Patel Brijesh (Orcid ID: 0000-0001-8973-8228)
Garg Lohit (Orcid ID: 0000-0002-9387-4369)
Agarwal Manyoo (Orcid ID: 0000-0002-0549-9440)
Agrawal Sahil (Orcid ID: 0000-0002-2075-7807)

Acute Kidney Injury requiring Dialysis and In Hospital Mortality in Patients with CKD and NSTE-ACS Undergoing Early vs Delayed PCI: A Nationwide Analysis

Brijesh Patel DO*[1], Philip Carson MD*[1], Mahek Shah MD[1], Lohit Garg MD[1], Manyoo Agarwal MD[2], Sahil Agrawal MD[3], Shilpkumar Arora MD[4], Susan Steigerwalt MD[5], Anthony Bavry MD MPH [6], Raman Dusaj MD[1], Nainesh Patel MD[1], Bruce Feldman DO*[1]

*Contributed equally to the manuscript

[1] Divison of Cardiology, Lehigh Valley Hospital, Allentown, PA

[2] Divison of Internal Medicine, Memphis, TN

[3] Divison of Cardiology, Bethlehem, PA

[4] Divison of Cardiology, Mount Sinai St. Luke's Roosevelt Hospital, New York, NY

[5] Divison of Nephrology, University of Michigan School of Medicine, Ann Arbor, MI

[6] Division of Cardiology, University of Florida, Gainesville, FL

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Corresponding author

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Brijesh Patel, DO
Lehigh Valley Health Network
1250 S Cedar Crest Blvd, Suite 300
Allentown, PA 18103
Email: b2patel@gmail.com

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Abstract

Background

Chronic kidney disease (CKD) is a well-known risk factor for coronary artery disease and is associated with poor outcomes following an acute coronary syndrome (NSTE-ACS). The optimal timing of an invasive strategy in patients with CKD and NSTE-ACS is unclear.

Method

We queried a National Inpatient Sample database (NIS) to identify cases with NSTEMI and CKD. Patients who underwent percutaneous coronary intervention (PCI) Day 0 or 1 vs. Day 2 or 3 after admission were categorized as early vs. delayed PCI, respectively. The primary outcomes of the study were in-hospital mortality and acute kidney injury requiring hemodialysis (AKI-D). The secondary outcomes were length of stay and hospital charges. Baseline characteristics were balanced using Propensity Scores Matching (PSM).

Results

After PSM, 3708 cases from the delayed PCI group were matched with 3708 cases from the early PCI group. The standardized mean differences between the two groups were substantially reduced after PSM. All other recorded variables were balanced between the two groups. In the early and delayed PCI groups, the incidence of AKI-D (2.5% vs. 2.3%; p=0.54) and in-hospital mortality (1.9% vs. 1.4%; p=0.12) was similar. Hospital charges and length of stay were higher in delayed PCI group.

Conclusion

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The incidence of AKI-D and in-hospital mortality among patients with CKD and NSTE-ACS was not significantly affected by the timing of PCI. However, delayed PCI added significant cost and length of stay. A prospective randomized study will be required to validate this concept.

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INTRODUCTION

The optimal timing of coronary angiography and revascularization for patients with chronic kidney disease (CKD) presenting with an acute non-ST elevation acute coronary syndrome (NSTE-ACS) is controversial. There are no studies examining the effect of an early versus delayed strategy for these patients on short-term outcomes such as in-hospital mortality and acute renal failure requiring dialysis (AKI-D). Although the current NSTEMI guidelines recommend an invasive strategy for patients with CKD and no other serious comorbidity or contraindication to the procedure, there are no specific recommendations on optimal timing.[1] The European guideline recommends an early invasive strategy for the high risk patient, wherein moderate to severe renal dysfunction is considered an intermediate risk factor.[2]

Many studies have shown that early invasive strategy, compared to a delayed invasive treatment strategy, reduces the incidence of cardiovascular death and myocardial infarction, while others have demonstrated no significant difference.[3-10] The concern with an immediate strategy is that early intervention on unstable plaque can lead to coronary emboli and microvascular obstruction. The concern of delayed invasive approach is it places patients at risk for recurrent ischemia and infarction. Very recently, a published meta-analysis concluded that an early invasive strategy does not reduce the risk for death of myocardial infarction compared with a delayed strategy.[11] However, none of the published studies examined the effect of an early versus delayed strategy on outcomes in patient with chronic kidney disease. To assess the value of early vs delayed PCI in patients with CKD and NSTEMI, we analyzed a large national

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database, comparing the incidence of acute kidney injury requiring dialysis (AKI-D) and in hospital mortality.

Method

We queried the National Inpatient Sample (NIS) from 2010 to 2014 to identify patients with CKD and NSTEMI. The NIS is part of the Healthcare Cost and Utilization Project and represents approximately 20% of all in-patient admissions from participating hospitals.[12] The publicly available database contains de-identified patient information. It provides International Classification of Diseases, ninth revision (ICD 9) diagnoses, procedure codes, demographic information and patient discharge status. It also contains Clinical Classification Software (CCS), which are clusters of similar diagnoses that can be used to identify diagnoses or procedures. Conditions such as obesity, hypertension, peripheral vascular disease, depression, fluid and electrolyte disorders, coagulopathy, chronic pulmonary disease and diabetes are also included in the database as Elixhauser comorbidities. Refer to Table 1 for ICD 9 diagnosis and procedure codes, and CCS used in the study.

We identified a cohort of patients with CKD who underwent PCI for NSTEMI. Patients with CKD were identified using ICD 9 codes 585.1-585.5 and 585.9. We included patients with NSTE-ACS who underwent PCI with bare metal or drug eluting stent(s), were age 18 or older. Patients with concomitant diagnosis of ST-elevation myocardial infarction were excluded. We

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restricted our cohort to those undergoing PCI. Patients undergoing PCI day 0 or 1 after admission were categorized as the early PCI group; patients undergoing PCI day 2 or 3 after admission were categorized as the delayed PCI group. Patients undergoing cardiac surgery during the same admission were excluded. When a patient underwent PCI on two separate days, the first day of stenting was considered the index day of the procedure. Patients whose index procedure day of stenting was on or after the fourth day of admission or had staged PCI any time after the index PCI during the same hospitalization were also excluded from the study. Elective admissions and cases with missing values for age, race, mortality data and timing of PCI were excluded (Table 2).

There is no single ICD9-CM code for contrast associated nephropathy (CIN). To identify patients with CIN requiring dialysis we used ICD 9 codes for acute kidney failure (AKI) plus ICD 9 codes for dialysis. We excluded patients who only had ICD 9 code for ESRD or a procedure code for dialysis without the mention of AKI. The primary outcomes of interest were in-hospital mortality and AKI-D. The secondary outcomes were total charges and length of stay.

Statistical Analysis

The statistical analysis was performed on IBM SPSS, version 24 (IBM Corporation, Armonk, NY, USA). For Propensity Score Matching (PSM), we used 1:1, logistic algorithm, nearest neighbor variable within caliper width of 0.01. Cases were matched for "Delayed" with

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"Early" group. The following variables were entered in the PSM algorithm: age, race, gender, weekend admission, prior history of myocardial infarction, smoking, dyslipidemia, diabetes mellitus, acute cerebrovascular accident, prior history of revascularization, chronic aspirin use, acute kidney injury, cardiogenic shock, chronic lung disease, coagulopathy, depressive disorders, hypertension, obesity, ventricular arrhythmias, fluid and electrolytes disorders and peripheral vascular disease. Since we analyzed more than one year of data, we included years 2010 to 2014 into PSM to control for year-to-year variations. We used unweighted, matched cases for further analysis and reported both before and after PSM data. Categorical and continuous variables were analyzed with chi-square and Mann-Whitney U test. A two-sided p-value of less than 0.05 was considered statistically significant. The categorical variables were reported as percentages, and continuous variables as median with interquartile range.

Results

Baseline Characteristics and Propensity Score Matching Analysis

The initial cohort prior to PSM included 7,705 unweighted cases in the early PCI and 3,946 cases in the delayed PCI group. After PSM, 3,708 cases were selected out of 3,946 cases (94%), and were matched with 3,708 cases from the early PCI group. The median age of the patients for both groups were 73 years. A higher proportion of patients admitted on weekends were more likely to have delayed PCI (34.9% vs. 17%; $p<0.001$). Before PSM, Caucasians, weekend admissions, acute kidney injury, chronic pulmonary disease, fluid and electrolyte

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disorders, and diabetics were proportionally higher in the delayed PCI group. The presence of dyslipidemia and cardiogenic shock were higher in the early PCI group patients. Otherwise, remaining variables, including year to year grouping were not statistically significant between the two groups (Table 2). After PSM, there was no statistical difference between the two groups, and standardized mean differences substantially reduced for all variables (<5%).

Outcomes

Before PSM, there was no statistically significant difference between the early and the delayed PCI group for in-hospital mortality (1.8 vs. 1.5%; p=0.19), or AKI-D (2.2 vs. 2.3%; p=0.83). The secondary outcomes, median total charges and length of stay were higher in the delayed groups ($77,616 vs. $68,413; p<0.001) and (4 vs. 3 days; p<0.001), respectively. After PSM, there was no statistically significant difference for in-hospital mortality (1.9 vs. 1.4%; p=0.12) or AKI-D (2.5 vs. 2.3%; p=0.54). The delayed PCI group had higher median cost ($77,529 vs. $70,554; p<0.001) and longer length of stay (4 vs. 3 days; p<0.001). (Table 3).

Discussion

Among the cohort of patients with CKD and NSTE-ACS identified in this large national database, early PCI was not associated with a significant increase in the incidence of AKI-D or in hospital mortality compared to delayed PCI. Early PCI was associated with reduced hospital charges and length of stay. Patients with chronic kidney disease are more likely to have significant comorbidities including diabetes mellitus, prior heart failure, prior MI, peripheral arterial disease and prior revascularization compared to those with normal renal function.[13]

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Among patients undergoing PCI, these comorbidities are associated with a high risk of adverse events including severe bleeding, the need for dialysis and in-hospital mortality.[13-15]

Patients with chronic kidney disease are a vital group to examine since CKD is strongly associated with in-hospital mortality and bleeding in NSTEMI patients undergoing PCI.[13-15] A subgroup analysis of the TACTICS-TIMI 18 study examined the interaction between creatinine clearance (CrCl), outcomes, and the use of an early invasive management strategy. They found that in patients with a mild to moderate decrease in renal function, early invasive management was superior to conservative approach.[17] The study was, however, limited to patients with creatinine <2.5mg/dl as the original trial excluded patients with serum creatinine >2.5mg/dl. In TIMACS trial, early intervention improved the composite outcome of mortality, MI and stroke at 6 months.[5] But, renal function was not identified in this study. We did not observe any mortality benefit based on timing of PCI. Although the early PCI group had higher prevalence of cardiogenic shock, there was no difference in the unadjusted mortality rate between the two groups (3.3 vs. 2.1%). After adjusting for cardiogenic shock, the mortality difference between the two group was not significant. We believe that low incidence, and 1.1% absolute difference of cardiogenic shock patients between both groups would not have significantly impacted the mortality. Moreover, comorbidity burden between the two groups is statistically insignificant, except for diabetes, dyslipidemia and acute renal injury, suggesting that the patient population in the two groups is similar.

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Chronic kidney disease is the greatest risk factor for contrast induced nephropathy.[19,20] AKI after angiography is a significant risk factor for long term mortality and end stage renal disease requiring dialysis.[19] Utilizing the NCDR Cath-PCI registry Tsai et al reported CKD was associated with a 2 to 28-fold increased risk of AKI-D.[14] Their study reported a 0.07% incidence of AKI-D post PCI in patients with normal renal function, compared to 4.3% in patients with severe CKD. Importantly, they observed AKI-D after PCI was associated with increased mortality.[16] We observed a lower incidence of AKI-D because our cohort consisted of all stages of CKD. The ACC/AHA/SCAI guidelines recommend hydration for 3-12 hours prior to undergoing angiography with contrast media.[14] Hydration and minimizing the dose of contrast administered are proven to reduce the risk of CIN.[21] A prospective study showed a very low (2.4%) incidence of CIN in patients who received guideline recommended hydration pre-contrast administration. None of their 747 patients required dialysis. In contrast, a recently published randomized trial showed that the rates of CIN were identical between patients who received IV hydration vs those who did not.[22] They also found that IV hydration added to cost and length of stay. A single -center retrospective coh participants with a high ratio of hydration volume to weight actually had higher rates of CI -AKI and worse outcomes overall.[23] Their findings challenge the established concept that IV hydration prevents CIN and suggest that it may even cause harm. However, these studies did not disclose if they analyzed patients with CKD. Many experts still insists that IV hydration is still the standard

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of care in patients with CKD.[24] Though we could not determine if patients in the delayed PCI group received adequate hydration, the delay did not reduce the incidence of post PCI AKI-D .

There are no randomized controlled trials evaluating the value of an early versus a delayed invasive strategy in patients with NSTEMI and CKD. The Optimized Procedure in Patients with NSTEMI and CKD (NSTEMI-CKD) trial was attempted (NCT02543177), but was terminated early due to poor enrollment.[25] Our retrospective analysis of a large population of patients with NSTEMI and CKD suggests cardiac catheterization and PCI should not be delayed because of renal dysfunction. A prospective randomized trial will be required to test this hypothesis.

There are important limitations to this study. The study was based on a database which may have errors in the assignment of appropriate diagnosis/procedure codes. Although we used propensity score matching to correct for confounding factors, the result may have been influenced by the nonrandomized assignment and inability to correct for confounding factors that were not included in the algorithm. We could not determine the clinical reasons influencing the timing of PCI. The delayed PCI group included patients with a significantly higher proportion of comorbidities including diabetes, fluid and electrolytes disorders, acute kidney injury and weekend admission. The creatinine level or glomerular filtration rate at the time of PCI is a critical piece of information that is not provided in database. Furthermore, a large proportion of patients had “unspecified” CKD (ICD 9 code: 585.9), therefore, a subgroup analysis of CKD stages was not practical. These factors could have influenced the timing of cardiac

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catheterization. One of the determinants of AKI-D is the volume of contrast. We could not control this variable because the information was not available in the database. All these limitations may have been minimized by PSM. After PSM, the net difference between the groups was significantly reduced, measured by standardized mean difference, mitigating the influence of the comorbidities on the timing of PCI.

Conclusion

Among patients with CKD and NSTE-ACS the incidence of AKI-D and in-hospital mortality was not significantly affected by the timing of PCI. However, delayed PCI added significant cost and length of stay. These findings suggest early PCI in patients with NSTEMI and CKD may be a preferred strategy. A prospective randomized study will be required to validate this concept.

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Table 1: Diagnosis and Procedure Codes

Table 2: Inclusion and Exclusion criteria

Table 3: Patient Characteristics Before and After Propensity Score Matching

Table 4: Outcomes of Patients Before and After Propensity Score Matching

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Table 2: Inclusion and Exclusion criteria

Table 1: Diagnosis and Procedure Codes	
Diagnosis or Procedure	**ICD9-CM or CCS codes**
Inclusion criteria	
Non-ST elevation myocardial infarction	410.7, 410.70-410.72, 411.1
Chronic kidney disease	585.1-585.5, 585.9
Bare metal and drug eluting stents	36.06, 36.07
Exclusion criteria	
End-Stage Renal Disease	585.6
Dialysis	39.95, 54.98
Valvular or coronary bypass surgery	Procedure CCS: 43 and 44
ST-elevation myocardial infarction	410.x1 (410-01-410-91)
Comorbidities	
Prior myocardial infarction	412
Smoking	V15.82, 305.1
Dyslipidemia	CCS code: 53
Acute cerebrovascular accident	CCS code: 109
Prior revascularization	V45.81, V45.82
Chronic aspirin use	V58.66
Acute kidney injury	584, 585.4-585.9
Family history of coronary artery disease	V17.3
Cardiogenic shock	785.51
Ventricular Arrhythmias	427.1, 427.4, 427.41, 427.42

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Inclusion Criteria
Age e 18 years
Chronic kidney disease
Percutaneous coronary intervention (PCI)
Non-ST elevation myocardial infarction
Exclusion Criteria
Missing information for in-hospital mortality data and timing of PCI
Elective admissions
End-stage renal disease without mention of acute kidney injury
ST-elevation myocardial infarction
Valvular or cardiac bypass surgery during the same admission
Pre-admission, index PCI on or after fourth day of admission
Repeat procedure (staged PCI) after index procedure

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Table 3: Patient Characteristics Before and After Propensity Score Matching						
	Before Matching			After Matching		
	Early PCI	**Delayed PCI**	**p-value**	**Early PCI**	**Delayed PCI**	**p-value**
Variables	n= 7705	n=3946		n=3708	n= 3708	
Age in years, median (IQR)	73 (64-80)	73 (65-81)	0.003	74 (65-81)	73 (65-81)	0.26
Caucasians, %	70.7	72.5	<0.001	73.1	72.1	0.76
Weekend admission, %	17.0	34.9	<0.001	30.6	30.9	0.76
Females, %	35.5	37.1	0.1	37.7	36.9	0.49
Chronic pulmonary disease	22.4	25.1	0.001	24.8	24.8	0.98
Coagulopathy	4.9	5.3	0.26	5.4	5.3	0.84
Depression	8.7	8.8	0.79	8.9	9.0	0.87
Hypertension	88.6	88.2	0.52	87.9	88.3	0.64
Fluid and electrolyte disorders	20.9	28.6	<0.001	26.8	27.8	0.36
Acute cerebrovascular accident	0.8	0.9	0.65	1.0	0.9	0.81
Obesity	20.5	20.8	0.68	21.0	20.9	0.93
Peripheral vascular disease	20.9	22.3	0.08	21.7	22.0	0.76
Diabetes Mellitus	57.0	59.9	0.003	59.1	59.5	0.74
Prior myocardial infarction	19.5	19.4	0.9	18.2	19.3	0.25
Smoking	34.0	33.2	0.39	34.1	33.3	0.46
Dyslipidemia	76.8	73.4	<0.001	72.9	74.1	0.23
Prior revascularization	33.8	34.1	0.76	33.3	33.8	0.59
Chronic aspirin use	19.8	19.5	0.68	19.9	19.6	0.75
Family history of CAD	8.1	7.6	0.39	7.6	7.6	1.00
Ventricular arrhythmia	4.7	5.0	0.54	5.1	4.8	0.56
Cardiogenic shock	3.3	2.1	<0.001	2.2	2.1	0.81
Acute kidney injury	31.8	39.9	<0.001	39.3	38.6	0.52
Year						
2010	14.2	13.5	0.34	13.5	13.3	0.84
2011	19.1	18.4		18.9	18.6	
2012	20.6	21.3		20.7	21.5	
2013	22.6	23.6		22.7	23.5	
2014	23.5	23.2		24.2	23.1	
CAD= coronary artery disease; IQR= Interquartile range; PCI= percutaneous coronary intervention						

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Table 4: Outcomes of Patients Before and After Propensity Score Matching				
Before Matching				
Variables	**Early stenting n= 7705**	**Delayed stenting n= 3946**	**Odd Ratio (95% CI)**	**p-value**
Died	1.8	1.5	0.81 (0.60-1.11)	0.19
Dialysis, %	2.2	2.3	1.03 (0.80-1.33)	0.83
Total charge in US dollar, (IQR)	68413 (48400-98889)[a]	77616 (55914-111156)[b]	-	<0.001
Length of stay in days (IQR)	3 (2-4)[a]	4 (3-6)[b]	-	<0.001
After Matching				
Variables	**Early stenting n= 3708**	**Delayed stenting n= 3708**	**Odd Ratio (95% CI)**	**p-value**
Died	1.9	1.4	0.75 (0.53-1.08)	0.12
Dialysis, %	2.5	2.3	0.91 (0.68-1.23)	0.54
Total charge in US dollar, (IQR)	70554 (50187-101885)[c]	77529 (55820-110470)[d]	-	<0.001
Length of stay in days (IQR)	3 (2-5)[c]	4 (3-6)[d]	-	<0.001
a=7568, b=3890, c=3638, d=3655; CI= confident interval, IQR= Interquartile range				

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