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Trends and Outcomes During Rollout Phase of Non-Primary PCI at Sites Without Surgery On-Site: The Michigan Experience

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Background

- ▶ Non-primary percutaneous coronary intervention (non-PPCI), or elective PCI, is defined as PCI for indications aside from ST-elevation myocardial infarction (STEMI), cardiac arrest, or cardiogenic shock
- ▶ Performance of non-PPCI at centers with cardiac surgery backup on-site has been under investigation, with the role of surgical presence remaining on ongoing debate
- ▶ 2011 ACC/AHA/SCAI Guideline for Percutaneous Coronary Intervention upgraded the recommendation for non-PPCI at facilities without on-site surgical support to Class IIb, as long as appropriate systems of care were developed and rigorous clinical and angiographic criteria were used for proper patient selection
- ▶ The use of centers without on-site cardiac surgery initially developed as a means to improve:
 - ▶ Door-to-balloon time and clinical outcomes in STEMI patients
 - ▶ Improve geographic expansion of cardiologic services to increase access in underserved areas
 - ▶ Economic factors
- ▶ State of Michigan approved the performance on non-PPCI at certificate of need (CON) centers in March 2016. Prior to this, centers without surgical support were only approved to perform primary PCI



Methods

► Data Source

- Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2)
- All non-PPCI cases between **April 2016 to March 2018** included
- **33 hospitals with on-site surgery** and **14 hospital without on-site surgery** included

► Primary Outcome:

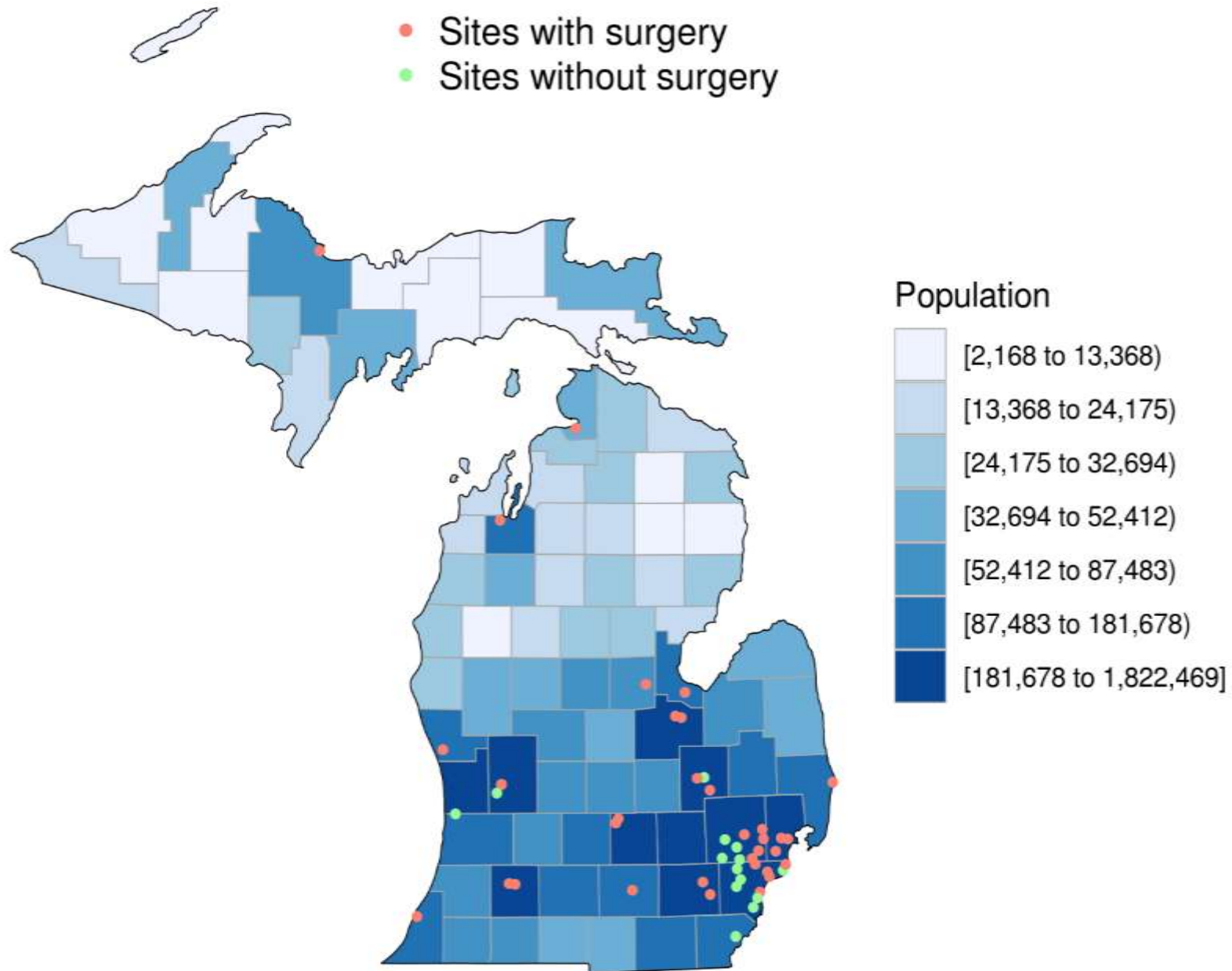
- Composite of all-cause, in-hospital mortality, contrast-induced nephropathy, NCDR defined bleeding, major bleeding, and stroke

► Secondary Outcomes:

- All-cause in-hospital mortality, major bleeding, RBC/whole blood transfusion, any bleeding event within 72 hours of PCI, other vascular complications requiring transfusion, CVA/stroke, heart failure, Q-wave myocardial infarction, subacute stent thrombosis, repeat PCI to same lesion, cardiac tamponade, new requirement for dialysis, urgent/emergent CABG, contrast-induced nephropathy (CIN), and length of stay

► Statistics

- 1:1 propensity score matching using logistic regression models adjusting for over 20 clinical and demographic variables to create matched cohorts of non-PPCI cases at sites with and without on-site surgery --> **4,463 matched patients**
- Baseline demographic, clinical and procedural variables, and in-hospital outcomes compared
- Absolute standardized difference threshold of >10% was used as a marker for clinically meaningful differences



Trends and Site-specific Distribution of PCI in the State of Michigan During the Study Period on a Quarterly Basis

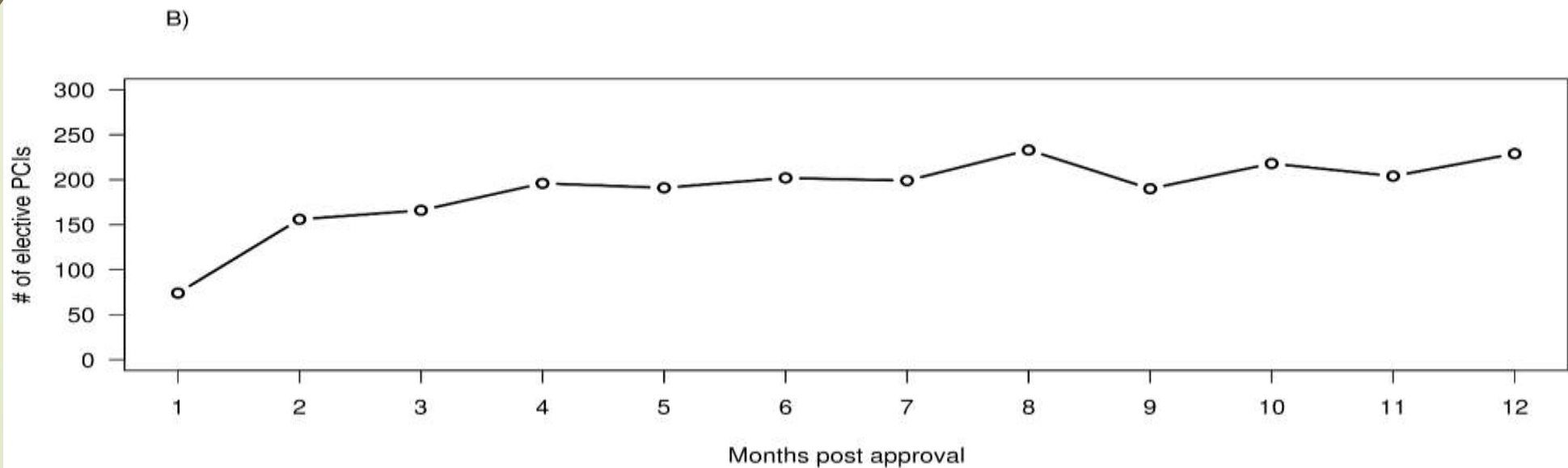
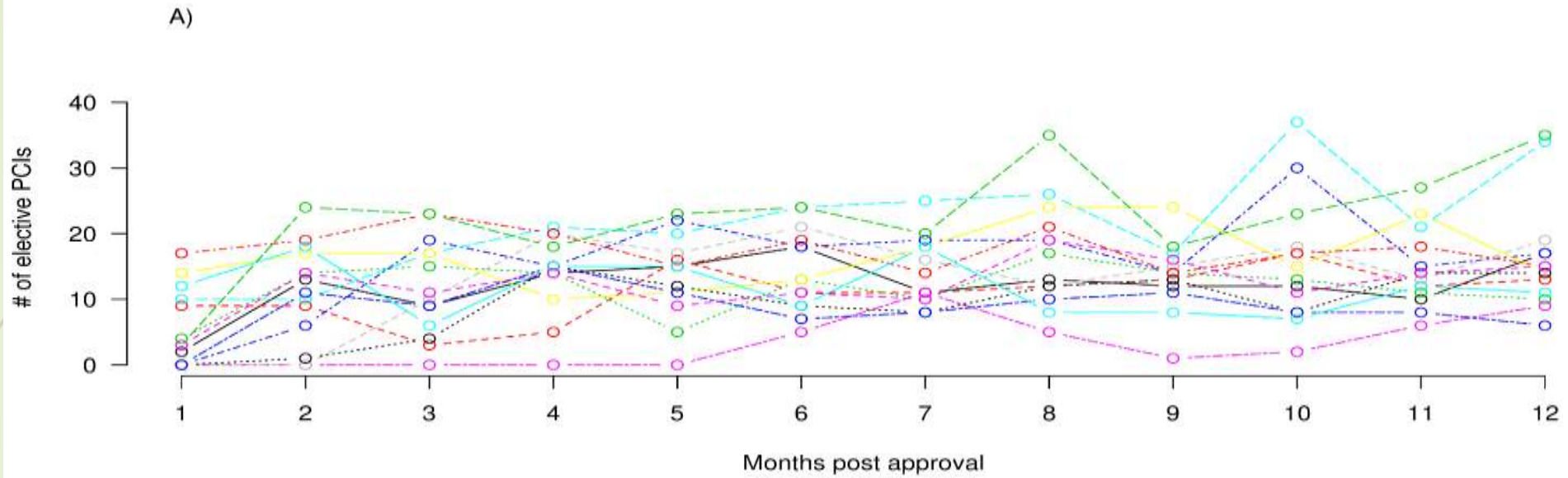
All PCI Cases



Non-PPCI Cases



Trends in Volume Ramp-Up of Non-PPCI at Sites Without Surgery During the First 12 Months Post-Approval



	Sites with Surgery	%Cases	Sites Without Surgery	%Cases	P-value	ASD (%)
N = 4,643						
<i>Demographics</i>						
Age, years	65.3 ± 11.9		65.0 ± 11.5		p = 0.184	2.75
Male	3,145	67.70%	3,023	65.10%	p = 0.008	5.54
White	3,909	84.20%	4,066	87.60%	p < 0.001	9.78
<i>Clinical History</i>						
Hypertension	4,087	88.00%	3,960	85.30%	p < 0.001	8.01
Dyslipidemia	3,816	82.20%	3,592	77.40%	p < 0.001	12.09
Diabetes Mellitus	1,917	41.30%	1,899	40.90%	p = 0.704	0.79
Current/Recent Smoker (<1 year)	1,221	26.30%	1,297	27.90%	p = 0.076	3.68
Prior Myocardial Infarction	1,674	36.10%	1,561	33.60%	p = 0.014	5.1
Prior PCI	2,261	48.70%	2,029	43.80%	p < 0.001	9.9
Prior CABG	824	17.80%	522	11.30%	p < 0.001	18.53
Prior Heart Failure	915	19.70%	764	16.50%	p < 0.001	8.45
Chronic Lung Disease	821	17.70%	810	17.50%	p = 0.768	0.61
Currently on Dialysis	136	2.90%	135	2.90%	p = 0.948	0.14
Cerebrovascular Disease	733	15.80%	589	12.70%	p < 0.001	8.89
Contrast Volume, mean mL + SD	157.1 ± 66.4		161.1 ± 66.8		p = 0.004	5.97
<i>Vessel Intervened Upon</i>						
Left Main	154	3.30%	49	1.10%	p < 0.0001	15.51
Left Anterior Descending	2072	44.60%	2019	43.50%	p = 0.2771	2.28
Left Circumflex	1366	29.40%	1256	27.10%	p = 0.0197	5.25
Right Coronary Artery	1534	33.00%	1536	33.10%	p = 0.9648	0.11
Bypass Graft	249	5.40%	162	3.50%	p = 0.0001	9.12
Chronic Total Occlusion	228	4.90%	88	1.90%	p < 0.0001	16.69
Bifurcation	368	7.90%	375	8.10%	p = 0.7890	0.56

	Sites with Surgery	%Cases	Sites Without Surgery	%Cases	P-value	ASD (%)
N = 4,643						
MACE	119	2.6%	131	2.8%	p = 0.443	1.60
In-Hospital Mortality	26	0.6%	21	0.5%	p = 0.465	1.52
Major Bleeding	19	0.5%	14	0.4%	p = 0.728	1.10
RBC/Whole Blood Transfusion	61	1.3%	53	1.1%	p = 0.452	1.56
Bleeding Event Within 72 hrs	82	1.8%	106	2.3%	p = 0.077	3.68
Other Vascular Complications Requiring Transfusion	14	0.3%	7	0.2%	p = 0.126	3.17
CVA/Stroke	19	0.4%	6	0.1%	p = 0.009	5.41
Cardiogenic Shock	37	0.8%	41	0.9%	p = 0.647	0.95
Heart Failure	87	1.9%	49	1.1%	p = 0.001	6.81
Subacute Stent Thrombosis	5	0.1%	6	0.1%	p = 0.774	0.63
Repeat PCI (same lesion)	15	0.3%	8	0.2%	p = 0.210	3.03
Cardiac Tamponade	8	0.2%	4	0.1%	p = 0.248	2.40
New Requirement for Dialysis	6	0.1%	5	0.1%	p = 0.763	0.62
CABG (urgent/emergent status)	22	0.5%	15	0.3%	p = 0.250	2.39
Contrast-Induced Nephropathy	72	1.8%	64	1.9%	p = 0.795	0.61
Length of Stay (days)	2.8 ± 5.6		2.6 ± 3.0		p = 0.117	3.25



Discussion

- Non-primary, or elective, PCI at sites without on-site cardiac surgery can be safely performed with no significant differences in in-hospital mortality and complication rates, when compared to sites with on-site surgery
- With regards to important quality measures, there were no statistically significant differences in rates of CIN, major bleeding, transfusion requirements, length of stay, or urgent/emergent CABG
- Even after exclusion of high risk cases (EF<30%, left main intervention, CTO, bifurcation lesions, or use of atherectomy devices) to create “truly elective cases” there were no differences in outcomes
 - Furthermore, while small in number (651 matched patients), the outcomes of these “high risk” cases were also similar with no major differences at the two sites
- The use of a robust system of data collection, auditing and quality improvement may provide a template for ensuring safe and optimal expansion of PCI services across centers with no cardiac surgery on site
- Is it time to readdress the guideline recommendations....?



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- ▶ Manuscript under review
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