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PREVALENCE AND RISK PROFILE OF ATHEROSCLEROTIC RENAL ARTERY STENOSIS IN RELATION TO ATHEROSCLEROTIC CORONARY ARTERY DISEASE.

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ABSTRACT

Background: Associations between patient demographic characteristics, coronary disease burden, extracoronary atherosclerosis, putative manifestations of RAS and the prevalence of RAS have not been prospectively and rigorously examined, particularly in Indian context, most importantly in this part of the subcontinent. **Objectives:** To determine the prevalence of atherosclerotic renal artery stenosis (ARAS) in patients with obstructive coronary artery disease during cardiac catheterization and to study the association of common atherosclerosis risk factors and other variables (if any), with ARAS. **Methods:** The observational study was done in the department of Cardiology, NRS Medical College, Kolkata, India over the period of one year. A total of 304 subjects were screened for renal artery stenosis by renal angiography among all patients whom we suspected atherosclerotic renal artery stenosis (ARAS) and who were undergoing non-emergent diagnostic cardiac catheterization for cardiac indication, at our hospital. The clinical characteristics of patients were compared using simple statistical methods. Correlation of atherosclerotic coronary artery disease, renal artery stenosis was evaluated and laboratory findings were analyzed once the complete data was available. **Results:** Among subjects with significant CAD, renal angiogram showed 4.61% had significant bilateral ARAS, 4.61% had unilateral RAS, 6.91% had insignificant RAS and 83.88% patients' revealed normal renal artery. It is evident that smoking is the only factor conclusively associated with ARAS. However, HTN has also shown a trend of association in our study and most of ARAS were present in subjects with multiple risk factors (≥2). **Conclusion:** Pre-test likelihood for the presence of significant ARAS is particularly high in elderly patients, with multi atherosclerotic risk factors, with reduced glomerular filtration rate and with multi vessel coronary artery disease.

KEYWORDS: Atherosclerosis, Renal artery stenosis, Coronary artery disease.

INTRODUCTION

Atherosclerosis of the renal artery resulting in renal artery stenosis (ARAS) associates with increased cardiovascular events and mortality. ARAS is an important cause of renal insufficiency, refractory hypertension and cardiac destabilization syndromes (unstable angina and flash pulmonary edema). Assessment of a general population by renal duplex ultrasound in individuals older than 65 years of age has revealed an approximately 7% prevalence of RAS, which increases to 20% to 30% in high-risk populations (e.g., patients with known atherosclerotic vascular disease). Renal artery stenosis (RAS) is a possibly curable cause of arterial hypertension and of renal insufficiency. The mortality risk depends on the severity of RAS. Clearly, the early diagnosis of RAS and the prevention of end-stage renal disease (ESRD) is an important goal.

The clinical diagnosis of atherosclerotic renal artery stenosis (RAS) remains problematic. In contrast to myocardial ischemia, the pathophysiologic manifestations of RAS (hypertension, renal dysfunction and acute left ventricular [LV] failure) are nonspecific and often attributed to other processes. This dilemma has hindered both the clinical detection of RAS in individuals at risk and the determination of RAS prevalence in populations at risk. Contrast angiography is a standard criterion for RAS; it is readily performed in combination with coronary angiography.

A correlation between coronary disease burden and the prevalence of RAS has already been established, but associations between patient demographic characteristics, coronary disease burden, extracoronary atherosclerosis, putative manifestations of RAS and the prevalence of RAS have not been prospectively and rigorously examined, particularly in Indian context, most importantly in this part of the subcontinent. It is on this background present observational study is conceived to determine the prevalence of atherosclerotic renal artery stenosis (ARAS) in patients with obstructive coronary artery disease during cardiac catheterization and to study the association of common atherosclerosis risk factors and other variables (if any), with ARAS.

We will be performing a study on this matter with objectives, to find out prevalence of ARAS in patients with atherosclerotic coronary artery disease and atherosclerosis in other vascular bed in our population and to determine the variables which could predicts high risk substrate in the population.

MATERIALS AND METHODS

The observational study was done in the department of Cardiology, NRS Medical College, Kolkata, a teaching institute in West Bengal over the period of one year. Total sample size was 304. We screened for renal artery stenosis by renal angiography among all patients whom we suspected (Table 1) atherosclerotic renal artery stenosis (ARAS) and who were undergoing non-emergent diagnostic cardiac catheterization for cardiac indication, at our hospital. Before catheterization, a protocol-based clinical examination was used to determine demographics, cardiac history, indications for cardiac catheterization, atherogenic risk factors, features of extracoronary vascular disease and related comorbidities.

Inclusion Criteria

1) We have categorized all patients according to the presence or absence of each selection criteria determined a priori (Table 1). The criteria were developed to identify patients with putative pathophysiologic manifestations of RAS (hypertension, renal dysfunction, or acute pulmonary edema) or advanced atherosclerosis in other vascular territories. Patients meeting at least one selection criterion before knowledge of the coronary anatomy had been invited to participate and asked to provide written consent before their cardiac and renal catheterization procedure.

2) Patients not meeting a selection criterion, before cardiac catheterization due to cardiac indication has been asked to provide written consent for renal angiography, if cardiac catheterizationdemonstrate obstructive coronary atherosclerosis.[4]

Table 1[8]

Hypertension	Onset of hypertension after 50 years of age and the hypertension is severe and resistant.
Kidney dysfunction	
Unexplained	C-G CrCl <50 ml/min without clearly established cause
ACEI-ARB induced	Documented acute renal dysfunction attributable to ACEI or ARB therapy
Acute pulmonary edema	Radiographic grade ≥III *and* no other recognized cause (e.g., EF <40%, AMI, severe valvular disease) *and* associated with acute hypertension (≥160/100 mm Hg) or chronic hypertension
Severe atherosclerosis (Abdominal aortic or lower extremity artery disease)	Causing stenosis ≥50% diameter; documented atherosclerotic aneurysm; Previous peripheral or aortic surgery; or Intermittent claudication with corroborative physical examination

ACEI = angiotensin-converting enzyme inhibitor; AMI = acute myocardial infarction; ARB = angiotensin receptor blocker; BP = blood pressure; CrCl = creatinine clearance; C-G = Cockcroft-Gault; EF = ejection fraction.

Exclusion Criteria[4,7] includes patient receiving renal replacement therapy, known or suspected acute renal failure. history of contrast nephropathy, baseline serum creatinin >2 mg/dl even if the cause is unexplained (to prevent development of CIN), hemodynamically unstable, physician preference, or refusal or inability to provide informed consent, when uncertainty in estimating degree of renal artery stenosis will remain and consensus could not be achieved. Baseline serum creatinine had been measured before the procedure;

estimated creatinine clearance (CrCl) calculated using the Cockcroft-Gault formula. Renal dysfunction (as an inclusion criterion) was based on Cockcroft-Gault CrCl <50 ml/min. Patients qualifying for inclusion on the basis of renal dysfunction alone, were excluded if a well-documented cause of renal dysfunction exist.

PARAMETERS TO BE STUDIED AND STUDY TOOLS

1) Age, Sex distribution,
2) Family history suggestive of atherosceloerotic diseases.
3) Major Risk Factors of atherosclerosis.
4) Clinical features suggestive of atherosclerotic coronary artery disease and atherosclerotic renal artery stenosis (according to Table 1).
5) Routine blood examination like Hb, Total count, Differential count, Platelet count. Blood biochemistry like Fasting and Post pandrial Blood Sugar, Urea, Creatinine (pre and 24 hour of post procedure) Sodium, Pottasium, Lipid profile, creatinine clearance estimation by Cockcroft-Gault formula.
6) ECG, Echocardiography (Ejection Fraction, Regional wall motion abnormality, Left ventricular hypertrophy, valve morphology and presence of regurgitant lesion, feature of pulmonary hypertension, pericardium, diastolic dysfunction).
7) Coronary angiography
8) Renal angiography
9) Lower limb peripheral angiography and carotid angiography (if clinically indicated).

STUDY TECHNIQUES

Between the above mentioned study period, we had screened all patients undergoing non-emergent diagnostic Coronary angiography at our hospital and evaluated them for study inclusion according to predetermined inclusion criteria. Before catheterization, a protocol-based clinical examination were used to determine demographics, cardiac history, indications for cardiac catheterization, atherogenic risk factors, features of extracoronary vascular disease and related comorbidities. We had categorized all patients according to the presence or absence of each selection criteria determined a priori (Table 1). The criteria are developed to identify patients with putative pathophysiologic manifestations of RAS (hypertension, renal dysfunction, or acute pulmonary edema) or advanced atherosclerosis in other vascular territories. Patients meeting at least one selection criterion before knowledge of the coronary anatomy were invited to participate and asked to provide written consent before their cardiac and renal catheterization procedure. Patients not meeting a selection criterion, before cardiac catheterization due to cardiac indication, were asked to provide written consent for renal angiography if cardiac catheterization demonstrated obstructive coronary atherosclerosis.

Renal artery angiography

Participating patients underwent either selective or nonselective renal angiography before completion of their cardiac catheterization procedure. After performing coronary angiogram, all of these patients underwent selective renal angiography using a right judkins catheter. No procedural related complications were reported. Dye used in the angiography was iohexol (Omnipaque). mined in the routine fashion.

Each operator categorically graded main and proximal renal arteries as normal or abnormal (any roughening or stenosis consistent with atherosclerosis) and further categorized abnormal arteries according to visually estimated diameter stenosis severity (<50% [mild], 50% to 70% [significant], >70% to 99% [severe], or 100% [totally occluded]) and according to stenosis location (aorto-ostial or other). The consensus of at least two experienced angiographers were required in cases where stenosis severity was initially uncertain. If the uncertainty remained and consensus could not be achieved, patients were excluded.

ANALYSIS OF DATA

Registry data on all participating patients were entered in a central study database. The clinical characteristics of patients were compared using simple statistical methods. Correlation of atherosclerotic coronary artery disease, renal artery stenosis was evaluated and lsab findings were analyzed once the complete data was available. Prevalence of atherosclerotic renal artery stenosis in coronary artery disease was estimated and significant variables were derived to predict presence of renal artery stenosis in subjects.

RESULTS

TABLE-1 SHOWING SEVERITY OF CAD AMONG ALL PATIENTS IN THE STUDY

Severity of CAD	No. of Patients	%
TVD/LMCA	106	34.86
DVD	92	30.26
SVD	106	34.86
Total	304	100

TABLE-2 SHOWING DISTRIBUTION OF RAS IN CVD

RENAL ARTERY LESION	NO. OF PATIENTS	%
BLRAS	14	4.61
ULRAS	14	4.61

INS RAS	21	6.91
NORMAL	255	83.88
TOTAL	304	100

TABLE 3-SHOWING DISTRIBUTION OF ARAS AMONG PATIENTS WITH CAD & PAD

	CAD+PAD
RAS PRESENT	5 (20%)
RAS ABSENT	20 (80%)
TOTAL	25 (100%)

Among 28 patients with significant renal artery stenosis whether bilateral or unilateral, 22 (78%) had hypertension, 20 (71%) patients were smoker, 12 (43%) had diabetes mellitus and only 6 (21%) patients had dyslipidemia.

TABLE 4-SHOWING CLINICAL VARIABLES AMONG RAS PATIENTS

RF	YES	NO	TOTAL PATIENTS
HTN	22 (78%)	6 (22%)	28
SMOKER	20 (71%)	8 (29%)	28
DM	12 (43%)	16 (57%)	28
DYSLIPIDEMEA	6 (21%)	22 (79%)	28

TABLE 5

Risk factors≥ 2	78.57%
Risk factors <2	21.43%
TOTAL	100%

In this **Table 6,** we presented the frequency of risk factors amongst patients of CAD with and without ARAS. This table also summarizes the Odd's ratio with 95% confidence interval of the risk factors.

Risk factors	Frequency of CAD patients with ARAS having the risk factor (n=28)	Frequency of CAD patients without ARAS having the risk factor (n=276)	Odd's ratio	95% confidence interval	P value
Smoking	22 (78%)	122(44%)	3.15	1.34 to 7.41	0.008*
Diabetes mellitus	20 (71%)	112 (41%)	1.09	0.50 to 2.41	0.815
Hypertension	12 (43%)	168 (61%)	2.35	0.92 to 6.00	0.072
Dyslipidaemia	6 (21%)	82 (30%)	0.64	0.25 to 1.65	0.360
Age >60 years	20 PATIENTS (71%)	186 (67%)	1.20	0.51 to 2.85	0.663

P<0.05*, n= sample size, CAD= coronary artery disease, ARAS= atherosclerotic renal artery stenosis.

The association of risk factors with patients with ARAS was evaluated through Odd's ratio with 95% confidence interval. The risk factors of ARAS were compared with patients of CAD without ARAS. From Table, this is to note that, smoking was the only risk factor under consideration, which had the lower bound of 95% confidence interval>1. In rest of the factors the 95% confidence interval of Odd's ratio extended from a negative to a positive value. From the p value and 95% CI it is evident that smoking is the only factor conclusively associated with ARAS. However, HTN has also shown a trend of association in our study.

TABLE 7-SHOWING DISTRIBUTION OF AGE IN PATIENTS WITH ARAS

AGE 60 ≥ YRS	20 PATIENTS (71%)
AGE < 60 YRS	8 PATIENTS (29%)
TOTAL	28 PATIENTS (100%)

TABLE 8- SHOWING DISTRIBUTION OF CRCL AMONG ARAS PATIENTS

CrCl < 60	20 patients (72%)
CrCl 60-90	4 (14%)
CrCl > 90	4(14%)
Total	28 (100%)

TABLE 9-SHOWING DISTRIBUTION OF SEVERITY & EXTENT OF CAD IN ARAS PATIENTS

SEVERITY OF CAD	PATIENTS WITH ARAS
TVD	16 (57%)
DVD	12 (43%)
SVD	0
TOTAL	28 (100%)

TABLE 10-SHOWING INCIDENCE OF SIGNIFICANT RAS & NO RAS IN PATIENTS WITH TVD & DVD CAD

	TVD/LMCA	DVD	TOTAL
RAS	16 (15%)	12 (13%)	28
NO RAS	90 (85%)	80 (87%)	170
TOTAL	106 (100%)	92 (100%)	

DISCUSSION

DISTRIBUTION OF SEVERITY OF CAD AMONG ALL PATIENTS IN THE STUDY: (Table 1)

A total of 304 patients were included in this study who had significant coronary artery disease as revealed on coronary angiography. Among 304 patients, 106 had TVD(triple vessel coronary artery disease and/or LMCA disease) [35%], 92 had DVD [30%] and 106 had single vessel coronary artery disease (SVD) [35%]. But the above mentioned data, is not similar to some of the well-known study of Christopher E. Buller[4] or study of D. Weber.[3] This discrepancy can be explained by small sample size of the present study.

DISTRIBUTION OF RAS IN CVD: (Table 2)

Among 304 patients with significant CAD, renal angiogram, showed, 14 patients had significant bilateral ARAS (BLRAS) [4.61%], 14 had unilateral RAS (ULRAS) [4.61%], 21 had insignificant RAS (INSRAS) [6.91%] and 255 patients revealed normal renal artery [83.88%]. A study from Bangladesh by MOHAMMAD SAFIUDDIN et al.[18], showed any degree severity of RAS present in 12%, with significant RAS was present in 6% (UL-4.5%, B/L- 1.5%). Indian study by Rath et al.[10] and by Sathyamurthy et al.[9] showed total RAS incidence in significant CAD was 10.3%, and among them 2.5% had significant RAS. A study by Weber et al.[3] showed no RAS was present in 89.3 %, insignificant RAS was found in 14.1%, Significant unilateral RAS was in 7.9% and significant bilateral RAS was found in 2.8%.

A study by Christopher E. Buller et al.[4] had significant RAS in 14% and insignificant RAS was in 22%. Another famous study by Harding et al.[11] showed normal renal artery in 70%, insignificant RAS in 15%, significant unilateral RAS in 11% and significant bilateral RAS in 4%. From the above studies, it can be said that western studies had RAS in more number of patients with CAD, but Indian studies or study from Bangladesh showed little less number of RAS in CAD patients, compared to the west. In our study incidence of RAS (significant or insignificant) and no RAS, in CAD patients are comparable to major famous studies, but incidence of unilateral and bilateral RAS is not similar to the above mentioned studies. This discrepancy can be explained by small sample size of the present study.

DISTRIBUTION OF ARAS AMONG PATIENTS WITH CAD & PAD: (Table 3)

Among all CAD patients with clinical indications, whom we did peripheral angiography (Carotid, Vertibral or lower limb), 25 patients showed atherosclerotic lesion in peripheral arteries. Among 25 patients with peripheral arterial disease and CAD, ARAS were present in 5 patients (20%) and remaining 20 patients (80%) had no RAS. All the patients with ARAS, PAD and CAD had triple or double vessel coronary artery disease. The study done by Kwok-Wai Mui et al.[6] showed RAS was present 26% of the patient with confirmed PAD. In the literature, it has been said that the prevalence of RAS is 5-40%. Hence the present study, prevalence of RAS in PAD is comparable.

DISTRIBUTION OF 4 MAJOR ATHEROSCLEROTIC RISK FACTORS (RF) AMONG SIGNIFICANT ARAS PATIENTS: (Table-4,5,6,)

Among 28 patients with significant renal artery stenosis whether bilateral or unilateral, 22 (78%) had hypertension, 20 (71%) patients were smoker, 12 (43%) had diabetes mellitus and only 6 (21%) patients had dyslipidemia. Among 28 patients with significant renal artery stenosis whether bilateral or unilateral, 78% had 2 or more than 2 major risk factors and 22% had less than 2 risk factors. A study from Bangladesh by MOHAMMAD SAFIUDDIN et al.[18] showed DM in 45%, HTN in 73%, Dyslipidemia in 67% and smoking history in 30%. Indian study by P.Rath et al.[10] and by I. Sathyamurthy et al.[9] showed HTN in 61%, DM in 44%, Dyslipidemia in 25% and smoking in 39%. A study by Weber et al.[3] showed in RAS group distribution of risk factors were, DM in 69%, HTN in 94%, dyslipidemia in 81% and smoking in 25%. A study by Christopher E. Buller et al.[4] showed DM present in 14% and smoking in 24%.Various studies had various results in respect to presence of risk factors associated with significant RAS. Even some studies had shown there is no independent RF associated with RAS but presence of multiple risk factors is strongly associated with RAS.

In the present study, smoking was the only risk factor under consideration, which had the lower bound of 95% confidence interval>1. In rest of the factors the 95% confidence interval of Odd's ratio extended from a negative to a positive value. From the p value and 95% CI it is evident that smoking is the only factor conclusively associated with ARAS. However, HTN has also shown a trend of association in our study and most of ARAS are present in subjects with multiple risk factors (≥2).

DISTRIBUTION OF AGE IN PATIENTS WITH ARAS: (Table-7)

In the present study, among 28 patients with significant ARAS, 20 patients (71%) had age more than or equal to 60 years and remaining (21%) had age less than 60 yrs. A study from Bangladesh by MOHAMMAD SAFIUDDIN et al.[18], showed that patients with significant RAS were older compared to those without significant disease. According to an Indian study by P. Rath et al.[10], mean age of ARAS patient was above 57 years. A study by Weber et al.[3] revealed that patients with significant RAS were older (>67 years). A study by Christopher E. Buller et al.[4], showed that most of the patients with significant ARAS were more than 60 years of age.

Another famous study by Harding et al.[11], showed mean age of ARAS patients were 66±10 years. So in my stud, the age distribution of RAS among subjects are comparable to other studies.

DISTRIBUTION OF CRCL AMONG ARAS PATIENTS: (Table-8)

Among 28 patients with significant RAS, 20 patients (72%) had creatinine clearance (CrCl) less than 60 ml/min, 4 (14%) had CrCl between 60-90 ml/min and remaining 4 (14%) had CrCl greater than 90 ml/min. So it is evident most of the patient with ARAS have diminished glomerular filtration rate, as 72% pt had stage 3 or more kidney disease. A study by Harding et al.[11] showed patients with almost all ARAS had serum creatinine more than 1.2 mg/dl. A study by Christopher E. Buller et al.[4] showed most of the ARAS patients had CrCl 64±25 ml/min.

A study by Weber et al.[3] pointed out that most of the ARAS patients had decreased GFR (61±16 ml/min). So in my study the reduced GFR values are almost similar to various other studies.

DISTRIBUTION OF SEVERITY & EXTENT OF CAD IN ARAS PATIENTS: (Table-9)

Among 28 patients with significant ARAS, 16 patients (57%) had TVD/LMCA disease, 12 patients (43%) had DVD and no patients with renal artery stenosis in this study had single vessel coronary artery disease.

INCIDENCE OF SIGNIFICANT RAS & NO RAS IN PATIENTS WITH TVD & DVD CAD: (Table-10)

Among total 304 CAD patients in the present study, no significant RAS were found in single vessel coronary artery disease. Only TVD/LMCA disease and DVD coronary artery disease had significant renal artery disease in this study. 15% of all TVD/LMCA coronary artery disease patients and 13% of all DVD patients had significant ARAS. A study by Weber et al.[3] concluded that the pretest likelihood for the presence of significant ARAS is particularly high in patients with more than 2 coronary artery lesions. A study from Bangladesh by MOHAMMAD SAFIUDDIN et al.[18], showed significant RAS was more common in patients with three vessel CAD compared to those with single or two vessel CAD. They found significant relationships between atherosclerotic involvement of LAD, LCX and RCA and RAS. As for number of coronaries involved, patients with three vessels CAD showed strong relationship with RAS and those with normal coronaries or insignificant CAD had a potent negative association with RAS. Indian study by P.Rath et al.[10] and by I. Sathyamurthy et al.[9] showed that highest incidence of ARAS were found in patients with triple vessel coronary artery disease. A study by Christopher E. Buller et al.[4] showed that significant RAS were found in 19% of DVD patients, 14% of TVD patients and 14% of LMCA disease patients. A study by Harding et. al.[11] also showed ARAS were found mostly in multivessel coronary artery disease. So in the present study, my findings are similar to various other studies.

CONCLUSION

Compared to western studies, prevalence of significant ARAS in Indian population with coronary artery disease is less. Prevalence of ARAS is more in patients with coronary artery disease and peripheral artery disease, than in CAD alone. In the present study, smoking was the only risk factor under consideration, which had the lower bound of 95% confidence interval>1. In rest of the factors the 95% confidence interval of Odd's ratio extended from a negative to a positive value. From the p value and 95% CI, it is evident that smoking is the only factor conclusively associated with ARAS. However, HTN has also shown a trend of association in our study and most of ARAS are present in subjects with multiple risk factors (≥2). Age is important non modifiable risk factor associated with ARAS, particularly above the age 60 years. Most of the subjects with ARAS has reduced glomerular filtration rate. Prevalence of significant ARAS, whether unilateral or bilateral are found in CAD with multi-vessel involvement (TVD or DVD) and not in single vessel CAD.

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