



Research Article

TO STUDY THE INCIDENCE OF CONTRAST-INDUCED NEPHROPATHY IN PATIENTS UNDERGOING CORONARY ANGIOGRAPHY AND RENAL ANGIOGRAPHY

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ABSTRACT

Aim: To study the incidence of contrast-induced nephropathy in patients undergoing coronary angiography and renal angiography **METHODS:** The present prospective study on “incidence of contrast-induced nephropathy” was conducted on the patients admitted in the cardiac care unit. Total of 254 patients were taken. All the subjects included in the study underwent coronary / renal angiography using 50-60ml of iohexol non-ionic radiopaque contrast media. All the patients were subjected to a detailed history, clinical examination and laboratory investigations which were recorded in the predesigned performa for this study. **Results:** Male to female ratio was 1.49:1. 118 (58.71%) males and 83 (41.29%) females had serum creatinine < 1.2. Twenty three 23 (60.53%) male and 15 (39.47%) female had serum creatinine between 1.2-2. 11 (73.33%) male and 4 (26.67%) female had serum creatinine >2. Eighty 80 (52.63%) males and 50 female were normal without risk factor. 41 (26.97%) males and 27 (26.47%) females were diabetic with no renal insufficiency. 16 (10.53%) males and 13 (12.75%) females have renal insufficiency without diabetes. 15 (9.87%) males and 12 (11.76%) females had both diabetes and renal insufficiency. 109 (42.91%) males and 69 (27.16%) females undergo diagnostic angiography. 43 (16.92%) male and 33 (12.99%) female undergo PCI (angioplasty). Incidence of CIN was 11.02%. Out of 254 patients 226 (88.97%) had no CIN. 28 patients (11.02%) had CIN. Out of 130 patients with no DM/RI 3 had CIN. Out of 68 patients with DM/ no RI 4 had CIN. Out of 29 patients with RI/ no diabetes 9 had CIN. Out of 27 patients with DM/RI 12 had CIN. Out of 130 patients without any risk factor, 2.31% developed CIN. Out of 68 patients with diabetes without RI, 5.88% developed CIN. Out of 29 patients with RI without DM, 31.03% developed CIN. Out of 27 patients with RI and DM, 44.44% developed CIN. Mortality in patients without CIN was 1.20%. Mortality in patients with CIN requiring dialysis was 16.40%. **Conclusion:** Contrast media (CM) are increasingly used in diagnostic and interventional procedure. This results in the rising incidence of iatrogenic renal function impairment caused by exposure to CM, a condition known as CIN

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INTRODUCTION

Contrast-Induced Nephropathy (CIN) is defined as a 25% increase in serum creatinine from the baseline value or an absolute increase of at least 0.5 mg/dl which appears within 48 hrs after the administration of radiographic contrast media and is maintained for 2-5 days (1). CIN is the third leading cause of hospital - acquired renal failure (2). CIN is significant but underestimated cause of iatrogenic acute renal failure in clinical practice.

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CIN is also known as contrast nephropathy / contrast - nephrotoxicity / contrast media nephropathy / contrast agent nephropathy. (Mc Cullough et al 1997), (3) reported an overall incidence of 14.5 % in patients undergoing coronary intervention. An overall incidence of CIN in general population is reported to be 0.6 - 2.3% (R. Mehran et al. 2006)(4). In patients with cardiovascular pathology undergoing angiographic procedures, the incidence of CIN is higher and ranges from 3.3% - 14.5% (3,5), (. Incidence rate may vary from 0% - 90% depending on the presence of risk factors, most notably chronic renal insufficiency, diabetes mellitus (DM), and high contrast volume administered. The incidence of CIN in patients with underlying chronic kidney

disease is extremely high, ranging from 14.8% - 55% (6). As shown in one of the studies, if baseline plasma creatinine levels is ≤ 1.2 mg/dl, the risk of CIN is only 2%. In patients with value of creatinine in the range of 1.4 - 1.9 mg/dl, the risk of CIN compared with that in the previous group increases five- fold (10.4%). As for patients with baseline creatinine level ≥ 2.0 mg/dl, more than half of them (62%) subsequently develop CIN (7). The incidence of CIN in diabetic patients varies from 5.7 to 29.4% (8) In one study, CIN occurred in 27 % of diabetic patients with baseline Serum creatinine 2.0 - 4.0 mg/dl and in 81 % of those with Serum creatinine > 4.0 mg/dl (8) . Dialysis as a result of CIN is required in 0.3% to 0.7% of patients undergoing angiography (3,5), quoted an in hospital mortality rate of 35.7% for patients requiring dialysis as a result of coronary angiography induced CIN and an 18.8%, 2-years- survival rate.

In- hospital mortality rate were relatively low for patients without CKD and diabetes, and for diabetic patients without CKD (0.7% and 1.0%, respectively); these rates were greatly increased for non-diabetics and diabetic patients with CKD (2.3% and 3.7% respectively) (8).

Thirty day mortality rate was 16.2%, compared with 1.2% for patients who did not develop CIN and 1-yr mortality rate (23.3%) compared with those who did not develop CIN (9).

CIN most commonly manifests as a non-oliguric and asymptomatic decline in renal functions (10). The serum creatinine levels begin to rise within 24 hrs after administration of contrast medium. Creatinine levels typically peaks on 2nd and 3rd day following contrast, returns to baseline within 10-14 days (11). Oliguric acute renal failure requiring hemodialysis can also occur. This condition presents with oliguric within 24 hr of contrast administration and typically persists for 2-5 days (12). Morbidity and Mortality rates are significantly higher in this group of patient when compared with those who have non-oliguric renal failure

MATERIAL AND METHODOLOGY

The present prospective study on “incidence of contrast-induced nephropathy” was conducted on the patients admitted in the cardiac care unit of the tertiary care hospital. The patients of acute coronary syndrome in whom coronary angiography was indicated comprised the study population. The patients were selected from Department of Cardiology and Medicine. Total of 254 patients were taken. All the subjects included in the study underwent coronary / renal angiography using 50-60ml of iohexol non-ionic radiopaque contrast media.

Methods

All the patients were subjected to a detailed history, clinical examination and laboratory investigations which were recorded in the predesigned performa for this study. Laboratory investigations will include: CBC, serum creatinine before and 48 hr after radiopaque administration, lipid profile, X-ray chest, ECG, USG abdomen for kidney blood sugar fasting and post prandial and urine routine.

Inclusion Criteria

1. Age > 19 years of either gender
2. Acute coronary syndrome: trop T +ve / Trop T- ve
3. With or without Diabetes Mellitus type 1 and type 2 on insulin or OHD

4. With or without Renal insufficiency- serum creatinine concentration > 1.5 mg/dl
5. With or without Multivessel disease

Exclusion Criteria

1. Intake of nephrotoxic drugs within previous 7 days
2. Renal transplantation and ESRD
3. History of serious reaction to iodinated contrast medium
4. Newly discovered unstable diabetes
5. Intravascular administration of an iodinated contrast medium within previous 48 hours
6. Pregnant/ lactating women

RESULTS

The present study was carried out in a tertiary care center. A total of 254 patients undergoing (coronary/ renal) angiography were selected and studied with respect to their clinical profile. All the patients under study were divided on the basis of risk factors. These include normal (no risk factor), diabetes mellitus/ no renal insufficiency, renal insufficiency/ no diabetes mellitus, and diabetes mellitus/ renal insufficiency.

Table No. 1 Baseline Serum Creatinine in mg/dl of Patients.

S.No	Serum Creatinine	Percentage of Creatinine	Male	%age	Female	%age	Total
1	< 1.2	78.35	118	58.71	83	41.29	201
2	1.2-2	15.75	23	60.53	15	39.47	38
3	> 2	5.91	11	73.33	4	26.67	15
	Total	100	152		102		254

118 (58.71%) males and 83 (41.29%) females had serum creatinine < 1.2 . 23 (60.53%) male and 15 (39.47%) female had serum creatinine between 1.2-2. 11 (73.33%) male and 4 (26.67%) female had serum creatinine > 2 .

Table No. 2 Baseline Characteristics of Patients

Baseline Characteristics of Patients	%age	Male	%age	Female	%age	Total
Normal (No risk factor)	51.18	80	52.63	50	49.02	130
Diabetes/No Renal Insufficiency	26.77	41	26.97	27	26.47	68
Renal Insufficiency/No Diabetes	11.42	16	10.53	13	12.75	29
Diabetes/Renal Insufficiency	10.63	15	9.87	12	11.76	27
Total	100	152	100	102	100	254

80 (52.63%) males and 50 (49.02%) female were normal without risk factor. 41 (26.97%) males and 27 (26.47%) females were diabetic with no renal insufficiency. 16 (10.53%) males and 13 (12.75%) females have renal insufficiency without diabetes. 15 (9.87%) males and 12 (11.76%) females had both diabetes and renal insufficiency.

Table No. 3 Diagnostic Angiography/PCI (Angioplasty)

Diagnostic			PCI		
Gender	No. of Patients	%age	Gender	No. of Patients	%age
Male	109	42.91	Male	43	16.92
Female	69	27.16	Female	33	12.99
Total	178		Total	76	

109 (42.91%) males and 69 (27.16%) females undergo diagnostic angiography. 43 (16.92%) male and 33 (12.99%) female undergo PCI (angioplasty).

Table No. 4 Incidence of CIN

S.No	Description of Patients	Percentage
1	No CIN	88.98
2	CIN	11.02

Incidence of CIN was 11.02%.

Table No. 5 Number of patients with No CIN/with CIN

S.No	Description of Patients	Number of Patient	95% CI
1	No CIN	226	-
2	CIN	28	7.18 to 14.86

Out of 254 patients 226 (88.97%) had no CIN. 28 patients (11.02%) had CIN.

Table No. 6 Incidence of CIN

S.No	Description if Patients	Number of Patients	CIN	95%CI
1	Normal (no risk factor)	130	3	-0.27 to 4.87
2	Diabetes/No Renal Insufficiency	68	4	.26 to 11.34
3	Renal Insufficiency/No Diabetes	29	9	14.17 to 47.83
4	Renal Insufficiency/Diabetes	27	12	25.67 to 63.13
	Total	254	28	

Out of 130 patients with no DM/RI 3 had CIN. Out of 68 patients with DM/ no RI 4 had CIN. Out of 29 patients with RI/ no diabetes 9 had CIN. Out of 27 patients with DM/RI 12 had CIN.

Table No. 7 Incidence of CIN in Percentage

S.No	Description of patients	Number of Patients	Percentage of CIN
1	Normal (no risk factor)	130	2.31
2	Diabetes/No Renal Insufficiency	68	5.88
3	Renal Insufficiency/No Diabetes	29	31.03
4	Renal Insufficiency/Diabetes	27	44.44
	Total	254	

Out of 130 patients without any risk factor, 2.31% developed CIN.

Out of 68 patients with diabetes without RI, 5.88% developed CIN. Out of 29 patients with RI without DM, 31.03% developed CIN. Out of 27 patients with RI and DM, 44.44% developed CIN.

Table No. 8 Mortality Percentage.

S.No	Mortality Percentage
1	Without CIN 1.20%
2	With CIN requiring dialysis 16.40%

Mortality in patients without CIN was 1.20%. Mortality in patients with CIN requiring dialysis was 16.40%.

DISCUSSION

CIN is the third leading cause of hospital-acquired renal failure. CIN is significant but underestimated cause of iatrogenic acute renal failure. An overall incidence of CIN in general population is reported to be 0.6-2.3%. Incidence rate may vary from 0% to 90% depending on the presence of risk factor, most notably chronic renal insufficiency, diabetes mellitus, age > 70 yr, and high contrast volume administered (4) Thirty-day mortality rate was 16.2%, compared with 1.2% for patients who did not develop CIN & 1-yr mortality rate (23.3%) compared with those who did not develop CIN, (9).

In this study, It was found that males had higher incidence of coronary artery disease and also it is a male dominance society. So male population was higher than female population. In the present study incidence of CIN was 11.02%. Mc Cullough *et al.* 1997 (3) reported an our all incidence of 14.5% in patients undergoing coronary intervention. Rehal *et al.* 2002(5) reported that in patients with cardio vascular pathology, the incidence of CIN is higher, and ranges from 3.3% to 14.5%. In the present study the incidence of CIN in patients with no risk factor i.e without diabetes and renal insufficiency was 2.31%. Lasser *et al* 1997(13) studied the incidence of CIN in patients exposed to Ionic and Non-ionic, low and high- osmolar contrast media, the incidence of renal failure was approximately 3.6 times higher with all low-osmolar contrast media (2.3%) than with high-osmolar media (0.6%). In a study of 7586 patients in 2002, Rihal (5) found an incidence of CIN in 254 (3.3%). In the present study, diabetes mellitus with no renal insufficiency the incidence of CIN was 5.88%. (8) 2004 studies the incidence of CIN in 1,575 diabetic patients who underwent PCI, 1,046 (66%) had preserved renal function, 492 (31%) had CKD without dialysis, and 37 (2.3%) were dependant on dialysis. CIN after PCI was found in 15% of patients without CKD. In a study of 394 patients 1991, Freeman and Laut(14) in the incidence in our group of patients was 10% for non-azotemic vs 30% for azotemic patients, non-azotemic patients vs 16% for diabetics. Zhao *et al* 2012(15) studied the risk factors of contrast- induced nephropathy in patients after coronary artery intervention. A total of 637 patients undergoing diagnostic coronary angiography intervention were enrolled.

According to them patients with diabetics and renal insufficiency had higher incidence of CIN at 15.5% and 22.5% respectively. In a retrospectively analysis of 114 diabetic patients Wang *et al.* 2011(16) who had undergone elective PCI. The incidence of CIN was 18.4%. Lee *et al.* 2011(17) compared the ability of Sodium bicarbonate plus NAC (N-acetyl cysteine) and Sodium chloride plus NAC to prevent CIN in diabetic patients. Diabetic patients (n=382) were randomly assigned to receive prophylactic NaCl (Saline gp., n= 109) or Sodium bicarbonate (n=193). The primary end point was met in 10 patients (5.3%) in the saline group and 17 (9.0) in the bicarbonate group. In the present study, the incidence of CIN in renal insufficiency with no diabetes is 31.03%. In a prospective analysis done by Davidson *et al.* 1989(18), in a series of 1,144 patients undergoing Cardial Catheterization, found a low risk of CIN in patients with normal renal functions, but a high risk in those with preexisting azotemia (Scr > 1.2mg/dl) The risk increased exponentially with serum concentration (eg 2% incidence in those with a serum creatinine levels of 2 mg/dl). Morre *et al.* 1992(19) found a highly significant relationship between increasing baseline level of serum creatinine and the frequency of nephrotoxicity (varying from 2% in those with baseline creatinine of < 1.5 mg/dl to 20% in those with levels of > 2.5 mg/dl. Ueda *et al.* 2011(20) found that in 59 patients with CKD were randomized to receive a bolus IV injections of 154 mEq/L of sodium bicarbonate (n=30) or Sodium Chloride (n=29) at the dose of 0.5 mg/kg, before contrast administration, followed by infusion of 154 mEq/L. Sodium bicarbonate at 1ml/kg for 6 hrs in both groups. The incidence of CIN was significantly lower in the Sodium bicarbonate group than in the Sodium Chloride group (3.3% vs 27.6%). Hall *et al.* 1992(7) carried a prospective study to identify those

patients at greater risk of developing CIN. 222 patients undergo angiographic procedure. Post angiographic elevation in creatinine occurred in 2,104 and 62% patients with baseline creatinine levels of < or = 1.2 mg/dl, 1.3 to 1.9 mg/dl and > 0r = mg/dl, respectively.

In the present study, the incidence of contrast-induced nephropathy in patients with both Diabetes and Renal insufficiency is 12 (44.44%). Nikolsky *et al.* 2004(8) studied the impact of chronic kidney disease on prognosis of patients with DM treated with PCI. Of 1575 diabetic patients who underwent PCI, 1,046 (66%) had preserved renal function, 492 (31%) had CKD without dialysis and 37 (2.3%) were dependant on dialysis. CIN was found in 15% of patients without CKD vs 27% of those with CKD. Manske *et al.* (21)1990 studied contrast induced nephropathy in azotemic diabetic patients undergoing angiography. 59 diabetic with a mean serum creatinine level of 522 μ mol/L (5.9 mg/dl) underwent coronary angiography. Contrast nephropathy occurred in 50% of patients and no controls. In the present study, mortality rate for patients developing CIN requiring dialysis was 16.7% and those without CIN was 1.2%. Sadeghi *et al.* 2003(9) in a prospective study in 2007 patients undergoing PCI the 30-day mortality rate was 16.2%, compared with 1.2% for patients who did not develop CIN.

Nikolsky *et al.* 2003 (8) carried a study on 1826 consecutive patients undergoing coronary intervention. The in-hospital mortality rate for the patients who developed CIN but who did not require dialysis was significantly greater than the patients who did not develop CIN (7.1 vs 1.1%) for patient requiring dialysis the in-hospital mortality rate was 35.7%. Rihal *et al.* 2002(5), studied that of the 7586 patients undergoing PCI induced in the analysis, 254 patients (3.3%) experience CIN, and the in-hospital mortality rate for these patients was 22% compared with a rate of 1.4% for the patients who did not develop CIN.

Summary

A total of 254 patients- 152 males and 102 females were included in the Present study.

The results of study are summarized as follow:

- Out of 254 patients 28 develop contrast induced nephropathy
- Incidence of contrast - induced nephropathy was 11.02%
- Incidence of contrast induced. Nephropathy in patients without any risk factor is 2.31%
- Incidence of CIN in diabetic patients without renal insufficiency was 5.88%.
- Incidence of CIN in renal insufficiency patients without DM was 31.03%.
- Incidence of CIN in RI and DM was 44.44%.
- Incidence of CIN increases with increase in risk factors..
- In-hospital mortality rate for patients developing CIN requiring dialysis was 16.2% and those without CIN was 1.2%.

CONCLUSION

Contrast media (CM) are increasingly used in diagnostic and interventional procedure. This results in the rising incidence of

iatrogenic renal function impairment caused by exposure to CM, a condition known as CIN. CIN is the third leading cause of hospital acquired renal failure. Among all procedures utilizing CM for diagnostic or therapeutic purposes, coronary angiography and percutaneous coronary interventional are associated with the highest rates of CIN. Thus in our study we found out that overall incidence of CIN to be 11.02%. The highest incidence of CIN was seen in patients with concomitant diabetes and renal insufficiency (44.44%) and the lowest incidence of 2.31% in patients with no risk factor. Although the risk is low in general population without risk factors, CIN occurs frequently in patients with underlying diabetes mellitus, renal dysfunction and the elderly. Thus a careful risk-benefit analysis must always be performed prior to the administration of CM to patient at risk of CIN.

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