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EFFECTIVENESS PROFILE OF AMLODIPINE AND LISINOPRIL IN HYPERTENSION OUTPATIENTS AT PRATAMA CLINIC SIDOARJO

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ABSTRACT

Hypertension is the leading cause of premature death worldwide. An estimated 1.28 billion adults aged 30-79 years worldwide have hypertension. Treatment of hypertension is usually aimed at preventing morbidity and mortality from hypertension. The choice of drugs for each patient's hypertension depends on the metabolic and subjective side effects caused. This study aims to determine the effectiveness profile of antihypertensive drugs amlodipine 10 mg or lisinopril 10 mg in outpatients at the Sidoarjo Pratama Clinic for January- March 2023. This research method is observational, with a cross-sectional approach and data collection. Quantitative analysis was then done using the statistical program SPSS 24 with univariate analysis. The results of the independent t-test showed a significance value for the systolic category of 0.780 > 0.05 and a significance value for the diastolic category of 0.931 > 0.05. Patients receiving therapy with amlodipine 10 mg or lisinopril 10 mg reached the target in 30 patients. After doing the independent t-test before and after therapy in both the systolic category and the diastolic category, it can be concluded that there is no significant difference in the effectiveness of the two groups.

Keywords: Amlodipine, Blood Pressure, Hypertension, Lisinopril

INTRODUCTION

Hypertension is the leading cause of premature death worldwide. An estimated 1.28 billion adults aged 30−79 years worldwide have hypertension. Most (2/3) live in low- to middle-income countries (Lau et al., 2023). An estimated 46% of adults with hypertension are unaware that they have the condition (Diwati & Sofyan, 2023). Less than 42% of cases of hypertension are diagnosed and treated, and about 21% of adults with hypertension can control it (Falconer et al., 2018). With a prevalence of 34.1%, and it is known that 8.8% were diagnosed with hypertension, and 32.3% did not take medication regularly. One of the reasons people with hypertension do not take medication is that 4.5% have drug side effects (Iskandar et al., 2018). Treatment of hypertension is usually aimed at preventing morbidity and mortality due to hypertension. The choice of drug for each patient with hypertension depends on side effects, metabolic and subjective results, the presence of other diseases that may be corrected or exacerbated for the selected antihypertensive, the presence of other drugs that may interact with antihypertensives given (Alrosyidi et al., 2022; Fatmawati et al., 2022). Based on the updated JNC, there are four groups of drugs recommended for first-line therapy, namely thiazide diuretics, β-blockers, CCB, ACE-I, and ARB (Fitriana et al., 2023; Supit et al., 2022). The ACE-I class is the most widely used antihypertensive drug, followed by the CCB and ARB groups (Suriyadi, 2020). This is in line with research conducted by Andhyka et al. (2023), the drugs commonly used are lisinopril and amlodipine in treating hypertension. Lisinopril is an ACE inhibitor (Lau et al., 2023) drug, and Amlodipine, namely calcium channel blocker (CCB) drugs, has high selectivity (Haryati et al., 2023; Sylvia et al.,

2021). Lisinopril prevents the conversion of angiotensin I to angiotensin II, a vasoconstrictor substance that is endogenous. Amlodipine works by inhibiting calcium influx into the vascular smooth muscle blood, thereby reducing peripheral resistance (Tulungen, 2019). At the Pratama Sidoarjo clinic, previously, there was no research on the antihypertensive drugs amlodipine and lisinopril. Based on several research and literature studies, data was also obtained that amlodipine and lisinopril have affordable prices, so researchers also considered this aspect. From their background, the researcher is interested in research to determine the profile of the effectiveness of antihypertensive drugs amlodipine or lisinopril in hypertensive patients outpatient period January−March 2023.

RESEARCH METHODS

This quantitative research uses observational methods and a prospective cross-sectional research approach, namely research for reduction comparisons of blood pressure with the antihypertensive drugs amlodipine and lisinopril. The study population consisted of patients with hypertension who met the inclusion criteria. This study uses a non-probability sampling technique, purposive sampling, with the inclusion criteria of 60 patients aged 20−70 years who underwent outpatient care at the Sidoarjo primary clinic. Have high blood pressure without or with comorbidities. Secondary data was collected prospectively before blood pressure measurements and after therapy while undergoing treatment at the clinic in January−March 2023. Research. According to Sugiyono (2014), if the sample is divided into categories, then the minimum sample for each category is 30, so the sample of this study is a given hypertension patient on amlodipine therapy with a total of 30 and lisinopril with a sample of 30. The sample required for this research is still limited, so the results of the analysis are not proportional to each other. Suggestions for further research are to carry out further analysis and research. The instruments used in This study consisted of tensimeters, prescriptions, questionnaires, informed consent, and observation sheets. A questionnaire was carried out for sample determination and initial recording of the respondent's blood pressure. Respondents who were used as samples were explained. That will be observed after one month of the use of amlodipine or lisinopril and given a time sheet for taking the patient's medication to be sure. The patient took medication regularly for one month. The initial data analysis carried out in this study was a characteristic univariate analysis of respondents based on age and gender. Then, do the normality test to test data from the distribution of groups or variables, aiming to determine whether the data or variables are normally distributed. Then, proceed with the difference in blood pressure reduction using the independent t-test statistic.

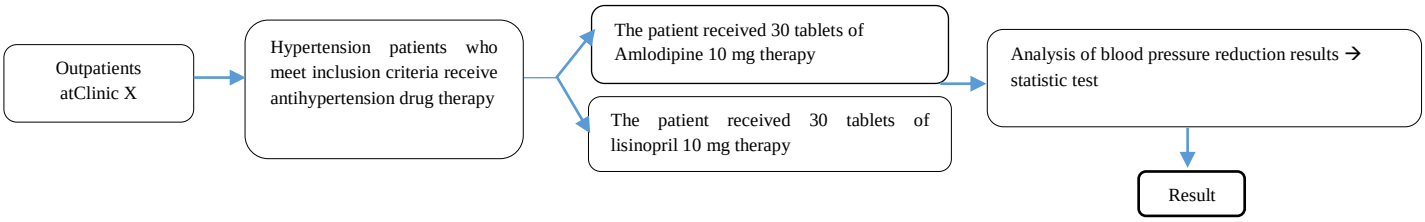

Figure 1. Method session

RESULTS AND DISCUSSION

Demographic Data

Patient characteristics (age, sex, comorbidities), use of antihypertensive drugs (amlodipine or lisinopril). Data that has been analyzed is presented as an observation table. The distribution of patients based on age and sex can be seen in **Table I**. In **Table I**, it can be seen that more respondents in this study were aged 41−70 years (53.6%). This is due to changes in physiology and decreased organ function. Physiological changes include the thickening of the artery walls due to the buildup of collagen in the muscle layer, which causes narrowing and vascular stiffness (Nyoman et al., 2022). Decreased organ function due to the aging process (damage to cells) decreases the production of hormones and enzymes

due to the buildup of collagen layers in muscles that cause narrowing and stiffness of blood vessels (V.A.R. Barao et al., 2022).

Table I. Demographic Data of Hypertensive Patients

Age	Amlodipine	Lisinopril	Number of patients	Percentage (%)
20-40	6	8	14	46.4
41- 70	9	7	16	53.6
Total	15	15	30	100
Gender				
Man	9	4	13	43.4
Woman	6	11	17	56.6
Total	15	15	30	100

Decreased organ function due to the aging process (damage to cells) decreases the production of hormones and enzymes due to the buildup of collagen layers in muscles that cause narrowing and stiffness of blood vessels (Himyatul, 2021). Decreased function of organs due to the aging process (damage to cells) reduces the production of hormones, enzymes, and substances that the body needs (Elsayanti & Lestari, 2021; Nilansari, 2020). The sex is primarily female (56.6%). This is due to the more complex hormonal conditions of women (Oktianti et al., 2021). Menopause can cause hormonal changes in the form of decreased estrogen levels, and androgens can trigger the release of renin, thereby increasing blood pressure.

Table II. Patient Characteristics Based on Disease Diagnosis

Diagnosis	Therapeutics					
	Amlodipin		Lisinopril		Total	Percentage (%)
	Total	(%)	Total	(%)		
Hypertension Without Complications	5	33.3	6	40	11	36.6
Hypertension With Complications	10	66.6	9	60	19	63.4
Total	15	100	15	100	30	100

The results of research related to disease diagnosis show that 36.3% of patients with hypertension are without complications, and 63.4% have complications. Because, in most cases, hypertension is detected during a physical examination for some reason. Patients with hypertension generally look healthy, so they do not realize they have high blood pressure. Long-term high blood pressure will damage the arterial endothelium, accelerate atherosclerosis, and cause complications in the form of organ damage to the heart, brain, kidneys, eyes, and peripheral blood vessels. Control of various risk factors in hypertension is significant to prevent cardiovascular complications. Modifiable risk factors include blood pressure, metabolic disorders (Diabetes Mellitus, blood lipids, gout, and obesity), smoking, alcohol, and inactivity, while those cannot be modified, including age, gender, and genetic factors (Romadhoni et al., 2023).

Result of Secondary Data Retrieval and Statistical Test

A health worker, such as a nurse, must measure blood pressure using a sphygmomanometer. The measurement results are then recorded on the resume sheet and collected in the patient's medical record folder. These blood pressure measurement results are used as secondary data for this study. The patient's initial blood pressure was measured when they checked themselves and obtained a prescription for amlodipine (group A) for (group B) receiving lisinopril given one month. After the patient underwent therapy for one month, the patient returned to the clinic for control, and blood pressure was measured again to be compared with the initial blood pressure. Blood pressure measurement during examination hours at the clinic. Specifically from 8 a.m to 2 a.m.

Table III. Initial and Final Blood Pressure Reduction Results of Patients using Amlodipine

		Mean	SD	Minimal Maximal	95% Cl Lower	95% Cl Upper
Systolic	Blood pressure before treatment	144.6	3.590	140-150	143.19	146.23
	Blood pressure after treatment	127.5	9.775	110-155	123.16	131.42
Diastolic	Blood pressure before treatment	93.04	6.104	70-100	90.46	95.62
	Blood pressure after treatment	81.13	7.595	70-90	77.92	84.33

The table above is known if, based on systolic pressure, administering amlodipine therapy with 10 mg of pressure blood before and after showed an average result of 144.60 mmHg and 127.25 mmHg with a standard deviation of 3,590 and 9,775. Blood pressure before and after therapy is at least 140 mmHg, and maximum blood pressure is 150 mmHg with a minimum of 110 mmHg and 155 mmHg. From the results of interval estimation, it can be concluded that the average blood pressure of amlodipine 10 mg patients was between 143.19−146.23 mmHg for systolic blood pressure before as well as the estimated interval of 123.16−131.42 mmHg for systolic blood pressure after. Blood pressure diastolic treatment with 10 mg of amlodipine showed an average result of 93.04 mmHg and 81.13 mmHg with a standard deviation of 6.104 and 7.595. Blood pressure before and after exercise: minimum therapy of 70 mmHg and a maximum blood pressure of 100 mmHg; a minimum of 70 mmHg and a maximum of 90 mmHg. From the interval estimation results, it can be concluded that the average blood pressure of amlodipine 10 mg patients is between 90.46−95.62 mmHg for pre-diastolic blood pressure and an estimated interval of 77.92−84.33 mmHg for pressure diastolic blood after that.

Table IV. Initial and Final Blood Pressure Reduction Results of Patients using Lisinopril

		Mean	SD	Minimal Maximal	95% Cl Lower	95% Cl Upper
Systolic	Blood pressure before treatment	144.82	4.135	140-152	143.23	146.55
	Blood pressure after treatment	126.25	11.44	110-155	121.42	130.30
Diastolic	Blood pressure before treatment	94.65	3.56	90-100	92.25	96.30
	Blood pressure after treatment	80.26	7.23	70-90	77.65	83.60

From the table above, it is known if it is based on systolic pressure. Giving pressure II therapy blood before and after therapy II showed an average result of 144.82 mmHg and 126.46 mmHg, with standard deviations of 4.135 and 11.44. Blood pressure before and after therapy should be at least 140 mmHg, with a maximum blood pressure of 150 mmHg, a minimum of 110 mmHg, and a maximum of 155 mmHg. From the results, interval estimation can be concluded if the average blood pressure of lisinopril patients is between 143.17−146.66 mmHg for systolic blood pressure before and an estimated interval of 121.62−130.30 mmHg for systolic blood pressure after that. Diastolic blood pressure with lisinopril therapy before and after therapy showed an average result of 94.65 mmHg and 80.92 mmHg, with standard deviations of 3.780 and 7.259. Blood pressure before and after therapy is at least 90 mmHg, with a maximum blood pressure of 100 mmHg, a minimum of 70 mmHg, and a maximum of 90 mmHg. From the results, interval estimation can be concluded if the average blood pressure of patients on therapy II is between 93.28 and 96.47 mmHg for the previous diastolic blood pressure and 77.85 and 83.98 mmHg for the diastolic blood pressure afterward.

Table V. Differences in Blood Pressure in the Amlodipine or Lisinopril Groups

		Mean	SD	Minimal Maximal	95% Cl Lower	95% Cl Upper
Amlodipine 10 mg	Systolic	17.21	9.79	-10-37	13.08	21.34
	Diastolic	11.71	8.37	025	8.17	15.24
Lisinopril 10 mg	Systolic	18.46	12.3	-5-5	13.26	23.65
	Diastolic	13.96	8.09	40-30	10.54	17.37

Based on the table, it is known that the difference in systolic blood pressure in the amlodipine group is 10 mg, which shows an average systolic result of 17.21 and an average diastolic result of 11.71 with a standard deviation for systolic and diastolic, namely 9.79 and 8.37. The difference in systolic blood pressure diastolic group lisinopril 10 mg shows an average systolic result of 18.46 and an average diastolic result of 13.96 with a standard deviation for systolic and diastolic, namely 12.3 and 8.089. Blood pressure can be controlled by selectively selective antihypertensive medications based on their mechanisms of action. The Joint National Committee (JNC VIII) classifies blood pressure into four levels, namely standard prehypertension, hypertension stage 1, and stage 2 hypertension (Untari et al., 2021). From these data, it can be explained that giving amlodipine or lisinopril as an antihypertensive may cause a decrease in blood pressure.

Table VI. Results of Normality Test of Systolic and Diastolic Blood Pressure with One Sample Kolmogorov-Smirnov

	N	SD	Test Statistic	Sig
Systolic blood pressure of hypertensive patients	30	9.344	0.129	.365
Diastolic blood pressure of hypertensive patients		3.489	0.135	.289

Table VI describes the normality test using one-sample Kolmogorov-Smirnov. Based on the normality test results above, the systolic and diastolic blood pressure of hypertensive patients showed that the significance value for systolic blood pressure data was 0.365 (p>0.05) and the blood pressure diastolic of 0.289 (p>0.05), which indicates that the systolic and diastolic blood pressure are normally distributed. Usually distributed data is followed by a statistical test, namely, the T-test is not in pairs (Independent Sample T-Test).

Table VII. Independent T-Test Test Results (Systolic and Diastolic Blood Pressure)

Before therapy	Drug	N	Mean	P value
Systolic	Amlodipine	15	140.00	0.720
	Lisinopril	15	140.54	
Diastolic	Amlodipine	15	85.92	0.82
	Lisinopril	15	86.50	
After therapy	**Drug**	**N**	**Mean**	**P value**
Systolic	Amlodipine	15	127.29	0.780
	Lisinopril	15	126.46	
Diastolic	Amlodipine	15	81.13	0.931
	Lisinopril	15	80.90	

Table VII describes the results of the independent t-test. Based on the test results obtained, the mean (average) after the therapy of the two drug groups was 127.29 for amlodipine and 126.04 for lisinopril, with a systolic significance of 0.780 (p>0.05). The mean results (average) of the two groups on diastolic pressure were 81.13 for amlodipine and 80.92 for lisinopril, with a significance value of 0.931 (p >0.05). There was a change in the mean systolic and diastolic values after administering amlodipine therapy and lisinopril therapy. This follows research that explains that a combination of CCB (Saban et al., 2021) and an ACE inhibitor can effectively control blood pressure. An effective mechanism of action is different. Calcium Channel Blocker (CCB), through peripheral vasodilation, can lower blood pressure simultaneously by increasing renin and angiotensin II production; in

this case, the CCB can also activate the sympathetic nervous system (Hastuti, 2022). This is what affects the effectiveness of reducing blood pressure. Based on statistical test results using the Independent T-Test, it can be concluded that from the significance of systolic blood pressure and diastolic, there was no significant difference in effectiveness between the amlodipine and -lisinopril groups (V.A.R. Barao et al., 2022).

CONCLUSION

There is no significant difference between the effectiveness of amlodipine or lisinopril in the systolic and diastolic categories. According to the guidelines, ACE inhibitor or CCB therapy can achieve targets in lowering blood pressure and has the advantage of increasing achievement in blood pressure and decreasing side effects. The results of this study can be used as a preliminary study. Other parameters need to be studied to see the long-term benefits of antihypertensives, namely parameters for death, cardiovascular events, stroke, or left ventricular ejection fraction.

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