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Research Article

COST ANALYSIS OF ORAL ANTIHYPERTENSIVE DRUGS: ASSESSING THE EFFECT OF DRUG PRICE CONTROL ORDER IN INDIA

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ABSTRACT

Objective: The study focuses on cost analysis of different available brands of oral antihypertensive drugs in India and assesses compliance with their ceiling prices fixed by drug price control order (DPCO).

Methods: This is an observational study conducted in the Department of Pharmacology, GSVM Medical College Kanpur, from May to June 2022. The ceiling price of oral antihypertensive drugs was obtained from the DPCO price list 2021 and dosage and prices of the different brands of antihypertensive drugs available in India were obtained from medguideindia.com and Current Index of Medical Specialities-CIMS (Jan–April 2022 edition, India). Thereafter, data analysis of oral antihypertensive drugs was done on Microsoft Excel Office 2019 version.

Results: Our study found a total 1575 brands of oral antihypertensive drugs available in market, 34% brands were having prices more than DPCO recommended ceiling price. Maximum price violation was noticed with capsule nifedipine 10 mg (83.33%) and tablet telmisartan 80 mg (60.98%). The maximum cost variation and cost ratio was seen with tablet propranolol 10 mg, that is, 3233.33% and 33.33, respectively, followed by tablet amlodipine 5 mg, that is, 2123.33% and 22.23.

Conclusion: Stringent regulation and monitoring of the DPCO price list should be done to ensure that all drugs and especially oral antihypertensive drugs are not sold above the ceiling price set by the order so that the compliance for the drugs is optimized and India could achieve its objective of reducing the prevalence of hypertension to <25% by 2025.

Keywords: Oral antihypertensives, Drug price control order, National pharmaceutical pricing authority, Cost ratio, Cost variation.

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INTRODUCTION

Hypertension has emerged as the leading risk factor for global morbidity and the loss of disability-adjusted life years. It is estimated that better hypertension control can prevent 400–500,000 premature deaths in India [1]. Once a public health challenge largely affecting high-income countries, it is now most prevalent in low- and middle-income countries. A national-level survey conducted by Ramakrishnan *et al.* found that the prevalence of hypertension was 30.7% among Indian adults which increased with age; with more men having hypertension in each age group, except in those with age 65 years, where an almost equal percentage of men and women had hypertension [2]. The World Health Organization states that almost 63% of total deaths in India are due to non-communicable diseases, of which 27% are attributed to cardiovascular disease which affects 45% of people in the 40–69 age group [3]. Hypertension is among the most important risk factors for cardiovascular diseases. Moreover, it remains poorly controlled due to low awareness about hypertension, lack of appropriate care through primary care, and poor follow-up [3]. The Government of India has launched the Indian Hypertension Control Initiative with an objective to reduce the prevalence of hypertension to 25% by 2025 [3]. Reducing the prevalence of hypertension depends on many factors, one of which is therapeutic compliance, influenced by drug prices.

The out-of-pocket expenditure in India is highest on antihypertensive drugs, that is, 64% [4]. There exists a great cost variation for these drugs and they are to be taken for life, even a small cost variation results in a huge financial burden on patients, especially on those who are of lower socioeconomic status in developing countries like India. To tackle this problem of extreme cost variation among drugs and ensure the availability and affordability of the drugs Government of India established National Pharmaceutical Pricing Authority (NPPA) in the year 1997. The drug price control order (DPCO) is one such effort issued by the Ministry of Chemicals and Fertilizers, which became effective in May 2013 and was implemented by NPPA with the aim of bringing down the cost of essential medicines [5,6]. They fix the price of essential drugs, which is termed the "ceiling price" of the drug, above which the drugs cannot be sold in the market by the manufacturers. The Drug Prices Control Order 2013 provision clearly specifies that "Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging" [6]. Despite the government's price control order, many pharmaceutical companies are still selling branded drugs above the recommended price and violating the price limit set by DPCO.

There exist very few studies, which compare the cost of drugs of different brands. Therefore, we decided to carry out a study that compares the cost of different brands of drugs used for the treatment of one of the most prevalent non-communicable diseases, that is, hypertension. The study focuses on cost analysis of different available brands of oral antihypertensive drugs in India and assesses compliance with their fixed ceiling prices given in the DPCO 2013 (updated in March 2021).

MATERIALS AND METHODS

The present record-based observational study was conducted in the Department of Pharmacology, GSVM Medical College Kanpur from May to June 2022. The ceiling price of oral antihypertensive drugs was

obtained from the DPCO price list 2021, which was downloaded from the government of India website http://nppaindia.nic.in [7]. For dosage and prices of the different brands of antihypertensive drugs available in India, medguideindia.com [8] and Current Index of Medical Specialities-CIMS (Jan–April 2022 edition, India) were chosen as sources of drug information. The unit prices for all oral antihypertensive formulations were taken, as the DPCO also fixes ceiling prices for one unit in rupees (INR).

Oral antihypertensive drugs which are enlisted in the DPCO list 2021 were included in the study. Injectable and combination formulations were excluded from the study. Drug formulations being manufactured by only a single brand were also excluded from the study.

The following parameters were analyzed:

1. Total number of brands available for every drug formulation.
2. Range of price difference for each formulation.
3. Percentage of brands having a price more than the DPCO ceiling price, which is calculated for each drug formulation as follows:

$$= \frac{\text{Number of brands having prices more than DPCO ceiling price}}{\text{Total number of brands}} \times 100$$

4. Cost ratio between the maximum and minimum cost of the same drug manufactured by different pharmaceutical companies was calculated as follows:

$$\text{Cost ratio} = \frac{\text{Maximum cost}}{\text{Minimum cost}}$$

5. Percentage variation between maximum and minimum prices [9]: Cost variation was calculated as follows:%

$$\%\ \text{Cost variation} = \frac{(\text{Maximum cost} - \text{Minimum cost})}{\text{Minimum cost}} \times 100$$

Microsoft Excel Office 2019 version was used for the statistical analysis.

RESULTS

In our study, we have considered brands and prices of oral antihypertensive drugs enlisted in the DPCO 2021 list. As per the list, a total of 13 oral antihypertensive drugs and their 37 different formulations were selected (Table 1).

A total of 1575 brands for all 37 formulations of oral antihypertensive drugs were retrieved. Among the total of 1575 brands, 535 (34%) brands were found to have prices more than DPCO recommended ceiling price while 1040 (66%) brands had prices less than the recommended limit (Fig. 1).

It was observed that the maximum number of brands that are available in the market are of tablet amlodipine 5 mg (185 brands) followed by tablet telmisartan 40 mg (142 brands) and tablet atenolol 50 mg (119). While it was observed that the minimum number of brands available in the market are for capsule Metoprolol 25 mg and tablet Methyldopa 500 mg with two brands for each formulation.

Maximum price violation was noticed with capsule nifedipine 10 mg with 10 out of 12 brands selling above DPCO price (83.33%) and

Table 1: Cost comparison of oral antihypertensive formulations with DPCO list 2021

Drug	Dosage form and Strength	DPCO price (1.4.21)	Range (Min–max) (Rs/unit)	No. of brands	Brands (%) with price >DPCO	Cost ratio	% Cost variation
Metoprolol	Tab 25 mg	3.12	1.08–5.57	31	45.16	5.16	415.74
	Cap 25 mg	4.24	1.07–5.76	2	50	5.38	438.32
	SR Tab 25 mg	4.04	1.9–10.61	52	44.23	5.58	458.42
	Tab 50 mg	4.73	0.7–7.89	34	41.18	11.27	1027.14
	SR Tab 50 mg	5.79	2.8–14.35	57	54.39	5.13	412.5
Amlodipine	Tab 2.5 mg	1.66	0.39–4.9	88	39.77	12.56	1156.41
	Tab 5 mg	2.61	0.3–8.6	185	28.11	22.23	2123.33
	Tab10 mg	5.08	0.79–11.67	70	22.86	14.77	1377.21
Verapamil	Tab 40 mg	0.74	0.5–1.1	6	33.33	2.2	120
	Tab 80 mg	1.40	0.91–1.9	5	20	2.09	108.79
Atenolol	Tab 50 mg	1.79	0.36–3.79	119	48.74	10.53	952.78
	Tab100 mg	3.49	0.9–5.48	54	27.78	6.09	508.89
Enalapril	Tab 2.5 mg	1.94	0.6–2.5	44	11.36	4.17	316.67
	Tab 5 mg	3.22	0.28–3.68	55	7.27	13.14	1214.29
Hydrochlorothiazide	Tab12.5 mg	0.99	0.6–1.4	9	44.44	2.33	133.33
	Tab 25 mg	1.69	0.9–1.85	10	50	2.06	105.56
Methyldopa	Tab 250 mg	2.45	1.53–7.17	8	50	4.69	368.63
	Tab 500 mg	4.70	4.64–10.95	2	50	2.36	135.99
Ramipril	Tab 2.5 mg	4.99	0.81–7.3	75	29.33	9.01	801.23
	Cap 2.5 mg	4.75	2.3–7.5	36	36.11	3.26	226.09
	Tab 5 mg	7.85	1.2–14.38	81	23.46	11.98	1098.33
	Cap 5 mg	7.41	3–11.22	39	43.59	3.74	274
Telmisartan	Tab 20 mg	3.66	1.5–6	74	45.95	4	300
	Tab 40 mg	6.61	1.8–11.92	142	38.73	6.62	562.22
	Tab 80 mg	10.07	2.55–18.48	41	60.98	7.25	624.71
Furosemide	Tab 40 mg	0.75	0.27–0.53	8	0	1.96	96.29
Nifedipine	Tab 10 mg	1.24	0.35–2.7	18	38.89	7.71	671.43
	Cap 10 mg	0.86	0.51–4.1	12	83.33	8.04	703.92
Propranolol	Tab 10 mg	1.17	0.3–10	24	20.83	33.33	3233.33
	Tab 40 mg	2.76	0.68–7.8	53	41.51	11.47	1047.06
	Cap 40 mg	3.81	0.68–5	11	36.36	7.35	635.29
	Tab 80 mg	5.01	2.31–5.62	10	20	2.43	143.29
	Cap 80 mg	5.79	3.1–6.06	7	28.57	1.95	95.48
Diltiazem	Tab 30 mg	2.40	1–3.25	40	12.50	3.25	225
	Tab 60 mg	4.90	0.38–5.13	35	5.71	13.5	1250
	SR Tab 90 mg	9.35	2.92–10.7	30	16.67	3.66	266.44
	Cap 90 mg	9.63	3.2–10.09	8	12.5	3.15	215.31

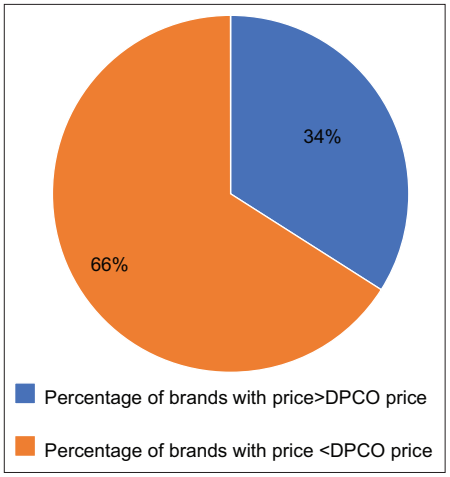

Fig. 1: Percentage of all scheduled antihypertensive formulations sold above and below DPCO 2021 list

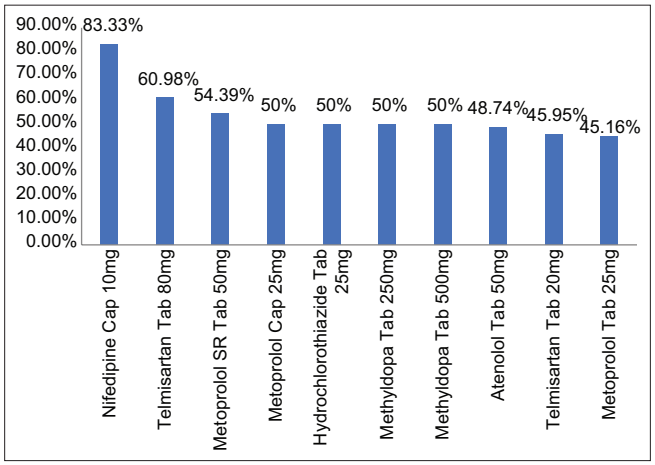

Fig. 2: Percentage of oral antihypertensive drugs sold above DPCO ceiling price list

tablet telmisartan 80 mg with 25 out 41 brands selling above DPCO recommended price (60.98%) (Fig. 2). Tablet furosemide 40 mg and tablet diltiazem 60 mg showed a minimum violation of price from the DPCO ceiling limit, that is, 0% and 5.71%, respectively.

Seven drug formulations were found to have more than (or equal to) 50% of brands having selling prices above the recommended DPCO price (capsule nifedipine 10 mg, tablet telmisartan 80 mg, tablet metoprolol SR 50 mg, capsule Metoprolol 25 mg, tablet Hydrochlorothiazide 25 mg, and tablet Methyldopa 250 mg and 500 mg) (Fig. 2).

The maximum cost variation and cost ratio was seen with tablet propranolol 10 mg, that is, 3233.33% and 33.33, respectively, followed by tablet amlodipine 5 mg, that is, 2123.33% and 22.23, respectively. The lowest cost variation and cost ratio was seen in capsule propranolol 80 mg, that is, 95.48% and 1.95, respectively, followed by tablet furosemide 40 mg, that is, 96.29% and 1.96, respectively (Figs. 3 and 4).

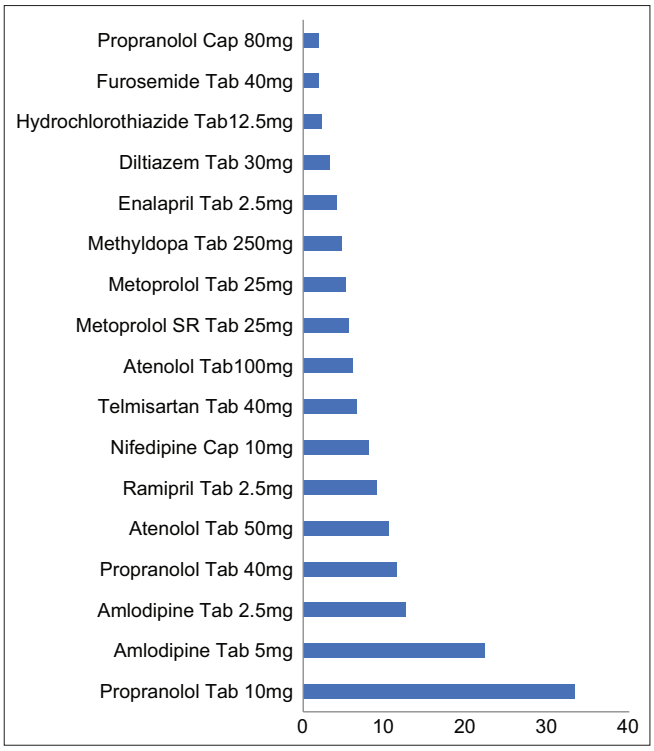

Fig. 3: Cost ratio of oral antihypertensive drugs

DISCUSSION

The Indian pharmaceutical market is predominantly a branded generic market where several companies sell a particular drug under numerous brand names apart from the innovator company. Hence, the number of pharmaceutical products available in the market is very high ranging from 60,000–70,000 products, leading to greater price variation among drugs marketed [10]. Subsequently, it can lead to poor compliance, especially in the case of drugs like antihypertensive which need lifelong therapy. Low patient compliance is a worldwide problem and can result in patients receiving inappropriate doses of medication [11]. In a large survey, a significant percentage of even high-income respondents indicated the cost of the drugs as an important factor [12]. Therefore, antihypertensive drugs were selected for cost analysis as hypertension is one of the major causes of morbidity and mortality and requires long-term treatment. A high-cost leads to poor compliance from the side of patients, as a higher cost may affect prescription patterns [13].

Our study showed a total of 1575 brands of oral antihypertensive drugs, which is quite a large number for 37 formulations. The maximum number of manufacturers was observed with tablet amlodipine 5 mg followed by tablet telmisartan 40 mg as these are the most commonly prescribed and popular antihypertensive drugs. In our study, 34% of brands were found to have priced more than the DPCO ceiling price which is comparable to another Indian study done by Kumar *et al.* for anti-hypertensive branded drugs in 2019 in which they observed that 39.12% of brands were having price more than that recommended by DPCO [14].

Maximum price violation was noticed with capsule nifedipine 10 mg with 83.33% brands selling above DPCO price and tablet telmisartan 80 mg with 60.98% brands selling above DPCO recommended, this is similar to the findings of the study done by Kumar *et al.* in which they observed that 80.55% brands were selling above DPCO recommended price in case of telmisartan 80 mg [14]. Tablet furosemide 40 mg and tablet diltiazem 60 mg showed a minimum violation of price from the DPCO ceiling limit, that is, 0% and 5.71%, respectively.

There was a very high fluctuation in the minimum and maximum price among several brands of oral antihypertensive formulations. The cost ratio was also observed to be very high. The maximum prices of most of the oral antihypertensive brands were more than double their minimum prices (percentage cost variation of more than 100%) which is not an acceptable situation for patients as these drugs are to be taken for a long time, Kamath and Satish in their study also found similar findings concerning price fluctuation and percentage price variation [15]. In our study, we observed that the maximum cost variation and cost ratio was seen with tablet propranolol 10 mg, that is,

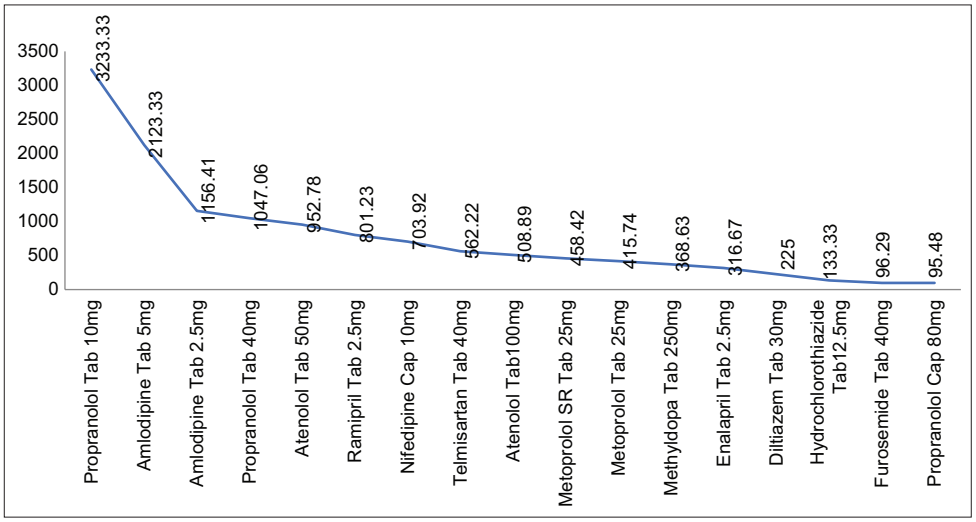

Fig. 4: Cost variation of oral antihypertensive drugs

3233.33% and 33.33, respectively, followed by tablet amlodipine 5 mg, that is, 2123.33% and 22.23, respectively, this finding is consistent with the findings of a study done by Karve *et al.* where they found maximum cost variation and cost ratio with tablet amlodipine 5 mg, that is, 1128.57% and 12.29, respectively [16]. The lowest cost variation and cost ratio was seen in capsule propranolol 80 mg, that is, 95.48% and 1.95, respectively, followed by tablet furosemide 40 mg, that is, 96.29% and 1.96, respectively, whereas in a similar study done by Deolakar *et al.* observed that minimum cost variation and cost ratio with Olmesartan medoxomil 40 mg was 28.57% and 1.28, respectively [17].

CONCLUSION

In our country, there exists a price regulatory body for pharmaceutical products, still, there is a huge price variation among the oral antihypertensive drugs manufactured by different companies. We concluded in our study that although there is a strong penalty for drug manufacturing companies selling above the ceiling price despite which a large number of brands are not following the regulations and are violating the price limit set by NPPA/DPCO. The DPCO has not attained its goal of bringing down the prices of medicines. Strong regulation and monitoring of the DPCO price must be implemented to ensure that the drugs are not sold above the ceiling price to optimize compliance. This will help in achieving the objective of reducing the prevalence of hypertension in India to <25% by 2025. Further studies are recommended in other therapeutic areas to increase awareness about the cost violations for more stringent regulatory checks by government authorities.

CONFLICT OF INTEREST

None declared.

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ETHICAL APPROVAL

Not required.

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