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Review Article

A Review: A Comparative Study of Branded and Generic Anti-Hypertensive Drugs

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A B S T R A C T

This comprehensive review investigates the market landscape of antihypertensive medications, undertaking a detailed comparative analysis of branded and generic options. In the face of rising global prevalence of hypertension, the study aims to provide a holistic perspective on the efficacy, safety, and market dynamics shaping the use of branded and generic drugs in the management of these chronic conditions.

Utilizing data derived from market trends, sales analytics, and consumer preferences, the review scrutinizes the market behaviors and forces influencing the adoption of branded and generic antihypertensive drugs. Factors such as cost-effectiveness, patient adherence, and healthcare provider preferences are explored to shed light on the complexities associated with medication selection in the context of chronic disease management.

Through an in-depth examination of industry strategies, regulatory frameworks, and the role of healthcare policies, the review aims to uncover the interplay between market dynamics and clinical considerations. It seeks to inform healthcare professionals, policymakers, and industry stakeholders about the evolving landscape of choices in antihypertensive therapies, fostering a nuanced understanding that can guide optimal decision-making in patient care and resource allocation.

Keywords: Antihypertensive, Generic Drug, Branded drug

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INTRODUCTION:

The term "generic drug" refers to a medication that shares the same chemical composition as a drug that was first covered by a chemical patent. Following the expiration of the patents on the original medications, generic medications may be sold. The medical profile of generic medications performs similarly to that of their proprietary counterparts since the active chemical ingredient is the same. A generic drug has the same active pharmaceutical ingredient (API) as the original, but it may differ in some characteristics such as the manufacturing process, formulation, excipients, color, taste, and packaging[1]. Generic products become available after the patent protections afforded to the drug's original developer expire. Definition of Generic Bioequivalence According to US FDA regulations, a generic drug product is one that is comparable to an innovator drug product in dosage form, strength, and route of administration, quality, performance characteristics and intended use[2].

Applications to the FDA for approval of generic drugs are considered “abbreviated” because they generally do not include preclinical (animal) and clinical (human) data in order to establish safety and efficacy. Generic drug manufacturers must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). To be considered bioequivalent, the generic version must deliver the same amount of active ingredients into the bloodstream in the same amount of time as the innovator drug[2]

Branded drugs

A drug that is patent-protected and sold by a pharmaceutical business under a particular brand name or trademark. Brand-

name medications may be bought over the counter or with a prescription. Any pharmaceutical product that is covered by the Plan's pharmacy benefit and is prescribed, including over-the-counter medications supplied in accordance with a prescription, medicine, agent, substance, device, supply, or other therapeutic product that is not a generic drug, is referred to as a "Brand Drug" or "Brand."[2]

The corporation must first file a New Drug Application and receive permission from the Food and Drug Administration (FDA) before they can promote and sell their product. The corporation provides information in this paperwork to prove the clinical safety and effectiveness of a medication. A medication considered innovative is one that was developed with its particular active component and was approved for use initially. The majority of medication patents are valid for 20 years. Until the patent expires, no other company is allowed to sell the identical medication throughout the patent term.[2]

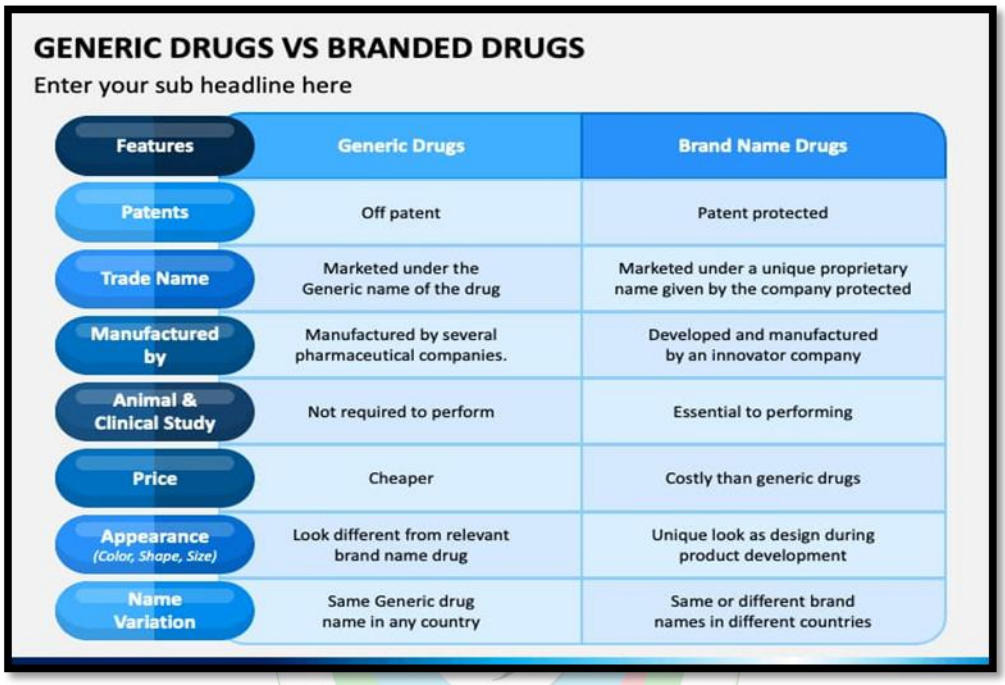

Figure 1: Comparison between Generic and Branded drug

Hypertension

- Hypertension is one of the significant risk factors for pre-ventable and premature deaths globally. Only a proportion of adults with hypertension are diagnosed and receive recommended treatment despite the avail- ability of inexpensive and efficacious treatment [3]
- Hypertension (HTN) has been recognized as the primary risk factor for death and is one of the strongest modifiable risk factors for cardiovascular, cerebrovascular, and ischemic heart disease and kidney disease. Hypertension is a common medical condition and a leading cause of cardiovascular diseases (CVDs) and stroke worldwide.[4]
- Hypertension was characterized as blood pressure ≥ 160/95 mmHg (from an average of two measurements), or the use of antihypertensive drugs illness.High blood pressure is often called a “silent killer” because you can have it and not know it. Over time, if you do not get treated for high blood pressure, you can get very sick or even die.[5]

Types of Hypertension:

A high blood pressure diagnosis usually comes after having your blood pressure checked and may be one of several different types of hypertension.

A) Essential Hypertension

You may have essential hypertension if your blood pressure is consistently high over three or more visits to the doctor. Even if you don't experience any other symptoms, headaches, vertigo, or exhaustion are typical.[6]

B) Secondary Hypertension

High blood pressure brought on by another medical disease is referred to as secondary hypertension. This could be caused by sleep apnea, hormonal changes, illnesses of the adrenal glands, thyroid problems, or a diet high in salt.[6]

C) Resistant Hypertension

The medical treatments for this type of hypertension are ineffective. Stroke, heart failure, and renal disease are more likely to affect those with resistant hypertension. People who don'thave unhealthy lifestyles might often be the cause of high blood pressure.[6]

D) Isolated Systolic Hypertension

There are two separate figures used to record your blood pressure. The first is the systolic pressure, which is the force your heart produces when it beats, and the second is the diastolic pressure, which is the force your heart produces when it is at rest in between beats. Only the systolic pressure is noted as being elevated in isolated systolic hypertension.[6]

Global scenario of hypertension

- Worldwide Awareness, diagnosis, and treatment coverage among adults have been reported as 46%, 42%, and 21%.[7]
- In particular low- and middle-income people have a high economic burden of hypertension, which is an important risk factor for reduced life expectancy.[7]
- In India, the prevalence of hypertension is 29.8%. India is third globally in terms of sales volume, with over 20,000 pharmaceutical businesses and an annual turnover of 22 billion dollars.[7]
- A little price difference causes a significant financial burden on patients with lower socioeconomic position in developing nations since hypertension medications must be used for the rest of their lives.[7]Patients in India pay for about 80% of all medical expenses.[8]

Treatment Strategies

The target blood pressure for treating hypertension is 140/90 mm Hg; however, in individuals who also have diabetes or kidney disease, the target blood pressure is much lower, at 130/80 mm Hg.According to India's fourth National Family Health Survey (NFHS), which was performed in 2015–2016, 18.1% of persons aged 15–49 have hypertension. Only three-fourths (76.1%) of all eligible subjects received the screening, and fewer than half (44.7%) received the diagnosis. 7.9% of people had their blood pressure under control, whereas 13% reported continuing their therapy.[9]

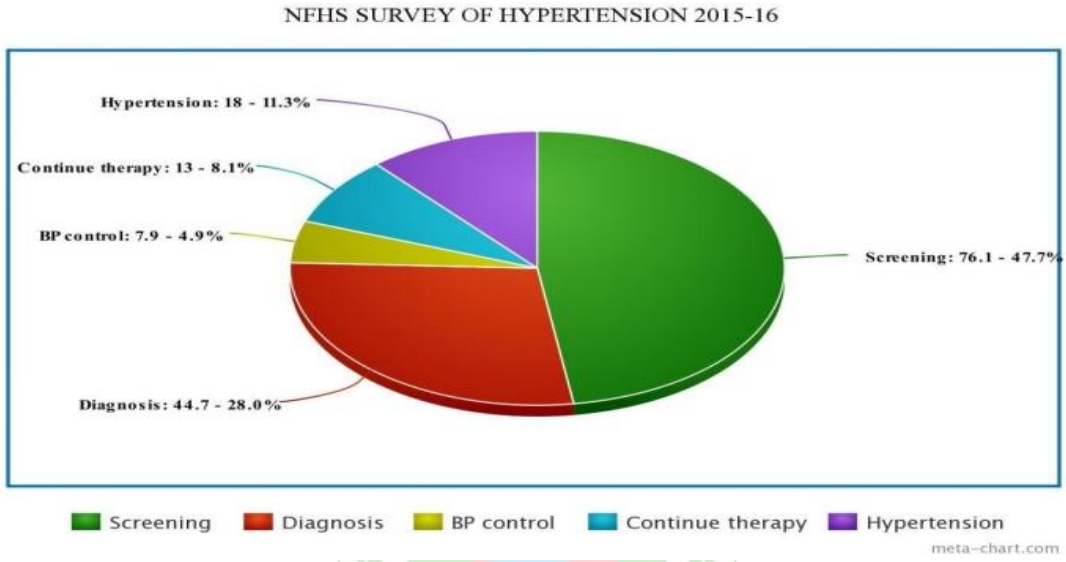

Figure 2: NFHS Survey of Hypertension 2015-16[9]

Sex /Regions	East	North	North East	South	West	Pooled
N	1628	1488	1335	1367	1404	7222
Men	13	9.9	26.3	26.2	18.3	17.9
Women	11.9	8.6	17.8	21.6	18.8	15.8
Pooled	12.4	9.3	21.7	23.5	18.6	16.8

Prevalence of hypertension according to sex and regions in India[9]

According to the first national NCD survey, which was performed in 2018–2019, 28.5% of people aged 18–49 had hypertension. According to the poll, 27.9%, 14.5%, and 12.6% of persons with hypertension were aware of their condition, were receiving treatment, and had their blood pressure under control.[10]

Hypertension treatment cascade at the national level

The nationwide prevalence of hypertension in the age range under study was 18.3% (95% CI: 18.1%-18.4%) and 16.3% (95% CI: 16.2%-16.4%) with three and two blood pressure measurements, respectively. 70.5% (95% CI: 70.3%-70.7%) of hypertensives had their blood pressure checked at some point ("screened"), 34.3% (95% CI: 34.1%-34.5%) had been diagnosed prior to the survey ("aware"), 13.7% (95% CI: 13.5%-13.8%) reported taking an anti-hypertensive medication ("on treatment"), and only 7.8% (95% CI: 7.7%-7.9%) had their blood pressure under control ("under control").[11]

The prevalence of hypertension was somewhat greater in males than in women (14.8%, 95% CI: 14.7%-14.9%) (21.6%, 21.5%-21.7%). The proportional differences between the screening to awareness, awareness to treatment,

and treatment to control phases were 51.4%, 60%, and 43.1%, respectively.[11]

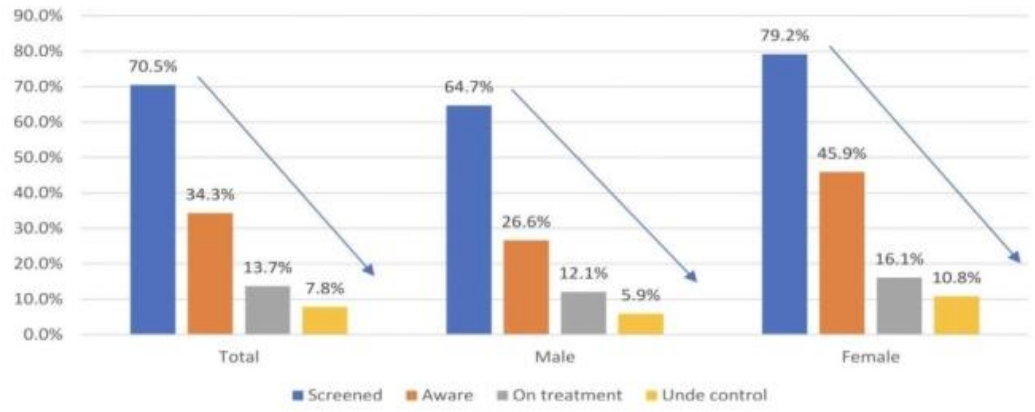

Figure 3: Prevalence of hypertensive Indian adults screened, aware, on treatment, and under control, NFHS-5, 2019–2021[11]

Discussion related to the antihypertensive drugs

- The initative taken by government for cost effectivenss of drugs.
- The National Pharmaceutical Pricing Authority (NPPA) was founded in 1997 to guarantee that medications would be accessible and reasonably priced. One such initiative under the NPPA is the Drug Price Control Order (DPCO) of 2013.[12]
- It establishes the maximum price for a planned formulation of any brand-name or generic medication produced by a pharmaceutical company with a market share more than or equal to 1%.[12]
- The theory of pharmaco-economics is used to compute the ceiling price of new drugs. Any new medication released by a pharmaceutical business, whether it be branded or generic, should cost less than or equal to the maximum amount set by the government for that :- Ceiling price is calculated as: Ceiling price = average price to retailer x (1 + percentage of margin to retailer[12]
- The FDA keeps an eye on adverse event reports and lack of effects for allapproved medications (generic or innovator), and it responds when there is data indicating that a licensed medication is not bioequivalent. The FDA has removed the 300 mg extended-release bupropion hydrochloride generic formulation from the market after finding non bioequivalence in a head-to-head bioequivalence examination of the innovator and generic medications[12]
- The FDA includes the new generic formulation in its Approved DrugProducts with Therapeutic Equivalence Evaluations (Orange Book) after bio equivalency data have been evaluated and approved. Approximately 90% of products are rated "A" (i.e., bioequivalent to an original, innovator formulation), and 10% are rated "B" (not bioequivalent).[13]
- The "Drug Price Competition and Patent Term Restoration Act of 1984,"also known as the Waxman-Hatch Act, introduced the practice of using bio equivalency as the foundation for authorizing generic versions of pharmaceutical drugs. This rule speeds up the availability of less expensive generic medications by allowing manufacturers to submit applications for clearance to commercialize generic copies of brand-name medications without having to pay for unnecessary and redundant clinical trials[14]

Generic medications:

The use of medications is steadily increasing, especially among patients undergoing costly, lifelong therapies for non-communicable disorders.The Center is eager to promote generic medications, which may drastically lowerprescription expenses by 50–90%.

Janaushadhi Kendra sells Telmisartan Tablets IP 40mg, an antihypertensive drug used to treat high blood pressure, for Rs 12 for 10 units. On the other hand, the identical medication, marketed under distinct labels, costs around Rs 30- 100 per unit.

The Indian government's Pradhan Mantri BharatiyaJanaushadhiPariyojana is a campaignpublic welfare programme. It was started by the Department of Pharmaceuticals to offer the general public access to high-quality medications at reasonable costs. PMBJP India's program for inexpensive generic medications, saw sales of INR 1,236 crore ($162 million) in the year 2022–2023.[15]

Rise of generics

- Generic medications have long been known to play a part in lowering healthcare costs.
- Numerous studies have demonstrated that by switching from more expensive branded medications to less expensive generic versions, consumers can save between 10% and 90%[16]
- In 2012, the government updated the National Pharmaceutical Pricing Policy with this in mind. It provided techniques for figuring out price ceilings for medications included by the 2011-modified National List of Essential Medicines (NLEM)[16]

Patient and Prescriber preferences regarding generic drugs

- Approximately 4 out of 10 doctors occasionally or frequently prescribe a brand-name medication to a

patient when a generic medication is available because the patient requested it, according to a national study of 1891 doctors in 7 specialist areas.

It is obvious that prescription innovative medications result in increased healthcare costs when bioequivalent generic equivalents are available.[17]

Classification of antihypertensive drugs

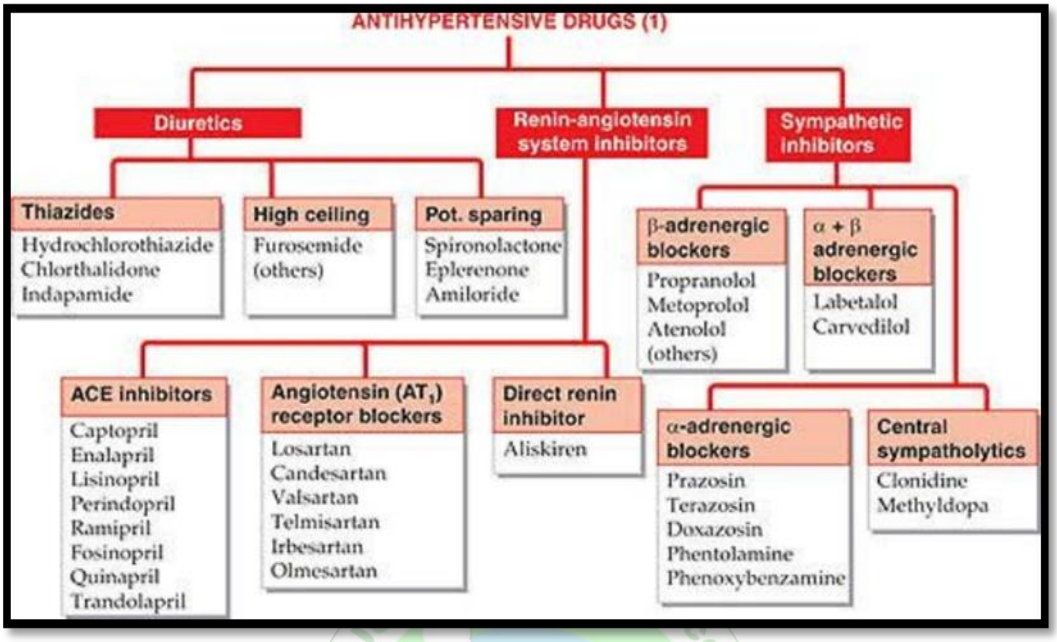

Figure 4: Classification of Hypertensive drugs

A) FDA-Approved Single-Agent Drugs for the Treatment of Hypertension

Diuretics	Beta-blockers	Calcium Antagonists	ACE inhibitors	ARBs	Others
amiloride	acebutolol	amlodipine	benazepril	azilsartan*	aliskiren*
bumetanide	atenolol	diltiazem	captopril	candesartan*	clonidine
chlorothiazide	bisoprolol	felodipine	enalapril	eprosartan	doxazosin
chlorthalidone	carvedilol	isradipine	fosinopril	irbesartan	guanabenz
eplerenone	labetalol	nicardipine	lisinopril	losartan	guanethidine
ethacrynic acid	metoprolol	nifedipine	moexipril	olmesartan*	guanfacine
furosemide	nadolol	nimodipine	perindopril	telmisartan*	methyldopa
indapamide	nebivolol*	nitrendipine	quinapril	valsartan	minoxidil
HCTZ	pindolol	verapamil	ramipril		prazosin
metolazone	propranolol		trandolapril		reserpine
spironolactone	timolol				terazosin
torsemide					
triamterene					

ACE angiotensin converting enzyme, ARB angiotensin receptor blocker, HCTZ hydrochlorothiazide,

*not currently available in a generic formulation

Figure 5: FDA approved single agent drugs for treatment of hypertension [13]

B) FDA-Approved Two and Three Agent Drug Products for the Treatment of. Hypertension

Diuretic + Beta-blocker	Diuretic + ACE inhibitor	Diuretic + ARB	Diuretic + Diuretic	Diuretic + Other	ACE inhibitor + Calcium Antagonist	ARB + Calcium Antagonist	Renin Inhibitor + Other	3-Drug Combinations
chlorthalidone + atenolol	HCTZ + benazepril	chlorthalidone + azilsartan*	HCTZ + amiloride	chlorthalidone + clonidine	benazepril + amlodipine	olmesartan + amlodipine*	aliskiren + amlodipine*	HCTZ + amlodipine + aliskiren*
HCTZ + bisoprolol	HCTZ + captopril	HCTZ + candesartan*	HCTZ + spironolactone	HCTZ + hydralazine	trandolapril + verapamil SR	telmisartan + amlodipine*	aliskiren + HCTZ*	HCTZ + amlodipine + olmesartan*
HCTZ + metoprolol	HCTZ + enalapril	HCTZ + eprosartan*	HCTZ + triamterene	HCTZ + methyldopa		valsartan + amlodipine*	aliskiren + valsartan*	HCTZ + amlodipine + valsartan*
HCTZ + propranolol	HCTZ + fosinopril	HCTZ + irbesartan						
HCTZ + timolol	HCTZ + lisinopril	HCTZ + losartan						
	HCTZ + moexipril	HCTZ + olmesartan*						
	HCTZ + quinapril	HCTZ + telmisartan*						
		HCTZ + valsartan						

ACE angiotensin converting enzyme, ARB angiotensin receptor blocker, HCTZ hydrochlorothiazide,

*not currently available in a generic formulation

Figure 6: FDA approved two and three agent drug products for treatment of Hypertension [13]

List for Cost of Generic blood pressure medication

A) Angiotensin- Converting Enzyme (ACE) Inhibitors

Generic name (Tablet)	Tablet	Cost
Benzapril 20 mg	30 tablet	₹ 232.80
Captopril 25 mg	10 tablet	₹35.70
Ramipril 10 mg	15 tablet	₹407.99
Trandolapril 4 mg	10 tablets	₹56.00
Qinapril 40 mg	10 tablets	₹121.65
Perindopril 4 mg	10 tablets	₹92.00
Moexipril 15 mg	100 tablets	$281.11
Lisinopril 20 mg	10 tablets	₹134.40
Fosinopril 40 mg	10 tablets	₹110.22
Enalpril 20 mg	10 tablets	₹18.75

The low cost of generics is an alternative to branded drugs and hence generics dominate, making up for 70 to 80% of the retail market. As India's population grows, especially theaging population has significantly increased the demand for generic medicines on account of their affordability and effectiveness, which is same as branded medicines.

List for Cost of branded drug

Generic name	Branded name	Tablets/Capsule	Cost	Retail price
Benzapril 20 mg	Benace	30 tablet	$4.00	$114.24
Captopril 25 mg	Aceten	90 tablet	$24.58	$111.52
Ramipril 10 mg	Cardace	30 cap	$4.00	$31.25
Trandolapril 2 mg	Zetpril	9 tablet	$22.04	$99.76
Qinapril 20 mg	Acupil	90 tablet	$20.37	$74.02
Perindopril 4 mg	Adpace	90 tablet	$34.74	$172.40
Moexipril 7.5 mg	Univasc	90 tablet	$26.30	$124.76
Lisinopril 20 mg	Lisoril	30 tablet	$3.44	$12.32
Fosinopril 20 mg	Fovas	90 tablet	$22.73	$103.64
Enalpril 5 mg	Invoril	60 tablet	$15	$41.63

Average unit price of different available branded options in India [18]

Drug class	Drug	Dosage form	No. of generic options available	Min. Unit price (INR)	Max Unit Price (INR)	Average Unit price (INR)
Calcium channel blockers	Amlodipine 5mg	Tablet	116	0.60	9.48	2.40
Beta blocker	Carvedilol 3.125 mg	Tablet	24	0.72	3.92	3.09
Beta blocker	Carvedilol 6.25 mg	Tablet	22	1.20	6.36	3.11
Calcium channel blockers	Cilnidipine 20 mg	Tablet	15	4.95	13	3.96
Diuretics	Chlorthalidone 12.5 mg	Tablet	6	1.33	6.43	6.52
ACE Inhibitors	Enalapri l5 mg	Tablet	37	0.42	7.22	2.31
ACE Inhibitors	Lisinopril 5 mg	Tablet	31	2.06	21.25	4.99
Beta blockers	Metoprolol 25 mg	Tablet	52	1.08	11.60	4.62
Angiotensin receptor blocker	Losartan 25 mg	Tablet	68	0.42	5.25	2.46
Beta blocker	Metoprolol 50 mg	Tablet	52	1.08	15.96	4.60
Beta blocker	Nebivolol 10 mg	Tablet	1	17.37	17.37	17.37
Angiotensin receptor blocker	Valsartan 80 mg	Tablet	4	11.4	19.02	14.45
Alpha Blocker	Prazosin 5 mg	Tablet	7	6.03	12.50	10.62

Percentage cost variation of commonly used antihypertensive drugs as a single drug therapy[19]

Drug	Doses	Minimum cost	Maximum cost	Cost Ratio	% Cost variation
Calcium channel Blockers					
Amlodipine	Amadav 2.5mg	6.50	27.60	4.24	324.61
	Amanat 5mg	12.50	70	5.6	460
Nifedipine	Depin 5mg	3.18	12.03	3.78	278.30
	Angifine 20mg	7.50	29.10	3.88	288
Beta blockers					
Atenolol	Tenolol 12.5mg	2	19.60	9.8	880
	Tenase 100mg	25.70	36.60	1.42	42.41
Metoprolol	Betaloc 12.5mg	33.30	54	1.62	62.16
	Betaloc 50mg	32.80	70.50	2.14	114.93
	Actocard 100mg	67	152.90	2.28	128.20
Alpha blocker					
Prazosin	2.5mg	94.60	125.80	1.32	32.98
	2.5mg	109.35	156.80	1.43	43.39
Terazosin	1mg	39.80	150.63	3.78	278.46
	2mg	69.50	223.20	3.21	221.15
Alpha+Beta blockers					
Labetalol	100mg	100	137	1.37	37
Carvedilol	3.125mg	9	32	3.55	255.55
	25mg	52	145	2.78	178.84
ARBs					
Losartan	25mg	16.50	38.35	2.32	132.42
	50mg	29.50	85.80	2.90	190.84
Telmisartan	20mg	15	42	2.8	180
	300mg	199.65	202	1.01	1.17
Diuretics					
Hydrochlorothiazide	12.5mg	7.6	10.30	1.35	35.52
	25mg	17.60	21.81	1.23	23.92
Torasemide	5mg	15.95	29.70	1.86	86.20
	40mg	154.20	163.35	1.05	5.93

Figure 7: Visit to generic and branded drugs store

Interview with Pharmacist

I started by asking some inquiries about the project "**Comparative Study of Generic and Branded drugs for the Hypertension in India**" at the drugstore in Harsh and Vishaka. The interview began as soon as they were responsible and engaged in discourse about my subject. The chemist explained to me the price of each anti-hypertensive medication and said that because the area is rural, a certain quantity of generic medications should be made available to patients based on their financial situation, as branded medications are expensive and cannot be afforded by underprivileged patients. However, branded medications provide more accurate results even though they cost more than generics. Although generics may not provide the same level of effectiveness or length of action, they can provide temporary relief and are still reasonably priced for those in need. When I asked the chemist why he had to sell generics instead of branded products so he could make more money, he said that pharmacists have a responsibility to the community as well as to themselves.He also gave me information on the price, efficacy, and comparison of branded and generic medications. The two chemists were really kind to me, gave me precise information, and I appreciate them sharing their knowledge.

Conclusion from survey work

Generic drugs are more cost effective and highly reliable drugs. They are easily available and have high consumption rate due to its minimum cost price.. According to consumer opinion the safety and efficacy of these drugs is similar to that of branded drugs. Due to consumption of generic medicine, a small portion of income is spent on consumption of hypertensive medicine, which can be spent on other necessary needs. Numerous studies have demonstrated that by switching from more expensive branded medications to less expensive generic versions, consumers can save between 10% and 90%. According to research, the average cost of generic medications is Rs 148.2, whereas the average cost of branded medications is Rs 1426.8

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REFERENCES

1. Prasad, Amit Mohan, Gautam Chakraborty, Sajjan Singh Yadav, and Salima Bhatia. "Addressing the social determinants of health through health system strengthening and inter-sectoral convergence: the case of the Indian National Rural Health Mission." *Global health action* 6, no. 1 (2013): 20135.

2. Bjerkedal,T.:Over weightand hypertension. Acta Med Scand159:13,1957.
3. a systematic analysis for the Global Burden of Disease Study 2016." *Lancet (London, England)[Internet]. Elsevier* 390 (2017): 1260-1344.
4. .Zhou, Bin, James Bentham, Mariachiara Di Cesare, Honor Bixby, Goodarz Danaei, Melanie J. Cowan, Christopher J. Paciorek et al. "Worldwide trends in blood pressure from 1975 to 2015: a pooled analysis of 1479 population-based measurement studies with 19· 1 million participants." *The Lancet* 389, no. 10064 (2017): 37-55.
5. Rodgers, Anthony, Majid Ezzati, Stephen Vander Hoorn, Alan D. Lopez, Ruey-Bin Lin, Christopher J. L. Murray, and Group Comparative Risk Assessment Collaborating. "Distribution of major health risks: findings from the Global Burden of Disease study." *PLoS medicine* 1, no. 1 (2004):
6. https://www.healthline.com/health/types-and-stages-of-hypertension.
7. 7.Moran, Andrew E., Michelle C. Odden, AnusornThanataveerat, Keane Y. Tzong, Petra W. Rasmussen, David Guzman, Lawrence Williams, Kirsten Bibbins-Domingo, Pamela G. Coxson, and Lee Goldman. "Cost-effectiveness of hypertension therapy according to 2014 guidelines." *New England Journal of Medicine* 372, no. 5 (2015): 447-455.
8. Banerji, Amit, and Maulana Azad. "Review of asia-pacific's healthcare systems with emphasis on the role of generic pharmaceuticals." *Academy of Health Care Management Journal* 9 (2013
9. Rathi, Komal, Preeti Kamboj, Priyanka Gupta Bansal, and G. S. Toteja. "A review of selected nutrition & health surveys in India." *The Indian journal of medical research* 148, no. 5 (2018): 596.
10. Prenissl, Jonas, Jennifer Manne-Goehler, Lindsay M. Jaacks, Dorairaj Prabhakaran, Ashish Awasthi, Anne Christine Bischops, Rifat Atun et al. "Hypertension screening, awareness, treatment, and control in India: a nationally representative cross-sectional study among individuals aged 15 to 49 years." *PLoS medicine* 16, no. 5 (2019): e1002801.
11. Mathur P, Kulothungan V, Leburu S, et al. National noncommunicable disease monitoring survey (NNMS) in India: estimating risk factor prevalence in adult population. PLoS One. 2021;16(3):e0246712.
12. Price, Ceiling. "National Pharmaceutical Pricing Authority." *paragraph* 13, no. 2 (2013).
13. Woodcock J, Khan M, Yu LX. Withdrawal of generic budeprion for nonbioequivalence. N Engl J Med. 2012;367:2463–5. Perhaps the most recent example of official FDA actions that resulted in removal of a nonbioequivalent drug product from the US market.
14. 14.Data, Exclusivity. "Orange book: approved drug products with therapeutic equivalence evaluations." (2017).
15. 15..Kesselheim, Aaron S., Alexander S. Misono, Joy L. Lee, Margaret R. Stedman, M. Alan Brookhart, Niteesh K. Choudhry, and William H. Shrank. "Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis." *Jama* 300, no. 21 (2008): 2514-2526.
16. Kotwani, Anita, Margaret Ewen, Dalia Dey, Shobha Iyer, P. K. Lakshmi, Archana Patel, Kannamma Raman et al. "Prices & availability of common medicines at six sites in India using a standard methodology." *Indian journal of medical research*125, no. 5 (2007): 645-654.
17. Amit, Guy, Amit Rosen, Avraham B. Wagshal, Dan Y. Bonneh, Tzvika Liss, Aviva Grosbard, Reuven Ilia, and Amos Katz. "Efficacy of substituting innovator propafenone for its generic formulation in patients with atrial fibrillation." *The American journal of cardiology* 93, no. 12 (2004): 1558-1560.
18. Campbell, Eric G., Genevieve Pham-Kanter, Christine Vogeli, and Lisa I. Iezzoni. "Physician acquiescence to patient demands for brand-name drugs: results of a national survey of physicians." *JAMA internal medicine* 173, no. 3 (2013): 237-239.
19. .A.H. Prabhakar, R. Giridhar, J. Pharm. Biomed. Anal., 2002, 27, 861.