

Study of Risk Factors and Applicability of Mehran Risk Score in Predicting Contrast Induced Nephropathy in Patients Undergoing Percutaneous Coronary Intervention Patients – A Prospective Observational Cohort Study

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Abstract

Background: Contrast induced nephropathy (CIN) is a grave but underdiagnosed complication of percutaneous coronary intervention that is associated with increased in-hospital morbidity and mortality. Our aim was to study the incidence, risk factors of CIN and applicability of Mehran risk score (MRS) in Indian population.

Methods: A total number of 432 patients were enrolled in the study. Patients of age ≥ 18 years with known CAD, ACS who underwent PCI were included. Patients were followed for development of CIN.

Results: Mean eGFR of 88.4 ± 30.65 ml/min/1.73 m² and mean contrast volume usage of 122.8 ± 41.9 ml. 64 patients (14.8%) developed CIN. On univariate analysis, age (p 0.435), gender (0.125), hypertension (0.679), diabetes (0.177), contrast volume (0.155) were not associated with development of CIN whereas, smoking (0.021), hypotension (<0.001), heart failure (<0.001), anemia (0.001) and median eGFR (p < 0.001) were significantly associated with development of CIN. The incidence of CIN was 2.7 fold higher (OR : 2.68, 95% CI : 1.299-5.540, p = 0.008) in the intermediate group (MRS 6-10), 5.4 fold higher (OR : 5.403, 95% CI : 2.249-12.978, p < 0.001) in the high risk group (MRS 11-15) and 51 fold higher (OR : 51.059, 95% CI : 18.195-143.278, p < 0.001) in the very high risk groups (MRS > 16) when compared to the low risk group (MRS < 5) respectively.

Conclusions: The incidence of CIN in the very high risk group (MRS > 16) was substantially higher in our study (77.8 %) as compared to same group in Mehran study (57.3 %).

Keywords: contrast induced nephropathy; mehran risk score; acute coronary syndrome; percutaneous coronary intervention

Abbreviations:

ACE Angiotensin converting enzyme

ACS Acute coronary syndrome

AKI Acute kidney injury

AKI-D Acute kidney injury requiring dialysis AMI Acute myocardial infarction

ARF Acute renal failure

BUN Blood urea nitrogen

CAG Coronary angiography

CHF Congestive heart failure
 CIN Contrast induced nephropathy
 CKD Chronic kidney disease
 CM Contrast media
 CS- CIN Clinically significant contrast induced nephropathy
 e- GFR Estimated glomerular filtration rate
 LVEF Left ventricular ejection fraction
 MRS Mehran risk score
 NSTEMI Non ST segment elevation myocardial infarction
 PCI Percutaneous coronary intervention
 STEMI ST segment elevation myocardial infarction

Introduction

Coronary heart disease is one of the leading causes of death worldwide and remains a substantial contributor to morbidity, mortality and healthcare expenditure. One of the modalities of treatment is revascularization using percutaneous coronary intervention (PCI). Advances in PCI technology have resulted in increasing numbers of patients undergoing coronary revascularization via this approach [1]. However, the use of such contrast media might result in acute events and injuries after the procedure. Contrast-induced acute kidney injury (CI-AKI) is a prevalent but underdiagnosed complication of PCI that is associated with increased in-hospital morbidity and mortality [2-5].

Acute kidney injury (AKI) in the setting after contrast media (CM) administration derives from many causes including ischemia, atheroembolism, or nephrotoxicity of the contrast media itself. The latter is referred to as contrast induced nephropathy (CIN) [6]. Contrast induced nephropathy is generally defined as an increase in serum creatinine concentration of > 0.5 mg/dl (>44 $\mu\text{mol/L}$) or 25% above baseline within 48 hours after contrast administration [7]. It occurs within 24-48 hours of exposure, with creatinine level typically peaking 3-5 days after procedure and returning to baseline or near baseline value in 1-3 weeks [8].

Several factors are associated with the development of AKI. Dehydration, congestive heart failure, advanced age, chronic kidney disease (CKD), anemia and diabetes mellitus are examples of potential predisposing factors. A number of these risk factors have been integrated into a well-known post-procedure risk scoring system and validated in a large cohort study by Mehran et al. We also tried to identify if the Mehran Risk Score (MRS) could be used to accurately predict the incidence of CIN in patients belonging to the respective risk groups in an Indian population. It should be noted that the well validated MRS was formulated in a western population where the incidence of CIN was found to be 13.1%. The population in the Indian subcontinent has higher atherogenic burden with a higher incidence of risk factors for CIN.

Aims and objectives

1. To study the incidence of contrast induced nephropathy (CIN) in post percutaneous coronary intervention patients.
2. To study the predictors of contrast induced nephropathy in these patients.
3. Applicability of Mehran risk score (MRS) in predicting the contrast induced nephropathy.

Materials and methods

Study Design: Prospective Observational Cohort Study
 Study Period: March 2019 to March 2020.

Recruitment and method: This study was done after explaining the study details in a language understandable to the patient. The patient was provided with information sheet and consent form. Informed consent was taken from the patients who were willing to get enrolled in the study.

A total number of 432 patients were enrolled in the study.

Inclusion Criteria

1. Patients (age ≥ 18 years) with the diagnosis of acute coronary syndrome (ACS).
2. Case of Coronary artery disease (CAD) who will be admitted to undergo percutaneous coronary intervention (PCI), between March 2019 and March 2020.

Acute coronary syndrome (ACS) diagnosis was based on fourth universal definition of myocardial infarction defined by standard criteria of elevation of cardiac troponin levels with presence of atleast one of the following - chest pain, ischemic changes in ECG, imaging evidence of new regional wall motion abnormality or identification of coronary thrombus by angiography.

Exclusion criteria

1. Pregnancy
2. Contrast media (CM) allergy
3. End stage kidney disease and on regular dialysis
4. Cardiogenic shock
5. Unwillingness to give consent.

Baseline characteristics Demographic data (age, sex), risk factors and indication for intervention was collected. Cardiac catheterization and PCI was performed in accordance with established clinical practice using standard diagnostic and guide catheters, wires, balloon catheters, and stents via the femoral/radial approach. The amount of contrast media administered was decided by the interventional cardiologist.

All patients were admitted to the hospital one day before cardiac catheterization. Risk stratification for development of CIN was calculated for all patients using the Mehran risk score. The risk score included hypotension (5 points, if systolic blood pressure <80 mm Hg for at least 1 h requiring inotropic support), use of intra-aortic balloon pump (5 points), congestive heart failure (5 points, if class III/IV by New York Heart association classification or history of pulmonary edema), age (4 points, if >75 years), anemia (3 points, if hematocrit $<39\%$ for men and $<36\%$ for women), diabetes mellitus (3 points), contrast media volume (1 point per 100 mL), estimated glomerular filtration rate (GFR; GFR in mL/min per 1.73 m²; 2 points, if GFR 60–40; 4 points, if GFR 40–20; 6 points, if GFR <20). A risk score of <5 , 6–10, 11–15, and >16 indicates a risk for CIN of 7.5%, 14%, 26%, and 57%, respectively.

Serum creatinine concentrations and GFR was determined at hospital admission (prior to the procedure), and at 24 hours and 48 hours after the procedure. The changes of serum creatinine level was analyzed. The eGFR was calculated according to the Modification of Diet in Renal Disease (MDRD) formula. CIN was defined as an increase in the serum creatinine level of more than 0.5 mg/dl or more than 25% from baseline within 48 hours after procedure without any other identifiable cause of acute kidney injury.

Outcomes

Number of patients who developed CIN post percutaneous coronary intervention (incidence of CIN) was measured by change in serum creatinine concentration.

Statistical Analysis

Data was entered in a Microsoft Excel spreadsheet and analysed using STATA 15. Continuous variables were summarized as mean and standard deviation. Categorical variables were summarized as percentage. Incidence of CIN was reported in percentage along with its 95%

confidence interval. Unadjusted Odds Ratio was reported for each individual risk factor. Chi-square test for independence was used to test the relationship between two categorical variables. A multivariate binary logistic regression model was used to assess the independent effect of potential risk factors on CIN. Adjusted odds ratio was reported along with their 95% confidence intervals. Two sided p values were reported and a p value <0.05 was considered as statistically significant.

Results

In our study, 432 patients who were enrolled for the study underwent percutaneous coronary intervention and were followed for the development of CIN. 132 patients who underwent optical coherence tomography (OCT) guided percutaneous coronary intervention were also included in the study. (Table 1)

Variable	Percentage/Mean
Age (years)	57.2 + 10.43
Males (%)	80.6
Hypertension (%)	59.5
Diabetes (%)	48.1
Smoking (%)	48.1
Anemia (%)	24.1
Heart failure (%)	22
eGFR (ml/min/1.73 m ²)	88.4 + 30.65
Contrast volume (ml)	122.8 + 41.9
Mehran risk score	5.44 + 4.78

eGFR Estimated glomerular filtration rate, Contrast volume (ml)

Table 1: Baseline characteristics and risk factors for Contrast induced nephropathy.

Values are given n (%), mean± Standard deviation

Patients were categorized into four groups based on Mehran risk score (MRS) into low risk (MRS < 5), intermediate risk (MRS 6-10), high risk (MRS 11-15) and very high risk groups (MRS > 16). (Table 2).

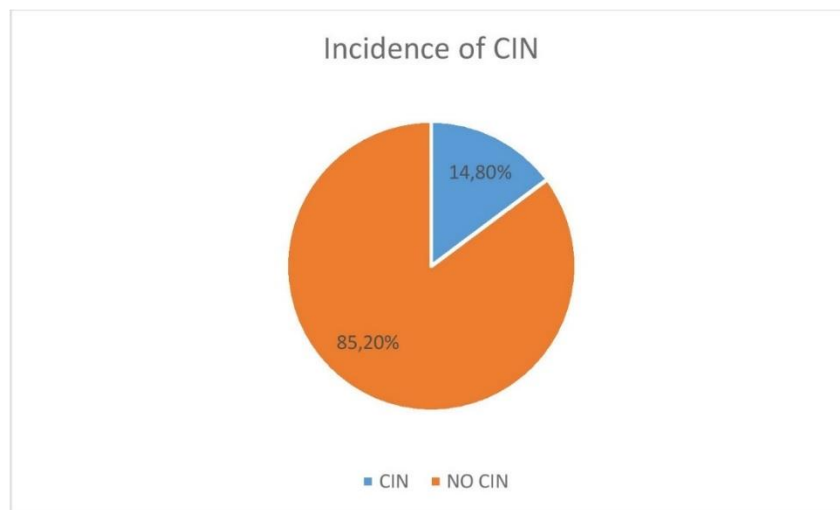
MRS	Risk category	N	Percentage (%)	Predicted risk of CIN from Mehran et al
< 5	Low	265	61.3	7.5 %
6-10	Intermediate	103	23.8	14 %
11-15	High	37	8.6	26 %
> 16	Very high	27	6.3	57.3 %
Total		432	100	

MRS Mehran risk score, n no of patients, CIN contrast induced nephropathy.

Values are given n (%), mean± Standard deviation

Table 2: Categorization of patients based on Mehran Risk score

The patients were followed for the development of CIN. Majority of the patients (61.3 %) belonged to the low risk category (MRS < 5). Only 6.3 % patients belonged to very high risk category (MRS > 16). Among the 432 patients who were followed for development of CIN, only 64 patients (14.8%) developed CIN. (Figure 1)



Values are given n (%), mean± Standard deviation

Figure 1: Incidence of CIN.

Variable		Patient %	Incidence of CIN %	p value	Odds ratio (OR)	95 % CI for OR Lower Upper	
Age > 75 yrs	Yes	4.9	28.6	0.074	2.434	0.908	6.530
	No	9	14.1				
Sex	Male	80.6	13.5	0.125	1.625	0.879	3.005
	Female	19.4	20.2				
Hypertension	Yes	59.5	15.6	0.679	1.16	0.671	2.004
	No	40.5	13.7				
Diabetes mellitus	Yes	48.1	17.3	0.177	1.465	0.858	2.501
	No	51.9	12.1				
Smoking	Yes	48.1	10.6	0.021	.513	0.294	0.893
	No	51.9	18.8				
Hypotension	Yes	5.6	62.5	< 0.001	12.211	5.072	29.399
	No	94.4	12				
IABP	Yes	0.9	50	0.106	5.903	0.816	42.868
	No	99.1	14.5				
CHF	Yes	22	38.9	< 0.001	7.324	4.143	12.949
	No	78	8				
Anemia	Yes	24.1	25	0.001	2.544	1.456	4.444
	No	75.9	11.6				

Table 3(a): Univariate logistic regression analysis of various risk factors with development of CIN. p value < 0.05 is significant.

CIN contrast induced nephropathy, OR Odds ratio, CI Confidence interval, IABP Intra aortic balloon counterpulsation, CHF Congestive heart failure

Variable	p value	Odds ratio	95 % CI for odds ratio Lower Higher	
Age >75 yrs	0.660	1.312	0.392	4.392
Sex	0.310	1.493	0.689	3.233
Smoking	0.104	0.569	0.288	1.124
Hypotension	< 0.001	6.706	2.514	17.891
CHF	< 0.001	5.778	3.056	10.923
Anemia	0.047	1.926	1.009	3.677

CI Confidence interval, CHF Congestive heart failure

Table 3(b): Multivariate logistic regression analysis of categorical variables with the development of CIN. CHF Congestive heart failure. p value < 0.05 is considered significant.

When the categorical variables were adjusted for other covariables, it was found out that hypotension, congestive heart failure and anemia were significantly associated with development of CIN, and however, smoking was not significantly associated with development of CIN (p 0.104).

Estimated glomerular filtration rate (eGFR) with development of CIN

Among our study population of 432 patients, median eGFR was 96 ml/min/1.73 m² (Table 10). Out of these, 64 patients who developed CIN, median eGFR was 58 ml/min/1.73 m² and among the 368 patients who

didn't develop CIN had a median eGFR of 98 ml/min/1.73 m² and the difference between two groups was found to be statistically significant. (p < 0.001).

Among the 432 patients, who were enrolled in the study, the median use of contrast volume was 100 ml. Out of these who developed CIN, median use of contrast volume was 120 ml, whereas those who didn't develop CIN, median use of contrast volume was 100 ml, however, the difference was not statistically significant (p 0.155).

MRS subgroup	No of patients	CIN		Total
		No	Yes	
< 5	N	248	17	265
	% within MRS subgroup	93.6%	6.4%	100.0%
6-10	N	87	16	103
	% within MRS subgroup	84.5%	15.5%	100.0%
11-15	N	27	10	37
	% within MRS subgroup	73.0%	27.0%	100.0%
>16	N	6	21	27
	% within MRS subgroup	22.2%	77.8%	100.0%
Total	N	368	64	432
	% of total patients	85.2%	14.8%	100.0%

MRS Mehran risk score, CIN contrast induced nephropathy, N Number of patients

Table 4: Incidence of CIN across various MRS subgroups.

Patients were categorized into four MRS subgroups based on Mehran Risk Score (MRS) as low (< 5), intermediate (6-10), high (11-15), very high risk (> 16) and the incidence of CIN in each subgroup was 6.4%, 15.5%, 27 % and 77.8 % respectively. Higher Mehran risk score was associated with increased incidence of CIN, and the observation was statistically significant. ($p < 0.001$). Patients belonging to the low MRS risk subgroup had lowest incidence of CIN and those belonging to very high risk group had the highest incidence of CIN respectively. (Table 4)

The incidence of CIN was 2.7 fold higher (OR : 2.68, 95% CI : 1.299-5.540, $p = 0.008$), 5.4 fold higher (OR : 5.403, 95% CI : 2.249-12.978, $p < 0.001$) and 51 fold higher (OR : 51.059, 95% CI : 18.195-143.278, $p < 0.001$) in the intermediate (MRS 6-10), high (MRS 11-15) and very high risk groups (MRS > 16) when compared to the low risk group (MRS < 5). (Table 5). In our study of 432 patients, out of 64 patient who developed CIN, dialysis was required only in 2 (3.1 %) patients with p value of 0.022.

MRS subgroup	P value	Odds ratio (OR)	95 % CI for OR	
			Lower	Higher
Intermediate (MRS 6-10)	0.008	2.68	1.299	5.540
High (MRS 11-15)	< 0.001	5.403	2.249	12.978
Very high risk (> 16)	< 0.001	51.059	18.195	143.278

MRS Mehran risk score, OR Odds ratio, CI Confidence interval

Table 5: Tabulated form of higher likelihood of CIN in intermediate, high and very high risk groups as compared to the low risk group (MRS < 5) (reference group)

Discussion

In our study of 432 patients, who were followed for development of contrast induced nephropathy (CIN), 64(14.8%) patients developed CIN whereas 368 (85.2 %) patients didn't develop CIN. Mehran et al (2004)⁹ in their study found an incidence of 13.1 % of contrast induced nephropathy in post percutaneous intervention patients.

In our study, it was seen that with increasing MRS the observed risk of CIN was exponentially higher. Our study and Mehran study were compared for the incidence of CIN across various MRS subgroups, and it was found that the incidence of CIN across low, intermediate and high risk groups were comparable between our study and Mehran study, however, the incidence of CIN among very high risk group patients was substantially higher than the Mehran study. (Table 6)

	MRS < 5	MRS 6-10	MRS 11-15	MRS > 16
Our study	6.4 %	15.5 %	27 %	77.8 %
Mehran study	7.5 %	14 %	26 %	57.3 %

Table 6: Comparison of observed risk of CIN in our study versus expected risk of CIN based on Mehran risk score.

Mehran risk score was formulated and validated in the western population, but its applicability in the Indian population holds true as well. The incidence of CIN in the very high risk group (MRS > 16) was substantially higher in our study (77.8 %) as compared to same group in Mehran study (57.3 %). Our observation was further validated by Sanjai Pattu Valappil et al¹⁰ who conducted a study on the predictors of contrast induced nephropathy and the applicability of the Mehran risk score in high risk patients undergoing coronary angioplasty—A study from a tertiary care center in South India and found that the Mehran risk score prediction for CIN is pertinent even in Indian population, however, the risk of CIN in high risk Mehran groups is substantially higher in the Indian population than in the western population. The incidence of CIN in the very high risk group (MRS > 16) was 83.3 % in their study which was comparable to our study (77.8 %) but significantly higher than the Mehran study (57.3%).

Limitations of the study

1. This was a single center study which was conducted to analyze the incidence and predictors of CIN in patients undergoing percutaneous coronary intervention.
2. Other parameters for evaluation of post PCI renal dysfunction like Neutrophil galectin associated lipocalyn {NGAL}, Cystatin C and Kidney injury molecule-1 (KIM-1) were not included in this study.
3. Latest Mehran study protocol was not included in this study.
4. Very high risk group had less sample size.

Conclusion

In our study of 432 patients,

1. Incidence of contrast induced nephropathy was 14.8 %.

2. Predictability of Mehran risk score for contrast induced nephropathy is pertinent even in Indian population.
3. Very high risk groups (MRS > 16) have a substantially higher incidence of contrast induced nephropathy in Indian population as compared to western population, but the difference may be because of the less sample size in very high risk group in our study compared to the Mehran study.
4. Periprocedural hypotension, anemia, congestive heart failure and baseline eGFR were significant predictors of contrast induced nephropathy.
5. Contrast induced nephropathy was associated with requirement of renal replacement therapy.

Conflict of Interest: None declared.

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