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Thoracic endovascular aneurysm repair, race, and volume in thoracic aneurysm repair

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Background: Volume-based disparities in surgical care are often associated with poorer results in African American patients. We examined the effect of treatment patterns and outcomes, by race, for isolated thoracic aortic aneurysm (TAA).

Methods: Using Medicare claims (1999-2007), we studied all patients undergoing repair of TAAs, via open surgery or thoracic endovascular aneurysm repair (TEVAR). We studied 30-day mortality and complications by race, procedure type, and hospital volume.

Results: We studied 12,573 patients who underwent open TAA repair (4% of whom were black) and 2732 patients who underwent TEVAR (8% of whom were black). In open repair, black patients had higher 30-day mortality than white patients (18% vs 10%; P < .001), while mortality rates were similar with TEVAR (8% black vs 9% white; P = .56). For open repair, black patients were more likely to undergo surgery at low-volume hospitals, where overall operative mortality was highest (14% at very low-volume hospitals, 7% at very high-volume hospitals; P < .001). However, for TEVAR, black patients were not more likely to undergo repair at low-volume hospitals, and mortality differences were not evident across volume strata (9% at very low-volume hospitals, 7% at very high-volume hospitals; P = .328). Multivariable analyses adjusting for age, sex, race, comorbidity, and volume confirmed that increased perioperative mortality was associated with black race for open surgery (OR, 2.0, 95% CI, 1.5-2.5; P < .001) but not TEVAR (OR, 0.9, 95% CI, 0.6-1.5; P = .721). *Conclusions:* While racial disparities in surgical care have a significant effect on mortality with open thoracoabdominal aortic aneurysm repair, black patients undergoing TEVAR obtain similar outcomes as white patients. New technology can limit the effect of racial disparities in surgical care. (J Vasc Surg 2013;57:56-63.)

For patients undergoing high-risk vascular surgery, a multitude of reports have established that volume-based disparities in surgical care are often associated with poorer results.¹⁻³ Further, volume-outcome disparities often disproportionately affect African American patients, who tend to seek care at low-volume hospitals.^{4,5} Examples of these patterns in vascular care have been well-described in peripheral bypass surgery, carotid revascularization, and abdominal aortic aneurysm surgery.⁶⁻⁸

Implementing policy-based solutions for volume-based disparities (such as regionalization strategies) has been dif-

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ficult, and largely unsuccessful, for several reasons.⁹⁻¹¹ First, there is often not enough access capacity in high-volume hospitals to allow all patients to have surgery at these centers.^{12,13} Second, patient preferences in choosing where to have surgery often considers several other variables more strongly than volume.⁹ Finally, cultural barriers to racial integration have been well documented,^{14,15} and therefore changing patterns of care in African American patients has become particularly difficult.

However, there may be alternative strategies, rather than simply regionalization, to improve vascular care for African American patients who seek care at low-volume hospitals. Rather than moving these patients to a highervolume hospital for open thoracic aortic aneurysm (TAA) repair, we hypothesized that dissemination of a lower-risk alternative, such as thoracic endovascular aneurysm repair (TEVAR), would potentially result in lower perioperative risks at both high- and low-volume centers. Therefore, we examined the interaction between new technology and high-risk vascular surgery, and race, using repair of thoracic aortic aneurysm as our study population, given its strong volume-outcome effect.^{16,17}

METHODS

Establishing a cohort of Medicare patients who underwent repair of TAA. We used the Medicare Physician/Supplier file and the Medicare Denominator file for these analyses, for the years 1998-2007. We selected from this cohort those patients who underwent TEVAR and open repair of TAA, using International Classification of

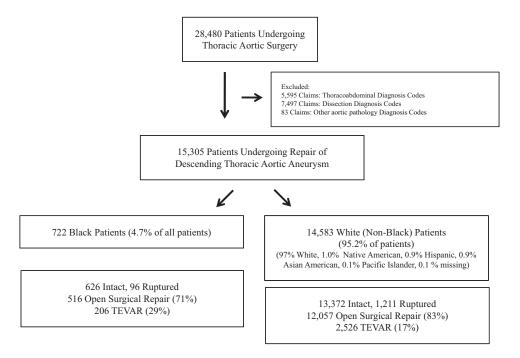


Fig 1. Derivation of the study cohort. TEVAR, Thoracic endovascular aneurysm repair.

Diseases, Ninth Revision (ICD-9) procedural codes as outlined in the Appendix. As outlined in Fig 1, we eliminated all claims that were not contained in the Medicare Denominator File, as well as patients not at least age 66. We required patients to have at least 1 year of Medicare eligibility prior to surgery and used this time period to establish comorbidities and construct patient-specific Charlson scores.¹⁸ The Charlson score contains 19 categories of comorbidity, based on ICD-9 diagnosis and procedure codes and has been validated in a variety of settings for use in administrative datasets.^{19,20}

In addition to the procedural codes for TAA, we required that each patient have a diagnosis code for TAA. Initially, we studied five distinct diagnoses, as indicated by their respective ICD-9 diagnosis codes (Appendix, online only). We excluded any patient with diagnosis codes for ascending thoracic aortic aneurysm or with procedural codes for cardiopulmonary bypass occurring with circulatory arrest. Further, we excluded patients with thoracoabdominal aneurysms, thoracic aortic dissections, and "other" aortic pathology from our analysis, as these entities are clinically distinct from TAAs. Lastly, we also excluded patients with ICD-9 procedural codes that may indicate the presence of "debranching" or other procedures to extend endovascular landing zones, such as 39.24 (aorto-renal bypass), 39.25 (aorta-iliac-femoral bypass). In situations wherein we encountered more than one procedure (open repair or TEVAR) per patient, we assigned the patient to the first procedure performed.

Exposure variables. Once we established a cohort of patients with diagnosis codes and procedural codes for TAA repair, we categorized patients by procedure type:

either open surgical repair or endovascular repair (TEVAR). Then, we stratified patients by our main exposure variables: race and volume. First, race was dichotomized as black or white, which was defined as all white patients. Next, hospital volume status was defined as total annual volume of the procedure at the center where the patient underwent repair, for each procedure type (open repair and TEVAR). Volume was assessed both continuously, as well as in five evenly sized groups (quintiles) ordered by the overall procedure-specific volume rate. After our main exposure variables, we defined demographic variables such as age, sex, and comorbidity score using the Charlson comorbidity index, as outlined above.

Main outcome measures. Our first main outcome measure was perioperative mortality. To define perioperative mortality, we sought to capture all deaths occurring in the period following surgery. Therefore, we defined perioperative mortality as death occurring within the index hospitalization (regardless of postoperative day), as well as any death within 30 days (irrespective of inpatient or outpatient status). The outcome of perioperative death was a binary categorical variable and was analyzed using χ^2 tests.

Our second main outcome measure was survival at 1 and 5 years, again established using the Medicare denominator file to establish the date of death. We censored those patients who survived until the end of our analysis (at December 31, 2007). Survival curves were estimated using Kaplan-Meier analysis, and life-table analysis was used to establish rates of 5-year survival with surrounding 95% CIs. Log-rank tests were used to determine significant differences in survival between groups, and *P*values of <.05 were

Characteristic	Overall (n = 15,305)	95% CI	Black (n = 722)	95% CI	White (n = 14,583)	95% CI	P value (black vs white)
Age	74.3	(74.2-74.4)	73.4	(72.9-73.7)	74.4	(74.3-74.5)	.001
Proportion male	55.8%	(55.0-56.6)	43.4%	(39.8-47.1)	56.4%	(55.6-57.2)	.02
Diabetes	4.90%	(4.5-5.2%)	11.60%	(9.2-13.9%)	4.50%	(4.2-4.9%)	.001
Myocardial infarction	5.4%	(5.0-5.7%)	7.40%	(5.5% - 9.4%)	5.30%	(4.9-5.6%)	.001
Congestive heart failure	10.5%	(10.0-11.0%)	19.10%	(16.2-21.9%)	10.10%	(9.6-10.6%)	.001
Cerebrovascular disease	3.7%	(3.4-4.0%)	4.00%	(2.5-5.4%)	3.60%	(3.3-4.0%)	.492
COPD	12.8%	(12.3-13.3%)	19.10%	(16.2-21.9%)	12.50%	(11.9-13.0%)	.001
Chronic renal failure	1.8%	(1.6-2.0%)	3.90%	(2.4-5.2%)	1.70%	(1.5-1.9%)	.001
History of malignancy	3.4%	(3.1-3.7%)	4.70%	(3.1-6.2%)	3.30%	(3.0-3.6%)	.001
Charlson comorbidity score	0.96	(0.93 - 0.98)	1.51	(1.36-1.67)	0.92	(0.90-0.95)	.001

Table I.	Patient demog	raphics, by r	ace and repair type
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CI, Confidence interval; COPD, chronic obstructive pulmonary disease.

considered significant. We categorized survival by race, for both open surgical repair and TEVAR.

Multivariable analyses to adjust for differences in patient race, by race and volume strata. To account for differences in patient characteristics by race, we used multivariable logistic regression to adjust for differences between black and white patients. We modeled patient age, gender, socioeconomic status, and hospital volume against our main outcome measure. We used backward stepwise regression and considered all variables with P < .2 for inclusion in the model. Model discrimination was assessed using the area under the receiver-operator characteristic curve, and model calibration was assessed using goodness-of-fit tests. All analyses were performed using SAS (SAS Institute, Cary, NC), and Stata 10 (Stata, College Station, Tex).

RESULTS

Characteristics of the cohort of patients undergoing TAA, by race. Overall, we studied 12,573 Medicare patients who underwent open procedures and 2732 patients who underwent TEVAR (Fig 1). Of these, 722 (4.7%) were black, and 14,583 (95.2%) were nonblack. The majority were of white race, (97% white, 1.0% Native American, 0.9% Hispanic, 0.9% Asian American, 0.1% Pacific Islander, 0.1% missing), and for clarity, this group is referred to as "white." By race, white patients were slightly older (74.5 vs 73.7 years; P < .001) (Table I). Further, black patients undergoing TAA repair were more likely to have diabetes, a history of myocardial infarction or congestive heart failure, and chronic obstructive pulmonary disease than white patients undergoing TAA repair.

Among patients presenting with intact TAAs, black patients were more likely to undergo TEVAR compared with white patients, as 29.3% of black patients underwent TEVAR, vs 16.8% of white patients with TAAs. In contrast, white patients were more likely to undergo open surgical repair compared with black patients. We found that 83.2% of white patients underwent open surgical repair, while fewer (70.7% of black patients) underwent open surgical repair in white patients (P < .001).

Among patients presenting with ruptured TAAs, black race was more prevalent than in intact repair (7.3% vs 4.4%;

P < .001). In terms of procedure type, black patients presenting with ruptured TAAs were just as likely to be treated with TEVAR as white patients, as 23.0% of both black and white patients were treated with endovascular approaches when representing with ruptured TAAs.

By volume strata, black patients undergoing open repair were most likely to undergo surgery in very lowvolume hospitals (P = .003). Moreover, 29% of all black patients who underwent open repair had their procedure performed in centers in the lowest quintile of hospital volume, where fewer than five procedures per year were performed (Fig 2). However, in TEVAR, black patients were more evenly distributed across volume strata. For example, 20% of TEVARs performed in black patients were performed in the lowest quintile of hospital volume, and 17% of TEVARs were performed in the highest quintile of hospital volume (P trend by volume strata = .908). In nonblack patients, there were no significant differences in patient distribution by volume strata, across procedure type. For open surgery, 21% of patients underwent surgery in hospitals in the lowest quintile of hospital volume, and 19% of patients underwent surgery in hospitals in the highest quintile of hospital volume (P = .347), and findings were similar for TEVAR.

Perioperative mortality and survival, by race. Overall, 30-day/in-hospital mortality was slightly lower for elective TEVAR compared with elective open surgical repair, although this difference was not statistically significant (6.1% TEVAR, 7.1% open surgical repair; P = .563). When we examined perioperative mortality by race and procedure type, we found that in open surgical repair, black race was associated with significantly higher perioperative mortality (6.8% white, 14.4% black; P < .001) (Fig 3). However, for TEVAR, there was no difference in perioperative mortality across racial groups (6.0% white, 7.1% black; P = .535).

For patients presenting with rupture, perioperative mortality was significantly higher with open surgical repair compared with TEVAR (45% open surgical repair, 28.4% TEVAR; P < .001). This effect was similar in both white (46.2% open surgical repair, 29.7% TEVAR; P < .001) and black patients (38% open surgical repair, 13% TEVAR; P < .02).

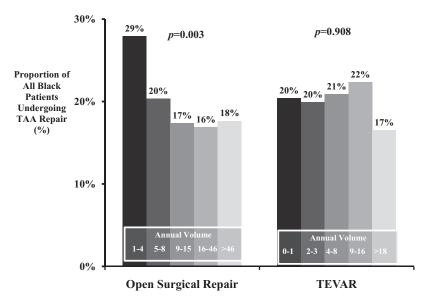


Fig 2. Distribution of patients across volume strata for African American patients. *TAA*, Thoracic aortic aneurysm; *TEVAR*, thoracic endovascular aneurysm repair.

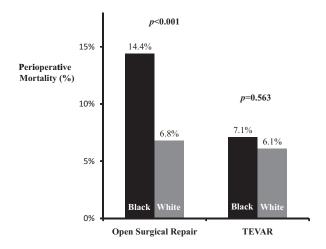


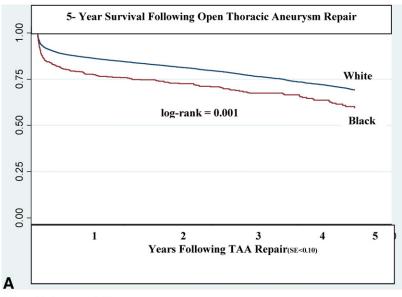
Fig 3. Perioperative mortality by race and procedure type. *TEVAR*, Thoracic endovascular aneurysm repair.

Next, we compared 5-year survival, by procedure type. Overall, patients with intact TAAs selected for TEVAR had poorer 5-year survival than patients undergoing open surgical repair (open surgical repair 5-year survival, 70%; 95% CI, 66%-72%; and TEVAR 5-year survival, 56%; 95% CI, 52%-60%; log-rank, P < .001) (Fig 3). As with perioperative mortality, 5-year survival in patients undergoing open surgical repair was worse for black patients compared with white patients (open surgical repair 5-year survival, 71%; 95% CI, 66%-72%; and TEVAR 5-year survival, 61%; 95% CI, 55%-66%; log-rank, P < .001). However, in TEVAR, there were no significant differences in 5-year survival across race strata (log-rank, P = .563) (Fig 4). These findings were similar in both aggregate analyses of all TAA repairs, as well as analyses stratified by rupture status.

Race, hospital volume, and mortality. We examined associations between hospital volume and race in terms of where patients seek care, as well as associations between hospital volume, race, and perioperative mortality. We found that annual hospital volume for open surgical repair ranged from one open surgical repair/year in very low-volume hospitals, to >46 open surgical repairs/year in very high-volume hospitals. The highest-volume hospital averaged more than 145 open surgical repairs annually (for isolated descending thoracic aneurysm) over the study period. For TEVAR, annual hospital volume ranged from one TEVAR per year in very high-volume hospitals to >18 TEVAR per year in very high-volume hospitals. The highest-volume TEVAR hospital completed more than 25 TEVARs for descending thoracic aneurysms annually in the last 3 years of the study period.

Hospital volume was inversely related to perioperative mortality for open surgical repair. As shown in Fig 5, there was a significant difference in perioperative mortality across volume strata for open surgical repair (13.5% in very low-volume hospitals, 7.3% in very high-volume hospitals; P < .001). However, there was no difference in perioperative mortality across volume strata for TEVAR (9.0% in very low-volume hospitals, 7.3% in very high-volume hospitals; P = .328).

Multivariable associations between race and perioperative mortality. We used multivariable logistic regression models to examine the interactions between race, hospital volume (as well as the other demographic and descriptive variables in our dataset), and perioperative mortality. As shown in Table II, for patients undergoing open surgical repair, black race was associated with higher operative mortality (OR, 2.0; 95% CI, 1.5-2.5; P < .0001) even when adjusting for age, hospital volume, and comorbidity score. However, for patients under-



(all standard errors <0.10)

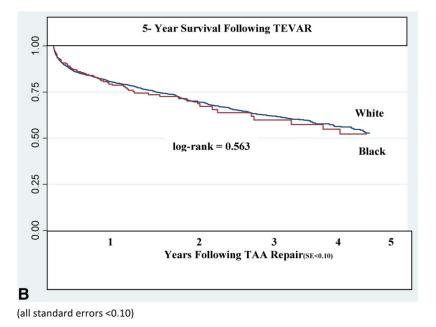


Fig 4. Overall 5-year survival by procedure type and race. TAA, Thoracic aortic aneurysm; TEVAR, thoracic endovascular aneurysm repair.

going TEVAR, while age, sex, and comorbidity continued to exhibit a significant association with perioperative mortality, neither black race (OR, 0.9; 95% CI, 0.5-1.6; P = .721) nor hospital volume (OR, 0.8; 95% CI, 0.5-1.2; P = .2111) were associated with a higher risk of perioperative mortality.

DISCUSSION

As with a variety of complex, high-risk surgical procedures, hospital volume is an important determinant of outcome following open surgical repair of TAAs.^{2,17} Further, as with many prior studies, disparities in hospital performance by volume disproportionately affect African American patients, who commonly seek care at low-volume hospitals, and thus, commonly receive worse outcomes in procedures with significant volume-outcome relation-ships.^{5,7,8,14} However, the dissemination and utilization of TEVAR may offer insight into ways to limit volume-outcome disparities, especially in African American patients. Without any complex, potentially disruptive regionalization strategy,²¹ without any large-scale implementation of health

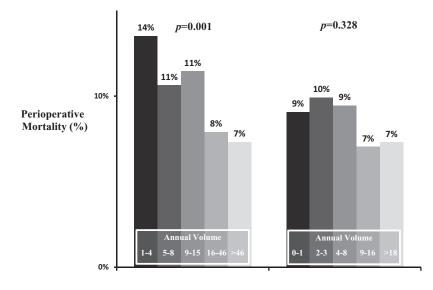


Fig 5. Mortality by hospital volume strata and procedure type.

Table II. Multivariable model association with perioperative mortality, by procedure type

	Open surgery model				TEVAR model				
	OR	95	% CI	P value	OR	95	% CI	P valu	
Age									
65-70	Referent								
71-75	1.4	1.2	1.7	<.001	1.0	0.6	1.6	.895	
76-80	1.7	1.4	2.0	< .001	1.6	1.0	2.5	.047	
81-85	2.8	2.3	3.5	< .001	1.5	0.9	2.3	.119	
85-90	5.1	3.8	6.9	< .001	2.4	1.4	4.1	.002	
90-95	12.5	4.7	33.1	< .001	2.3	0.8	6.3	.12	
>95	(Omitted)				6.5	1.1	37.5	.035	
Male sex	0.9	0.8	1.1	.288	0.8	0.6	1.0	.041	
Black race	2.0	1.5	2.5	0	0.9	0.5	1.6	.721	
Hospital volume									
Very low volume	Referent				Referent				
Low volume	0.7	0.6	0.9	.001	1.1	0.7	1.6	.778	
Medium volume	0.8	0.7	0.9	.007	1.0	0.7	1.5	.984	
High volume	0.5	0.5	0.7	< .001	0.7	0.5	1.1	.148	
Very high volume	0.5	0.4	0.6	<.001	0.8	0.5	1.2	.211	
Charlson score >3	1.6	1.4	1.8	<.001	1.4	1.0	1.8	.022	
	AUC = 0.74				AUC = 0.73				

AUC, Area under the curve; CI, confidence interval; OR, odds ratio; TEVAR, thoracic endovascular aneurysm repair.

policy,²² and without moving any patient farther from their family and local support environment,²³ vascular care for African American patients with TAAs has improved, and the effect of volume-based disparities disappeared.

Disparities in care resultant from volume-outcome relationships have been described in vascular surgery, across a variety of procedures. Similarly, health policy changes to address these disparities have varied from limited efforts aimed at educating patients, to more extensive and contentious policy changes such as reimbursement guidelines based on volume, certificate of need programs, and selective referral policies.²⁴ However, many of these policies have proven unpopular or unsuccessful, as patients are often unwilling, because of perceived or actual limitations in access to care, or unable to seek care at hospitals distant from their home, and their families may be unable to participate in their care if it is delivered in a distant center.^{25,26} Further, other studies suggest that the additional capacity necessary to perform all high-risk procedures in high-volume centers would far exceed the number of available surgical beds in the region.¹³

Racial disparities, which often reflect volume-outcome disparities, have also been especially apparent in structural aspects of surgical care^{4,7,8} and, in particular, cardiovascular

care.²⁷ For example, in a large study of over a million patients treated with acute myocardial infarction, Skinner et al demonstrated that black patients with similar levels of comorbidities had poorer outcomes when treated at hospitals that primarily treat black patients.²⁸ Further, black patients have been shown to be less likely to receive endovascular aneurysm for infrarenal abdominal aortic aneurysm, even when controlling for differences in patient characteristics and hospitals where they receive care.⁶ Finally, patients in predominantly poor, black regions have a significantly lower likelihood of undergoing revascularization prior to amputation for critical limb ischemia.²⁹ Our study, at least for patients undergoing open surgical repair, adds to this broad body of evidence describing unfavorable disparities in care for black patients.

However, our study of patients undergoing TEVAR demonstrates that well-disseminated technical innovation was an effective strategy in reducing the gap in racial disparities. While limited to a single procedure, in this setting, innovation in surgical technology transformed a complex open surgical procedure with a significant volume-outcome effect into a less-complex endovascular procedure with no volume-outcome effect. Further, TEVAR disseminated widely and rapidly across hospitals – even hospitals that disproportionally treat black patients.

Several have challenged surgeons and health services researchers to devise potential solutions, rather than to continue to simply outline the current state of disparity.⁸ While inferences from our dataset have obvious limitations, the model reviewed in our manuscript, wherein creating reproducible, effective technology that is dispersed across a variety of settings, has been an effective solution in reducing racial disparities in TEVAR.

But besides hoping for another "endovascular revolution," how can future health policy limit racial disparities? First, especially in the era of accountable care organizations and cost containment, surgical investigators and funding agencies should focus their efforts on designing and implementing new treatments that will be easily generalized across practice settings and hospitals, so these innovations might affect a broad spectrum of patients. Second, our study implies that it is necessary for policymakers to ensure that new technology is available in both academic centers and community settings, to allow care to reach diverse and disadvantaged populations, rather than simply those with access to tertiary centers.

Our study has several limitations. First, inspection of our study cohort reveals that we had a relatively small number of black patients undergoing repair of TAAs. However, this cohort remains among the largest described for TAA repair, both overall and among black patients. Second, because of the relatively small sample of black patients, volume-strata-specific comparison of black and white mortality rates was not possible, especially given the small number of black patients undergoing surgery at highvolume hospitals. However, this fact, in and of itself, suggests that patients are not distributed evenly among hospitals, a disparity highlighted in our analysis. Third, while TEVAR managed to limit racial disparities for TAA repair, similar analyses beyond the scope of this work suggest that the same finding may not translate to infrarenal AAA repair. This may result from the smaller baseline mortality rates for both procedures but more notably infrarenal endovascular aneurysm repair. Further, it is important to note that our study suggests that implementation of endovascular programs can be accomplished in settings that routinely treat African American patients. Fourth, our dataset involved the time period within which TEVAR "came of age" and began to be used commonly. While repeating our analyses limited to only those years wherein TEVAR was used commonly (2005-2007), following Food and Drug Administration approval in 2005, resulted in much smaller sample size, neither the magnitude nor the direction of effect of our findings changed significantly. And finally, the limitations in the use of administrative data in adjusting for selection bias across procedures are well described. While we cannot be completely certain that patients undergoing open surgical repair and TEVAR were identical anatomically, and our results must be considered in the context of administrative data, it is important to note that our analysis took several steps to generate a cohort of patients who could have received either type of repair. As described in our prior efforts,30,31 we generated our cohort by excluding all patients with billing or diagnosis codes, indicating extent of their TAA such that we excluded any patient in whom surgical or endovascular intervention involving the subclavian artery, the visceral segment, or cardiopulmonary bypass was required. The similarity of these groups was evidenced in these analyses, when risk-adjusted and propensity-matched analyses generated similar findings, in terms of both perioperative and longterm survival. And fifth, we used a categorization scheme of black and white (ie, nonblack) patients in this analysis. While health care disparities in Hispanic, Native American, and other ethnic groups have been reported, these groups constituted fewer than 0.5% of the patients in our analysis, and evidence surrounding health disparities (especially in Hispanic patients) has been difficult to quantify.³²

In conclusion, our study suggests that while racial disparities in surgical care have a significant effect on mortality with open thoracoabdominal aortic aneurysm repair, black patients undergoing TEVAR obtain similar outcomes as white patients. New technology can limit the effect of racial disparities in cardiovascular care. While regionalization and selective referral strategies will undoubtedly continue to evolve, leaders in developing health policy in surgery should also encourage the development of broadly applicable, generalizable solutions to surgical problems affected by racial disparities.

AUTHOR CONTRIBUTIONS

Conception and design: PG, BB, JW, LT, LL, DG, JC, DS Analysis and interpretation: PG BB, JW, LT, LL, DG, JC, DS

Data collection: PG BB, JW, LT, LL, DG, JC, DS Writing the article: PG BB, SD Critical revision of the article: PG JW, DG, JC, DS

Final approval of the article: PG BB, JW, LT, LL, DG, JC, DS

Statistical analysis: PG, BB, JW, LT, LL, DS

Obtained funding: PG

Overall responsibility: PG

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Appendix (online only). ICD-9 diagnosis and procedure codes used to define the cohort

	ICD-9 diagnosis codes	Open ICD-9 procedure codes	TEVAR ICD-9 procedure code
Intact thoracic aneurysms Ruptured thoracic aneurysms Intact thoracoabdominal aneurysms Ruptured thoracoabdominal aneurysms Thoracic aortic dissection Other thoracic aortic pathology	$\begin{array}{r} 441.2\\ 441.1, 441.5\\ 441.7\\ 441.6\\ 441.00, 441.01, 441.03\\ 441.9\end{array}$	38.35, 38.45	39.73, 39.79

ICD-9, International Statistical Classification of Diseases, Ninth Revision; TEVAR, thoracic endovascular aneurysm repair.