

## ORIGINAL RESEARCH ARTICLE

# Association Between Hospital Volume, Processes of Care, and Outcomes in Patients Admitted With Heart Failure

## Insights From Get With The Guidelines-Heart Failure

**BACKGROUND:** Hospital volume is frequently used as a structural metric for assessing quality of care, but its utility in patients admitted with acute heart failure (HF) is not well characterized. Accordingly, we sought to determine the relationship between admission volume, process-of-care metrics, and short- and long-term outcomes in patients admitted with acute HF.

**METHODS:** Patients enrolled in the Get With The Guidelines-HF registry with linked Medicare inpatient data at 342 hospitals were assessed. Volume was assessed both as a continuous variable, and quartiles based on the admitting hospital annual HF case volume, as well: 5 to 38 (quartile 1), 39 to 77 (quartile 2), 78 to 122 (quartile 3), 123 to 457 (quartile 4). The main outcome measures were (1) process measures at discharge (achievement of HF achievement, quality, reporting, and composite metrics); (2) 30-day mortality and hospital readmission; and (3) 6-month mortality and hospital readmission. Adjusted logistic and Cox proportional hazards models were used to study these associations with hospital volume.

**RESULTS:** A total of 125 595 patients with HF were included. Patients admitted to high-volume hospitals had a higher burden of comorbidities. On multivariable modeling, lower-volume hospitals were significantly less likely to be adherent to HF process measures than higher-volume hospitals. Higher hospital volume was not associated with a difference in in-hospital (odds ratio, 0.99; 95% confidence interval [CI], 0.94–1.05;  $P=0.78$ ) or 30-day mortality (hazard ratio, 0.99; 95% CI, 0.97–1.01;  $P=0.26$ ), or 30-day readmissions (hazard ratio, 0.99; 95% CI, 0.97–1.00;  $P=0.10$ ). There was a weak association of higher volumes with lower 6-month mortality (hazard ratio, 0.98; 95% CI, 0.97–0.99;  $P=0.001$ ) and lower 6-month all-cause readmissions (hazard ratio, 0.98; 95% CI, 0.97–1.00;  $P=0.025$ ).

**CONCLUSIONS:** Our analysis of a large contemporary prospective national quality improvement registry of older patients with HF indicates that hospital volume as a structural metric correlates with process measures, but not with 30-day outcomes, and only marginally with outcomes up to 6 months of follow-up. Hospital profiling should focus on participation in systems of care, adherence to process metrics, and risk-standardized outcomes rather than on hospital volume itself.

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## Clinical Perspective

### What Is New?

- Although hospital volumes have traditionally been used as a structural measure of quality of care for patients undergoing cardiovascular procedures, there is increasing interest in using volume as a metric for medical conditions such as heart failure (HF).
- Lower-volume hospitals have worse adherence to important HF process measures than higher-volume hospitals.
- There was no association between risk-adjusted in-hospital mortality and hospital HF admission volume among older patients.
- After adjusting for adherence with process measures at discharge, annual HF admission volume had a minimal association with mortality and readmissions up to 6 months postdischarge.

### What Are the Clinical Implications?

- From a systems-of-care perspective, quantifying superior systems of care at higher-volume hospitals may go a longer way in homogenizing care and potentially reducing costs for HF admissions than focusing attention on annual case volumes alone.
- These results are similar to those noted in more contemporary analyses for procedures such as angioplasty for coronary artery disease.
- Hospital-profiling efforts should further focus on participation in quality improvement initiatives, adherence to process metrics, and risk—standardized outcomes rather than on hospital volume itself.

**H**eat failure (HF) remains one of the most common and expensive medical conditions within Medicare.<sup>1</sup> Following initial diagnosis, 83% of patients are hospitalized at least once and 43% at least 4 times.<sup>2</sup> Mortality rates are ≈30% within the first year, and readmission rates are ≈23% at 30 days.<sup>3</sup> Given these woeful numbers, clinicians, policy makers, and payers are under increasing pressure to identify strategies that can improve the quality of care in this patient population.<sup>4</sup>

Ross and colleagues<sup>5</sup> assessed Medicare fee-for-service (FFS) beneficiaries admitted with HF between 2004 and 2006 and observed that there was an inverse correlation between hospital volume and risk-adjusted 30-day mortality. Similarly, Joynt and colleagues<sup>6</sup> analyzed Medicare FFS HF patients admitted between 2006 and 2007, and reported an inverse relationship between HF volume and 30-day mortality and readmission rates, particularly when the admission volume was <400/y. These reports supported

the notion that volume might be a good surrogate for quality in delivery of care for patients with HF.

Volume as a metric appears to be fairly intuitive and is rather easy to collect, interpret, and monitor. However, an important limitation of using hospital volume as a stand-alone metric is that it does not account for processes of care at higher-volume hospitals.<sup>7–11</sup> Both the above studies were limited by the lack of availability of patient-level data on process-of-care measures. Moreover, longer-term outcomes were not available. Accordingly, we sought to assess the relationship between hospital HF admission volume, prospectively collected process-of-care measures, and 30-day and 6-month outcomes in the American Heart Association's Get With The Guidelines (GWTG)-HF registry.

## METHODS

The data, analytic methods, and study materials will not be made available to other researchers for purposes of reproducing the results or replicating the procedure.

### Data Source

GWTG-HF is an ongoing, national, voluntary hospital-based quality improvement program initiated by the American Heart Association in 2005. The details of the GWTG-HF registry have been previously published.<sup>12</sup> In brief, patients hospitalized at participating centers with a diagnosis of new or worsening HF or who develop significant HF symptoms during the hospitalization (HF becomes the primary discharge diagnosis) are included. Trained personnel prospectively collect patient-level data using an Internet-based patient management tool (Quintiles Real-World and Late Phase Research). Data collected include patient demographics, socioeconomic status, medical history, medications, laboratory data, in-hospital treatment, in-hospital outcomes, discharge medications, and discharge status. All participating centers are required to follow local regulatory and privacy guidelines and to obtain institute review board approval for the GWTG-HF protocol. Because data were used primarily at the local site for quality improvement, sites were granted a waiver of informed consent under the common rule. Quintiles served as the data collection coordination center for American Heart Association GWTG programs. The Duke Clinical Research Institute (Durham, NC) served as the data analysis center and has institutional review board approval for analyzing the aggregate deidentified data for research purposes.

### Study Population

For the purpose of this analysis, we included patients in the GWTG-HF registry with linked Medicare inpatient data by using a previously described method.<sup>13</sup> The Medicare data included Part A (inpatient) claims and the associated denominator file. The primary inclusion criteria were as follows: (1) admitted to hospitals in GWTG-HF registry and ≥75% complete data on medical history; (2) primary HF diagnosis; (3)

age  $\geq 65$  years old with a GWTG-HF hospitalization probabilistically linked to Medicare; and (4) admitted between January 4, 2005 and December 31, 2014. Patients were excluded from the study if they left against medical advice, got transferred out, or had discharge information missing. Furthermore, patients who were treated at hospitals submitting data for  $<4$  consecutive quarters to GWTG over the 10-year duration of the study were excluded to minimize selection bias attributable to underreporting. For postdischarge outcomes (mortality and readmissions at 30 days and 6 months), patients who died in the hospital or were discharged to hospice/comfort measures or patients who were not enrolled in FFS Medicare at discharge were further excluded. If multiple hospitalizations existed for a patient, the first hospitalization meeting the above criteria was kept as the index hospitalization for this analysis (Figure in the online-only Data Supplement).

## Assessment of Hospital Volume, Process Measures, and Outcomes

The chief independent variable was annual hospital HF admission volume:

$$\frac{\text{Total number of eligible HF patients} \geq 65 \text{ years old in each hospital}}{\text{Total number of quarters for which the hospital reports data to GWTG}} \times 4$$

Hospitals were divided into quartiles based on the annual HF admission volume as very low (5–38), low (39–77), medium (78–122), and high (123–457).

The primary process measures (among candidates for therapy) were assessed at a patient level based on the index hospitalization and included (1) HF achievement measures, including prescription of angiotensin-converting enzyme inhibitors/angiotensin receptor blockers; (2) HF quality measures, including prescription of an aldosterone antagonist and cardiac resynchronization therapy (defibrillator-pacemaker or pacemaker only) placed/prescribed; (3) HF reporting measures, including any  $\beta$ -blocker, implantable cardioverter defibrillator (ICD) placed/prescribed; and finally (4) a composite HF defect-free measure, a composite of appropriate discharge instructions, measurement of left ventricular function, prescription of angiotensin-converting enzyme inhibitors/angiotensin receptor blockers, and prescription of  $\beta$ -blockers (see the online-only Data Supplement for a detailed list of measures). The primary outcome measures were also assessed at a patient level and included (1) in-hospital mortality and length of stay, (2) 30-day all-cause mortality and readmissions, and (3) 6-month all-cause mortality and readmissions.

## Statistical Analysis

Volume was analyzed both as a categorical (quartiles) and as a continuous variable. The hospital was the unit of analysis for assignment to a hospital-volume group. However, the patient was the unit of analysis for clinical variables, process measures, and outcomes. Cochran-Mantel-Haenszel non-zero correlation tests were used for continuous variables and

Cochran-Mantel-Haenszel row mean scores tests for categorical variables among the quartiles.

Multivariable logistic regression models were constructed to study the relationship between volume and process measures and in-hospital outcomes. Estimation with generalized estimating equations with an exchangeable working correlation matrix was used to adjust for clustering within hospitals.<sup>14</sup> This correlation structure assumes that hospitals are independent and patients within hospitals are equally correlated. The final regression models were adjusted for age, sex, race (white versus nonwhite), anemia, ischemic history, cerebrovascular accident or transient ischemic attack, diabetes mellitus, hyperlipidemia, hypertension, chronic obstructive pulmonary disease or asthma, peripheral vascular disease, renal insufficiency, smoking, systolic blood pressure, heart rate, serum sodium, serum urea nitrogen, ejection fraction, hospital region, and teaching hospital. Ejection fraction was removed from the analysis for the process measures of angiotensin-converting enzyme inhibitors/angiotensin receptor blockers, any  $\beta$ -blocker, aldosterone antagonist, cardiac resynchronization therapy, and ICD placed/prescribed (all at discharge), because these were assessed only for patients with HF with reduced ejection fraction (ejection fraction  $<40\%$  or  $\leq 35\%$ <sup>15</sup>). Medical history of smoking was not included in the analysis for the measure of smoking cessation counseling, because all patients for this measure had a smoking history. Cox proportional hazards models for postdischarge mortality and readmission were further adjusted for 100% compliance with defect-free measures at discharge. The robust variance estimation method was used to account for clustering within hospitals.

For missing adjustment variables, medical history variables were imputed to “no,” because data abstractors were likely to skip this section of the data collection form when none applied; multiple imputation with 25 imputations was used for other patient covariates. Hospital characteristics were not imputed. The linearity of the relationship between hospital volume and outcomes was tested for each model. Flexible spline transformations of the continuous adjustment variables were used and linear splines of annual HF admission volume were fitted when appropriate.

All statistical analyses were performed using SAS version 9.4 (SAS Institute). All *P* values were 2-tailed, with statistical significance set at 0.05. All confidence intervals (CIs) were calculated at the 95% level.

## RESULTS

A total of 125 595 patients admitted with HF at 342 hospitals across the United States were included in our analysis. The mean and median annual HF admission volumes were 89.0 and 77.3 patients, respectively. Baseline characteristics of the study population across the quartiles (Qs) of annual HF volume (5–38, 39–77, 78–122, 123–457) are presented in Table 1. Patients presenting to higher-volume hospitals tended to be older, white, with a higher prevalence of comorbidities, with the exception of insulin-dependent diabetes mellitus and smoking, which were more prevalent in

**Table 1. Baseline Characteristics of Study Population**

Characteristic	Q1 Hospitals (n=6969)	Q2 Hospitals (n=19948)	Q3 Hospitals (n=33035)	Q4 Hospitals (n=65643)	P Value
Sociodemographic information					
Age, y	79.9±8.6	80.0±8.5	80.6±8.4	80.6±8.3	<0.001
Female	57.5	54.4	54.0	53.8	<0.001
Body mass index, kg/m <sup>2</sup>	28.2±7.8	28.1±7.7	27.9±7.5	28.0±7.5	0.90
Race					<0.001
White	71.7	72.4	80.7	85.6	
Black	10.7	13.0	10.2	8.4	
Hispanic	11.5	8.1	5.3	2.7	
Other	6.2	6.5	3.8	3.3	
Medical history					
Insulin-treated diabetes mellitus	18.9	18.0	17.8	16.7	<0.001
Hyperlipidemia	38.3	45.6	48.5	51.5	<0.001
Hypertension	75.3	76.3	77.3	78.4	<0.001
Peripheral vascular disease	9.2	11.1	12.7	14.3	<0.001
Known coronary artery disease	43.2	48.9	50.6	52.8	<0.001
Prior myocardial infarction	15.4	16.6	17.9	19.4	<0.001
Prior admission for heart failure	56.8	60.7	59.9	59.5	0.76
Ischemic cardiomyopathy	50.7	55.7	56.9	58.6	<0.001
CVA/TIA	12.3	15.4	15.9	17.3	<0.001
Chronic or recurrent AF	34.0	37.6	40.4	41.8	<0.001
COPD or asthma	29.7	30.1	28.7	29.3	0.32
Smoking history	11.0	9.1	7.9	8.6	0.002
Chronic renal insufficiency	17.6	22.3	23.1	19.9	<0.001
Anemia	19.2	18.4	19.6	20.3	<0.001
Depression	10.5	8.8	10.5	11.2	<0.001
Admission characteristics					
Systolic blood pressure, mm Hg	141.9±28.8	140.8±29.3	141.8±29.6	141.3±29.2	0.53
Diastolic blood pressure, mm Hg	75.2±17.2	74.2±17.1	75.1±17.4	74.6±17.1	0.48
Heart rate (beats per minute)	84.8±20.4	84.0±20.2	84.0±20.0	83.3±19.9	<0.001
Laboratory and echocardiographic data					
Serum sodium, mEq/L	136.6±11.1	137.2±8.0	136.2±12.0	137.4±7.3	0.001
Serum BNP, pg/mL	1316.9±1688.6	1437.1±1797.6	1258.7±1323.4	1162.6±1349.3	<0.001
Serum urea nitrogen, mg/dL	30.1±18.4	31.1±19.2	30.4±18.1	30.8±18.6	0.18
Serum creatinine, mg/dL	1.3±0.5	1.4±0.5	1.4±0.5	1.3±0.5	<0.001
Total cholesterol, mg/dL	142.0±43.0	139.0±42.8	137.7±42.1	139.9±41.2	0.06
Ejection fraction, %	43.8±17.2	43.9±16.8	44.4±16.8	44.3±16.6	0.005
Ejection fraction <40%	39.4	38.8	37.4	36.7	<0.001
Hospital characteristics					
Hospital size, beds	183.1±174.8	367.3±265.7	307.1±152.1	445.3±166.2	<0.001
Academic hospital	30.9	50.2	51.6	66.2	<0.001
Rural location	24.2	10.9	8.5	3.2	<0.001
Region, %					<0.001
Northeast	16.0	22.5	36.3	35.5	
Midwest	29.4	19.3	18.4	26.8	
South	35.4	40.4	32.2	30.9	

(Continued)

**Table 1. Continued**

Characteristic	Q1 Hospitals (n=6969)	Q2 Hospitals (n=19948)	Q3 Hospitals (n=33035)	Q4 Hospitals (n=65643)	P Value
West	19.2	17.9	13.1	6.8	
Cardiac transplant capacity	4.5	14.8	9.4	10.1	<0.001
Medication use before admission					
ACE inhibitor	35.8	35.2	32.3	32.8	<0.001
ARB	13.3	14.6	15.3	16.0	<0.001
β-Blocker	45.1	55.4	54.7	51.8	0.010
Diuretic	61.8	63.0	60.2	61.8	0.95
Nitrates	16.7	18.4	15.8	15.8	<0.001
Aldosterone antagonist	7.9	7.8	8.5	7.7	0.10
Aspirin	42.9	47.3	47.4	47.2	0.023
Statin	38.2	47.7	47.0	46.5	0.001
Digoxin	14.1	13.5	14.0	14.5	0.005
Warfarin	23.7	25.7	26.7	28.8	<0.001
None	2.3	1.7	1.2	1.1	<0.001
Procedures performed during index hospitalization					
Coronary angiography	4.1	7.0	6.8	8.2	<0.001
Right heart catheterization	1.3	3.2	1.8	2.6	0.012
Percutaneous coronary intervention with stent	0.4	0.9	1.0	1.2	<0.001
Intra-aortic balloon pump or left ventricular assist device	0.1	0.2	0.2	0.2	0.97
Dialysis	1.6	2.3	2.7	2.6	0.003
Mechanical ventilation	3.1	1.6	2.5	2.6	0.001
ICD implantation	0.6	1.7	1.9	2.5	<0.001
CRT implantation	0.8	1.8	3.1	3.2	<0.001

Numbers represent mean±SD for continuous variables and % for categorical variables.

ACE indicates angiotensin-converting enzyme; AF, atrial fibrillation; ARB, angiotensin receptor blocker; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; CVA indicates cerebrovascular accident; ICD, implantable cardioverter defibrillator; Q, quartile; and TIA, transient ischemic attack.

lower-volume hospitals. No differences were noted in blood pressure on admission. A greater proportion of patients presenting to lower-volume hospitals had an ejection fraction<40% (mean ejection fraction 43.8% versus 43.9% versus 44.4% versus 44.3% for Q1 through Q4 hospitals,  $P<0.001$ ), and were more likely to be nonischemic in etiology. Overall, only ≈1% were on no medications before admission; this number was greatest in the lowest-volume quartile. Higher-volume hospitals had a larger number of beds and were more likely to be academic institutions. Q2 hospitals were most likely to have a heart transplant program. Nearly a quarter (24.2%) of Q1 hospitals were in rural locations in comparison with 3.2% of Q4 hospitals ( $P<0.001$ ).

In comparison with Q4 hospitals, patients presenting to lower-volume hospitals were less likely to undergo a cardiac procedure during admission, including coronary angiography with or without cardiac catheterization (4.1% versus 7.0% versus 6.8% versus 8.2%,  $P<0.001$ ), or percutaneous coronary intervention (0.4% versus 0.9% versus 1.0% versus 1.2%,  $P<0.001$ ).

Rates of placement of intra-aortic balloon pump or left ventricular assist device were similar (0.1% versus 0.2% versus 0.2% versus 0.2%,  $P=0.97$ ).

### Annual HF Volume and Process-of-Care Measures

For almost all metrics assessed, Q1 hospitals were least likely to be adherent and Q4 hospitals most likely (Table 2). Q2 hospitals were also less likely than Q4 hospitals to place/prescribe an ICD in appropriate patients (odds ratio, 0.69; 95% CI, 0.50–0.93;  $P=0.017$ ). As a continuous variable, the association of volume with most HF process measures was nonlinear. To address the latter issue, linear spline transformation with a knot at 125 was chosen. Higher volume was associated with a higher likelihood of measuring left ventricular function, prescribing anticoagulation for patients with concomitant atrial fibrillation, prescribing a β-blocker at discharge, placement/prescription of an ICD at discharge, smoking cessation counseling in current smokers and 100% compliance with defect-

**Table 2. HF Volume and Important Quality-of-Care Measures in Eligible Patients Among Quartiles of Volume (Columns 2–4) and With Volume as a Continuous Measure, for Each 50 Admissions/y Increase (Column 5)**

Quality-of-Care Measure	Q1 vs Q4 Adjusted OR (95% CI), P Value	Q2 vs Q4 Adjusted OR (95% CI), P Value	Q3 vs Q4 Adjusted OR (95% CI), p-value	Continuous,* Adjusted OR (95% CI), P Value
HF achievement measures				
ACE inhibitors or ARBs at discharge	89.4% vs 91.7% 0.67 (0.47–0.95); <i>P</i> =0.025	92.1% vs 91.7% 0.99 (0.72–1.36); <i>P</i> =0.95	92.1% vs 91.7% 0.96 (0.69–1.32); <i>P</i> =0.80	– 1.01 (0.89–1.14); <i>P</i> =0.89
Measure LV function	93.1% vs 98.3% 0.26 (0.17–0.41); <i>P</i> <0.001	98.1% vs 98.3% 0.93 (0.57–1.50); <i>P</i> =0.75	97.6% vs 98.3% 0.75 (0.42–1.34); <i>P</i> =0.34	– (a) 1.99 (1.40–2.82); <i>P</i> <0.001 (b) 0.81 (0.62–1.05); <i>P</i> =0.12
HF quality measures				
Aldosterone antagonist at discharge	26.0% vs 26.8% 0.81 (0.62–1.06); <i>P</i> =0.13	26.3% vs 26.8% 0.92 (0.74–1.15); <i>P</i> =0.47	29.1% vs 26.8% 0.99 (0.80–1.23); <i>P</i> =0.93	– (a) 1.12 (0.98–1.27); <i>P</i> =0.09 (b) 0.94 (0.87–.02); <i>P</i> =0.12
CRT placed or prescribed at discharge†	32.3% vs 48.0% 0.42 (0.23–0.78); <i>P</i> =0.006	37.8% vs 48.0% 0.74 (0.50–1.09); <i>P</i> =0.13	46.1% vs 48.0% 1.00 (0.68–1.48); <i>P</i> =1.00	– 1.17 (1.04–1.32); <i>P</i> =0.009
Anticoagulation for atrial fibrillation	63.8% vs 74.1% 0.59 (0.47–0.74); <i>P</i> <0.001	70.5% vs 74.1% 0.87 (0.70–1.09); <i>P</i> =0.23	70.9% vs 74.1% 0.86 (0.70–1.06); <i>P</i> =0.15	– (a) 1.28 (1.14–1.44); <i>P</i> <0.001 (b) 0.93 (0.87–0.99); <i>P</i> =0.030
HF reporting measures				
Any β-blocker at discharge	92.3% vs 94.9% 0.60 (0.43–0.83); <i>P</i> =0.002	95.5% vs 94.9% 1.08 (0.77–1.52); <i>P</i> =0.65	95.4% vs 94.9% 1.03 (0.73–1.44); <i>P</i> =0.86	– (a) 1.24 (1.03–1.49); <i>P</i> =0.022 (b) 0.91 (0.82–1.02); <i>P</i> =0.10
ICD placed or prescribed at discharge	29.8% vs 47.7% 0.41 (0.28–0.58); <i>P</i> <0.001	41.2% vs 47.7% 0.69 (0.50–0.93); <i>P</i> =0.017	46.3% vs 47.7% 0.95 (0.71–1.26); <i>P</i> =0.71	– (a) 1.56 (1.31–1.85); <i>P</i> <0.001 (b) 0.98 (0.82–1.16); <i>P</i> =0.79
Appropriate discharge instructions	86.2% vs 91.2% 0.58 (0.39–0.87); <i>P</i> =0.008	92.8% vs 91.2% 1.12 (0.76–1.67); <i>P</i> =0.56	91.3% vs 91.2% 0.95 (0.66–1.37); <i>P</i> =0.79	– 1.14 (1.01–1.30); <i>P</i> =0.042
Smoking cessation counseling	89.5% vs 95.4% 0.55 (0.34–0.89); <i>P</i> =0.016	94.6% v. 95.4% 0.97 (0.59–1.62); <i>P</i> =0.92	95.6% vs 95.4% 1.21 (0.75–1.95); <i>P</i> =0.44	– (a) 1.52 (1.16–2.01); <i>P</i> =0.003 (b) 0.86 (0.65–1.13); <i>P</i> =0.28
100% defect-free compliance	79.6% vs 88.3% 0.54 (0.39–0.75); <i>P</i> <0.001	89.5% vs 88.3% 1.16 (0.83–1.61); <i>P</i> =0.39	87.9% vs 88.3% 1.10 (0.80–1.50); <i>P</i> =0.57	– (a) 1.46 (1.22–1.75); <i>P</i> <0.001 (b) 0.80 (0.70–0.92); <i>P</i> =0.002

All models were adjusted for sociodemographic characteristics: age, sex, race (white versus nonwhite); medical history: anemia, ischemic history, CVA/TIA, diabetes mellitus, hyperlipidemia, hypertension, COPD or asthma, peripheral vascular disease, renal insufficiency, smoking; admission characteristics: systolic BP, heart rate, serum sodium, serum urea nitrogen, ejection fraction; and hospital characteristics: region and teaching hospital. Ejection fraction was not included for the process measures of ACEI/ARB at discharge, any β-blocker at discharge, aldosterone antagonist at discharge, CRT placed or prescribed at discharge, ICD placed or prescribed at discharge. Medical history of smoking not included for the measures of smoking cessation counseling (see text for details). ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; BP, blood pressure; CI, confidence interval; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; CVA indicates cerebrovascular accident; HF, heart failure; ICD, implantable cardioverter defibrillator; LV, left ventricular; OR, odds ratio; Q, quartile; and TIA, transient ischemic attack.

\*For linearly distributed outcomes, only 1 OR is listed. For nonlinearly distributed outcomes, linear spline transformation was performed with a knot at 125. For the latter variables, 2 ORs are reported: (a) per 50 admissions/y increase up to 125 and (b) per 50 admissions/y increase beyond 125.

†New from July 2008.

free care, in particular, up to an annual volume of 125 patients. Placement/prescription of a cardiac resynchronization therapy device at discharge and appropriate provision of discharge instructions at discharge had a steady and positive linear association with volume across the entire spectrum of volume assessed.

### Annual HF Volume and In-Hospital Outcomes

In-hospital mortality was similar across the 4 groups (3.5% versus 3.2% versus 3.4% versus 3.4%, *P*=0.54) (Table 3). This was true for patients with both HF with

reduced ejection fraction and HF with preserved ejection fraction (*P*<sub>interaction</sub>=0.15). Assessing volume as a continuous variable rather than categorical yielded similar results for in-hospital mortality (odds ratio, 0.99; 95% CI, 0.94–1.05; *P*=0.78, per 50 admissions/y increase). In comparison with higher-volume hospitals, patients presenting to lower-volume hospitals were less likely to have a length of stay >4 days (40.5% versus 47.5% versus 46.7% versus 49.2%, *P*<0.001; odds ratio<sub>Q1 versus Q4</sub>† 0.71; 95% CI, 0.61–0.83; *P*<0.001), and were more likely to be discharged home (71.3% versus 68.2% versus 67.5% versus 67.2%, *P*=0.009; odds ratio<sub>Q1 versus Q4</sub>† 1.25; 95% CI, 1.09–1.43; *P*=0.001).

**Table 3. Multivariable Adjusted Logistic and Cox Regression Models Demonstrating Associations Between Annual Hospital HF Volume and Outcomes**

Outcome of interest	Q1 vs Q4 Adjusted OR (95% CI),* P Value	Q2 vs Q4 Adjusted OR (95% CI),* P Value	Q3 vs Q4 Adjusted OR (95% CI),* P Value	Continuous† Adjusted OR (95% CI), P Value
Mortality				
In-hospital	1.15 (0.92–1.43); P=0.23	0.97 (0.82–1.13); P=0.68	1.01 (0.87–1.17); P=0.86	0.99 (0.94–1.05); P=0.78
30-day‡	1.05 (0.92–1.19); P=0.45	1.12 (1.03–1.23); P=0.012	1.06 (0.97–1.16); P=0.21	0.99 (0.97–1.01); P=0.26
6-month‡	1.06 (0.99–1.14); P=0.11	1.09 (1.02–1.15); P=0.005	1.03 (0.98–1.09); P=0.28	0.98 (0.97–0.99); P=0.001
Readmission				
30-day‡	1.04 (0.94–1.15); P=0.47	1.08 (1.02–1.16); P=0.015	1.02 (0.96–1.08); P=0.62	0.99 (0.97–1.00); P=0.10
6-month‡	1.04 (0.96–1.12); P=0.38	1.09 (1.04–1.14); P=0.001	1.03 (0.98–1.08); P=0.29	0.98 (0.97–1.00); P=0.025

All models were adjusted for sociodemographic characteristics: age, sex, race; medical history: anemia, ischemic history, CVA/TIA, diabetes mellitus, hyperlipidemia, hypertension, COPD or asthma, PVD, renal insufficiency, smoking; admission characteristics: systolic BP, heart rate, serum sodium, serum urea nitrogen, EF group; hospital characteristics: region, hospital type (teaching/nonteaching). BP indicates blood pressure; CI, confidence interval; COPD, chronic obstructive pulmonary disease; CVA indicates cerebrovascular accident; EF, ejection fraction; HF, heart failure; HR, hazard ratio; PVD, peripheral vascular disease; Q, quartile; and TIA, transient ischemic attack.

\* HRs and corresponding 95% CIs for 30-day and 6-month models.

† For every 50 admissions/y increase.

‡ Among patients discharged alive; also adjusted for compliance with defect-free HF measures during index hospitalization.

## Annual HF Volume and 30-Day and 6-Month Outcomes (n=109 343)

Thirty-day mortality (HR<sub>Q1 versus Q4</sub>, 1.05; 95% CI, 0.92–1.19; P=0.45; HR<sub>Q2 versus Q4</sub>, 1.12; 95% CI, 1.03–1.23; P=0.012; HR<sub>Q3 versus Q4</sub>, 1.06; 95% CI, 0.97–1.16; P=0.21) and readmission rates (HR<sub>Q1 versus Q4</sub>, 1.04; 95% CI, 0.94–1.15; P=0.47; HR<sub>Q2 versus Q4</sub>, 1.08; 95% CI, 1.02–1.16; P=0.015; HR<sub>Q3 versus Q4</sub>, 1.02; 95% CI, 0.96–1.08; P=0.62) were both higher in Q2 hospitals but not Q1 or Q3 hospitals in comparison with Q4 (Table 3). As a continuous variable, there was no association between annual hospital volume and 30-day mortality (HR, 0.99; 95% CI, 0.97–1.01; P=0.26) or 30-day readmissions (HR, 0.99; 95% CI, 0.97–1.00; P=0.10). At 6 months, there was a similar small increase in mortality (HR<sub>Q2 versus Q4</sub>, 1.09; 95% CI, 1.02–1.15; P=0.005) and readmissions (HR<sub>Q2 versus Q4</sub>, 1.09; 95% CI, 1.04–1.14; P=0.001) among Q2 in comparison with Q4 hospitals; no significant differences were observed for Q1 or Q3 in comparison with Q4 hospitals. As a continuous variable, higher hospital volume was associated with slightly lower 6-month mortality (HR, 0.98; 95% CI, 0.97–0.99; P=0.001, per 50 admissions/y increase) and 6-month readmissions (HR, 0.98; 95% CI, 0.97–1.00; P=0.025, per 50 admissions/y increase).

## DISCUSSION

Our analysis of a large contemporary prospectively collected registry with >125 000 patients admitted with HF at 342 hospitals across the United States suggests that patients presenting to lower-volume hospitals are less likely to experience better process-of-care measures in comparison with higher-volume hospitals for most HF process-of-care measures. In contrast, risk-adjusted

outcomes including in-hospital mortality were similar up to 30 days following discharge, but there was a weak association of higher volume with lower risk-adjusted mortality and readmission at 6 months.

In a seminal narrative, Donabedian<sup>16</sup> defined 3 domains in quality of care: structure, process, and outcomes. Over the past 3 decades, hospital volume has evolved into an important structural metric, particularly for procedural fields such as cardiac surgery and percutaneous coronary intervention.<sup>17,18</sup> Conflating an observed association between hospital volume and mortality as indicative of a causal relationship, guidelines and payers have endorsed volume minimums as surrogates for quality of care.<sup>9,10,19–21</sup> However, the relationship between volume and outcomes is much more intricate. There is a complex interplay between structural and process metrics, such that focusing on a structural metric in isolation ignores a sometimes greater contribution from process metrics.<sup>10,11</sup> For instance, for patients undergoing primary angioplasty, we earlier reported that high-volume hospitals were more likely to achieve door-to-balloon times and uniformly adhere to evidence-based metrics than low-volume hospitals. The association of volume with mortality was marginal, in particular, after accounting for higher systems of care at higher-volume hospitals.<sup>8</sup>

In the past few years, the use of volume as a surrogate for quality has gained traction for acute medical care conditions such as HF and acute myocardial infarction.<sup>5,6,11</sup> For instance, annual case volumes for acute myocardial infarction and HF are important components of the Hospital Quality Index used by the *U.S. News & World Report* Best Hospitals to rank cardiology programs. Not only does this become self-fulfilling (higher volumes drive higher scores which increase re-

ferrals and patient visits), but it also impacts third-party reimbursements (which can further exacerbate differences by reducing available resources at lower-volume hospitals to enhance systems of care).<sup>22</sup> Patients in rural areas may be disproportionately affected because rural hospitals are frequently lower-volume hospitals<sup>9</sup>; in the current analysis, nearly a quarter of Q1 hospitals were rural in comparison with  $\approx 3\%$  of Q4 hospitals.

Against this background, our current study provides several important perspectives. First, as for primary angioplasty, we found that higher-volume hospitals are more adept at the administration of process-of-care measures than lower-volume hospitals. Although there were minor differences in medication management based on volume, gaps in the placement or prescription of ICD or cardiac resynchronization therapy devices were particularly high between low- and high-volume hospitals. This is an important observation because other studies have similarly noted a high penetration of these drugs in contemporary HF inpatient practice.<sup>23</sup> Next, volume had minimal association with short-term mortality and readmissions (Q2 hospitals were associated with an 8%–12% higher 30-day mortality and readmission rates than Q4 hospitals). At 6 months, an increase in 50 annual admissions for HF was associated with a 2% reduced hazard of 6-month mortality and readmission rates after accounting for case-mix and appropriate use of evidence-based therapies at discharge. We assessed both mortality and readmission risks because they can have an inverse association in HF patients.<sup>24</sup> Quantifying superior systems of care at higher-volume hospitals (for instance, are there routine pathways or order sets that are uniformly being applied to all HF admissions; is every HF admission staffed by a cardiologist; are discharge parameters uniformly applied) may thus go a longer way in homogenizing care and potentially reducing costs for HF admissions than focusing attention on annual case volumes alone. This may also perhaps help reduce racial disparities in healthcare delivery for HF,<sup>25</sup> since as noted in our analysis, nearly 1 in 5 patients admitted to low-volume hospitals was either black or Hispanic.

This is not to completely undermine the role of case volumes. Undoubtedly, physician and ancillary personnel experience and repetition do matter (the practice makes perfect hypothesis).<sup>7,26,27</sup> Moreover, as we note here, higher-volume hospitals are more likely to be urban teaching hospitals, which are more likely to have both the availability and the experience for cutting-edge techniques and devices. On categorical analysis, in comparison with Q4 hospitals, Q2 hospitals (but not Q1 hospitals) had higher 30-day and 6-month mortality and readmission rates, despite similar adherence to process metrics. This could represent a chance finding, but merits further investigation.

The results of this study are contrary to other published studies in patients with HF.<sup>5,6</sup> Two earlier studies reported an inverse association between hospital volume and 30-day mortality using Medicare FFS data.<sup>5,6</sup> However, our results are complementary to another Medicare FFS data set analysis. Chen and colleagues<sup>3</sup> observed that hospital volume accounted for only 23% of hospital-level variation in risk-adjusted mortality for patients admitted with HF. An important distinction is that patient vital signs and laboratory data, and detailed process-of-care measures, as well, were prospectively collected in the current study, versus obtained at an aggregate hospital level in the other 3. Furthermore, because our study is more contemporary and GWTG-HF is specifically designed for quality improvement, process measures were collected with a high level of granularity. It is important to note that appropriate patient-level risk adjustment was done using prospectively collected data. This is a critical element for calculating and comparing risk-adjusted outcomes and can be problematic from administrative data sets.<sup>28</sup> The categorical thresholds that we used to classify hospitals are different from these prior studies, but at least 1 prior study suggests the volume-outcomes relationship for HF is strongest for hospitals with <400 annual HF admissions.<sup>6</sup> There is an important distinction between the current analysis and prior studies in the definition of annual hospital volume as well, which may explain the lower median volume noted in our study. Rather than including all Centers for Medicare & Medicaid Services-eligible HF admissions at participating hospitals, we included only Centers for Medicare & Medicaid Services-eligible unique HF admissions. Thus, if the same patient was subsequently readmitted to the same hospital within 1 year, he or she does not contribute to the volume calculation. In our opinion, this allows for a more reliable assessment of volume and outcomes, because hospitals with higher 1-year readmission rates could skew the volume relationship (by artificially inflating the volume). Another important aspect of our study is the inclusion of 6-month mortality and readmission data, providing a longer-term assessment of factors in play during the index hospitalization. To our knowledge, this is the first study to perform this long-term assessment.

We acknowledge the limitations of our study. Data for the GWTG-HF registry are collected by voluntary participating hospitals, and thus are not generalizable to all hospitals.<sup>29</sup> To assess outcomes beyond hospital discharge, we could only include Medicare-eligible patients, again limiting its overall generalizability. Volume may not have an important influence on outcomes in the setting of a quality improvement system such as GWTG-HF, or may not represent a valid structural assessment for HF care. However, as discussed earlier, it is increasingly being considered as such. Our 30-day and 6-month models were carefully adjusted for process-of-

care measures at discharge, but postdischarge measures were not available, which may also influence both 30-day and 6-month outcomes. Finally, the study followed patients for 6 months beyond hospital discharge only. It is possible that, with longer observation, a difference may have emerged. For example, less referral for ICD or cardiac resynchronization therapy implantation would not be likely to manifest as a potential increase in mortality within 6 months. However, the analysis may also get more complicated with longer-term follow-up because factors associated with the index hospitalization may become progressively less relevant in the face of longitudinal provider-patient interactions following hospital discharge.

In conclusion, our analysis of a large contemporary prospective national registry of patients with HF indicates that hospital volume as a structural metric correlates with process measures, but not with 30-day outcomes and only marginally with outcomes of up to 6 months of follow-up in older patients with HF. Hospital profiling for HF should focus on participation in systems-of-care endeavors, adherence to process metrics, and risk-standardized outcomes rather than on hospital volume itself.

## ARTICLE INFORMATION

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**Association Between Hospital Volume, Processes of Care, and Outcomes in Patients Admitted With Heart Failure: Insights From Get With The Guidelines-Heart Failure**  
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**"SUPPLEMENTAL MATERIAL."**

**Supplemental figure legend:** CONSORT flow diagram of study population

