



**Maryland Health Care Commission
Final Report -
Analyze Patient-level Data from the
American College of Cardiology's National
Cardiovascular Data Registry**

(MHCC 21-005R)

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EXECUTIVE SUMMARY

Coronary angiography and revascularization through percutaneous coronary intervention (PCI) is a common procedure performed for the treatment in non-ST-segment elevation myocardial infarction (NSTEMI) and ST-segment elevation myocardial infarction (STEMI). The use and timing of PCI depends on the ischemic status of the patient and the capabilities of the hospital in which the myocardial infarction is being treated. Medical management may be the preferred treatment for NSTEMI. Emergency PCI is the primary response to a STEMI. Maryland hospitals need approval to establish a PCI program for emergency PCI services or elective PCI services. Elective PCI services are used to treat patients with NSTEMI or other cardiac conditions. For some higher risk patients who require PCI services, expert guidelines recommend that cardiac surgery be available on-site. Maryland regulations require hospitals to follow expert guidelines for patient selection.

The primary objective of this analysis is to evaluate the impact of NSTEMI PCI volume and STEMI PCI volume on inpatient mortality and acute kidney injuries (AKI) rates. The secondary objective is to assess the extent to which the currently employed method of calculating the confidence intervals surrounding mortality and AKI rates (i.e., Clopper-Pearson) are appropriately robust with respect to a hospital's identification as an outlier.

Data for this analysis were provided by MHCC staff who receive data from hospitals that is a duplicate of the information submitted to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI. Hospitals submit detailed data to this registry and receive feedback on their quarterly performance for processes of care and outcomes metrics relative to previous performance and are benchmarked against the national performance of all participants in the ACC-NCDR CathPCI.

The two primary variables of interest for this analysis are inpatient mortality and PCI-related complication rates as assessed through acute kidney injuries. The repeated observations of PCI performed on many patients was modeled using a multilevel logistic regression to estimate separately the proportion of NSTEMI and STEMI PCI patients with an inpatient death or AKI after controlling for demographic characteristics and clinical factors. PCI volume is included as a factor in these models to estimate or function as a proxy for the experience, economies of scale, and other phenomena associate with higher volumes.

For the analysis of confidence interval calculations, three methods were used for each of the effects generated by the volume-dependency model. The first method is the typical confidence interval calculation that uses the Clopper-Pearson (i.e., 'exact') Method, which is the method currently employed by the ACC for the CathPCI NCDR. The second and third methods are more recently developed alternatives to Clopper-Pearson. These newer methods form the basis of the robustness assessment for identifying outlier hospitals using the currently employed

confidence intervals and models. The two selected alternative approaches for forming the confidence intervals are the Agresti-Coull and Jeffreys methods.

The three key findings to emerge from this study are as follows: 1) hospitals with relatively high STEMI PCI volume have lower mortality and kidney injury rates, after controlling for demographic and clinical factors 2) impacts on outcomes of care related to NSTEMI PCI volume are modest, at best, and explained by variance in patient severity, and 3) the method used to calculate standard errors and confidence intervals for inpatient deaths and acute kidney injury proportions does not make a substantive difference in identifying outlier hospitals for STEMI cases or NSTEMI cases.

INTRODUCTION

Chest pain is a common complaint in the emergency department with 15 percent of presentations resulting from acute coronary syndrome (ACS) (Chang, 2018). ACS could be a myocardial infarction or unstable angina. Physicians determine the type and severity of the ACS, to distinguish an ST-elevation myocardial infarction (STEMI), a non-ST-elevation myocardial infarction (NSTEMI), and angina. In STEMI patients, one or more coronary arteries are completely blocked, and for NSTEMI patients, there is partial blockage of one or more coronary arteries. A percutaneous coronary intervention (PCI) can be used to restore blood supply to the heart.

Maryland hospitals need approval to establish an emergency or elective PCI program, as well as cardiac surgery services. A small number of hospitals provide only emergency PCI services or did for part of the period of data reviewed. For some higher risk patients who require PCI services, expert guidelines recommend that cardiac surgery be available on-site. Maryland regulations require hospitals to follow expert guidelines for patient selection.

The primary objective of this analysis is to evaluate the impact of NSTEMI PCI volume and STEMI PCI volume on inpatient mortality and AKI rates. The secondary analysis uses three distinct methods to calculate the standard errors and confidence intervals for each of the effects generated by the volume-dependency model. The first method is the typical confidence interval calculation that uses the Clopper-Pearson (i.e., 'exact') Method and is currently in use by the American College of Cardiology (ACC) for the CathPCI National Cardiovascular Data Registry (NCDR) data for reporting purposes. Two more recently developed alternative methods were also used to assess the impact of assumptions behind the confidence intervals for the proportions of inpatient deaths and complications following an NSTEMI PCI. The two selected alternative approaches for forming the confidence intervals are the Agresti-Coull (Agresti, 1998) and Jeffreys (Brown, 2001) methods.

Analysis #1: The Impact of NSTEMI PCI Volume on Mortality and Acute Kidney Injury Rates

Background

Coronary angiography and revascularization through percutaneous coronary intervention (PCI) is a common procedure performed for the treatment in non-ST-segment elevation myocardial infarction (NSTEMI). The use and timing of the procedure depends on the ischemic status of the patient and the capabilities of the hospital in which the NSTEMI is being treated (Banning, 2018). Medical management may be the preferred treatment for NSTEMI. Not all hospitals perform elective PCI services, even when they perform emergency PCI services for patients with ST-segment elevation myocardial infarction (STEMI). The purpose of this analysis is to evaluate the impact of NSTEMI PCI volume on mortality and AKI rates using three different types of confidence intervals that are well-supported in the literature and, by doing so, provide guidance to the

Maryland Health Care Commission (MHCC) on the impact that the choice of confidence interval methodologies (i.e., traditional or updated) may yield on the selection of outlier hospitals.

Methods

Data

Data for this analysis were provided by MHCC staff who receive from hospitals duplicate information previously submitted to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI. Hospitals submit detailed data to the registry, and participating hospitals receive feedback on their quarterly performance for processes of care and outcomes metrics relative to previous performance and are benchmarked against the national performance of all participants in the ACC-NCDR CathPCI.

Dependent Variables

The two primary variables of interest are inpatient mortality and PCI-related complication rates as assessed through AKIs. Inpatient mortality is identified by the discharge disposition of the individual who received a PCI for a STEMI. AKI is identified through criteria modified from the Acute Kidney Injury Network (AKIN) criteria (Tsai, 2014), which included the following: a new need for dialysis, an absolute increase of ≥ 0.3 mg/dL in serum creatinine pre- and post-PCI, or a relative increase of 50% in serum creatinine pre- and post-PCI.

Explanatory and Risk-Adjustment Variables

NSTEMI PCI volume is the total count of NSTEMI PCI procedures performed per hospital as identified by the PCI indication variable in the CathPCI databases. A case is identified as a STEMI encounter if the PCI Indicator reason is: Immediate PCI for STEMI; PCI for STEMI (Unstable, >12 hours from symptom onset); PCI for STEMI (Stable, >12 hours from symptom onset); PCI for STEMI (Stable after successful full-dose Thrombolysis); or Rescue PCI for STEMI (after failed full-dose lytics). An NSTEMI PCI encounter is identified in the ACC-NCDR CathPCI by the field called PCI Indication with values or information that correspond to PCI for high risk Non-STEMI or unstable angina. The PCI volume is either equal to or greater than the count of NSTEMI PCI admissions as multiple procedures may be performed for a given hospital admission and NSTEMI PCIs may be performed during a STEMI PCI admission.

Mortality risk-adjustment variables include age, race, sex, body mass index, previous congestive heart failure, previous cerebrovascular disease, peripheral vascular disease, chronic lung disease, previous PCI, diabetes, admission symptom presentation, cardiogenic shock, pre-operative intra-aortic balloon pump, ejection fraction, and PCI status (elective, urgent, emergent, salvage). The AKI risk-adjustment variables include age, sex, body mass index, previous congestive heart failure, diabetes, hypertension, previous myocardial infarction (MI), previous PCI, previous coronary artery bypass grafting (CABG), previous cerebrovascular disease (CVD), previous peripheral arterial disease (PAD), chronic lung disease, and multiple PCI procedures. The variable identification from the NCDR data is specified in Appendix 2.

Analytic Approach

The performance reporting measures that hospitals receive from the ACC related to outcomes, such as mortality and adverse events, are risk adjusted to compare expected to actual outcome rates. The ACC statistical analyses use logistic models to estimate risk-adjusted rates and confidence intervals. The models do not use hospital or procedure volume for risk adjustment, but rather estimate hospital effects through a hierarchical model (American College of Cardiology, 2011).

Volume-Outcome Relationship

The impact of NSTEMI PCI volume on outcomes of care was modeled first using a two-indicator approach that categorizes hospitals into low and high volume hospitals based on the median counts of NSTEMI PCI procedures by hospital for NSTEMI indication from 2015 to 2019. The second assessment categorizes hospitals into three groups by terciles, using the 33rd and 66th percentile PCI counts by hospital for NSTEMI indication.

Hierarchical Logistic Regression Models

To analyze the impact of STEMI PCI volume on a hospital's status as an outlier with respect to national mortality rates, the research team used a hierarchical logistic model with a random-effect to estimate risk-adjusted mortality rates. This approach mirrors the risk-adjusted methodology that ACC uses for the estimation of the hospital-specific mortality rates and comparisons to national rates.

The parameter estimates using a logistic regression are interpreted as odds ratios; that is, the odds of a patient dying in the hospital or experiencing an acute kidney injury following a PCI procedure in a high-volume hospital relative to a low-volume hospital. The analytic model estimates the expected mortality and AKI rate based on the medical conditions that patients have and other factors such as age. The contribution of NSTEMI PCI volume to the odds ratio is also estimated.

Risk-Adjustment

Demographic and clinical measures were identified as factors from the literature on PCI procedures for myocardial infarction. Past diagnoses and previous procedures performed that are related to cardiac severity or kidney problems were identified. The risk-adjustment variables are designed to control for the patient level factors which are independent of the quality of care that a patient receives.

Annual Evaluation of Mortality and Complication Rates, 2015-2019

The ACC performs annual assessments of hospitals that include more than 2,400 contributing hospitals. The sample for the current analysis was created from 21 hospitals in Maryland that

perform elective PCI and participate in the ACC NCDR CathPCI registry.¹ The unadjusted and risk-adjusted mortality rates and AKI rates were calculated on an annual basis from 2015 to 2019 and on aggregate basis over the same time period.

Repeated Cross-Sectional Model

Patients receiving a PCI for an NSTEMI are clustered by hospital. The repeated observations of PCI performed on many patients was modeled using a multilevel logistic regression to estimate the proportion of NSTEMI PCI patients with an inpatient death or AKI after controlling for demographic characteristics and clinical factors. NSTEMI PCI volume is employed as a predictive factor in these models to estimate (or function as a proxy for) the experience, economies of scale, and other phenomena associate with higher volumes of PCI procedures.

Results

Unadjusted Rates

Table 1 presents the counts of PCI procedures performed for NSTEMI indication by hospital by year from 2015 to 2019. The total NSTEMI PCI volume forms the basis for the two indicators used to assess the impact of NSTEMI PCI volume. In the two-group assessment, 11 hospitals performed 944 or fewer NSTEMI PCIs between 2015 and 2019 while another 10 hospitals performed more than 944. For the low/medium/high volume assessment of NSTEMI PCI volume, seven hospitals performed 853 or fewer NSTEMI PCIs, seven hospitals performed between 645 and 1,256 NSTEMI PCIs, and seven hospitals more than 1,296 NSTEMI PCIs between 2015 and 2019.

¹ Holy Cross Hospital, Howard County General Hospital, and Medstar Franklin Square Medical Center are Maryland hospitals not included in this analysis as each had fewer than five NSTEMI PCI discharges per year between 2015 and 2019.

Table 1 - NSTEMI PCI VOLUME BY HOSPITAL, 2015-2019

Hospital	High/Low	High/Medium/Low	2015	2016	2017	2018	2019	TOTAL
Adventist White Oak	High	High	438	435	474	303	250	1,900
Adventist Shady Grove	Low	Low	112	122	110	86	85	515
Anne Arundel Medical Center	Low	Low	160	167	196	198	125	846
Ascension Saint Agnes	High	Medium	287	297	319	202	136	1,241
Carroll Hospital Center	Low	Low	114	137	103	78	92	524
Frederick Hospital	Low	Medium	209	209	220	145	144	927
Johns Hopkins Bayview	Low	Low	123	88	123	86	97	517
Johns Hopkins Hospital	High	High	279	349	420	376	293	1,717
MedStar Southern Maryland	Low	Medium	132	151	187	241	190	901
MedStar Union	High	High	848	874	877	512	534	3,645
Meritus Medical Center	Low	Low	123	122	118	103	124	590
Peninsula Regional Medical Center	High	High	323	327	305	360	323	1,638
Sinai Hospital	High	High	348	367	420	211	123	1,469
Suburban Hospital	High	Medium	274	321	240	205	136	1,176
UM Prince George's	Low	Low	129	159	150	152	96	686
UM Baltimore Washington	Low	Medium	195	199	180	121	171	866
UM Medical Center	High	Medium	273	254	254	193	272	1,246
UM Shore Regional	Low	Low	0	0	97	90	78	265
UM St. Joseph	High	High	699	595	626	533	347	2,800
UM Upper Chesapeake	High	High	223	254	315	288	240	1,320
UPMC Western Maryland	Low	Medium	223	196	232	168	125	944
Median			223	209	232	198	136	944
First Tercile			141	162	182	147	124	853
Second Tercile			277	313	312	231	223	1,295

The comparison of unadjusted mortality rates between low and high volume hospitals is presented in Table 2. Inpatient death is a rare event for patients receiving a NSTEMI PCI in either a low volume (1.2 percent) or high volume (1.0 percent) hospitals. The difference in outcomes between the two categories of hospitals is not statistically significant at the five percent level for any of the five assessed years individually or in the aggregate across all five years.

Table 2 - NSTEMI PCI MORTALITY RATES BY LOW VS HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			High Volume			p value
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	
2015	3,557	0.006	0.002	4,035	0.011	0.002	0.081
2016	3,482	0.010	0.003	4,152	0.012	0.002	0.515
2017	3,694	0.010	0.002	4,315	0.009	0.001	0.795
2018	2,636	0.010	0.003	3,270	0.013	0.002	0.395
2019	2,360	0.010	0.003	2,703	0.015	0.002	0.146
Total	7,502	0.012	0.001	17,962	0.010	0.001	0.059

Table 3 presents the difference in AKI rates between low and high volume hospitals. The five-year aggregate rate of AKI is 7.3 percent in low volume hospitals and 8.1 percent in high volume hospitals for patients who received an NSTEMI PCI. The differences between hospital volume groups are only statistically significant in the aggregated assessment ($p = 0.026$).

Table 3 - NSTEMI PCI ACUTE KIDNEY INJURY RATES BY LOW VS HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			High Volume			p value
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	
2015	3,557	0.066	0.006	4,036	0.076	0.004	0.227
2016	3,482	0.075	0.007	4,152	0.081	0.004	0.412
2017	3,694	0.074	0.006	4,315	0.081	0.004	0.342
2018	2,636	0.078	0.007	3,270	0.081	0.005	0.730
2019	2,360	0.072	0.007	2,703	0.089	0.006	0.061
Total	7,502	0.073	0.003	17,962	0.081	0.002	0.026

The difference in NSTEMI PCI inpatient mortality between the low, medium, and high volume hospitals is presented in Table 4. Differences in inpatient mortality was not apparent for the volume categories in the yearly or aggregate data. An issue for the NSTEMI PCI mortality data is that inpatient death is a very rare event, which requires a very large sample to detect a statistically significant difference between a 1.0 percent rate in high volume hospitals, for example, and a 1.3 percent rate in low PCI volume hospitals.

Table 4 - NSTEMI PCI MORTALITY RATES BY LOW, MEDIUM, AND HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			Medium Volume			High Volume			p values		
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	Observations	Proportion	S.E.	Medium vs Low	High vs Low	High vs Medium
2015	749	0.009	0.004	1,574	0.007	0.002	3,101	0.011	0.002	0.590	0.628	0.159
2016	779	0.014	0.004	1,607	0.010	0.002	3,165	0.011	0.002	0.368	0.517	0.662
2017	882	0.014	0.004	1,611	0.011	0.003	3,380	0.008	0.002	0.550	0.108	0.237
2018	791	0.013	0.004	1,269	0.017	0.004	2,575	0.010	0.002	0.434	0.570	0.088
2019	697	0.013	0.004	1,174	0.015	0.004	2,110	0.013	0.002	0.662	0.982	0.547
Total	3,898	0.013	0.002	7,235	0.012	0.001	14,331	0.010	0.001	0.645	0.267	0.449

Table 5 presents the yearly and aggregate AKI rate differences between low, medium, and high NSTEMI PCI volume hospitals. While several years demonstrated a difference in AKI rates by volume, the aggregate effect did show a statistically significant difference; the direction of the effect from year to year was not consistent.

Table 5 - NSTEMI PCI ACUTE KIDNEY INJURY RATES BY LOW, MEDIUM, AND HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			Medium Volume			High Volume			p values		
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	Observation	Proportion	S.E.	Medium vs Low	High vs Low	High vs Medium
2015	749	0.067	0.009	1,574	0.070	0.006	3,101	0.076	0.005	0.787	0.362	0.417
2016	779	0.073	0.009	1,607	0.083	0.007	3,165	0.080	0.005	0.417	0.551	0.705
2017	882	0.066	0.008	1,611	0.104	0.008	3,380	0.071	0.004	0.001	0.627	<0.001
2018	791	0.078	0.010	1,269	0.095	0.008	2,575	0.073	0.005	0.167	0.626	0.016
2019	697	0.062	0.009	1,174	0.104	0.009	2,110	0.078	0.006	0.001	0.170	0.010
Total	3,898	0.069	0.004	7,235	0.090	0.003	14,331	0.075	0.002	<0.001	0.205	<0.001

Summary Statistics

Outcomes of care empirically seem to vary by volume somewhat due to the demographic composition and clinical severity of the population served. Table 6 shows the demographic and clinical characteristics by NSTEMI PCI volume category. Age is an independent determinant of the outcomes of care following an NSTEMI PCI. As age progresses, the likelihood increases that a patient's NSTEMI PCI will be performed at a higher volume hospital. Table 6 also shows that

patient race profiles vary by NSTEMI PCI volume hospitals. Hospital volume with respect to NSTEMI PCI does not appear to vary by race. The sharpest differences are found in the clinical characteristics with higher volume hospitals performing NSTEMI PCI procedures on patients with more comorbid conditions. The number and types of comorbidities may increase the risk of post-procedure complications. The standard errors for the pairwise comparisons of means were created using the Clopper-Pearson (Exact) method; a comparison of the Clopper-Pearson method with two alternative methods is presented in the section of this report titled, "The Impact of Selected Standard Errors and Confidence Intervals on Outlier Status Relative to Mortality and Acute Kidney Injury."

Table 6 - DEMOGRAPHIC AND CLINICAL CHARACTERISTICS BY NSTEMI PCI VOLUME MEASURES

Variable	Low vs High Volume					Low vs Medium vs High Volume								
	Low Volume (n = 7,502)		High Volume (n = 17,962)		p value	Low Volume (n = 3,898)		Medium Volume (n = 7,235)		High Volume (n = 14,331)		Pairwise Comparison of Means (p values)		
	Mean	S.D.	Mean	S.D.			Mean	S.D.	Mean	S.D.	Mean	S.D.	M vs L	H vs L
Age	64.246	11.857	66.872	11.958	<0.001	64.261	11.974	65.169	11.973	67.068	11.904	<0.001	<0.001	<0.001
Age: ≤ 25	0.000	0.000	0.000	0.015	0.196	0.000	0.000	0.000	0.000	0.000	0.017	1.000	0.218	0.123
Age: 25 - 35	0.006	0.078	0.004	0.063	0.019	0.007	0.083	0.005	0.068	0.004	0.062	0.097	0.013	0.417
Age: 35 - 45	0.042	0.200	0.030	0.171	<0.001	0.042	0.201	0.042	0.200	0.027	0.162	0.900	<0.001	<0.001
Age: 45 - 55	0.180	0.384	0.129	0.335	<0.001	0.180	0.385	0.155	0.362	0.128	0.334	<0.001	<0.001	<0.001
Age: 55 - 65	0.302	0.459	0.278	0.448	<0.001	0.298	0.457	0.300	0.458	0.274	0.446	0.850	0.003	<0.001
Age: 65 - 75	0.274	0.446	0.295	0.456	0.001	0.274	0.446	0.280	0.449	0.297	0.457	0.501	0.005	0.010
Age: > 75	0.196	0.397	0.264	0.441	<0.001	0.198	0.399	0.218	0.413	0.269	0.444	0.018	<0.001	<0.001
Male	0.662	0.473	0.656	0.475	0.367	0.673	0.469	0.652	0.476	0.656	0.475	0.021	0.047	0.491
Female	0.338	0.473	0.344	0.475	0.367	0.327	0.469	0.348	0.476	0.344	0.475	0.021	0.047	0.491
Race: White	0.759	0.428	0.736	0.441	<0.001	0.731	0.444	0.732	0.443	0.752	0.432	0.875	0.008	0.002
Race: Black	0.200	0.400	0.219	0.414	0.001	0.209	0.407	0.226	0.418	0.208	0.406	0.032	0.927	0.002
Race: Asian	0.026	0.160	0.040	0.197	<0.001	0.037	0.189	0.037	0.190	0.035	0.185	0.945	0.575	0.425
Race: American Indian	0.003	0.059	0.002	0.045	0.031	0.003	0.058	0.003	0.056	0.002	0.043	0.873	0.088	0.055
Race: Native Hawaiian	0.001	0.033	0.001	0.037	0.580	0.001	0.028	0.002	0.042	0.001	0.033	0.144	0.588	0.183
Ethnicity: Hispanic	0.027	0.163	0.020	0.138	<0.001	0.041	0.199	0.021	0.143	0.017	0.130	<0.001	<0.001	0.084
Body Mass Index (BMI)	31.087	7.429	30.408	8.045	0.078	30.954	7.814	30.571	7.237	30.531	8.191	0.015	0.003	0.723
BMI: < 18.5	0.015	0.122	0.012	0.110	<0.001	0.008	0.090	0.018	0.133	0.012	0.109	<0.001	0.070	<0.001
BMI: 18.5 - 25	0.153	0.360	0.186	0.389	0.137	0.158	0.365	0.176	0.381	0.181	0.385	0.017	0.001	0.434
BMI: 25 - 30	0.334	0.472	0.344	0.475	<0.001	0.341	0.474	0.344	0.475	0.340	0.474	0.757	0.939	0.601
BMI: > 30	0.498	0.500	0.458	0.498	0.058	0.493	0.500	0.462	0.499	0.467	0.499	0.002	0.005	0.448
On Current Dialysis	0.032	0.175	0.037	0.188	<0.001	0.034	0.182	0.041	0.198	0.032	0.177	0.068	0.535	0.001
Hypertension	0.813	0.390	0.856	0.351	<0.001	0.806	0.396	0.831	0.375	0.860	0.347	<0.001	<0.001	<0.001
Prior Myocardial Infarction	0.268	0.443	0.338	0.473	<0.001	0.259	0.438	0.304	0.460	0.340	0.474	<0.001	<0.001	<0.001
Prior Heart Failure	0.119	0.323	0.169	0.375	<0.001	0.111	0.314	0.160	0.366	0.163	0.369	<0.001	<0.001	0.512
Prior PCI	0.360	0.480	0.425	0.494	<0.001	0.346	0.476	0.384	0.486	0.433	0.496	<0.001	<0.001	<0.001
Prior CABG	0.154	0.361	0.206	0.404	<0.001	0.129	0.335	0.169	0.375	0.218	0.413	<0.001	<0.001	<0.001
Prior CVD	0.113	0.317	0.152	0.359	<0.001	0.114	0.318	0.133	0.339	0.152	0.359	0.008	<0.001	<0.001
Prior PAD	0.086	0.281	0.137	0.344	<0.001	0.086	0.281	0.112	0.316	0.137	0.344	<0.001	<0.001	<0.001
Chronic Lung Disease	0.132	0.338	0.158	0.365	<0.001	0.124	0.330	0.148	0.355	0.158	0.365	0.001	<0.001	0.053
Diabetes	0.398	0.489	0.428	0.495	<0.001	0.388	0.487	0.414	0.493	0.431	0.495	0.008	<0.001	0.019

Note: L, M, and H denotes Low, Medium, and High Volume respectively

Risk-Adjusted Findings

Table 7 presents the impact of high NSTEMI PCI volume relative to low volume, after controlling for demographic and clinical factors, on inpatient mortality. The impact of NSTEMI PCI volume was negligible (i.e., lack of statistical significance is seen through all confidence intervals having 1.0 between their lower and upper confidence interval limits).

Table 7- IMPACT OF HIGH VS LOW NSTEMI PCI VOLUME ON MORTALITY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	1.463	0.621	0.637	3.361
2016	0.988	0.367	0.477	2.045
2017	0.797	0.329	0.355	1.789
2018	1.035	0.371	0.512	2.090
2019	1.034	0.447	0.443	2.414
2015-2019	1.050	0.233	0.680	1.622

The incremental effect of moving from low to medium to high NSTEMI PCI volume, after controlling for demographic and clinical characteristics, are presented in Table 8. Similar to the high-vs-low analysis, volume does not appear to be a primary contributor to variation in inpatient mortality rates for NSTEMI PCI admissions.

Table 8 - INCREMENTAL EFFECT OF INCREASING NSTEMI PCI VOLUME ON MORTALITY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	1.049	0.263	0.642	1.714
2016	0.837	0.183	0.545	1.285
2017	0.697	0.163	0.441	1.102
2018	0.755	0.147	0.515	1.106
2019	0.866	0.221	0.525	1.430
2015-2019	0.846	0.109	0.658	1.088

Table 9 further supports the results in Tables 7 and 8 above, showing that the impact of volume on NSTEMI PCI admissions is not statistically significant in either the medium volume compared to low volume or high volume compared to low volume because the upper limit of the confidence interval is above 1.0 in all years.

Table 9 - EFFECT OF MEDIUM AND HIGH NSTEMI PCI VOLUME ON MORTALITY COMPARED TO LOW VOLUME

Year	Medium Relative to Low Volume				High Relative to Low Volume			
	Odds Ratio	S.E.	95% Confidence Interval		Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit			Lower Limit	Upper Limit
2015	0.597	0.332	0.201	1.774	0.921	0.457	0.348	2.434
2016	0.555	0.264	0.219	1.408	0.632	0.274	0.270	1.479
2017	0.678	0.336	0.257	1.790	0.484	0.228	0.192	1.217
2018	1.038	0.426	0.465	2.318	0.610	0.242	0.281	1.327
2019	0.719	0.404	0.239	2.165	0.726	0.376	0.263	2.005
2015-2019	0.677	0.184	0.397	1.155	0.692	0.178	0.418	1.146

Table 10 presents the impact of high NSTEMI PCI volume relative to low volume on AKI rates. The impact of NSTEMI PCI volume was negligible because the upper limit of the confidence interval is above 1.0 in all years.

Table 10 - IMPACT OF HIGH VS LOW NSTEMI PCI VOLUME ON ACUTE KIDNEY INJURY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	1.020	0.263	0.615	1.690
2016	0.912	0.195	0.600	1.386
2017	0.980	0.195	0.663	1.447
2018	0.874	0.177	0.588	1.300
2019	0.912	0.156	0.652	1.276
2015-2019	0.981	0.155	0.719	1.338

Table 11 shows the incremental effect of moving from low to medium to high NSTEMI PCI volume, after controlling for demographic and clinical characteristics, on AKI rates. The impact was not statistically significant in the yearly or the aggregate analyses because the upper limit of the confidence interval was above 1.0 in all years.

Table 11 - INCREMENTAL EFFECT OF INCREASING NSTEMI PCI VOLUME ON ACUTE KIDNEY INJURY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	1.069	0.173	0.779	1.467
2016	1.000	0.137	0.764	1.307
2017	0.931	0.115	0.732	1.186
2018	0.877	0.106	0.692	1.111
2019	0.985	0.108	0.794	1.222
2015-2019	1.009	0.099	0.832	1.224

The absence of a volume effect on AKI rates for NSTEMI PCI is shown in Table 12 by comparing the medium volume to low volume and the high volume compared to low volume.

Table 12 - IMPACT OF HIGH VS LOW NSTEMI PCI VOLUME ON ACUTE KIDNEY INJURY

Year	Medium Relative to Low Volume				High Relative to Low Volume			
	Odds Ratio	S.E.	95% Confidence Interval		Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit			Lower Limit	Upper Limit
2015	0.913	0.306	0.474	1.759	1.112	0.362	0.588	2.103
2016	1.136	0.326	0.648	1.993	1.026	0.286	0.594	1.772
2017	1.337	0.323	0.832	2.147	0.918	0.216	0.579	1.457
2018	1.067	0.263	0.658	1.730	0.791	0.188	0.496	1.261
2019	1.458	0.317	0.953	2.232	1.066	0.224	0.707	1.609
2015-2019	1.204	0.234	0.822	1.763	1.030	0.198	0.706	1.502

Discussion

Two key findings arose from this work. First, while the incidence of inpatient mortality is already low for patients receiving an PCI for an NSTEMI indication, neither the unadjusted nor the risk-adjusted NSTEMI PCI volume effects demonstrate an impact on inpatient mortality rates. Second, although the incidence of AKI is higher than the mortality rates and the unadjusted results suggest a decrease in AKI rates as volume increases, the volume effect evaporates once the clinical measures associated with AKI are included in the model. An important note is that even though the analysis is at the admission level, the PCI volume

analysis for the risk-adjusted models has the volume as a hospital-level effect. So, while there are more than 34,000 observations, there are still only 21 hospitals included in the analysis.

Analysis #2: The Impact of STEMI PCI Volume on Mortality and Acute Kidney Injury Rates

Background

Emergency PCI is the primary response to a STEMI (Morrison, 2007). The ST-elevation is due to an occluded, infarcted artery that requires remedy to restore blood flow to the heart. All hospitals that perform PCI procedures will perform STEMI PCIs. If a PCI volume effect exists with respect to inpatient mortality, it will most likely be visible in the treatment of STEMIs because the likelihood of dying is higher than for NSTEMI and that likelihood is related to the application of timely and effective care. A potential impact on AKI rates related to PCI volume is unknown. The purpose of this analysis to evaluate the extent to which variation in STEMI PCI volume explains variation in mortality or AKIs for patients presenting with a STEMI.

Methods

Data

Data for this analysis were provided by MHCC staff who receive data from hospitals that is a duplicate of the information submitted to the ACC-NCDR CathPCI registry. Hospitals submit detailed data to this registry and, by doing so, receive feedback on their quarterly performance for processes of care and outcomes metrics relative to previous performance and benchmarked against the national performance of all participants in the ACC-NCDR CathPCI.

Dependent Variables

The two primary variables of interest are inpatient mortality and PCI-related complication rates as assessed through AKI. Inpatient mortality is identified by the discharge disposition of the individual who received a PCI for a STEMI. AKI is identified through criteria modified from the Acute Kidney Injury Network (AKIN) criteria (Tsai, 2014). AKI was identified by a new need for dialysis, an absolute increase of ≥ 0.3 mg/dL in serum creatinine pre- and post-PCI, or a relative increase of 50% in serum creatinine pre- and post-PCI.

Explanatory and Risk-Adjustment Variables

STEMI PCI volume is the total count of STEMI PCI procedures performed per hospital as identified by the variable for PCI indication. The PCI volume is either equal to or greater than the count of STEMI PCI admissions as multiple procedures may be performed for a given hospital admission.

Mortality risk-adjustment variables include age, race, sex, body mass index, previous congestive heart failure, previous cerebrovascular disease, peripheral vascular disease, chronic lung disease, previous PCI, diabetes, admission symptom presentation, cardiogenic shock, pre-operative intra-aortic balloon pump, ejection fraction, and PCI status (elective, urgent, emergent, salvage) (Anderson, 2007). The AKI Risk-adjustment variables include age, sex, body

mass index, previous congestive heart failure, diabetes, hypertension, previous MI, previous PCI, previous coronary artery bypass grafting (CABG), previous cerebrovascular disease (CVD), previous peripheral arterial disease (PAD), chronic lung disease, and multiple procedures (Tsai, 2014). The list of risk-adjustment variables included for the analyses is in Appendix 2.

Analytic Approach

The performance reporting results that hospitals receive from the ACC related to outcomes, such as mortality and adverse events, are risk adjusted to compare expected to actual outcome rates. The ACC statistical analyses use logistic models to estimate risk-adjusted rates and confidence intervals. The models do not use hospital or procedure volume for risk adjustment, but rather estimate hospital effects through a hierarchical model (American College of Cardiology, 2011).

Volume-Outcome Relationship

The impact of STEMI PCI volume on outcomes of care was modeled first using a two-indicator approach that categorizes hospitals into low and high volume hospitals based on the median counts of PCI procedures by hospital for STEMI indication from 2015 to 2019. The second assessment categorizes hospitals into three groups by terciles, using the 33rd and 66th percentile PCI counts by hospital for STEMI indication.

Hierarchical Logistic Regression Models

To analyze the impact of STEMI PCI volume on a hospital's status as an outlier with respect to national mortality rates, the research team used a hierarchical logistic model with a random-effect to estimate risk-adjusted mortality rates. This approach mirrors the risk-adjusted methodology that the ACC uses for the estimation of the hospital-specific mortality rates and the comparisons to national rates. The parameter estimates using a logistic regression are interpreted as odds ratios.

Risk-Adjustment

Demographic and clinical measures were used as factors that may be independently associated with or contributing to an increased probability of death and kidney injury. The risk-adjustment variables were used to control for who hospitals treat for an NSTEMI, rather than how hospitals treat patients with an NSTEMI PCI.

Annual Evaluation of Mortality and Complication Rates, 2015-2019

The ACC performs annual assessments of hospitals, drawing on a sample of more than 2,400 contributing hospitals. The sample for the current analysis was created from 24 hospitals in Maryland that participate in the ACC NCDR CathPCI registry. The unadjusted and risk-adjusted mortality and AKI rates were calculated on an annual basis from 2015 to 2019 and on an aggregate basis across the same time period.

Repeated Cross-Sectional Model

Patients receiving a PCI for a STEMI are naturally clustered by hospital. The repeated observations of PCI performed on many patients were modeled using a multilevel logistic regression, using the GLIMMIX procedure in SAS Enterprise Guide 7.1 with a logistic link function, to estimate the proportion of STEMI PCI patients with an inpatient death or AKI after controlling for demographic characteristics and clinical factors. STEMI PCI volume is a factor in these models to estimate or proxy for the experience, economies of scale, and other phenomena associate with higher volumes.

Results

The counts of PCI procedures performed for STEMI indication by hospital by year from 2015 to 2019 are presented in Table 13. The total STEMI PCI volume forms the basis for the two indicators used to assess the impact of STEMI PCI volume (i.e., inpatient death and AKI). In the two-indicator assessment, 12 hospitals performed 482 or fewer STEMI PCIs between 2015 and 2019 while another 12 hospitals performed more than 482. For the low/medium/high volume assessment of STEMI PCI volume, eight hospitals performed 371 or fewer STEMI PCIs, eight hospitals performed between 371 and 517 STEMI PCIs, and eight hospitals more than 517 STEMI PCIs between 2015 and 2019.

Table 13 - STEMI PCI VOLUME BY HOSPITAL, 2015-2019

Hospital	High/Low	High/Medium/Low	2015	2016	2017	2018	2019	TOTAL
Adventist White Oak	Low	Low	54	45	49	38	35	221
Adventist Shady Grove	High	High	144	159	129	130	128	690
Anne Arundel Medical Center	High	High	146	115	149	132	138	680
Ascension Saint Agnes	High	Medium	126	98	85	89	91	489
Carroll Hospital Center	Low	Low	89	83	72	65	61	370
Frederick Hospital	High	High	132	103	97	111	124	567
Holy Cross Hospital	Low	Low	76	71	55	66	71	339
Howard County Hospital	High	Medium	97	99	90	117	97	500
Johns Hopkins Bayview	Low	Low	58	73	60	57	66	314
Johns Hopkins Hospital	Low	Low	63	41	64	36	40	244
MedStar Franklin Square	High	Medium	111	96	107	101	99	514
MedStar Southern Maryland	High	High	143	106	131	132	149	661
MedStar Union	Low	Medium	118	85	88	82	64	437
Meritus Medical Center	High	Medium	109	104	99	87	103	502
Peninsula Regional Medical Center	High	High	161	170	163	151	152	797
Sinai Hospital	Low	Medium	116	86	85	90	98	475
Suburban Hospital	Low	Low	41	77	79	75	70	342
UM Prince George's	Low	Medium	69	97	62	80	66	374
UM Baltimore Washington	High	High	101	98	104	97	118	518
UM Medical Center	Low	Medium	74	85	69	91	81	400
UM Shore Regional	Low	Low	0	0	15	80	71	166
UM St. Joseph	High	High	131	114	93	102	86	526
UM Upper Chesapeake	High	High	130	135	137	106	120	628
UPMC Western Maryland	Low	Low	54	71	68	75	67	335
Median			105	97	87	90	89	482
First Tercile			75	84	70	80	70	371
Second Tercile			123	102	98	102	102	517

The comparison of unadjusted mortality rates between low and high volume hospitals is presented in Table 14. Inpatient mortality rate for STEMI PCI at low volume hospitals was 7.4

percent compared to 5.1 percent at high volume hospital over the years 2015 to 2019. The difference of 2.3 percent is statistically significant ($p < 0.001$). From 2016 through 2019, high-volume hospitals had significantly lower inpatient mortality rates than low-volume hospitals each year, in addition to being statistically lower across four of the five assessed years.

Table 14 - STEMI PCI MORTALITY RATES BY LOW VS HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			High Volume			p value
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	
2015	807	0.063	0.009	1,512	0.054	0.006	0.378
2016	809	0.082	0.010	1,385	0.058	0.006	0.025
2017	757	0.071	0.009	1,381	0.030	0.005	<0.001
2018	833	0.072	0.009	1,354	0.051	0.006	0.040
2019	790	0.082	0.010	1,405	0.048	0.006	0.001
Total	3,996	0.074	0.004	7,037	0.049	0.003	<0.001

Table 15 presents the difference in AKI rates between low and high-volume hospitals. The rate of AKI is 13.7 percent in low volume hospitals and 8.5 percent in high volume hospitals for patients who received a STEMI PCI. High volume hospitals had a lower unadjusted AKI rate compared to low volume hospitals for all years ($p < 0.001$).

Table 15 - STEMI PCI ACUTE KIDNEY INJURY RATES BY LOW VS HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			High Volume			p value
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	
2015	807	0.138	0.012	1,512	0.077	0.007	<0.001
2016	809	0.164	0.013	1,385	0.087	0.008	<0.001
2017	757	0.128	0.012	1,381	0.097	0.008	0.023
2018	833	0.122	0.011	1,354	0.085	0.008	0.005
2019	790	0.124	0.012	1,405	0.071	0.007	<0.001
Total	3,996	0.135	0.005	7,037	0.083	0.003	<0.001

Table 16 presents the yearly and aggregate mortality rate differences between low, medium, and high STEMI PCI volume hospitals. Only 2017 demonstrated a statistically significant difference in mortality rates by volume and then only for the high versus low volume comparison ($p = .038$). The aggregated effect across all five years, however, did show a statistically significant difference at the high compared to low volume ($p = 0.014$) and high compared to medium volume ($p = 0.011$). Due to the low versus medium volume effects not being statistically different, the conclusion is made that only being at a high-volume facility matters compared with being treated by either low or medium volume facilities.

Table 16 - STEMI PCI MORTALITY RATES BY LOW, MEDIUM, AND HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			Medium Volume			High Volume			p values		
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	Observations	Proportion	S.E.	Medium vs Low	High vs Low	High vs Medium
2015	431	0.056	0.011	812	0.070	0.009	1,076	0.048	0.007	0.295	0.579	0.043
2016	457	0.072	0.012	747	0.079	0.010	990	0.056	0.007	0.648	0.239	0.053
2017	453	0.066	0.012	684	0.054	0.009	1,001	0.029	0.005	0.333	0.001	0.014
2018	490	0.065	0.011	737	0.069	0.009	960	0.048	0.007	0.777	0.184	0.065
2019	481	0.077	0.012	699	0.076	0.010	1,015	0.042	0.006	0.938	0.009	0.004
Total	2,312	0.067	0.005	3,679	0.070	0.004	5,042	0.045	0.003	0.700	<0.001	<0.001

The yearly and aggregate AKI rate differences between low, medium, and high STEMI PCI volume hospitals are presented in Table 17. Three of the five years (2015, 2016, and 2019) demonstrated a difference in AKI rates by volume and the aggregate effect did show a statistically significant difference at the high compared to low volume ($p < 0.001$) and high compared to medium volume ($p < 0.001$). Again, due to the low versus medium volume effects not being statistically different, the conclusion is made that only being at a high volume facility matters compared with being treated by either low or medium volume facilities.

Table 17 - STEMI PCI ACUTE KIDNEY INJURY RATES BY LOW, MEDIUM, AND HIGH VOLUME HOSPITALS, 2015-2019

Year	Low Volume			Medium Volume			High Volume			p values		
	Observations	Proportion	S.E.	Observations	Proportion	S.E.	Observations	Proportion	S.E.	Medium vs Low	High vs Low	High vs Medium
2015	431	0.146	0.017	812	0.108	0.011	1,076	0.072	0.008	0.033	<0.001	0.008
2016	457	0.168	0.018	747	0.129	0.012	990	0.081	0.009	0.034	<0.001	0.002
2017	453	0.117	0.015	684	0.123	0.013	1,001	0.094	0.009	0.757	0.189	0.061
2018	490	0.104	0.014	737	0.130	0.012	960	0.073	0.008	0.132	0.060	<0.001
2019	481	0.112	0.014	699	0.112	0.012	1,015	0.065	0.008	0.968	0.003	0.001
Total	2,312	0.129	0.007	3,679	0.120	0.005	5,042	0.077	0.004	0.275	<0.001	<0.001

Summary Statistics

Outcomes of care empirically vary by volume, somewhat due to the demographic composition and clinical severity of the population served. Table 18 shows the demographic and clinical characteristics by STEMI PCI volume category. Patients are transported to the nearest hospital for the treatment of a STEMI. Whereas age is a determinant of outcomes of a STEMI PCI procedure, patients are distributed across hospitals for reasons other than STEMI PCI volume. The highest volume hospitals tend to perform STEMI PCIs of patients with conditions such as hypertension, PAD, CVD, COPD, and diabetes. The patient profile by race varies by STEMI PCI volume hospitals. The sharpest differences are found in the clinical characteristics with higher volume hospitals performing STEMI PCI procedures on patients with more comorbid conditions.

Table 18 - DEMOGRAPHIC AND CLINICAL CHARACTERISTICS BY STEMI PCI VOLUME MEASURES

Variable	Low vs High Volume					Low vs Medium vs High Volume								
	Low Volume (n = 3,996)		High Volume (n = 7,037)		p value	Low Volume (n = 2,312)		Medium Volume (n = 3,679)		High Volume (n = 5,042)		Pairwise Comparison of Means (p values)		
	Mean	S.D.	Mean	S.D.		Mean	S.D.	Mean	S.D.	Mean	S.D.	M vs L	H vs L	H vs M
Age	62.874	12.685	63.183	12.625	0.218	63.298	12.865	62.500	12.559	63.383	12.599	0.017	0.788	0.001
Age: ≤ 25	0.001	0.027	0.000	0.021	0.482	0.000	0.000	0.001	0.033	0.000	0.020	0.079	0.498	0.172
Age: 25 - 35	0.011	0.104	0.008	0.090	0.144	0.010	0.101	0.010	0.098	0.008	0.091	0.815	0.394	0.483
Age: 35 - 45	0.062	0.242	0.058	0.233	0.324	0.059	0.235	0.063	0.243	0.057	0.232	0.499	0.749	0.231
Age: 45 - 55	0.192	0.394	0.201	0.401	0.274	0.194	0.396	0.205	0.404	0.195	0.396	0.322	0.955	0.251
Age: 55 - 65	0.315	0.465	0.309	0.462	0.477	0.309	0.462	0.312	0.463	0.311	0.463	0.821	0.855	0.948
Age: 65 - 75	0.242	0.428	0.248	0.432	0.483	0.237	0.425	0.247	0.431	0.249	0.433	0.359	0.247	0.828
Age: > 75	0.176	0.381	0.176	0.381	0.959	0.191	0.393	0.162	0.369	0.179	0.383	0.005	0.223	0.042
Male	0.682	0.466	0.708	0.455	0.005	0.692	0.462	0.679	0.467	0.715	0.451	0.278	0.051	<0.001
Female	0.318	0.466	0.292	0.455	0.005	0.308	0.462	0.321	0.467	0.285	0.451	0.278	0.051	<0.001
Race: White	0.632	0.482	0.777	0.416	<0.001	0.783	0.412	0.605	0.489	0.785	0.411	<0.001	0.863	<0.001
Race: Black	0.321	0.467	0.152	0.359	<0.001	0.160	0.367	0.336	0.472	0.148	0.355	<0.001	0.206	<0.001
Race: Asian	0.040	0.196	0.055	0.227	0.001	0.048	0.214	0.052	0.223	0.048	0.213	0.439	0.969	0.321
Race: American Indian	0.005	0.067	0.004	0.060	0.441	0.006	0.078	0.003	0.055	0.004	0.060	0.064	0.112	0.668
Race: Native Hawaiian	0.001	0.022	0.000	0.021	0.860	0.000	0.021	0.000	0.016	0.001	0.024	0.776	0.761	0.484
Ethnicity: Hispanic	0.045	0.206	0.027	0.161	<0.001	0.058	0.234	0.024	0.152	0.029	0.167	<0.001	<0.001	0.196
Body Mass Index (BMI)	29.810	10.507	29.661	9.725	0.452	29.678	10.483	29.817	9.169	29.657	10.381	0.601	0.932	0.459
BMI: < 18.5	0.014	0.117	0.012	0.111	0.531	0.012	0.107	0.017	0.128	0.011	0.103	0.101	0.732	0.016
BMI: 18.5 - 25	0.210	0.407	0.206	0.405	0.675	0.216	0.411	0.203	0.403	0.207	0.405	0.245	0.379	0.687
BMI: 25 - 30	0.257	0.437	0.269	0.444	0.143	0.258	0.438	0.257	0.437	0.273	0.446	0.956	0.161	0.091
BMI: > 30	0.399	0.490	0.398	0.489	0.877	0.385	0.487	0.415	0.493	0.393	0.488	0.023	0.518	0.042
On Current Dialysis	0.016	0.127	0.010	0.099	0.003	0.011	0.103	0.017	0.128	0.010	0.097	0.047	0.639	0.003
Hypertension	0.716	0.451	0.656	0.475	<0.001	0.669	0.471	0.712	0.453	0.656	0.475	0.001	0.244	<0.001
Prior Myocardial Infarction	0.204	0.403	0.173	0.378	<0.001	0.189	0.392	0.195	0.396	0.174	0.379	0.593	0.113	0.013
Prior Heart Failure	0.076	0.265	0.054	0.227	<0.001	0.064	0.244	0.063	0.243	0.061	0.240	0.903	0.706	0.775
Prior PCI	0.211	0.408	0.196	0.397	0.052	0.216	0.411	0.197	0.398	0.198	0.398	0.074	0.071	0.929
Prior CABG	0.046	0.209	0.049	0.216	0.445	0.045	0.208	0.049	0.217	0.048	0.213	0.473	0.654	0.719
Prior CVD	0.090	0.287	0.075	0.264	0.005	0.078	0.268	0.095	0.293	0.071	0.257	0.017	0.333	<0.001
Prior PAD	0.065	0.246	0.044	0.205	<0.001	0.054	0.227	0.065	0.246	0.040	0.197	0.081	0.010	<0.001
Chronic Lung Disease	0.087	0.282	0.080	0.271	0.171	0.072	0.259	0.101	0.302	0.073	0.261	<0.001	0.900	<0.001
Diabetes	0.311	0.463	0.279	0.449	<0.001	0.279	0.449	0.325	0.468	0.271	0.445	<0.001	0.479	<0.001

Note: L, M, and H denotes Low, Medium, and High Volume respectively

Table 19 presents the impact of high STEMI PCI volume as odds ratios relative to low volume on inpatient mortality, after controlling for demographic and clinical factors. The impact of STEMI PCI volume was statistically less than 1.000 from 2017 to 2019 and in aggregate. The implication is that the odds of dying in the inpatient setting following a STEMI PCI was lower in high-volume hospitals relative to low-volume hospitals, after controlling for other risk factors.

Table 19 - IMPACT OF HIGH VS LOW STEMI PCI VOLUME ON MORTALITY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	0.941	0.197	0.625	1.418
2016	0.759	0.140	0.529	1.090
2017	0.387	0.087	0.249	0.602
2018	0.613	0.141	0.391	0.963
2019	0.623	0.119	0.429	0.905
2015-2019	0.650	0.075	0.518	0.815

The risk-adjusted hospital results for the incremental differences from low-to-medium and medium-to-high-volume status, represented as odds ratios, are shown in Table 20. The overall impact in the aggregate across the five years was that inpatient mortality tended to decrease as

STEMI PCI volume increased, but that finding was not statistically significant for 2015, 2016, and 2018. Further, the upper limit being at 0.919 suggests that the results might be overly influenced by the exact amount of power in the analyses, rather than by the size of the effect being found.

Table 20 - INCREMENTAL EFFECT OF INCREASING STEMI PCI VOLUME ON MORTALITY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	0.877	0.110	0.686	1.122
2016	0.908	0.105	0.724	1.141
2017	0.636	0.099	0.469	0.863
2018	0.796	0.117	0.596	1.062
2019	0.717	0.083	0.571	0.899
2015-2019	0.794	0.059	0.686	0.919

Table 21 shows the impact of medium-volume hospitals and high-volume hospitals compared to low volume. After controlling for factors that could impact inpatient mortality, the STEMI PCI volume had a measurable impact in the high-volume hospitals compared to low volume hospitals for the aggregate findings from 2015 to 2019. The impact of STEMI PCI volume is not found in the medium-volume hospitals compared to the low-volume hospitals.

Table 21 - EFFECT OF MEDIUM AND HIGH STEMI PCI VOLUME ON MORTALITY COMPARED TO LOW VOLUME

Year	Medium Relative to Low Volume				High Relative to Low Volume			
	Odds Ratio	S.E.	95% Confidence Interval		Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit			Lower Limit	Upper Limit
2015	1.268	0.341	0.748	2.148	0.847	0.227	0.500	1.433
2016	1.234	0.294	0.774	1.968	0.867	0.206	0.544	1.383
2017	0.796	0.246	0.435	1.457	0.406	0.128	0.219	0.752
2018	1.116	0.322	0.633	1.966	0.653	0.189	0.370	1.152
2019	0.981	0.234	0.614	1.567	0.525	0.126	0.327	0.842
2015-2019	1.046	0.142	0.802	1.365	0.645	0.088	0.494	0.842

Table 22 presents the impact of high STEMI PCI volume relative to low volume on AKI rates. STEMI PCI volume was protective against AKI in the high-volume hospitals compared to low volume.

Table 22 - IMPACT OF HIGH VS LOW STEMI PCI VOLUME ON ACUTE KIDNEY INJURY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	0.541	0.133	0.334	0.877
2016	0.561	0.135	0.350	0.900
2017	0.785	0.173	0.510	1.210
2018	0.702	0.190	0.413	1.193
2019	0.604	0.128	0.399	0.915
2015-2019	0.659	0.125	0.455	0.955

Table 23 shows the incremental effect of moving from low to medium to high STEMI PCI volume, after controlling for demographic and clinical characteristics, on AKI rates. The impact was statistically significant in the yearly 2015, 2016, and 2019 data, as well as in the aggregate analyses.

Table 23 - INCREMENTAL EFFECT OF INCREASING STEMI PCI VOLUME ON ACUTE KIDNEY INJURY

Year	Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit
2015	0.654	0.094	0.493	0.866
2016	0.705	0.105	0.527	0.944
2017	0.886	0.121	0.679	1.158
2018	0.803	0.133	0.581	1.110
2019	0.708	0.088	0.556	0.903
2015-2019	0.783	0.091	0.623	0.983

As shown in Table 24, the AKI rate for the medium-volume hospitals was similar to the rate for low-volume hospitals. High-volume hospitals tended to have lower odds ratios for 2015, 2016, 2019, and in aggregate compared to low STEMI PCI volume hospitals.

Table 24 - IMPACT OF HIGH VS LOW STEMI PCI VOLUME ON ACUTE KIDNEY INJURY

Year	Medium Relative to Low Volume				High Relative to Low Volume			
	Odds Ratio	S.E.	95% Confidence Interval		Odds Ratio	S.E.	95% Confidence Interval	
			Lower Limit	Upper Limit			Lower Limit	Upper Limit
2015	0.643	0.185	0.366	1.131	0.427	0.123	0.243	0.750
2016	0.728	0.216	0.406	1.303	0.498	0.148	0.278	0.894
2017	0.987	0.276	0.571	1.707	0.794	0.217	0.465	1.357
2018	1.060	0.343	0.563	1.998	0.652	0.213	0.344	1.236
2019	0.833	0.207	0.512	1.356	0.507	0.126	0.312	0.823
2015-2019	0.890	0.206	0.565	1.402	0.614	0.142	0.390	0.967

Discussion

STEMI PCI volume is a substantively significant explanatory variable for inpatient mortality. STEMI PCI volume does not seem to influence mortality in comparing mortality rates for low-volume and medium-volume hospitals, but it does when comparing mortality rates for low or medium-volume hospitals to rates for high STEMI PCI volume hospitals. The high volume effect

is likely due to a combination of very experienced interventional cardiologists with the economies of scale that supports specialized nursing units and personnel.

Increasing STEMI PCI volume tends to decrease AKI rates when comparing low volume hospitals to high-volume hospitals. When separating STEMI PCI volume into three groups, the impact is not apparent until high-volume hospitals are compared to the medium and low volume hospitals. The implication, similar to the findings for mortality rates, is that there is a threshold effect with respect to STEMI PCI volume.

The high-volume versus low-volume analysis creates a comparison of 12 hospitals to 12 hospitals and the three group (low/medium/high) analysis on PCI volume has eight hospitals in each group. Although there are thousands of STEMI PCI cases, the hospital-specific effects compare small samples. Small samples can capture large effects, but it would likely take 50 hospitals per group to capture small effect differences between hospitals (Ali, 2019)

Analysis #3: The Impact of Selected Standard Errors and Confidence Intervals on Outlier Status Relative to Mortality and Acute Kidney Injury

Background

The counts and, thereby, proportions of inpatient deaths and AKIs identified at each hospital reflect the severities of illness, the quality of care provided by physician performing the PCI for the STEMIs and NSTEMIs, and the quality of care provided by hospital staff during the inpatient stay. The proportions of inpatient deaths and AKIs are risk-adjusted to assess the differences between the actual mortality and complication rates and the risk-adjusted expected rates.

Methods

One of the earliest methods used to construct confidence intervals in this situation was the Wald-type interval which employed the asymptotic, normality properties of the estimation procedure (Vollset, 1993). The Wald method performs well when a sample is large, and the estimation was notably wrong when the proportions were close to zero or to one. Alternatively, an early method to address the problem with applying a continuous probability distribution function (PDF) to approximate a discrete PDF was done by creating a continuity corrected score interval; commonly referred to as the Wilson method (Wilson, 1927). The most popular confidence interval for binomial proportions is the Clopper-Pearson (C-P) “exact” method that is based on the binomial distribution and solving for the lower and upper bounds of the range. The main point raised against the C-P method is that the confidence intervals are conservative, having coverage levels nearing 99% for a 95% confidence interval (Agresti, 1998). More recent methodological research has focused on modifying the Wilson interval. The first approach is to apply a ‘non-informative’ Jeffreys prior and numerically compute a Bayesian interval. The second approach is the Agresti-Coull method which solves for the upper and lower limits of the confidence intervals separately. The Agresti-Coull method has been endorsed as a universal replacement to the C-P method for all confidence interval estimates for binomial proportions because it does not strongly depend on sample size or proportions (NIST, 2014); however, the

Jeffreys method may outperform the Agresti-Coull for small sample estimates (Dunnigan, 2008).

Data

Data for this analysis were provided by MHCC staff who receive data from hospitals that is a duplicate of the information submitted to the ACC-NCDR CathPCI registry. Hospitals submit detailed data to the registry and, by doing so, receive feedback on their quarterly performance for processes of care and outcomes metrics relative to previous performance, benchmarked against the national performance of all participants in the ACC-NCDR CathPCI registry.

Analytic Approach

The analysis of the potential impact of the method through which standard errors and confidence intervals for proportions were calculated is divided into two parts. The first part is the effect of the calculation method on the proportions of inpatient deaths and acute kidney injuries for admissions for NSTEMI and STEMI PCI procedures explored per hospital. The second part uses the multilevel logistic regressions from the previous report sections to calculate risk-adjusted or expected outcomes per hospital after controlling for hospital PCI volume and patient-level demographic and clinical factors related to inpatient mortality and AKI. The confidence intervals on the actual minus expected rates, using the Clopper-Pearson, Agresti-Coull, and Jeffreys Methods, were used to assess the extent to which the identification of outlier hospitals (high or low) was affected by these methods.

Results

Summary Statistics of Three Methods of Calculating Standard Errors and Confidence Interval for Proportions

Table 25 presents the proportion or rates for inpatient mortality for NSTEMI PCI admissions, along with the confidence intervals around the proportions for each of the hospitals in the sample. One hospital (Nanticoke) showed a slightly lower mortality rate using the Jeffreys Method. Following the literature on outlier hospitals using the CathPCI NCDR data, the analysis uses a significance level of 95 percent (Waldo, 2017).

Table 25 - The Proportion of Inpatient Deaths for NSTEMI PCI per Hospital, 2015 – 2019

Hospital	Observations	Proportion	Clopper-Pearson (Exact)		Agresti-Coull		Jeffreys	
			90% Confidence Interval		90% Confidence Interval		90% Confidence Interval	
			Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Adventist White Oak	1,880	0.010	0.006	0.015	0.006	0.015	0.006	0.015
Adventist Shady Grove	509	0.016	0.007	0.031	0.007	0.031	0.007	0.029
Anne Arundel Medical Center	839	0.006	0.002	0.014	0.002	0.014	0.002	0.013
Ascension Saint Agnes	1,220	0.012	0.007	0.020	0.007	0.020	0.007	0.020
Carroll Hospital Center	520	0.010	0.003	0.022	0.003	0.023	0.004	0.021
Frederick Hospital	917	0.009	0.004	0.017	0.004	0.017	0.004	0.016
Johns Hopkins Bayview	505	0.014	0.006	0.028	0.006	0.029	0.006	0.027
Johns Hopkins Hospital	1,695	0.019	0.013	0.027	0.014	0.027	0.014	0.027
MedStar Southern Maryland	896	0.003	0.001	0.010	0.001	0.010	0.001	0.009
MedStar Union	3,620	0.008	0.005	0.011	0.005	0.011	0.005	0.011
Meritus Medical Center	588	0.012	0.005	0.024	0.005	0.025	0.005	0.023
Peninsula Regional Medical Center	1,633	0.007	0.004	0.013	0.004	0.013	0.004	0.012
Sinai Hospital	1,444	0.017	0.011	0.025	0.012	0.026	0.012	0.025
Suburban Hospital	1,172	0.008	0.004	0.015	0.004	0.015	0.004	0.014
UM Prince George's	674	0.022	0.013	0.036	0.013	0.037	0.013	0.036
UM Baltimore Washington	860	0.005	0.001	0.012	0.001	0.012	0.002	0.011
UM Medical Center	1,239	0.032	0.023	0.044	0.024	0.044	0.024	0.043
UM Shore Regional	263	0.008	0.001	0.027	0.000	0.029	0.002	0.024
UM St. Joseph	2,744	0.008	0.005	0.013	0.006	0.013	0.005	0.012
UM Upper Chesapeake	1,315	0.008	0.004	0.015	0.004	0.015	0.004	0.014
UPMC Western Maryland	931	0.005	0.002	0.012	0.002	0.013	0.002	0.012
Total	25,464	0.011	0.010	0.012	0.010	0.012	0.010	0.012

The proportion of AKI for NSTEMI PCI admissions are presented in Table 26 by hospital. The confidence intervals around the hospital-specific proportions are also presented. One hospital (Meritus) had a trivially lower AKI rate using the Jeffreys Method compared to the Clopper-Pearson.

Table 26 - The Proportion of Acute Kidney Injuries for NSTEMI PCI per Hospital, 2015 – 2019

Hospital	Observations	Proportion	Clopper-Pearson (Exact)		Agresti-Coull		Jeffreys	
			90% Confidence Interval		90% Confidence Interval		90% Confidence Interval	
			Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Adventist White Oak	1,880	0.066	0.056	0.079	0.056	0.079	0.056	0.078
Adventist Shady Grove	509	0.065	0.045	0.090	0.046	0.090	0.046	0.089
Anne Arundel Medical Center	839	0.037	0.025	0.052	0.026	0.052	0.026	0.051
Ascension Saint Agnes	1,220	0.111	0.094	0.130	0.095	0.130	0.095	0.130
Carroll Hospital Center	520	0.021	0.011	0.038	0.011	0.038	0.011	0.036
Frederick Hospital	917	0.072	0.056	0.091	0.057	0.091	0.057	0.090
Johns Hopkins Bayview	505	0.113	0.087	0.144	0.088	0.144	0.087	0.143
Johns Hopkins Hospital	1,695	0.136	0.120	0.154	0.121	0.153	0.121	0.153
MedStar Southern Maryland	896	0.098	0.080	0.120	0.080	0.120	0.080	0.119
MedStar Union	3,620	0.070	0.062	0.078	0.062	0.078	0.062	0.078
Meritus Medical Center	588	0.063	0.045	0.086	0.046	0.086	0.045	0.085
Peninsula Regional Medical Center	1,633	0.058	0.047	0.070	0.047	0.070	0.047	0.070
Sinai Hospital	1,444	0.089	0.074	0.104	0.075	0.104	0.075	0.104
Suburban Hospital	1,172	0.038	0.027	0.050	0.028	0.050	0.028	0.050
UM Prince George's	674	0.128	0.103	0.155	0.104	0.155	0.104	0.154
UM Baltimore Washington	860	0.048	0.034	0.064	0.035	0.064	0.035	0.063
UM Medical Center	1,239	0.159	0.139	0.181	0.140	0.180	0.139	0.180
UM Shore Regional	263	0.057	0.032	0.092	0.034	0.093	0.034	0.090
UM St. Joseph	2,744	0.064	0.055	0.074	0.055	0.074	0.055	0.073
UM Upper Chesapeake	1,315	0.058	0.046	0.072	0.046	0.072	0.046	0.071
UPMC Western Maryland	931	0.088	0.071	0.108	0.071	0.108	0.071	0.108
Total	25,644	0.079	0.075	0.082	0.075	0.082	0.075	0.082

Table 27 presents the proportion or rates for inpatient mortality for STEMI PCI admissions, along with the confidence intervals around the proportions for each of the hospitals in the sample. Hospitals had comparable findings with respect to outlier status using all three methods to calculate standard errors.

Table 27 - The Proportion of Inpatient Deaths for STEMI PCI per Hospital, 2015 – 2019

Hospital	Observations	Proportion	Clopper-Pearson (Exact)		Agresti-Coull		Jeffreys	
			90% Confidence Interval		90% Confidence Interval		90% Confidence Interval	
			Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Adventist White Oak	220	0.045	0.022	0.082	0.024	0.083	0.024	0.079
Adventist Shady Grove	689	0.052	0.037	0.072	0.038	0.072	0.037	0.071
Anne Arundel Medical Center	674	0.043	0.029	0.061	0.030	0.061	0.030	0.060
Ascension Saint Agnes	483	0.087	0.063	0.116	0.065	0.116	0.064	0.115
Carroll Hospital Center	368	0.060	0.038	0.089	0.039	0.089	0.039	0.088
Frederick Hospital	566	0.049	0.033	0.071	0.034	0.071	0.034	0.070
Holy Cross Hospital	337	0.080	0.053	0.114	0.055	0.114	0.055	0.113
Howard County Hospital	498	0.030	0.017	0.049	0.018	0.050	0.018	0.048
Johns Hopkins Bayview	314	0.064	0.039	0.097	0.041	0.097	0.041	0.095
Johns Hopkins Hospital	236	0.110	0.073	0.157	0.076	0.157	0.075	0.155
MedStar Franklin Square	513	0.064	0.045	0.089	0.046	0.089	0.046	0.088
MedStar Southern Maryland	661	0.056	0.040	0.076	0.041	0.076	0.040	0.075
MedStar Union	435	0.080	0.057	0.110	0.058	0.110	0.058	0.109
Meritus Medical Center	501	0.054	0.036	0.077	0.037	0.078	0.037	0.076
Peninsula Regional Medical Center	793	0.039	0.027	0.055	0.027	0.055	0.027	0.054
Sinai Hospital	475	0.080	0.057	0.108	0.059	0.108	0.058	0.107
Suburban Hospital	340	0.065	0.041	0.096	0.043	0.096	0.042	0.095
UM Prince George's	374	0.072	0.048	0.103	0.050	0.103	0.049	0.102
UM Baltimore Washington	515	0.033	0.019	0.052	0.020	0.053	0.020	0.051
UM Medical Center	400	0.100	0.072	0.134	0.074	0.134	0.073	0.132
UM Shore Regional	164	0.079	0.043	0.132	0.046	0.132	0.045	0.128
UM St. Joseph	520	0.044	0.028	0.066	0.029	0.066	0.029	0.064
UM Upper Chesapeake	624	0.038	0.025	0.057	0.026	0.057	0.025	0.056
UPMC Western Maryland	333	0.048	0.028	0.077	0.029	0.077	0.029	0.075
Total	11,033	0.058	0.054	0.062	0.054	0.062	0.054	0.062

The proportion of AKI for STEMI PCI admissions are presented in Table 28 by hospital. Hospitals had comparable findings with respect to outlier status using all three methods to calculate standard errors.

Table 28 - The Proportion of Acute Kidney Injuries for STEMI PCI per Hospital, 2015 – 2019

Hospital	Observations	Proportion	Clopper-Pearson (Exact)		Agresti-Coull		Jeffreys	
			90% Confidence Interval Lower Limit	90% Confidence Interval Upper Limit	90% Confidence Interval Lower Limit	90% Confidence Interval Upper Limit	90% Confidence Interval Lower Limit	90% Confidence Interval Upper Limit
Adventist White Oak	220	0.109	0.071	0.158	0.074	0.158	0.073	0.155
Adventist Shady Grove	689	0.081	0.062	0.104	0.063	0.104	0.063	0.103
Anne Arundel Medical Center	674	0.059	0.043	0.080	0.044	0.080	0.043	0.079
Ascension Saint Agnes	483	0.180	0.147	0.217	0.148	0.217	0.148	0.216
Carroll Hospital Center	368	0.041	0.023	0.066	0.024	0.067	0.024	0.065
Frederick Hospital	566	0.067	0.048	0.091	0.049	0.091	0.049	0.090
Holy Cross Hospital	337	0.119	0.086	0.158	0.088	0.158	0.087	0.156
Howard County Hospital	498	0.058	0.039	0.083	0.041	0.083	0.040	0.081
Johns Hopkins Bayview	314	0.137	0.101	0.180	0.103	0.180	0.102	0.178
Johns Hopkins Hospital	236	0.301	0.243	0.364	0.246	0.362	0.245	0.362
MedStar Franklin Square	513	0.099	0.075	0.129	0.076	0.129	0.076	0.128
MedStar Southern Maryland	661	0.092	0.071	0.117	0.072	0.117	0.072	0.116
MedStar Union	435	0.140	0.109	0.176	0.111	0.176	0.110	0.175
Meritus Medical Center	501	0.064	0.044	0.089	0.045	0.089	0.045	0.088
Peninsula Regional Medical Center	793	0.069	0.053	0.089	0.054	0.089	0.053	0.089
Sinai Hospital	475	0.093	0.068	0.122	0.070	0.122	0.069	0.121
Suburban Hospital	340	0.097	0.068	0.134	0.070	0.133	0.069	0.132
UM Prince George's	374	0.147	0.113	0.187	0.115	0.187	0.114	0.186
UM Baltimore Washington	515	0.064	0.045	0.089	0.046	0.089	0.045	0.088
UM Medical Center	400	0.208	0.169	0.251	0.171	0.250	0.170	0.249
UM Shore Regional	164	0.061	0.030	0.109	0.032	0.110	0.032	0.105
UM St. Joseph	520	0.108	0.082	0.138	0.084	0.137	0.083	0.137
UM Upper Chesapeake	624	0.077	0.057	0.101	0.058	0.101	0.058	0.100
UPMC Western Maryland	333	0.186	0.146	0.232	0.148	0.232	0.147	0.231
Total	11,033	0.102	0.097	0.108	0.097	0.108	0.097	0.108

Actual Compared to Risk-Adjusted Proportions

Table 29 presents the variation confidence intervals for the actual minus risk-adjusted mortality proportions for the NSTEMI PCI admissions by hospital. One hospital (Howard) had a positive actual minus risk-adjusted rate using both the Agresti-Coull and Jeffreys Method compared to the Clopper-Pearson. This finding relies on differences in confidence intervals at the third decimal place, which is reasonably a misplaced specification from a perspective of program relevance.

Table 29 - Comparison of Actual Minus Risk-Adjusted NSTEMI Mortality Proportions Using Clopper-Pearson (Exact), Agresti-Coull, and Jeffreys Methods to Calculate Standard Errors, 2015 – 2019

Hospital	Actual Rate	Risk-Adjusted Rate	Actual - Expected	Clopper-Pearson (Exact) 90% Confidence Interval		Agresti-Coull 90% Confidence Interval		Jeffreys 90% Confidence Interval	
				Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Adventist White Oak	0.010	0.010	0.000	-0.004	0.006	-0.004	0.006	-0.004	0.005
Adventist Shady Grove	0.016	0.013	0.003	-0.006	0.018	-0.005	0.018	-0.005	0.017
Anne Arundel Medical Center	0.006	0.008	-0.002	-0.006	0.006	-0.006	0.006	-0.006	0.005
Ascension Saint Agnes	0.012	0.011	0.001	-0.004	0.009	-0.004	0.009	-0.004	0.009
Carroll Hospital Center	0.010	0.011	-0.001	-0.007	0.012	-0.007	0.012	-0.007	0.010
Frederick Hospital	0.009	0.009	0.000	-0.005	0.009	-0.004	0.009	-0.004	0.008
Johns Hopkins Bayview	0.014	0.015	-0.001	-0.009	0.014	-0.009	0.014	-0.008	0.012
Johns Hopkins Hospital	0.019	0.018	0.002	-0.004	0.010	-0.004	0.010	-0.004	0.009
MedStar Southern Maryland	0.003	0.006	-0.003	-0.006	0.003	-0.006	0.004	-0.005	0.003
MedStar Union	0.008	0.009	-0.001	-0.003	0.003	-0.003	0.003	-0.003	0.002
Meritus Medical Center	0.012	0.011	0.000	-0.007	0.013	-0.006	0.013	-0.006	0.012
Peninsula Regional Medical Center	0.007	0.008	0.000	-0.004	0.005	-0.004	0.005	-0.004	0.005
Sinai Hospital	0.017	0.015	0.002	-0.004	0.010	-0.003	0.010	-0.004	0.010
Suburban Hospital	0.008	0.008	0.000	-0.005	0.006	-0.004	0.007	-0.004	0.006
UM Prince George's	0.022	0.018	0.004	-0.006	0.018	-0.005	0.019	-0.005	0.017
UM Baltimore Washington	0.005	0.006	-0.001	-0.005	0.006	-0.005	0.006	-0.005	0.005
UM Medical Center	0.032	0.028	0.004	-0.005	0.016	-0.004	0.016	-0.005	0.015
UM Shore Regional	0.008	0.011	-0.004	-0.011	0.016	-0.011	0.018	-0.010	0.013
UM St. Joseph	0.008	0.008	0.000	-0.003	0.004	-0.003	0.004	-0.003	0.004
UM Upper Chesapeake	0.008	0.009	0.000	-0.004	0.006	-0.004	0.007	-0.004	0.006
UPMC Western Maryland	0.005	0.008	-0.002	-0.006	0.005	-0.006	0.005	-0.005	0.004
Total	0.012	0.011	0.001	-0.001	0.001	-0.001	0.001	-0.001	0.001

Table 30 presents the variation confidence intervals for the actual minus risk-adjusted AKI proportions for the NSTEMI PCI admissions by hospital. Hospitals had comparable findings with respect to outlier status using all three methods to calculate standard errors.

Table 30 - Comparison of Actual Minus Risk-Adjusted NSTEMI Mortality Portions Using Clopper-Pearson (Exact), Agresti-Coull, and Jeffreys Methods to Calculate Standard Errors, 2015 – 2019

Hospital	Actual Rate	Risk-Adjusted Rate	Actual - Expected	Clopper-Pearson (Exact) 90% Confidence Interval		Agresti-Coull 90% Confidence Interval		Jeffreys 90% Confidence Interval	
				Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Adventist White Oak	0.066	0.067	-0.001	-0.012	0.012	-0.011	0.012	-0.011	0.011
Adventist Shady Grove	0.065	0.064	0.001	-0.019	0.026	-0.017	0.026	-0.018	0.025
Anne Arundel Medical Center	0.037	0.041	-0.004	-0.015	0.012	-0.015	0.012	-0.015	0.011
Ascension Saint Agnes	0.111	0.110	0.002	-0.016	0.021	-0.015	0.021	-0.015	0.020
Carroll Hospital Center	0.021	0.031	-0.010	-0.021	0.006	-0.020	0.007	-0.020	0.005
Frederick Hospital	0.072	0.071	0.001	-0.015	0.019	-0.015	0.019	-0.015	0.019
Johns Hopkins Bayview	0.113	0.106	0.007	-0.020	0.038	-0.018	0.037	-0.019	0.037
Johns Hopkins Hospital	0.136	0.133	0.003	-0.013	0.020	-0.012	0.020	-0.013	0.020
MedStar Southern Maryland	0.098	0.098	0.001	-0.018	0.022	-0.017	0.022	-0.018	0.021
MedStar Union	0.070	0.071	-0.001	-0.009	0.008	-0.009	0.008	-0.009	0.008
Meritus Medical Center	0.063	0.061	0.002	-0.016	0.025	-0.015	0.025	-0.015	0.024
Peninsula Regional Medical Center	0.058	0.058	0.000	-0.011	0.012	-0.011	0.012	-0.011	0.012
Sinai Hospital	0.089	0.088	0.001	-0.013	0.017	-0.013	0.017	-0.013	0.016
Suburban Hospital	0.038	0.042	-0.005	-0.015	0.008	-0.014	0.008	-0.014	0.008
UM Prince George's	0.128	0.123	0.005	-0.020	0.032	-0.019	0.032	-0.019	0.031
UM Baltimore Washington	0.048	0.050	-0.003	-0.016	0.014	-0.015	0.014	-0.015	0.013
UM Medical Center	0.159	0.158	0.001	-0.019	0.023	-0.018	0.023	-0.018	0.022
UM Shore Regional	0.057	0.059	-0.002	-0.027	0.033	-0.025	0.034	-0.025	0.031
UM St. Joseph	0.064	0.064	0.000	-0.009	0.010	-0.009	0.010	-0.009	0.010
UM Upper Chesapeake	0.058	0.059	-0.001	-0.013	0.013	-0.012	0.013	-0.012	0.013
UPMC Western Maryland	0.088	0.086	0.002	-0.016	0.022	-0.015	0.022	-0.015	0.021
Total	0.079	0.079	0.000	-0.003	0.003	-0.003	0.003	-0.003	0.003

Table 31 presents the variation confidence intervals for the actual minus risk-adjusted mortality proportions for the STEMI PCI admissions by hospital. Hospitals had comparable findings with respect to outlier status using all three methods to calculate standard errors.

Table 31 - Comparison of Actual Minus Risk-Adjusted STEMI Mortality Portions Using Clopper-Pearson (Exact), Agresti-Coull, and Jeffreys Methods to Calculate Standard Errors, 2015 – 2019

Hospital	Actual Rate	Risk-Adjusted Rate	Actual - Expected	Clopper-Pearson (Exact) 95% Confidence Interval		Agresti-Coull 95% Confidence Interval		Jeffreys 95% Confidence Interval	
				Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Adventist White Oak	0.045	0.057	-0.012	-0.035	0.025	-0.033	0.026	-0.034	0.022
Adventist Shady Grove	0.052	0.051	0.001	-0.015	0.020	-0.014	0.020	-0.014	0.019
Anne Arundel Medical Center	0.043	0.045	-0.002	-0.016	0.016	-0.015	0.016	-0.016	0.015
Ascension Saint Agnes	0.087	0.077	0.010	-0.013	0.039	-0.012	0.039	-0.013	0.038
Carroll Hospital Center	0.060	0.064	-0.004	-0.026	0.025	-0.025	0.025	-0.025	0.023
Frederick Hospital	0.049	0.054	-0.004	-0.020	0.017	-0.019	0.017	-0.020	0.016
Holy Cross Hospital	0.080	0.075	0.005	-0.021	0.040	-0.020	0.040	-0.020	0.038
Howard County Hospital	0.030	0.041	-0.011	-0.024	0.008	-0.024	0.008	-0.024	0.007
Johns Hopkins Bayview	0.064	0.063	0.000	-0.024	0.033	-0.022	0.034	-0.023	0.032
Johns Hopkins Hospital	0.110	0.089	0.021	-0.016	0.068	-0.013	0.068	-0.014	0.066
MedStar Franklin Square	0.064	0.060	0.004	-0.016	0.029	-0.014	0.029	-0.015	0.028
MedStar Southern Maryland	0.056	0.051	0.005	-0.012	0.025	-0.011	0.025	-0.011	0.024
MedStar Union	0.080	0.073	0.007	-0.017	0.037	-0.015	0.037	-0.016	0.036
Meritus Medical Center	0.054	0.055	-0.002	-0.020	0.022	-0.018	0.022	-0.019	0.021
Peninsula Regional Medical Center	0.039	0.043	-0.004	-0.016	0.012	-0.015	0.012	-0.016	0.011
Sinai Hospital	0.080	0.073	0.007	-0.015	0.035	-0.014	0.035	-0.015	0.034
Suburban Hospital	0.065	0.069	-0.004	-0.028	0.027	-0.027	0.027	-0.027	0.025
UM Prince George's	0.072	0.063	0.010	-0.014	0.041	-0.013	0.041	-0.013	0.039
UM Baltimore Washington	0.033	0.042	-0.009	-0.023	0.010	-0.022	0.010	-0.022	0.009
UM Medical Center	0.100	0.086	0.014	-0.013	0.048	-0.012	0.048	-0.012	0.047
UM Shore Regional	0.079	0.074	0.005	-0.031	0.058	-0.028	0.058	-0.029	0.054
UM St. Joseph	0.044	0.051	-0.007	-0.023	0.015	-0.021	0.015	-0.022	0.014
UM Upper Chesapeake	0.038	0.043	-0.004	-0.018	0.014	-0.017	0.014	-0.017	0.013
UPMC Western Maryland	0.048	0.059	-0.011	-0.031	0.018	-0.030	0.018	-0.030	0.016
Total	0.058	0.058	0.000	-0.004	0.005	-0.004	0.005	-0.004	0.005

Table 32 presents the variation confidence intervals for the actual minus risk-adjusted AKI proportions for the STEMI PCI admissions by hospital. Hospitals had comparable findings with respect to outlier status using all three methods to calculate standard errors.

Table 32 - Comparison of Actual Minus Risk-Adjusted STEMI Acute Care Injury Proportions Using Clopper-Pearson (Exact), Agresti-Coull, and Jeffreys Methods to Calculate Standard Errors, 2015 – 2019

Hospital	Actual Rate	Risk-Adjusted Rate	Actual - Expected	Clopper-Pearson (Exact)		Agresti-Coull		Jeffreys	
				90% Confidence Interval		90% Confidence Interval		90% Confidence Interval	
				Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Adventist White Oak	0.109	0.111	-0.002	-0.040	0.047	-0.037	0.047	-0.038	0.044
Adventist Shady Grove	0.081	0.080	0.001	-0.018	0.024	-0.017	0.024	-0.018	0.023
Anne Arundel Medical Center	0.059	0.060	-0.001	-0.018	0.019	-0.017	0.019	-0.017	0.019
Ascension Saint Agnes	0.180	0.173	0.007	-0.028	0.043	-0.026	0.043	-0.027	0.042
Carroll Hospital Center	0.041	0.054	-0.013	-0.030	0.013	-0.029	0.014	-0.029	0.012
Frederick Hospital	0.067	0.070	-0.003	-0.021	0.022	-0.020	0.022	-0.021	0.021
Holy Cross Hospital	0.119	0.119	-0.001	-0.033	0.039	-0.031	0.038	-0.032	0.037
Howard County Hospital	0.058	0.063	-0.005	-0.024	0.019	-0.023	0.019	-0.023	0.018
Johns Hopkins Bayview	0.137	0.132	0.005	-0.033	0.046	-0.031	0.046	-0.031	0.045
Johns Hopkins Hospital	0.301	0.272	0.029	-0.034	0.086	-0.032	0.085	-0.032	0.084
MedStar Franklin Square	0.099	0.097	0.002	-0.025	0.029	-0.024	0.029	-0.024	0.028
MedStar Southern Maryland	0.092	0.091	0.001	-0.020	0.026	-0.019	0.026	-0.019	0.025
MedStar Union	0.140	0.138	0.002	-0.031	0.037	-0.029	0.036	-0.030	0.035
Meritus Medical Center	0.064	0.068	-0.004	-0.025	0.020	-0.023	0.020	-0.024	0.019
Peninsula Regional Medical Center	0.069	0.071	-0.001	-0.018	0.019	-0.017	0.019	-0.017	0.018
Sinai Hospital	0.093	0.096	-0.003	-0.029	0.026	-0.027	0.026	-0.028	0.025
Suburban Hospital	0.097	0.100	-0.003	-0.032	0.034	-0.030	0.034	-0.031	0.032
UM Prince George's	0.147	0.142	0.005	-0.031	0.043	-0.029	0.043	-0.030	0.042
UM Baltimore Washington	0.064	0.068	-0.003	-0.020	0.024	-0.019	0.024	-0.019	0.023
UM Medical Center	0.208	0.198	0.009	-0.031	0.050	-0.030	0.050	-0.030	0.049
UM Shore Regional	0.061	0.080	-0.019	-0.051	0.029	-0.048	0.030	-0.048	0.025
UM St. Joseph	0.108	0.106	0.002	-0.023	0.032	-0.021	0.032	-0.022	0.031
UM Upper Chesapeake	0.077	0.078	-0.001	-0.020	0.023	-0.019	0.023	-0.019	0.023
UPMC Western Maryland	0.186	0.176	0.010	-0.032	0.054	-0.030	0.054	-0.031	0.053
Total	0.102	0.102	0.000	-0.006	0.006	-0.006	0.006	-0.006	0.006

Discussion

The use of Clopper-Pearson to estimate the standard errors and confidence intervals, relative to the Agresti-Coull and Jeffreys methods, for portions related to mortality and AKI makes very little difference in the identification of outlier hospitals at the 95 percent confidence level. The Agresti-Coull and Jeffreys confidence intervals are slightly smaller than Clopper-Pearson, so there are a few facilities that have “better than average” outcomes using the alternative measures and none that stop being “worse than average” outcomes. For the “actual-expected” analysis, the use of the alternative methods to calculate standard errors and confidence intervals affects one hospital (Howard) and only with respect to NSTEMI mortality. No policy changes appear to be warranted respect to the method in which standard errors and confidence intervals are calculated in the assessment of outlier hospitals.

CONCLUSION

Key Findings

The three key findings to emerge from this study are as follows: 1) hospitals with relatively high STEMI PCI volume have lower mortality and kidney injury rates after controlling for demographic and clinical factors 2) impacts on outcomes of care related to NSTEMI PCI volume are modest, at best, and explained by variance in patient severity, and 4) the method used to calculate standard errors and confidence intervals for inpatient deaths and acute kidney injury proportions does not make a substantive difference in identifying outlier hospitals for STEMI PCI cases and NSTEMI PCI cases. No NSTEMI PCI volume effect was identified for mortality or AKI outcomes. With respect to STEMI PCI volume effects, the impacts appear to be most prevalent in the high-volume hospitals compared to low-volume hospitals, with a modest effect for medium-volume hospitals compared to low-volume hospitals. The volume impact of STEMI PCI cases was observed more frequently for inpatient mortality than for AKI rates, across several years and over the aggregated time period. The findings for the highest volume hospitals with respect to STEMI PCI procedures suggests that there may be a threshold effect for hospital procedure volume.

With respect to the current method used to calculate standard errors and confidence intervals, the Clopper-Pearson method, for inpatient deaths and acute kidney injury proportions, no policy changes appear warranted. Among the different methods compared, the differences in outlier classification of hospitals rely on statistical differences observed at the third decimal place. Such small differences may not reflect meaningful differences in the quality of care provided by hospitals. The analysis presented here does not support a move away from using the standard Clopper-Pearson Method to calculate standard errors and confidence intervals for quality related outcomes and complications.

Limitations

Although there were thousands of admission-level observations for NSTEMI and STEMI PCI procedures for each year, the analysis of the extent to which hospitals are outliers depends on the results from Maryland hospitals. A national assessment of hospital outliers using the full NCDR database could include approximately 2,400 hospitals. The ability to detect differences in hospital outcomes is easier with a larger sample.

The definition of outlier affects the number of hospitals identified as outliers. In a study by Waldo and colleagues (2017), 39 out of 86 hospitals were identified as outliers for excess mortality. That study defined outliers as having statistically higher proportion of inpatient deaths than the mean for the sample. The purpose of that report was to explain the differences in the outlier hospitals. Once the differences in patient severity was accounted, the risk-adjusted differences between the hospitals were trivial. In the current analysis, outliers are identified as having statistically non-zero actual minus expected (risk-adjusted) mortality or AKI rate at the 95 percent confidence interval.

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APPENDIX 1 – ACRONYMS

ACC	American College of Cardiology
ACS	Acute coronary syndrome
AKI	Acute kidney injury
AKIN	Acute Kidney Injury Network
CABG	Coronary artery bypass grafting
CKD	Chronic kidney disease
CVD	Cerebrovascular disease
ECG	Electrocardiogram
MHCC	Maryland Health Care Commission
mg/dL	Milligrams per deciliter
NCDR	National Cardiovascular Data Registry
NSTEMI	non-ST segment elevation myocardial infarction
PAD	Peripheral arterial disease
PCI	Percutaneous coronary intervention
PVD	Peripheral vascular disease
S.D.	Standard deviation
S.E.	Standard error
STEMI	ST-elevation myocardial infarction

APPENDIX 2 – RISK-ADJUSTMENT VARIABLES

NCDR Variable	Notes
NCDRPatientID	Unique subject ID
DOB	Used to calculate age at time of admission
Sex	Identifies with Male or Female
RaceWhite	Race identification
RaceBlack	Race identification
RaceAsian	Race identification
RaceAmIndian	Race identification
RaceNatHaw	Race identification
HispOrig	Ethnicity identification
ArrivalDate	Used to verify unique encounter for same patient ID
Hypertension	Comorbid condition
PriorMI	Comorbid condition
PriorHF	Comorbid condition
ValveSurgery	Prior procedure
PriorPCI	Prior procedure
PriorCABG	Prior procedure
Height	Used to create BMI
Weight	Used to create BMI
CurrentDialysis	Comorbid condition
PriorCVD	Comorbid condition
PriorPAD	Comorbid condition
ChronicLungDisease	Comorbid condition
Diabetes	Comorbid condition
ProcedureDate	Used to identify multiple procedures
CABG	Comorbid condition
DCStatus	Used to identify inpatient death
DeathCause	Used to verify inpatient death

APPENDIX 3 – HOSPITAL NAMES

Hospital Abbreviation	Hospital Name
Adventist White Oak	Adventist HealthCare White Oak Medical Center
Adventist Shady Grove	Adventist HealthCare Shady Grove Medical Center
Anne Arundel Medical Center	Anne Arundel Medical Center
Ascension Saint Agnes	Ascension Saint Agnes Hospital
Carroll Hospital Center	Carroll Hospital Center
Frederick Hospital	Frederick Health Hospital
Holy Cross Hospital	Holy Cross Hospital
Howard County Hospital	Howard County General Hospital
Johns Hopkins Bayview	Johns Hopkins Bayview Medical Center
Johns Hopkins Hospital	Johns Hopkins Hospital
MedStar Franklin Square	Medstar Franklin Square Medical Center
MedStar Southern Maryland	MedStar Southern Maryland Hospital Center
MedStar Union	MedStar Union Memorial Hospital
Meritus Medical Center	Meritus Medical Center
Peninsula Regional Medical Center	Peninsula Regional Medical Center
Sinai Hospital	Sinai Hospital Of Baltimore
Suburban Hospital	Suburban Hospital
UM Prince George's	Univeristy of Maryland Prince George's Hospital Center
UM Baltimore Washington	University of Maryland Baltimore Washington Medical Center
UM Medical Center	University of Maryland Medical Center
UM Shore Regional	University of Maryland Shore Regional Health
UM St. Joseph	University of Maryland St. Joseph Medical Center
UM Upper Chesapeake	University of Maryland Upper Chesapeake Medical Center
UPMC Western Maryland	University of Pittsburgh Medical Center (UPMC) Western Maryland

APPENDIX 4 – IMPACT OF NSTEMI PCI VOLUME ON STEMI PCI OUTCOMES

This technical appendix provides an assessment of whether STEMI PCI outcomes tend to be better when the hospital has higher NSTEMI PCI volume. The method used to evaluate this relationship is the introduction of an interaction term to the multilevel logistic regression. This regression presents the independent impact of STEMI PCI volume and the relationship when NSTEMI PCI volume is higher.

Appendix table 4.1 presents the findings for the overall data on the STEMI PCI volume effects and the interaction mortality effects with the NSTEMI PCI volume. The high STEMI PCI volume hospitals have better risk-adjusted outcomes compared to low volume hospitals, similar to the conclusions from the primary analysis presented in Section 2 of the report. The interaction effects for either the medium or high volume STEMI PCI hospitals with their NSTEMI PCI volume has no statistically significant findings. This finding suggests that the impact of STEMI PCI volume on mortality is independent of the volume of NSTEMI PCIs performed.

Appendix Table 4.1 – Impact of STEMI PCI Volume on Mortality with Interaction Effects of NSTEMI PCI Volume

	Odds Ratio	S.E.	p-value	95% Confidence Interval	
STEMI PCI Volume					
Medium vs Low	0.879	0.133	0.393	0.654	- 1.182
Large vs Low	0.721	0.100	0.018	0.549	- 0.946
NSTEMI PCI Volume					
	1.099	0.196	0.597	0.775	- 1.558
Interactions					
Medium STEMI PCI Volume × NSTEMI PCI Volume	1.346	0.303	0.187	0.866	- 2.091
High STEMI PCI Volume × NSTEMI PCI Volume	0.751	0.174	0.218	0.477	- 1.184

The conclusion of the supplementary analysis is that the impact of STEMI PCI volume on post-procedure mortality is dependent on the STEMI PCI volume rather than the overall PCI volume from STEMI and NSTEMI PCIs. Given the impact of high STEMI PCI volume and the non-impact of NSTEMI PCI volume on STEMI PCI mortality, the interaction is unlikely to change, even with an increase in the total observations in the regression analysis.