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A Study of Risk of Contrast Induced Nephropathy (CIN) After Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention



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ABSTRACT

Contrast induced nephropathy (CIN) is a common renal dysfunction occurring after the administration of contrast dye for diagnostic purposes. The administration of such contrast is risk for certain patients. The aim of the study is to find out the incidence of contrast induced nephropathy in patients undergoing percutaneous coronary intervention and cardiac catheterization, to find out patient group who are at high risk and also to determine the correlation of the amount of contrast agent and change of serum creatinine concentration. The study depicts that about 7% of the total patients had developed contrast induced nephropathy after administering the contrast using guideline based recommendations for prophylaxis of contrast induced nephropathy. It has been found that the patients with diabetes and anaemia with renal insufficiency were more prone to develop contrast induced nephropathy. In the study, contrast induced nephropathy and non-contrast induced nephropathy patients are compared on the basis of age, gender, coronary artery disease (single, double, triple vessel disease), baseline creatinine clearance (<30, 30-59, ≥60 ml/min) diabetic versus non diabetic, anaemic versus nonanaemic, pre-existing renal dysfunction, percutaneous coronary intervention versus nonpercutaneous coronary intervention and so on. All the parameters were compared individually with the baseline creatinine clearance. This article seeks to discuss the incidence of contrast induced nephropathy occurring after percutaneous coronary intervention and cardiac catheterization.

INTRODUCTION

Contrast-induced nephropathy (CIN) is defined as the impairment of renal function and is measured as either a 25% increase in serum creatinine (SCr) from baseline or 0.5 mg/dL (44 µmol/L) increase in absolute value, within 48-72 hours of intravenous contrast administration.

For renal insufficiency (RI) to be attributable to contrast administration, it should be acute, usually within 2-3 days, although it has been suggested that RI up to 7 days post-contrast administration be considered CIN; it should also not be attributable to any other identifiable cause of renal failure. A temporal link is thus implied.^[1] Following contrast exposure, SCr levels peak between 2 and 5 days and usually return to normal in 14 days.

CIN is one of the leading causes of hospital-acquired acute kidney injury. It is associated with a significantly higher risk of in-hospital and 1-year mortality, even in patients who do not need dialysis.

Non-renal complications include procedural cardiac complications (eg, Q-wave MI, coronary artery bypass graft [CABG], hypotension, shock), vascular complications (eg, femoral bleeding, hematoma, pseudoaneurysm, stroke), and systemic complications (eg, acute respiratory distress syndrome [ARDS], pulmonary embolism).

There is a complicated relationship between CIN, comorbidity, and mortality. Most patients who develop CIN do not die from renal failure. Death, if it does occur, is more commonly from either a pre-existing non-renal complication or a procedural complication. Exact underlying mechanisms of nephrotoxicity are unclear but likely involve the interplay of several pathogenic factors such as direct toxicity of reactive oxygen species, (ROS), contrast-induced diuresis, increased urinary viscosity, increased oxygen consumption, imbalance of vasoconstriction vs vasodilation.

An enormous number of patients receive contrast agents. For example, in 2000 approximately 1,131,800 diagnosed cardiac catheterization and 561,000 percutaneous transluminal coronary angioplasty (PTCA) procedures were performed, which are just two of the many procedures in which contrast is used. There are mainly 3 categories of contrast agents. They are High Osmolar Contrast Media (HOCM), Low Osmolar Contrast Media (LOCM) and IsoOsmolar Contrast Media (IOCM).

HOCM is associated with more adverse events including CIN than LOCM and IOCM. Therefore, the evidence clearly shows that HOCM should be avoided in patients with renal impairment. Furthermore, the nephrotoxic effects in high-risk patients undergoing angiography study showed that use of the IOCM reduces the incidence of CIN in high-risk diabetic patients when compared with LOCM.

The earliest contrast agents were ionic containing a sodium atom that dissociated from the molecule in aqueous solution. Each molecule of the agent carried three iodine atoms. Therefore, these agents required two osmotically active particles to deliver three iodine atoms and they had high osmolalities and so called as HOCM, used until 1980's. The next generation introduced in 1980's and still the predominant CM in use are non-ionic. Since therefore need only one osmotically active particle to deliver three iodine atoms, their osmolality is low and are called as LOCM. Both these types of agents are monomers with one benzene ring and three iodine atoms. Dimer molecules consisting of two joined benzene rings containing a total of six iodine atoms per molecule. They have osmolality similar to that of LOCM.

AIM AND OBJECTIVE

The purposes of the study were:

- a) To assess the incidence of Contrast Induced Nephropathy (CIN) in different groups undergoing diagnostic cardiac catheterization and percutaneous coronary intervention cardiac catheterization (PCI) using optimal, guideline based prophylactic treatment of Contrast Induced Nephropathy (CIN).
- b) To define patient groups who are at high risk for Contrast Induced Nephropathy (CIN) after cardiac catheterization and percutaneous coronary intervention.
- c) To find the correlation between the amounts of contrast agent administered and change of serum creatinine concentration or incidence of Contrast Induced Nephropathy.

REVIEW OF LITERATURE

- In a study performed by Lautinet al.¹¹⁰ it was found that the incidence of CIN was rather low (2%) in patients with neither diabetes nor azotemia, significantly higher (16%) in individuals with diabetes but preserved renal function and much higher (38%) in patients who had both diabetes and azotemia.

- In a study done by Rihalet al.¹² the incidence of CIN was found to be 2% in patients without diabetes and 3.7% in patients with diabetes with a baseline creatinine concentration of 1.1 mg/dl or less. When the renal function is mildly impaired (serum creatinine level 1.2-1.9 mg/dl) the risk of CIN in patients with diabetes mellitus increases to 4.5%.
- Parfrey et al.¹¹ in an earlier study of patients with diabetes and a normal renal function developed clinically significant CIN. However, given that those with diabetes alone were found to be at a slightly higher risk of developing CIN than the general population.
- In a recent prospective cohort study of 219 non-diabetic elderly patients with reduced kidney function who underwent coronary angiography¹²⁰, they reported that metabolic syndrome was a risk indicator of CIN. CIN occurred in 14% of the patients of the metabolic syndrome group and in 3.6% of those of non-metabolic group. Impaired fasting glucose, high triglyceride levels and multivessel involvement in the metabolic syndrome group were the 4 predictors of CIN.
- In 2003, Aspelinet al.¹²¹ published the NEPHRIC study which was a double blind randomized multicenter study in 129 patients who had undergone coronary angiography. All patients had a combination of diabetes and impaired renal function and the main objective was to measure the mean peak increase in serum creatinine from baseline to day three compared with baseline. They found a frequency of CIN of 26.2% in the patients where LOCM is used and 3.1% of patients where IOCM is used.
- Sadeghiet al.¹¹⁸ had done a study in 2082 patients who underwent PCI after myocardial infarction. He reported a more than sevenfold increase in the 1 year mortality in patients who developed CIN.
- A prospective randomized study involving 1196 patients who underwent angiocardiology showed a lower incidence of CIN with LOCM than HOCM¹²². It was especially evident among patients with diabetes and decreased renal function.
- In a study by Giancarlo Marenzi¹²⁵ et al, considered 208 consecutive acute myocardial infarction patients undergoing primary PCI. They found that CIN had occurred in 40 (19%) patients. Of the 160 patients with baseline creatinine clearance \leq 60ml/min, only 21 (13%) patients developed CIN.

MATERIALS AND METHODS

This study was conducted in MEENAKSHI MISSION HOSPITAL AND RESEARCH CENTRE (MMHRC) in Madurai city under the guidance of Dr. SELVAMANI, DNB (GM), DNB (Cardio), Chief Consultant and Interventional Cardiologist during August 2007 to

January 2008. The subject group consists of 100 patients who had undergone coronary angiography and coronary intervention procedure. All patients underwent guideline based prophylactic measures to prevent Contrast Induced Nephropathy. Among them, 80 were men and 20 were women. Median age was 54 years [23-85 years].

A coronary interventional procedure was performed in 30 patients and diagnostic cardiac catheterization was performed in 70 patients. A non-ionic, low-osmolality contrast agent was used in the Cath lab. Serum Creatinine values were measured before and within 48 hours of administration of contrast agents, further measurement was performed in all CIN patients. Contrast Induced Nephropathy was defined as an increase in serum creatinine concentration of ≥ 0.5 mg/dl from preprocedural values. Creatinine Clearance (CrCl) was calculated by applying the Cockcroft-Gault formula to the baseline serum creatinine level. Patients were divided into three categories of renal function by their baseline creatinine clearance. They are ≥ 60 ml/min, 30-59 ml/min and < 30 ml/min.

The data were collected, compiled and statistically analysed by Graph Pad Software version 3.

RESULTS AND DISCUSSION

1. INCIDENCE OF CIN AFTER DIAGNOSTIC CORONARY ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTION.

Out of the 100 patients, 7 suffered Contrast Induced Nephropathy (CIN) after cardiac catheterization. The mean amount of contrast medium administered was 152.86ml. In these patients, the mean serum creatinine level increased from $1.45 \pm .55$ mg/dl to 1.6 ± 3.15 mg/dl. The mean difference in serum creatinine was 1.24mg/dl. The distribution of clinical, laboratory, angiographic and procedural baseline data are shown below.

CLINICAL CHARACTERISTICS

The baseline clinical characteristics of patients with CIN and Non-CIN are summarized in the table. Of the 100 patients in the study, diabetes was present in 46 patients (46%) and anemia in 50 patients (50%) at baseline. 7 out of 100 patients experienced CIN after the procedure. These patients were significantly older, had a lower diastolic BP and a higher incidence of anaemia.

BASELINE CLINICAL DATA IN PATIENTS WITH AND WITHOUT CIN

CLINICAL DATA		CIN(7)	NON-CIN(93)
Average age		60.71	52.63
Age \geq 75		1 (14.29%)	0
Sex	Male	6 (86%)	74 (79.57%)
	Female	1 (14.29%)	19 (20.43%)
Diabetes Mellitus		5 (71.43%)	42 (45.16%)
Hypertension		4 (57.14%)	82 (88.17%)
Hypotension		2 (28.57%)	2 (2.15%)
Anemia		4 (57.14%)	46 (49.46%)
Renal function	Normal	1 (14.29%)	10 (11%)
	Mild	2 (28.57%)	50 (53.76%)
	Moderate	3 (42.86%)	29 (31.18%)
	Severe	1 (14.29%)	4 (4.3%)
Cardiac complication	Stable Angina	0	13 (13.98%)
	Unstable angina	0	20 (21.51%)
	Myocardial infarction	7(100%)	52 (55.91%)
	Other complications	0	8 (8.6%)
PTCA		3 (42.86%)	2 8(30.11%)

LABORATORY DATA

Patients who developed CIN had a higher baseline serum creatinine and a lower creatinine clearance. In comparison to patients without CIN, patients with CIN had higher blood glucose level and more often presented with lower hemoglobin values.

Laboratory Data in Patients with and without CIN

LABORATORY DATA		CIN	NON- CIN
Average serum creatinine	Baseline	1.36	1.19
	After catheterization	2.59	1.17
Baseline Serum creatinine ≥ 1.5		3 (42.86%)	14 (15.05%)
Average Creatinine Clearance	Baseline	54.56	68.52
	After catheterization	29.1	70
Average sodium		133.29meq/l	135.49meq/l
Average potassium		3.99meq/l	3.81meq/l
Average haemoglobin		11gm%	13.5gm%
Average Left Ventricular Function		38%	51.68%

ANGIOGRAPHIC DATA

The angiographic baseline data of patients with and without CIN are given below

Characteristics	Coronary Artery Disease			
	Single vessel disease	Double vessel disease	Triple vessel disease	Others
CIN (n = 7)	1 (14.29%)	1 (14.29%)	17 (18.28%)	1 (14.29%)
Non CIN (n=93)	26 (27.96%)	4 (57.14%)	14 (15.05%)	14 (15.05%)

In this study, the incidence of CIN is higher in patients with triple vessel disease and the mean LV functions were lower than the Non-CIN patients.

PROCEDURAL DATA

The amount of contrast agent administered to the CIN and Non-CIN group was similar (152.86ml vs 150ml). In addition, the radiation time (13±11vs12±12min) and duration of examination (66±30 vs 60±34 min) showed no significant difference of proportion in diagnostic procedure and PCI for the CIN and Non-CIN group.

7.2 SUBGROUP ANALYSIS

1. Elderly patients ≥ 70 years

a) Incidence of CIN in Elderly subgroup

Table 1-a).1

Age	No. of patients	CIN
Patients ≥ 70 years	2 (n=7)	28.57 %
Patients < 70 years	5 (n=93)	5.38 %

Although the age differed between CIN and Non-CIN group, the incidence of CIN in patients older than 70 years were higher when compared with younger patients (28.57% vs. 5.38%).

The Graphical representation is shown in Figure 1;

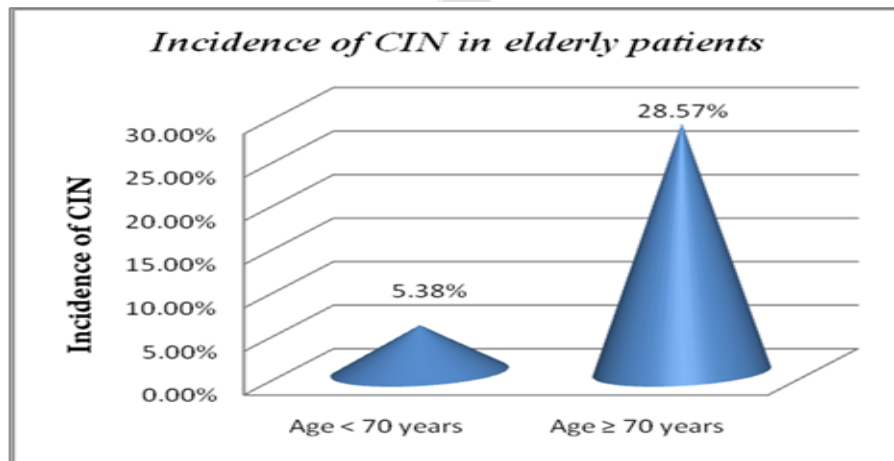


Figure 1

Summary of Statistical Data showing the Incidence of CIN in Elderly Patients

Table 1-a).2

Data	Age < 70 years	Age ≥ 70 years	p-value
Mean	0.06556	0.1000	0.4450
SD	0.4256	0.5132	
SEM	0.04487	0.1949	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.4450. Since the p -value is greater than 0.05, the incidence of CIN in elderly patients is not statistically significant.

b) Amount of Contrast Media

Table 1-b).1

Baseline Creatinine Clearance (ml/min)	CIN	Non-CIN
< 30	175 ± 75 ml	150 ± 50 ml
30 – 59	150 ± 50 ml	225 ± 25 ml
≥ 60	200 ± 100 ml	175 ± 25 ml

Amount of contrast media administered was similar for patients above and under 70 years. There were no significant differences regarding the amount of contrast agent administered in CIN and Non-CIN group with different baseline creatinine clearance.

Summary of statistical analysis showing the amount of CM used in elderly patients stratified by baseline creatinine clearance < 30 ml/min.

Table 1-b).2

Data	CIN	Non CIN	p-value
Mean	175.00	150.00	0.8743
SD	106.07	70.711	
SEM	75.00	50.00	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.8743. Since the p -value is greater than 0.05, the amount of CM used in elderly patients stratified by baseline creatinine clearance < 30 ml/min is not statistically significant.

Summary of statistical analysis showing the amount of CM used in elderly patients stratified by baseline creatinine clearance between 30-59 ml/min.

Table 1-b).3

Data	CIN	Non-CIN	p-value
Mean	150.00	225.00	0.5000
SD	50.000	35.355	
SEM	28.868	25.000	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.5000. Since the p -value is greater than 0.05, the amount of CM used in elderly patients stratified by baseline creatinine clearance 30-59 ml/min is not statistically significant.

Summary of statistical analysis showing the amount of CM used in elderly patients stratified by baseline creatinine clearance between ≥ 60 ml/min.

Table 1-b).3

Data	CIN	Non CIN	p-value
Mean	166.67	175.00	0.7952
SD	115.47	35.355	
SEM	66.667	25.000	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.7952. Since the p -value is greater than 0.05, the amount of CM used in elderly patients stratified by baseline creatinine clearance ≥ 60 ml/min is not statistically significant.

2. Diabetes Mellitus

a) Incidence of CIN in Diabetic Patients

Table 2-a).1

Category	No. of Patients	Incidence of CIN
Diabetic	4 (n=53)	7.55%
Non- Diabetic	3 (n=47)	6.38%

The comparison of incidence of CIN in Diabetic and Non-diabetic patients did not show any significant difference. The graphical representation is shown in Figure 2.

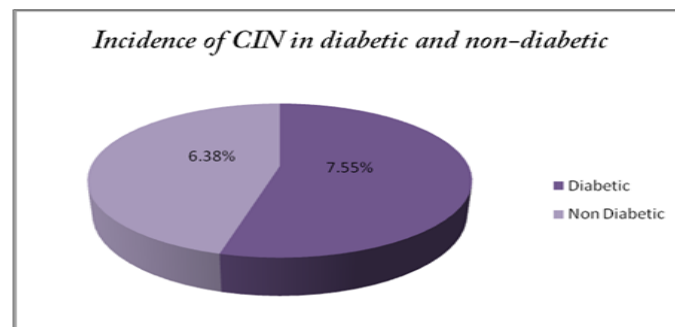


Figure 2

Summary of statistical analysis showing incidence of CIN in DM and Non-DM patients

Table 2-a).2

Data	DM	Non DM	p-value
Mean	0.4528	0.0787	0.6721
SD	0.4672	0.3759	
SEM	0.0642	0.0548	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.6721. Since the p -value is greater than 0.05, the incidence of CIN in DM and Non-DM patients is not statistically significant.

b) Incidence of CIN stratified in DM and Non-DM patients on the basis of Baseline Creatinine Clearance.

Table 2-b).1

Baseline Creatinine Clearance	Diabetic patients	Non-diabetic patients	% of CIN in Diabetic patients	% of CIN in Non-diabetic patients
≥60 ml/min	1 (n=28)	1 (n=29)	3.57 %	3.45 %
30-59 ml/min	2 (n=23)	1 (n=15)	8.7 %	6.67 %
< 30 ml/min	1 (n=2)	1 (n=3)	50 %	33.33 %

On the basis of pre-existing renal function, there is no significant difference in the incidence of CIN in Diabetic and Non-Diabetic patients with baseline creatinine clearance ≥ 60 ml/min and 30-59 ml/min (3.57% vs 3.45% and 8.7% vs 6.67%). However, a high proportion of both Diabetic and Non-Diabetic patients experienced CIN when the baseline creatinine clearance was < 30 ml/min (50% vs 33.33%).

The graphical representation is shown in Figure 3.

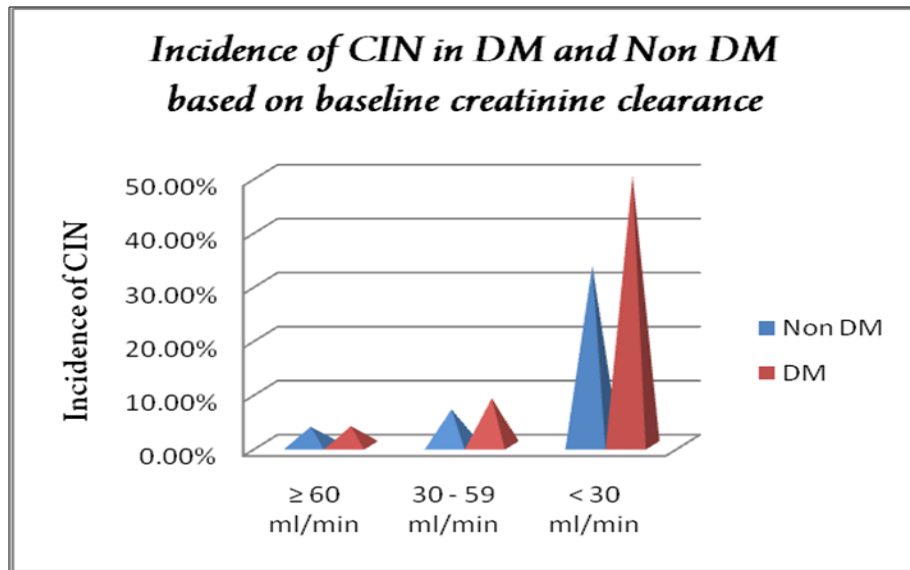


Figure 3

Summary of statistical analysis showing incidence of CIN in DM and Non-DM patients with baseline creatinine clearance < 30 ml/min.

Table 2-b).2

Data	DM	Non-DM	p-value
Mean	0.5500	0.1333	0.3743
SD	0.6364	0.3215	
SEM	0.4500	0.1856	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.3743. Since the p -value is greater than 0.05, the incidence of CIN in DM and Non-DM patients with baseline creatinine clearance < 30 ml/min is not statistically significant.

Summary of statistical analysis showing incidence of CIN in DM and Non-DM patients with baseline creatinine clearance 30-59 ml/min.

Table 2-b).3

Data	DM	Non-DM	p-value
Mean	0.0217	0.0467	0.1264
SD	0.6346	0.1642	
SEM	0.1323	0.0424	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.1264. Since the p -value is greater than 0.05, the incidence of CIN in DM and Non-DM patients with baseline creatinine clearance 30-59 ml/min is not statistically significant.

Summary of statistical analysis showing incidence of CIN in DM and Non-DM patients with baseline creatinine clearance ≥ 60 ml/min.

Table 2-b).4

Data	DM	Non-DM	p-value
Mean	0.075	0.0241	0.3319
SD	0.2977	0.1091	
SEM	0.0563	0.0203	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.3319. Since the p -value is greater than 0.05, the incidence of CIN in DM and Non-DM patients with baseline creatinine clearance ≥ 60 ml/min is not statistically significant.

c) Amount of contrast media used in Diabetic and Non-diabetic patients

Table 2-c).1

Category	Amount of CM
DM	200 \pm 50 ml
Non-DM	150 \pm 25 ml

The comparison of the amount of contrast agent administered to diabetic and non-diabetic patients are shown in the graph below. The amount of contrast administered in diabetic patients was slightly higher than that in non-diabetic patients.

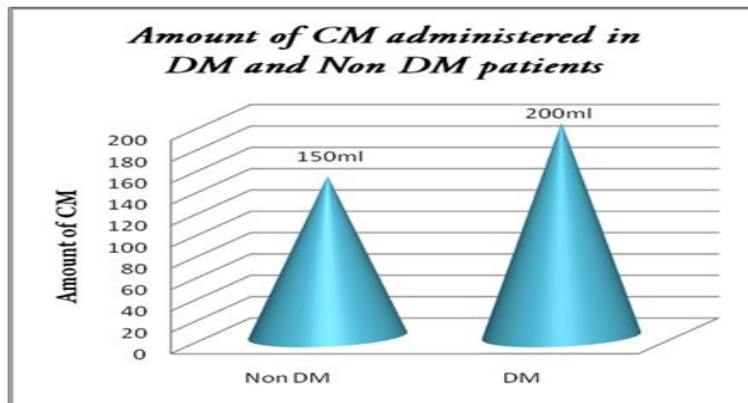


Figure 4

Summary of statistical analysis showing the amount of CM used in DM and Non-DM patients

Table 2-c).2

Data	DM	Non-DM	p-value
Mean	137.36	114.26	0.0400
SD	57.551	39.932	
SEM	7.905	5.825	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.0400. Since the p -value is less than 0.05; the amount of CM used in DM and Non-DM patients were found to be statistically significant.

3) Pre-existing Impairment of Renal function

a) Incidence of CIN in patients with baseline creatinine clearance ≥ 60 ml/min and < 60 ml/min

The incidence of CIN in patients with pre-existing impairment of renal function (baseline creatinine clearance < 60 ml/min) was 10.81% vs 4.76% in patients with normal renal function (baseline creatinine clearance ≥ 60 ml/min).

Table 3-a).1

Baseline Creatinine Clearance (ml/min)	No. of patients	Incidence of CIN
≥ 60 ml/min	3 (n=63)	4.76%
< 60 ml/min	4 (n=37)	10.81%

The graphical representation is shown in Figure 5.

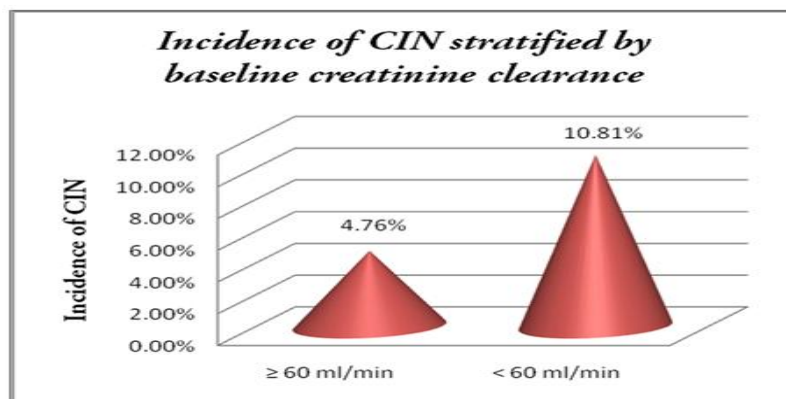


Figure 5

Summary of statistical analysis showing the incidence of CIN in patients with baseline creatinine clearance ≥ 60 ml/min and < 60 ml/min.

Table 3-a).2

Data	≥ 60 ml/min	< 60 ml/min	p-value
Mean	0.0905	0.0405	0.0493
SD	0.3491	0.2671	
SEM	0.0439	0.0439	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.0493. Since the p -value is less than 0.05; the incidence of CIN in patients between baseline creatinine clearance ≥ 60 ml/min and < 60 ml/min are found to be statistically significant.

b) Incidence of CIN in patients with baseline creatinine clearance 30- 59 ml/min and < 30 ml/min.

The incidence of CIN in patients with baseline creatinine clearance < 30 ml/min is found to be higher than those with 30-59 ml/min (9.38% vs 20%).

Table 3-b).1

Baseline Creatinine Clearance (ml/min)	No. of patients	Incidence of CIN
30-59 ml/min	3 (n=32)	9.38%
< 30 ml/min	1 (n=5)	20%

The graphical representation is shown in Figure 6.

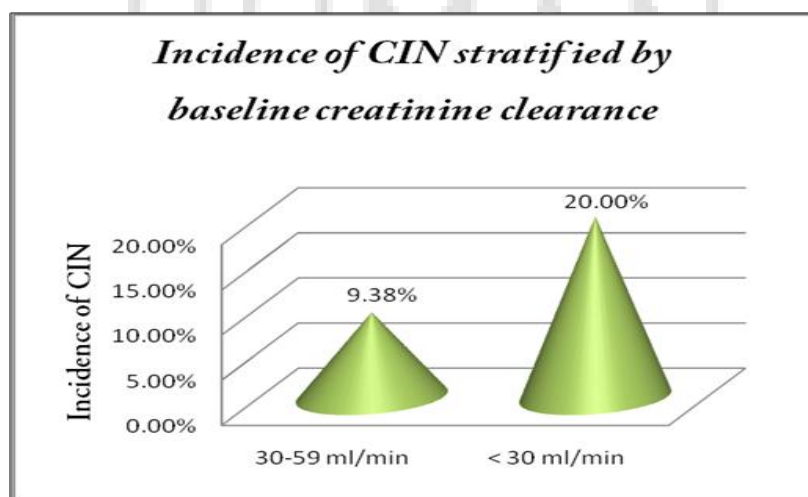


Figure 6

Summary of statistical analysis showing the incidence of CIN in patients with baseline creatinine clearance 30-59 ml/min and < 30 ml/min.

Table 3-b).2

Data	30-59 ml/min	< 30 ml/min	p-value
Mean	-0.1156	1.080	0.0495
SD	0.2343	1.0520	
SEM	0.0414	0.4705	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.0495. Since the p -value is less than 0.05; the incidence of CIN in patients between baseline creatinine clearance 30-59 ml/min and < 30 ml/min are found to be statistically significant.

The above data shows that the incidence of CIN increases with decrease in baseline creatinine clearance.

c) Amount of contrast administered in patients with pre-existing renal impairment.

Table 3-c).1

Baseline Creatinine Clearance	CIN	Non-CIN
< 30 ml/min	200 (n=1)	150 ± 50 (n=4)
30-59 ml/min	175 ± 75 (n=3)	225 ± 175 (n=29)
≥ 60 ml/min	125 ± 25 (n=3)	175 ± 125 (n=60)

There was no difference regarding the amount of contrast agents administered in patients with different baseline creatinine clearance.

Summary of statistical analysis showing the amount of CM used in patients with baseline creatinine clearance <30ml/min.

Table 3-c).2

Data	CIN	Non-CIN	p-value
Mean	125.00	150.000	0.5000
SD	50.000	70.711	
SEM	25.000	50.000	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.5000. Since the p -value is greater than 0.05; the amount of CM used in patients with baseline creatinine clearance < 30 ml/min are found to be not statistically significant.

Summary of statistical analysis showing the amount of CM used in patients with baseline creatinine clearance ≥ 60 ml/min.

Table 3-c).3

Data	CIN	Non-CIN	p-value
Mean	132.07	166.67	0.6914
SD	69.713	76.376	
SEM	12.945	44.096	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.6914. Since the p -value is greater than 0.05; the amount of CM used in patients with baseline creatinine clearance 30-59 ml/min are found to be not statistically significant.

Summary of statistical analysis showing the amount of CM used in patients with baseline creatinine clearance ≥ 60 ml/min.

Table 3-c).4

Data	CIN	Non-CIN	p-value
Mean	140.50	135.000	0.2578
SD	64.609	21.213	
SEM	8.341	15.000	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.2578. Since the p -value is greater than 0.05; the amount of CM used in patients with baseline creatinine clearance ≥ 60 ml/min are found to be not statistically significant.

4. Percutaneous Coronary Intervention (PCI subgroup)

Patients who had undergone PCI and Non-PCI were considered. PCI subgroup consists of patients who underwent Percutaneous Coronary Intervention (Angioplasty) and the Non-PCI group consists of patients who underwent Diagnostic Cardiac Catheterization (Coronary Angiogram).

a) Incidence of CIN

The incidence of CIN between PCI and Non-PCI group did not show any significant difference (6.67% vs 7.14%).

Table 4-a).1

Category	CIN	Incidence of CIN
PCI	2 (n=30)	6.67%
Non-PCI	5 (n=70)	7.14%

The graphical representation is shown in Figure 7.

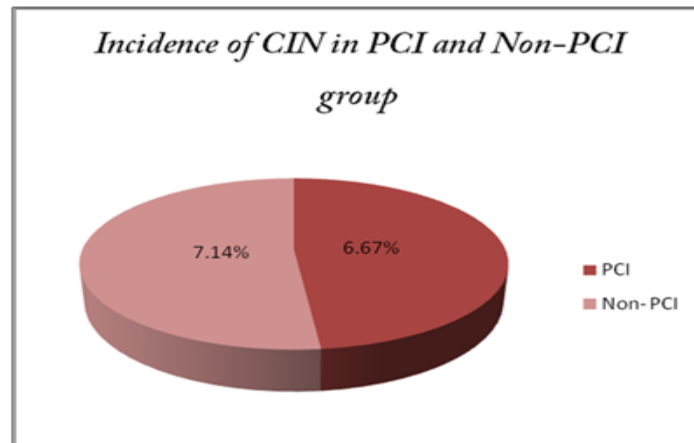


Figure 7

Summary of statistical analysis showing the incidence of CIN in PCI and Non-PCI group.

Table 4-a).2

Data	PCI	Non-PCI	p-value
Mean	0.1167	0.0400	0.2661
SD	0.5266	0.3763	
SEM	0.0961	0.0449	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.2661. Since the p -value is greater than 0.05; the incidence of CIN in PCI and Non-PCI groups are not statistically significant.

b) Amount of contrast administered in PCI group

As shown in the table, there were no significant differences regarding the amount of contrast agent administered in PCI and Non-PCI sub-group.

Table 4-b).1

Amount of Contrast Media	
PCI	200 ± 100
Non-PCI	250 ± 150

Summary of statistical analysis showing the incidence of CIN in PCI and Non-PCI group.

Table 4-b).2

Data	PCI	Non-PCI	p-value
Mean	212.86	200	0.3145
SD	68.088	35.355	
SEM	12.8670	25.000	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.3145. Since the p -value is greater than 0.05; the incidence of CIN in PCI and Non-PCI groups are not statistically significant.

5. Anemia

a) Incidence of CIN

The incidence of CIN in Anaemic patients (hemoglobin < 12 gm/dl in women and < 13gm/dl in men) are significantly higher than Non-Anaemic patient.

Table 5-a).1

Category	CIN	Incidence of CIN
Anaemic	4 (n=33)	12.12%
Non-Anaemic	3 (n=67)	4.48%

The graphical representation is shown in Figure 8.

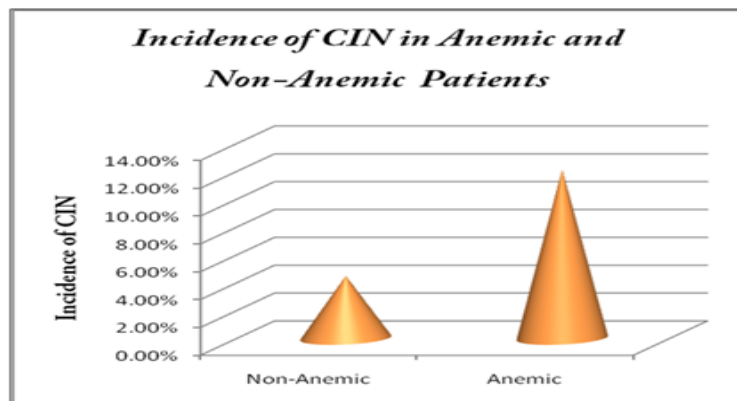


Figure 8

Summary of statistical analysis showing the incidence of CIN in Anaemic and Non-Anaemic Patients.

Table 5-a).2

Data	Anaemic	Non-Anaemic	p-value
Mean	0.1242	-0.02985	0.0497
SD	0.5166	0.1508	
SEM	0.0899	0.0184	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.0497. Since the p -value is less than 0.05; the incidence of CIN in Anaemic and Non-Anaemic patients is found to be statistically significant.

b) Incidence of CIN in Anaemic and Non-Anaemic patients stratified by Baseline Creatinine Clearance

The incidence of CIN increased with the decrease of baseline creatinine clearance in both Anaemic and Non- Anaemic patients.

Table 5-b).1

Baseline Creatinine Clearance	Anaemic patients	Non-Anaemic patients	% of CIN in Anaemic patients	% of CIN in Non-Anaemic patients
≥60 ml/min	1 (n=22)	2(n=41)	4.55%	4.88%
30-59 ml/min	1 (n=21)	1 (n=15)	10%	4.76%
< 30 ml/min	1 (n=2)	1 (n=4)	50%	25%

In patients with baseline creatinine clearance < 30 ml/min, a high proportion of both Anaemic and non-Anaemic patients experienced CIN (50% vs 25%). When the baseline creatinine clearance was 30-59 ml/min, the incidence of CIN in Anaemic patients was two-fold higher than in non-Anaemic patients (10% vs 4.76%). Among the patients with baseline creatinine clearance 60 ml/min and above, there was no significant difference between Anaemic and non-Anaemic patients (4.55% vs 4.88%).

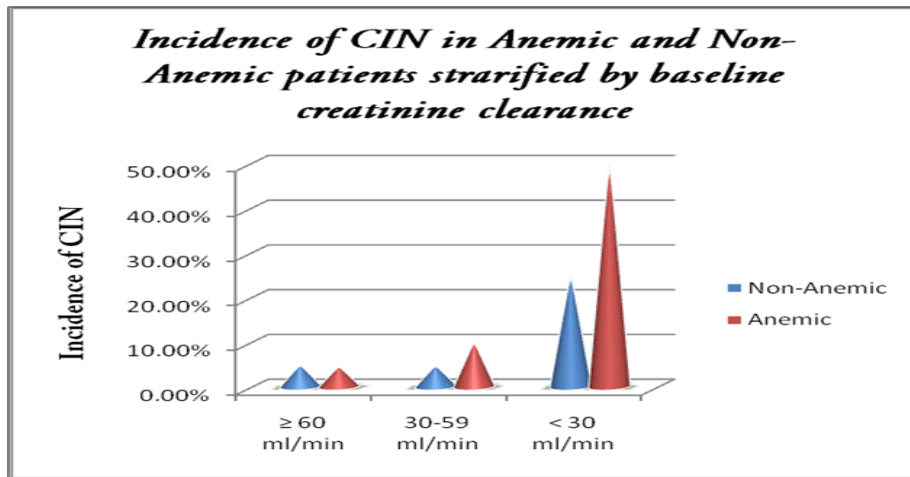


Figure 9

Summary of statistical analysis showing the incidence of CIN in Anaemic and Non-Anaemic Patients with baseline creatinine clearance < 30 ml/min.

Table 5-b).2

Data	Anaemic	Non-Anaemic	p-value
Mean	0.5500	0.7000	0.5374
SD	0.6364	1.3340	
SEM	0.4500	0.6671	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.5374. Since the p -value is greater than 0.05; the incidence of CIN in Anaemic and Non-Anaemic patients with baseline creatinine clearance < 30 ml/min is found to be not statistically significant.

Summary of statistical analysis showing the incidence of CIN in Anaemic and Non-Anaemic patients with baseline creatinine clearance 30-59 ml/min.

Table 5-b).3

Data	Anaemic	Non-Anaemic	p-value
Mean	0.1500	0.1250	0.0422
SD	0.4859	0.2017	
SEM	0.1537	0.0504	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.0422. Since the p -value is less than 0.05; the incidence of CIN in Anaemic and Non-Anaemic patients with baseline creatinine clearance 30-59 ml/min is found to be statistically significant.

Summary of statistical analysis showing the incidence of CIN in Anaemic and Non-Anaemic patients with baseline creatinine clearance ≥ 60 ml/min.

Table 5-b).4

Data	Anaemic	Non-Anaemic	p-value
Mean	0.1500	0.0143	0.0699
SD	0.4867	0.1541	
SEM	0.1038	0.220	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.0699. Since the p -value is greater than 0.05; the incidence of CIN in Anaemic and Non-Anaemic patients with baseline creatinine clearance ≥ 60 ml/min is found to be not statistically significant.

c) Amount of Contrast media

There was no significant difference regarding the amount of contrast agent administered in anaemic patients and Non-Anaemic patients.

Table 5-c).1

Amount of Contrast Media	
Anaemic	225 \pm 175
Non-Anaemic	175 \pm 25

Summary of statistical analysis showing the amount of CM administered in Anaemic and Non-Anaemic Patients.

Table 5-b).4

Data	Anaemic	Non-Anaemic	p-value
Mean	131.21	140.30	0.1389
SD	66.977	63.245	
SEM	11.659	7.727	

Statistical analysis using paired t- test shows that the two tailed p- value is 0.1389. Since the p -value is greater than 0.05; the amount of CM administered in Anaemic and Non-Anaemic patients is found to be not statistically significant.

CONCLUSION

The incidence of CIN after diagnostic cardiac catheterization or Percutaneous Coronary Intervention (PCI) in the present study population using guideline based recommendations for prophylaxis of CIN was found to be 7%. It has been found that within 2 days there is a high risk for CIN in patients with diabetes and anaemia with pre-existing renal insufficiency, but it was not able to assess the cases of CIN patients after the discharge.

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