International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

A Pharmacoeconomic Analysis On the Usage of Combination of Telmisartan & Hydrochlorothiazide Versus Combination of Losartan & Hydrochlorothiazide in Treatment of Patients with Stage II Hypertension

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OPEN ACCESS

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Received: 06-12-2025
Accepted: 22-12-2025
Available online: 11-01-2026

ABSTRACT

Background: Hypertension is one of the common ailments causing significant morbidity and mortality all over the world and also in our country. Hypertension is defined as a clinical entity where systolic blood pressure is over 130 mm of Hg and diastolic blood pressure over 90 mm of Hg. The prevalence is about 27.6% in rural and 33.8% in urban India. Stage II hyper tension refers to systolic pressure more than 160 mm of Hg and diastolic more than 100 mm of Hg. Pharmacoeconomics is analysis of cost of treatment in a health care system. It includes cost of drug therapy and other health services. Cost includes direct medical cost, indirect cost, intangible cost and direct nonmedical cost.

Aim: To analyse the pharmacoeconomics in two groups, where group A received combination of Telmisartan & hydrochlorothiazide and group B received combination of Losartan & hydrochlorothiazide in patients with stage II hypertension.

Objectives: To assess the Incremental cost effective ratio (ICER) of two different treatments, that is telmisartan &hydrochlorothiazide and losartan & hydrochlorothiazide using cost effective analysis. The other objective is to determine quality of life (QoL)using EQ-5D scale among stage II hypertension in both the groups stated above.

Material and Methods: A prospective and randomized study was done in SVRRGG Hospital, Tirupati on 210 patients with stage II hypertension. ICER is also calculated by comparing the cost of treatment and QALY (quality adjusted life year). QoL is calculated using EQ-5D scale (likert scale)

Result: ICER was found to be 736 rupees/QALY. The p value for all the parameters of EQ-5D was calculated which is as follows, that is mobility(p=1.0), self care (p=0.86) usual activities (p=0.60) pain & discomfort(p=0.87) and anxiety & depression (p=0.74).

Conclusion: ICER values indicate treatment with group A was more pharmacoeconomical than group B. The p value of the all 5 parameters of QOL was less than 0.5, which was statistically nonsignificant.

Keywords: *Telmisartan, losartan, hydrochlorothiazide, Incrementalcost effective ratio and Quality of life.*

INTRODUCTION

Hypertension or high blood pressure (BP)is a common clinical entity causing medical issues like myocardial infarction, stroke, kidney disease and other health problems when left unmanaged.{1}

Normal BP is 120/80mm of Hg, Stage I is about 140-150/90-99 mm of Hg and Stage II is about >160/>110 mm of Hg[2].Antihypertensive drugs available in pharmaceutical market are abundant.[3]Prominent among them are diuretics, Angiotensin converting enzyme inhibitors(ACEIs),Angiotensin receptor blockers(ARBs), betablockers and calcium channel blockers[4].

Diuretics drugs include hydrochlorothiazide and chlorthalidone. ACEI s include enalapril, lisinipril, ARBs include telmisartan and losartan, Betablockers include metaprolol, acebutalol, carvedilol, labetalol and calcium channel blockers include amlodipine and nifidepine.

Hydrochlorothiazide (HTZ), telmisartan and losartan are very popular firstline drugs for stage I hypertension, while combination of HTZ & temisartan and HTZ & losartan are used for stage II hypertension.

Telmisatran is a angiotensin receptor blocker. Angiotensin is primarily involved in vasoconstriction and production of aldosterone, both are culprits for hypertension. The average bioavailability is about 50%, plasma protein binding (PPB)is over 99.5%. It is metabolised by glucornidation and plasma half life is 24 hours. Adverse effects include, variations in heart rate, hypotension, edema and allergy. The usual dosage is 40mg per day and maximum dose is 80mg per day.

Losartan is another ARB with following pharmacokinetic data, bioavilability -25-35%, PPB -99.7%, metabolised in liver by CYP3A4, plasma half life is 2 hours and excreted by kidney. Common ADR s are muscle cramps, stuffynose, cough, hyperkalemia and anemia. Dosage includes 50-200mg per day.

Hydrochlorothiazide is a diuretic which is primarily excreted in kidney. Bioavailability is about 70% and elimination half life is about 5.6-14.8%. Side effects include electrolyte imbalance, increased glucose and uric acid levels and rarely pancreatitis. Dosage is about 12.5 mg per day.

Pharmacoeconomics is study of expenses of drug and cost of services from health care professionals[5].Key concepts are cost benefit analysis, cost minimisation analysis, cost effective analysis and cost utility analysis[6].

Incremental cost effective ratio is that a statistic from cost effective analysis that measures the cost of an intervention per unit of additional benefit it provides. The units often represent the cost per unit of health outcome, such as rupees per quality adjusted life year (QALY) gained. Quality of life (QOL)is a subjective assessment of an individual s wellbeing, that includes health, happiness, socialrelation ship viewed with context of personal goals.

There are already few studies comparing efficacy and safety of telmisartan & HTZ versus losartan & HTZ. But studies done on pharmacoeconomic analysis on the above combinations are nil.
Objective of this study is to assess ICER and QOL in patients taking telmisartan & HTZ versus losartan & HTZ.

MATERIALS AND METHODS

This was a prospective randomised study done in outpatient department of general medicine Sri Venkateswara Ramnarain Ruia Government General Hospital, Tirupati and department of pharmacology, Sri venkateswara medical college, Tirupati. This study was done after getting approval from scientific committee and ethics committee of Sri venkateswara medical college. Study population includes stage II hypertensive patients who attended in outpatient department of general medicine Sri Venkateswara Ramnarain Ruia Government General Hospital. Both male and female patients above 35 years with out comorbidities with stage II hypertension were included in study. Sample size for this observational study assuming 95 % confidence interval is

$n = (Z_{\alpha/2})^2 PQ / d^2$

where $Z_{\alpha/2}$ = standard normal variate = 1.96 (from Z table)
P = pooled prevalence of drug combinations = 5.2 %
Q = 100-P = 94.8 %
d = absolute precision of 3 %

n = 1.96 * 1.96 * 5.2 * 94.8 / 3 * 3
= 210

Hence, a total of 105 participants were included in each group. Studyvariables include ICER, QALYs and Quality of life and study tools were cost, mean life years, mean utility vauesand ED-5D scale. A total of 210 patients were divided into two groups A & B, with 105 patients in each group by simple randomised technique.

Group A received telmisartan (40mg) & HTZ(12.5 mg),one single dose at night time.[7,8]
Group B received losartan[9] (50mg) & HTZ[10,11](12.5 mg),one single dose at night time.

ICER [12.13]is calculated by following formula:
Difference in cost of treatment group A and group B divided by difference in mean QALYS.
Cost of treatment of group A and group B was obtained from internet research.

Mean QALYs [14,15]is calculated by multiplying mean life years and mean utility. Mean life years refers to the average number of years a person is expected to live or the average duration of life gained due to medical intervention. The above data was obtained from online data collection and internet research.
Utility values are typically scaled from 0(dead) to 1(perfect health).

QOL [16,17] was calculated by using ED-5D[18,19] scale for assessing 5 parameters namely mobility, selfcare, usaualactivity, pain & discomfort and lastly anxiety & depression. For this likert scale[20,21] from 1 to 0 is used for all parameters and p value calculated. p value less than 0.5 is taken as statistically significant. In likert scale 0 represents least value while 7 represents maximum value.0

Ethical considerations
This study was done after approval from scientific committee in December 2024 and from ethics committee of S.V. Medical college in febraury 2025.Informed consent was taken from all the study subjects.

RESULTS
In 210 patients male patients were about 125 and females were about 85
(table I). Patients aged between 35-60 years were about 103 and aged above 60years were about 107(table II).

TABLE I (gender wise distribution of treatment groups)

SEX	GROUP A	GROUP B	TOTAL
MALE	65	60	125
FEMALE	40	45	85

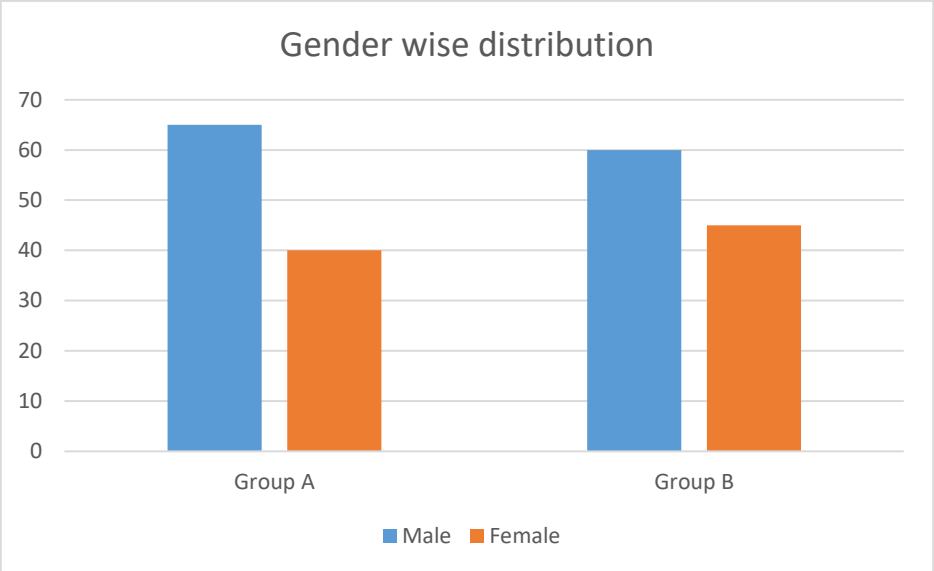
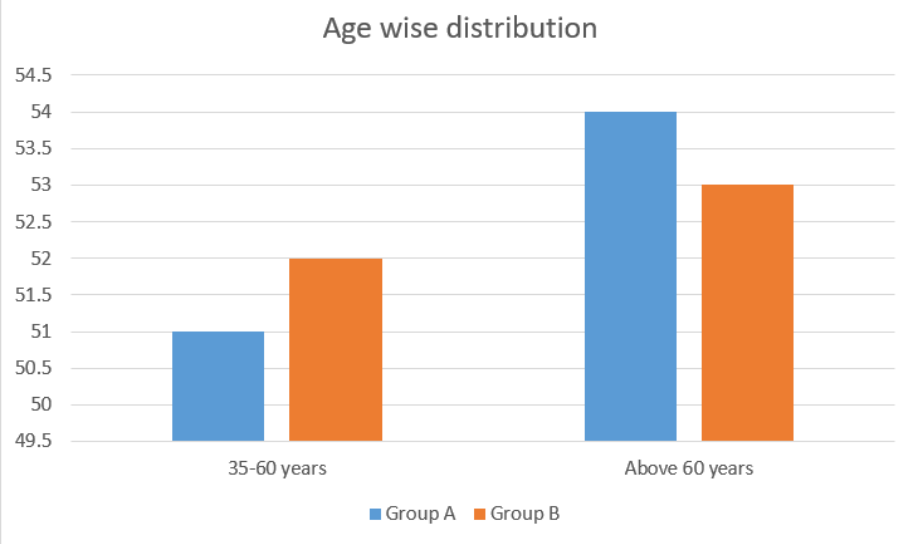


TABLE II (Age wise distribution of treatment grpups)

AGE IN YEARS	GROUP A	GROUP B	TOTAL
35-60 YEARS	51	52	103
ABOVE 60 YEARS	54	53	107



Cost of tablets were calculated and depicted in the TABLE III

DRUG	QUANTITY	DOSE(mg)	CEILING PRICE	MINIMUM PRICE	AVERAGE PRICE	TOTAL PRICE
TELMISARTAN & HYDROCHLOROTHIAZIDE	90 tablets	40/12.5	150	70	110	990
LOSARTAN &HYDROCHLOROTHIAZIDE	90 tablets	50/12.5	100	48	74	666

Calculation of mean QALYs TABLE IV

GROUP	MEAN LIFE YEAR	MEAN UTILITY	MEAN QALYs
A	10.4	0.62	6.44
B	10	0.6	6

ICER=990-666/6.44_6= 324/0.44=736 rupees/QALYs

ASSESSMENT OF QUALITY OF LIFE-EQ-5D
TABLE: V
TABLE V (MOBILITY)

MEAN(MOBILITY)	GROUP A	GROUP B
1ST WEEK	5	6
8th WEEK	6	6
12 th week	7	7
Change in 1st and 12 th week	2	1
t-value	.01	
P value	1.00	

P value is nonsignificant

TABLE: VI

MEAN (SELF CARE)	GROUP A	GROUP B
1ST WEEK	4	5
8th WEEK	5	6
12 th week	7	7
Change in 1st and 12 th week	3	2
t-value	0 .18	
P value	0.86	

P value is nonsignificant

TABLE: VII

MEAN(USUAL ACTIVITES)	GROUP A	GROUP B
1ST WEEK	5	4

8th WEEK	6	5
12 th week	7	6
Change in 1st and 12 th week	2	3
t-value	0.54	
P value	0.605	

P value is nonsignificant

TABLE: VIII

MEAN (PAIN &DISCOMFORT)	GROUP A	GROUP B
1ST WEEK	4	6
8th WEEK	5	
12 th week	7	
Change in 1st and 12 th week	3	
t-value	0.17	
P value	0.87	

P value is nonsignificant

TABLE: IX

MEAN (ANXIETY&DEPRESSION)	GROUP A	GROUP B
1ST WEEK	5	4
8th WEEK	6	6
12 th week	7	6
Change in 1st and 12 th week	2	2
t-value	0.34	
P value	0.74	

P value is nonsignificant

DISCUSSION

On analysing demographic data, it is found that 65 patients in group A and 60 patients in group B are males.40 patients in group A and 45 patients in group B were female. (table I).In group A 51 patients were aged between 35 to 60 years, while 54 were above 60 years. In group B, 52 were aged between 35 to 60 years, while 53 were above 60years. (table II).

Ceiling price of telmisartan (40mg) & HTZ(12.5mg) of 10 tablets was about 150 rupees, while minimum price was 70 rupees and average price was 110 rupees. The total cost for 3 months was 990 rupees.100rupees was the ceiling price for 10 tablets of losartan(50mg) &HTZ (12.5 mg), minimum price was about 48 rupees and average price was about 74 rupees. Total cost for 3 months comes around 666 rupees. (table III). The above data was obtained from online data collection and internet research.

Difference of costs for treatment with group A and group B was about 324 rupees.

In table IV, mean life years for patients in group A and group B was depicted as 10.4 years and 10 years. The above data was gathered through online data collection and internet research. The mean utility values for patients in group A and group B were found to be 0.62 and 0.6. These values where scaled from 0(dead) to 1(perfect health).QALYs which was product of mean life year and utility value was found to be was as follows, group A patients was about 6.44 and for group was 6.The difference of QALYs was found to be 0.44.

ICER was calculated by dividing the difference of cost of group A and group B with difference of QALYs in both the goups. That is dividing 324 with 0.44, which is about 736 rupees per QALYs.

This indicates that group A was superior to group B economically.

Assessment of QOL was done with EQ-5D which includes 5 parameters. They are mobility, selfcare, usualactivities, pain & discomfort and lastly anxiety & depression. Inlikert scale 0-7 was employed.0 indicates the least and 7 indicates the maximum parameter. The p value for was calculated for all the parameters, by comparing the change in value in 1st and 12thweeks.For mobility it was 1.00, self care it was 0.86, usual activites it was 0.656, pain & discomfort it was 0.87and anxiety &depression it was 0.74.On observation p values for all the parameters in ED-5D,it was found to be greater than .05,which is statiscallynonsignificant. Thus null hypothesis was not rejected. This conveys that difference of out come with treatment A and treatment B is not significant.

According to a study by Joel M.Neutel e tal, in 2005[22]it was concluded that combination of telmisartan with HTZ was statiscally, significantly superior to losartan with HTZ in reducing blood pressure. However this study did not compare pharmacoeconomic analysis, which is done in this study.

CONCLUSION

This study concludes that tablet with combination telmisartan with HTZ is pharmacoeconomically superior to losartan with HTZ. Further studies are required to compare the above combinations to know the clinical superiority and incidence of adverse effects.

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