

KENTUCKY PILOT PROJECT FOR PRIMARY PCI WITHOUT ONSITE CABG

Statistical Report

Summary of the statistical analysis conducted that evaluated whether primary PCI should be allowed to be performed at facilities in the state of Kentucky that do not have onsite CABG capabilities. In addition, recommendations are made whether this study should be expanded and guidelines are presented concerning a similar pilot study addressing elective PCI being performed at sites without onsite CABG capabilities.

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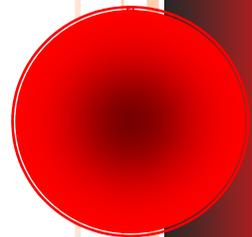
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Objective

The objective of this statistical analysis was to provide information that allows the Cabinet for Family and Health Services to address the question, “Does data collected as part of the Kentucky Pilot Project support allowing hospitals without backup emergency open heart (OH) surgical capabilities to perform primary percutaneous coronary intervention (PCI) in the State of Kentucky?”

Data

Data was collected from two hospitals; T. J. Samson Community Hospital (TJSCH) in Glasgow, KY and Ephraim McDowell Regional Medical Center (EMRMC) in Danville, KY. Both hospitals are without onsite emergency coronary artery bypass graft surgery (CABG) capabilities and have been participating in a pilot study performing primary PCIs for more than three years. The study population was comprised of 235 individuals (TJSCH – 158, EMRMC – 77) who received a primary/rescue PCI procedure during the period of July 2005 – August 2008.

Outcome measures collected and subsequently analyzed included: 1.) Mortality; 2.) Door-to-Balloon Time (DBT, minutes) and Proportion of patients with DBT less than or equal to 90 minutes; 3.) Cardiac arrests as a result of PCI; and 4.) Emergent surgery performed (CABG) as a result of PCI.

Statistical Methods

Descriptive statistics for patient demographics and cardiac risk factors were summarized by study site as well as overall. Continuous variables are expressed as mean \pm SD and qualitative variables are

expressed as percentages along with 95% confidence intervals (for outcome measures only). Testing for differences between the study sites and established national values (for both sites with and without backup capabilities) were done using one-sample t-tests and binomial tests for proportions (using exact methods where appropriate).

Results

Table 1 displays that the sample of 235 study participants included 28.9% women, 22.1% diabetics, 60.4% individuals with hypertension, and 12.8% previously experienced a myocardial infarction (MI). These results are consistent and similar to national samples. The mean age for the sample population was 59 ± 13 years of age and is consistent with national samples. In addition, the stratified results in table 1 may suggest that patients presented at EMRMC were healthier than those presented at TJSCH; however, both hospitals had nationally representative samples. The TJSCH had higher rates of previous MIs, previous PCI, previous CABG, hypertension and diabetes.

Table 1: Patient demographics and cardiac risk factors

Characteristic	Mean Value \pm SD or No. of Procedures (%)		
	TJSCH (n = 158)	EMRMC (n = 77)	Both (n = 235)
Age (yr)	59 \pm 14	60 \pm 13	59 \pm 13
Age > 70	34 (21.5%)	14 (18.2%)	48 (20.4%)
Female	47 (29.8%)	21 (27.3%)	68 (28.9%)
Previous MI (>7 days)	29 (18.4%)	1 (1.3%)	30 (12.8%)
Previous PCI	27 (17.1%)	5 (6.5%)	32 (13.6%)
Previous CABG	11 (7.0%)	1 (1.3%)	12 (5.1%)
Hypertension	108 (68.4%)	34 (44.2%)	142 (60.4%)
Diabetes	40 (25.3%)	12 (15.6%)	52 (22.1%)
Cardiogenic shock	7 (4.4%)	5 (6.5%)	12 (5.1%)
Diseased vessels ($\geq 70\%$ stenosis)			
0	2 (1.3%)	2 (2.6%)	4 (1.7%)
1	114 (72.2%)	61 (79.2%)	175 (74.5%)
2	31 (19.6%)	10 (13.0%)	41 (17.5%)
3	11 (7.0%)	4 (5.2%)	15 (6.4%)
Left main ($\geq 50\%$ stenosis)	1 (0.6%)	3 (3.9%)	4 (1.7%)
Left ventricular ejection fraction (%)	49 \pm 9	62 \pm 14	53 \pm 13

Paramount to testing for differences among the Kentucky Pilot project population and national values, is establishing national values in which to use for comparisons. Table 2 reviews the reference values used for comparisons with results from the study population. These values were selected based on

criterion developed by the authors. The criterion evaluation included, but was not limited to, the study population, the study design and the sample size of the study. In addition, we considered the journal in which the reference values were published.

Table 2: Reference Values

Outcome	Reference Values		Reference
	W/ onsite CABG	W/O onsite CABG	
Mortality - Overall	2.2%	2.2%	Johns Hopkins Med. Institutions (9)
Door-to-Balloon Time	100.4 mins	94.0 mins	Bradley et al. (3), Wharton et al. (1)
Door-to-Balloon Time ≤ 90 minutes	44.8%	44.8%	Thom et al. (4), Johns Hopkins Med. Institutions (9)
Cardiac Arrests - PCI Related	0.4%	NA	Garot et al. (8)
Emergencies Surgeries Performed - PCI Related	0.4%	0.3%	Kutcher et al. (5)

NA – Not Available

Stratified Analyses. Tables 3 and 4 display the results associated with TJSCH and EMRMC respectively. First, the in-hospital mortality rates at neither TJSCH 2.5% (95% C.I., 0.7-6.4) nor EMRMC 2.6% (95% C.I., 0.3-9.1) were significantly different from the national average of 2.2% for in-hospital mortality at hospitals with and without onsite CABG. Second, the average door-to-balloon times (DBT) at TJSCH and EMRMC were 92.7 mins (95% C.I., 84.4-101.0) and 100.1 mins (95% C.I., 90.5-109.7), respectively; neither value was significantly different from the national average of 100.4 mins for hospitals with onsite CABG and 94.0 mins for hospitals without onsite CABG. However, the proportion of DBT ≤ 90 mins for TJSCH and EMRMC (57% and 50% respectively) were higher (better) than the national average of 44.8% for hospitals with and without onsite CABG; but, only TJSCH had a statistically significantly higher proportion comparatively (p=0.003). Finally, neither TJSCH nor EMRMC had any PCI related cardiac arrests or emergency CABGs performed. As a result, the comparisons to the respective national averages were clearly not significant.

Table 3: Comparisons of TJSCH Outcome Measures

Outcome	TJSCH (n = 158)	Reference Values	p-value
Mortality			
- In-hospital, n (% , 95% CI)	4 (2.5 , 0.7-6.4)	2.2%	0.919 (NS)
- W/ onsite CABG		2.2%	0.919 (NS)
- W/O onsite CABG			
Door-to-Balloon Time	92.7 mins		
- W/ onsite CABG		100.4 mins	0.073 (NS)
- W/O onsite CABG		94.0 mins	0.763 (NS)
Door-to-Balloon Time ≤ 90 minutes			
- n (% , 95% CI)	90 (57.0 , 49.2-64.7)		
- W/ onsite CABG		44.8%	0.003 (*)
- W/O onsite CABG		44.8%	0.003 (*)
Cardiac Arrests			
- PCI Related, n (% , 95% CI)	0 (0.0 , 0.0-2.3)	0.4%	1.0 (NS)
- W/ onsite CABG		NA	NA
- W/O onsite CABG			
Emergency OH Surgeries Performed,			
- PCI Related, n (% , 95% CI)	0 (0.0 , 0.0-2.3)	0.4%	1.0 (NS)
- W/ onsite CABG		0.3%	1.0 (NS)
- W/O onsite CABG			

NA – Not Available, NS – Not Significant, * – Significant at the 5% level.

Table 4: Comparisons of EMRMC Outcome Measures

Outcome	EMRMC (n = 77)	Reference Values	p-value
Mortality			
- In-hospital, n (% , 95% CI)	2 (2.6 , 0.3-9.1)	2.2%	1.0 (NS)
- W/ onsite CABG		2.2%	1.0 (NS)
- W/O onsite CABG			
Door-to-Balloon Time	100.1 mins		
- W/ onsite CABG		100.4 mins	0.952 (NS)
- W/O onsite CABG		94.0 mins	0.217 (NS)
Door-to-Balloon Time ≤ 90 minutes			
- n (% , 95% CI)	28 (50.0 , 36.9-63.1)		
- W/ onsite CABG		44.8%	0.516 (NS)
- W/O onsite CABG		44.8%	0.516 (NS)
Cardiac Arrests			
- PCI Related, n (% , 95% CI)	0 (0.0 , 0.0-4.7)	0.4%	1.0 (NS)
- W/ onsite CABG		NA	NA
- W/O onsite CABG			
Emergency OH Surgeries Performed,			
- PCI Related, n (% , 95% CI)	0 (0.0 , 0.0-4.7)	0.4%	1.0 (NS)
- W/ onsite CABG		0.3%	1.0 (NS)
- W/O onsite CABG			

NA – Not Available, NS – Not Significant, * – Significant at the 5% level.

Non-stratified Analyses. Table 5 displays the results associated with the entire non-stratified sample. Similar to above, there were no significant difference between mortality rates, DBT times,

cardiac arrests as a result of PCI, and emergency surgery as a result of PCI between the sample population and the national reference values. Similar to TJSCH, the proportion of the sample population that had a DBT ≤ 90 mins was significantly lower than the national reference values ($p=0.003$). This result is not surprising since a majority of the data was obtained from TJSCH.

Table 5: Comparisons of Both Hospitals' Outcome Measures

Outcome	Both (n = 235)	Reference Values	p-value
Mortality			
- Overall, n (% , 95% CI)	6 (2.6, 0.9-5.5)		
- W/ onsite CABG		2.2%	0.828 (NS)
- W/O onsite CABG		2.2%	0.828 (NS)
Door-to-Balloon Time	94.7 mins		
- W/ onsite CABG		100.4 mins	0.092 (NS)
- W/O onsite CABG		94.0 mins	0.848 (NS)
Door-to-Balloon Time ≤ 90 minutes			
- n (% , 95% CI)	118 (55.1, 44.5-61.8)		
- W/ onsite CABG		44.8%	0.003 (*)
- W/O onsite CABG		44.8%	0.003 (*)
Cardiac Arrests			
- PCI Related, n (% , 95% CI)	0 (0.0, 0.0-1.6)		
- W/ onsite CABG		0.4%	0.780 (NS)
- W/O onsite CABG		NA	NA
Emergency Surgeries Performed,			
- PCI Related, n (% , 95% CI)	0 (0.0, 0.0-1.6)		
- W/ onsite CABG		0.4%	0.780 (NS)
- W/O onsite CABG		0.3%	0.987 (NS)

NA – Not Available, NS – Not Significant, * – Significant at the 5% level.

Since time related data can be skewed and heavily influenced by outliers and extreme values, summary statistics for door-to-balloon times are presented in Table 6.

Table 6: Summary statistics for Door-to-Balloon Time

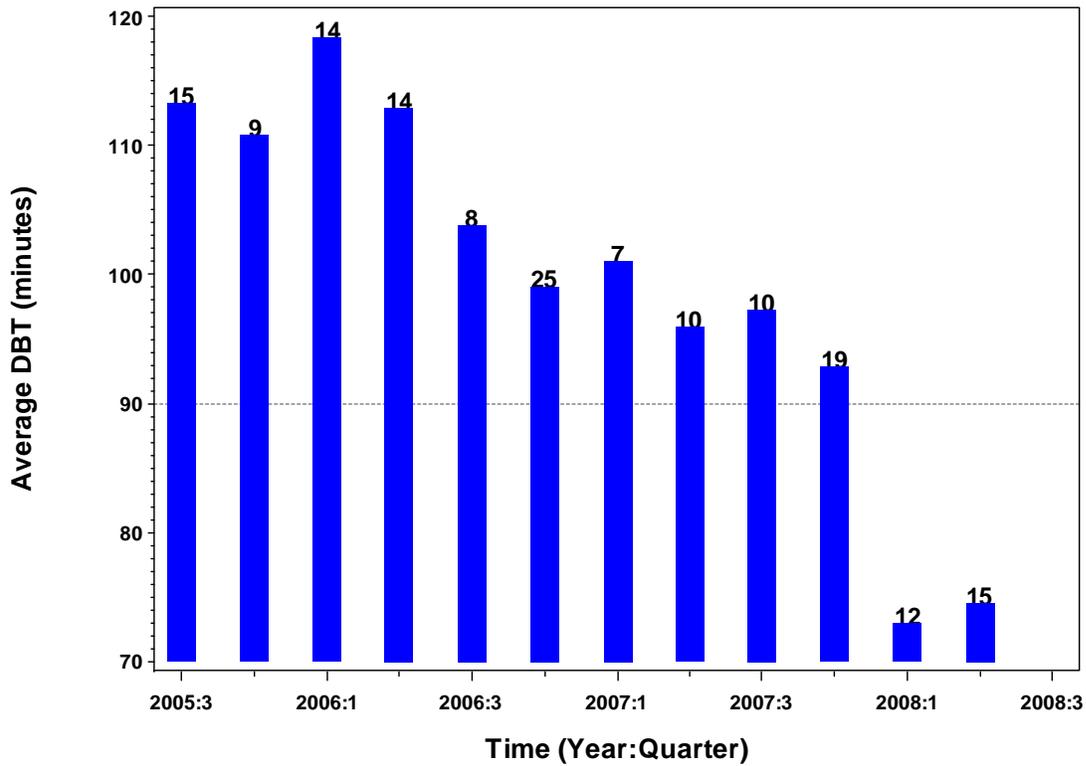
Study Sites	N	N Missing*	Mean	SD	Median	Minimum	Maximum
TJSCH	158	0	92.7	53.5	84	11	365
EMRMC	56	21	100.1	36.6	90	40	252
Both	214	21	94.7	49.6	87	11	365

* Reasons for missing DBTs: In patient (8), NA (2), Repeat EKG (2), Rescue (1), Transfer (28), Transfer from another facility for PCI (5).

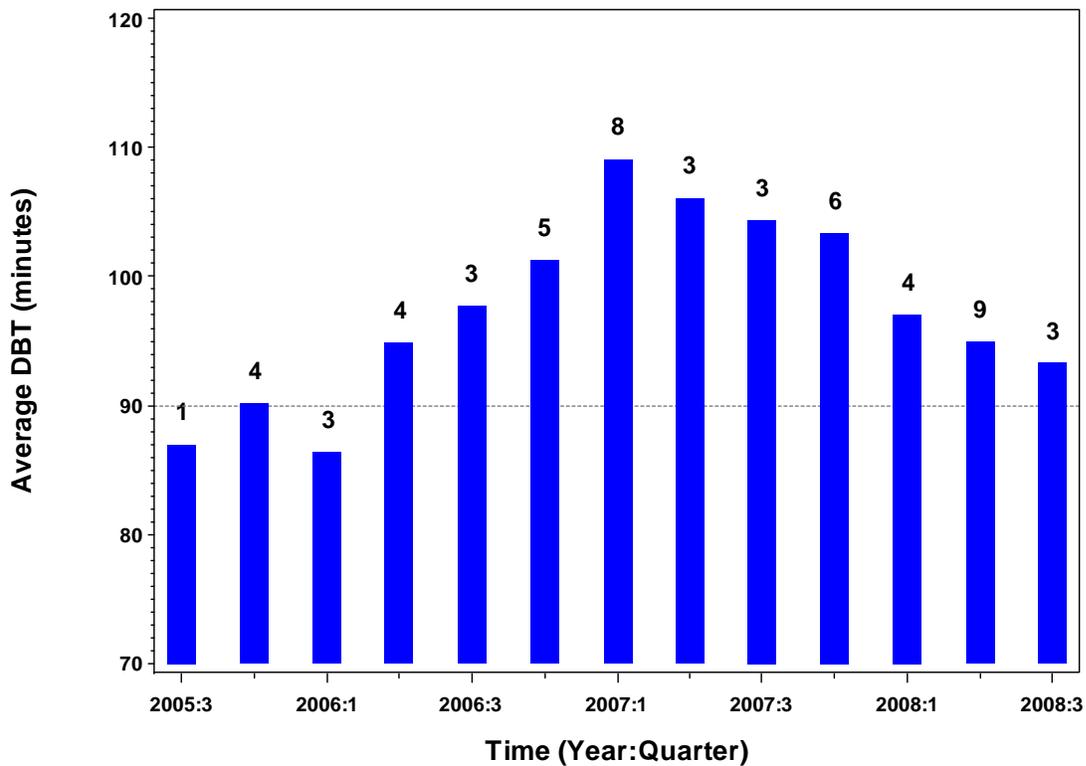
Figures 1-3 present the rolling four-quarter DBT activity for TJSCH, EMRMC, and Both hospitals. These figures suggest that there is a learning phase subsequent to be allowed to perform primary PCI.

Figures 1-3: *Rolling Four-Quarter DBT Activity at TJSCH, EMRMC, and Both Hospitals*

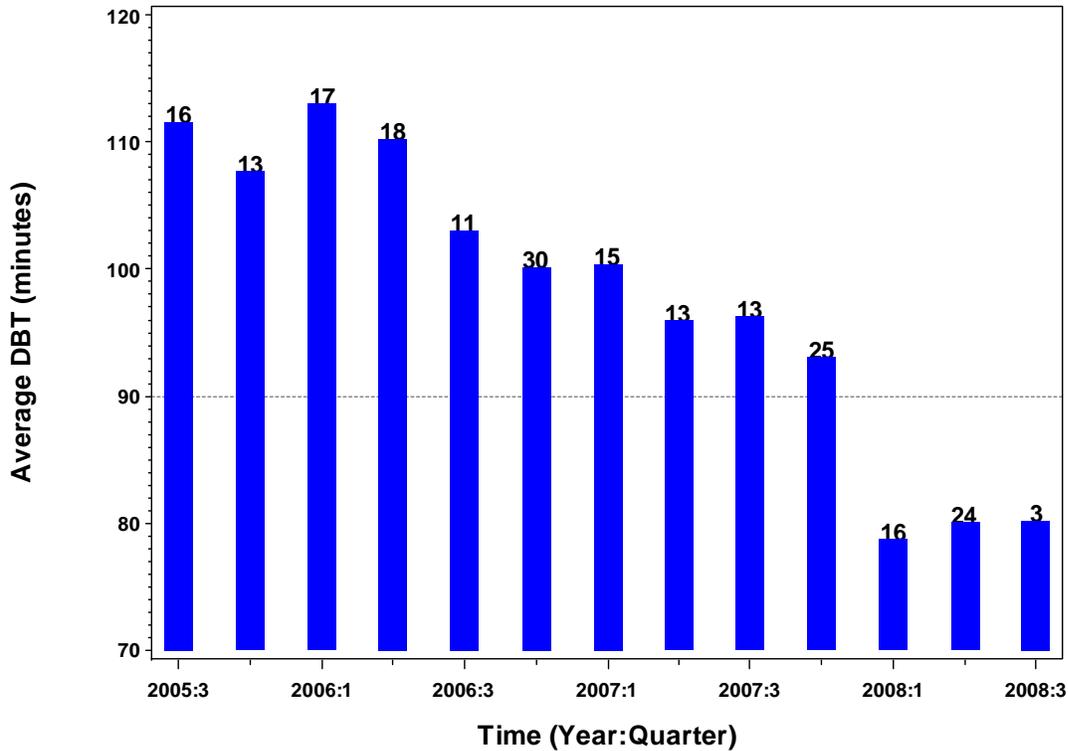
Rolling Four Quarters Door-to-Balloon Time (DBT) Activity at TJSCH



Rolling Four Quarters Door-to-Balloon Time (DBT) Activity at EMRMC



Rolling Four Quarters Door-to-Balloon Time (DBT) Activity at Both Hospitals



Conclusions

Overall mean time from arrival to emergency department to reperfusion time was 94.7 minutes. The in-hospital mortality for the entire study population was 2.6%. Of those without initial cardiogenic shock, the in-hospital mortality was 1.4%. No patient died or had a cardiac arrest or needed emergent surgery (CABG) as a result of a complication of the cardiac catheterization or the PCI procedure.

Our results suggest that there is *no significant difference in any of the outcome variables studied* between the two facilities included in the pilot study and other facilities nationwide both with and without onsite CABG.

Discussion

Primary PCI. Facilities without onsite CABG capabilities meeting the operator and institutional requirements set by the ACC/AHA should be allowed to provide primary PCI to patients. The facilities will need to be continually monitored with regard to outcome quality measures to ensure patient care is

held at a high standard. It is recommended that the performance of the facilities be reviewed periodically by an external group.

Recommendations regarding Primary PCI without Onsite CABG

Hospitals

- Cardiac catheterization laboratory must be located in an acute care hospital.
 - Cardiac catheterization laboratory must be performing at least 300 catheterizations per year.
 - The catheterization laboratory must perform a minimum of 36 primary PCI procedures per year after the second year of operation and annually thereafter.
 - The nursing and technical catheterization laboratory staff must be experienced and participate in a 24-hours-per-day, 365-days-per-year call schedule.
 - The catheterization lab must be equipped, with optimal imaging systems, resuscitative equipment, and IABP support, and must be well-stocked with a broad array of interventional equipment.
 - The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
 - The hospital administration must fully support the program.
 - Primary PCI must be performed routinely as the treatment of around the clock for a large proportion of patients with AMI.
 - Case selection for the performance of primary PCI must be rigorous.
 - Provide support for a quality-assurance staff person (e.g., nurse) to monitor complications.
 - There must be an ongoing program of outcomes analysis and formalized periodic case review.
 - Institutions should participate in a 3- to 6-month period of implementation.
 - There must be formalized written protocols in place for immediate and efficient transfer of patients to a large volume cardiac surgical facility that is reviewed/tested on a regular basis.
 - A DICOM (Catheterization) Image Transfer System must be in place between the hospital and the backup surgical facility and availability for immediate consultation between the cardiologist and the surgeon or consulting interventional cardiologist.
 - Interventional program director (at large volume facility) has a career experience of more than 500 PCI procedures and who is board certified by the ABIM in interventional cardiology.
 - Establishment of a mentoring program for operators who perform fewer than 75 procedures per year by individuals who perform at least 150 procedures per year.
 - The hospital must participate in the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) quality measurement program and report to the state CON Board and be published on a hospital website with the national means and available to the public.
 - Data from new programs should be reviewed by an outside consultant after the first two years of the program to verify the quality of the program risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. If not within two standard deviations of the mean, the program will not be continued.
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Physicians

- Board certification by American Board of Internal Medicine in interventional cardiology.
 - The cardiologist must be an experienced interventionalist who regularly performs greater than or equal to 75 PCI's per year.
 - Ongoing quality assessment comparing results with current benchmarks, with risk stratification of complication rates.
 - Continuation of privileges based on outcome benchmark rates, with consideration of not granting privileges to operators who exceed adjusted case mix benchmark complication rates for a 2-year period.
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Patient Selection

- **Avoid intervention in hemodynamically stable patients with:**
 - Significant (greater than or equal to 60%) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.
 - Extremely long or angulated infarct-related lesions with TIMI grade 3 flow.
 - Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease.
 - Infarct-related lesions of small or secondary vessels.
 - Hemodynamically significant lesions in other than the infarct artery.
- **Transfer for emergency aortocoronary bypass surgery patients with:**
 - High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability present after primary PCI of occluded vessels, preferably with IABP support.

Recommendations regarding elected PCI without onsite CABG

These recommendations are much more difficult because there is very little published data to support this premise. However, it is my opinion that it is reasonable to begin a control study at a limited number of facilities the results of which should be evaluated after the first two years by an independent consultant. For a hospital to be considered in the study they should meet the following criteria:

- Meet all of the above criteria for elected angioplasty.
- Have successfully demonstrated good outcomes in performing primary PCI's as defined above.
- Or perform a minimum of 800 catheterizations per year.
- Demonstrate a minimal institutional performance activity of 200 interventions per year, with ideal minimum of 400 interventions per year by the second year of operation.
- Participate in the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) quality measurement program.
- Outcomes data published on hospital website yearly.
- If outcomes is not within two standard deviations of the national means for two consecutive years the CON to do elective angioplasties will be revoked.

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Appendix

Additional Tables

Table 7a: Additional Outcomes of Primary PCI

Outcome	Mean Value \pm SD or No. of Procedures (%)		
	TJSCH (n = 219)	EMRMC (n = 97)	Both (n = 316)
Post-PCI TIMI flow grade			
0-1	0	3 (3.1%)	3 (0.9%)
2	1 (0.5%)	5 (5.2%)	6 (1.9%)
3	218 (99.5%)	89 (91.8%)	307 (97.2%)
Post-PCI % stenosis	10 \pm 5	3 \pm 17	8 \pm 11
PCI success	218 (99.5%)	89 (91.8%)	307 (97.2%)

Table 7b: Additional Outcomes of Primary PCI

Outcome	Mean Value \pm SD or No. of Procedures (%)		
	TJSCH (n = 158)	EMRMC (n = 77)	Both (n = 235)
In-hospital mortality	4 (2.5%)	2 (2.6%)	6 (2.6%)
Presenting with cardiogenic shock (n=7, 5, 12 respectively)	1 (14.3%)	2 (40.0%)	3 (25.0%)
Presenting without shock (n=151, 72, 223 respectively)	3 (2.0%)	0 (0.0%)	3 (1.4%)

Table 8: Cardiac Catheterization Laboratory Complications

Complication	No. of Patients (%)		
	TJSCH (n = 158)	EMRMC (n = 77)	Both (n = 235)
Any complication	19 (12.0%)	3 (3.9%)	22 (9.4%)
Periprocedural MI	0	0	0
Cardiogenic Shock	6 (3.8%)	3 (3.9%)	9 (3.8%)
CHF	3 (1.9%)	0	3 (1.3%)
CVA/Stroke	1 (0.6%)	0	1 (0.4%)
Tamponade	0	0	0
Renal Failure	0	0	0
Emergency PCI	0	0	0
Bleeding at Percutaneous Entry Site	4 (2.5%)	0	4 (1.7%)
Retroperitoneal Bleeding	1 (0.6%)	0	1 (0.4%)
Gastrointestinal Bleeding	2 (1.3%)	0	2 (0.9%)
Genital Urinary Bleeding	4 (2.5%)	0	4 (1.7%)
Bleeding – Other Unknown Cause	4 (2.5%)	0	4 (1.7%)
Access Site Occlusion	0	0	0