Original Article

Cost Variation Analysis of Oral Antihypertensive Drugs Currently Available in Indian Pharmaceutical Market: A Pharmacoeconomic Study

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Abstract

Background: The hypertension is one of the most common chronic diseases, therefore treatment for the same should be affordable. Antihypertensive drugs of the same strength are available in the market at different costs. This study was conducted to raise awareness among health care workers and patients about the cost difference between different brands of the same antihypertensive drug, so that, whenever possible, a cheaper effective brand can be prescribed to ensure better patient adherence.

Methods: Maximum retail price (MRP) of various antihypertensive drugs of same strength, manufactured by different pharmaceutical companies was obtained from various offline and online sources. The minimum and maximum cost of 10 tablets/capsules noted. The cost ratio and percentage cost variation was calculated for single drug and fixed dose combinations. The ceiling price (as per DPCO) of essential antihypertensives (as per national list of essential medicines) was compared with their maximum cost.

Results: The formulations of single antihypertensive drugs and fixed dose combinations of two drugs were included in the study. Among the single antihypertensives analyzed the highest cost variation was of metoprolol (50 mg) as high as 12144.89%. The cost ratio was seen to be highest for Metoprolol 50mg ER(80.321) followed by Metoprolol 25mg (78.431), Telmisartan 40mg(66.98)Among fixed dose combination of two drugs analyzed highest cost variation was found that of Amlodipine 5mg + Atenolol 50mg combination(9566.66%).

Conclusions: There was a huge price variation among the antihypertensive drugs manufactured by various companies. Some measures must be taken by the government to bring the uniformity in the price that will help to reduce the economic burden on the patients.

Keywords: Antihypertensive, Pharmacoeconomic, Cost variation, Drug prices control order

Aim of the Study: The aim of the study was to analyze cost variations of different brands of antihypertensive drugs marketed in India.

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Introduction

In the modern world, hypertension is one of the main chronic illnesses that causes a significant death and morbidity rate[1, 2]. It is a significant issue for public health worldwide. It is the most common non-communicable disease in India, accounting for 10% of all deaths. Type 2 diabetes and hypertension are frequent co-occurring conditions. Patients with diabetes have twice as many cases of hypertension as people without the disease. Furthermore, compared to people with normotension, persons with hypertension frequently show signs of insulin resistance and are more likely to develop diabetes. Cardiovascular disease is the primary cause of morbidity and mortality in people with diabetes, and it is made worse by hypertension. Diabetes and hypertension are therefore tightly related due to shared risk factors, including dyslipidemia, obesity, atherosclerosis, vascular inflammation, endothelial dysfunction, and arterial remodeling. Additionally, there is a significant overlap between the cardiovascular problems associated with hypertension and diabetes, which are mostly linked to macrovascular and microvascular diseases.

According to recent studies, the prevalence of hypertension in India is 10% in rural areas and 25% in urban areas. It has a significant negative impact on India's health care systems and cardiovascular health condition. Treatment with antihypertensives effectively lowers morbidity and death associated with hypertension. Effective treatment has always been hampered by the expense of prescription drugs. The use of cost-efficient treatments is necessary for the effective management of hypertension due to its rising prevalence. India is still a developing nation, with the bulk of its people hailing from middle-class or lower-class backgrounds. As per the Planning Commission study, 1.21 billion Indians, or 29.5% of the population, live below the poverty line.[3] Given that hypertension is prevalent in developing nations, this poses a significant burden on people living in lower socioeconomic strata to buy medicines especially if they have to be taken for prolonged periods of time.

Cost analysis is a type of pharmacoeconomic evaluation that compares the expenses of two or more different medications without taking the patient's result into account.[4,5] Within the field of health economics, pharmacoeconomics examines the advantages and disadvantages of medication therapy[6], offering a foundation for the distribution, application, and formulation of health policy [7]. Cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis are the four methods utilized in economic evaluation. The type of results and the situation in which decisions must be made influence the assessment method selection.

In most developed nations, pharmaceutical expenses are the area of health care spending that is expanding at the quickest rate. Patient outcomes have been demonstrated to be adversely affected by higher drug expenses. Research indicates that physicians may not be well-informed on prescription drug prices [3].Patients are impacted by the high cost of medications, and even if their symptoms go better, if their regimen is expensive, they may not comply with it as well .[4] For any medication molecule, there are numerous branded formulations available in the Indian market and it is common for different brands of the same formulation to have varied prices.[5]For this reason, getting a precise and pertinent medicine cost is crucial for the patient's compliance.

The national pharmaceutical pricing authority (NPPA) regulates the prices of pharmaceutical drugs in India. The implementation of the NPPA, 2012 and the drugs prices control order (DPCO), 2013 was brought about by NPPA. It safeguards the interest of both the manufacturer and the consumers by ensuring the availability of essential medicines at affordable prices. Also, none of the combinations of antihypertensive drugs are included in DPCO list 2018. Many hypertensive patients need combination drug therapy during the course of the disease. Hence, it is desired that the government should bring all lifesaving drugs and combinations under price control.[6,7]

During last few decades, the demand for healthcare has increased rapidly resulting in high expenditure. To spend financial resources as efficiently as possible, cost containment has assumed significant importance.[3] Limited studies are available in Indian scenario, which compare the cost of drugs of different brands. Hence, this study was carried

out to compare the cost of different brands of drugs used for treatment. The present study was aimed at investigating the cost differences in various brands of same antihypertensive drug, so that whenever possible, a cheaper effective brand could be prescribed.

Materials and Methods

This analytical study was conducted in the Department of Pharmacology at Assam Medical College and Hospital over a period of 3 months. ''Current Index of Medical Specialities (CIMS)'' April-July, 2023 and "Indian Drug Review (IDR) 2023'' drug manuals was used to analyze the prices of antihypertensive drugs. The NPPA website was used to gather information about the generic drug pricing set by the NPPA (National Pharmaceutical Pricing Authority)[15] under the DPCO (Drug price control order).

The cost was cross-checked at pharmacy shops (retail drug stores). The fixed dose combinations (FDC) of antihypertensive drugs was analyzed for the cost differences. The FDC is the formulation including two or more active pharmaceutical ingredients combined in a single dosage form. FDCs included in the study were formulations containing two or three active ingredients combined in single dosage form.

The cost of a particular drug (single drug or drug combinations) in the same strength and number of brands being manufactured by different companies were compared in Indian rupees per 10 tablets/capsules. The drugs manufactured by only one company or by different companies, however, in different strengths were excluded. Parenteral formulations werealso excluded. The following formulas [5,8,9] were used to calculate the Cost ratio and Cost variance.

$$\text{Cost ratio} = \frac{\text{Highest cost}}{\text{Lowest cost}}$$

$$\text{Cost Variance} = \frac{\text{Price of the most expensive brand} - \text{Price of the least expensive brand}}{\text{Price of the least expensive brand}} \times 100$$

The maximum cost of essential antihypertensives (as per NLEM) were compared with their ceiling price (as per DPCO). Ceiling prices of 10 tablets/ capsules were calculated. The cost difference between maximum cost and ceiling price will be analyzed.

To compare the prices of brand drug with generic drug, http://janaushadhi.gov.in/ ProductList.aspx were used as source for generic drug price.[10]

Statistical Analysis: The data was compiled in the form tables and results were expressed in numbers and percentages after entering the data into MS Excel Worksheet.

Results

The prices of a total of 24 drugs (10 single and 14 combination preparation), available in 44 different formulations were analyzed. All formulation were manufactured by different pharmaceutical companies.

The results were formulated using this tables.

Table 1: Cost variation % of single drug preparations

Classification	Strength formulation(in mg)	No. of Tablets/ Capsules	Minimum Price	Maximum Price	Cost Ratio	Cost Difference	Cost Variation %
CCB	Amlodipine 2.5mg	10	4.5	20.9	4.64	16.4	364.4
	Amlodipine 5mg	10	6.8	66.66	9.80	59.86	880.29
	Amlodipine 10mg	10	12	116.66	9.72	104.66	872.16
	Cilnidipine 5mg	10	41.5	64.6	1.55	23.1	55.66
	Cilnidipine 10mg	10	10.68	108.3	10.14	97.62	914.04
	Cilnidipine 20mg	10	98	115.5	1.17	17.5	17.85
	Nifedipine 5mg(capsules)	10	3.18	11.72	3.68	8.54	268.55

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	Nifedipine 10mg(capsules)	10	5.12	15.75	3.07	10.63	207.61
	Nifedipine 20mg(capsules)	10	14.6	23.5	1.60	8.9	60.95
	Nifedipine 10mg	10	7.9	14.9	1.88	7	88.60
	Nifedipine 20mg	10	7.5	19.94	2.65	12.44	165.86
Beta blockers	Atenolol 25mg	10	3.92	21.5	5.48	17.58	448.46
	Atenolol 50mg	10	5.71	23.52	4.11	17.81	311.90
	Atenolol 100mg	10	14	38.7	2.76	24.7	176.42
	Metoprolol 25mg	10	15	400	26.66	385	2566.66
	Metoprolol 50mg	10	4.9	600	122.44	595.1	12144.89
	Metoprolol 100mg	10	42.9	126	2.93	83.1	193.70
ACE Inhibitors	Enalapril 2.5mg	10	5.13	20.26	3.94	15.13	294.93
	Enalapril 5mg	10	0.66	33.7	51.06	33.04	5006.06
	Enalapril 10mg	10	12	54.9	4.575	42.9	357.5
	Ramipril 2.5mg	10	26.5	70	2.64	43.5	164.15
	Ramipril 5mg	10	43	82.43	1.91	39.43	91.69
	Ramipril 2.5mg(capsules)	10	25.82	66.65	2.58	40.83	158.13
	Ramipril 5mg(capsules)	10	49.2	111.06	2.25	61.86	125.73
ARB	Losartan 25mg	10	10	34.90	3.49	24.9	249
	Losartan 50mg	10	19	475	25	456	2400
	Telmisartan 20mg	10	28	38.3	1.36	10.3	36.78
	Telmisartan 40mg	10	15	646	43.06	631	4206.66
	Telmisartan 80mg	10	25	165.16	6.60	140.16	560.64
Diuretics	Hydrochlorothiazide 12.5mg	10	7.6	10.3	1.35	2.7	35.52
	Hydrochlorothiazide 25mg	10	13.94	16.8	1.20	2.86	20.51

Among the single drug formulations in our study, the cost variation observed in the present study was as high as 12144.89% in case of Metoprolol 50mg, Enalapril 5mg(5006.06%), Telmisartan 40mg(4206.66%), Metoprolol 25mg (2566.66%). Also, significant variations were seen in case of Amlodipine 5mg(880.29%), Atenolol 25mg(448.46%) & Cilnidipine 10mg(914.04%).

Table 2: Cost difference in combinations of anti-hypertensive drugs

Sl.No	Drug Combinations	No. Of Tablets	Minimum cost	Maximum cost	Cost ratio	Cost Difference	Cost Variation %
1	Amlodipine 5mg+ Atenolol 50mg	10	3	290	96.66	287	9566.66
2	Amlodipine 5mg+ Telmisartan 40mg	10	8	197	24.62	189	2362.5

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3	Telmisartan 40mg+ Hydrochlorothiazide 12.5mg	10	6.9	147	21.30	140.1	2030.43
4	Telmisartan 80mg+ Hydrochlorothiazide 12.5mg	10	110	223	2.02	113	102.72
5	Telmisartan 40mg+ Chlorthalidone 12.5mg	10	60	133.56	2.22	73.56	122.6
6	Telmisartan 80mg+ Chlorthalidone 12.5mg	10	73.5	196.9	2.67	123.4	167.89
7	Ramipril 2.5mg+ Hydrocholorothiazide 12.5mg	10	43	134.65	3.13	91.65	213.13
8	Ramipril 5mg+ Hydrocholorothiazide 12.5mg	10	55	241.2	4.38	186.2	338.54
9	Losartan 50mg+ Hydrocholorothiazide 12.5mg	10	5.5	129.2	23.49	123.7	2249.09
10	Amlodipine 5mg+ Losartan 50mg	10	8	120	15	112	1400
11	Telmisartan 40mg+ Metoprolol 50mg	10	87	213	2.44	126	144.82
12	Telmisartan 40mg+ Metoprolol 25mg	10	80	174	2.17	94	117.5
13	Telmisartan 40mg+ Hydrocholorothiazide 12.5+ Amlodipine 5mg	10	60	180	3	120	200
14	Amlodipine 5mg + Enalapril 5mg	10	31	84.75	2.73	53.75	173.38

Among the fixed drug combinations, the maximum cost variations were seen in case of Amlodipine 5mg+Atenolol 50mg(9566.66%), Losartan 50mg +Hydrochlorthiazide 12.5mg (2249.09%), Telmisartan 40mg+ Hydrochlorothiazide 12.5mg (2030.42%), Amlodipine 5mg+Losartan 50mg(1400%).

Table 3: Maximum cost vs ceiling prices of drugs as per annual wholesale price index 2023

Sl.No	DRUGS	UNITS	CELING PRICE(A)	MAXIMUM PRICE(B)	MAXIMUM PRICE-CEILING PRICE
1	AMLODIPINE 2.5mg	10	17.9	20.9	3
2	AMLODIPINE 5mg	10	25	66.66	41.66
3	AMLODIPINE 10mg	10	54	116.66	62.66
4	ENALAPRIL 5mg	10	37	33.7	-3.3
5	ENALAPRIL 2.5mg	10	21.8	20.26	-1.54
6	HYDROCHLOROTHIAZIDE 12.5mg	10	10.4	10.3	-0.1

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7	HYDROCHLOROTHIAZIDE 25mg	10	17.4	16.8	-0.6
8	METOPROLOL 25mg	10	42	400	358
9	METOPROLOL 50mg	10	58.4	600	541.6
10.	METOPROLOL 100MG mg	10	113.3	126	12.7
11.	METOPROLOL 100mg MR	10	149.9	126	-23.9
12.	NIFEDIPINE 10mg	10	15.3	14.9	-0.4
13.	TELMISARTAN 20mg	10	38.7	38.3	-0.4
14.	TELMISARTAN 40mg	10	67.6	646	578.4
15.	TELMISARTAN 80mg	10	104	165.14	61.14
16.	AMLODIPINE 10mg	10	54	116.66	62.66
17.	ENALAPRIL 5mg	10	37	33.7	-3.3

As per the most recent changes to the DPCO 2013,the prices of a total 384 drugs and 476 formulations are under price control. However in the NLEM 2022, we find that only few antihypertensive drugs namely Amlodipine, Enalapril, Labetalol, Ramipril, Telmisartan, Sodium Nitroprusside, Metoprolol, Nifidipine and Hydrochlorothiazide) were included. Atenolol was removed from the list in 2022.

Table 4: Difference between Max. price & Jan Aushadhi (Generic) Price

Sl.No	Drugs	No. of Tablets	Generic Prices	Min. Price	Max. Price	Cost Ratio	Difference Between Max. Price Vs Generic Price
1	Amlodipine 5mg+ Atenolol 50mg	10	5	3	290	58	285
2	Amlodipine 5mg	10	2.9	6.8	66.66	22.98	63.76
3	Atenolol 50mg	10	3.58	5.71	23.52	6.56	19.94
4	Atenolol 25mg	10	2	3.92	21.5	10.75	19.5
6	Enalapril 5mg	10	3.5	0.66	33.7	9.62	30.2
8	Hydrochlorothiazide 12.5mg	10	4.21	7.6	10.3	2.44	6.09
10	Losartan 50mg + HCT 12.5 mg	10	9.05	5.5	129.2	14.27	120.15
11	Losartan 25mg	10	5.04	10	34.9	6.92	29.86
12	Losartan 50mg	10	9	19	475	52.77	466
13	Metoprolol 25mg	10	5.1	15	400	78.43	394.9
14	Metoprolol extended release 50mg tablets	10	7.47	4.9	600	80.32	592.53
15	Ramipril 2.5mg	10	6.75	26.5	70	10.37	63.25
16	Ramipril 5mg	10	9.68	43	82.43	8.51	72.75
17	Telmisartan 20mg	10	6.73	28	38.3	5.69	31.57
18	Telmisartan 40mg	10	9.6	15	643	66.97	633.4
19	Telmisartan 40mg+ HCT 12.5mg	10	15.3	6.9	147	9.60	131.7
20	Ramipril 5mg+ HCT 12.5 mg	10	12.9	55	241.2	18.69	228.3

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21	Telmisartan 40mg + Chlorthalidone 12.5mg	10	15.5	60	133.56	8.61	118.06
22	Nifedipine prolonged release 20mg tablets	10	7.09	7.5	19.95	2.81	12.86
23	Metoprolol 50mg + Amlodipine 5mg	10	13.85	29.75	92	6.64	78.15
25	Losartan 50mg + Hydrochlorothiazide 5mg	10	9.6	5.5	129.2	13.45	119.6
27	Telmisartan 40mg+ metoprolol 50mg	10	25.97	87	213	8.20	187.03
28	Telmisartan 80mg+ HCT 12.5mg	10	19.1	110	223	11.67	203.9
29	Telmisartan 40mg+Metoprolol 25mg	10	30	80	174	5.8	144
30	Telmisartan 40mg+ Amlodipine 5mg	10	11.77	8	197	16.73	185.23
31	Cilnidipine 20mg	10	37.7	98	115.5	3.06	77.8

Maximum cost difference between maximum price of branded formulations & generic medicines(Jan Aushadhi) was found in case of Telmisartan 40mg(633.4 rupees),Metoprolol Extended release 50mg(592.53 rupees), Losartan 50mg(466 rupees), Metoprolol 25mg(394.9 rupees),Amlodipine 5mg + Atenolol 50mg (285 rupees) & Ramipril 5mg + Hydrocholorothiazide 12.5mg(228.3 rupees).The cost ratio was seen to be highest for Metoprolol 50mg ER(80.321) followed by Metoprolol 25mg (78.431), Telmisartan 40mg(66.98) and the combination of Amlodipine 5mg+ Atenolol 50mg(58).

As per our study we have seen that, there are very few medicines under drug prices control order presently.FDCs of antihypertensive drugs are not included in NLEM which should be taken into consideration while revising the list.

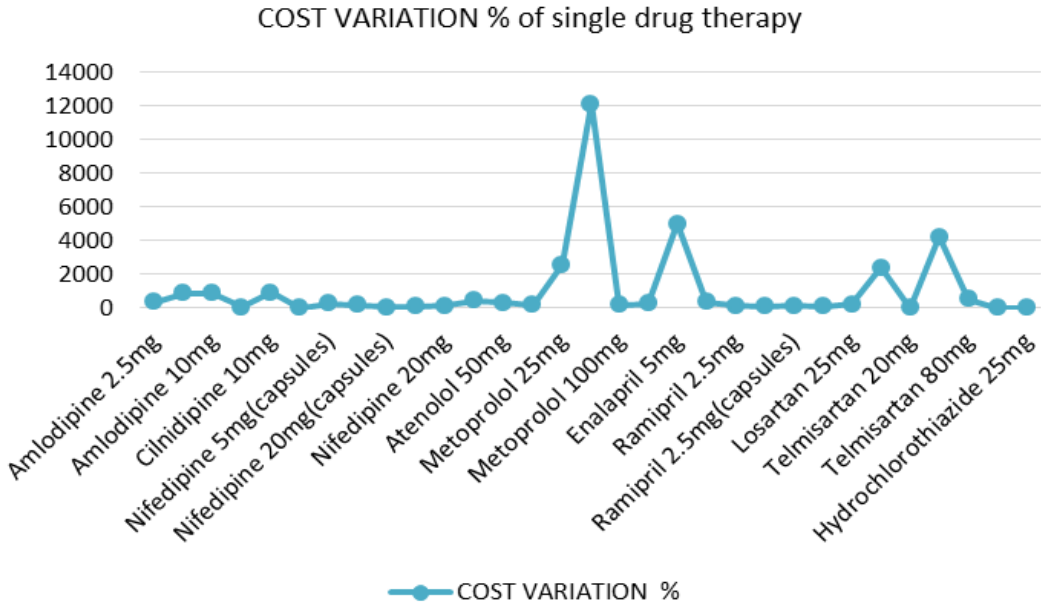

Figure 1: Cost Variation % of common antihypertensives used as single drug therapy

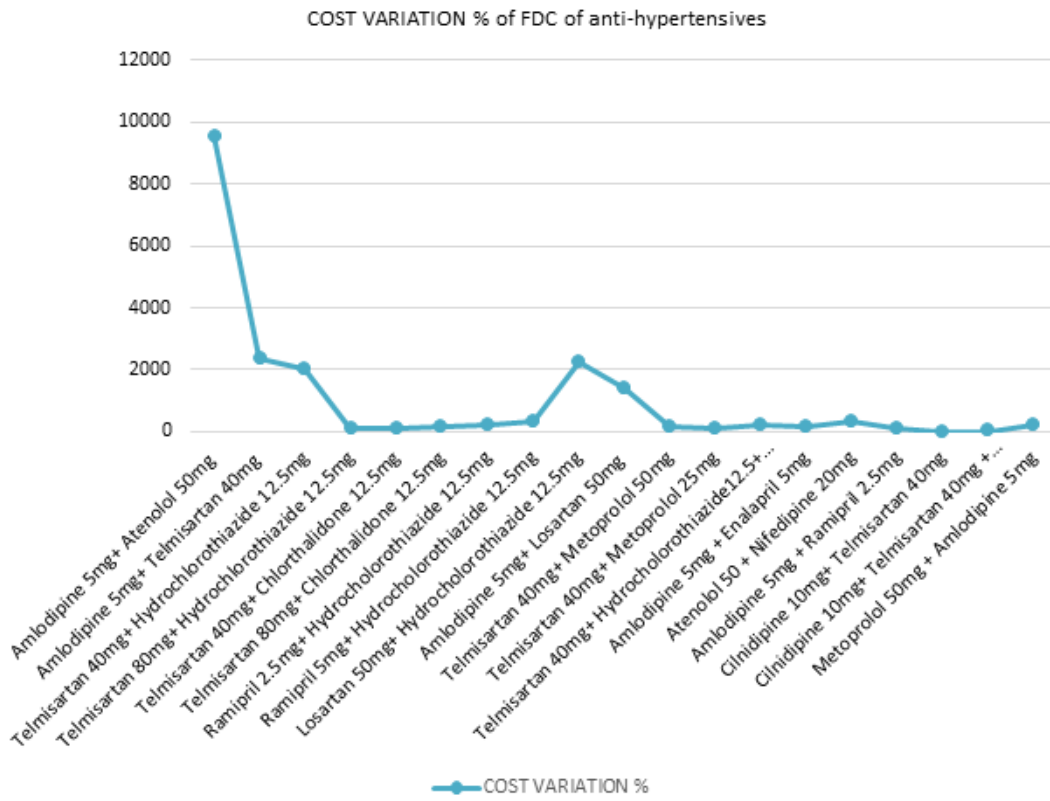

Figure 2: Cost Variation % of common antihypertensives used as combination drug therapy

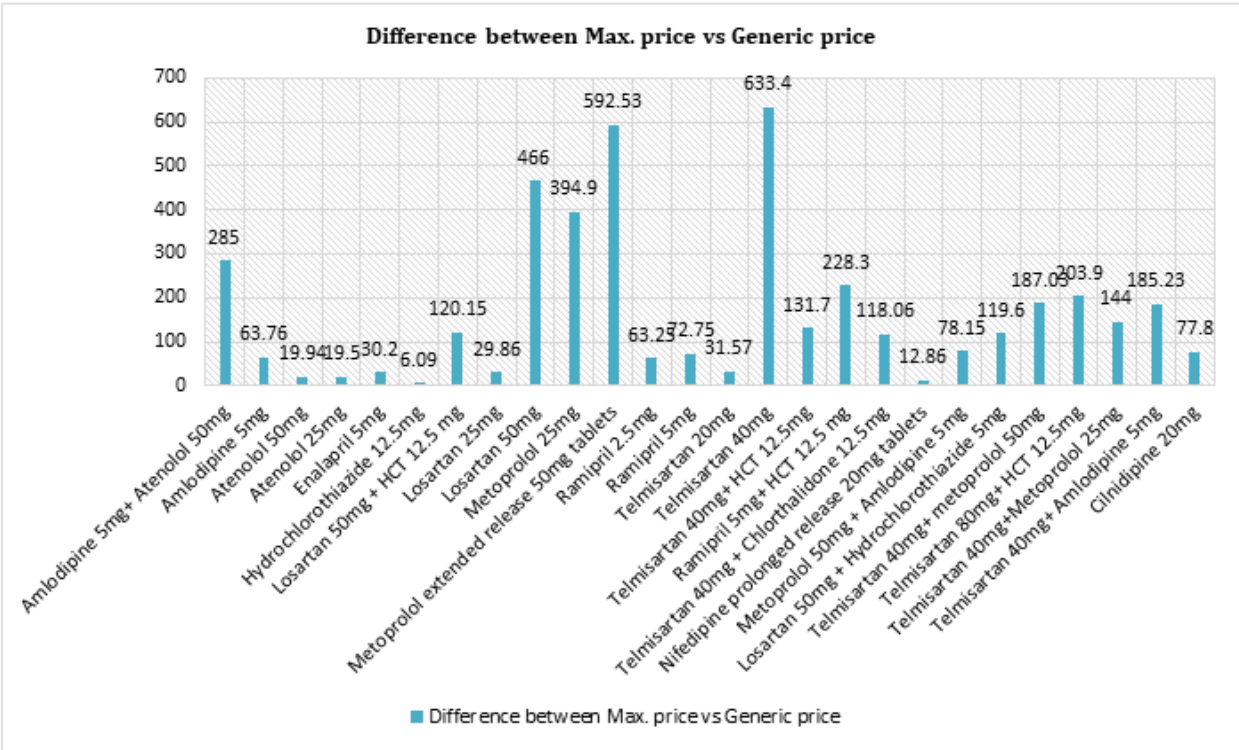

Figure 3: Cost difference between maximum price of branded formulations and the generic (Jan Aushadhi) prices of common anti-hypertensive drugs

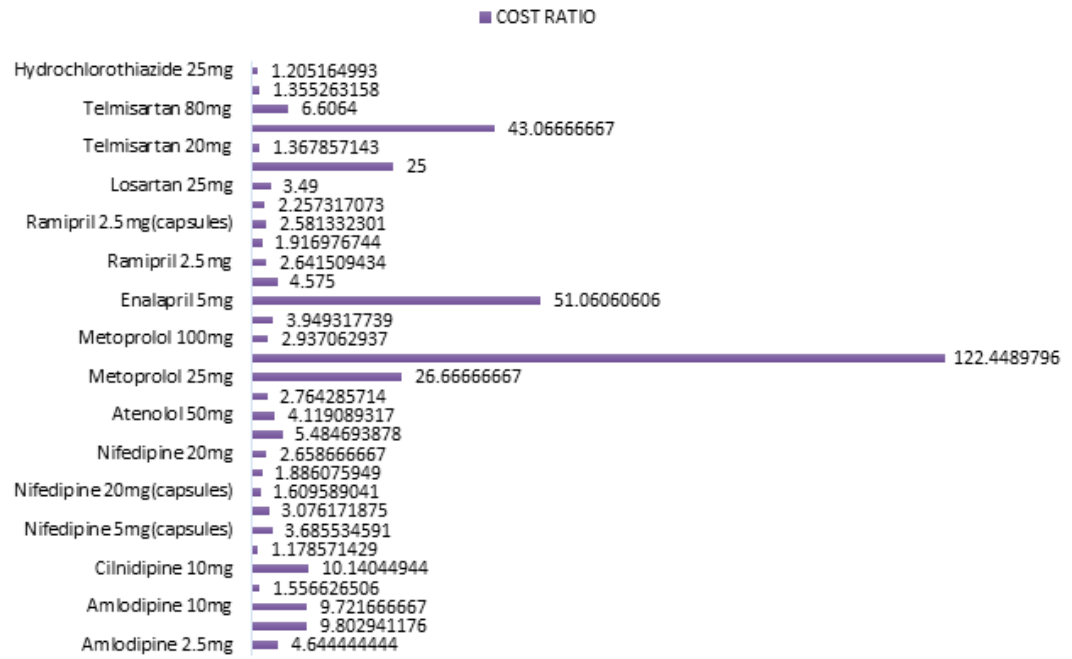

Figure 4: Cost ratio of single therapy anti-hypertensive agents

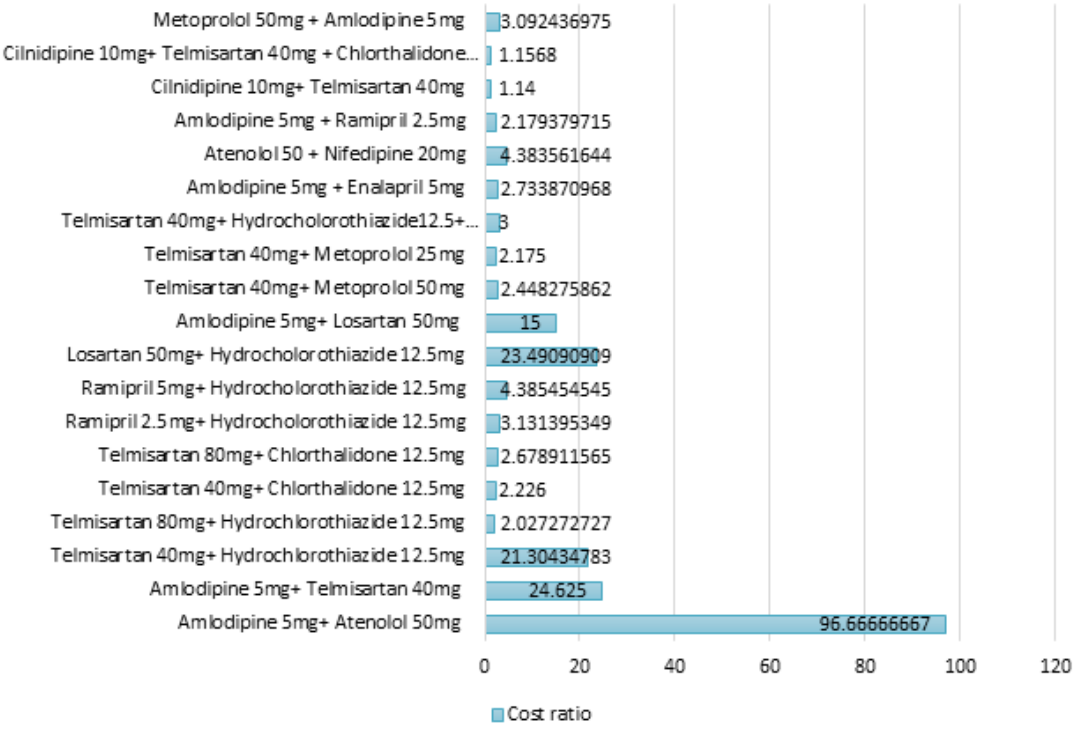

Figure 5: Ratio of combination of anti-hypertensive therapy

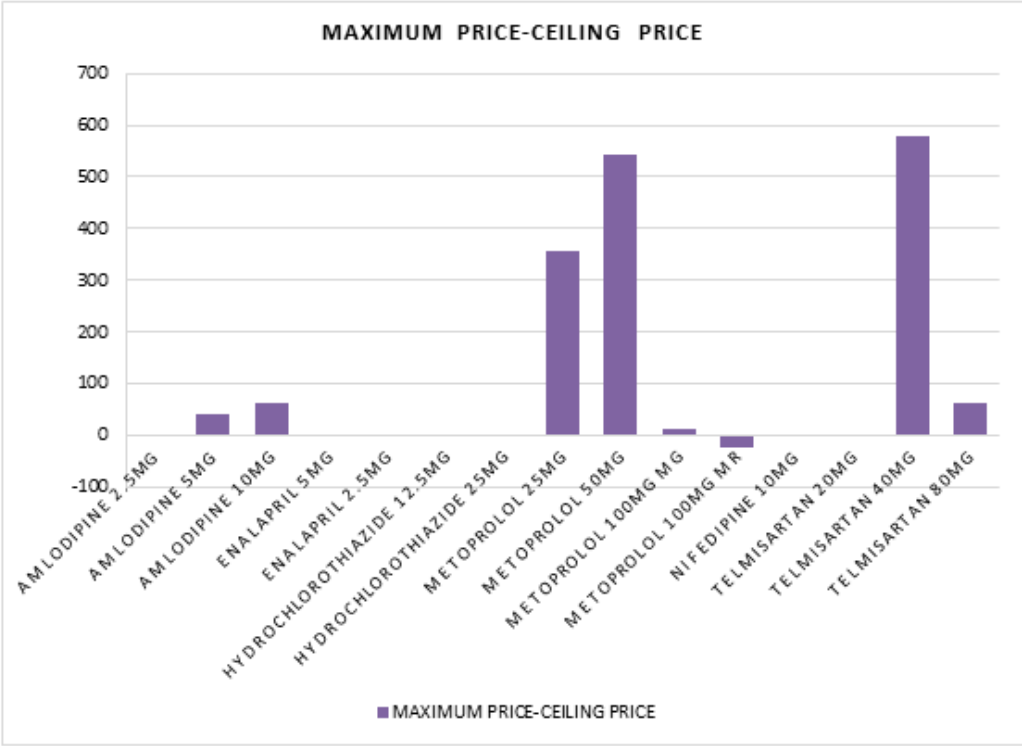

Figure 6: Difference between the maximum price of branded formulations and the ceiling price as per the DPCO regulation

Discussion

In our study findings showed a very high fluctuation in the minimum and maximum price of antihypertensive drugs. The cost ratio was also observed to be very high. The percentage variation in the cost was above 100% with most of the commonly used antihypertensive drugs and also with combination form of antihypertensive drugs.

Similar results were found as per study done by Ahmed et al stated high as 2337.50% for hydralazine,1315.25% (telmisartan +hydrochlorthiazide), 870.58% (amlodipine), 558.34% (amlodipine +atenolol), 537.68% (valsartan), 394.44% (metoprolol), 344.44% (enalapril), 316.22% (propranolol), 300% (lisinopril).The study done by Karve et al revealed that the prices of most of the antihypertensive brands have percentage price variation above 100% which has been found to be similar to our study.[11]

According to study done by Laxminarayana Kamath[12] and G. R. Satish in 2016,the percentage variation in the cost was above 100% with most of the commonly used antihypertensive drugs like Amlodipine (2.5 mg) 1040.58%, Atenolol (50 mg) 564.10%, Telmisartan (40 mg) 542.22% and Ramipril (10 mg) 478.39%. Among the combination therapy Atenolol + Hydrochlorothiazide (50 + 12.5 mg)504.82%, Amlodipine + Atenolol (5 + 50 mg) 437.86% and Lisinopril + Hydrochlorothiazide (5 + 12.5 mg) 403.33% variation.Similar study done by Karve AV et al. In 2014 and Limaye. D. et al. in 2017[13] also showed significant higher price variations in different brands of the same antihypertensive drug.

Conclusion

This study found that there is a significant pricing difference between antihypertensive medications manufactured by different pharmaceutical companies. As a result,it is essential that the Indian government must implement price controls on all life-saving and vital drugs.The government must take some steps to ensure price uniformity, which will help to alleviate the financial strain on patients. There is an urgent need to raise awareness of this massive pricing disparity among the general public, health care professionals, payers, government

agencies, policymakers, and pharmacists in order to implement appropriate interventions to lessen the cost burden on patients and the healthcare system. The evaluation and management of marketing medications should be geared toward maximizing the advantages of therapy while limiting unfavorable personal and economic consequences.

Ethical Clearance: Taken(Letter no.AMC/EC/11834)

Source of Funding: None

Conflict of Interest: None

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