

Patients Opinion on the use of Generics and Factors Associated with it: A Cross-sectional Study

Jaykaran Charan^{1*}, Mayur Chaudhari², Deepak Saxena³, Pankaj Bhardwaj⁴, Pradeep Dwivedi¹, Sneha Ambwani¹

¹Department of Pharmacology, All India Institute of Medical Sciences, Jodhpur, Rajasthan, INDIA.

²Department of Pharmacology, Government Medical College, Surat, Gujarat, INDIA.

³Department of Epidemiology, Gandhinagar, Gujarat, INDIA.

⁴Department of Community and Family Medicine, All India Institute of Medical Sciences, Jodhpur, Rajasthan, INDIA.

ABSTRACT

Background: Generic drugs (Generics) are low cost, equal efficacy alternatives to the branded drugs. Generics are medicines on which patents have expired. They are sold either as branded products or as unbranded products under generic names. These generic names are internationally agreed short names called International Non-Proprietary Names. Due to its low cost, it reduces the overall expenditure for patient care. Government of India (GOI) has been pushing to increase the prescription practice of doctors for generics and acceptability of generic in the community. Present study assesses the current opinion of patients about the generics and documents factors affecting the knowledge, perception and opinion about the generics. **Objectives:** Present study was designed to investigate about the opinion of patients about the generics and to document different factors associated with their perceptions. **Materials and Methods:** A pre-validated pre-tested questionnaire was used to collect the data from patients attending various outpatients in a Tertiary Care hospital in Jodhpur. Trained Research Associate visited various Out Patient Department (OPD) of different specialties for two consecutive days to seek consent and collected data from the patients visiting the OPD and consented to participate. Patient's knowledge, prior experience of use and general opinion about the generics was gathered. Descriptive statistics was used in the form of frequency and percentages. **Results:** Out of the 643 patients, 147 (22.9%) had heard about the generics. Out of the different sociodemographic predictors, age with a class intervals 45 years-55 years (OR – 2.52), 55 years -65 years (OR – 3.26) and > 65 years (OR –3.09)

and educational qualifications namely higher secondary (OR – 3.07) and graduation (OR – 5.98) were found to be the statistically significant predictors for the opinion on generics; however, gender, marital status, family income and occupation were not significant statistically. Out of the 147 patients who had heard about the generics only 38% had used them in last six months, 65.8% agreed that generics are safe and 36.7% opined that generics are as effective as branded drugs. Around 44% of the patients disagreed that generics have more side effects. On inquiring about the most common reason for no usage of the generic drug, distrust on the efficacy was found to be the most common one. **Conclusion:** Majority of patients had never heard about the generic drugs. Age and Education were the positive predictors for better awareness about the generic drugs. Patients perception for generics can be changed with better advocacy as well as informed prescription by the treating physicians.

Key words: Generic Drugs, Brand Drugs, Opinion, Patients, Physicians, India.

Correspondence

Dr. Jaykaran Charan, Assistant Professor, Department of Pharmacology, All India Institute of Medical Sciences, Jodhpur, Rajasthan, INDIA.

Phone: +91-9825219196

Email: dr.jaykaran78@gmail.com

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INTRODUCTION

As per United States Food and Drug Administration (FDA), a generic drug is intended to work same as approved branded drug in dosage form, safety, route of administration, quality and performance. It contains same active ingredient as branded counterpart.¹ *Generic drug* (Generics) is expected to provide same benefits as branded drugs with low cost but with same quality. World Health Organization (WHO) labeled generics as Multisource pharmaceutical product which is pharmaceutically equivalent to innovator product.² It is hypothesized that with the increase in acceptance of generics by all the stakeholders, costs of medical care will decrease and hence many countries took initiative to promote use of generics in patient care and India is one of them.

Government of India launched an innovative scheme Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in 2016. Under this scheme, Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK) were opened in 850 centers, across 28 states to provide generics at affordable cost Jan Aushadhi stores are operated by Bureau of Pharma Sector Undertakings (BPSU) of India, Department of Pharmaceuticals. Generics through these stores can be purchased at cheaper rates due to the lower tax rate levied on these medicines.³ Success of PMBJP depends on intensity of

efforts to change the opinion and perception about the generics drugs amongst stakeholders including patients, doctors and pharmacists.

Indian Medical Council regulations 2002 passed an amendment in 2016 to direct all the physicians registered under MCI to prescribe generic drugs,⁴ However, one of the important stake holders for generics is the consumer himself. It's consumer demand on prescription of generics from the treating physician and/or request for switching brand with generic to pharmacist will be key to success of PMBJP. Acceptability of generics by the patients depends on various factors like their perceptions, opinion and factors that may affect their perception regarding generics drugs. There has been anecdotal evidence regarding misconceptions and trust issues for the generic medicines as reported by the patients. Majority of evidence for perception of generic medicine are available from western countries where generic substitution is a common practice, however, there are very few studies documenting opinion of Indian patients about generics.⁵ Majority of these studies have a smaller sample size along with other limitation of serious methodological issues. Hence there was an urgent need for a robust study to know the patient's perception toward the generics and to explore various factors which may

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affect patient's awareness about the same. Such insights will be valuable in designing information and educational interventions.

MATERIALS AND METHODS

Study sample

Present study was conducted at an institute of National Importance and tertiary level care health facility in Jodhpur - Rajasthan. Permission from the Institution Ethics Committee was obtained before initiating the study (AIIMS/IEC/2017/279). The study was conducted between February and March 2017. Samples of 643 patients were chosen from the patients attending different OPDs. Patients with more than 18 years of age and visiting OPDs of AIIMS Jodhpur were included in the study after obtaining informed consent. Patients from any department except from Psychiatry and Physiotherapy OPD were included in the study. The sample size was calculated by the Open Epi software Version 3.01. The estimated sample size was based on the pilot study conducted at same tertiary care institution before initiation the study. In the pilot study, the awareness about the generics was observed in 41% of the patients, hence at a proportion of patients with the correct knowledge on generics as 41%, 5% permissible error and 99% confidence interval, the sample size was found to be 642 patients.

The non-response rate for participation in present study was 6.8%. There was no significant difference between age, gender and locality (Rural/Urban) between those who participated in the study and who had not consented to participate in study.

Survey Instrument development and data collection

The survey instrument was prepared in vernacular language by undertaking a descriptive review of the previous published studies in the domain of generics. The draft instrument was further discussed amongst the investigators and was sent to experts for validation based on face, content and constructs validity. The tools were pre-tested and the initial draft was revised based on observations of pre-testing before actual execution to the patients.

The data collection was done by a data collector, trained for conducting the patient interview based on the survey instrument. Only those who consented to be a part of study were included. The questions were asked from the proforma both in Hindi as well as Rajasthani language. The data collector visited each of OPD for two days. The schedule for visit to OPD was fixed randomly by using simple randomization through computer generated numbers. All patients who visit on the day of data collection were offered to participate. Survey instrument was having both closed as well as open ended questions.

Statistical analysis

Statistical Analysis Frequency and percentages were used for descriptive analysis. Logistic regression was used to assess the sociodemographic factors which may affect patient's awareness about the generic drugs. SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc. was used for analysis.

RESULTS

Information from a total of 643 patients was gathered from the different OPDs of the institution. Out of these 643 patients, majority were below 65 years of age. Median age of the patients was 37 years. Around 62% were males and around 48% were residing in urban locality. Almost one-third of the patient had educational qualification of graduation level or above. Monthly family income of almost 70% of patients was less than 40000 INR per months and around 7% of the patients were employed in government jobs while majority of the females were house wives. [Table 1]

Out of 643 patients, 147 (22.9%) had heard about the generics previously and had some understanding about it. Age with a class intervals 45 years - 55 years (OR - 2.52), 55 years - 65 years (OR - 3.26) and > 65 years (OR - 3.09) and educational qualifications namely higher secondary (OR - 3.07) and graduation (OR - 5.98) were found to be the significantly associated with the awareness about generic drugs. Amongst the educational qualifications higher secondary (OR - 3.07) and graduation (OR - 5.98) were significantly associated with the awareness about the generic drugs. There was no significant association found between

Table 1: Sociodemographic characteristics of patients included in the study.

Sociodemographic Parameters	Frequency (Percentages)
Age Group (Years)	
≤ 25	183 (28.5)
25 - 35	120 (18.7)
35- 45	125 (19.4)
45-55	101 (15.7)
55-65	73 (11.4)
>65	41 (6.4)
Gender	
Male	399 (62.1)
Female	244 (37.9)
Locality	
Urban	309 (48.1)
Rural	334 (51.9)
Marital Status	
Married	504 (78.4)
Unmarried	139 (21.6)
Education Qualification	
No formal education	157 (24.4)
Primary	98 (15.2)
Secondary	98 (15.2)
Higher Secondary	92 (14.3)
Graduation	198 (30.8)
Family Income (INR)/Month	
≤ 20000	434 (67.5)
20000-40000	131 (20.4)
40000-60000	53 (8.2)
60000-80000	8 (1.2)
> 80000	17 (2.6)
Occupation	
Daily Labourer	47 (7.3)
Self-employed	75 (11.7)
Government Job	47 (7.3)
Private Job	70 (10.9)
House-Wife	191 (29.7)
Not Working	41 (6.4)
Student	116 (18)
Others	56 (8.7)

Values in parenthesis are percentages.

Table 2: Factors affecting knowledge of generics drugs in patients included in the study.

Variables	OR	95% CI of OR	P Value
Age Group (Years)			
≤ 25	1.00		
25 – 35	0.91	0.42 – 1.93	0.797
35- 45	1.50	0.64- 3.50	0.350
45-55	2.52	1.04 - 6.08	0.040
55-65	3.26	1.28 - 8.27	0.013
>65	3.09	1.02 - 9.31	0.045
Gender			
Male	1.00		
Female	0.83	0.41 - 1.68	0.607
Locality			
Urban	1.00		
Rural	1.12	0.72 - 1.73	0.619
Marital Status			
Married	1.00		
Unmarried	1.01	0.41 - 2.52	0.972
Education Qualification			
No formal education	1.00		
Primary	0.83	0.33 - 2.07	0.682
Secondary	2.00	0.86 - 4.71	0.109
Higher Secondary	3.07	1.32 - 7.13	0.009
Graduation	5.98	2.76 - 12.97	0.000
Family Income (INR)/Month			
≤ 20000	1.00		
20000-40000	1.56	0.94 - 2.61	0.087
40000-60000	1.39	0.69 - 2.78	0.354
60000-80000	1.79	0.38- 8.44	0.462
> 80000	2.12	0.72 - 6.26	0.174
Occupation			
Daily Labourer	1.0		
Self-employed	1.67	0.42 - 6.60	0.464
Government Job	3.56	0.87 - 14.52	0.077
Private Job	3.26	0.85 - 12.50	0.084
House-Wife	3.07	0.72 - 13.14	0.130
Not Working	1.42	0.32 - 6.40	0.644
Student	2.84	0.66 - 12.20	0.162
Others	1.22	0.27 - 5.39	0.797

gender, marital status, family income and occupation with the awareness of generic drugs. [Table 2]

Out of the 147 patients who had heard about the generic drugs, 38% had used them in last six months. 66 % patients either agree or strongly agree for the statement that generics are safe while around 37% agree or strongly agree for the statement that generics are as effective as brands. Around 43% patients disagree with the view that generic drug causes more side effects than brand name drugs. Majority of the patients strongly felt that generics are cheaper than brand name drugs. Around half of

Table 3: Perception of patients regarding generics.

Have you ever heard about generic drugs? (n= 643)	
Yes	147 (22.9)
No	495 (77.1)
Have you used generics in the last 6 months? (n=147)	
Yes	56 (38%)
No	91 (62%)
Generics are safe (n=114)	
Strongly Agree	23 (20.2)
Agree	52 (45.6)
Neutral	20 (17.5)
Disagree	13 (11.4)
Strongly Disagree	6 (5.3)
Generics are as effective as branded drugs (n=109)	
Strongly Agree	12 (11)
Agree	28 (25.7)
Neutral	44 (40.3)
Disagree	21 (19.3)
Strongly Disagree	4 (3.7)
Can cause more side effects than brand drug (n=103)	
Strongly Agree	7 (6.8)
Agree	17 (16.5)
Neutral	34 (33)
Disagree	42 (40.8)
Strongly Disagree	3 (2.9)
are cheaper than brand drug (n=117)	
Strongly Agree	88 (75.2)
Agree	11 (9.4)
Neutral	11 (9.4)
Disagree	4 (3.4)
Strongly Disagree	3 (2.6)
Do you trust Generic Drug are effective? (n=147)	
Yes	79 (53.7)
No	68 (46.3)
Are you willing to use generics now a days? (n=147)	
Yes	73 (49.7)
No	74 (50.3)
If no, which are the reasons preventing you from using generics (n=66)	
I do not know about them	18 (27.3)
My physician does not know about them	2 (3)
My pharmacist does not know about them	0
I do not trust them	39 (59.1)
I had a bad experience in the past	1 (1.6)
I cannot find them easily at my pharmacy	6 (9)
Has ever a physician or a pharmacist proposed/ recommended you substitute a branded drug with a generic drugs? (n=135)	
Yes	119 (88.1)

Continued...

Table 3: Cont'd.

No	16 (11.9)
I don't know	
If yes, have you followed that proposition/ recommendation? (n=119)	
Yes	117 (98.3)
No	2 (0.7)
Have you used a generic drug, after having used the relevant branded? (n= 79)	
Yes	17 (21.5)
No	62 (78.5)
If yes, were you satisfied with the generic drug? (n=17)	
Yes	16 (94.1)
No	1 (5.9)
I don't know	
Please indicate the level of agreement with the following statements	
I would substitute a branded drug with a generic because (n=75)	
My doctor recommend it	74 (98.6)
My pharmacist recommend it	0
Friends/relatives recommend it	0
The generics is cheaper	1 (1.4)

Values in parenthesis are percentages.

the patients supported the efficiency of generics and were willing to use generics in future. Most common reason for not using generic drugs was not trusting the efficiency of these drugs. [Table 3]

DISCUSSION

This study was conducted to know the knowledge and perception of patients about the generic use. It was observed that overall awareness about the generics was inadequate. Age between 45-55 years and education above higher secondary were significant predictors for the awareness about generic drugs. Regarding the efficacy of generics, the opinion was shared, half of the patients considered the efficacy of generic drug as good as brand and were willing to use it in future while rest did not trust the efficacy of these drugs and did not want to use generics in future. Inadequate awareness about the generics was also observed in other published studies amongst non-Indian patients but overall awareness in present study was less as compared to other studies published for non-Indian patients.⁶⁻⁹ There is a paucity of quality studies published from India regarding the patients' perception about the generic drugs. In spite of various promotional activities undertaken by government regarding generics, a very poor awareness was documented in present study. Recently some aggressive steps are further taken by the government to promote use of generics in the day-to-day practice, but these steps are largely directed to the prescribers and but not to the consumers / patients. Better communication between patients and doctors is key for generating better awareness about the generic medicines.¹⁰ In this study almost 100% patients (out of those who knows about generic drugs) agreed to substitute the brand with generic if it is suggested by the physician. Similar results were also observed in some studies published for other countries.¹¹ Physician can communicate information about efficacy and cost of generics to the patients and that may not only increase the awareness but also enhance the acceptability of generics and change

in the perception towards its use.^{12,13} In a published study, poor communication with the physician was negative predictor for the use of generic drugs.¹⁴ Role of physician hence becomes very important for spreading the right information about the generics to patients and can only be possible if physicians themselves believe in the equal efficacy and less cost of generics as compared to brands.^{15,16} Physicians normally have an individual choices for prescribing drugs which is largely based on brand names. Change in focus from brands to generics will requires adequate efforts by the administrators, physicians' associations and government. It is also important to assess their belief about the generics as few studies suggest that many physicians are not aware about the bioequivalence criteria for the generics which equates the effect of generics with branded drugs.¹⁷⁻¹⁹

In the present study out of 23% of patients those who had heard about the generics, only 38% had used the generics in last six months narrating a low use of generics. The main reason could be, conventionally, the choice of drug is decided by physicians and patients have a very limited role. This also might lead to poor awareness along with the misconceptions about the generic drugs. There are consistent findings in various studies which shows that even after having awareness about the generic drugs, patients don't wish to use it because of various misconceptions.^{19,20} In present study, out of all patients who had heard about generics only 53.7% trusted their efficiency, similar findings were observed in other studies published from many countries.^{15,20,21-24}

In present study out of all the patients who had heard about generics, 75% strongly agreed that these drugs are cheaper as compared to brand. As per the previously published studies, patients associate less cost with the less quality and this may be the reason for not using the generics instead of knowing about it.^{15,20,23} This finding is interesting because the main rationale of use of generic drug is to reduce the cost while the same logic is used to consider the drug of inferior quality and this goes against the efforts to promote the generic drug in standard clinical practice. As per the published literature, all the factors which may increase the use of generics like lower income, poor health and high out of pocket expenditure are not found to be associated with use of generic drugs. This shows that right information has not yet reached to patients. More efforts are needed towards advocacy for the use of generic drugs.

Two factors which were found to be associated with the awareness of generics in this study were age above middle age and high education. Association between education and awareness of generic drug was also observed in previously conducted research.^{22,24-26} Higher age is also found to be associated with awareness of generics in other studies. It is observed that people having more age are usually consuming more drugs and having more educational qualifications which may increase the chance of knowing more about the generic drugs. There was no association found between gender, family income and occupation with awareness of generic drugs. In few studies it was observed that females have more awareness about the generics as compared to males while in some other studies no such differences were found.^{27,28} In this study majority of the females were housewives and having less education so it might have negatively affected the awareness about the generic drugs.

This study was conducted at a government run tertiary care center. So, findings cannot be generalized to all Indian patients. Patients attending private health care facilities, may have different socioeconomic status in comparison to patients attending government facility, which may affect awareness understanding about generic drugs. As the aim of the study was to evaluate overall opinion about the generic drugs hence no comparison was done for the different categories of drugs and data related to disease conditions were not collected. Acute and Chronic disease conditions may affect the opinion of patients about the generic drugs hence such information if collected, may enhance the robustness

of the study. To the best of our awareness, there is no published study with adequate sample size from the India wherein patients' opinion or perception is assessed about the generics and this is an honest attempt to get first glimpse of it. We observed that awareness and acceptability of generics is very inadequate and there is a need of proper dissemination of information as well as advocacy to patients. There is also a need to arrange proper training of physicians regarding various myths affecting the use of generics in Indian setting. Patient being a very important stakeholder has all rights to demand generic drug prescription form physicians but to reach that stage patient must have good awareness about basics of the generic drugs. Ideally it is expected from a physician to provide correct and adequate information about generics for making informed choice by patients but either the physicians are prejudiced or have no adequate time to inform patients or they themselves have misconceptions. Strong advocacy by doctors by sharing information with the patients about generic drug may not only increase the awareness but may change the perception and help the informed patients in the decision process.²⁹⁻³²

CONCLUSION

Awareness about the generics are very low in population included in this survey. Age and education of the participants were positively associated with the awareness about the generic drugs.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

FDA: Food and Drug Administration; **WHO:** World Health Organization; **PMBJP:** Pradhan Mantri Bhartiya Janaushadhi Pariyojana.

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