

## Pharmacoeconomic comparison of losartan and amlodipine in patients of hypertension in a tertiary care teaching hospital

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### ABSTRACT

**Background:** To conduct a pharmacoeconomic comparison (cost-effectiveness analysis) and to evaluate the overall safety and efficacy of Losartan and Amlodipine in reducing the Mean blood pressure per mm Hg in hypertensive patients.

**Methods:** This was a prospective, randomized, open label, observational analysis of cost-effectiveness; into compare the cost of Losartan 50mg and Amlodipine 5mg in hypertensive patients using either of the two drugs. A total of 80 newly diagnosed drug naïve hypertensive patients were considered for the comparison, of which 40 patients were prescribed Losartan and the other 40 were prescribed Amlodipine as per the recommended dosage. Based on the data, statistical analysis was carried out using SPSS Software Version 21.

**Results:** The two drugs were found to be equi-effective in reducing the blood pressure to the target goal, at their respective equivalent doses. Moreover, the cost of reducing 1 mm of Hg mean blood pressure with Losartan was 103.42 INR, whereas that of Amlodipine was 57.11 INR. Hence the cost incurred in treating elevated BP was markedly lower with the Amlodipine group as compared to the Losartan group.

**Conclusions:** This pharmacoeconomic analysis shows that Amlodipine is more cost-effective as compared to Losartan when the cost per mm Hg reduction in mean blood pressure is considered. Hence in India, where the cost of drug is a significant deterrent to patient compliance, cost-effective therapy of chronic disease like hypertension is of prime importance.

**Keywords:** Amlodipine, Cost-effectiveness, Hypertension, Losartan, Pharmacoeconomics

### INTRODUCTION

Hypertension (HTN), is an increasingly prevalent chronic condition and is associated as a reversible risk factor for myocardial infarction, heart failure, stroke, kidney disease and blindness.<sup>1</sup> Hypertension or high blood pressure is defined as systolic blood pressure of more than 140mm Hg and diastolic blood pressure of more than 90 mm Hg, by the World Health Organization. At the turn of the millennium the global data revealed that 972 million adults or 26.4% of the adult population had HTN.<sup>2</sup> Persistently elevated blood pressure is estimated to be the underlying cause for about 54% of stroke, 47% of ischemic heart disease, and 25% of other

cardiovascular diseases worldwide.<sup>3</sup> The number of adults with HTN in 2025 is projected to escalate by 60% to 1.56 billion.<sup>4</sup> Collected data from various epidemiological studies conclude that the average prevalence of hypertension in India is 25% in urban and 10% in rural population.<sup>5</sup> 23.10% men and 22.60% women over the age of 25 years suffer from elevated Blood Pressure in India.<sup>6</sup>

There are many classes of antihypertensive drugs in the pharmaceutical armamentarium with different mechanisms of action. Among the most important and most widely used are the calcium channel blockers (CCBs), beta blockers, angiotensin-converting enzyme

inhibitors, angiotensin II receptor blockers (ARBs) and the thiazide diuretics. ARBs are a newer and safer class of antihypertensive agents because of their superior efficacy and good tolerance.<sup>7</sup> Data from various Clinical trials like ELITE, VALIANT, LIFE, etc. have approved ARBs for diabetic nephropathy, stroke prophylaxis, heart failure and to reduce cardiovascular mortality in clinically stable patients with left ventricular dysfunction following myocardial infarction.<sup>8</sup>

CCBs is another frequently prescribed antihypertensive. Amlodipine make up more than 85% of all CCBs prescribed.<sup>9</sup> Clinical trials like HOT, STOP-and ALLHAT have also found CCBs equi-effective as diuretics/ $\beta$  blockers/ACE inhibitors in reducing cardiovascular Mortality and in reducing the risk of fatal stroke by 44% to 55%. CCBs are especially suitable for the treatment of senior hypertensive patients and can be safely given in patients of asthma and PVD.<sup>10</sup>

There have been several studies which have concluded that Losartan 50mg has equal anti-hypertensive efficacy as 5mg of Amlodipine Monotherapy.<sup>11-13</sup> The selection of a first-line antihypertensive agent must be based not only on efficacy and outcome, but also tolerability and compliance, which includes both quality-of-life considerations and cost.<sup>14</sup> The associated morbidities, rising prevalence rates, and the chronic nature of hypertension exert substantial economic burden for both the patient and the healthcare system.<sup>15</sup>

Pharmacoeconomic studies attempts to weigh the cost of alternative drugs and interventions against the benefits they achieve to guide decisions.<sup>16,17</sup> A large number of studies on the economic evaluation of hypertension treatment have been published, obtaining a wide time-frame of analysis (>20 years) in which the outcome is based on the "cost per quality adjusted life year gained" ratio. However, some authors suggest that in order to acquire a "full picture" of the economics of hypertension treatment, those data should also be accompanied by clinically meaningful cost-effectiveness evidence, such as the cost per patient of achieving BP control or the cost per mmHg reduction in the systolic or diastolic BP.<sup>18</sup>

In this light, the objective of the present study was to conduct a pharmacoeconomic comparison of Losartan 50mg versus Amlodipine 5mg following a short-term time horizon of 12 weeks and applying the costs to clinically meaningful endpoints such as cost per mmHg reduction of Mean Blood Pressure and the cost per patient of achieving BP control alongwith comparing the overall efficacy and safety of the two antihypertensive agents to determine the better drug in totality.

## METHODS

A prospective, randomized, observational open label comparative clinical study of three months duration (May 2016- July 2016) was conducted in the department of

Pharmacology in collaboration with the department of Medicine, Rohilkhand Medical College and Hospital Bareilly.

Patients of age 18-65 years, of both sexes, attending Medicine OPD were examined. Drug naïve newly diagnosed patients of hypertension (conforming to Stage 1 JNC VIII) were enrolled. Written informed consent from all the participants/relatives was undertaken before the commencement of the study. The study protocol was approved by Institutional Ethical Committee. Patients of secondary hypertension, patients having significant cardiac disease, patients with impaired liver and/or kidney function, pregnant and lactating females and females taking oral contraceptive pill were excluded from the study. Thus a total of 80 eligible patients who fulfilled the inclusion criteria were enrolled in the study.

The study involved the use of a structured pretested and predesigned questionnaire to collect the demographic information and to measure subject's blood pressure. BP was recorded with standardized protocol using mercury column type sphygmomanometer and stethoscope. All BP values were expressed as the average of three measurements obtained at an interval of 15 minutes each. A total of 80 patients were then randomly divided into two groups. One group was treated with Losartan 50 mg once daily and the other group received Amlodipine 5mg once daily. The selection of doses of these two agents was based on previous studies which showed that Losartan 50 mg once daily and Amlodipine 5mg once daily caused almost equal reduction of BP in patients of stage 1 Hypertension. Hence the two doses are considered equi-effective. Relevant Laboratory tests were carried out before the initiation of therapy and after twelve weeks of completion of treatment. Patients under treatment were subsequently monitored and re-assessed at regular follow-ups for evaluation of BP reduction or control and monitoring of adverse effects. Throughout the study period BP <140/90 mm Hg was targeted.

For pharmacoeconomic evaluation, cost effectiveness analysis was performed. For the purpose of the present study, cost was expressed in currency, as the cost of acquisition of the drug. Three different brands of Losartan and Amlodipine are available in our hospital pharmacy supply. The brands with the lowest price were chosen. Effectiveness was taken as the average reduction in Mean BP values, and the proportion (percent) of the patients reaching the goal values of BP with fixed dose schedule of antihypertensive in both the groups. The cost-effectiveness was calculated by using incremental cost for per mmHg BP reduction.

ICER= Cost of A - Cost of B / Effect of A- Effect of B

## RESULTS

A total number of 80 patients were enrolled in the study. They were then randomized to receive treatment with

either Losartan (50mg) i.e. LST Group (n=40) or Amlodipine (5mg OD) i.e. AMLO Group (n=40). None of the patients were lost during the follow-up period. Majority of the patients were in the age group of 40-50 years, although the incidence of Hypertension seems to be increasing from the age of 31 years onwards.

**Table 1: Baseline characteristics of randomized patients.**

Baseline variables			
	LST	AMLO	Total
No of Patients	40	40	80
1 Male	22	24	46
2 Female	18	16	34
3 Rural	17	18	35
4 Urban	23	22	45
5 Age, mean $\pm$ SD (years)	46.7 $\pm$ 10.6	46.8 $\pm$ 11.2	
6 SBP, mean $\pm$ SD (mmHg)	154.86 $\pm$ 6.86	154.64 $\pm$ 5.12	
7 DBP, mean $\pm$ SD (mmHg)	96.17 $\pm$ 4.2	96.45 $\pm$ 3.6	
8 Mean, BMI mean $\pm$ SD (Kg/m <sup>2</sup> )	21.24 $\pm$ 1.46	20.84 $\pm$ 1.22	

As shown in Table 1, Out of the 80 newly diagnosed cases of hypertension, males showed a higher prevalence (57.5%) of hypertension as compared to females (42.5%) and a greater number of patient's belonged to urban areas (45) as compared to rural areas (35).

The two groups were well balanced with regard to initial systolic and diastolic blood pressures for comparative evaluation. Mean SBP and Mean DBP being 154.86 $\pm$ 6.86 mm Hg and 96.17 $\pm$  4.2 mm Hg for LST group and 154.64  $\pm$  5.12 mm Hg and 96.45 $\pm$ 3.6 mm Hg for AMLO group. In the Losartan group the mean ( $\pm$  SD) age of patients was found to be 46.7  $\pm$  10.6years and the mean ( $\pm$  SD) Body Mass Index (BMI) value was 21.24 $\pm$ 1.46 kg/m<sup>2</sup> and in the Amlodipine group the mean ( $\pm$  SD) age of patients was calculated to be 46.8 $\pm$ 11.2 years and mean ( $\pm$  SD) BMI value was 20.84 $\pm$ 1.22 kg/m<sup>2</sup>.

Table 2 shows the comparative evaluation of changes in mean SBP between the two groups. It was observed that although both the regimens, individually produced statistically significant reductions in SBP (p <0.0001 for both groups), but there was no statistically significant difference (p>0.05) when the mean values of SBP, of both the regimens, were compared at each follow-up.

Table 3 shows similar results regarding comparative DBP reduction between two regimens at each follow-up.

**Table 2: Comparative evaluation of SBP with two regimens.**

(Mean BP $\pm$ SD) LST	(Mean BP $\pm$ SD) AMLO	t-value	df	p-value
Baseline 154.86 $\pm$ 6.86	Baseline 154.64 $\pm$ 5.12	0.1625	78	0.8713 Not significant
1st follow-up 149.34 $\pm$ 5.24	1st follow-up 148.23 $\pm$ 4.12	1.0532	78	0.2955 Not significant
2nd follow-up 139.12 $\pm$ 4.85	2nd follow-up 140.68 $\pm$ 5.42	1.3565	78	0.1788 Not significant
3rd follow-up 131.96 $\pm$ 4.82	3rd follow-up 132.14 $\pm$ 5.26	0.1596	78	0.8736 Not significant
p-value <0.0001	p-value <0.0001			

(P<0.05- significant, p<0.001- highly significant and p>0.05- not significant)

**Table 3: Comparative evaluation of DBP with two regimens.**

(Mean BP $\pm$ SD) LST	(Mean BP $\pm$ SD) AMLO	t-value	df	p-value
Baseline 96.17 $\pm$ 4.2	Baseline 96.45 $\pm$ 3.6	0.3201	78	0.7497 Not significant
1st follow-up 89.24 $\pm$ 3.12	1 <sup>st</sup> follow-up 90.28 $\pm$ 2.12	1.7437	78	0.0851 Not significant
2nd follow-up 85.72 $\pm$ 3.14	2 <sup>nd</sup> follow-up 86.68 $\pm$ 2.42	1.5315	78	0.1297 Not significant
3rd follow-up 80.94 $\pm$ 3.64	3 <sup>rd</sup> follow-up 81.12 $\pm$ 2.28	0.2651	78	0.7917 Not significant
p-value < 0.0001	p-value < 0.0001			

(P<0.05- significant, p<0.001- highly significant and p>0.05- not significant)

**Table 4: Difference in mean BP (MBP) of two regimens.**

Groups	MBP $\pm$ SD Baseline	MBP $\pm$ SD Final visit	Mean difference $\pm$ SD	P-value
LST	115.73 $\pm$ 3.84	97.94 $\pm$ 4.16	17.79 $\pm$ 0.32	0.4319
AMLO	115.84 $\pm$ 3.96	98.12 $\pm$ 4.42	17.72 $\pm$ 0.46	

(P<0.05- significant, p<0.001- highly significant and p>0.05- not significant)

Table 4 depicts the comparative changes in Mean BP (MBP) in both the groups at baseline and at the end of the treatment. The result comes out to be statistically insignificant ( $p=0.4319$ ), which again reinforces the fact

that both Losartan and Amlodipine in given doses are equi-effective in reducing the BP to target levels in case of stage 1 Hypertension.

**Table 5: Cost effectiveness analysis of two regimens based on MBP.**

Drugs	Total Cost	Average MBP reduction (mm Hg)	% patients who achieved target BP	Cost/mmHg MBP reduction	Cost/target BP
LST	1840	17.79	80	103.42	23
AMLO	1012	17.72	76	57.11	13.31

**Table 6: Incremental cost effectiveness ratio.**

Parameters	LST	AMLO	Difference in cost	Difference in effectiveness	ICER
Cost/mm Hg MBP reduction	103.42	57.11	46.31	0.07	661.5
Average Fall in MBP	17.79	17.72			

The comparative cost evaluation of different equivalent doses of the two drugs is presented in Table 5. The cost of Losartan per 10 tablets was 20.0 INR at 50mg daily dose, whereas that of Amlodipine 5mg was 11.0INR/10 tablets. Hence the total cost of treatment of LST group was Rs. 1840 and AMLO group was Rs. 1012 for the entire study duration of 12 weeks. Cost comparison and evaluation showed that the cost required for a 1 mmHg reduction in Mean blood pressure for LST group was 103.42 INR, whereas the same for AMLO group was Rs.57.11 INR. Thus, at low equivalent doses, the cost for an equivalent reduction in mean blood pressure was markedly less for the AMLO group as compared to the LST group.

Table 5 also reveals no significant difference in the response rates for the LST group (80%) and the AMLO group (76%). Hence the number of patients reaching the goal BP/normotension (<140/90 mm Hg according to JNC VIII criteria) were comparable between the two regimens. Hence regarding achieving the target BP, again Amlodipine was found to be the cost-effective drug (i.e. Rs.13.31 Vs Rs.23 per target BP).

Table 6, depicts the Incremental Cost Effectiveness Ratio between the two regimens. Fall in MBP of LST group was  $17.79 \pm 0.32$  mmHg and that of AMLO group was  $17.72 \pm 0.46$  mm Hg. Cost per mmHg MBP reduction was found to be 103.42 and 57.11 INR in LST and AMLO group respectively. ICER was calculated by dividing the difference in the cost of treatment of both the groups to difference in effectiveness in reduction of MBP of both the groups. Its value comes out to be Rs. 661.5 i.e. In the Losartan group to reduce the MBP by one mm Hg additional cost of Rs661.5 has to be paid by the patient. It can therefore be assumed that in cases of stage1 Hypertension, it is exclusively the drug price rather than

the effectiveness/efficacy, which is more important determinant of cost-effectiveness.

Table 7 focuses on the common adverse effects noted the two groups of drugs. Dizziness was observed as the most common adverse effect seen with LST in 3.5% of the cases, followed by headache in 1.5% of the patients. Cough was seen in 0.5% of the patients. Similarly in the AMLO group pedal edema ranks highest (10%) amongst adverse effects followed by palpitations (2.2%).

**Table 7: List of adverse effects commonly seen with LST and AMLO.**

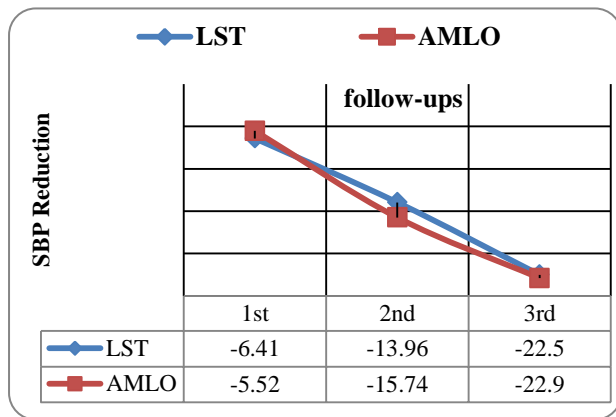
Adverse effects	(%) Of patients LST group	(%) Of patients AMLO group
Dizziness	3.5%	1.2%
Headache	1.5%	0.9%
Palpitations	1.0%	2.2%
G.I. upset	0.8%	0.7%
Cough	0.5%	0%
Emotional distress	1.0%	0.8%
Pedal edema	0.6%	10%
Hot flushes	0.4%	0.5%

## DISCUSSION

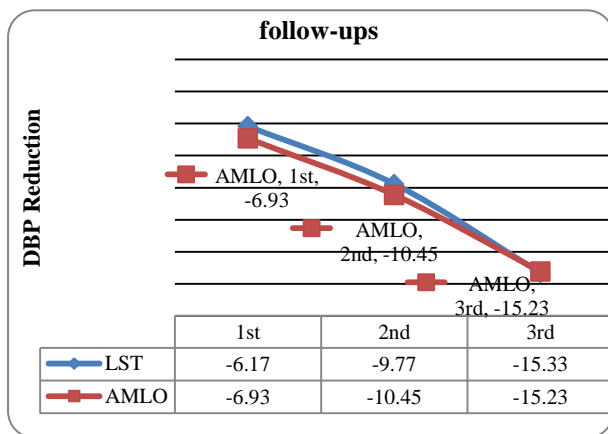
Hypertension is an alarming health problem and its associated morbidity and mortality places a great socioeconomic burden on the society. The expenditure incurred in the treatment of hypertension account for a significant proportion of health resources internationally.<sup>19</sup> Meta-analysis of randomized controlled trials have showed that treating systolic blood pressure (SBP) and diastolic blood pressure (DBP) to targets that are <140/90 mmHg is associated with a 30%-40%



reduction in stroke risk and reduces the risk of coronary death by 27-35%.<sup>20</sup>



**Figure 1: Reduction of SBP with two regimens.**



**Figure 2: Reduction of DBP with two regimens.**

Pharmacoeconomic research identifies, measures and compares the cost (i.e. Resources consumed) and consequences (i.e. Clinical, economic, humanistic) of pharmaceutical products and services on the health care society and system.<sup>21</sup> A number of studies have concluded that treatment of hypertension in its initial stages represents extremely favourable cost-effectiveness ratios by preventing its impending complications like stroke, MI and CKD.<sup>22</sup> Following this line of thought, we conducted a cost-effectiveness analysis of hypertension treatment focusing on clinical endpoints such as cost per mmHg reduction in the MBP over a short time horizon of 12 weeks. The goal was to find the treatment with least cost for the greatest level of effectiveness.

In the present study we noted that both the antihypertensive agents have caused almost equal magnitude of fall in systolic as well as diastolic BP, hence the equal antihypertensive efficacy between the two groups can be well accounted for. Our findings were consistent with those of other authors in the field who also reported similar findings with regard to the degree of blood pressure reduction with these two agents.<sup>11-13</sup>

The pharmacoeconomic analysis in the present study proves Amlodipine to be markedly cost-effective over Losartan. The study results showed significant differences in the cost of both the drugs. The cost per mmHg Mean BP reduction was found to 103.42 INR for Losartan, whereas the same being 57.11 INR for Amlodipine at equivalent antihypertensive doses respectively. Difference in the cost of treatment of both the groups was 46.31 INR. Difference in the effectiveness in the reduction of Mean BP of both the groups was 0.07. Incremental Cost Effectiveness Ratio (ICER) value was calculated to be 661.5 INR, which implies that in the Losartan group to reduce the MBP by one mm Hg, additional cost of Rs661.5 has to be paid by the patient. Hence the ICER indicated the most favourable cost-effectiveness outcome for Amlodipine with lower cost, effective control of BP, acceptable tolerability and the potential to allay associated morbidity and mortality. Similar observations in terms of cost-effectiveness of Amlodipine were reported by Yanfei Wu et al who in their study in 2013 concluded that Amlodipine is a cost-saving therapy compared with ARBs (like LOSARTAN) for the management of HTN with lower long-term cost and higher QALY gained.<sup>23</sup>

Our results are also in corroboration with the results of other authors in the same field. Pharmacoeconomic Review of the available outcome trials conducted in US and Europe for evaluating clinical effectiveness of Amlodipine in hypertensive patients or in patients with CAD concluded Amlodipine to be not only cost effective but also predicted to be cost-saving when compared to ARBs in terms of BP reduction, more protection against stroke and MI and lesser need for hospitalization.<sup>24</sup> A meta-analysis study by Wang et al examined the effects of Amlodipine and ARBs in the prevention of stroke and MI in patients with HTN.<sup>25</sup> The study included 12 trials of 94,338 patients. The results of this meta-analysis demonstrated that compared with ARBs, Amlodipine reduced the incidence of stroke and MI by 16% and 17% respectively, with better blood pressure control.

Drug side-effects are an important cause of non-compliance and prescribing a well-tolerated agent that promotes good compliance is therefore the key to the cost-effective management of hypertension. In our study it was observed that both Losartan and Amlodipine had minimal adverse effects and showed fairly good tolerability. It may be mentioned that none of the patient suffered serious adverse event or prolonged morbidity or mortality it can therefore be assumed that in cases of stage 1 hypertension, it is actually the drug price rather than the efficacy or adverse effects which is more important determinant of cost effectiveness.

Like any other study our study also has some limitations which must be acknowledged. In hypertension, the reduction of blood pressure in mm Hg is not the best measurement of the effectiveness of an antihypertensive treatment. Cost per life-year saved is an important

parameter of effectiveness which must have been worked out in this study. Since hypertension is clinically silent, hence survival is the ultimate measure of antihypertensive efficacy. Life years saved usually depend on the number of coronary and cerebral events avoided, which is greater in high risk population. This aspect has not been worked out, since in the present study the patients were of stage 1 hypertension and hence were at a lesser risk of any complications.

Another limitation of this study is that only the cost of drug acquisition has been taken into account. The costs that must be considered are the direct as well as the indirect medical cost. The acquisition cost is only a part of the total cost of treatment. Similar studies on a wider time-frame would help eliminate this error and help make a more powerful conclusion about the overall superiority of Amlodipine over Losartan.

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