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ORIGINAL CONTRIBUTION

Differential benefits of cardiac care regionalization based on driving time to percutaneous coronary intervention

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Abstract

Background: Patients with ST-elevation myocardial infarction (STEMI) require timely reperfusion, and percutaneous coronary intervention (PCI) decreases morbidity and mortality. Regionalization of STEMI care has increased timeliness and use of PCI, but it is unknown whether benefits to regionalization depend on a community's distance from its nearest PCI center. We sought to determine whether STEMI regionalization benefits, measured by access to PCI centers, timeliness of treatment (same-day or in-hospital PCI), and mortality, differ by baseline distance to nearest PCI center.

Methods: Using a difference-in-difference-in-differences model, we examined access to PCI-capable hospitals, receipt of PCI either on the day of admission or during the care episode, and health outcomes for patients hospitalized from January 1, 2006, to September 30, 2015.

Results: Of 139,408 patients (2006 to 2015), 51% could reach the nearest PCI center in <30 minutes, and 49% required ≥30 minutes driving time. For communities with baseline access ≥30 minutes, regionalization increased the probability of admission to a PCI-capable hospital by 9.4% and also increased the likelihood of receiving same-day PCI (by 11.2%) and PCI during the hospitalization (by 7.4%). Patients living within 30 minutes did not accrue significant benefits (measured by admission to a PCI-capable hospital or receipt of PCI) from regionalization initiatives. Regionalization more than halved access disparities and completely eliminated treatment disparities between communities ≥30 minutes and communities <30 minutes from the nearest PCI hospital.

Conclusions: Measured by likelihood of admission to a PCI-capable facility and receipt of PCI, benefits of STEMI regionalization in California accrued only to patients whose nearest PCI center was ≥30 minutes away. We found no mortality benefits of regionalization based on distance from PCI center. Our results suggest that policymakers focus STEMI regionalization efforts in communities that are not already well serviced by PCI-capable hospitals.

INTRODUCTION

Patients with ST-elevation myocardial infarction (STEMI), a life-threatening subtype of acute myocardial infarction (AMI), require access to timely reperfusion, particularly percutaneous coronary

intervention (PCI). PCI has been shown to decrease mortality as well as other adverse events but is not provided in all hospitals.¹ For conditions requiring limited availability specialized interventions, the Institute of Medicine has supported regionalization, broadly defined as “an established network of resources that delivers specific care

to a defined population of patients or within a defined geography.” Since 2006, the American Heart Association (AHA) has advocated the implementation of regionalized care for STEMI patients²; in collaboration with the American College of Cardiology (ACC), these were formalized into guidelines in 2013.³

STEMI regionalization has been associated with an increase in the timeliness and use of PCI.^{4–6} However, no published literature describes whether there are differential benefits to regionalization based on a community's baseline access, measured by driving times to its nearest PCI center within the regionalization network. In other words, in communities that already have timely access to a PCI center, does STEMI regionalization in those communities confer different benefits compared with regionalization of communities with more distal baseline access to PCI-capable centers? This is especially important given that regionalization of STEMI care requires a complex coordination of physician groups, hospitals, health systems, and emergency medical services (EMS) agencies within the designated region, all using coordinated protocols, with regular feedback and reporting of metrics to central agencies. While less than 40% of hospitals have PCI capability,⁷ 84% of Americans live within 60 minutes' driving time to a PCI center, and the median prehospital time to the nearest PCI center is 33 minutes.⁸ We hypothesized that communities may experience differential benefits (measured according to drive-time access to PCI centers) from regionalization efforts.

We analyzed whether the effects of STEMI regionalization on access to PCI centers, treatment received (same-day PCI and in-hospital PCI), and mortality differ according to drive time to a community's nearest PCI center within a regionalized network. We further hypothesized that not all regions reap the same benefit from regionalization networks, and such networks may be more beneficial for populations where the closest PCI center is >30 minutes away. These findings are crucial for health system stakeholders as they consider mandating allocation of resources for condition-specific services across communities. Implications should be considered for regionalization of other conditions, such as trauma and stroke; resource-intensive conditions such as neurosurgical or pediatric emergencies should be considered as well.

METHODS

Data sources

This quasi-experimental cohort study linked patient, hospital, and community data sources. Nonpublic inpatient data from January 1, 2006, to September 30, 2015, were obtained from the California Office of Statewide Health Planning and Development (OSHPD), which contains information on patients' zip codes, admission dates, sources of admission, demographics (e.g., age, sex, race/ethnic groups), insurance status at the time of admission, ICD-9 diagnostic codes, treatments received (identified through 21 ICD-9 procedure codes as well as their dates), comorbidities, and dispositions. These inpatient data were linked with vital statistics data to capture date of death using a unique patient identifier as well as nonpublic emergency department (ED) data from

OSHPD to capture a complete patient cohort of anyone who had been seen or admitted to any nonfederal ED or hospital in California. We then used data from a validated survey (fully described elsewhere)^{9,10} from all 33 local EMS agencies, comprising all 58 counties in the state. This data set identifies dates of implementation of STEMI regionalization and details of these protocols from each local EMS agency. Communities' geographical coordinates and shares of Black and Hispanic populations were identified using zip code-level information from the 2010 U.S. Census. Additionally, facility data were linked to three other data sets to capture a full range of hospital characteristics: the AHA annual surveys provided ownership, system membership, and number of hospital beds; the Healthcare Cost Reporting Information System from the Centers for Medicare & Medicaid Services furnished teaching status, case mix index, occupancy rate, and total discharges; and OSHPD facility utilization data supplied facility procedure volume. Finally, geographical coordinates of a hospital's heliport (if available) or physical address were obtained from a previous study¹¹ and were further supplemented by the AHA annual surveys.

Definition of regionalization

A regionalized STEMI network requires complex coordination of resources across the majority of hospitals, physician groups, health systems, and EMS agencies within a region implementing shared protocols, with regular feedback and measurement. We designed a survey (described fully elsewhere^{9,10}) that uses Class I recommendations from the AHA and ACC to objectively categorize the degree of regionalization of a STEMI network requiring: 1) an EMS in which patients with STEMI are directly transported to facilities that offer emergent PCI, bypassing hospitals that do not offer this care; and 2) interhospital transfer protocols specifically for patients with STEMI.¹² All local EMS agencies in California were surveyed, with a 100% response rate. For the main model, counties with any degree of regionalization were considered regionalized, although additional sensitivity analyses included models using three gradations of regionalization.

Patient cohort

Using a previously validated approach,^{13,14} patients with STEMI were identified by primary diagnosis of ICD-9-CM 410.x0 or 410.x1, excluding 410.7x.

Patient outcomes

Outcomes included: 1) access to PCI-capable hospitals, 2) treatment defined as receipt of PCI either on the day of admission or during the care episode; and 3) health outcomes (30-, 90-, and 365-day mortality). Access to PCI-capable hospitals was defined by admission to a PCI-capable hospital using an all-payer volume threshold of 50 PCIs per year from prior literature.¹⁵

Because the patient cohort was patients diagnosed with STEMI, coronary angiography was included in our definition of PCI to capture attempts at intervention. While PCI is generally the definitive treatment for STEMI, inclusion of coronary angiography accounts for clinical realities of failed PCI attempts, false-positive diagnoses of STEMI, and referral to coronary artery bypass grafting in cases where such intervention would be clinically preferred over PCI.¹⁶

Calculation of driving time to nearest PCI-capable facility

Communities were categorized based on projected driving time to the closest PCI-capable hospital. Following prior literature,^{8,17} driving time included: 1) time to obtain ambulance dispatch (estimated to be 1.4 minutes in urban and 2.9 minutes in rural areas), 2) time spent on scene (estimated to be 8 minutes in urban and 9 minutes in rural areas), and 3) drive time from ambulance depot to the patient and from patient to the PCI-capable hospital.^{17,18} Driving time was calculated as follows: first, we obtained actual driving time (under normal traffic conditions) between a zip code's geographic center and each hospital's geocode using a programming interface between Stata and map API by HERE developer.^{19,20} Based on the driving time query, the closest PCI-capable hospital for a given community was identified for each year. Because precise physical addresses were not known for patients, driving time was best interpreted as the average driving time for a typical patient from that community to his or her closest PCI-capable hospital. Second, following prior literature, this driving time was multiplied by a factor of 1.6 for urban and 1.4 for rural areas to account for the overall round-trip driving time (between the three points).^{8,17} These three components of the driving time were totaled, which allowed communities to be categorized as those with driving times <30 minutes (henceforth, "easy access to PCI") at baseline (2006) and those with ≥30 minutes of driving time to the closest PCI hospital (henceforth, "difficult access to PCI") at baseline. In a sensitivity analysis, we further refined communities into three categories, <30 minutes, 30 to 60 minutes, and 60+ minutes, and did not find these more refined categories to provide additional insights.

Because this was patient-level analysis, if a PCI-capable hospital closed, there would be an increase in prehospital time for patients in the affected zip code community. However, for the purposes of this analysis, we used the baseline prehospital time to categorize communities because we estimated the net effect of regionalization, and hospital closures and openings (as well as closures or openings of PCI service lines) can be the byproduct of regionalization.

Data analyses

This analysis uses longitudinal data to compare *differences* in pre-post regionalization changes in access, treatment, and health outcomes between patients in communities with easy and difficult access to PCI, when both communities undergo regionalization. This

difference-in-difference-in-differences (DDD) design incorporates county-level fixed effects. This framework compares changes in PCI access, PCI received, and health outcomes between communities with difficult versus easy access to PCI centers before and after STEMI regionalized networks were incorporated, taking into account time-invariant underlying differences across counties. As published in detail elsewhere,¹⁰ in 2006, only eight of 56 counties had regionalized, and the remaining 47 counties initiated their regionalization networks throughout the study period. By 2014, all 56 counties had at least partially regionalized. The differences in the onset timing of regionalization across counties allowed us to implement the DDD design.

We used a linear probability model with county fixed effects. Even though a probit or logit model is a natural choice for estimating a dichotomous variable in cross-sectional data, these models would result in inconsistent estimators in panel data because we included a large number of fixed effects.²¹ The linear probability model can consistently estimate the effect of STEMI on dichotomous outcomes.²² One drawback of the model is that the predicted probability can be out of bounds. However, in our prior work analyzing a dichotomous outcome for AMI patients, we obtained virtually no out-of-bound predictions among the 1.49 million observations in our analysis. Another concern is that error term is heteroskedastic. We corrected this problem by estimating heteroskedasticity-robust standard errors that include adjustment for clustering within counties, and such an estimate was consistent in the fixed-effects model.²³

We included three key, binary indicator variables. The first binary indicator received a value of 1 if a community required at least 30 minutes of driving time to reach the closest PCI-capable hospital, and we captured the overall differences in outcomes between communities with easy and difficult access to PCI centers in the preregionalization period. The second binary indicator received a value of 1 on and after the year that a patient's community switched to a STEMI regionalized network. The third binary indicator was an interaction term between the baseline access indicator and the regionalization indicator and was used to distinguish differential changes in outcomes between communities with easy and difficult access to PCI when both switched to a regionalization network. This interaction term indicator was the key to identify potential differences that regionalization might bring to the two types of communities. Finally, county fixed effects and time dummies were included to remove unobserved underlying differences in patient population and practice patterns across counties as well as to account for secular trends in dependent variables that were common across all counties.

All models controlled for patient demographics, including age groups, sex, race and ethnicity, and health insurance (private, Medicare, Medicaid, indigent care, uninsured/self-pay, and others). We also controlled for 22 Elixhauser patient comorbid indicators and prior 12-month history of AMI to adjust for underlying individual patient health conditions.^{14,24}

Because our main objective was to estimate the net effect of regionalization, we did not control for interhospital transfer in our

primary model—interhospital transfer protocol is one of many components in a regionalization policy. Similarly, we did not control for PCI capacity of admitting hospital in our primary model. We ran a separate set of models including a binary indicator for patients who were transferred. Not surprisingly, transfer patients had better outcomes, but our key findings remained the same. Institutional review board approval for this study was provided by the University of California, San Francisco.

RESULTS

We studied 139,408 patients between 2006 and 2015, 51% of whom could reach the nearest PCI center in <30 minutes prehospital time and 49% of whom required ≥ 30 minutes prehospital time. Data Supplement S1, Figure S1 (available as supporting information in the online version of this paper, which is available at <http://onlinelibrary.wiley.com/doi/10.1111/acem.14195/full>), shows the distribution of patients between easy and difficult PCI access communities and their regionalization status over time. Table 1 presents demographic, clinical, and hospital characteristics. There was a similar mix of male and female patients in both cohorts (67% male and 33% female). A higher proportion of racial/ethnic minorities (19% Hispanic, 7% Black, 12% Asian, and 6% other; 56% non-Hispanic White) composed the group with easy baseline access compared with the difficult-access group (68% non-Hispanic White). Age distribution, payer mix, and comorbidities of patients with STEMI did not differ substantially between the groups. Communities with easy baseline access to PCI had a higher proportion of for-profit hospitals (16% vs 14%) and a lower proportion of government-owned hospitals (12% vs 16%) compared with communities with difficult access as well as a larger share of teaching hospitals (14% vs 8%) and more competitive markets (Herfindahl-Hirschman Index 0.11 vs 0.31). Areas with better baseline PCI access tended to be more populous and located in areas with higher income.

Figure 1 shows that over time, the access and treatment of patients with STEMI admitted to a PCI-capable hospital, receipt of same-day PCI, and in-hospital PCI improved for both types of communities, but significantly more for those in communities with difficult access (blue line). For these outcomes, the gap between the two communities decreased over time. Figure 2 shows that mortality has improved for both communities over time but not differentially so for either community.

The top panel of Table 2 presents results of the three key variables from our multivariate models of access and treatment outcomes (see Data Supplement S1, Table S1, for complete results). In the preregionalization period, the probability of being admitted to a PCI-capable hospital was 12.27 percentage points lower (95% confidence interval [CI] = -18.47 to -6.06) in communities with difficult PCI access relative to communities with easy PCI access. Regionalization had no statistically significant effect on the probability of admission to a PCI hospital for communities with easy PCI

access (0.15 percentage points; 95% CI = -3.66 to 3.97). In the interaction term between the first two indicators, regionalization increased the probability of admission to a PCI-capable hospital by 6.69 percentage points (95% CI = 1.13 to 12.25) among communities with difficult PCI access, relative to regionalization of communities with easy access. In essence, regionalization reduced the disparity in access between easy and difficult access communities by about half (i.e., it reduced the baseline gap of 12.27 percentage points to $12.3 - 6.7 = 5.6$ percentage points). The net benefit of regionalization for communities with difficult access was an improvement in PCI hospital admission by $6.69 + 0.15 = 6.84$ percentage points, representing a relative increase of 10.7% (baseline mean was 64% for difficult access communities) for patients with STEMI who were admitted to a PCI-capable hospital.

Treatment outcomes were similar (Table 2). Regionalization was not associated with improvement in the likelihood of receiving PCI for patients with baseline easy access to PCI facilities (Table 2, second row). However, among patients in communities with difficult baseline access, regionalization was associated with an improvement in the probability of receiving PCI on the same day of admission by 5.96 percentage points (95% CI = 1.81 to 10.11) relative to patients in communities with easy access. Given that communities with difficult access at baseline had a lower probability of receiving PCI on the same day by 6.62 percentage points (95% CI = -11.01 to -2.23) in the preregionalization period, STEMI regionalization effectively eliminated the disparity in PCI treatment. Likewise, the probability of receiving PCI during the care episode was improved by 5.23 percentage points (95% CI = 0.67 to 9.79) among communities with difficult access relative to communities with easy access, while the preregionalization difference was 7.30 percentage points (95% CI = -12.10 to -2.49). These improvements translated into a net improvement due to regionalization of 11.9 and 7.7% for same-day and in-hospital PCI, respectively, for patients with STEMI in communities with difficult access.

After the admitting hospital's PCI capacity was controlled for, communities with difficult access still showed a small benefit relative to communities with easy access when measuring receipt of same-day PCI (2.27; 95% CI = 0.30 to 4.24), but not for PCI treatment during hospitalization (Table 2, bottom panel).

As shown in Table 3, the results of the regression of regionalization on mortality did not show any statistically significant differences in pre- and postregionalization mortality rates, although the direction of the results trended toward lower mortality for regionalization in general and slightly higher mortality for those living farther from the nearest PCI hospital.

To investigate whether the benefit of regionalization grew linearly with driving time to the nearest PCI hospital, a sensitivity analysis classified the baseline community PCI access into three groups (<30, 30 to <60, and ≥ 60 minutes). The regionalization effect appeared to be similar whether the driving time for an individual patient at baseline was between 30 and 60 minutes or 60 minutes and beyond (Data Supplement S1, Table S2).

An additional sensitivity analysis addressed a potential concern that a pretrend in health outcomes could differ by regionalization

TABLE 1 Summary statistics of patient population

	All patients	Driving time to PCI in baseline		p-value for differences
		Under 30 minutes	30 minutes or more	
Number (%)	139,408 (100%)	71,072 (100%)	68,336 (100%)	
Sex				
Male	93,648 (67%)	47,562 (67%)	46,086 (67%)	0.87
Female	45,760 (33%)	23,510 (33%)	22,250 (33%)	
Race/ethnicity				
White (non-Hispanic)	86,319 (62%)	39,811 (56%)	46,508 (68%)	<0.001
Hispanic	24,769 (18%)	13,631 (19%)	11,138 (16%)	0.625
Asian	12,620 (9%)	8,594 (12%)	4,026 (6%)	0.001
Other/mixed	7,896 (6%)	4,206 (6%)	3,690 (5%)	0.740
Black (non-Hispanic)	7,804 (6%)	4,830 (7%)	2,974 (4%)	0.116
Age (years)				
<40	3,303 (2%)	1,762 (2%)	1,541 (2%)	0.827
40–54	28,552 (21%)	14,580 (21%)	13,972 (20%)	0.978
55–64	35,376 (25%)	17,698 (25%)	17,678 (26%)	0.744
65–69	16,412 (12%)	8,155 (11%)	8,257 (12%)	0.781
70–74	13,818 (10%)	6,785 (10%)	7,033 (10%)	0.713
75–79	12,852 (9%)	6,605 (9%)	6,247 (9%)	0.937
80–84	12,416 (9%)	6,491 (9%)	5,925 (9%)	0.809
85–99	16,442 (12%)	8,865 (12%)	7,577 (11%)	0.524
Insurance (expected source of payment)				
Private	44,042 (32%)	22,427 (32%)	21,615 (32%)	0.981
Medicare	67,845 (49%)	34,070 (48%)	33,775 (49%)	0.66
Medicaid	13,223 (9%)	7,303 (10%)	5,920 (9%)	0.415
Indigent (county or other)	3,910 (3%)	2,051 (3%)	1,859 (3%)	0.882
Self-pay	7,237 (5%)	3,764 (5%)	3,473 (5%)	0.887
Other	3,151 (2%)	1,457 (2%)	1,694 (2%)	0.669
Transfer status				
Transferred from another hospital	23,079 (17%)	7,848 (11%)	15,231 (22%)	<0.001
Patient comorbid conditions				
Peripheral vascular disease	12,590 (9%)	6,580 (9%)	6,010 (9%)	0.811
Chronic pulmonary disease	3,653 (3%)	1,851 (3%)	1,802 (3%)	0.976
Diabetes	44,243 (32%)	23,167 (33%)	21,076 (31%)	0.577
Renal failure	19,489 (14%)	10,677 (15%)	8,812 (13%)	0.364
Liver disease	2,094 (2%)	1,100 (2%)	994 (1%)	0.91
Cancer	3,704 (3%)	1,984 (3%)	1,720 (3%)	0.801
Dementia	2,823 (2%)	1,501 (2%)	1,322 (2%)	0.852
Valvular disease	11,849 (8%)	5,943 (8%)	5,906 (9%)	0.882
Hypertension	93,487 (67%)	48,187 (68%)	45,300 (66%)	0.634
Pulmonary circulation disorders	21,349 (15%)	10,206 (14%)	11,143 (16%)	0.424
Rheumatoid arthritis/collagen vascular	2,580 (2%)	1,350 (2%)	1,230 (2%)	0.913
Coagulation deficiency	6,076 (4%)	3,311 (5%)	2,765 (4%)	0.657
Obesity	17,948 (13%)	8,881 (12%)	9,067 (13%)	0.733
Substance abuse	8,195 (6%)	4,225 (6%)	3,970 (6%)	0.932
Depression	6,542 (5%)	3,283 (5%)	3,259 (5%)	0.917

(Continues)

TABLE 1 (Continued)

	All patients	Driving time to PCI in baseline		p-value for differences
		Under 30 minutes	30 minutes or more	
Psychosis	3,233 (2%)	1,886 (3%)	1,347 (2%)	0.502
Hypothyroidism	11,592 (8%)	5,728 (8%)	5,864 (9%)	0.78
Paralysis and other neurologic disorder	9,593 (7%)	5,109 (7%)	4,484 (7%)	0.714
Chronic peptic ulcer disease	58 (0%)	37 (0%)	21 (0%)	0.877
Weight loss	3,109 (2%)	1,720 (2%)	1,389 (2%)	0.698
Fluid and electrolyte disorders	24,409 (18%)	13,126 (18%)	11,283 (17%)	0.446
Anemia	20,758 (15%)	11,562 (16%)	9,196 (13%)	0.243
Admitting hospital characteristics				
Ownership				
For-profit	20,775 (15%)	11,200 (16%)	9,575 (14%)	0.468
Government	17,375 (14%)	7,669 (12%)	9,706 (16%)	0.106
Teaching hospital ^a	13,940 (11%)	9,108 (14%)	4,832 (8%)	0.008
Hospital is part of a system	88,585 (75%)	44,976 (74%)	43,609 (76%)	0.577
Number of beds, median (IQR)	293 (212–375)	313 (231–390)	273 (183–370)	<0.001
Occupancy rate, mean (±SD) ^b	0.66 (±0.14)	0.66 (±0.14)	0.66 (±0.14)	0.233
HHI within 15 miles based on total discharge, median (IQR) ^c	0.14 (0.23)	0.08 (0.11)	0.24 (0.31)	<0.001
CABG availability	103,618 (76%)	55,222 (79%)	48,396 (73%)	0.039
PCI lab availability ^d	112,294 (81%)	60,382 (85%)	51,912 (76%)	0.001
Admitting hospital is the closest PCI lab	58,377 (41.9%)	30,999 (43.6%)	27,378 (40.1%)	0.287
Community financial characteristics				
County population, median (IQR)	2,017,673 (251,940)	3,010,759 (8,421,128)	1,049,025 (1,831,983)	<0.001
Per-capita income, median (IQR)	42,265 (15,326)	44,474 (10,669)	37,700 (14,906)	<0.001
Community demographic characteristics				
Live in communities with high share of Black population	42,350 (30%)	23,345 (33%)	19,005 (28%)	0.105
Live in communities with high share of Hispanic population	39,191 (28%)	23,612 (33%)	15,579 (23%)	0.001

Abbreviations: CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; IQR, interquartile range.

^aIf resident-to-bed ratio > 0.25.

^bTotal inpatient days/available beds.

^cHHI, Herfindahl-Hirschman Index, measure of hospital market's competitiveness and ranges from 0 (perfectly competitive) to 1 (monopoly). It is calculated as squaring the market share (as measured by total discharges) of each hospital within 15-mile radius and then summing the resulting numbers.

^dPCI lab availability follows a volume-based definition of 50 or more PCI procedures in a given year.

status. Using the propensity score matching method, we limited the analysis to patients whose counties had similar mortality trends during the preregionalization period. The results were similar to our main analysis using the whole California sample (Data Supplement S1, Table S3). Results using a more conservative definition of PCI that excludes cardiac catheterization remained robust (Data Supplement S1, Table S4). Results remained robust using a lower threshold of five cases annually to designate PCI capacity (Data Supplement S1, Table S5). Finally, the regionalization effect was stronger among communities with a greater than 30-minute prehospital time at baseline when examining whether a patient was admitted to the closest PCI hospital (Data Supplement S1, Table S5).

DISCUSSION

Regionalization of PCI services was beneficial for patients living farther away from PCI centers, increasing their likelihood of being admitted to a PCI facility by 9.4% and their likelihood of receiving same-day PCI by 11.2%. Their likelihood of receiving in-hospital PCI increased by 7.4%. Patients already living near PCI facilities (within a 30-minute drive) did not experience such benefits from regionalization.

STEMI regionalization appears to have its greatest effect on getting patients to a PCI center, as opposed to increasing the likelihood of a center performing PCI once admitted. In this case, access

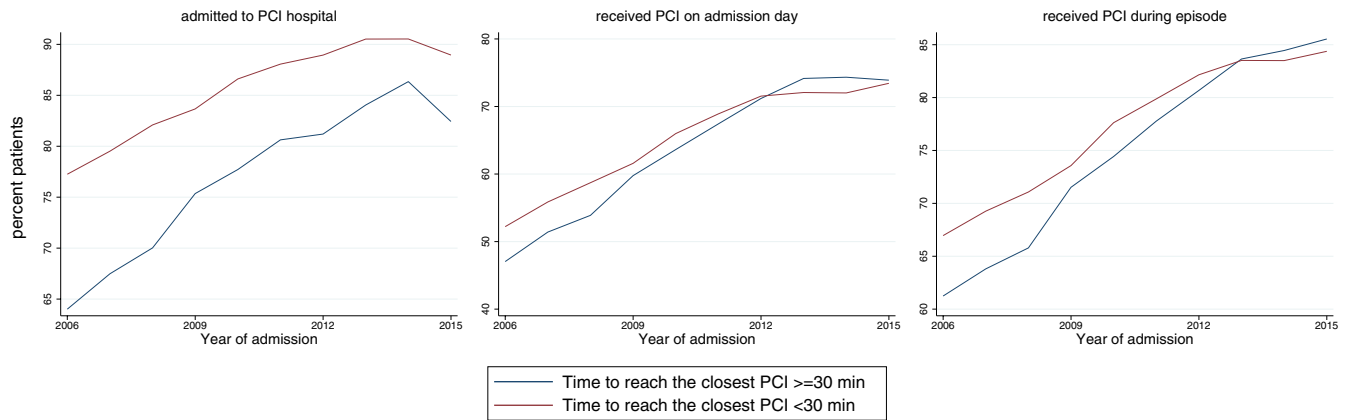


FIGURE 1 Outcomes trends for patients with STEMI in communities with closest PCI facility <30 minutes and patients with STEMI in communities with closest PCI facility \geq 30 minutes over study period (2006–2015). PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction

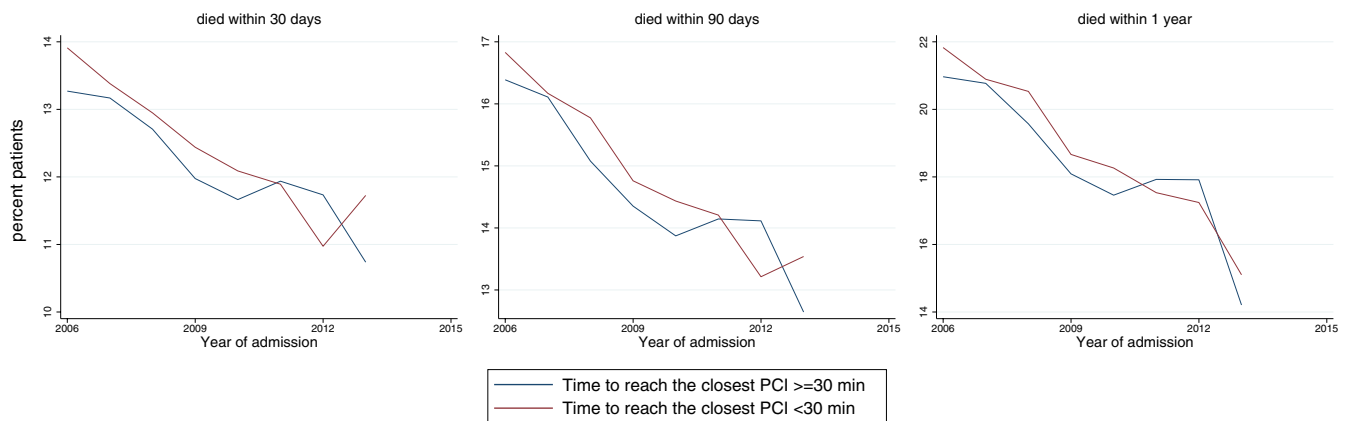


FIGURE 2 Mortality trends for patients with STEMI in communities with closest PCI facility <30 minutes and patients with STEMI in communities with closest PCI facility \geq 30 minutes over study period (2006–2015). PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction

to a hospital with identified capabilities was the most important mechanism by which patients experienced a higher likelihood of receiving PCI. Second, our findings of differential benefits suggest that regionalization may not be as necessary in areas that already have easy access to PCI centers. With limited resources, stakeholders may rationally choose to focus regionalization efforts on communities that will derive greater benefit. Third, regionalization may be a potential way to reduce gaps in access and treatment for patients with STEMI who are more geographically underserved. Our findings show that regionalization more than halved (56%) the disparity in access (when defined as likelihood of being admitted to a hospital with PCI capacity) between communities with difficult and easy access at baseline.

Nonetheless, the null findings on mortality raise the question of why regionalization efforts, in this study and others, have not decreased mortality, despite improving metrics of time-to-PCI treatment and PCI availability.^{25–27} Previous literature has demonstrated that reperfusion with primary PCI confers a significant benefit for those who are at highest risk but provides marginal benefits for

low-risk patients, who comprise the majority of patients with STEMI. It is therefore possible that, as cautioned by even proponents of regionalization, creating regionalized systems, paradoxically, increases time to treatment for low-risk patients with STEMI and that this increased time to primary PCI may outweigh a more prompt delivery of fibrinolytic therapy.^{28,29} In our study, the direction of the mortality estimates suggested a reduction in mortality for regionalization in general and a trend toward higher mortality for those living farther from the nearest PCI hospital. While none of these trends were significant, they further confirm the complexities of the regionalization of care of patients with STEMI, where two good alternatives for revascularization exist. The exact tradeoffs between the therapies are not always clear, especially when patients present at different times in the course of their disease. In other work evaluating the effects of STEMI regionalization in California, White patients living in nonminority communities have been the only racial/ethnic group to experience 30-day, 60-day, and 1-year mortality benefits, which could be due to differential quality of hospitals available to different segments of the population.¹⁵ Thus, it is difficult to draw conclusions

	Admitted to PCI hospital	Received same-day PCI	Received PCI during the episode
Number of patients	139,171	139,171	139,171
Sample mean at baseline (%)	70.8%	49.7%	64.2%
Unadjusted for site of care PCI capacity			
Driving time to PCI is ≥ 30 min (regardless of regionalized status)	-12.27 ^{***}	-6.62 ^{**}	-7.30 ^{**}
95% CI	-18.47 to -6.06	-11.01 to -2.23	-12.10 to -2.49
p-value	0.000	0.004	0.004
On and after county is regionalized (regardless of driving time)	0.15	-0.37	-0.48
95% CI	-3.66 to 3.97	-3.56 to 2.83	-3.44 to 2.48
p-value	0.936	0.819	0.749
Interaction between regionalized indicator and ≥ 30 min to PCI	6.69 [*]	5.96 ^{**}	5.23 [*]
95% CI	1.13 to 12.25	1.81 to 10.11	0.67 to 9.79
p-value	0.019	0.006	0.025
Adjusted for site-of-care PCI capacity			
Driving time to PCI is ≥ 30 min (regardless of regionalized status)		0.14	0.20
95% CI		-1.53 to 1.81	-1.46 to 1.86
p-value		0.865	0.812
On and after county is regionalized (regardless of driving time)		-0.45	-0.57
95% CI		-3.07 to 2.16	-2.99 to 1.85
p-value		0.730	0.640
Interaction between regionalized indicator and ≥ 30 min to PCI		2.27 [*]	1.14
95% CI		0.30 to 4.24	-0.70 to 2.99
p-value		0.025	0.220

TABLE 2 Comparing changes in process outcomes between counties that changed regionalization status and counties that did not during the same period

Abbreviation: PCI, percutaneous coronary intervention.

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

about the longer-term effects of regionalization on mortality—regardless of baseline access to PCI.

Regionalization of STEMI care was first recommended in Europe, with initial studies done in smaller geographic regions with centralized and more universalized health care systems.^{30–32} In the United States, the powerful financial incentives for providing PCI and other specialized services may induce redundancy of high-revenue services following regionalization, particularly in areas with existing capacity.^{7,33,34} In fact, prior research has already demonstrated a 44% growth in the number of PCI centers within a 5-year span and evidence of systemic duplication of new PCI centers.^{7,33} In these market-based contexts, regionalization may not accrue additional benefits where services already exist, especially when hospitals are not incentivized to coordinate care.

There are several important limitations to this study. First, our data source was an administrative, not a clinical, database. Granularities regarding severity of patient illness beyond comorbidities were not possible to obtain, and time-to-treatment metrics were not available. However, the alternative of using hospital-based or patient registries, such as the ACC/AHA's ACTION Registry-Get With The Guidelines (GWTG) and CathPCI Registry would precisely preclude this population-based study, since most ACTION participants are STEMI-providing hospitals. The absence of STEMI referral hospitals would prevent us from determining differences among communities and also does not capture out-of-hospital mortality. We would therefore be unable to evaluate integrated STEMI systems that included all patients in the community (as opposed to only those patients who receive

TABLE 3 Comparing changes in health outcomes between counties that changed regionalization status and counties that did not during the same period

	30-day mortality	90-day mortality	1-year mortality
Number of patients	117,814	117,814	117,814
Sample mean at baseline (%)	13.6%	16.6%	21.4%
Unadjusted for site of care PCI capacity			
Driving time to PCI is ≥ 30 min (regardless of regionalized status)	-0.21	-0.15	-0.15
95% CI	-1.00 to 0.58	-0.87 to 0.58	-1.01 to 0.70
p-value	0.590	0.685	0.721
On and after county is regionalized (regardless of driving time)	-0.69	-0.65	-0.59
95% CI	-1.46 to 0.08	-1.46 to 0.16	-1.35 to 0.16
p-value	0.078	0.113	0.121
Interaction between regionalized indicator and ≥ 30 min to PCI	0.34	0.38	0.41
95% CI	-0.46 to 1.14	-0.38 to 1.14	-0.40 to 1.21
p-value	0.394	0.316	0.317
Adjusted for site-of-care PCI capacity			
Driving time to PCI is ≥ 30 min (regardless of regionalized status)	-0.64	-0.62	-0.73
95% CI	-1.42 to 0.14	-1.29 to 0.04	-1.49 to 0.03
p-value	0.106	0.064	0.058
On and after county is regionalized (regardless of driving time)	-0.64	-0.60	-0.53
95% CI	-1.45 to 0.16	-1.41 to 0.22	-1.27 to 0.21
p-value	0.116	0.149	0.159
Interaction between regionalized indicator and ≥ 30 min to PCI	0.55	0.62	0.69
95% CI	-0.26 to 1.35	-0.13 to 1.36	-0.06 to 1.43
p-value	0.177	0.102	0.071

Abbreviation: PCI, percutaneous coronary intervention.

treatment in participating registry hospitals). Second, although all regionalized systems included the crucial element of nearest hospital bypass to the closest PCI facility whenever possible within guidelines, regionalized systems may vary in their emphases and protocols for interhospital transfer, ambulance personnel (i.e., emergency medical technicians, paramedics) as well as processes such as prehospital electrocardiograms. As in other studies evaluating regionalization, there is no single approach to regionalization for STEMI. Therefore, our results are best interpreted as capturing the *net effect* of regionalization. Third, while the county and year fixed effects in our models allow us to remove systematic time-invariant differences across counties and time-varying macro trends that affect all counties, this DDD framework does not eliminate time-varying differences across counties. Our sensitivity analysis of matching counties with similar preregionalization mortality trends (Data Supplement S1, Table S3) partially addresses this concern, but we recognize that some biases can still remain. Finally, the study sample was composed of patients and regionalization initiatives in the state of

California. Although diverse and representing 12% of the U.S. population, these results may not be generalizable to the remainder of the country.

CONCLUSIONS

When measured by likelihood of admission to a percutaneous coronary intervention-capable facility and receipt of percutaneous coronary intervention, the benefits of ST-elevation myocardial infarction regionalization in California accrued only to patients living in communities whose baseline access to percutaneous coronary intervention center was ≥ 30 minutes away. Our study revealed no mortality benefits of regionalization based on distance from percutaneous coronary intervention center. These findings suggest that policymakers focus ST-elevation myocardial infarction regionalization efforts in communities that are not already well serviced by percutaneous coronary intervention-capable hospitals.

AUTHOR CONTRIBUTIONS

Y.C.S.—study concept and design, acquisition of the data, analysis and interpretation of the data, drafting of the manuscript, statistical expertise, and acquisition of funding. R.Y.H.—study concept and design, acquisition of the data, analysis and interpretation of the data, drafting of the manuscript, and acquisition of funding.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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