, are open total aortic arch operations that require circulatory arrest and are performed to treat pathology that extends into the descending thoracic or thoracoabdominal aorta. The FET, according to Bavaria and colleagues' classification, 11 is a hybrid type III approach, but the endovascular component of the operation involves the descending thoracic aorta and not the transverse aortic arch or the ascending aorta; for this reason, we classified these patients' procedures as open TAARs. These repairs involve a 1-stage procedure with the intent to treat all the pathology ("megaaorta") at once or a 2-stage repair in which a "stented"

landing zone is created within the ET to facilitate a future endovascular repair.

Few published reports compare traditional open aortic arch replacement with hybrid aortic arch repair. 14,20-24 In our report, we present our experience with 274 open and 45 hybrid TAARs (proximal landing zone 0). Our univariate analysis of baseline characteristics for both patient groups agrees with others (ie, older age, preoperative coronary events, cardiac disease, chronic obstructive pulmonary disease, and preoperative renal dysfunction were more frequent in the hybrid group) (Table 1).<sup>21,22,24</sup> Higher logistic European System for Cardiac Operative Risk Evaluations for hybrid patients have been reported in other series. 22,24 Tokuda et al<sup>24</sup> and Iba and colleagues<sup>22</sup> used propensity-score matching to show that early mortality and morbidity rates were similar between their open and hybrid groups and that the hybrid group had a higher reintervention rate with regard to aortic events. We had similar results with our analysis of the propensity-matched patients' data, which showed no difference between the 2 groups in permanent adverse outcome, mortality, or total and permanent neurologic events (Table 3), but overall stroke rate was higher in the hybrid group (P = .050), although permanent stroke at discharge was not (P = .23). This can be explained by the fact that the hybrid group had more preoperative cerebrovascular events than the traditional group (20% vs 4%; P = .19). In addition, history of stroke or TIA was an independent predictor of permanent stroke or neurologic events. This greater overall risk of stroke in the hybrid cohort makes careful wire manipulation mandatory.



**FIGURE 2.** A, Kaplan–Meier survival curves for the propensity-matched patients who underwent traditional and hybrid replacement of the total aortic arch and survived the operative period. Median follow-up period was 3.0 years (95% CI, 2.1-4.5). Survival was 77.3% (34/44) overall and did not differ significantly between the hybrid group (18/21; 85.7%) and the traditional group (16/23; 69.6%) (P = .29). Wilcoxon P value comparing hybrid versus traditional survival curves = .38. B, Kaplan–Meier survival curves for all the propensity-matched patients who underwent traditional and hybrid replacement of the total aortic arch (includes the operative deaths). Median follow-up period was 3.0 years (95% CI, 2.1-4.5). Survival was 68.0% (34/50) overall and did not differ significantly between the hybrid group (18/25; 72.0%) and the traditional group (16/25; 64.0%) (P = .54). Wilcoxon P value comparing hybrid versus traditional survival curves = .59. Log-rank P value comparing hybrid versus traditional survival curves = .90.

Milewski and colleagues<sup>14</sup> showed in their series that although in-hospital mortality and permanent cerebral neurologic deficit rates were similar between their hybrid and open repair groups, there was a significant difference in mortality between patients aged less than 75 years and more than 75 years. In our series, age did not appear to affect outcome. In a recent meta-analysis of studies of hybrid aortic arch replacement, Benedetto and colleagues<sup>20</sup> identified 4 comparative observational studies of open total arch replacement versus hybrid thoracic endovascular aortic repair for aortic arch aneurysm that included a total of 378 cases (269 open, 109 hybrid). Their report showed a trend toward greater late mortality in the hybrid group. In our cohort, survival during a median follow-up of 4.5 years (95% CI, 3.9-4.9) was similar between the hybrid and traditional groups (87.5% vs 77.2%, P = .14). Of note, the 2 propensity-matched subgroups did not differ with regard to survival, which was 85.7% for the hybrid and 69.6% for the traditional group (P = .29) (Figure 2, A and B). The median follow-up for both groups was 3 years (95% CI, 2.1-4.5). Finally, concomitant CABG and previous cerebrovascular events were independent risk factors for permanent stroke and overall permanent neurologic events in our entire series. Iba and colleagues,<sup>22</sup> in their experience with open arch repair, found that concomitant CABG and previous cerebrovascular events (ie, stroke or TIA) were independent risk factors for permanent neurologic events. This can be explained by the fact that CABG and prior cerebrovascular events are markers for atherosclerotic pathophysiology, which make patients susceptible to adverse neurologic events.

Although we acknowledge that the Society of Thoracic Surgeons score is primarily for valves and CABG, and the judgment of high risk in these patients includes aspects that are unique to aortic surgery, such as dissection, intraluminal thrombus, aortic wall calcification, and atherosclerotic load, the selection process over the time period of this study was primarily a judgment call, which led to the inclusion in the hybrid group of those who were considered by the surgical team frail and at high risk for conventional open surgery and were anatomically suitable for hybrid therapy.

#### **Study Limitations**

The inherent bias associated with retrospective designs is the main limitation of our study. Also, comparing 2 heterogeneous patient populations and surgical treatment options is challenging. Nevertheless, attempting to make a fair comparison is important. This study, to our knowledge, is one of the few comparative observational studies of open total arch replacement versus hybrid total arch exclusion for aortic arch aneurysm to include a propensity-matched analysis, as well as a multivariable analysis that enabled us to use the entire cohort. In addition, it is one of the largest comparative studies that includes only patients in the hybrid group who had zone 0 as a proximal landing zone, in an attempt for a fair comparison.

#### **CONCLUSIONS**

Traditional and hybrid TAAR have respectable results. We currently favor an individualized approach based on a patient's clinical factors when selecting the type of TAAR to

perform. Prior cardiac disease, past or current smoking, and CHF predict adverse outcomes after TAAR. No significant difference between the hybrid procedure and traditional open repair was found with regard to permanent adverse outcome, permanent stroke, or permanent neurologic events. The type of repair was not an independent predictor of stroke. Nevertheless, the higher overall stroke rate associated with hybrid procedures makes wire manipulation and catheter skills mandatory for operators.

#### **Conflict of Interest Statement**

During the past 2 years, O.P. has received consulting fees of less than \$US10,000 from Medtronic, Inc. S.A.L. currently receives funding from Vascutek Terumo. J.S.C. currently receives grant support of less than \$US10,000 from Medtronic, Inc, Vascutek Terumo, and Gore & Associates, has received consulting fees of less than \$US10,000 from Medtronic, Inc, Vascutek Terumo, and Gore & Associates during the past 2 years, and has received travel fees for lectures from Vascutek Terumo. All other authors have nothing to disclose with regard to commercial support.

You can watch a Webcast of this AATS meeting presentation by going to: http://webcast.aats.org/2015/Video/Tuesday/04-28-15\_612\_1500\_Preventza.mp4

Stephen N. Palmer, PhD, ELS, contributed to the editing of the article.

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**Key Words:** aorta, total aortic arch replacement, hybrid aortic arch repair, traditional open arch repair

#### Discussion

**Dr J. Bavaria** (*Philadelphia*, *Pa*). I congratulate Preventza and colleagues from Baylor on a well-researched and thought-out analysis of 319 aortic arch procedures comparing a traditional open approach with the hybrid concept using zone 0 TEVAR and supra-aortic vessel debranching. Although this comparison is difficult, the authors presented a large series and an appropriate, largely successful attempt at propensity analysis.

The basic overall results revealed approximately equivalent outcomes between the 2 operations despite the fact that they are used in different patient populations and different anatomic aortic presentations.

I congratulate the authors on their excellent results, always realizing how sick and challenging these patients are. Also, I

congratulate them on the use of a robust composite end point that we should all use, and I noticed that Dr Coselli used it yesterday on the permanent adverse outcome composite. I think we should all start using that outcome measure.

I have a few questions. The first one is a quick definitional issue because I had the article. Why did you not include ACP time in the total bypass time? That seems to be the standard to actually put these 2 together. I didn't quite understand that.

**Dr Preventza.** Everybody knows how progressive you are and the work that you have done with the classification of hybrid procedures. We don't include ACP time when we calculate the CPB time. In the past when we included the ACP time in the CPB time, we did not see any difference. The reality is that we are not using CPB when we give ACP. When we shut the pump down and there is complete circulatory arrest, we are not using CPB. We include both times in our article, which can simply be added together.

**Dr Bavaria.** In the hybrid group, what was the combined retrograde type A, retrograde type A aortic dissection, and type IA endoleak rate? As you know, many of us are trending toward the type II hybrids with a replaced ascending aorta, which you used 3 times, to graft zone 0 to minimize zone 0 complications and decrease cerebrovascular accident risk. Did you have any or zero?

**Dr Preventza.** With regard to the retrograde type A dissection, we did not have any retrograde type A dissections in this zone 0 group. We strongly believe, as do others, that retrograde type A aortic dissection is mainly a result of wire, catheter, and stent graft manipulation rather than a specific pathology. Before placing the partial occluding clamp into the ascending aorta to complete the proximal anastomosis, we momentarily decrease and keep the mean blood pressure at 50 to 60 mm Hg. When we perform the head vessel reconstruction, we keep the mean blood pressure at 90 to 100 mm Hg.

**Dr Bavaria.** The hybrid and open groups were different. Hybrid cases were older and sicker, had chronic obstructive pulmonary disease and coronary artery disease, were women, were frail, and had renal dysfunction. But the open cases were really more technically challenging and more extensive, including more dissections and more redos. How difficult was it to reconcile this with your propensity analysis?

**Dr Preventza.** This is why we used the propensity score match. Every patient based on the preoperative and intraoperative characteristics gets a score. On the basis of the score, we created the matching pairs. Among the 274 patients who had total open arch replacement and the 45 patients who had the hybrid procedure, we had a total of 50 patients, or 25 matched pairs. With the propensity matching score, we eliminated all the observable differences, but still there is bias.

Dr Bavaria. Thank you.

**Dr A. Estrera** (*Houston, Tex*). That was a nice presentation, but to get to the bottom line, the reality is no matter what statistical method you use, these are 2 really different groups of patients. So what we want to know from the audience's standpoint is when do you use these hybrid procedures versus open repair? Your open results are good. I want to know what you are thinking with regard to when you're going to use this hybrid technique versus a standard traditional open repair.

**Dr Preventza.** This is why we did this study. In the evolution of the adaptation of the new technology, this work exemplifies the implementation of innovation in a high-risk group before generalizing in a low-risk category. We wanted to see how this high-risk group of patients who underwent the hybrid repairs did and how they compared with the open group before we generalize the procedure into a lower-risk group.

**Dr Estrera.** So what's high risk? The redo in the 85-year-old? I can see that being high risk.

**Dr Preventza.** The patients in this group who had the hybrid repair had more comorbidities and more urgent procedures.

**Dr A. Martens** (*Hannover, Germany*). I want to redirect the attention to the traditional risk factor of cardiac ischemia time during arch surgery. Because we talked about the beating heart technique, and you told us that in the traditional group, you had the same risk factor. Cardiac ischemia time or CPB time? You mentioned it in your slides.

I want to make sure that we brought down our mortality rate by reducing the cardiac ischemia time of approximately 100 minutes during arch surgery and brought the mortality down approximately 10%. And now we're doing a risk analysis, and we didn't find any kind of CPB time and ischemia time as a risk factor for arch surgery.

So whether you do beating heart or a kind of hybrid arch approach, I believe one really important thing is that you reduce the ischemia time of the heart for the whole procedure. Either it switches into 2 procedures or you do it in the beginning, do a total arch like we do and reduce the ischemia time for the heart.

**Dr Preventza.** We do not perform the open traditional arch operation on a beating heart. Second, in the hybrid group, only 3 patients who had concomitant root or aortic valve replacement had CPB. So we couldn't really compare the operative times between the 2 groups. The multivariable analysis showed that increasing the CPB time was associated with mortality in the traditional open repair group.

**Dr E. Roselli** (Cleveland, Ohio). We've heard the difficulties of comparing these groups statistically. In our experience, we've chosen this hybrid technique in situations where we don't think the traditional one is an option. Although statistically you couldn't show a difference between the 2 groups, you did have a 13% stroke risk in your hybrid operations.

When you look at a small group of patients, you can still learn a lot when you look closely at them. Can you tell us something that you learned when you looked closely at those 13% strokes? For example, would you have used CPB in those patients or done something else to protect their brains during the operation that we can learn from when we're in that situation when we think we need to use this hybrid technique?

**Dr Preventza.** That's an excellent point. We also use the hybrid technique when we believe that the patient is too high risk to undergo hypothermic circulatory arrest. It's true that our hybrid group had higher neurologic events, and this is the Achilles' heel of this procedure. Although there is an incidence of stroke in the hybrid cases, representing in part a learning curve, we believe it would have been even higher under circulatory arrest in this group of patients with significant comorbidities, and it should not deter us from pursuing these alternative therapies. When we look back at our results, the patients in the hybrid group had more prior strokes compared with the patients who had the

traditional open repair. On the multivariable analysis, history of stroke was one of the independent risk factors for stroke or a permanent neurologic event.

**Dr Roselli.** Sure. So the strokes that you saw, were they atheroembolic or related to low flow? You said you decreased the pressure down to 50 to 60 mm Hg. You could see how if you used partial CPB to support flow to the brain that you could protect the brain better or something like that. Did you find any of those details in your analysis?

**Dr Preventza.** The patients in the hybrid group had more atherosclerotic aneurysms. We do keep the mean blood pressure at 50 to 60 mm Hg when we perform the proximal anastomosis, and we have a partial occluding clamp on the ascending aorta. When we reconstruct the head vessels, we keep the MAP at 90 to 100 mm Hg, and we follow the near-infrared spectroscopy.

Dr Roselli. Sure.

Dr Preventza. Your point is well taken.

Dr Roselli. Thank you.

### EDITORIAL COMMENTARY

## Zone 0 hybrid arch exclusion: What for?

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Received for publication Sept 1, 2015; accepted for publication Sept 2, 2015; available ahead of print Oct 15, 2015.

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J Thorac Cardiovasc Surg 2015;150:1600-1

0022-5223/\$36.00

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http://dx.doi.org/10.1016/j.jtcvs.2015.09.013

In their article entitled, "Total Aortic Arch Replacement: A Comparative Study of Zone 0 Hybrid Arch Exclusion versus Traditional Open Repair," which appears in the current issue of the *Journal*, Preventza and coworkers<sup>1</sup> report on a rarely addressed matter. Although retrospective and observational, this study represents a very interesting attempt to point out whether either technique for total aortic arch repair (TAAR) might be superior to the other. This sort of comparison and assessment seems to be more and more important in an era in which hybrid and endovascular procedures are increasingly being used worldwide.

To establish their comparison and to make it the least questionable possible, Preventza and coworkers<sup>1</sup> have used a fine and appropriate methodology. They have, indeed, included 2



Jean Bachet, MD, FEBTCS

#### Central Message

If there is no difference in outcome between conventional aortic arch and zone 0 hybrid repair, should the hybrid technique be used?

See Article page 1591.

See Editorial page 1399.