The Potential Impact of “Take the Volume Pledge” on Outcomes After Carotid Artery Stenting

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BACKGROUND: The “Volume Pledge” aims to centralize carotid artery stenting (CAS) to hospitals and surgeons performing ≥ 10 and ≥ 5 procedures annually, respectively.

OBJECTIVE: To compare outcomes after CAS between hospitals and surgeons meeting or not meeting the Volume Pledge thresholds.

METHODS: We queried the Nationwide Inpatient Sample for CAS admissions. Hospitals and surgeons were categorized as low volume and high volume (HV) based on the Volume Pledge. Multivariable hierarchical regression models were used to examine the impact of hospital volume (2005–2011) and surgeon volume (2005–2009) on perioperative outcomes.

RESULTS: Between 2005 and 2011, 22 215 patients were identified. Most patients underwent CAS by HV hospitals (86.4%). No differences in poor outcome (composite endpoint of in-hospital mortality, postoperative neurological or cardiac complications) were observed by hospital volume but HV hospitals did decrease the likelihood of other complications, nonroutine discharge, and prolonged hospitalization. From 2005 to 2009, 9454 CAS admissions were associated with physician identifiers. Most patients received CAS by HV surgeons (79.2%). On multivariable analysis, hospital volume was not associated with improved outcomes but HV surgeons decreased odds of poor outcome (odds ratio [OR] 0.76, 95% confidence interval [CI] 0.59–0.97; $P = .028$), complications (OR 0.56, 95% CI 0.46–0.71, $P < .001$), nonroutine discharge (OR 0.70, 95% CI 0.57–0.87; $P = .001$), and prolonged hospitalization (OR 0.52, 95% CI 0.44–0.61, $P < .001$).

CONCLUSION: Most patients receive CAS by hospitals and providers meeting the Volume Pledge threshold for CAS. Surgeons but not hospitals who met the policy’s volume standards were associated with superior outcomes across all measured outcomes.

KEY WORDS: Hospital volume, Surgeon volume, Carotid artery stenting, Centralization, Outcomes, Health policy

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High-volume hospitals (HVHs) and high-volume surgeons (HVSs) have been associated with improved outcomes for a variety of complex procedures, supporting efforts for the centralization of surgical care.^{1–4} To translate these findings into policy, 3 major academic health systems established the “Take the Volume Pledge” initiative in 2015.⁵ The Pledge set minimum hospital and surgeon

volume standards for 10 complex gastrointestinal, cardiovascular, and orthopedic operations, challenging other health systems to join in order to promote optimal outcomes.⁶

Carotid artery stenting (CAS) was among the selected procedures of the Pledge, establishing a minimum volume of 10 annual procedures for hospitals and 5 annual procedures for surgeons.⁵ Clinical trials have identified the endovascular procedure as an efficacious and safe therapeutic alternative to carotid endarterectomy for the treatment of carotid artery stenosis in select patients.^{7,8} Most prior studies have demonstrated lower rates of mortality and stroke after carotid stenting procedures performed by HV institutions and providers.^{9–15} Notably, among Medicare beneficiaries, patients treated by low-volume (LV) operators were twice as likely to die

ABBREVIATIONS: CAS, carotid artery stenting; CI, confidence interval; CREST, Carotid Revascularization Endarterectomy Trial Versus Stenting Trial; LOS, length of stay; LVH, low-volume hospital; LVS, low-volume surgeons; HVS, high-volume surgeons; HVH, high-volume hospital; ICD-9, International Classification, Ninth Revision; LOS, length of stay; NIS, Nationwide Inpatient Sample; OR, odds ratio

within 30 d after stenting compared to patients treated by HVSS.¹⁴

While the Pledge aims to improve patient outcomes, providers and policymakers have raised concerns regarding the potential unintended consequences that centralization policies may have on access to high-quality surgical care.^{16,17} Minorities and underinsured patients are less likely to receive complex surgery at HV centers,¹⁸ and an increase in travel burden decreased surgical access for rural communities, and barriers in the continuity of care may further exacerbate health disparities in already vulnerable patient populations.¹⁹

To date, limited knowledge exists regarding the potential impact of Volume Pledge on access to CAS care and outcomes if it were broadly implemented. The primary objective of this study was to evaluate the impact of the Pledge's minimum volume standards for hospitals and surgeons on outcomes after CAS. We also sought to determine differences in patient characteristics and the proportion of patients who receive care by hospitals and surgeons that meet or do not meet the Volume Pledge.

METHODS

Inclusion and Exclusion Criteria

We queried the Nationwide Inpatient Sample (NIS) from 2005 to 2011 for adult patients who underwent CAS for carotid artery stenosis. The NIS is the largest all-payer inpatient administrative database comprised of patient discharge data from a 20% stratified sample of US nonfederal hospitals.²⁰ Cases with an International Classification, Ninth Revision (ICD-9) diagnosis code of asymptomatic (443.10, 433.30) and symptomatic (433.11, 433.31) carotid artery stenosis that underwent CAS (ICD-9 00.63) were extracted.²¹ This study was exempt from institutional review board approval as the NIS is a publicly available database and contains no personal identifying information.

Hospital Volume and Surgeon Volume

Our 2 primary exposures of interest were hospital volume and surgeon volume. Based on the volume standards established by the Volume Pledge for CAS, hospitals were categorized as LVH or HVH if they performed <10 or ≥10 annual procedures, respectively. Similarly, surgeons were categorized based on the Volume Pledge as LV surgeons (LVSS) and HVSS if they performed <5 and ≥5 procedures per year, respectively.

Outcomes

The primary outcome of interest was poor outcome: a composite endpoint of either in-hospital mortality or postoperative neurological (iatrogenic ischemic stroke or intracranial hemorrhage; ICD-9997.0-.09) or postoperative cardiac complications (cardiac arrest, failure, or insufficiency; ICD-9997.10). Secondary outcomes included other periprocedural complications, nonroutine discharge, and prolonged length of stay (LOS). Periprocedural complications included respiratory failure (518.4, 518.5, 518.8, 518.81), pneumonia (482.3, 482.8, 486, 581), myocardial infarction (410.00-410.9), venous thromboembolism (451.1, 451.2, 451.81, 451.9, 453.1, 453.2, 453.8, 453.9), gastrointestinal hemorrhage (530.82, 531.00-531.21, 531.40, 531.41, 531.60, 531.61, 532.00-532.21, 532.40, 532.41, 532.60, 532.61, 533.00-533.21, 533.40,

533.41, 533.60, 533.61, 534.00-534.21, 534.40, 534.41, 534.60, 534.61, 535.01, 535.11, 535.21, 535.31, 535.41, 535.51, 535.61, 578.9), acute kidney injury (584.5, 584.6, 584.7, 584.9), urinary tract infection (559.0, 509.09), and surgical site infection (998.5, 998.51, 998.59, 998.6). Discharge disposition was categorized as routine (home with or without home healthcare) or nonroutine (discharge to skilled nursing, short-term recovery, rehabilitation hospitals or institutions or in-hospital mortality). Prolonged LOS was defined as LOS ≥ 75th percentile for the study cohort.²²⁻²⁴

Patient and Hospital Variables

The NIS provides patient demographic information such as age, sex, race/ethnicity, insurance status, emergent vs nonemergent admission, and hospital characteristics including teaching status, urban or rural location, bed size and geographic region. Patients were categorized into three age groups: 18 to 64, 64 to 79, and 80+ yr of age. The Charlson Comorbidity Index was calculated to assess for patient comorbidities.²⁵ We also controlled for hypertension, coronary artery disease, congestive heart failure, dyslipidemia, diabetes mellitus, atrial fibrillation, valve disease, obesity, coagulopathy, alcohol abuse, tobacco use, chronic kidney disease, and chronic lung disease. Patients were categorized as symptomatic if they had an ICD-9 of 433.11, 433.31 corresponding to carotid artery stenosis with stroke or a diagnosis of carotid artery without stroke (443.10, 433.30) with a subsequent code for transient ischemic attack (435).²¹

Statistical Analysis

Patients treated by LVHs and HVHs and HVSSs were compared using Wilcoxon-rank sum tests for continuous variables and Pearson chi-square tests for categorical variables. Hierarchical mixed-effects logistic regression models were used to examine the association between Volume Pledge threshold and outcomes (poor outcome, complications, nonroutine discharge, prolonged hospital stay), and to account for hospital clustering. All multivariable regression models were adjusted for patient demographic, clinical, and hospital characteristics. The impact of hospital volume on outcomes was analyzed between 2005 and 2011. To analyze the effect of surgeon volume threshold on outcomes, an analysis was conducted between 2005 and 2009 as the NIS only provides unique physician identifiers up to 2009.²⁰ Cases with missing physician identification numbers were excluded (n = 12 761, 57.4%) from surgeon volume analysis. Three hierarchical multivariable logistic regression models were performed to examine the effect of surgeon volume: Model 1 adjusted for surgeon volume without hospital volume, model 2 adjusted for hospital volume without surgeon volume, and model 3 adjusted for both surgeon and hospital volume. Analyses were performed using Stata SE Version 15.1 (StataCorp LLC, College Station, Texas). All tests were 2-sided with *P* < .05 considered statistically significant.

RESULTS

Hospital Volume Pledge Threshold

A total of 22 215 CAS admissions met inclusion criteria. The majority of patients underwent CAS at HVH (86.4%), accounting for 43.2% of the total 815 hospitals captured in our analysis (Table 1). LVH treated 13.6% of cases and constituted a larger proportion of hospitals (n = 463, 56.8%). The median

TABLE 1. Baseline Characteristics Stratified by Hospital Volume Pledge Thresholds (2005-2011)

Characteristics Carotid artery stenting (n = 22 215)	Volume pledge category		P value
	LVH (n = 3025, 13.6%)	HVH (n = 19 190, 86.4%)	
Annual volume, median [IQR], cases/yr	6 [4-8]	34 [21-53]	<.001
Hospitals	463 (56.8)	352 (43.2)	<.001
Age, median [IQR], yr	72 [64-78]	72 [65-78]	.06
Female, n (%)	1201 (39.7)	7518 (39.2)	.58
Race/ethnicity, n (%)			<.001
White	2008 (66.4)	13 563 (70.7)	
Black	152 (5.0)	721 (3.8)	
Hispanic	139 (4.6)	697 (3.3)	
Other	109 (3.6)	804 (3.9)	
Unknown	617 (20.4)	3405 (17.7)	
Insurance, n (%)			.56
Private	621 (20.5)	3888 (20.3)	
Medicare	2165 (71.6)	13 875 (72.3)	
Medicaid	122 (4.0)	693 (3.6)	
Uninsured	55 (1.8)	304 (1.6)	
Other	57 (1.9)	375 (2.0)	
Symptomatic, n (%)	307 (10.1)	1315 (8.6)	.005
Emergent admission, n (%)	901 (29.8)	5233 (27.3)	<.001
Charlson Comorbidity Index (CCI), n (%)			.039
CCI = 1	985 (32.3)	6192 (32.3)	
CCI = 2	935 (30.5)	6349 (33.0)	
CCI ≥ 3	1105 (36.5)	6649 (34.6)	
Comorbidities			
Hypertension	2279 (75.4)	14 488 (75.5)	.85
Diabetes	982 (32.5)	6039 (31.5)	.27
Dyslipidemia	1620 (53.6)	11 142 (58.1)	<.001
Coagulopathy	53 (1.8)	245 (1.3)	.035
Coronary artery disease	850 (28.1)	6375 (33.2)	<.001
Congestive heart failure	280 (9.3)	2063 (10.8)	.013
Atrial fibrillation	273 (9.0)	1895 (9.9)	.14
Valve disease	203 (6.7)	1397 (7.3)	.26
Obesity	196 (6.5)	1043 (5.4)	.020
Chronic kidney disease	305 (10.1)	1699 (8.9)	.028
Chronic pulmonary disease	645 (21.3)	3971 (20.7)	.43
Alcohol abuse	40 (1.3)	237 (1.2)	.69
Tobacco use	1007 (33.3)	6050 (31.5)	.053
Missing	24 (1.1)	133 (0.8)	
Hospital Location, n (%)			<.001
Rural	209 (6.9)	476 (2.5)	
Urban	2792 (92.3)	18 581 (96.8)	
Missing	24 (1.1)	133 (0.8)	
Hospital bedsize, n (%)			<.001
Small	323 (10.7)	1692 (8.8)	
Medium	844 (27.9)	3293 (17.2)	
Large	1834 (60.6)	14 072 (73.3)	
Missing	24 (1.1)	133 (0.8)	
Geographic region, n (%)			<.001
Northeast	465 (15.4)	3561 (18.6)	
Midwest	807 (26.7)	4139 (21.6)	
South	1105 (36.5)	8046 (41.8)	
West	648 (21.4)	3444 (17.9)	

HVH, high-volume hospital; IQR, interquartile range; LVH, low-volume hospital.

annual CAS volume for LVHs and HVHs was 6 (interquartile range: 4-8) and 34 (21-53), respectively.

Patient age and sex did not differ between HVHs and LVHs (Table 1). However, a greater proportion of black (5.0% vs 3.8%), Hispanic (4.6% vs 3.3%), and Medicaid (4.0% vs 3.6%) patients underwent CAS at LVH relative to their HVH counterparts. Admissions to LVH were also more likely to be emergent (29.8% vs 27.3%), symptomatic (10.1% vs 8.6%), and have a Charlson score ≥ 3 (36.5% vs 34.6%). Compared to LV patients, coronary artery disease (33.2% vs 28.1%) and dyslipidemia (58.1% vs 50.7%) were more common in patients treated at HVH. In contrast, LV patients were more likely to have obesity, chronic kidney disease, and coagulopathy. A larger proportion of HVH were large teaching centers and LVH were more likely to be located in rural areas (2.5% vs 6.9%).

Rates of in-hospital mortality, postoperative neurological complications, and postoperative cardiac complications did not differ between HVH and LVH (Table 2). No significant differences between HVH and LVH were observed for the composite endpoint poor outcome (4.9% vs 4.7%, $P = .62$, respectively). However, LVH had a higher proportion of other periprocedural complications (9.5% vs 7.6%, $P < .001$), nonroutine discharge (11.7% vs 8.8%, $P < .001$), and prolonged LOS (30.8% vs 25.6%, $P < .001$). Patients treated at LVH experienced higher rates of pneumonia, acute kidney injury, and urinary tract infections.

On adjusted analysis, HVH did not significantly predict decreased odds of poor outcome (odds ratio [OR] = 0.90, 95% confidence interval [CI] 0.73-1.10; $P = .31$; Table 3). However, treatment at HVH decreased the likelihood of other complications (OR 0.84, 95% CI 0.70-0.99, $P = .044$), nonroutine discharge (OR 0.80, 95% CI 0.68-0.94; $P = .008$), and prolonged LOS (OR 0.84, 95% CI 0.72-0.97, $P = .014$).

Surgeon Volume Pledge Threshold

A total of 9454 patients treated between 2005 and 2009 had a corresponding surgeon identification number to meet inclusion criteria. Of these, the majority were treated by HVS ($n = 7448$, 79.2%), representing a third of surgeons included in the analysis (Table 4). The median CAS annual volume for LVS and HVS was 2 [1-3] and 17 [9-32], respectively. Of patients treated by LVS, 63.7% were treated at HVH. In contrast, 95.2% of patients treated by HVS underwent CAS at HVH ($P < .001$).

Similar results found in the hospital volume analysis were observed for surgeon volume (Table 4). A greater proportion of black (5.0% vs 3.6%), Hispanic (5.4% vs 3.6%), emergent (37.8% vs 28.2%), and symptomatic (12.0% vs 6.9%) patients, as well those with a greater comorbidity burden (37.1% vs 32.0%) underwent CAS by LVS. Compared to LV patients, coronary artery disease (32.6% vs 29.3%) and dyslipidemia (56.5% vs 51.7%) were more common in patients treated by HVS, while LV patients were more likely to have chronic kidney disease, coagulopathy, and use tobacco. A similar proportion of LVSs and

HVSs were associated with teaching and rurally located hospitals. However, LVS were more likely to operate at large hospitals (74.0% vs 69.5%).

The rate of poor outcome was lower for HVS (4.3% vs 6.5%; $P < .001$; Table 5). HVS had lower rates of in-hospital mortality (0.8% vs 1.3%, $P = .03$) and postoperative neurological complications (1.9% vs 3.2%, $P < .001$). LVS were associated with higher rates of respiratory failure, pneumonia, myocardial infarction, acute kidney injury, urinary tract, and surgical site infection (all $P < .001$). Rates of any adverse complication (12.2% vs 5.9%, $P < .001$), nonroutine discharge (12.5% vs 4.3%, $P < .001$), and prolonged hospitalization (38.1% vs 22.3%, $P < .001$) were higher among patients treated by LVS.

On multivariable analysis, HVS predicted decreased odds of poor outcome (OR 0.79, 95% CI 0.62-0.99; $P = .042$), complications (OR 0.61, 95% CI 0.50-0.75, $P < .001$), nonroutine discharge (OR 0.72, 95% CI 0.59-0.88; $P = .001$), and prolonged LOS (OR 0.53, 95% CI 0.45-0.62, $P < .001$) compared to LVS (model 1, Table 6). On adjusted analysis without surgeon volume, hospital volume was not associated with differences in outcomes (model 2). After adjusting for both surgeon and hospital volume, HVS remained predictive of improved outcomes (model 3).

DISCUSSION

Hospital and surgeon volume have long been recognized as a metric for the quality and safety of surgical care.^{1,4} To optimize patient outcomes, 3 major academic health systems announced "Take the Volume Pledge"—a policy that aims to centralize surgical care to hospitals and providers meeting minimum volume standards for complex procedures.^{5,6} In this study, we assessed the potential impact of the Pledge on outcomes after CAS if the policy were broadly implemented. We found that the overwhelming majority of patients underwent CAS by hospitals and surgeons meeting the Pledge's volume thresholds for the endovascular intervention. Superior outcomes were largely driven by the Pledge's volume standards for surgeons and were significantly associated with a decreased risk of poor outcome, periprocedural complications, nonroutine discharge, and prolonged hospitalization.

The impact of the Pledge's volume threshold for hospitals was less clear. In our analysis of hospital volume, hospitals that met the Pledge's criteria did not improve our primary endpoint. Although they were significantly associated with a lower risk of other complications, nonroutine discharge, and prolonged hospitalization, these benefits were not observed in our analysis of surgeon volume. Despite this, 95% of patients who underwent CAS by HV providers were also cared for at a HV center. In comparison, about two-thirds of patients who were treated by LV operators were managed at HV centers. Our data suggest that the Pledge's surgeon volume standards may be more important in improving outcomes compared to their

TABLE 2. Baseline Characteristics Stratified by Surgeon Volume Pledge Thresholds (2005-2009)

Characteristics Carotid artery stenting (n = 9454)	Volume pledge category		P value
	LVS (n = 1966, 20.8%)	HVS (n = 7488, 79.2%)	
Annual surgeon volume, median [IQR], cases/yr	2 [1-3]	17 [9-32]	<.001
Surgeons	981 (69.0)	441 (31.0)	
Annual hospital volume, median [IQR], cases/yr	15 [7-31]	37 [22-57]	<.001
Hospital volume (≥10 procedures/annually)	1254 (63.7%)	7132 (95.2%)	<.001
Hospitals	193 (53.9)	167 (46.1)	<.001
Age, median [IQR], yr	71 [63-77]	72 [65-78]	<.001
Female, n (%)	784 (39.9)	2901 (38.7)	.36
Race/ethnicity, n (%)			<.001
White	1513 (77.0)	5915 (79.0)	
Black	99 (5.0)	268 (3.6)	
Hispanic	106 (5.4)	268 (3.6)	
Other	71 (3.6)	268 (3.6)	
Unknown	177 (9.0)	769 (10.3)	
Insurance, n (%)			.13
Private	436 (22.2)	1581 (21.1)	
Medicare	1384 (70.4)	5427 (72.6)	
Medicaid	61 (3.1)	215 (2.9)	
Uninsured	34 (1.7)	121 (1.6)	
Other	46 (2.3)	126 (1.7)	
Symptomatic, n (%)	236 (12.0)	518 (6.9)	<.001
Emergent admission, n (%)	744 (37.8)	2111 (28.2)	<.001
Charlson Comorbidity Index (CCI), n (%)			<.001
CCI = 1	620 (31.5)	2585 (34.5)	
CCI = 2	616 (31.3)	2508 (33.5)	
CCI ≥ 3	730 (37.1)	2395 (32.0)	
Comorbidities			
Hypertension	1456 (74.1)	5556 (74.3)	.81
Diabetes	617 (31.4)	2256 (30.1)	.28
Dyslipidemia	1016 (51.7)	4228 (56.5)	<.001
Coagulopathy	35 (1.8)	67 (0.9)	<.001
Coronary artery disease	577 (29.3)	2439 (32.6)	.006
Congestive heart failure	204 (10.4)	767 (10.2)	.86
Atrial fibrillation	201 (10.2)	696 (9.3)	.21
Valve disease	141 (7.2)	553 (7.4)	.75
Obesity	104 (5.3)	362 (4.8)	.41
Chronic kidney disease	180 (9.2)	550 (7.3)	.007
Chronic pulmonary disease	453 (23.0)	1508 (20.1)	.005
Alcohol abuse	24 (1.2)	92 (1.2)	.98
Tobacco use	615 (31.3)	2139 (28.6)	.018
Teaching hospital, n (%)	1202 (61.1)	4394 (58.7)	.060
Missing	12 (0.6)	62 (0.8)	
Hospital location, n (%)			.24
Rural	53 (2.7)	240 (3.2)	
Urban	1901 (96.7)	7186 (96.0)	
Missing	12 (0.6)	62 (0.8)	
Hospital bedsize, n (%)			<.001
Small	137 (7.0)	830 (11.1)	
Medium	363 (18.5)	1395 (18.6)	
Large	1454 (74.0)	5201 (69.5)	
Missing	12 (0.6)	62 (0.8)	
Geographic region, n (%)			<.001
Northeast	472 (24.0)	2082 (27.8)	
Midwest	261 (13.3)	1003 (13.4)	
South	1010 (51.4)	3283 (43.8)	
West	223 (11.3)	1120 (15.0)	

HVH, high-volume hospital; IQR, interquartile range; LVH, low-volume hospital.

TABLE 3. Unadjusted Outcomes Stratified by Hospital Volume Pledge Thresholds (2005-2011)

Characteristics Carotid artery stenting (n = 22 215)	Volume pledge category		P value
	LVH (n = 3025, 13.6%)	HVH (n = 19 190, 86.4%)	
Outcome			
In-hospital mortality	30 (1.0)	166 (0.9)	.49
Neurological complication	72 (2.4)	399 (2.1)	.29
Cardiac complication	62 (2.0)	412 (2.1)	.73
Composite outcome	149 (4.9)	906 (4.7)	.62
Complications			
Respiratory failure	64 (2.1)	345 (1.8)	.23
Pneumonia	37 (1.2)	156 (0.8)	.024
Myocardial infarction	61 (2.0)	323 (1.7)	.40
Venous thromboembolism	^a (0.2)	41 (0.2)	.86
Gastrointestinal hemorrhage	11 (0.4)	78 (0.4)	.73
Acute kidney injury	107 (3.5)	484 (2.5)	.001
Urinary tract infection	95 (3.1)	468 (2.4)	.022
Surgical site infection	^a (0.1)	20 (0.1)	.94
≥1 complication	287 (9.5)	1449 (7.6)	<.001
Discharge disposition			
Routine discharge	2672 (88.3)	17 492 (91.2)	
Nonroutine discharge	353 (11.7)	1698 (8.8)	
LOS, median, d	1 [1-4]	1 [1-3]	<.001
Prolonged LOS (≥3 d)	932 (30.8)	4910 (25.6)	<.001

CI, confidence interval; LOS, length of stay; HVH, high-volume hospital; LVH, low-volume hospital; OR, odds ratio.

^aDenotes very small number, ≤ 10**TABLE 4. Multivariable Analysis of Outcomes by Hospital Volume Pledge Thresholds (2005-2011)**

Hospital HV vs LV	Outcomes	
	OR (95% CI)	P value
Poor Outcome	0.90 (0.73-1.10)	.31
Complication	0.84 (0.70-0.99)	.044
Nonroutine discharge	0.80 (0.68-0.94)	.008
Prolonged LOS	0.84 (0.72-0.97)	.014

CI, confidence interval; LOS, length of stay; HV, high volume; LV, low volume; OR, odds ratio.

corresponding hospitals volume requirements. Birkmeyer et al previously demonstrated that for many cardiac and oncologic procedures, the association for hospital volume and operative mortality is largely mediated by surgeon volume.⁴ In patients enrolled in the Carotid Revascularization Endarterectomy Trial Versus Stenting Trial (CREST), higher center enrollment volume did not predict improved outcomes, likely due to the proficiency requirements of CREST providers, potentially eliminating the effect of hospital volume.^{12,26}

Prior studies examining the effect of hospital volume highlight the challenges in developing centralization policies.^{9,10,15,27} An

analysis of the NIS found that hospitals performing <38 CAS procedures per year were associated with a 19% increased risk in poor outcome (composite of in-hospital mortality, postoperative stroke, and discharge to a long-term facility).²⁷ Similarly, Medicare beneficiaries experienced lower 30-d mortality at HV centers (≥40 procedures annually) compared to LVH (<10 procedures).¹⁵ In contrast, a study in Germany found no differences between HV (≥27 procedures for a 2-yr period) and LV centers in postoperative mortality or major stroke.¹⁰ Differences in the study population, endpoints analyzed, and methodologies used to determine volume emphasize the difficulty in establishing an optimal volume cut-off for hospitals that will consistently deliver superior outcomes.

Our results are consistent with prior literature documenting improved mortality and morbidity after CAS performed by HV operators.^{11,13,15,28-30} Among Medicare beneficiaries treated between 2005 and 2007, very LVs (<6 annual procedures) had higher 30-d risk-adjusted mortality rates (OR 1.9) compared to HV operators (≥24 procedures).¹⁴ Another study of Medicare patients (2005-2009) demonstrated decreased 30-d mortality rates with increasing operator volume.¹⁵ In a pooled analysis of symptomatic patients from European randomized clinical trials comparing the efficacy of CAS and endarterectomy, operators performing <6 annual CAS procedures experienced a higher 30-d risk of stroke or death.²⁹ Our data support the previously

TABLE 5. Outcomes by Surgeon Volume Pledge Thresholds (2005-2009)

Characteristics Carotid artery stenting (n = 9454)	Volume pledge category		P value
	LV (n = 1966, 20.8%)	HV (n = 7488, 79.2%)	
Outcome			
In-hospital mortality	26 (1.3)	60 (0.8)	.030
Neurological complication	62 (3.2)	144 (1.9)	<.001
Cardiac complication	49 (2.5)	156 (2.1)	.27
Composite outcome	127 (6.5)	325 (4.3)	<.001
Complications			
Respiratory failure	61 (3.1)	94 (1.3)	<.001
Pneumonia	29 (1.5)	48 (0.6)	<.001
Myocardial infarction	65 (3.3)	97 (1.3)	<.001
Venous thromboembolism	^a (0.3)	12 (0.2)	.19
Gastrointestinal hemorrhage	11 (0.6)	20 (0.3)	.044
Acute kidney injury	76 (3.9)	151 (2.0)	<.001
Urinary tract infection	69 (3.5)	150 (2.0)	<.001
Surgical site infection	^a (0.4)	^a (0.1)	<.001
≥1 complication	240 (12.2)	445 (5.9)	<.001
Discharge disposition			
Routine discharge	1720 (87.5)	7163 (95.7)	
Nonroutine discharge	246 (12.5)	325 (4.3)	
LOS, median, d	1 [1-5]	1 [1-2]	<.001
Prolonged LOS (≥3 d)	750 (38.1)	1673 (22.3)	<.001

LOS, length of stay; HV, high volume; LV, low volume.

^aDenotes very small number, ≤ 10**TABLE 6. Multivariable Analysis of Outcomes by Surgeon and Hospital Volume Pledge Thresholds (2005-2009)**

	Model 1 ^a		Model 2 ^b		Model 3 ^c	
	OR (95% CI)	P value	OR (95% CI)	P value	OR (95% CI)	P value
Surgeon HV vs LV						
Poor outcome	0.79 (0.62-0.99)	.042	—	—	0.76 (0.59-0.97)	.028
Complication	0.61 (0.50-0.75)	<.001	—	—	0.57 (0.46-0.71)	<.001
Nonroutine discharge	0.72 (0.59-0.88)	.001	—	—	0.70 (0.57-0.87)	.001
Prolonged LOS	0.53 (0.45-0.62)	<.001	—	—	0.52 (0.44-0.61)	<.001
Hospital HV vs LV						
Poor outcome	—	—	1.00 (0.72-1.39)	0.99	1.16 (0.81-1.65)	.42
Complication	—	—	0.96 (0.75-1.22)	0.72	1.31 (0.96-1.80)	.089
Nonroutine discharge	—	—	0.91 (0.70-1.21)	0.54	1.10 (0.81-1.48)	.55
Prolonged LOS	—	—	0.82 (0.64-1.03)	0.08	1.13 (0.88-1.45)	.33

CI, confidence interval; LOS, length of stay; HV, high volume; LV, low volume; OR, odds ratio.

^aModel 1: adjusted for surgeon volume only.^bModel 2: adjusted for hospital volume only.^cModel 3: adjusted for both surgeon and hospital volume.

documented inverse relationship between surgeon volume and patient outcomes following CAS, and validates the Pledge's volume standards for operators as an adequate target in improving patient outcomes.

Carotid stenting is a technically demanding procedure associated with a substantial learning curve.³¹ In addition to

increased operative experience, utilization of greater technological services and enhanced patient selection may contribute to superior outcomes observed in HVs. Among Medicare beneficiaries, Nallamothu et al found that LV operators were significantly less likely to use embolic protection devices for CAS.¹⁴ In another study of Medicare claims data, HVs were more likely to

perform CAS on healthier patients compared to LV providers.¹⁵ This is consistent with our data in which LV operators were more likely to perform CAS on patients who were symptomatic, emergently admitted, and had a higher comorbidity burden. While this may be due in part to more aggressive management by LVs prior to medical optimization, it may also reflect higher disease severity in the patient population that these providers serve.

While there is no doubt that the Volume Pledge is intended to improve patient outcomes, providers and policymakers have raised concerns regarding unintended consequences of centralization policies.^{16,17,19,32} We found that minorities and rural patients were more likely to undergo CAS at hospitals or with providers that did not meet the Volume Pledge, supporting prior literature documenting decreased access to HV centers for vulnerable patient populations.¹⁸ Efforts to regionalize CAS should also aim to support strategies that mitigate potential barriers in access such as travel burden, limited health literacy, and discontinuity of care.¹⁹ While volume remains a useful metric for improved outcomes, it should not be an exclusive measure of the quality and safety of surgical care. HV centers have greater access to experienced surgeons, multidisciplinary teams, well-resourced intensive care units, and greater technological services;^{1,4} however, other structural processes play a critical role in improving outcomes such as the utilization of protocols or checklists and quality improvement initiatives.³³ Furthermore, development of these policies should adequately reflect both health system and patient-centered outcomes.³⁴

Limitations

This study carries limitations inherent to a large administrative database such as a retrospective study design, coding inaccuracies, and selection biases. Potential confounding factors such as the degree of carotid stenosis, use of antiplatelet/anticoagulation or other medical therapy, angiographic data, and use of stent protection devices are not available in the NIS. Our study was limited to short-term in-hospital outcomes, and we were unable to assess longitudinal periprocedural endpoints assessed in clinical trials.^{7,8,35,36} Beginning in 2012, the NIS changed its sampling design to 20% of all patients from 20% of all hospitals. Thus, we were unable to calculate hospital volume after 2011 to include more recent data²⁰ and account for advancements in stent designs and embolic protection filters that may diminish the effect of volume on outcomes over time. Similarly, surgeon identifiers were only provided in the NIS from 2005 to 2009, and we did not determine the type of surgeon who performed the procedure. However, the Volume Pledge thresholds established for CAS are not dependent on the operator's specialty. Despite these limitations, this is the first study to examine the potential impact of broadly implementing a centralization policy for CAS. While prior studies have evaluated the volume–outcome relationship based on statistical methods, our study is the first to assess the impact of volume based on an existing health systems policy.^{5,6} Furthermore, our study informs further research into the impact

of centralization policies in the context of patients treated with CAS.

CONCLUSION

The majority of patients underwent CAS at hospitals and by surgeons meeting the Volume Pledge threshold. Our study validates the Volume Pledge's surgeon thresholds for CAS as surgeons that met the policy's volume standards were associated with superior outcomes. The relationship between the Pledge's volume standards for hospitals on outcomes after CAS is less clear. Volume policies should aim to address potential disparities in access to HV centers resulting from the regionalization of surgical care. Further research is warranted to elucidate the volume–outcome relationship in CAS that will optimize outcomes for all patients.

Disclosures

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COMMENT

The authors report their findings of outcomes of carotid artery stenting (CAS) procedures from a large national database. They sought to determine if centers and operators who meet the "volume pledge" for CAS have superior outcomes. The volume pledge for CAS was determined to be > 10 CAS per center per year and > 5 CAS per surgeon annually. The manuscript is thoughtful and well-written. The authors found that complications related to CAS were not significantly different between low and high volume centers. However, the experience of the surgeon was a significant factor in outcome. It was interesting that the majority of patients who "underwent CAS by high-volume providers were also cared for at a high-volume centers... about two-thirds of patients who were treated by low-volume operators were managed at high-volume centers." In other words, treatment at a high-volume center does not guarantee a highly experienced operator. It is therefore difficult, based on the authors' findings to advocate all patients requiring CAS be transferred to a high-volume center when the experience of the surgeon may be in question. In these cases, it stands to reason that the more experienced surgeons at high-volume centers should be performing CAS. Whether that means taking a "volume pledge" or just having a departmental volume requirement for each surgeon, that makes sense for patients. In addition, many of the "low volume" centers are now covered by operators from high-volume centers who may take call at smaller community or rural hospitals. These operators have the experience and can bring their protocols for post-op care to the centers to avoid postoperative complications. We are seeing this increasingly as more hospitals want to bring stroke care to their communities. The sprawl of experienced surgeons to community hospitals may change this picture a bit as well. The authors report responsibly on this topic and based on their findings it seems feasible that experienced operators can provide safe care at smaller, low volume centers if basic infrastructure and protocols are in place.

It is a challenge when making determinations about volume and whether or not surgeons/centers should be performing certain operations. The volume requirement is often arbitrary, does not take into account operator's prior years of experience, and can serve to limit access to patients in rural areas or without access to nearby high-volume centers. Although rural or low-volume centers may have operators who can perform the procedure, the surgeon may not offer it due to a perceived liability of not meeting arbitrary volume requirements. That said, as the authors state, it is established for a number of procedures, that outcomes are better in centers that are high volume with very experienced surgeons. Therefore, it can be difficult to know how to achieve the best patient outcomes while also giving patients the best access to care. Strict guidelines serve as just that—a guideline—but are often imperfect and impractical. This manuscript describes that well.

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