Validation of Modified Contrast Induced Nephropathy Scoring System in Patient Undergoing Angiography and Precutaneous Coronary Angioplasty in Tertiary Care Centre

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Abstract:

Aim: The aim of the present study was estimate the incidence of contrast-induced nephropathy in a prospective cohort of consecutive patients undergoing coronary angiography and angioplasty.

Methods: An observational, analytical, cohort study was conducted in the Department of Cardiology of RIMS, Ranchi. The data collection was done from July 2021 to June 2022. Patients admitted to Coronary Care Unit of RIMS for Angiography and Angioplasty. A total of 800 consecutive patients undergoing CAG or PCI were enrolled in the study. Of them, 4 were lost to follow-up resulting in a total of 796 patients during a one-year period.

Results: The study participants comprised mostly males (68.7%) compared to females (31.3%). More than 90% of the participants were less than 75 years, 93.7%. About 10% of the participants had the history of diabetes mellitus and 12.6% had a history of hypertension. Congestive heart failure was present in only 5.3% of the participants. Out of 796 participants only 2 and 10 had the history of Tia or stroke and vascular disease respectively. Almost 70% of them had the history of unstable angina while 30% had suffered myocardial infarction. Angiography was conducted on most of the participants while 12.6% underwent PCI. The mean laboratory parameters conducted on the study participants before the intervention. The mean haemoglobin of the participants was 11.7, the serum creatinine was 0.902 mean serum uric acid was 5.68 while the serum urea was 15.3. The risk stratification of CIN based on age categories was insignificant statistically (p 0.22). Out of 42 participants who had congestive heart failure 18 developed contrast-induced nephropathy and this difference was statistically significant (p < 0.01).

Conclusion: The incidence of CIN was 2.62% in patients undergoing angiography or PCI, which is less than the reported average at national-level. CIN was common among patients undergoing PCI than angiography. The logistic model for predictor of contrast-induced nephropathy (chi square 182 (7), p<0.001) explains the 66.4% variance in CIN (Nagelkar R 2 66.4%). A multicentric study should planned to develop a scoring system for risk stratification of patients undergoing angiography or PCI.

Keywords: Contrast-Induced Nephropathy, Coronary Angiography, Angioplasty

Introduction

In the last few decades, the number of percutaneous coronary interventions (PCI) has increased significantly. The use of iodinate contrast media (CM) is essential for cardiovascular imaging and invasive coronary procedures. Contrast-induced nephropathy (CIN) might represent a potentially serious complication after the administration of iodinate CM. [1,2] The Second International Consensus Conference of the Acute Dialysis Quality Initiative (ADQI) group developed the RIFLE classification (Risk of Renal Dysfunction, Injury to the Kidney, Failure of Kidney function, Loss of Kidney Function and End-Stage Renal Disease), which defines CIN as a low glomerular filtration rate (GFR) or as urine excretion. [3,4]

However, nowadays, there are few studies that use this definition, with the most-used based on an increase in creatinine level. CIN can be simulated by several other diseases. Cholesterol embolism could lead to an impairment of renal function with

a similar presentation to CIN. However, the presentation of cholesterol embolism is more frequently subacute and becomes evident between 3 and 8 weeks after a procedure. Renal failure caused by atheroembolism characteristically occurs in older patients with diffuse atherosclerotic disease and multiple risk factors. Moreover, it is usually related to other clinical manifestations such as skin signs, Hollenhorst plaque, eosinophilia and hypocomplementemia. [5-8]

At least two significant processes are involved in its pathophysiology of contrast induced nephropathy: 1) vasoconstriction resulting in medullary hypoxia and 2) direct toxicity caused by the contrast media to renal tubular cells. This lead to decreased prostaglandin and nitric oxide induced vasodilatation, impaired endothelial function, increase in renal adenosine concentration, increase in oxygen free radicals in response to hyperosmotic load, increased intratubular pressure owing to contrast induced diuresis, increased urinary viscosity and obstruction of the tubules.

Two novel biomarkers have been proposed to identify early subclinical acute kidney injury (AKI) following contrast injection: Serum or urine neutrophil gelatinase-associated lipocalin (NGAL) levels and Serum Cystatin C levels. Prevention of CIN should start with identifying the patients at high risk, intravenous fluid volume loading with isotonic saline (normal saline) is the single most important measure. N-Acetylcysteine (NAC) has been widely used for the prevention of CIN in high risk patients other modalities are electrolytes balance, serial serum creatinine monitoring and temporary dialysis may be required in severe cases. Patients with CKD have a higher risk of cardiovascular events compared to the general population. [9-11] Cardiovascular disease accounts for more than half of end-stage renal disease (ESRD) deaths. [12] Reduced renal function has been seen to be independently associated with risk of death, cardiovascular events, and hospitalization in large, community-based populations. [11,13]

The aim of the present study was estimate the incidence of contrast-induced nephropathy in a prospective cohort of consecutive patients undergoing coronary angiography and angioplasty.

Materials and Methods

An observational, analytical, cohort study was conducted in the Department of Cardiology of RIMS, Ranchi. The data collection was done from July 2021 to June 2022. Patients admitted to Coronary Care Unit of RIMS for Angiography and Angioplasty. A total of 800 consecutive patients undergoing CAG or PCI were enrolled in the study. Of them, 4 were lost to follow-up resulting in a total of 796 patients during a one-year period. All patients were included in the study according to inclusion /exclusion criteria and informed consent was taken. The planned procedure was conducted on the patients and the tests (Serum creatinine and urea) were repeated on the patients after 48 hours. The data collection phase was started after ethical approval from the Institutional Ethical Committee.

Inclusion Criteria:

- Age > 18 years
- Undergoing coronary angiography or angioplasty in the Dept. of Cardiology RIMS.
- Calculated eGFR >15 ml/min/m2 by CKD EPI formula.
- Patients willing and consenting to be part of the study

Exclusion Criteria:

- e GFR <15 ml/min/m2 by CKD EPI formula.
- Patients on chronic peritoneal or haemodialysis treatment
- Hypersensitivity to radio opaque contrast media
- Concomitant causes of renal dysfunction i.e. sepsis, obstructive uropathy.

Study Tools:

A predesigned, pretested semi-structured performa containing different parameters including clinical evaluation and relevant investigations was used for data collection. Medical history included: questions on personal information and the duration of any disease or comorbidity. The baseline clinical, laboratory, ECG, 2d echo and procedural characteristics of the patients would be undertaken.

The following details were noted for each patient:

Independent Variables:

Age: Age in years

Gender: Male/ Female

Blood Pressure (systolic and diastolic) in mm of Hg: Blood pressure was measured in sitting posture after 15 mins of rest using a digital sphygmomanometer. All the prerequisites were fulfilled while taking the reading. A systolic blood pressure above 140 mm of Hg and diastolic blood pressure above 90 mm of Hg was labelled as hypertension. A systolic blood pressure of less than 80 mm of Hg was labelled as hypotension.

- History of congestive cardiac failure
- History of Previous TIA/ stroke
- History of vascular disease
- History of nephrotoxic medication
- History of diastolic dysfunction
- Left ventricular ejection fraction

Anaemia: Based on Hb reading; less than 12 for females and less than 13 for males

Random blood glucose level: Measured using a glucometer. The finger was pricked with the lancet and blood was collected on the test strip. The reading on the glucometer was noted. A blood glucose level of more than 126 mg/dl is marked as diabetes mellitus.

Type of Cardiac Disease:

- Myocardial Infarction or Unstable Angina
- Contrast Volume used (ml)
- Baseline and at 48 hours laboratory investigations:
- Serum creatinine (mg/dl)

Serum Uric Acid

- Blood urea
- Glomerular Filtration Rate (eGFR)

Dependent Variables:

Contrast-induced nephropathy: It is defined as an elevation of serum creatinine (Scr) of more than 25% or ≥ 0.5 mg/dl (44 μmol/l) from baseline within 48 h.

Mehran Score: Following eight variables are used for calculation of Mehran score:

i)   hypotension for more than 1 h requiring inotropes,

ii)   use of IABP within 24 h of the procedure,

iii)   CHF New York Heart Association (NYHA) class III or IV,

iv)   Age >75 years,

v)   Anemia with hematocrit value <39% for men and <36% for women,

vi)   Diabetes Mellitus,

vii)   Contrast volume (1 point for each 100 ml),

viii)   Baseline Serum creatinine >1.5 mg/dl (132 μmol/l).

Table 1: Risk stratification based on Mehran score

Total score	Risk stratification category
≤5	Low
6-10	Moderate
11-16	High
>=16	Very High

Statistical Analysis: The data was entered in Microsoft excel and all the analysis was done on STATA 12.0. The quantitative variables were summarised as mean (standard deviation) or median (IQR) depending on the normality of the data (visual inspection of Q-Q plot). The categorical variables are summarised as frequency and percentage. The univariate analysis was conducted to identify the individual risk factors.

Significant individual risk factors were used as independent variables and CIN as the dependent variable in the final logistic regression model. Forward step wise logistic regression analysis was used to elucidate the final risk factors with the strongest prediction of CIN.

Results

Table 2: Distribution of study participants based on background characteristics and comorbidities

Age categories	N	%
Less than or equal to 75 years	746	93.70%
More than 75 years	50	6.30%
Gender		
Female	249	31.3 %
Male	547	68.7 %
History of Diabetes Mellitus		
Absent	716	89.90%
Present	80	10.10%
History of Hypertension		
Absent	696	87.45%
Present	100	12.60%
History of CHF		
Absent	754	94.7 %
Present	42	5.3 %
History of TIA/Stroke		

The study participants comprised mostly males (68.7%) compared to females (31.3%). More than 90% of the participants were less than 75 years, 93.7%. About 10% of the participants had the history of diabetes mellitus and 12.6% had a history of hypertension. Congestive heart failure was present in only 5.3% of the participants. Out of 796 participants only 2 and 10 had the history of

Tia or stroke and vascular disease respectively. Almost 70% of them had the history of unstable angina while 30% had suffered myocardial infarction. Angiography was conducted on most of the participants while 12.6% underwent PCI. Most common type of Diastolic dysfunction was Type 1(63.1%). only 11 out of 796, were on Nephrotoxic medication. The left ventricular ejection fraction was less than 50%. In almost 30% of the participants, the most common route of intervention was radial compared to femoral (84.2% versus 15.6%).

Table 3: Baseline laboratory parameters of the study participants undergoing Angioplasty and PCI

Baseline laboratory investigations	Mean (SD)	95% CI	
		Lower Bound	Upper Bound
Mean Hemoglobin	11.7 (0.873)	11.7	11.8
Mean Creatinine	0.902 (0.151)	0.891	0.912
Mean Serum uric acid	5.68 (1.21)	5.6	5.76
Mean Serum Urea	15.3 (5.32)	15	15.7

The mean laboratory parameters conducted on the study participants before the intervention. the mean haemoglobin of the participants was 11.7, the serum creatinine was 0.902 mean serum uric acid was 5.68 while the serum urea was 15.3.

Table 4: Risk stratification of CIN based on age, Congestive Cardiac Failure, type of cardiac interventions, Cardiac disease and left ventricular ejection of study participants

Age categories		Contrast- induced Nephropathy		χ^2 (df)	P- value
		Absent	Present		
Mean age (SD)		58.14 (11.77)	64.11 (11.79)		0.0030
Age <75 years	Observed	714	32	1.49 (1)	0.222
	% within row	95.7 %	4.3 %		
Age > 75 years	Observed	46	4		
	% within row	92.0 %	8.0 %		
Total	Observed	760	36		
	% within row	95.5 %	4.5 %		
Congestive Heart Failure		Contrast- induced Nephropathy		χ^2 (df)	p- value
		Absent	Present		
Absent	Observed	736	18	151 (1)	<0.001
	% within row	97.6 %	2.4 %		
Present	Observed	24	18		
	% within row	57.1 %	42.9 %		
Total	Observed	760	36		
	% within row	95.5 %	4.5 %		
Type of cardiac intervention		Contrast- induced Nephropathy		χ^2 (df)	p- value
		Absent	Present		
Angiography	Observed	660	17	42.4 (1)	<0.001
	% within row	97.5%	2.5 %		
PCI	Observed	100	19		
	% within row	84 %	16 %		
Total	Observed	760	36		
	% within row	95.5 %	4.5 %		
Cardiac Disease		Contrast- induced Nephropathy		χ^2 (df)	p- value
		Absent	Present		
Myocardial Infarction	Observed	216	28	39.4 (1)	<0.01
	% within row	88.5 %	11.5 %		
Unstable Angina	Observed	544	8		
	% within row	98.6 %	1.4 %		
Total	Observed	760	36		
	% within row	95.5 %	4.5 %		
LEVF		Contrast- induced Nephropathy		χ^2 (df)	p- value
		Absent	Present		

Left Ventricle Ejection Fraction> 50%	Observed	548	8	40.6 (1)	<0.001
	% within row	98.6 %	1.4 %		
Left Ventricle Ejection Fraction< 50%	Observed	212	28		
	% within row	88.3 %	11.7 %		
Total	Observed	760	36		
	% within row	95.5 %	4.5 %		

The risk stratification of CIN based on age categories was insignificant statistically (p 0.22). Out of 42 participants who had congestive heart failure, 18 developed contrast-induced nephropathy and this difference was statistically significant (p < 0.01). Most of the participants underwent pci compared to angiography and all the participants who had developed contrast-induced nephropathy had undergone pci and this difference was statistically significant (p 0.02). Out of 36 participants who had developed contrast-induced nephropathy 28 of them had a history of myocardial infarction and this difference was statistically significant (p <0.001). Almost 3/ 4th of the participants who developed contrast-induced nephropathy had left ventricular ejection fraction less than 50% and this difference was statistically significant (p <0.001).

Table 5: Risk stratification of CIN based on Laboratory parameters among study participants

Base line Laboratory Parameters		CIN (-)	CIN (+)	Test- Statistics	degree of freedom	P-value
Haemoglobin	Mean	11.78	10.561	8.542	794	< .001
	(SD)	0.832	0.917			
Serum Creatinine	Mean	0.902	0.892	0.383	794	0.702
	(SD)	0.151	0.159			
Serum Urea	Median	16	13	1.725*	40.3	0.092
	IQR	9	6			
Uric acid	Median	5.5	5.75	2.612*	35.6	0.013
	IQR	1	1.5			
eGFR	Mean	107.44	108.13	-0.343	794	0.732
	(SD)	11.73	12.122			
Laboratory Parameters at 48 hours						
Serum Creatinine	Median	0.9	1.7	-11.185	35.4	< .001
	IQR	0.2	0.8			
Serum Urea	Median	18	19.5	-4.201	35.1	< .001
	IQR	8.25	39			
eGFR	Mean	106.682	85.27	11.192	794	< .001
	(SD)	11.251	10.432			
*Welch's statistics as Levene's test <0.005						

The lab parameters before and after the intervention among CIN and Non- CIN patients and statistically significant difference in baseline values of mean hemoglobin and uric acid was seen among the patients who developed CIN and those who did not developed CIN (p <0.001 & 0.013 respectively).

Table 6: Comparison of laboratory parameters pre- and 48 hours post intervention

Laboratory Parameters		Pre intervention	Post-intervention	Test- Statistics	degree of freedom	P-value
Serum Creatinine	Median	0.9	0.9	90236	794	< .001
	IQR	0.2	0.2			
Serum Urea	Median	16	18	12697	794	<0.001
	IQR	9	9			
eGFR	Mean	107.47	105.714	1.725*	40.3	<0.001
	(SD)	11.741	12.061			

The lab parameters before and after the intervention among study participants and statistically significant difference was observed between mean values of Serum creatinine, serum urea and eGFR (p <0.001). The median value of serum urea increased from 16 to 18 while that of eGFR decreased from 107.47 to 105.71. The serum creatinine, serum urea did not follow normal distribution therefore these are expressed as median and interquartile range and the difference in pre

and post-median values was assessed using   Wilcoxan Rank test of significance.

Table 7: Logistic model for prediction of Contrast-induced Nephropathy among study participants

Predictors	Unadjusted Odds ratio	95% Confidence Interval		P- value
		Lower	Upper	
Gender				
Female-Male	3.435	1.16221	10.153	0.026
Contrast volume	0.9912	0.96853	1.014	0.452
Route of intervention				
Femoral-Radial	7.6916	0.36991	159.93	0.188
Anaemia				
Present-Absent	0.048	0.01437	0.16	< .001
Diabetes Mellitus				
Present-Absent	20.0487	4.40527	91.243	< .001
Hypertension				
Present-Absent	2.2372	0.49294	10.153	0.297
GFR category				
<90- >90	28.3324	9.87999	81.247	< .001

The predictor of contrast-induced nephropathy (chi square 182 (7), p<0.001). The model explains the 66.4% variance in CIN (Nagelkar R 2 66.4%). The predictors found significant are gender, GFR <90, trans-femoral route of intervention, anaemia and diabetes. The male gender had 3.7 times odds of developing CIN compared to female. The trans-femoral route of intervention was 10. 85 times higher risk of developing CIN compared to trans-radial route. Similarly, the patients having GFR less than 90 were at 22.9 times more risk of developing CIN compared to those having GFR more than 90 the risk of developing CIN among Diabetics was 10.9 times more than non-diabetics.

Table 8: Relevance of Mehran risk score for prediction of CIN

Risk category based on Mehran Score	Contrast-Induced Nephropathy		Total
	Present	Absent	
Low (0-5)	08	670	678
Moderate (06-10)	12	72	84
High (11-15)	16	18	34
Total	36	760	796
Diagnostic accuracy of Cord blood toxic granules		Lower and upper bounds 95% CI	
Sensitivity	60.00%	56.52%- 63.48%	
Specificity	90.30%	88.19% - 92.4%	
Positive predictive value	14.29%	11.80%- 16.77%	
Negative predictive value	98.82%	98.05%- 99.59%	

The predictive measures of risk stratification based on Mehran Score against CIN. It can be deduced from the table that a total of 36 patients who had CIN, 16 were classified to have a high risk of developing of CIN (true positive). The sensitivity of Mehran score was calculated to be 60% and the specificity of was 90.3%. The positive predictive value depicts the ability of a test to correctly identify those who have the condition of interest. So, it can be observed that the PPV is only 14.3%. However, the ability of these tests to correctly identify those who do not have risk of CIN was 98.82%.

Discussion

Contrast induced nephropathy (CIN) is the Achilles heel of interventional cardiology. It carries significant morbidity and mortality. Despite burgeoning advances in the field of cardiac catheterization, and overall improvements in the hardware, scientists have been unable to tackle this serious complication. CIN is the acute worsening of renal function after parenteral administration of contrast media once other causes of deteriorating renal function have been excluded. CIN is currently the third most common cause of hospital acquired acute renal failure accounting for 10% of all cases. [14] The European Society of Urogenital Radiology {ESUR} defined CIN as an increase in the serum creatinine concentration of 0.5 mg/dL (44 mol/L) or 25% above the baseline within 48 h after contrast administration. [15]

Out of the total of 796 patients, 36 developed Contrast-Induced Nephropathy (CIN) resulting in an incidence of 4.5% of CIN. An incidence of 5.2%was reported in a study conducted in a tertiary care centre in South India. [16] While a study

conducted in Pune by Kumar et al, reported that the CIN incidence was 2.4%. [17] Unlike, the above findings, an incidence of 29% was reported in a study conducted in Trivandrum, Kerala. [18] In the current study, the males were predominant and most of them were aged less than 75 years. However, a significant age difference was noted in patients with CIN (64.1 (11.79)) and without CIN (58.14 (11.77)). A study conducted by Sashidharan M et al in South India reported almost similar findings; the Mean age of patients with CIN was 61.40±13.86 y (median- 63 y, range- 26-79 y) and for those without CIN, the mean age was 60.55±10.13 y (median- 61 y, range- 23-86 y). The study also reported that patients with risk factors such as hypertension (19/25, 76%), diabetes mellitus (17/25, 68%), patients who received less than 100 ml of contrast media (25/25, 100%, p0.001), and patients older than 75 years (6/25, 24%) were shown to have a higher incidence of CIN. [16] In our study, the mean baseline serum creatinine concentrations were 0.892 mg/dl in the CIN (+) group and 0.902 mg/dl in the CIN (-) group(p 0.702); however, the median serum creatinine concentrations at 48 hours were 1.7 mg/dl and 0.9 mg/dl, respectively, in the CIN (+) and CIN (-) groups, and there was a significant difference (p <0.001).

In the current study, it was observed that the femoral route was used opted for intervention in 28 of the participants out of 36 who developed CIN. Thus, femoral route was significantly associated with CIN (p <0.001). Similar findings were reported by Mann et al. who compared the radial technique with the femoral route for coronary stenting in patients with acute coronary syndromes and found that the former is more effective than the latter. The study involved 142 patients. [19] A CIN risk classification scoring system developed by Mehran et al [20] was used in the current study, with a higher score suggesting a higher risk of CIN. The average Mehran risk score of 3.29. A majority of the patients (678/796, 85.2%), were in the low-risk group, and 10.6% (84/796) in moderate group, compared to 4.3% (34/796) in the extremely high-risk group. It is emphasized that those in extremely high-risk category developed the CIN (16/34; 44.4%) compared to patients in moderate (12/36; 33.3%) and low risk category (08/36; 22.2%). But a few studies reported that those in very high Mehran risk category (score >15) had a lower incidence (2/25, 8 %) of CIN as compared to patients of high (4/25, 16 %), moderate (5/25, 20 %) and low (14/25, 56 %) Mehran risk categories.[21]

In the univariate analysis the risk factors identified to be significantly associated with CIN are congestive cardiac failure, mode of cardiac intervention, history of nephrotoxic medication, trans-femoral route of intervention, Anaemia,

diabetes mellitus, hypertension and low GFR<90. But the five predictors which were significantly associated in multivariate analysis were; female gender, trans-femoral route of intervention, Anaemia, diabetes mellitus and low GFR<90. Thus, the only factor found significant from Mehran's score was diabetes mellitus. This could be due to lower incidence of CIN in the present study. Although many studies have found Mehran's score reliable for predicting CIN incidence, its relevance has been challenged in a few French studies. [21-24] The predictive measures for low, moderate and high categories had a high specificity (90.3%) but a low sensitivity (60%). Almost similar findings were reported in studies from South- India. A systematic review on risk prediction models for CIN reveals that most of the models have only modest predictive ability and there is a need to develop better models for clinical decision making. [25]

Conclusion

The incidence of CIN was 2.62% in patients undergoing angiography or PCI, which is less than the reported average at national-level. CIN was common among patients undergoing PCI than angiography. CIN was more common among patients presenting with myocardial infarction than Unstable angina CIN developed more commonly among patients on whom intervention was done through trans-femoral route than trans-radial route. CIN was more common among patients with anaemia, diabetes mellitus and hypertension. The logistic model for predictor of contrast-induced nephropathy (chi square 182 (7), p<0.001) explains the 66.4% variance in CIN (Nagelkar R 2 66.4%). The predictors found significant are gender, GFR <90, trans-femoral route of intervention, anaemia, and diabetes. The mean Mehran score was 3.62 (2.5) and the sensitivity of the score was 60% and specificity was 90.3%. A multicentric study should planned to develop a scoring system for risk stratification of patients undergoing angiography or PCI.

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