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Research Article

A CROSS-SECTIONAL STUDY ON THE PREVALENCE OF PERIPHERAL ARTERIAL DISEASE IN CHRONIC RENAL DISEASE USING ANKLE BRACHIAL INDEX AMONG ADULTS

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A R T I C L E I N F O

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Peripheral arterial disease, Chronic renal failure, Creatinine clearance, Ischemic heart disease.

A B S T R A C T

Background: The presence of peripheral arterial disease in chronic renal failure portends a dismal prognosis due to the increased morbidity and mortality from cardiovascular events. Peripheral arterial disease is asymptomatic in about 40%.

Aims: The study was designed to identify the prevalence of the peripheral arterial disease in chronic renal failure, which is a state of accelerated atherosclerosis.

Materials and methods: It is cross-sectional study of 50 patients with chronic renal failure attending the outpatient were assessed for the prevalence of peripheral arterial disease by measuring the Ankle-brachial index. Age, gender, hypertension, and ischemic heart disease profiles of the sample were analyzed for association with peripheral arterial disease.

Results; The majority of the patients belonged to the age group 41-50 years. 46 were males, 4 were female patients. 4 out of 50 patients in the sample had symptoms suggestive of peripheral arterial disease. 20% (n=10) had evidence of ischemic heart disease. Hypertension was present in 40% (n=20) of the patients. 50% of the patients belonged to CRF stage 4.The prevalence of peripheral arterial disease as determined by and ABI<0.9 was 30%. Among the variables studied, the presence of IHD (p=0.008) and creatinine clearance(p=0.0002) were identified as having a significant association with increased prevalence of PAD. All symptomatic patients had the peripheral vascular disease (ABI<0.9) but of the asymptomatic patients23.7%(n=11) had evidence of PAD. There was an inverse correlation between creatinine clearance and the prevalence of PAD.

Conclusion: There was a significant relationship between the prevalence of peripheral arterial disease and the stage of chronic renal failure, the higher the degree of renal insufficiency the higher was the prevalence of the peripheral arterial disease

INTRODUCTION

As the morbidity and mortality from infectious diseases decline, life expectancy increases, and chronic degenerative diseases have become more prevalent. CKD is unique amongst the chronic- non-infectious illnesses in that there is a very real window of opportunity to continue living comfortably despite being terminally ill. It has been estimated from population survey data that at least 6% of the adult population in the United States has chronic kidney disease at stages 1 and 2.[1] An unknown subset of this group will progress to more advanced stages of CKD. An additional 4.5% of the U.S. population is estimated to have stages 3 and 4 CKD.

The most frequent cause of CKD is diabetic nephropathy, most often secondary to Type 2 Diabetes mellitus[2].

India, being the Diabetic capital of the world and diabetic nephropathy being the commonest cause of CKD, the prevalence of PVD is on the rise. There are about 17% CKD patients in India[3].

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Cardiovascular disease is the leading cause of morbidity and mortality in patients at every stage of CKD. The incremental risk of cardiovascular disease in those with CKD compared to the age and sex-matched general population ranges from 10-20 folds, depending on the stage of CKD[2].The increased incidence of Peripheral vascular disease in CKD is due to the higher susceptibility to atherosclerosis. While due attention is provided to the detection of coronary artery disease in CKD patients, PAD, which is associated with a high mortality rate is not usually assessed in these patients. This is not only due to the lack of awareness of the remarkably high prevalence of PAD among CKD patients but to the asymptomatic nature of the disease, fewer than 50% of patients with PAD are symptomatic, thus defining a population with subclinical PAD[2].

The alarming increase in the number of patients with clinical and subclinical peripheral vascular disease in chronic renal failure calls for the need of screening all patients with CKD for PAD. A risk-free, cost-effective, non-invasive approach to screen all patients with CKD for PAD is necessary. The resting

ABI (Ankle Brachial Index) is a sensitive and specific screening test used for establishing the diagnosis of PAD[4]. Individuals with asymptomatic PAD should be identified to offer therapeutic interventions known to diminish their increased risk of myocardial infarction, stroke, and death. This study is designed to determine the prevalence of PAD.

MATERIALS AND METHODS

Subjects and Sample size: 50 Patients attending or admitted in the department of Medicine or in Nephrology who fulfilled the inclusion and exclusion criteria were the subjects of the study.

Study design: a cross-sectional study.

Ethical committee approval: The Ethical committee approval was obtained to carry out the study in the hospital.

Study setting: Osmania General Hospitals, Hyderabad.

Study duration: December 2018 – December 2019.

Study criteria Inclusion criteria

1. Renal insufficiency defined as an estimated Creatinine clearance of <60ml/min/1.73m^2 (stages 3,4,5)
2. No previous diagnosis of Peripheral arterial disease.

Exclusion criteria

- Patients with an established diagnosis of Peripheral arterial disease
- Patients with congestive cardiac failure, aortic regurgitation, foot gangrene, connective tissue disease.
- Patients with both lower limb amputation, foot gangrene.
- Patients with an established diagnosis of Diabetes mellitus and Smokers.

Study Protocol: Patients admitted/attending the outpatient department of Nephrology or Medicine in OGH was the study group. A well designed proforma was used to collect the demographic and clinical details of the patients.

Collaborating department

Department of Medicine and Department of Nephrology, Department of Radiology under Osmania General Hospital, Hyderabad.

Sample collection

A sample of 50 patients was collected defining the stage 3-5 CKD. Serum creatinine was measured using the modified kinetic Jaffe method. Because several factors, such as age, ethnicity, and gender, can influence serum creatinine, the level of kidney function was ascertained by eGFR, which was calculated using the formula that was developed and validated in the Modification of Diet in Renal Disease (MDRD) study.

The MDRD formula is as follows:
eGFR = 186.3x (serum creatinine-1.154) x(age-0.203) x 1.212 (if black) x0.742 (if female).

eGFR was divided into the following categories based on the National Kidney Foundation guidelines

Ankle Brachial Index

The systolic BP (SBP) was measured in the posterior tibial and dorsalis pedis arteries of both lower limbs and the brachial artery of both upper limbs.

The value of the ABI was calculated using the greater SBP obtained in the lower limbs divided by the SBP of whichever was the higher in the upper limbs. The lowest ABI so obtained for each patient was used in the subsequent statistical analyses. A value of ABI <0.9 was considered pathologically low.

Normal value - 0.9- 1.3
Mild occlusion – 0.6 -0.89
Moderate occlusion – 0.4 -0.59
Severe occlusion -<0.4

Prevalent CHD was defined as a previous MI by electrocardiogram, coronary artery bypass surgery, coronary angioplasty.

Prevalent hypertension: The diagnosis of hypertension required that the patient had such a diagnosis made previously by the treating physician, a BP≥140/90 mmHg in patients without diabetes or BP≥130/80 mmHg in patients with diabetes recorded on two separate occasions, or treatment with antihypertensive drugs.

Statistical Analysis

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of a computer using Epidemiological Information Package (EPI 2002). Using this software, range, frequencies, percentages, means, standard deviations, chi- square, and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance of the difference between quantitative variables and Yates's test for qualitative variables. A 'p' value less than 0.05 is taken to denote a significant relationship.

RESULTS

Table 1 Demographic variables in present study

Age group	Cases	
	NO	%
Up to 30 years	3	6
31-40	12	24
41-50	19	38
51-60	8	16
Above 60	8	16
Total	50	100
Range	22-68 years	
Mean	47.3	
SD	11.8	
Gender		
Male	46	92
Female	4	8
Symptoms		
Symptomatic	4	8
Asymptomatic	46	92
Positive ABI		
Yes	15	30
No	35	70
CRF Stage		
III	11	22
IV	25	50
V	14	28

Most of the patients in the sample were in the age group of 41-50 years. The range was from 22-68 years. Of the 50 patients in the sample, 46 patients were males and 4 patients were females. Of the 50 patients with chronic kidney disease, the majority (92%) did not have any symptoms of peripheral arterial disease, while 4 patients were symptomatic. The number of patients with a positive ABI (defined as a case of Peripheral arterial Disease) is 15. The prevalence of PAD in

this sample of patients was 30%. Of the 50 patients in this sample of CKD, 11 patients belonged to Stage III, 25 patients belonged to Stage IV and 14 patients belonged to Stage V.

Table 2 Riskfactors

Risk Factor	Present		Absent	
	NO	%	NO.	%
HTN	20	40	30	60
IHD	10	20	40	80

20 were hypertensives and 10 have ischemic heart disease.

Table 3 AGE and PAD

Age Group	PAD			
	Present		Absent	
	NO.	%	NO.	%
Up to 30(3)	0	0	3	100
31-40(12)	3	25	9	75
41-50(19)	6	31.5	13	68.4
51-60(8)	3	37.5	5	62.5
Above 60(8)	3	25	6	75
Mean age		48.6		46.8
SD		10.3		12.4
„p“			0.4288 Not Significant	

The mean age of chronic renal failure patients with PAD is 48.6 years. Out of which 3(25%) are in the age group of 31 to 40 years, 6 (31.5%) are in the age group of 41 to 50 years, 3 (37.5%) are in the age group of 51 to 60 years, 3 (25%) are in age group more than 60years.Applying the chi-square test, the difference showed no statistical significance.

Table-4: Gender and PAD

Sex	PAD			
	Present		Absent	
	NO.	%	NO.	%
Male(46)	13	28.3	33	71.7
Female(4)	2	50	2	50
„p“			0.6875 Not significant.	

The peripheral arterial disease was present in 28.3% of males (n=13) and 50% of females (n=2).Applying the chi-square test, the difference did not show statistical significance (p=0.6875)

Table 5 Symptoms and PAD

Symptoms	PAD			
	Present		Absent	
	NO.	%	NO.	%
Symptomatic (4)	4	100	-	-
Asymptomatic (46)	11	23.7	35	76.3
„p“			0.0001 Significant.	

Of the 50 patients screened, all the patients (n=4) who were symptomatic had the peripheral vascular disease and 23.7% (n =11) who were asymptomatic had peripheral vascular disease. The difference was statistically significant as determined by the chi-square test. The prevalence of the asymptomatic peripheral vascular disease in CKD patients in the present study is 23.7%. 20 patients had hypertension in the study group.

Abnormal ABI was present in 35% of the hypertensive patients whereas abnormal ABI was seen in 26.6%, which had no statistical significance.

Table 6 IHD and PAD

IHD			PAD	
Present			Absent	
NO.	%		NO.	%
Present (10)	7	70	3	30
Absent (40)	13	32.5	27	67.5
„p“			0.0002 Significant	

10 patients in the study group had coronary artery disease. The analysis showed that of patients with ischemic heart disease 7 (70%) had peripheral arterial disease whereas 32.5% of patients without IHD had the peripheral arterial disease. The difference was not found to be statistically significant.

Table 7 CRF stage and PAD

CRF	PAD			ABI	
Present	Absent		Mean	SD	
NO.	%		NO.		%
III (11)	2	18.1	9	81.9	1.02	0.14
IV (25)	8	32	17	68	0.95	0.1
V (14)	5	35.7	9	64.3	0.92	0.14
„p“				0.0427 Significant		

Of the 50 patients in the study group, 25 patients had Stage 4 CKD. The prevalence of Peripheral arterial disease (ABI<0.9) was 18.1% in patients with Stage III CKD and 32and 35.7% in stage IV and stage V CKD respectively. The higher the stage of CKD, the higher the prevalence of Peripheral arterial disease. This correlation of PAD with increasing stages of CRF was found to be statistically significant.

DISCUSSION

Of the 50 sampled patients with CKD, the prevalence of PAD in our study was 30%. This correlated with other studies as in NHANES survey 1999-2000[5], studies by Guerrero *et al*[6]and De Vinuesa *et al*[7], **Andrew Wilson *et al*[8]**in which the prevalence of PAD was 24%, 19%, 32%, and 29% respectively.

The mean age group of patients in the study was 48.6 years and the highest number of patients was in the age group of 41-50 years. Of the 19 patients in this age group, 6 had peripheral arterial disease accounting for 31.5%, which was not statistically significant.

Further, there was no correlation between increasing age and the increased prevalence of PAD in agreement with **Guerrero** *et al* [6]study. Studies by de Vinuesa *et al*[7] and Andrew Wilson *et al*[8] showed that the prevalence of PAD in CKD increased with age.

The variation in this study could be explained by the smaller size of the sample as compared to the study by Wilson *et al* [8] wherein the study had a sample of 1067 subjects. Further, the study by Wilson *et al*. was in patients undergoing elective coronary angiography for exertional chest pain and/or dyspnoea, a subset of patients known to have a high prevalence of PAD, significantly higher than in patients without symptoms suggestive of coronary arterydisease. The study by de Vinuesa *et al*[7] had a sample size of 102, but the mean age of the sample was 70±11years but in our study, the mean age group was 48.6 years which could account for the absence of correlation between increasing age and prevalence of PAD

There were 46 male and 4 female patients in the study.13 of the 46 males and 2 out of 4 females had peripheral vascular disease which accounts for 28.3% and 50% respectively, none of which was statistically significant. In our study, gender was not found to be a significant risk factor for peripheral arterial disease in chronic renal failure patients.

While studies by de Vinuesa *et al*,[7] Guerrero *et al*[6] showed an increased prevalence of the peripheral vascular disease in males, Mostaza *et al*[9] found an increased prevalence in females.

The HEMO study[5]also does not find a significant statistical association between male sex and prevalence of PAD in patients with ESRD

The variation insignificance is explained by the smaller size of the sample for the study.

Further inclusion of patients with diabetes and smoking in de Vinuesa *et al*[7], Guerrero e al [6] increase the proportion of males in the study.

Table 9 Comparision of our study in various parameters with other studies

Mean Age	Percentages in various studies
Guerrero *et al*[6]	48.5
De Vinuesa *et al*[7]	58.2
Al Zahrani HA. *et al*[10]	59.1
Suominen *et al*[11]	69.5
MERITO II[9]	74.3
Our study	48.6
Male %	
De Vinuesa *et al*[7]	64
Guerrero *et al*[6]	59.1
Al Zahrani *et al*[10]	63.9
MERITO II[9]	64
Our study	92
Female %	
De Vinuesa *et al*[7]	36
Guerrero *et al*[6]	40.9
Al Zahrani *et al*[10]	36.1
MERITO II[9]	36
Our study	8
Symptomatic Patient With PAD (%)	
Suominen et. Al[11]	83
Guerrero *et al*[6]	78
De vinuesa *et al*[7]	17
Our study	100
Hypertension And PAD	
HEMO STUDY[12]	93.7
Suominen *et al*[11]	53
ARIC study[5]	43
MERITO II[9]	79.2
Our study	35
Ischemic Heart Disease and PAD	
HEMO[12]	27.5
Suominen *et al*[11]	65.3
ARIC study[5]	46.3
Guerrero *et al*[6]	20
De vinuesa *et al*	29

All symptomatic patients (4) were found to have evidence of peripheral vascular disease, while among the asymptomatic group (46), 11 had evidence of PAD accounting for about 23.7%.

This is in agreement with the study by **Suominen *et al*[11]**in Finland wherein the prevalence of PAD was significantly more among subjects with severe symptoms (rest pain, ulcers, or gangrene) accounting for about 83.8%. However, the number of asymptomatic patients detected to have PAD was 11 accounting for about 23.7%. Only about 10%-30% of patients diagnosed with PAD based on ABI had classic symptoms of intermittent claudication.

7 of the 20 patients who had hypertension had PAD which is about 35% which is not statistically significant. This agrees with the HEMO study wherein hypertension was not an independent risk factor for PAD in patients with ESRD.

The Data obtained in the MERITO study in a population of patients with hypertension and with no known cardiovascular disease demonstrated that a GFR <60 ml/min per 1.73 m2 and the presence of albuminuria, both were associated with a reduced ABI and that these relationships were independent of other classical risk factors of cardiovascular disease.

More than one-quarter of the participants with a reduced GFR or with albuminuria had a low ABI, and this prevalence increased up to 50% in the group of patients with both disorders.

The incidence of PAD in the hypertensive population in the ARIC study was 43%. Of the 10 patients with Ischemic heart disease, 7 had PAD which amounts to about 70%, which was statistically significant. This association of the presence of CAD and increased prevalence of PAD in our study was similar to other studies. The ARIC study, studies by Suominen *et al* (OR 3.44), de Vinuesa *et al*[7] and Guerrero *et al*[6] wherein a strong association has been found between the presence of CAD and Peripheral vascular disease in patients with CKD.
Over three-fold (OR 3.44, 95% CI) among those with coronary heart disease (Suominen *et al*[11])

Of the 11 patients in Stage 3, 25 patients in stage 4, and 14 patients in stage 5 the prevalence of PAD in our study was 18.1%, 32%, and 35.7% respectively, which shows an increased prevalence of peripheral vascular disease with increasing severity of the renal failure.

This was in correlation with studies by de Vinuesa *et al*[7] and Guerrero *et al*[6].O'Hare and colleagues reported that 24% of persons with CKD stage 3 or greater (creatinine clearance of <60 mL/min/1.73m2) had PAD as objectively defined by an ankle-brachial index (ABI) <0.9.[4]

PAD incidence has been studied to a greater extent in dialysis patients, compared to non-dialysis CKD patients These findings were recently confirmed in persons with stage 3-5 CKD not on dialysis using data from the Chronic Renal Insufficiency Cohort (CRIC) study.[13]

Limitations

- The sample size is small.
- The ankle-brachial index is used as the absolute criterion for diagnosing peripheral vascular disease in our study. The ankle-brachial index is 95%sensitive and 99% specific for peripheral vascular disease; false positive and false negative results are possible rarely.
- False-positive results could be ruled out by following up all abnormal ABI with Duplex ultrasonographic probe which was not done in our study.
- The number of false-negative results could be decreased further by doing the exercise ABI, which was not done in our study.
- Diabetics and smokers are not included in the study.
- Patients with diabetes mellitus and renal failure may have falsely elevated ABI's due to non-compressible

and calcified lower extremity arteries. This would result in spuriously high ABI values ABI level (>1.5), this was not taken into consideration in our study.

- In renal failure patients with non-compressible vessels, a toe brachial index (TBI) can be measured using a small toe cuff and PPG (Photoplethysmography), which was not done in our study.
- The patients in our study comprised of Stage 3, 4, or 5 and many were on intermittent dialysis. The ankle-brachial index in patients on dialysis and non- dialyzed patients varies to a considerable extent. This factor was not taken into account in our study.

CONCLUSION

The prevalence of the peripheral arterial disease in patients with chronic renal failure was 30%. There was a significant relationship between the prevalence of peripheral arterial disease and the stage of chronic renal failure, the higher the degree of renal insufficiency the higher was the prevalence of the peripheral arterial disease. The prevalence of the peripheral arterial disease in chronic renal failure was increased in patients with ischemic heart disease. Age, gender, and hypertension were not associated with an increased prevalence of the peripheral arterial disease in patients with chronic renal failure.

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