Study of Comparative Evaluation of Atorvastatin and Salicinol (Salacia Roxburghii) on GFR and Carotid Intima Media Thickness in Patient of Chronic Kidney Disease with Hypertension

Dr. Manish Kumar Bhaskar, Prof. R.G Singh, Dr.Pallavi V.Latpate

Department Of Nephrology, Sir Sundarlal Hospital, Bhu, Varanasi

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***Abstract*- Background:** We have ample of evidence that progression of renal failure can be slowed down but we still need more definite information whether established renal failure can be reversed. Retarding the progression of renal failure is one of the most important task for the nephrologists as it not only improves the quality of life of the patient but also delays the development of end stage renal disease, This also forestalls the considerable financial burden of dialysis, transplantation and immunosuppressive drugs. This pilot clinical study was planned to explore the therapeutic potential of salicinol in retardation of chronic kidney disease progression and anti-atherosclerotic property by looking for if reduction in CIMT is possible.

OBJECTIVES: To Study of Comparative Evaluation Of Atorvastatin And Salicinol (Salacia Roxburghii) On GFR And Carotid Intima Media Thickness In Patient Of Chronic Kidney Disease With Hypertension

METHODS: Eighty patients of mild to moderate stable chronic renal failure with hypertension attending Nephrology OPD or admitted in Nephrology ward from May 2016 to June 2017 were included in the study. Patient with acute MI, congestive heart failure, unstable angina, myopathy. Non-compliant patient & those patient taking medicines for their disease which is known to improve lipid profile (lipid lowering agent other than atorvastatin) were excluded from the study

RESULTS: There was male preponderance in our patients. Overall 65% of patient were male & 35% were female. In Atorvastatin+Salicinol group 62.5% were male & in Atorvastatin group 67.5% were male. Mean serum creatinine at the initial visit was 4.6±2.1mg in Group-I ranging from 1.7mg to 9.6 mg and 5.6±2.5mg in Group-Il ranging from 1.6 mg t09.6mg. Difference was significant on subsequent visit in Group-I and Group-II. On intergroup comparison differences were statistically significant at six months. Mean CIMT in Group-I at baseline was 0.99±0.08 ranging from 0.68 to 1.42, while in Group-Il 0.85±0.10 ranging from 0.68 tol.18, at baseline and was statistically significant on subsequent visit. While on intergroup comparison, changes were statistically significant at three and six months. Mean GFR in group –I at baseline in 21.8±15.7,ranging from 5.1 to 61.8, while in group-II 20.08±14.4 ranging from 5.1 to 61.8. GFR was statistically significant in group-I on subsequent follow up.in between group comparision GFR changes were insignificant.

CONCLUSION: . The male patients dominated over the female patients with a male to female ratio of 2:1. Age of the patient ranged from 20yrs onward. Majority of the patient were above 40yrs of age. Commonest symptom was weakness in all the groups followed by anorexia, swelling over body, pallor & sleep disorders. No significant effect of the drug was seen on 24hrs urinary protein, blood pressure, hemoglobin & GFR. In patient treated with Atorvastatin and Salicinol serum creatinine showed significant changes (<0.05) at the end of six months. In patient treated with Atorvastatin and Salicinol, carotid intima media thickness showed significant decrease (<0.001) at three month and at the end of study.

I. Introduction

Hippocrates in 5th century B.C blamed malfunctioning kidney tor certain signs and symptoms. He commented that suppression of urine was a sign and could be followed by smell of urine in the breath, coma and convulsions since then our understanding of Nephrology has had revolutionary changes. Most of the newer concepts in Nephrology developed in the 19th and 20th century. At the beginning of this century even the term Nephrology did not exist.

No one could foresee the introduction of medication such as diuretics. Antihypertensive agents and immunosuppressive drugs that have brought a scientific revolution in the treatment ol renal diseases. These considerations make one humble and one wonders whether our current management of renal disease will look any better to future Nephrologists at the end of the next century. Progression of renal failure is an area of Nephrology where our understanding has improved appreciably in the last century but still our knowledge is like a drop in ocean.

We have ample of evidence that progression of renal failure can be slowed down but we still need more definite information whether established renal failure can be reversed. Retarding the progression of renal failure is one of the most important task for the nephrologists as it not only improves the quality of life of the patient but also delays the development of end stage renal disease, This also forestalls the considerable financial burden of dialysis, transplantation and immunosuppressive drugs. All possible areas shall be explored, where one can see even a slightest ray of hope

new drugs for retardation or reversing the progression of renal failure of It is with this motive that we looked towards traditional medicines, which have followers of allopathic system mostly received step motherly treatment from the of medicine.

This pilot clinical study was planned to explore the therapeutic potential of salicinol in retardation of chronic kidney disease progression and anti-atherosclerotic property by looking for if reduction in CIMT is possible.

In various experimental and clinical studies it has been demonstrated that salacia species containing salicinol has shown anti-inflammatory, Anti proteinuric and Hypolipidemic action with improvement in endothelial dysfunction. With these property the anti-inflammatory anti proteinuric and anti-atherosclerotic property of salicinol along with Adiponectin enhancing potential of salicinol has been evaluated in the present clinical trial.

In view of the need for the drugs to retard or reverse the progression of renal failure and atherosclerosis scavenzing property and also in view of the unchartered wealth of traditional medicines which is found in India, this study was planned to explore the therapeutic potentials of the traditional medicines in case of chronic renal failure especially with respect to retarding its progression and atherosclerosis scavenging properties.

II. MATERIAL AND METHODS

The present study was conducted in the Department of Nephrology, Institute of Medical Sciences, Banaras Hindu University, Varanasi. Eighty patients of mild to moderate stable chronic renal failure with hypertension attending Nephrology OPD or admitted in Nephrology ward from May 2016 to June 2017 were included in the study. Patient with acute MI, congestive heart failure, unstable angina, myopathy. Non-compliant patient & those patient taking medicines for their disease which is known to improve lipid profile (lipid lowering agent other than atorvastatin) were excluded from the study.

Initially patients were explained in detail about the experimental nature of the drugs and plan of study and only willing patient were included in the study after signing of the written consent. Before starting the drugs a through history was taken and clinical examination was done. The patients were then subjected to baseline urine, hematological, biochemical and immunological investigation.Subsequently patients were allocated randomly to one of the two groups, the first group consisted of patient treated with atorvastatin salicinol and second group was treated with atorvastatin only.

III. OSERVATIONS:

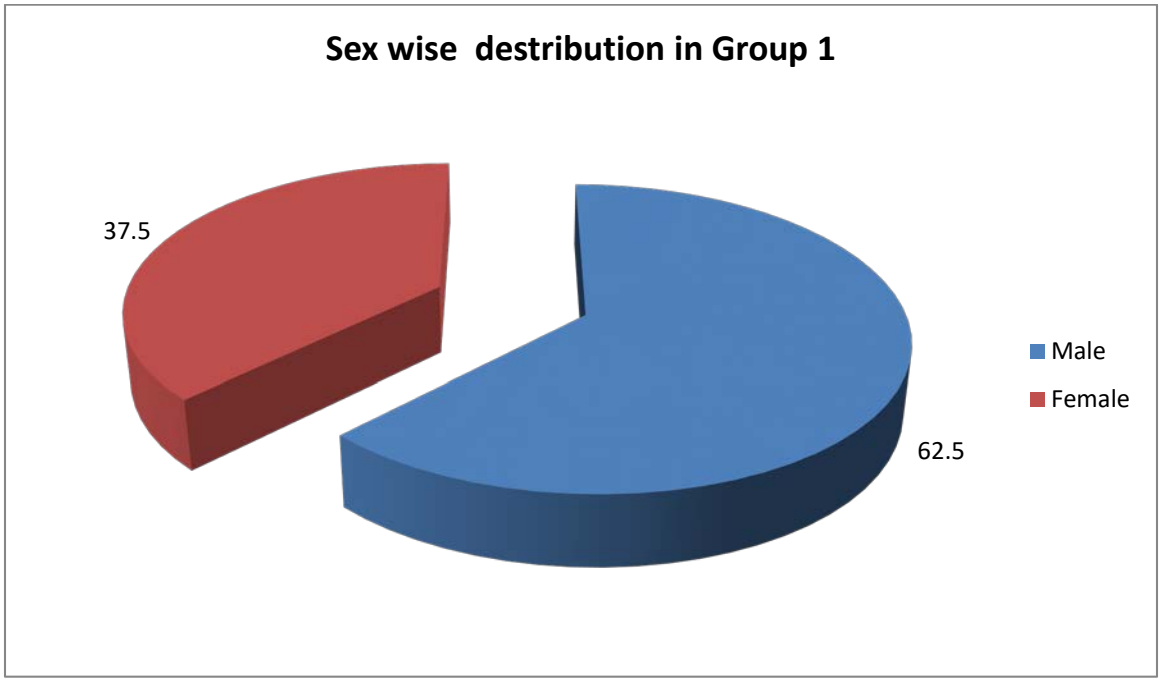
Ninety five patients of mild to moderate chronic renal failure with abnormal lipid profile were included in the study. Each was randomized to two groups. Group-I was treated with Atorvastatin & Salicinol, Group-Il with Atorvastatin. Overall 80 patients completed the six months follow-up and were finally included in the study. Atorvastatin and Salicinol group finally had 40 patients and there were 40 patients in Atorvastatin group.

Table 1: Sex wise distribution in group 1 and group 2

Sex	Group 1		Group 2	
	No.	%	No.	%
Male	25	62.5	27	67.5
Female	15	37.5	13	32.2
Total	40	100	40	100

$X^2 = 0.220$; $p = 0.639$

There was male preponderance in our patients. Overall 65% of patient were male & 35% were female. In Atorvastatin+Salicinol group 62.5% were male & in Atorvastatin group 67.5% were male.



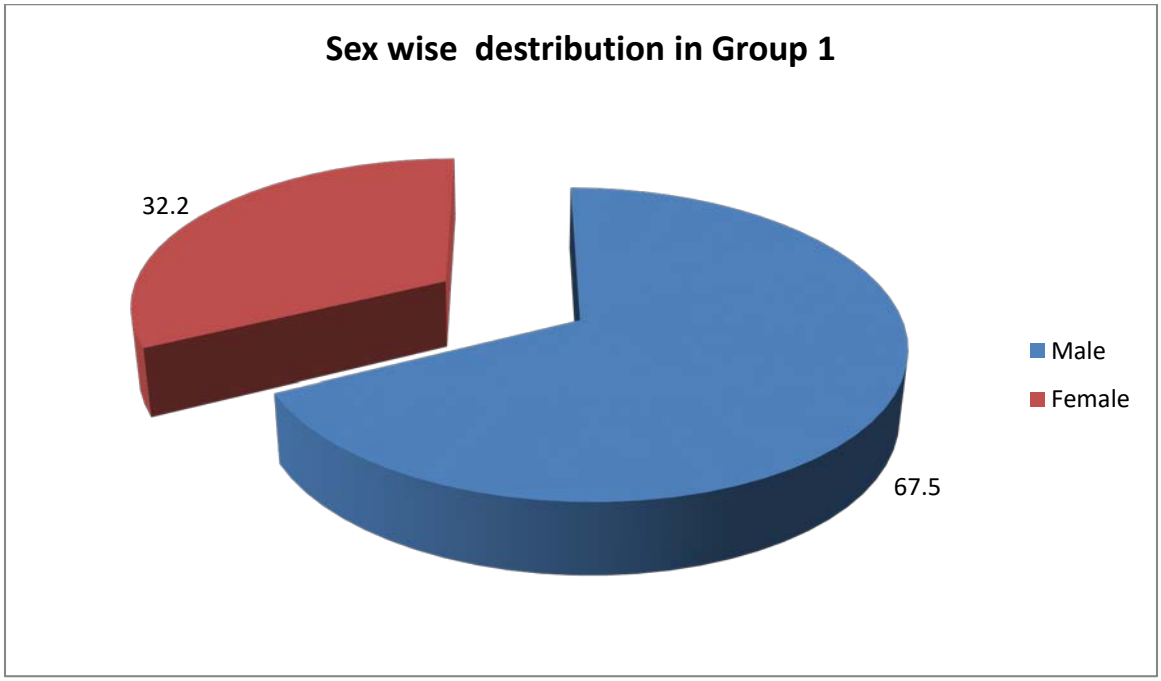
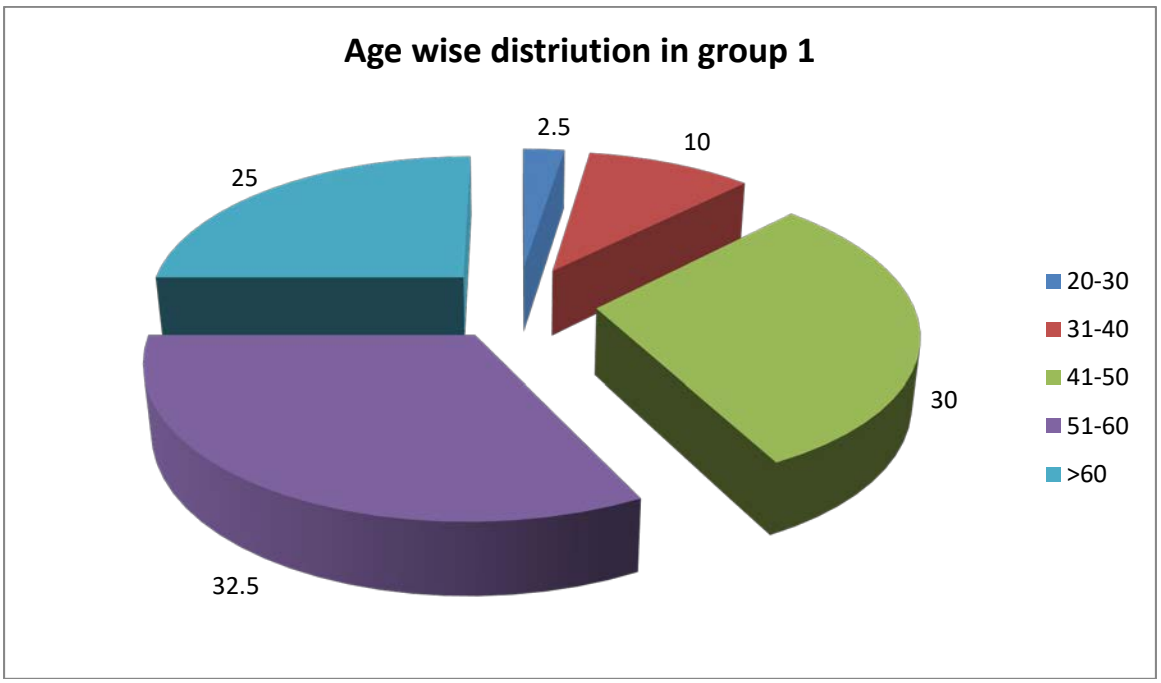


Table 2: Age wise distribution in group 1 and group 2

Age group (years)	Group 1		Group 2	
	No.	%	No.	

20-30	1	2.5	3	7.5
31-40	4	10	0	
41-50	12	30	17	42.5
51-60	13	32.5	13	32.5
> 60	10	25	7	17.5
Total	**40**	**100**	**40**	**100**

Age of patient ranged from 20 years onwards. Mean age of patient in group-I was 53.9yrs ranging from 23yrs to 80yrs while mean age of pt. in group[I was 51.7yrs ranging from 23 yrs. to 68 yrs. Mean age of patients in various groups were well matched and there was no significant statistical difference.



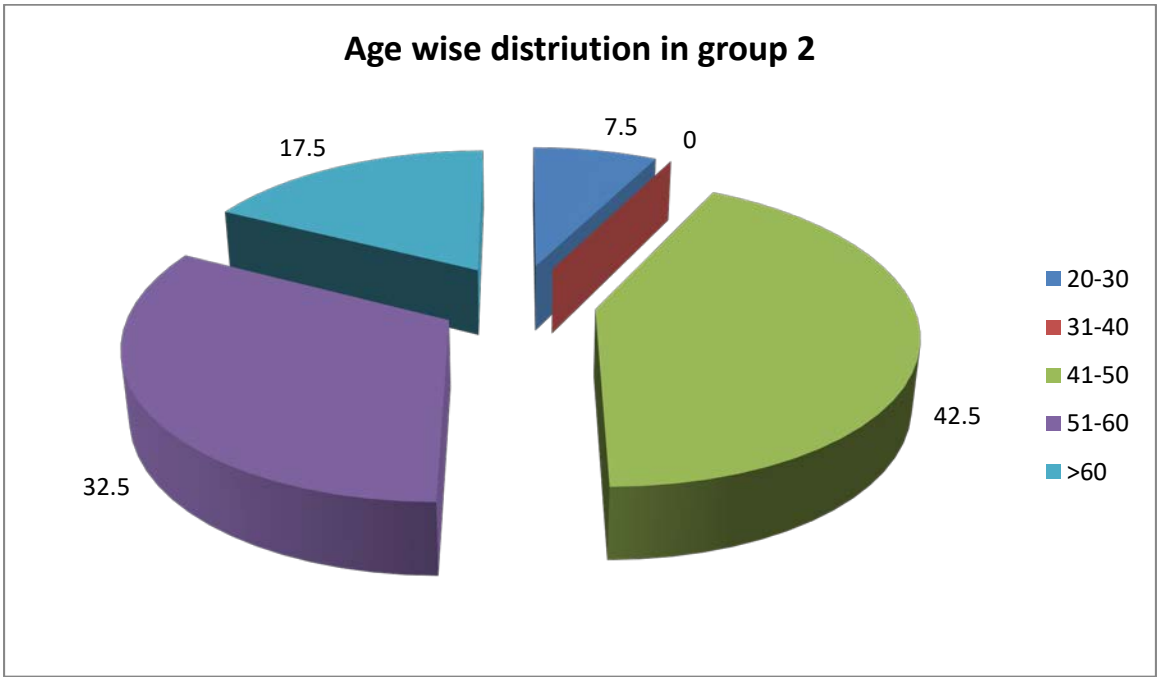


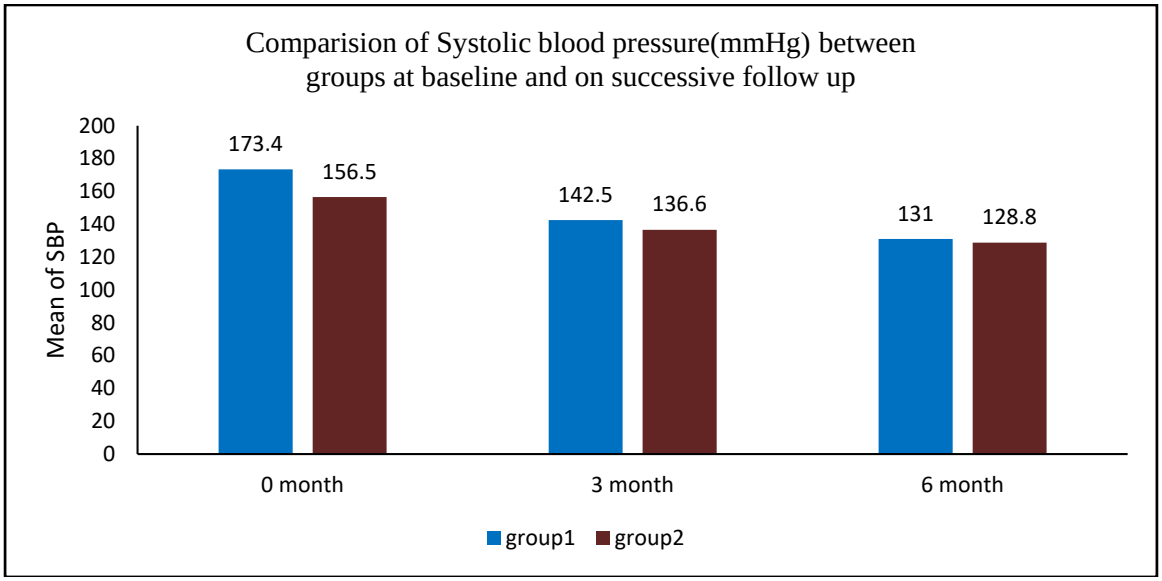
Table 5 : Comparison of systolic Blood pressure (mmHg) between groups And Within Group at base line and on successive follow up

Group	Systolic Blood pressure (Mean+-SD)			Within the group comparison paired 't' test	
	0 month	3 month	6 month	0 vs 3	0 vs 6
Group 1	173.4±21.8	142.5±9.9	131.0±6.2	14.2 P<0.001	13.7 P<0.001
Group 2	156.5±12.1	136.6±6.2	128.8±5.3	16.4 P<0.001	14.3 P<0.001
t-value	4.280	3.214	1.694	-	-
p-value	<0.001	0.002	0.094		

Table 6: Comparison of Diastolic blood pressure (mmhg) between Groups and within group on successive follow up

Group	DBP(Mean±SD)			Within the group comparison paired 't' test	
	0 Month	3 month	6 month	0 vs 3	0 vs 6
Group 1	99.4±10.8	89.7±6.5	83.7±3.7	11.110 P<0.001	10.794 P<0.001
Group 2	94.5±6.8	85.3±4.8	82.3±3.0	15.937 P<0.001	12.334 P<0.001
t-value	2.418	3.424	1.838	-	-
p-value	0.018	0.001	0.070		

Systolic and diastolic blood pressure in Group-I were 173.5±21.8 and 99.4±10.8 mm of Hg before the start of the drug & there was statistically significant change on subsequent visit. The systolic & Group-Il were 156.5±12.1 and 94.55±6.9 respectively significant changes was seen on subsequent visit. There was significant difference between the groups with respect to systolic and diastolic blood pressure.



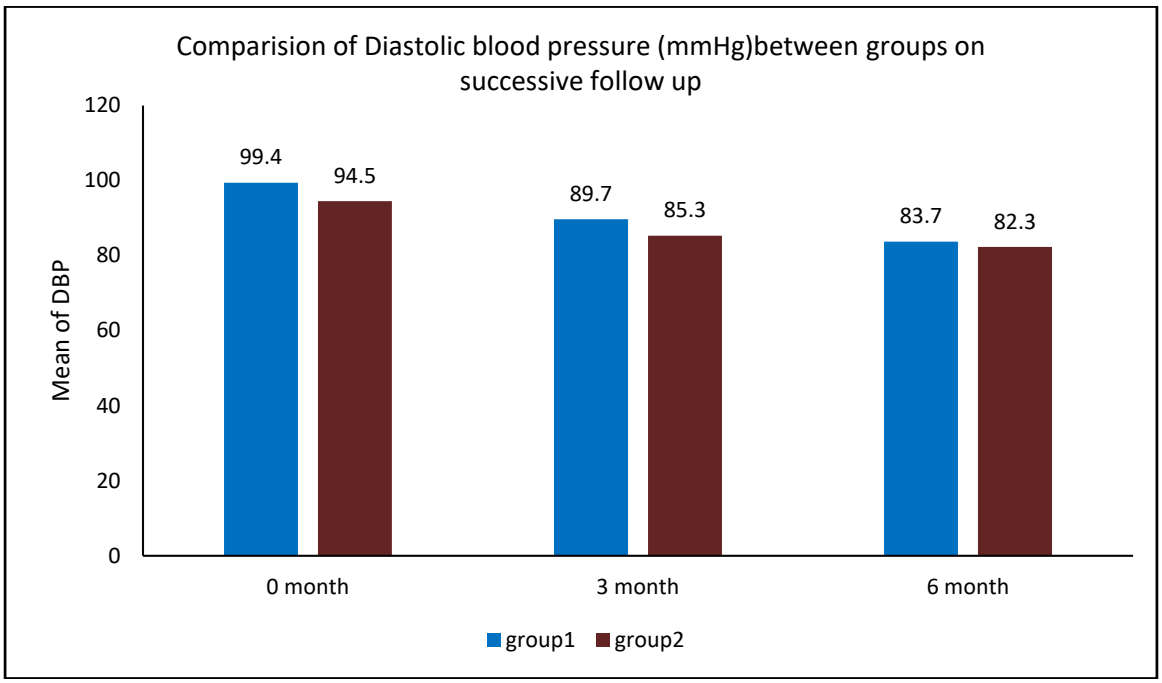


Table 9: Comparison of Creatinine between groups and within group on successive follow up.

Group	Creatinine (Mean+-SD)			Within the group comparison paired 't' test	
	0 month	**3 month**	**6 month**	**0 vs 3**	**0 vs 6**
Group 1	4.6±2.1	5.3±2.5	5.4±2.1	-3.074 P=0.004	4.279 P<0.001
Group 2	5.6±2.5	6.3±3.0	6.8±3.4	-1.700 P=0.097	-2.194 P=0.034
t-value	-2.026	-1.696	-2.271	-	-

p-value	0.046	0.094	0.026		

Mean serum creatinine at the initial visit was 4.6±2.1mg in Group-I ranging from 1.7mg to 9.6 mg and 5.6±2.5mg in Group-Il ranging from 1.6 mg t09.6mg. Difference was significant on subsequent visit in Group-I and Group-fl. On intergroup comparison differences were statistically significant at six months.

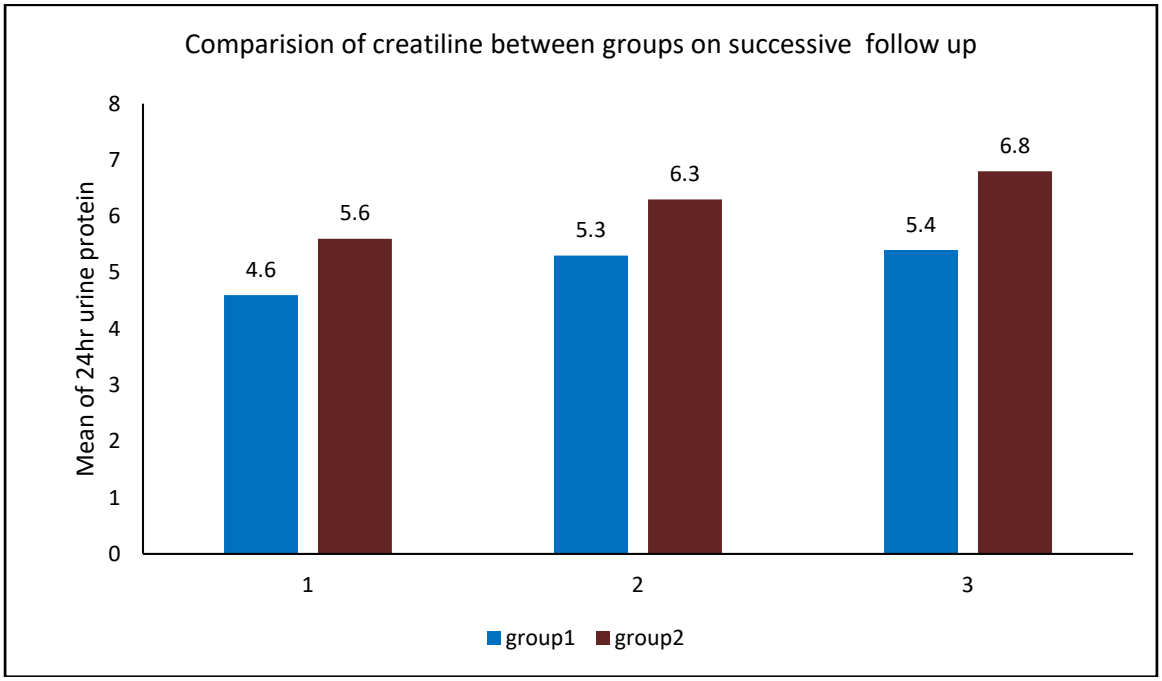


Table 13: Comparison of CIMT between groups and within group on successive follow up

Group	**CIMT (Mean+-SD)**			**Within the group comparison paired 't' test**	
	0 month	**3 month**	**6 month**	**0 vs 3**	**0 vs 6**
Group 1	0.99±0.08	0.98±0.16	0.90±0.12	-3.894 P<0.001	-773 P=0.444
Group 2	0.85±0.10	0.81±0.08	0.78±0.07	7.714 P=0.001	7.181 P<0.001
t-value	1.662	5.957	5.510	-	-
p-value	.100	<0.001	<0.001		

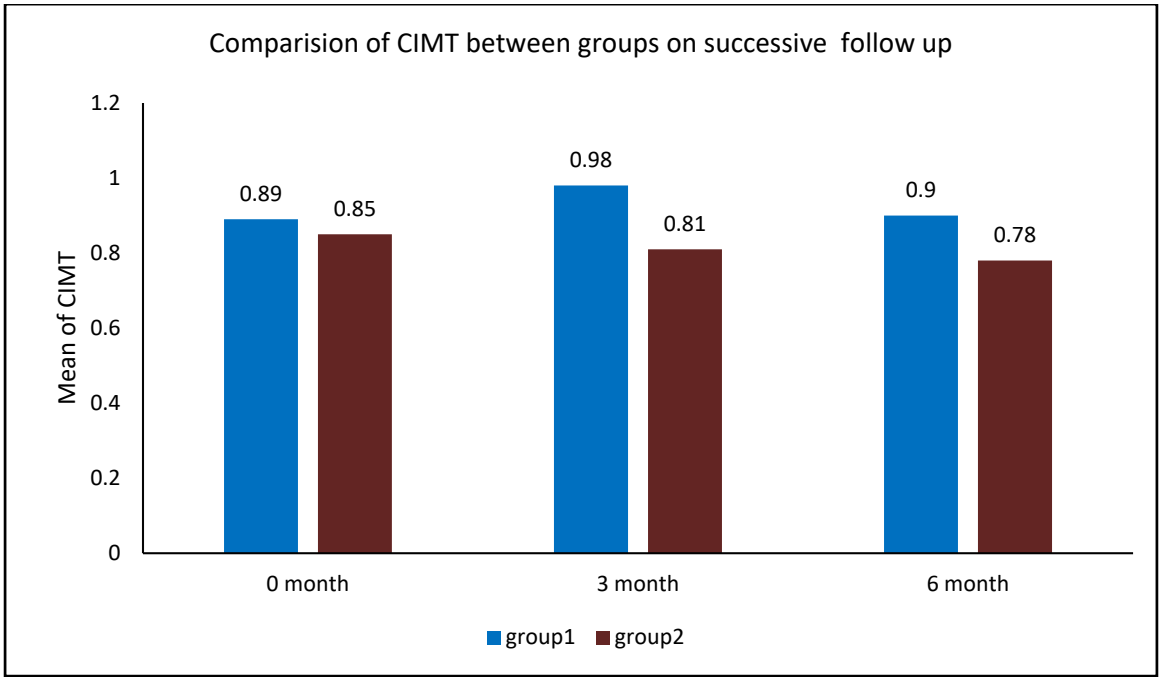
Mean Carotid Intima Media Thickness in Group-I at baseline was 0.99±0.08 ranging from 0.68 to 1.42, while in Group-Il 0.85±0.10 ranging from 0.68 tol.18, at baseline and was statistically significant on subsequent visit. While on intergroup comparison, changes were statistically significant at three and six months.

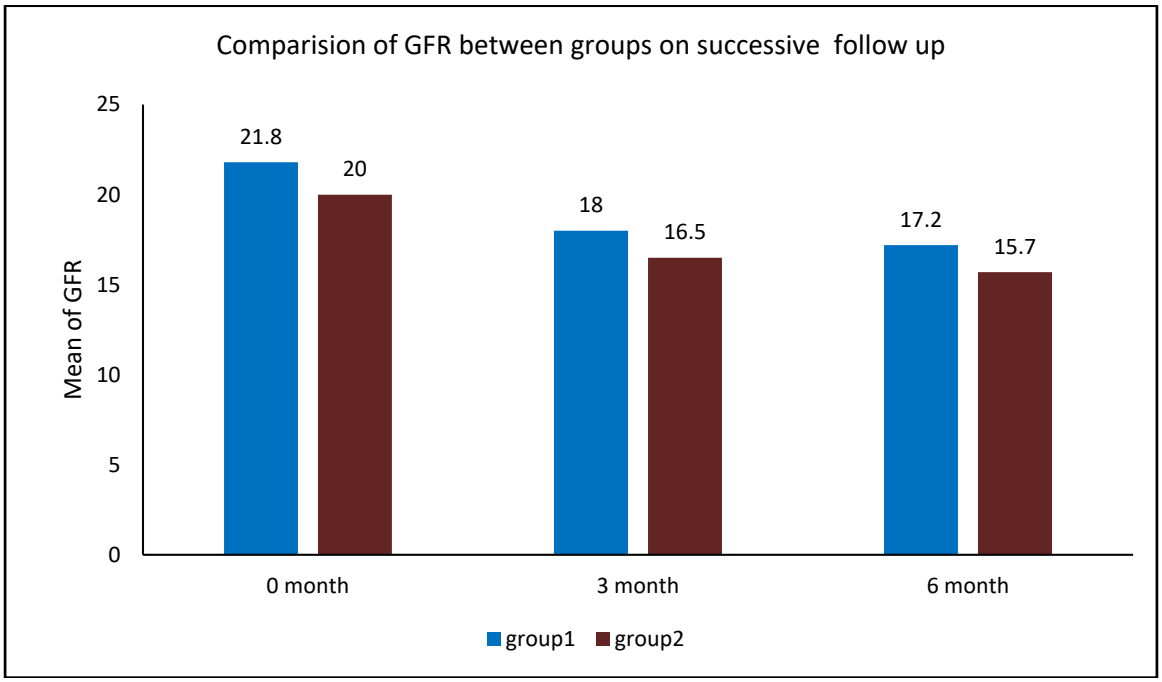
Table 14: Comparison of GFR between groups and within group on successive follow up

Group	**GFR (Mean+-SD)**			**Within the group comparison paired 't' test**	
	0 month	**3 month**	**6 month**	**0 vs 3**	**0 vs 6**
Group 1	21.8±15.7	18.7±11.1	17.2±10.4	3.280 P<0.002	3.503 P=0.001

Group 2	20.0±14.4	16.5±9.4	15.7±9.5	1.660 P=0.105	1.901 P<0.065
t-value	0.535	0.645	0.643	-	-
p-value	0.594	0.521	0.522		

Mean GFR in group –I at baseline in 21.8±15.7, ranging from 5.1 to 61.8, while in group-II 20.08±14.4 ranging from 5.1 to 61.8. GFR was statistically significant in group-I on subsequent follow up.in between group comparison GFR changes are insignificant.





IV. Discussion

There is an urgent need to focus new concepts and targets for the managements of chronic diseases. As in the present investigation, we are concentrating on the treatment modalities for chronic kidney disease with hypertension with abnormal lipid profile.

Among 95 patients of chronic renal failure taken for study, Eighty patient of chronic renal failure with hypertension completed the six months follow-up and were finally included in the study. Group-I consisted of forty patients treated with Salicinol and Atorvastatin, group-Il consisted of forty patients treated with Atorvastatin only.

Age of patient ranged from 20 years onwards. Mean age of patient in various group were well matched & there was no significant statistical differences. Mean age of group-I was 53.9 yrs & Mean age of Group-Il was 51.75

There was male preponderance in our patient. Overall 65% patients were male & 35% were female. In Group-1 623% patient were male while in Group-Il

67.5% were male. The male predominance in our patient is probably a reflection of male dominance in the social structure of our society. We have a society where male children are more cared for and adult male is the bread earner of the family. So. probably male patient are brought for the treatment to the hospital more frequently.

Most common presenting features was the subjective feeling of weakness in 100% of patients in all groups Other common symptoms were anorexia, edema, nausea vomiting and sleep disorder. Patients were evaluated for any improvement or deterioration of symptoms like pallor & edema on subsequent visits. Pallor in Group-I present in 72.5% of cases at the time of start of study but on follow up after 6 months. it was present only in 37.5% of cases. While in Group-Il pallor was present in 72.5%. at the start of study while after 6 months was present in 50% of cases. Similarly edema at baseline in Group-I was 75% but after 6 months of follow up. it was present in 17.5%. while in group-ll. at baseline edema was present in 57.5% but after 6 months of follow up was present in 12.5% of patients.

Systolic blood pressure & Diastolic blood pressure in Group-I at baseline were173.4±21.8 & 99.4±10.8 while in Group-Il were 156.5±12.1 & 94.5±6.8 respectively. On Subsequent follow up SBP & DBP were statistically significant. probably because of tight control of blood pressure by using anti hypertensive therapy along With .

Serum Creatinine at baseline in Group-I & Group-Il were 4.6±2.1 & 5.6±2.5 respectively changes were statistically significant on subsequent visit at three and six months. On intergroup comparison changes were statistically significant at six month, probably role on salicinol in retardation of CKD progression.

Mean carotid intima media thickness at baseline in Group-I & Group-II 0.89±0.08 & 0.85±0.10. Reduction in CIMT value were statistically significant on subsequent visit at three & six months. On intergroup comparison in CIMT were statistically significant at three and six months suggesting atherosclerosis scavenging role of salicinol.

Mean GFR in Group-I & Group-Il at baseline were 21.8±15.7 & 20.0±14.4. On subsequent visit, changes were statistically significant in Group-I only. On intergroUP comparison, changes were statistically insignificant, suggesting probably no role of salicinol on GFR changes.

V. Summary and Conclusion

Present study entitled "Study of Comparative evaluation of atorvastatin and salicinol (salacia Roxburghii) on GFR and carotid intima media thickness in patient of chronic kidney disease with hypertension" was conducted at the Department of Nephrology, Institute of Medical Sciences, Banaras Hindu University, Varanasi between the period of May 2016 to June 2017.

Eighty patient of mild to moderate chronic renal failure were included in the study. Forty patient, each were randomized to two groups. Group-I were on Atorvastatin & Salicinol while Group-Il were kept on Atorvastatin only. The salient features of this study are :

1. The male patients dominated over the female patients with a male to female ratio of 2:1.

2. Age of the patient ranged from 20yrs onward. Majority of the patient were above 40yrs of age.

3. Commonest symptom was weakness in all the groups followed by anorexia, swelling over body, pallor & sleep disorders.

4. No significant effect of the drug was seen on 24hrs urinary protein, blood pressure, hemoglobin & GFR.

6. In patient treated with Atorvastatin and Salicinol serum creatinine showed significant changes (<0.05) at the end of six months.

9. In patient treated with Atorvastatin and Salicinol, carotid intima media thickness showed significant decrease (<0.001) at three month and at the end of study.

Thus on overall favorable effect of salicinol was seen with respect to , serum creatinine& carotid intima media thickness. However in this study the follow-up period was only six months which is relatively a short period to assess the effect of salicinol on GFR & CIMT which has a natural course running into years, A large prospective study is recommended to further establish the findings of this study.

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AUTHORS

First Author – Dr. Manish Kumar Bhaskar, Departmentof Nephrology, Sir Sundarlal Hospital, BHU, Varanasi
Second Author – Prof. R.G Singh, Departmentof Nephrology, Sir Sundarlal Hospital, BHU, Varanasi
Third Author – Dr.Pallavi V.Latpate, Departmentof Nephrology, Sir Sundarlal Hospital, BHU, Varanasi