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A study of various existing interventions for the treatment of hypertension in the Indian market under the Jan Aushadhi Scheme: A price control aspect for consideration

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Authors:

Deeksha Joshi[1]
orcid.org/0000-0001-9729-5447
Saurabh Gupta[1]
orcid.org/0000-0002-4783-0293
Thakur Gurjeet Singh[1]
orcid.org/0000-0003-2979-1590
Abhimanyu Prashar[1]
Swati Gauniyal[2]
Sachin Kumar Singh[3]
orcid.org/0000-0003-3823-6572

1 - Chitkara College of Pharmacy, Chitkara University, Rajpura India
2 - KLE College of Pharmacy, Hubballi, Karnataka, India
3 - School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, India

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Corresponding author: Deeksha Joshi dikshajoshi024@gmail.com

Abstract

Aim: Analysis of the percentage price differences among the widely prescribed antihypertensive drugs available on the Indian retail market and under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) or the Jan Aushadhi scheme.

Materials and Methods: The prices of frequently prescribed various antihypertensive brands were collected and organized by using latest Monthly Index of Medical Specialties. The price of 1 dosage form in INR of each brand was extracted. Based on the price of various brands, average price of each drug was calculated and compared with the price of PMBJP drugs. Additionally, literature review was performed to place the results in perspective.
Results: The prices of prescribed antihypertensive medicines were analyzed and compared with PMBJP drugs. In monotherapy, Metoprolol 25 mg showed a maximum price difference of 89.08%; in combination therapy, Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg indicates maximum price difference of 90.76%. In addition, Telmisartan 40 mg demonstrate 88.59%, Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg demonstrate 90.76%, Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg and Amlodipine 5 mg indicates 90.38% price variation in one treatment course based on the grading of hypertension. Further, on literature review 11 relevant articles were found which were consistent with the results of this study.
Conclusion: The results of our study show huge differences between the prices of PMBJP drugs and branded drugs available in India. It suggests that moving towards PMBJP drugs may lessen the financial strain on the patients and their caregivers. The prescriber should make an informed decision and choose the cheaper antihypertensive drugs to lessen the financial burden on the patient leading to maximum patient adherence.

INTRODUCTION

Pharmaceuticals are intended to alter or explore physiological or pathological states for the benefit of the patient to improve patient's life expectancy and quality of life. They are often used to cure a condition, relieve symptoms, delay the onset of a disease and prevent complications and hence are worth the money.[1] However, recent price increment in the pharmaceutical sector raise a number of concerns. New effective medicines are not always reasonably priced for the patients and create pressure on individual's health care budget. These trends raise questions about the viability of present pricing models.[1]

To deal with determining, evaluating, and comparing the costs and outcomes of medical products and services, there is a branch of health economics, known as 'Pharmacoeconomics' It is an important part of our healthcare system which generally a patient is not aware of. The increasing costs of drug may have a direct impact on the patient adherence towards prescribed medicines. As per the World Health Organization (WHO) Guide to Good Prescribing, the prescribers should recommend a medicine keeping in mind the efficacy, safety and cost-effectiveness.[2]

In this review article, three terms have been used, i.e., an original product, generic product and a third category which is an initiative of Indian government, known as 'Jan Aushadhi product'. An original product or branded medication is the innovator product that was developed after extensive testing and trials by a pharmaceutical company to ensure its efficacy for which the product is indicated and its safety for use in human.[3] Branded drugs are thus the more well-known, costly and reliable type of medications.[4]

Generic drugs work the same way as their brand-name equivalents and have the same therapeutic benefits and hazards. Other pharmaceutical companies demonstrating that the generic medicine can be effectively substituted and provide the same clinical benefit as the brand-name medicine can apply for the approval of their generic drugs once the patent on the original drug has expired. Generic drugs usually cost less in comparison to their brand equivalents because they don't have to repeat pre-clinical and clinical studies to establish safety and efficacy.[3]

In the worldwide pharmaceuticals sector, the Indian pharmaceuticals industry is a major player. India is the world's third-largest producer by volume and the fourteenth-largest producer by value. The country is the world's largest provider of generic medications, accounting for 20% of worldwide supply by volume, and the world's leading vaccine manufacturer. Outside of the United States, India

boasts the biggest number of US-FDA approved pharma plants, with over 3,000 pharma businesses and a robust network of over 10,500 manufacturing facilities, as well as a highly skilled workforce.[4]

In India, there are 60,000 generic products available over 60 therapeutic categories. Generic medications, over-the-counter medicines, API/bulk drugs, vaccines, contract research and manufacturing, biosimilars, and biologics are all major segments. Although India has become one of the largest manufacturers of generic medicines, the medicines have not become cost-effective for patients. It was expected that the generic drugs will cost less in comparison to their brand equivalents but due to increase in the number of generic products, they are marketed at a price almost equal to the innovator brands.[3-4]

In India, the physicians usually prescribe those generic drugs which they are commonly aware of, or the one which were publicize/familiarize to them by the sales team of that particular company, irrespective of their prices. There are a huge options available from different companies for a medicinal product and the difference between their prices is significant. Patients are not very familiar of the concept of pharmacoeconomics, therefore, they go with the prescribed options only. Treatment of chronic conditions with the prescribed drugs may not be very economical for patients as they are often costlier.[5]

A population of around 60% (499-649 million) in India lacks daily accessibility of essential drugs due to increased expenditure on medicines. Approximately, 6090% of poor people's healthcare expenditure is for medicines which in turn leading to an increased financial burden on the population.[6, 7]

Although India has become one of the largest manufacturers of generic medicines, the medicines have not become cost-effective for patients.[7] This is due to several factors like an increase in the number of generic products which are marketed at a price almost equal to the innovator brands.[7, 8]

A study carried out in Delhi to determine the cost of prescription medicines and the treatment of community-acquired pneumonia concluded that the rising price of medicinal products in India is making the treatment less accessible for the poor sections of the society.[6]

Essential medicines are inaccessible to 1/3rd population of the world due to high costs. A study conducted in 2017 found that the medicines in Vietnam were 47 times costlier than the innovator brands and eleven times costlier than their generic counterparts.[9, 10] According to the World Health Organization, healthcare is a human right and an important factor for social welfare.[10, 11] Therefore, it is important to provide affordable healthcare to the entire population.[12, 13]

The Indian government has brought forth some innovative schemes to improve population health and turned them into policies. One such campaign, the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) also known as the Jan Aushadhi scheme, led by the Bureau of Pharma PSUs of India (BPPI) under Department of Pharmaceuticals, Government of India was launched in the year 2008.[14] The PMBJP aims to provide inexpensive quality medicine to people. Under this campaign, specific channels named as Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK) were established in various districts of Indian states and union territories. The first PMBJK was opened on 25 November 2008 at Amritsar in Punjab. The medicines provided in the PMBJK are comparable in quality, efficacy and safety to the costly generic medicines. The PMBJP aims to create awareness regarding generic medicines through education. One of its objectives is to create demand for cheap generic medicines by encouraging medical practitioners to prescribe only medicines by its INN. The mission of PMBJP is to make available all generic medicines currently used, targeting all therapeutic groups.[14] As of 30 June 2021, over 7500 PMBJKs have been opened and are operational across the country.[15]

The number of published studies comparing the cost of different available generic drugs with Jan Aushadhi drug in India is very limited. Therefore, we decided to analyze the costs of different generic options available from various companies to treat hypertension. As, hypertension is advancing towards becoming a potential epidemic. About 17-21% of the Indian population is reported to be suffering from hypertension and approximately 10% of the death are caused by hypertension.[16-17] An estimated burden of hypertension in India was 200 million. Along with the increase in prevalence of hypertension in India, the awareness, treatment and control are also on the rise. Hence, treatment cost should be given importance while prescribing antihypertensive medicines. The differences between the different available options of antihypertensive drugs are significant and prescribing the cheaper generic drugs will be more feasible for the patient. Less financial burden will lead to improved patient compliance thus leading to a better management of hypertension in the patient. We calculated the average cost- of different medicines available for the treatment and analyzed the cost-differences of various existing interventions for the treatment of hypertension in Indian market and under the PMBJP.

MATERIALS AND METHODS

Selection of Database

The "Monthly Index of Medical Specialties (MIMS)"[18] repository accessed in October 2020 was used as a source to obtain the prices of the drug available from different manufacturers. MIMS Drug Directory is a time-tested database of latest information. It provides detailed and reliable drug data that medical practitioners regularly refer to in their everyday practice.[18]

The price of medicines listed under PMBJP was collected in October 2020 from the official website of Jan Aushadhi[19] run by the government of India.

Selection of Medicines

The monotherapy and the combination therapy of anti-hypertensive drugs available under PMBJP were compared with the one mentioned in MIMS. The drugs with the same strength and formulation available under both the databases were extracted out and a common list is prepared. The list included 16 monotherapy (Amlodipine 5 mg, Carvedilol 3.125 mg, Carvedilol 6.25 mg, Chlorthalidone 12.5 mg, Cilnidipine 20 mg, Enalapril 5 mg, Lisinopril 5 mg, Losartan 25 mg, Metoprolol 25 mg, Metoprolol 50 mg, Nebivolol 10 mg, Olmesartan 40 mg, Prazosin 5 mg, Ramipril 5 mg, Telmisartan 40 mg and Valsartan 80 mg) and 7 combination therapy (Amlodipine 5 mg plus Atenolol 50 mg, Amlodipine 5 mg plus Lisinopril anhydrous 5 mg, Amlodipine 5 mg plus Losartan potassium 50 mg, Nebivolol hydrochloride 5 mg plus Hydrochlorothiazide 12.5 mg, Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg, Telmisartan 40 mg plus Amlodipine 5 mg and Telmisartan 40 mg plus Hydrochlorothiazide 12.5 mg).

Literature Screening

To place the results in perspective, we review recent studies on prices of Jan Aushadhi and other generic options available in India using different search engines; we screened Medline, PubMed and Scopus database with the keywords like 'Price Analysis AND Jan Aushadhi', Price Variation AND Jan Aushadhi, Cost Analysis AND Jan Aushadhi, Price Control AND Jan Aushadhi, Jan Aushadhi. All the studies focusing on the evaluation of Jan Aushadhi scheme were included in this study. Studies which were just comparing the prices of branded/innovator medicines and generic medicines (from different company) were excluded.

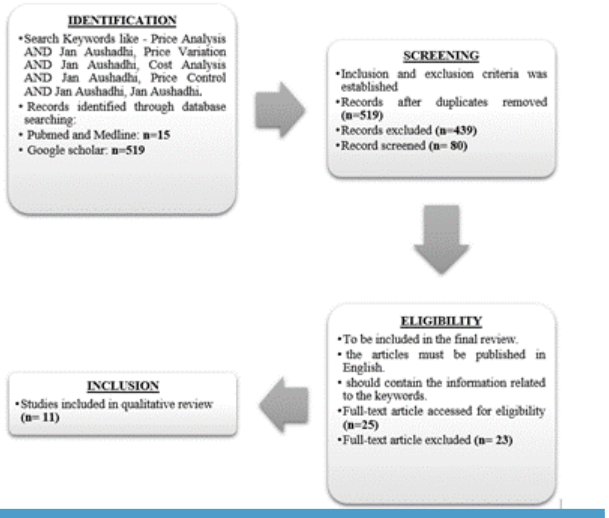

Figure 1. Process of Literature Screening

Price Calculation

The average price of available generic options from different manufacturer was calculated. Price difference between the average price of the drug manufactured by different pharmaceutical companies and price of same drug under PMBJP was calculated as follows:

Price Difference = Average Price - Jan Aushadhi Price

Percentage Price variation was calculated as follows:

% Price Variation = Price Difference/Average Price × 100

Calculation of Price Variation in One Treatment Course

The price difference of one treatment course between various generic options and Jan Aushadhi drugs was measured to offer an idea of cost savings as the treatment of hypertension is a lifelong intervention. One treatment course is typically prescribed for 2-4 weeks; therefore, the estimate was made for a maximum period i.e. 4 weeks (or 28 days). The guidelines[20] issued by the 'Ministry of Health & Family Welfare, Government of India' for managing primary hypertension in adults have been directed for the different regimens recommended to treat the various stages of hypertension.

RESULTS

Price Comparison and Percentage Price Variation

The easily available generic options of antihypertensive drugs from different manufacturer in India were evaluated. Table 1 shows the average price per unit of generic options available in India.

The prices of widely used antihypertensive medicines (16 monotherapy + 7 combination therapy) developed by different pharmaceutical firms have been analyzed. Table 2 indicates the percentage price difference of widely used 16 antihypertensive drugs available as a monotherapy and 7 antihypertensive drugs available as combination therapy.

Table 1. Average Unit Price Of Different Available Generic Options In India

Drug Class	Drug	Dosage form	No. of generic options available	Min Unit Price (INR)	Max Unit Price (INR)	Average Unit Price (INR)
Monotherapy						
Calcium channel blockers	Amlodipine 5 mg	Tablets	116	0.60	9.48	2.40
Beta blockers	Carvedilol 3.125 mg	Tablets	24	0.72	3.92	3.09
Beta blockers	Carvedilol 6.25 mg	Tablets	22	1.20	6.36	3.11
Diuretic	Chlorthalidone 12.5 mg	Tablets	6	1.33	6.43	3.96
Calcium channel blockers	Cilnidipine 20 mg	Tablets	15	4.95	13.00	6.52
ACE inhibitors	Enalapril 5 mg	Tablets	37	0.42	7.22	2.31
ACE inhibitors	Lisinopril 5 mg	Tablets	31	2.06	21.25	4.99
Angiotensin-receptor blockers	Losartan 25 mg	Tablets	68	0.42	5.25	2.46
Beta blockers	Metoprolol 25 mg	Tablets	52	1.08	11.60	4.62
Beta blockers	Metoprolol 50 mg	Tablets	57	0.70	15.96	4.60
Beta blockers	Nebivolol 10 mg	Tablets	1	17.37	17.37	17.37
Angiotensin-receptor blockers	Olmesartan 40 mg	Tablets	46	4.50	23.00	13.00
Alpha blockers	Prazosin 5 mg	Tablets	7	6.03	12.50	10.62
ACE inhibitors	Ramipril 5 mg	Tablets	51	0.81	32.45	8.17
Angiotensin-receptor blockers	Telmisartan 40 mg	Tablets	150	2.48	13.00	7.63
Angiotensin-receptor blockers	Valsartan 80 mg	Tablets	4	11.34	19.02	14.45
Combination Therapy						
Calcium channel blockers and Beta blockers	Amlodipine 5 mg plus Atenolol 50 mg	Tablets	170	1.50	12.88	3.65
Calcium channel blockers and ACE inhibitors	Amlodipine 5 mg plus Lisinopril anhydrous 5 mg	Tablets	26	1.20	17.26	6.59
Calcium channel blockers and Angiotensin-receptor blockers	Amlodipine 5 mg plus Losartan potassium 50 mg	Tablets	39	0.94	11.50	6.05
Beta blockers and Diuretic	Nebivolol hydrochloride 5 mg plus Hydrochlorothiazide 12.5 mg	Tablets	16	5.48	14.07	9.37
ACE inhibitors and Diuretic	Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg	Tablets	21	4.00	18.12	9.85
Calcium channel blockers and Beta blockers	Telmisartan 40 mg plus Amlodipine 5 mg	Tablets	57	3.80	14.50	7.67
Calcium channel blockers and ACE inhibitors	Telmisartan 40 mg plus Hydrochlorothiazide 12.5 mg	Tablets	129	0.84	39.78	7.63

Key: INR= Indian Rupee

Table 2. Percentage Unit Price Variation Of Commonly Used Antihypertensive Drugs

Drug Class	Drug	Dosage form	Average Unit Price (INR)	Jan Aushadhi Unit Price (INR)	Unit Price Difference (INR)	% Unit Price Variation
Monotherapy						
Calcium channel blockers	Amlodipine 5 mg	Tablets	2.40	0.27	2.13	88.84
Beta blockers	Carvedilol 3.125 mg	Tablets	3.09	0.55	2.54	82.34
Beta blockers	Carvedilol 6.25 mg	Tablets	3.11	0.58	2.52	81.24
Diuretic	Chlorthalidone 12.5 mg	Tablets	3.96	1.13	2.83	71.45
Calcium channel blockers	Cilnidipine 20 mg	Tablets	6.52	3.77	2.75	42.22
ACE inhibitors	Enalapril 5 mg	Tablets	2.31	0.29	2.02	87.61
ACE inhibitors	Lisinopril 5 mg	Tablets	4.99	0.72	4.27	85.65
Angiotensin-receptor blockers	Losartan 25 mg	Tablets	2.46	0.50	1.96	79.52
Beta blockers	Metoprolol 25 mg	Tablets	4.62	0.50	4.11	89.08
Beta blockers	Metoprolol 50 mg	Tablets	4.60	0.48	4.13	89.66
Beta blockers	Nebivolol 10 mg	Tablets	17.37	2.58	14.80	85.18
Angiotensin-receptor blockers	Olmesartan 40 mg	Tablets	13.00	2.67	10.33	79.45
Alpha blockers	Prazosin 5 mg	Tablets	10.62	1.76	8.86	83.43
ACE inhibitors	Ramipril 5 mg	Tablets	8.17	0.97	7.20	88.15
Angiotensin-receptor blockers	Telmisartan 40 mg	Tablets	7.63	0.87	6.76	88.59
Angiotensin-receptor blockers	Valsartan 80 mg	Tablets	14.45	3.00	11.46	79.28
Combination Therapy						
Calcium channel blockers and Beta blockers	Amlodipine 5 mg plus Atenolol 50 mg	Tablets	3.65	0.35	3.30	90.31
Calcium channel blockers and ACE inhibitors	Amlodipine 5 mg plus Lisinopril anhydrous 5 mg	Tablets	6.59	0.82	5.77	87.53
Calcium channel blockers and Angiotensin-receptor blockers	Amlodipine 5 mg plus Losartan potassium 50 mg	Tablets	6.05	0.96	5.09	84.14
Beta blockers and Diuretic	Nebivolol hydrochloride 5 mg plus Hydrochlorothiazide 12.5 mg	Tablets	9.37	4.00	5.37	57.30
ACE inhibitors and Diuretic	Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg	Tablets	9.85	0.91	8.94	90.76
Angiotensin-receptor blockers and Calcium channel blockers	Telmisartan 40 mg plus Amlodipine 5 mg	Tablets	7.67	1.77	5.91	76.98
Angiotensin-receptor blockers and Diuretics	Telmisartan 40 mg plus Hydrochlorothiazide 12.5 mg	Tablets	7.63	1.53	6.10	79.95

Key: INR= Indian Rupee

In monotherapy, Metoprolol 25 and 50 mg indicates maximum price difference of 89.08% and 89.66%, respectively and Cilnidipine 20 mg indicates minimum price difference of 42.22%. In combination therapy, Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg indicates maximum price difference of 90.76 % and Nebivolol hydrochloride 5 mg plus Hydrochlorothiazide 12.5 mg indicates least price difference of 57.30 %.

Overall Price Variation in One Treatment Course

The maximum price difference in one treatment course for Grade I and Grade II hypertension using single drug therapy of ACE or ARB or CCB or DU is shown by Telmisartan 40 mg and Amlodipine 5mg. Telmisartan 40 mg demonstrate 88.59 % variation in price and Amlodipine showed 88.84 % of price variation.

The guidelines issued by the 'Ministry of Health & Family Welfare, Government of India' recommended to use two drugs of different class when the target blood pressure has not been achieved by using single drug in Grade I and Grade II Hypertension and in the initial treatment of Grade III Hypertension. The combination drug Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg and Amlodipine 5 mg plus Lisinopril anhydrous 5 mg indicates maximum cost variation of 90.76% and 87.53% respectively.

Furthermore, it is advised that a third drug from a different class be added when the initial therapy with the two medications is not sufficient to reach the target blood pressure. Based on this recommendation, the price variation of three drugs from different classes was estimated. Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg and Amlodipine 5 mg indicates maximum price variation of 90.38% and Telmisartan 40 mg plus Hydrochlorothiazide 12.5 mg and Amlodipine 5 mg indicates price variation of 82.08%.

Figure 2 shows the graphical presentation of the price differences of available hypertensive medications between the different generic options vs the Jan Aushadhi medications.

Table 3. Percentage Price Difference Of One Treatment Course Based On Hypertension Grading

Category	Class of Drug	Drug	Average Price of various generic options available for one treatment course (28 days)	Jan Aushadhi Price for one treatment course (28 days)	% Price Difference
Grade I* and Grade II** Hypertension	ACE	Enalapril 5mg	64.66	8.01	87.61
	ARB	Telmisartan 40 mg	213.55	24.36	88.59
	CCB	Amlodipine 5 mg	67.26	7.50	88.84
	DU	Chlorthalidone 12.5mg	110.93	31.67	71.45
Failure of treatment by using single drug in Grade I* and Grade II** Hypertension/ Initial treatment of Grade III*** Hypertension	CCB plus ACE	Amlodipine 5 mg plus Lisinopril anhydrous 5 mg	184.53	23.02	87.53
	ACE plus DU	Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg	275.78	25.48	90.76
	ARB plus DU	Telmisartan 40 mg plus Hydrochlorothiazide 12.5 mg	213.71	42.84	76.98
	ARB plus CCB	Telmisartan 40 mg plus Amlodipine 5 mg	214.81	49.45	79.95
Failure of treatment by using two drugs in Grade III*** hypertension	CCB plus ACE and DU	Amlodipine 5 mg plus Lisinopril anhydrous 5 mg and Chlorthalidone 12.5 mg	295.46	54.68	81.49
	ACE plus DU and CCB	Ramipril 5 mg plus Hydrochlorothiazide 12.5 mg and Amlodipine 5 mg	343.05	32.98	90.38
	ARB plus CCB and DU	Telmisartan 40 mg plus Amlodipine 5 mg and Chlorthalidone 12.5 mg	325.74	81.12	75.10
	ARB plus DU and CCB	Telmisartan 40 mg plus Hydrochlorothiazide 12.5 mg and Amlodipine 5 mg	280.98	50.34	82.08

Keys: ACE = Angiotensin Converting Enzyme, ARB = Angiotensin Receptor Blocker, CCB = Calcium Channel Blocker, DU = Diuretics

*Grade I Hypertension: systolic 140-159 mm and/or diastolic 90-99 mm [19]

**Grade II Hypertension: systolic 160-179 mm and/or diastolic 100-109 mm [19]

***Grade III Hypertension: systolic 180 mm or above and/or diastolic 110 mm or above [19]

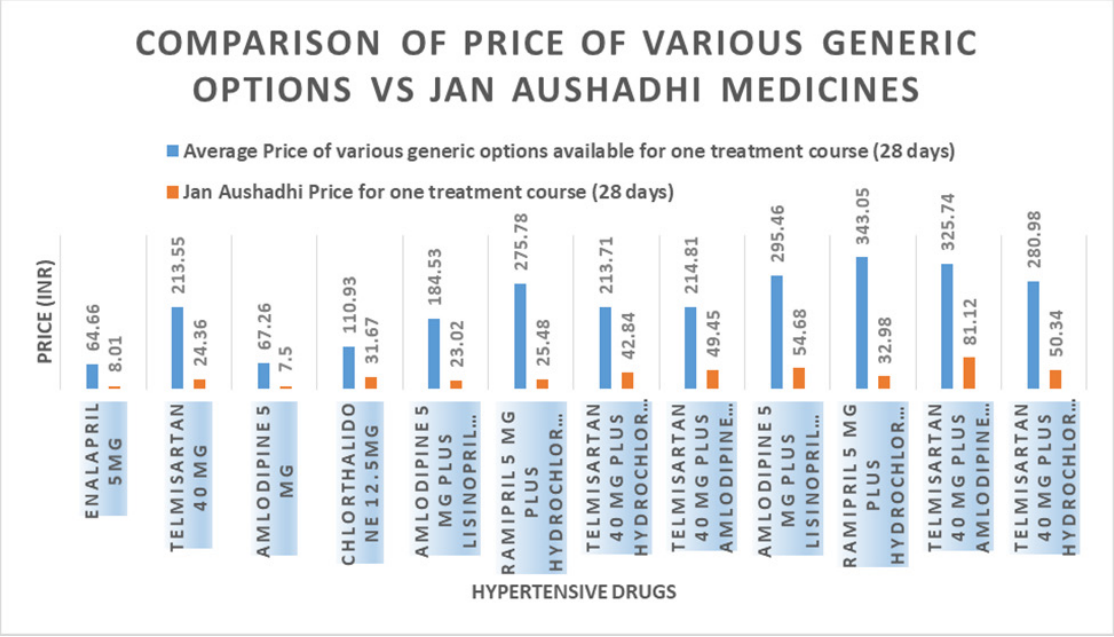

Figure 2. Comparison of Price of various generic options vs Jan Aushadhi Medicines for the treatment of Hypertension

Literature Review

A further literature review was done to place the above mentioned results in perspective. Based on the search criteria, there were not much comparative studies found evaluating the Jan Aushadhi scheme/ medicines. A total of 11 similar studies were identified, of which 10 studies[21-30] have compared prices of Jan Aushadhi medicines with available branded/generic medicines focusing on other therapeutic areas. The remaining 1 study[31] has performed an in vitro comparison of Jan Aushadhi medicine with other available generic options. These studies have been included in the discussion to build the strength of this study and the summary of these studies is provided in Table 4 as supplementary information.

DISCUSSION

The pharmaceutical industry of India exports around 50% of vaccines globally, 40% of generic medicines in the United States and 25% of all the medicines in the United Kingdom.[32] The Indian pharmaceutical zone is expected to grow 3 times in the next decade and is estimated at US$ 42 billion in 2021 and likely to reach US$ 65 billion by 2024. It is estimated to reach ~US$ 120-130 billion by 2030.

Throughout 2017, United States Food and Drug Administration (US FDA) also granted 304 abbreviated new drug application (ANDA) approvals to Indian manufacturers.[32]

From the data mentioned above, we can conclude that India is an immense supplier of medicines globally at low cost but there is a deprivation of quality and affordable medicines for Indian patients. There are around 100,000 formulations on the market and a lack of regulation to control the production of similar formulations under different names. Apart from the innovator, a single formulation is being sold by many other companies under different names which led to a huge price variation among different available options. The disproportional prices of the most frequently used medicines has a direct impact on the Indian economy.

Unlike developed countries, the people in developing countries often aren't covered by medical insurances and therefore bear the medical expenses. An 80% of the treatment costs are paid by patients and their families.[33-35] The poor population of the country faces the problem to decide whether to pay for thee costly medicines or to buy food and other basic necessities of life for themselves. Preferably, the cheaper available options should be prescribed by the doctors so that the low income population can comply with the treatment.[36] This can be improved by creating awareness in physicians about the price variation among different available options. Various studies have revealed that a guidebook containing the comparative drug prices annotated with the advice on prescription have reduced the financial burden of the patients for long term treatment like hypertension.[36] Ideally, a sensible prescribing includes choosing the cost-effective treatment.

Reasons for high drugs prices

A variety of considerations have been given to balance rising product costs through various studies conducted in the US. These rationales can be considered equally applicable in the Indian scenarios as well when comparing the prices of branded medicines vs generics, however, this explanation won't completely justify the huge price difference among various generic options.

The pharmaceutical industry has argued that rising product rates represent the expense of research and development paid by a manufacturer or to pay for potential investment expenses to create new medicines, or both.[37, 38] Such claims have been made to defend rising prices on the basis that the production of new drugs would be negatively impacted if the cost of the drugs are limited. A few economic analyses supported by the pharmaceutical companies suggest that developing a new product renders it marketable costs around $2.6 billion.[39]

The different positions of patients, physicians and payers has historically shielded physicians from learning about medication costs or weighing certain rates in their professional decision-making phase and it may exclude patients with decent prescription coverage considering the price of the medications they purchase.[40, 41]

Nevertheless, the entry of generic products onto the industry is often late. The 'life-cycle management' of a drug for pharmaceutical suppliers includes avoiding generic competition and maintaining elevated costs by increasing the brand exclusivity. It would be done by gaining extra patents on certain parts of a medication, including its formulation, salt moiety, coating[42] and route of administration.[43]

Prescription drug costs remain a reason of worry for patients, caregivers, and policymakers in the United States. In a study of adults in the United States, 77 percent of respondents of various political parties believed prescription medicine expenses were "unreasonable".[44] Prescription drugs cost $450 billion in 2016, contributing to 14% of overall health-care spending, and $610 billion cost in 2021. There are many reasons behind this, previous research has shown that medications with larger sales before patent expiry and exclusivity had a higher number of generic manufacturers joining the market.[45 46] There are fewer generic competitors for medications that serve tiny patient populations, such as many orphan pharmaceuticals. Another factor contributing to recent price increases is the increasing number of generic manufacturers entering and quitting the market. The number of manufacturers leaving the market has begun to outnumber those entering it in the previous five years.[47, 48]

Possible Solutions

The regulatory authority, prescribers, pharmacists and the patients need to take a robust step to tackle this price disparity. The pharmaceutical companies and traders also need to contribute in providing economical medicines to the consumers.[49]

To control the surge in drug prices, the government issues an order named the Drug price control order (DPCO). The medicines mentioned in the DPCO cannot be priced higher than the designated ceiling price thus ensuring the availability of good quality essential medicines at affordable price. The DPCO 2021 list contains a total of 866 medicines including antihypertensive medicines.[50, 51] Another solution devised by the government to provide affordable drugs to the poor people was the PMBJP. Of the antihypertensive medicines included under DPCO list, some medicines used as monotherapy (amlodipine 5mg, enalapril 5mg, metoprolol 25 mg, metoprolol 50 mg, ramipril 5 mg and telmisartan 40 mg) and combination therapies are also available under the PMBJP.

In our study, we found price variations between the prices of PMBJP drugs with the ceiling price stated by DPCO as well for the above-mentioned drugs. A lot patients in whom hypertension cannot be controlled by monotherapy need combination therapy. Therefore, the government needs to take an initiative to include combination antihypertensive medicines in the DPCO list in order to control the unreasonable price variation.

This is India's first study which focuses on cost savings per treatment course for hypertension. The study presented the percentage price variation between the various generic options and PMBJP anti-hypertensive drugs. The results of our study revealed huge price disparities between the PMBJP drugs and the available generic options from different pharmaceutical companies for the treatment of hypertension which indicates, substitution of various generic options with PMBJP drugs will be cost-effective.

The percentage price variation of a treatment course is calculated to give a rough idea of cost savings of different regimens based on the grading of hypertension. Comparing the differences in the price of a treatment course, it can be inferred that substituting the various generic options with PMBJP drugs would improve patient adherence to the long term therapy of anti-hypertensive drugs. It is a well-known fact that hypertension is a chronic, asymptomatic and persistent condition that needs long-term treatment for its maintenance and control. Therefore, management of hypertension should be cost-effective which could significantly reduce the risk of associated diseases such as heart failure, coronary artery disease, stroke and renal failure etc.

Very few studies have been published conducting a comparative price evaluation of PMBJP drugs. Two studies[21,22] published in 2015, comparing market prices of generic antidiabetic drugs with PMBJP drugs, found significant price differences, i.e., PMBJP drugs were much better value for money than the various generic options. In order to compare the expense of various generic anti-cancer agents used for the treatment of breast cancer, Kashyap et al[23] conducted a cost minimization study and stated that the chemotherapeutic drugs available at Jan Aushadhi will reduce the therapy cost as compared to the available generic medications. In a cost analysis of psychotropic drugs, the author concluded, considering the quality of Jan Aushadhi medicines in comparison with other available generics on the market, psychiatrists may use these, especially in the treatment of patients with poor economic resources to encourage adherence to psychotropic drugs.[24] Another study focused on the challenges which are limiting insulin availability and affordability and concluded that government should optimize insulin supply chains at different levels and encourage patients to opt subsidized schemes such as PMBJP for lower prices.[25] Ahmad et al[26], evaluated the cost of antimalarial medicines and observed that the prices of Jan Aushadhi are considerably lower when compared with the highest price generics on the market. A similar study has shown a very significant price disparity between various generics and Jan Aushadhi drugs and emphasize that there should be measures to support Jan Aushadhi drugs and to eliminate myths regarding low efficacy of these drugs.[27]

Further, few laboratory studies have shown that the quality of PMBJP drugs is comparable with that of other generics. The quality of four PMBJP drugs (alprazolam, cetirizine, ciprofloxacin and fluoxetine) were compared in a study by Singhal et al[28], with the corresponding available generics. In the study, the PMBJP drugs passed all applicable pharmacopoeial tests, showing that their quality is as good as the other available generics. In a similar study, Singh et al[29] found, the quality of metformin available under PMBJP is equivalent to its generic counterpart. A study compared the quality of Jan Aushadhi's glimepiride with its generic product as per Indian Pharmacopoeial norms and found that both generic and Jan Aushadhi's glimepiride tablets met the IP 2007 standards.[30] According to a study by Tank et al[31], ceftazidime in PMBJP shows no difference in in-vitro antimicrobial activity when compared to the generic drug indicating an antimicrobial equivalent activity.

Reasons for Slow Progress of PMBJP Campaign

There are some important problems that cannot be overlooked and that need to be resolved in order to strengthen patient treatment and make the PMBJP more effective. If all of these problems are resolved, we expect that PMBJP may take over the Indian drug market.[52]

The inference, hereby, is that the only characteristic that prohibits the masses from allowing use of generic drug facilities is the psychological mistakes and the taboos they have in their heads. Eradicating those misconceptions is a huge obstacle to overcome and therefore a very challenging area to work in. The principal individuals who would have played a key role in this assignment would be Physicians, Pharmacists and General public themselves, along with the direction and oversight of the Government of India.[53] The concerns that need to be resolved are as follows:

Patient-related issues: Less PMBJKs compared to neighborhood clinics, less medications available, low awareness, no health services given, and many PMBJKs are not connected to government hospitals.[52]

Issues related to owners of PMBJKs: When compared to traditional neighborhood pharmacies less profit, less/no benefit share, lower medication costs, less patient burden, slower drug distribution, less medications and available strengths, less prescriptions sent to PMBJKs by clinicians (both government and privately established), weak knowledge of JAS or generic medicines, less margin.[52]

Physician-related issues: Fewer doctors (even in government hospitals) prescribe the use of JA or prescription products. The reasons may be low substance literacy, lack of educational programmes on generic drugs, etc. Resident physicians are well aware of generic drugs and their regulations, however, concerns over the safety and effectiveness and affordability of generic drugs are main reasons for choosing brand medicines.[54]

Issues related to pharmacy students: Fewer exposure to PMBJP during pharmacy/student life.[54]

Issues related to Government: Government efforts in this direction need to be appreciated, but there is room for further investment in both the manufacture and awareness-raising of generic medicines. The steady rise in revenue and the number of new stores being opened speaks for itself of the good will of the government but sales per outlet are dismally poor. It can be concluded from the same that the revenues from these stores are not sufficiently enticing to businesses for long-term growth and profitability. More generic drugs are required to satisfy demand. There is a need to establish a surveillance system to know whether or not doctors are recommending generic drugs to their patients, as this should be made mandatory by the government. Pharmaceutical companies need to be questioned about their promotional expenditure in the name of sponsorship of medical conferences. A lot of work needs to be undertaken on the ground by the government to ensure the effectiveness of the project. No matter how successful an idea is if the plan is not properly implemented,

there will be no outcomes. That seems to be the case for the Jan Aushadhi software at the moment.[54]

Improvements needed to reduce out of pocket expenditure

Although the government has started PMBJP as a noble cause, it is yet to be a success. Many KAP studies[52-54] were performed to check the knowledge and awareness of physicians and consumers and in one study it was found that the variables that discriminated against non-consumers were 'effectiveness,' 'doctor's advice,' 'lower price,' 'quality,' 'less costly than other marketed drugs,' 'doctor's prescription,' 'convenience,' 'doctor informs,' 'home delivery' and 'market reputation.' Results found that 'prescription doctor,' 'lower price,' 'availability of Jan Aushadhi outlet,' 'cost of generic medication' and 'recommendation from others' had a substantial effect on the adoption of Jan Aushadhi. The study therefore advises that doctors prescribe generic drugs, increase the number of Jan Aushadhi outlets and raise awareness of the consistency and effectiveness of Jan Aushadhi.[54]

Knowledge of resident physicians on the definition and regulations of generics drugs are sufficient. While they recommend a good number of generics drugs, questions about quality, protection and affordability are prevalent in this community. Therefore, educational and regulatory measures to resolve these issues are required.[54] As it has already been seen that the different states in our country are doing extremely well in the field of generics, as in the case of the FPMS Scheme (2012) in West Bengal; the Karunya Pharmacy Project, Kerala; the Public Health Centers (PHCs), Pondicherry, these kinds of proposals should be strengthened and encouraged to be adopted in all states. It was also found that the audio and video media themselves have the ability to spread the idea of generic drugs and bring about a psychological change among the population. Therefore this mode of communication is likely to serve as a propulsion for this field of study.[54]

By undertaking different ways of disseminating information and encouraging lay people to grasp this term, support from the media as a whole may be used. The different media like: publishing (pamphlets, brochures, posters, magazines, Press, etc.), audio support (log tape cassettes, speeches, digital CDs), and videos can be used.[52]

LIMITATION OF THIS STUDY

The physician's awareness and understanding behind not prescribing the generic drugs using the active ingredients rather than prescribing specific brand of the drug was beyond the scope of this study. Also, there is a scope to find out the reasons behind the lack of government education policies/communication strategy that apparently results in the poor people failing to take advantages of these lower prices.

Moreover, this cost analysis was limited to the indication 'hypertension' as it is the most common and persistent condition that requires continuous treatment and monitoring in order to control it. Although there are several reports of sub-standard drugs being marketed in India but no specific substandard drug reports on PMBJP drugs were published and therefore it can be suggested that generics and PMBJP drugs have similar quality, efficacy and safety. Also, there is a scope of further studies in other therapeutic areas to evaluate the cost savings in regimens using PMBJP medicines.

CONCLUSION

The results of our study show huge differences between the prices of PMBJP drugs and various generic options available in India. It suggests that moving towards the PMBJP drugs may lessen the financial strain on the patients and their caregivers. The healthcare system of the country may also benefit from switching to generic drugs. To achieve this goal of reduced economic burden, the patients need to be made aware about the significant price differences between the PMBJP drugs and generic drugs. Awareness should be spread among all stakeholders including the patients, prescribers and pharmacists. Results of our study inform the prescriber about the anti-hypertensive drugs under PMBJK and the price variations of various available generics. Subsequently, the prescriber can make an informed decision and choose the cheaper antihypertensive drugs to minimize the financial burden on the patient leading to maximum patient adherence. Similarly, the problem of increasing cost of generic drugs is arising worldwide, the option for attracting more competition in medical markets with few rivals and little demand is to establish a non-profit generic drug producer with the explicit goal of delivering a stable supply of cheap medicines. Patients could be given cheaper generics, by following similar approach done by the Indian government. All developing countries with health policies that aren't always enforced by the government can take such steps to strengthen the country's healthcare system.

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DECLARATION OF INTEREST

This article was prepared by the authors in their personal capacity. The opinions expressed in this article are the authors' own and do not reflect the view of the affiliating institutions/organizations. We know of no conflict of interest associated with this publication.

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ONLINE SUPPLEMENTAL MATERIAL

Table 4. A Brief Summary of Relevant Literature

Year of Publication	Author/s	Title	Source	Summary
2015	Janodia M	Differences in price of medicines available from pharmaceutical companies and "Jan Aushadhi" stores	Value Health	The three anti-diabetic drugs Glibenclamide, Metformin and Glimepiride in various strengths specified in the "Jan Aushadhi" price list have been evaluated in comparison to the products marketed by pharmaceutical firms and available on the market. The absolute price differential has been measured and there are significant price disparities found between a few brands available in the industry and the drugs offered in the "Jan Aushadhi" shops.
2015	Nallani VR	Cost analysis study of oral anti diabetic drugs available in Indian govt. generic (Jan Aushadhi, Jeevandhara) drugs and brand drugs market in rural/urban area of Guntur, Andhrapradesh, India	Value Health	Cost of single and combination oral anti-diabetics manufactured by different companies, in the same strength, number and dosage form was compared and significant price differences was found. Jan Aushadhi drugs were cheaper than the other brand available in the market.
2019	Kashyap A, Balaji MN, Chhabra M, Rashid M, Muragundi PM	Cost analysis of various branded versus generic chemotherapeutic agents used for the treatment of early breast cancer-a deep insight from India.	Expert review of pharmacoeconomics & outcomes research.	The percentage of cost variance and possible cost savings, especially for Breast Cancer regimens, on the replacement of available generic drugs, was determined and concluded that substituting generic chemotherapy drugs available at Jan Aushadhi scheme could lead to possible cost savings.
2018	Uvais NA	A cost analysis of the psychotropic medicines sold in the jan aushadhi generic drug stores in India	Asian journal of psychiatry	In conclusion, considering the quality of JAS medicines at the same level as other brands available on the market, psychiatrists, in particular, can use them. In treating people with poor economic means, reduce the cost of treatment and thereby encourage commitment to psychotropic medicines.
2019	Satheesh G, Unnikrishnan MK, Sharma A	Challenges constraining availability and affordability of insulin in Bengaluru region (Karnataka, India): evidence from a mixed-methods study.	Journal of pharmaceutical policy and practice	Insulin supply in Bengaluru's public sector is less than the WHO goal of 80 per cent. Insulin is therefore unaffordable in both the private and public sectors. Government could streamline insulin to increase insulin supply and affordability. Acquisition and supply chains at various stages, require biosimilar prescriptions, train doctors to follow evidence-based prescriptions, and motivate brand replacement pharmacists. Patients must be allowed to browse around for cheaper rates from discounted programmes such as the JAS.

Table 4. A Brief Summary of Relevant Literature

Year of Publication	Author/s	Title	Source	Summary
2014	Ahmad A, Patel I, Sanyal S, Balkrishnan R, Mohanta GP	Availability, Cost and Affordability of Antimalarial Medicines in India!	People	The high cost of pharmaceutical drugs in India makes healthcare less available for deprived parts of the population. Jan Aushadhi rates are not the lowest as per popular belief, but are considerably lower than the top cost generic drugs offered on the market. The Government should consider accelerating the process of creating more Jan Aushadhi stores across the country for the benefit of the public.
2019	Rakshitha BV, Divyashree CR	Analysis of cost between branded medicines and generic medicines in a tertiary care hospital.	International Journal of Basic & Clinical Pharmacology	This research revealed a very large price gap between marketed and generic medications. Efforts should be made to support generic drugs. Misconceptions regarding the poor effectiveness of generic medications should be erased.
2011	Singhal GL, Kotwani A, Nanda A	Jan Aushadhi stores in India and quality of medicines therein	International Journal of Pharmacy and Pharmaceutical Sciences	This research is one of the first such studies which compares the quality of four widely used drugs - Alprazolam, Cetrizine, Ciprofloxacin, Fluoxitine, available as generics from the Jan Aushadhi Stores, with that of the respective leading brands, Restyl, Alerid, Ciprobid and Fludac. These drugs have been evaluated in compliance with the Indian Pharmacopoeial Guidelines. Results show that all four pairs of generics vs. common branded medicines pass the related pharmacopoeial exams, underlining that generics are of as high quality as branded medicines. The study emphasises the importance of raising consciousness among prescribers and the public about the quality of generics.
2016	Singh B, Nanda A, Budhwar V, Marwaha RK	A comparative evaluation of the quality & price of generic medicine with their branded counterparts	PharmaTutor	This report determine the quality of pharmaceutical drugs sold in Jan Aushadhi's generic shops. The study showed that the medicines checked after purchasing from Jan Aushadhi suppliers are of equal and similar quality to the marketed medicines present on the market. The four paired drugs were compatible with all qualitative as well as quantitative assessments administered during the analysis. The shops of Jan Aushadhi, which are currently limited to the Government sector services can only be outsourced to grow their scope to the private sector in order to make use of its benefits to the general public, rather than the small public sector only. List of the drugs sold in these shops ought to be extended immediately to meet the need for a prescription. Such stores are to be developed in towns, villages and rural areas where there is a severe issue of essential drugs. By broadening the reach of those sources, usage of generic drugs can be increased.
2019	Sharma R, Maheshwari P	A comparative study of generic (Jan Aushadhi) and ethical glimepiride.	International Journal of Pharmacy & Life Sciences	The study aims to assess and equate the quality of generic glimepiride with its ethical substance available at Jan Aushadhi stores according to Indian Pharmacopoeial criteria and other validated methods for the widely prescribed type II diabetes medication (Glimepiride). Studies have been done as per Indian Pharmacopoeia 2007. Tests conducted for assessment shall include weight uniformity, in vitro dissolution, disintegration, friability, assay, hardness, thickness. The study showed that all ethical and generic glimepiride tablets complied with the requirements laid down in the Indian Pharmacopoeia.
2016	Tank ND, Bhansali NB, Karelin BN	In vitro comparison of generic and branded formulations of ceftazidime using standard strain of pseudomonas	National Journal of Integrated Research in Medicine	The findings of the study revealed that there was no distinction between generic and branded drugs in in vitro antimicrobial action, which may help to shift the mistaken perception of many citizens, some doctors and pharmacists, who think that the more expensive the product the more effective. The cost of generic drugs was so low that it favour the use of generic drugs, especially in the developing countries.

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