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A STUDY ON ASSESSMENT OF INCIDENCE AND RELATED RISK FACTORS ASSOCIATED WITH CONTRAST-INDUCED NEPHROPATHY IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION

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ABSTRACT: Contrast-induced nephropathy (CIN) is a frequent cause of hospital-acquired acute kidney injury (AKI) and is associated with adverse clinical outcome. It occurs often among patients with multiple comorbidities and compromised renal function. This study is aimed to determine the prevalence of the risk factors associated with contrast-induced nephropathy in patients undergoing various percutaneous coronary interventions (PCI). A prospective observational cross-sectional study was conducted in a tertiary care hospital for 12 months. Patients undergoing PCI were recruited in accordance with the eligibility criteria. The baseline characteristics as well as laboratory and cath-lab procedure data, were obtained from their case files. The prevalence of risk factors among the patients was assessed using the Mehran score and the association of risk factors with CIN was analysed using binary logistic regression. CIN was prevalent in 30 (15%) out of 200 recruited patients. The prevalence of risk factors among the recruited patients was 8.5% aged > 75 yrs, 11% hypotensive, 9% requiring an intra-aortic balloon pump, 44% anaemic, 36% diabetic, and 4.5% having serum creatinine levels > 1.5mg/dL. The prevalence of patients with high, moderate and low risk for CIN was found to be 9.5%, 29.5%, and 60% respectively. CIN was prevalent among the patients undergoing PCI, with a significant prevalence of the risk factors for nephropathy. A significant association was established between pre-procedural elevated serum creatinine levels and CIN development. Contrast administration should be closely monitored, and preventive approaches should be practised in these patients for better patient outcomes.

INTRODUCTION: The development of Percutaneous Transluminal Coronary Intervention (PTCI) has been paramount in the early detection and intervention of cardiovascular disease leading to a significant reduction in the morbidity and mortality rate of cardiovascular disease.

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Most of these coronary interventions use contrast media (CM), which has notably increased over the past 40 years for better prognosis and medical care. Unfortunately, the use of contrast media has adversely led to the development of renal impairment.

This occurrence of renal injury secondary to the use of contrast media is called contrast-induced nephropathy (CIN) [1]. The criteria for diagnosing CIN is defined as acute renal impairment following exposure to contrast media, at least 44 mmol/ L (≥0.5 mg/dL) absolute rise in serum creatinine or

relative rise in serum creatinine of at least 25% from baseline within 48 hours with no other cause for renal injury [2]. Cardiovascular disease morbidity, which can be attributed to the current lifestyle, has led to an increase in contrast-based percutaneous coronary intervention; hence, CIN remains a substantial problem. The prospective study by Nash K *et al.* on hospital-acquired renal insufficiency (HARI) showed that 11% of the HARI resulted from contrast media use and is the third leading cause [3]. Often, renal injury due to contrast media use is ephemeral but can be acute enough for some patients to undergo dialysis and, rarely, renal damage can be permanent [4]. The in-hospital morbidity and mortality rate, cost of medical care, and hospital stay have been relatively increased in patients who develop CIN and is higher in patients requiring dialysis, as demonstrated in a number of studies conducted [5, 6].

In a general population, a cumulative incidence of CIN is recorded to be 1-2% [4]. Khalfallah M *et al.* conducted a study to determine the incidence of CIN among patients undergoing PCI, in which 59 out of 550 patients (10.6%) developed CIN [7]. In addition, a meta-analysis of twelve articles conducted by He H *et al* described the pooled incidence of CIN as 13.3% [8]. These studies further emphasise the rising incidence of CIN over the years, reiterating the requirement of urgent measures to prevent CIN, while reducing the morbidity and mortality of it. Although the relationship between renal injury following exposure to contrast media is clearly understood, there is no definitive treatment modality for CIN. Hence, identifying the risk for the development of CIN and preventing it is the cornerstone [4]. Several studies have identified the predisposing factors for developing CIN, which include volume and type of CM, dehydration, anaemia, nephrotoxic drug use, pre-existing renal failure, diabetes mellitus, age, congestive heart failure, renal transplant, haemodynamic instability and nephritic syndrome [9, 10]. Various pharmacological and non-pharmacological methods have been identified for the prevention of CIN. Hydration is the mainstay in the prevention of CIN. A randomized prospective trial by Trivedi *et al* reported that the incidence of CIN was lower in patients administered with IV fluids (0.9% saline) for 24 hrs starting 12 hrs before the percutaneous coronary intervention than in patients receiving unrestricted oral intake (3.7 % vs. 34.6%) [11]. Antioxidants (N-acetyl cysteine, ascorbic acid), vasodilators (theophylline, amlodipine, fenoldopam), statins, haemodialysis, and hemofiltration, have all been studied in the prevention of CIN but showed controversial results. Other preventive strategies include modifying the risk factors like administration of contrast media once the haemodynamic status is corrected [12, 13, 14]. Iso-osmolar and low osmolarity contrast use have a lesser incidence of CIN than high osmolar contrast; hence, high osmolarity contrast use is contraindicated [14, 15].

The risk of developing CIN increases with the number of risk factors. Hence, a number of risk stratification scoring systems have been developed to help clinicians and patients weigh the risks and benefits associated with CM exposure [16]. One such scoring system was developed by Bartholomew and his colleagues using eight variables which included creatinine clearance <60 mL/min, use of intra-aortic balloon pump (IABP), urgent coronary procedure, congestive heart failure (CHF), diabetes, hypertension, peripheral vascular disease, and contrast volume in 20,479 patients and the highest risk score had 17% of death, while 28% developed CIN [16]. Mehran et al. developed another risk scoring system, which is popularly used in risk prediction [16]. An odds ratio was derived from a multivariate logistic regression model based on which eight variables were allocated with integer scores [12]. The total of these scores is the additive risk in patients for developing CIN and requiring dialysis. These variables include hypotension, intra-aortic balloon pump, congestive heart failure, chronic kidney disease, diabetes, age >75 years, anaemia, and volume of contrast (Table 1). CIN was developed in 7.5% of the patients with a low-risk score and in 57.3% with a high-risk score **Table 2** [17].

TABLE 1: MEHRAN RISK-ASSESSMENT SCORE FOR PREDICTING CIN POST-PCI [17]

Risk Factor	Integer Score
Hypotension systolic blood pressure <80 mm Hg for at least 1 h requiring inotropic support with medications	5
Intra-aortic balloon pump use	5

CHF e class III–IV by the New York Heart Association classification and/or history of pulmonary edema	5
Serum creatinine (>1.5mg/dL or >133µmol/L)	4
Or estimated GFR in ml/min/1.73m^2 by Modification of Diet in Renal Disease formula	6 for <20, 4 for 20-40, 2 for 40-60
Age >75 years	4
Diabetes mellitus	3
Anaemia: baseline haematocrit value <39% for men and <36% for women	3
Volume of CM	1 for each 100mL used

TABLE 2: STRATIFICATION OF RISK FOR CIN POST-CIN BASED ON MEHRAN RISK ASSESSMENT SCORE [17]

Risk Score	Risk Category	Risk of CIN	Risk of Dialysis
0-5	Low	7.5%	0.04%
6-10	Moderate	14%	0.12%
11-15	High	26.1%	1.09%
≥ 16	Very high	57.3%	12.6%

Regardless of the volume of evidence on CIN and the importance of its prevention to decrease the morbidity and mortality rate and improve the quality of life in patients with existing cardiovascular disease, the use of risk assessment scores in clinical settings is limited. Thus, this study aims to assess the incidence of contrast-induced nephropathy along with the use of nephrotoxic agents in the development of CIN, the incidence of risk factors associated with the development of CIN among patients undergoing PTCI and to identify the patients at risk for it using Mehran risk assessment score.

METHODOLOGY:

Study Design: The study was a prospective observational study conducted at the Department of Cardiology, Tertiary care Hospital, Bengaluru for a period of 12 months from January 2021 to December 2021. The Scientific Ethics Committee, Tertiary care Hospital, Bengaluru approved the study.

Eligibility Criteria: The study population included adult patients above the age of 18 years with coronary artery disease (CAD) who were admitted for elective PCI in the Department of Cardiology, Mallya Hospital, Bengaluru. The creatinine clearance for all patients who had a serum creatinine measurement before and 24-48 h after the coronary intervention was calculated by the Cockcroft- Gault formula. Patients with end-stage renal failure with the need for haemodialysis were excluded to avoid confounding. These patients were prospectively evaluated for the development of CIN.

Data Collection Procedure: Patients from the Department of cardiac care unit were recruited based on the inclusion and exclusion criteria.

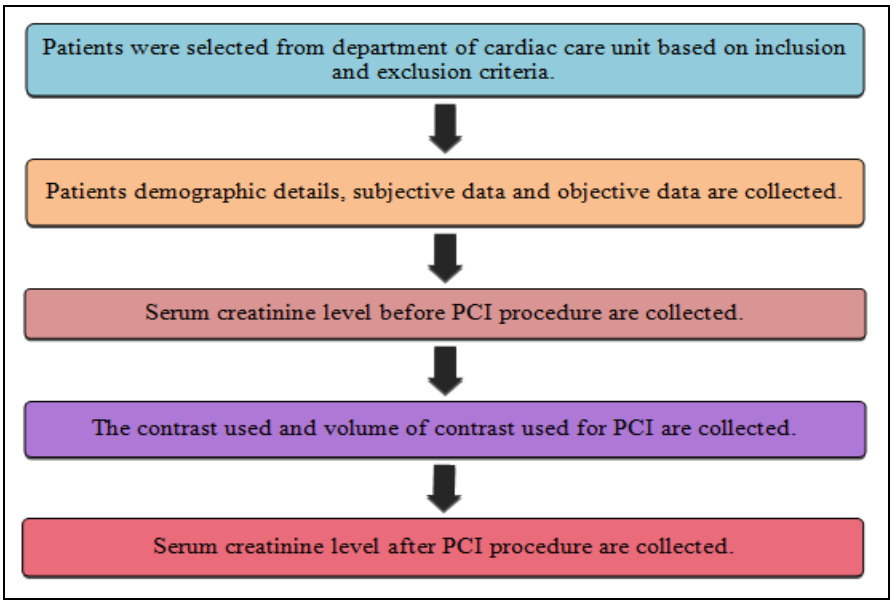

FIG. 1: DATA COLLECTION PROCEDURE

The data pertaining to their demographic details, medical history, and laboratory investigations were collected from the patient's case file using a self-designed data collection form. The information on the type and volume of contrast used was also collected **Fig. 1**. Prompts were used while taking the medical history to avoid recall bias. Single blinding method was used, where the physician was blinded from the ongoing study to prevent selection bias. The primary outcome was the prevalence of risk factors of CIN among patients undergoing PTCI. The secondary outcomes were the association of the risk factors with CIN and the proportion of patients within each risk category as per Mehran risk score.

Statistical Analysis: Mehran risk-assessment score for CIN, developed by Mehran *et al*, was used to identify patients at risk for developing CIN. The score considers the risk factors of hypotension, intra-aortic balloon pump, congestive heart failure, chronic kidney disease, diabetes, age >75 years, anaemia, and volume of contrast, which are each assigned with specific scores based on their extent of association with CIN, to stratify patients at risk for CIN into low, moderate, high and very high-risk categories. The prevalence of each of the factors among the patients was analysed. Patients with a total score of <5 were classified under low risk, with that between 6-10 under moderate risk, between 11-15 under high risk, and ≥16 under very high-risk categories for CIN. The prevalence of patients under each of these categories was determined, along with that of patients with CIN in them. The data collection form was statistically assembled using Microsoft Excel. A structured study proforma was used to document the study subjects' relevant demographic and clinical data in real-time. Continuous variables were expressed as minimum and maximum values, mean and standard deviation (SD), while qualitative data were presented as percentages and frequencies. Continuous variables were analyzed by the student t-test and categorical variables by the Chi-square test where appropriate. The statistical analysis was performed with SPSS software (version 17.0). Binary Logistic regression analysis was used to identify the independent risk factors associated with CIN. The results of this model were presented as an Odds Ratio (OR) and a 95% confidence interval (95% CI) for OR, considering a maximum of 5% error. A two-sided probability value of 0.05 was considered to indicate statistical significance throughout the analysis.

RESULTS: A total of 272 patients posted for PTCI were screened, out of whom 53 were excluded due to existing renal abnormality with or without requiring hemodialysis. A total of 6 pregnant women were also excluded. The relevant data of the remaining 213 patients were collected. Later, due to missing variables, the data from 13 patients were not considered for statistical analysis. Therefore, 200 patients were included in the study **Fig. 2.**

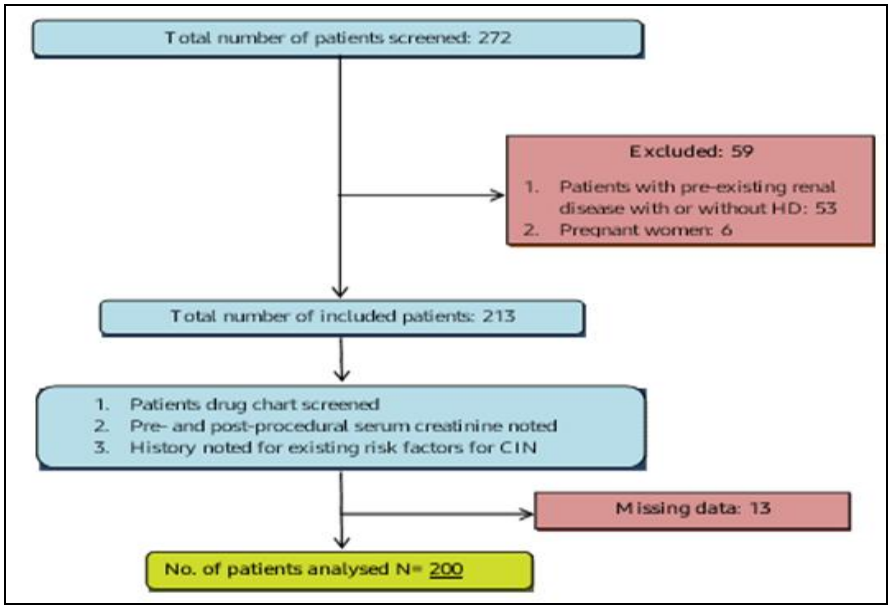

FIG. 2: NUMBER OF PATIENTS AT EACH STAGE OF THE STUDY

Out of 200 subjects in the study undergoing coronary intervention, 15% (30 patients) developed CIN. Most subjects were aged between 30-75 years (91.5%) and were mostly male patients (76.5%). The majority of the subjects had a diagnosis of angina (42%) followed by MI (29%), IHD (12%), ACS (4%), and CABG (3.5%). A significant proportion (44%) of the patients were anaemic. Most of the subjects (91.5%) underwent elective PCI while emergency PCI was performed in 8.5% of the subjects. 53% of subjects underwent PTCA while 47% did not.

A large proportion of the subjects (91%) did not have IABP placed. 47% and 32.5% of the subjects were administered 50mL and 150ml of contrast dye, respectively, while a smaller proportion of the patients received 150mL (17%), 200mL (2.5%) and 250mL (1%) of contrast dye as part of the procedure. Anticoagulants and antiplatelets were administered to 39% and 32% of the subjects, respectively, as prophylaxis for thrombosis. While most patients were fine post-procedure, hypotension was observed in 13.5% of the patients as a complication of the procedure **Table 3.** Being patients with cardiac anomalies, most patients received medications for their underlying pathology and symptomatic relief. However, some of these drugs are nephrotoxic in nature. The drugs causing nephrotoxicity that were prescribed post-procedure to the subjects were ACE inhibitors, eptifibatide, fentanyl, ondansetron, and adrenaline. ACE inhibitors were prescribed prevalently (36%), with the highest incidence of CIN (43.33%) in patients administered these drugs **Table 4.**

TABLE 3: BASELINE CHARACTERISTICS (N=200)

Characteristic	Percentage (%)
Age in years	
18-30	0
30-75	91.5
75-100	8.5
Gender	
Male	23.5
Female	76.5
Diagnosis at admission	
ACS	4
Angina	42
MI	29
CABG	3.5
IHD	12
Status for Coronary Intervention	
Elective	91.5
Emergency	8.5
Underwent PTCA	53.0
IABP Placed	9.0
Volume of Contrast administered	
50ml	47.0
100ml	17.0
150ml	32.5
200ml	2.5
250ml	1.0
Pre-procedural medications used	
ACE inhibitors	3.5
Anticoagulants	39
Antiplatelets	32
Diuretics	0.5
Beta-blockers	0.5
No medications	47
Complications of PCI	
Chest pain or MI	2
Hypotension	13.5
Asystole	2
Coronary spasm	0.5
No complication	87
Co-morbid conditions	
DM	36
Anaemia	44

TABLE 4: DRUG CAUSING NEPHROTOXICITY

Nephrotoxic Drugs	With CIN	Without CIN	Total (N=200)	Percentage (%)	P-value
ACE inhibitors	13	63	76	36	0.387
Eptifibatide	4	25	29	14.5	0.637
Fentanyl	3	8	11	5.5	0.155
Ondansetron	0	4	4	2	0.999
Adrenaline	0	3	3	1.5	0.999

The incidence of risk factors for CIN, considered by the Mehran risk assessment score, was assessed. Anaemia was the most prevalent risk factor among the subjects (44%), followed by Diabetes Mellitus, which was prevalent in 36% of the patients. 40% of subjects who developed CIN had anaemia [OR=0.66 (0.26-1.65); p-value=0.37], while 33% of them had Diabetes Mellitus [OR=0.95 (0.38-2.39); p-value=0.91]. 30% of subjects with CIN had CHF [OR=1.29 (0.48-3.45); p-value=0.61], while 23.33% of them had serum creatinine levels >1.5 mg/dL [OR=23.99 (4.20-137.12); p-value=0.0004]. Among all the risk factors, a significant association with CIN was found only for elevated serum creatinine levels **Table 5.**

TABLE 5: DISTRIBUTION OF RISK FACTORS AS CONSIDERED IN MEHRAN RISK ASSESSMENT SCORE

Risk Factors	With CIN	Without CIN	Total (N=200)	Percentage (%)	ODDS Ratio	P Value
IABP	5	13	18	9	2.01 (0.56-7.17)	0.28
CHF	9	38	47	23.5	1.29 (0.48-3.45)	0.61
Hypotension	4	18	22	11	1.40 (0.41-4.79)	0.59
DM	10	62	72	36	0.95 (0.38-2.39)	0.91
CV 100	8	26	34	17	1.63 (0.52-5.12)	0.40
CV150	8	57	65	34.5	1.01 (0.37-2.76)	0.9803
CV 200	0	5	5	2.5	0.00	0.97
CV 250	1	1	2	1	10.19 (0.50-209.01)	0.13
Sr. Cr levels (>1.5 mg/dL)	7	2	9	4.5	23.99 (4.20-137.12)	0.0004*
Anaemia	12	76	88	44	0.66 (0.26-1.65)	0.37
AGE> 75yrs	2	15	17	8.5	0.57 (0.09-3.68)	0.55

* Statistically significant association i.e., p-value<0.05.

The risk for developing CIN was quantified using the Mehran risk assessment score. The subjects were categorized under very high, high, moderate and low-risk categories based on the cumulative score. Among the subjects, 120 (60%) subjects were categorized under low-risk, 59 (29.5%) subjects under moderate-risk, 19 (9.5%) subjects under high-risk and 2 (1%) subjects under very high-risk categories for developing CIN. Among those under the very high-risk category, 50% of the subjects developed CIN. 47.36% of subjects within the high-risk category developed CIN, while 22.03% and 5.83% of subjects within moderate and low-risk categories developed CIN, respectively **Table 6.**

TABLE 6: STRATIFICATION OF PATIENTS INTO DIFFERENT RISK CATEGORIES AS PER THE MEHRAN SCORE

Mehran Score	With CIN	Without CIN	Total (N=200)	Percentage (%)	P-value
<5 (Low-risk)	7	113	120	60	<0.001*
6 to 10 (Moderate-risk)	13	46	59	29.5	
11 to 15 (High-risk)	9	10	19	9.5	
>16 (Very high-risk)	1	1	2	1	

* Statistically significant association i.e., p-value<0.05.

The results depict that the subjects categorized under the very high-risk category as per Mehran Risk Assessment Score for CIN had a higher incidence of CIN, while those under the low-risk category had a lower incidence of it.

DISCUSSION: Out of 200 subjects included in the study, 15% (30) of them developed CIN by the end of the study period. In patients administered with nephrotoxic drugs post coronary intervention, ACE inhibitor showed the highest incidence (36%) of CIN but had no statistical significance, whereas patients administered with ondansetron and adrenaline did not develop CIN. This could be attributed to a smaller sample size and, as nephrotoxic drugs are not included as a risk factor in Mehran risk assessment score, further studies are warranted to understand the influence of nephrotoxic drugs used post-coronary procedure over the development of CIN. Among the risk factors considered according to the Mehran risk assessment score, anaemia was the most prevalent risk factor (44%) and 40% of the patients, who developed CIN were anaemic. Type-II Diabetes Mellitus was the next most prevalent risk factor (36%) following anaemia, and 33% of patients who developed CIN were diabetic. This depicts that the patients with risk factors had a notable association in the development of CIN post-coronary intervention, but statistical significance was not established due to the skewed distribution of risk factors among patients and the smaller sample size.

Statistical significance in the development of CIN was established with only elevated serum creatinine of >1.5 mg/dL prior to the coronary intervention. Among the nine patients with elevated serum creatinine, 7 (77.77%) of them developed CIN, drawing towards the interpretation of the contribution of existing renal abnormalities to the development of CIN. According to the Mehran risk assessment score, the patients categorized into the

high-risk category had the highest incidence of CIN (47.36%), while patients categorized into the low-risk category had a lower incidence of CIN (5.83%). This depicts that the Mehran risk assessment score precisely predicts the development of CIN by utilizing the included risk factors for prediction. Hence, considering that treatment options for CIN are minimal, it is essential to categorise patients undergoing coronary intervention using the Mehran risk assessment score as high, moderate or low risk for developing CIN, which can help maintain the patients' quality of life for a longer term.

CONCLUSION: The study reported that Contrast-Induced Nephropathy is prevalent among patients who have undergone percutaneous coronary interventions. A notable number of patients who underwent PCI developed CIN; the major contributing risk factors were age, gender, hypotension, diabetes mellitus, serum creatinine levels and contrast volume.

A considerable association was found between serum creatinine levels ≥1.5mg/dl and CIN. A significant association was identified using the Mehran score to assess the risk of developing CIN. Inclusion of the Mehran score into clinical practice can effectively enhance patient safety by aiding in stratifying the patients into risk categories for the development of CIN and making appropriate therapeutic modifications, which can prevent the development of CIN and reduce the incidence of adverse reactions following the administration of contrast media and improve patients' therapeutic outcomes and quality of life.

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