

# Generic versus branded medicines: An observational study among patients with chronic diseases attending a public hospital outpatient department

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## Abstract

**Background:** The concept of generic prescription is widely accepted in various parts of the world. Nevertheless, it has failed to gain popularity in India due to factors such as nonavailability and distrust on the product quality. However, since 2012, the Government of West Bengal, India, has initiated exclusive generic drug outlets called “fair price medicine shop” (FPMS) inside the government hospital premises in a “public-private-partnership” model. This study was undertaken to evaluate the experience and attitude of patients who were consuming generic drugs purchased from these FPMS. **Materials and Methods:** It was a questionnaire-based cross-sectional study where we have interviewed 100 patients each consuming generic and branded drugs, respectively. The perceived effectiveness, reported safety, medication adherence, cost of therapy, and availability of drugs was compared between two mentioned groups. Medication adherence was estimated through Drug Attitude Inventory-10. **Results:** 93% of generic and 87% branded drug users believed that their drugs were effective ( $P = 0.238$ ) in controlling their ailments. No significant difference (9% generic, 10% branded drug users,  $P = 1.000$ ) was observed in reported adverse effects between generic and branded drug users. 82% and 77% of patients were adherent generic and branded drugs, respectively ( $P = 0.289$ ). As expected, a significantly lower cost of generic drugs was observed compared to its branded counterpart. **Conclusion:** The policy of FPMS implemented by the Government of West Bengal, India appeared to be promising in terms of perceived effectiveness, safety, and adherence of generic drugs from FPMS compared to drugs purchased from open market retailers. Therefore, this study might act as an impetus for the policy-makers to initiate similar models across the country.

**Key words:** Branded drug, cost of therapy, generic prescription, health policy, medication adherence

## INTRODUCTION

The use of generic medicines, compared to their branded counterparts, has the potential to substantially

reduce out-of-pocket expenditure on drugs for patients with chronic diseases.<sup>[1]</sup> Generic substitution of brand prescriptions is an accepted practice in many parts of the

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world, and this is often done for economic reasons.<sup>[2,3]</sup> In India, however, generic substitution is not a universally accepted practice. This results from various factors including nonavailability of generic formulations, distrust of generic medicines by practitioners often due to perceived inferior quality and counterfeiting of drugs.<sup>[4,5]</sup> Implementation of generic prescribing policy is however ongoing in institutional settings, where drugs can be procured in bulk and dispensed from the institutional inventory with appropriate quality control measures.

With the idea of promoting generic prescriptions in public sector hospitals, the Ministry of Health and Family Welfare, West Bengal, has been implementing a “fair price medicine shop (FPMS)” scheme run through public-private-partnership (PPP) from 2012.<sup>[6]</sup> The government provides space and physical infrastructure for the medicine outlets within the hospital premises while the private partner undertakes procurement and dispensing activities under mutually agreed terms. The items are supplied at substantial discount to the maximum retail price. There is a mandatory list of items that are to be stocked for supply to hospital patients as well as many other items that are supplied under the supervision of local FPMS monitoring committees. In addition to this state government initiative, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, has, since 2008, opened dedicated outlets called “Jan Aushadhi Stores” where generic medicines are sold at low prices. So far, 157 “Jan Aushadhi Stores” have been opened across 12 states of India including West Bengal.<sup>[6]</sup> Through these initiatives, more and more patients, are now getting exposed to the generic drugs concept and can compare its advantages and disadvantages to purchase of branded drugs from the open market.

The experience and attitude toward generic drugs are not uniform among physicians across countries as reported by investigators from India and abroad.<sup>[7-13]</sup> The scientific data regarding experience and attitude of consumers toward generic drugs is necessary for sustaining a generic drug use policy but have been explored to a limited extent. Reports on consumer attitudes and preferences are mostly available from countries where generic drug substitution in retail pharmacies is an accepted practice, unlike in India.<sup>[14-22]</sup> In particular, recent reports on consumer behavior, since the introduction of above initiatives, are lacking. We, therefore, undertook this study to evaluate the experiences and attitudes of patients toward generic drugs purchased from FPMS of a state government sponsored public hospital, comparing the same with the experience regarding branded medicines purchased from retail medicine shops in the same or adjoining localities.

## MATERIALS AND METHODS

This questionnaire-based cross-sectional study was conducted among patients attending internal medicine outpatient department (OPD) of a Government Medical College Hospital located in suburban Kolkata between May and July 2015. Patients with chronic diseases who consumed generic medicines purchased from FPMS for at least 3 months were included after obtaining written informed consent. The same questionnaire was administered to an equal number of patients attending the OPD of a private hospital and using branded medicines purchased from the open market. The sampling strategy was purposive. Patients suffering from simultaneous acute medical problems, cognitive impairment, or psychiatric diseases were excluded from the study. Approval from the Institutional Ethics Committees was obtained before the initiation of the data collection.

The questionnaire consisted of three parts. The first part captured data pertaining to the sociodemographic, morbidity, and medication profile of the patient. The second part consisted of eight structured closed-ended items assessing the experience and attitudes toward generic or branded drug usage. The last part was a validated questionnaire evaluating medication adherence, called Drug Attitude Inventory-10 (DAI-10). This instrument, condensed from its original 30-item version, contains ten closed-ended items with binary response to assess medication adherence based on psychometric profiling.<sup>[23,24]</sup> A total score of 5–10 indicates a perfectly adherent patient, 0–5 a moderately adherent patient, and a negative total score, a completely nonadherent patient.<sup>[25]</sup> The entire questionnaire, including DAI-10 rating, was translated into regional languages (Hindi and Bengali) followed by validation through independent back-translation.

Data were analyzed using IBM SPSS statistics Version 20 New York, United States. Summary statistics were expressed using mean and standard deviation (SD) for numerical variables (median and interquartile ranges [IQRs] when skewed) and counts and percentages for categorical variables. Numerical variables were compared between generic and branded drug users using Student’s independent samples *t*-test when normally distributed and Mann–Whitney U-test when skewed. Fisher’s exact test was employed for intergroup comparison of categorical variables. Comparisons were two-sided, and  $P < 0.05$  was taken to be statistically significant.

## RESULTS

We approached 116 generic medicine users of whom 100 agreed to participate, giving a nonresponder rate of 7.41%.

The nonresponder rate among branded medicine users was 9.91% to achieve 100 who agreed to participate.

The sociodemographic, morbidity, and drug use profile of the two study groups are presented and compared in Table 1. Evidently, age and gender distributions and primary disease duration were comparable. However, branded medicine users were better educated, had a higher per capita monthly family income and used more drugs and doses per day. They also bore higher medication cost for their prescriptions. The medication adherence score, as measured through DAI-10, indicated moderate to good adherence in both groups with the mean score showing no statistically significant difference. Branded drug users had a mean DAI-10 score of 6.3 (SD 2.61) while the value for generic drug users was 6.3 (SD 2.80).

The primary diagnosis for patients is presented in Figure 1. Apart from common chronic diseases such as hypertension, type 2 diabetes, and chronic airway diseases, there were also patients with dyslipidemia, ischemic heart disease, hyperuricemia, epilepsy, osteoporosis, and chronic dyspepsia who have been clubbed into the others category. All were receiving medication for prolonged periods.

Across the 200 prescriptions analyzed, 45 brands and 29 generic drugs were prescribed by 17 prescribers.

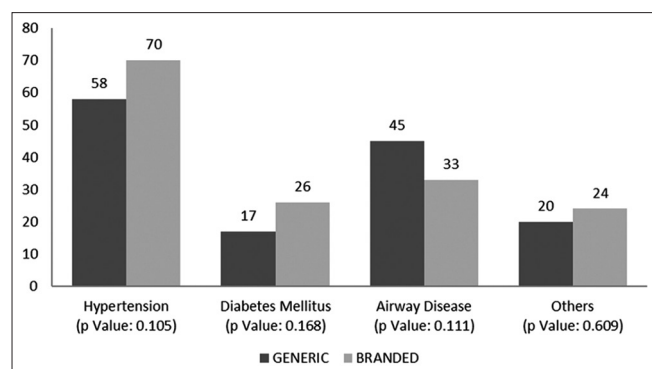


Figure 1: Primary diagnosis of the patients with chronic diseases using either generic or branded drugs

The prescription frequency of 15 selected branded, and generic drugs are graphically compared in Figure 2. Interestingly, multivitamin formulations were prescribed to thirty patients among branded drug users; however, none from the other group received such a prescription. Among the total number of prescribed drugs 65% and 56% were from “National Essential Drug List,” 2011 respectively in generic prescription and branded prescription categories ( $P = 0.027$ ).

The experience and attitude of the patients consuming branded and generic drugs are presented in Table 2. In our sample, 93% of generic drug users and 87% branded drug users believed that their medicines were sufficiently effective ( $P = 0.238$ ) for controlling the disease condition.

## DISCUSSION

In spite of encouragement from policy-makers, generic drug use in India is yet to gain widespread popularity, and the practice so far has remained confined mostly to institutional settings in small pockets of the country. The economic benefits of generic drug use are however well-known and undisputed. The limited availability of quality generic formulations appears to be an important

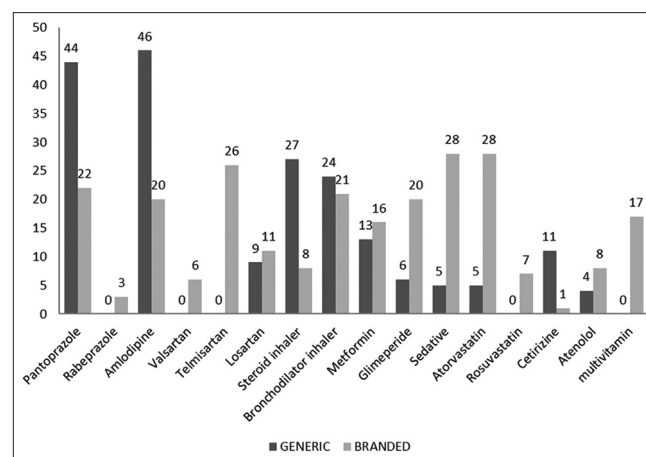


Figure 2: Prescription frequency of selected branded and generic drugs

Table 1: Sociodemographic, disease- and drug-related variables compared between generic and branded drug users

|                                   | Generic drug user (n=100) | Branded drug user (n=100) | P      |
|-----------------------------------|---------------------------|---------------------------|--------|
| Age (year)                        | 52.1±14.82                | 51.1±10.85                | 0.587  |
| Gender (male:female)              | 44:56                     | 57:43                     | 0.089  |
| Per capita monthly income (INR)   | 1000 (1000-2043.6)        | 10,000 (6666.67-12,375)   | <0.001 |
| Duration of disease (months)      | 43.5 (24-72)              | 48 (24-72)                | 0.727  |
| Number of drugs consumed per day  | 3 (2-4)                   | 4 (3-5)                   | <0.001 |
| Number of doses consumed per day  | 4 (2-5)                   | 4 (3-8)                   | <0.001 |
| Total cost of medicines per month | 500 (400-625)             | 1500 (900-2000)           | <0.001 |
| Unit cost of medicine per dose    | 53.33 (33.33-83.33)       | 200 (92.5-358.33)         | <0.001 |
| Total DAI score                   | 8 (6-8)                   | 8 (6-8)                   | 0.834  |

Values depict mean±SD for age and median (IQR) for other variables. SD: Standard deviation, IQR: Interquartile range, DAI: Drug attitude inventory, INR: Indian rupees

**Table 2: Experience and attitude of patients consuming generic and branded drug formulations**

| Variable                                   | Status              | Generic drug user (n=100) | Branded drug user (n=100) | P     |
|--|---------------------|---------------------------|---------------------------|-------|
| Medication adherence status                | Not adherent        | 3                         | 5                         | 0.721 |
|  | Adherent            | 97                        | 95                        |       |
| Medication adherence grade                 | Not adherent        | 3                         | 1                         | 0.289 |
|  | Moderately adherent | 15                        | 22                        |       |
|  | Perfectly adherent  | 82                        | 77                        |       |
| Adverse effects                            | Not experienced     | 91                        | 90                        | 1.000 |
|  | Experienced         | 9                         | 10                        |       |
| Satisfied with instruction provided        | Not satisfied       | 7                         | 5                         | 0.767 |
|  | Satisfied           | 93                        | 95                        |       |
| Confident about the regimen                | Not confident       | 16                        | 11                        | 0.408 |
|  | Confident           | 84                        | 89                        |       |
| Awareness about beneficial effect of drugs | Not fully aware     | 93                        | 84                        | 0.074 |
|  | Aware               | 7                         | 16                        |       |
| Problems due to nonavailability            | Faced problem       | 46                        | 40                        | 0.475 |
|  | Never faced problem | 54                        | 60                        |       |
| Storage of drugs                           | Problematic         | 8                         | 10                        | 0.806 |
|  | Not problematic     | 92                        | 90                        |       |

hindrance to the widespread adoption of generic prescribing and dispensing activity.

Since 2012, Ministry of Health and Family Welfare, Government of West Bengal, has started implementing the policy of “mandatory generic drug use” in state government-funded hospitals. Simultaneously, to ensure availability of generic drugs which are seldom available in the open market, the FPMS scheme on a PPP model has been launched in larger public hospitals all across the state. Out of 121 proposed FPMS, 93 have become operational providing generic medicines at low retail price. This initiative has the potential to create public awareness and to increase faith to generic medicines. This prompted us to carry out a pilot study for evaluation of the experience of generic drug usage among patients of chronic diseases attending government hospitals.

In this study, we observed that over 90% of the patients believed that generic drugs were as effective as branded drugs. This finding is encouraging since public faith in generic formulations is not universal. For instance, in a focus group interview conducted in Alabama, USA, among African American citizens<sup>[21]</sup> multiple concerns regarding the use of generic medications were voiced. The participants thought that generics might be less potent than branded medications. A perception that generics are not “real” medicines and thus only appropriate for mild ailments also prevailed. However, poor people are forced to “settle” for generics due to low therapeutic cost. Contrarily, in Finnish patients,<sup>[16]</sup> it was observed that 81% of the participants opined that cheaper generics were effective. Palagyi and Lassanova (2008) reported that 17% of the study populations considered generics inferior to brand-name drugs in terms of quality among patients from Slovakia.<sup>[19]</sup> Another study from a nationwide survey conducted among

5000 individuals from Brazil<sup>[18]</sup> reported that 30.4% of the respondents considered generic drugs to be less effective than branded medicines. Himmel *et al.*<sup>[17]</sup> conducted a survey among primary care patients in Germany about their thoughts on generic drug use. Almost a third of the respondents thought the relatively inexpensive generic drugs to be qualitatively inferior than, or altogether different from, branded drugs. This view was more frequently expressed by patients who were more than 60 years of age, chronically ill, and/or without higher education. In this study, patients attending the public hospital were socioeconomically as well as educationally constrained, but they still believed that generic drugs available from FPMS were effective. The extent of side effect reported by patients after consuming both generic and branded drugs was around 10% with no significant difference. This contrasts with the observation it was reported that 13% of primary care patients in Germany suffered from new side effects after generic substitution.<sup>[17]</sup> In an American survey,<sup>[22]</sup> it is reported that about 10% believed that generic drugs could cause more side effects than brand-name drugs. Another study<sup>[16]</sup> among the Finnish patients observed that 85% did not consider generics substitution unsafe. However, in contrast to the global picture, over 80% of participants believed that generics are relatively less safe for use than branded equivalent in a recent survey<sup>[26]</sup> conducted in Maharashtra, India. In the Brazilian survey,<sup>[18]</sup> 28.1% of the entire sample believed that generics cause more side effects compared to branded drugs.

The proportion of perfectly adherent patients in our sample was 82% and 77% for generic and branded drugs, respectively, with no statistically significant difference. In contrast, in a mixed-method study among Australian seniors,<sup>[14]</sup> generic drug usage emerged as an important factor in nonadherence to medication. Several investigators also reported that generic substitution is a source of

confusion and therefore medication error among patients. However, in this study, 89% of the generic drug users perceived that they were confident about their drug regimen and 95% were satisfied regarding the instruction provided to them for use of the medicines.

In addition to the three major areas of concern regarding generics, namely, perception regarding effectiveness, safety, and medication adherence, we also evaluated some other perspectives of drug use. It was noted that in generic prescriptions the median number of drugs (3 [IQR 2–4] drugs/day vs. 4 [IQR 3–5] drugs/day,  $P < 0.001$ ) and number of drug doses (4 [IQR 2–5] doses/day vs. 4 [IQR 3–8] doses/day,  $P < 0.001$ ) were lower compared to branded prescriptions. Although the exact reason for this difference was not apparent from this study, the high usage of multivitamin formulations might have contributed to higher numbers of branded medicine use. The total cost and unit cost of medication was found to be significantly low among generic compared to branded drug users. Apart from the direct cost of the medication, the usage of newer congeners within a therapeutic class tends to increase cost in brand prescriptions. For instance, newer drugs such as rosuvastatin, olmesartan, and telmisartan, was observed exclusively among brand prescriptions, whereas generic drug prescribers used atorvastatin, losartan, etc., in similar situations. The proportion of use of essential drugs was also higher among generic drug prescribers. All these factors also add to the cost for brand prescriptions. This difference in prescription pattern between prescriptions generated from government and private hospitals in India was earlier detected in a prescription audit conducted in Rajasthan, India.<sup>[27]</sup> Consistent with our observation, researchers had identified that average number of drugs prescribed per prescription and number of multivitamin formulations were more in private hospital OPDs compared to Government Hospital OPDs. The usage of generic drugs and essential medicine were significantly higher among doctors from government hospitals.<sup>[27]</sup>

The availability of medication and their storage were comparable between the generic and brand groups. However, 46% of branded users and 40% of generic drug users faced problem while purchasing due to unavailability of the medicines concerned. This is an issue of concern and might lead to ineffectiveness of the policy in future. However, it is likely that as of now all FPMS are not yet fully able to cope with the demand for various drugs leading to stock-out situations. In the public interest, the government must keep the FPMS retailers informed of the drugs that need to be stocked and their optimum inventory. A local FPMS catalog and strong inventory management mechanism are needs of the hour.

This study has its share of limitations. It is hospital based, addresses only chronic diseases and the control group selected is not identical regarding the major determinants of drug usage, as branded and generic prescribing are not practiced in the same setting in West Bengal, India. The public hospitals are the major source of generic prescription, and they primarily cater to a population with lower income and education, compared to the private setting (source of branded prescription). Hence, further studies with probability sampling and appropriate stratification are necessary to ensure the generalization of our observations.

Nevertheless, the results are encouraging regarding the future of generic prescribing policy in the state and indicate that it would be worthwhile to pursue its full implementation. The perceptions of patients regarding effectiveness, safety, and adherence needs of generic drugs were comparable to branded medicines. Therefore, the availability of generic drugs should be ensured in FPMS by the policy-makers. Attempts should also be made to adopt the same model in other states of the country to enable wider penetration of generic medicine benefits.

## CONCLUSION

The government of West Bengal, India has initiated exclusive generic drug outlets called 'Fair price medicine shop' (FPMS) inside the government hospital premises in a 'Public Private Partnership' (PPP) model since 2012. The policy appeared to be promising in terms of perceived effectiveness, safety and adherence to treatment for the patients who acquire generic drugs from FPMS compared to drugs purchased from open market retailers. Therefore, this study might act as an impetus for the policy-makers to initiate similar models across the country.

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### Conflicts of interest

The authors are either employee of Government of West Bengal or students of medical college under the same administration. However, no tangible or intangible support was sought from the concerned department during the designing, conduct, or publication of the study.

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