

# Relation of Postdischarge Care Fragmentation and Outcomes in Transcatheter Aortic Valve Implantation from the STS/ACC TVT Registry



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**Fragmented care following elective surgery has been associated with poor outcomes. The association between fragmented care and outcomes in patients undergoing transcatheter aortic valve implantation (TAVI) is unknown. We examined patients who underwent TAVI from 2011 to 2015 at 374 sites in the STS/ACC TVT Registry, linked to Center for Medicare and Medicaid Services claims data. Fragmented care was defined as at least one readmission to a site other than the implanting TAVI center within 90 days after discharge, whereas continuous care was defined as readmission to the same implanting center. We compared adjusted 1-year outcomes, including stroke, bleeding, heart failure, mortality, and all-cause readmission in patients who received fragmented versus continuous care. Among 8,927 patients who received a TAVI between 2011 and 2015, 27.4% were readmitted within 90 days of discharge. Most patients received fragmented care (57.0%). Compared with the continuous care group, the fragmented care group was more likely to have severe chronic lung disease, cerebrovascular disease, and heart failure. States that had lower TAVI volume per Center for Medicare and Medicaid Services population had greater fragmentation. Patients living > 30 minutes from their TAVI center had an increased risk of fragmented care 1.07 (confidence interval [CI] 1.06 to 1.09,  $p < 0.001$ ). After adjustment for comorbidities and procedural complications, fragmented care was associated with increased 1-year mortality (hazards ratio 1.18, CI 1.04 to 1.35,  $p = 0.010$ ) and all-cause readmission (hazards ratio 1.08, CI 1.00 to 1.16,  $p = 0.051$ ). In conclusion, fragmented readmission following TAVI is common, and is associated with increased 1-year mortality and readmission. Efforts to improve coordination of care may improve these outcomes and optimize long-term benefits yielded from TAVI. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:912–919)**

Transcatheter aortic valve implantation (TAVI) has been found to be as effective as surgical aortic valve replacement for high risk patients with severe aortic stenosis.<sup>1,2</sup> The Center for Medicare and Medicaid Services (CMS) currently has strict guidelines on which centers will be

reimbursed for performing TAVI. These guidelines attempt to ensure quality of care<sup>3</sup> but may limit care to centers with sufficient volume and resources to afford the fixed costs of starting and continuing a TAVI program. Subsequently, patients living in more remote areas may be required to travel significant distances to a referral center in order to receive their TAVI evaluation and procedure. If these patients require rehospitalization after their procedure, they may be more likely to receive it at a center different than where they received their TAVI, leading to fragmented care. The role that continuity of care plays in patients who receive a TAVI has not been assessed and we hypothesize that fragmentation of TAVI postprocedural care may be associated with negative outcomes. Utilizing the STS/ACC Transcatheter Valve Therapy (TVT) registry, we aimed to (1) analyze the association between fragmented care and patient outcomes, (2) determine whether longer driving times were associated with increased rates of fragmented care, and (3) assess population standardized rates of TAVI in order to identify populations with reduced geographic access to TAVI.

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See page 918 for disclosure information.

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## Methods

The STS/ACC TVT registry is a large database that captures detailed information on patient characteristics, procedural variables, and outcomes for all commercial TAVI cases in the United States. Data from the TVT Registry was used to identify patients who received a TAVI from November 2011 to September 2015.<sup>4</sup> The development and maintenance of the TVT Registry has been previously described. Briefly, information on all patients who receive FDA-approved TAVI devices is prospectively collected and entered into the database. The registry encompasses in-hospital, 30-day and 1-year outcomes with completeness and accuracy of data entry monitored and audited both internally and by an independent third party.

Only patients who were  $\geq 65$  years, linked to CMS, and were readmitted within 90 days of TAVI discharge were included. Fragmented care was defined as a patient having at least 1 readmission to a center different than their TAVI center within 90 days after discharge. Continuous care was defined as a patient having all readmissions to the same center as their TAVI center within 90 days after discharge. A 90-day interval was chosen because the TAVI population is often high-risk and thus may benefit from a longer duration of continuous care. For 1-year outcomes analysis, patients who were readmitted but died in the 90-day interval or who lost CMS coverage were excluded. Readmissions were subclassified as for cardiovascular causes versus noncardiovascular causes, as per previously defined algorithms (Appendix Table 1).<sup>5,6</sup>

However, since 30-day readmission is frequently used as a quality metric and monitored for CMS reimbursement, we performed a sensitivity analysis and defined fragmented care as patients who were readmitted to a center different than their TAVI center within 30 days of discharge. For this sensitivity analysis, patients who were readmitted but died in the 30-day interval or who lost CMS coverage were excluded.

The primary outcome of interest was 1-year mortality. Secondary outcomes included rehospitalization for bleeding, stroke, heart failure, and all-cause readmission ascertained using CMS claims data (Appendix Table 2). Since the exposure variable of fragmented versus continuous care was assessed in first 90 days after discharge, outcomes were ascertained from 90 days to 1 year. For the 30-day sensitivity analysis, outcomes were ascertained from 30 days to 1 year.

Driving time from patient residence to TAVI center was estimated based on residential zip code and address of TAVI center. Patient residences and TAVI centers were geocoded by converting zip+4 codes and street addresses into latitudes and longitudes. Geocoded latitude and longitude coordinates were then used to calculate the shortest driving time from patient residence to TAVI center on Google Maps. The association between driving time and fragmented care was assessed with a logistic regression model. Patients with missing driving time (because the residential zip code could not be geocoded or a driving route could not be calculated) or a driving time longer than 5 hours were excluded from the model. Since the assumption of linearity between driving time and fragmentation was violated, linear splines with one knot were used to model the nonlinear relation. Clustering of patients within TAVI centers was

taken into account by the use of robust sandwich estimates of standardized errors.

CMS linked patients were grouped into 50 states based on residential zip codes. For each state, annual TAVI volume was defined as the number of TAVI procedures (successful and aborted) performed between October 1, 2014 and September 30, 2015 on patients in that state. The ratio of annual TAVI volume relative to the population insured by CMS in 2015<sup>7</sup> was calculated. State-level ratios were then categorized into quintiles and displayed on a heat map with darker colors indicating higher values. Rates of fragmented care were similarly calculated by state, categorized into quintiles, and plotted into a heat map.

Baseline, procedural characteristics, and in-hospital outcomes are presented by fragmented versus continuous care. Continuous variables were presented as medians (1st to 3rd quartiles) and compared using the Wilcoxon rank sum test; categorical variables were presented as counts (percentages) and compared using the Pearson chi-square test or Fisher's exact test. Cumulative incidence of adverse outcomes was compared between fragmented and continuous care using Gray's method with death as a competing risk for nonfatal outcomes. To adjust for potential confounders, Cox proportional hazards models were used to assess the association of fragmented care with mortality. Nonfatal outcomes of bleeding, stroke, heart failure, and all-cause readmission were assessed using the Fine and Gray's proportional subdistribution hazards models with death as a competing risk. Clustering of patients within TAVI sites was taken into account using a robust variance estimation method. Each outcome was adjusted for predetermined clinically relevant comorbidities and postprocedural complications during the index admission, as well as acuity of the readmissions within the fragmentation ascertainment period (Appendix Table 3). Readmission acuity was derived from Medicare admission type coding<sup>8</sup> and categorized into 3 levels based on the percentage of emergent or traumatic readmissions for each patient—0%,  $\leq 50\%$ , and  $> 50\%$ . Outcomes were adjusted in a stepwise fashion—first for clinically relevant covariates and readmission acuity followed by a second model adjusted for the same covariates with the addition of driving time. Missing data were handled with single imputation given low missing rates for all covariates. Missing values were imputed to median for continuous variables and to mode for categorical variables. All statistical analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, North Carolina).

## Results

Among 8,927 patients who received a TAVI between 2011 and 2015, 27.4% were readmitted within 90 days of discharge. Most patients received fragmented care (57.0%). In patients who received fragmented care, 89.3% had fragmented care with their first readmission, 9.0% on their second readmission, and 1.7% on their third or later readmission. In a total of 13,052 readmissions, readmission for cardiovascular causes occurred in 52.0%.

Compared with patients who received continuous care, patients who received fragmented care were more likely to

Table 1  
Baseline characteristics of patients receiving fragmented and continuous care within 90 days after discharge

Baseline characteristics	Overall (N = 8,927)	Fragmented Ccare (N = 5,084)	Continuous care (N = 3,843)	p Value
Age (years)	84.0 (79.0-88.0)	84.0 (79.0-88.0)	84.0 (79.0-88.0)	0.254
Male	4,560 (51.1%)	2,595 (51.1%)	1,965 (51.2%)	0.934
White	8,506 (95.8%)	4,897 (96.8%)	3,609 (94.4%)	<0.001
Black	279 (3.1%)	118 (2.3%)	161 (4.2%)	
Driving distance to TAVI center, (miles)	28.8 (11.9-70.3)	42.9 (20.1-91.7)	15.5 (6.7-39.1)	<0.001
Driving time to TAVI center, minutes	38.0 (21.0-77.5)	52.0 (30.0-97.0)	24.0 (15.0-47.0)	<0.001
Insurance Payor (Private health insurance)	5,406 (60.6%)	3,064 (60.3%)	2,342 (60.9%)	0.519
Median income (dollars)	54,701.0 (43,380.0-72,640.0)	54,541.0 (43,371.0-72,721.0)	55,026.0 (43,405.0-72,568.0)	0.459
Hypertension	8,085 (90.6%)	4,574 (90.0%)	3,511 (91.4%)	0.029
Diabetes mellitus	3,378 (37.9%)	1,960 (38.6%)	1,418 (37.0%)	0.114
Moderate/severe chronic lung disease	2,791 (31.5%)	1,657 (32.9%)	1,134 (29.6%)	0.001
Cerebrovascular disease (stroke, TIA or carotid stenosis)	3,044 (39.6%)	1,769 (40.8%)	1,275 (37.9%)	0.010
Peripheral arterial disease	3,008 (33.8%)	1,714 (33.8%)	1,294 (33.7%)	0.913
Current/recent smoker	407 (4.6%)	227 (4.5%)	180 (4.7%)	0.629
Dialysis	492 (5.5%)	276 (5.4%)	216 (5.6%)	0.699
Prior myocardial infarction	2,240 (25.2%)	1,286 (25.4%)	954 (24.9%)	0.570
Atrial fibrillation/flutter	4,299 (48.3%)	2,446 (48.2%)	1,853 (48.3%)	0.940
Heart failure within 2 weeks	7,091 (79.6%)	4,118 (81.3%)	2,973 (77.4%)	<0.001
Prior percutaneous coronary intervention	3,242 (36.4%)	1,850 (36.4%)	1,392 (36.3%)	0.867
Prior coronary artery bypass grafting	2,595 (29.1%)	1,504 (29.6%)	1,091 (28.4%)	0.206
Prior aortic valve procedure	1,385 (15.5%)	844 (16.6%)	541 (14.1%)	0.001
Prior other cardiac surgery	596 (6.7%)	334 (6.6%)	262 (6.8%)	0.645
KCCQ-12 overall summary score	35.4 (20.8-54.2)	34.9 (19.8-53.1)	36.5 (21.4-55.2)	0.012
Five meter walk test (seconds)	8.3 (6.3-11.0)	8.3 (6.7-11.0)	8.0 (6.3-10.7)	0.026
Left ventricular ejection fraction (%)	57.0 (45.0-63.0)	57.0 (45.0-63.0)	57.0 (45.0-63.0)	0.575
Moderate/severe aortic regurgitation	1,570 (17.7%)	879 (17.4%)	691 (18.1%)	0.441
Moderate/severe mitral regurgitation	2,871 (32.4%)	1,641 (32.5%)	1,230 (32.1%)	0.684

have emergent/traumatic readmissions (81.5% vs 68.4%,  $p < 0.001$ ). Of patients who received fragmented care, 18.5%, 10.5%, and 71.0% had no,  $\leq 50\%$ , and  $>50\%$  emergent/traumatic readmissions, respectively. Of patients who received continuous care, 31.6%, 4.9%, and 63.5% had no,  $\leq 50\%$ , and  $>50\%$  emergent/traumatic readmissions, respectively. Patients who received fragmented care were more likely to have moderate-to-severe chronic lung disease, cerebrovascular disease, and heart failure within 2 weeks (Table 1). Procedural characteristics of patients who received fragmented versus continuous care are described in Appendix Table 4.

In-hospital outcomes between patients who received fragmented or continuous care were similar for major co-morbidities including atrial fibrillation, stroke, new dialysis, and VARC bleeding (Table 2). Patients who received fragmented care were statistically more likely to have had a perforation with or without tamponade, fewer vascular access site complications, and more device embolization in the aorta.

Patients who died (N = 1323) or lost CMS coverage (N = 618) within the 90 day fragmentation ascertainment period were excluded from the 1-year outcomes analyses. There were 3,971 patients in the fragmented care group and 3,015 in the continuous care group. In unadjusted analyses, patients who received fragmented care had a higher incidence of mortality (24.3% vs 19.3%  $p < 0.001$ ), bleeding (16.2% vs 14.6%,  $p = 0.032$ ), and all-cause readmission (56.5% vs 53.7%,  $p < 0.001$ ) compared with patients who received continuous care (Figure 1). After adjustment for

major co-morbidities, postprocedural complications, and acuity of readmission, fragmented care remained associated with increased mortality and all-cause readmission at 1 year (Figure 2), but not other 1-year outcomes.

For the 30-day sensitivity analysis, there were 2,682 patients who received fragmented care, and 2,921 who received continuous care. In a total of 6,639 30-day readmissions, readmission for cardiovascular reasons occurred in 55.0%. After excluding patients who died or lost CMS coverage before 30 days after discharge, there were 2,400 patients with fragmented care and 2,654 with continuous care remained in the outcomes analysis. After adjustment for covariates, patients who received fragmented care did not have significantly different mortality (hazards ratio 1.03, confidence interval [CI] 0.90 to 1.17,  $p = 0.660$ ) or all-cause readmission (hazards ratio 0.98, CI 0.91 to 1.06,  $p = 0.614$ ).

Compared with continuous care, patients who received fragmented care lived further (42.9 vs 15.5 miles,  $p < 0.001$ ) and had longer driving times (52 vs 24 minutes,  $p < 0.001$ ) to their TAVI center. Longer driving times were significantly associated with increased rates of fragmented care (Appendix Figure 1), though this association was nonlinear. In the first 30 minutes of driving time, patients had 2.48 times the odds of experiencing fragmented care (CI 2.26 to 2.72,  $p < 0.001$ ) for every 10 minutes of extra driving. After the first 30 minutes of driving, every extra 10-minute increase in driving time resulted in 1.07 times the odds of experiencing fragmented care (CI 1.06 to 1.09,  $p < 0.001$ ).

Table 2

In-hospital outcomes of patients receiving fragmented and continuous care within 90 days after discharge

In-hospital events	Overall (N = 8,927)	Fragmented care (N = 5,084)	Continuous care (N = 3,843)	p Value
Myocardial infarction	38 (0.4%)	23 (0.5%)	15 (0.4%)	0.651
Coronary compression or obstruction	19 (0.2%)	12 (0.2%)	7 (0.2%)	0.582
Conduction/native pacemaker disturbance requiring pacemaker/ICD	935 (10.5%)	540 (10.7%)	395 (10.3%)	0.578
Cardiac arrest	237 (2.7%)	135 (2.7%)	102 (2.7%)	0.985
Atrial fibrillation	631 (7.1%)	371 (7.3%)	260 (6.8%)	0.319
Annular dissection	13 (0.1%)	10 (0.2%)	3 (0.1%)	0.145
Aortic dissection	20 (0.2%)	14 (0.3%)	6 (0.2%)	0.236
Perforation with or without tamponade	86 (1.0%)	58 (1.1%)	28 (0.7%)	0.047
Transient ischemic attack	34 (0.4%)	18 (0.4%)	16 (0.4%)	0.640
Stroke	211 (2.4%)	132 (2.6%)	79 (2.1%)	0.093
Major/minor vascular access site complication	435 (4.9%)	226 (4.5%)	209 (5.4%)	0.033
Valve academic research consortium (VARC) bleeding	7,976 (90.1%)	4,564 (90.6%)	3,412 (89.4%)	0.086
No VARC major or life threatening bleeding				
Major bleeding	470 (5.3%)	247 (4.9%)	223 (5.8%)	
Life threatening or disabling bleeding	408 (4.6%)	228 (4.5%)	180 (4.7%)	
Device migration	26 (0.3%)	13 (0.3%)	13 (0.3%)	0.477
Device embolization left ventricle	26 (0.3%)	11 (0.2%)	15 (0.4%)	0.132
Device embolization aorta	37 (0.4%)	28 (0.6%)	9 (0.2%)	0.021
Device recapture or retrieval	46 (0.5%)	28 (0.6%)	18 (0.5%)	0.586
Moderate to severe perivalvular aortic regurgitation	408 (6.0%)	226 (5.8%)	182 (6.3%)	0.337
New requirement for dialysis	115 (1.3%)	70 (1.4%)	45 (1.2%)	0.387
Aortic valve reintervention	25 (0.3%)	11 (0.2%)	14 (0.4%)	0.192
Unplanned other cardiac surgery or intervention	142 (1.6%)	81 (1.6%)	61 (1.6%)	0.973
Unplanned vascular surgery or intervention	375 (4.2%)	214 (4.2%)	161 (4.2%)	0.948
Percutaneous coronary intervention	43 (0.5%)	21 (0.4%)	22 (0.6%)	0.284
Postprocedural length of stay (days)	6 (4-8)	6 (3-8)	5 (4-8)	0.416

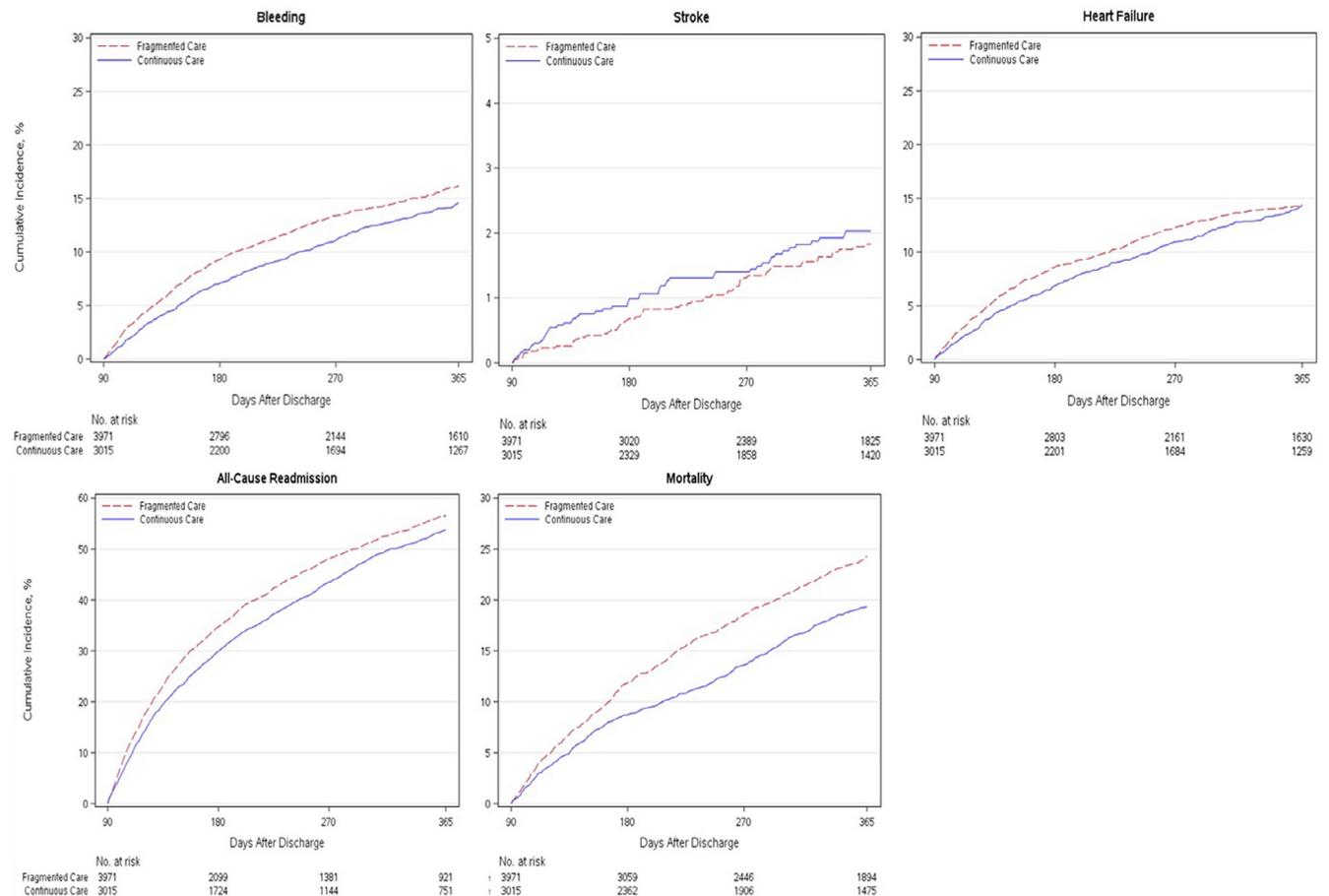


Figure 1. Unadjusted outcomes comparing fragmented versus continuous care.

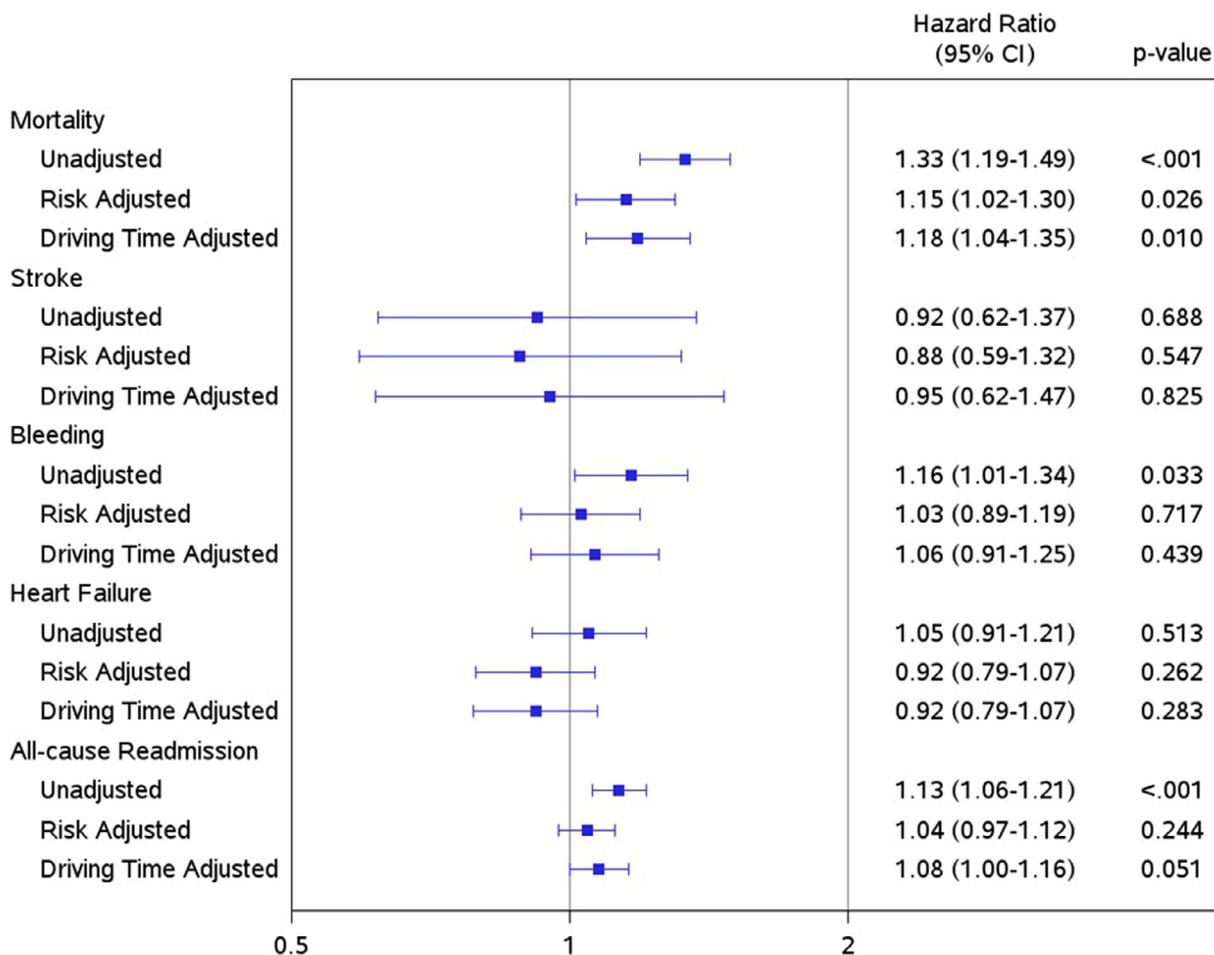


Figure 2. Unadjusted and adjusted Associations between fragmented care and 1-year outcomes.

TAVI volume per Medicare population in each state was compared across the country (Figure 3). In general, states in the Northeast and Midwest had higher TAVI volume per CMS population. Rates of fragmented care for each state were determined and similarly compared (Figure 3). In general, states that had lower TAVI volume per population had greater fragmented care.

## Discussion

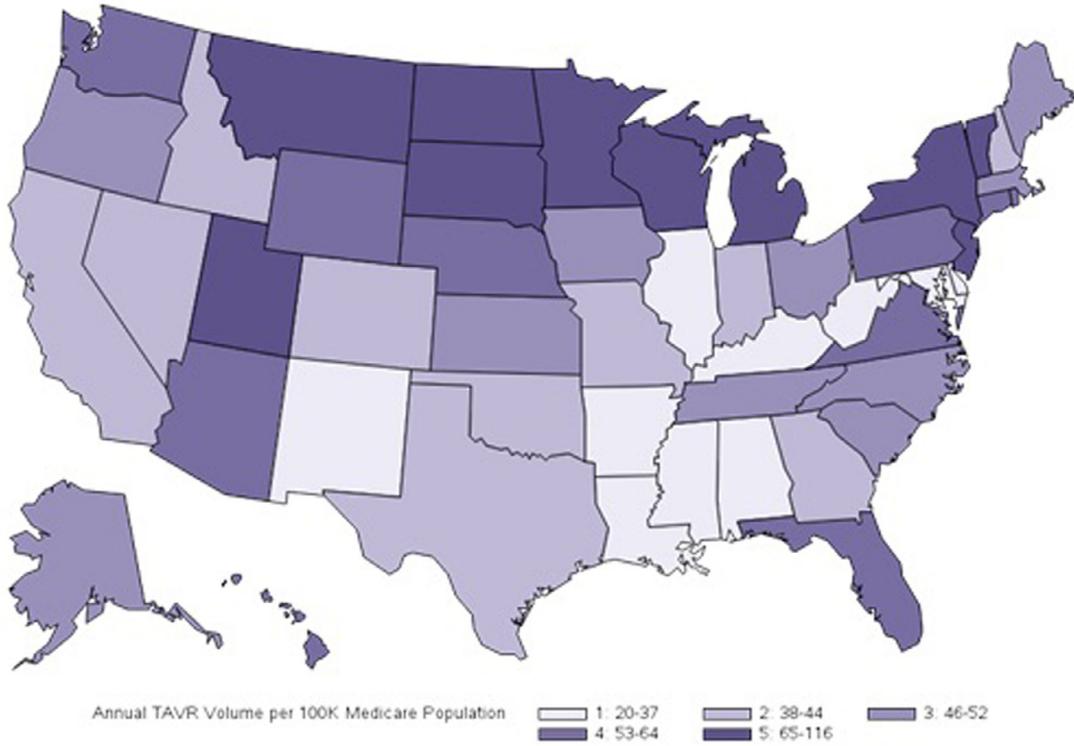
There are 3 central findings in this analysis: First, fragmented care was common after TAVI and was significantly associated with increased mortality and all-cause readmissions at 1 year. Second, longer driving times were associated with higher rates of fragmented care. Lastly, there is currently an unequal geographic distribution of TAVI volume relative to population insured by CMS and of fragmented care.

The association between fragmented care and poor outcomes has been supported by studies in other clinical scenarios.<sup>9-11</sup> Patients who received fragmented readmission care after major surgery have been associated with increased mortality and readmission.<sup>8,12,13</sup> Importantly, in our cohort, fragmented care was not associated with increased TAVI related complications of stroke, bleeding,

or heart failure and thus, the increase in mortality and readmission may be related to a high-risk population that may benefit from continuous care to manage their multiple comorbidities. Studies have demonstrated that early readmissions are more frequently due to procedural related complications, whereas noncardiovascular causes such as sepsis and patient co-morbidities are common reasons of longer term readmission and mortality.<sup>14-18</sup> We found a greater percentage of cardiovascular readmissions when we defined fragmented care in the first 30 days after TAVI discharge as compared with the first 90 days after TAVI discharge. Additionally, because fragmented care in the first 90 days after TAVI discharge was associated with increased 1-year mortality, fragmented care in the first 30 days after discharge was not. As a recent analysis demonstrated that nearly half of all deaths within and after the first 30 days after TAVI were noncardiovascular, it is not surprising that the association between fragmentation and all-cause mortality may differ from the association between fragmentation and cardiovascular end points.<sup>14</sup> Fragmented care may be more deleterious to high-risk patients with multiple comorbidities that would make them more susceptible to noncardiovascular rehospitalizations unrelated to TAVI.

In addition to understanding the effect of post-TAVI care fragmentation on outcomes, we aimed to determine

**A**



**B**

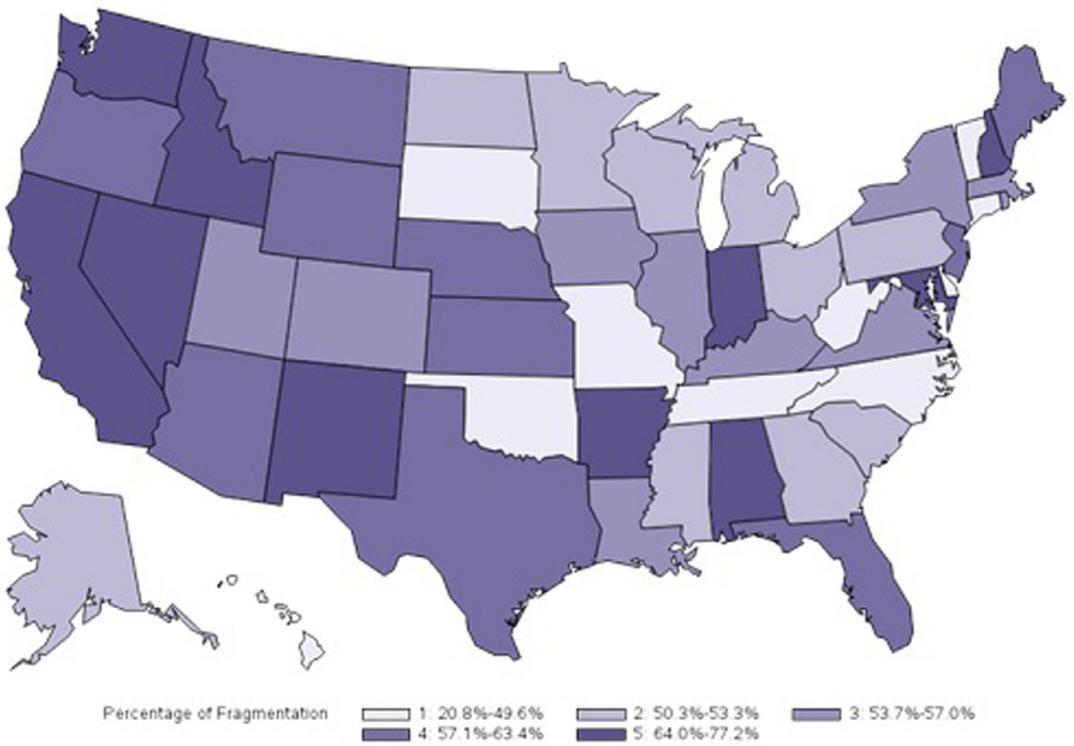


Figure 3. National heat map; (A) Annual TAVI volume relative to medicare population by state. (B) Percentage of 90-day fragmented care by state.

potential effects of driving time on fragmentation. In our cohort, driving time was significantly associated with increased fragmentation of care after TAVI. Although increased driving time was associated with increased care fragmentation regardless of driving time, we did note a decrease in magnitude of effect after approximately 30 minutes. Increased acuity of readmission is unlikely to explain this decrease in magnitude because a more acute readmission would more likely increase the odds of fragmented care with longer travel distances in the setting of transport to the nearest available hospital. This difference may be a result of a greater number of hospitals and subsequently, greater availability of choice, in more urbanized areas.<sup>19,20</sup> Prolonged driving distances has been found to be associated with poor outcome in other studies. In patients who undergo cardiac surgery, increased distance traveled has been associated with worse short-term outcomes including higher rates of death and readmissions.<sup>21–23</sup> We found that driving time was significantly associated with increased fragmented care; however, the direct relation between driving time and patient outcomes after TAVI requires further investigation.

We have also demonstrated that there is an unequal distribution of care fragmentation across the country and that there is an unequal distribution of TAVI volume relative to Medicare patients at the state level. Assuming a relatively homogenous distribution of patients  $\geq 65$  years with severe aortic stenosis, this may represent unequal geographic access to TAVI centers. From a societal perspective, there is a balance between high volume, specialized hospitals and equal distribution, and geographic access to care. The association between higher volumes and better outcomes has been observed for specialized procedures in thoracic, cardiovascular, and gastrointestinal surgery.<sup>24–26</sup> Further, regionalization of care has been supported to optimize management of myocardial infarction and cardiac arrest.<sup>27,28</sup> Previous studies have also shown, however, that the presence of specialized hospitals can lead to unequal access to care for myocardial infarctions, stroke, and specialized surgeries, in part due to patient geographic barriers.<sup>29,30</sup> The present data suggest that TAVI is currently unequally distributed relative to population within the United States and that driving distance is associated with care fragmentation. Care fragmentation was not associated with TAVI specific outcomes; however, its association with 1-year mortality and all cause admission demonstrates for the first time that continuity of care and geographic access to TAVI services are important considerations.

There are limitations to this analysis. Although we adjusted for clinically relevant factors, the TVT registry does not capture all clinically relevant variables that may affect outcomes, which may result in residual confounding. The TVT registry also only encompasses information on patients who received commercial TAVI valves, and the analysis did not include patients without CMS linkage. Differences in baseline characteristics between CMS linked and nonlinked patients, however, were not clinically significant (Appendix Table 5). Furthermore, we have excluded patients who died within the first 90 days after TAVI and thus our findings should be interpreted in those who survive the first 90 days after TAVI. Lastly, for the purposes of

establishing population standardized TAVI volume, we used CMS population as the denominator. To truly assess the geographic distribution of TAVI, it would be more appropriate to index TAVI volume to the population of those with severe, symptomatic aortic stenosis. Unfortunately, there is currently no accurate national census of the population with severe, symptomatic aortic stenosis.

There is currently an unequal distribution of TAVI volume in the US with varying rates of fragmented care. Although fragmented care was not significantly associated with TAVI related stroke, bleeding, and readmission for heart failure, it was associated with increased 1-year mortality and readmission. Efforts to improve coordination of care may improve long-term outcomes for this high-risk population and optimize benefits yielded from TAVI.

## Disclosures

Alice Wang MD MHS, Zhuokai Li PhD, Andrzej S. Kosinski PhD, Babatunde Yerokun MD MHS, Morgan L. Cox MD, Brian C. Gulack MD MHS, and Renato D. Lopes PhD, and David Holmes and G. Chad Hughes and Peter K Smith have no relevant disclosures to report.

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## Supplementary materials

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