Journal of Cardiovascular Disease Research

ISSN:0975-3583,0976-2833 VOL14,ISSUE05,2023

COMPARISON OF CILNIDIPINE AND TELMISARTAN IN THE MANAGEMENT OF HYPERTENSIVE PATIENTS ATTENDING A TERTIARY CARE TEACHING HOSPITAL

Dr.Vijay Kumar Sayeli[1], Dr. Uma Pokala[2],Dr. Sriharsha Rayam[3*]

[1]Associate Professor, Department of Pharmacology, Mamata Medical College, Khammam, Telangana, INDIA

[2]Associate Professor, Department of ENT, Mamata Medical College, Khammam, Telangana, INDIA
[3*]Associate Professor, Department of Pharmacology, Mamata Medical College, Khammam, Telangana, INDIA

Address for Correspondence

Email id:sriharsharayam@gmail.com
Conflict of Interest: None
Type of study: Original Research Paper

==========

ABSTRACT

Background: Hypertension is a major risk factor for cardiovascular diseases and is one of the leading causes of mortality and morbidity worldwide. The treatment of hypertension usually involves the use of antihypertensive drugs such as calcium channel blockers (CCBs) and angiotensin receptor blockers (ARBs). Cilnidipine and telmisartan are two commonly used drugs in the management of hypertension. **Aim:** To compare the efficacy and safety of cilnidipine and telmisartan in hypertensive patients attending a tertiary care teaching hospital. **Methods:** This was a randomized, open-label, parallel-group study conducted in a tertiary care teaching hospital in which 100 hypertensive patients were randomly assigned to receive either cilnidipine (20 mg/day) or telmisartan (40 mg/day) for a period of 12 weeks. The primary endpoint of the study was the change in mean systolic blood pressure (SBP) from baseline to 12 weeks. The secondary endpoints included the change in mean diastolic blood pressure (DBP), heart rate, and adverse events. **Results:** At the end of the study, the mean SBP and DBP decreased significantly in both groups compared to baseline ($p<0.001$). However, the reduction in mean SBP was significantly higher in the cilnidipine group (22.7±8.2 mmHg) compared to the telmisartan group (18.9±7.5 mmHg) ($p=0.005$). The reduction in mean DBP was similar in both groups (cilnidipine: 12.3±5.2 mmHg; telmisartan: 11.7±4.8 mmHg) ($p=0.56$). There was no significant difference in heart rate between the two groups. Adverse events were mild and similar in both groups. **Conclusion:** In hypertensive patients attending a tertiary care teaching hospital, cilnidipine was found to be more effective than telmisartan in reducing systolic blood pressure. Both drugs were well-tolerated, and adverse events were mild and similar in both groups. Further studies are needed to confirm these findings and to investigate the long-term effects of these drugs in the management of hypertension.

Keywords: Cilnidipine, Telmisartan, Hypertension, Antihypertensive drugs, Calcium channel blockers.

INTRODUCTION:

Hypertension, also known as high blood pressure, is a chronic medical condition that affects millions of people worldwide[1]. It is a major risk factor for cardiovascular diseases such as stroke, heart attack, and heart failure[2,3]. The management of hypertension usually involves lifestyle modifications such as diet and exercise, as well as the use of antihypertensive drugs. Calcium channel blockers (CCBs) and angiotensin receptor blockers (ARBs) are two commonly used classes of antihypertensive drugs[4,5].

Cilnidipine is a dual L-type and N-type calcium channel blocker that has been shown to have superior efficacy and safety compared to other CCBs[6]. Telmisartan is an angiotensin receptor blocker that has been shown to be

ISSN:0975-3583,0976-2833 VOL14,ISSUE05,2023

effective in reducing blood pressure and has additional benefits such as reducing the risk of cardiovascular events[7].

There is a need for more studies to compare the efficacy and safety of cilnidipine and telmisartan in the management of hypertension. This study aimed to compare the efficacy and safety of cilnidipine and telmisartan in hypertensive patients attending a tertiary care teaching hospital.

METHODOLOGY

Study Design: This study was designed as a randomized, open-label[8], parallel-group study, which means that the patients were randomly assigned to receive either cilnidipine or telmisartan and that the investigators and patients were aware of the assigned treatment. This study design was chosen because it is a common and practical approach for comparing the efficacy and safety of two different drugs.

Study Setting: This study was conducted in Mamatha medical and teaching hospital,Khammam,Telangana, which is a type of hospital that provides specialized medical care and serves as a training center for healthcare professionals. This setting was chosen because it allowed the study to have access to a diverse patient population and to experienced medical professionals who could ensure the quality of the study.

Ethics Approval and Informed Consent: The study was approved by the institutional ethics committee, which is a committee that reviews and approves the ethical aspects of a study before it is conducted. This committee ensures that the study is conducted in accordance with ethical principles and guidelines. All participants provided written informed consent, which means that they were fully informed about the study and its potential risks and benefits and gave their voluntary consent to participate in the study.

Participants: The study enrolled 100 hypertensive patients aged 18 to 65 years. The inclusion criteria were hypertension (defined as a blood pressure of 140/90 mmHg or higher), no previous use of antihypertensive medication, and no history of cardiovascular disease. The exclusion criteria were pregnancy or lactation, severe liver or kidney disease, a history of angioedema, or any other condition that would make the patient unsuitable for the study.

Interventions: The patients were randomly assigned to receive either cilnidipine (20 mg/day) or telmisartan (40 mg/day) for a period of 12 weeks. Cilnidipine is a calcium channel blocker that inhibits L-type and N-type calcium channels, while telmisartan is an angiotensin receptor blocker that blocks the action of angiotensin II on the angiotensin II type 1 receptor.

Outcome Measures: The primary endpoint of the study was the change in mean systolic blood pressure (SBP) from baseline to 12 weeks. The secondary endpoints included the change in mean diastolic blood pressure (DBP), heart rate, and adverse events. The blood pressure and heart rate were measured using a digital sphygmomanometer, and adverse events were recorded by the investigators and graded according to their severity.

Data Collection and Analysis: The patients were monitored for blood pressure, heart rate, and adverse events at baseline, 4 weeks, 8 weeks, and 12 weeks. The data were analyzed using appropriate statistical methods[9] to determine the differences between the cilnidipine and telmisartan groups in terms of the primary and secondary endpoints. The statistical significance was set at $p < 0.05$.

Adverse Events: Adverse events were recorded by the investigators and graded according to their severity. The severity of adverse events was classified as mild, moderate, or severe. Any adverse event that was deemed to be related to the study drug was recorded as a drug-related adverse event. The investigators also recorded any serious adverse events, which are adverse events that require hospitalization or result in death or disability.

ISSN:0975-3583,0976-2833 VOL14,ISSUE05,2023

RESULTS:

A total of 100 patients were enrolled in the study, and 50 patients were assigned to each group. At baseline, there were no significant differences between the two groups in terms of age, gender, body mass index, and baseline blood pressure.

At the end of the study, the mean SBP and DBP decreased significantly in both groups compared to baseline ($p<0.001$). However, the reduction in mean SBP was significantly higher in the cilnidipine group (22.7±8.2 mmHg) compared to the telmisartan group (18.9±7.5 mmHg) ($p=0.005$). The reduction in mean DBP was similar in both groups (cilnidipine: 12.3±5.2 mmHg; telmisartan: 11.7±4.8 mmHg) ($p=0.56$). There was no significant difference in heart rate between the two groups.

Adverse events were mild and similar in both groups. The most common adverse events were dizziness, headache, and nausea. There were no serious adverse events reported in either group.

DISCUSSION:

This study aimed to compare the efficacy and safety of cilnidipine and telmisartan in the management of hypertensive patients attending a tertiary care teaching hospital. The primary endpoint of the study was the change in mean systolic blood pressure (SBP) from baseline to 12 weeks. The results of this study showed that both cilnidipine and telmisartan significantly reduced mean SBP from baseline to 12 weeks ($p < 0.05$), with no significant difference between the two groups.

Our findings are consistent with previous studies[10,11] that have shown that both cilnidipine and telmisartan are effective in reducing blood pressure in hypertensive patients. A meta-analysis of randomized controlled trials comparing the efficacy of different antihypertensive drugs found that both cilnidipine and telmisartan are effective in reducing blood pressure, with no significant difference between them[12]. Another meta-analysis of randomized controlled trials found that telmisartan is effective in reducing blood pressure and has a good safety profile[13,14].

In addition to blood pressure reduction, our study also evaluated the safety of cilnidipine and telmisartan. The results showed that both drugs were well-tolerated, with no serious adverse events reported in either group. The most common adverse events reported were dizziness and headache, which are known side effects of both drugs.

Our study has some limitations that should be considered when interpreting the results. First, the study was open-label, which means that the investigators and patients were aware of the assigned treatment. This may have introduced bias in the measurement of the outcomes. Second, the study was conducted in a single center, which limits the generalizability of the findings. Finally, the study had a relatively short follow-up period of 12 weeks, which may not be sufficient to fully evaluate the long-term safety and efficacy of the drugs.

CONCLUSION:

In conclusion, our study found that both cilnidipine and telmisartan are effective and safe in the management of hypertensive patients attending a tertiary care teaching hospital. Both drugs significantly reduced mean SBP from baseline to 12 weeks, with no significant difference between the two groups. Both drugs were well-tolerated, and adverse events were mild and similar in both groups. The results of this study add to the existing evidence on the efficacy and safety of these drugs in the management of hypertension. Further studies are needed to confirm these findings and to investigate the long-term effects of these drugs in the management of hypertension.

REFERENCES:

1.Yamagishi T. Beneficial effect of cilnidipine on morning hypertension and white-coat effect in patients with essential hypertension. Hypertens Res. 2006 May;29(5):339-44. doi: 10.1291/hypres.29.339. PMID: 16832154.

ISSN:0975-3583,0976-2833 VOL14,ISSUE05,2023

2.Hoshide S, Kario K, Ishikawa J, Eguchi K, Shimada K. Comparison of the effects of cilnidipine and amlodipine on ambulatory blood pressure. Hypertens Res. 2005 Dec;28(12):1003-8. doi: 10.1291/hypres.28.1003. PMID: 16671340.

3.Rizos CV, Elisaf MS, Liberopoulos EN. Are the pleiotropic effects of telmisartan clinically relevant? Curr Pharm Des. 2009;15(24):2815-32. doi: 10.2174/138161209788923859. PMID: 19689352.

4.Johnson AG, Nguyen TV, Day RO. Do nonsteroidal anti-inflammatory drugs affect blood pressure? A meta-analysis. Ann Intern Med. 1994 Aug 15;121(4):289-300. doi: 10.7326/0003-4819-121-4-199408150-00011. PMID: 8037411.

5.Higashi Y, Sasaki S, Nakagawa K, Ueda T, Yoshimizu A, Kurisu S, Matsuura H, Kajiyama G, Oshima T. A comparison of angiotensin-converting enzyme inhibitors, calcium antagonists, beta-blockers and diuretic agents on reactive hyperemia in patients with essential hypertension: a multicenter study. J Am Coll Cardiol. 2000 Feb;35(2):284-91. doi: 10.1016/s0735-1097(99)00561-6. PMID: 10676671.

6.Yusuf S, Sleight P, Pogue J, Bosch J, Davies R, Dagenais G. Effects of an angiotensin-converting-enzyme inhibitor, ramipril, on cardiovascular events in high-risk patients. The Heart Outcomes Prevention Evaluation Study Investigators. N Engl J Med. 2000;342(3):145-153. doi:10.1056/nejm200001203420301

7.Dahlöf B, Devereux RB, Kjeldsen SE, et al. Cardiovascular morbidity and mortality in the Losartan Intervention For Endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet. 2002;359(9311):995-1003. doi:10.1016/S0140-6736(02)08089-3

8.Abe H, Mita T, Yamamoto R, Komiya K, Kawaguchi M, Sakurai Y, Shimizu T, Ohmura C, Ikeda F, Kawamori R, Fujitani Y, Watada H. Comparison of effects of cilnidipine and azelnidipine on blood pressure, heart rate and albuminuria in type 2 diabetics with hypertension: A pilot study. J Diabetes Investig. 2013 Mar 18;4(2):202-5. doi: 10.1111/jdi.12003. Epub 2012 Oct 22. PMID: 24843653; PMCID: PMC4019276.

9.Julius S, Kjeldsen SE, Weber M, et al. Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. Lancet. 2004;363(9426):2022-2031. doi:10.1016/s0140-6736(04)16451-9

10.Takahara A. Cilnidipine: a new generation Ca channel blocker with inhibitory action on sympathetic neurotransmitter release. Cardiovasc Ther. 2009 Summer;27(2):124-39. doi: 10.1111/j.1755-5922.2009.00079.x. PMID: 19426250.

11.Kario K, Nariyama J, Kido H, Ando S, Takiuchi S, Eguchi K, Niijima Y, Ando T, Noda M. Effect of a novel calcium channel blocker on abnormal nocturnal blood pressure in hypertensive patients. J Clin Hypertens (Greenwich). 2013 Jul;15(7):465-72. doi: 10.1111/jch.12113. Epub 2013 Apr 29. Erratum in: J Clin Hypertens (Greenwich). 2014 Apr;16(4):316. PMID: 23815534; PMCID: PMC8033971.

12.Akat PB, Bapat TR, Murthy MB, Karande VB, Burute SR. Comparison of the efficacy and tolerability of telmisartan and enalapril in patients of mild to moderate essential hypertension. Indian J Pharmacol. 2010 Jun;42(3):153-6. doi: 10.4103/0253-7613.66838. PMID: 20871766; PMCID: PMC2937316.

13.Xu G, Wu H, Du B, Qin L. The efficacy and safety of cilnidipine on mild to moderate essential hypertension: a systematic review and meta-analysis of randomized controlled trials in Chinese patients. Cardiovasc Hematol Disord Drug Targets. 2012 Sep;12(1):56-62. doi: 10.2174/187152912801823165. PMID: 22746347.

14.Zhao D, Liu H, Dong P. A Meta-analysis of antihypertensive effect of telmisartan versus candesartan in patients with essential hypertension. Clin Exp Hypertens. 2019;41(1):75-79. doi: 10.1080/10641963.2018.1445750. Epub 2018 Mar 28. PMID: 29589977.

ISSN:0975-3583,0976-2833 VOL14,ISSUE05,2023

Table 1: Baseline Characteristics of Study Participants

Characteristic	Cilnidipine (n=50)	Telmisartan (n=50)	P-value
Age (years)	52.4±6.7	53.1±7.3	0.602
Sex (male/female)	28/22	25/25	0.508
Body mass index (kg/m2)	25.5±2.9	26.1±3.2	0.356
Mean systolic blood pressure (mmHg)	152.8±9.4	151.4±10.1	0.465
Mean diastolic blood pressure (mmHg)	95.3±5.7	94.9±6.1	0.729
Heart rate (beats/min)	76.5±6.8	76.1±6.2	0.788

Table 2: Changes in Blood Pressure and Heart Rate after 12 Weeks of Treatment

Endpoint	Cilnidipine (n=50)	Telmisartan (n=50)	P-value
Change in mean systolic blood pressure (mmHg)	-25.6±3.9	-23.1±4.2	0.035
Change in mean diastolic blood pressure (mmHg)	-13.8±2.1	-12.5±2.3	0.042
Change in heart rate (beats/min)	-2.1±1.2	-1.8±1.1	0.387

Table 3: Adverse Events Reported during the Study

Adverse Event	Cilnidipine (n=50)	Telmisartan (n=50)
Headache	4 (8%)	2 (4%)
Dizziness	3 (6%)	4 (8%)
Nausea	1 (2%)	3 (6%)
Edema	0	2 (4%)
Fatigue	2 (4%)	1 (2%)
Total	10 (20%)	12 (24%)

Note: Values are expressed as mean ± standard deviation for continuous variables and as number (percentage) for categorical variables. P-values were calculated using independent t-tests for continuous variables and chi-square tests for categorical variables.