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Studies On Valsartan And Losartan In Patients With Mild And Moderate Hypertension In Tertiary Care Teaching Hospital

Madhan L[1], Murugesan. P[2], Moorthy. A[2] And Sampath Kumar K.P[3]
1.Department of Pharmacology, Coimbatore medical College, Coimbatore 641 014, TN
2.Department of Physiology, Coimbatore medical College, Coimbatore 641 014, TN
3.Department of Pharmacy, Coimbatore medical College, Coimbatore 641 014, TN
**Corresponding Author: Madhan L*

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I. Introduction

Blood pressure control in essential Hypertension can be achieved by blocked of Renin Angiotensin and Aldosterone system (RAAS) at various stages of the biochemical cascade. The essential hypertension effects 15-25% of adult in most countries and is associated with an increased risk of coronary heart disease (CHD) and cerebrovasular disease. Reducing morbidity and mortality of HTN represents major Challenges.

The blocked of RAAS at Various levels of biochemical cascade can be control the blood pressure in essential hypertension. The ACEI are the potential drugs to inhibits the conversion of inactive Angiotension I to acetive Angiotension II . Generally the effect of administration have Cough and Angioneurotic edema are mild.

Valsartan is a new potentially selective AT1 receptor blocker. It shows remarkable efficacy and tolerability when administered as 80mg and 160mg. Losartan also a selective, competitive blocker of Angiotensin II receptor type 1 (AT1) and decreases peripheral vascular resistance and has minimal uricosuric action.

The main aim of the study to assess the clinical efficacy and tolerability of Valsartan in mild and moderate Hypertension compared with Losartan

II. Design And Methology

The study was designed a single blind,randomized, comparative and step up dosing trial. Total duration of study period was 6 weeks. First 2 Weeks of placebo period and followed by 4 weeks of drug trial period.

Visit 1 : Base – Placebo– 1st week
- Placebo– 2nd week

Visit 2 : Trial drugs either valsartan80 OD/ Losartan 50 OD
Visit 3 : 2 Weeks – either valsartan80 OD/ Losartan 50 OD or valsartan160 OD/ Losartan 100 OD
Visit 4 : Final visit – BP was monitored and recorded

Inclusion criteria

Essential hypertension of both sexes
Uncomplicated stage - I and Stage II Hypertension with sitting Diastolic BP between 90-109 mm of Hg.
Patients may be newly diagnosed hypertension
Therapeutic failure of other anti-HT agents, or hypertensive drugs with dosage inconvenience.

Exclusion criteria:

Patients with Diastolic BP > 110mm of HG
Secondary HT
Failure with ACEI or ATI Blockers
H/O MI, CVA, CAD. Cardiac surgery, Cardiac intervention in the past 3 months
H/O with severe heart future, renal artery stenosis H/O angio neurotic edema
H/O oliguria or Progressive Azotaemia with ACEI or AT1 Blockers
Patient with severe dehydration due to diuretic therapy in the past 4 weeks
Pregnant, Breast feeding mother or women not using reliable contraception
Clinically significant hepatic, renal, neurological, gastro intestinal, endocrinal hematological, Psychological disorders and severe concurrent illness.
Patient with SGOT/SGPT>1.5 times higher

Serum Alkaline Phosphatase and Serum bilurubin- 1.2 Times Higher and
Serum Creatinine > 1.2 mg/dl
Patients with H/O hypersensitivity to Valsartan or Losartan
Patients received other investigational drugs in the last three months

Clinical Assessment

Clinical assessment done once in a 2 weeks in Ist visit placebo was given for 2 weeks If any untoward reactions occur during period end of the 1st week were instructed to report immediately in hypertension clinic. In 2 nd visit, the test drug was given to the patient after confirm Diastolic blood pressure between 90 to 109 mm of Hg. Then patients were reviewed for 2 weeks. In 3 rd visit, the BP was rechecked, during the study BP was in controlled, the same dose of the drug was repeated for another 2 weeks. If BP was not under controlled the same dose level and the dose were increased to double strength. In the 4 th visit the final clinical assessment was done.

Investigations

In investigations routine Hemogram and Biochemical Investigations were done along with X-ray chest, ECG and protein analysis from pre and post observational study.

During clinical visit the weight, height, temperature, respiratory rate, Pulse rate, sitting and standing systolic and Diastolic BP were observed and recorded.

III. Results And Discussion

The optimal treatment treatment of HT invoves smooth, usually gradual reduction in both systolic and diastolic BP, which sustained throughout the day and night.

In this, study the Valsartan group 12 patients were completed out of 14 patients. In Losartan group 12 Patients were completed out of 13 Patients.

Reductions in BP in both systolic and Diastolic BP were recorded. Systolic and Diastolic BP reduction starts form end of 4 th visit onwards and maintained upto 5 th visit.The reduction of BP is more significantly seen in valsartan group when compared with Losartan and p-value is more significant in valsartan received patients.

After assessment of the treatment the Systolic and Diastolic BP in both groups were monitored. The reduction of systolic and Diastolic in standing of position move significantly reduction valsartan group than Losartan group. P-value is more significant in Valsartan group.

The mean reduction of BP reduction in both groups were entered and plotted .This was significant in both groups.

Pulse rate changes observed in both groups . Pulse rate in reduced in both groups not producing and alarming effect or not to the level of bradycardia

Few number of patients are required for double dose to achieve to optimal level of BP . About 25 % of patients in Valsartan group required dosage adjustment to normalize the BP to increased the dose from 80 to 160 mg, where as in Losartan group 67% Patients the dose was increased from some to 100mg.

Both drugs are produce no significant adverse effects and are well tolerated. Among the valsartan is more effective in reducing Blood Pressure because of its 5 fold affinity to angiotensin receptor I. And there is no significant Change in pre and post study investigations.

Conclusion

Valsartan is an effective antihypertensive agent in mild to moderate hypertension. Valsartan is at the dose of 80mg and 160mg per day produce statistically and clinically significant antihypertensive .That are well maintained in the long term therapy.

Based in the clinical evaluation we conclude that the Valsatan is find more effective antihypertensive drug mild to moderate hypertension compared to Losartan.

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Sex Distribution

	Valsartan	Losartan
Male	2 (16%)	1 (8.3%)
Female	10 (85.3%)	11 (91.7%)

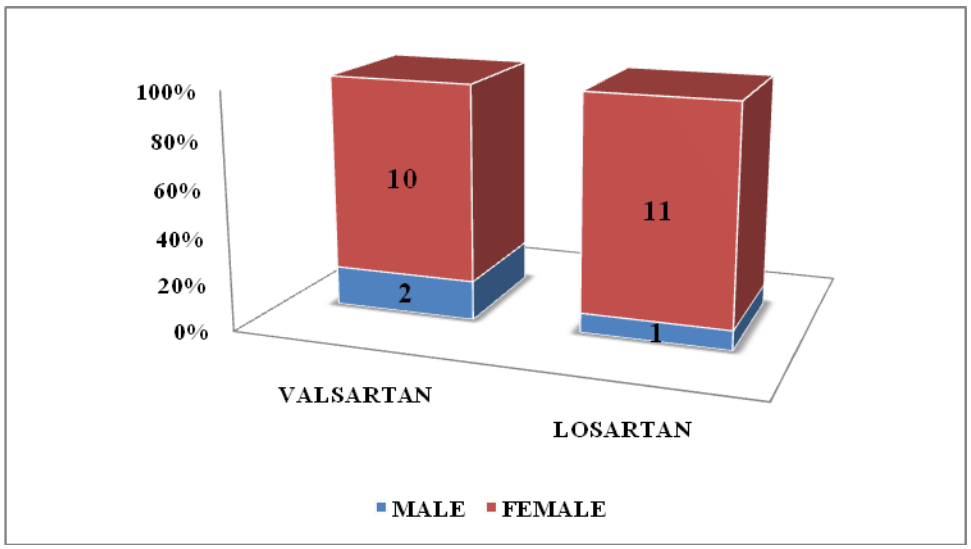


Table - 1

	Visit	Valsartan	Losartan
Systolic	I	167.5	157.5
	II	166.5	158.1
	III	149.8	150.6
	IV	134.5	145.5
		T 6.38 p<0.001/HS	T 2.56 P<0.005 significant
Diastolic	I	101.8	102.9
	II	101.6	102.0
	III	92.2	99.4
	IV	84.8	95.1
		T 10.78 P<0.001/HS	T 5.44 P<0.001 HS

Systolic		Diastolic	
Sitting	Standing	Sitting	Standing
T= 3.01	T= 3.33	T= 4.29	T= 4.37
P<0.001	P<0.01	P<0.001	P<0.001

Table – 2.

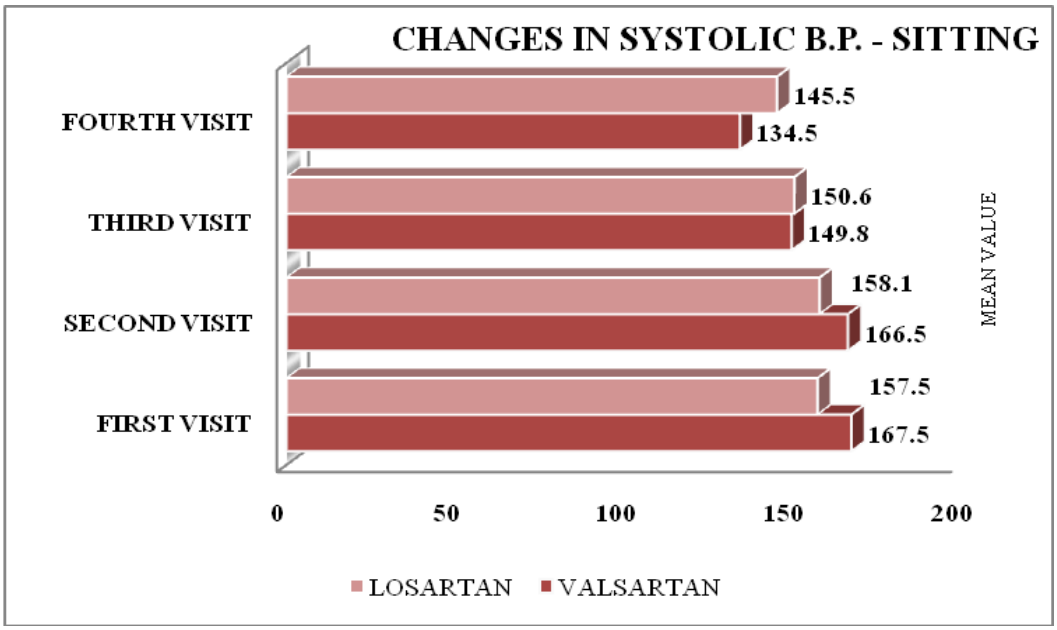
	Visit	Valsartan	Losartan
Systolic	I	163.0	157.7
	II	166.6	157.9
	III	149.8	150.5
	IV	134.5	145.5
		T 6.38 p<0.001/Hs	T 2.64 P<0.05 significant
Diastolic	I	102.4	102.7
	II	101.5	101.7
	III	92.2	99.4
	IV	84.8	95.1
		T 10.6 P<0.001/Hs	T 4.2 P<0.05 Significant

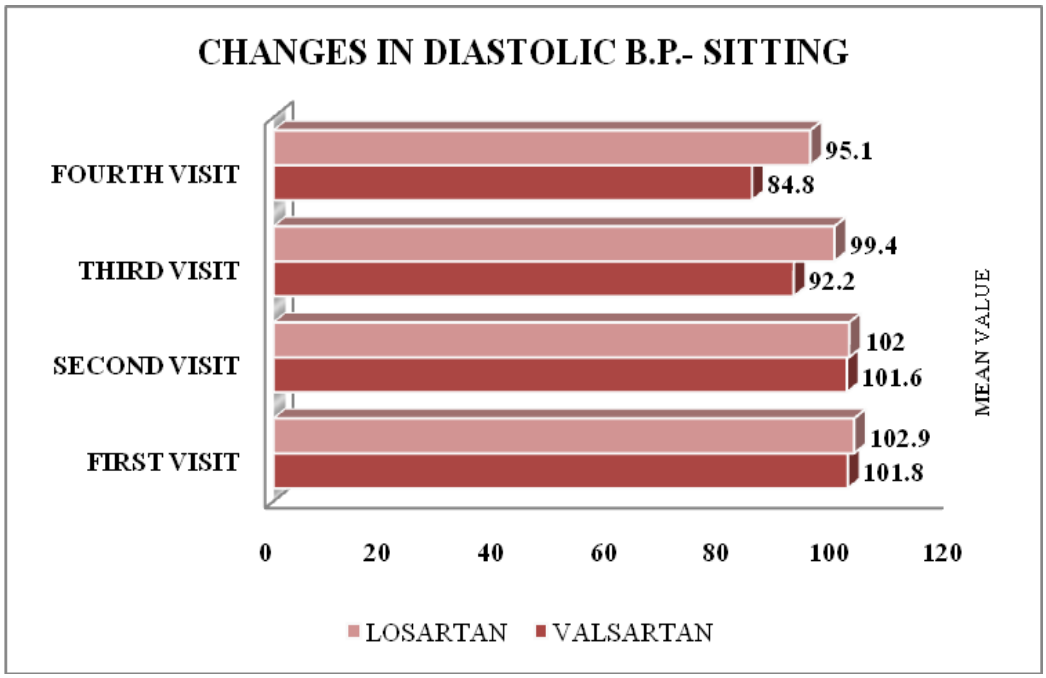
Table – 3.
Pulse Rate

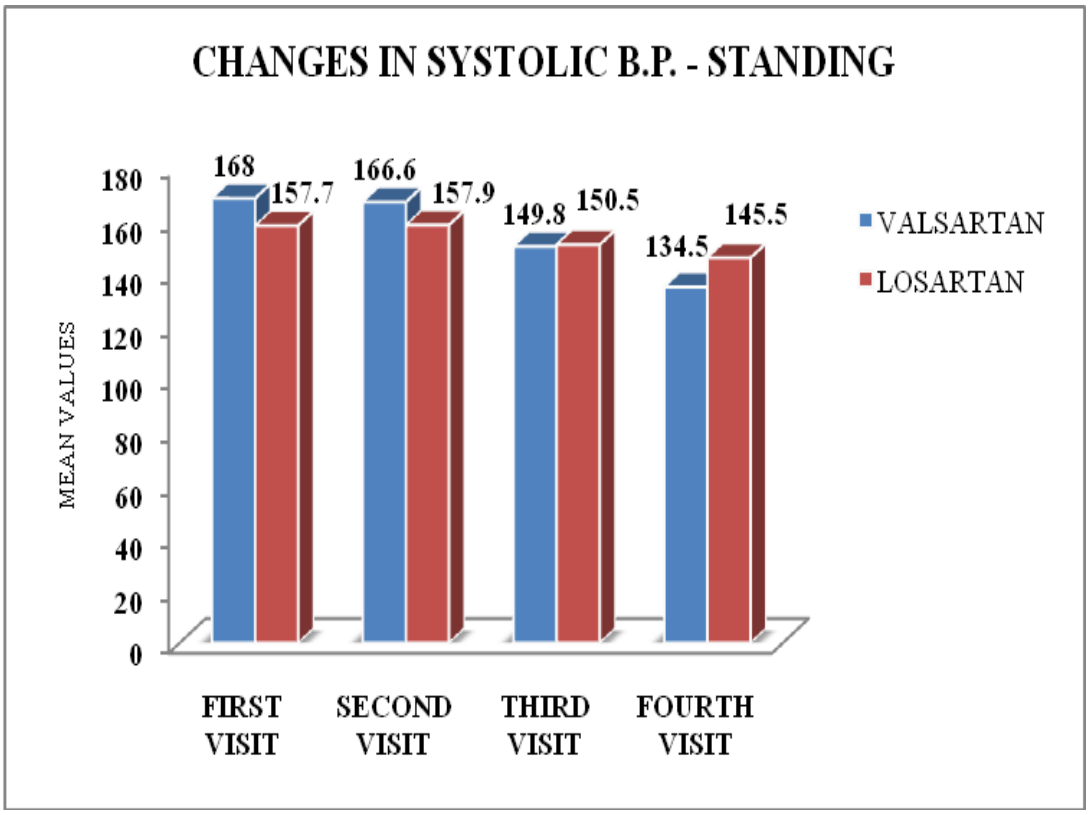
Visit	Valsartan		Losartan	
	Sitting	Standing	Sitting	Standing
I	77.5	80.17	73.33	75.58
II	73.42	73.5	74.25	76.08
III	71.75	71.83	75.08	76.50
IV	67.58	67.25	75.83	76.83
	T= 5.63 P<0.001/Hs	T= 6.23 P<0.001/Hs	T= 4.38 P<0.001	T= 1.53 P=0.15 NS

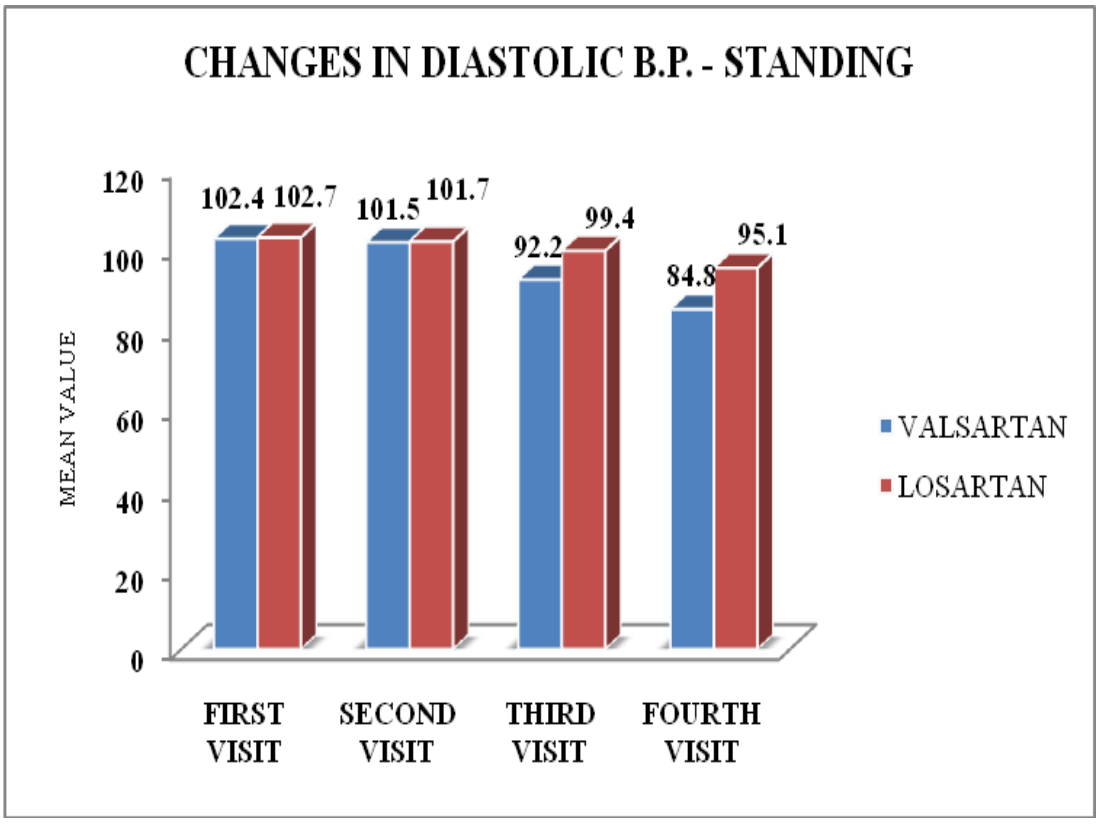
	Valsartan	Losartan
Single dose	9 pts 80 mg 75%	4 Pts 50 mg 33.3%
Double dose	3 pts 160 mg 25%	8 Pts 100 mg 66.07%

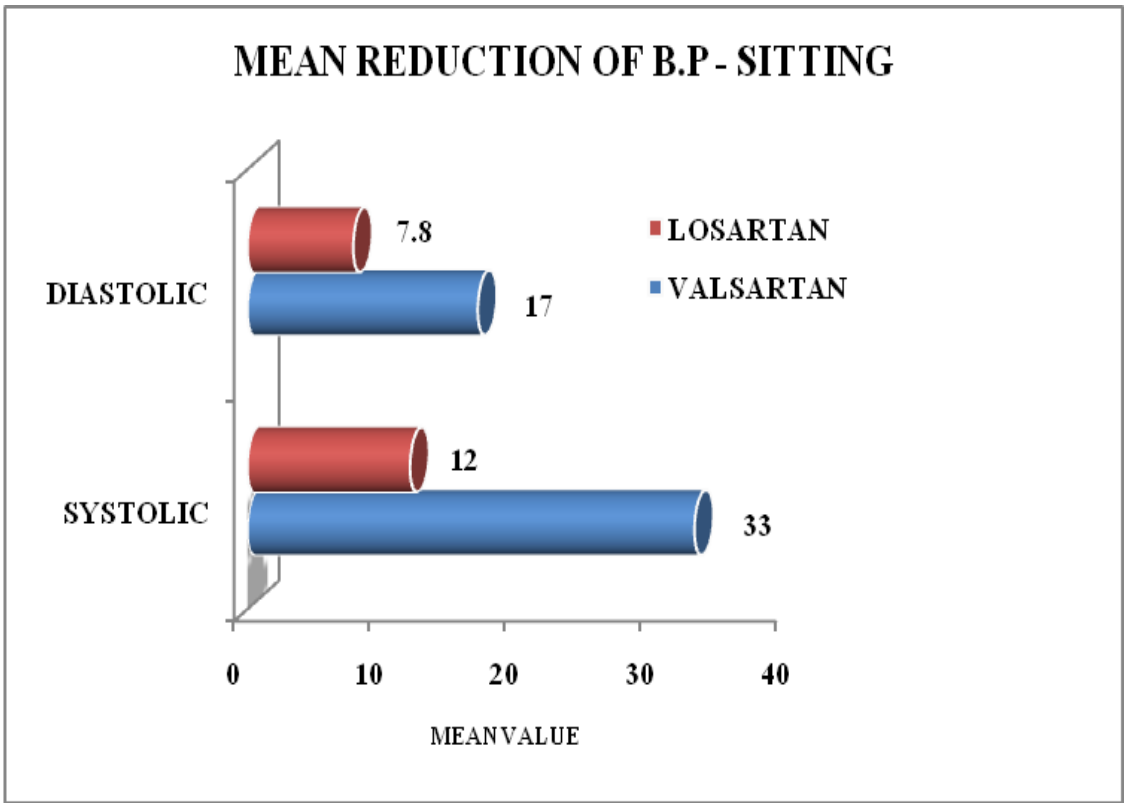
1.

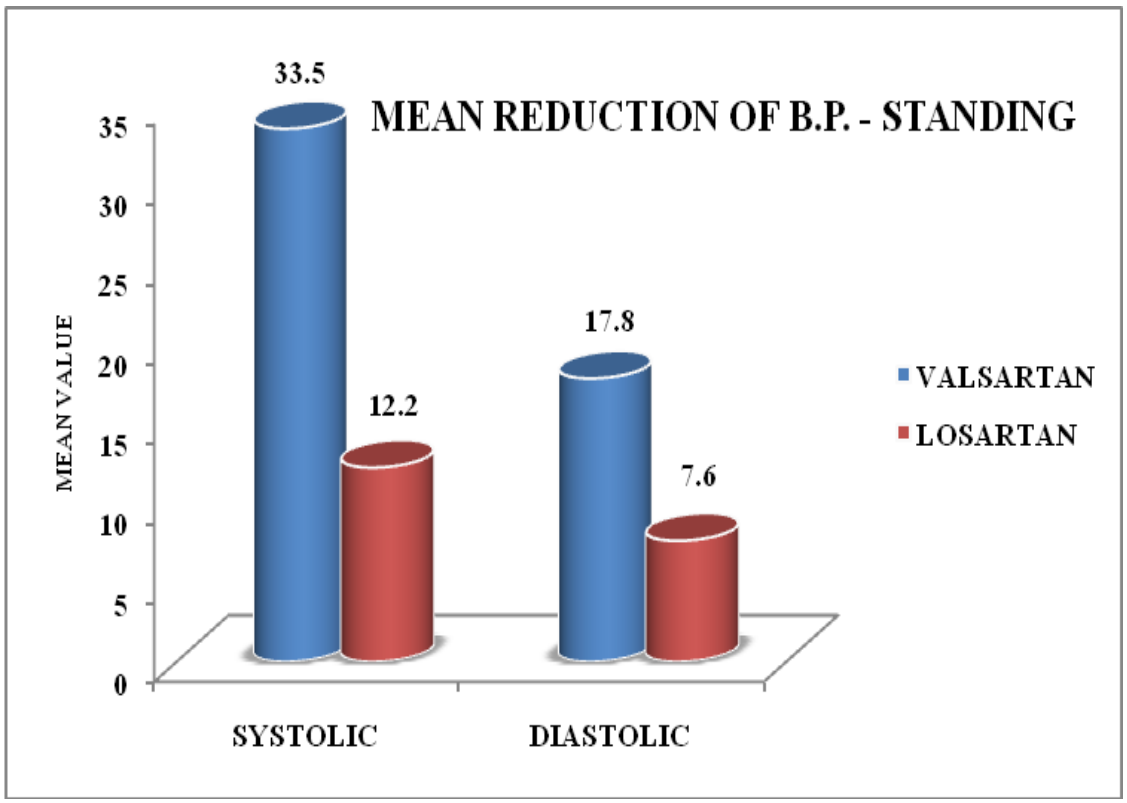


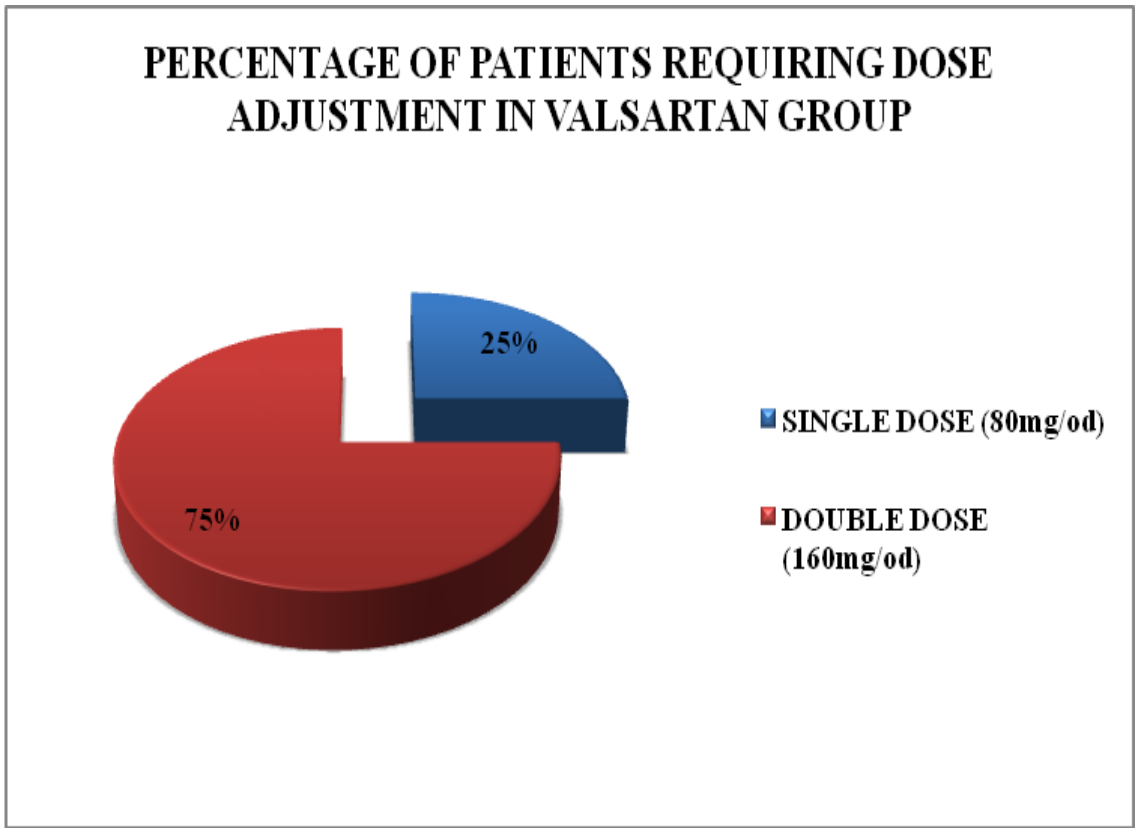


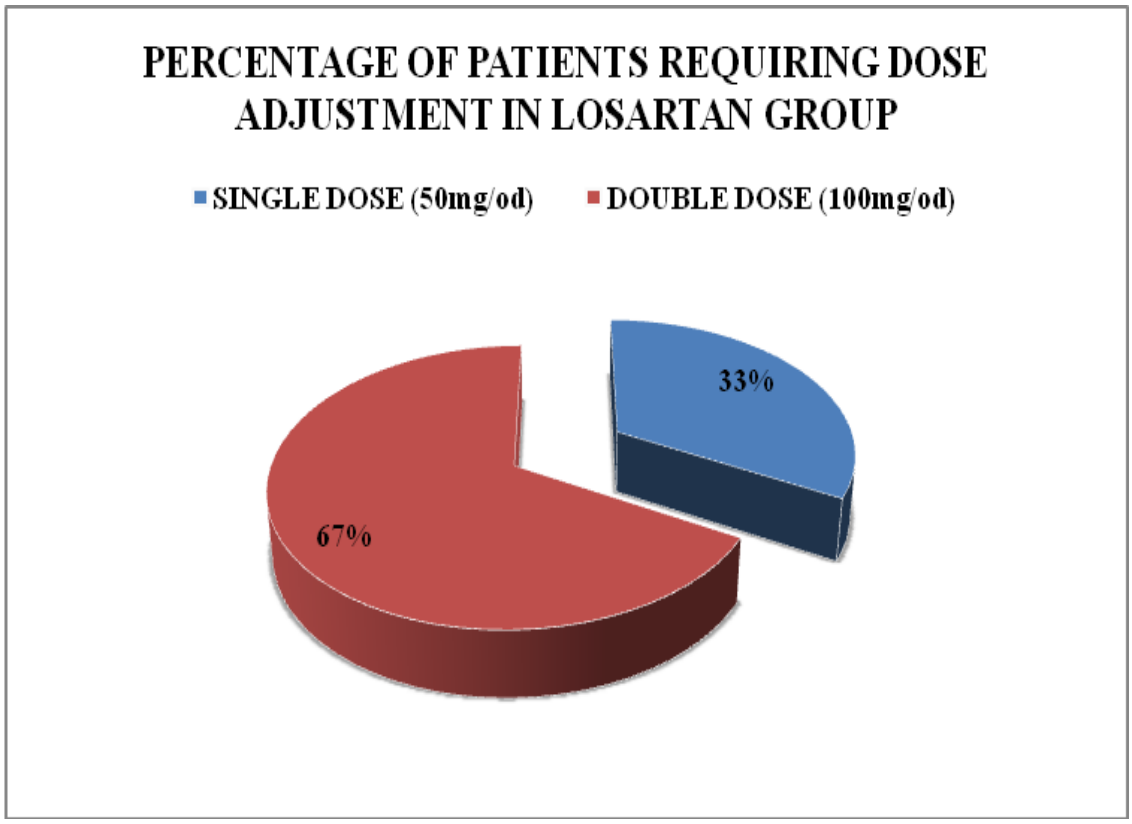

CHANGES IN SYSTOLIC B.P. - STANDING
MEAN VALUES
180
160
140
120
100
80
60
40
20
0
168
157.7
166.6
157.9
149.8
150.5
134.5
145.5
FIRST VISIT
SECOND VISIT
THIRD VISIT
FOURTH VISIT
VALSARTAN
LOSARTAN

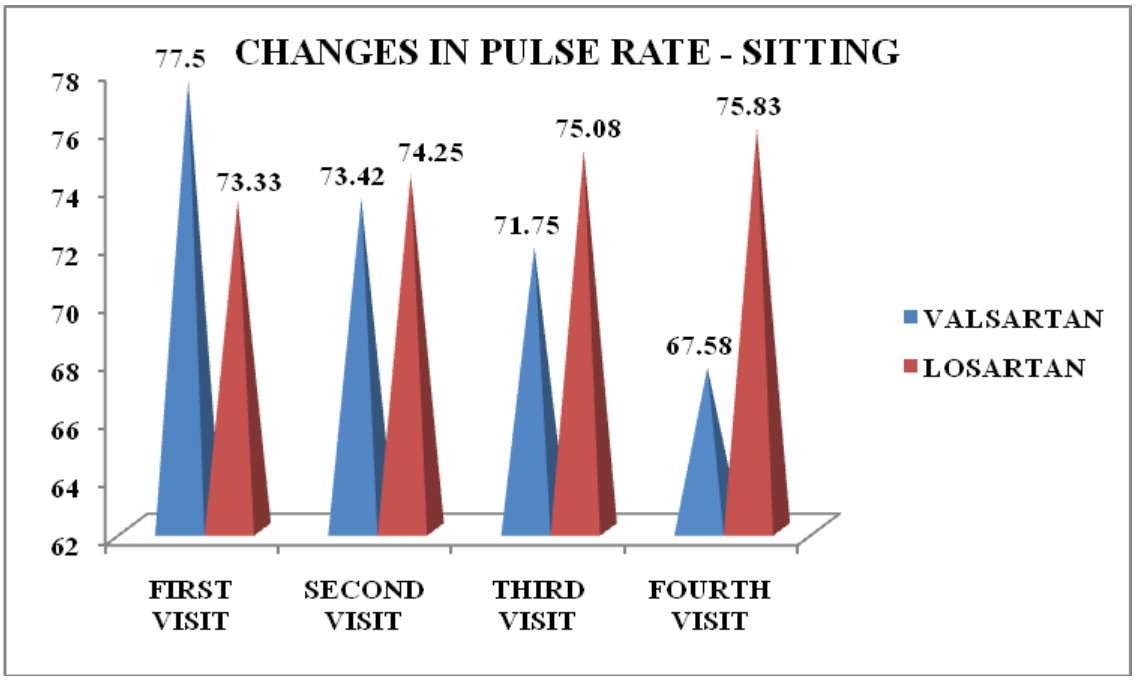

CHANGES IN DIASTOLIC B.P. - STANDING
MEAN VALUE
120
100
80
60
40
20
0
102.4
102.7
101.5
101.7
92.2
99.4
84.8
95.1
FIRST VISIT
SECOND VISIT
THIRD VISIT
FOURTH VISIT
VALSARTAN
LOSARTAN

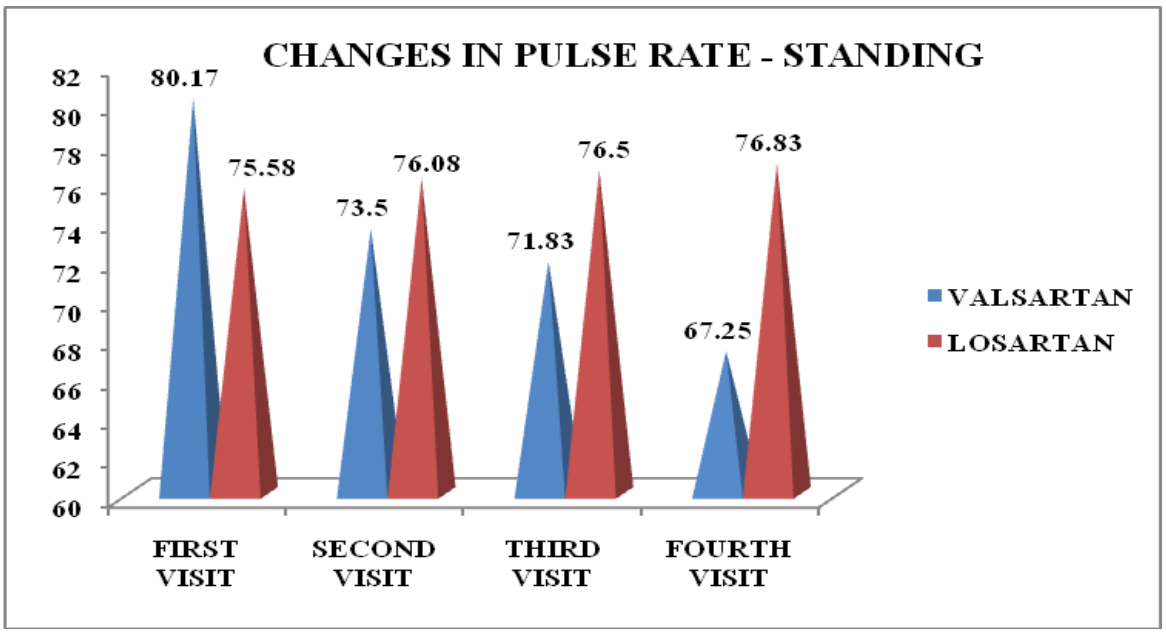

MEAN REDUCTION OF B.P - SITTING
DIASTOLIC
SYSTOLIC
7.8
17
12
33
LOSARTAN
VALSARTAN
0
10
20
30
40
MEANVALUE


MEAN REDUCTION OF B.P. - STANDING
MEAN VALUE
35
30
25
20
15
10
5
0
33.5
12.2
17.8
7.6
SYSTOLIC
DIASTOLIC
VALSARTAN
LOSARTAN


PERCENTAGE OF PATIENTS REQUIRING DOSE ADJUSTMENT IN VALSARTAN GROUP
25%
75%
SINGLE DOSE (80mg/od)
DOUBLE DOSE (160mg/od)


PERCENTAGE OF PATIENTS REQUIRING DOSE ADJUSTMENT IN LOSARTAN GROUP
SINGLE DOSE (50mg/od)
DOUBLE DOSE (100mg/od)
33%
67%





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