Original Article

Opinion of patients seeking primary care regarding prescription of generic drugs: A cross-sectional study

Jaykaran Charan[1], Deepak Saxena[2], Mayur Chaudhari[3], Siddhartha Dutta[1], Rimple Jeet Kaur[4], Pankaj Bhardwaj[5]

[1]Department of Pharmacology, All India Institute of Medical Sciences, Jodhpur, Rajasthan, [2]Department of Epidemiology, Indian Institute of Public Health, Gandhinagar, Gujarat, [3]Department of Pharmacology, Govt. Medical College, Surat, Gujarat, [4]Department of Pharmacology, S. N. Medical College, Jodhpur, Rajasthan, [5]Department of Community and Family Medicine, All India Institute of Medical Sciences, Jodhpur, Rajasthan, India

Abstract

Background: Generic drugs are low-cost alternatives to branded drugs. The government of India is encouraging physicians to prescribe the generics to decrease out-of-pocket expenditure of health care. Looking at India's low-prescription on generic drugs, it is crucial to analyze the factors responsible for it. A patient's unawareness may be an important factor; hence, it should be evaluated systematically. **Objectives:** This study was designed with the aim of assessing knowledge and perception of generics among patients visiting the outpatient department of primary care physicians at the Patan city of Gujarat. **Material and Methods:** A trained research associate visited the OPDs of various general practitioners to collect the data. A prevalidated questionnaire was administered to these patients. The data was analyzed with the help of statistical software. Descriptive statistics were used to analyze the data. **Results:** Among 345 patients, only 33.6% reportedly heard about generics. Of these only a few patients (<13%) had used the generic drugs in past. The majority (>60%) believed that generics are safe. Those who were not willing to take generics reported efficacy as the major concern. Out of various factors that may affect knowledge of generic drugs, young age (OR = 5.3) and education (Primary (OR = 8.01), Secondary (OR = 6.19), and Higher secondary (OR = 3.07) were statistically significant. **Conclusion:** Awareness about the generic drugs was low among the patients visiting the primary care physician. The young age and primary and secondary education levels were significantly associated with the awareness regarding generics.

Keywords: Generic drugs, India, opinion, patients, primary care

Introduction

India as a nation contains the second largest population of the world and also has a huge burden of various diseases to deal with.[1] Medicines are indispensable in the treatment of various diseases and with the increase in the number of diseases, the cost of prescription also goes up. The cost of treatment as assessed by the percentage of monthly per capita expenditure (MPCE) of the median costs of the prescriptions spent ranged from 11.65%–16.59% in India.[2] The population covered by health insurance is only about 15% and therefore the expenditure on health care through out-of-pocket payments is really high and exerts a huge burden on the population of India.[3,4] The rising costs and affordability of medicine has become a worldwide concern to cope with for both governments and patients. About 60% of Indians are devoid of easy access to essential medicines and the prime factor is the cost of the medicines.[5] The branded medicines are a bit costlier than the generic ones and hence

Address for correspondence: Dr. Siddhartha Dutta, Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Jodhpur, Rajasthan, India.
E-mail: siddhartha.dutta87@gmail.com

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enhanced usage of generic medicines would reduce the costs without sacrificing the quality of the medicines. Across the globe, regions like the USA, Europe, India and many Low and Middle-income Countries are pushing toward the use of generic drugs to cut down the healthcare cost and financial burden.[6,7] A Generic Drug is an identical copy that is almost the same as a branded drug in dosage, safety, strength, route of administration, quality, performance, and intended use.[8] The usage of a generic drug can have the same therapeutic effect with reduced treatment cost which has even proven to enhance the adherence to the treatment.[9] There are few common misconceptions as identified by the Food and Drug Administration (FDA) about generic medications like less effective, delayed benefit, unsafe, and are substandard in nature.[10] Hence, a proper knowledge and perception regarding generic drugs are essential among the patients to increase the usage and acceptability of generics. The World Health Organization (WHO) recommends the essential medicines should be freely accessible and affordable to the population but the literature search has revealed an unfavorable perception of patients regarding generic medicines.[11-13] In 2015, the Government of India launched Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) with an objective of making the quality unbranded medicines affordable and available for all, especially for poor and disadvantaged through exclusive retails stores named as "Pradhan Mantri Bhartiya Janaushadhi Kendras" which are pharmacies selling mainly generic name medicines to the maximum extent possible with an aim of reducing out-of-pocket expenditures from patients.[14] Despite many steps taken by the government generic medicines are underused in our country. There are many hurdles in the promotion of generic medicines and the acceptability of generics by the patients depends on multiple factors along with their perceptions and opinion regarding generics. Literature from western countries, where generic substitution is an established practice, shows evidence of the perception of generic medicine among patients but there are very few studies in India reporting perception of Indian patients about generics and the majority of these studies have a smaller sample size.[12,13,15-19] Hence, this study was planned to assess knowledge and perception of generic drugs among patients visiting the outpatient department of primary care physicians at the Patan city of Gujarat. The objective was to study knowledge and perception about generics among patients coming to the outpatient department of tertiary health care institute.

Methods

This was a population-based cross-sectional survey funded by the ICMR Adhoc extramural project conducted in the city of Patan, Gujrat, India. A tool was developed for quantitative data collection based on the previous work and comments of the experts and was pilot tested. The tool was revisited and were modified based on the observations from piloting and after finalization tools were administered to the patients attending the OPD and Hospitals of the selected primary care physicians by a trained research associate. Due to a lack of similar studies in India, the sample size calculation was done on the basis of a study conducted in Japan on patient's knowledge, attitude toward generic drug substitution which was 68.4% in that study.[20] The calculation was done by an online software named "Open Epi software"(Available from: http://www.openepi.com/OE2.3/Menu/OpenEpiMenu.htm). Considering 5% error and 95% Confidence interval, the sample size came out to be 335. The ethical clearance was taken from the Institute ethics committee on 29-04-2014 and written informed consent was taken from all interested patients/relatives before enrollment of the participants. The questionnaire was translated into Hindi as well as the Gujarati language for the ease of patients and relatives.

Statistical analysis

Descriptive statistics were used for analysis and data was reported in the form of frequency, percentages, Mean and Standard Deviation. Logistic regression was used to see the effect of various parameters on patient's understanding of generic drugs. Statistical Package for Social Science (SPSS) vs 21 was used for the analysis.

Results

Quantitative observations of participants regarding the generic drugs

A total of 345 patients were surveyed in the Patan district of Gujarat, India. The majority of the patients were between 25 and 65 years of age; only 9.6% of patients were > 65 years of age. The mean age of the patients was 45.1 years (SD = 15.78). The mean age of males was 45.9 years with a standard deviation of 15.9, while for females it was 44.2 years with a standard deviation of 15.6 [Table 1]. The proportion of male-female patients was found almost equal. Further, half of the sample population had taken an education up to secondary or higher secondary, and around 20% of patients were uneducated. More than half of the patients were belonging to rural areas (60%). There were only 13% of patients had an occupation of either government or private jobs. The rest majority of patients were self-employed (31%) and homemakers (31%). Almost 90% of patients reported < 20000 income of the whole family per month. The sociodemographic profile of the patients is discussed in Table 1.

On inquiring reasons for seeking care, 43.5% reported acute and 56.5% reported chronic disease condition. Further analysis of knowledge and awareness of generic drugs was done. Out of a total of 345 patients, only 33.6% reportedly heard about the generic drugs.

Among those who had heard about generics, very few participants (<13%) had used generic drugs in the past 6 months. The majority (60%) of the participants agreed that generic drugs are safe and as effective as branded drugs. However, 17% of participants agreed that generic drugs can cause more side effects as compared to branded ones.

On documenting the perception regarding the cost, around 80% agreed or strongly agreed that generic drugs are

Table 1: Sociodemographic characteristics of patients included in the study

Sociodemographic Parameters	Frequency (Percentages)
Age Group (Years)	
≤25	45 (13)
25-35	63 (18.3)
35-45	74 (21.4)
45-55	71 (20.6)
55-65	59 (17.1)
>65	33 (9.6)
Gender	
Male	174 (50.4)
Female	171 (49.6)
Locality	
Urban	136 (39.4)
Rural	209 (60.6)
Disease	
Acute	150 (43.5)
Chronic	195 (56.5)
Marital Status	
Married	311 (90.1)
Unmarried	34 (9.9)
Education Qualification	
No formal education	68 (19.7)
Primary	105 (30.4)
Secondary	96 (27.8)
Higher Secondary	32 (9.2)
Graduation	44 (12.7)
Family Income (INR)/Month	
≤20000	309 (89.6)
20000-40000	29 (8.4)
40000-60000	5 (1.4)
60000-80000	1 (0.3)
>80000	1 (0.3)
Occupation	
Daily Labourer	22 (6.4)
Self-employed	105 (30.4)
Government Job	24 (7.0)
Private Job	21 (6.1)
House-Wife	110 (31.9)
Not Working	41 (11.9)
Student	12 (3.5)
Others	10 (2.9)

Values in parenthesis are percentages

comparatively cheaper to branded ones. Out of those who heard about the generic drugs, 61% said that they trust the efficacy of generics and around 50% were willing to use the generics if need be.

Out of those who were not willing to use generic drugs, the majority (78.6%) of the participant did not trust the efficacy of the generic drugs. The majority of participants (81%) were not recommended any generic drugs by physicians or pharmacists in past. Those who used generic drugs after using brand drugs, the majority (90%) were satisfied with the generics. The majority (66.7%) participants were ready to switch brands with generics if it is recommended by doctors [Table 2].

In the case of logistic regression analysis, various factors like age, gender, locality (rural/urban), disease (acute/chronic), marital status, educational qualification, family income, and education were used to analyze its effect on patients' knowledge about the generic drugs. It was found that no such factors were having any significant impact on patient's knowledge except the age [25–35 Years (OR = 5.3)] and education [Primary (OR = 8.01), Secondary (OR = 6.19) and Higher secondary (OR = 3.07)] [Table 3].

Discussion

The present study was an attempt in assessing the patient's perception regarding generic medicines. Our study reported that only one-third of patients heard about the generic drugs which clearly denotes a low level of awareness regarding generics. The use of generics was even low in a patient with adequate awareness, but the majority agreed that generic drugs are safe and as effective as branded ones.

The level of awareness of patients regarding generic medicine was low (33.6%) in our study. In India, Choulera *et al.* reported similar results where 35.21% of patients had a good awareness of the generic drugs.[12] Studies by Tripathi and Bhattacharya in northern India reported that 72% and Jangra *et al.* reported 92% of participants were aware or heard about generic medicines which were quite higher as compared to our study but the sample size of these studies were relatively lesser than our study.[13,19] We could not find large observational studies in India in support of our studies but similar studies conducted around the world reported varied results. Stuart *et al.* in Trinidad and Tobago reported that only 25.25% of patients were aware of generic drugs.[16] A study conducted by Skaltsas and Vasileiou in Greece reported almost half and Kobayashi *et al.* from Japan reported 64% of the participants in their study knew the term "generic."[17,20] Babar *et al.* reported 51.6% of patients had previous knowledge of generics.[18] The use of generics in our study was low as only 13% of patients reported using generics in the last 6 months. The reason can be due to low prescribing by the doctors or patients doubting the efficacy of the generic medicines. Similar results were also reported by Choulera *et al.* (18.31%).[12]

In this study, it is worth noting that about 34.5% strongly agreed and 47% agreed that the generic drugs are cheaper as compared to the branded ones. The result was consistent with a study conducted by Jangra *et al.* (86%), Tripathi and Bhattacharya (67%), and Kobayashi *et al.* (86.0%).[13,19,20] Only 13% used generics in the last 6 months. Similar low use of generics has been reported by Choulera *et al.* (18.31%).[12] The probable reason behind low use could be the decision of prescription being taken by physicians and patients have a restricted role in deciding the type of medication. This study also reported that 78.6% of patients do not trust generic medicines. This is basically due to low awareness among the patients regarding generics and can be overcome by better

Table 2: Perception of patients regarding generics

Items	Number of patients(%)
Have you ever heard about generic drugs? (*n*=345)	
Yes	116 (33.6)
No	229 (66.3)
Have you used generics in the last 6 months? (*n*=116)	
Yes	15 (12.9)
No	100 (86.2)
Don't know	1 (0.8)
Generics are safe (*n*=116)	
Strongly Agree	3 (2.6)
Agree	68 (58.6)
Neutral	37 (31.9)
Disagree	6 (5.2)
Strongly Disagree	2 (1.7)
Generics are as effective as branded drugs (*n*=110)	
Strongly Agree	1 (0.9)
Agree	65 (59.1)
Neutral	34 (30.9)
Disagree	8 (7.3)
Strongly Disagree	2 (1.8)
Can cause more side effects than brand drug (*n*=106)	
Strongly Agree	2 (1.9)
Agree	16 (15.1)
Neutral	63 (59.4)
Disagree	25 (23.6)
Strongly Disagree	0 (0)
Are cheaper than brand drug (*n*=113)	
Strongly Agree	39 (34.5)
Agree	53 (46.9)
Neutral	16 (14.2)
Disagree	4 (3.5)
Strongly Disagree	1 (0.9)
Do you trust Generic Drugs are effective? (*n*=116)	
Yes	71 (61.2)
No	13 (11.2)
No opinion	32 (27.6)
Are you willing to use generics nowadays? (*n*=114)	
Yes	99 (49.7)
No	74 (50.3)
If no, which are the reasons preventing you from using generics (*n*=14)	
I do not know about them	1 (7.1)
My physician does not know about them	1 (7.1)
My pharmacist does not know about them	0 (0)
I do not trust them	11 (78.6)
I had a bad experience in the past	0 (0)
Not available easily	1 (7.1)
Has ever a physician or a pharmacist proposed/recommended you to substitute a branded drug with a generic drug? (*n*=116)	
Yes	15 (12.9)
No	94 (81.0)
I don't know	7 (6.0)
If yes, have you followed that proposition/ recommendation? (*n*=14)	
Yes	10 (71.4)
No	4 (28.6)
Have you used a generic drug, after having used the relevant branded? (*n*=93)	
Yes	20 (21.5)
No	69 (74.2)
I don't know	4 (4.3)
If yes, were you satisfied with the generic drug? (*n*=20)	
Yes	18 (90)
No	1 (10)
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=42)	
My doctor recommends it	28 (66.7)
My pharmacist recommends it	3 (7.1)
Friends/relatives recommend it	3 (7.1)
The generics is cheaper	8 (19.0)

Values in parenthesis are percentages

physician-patient communication.[21] The prescribing physician should explain the concept of generics regarding comparable efficacy and lower cost to the patients which might increase the knowledge and acceptability of generics. Literature reveals that poor patient-physician communication has been found to be a negative predictor of generic drug use.[22] About 81.0% of patients in this study denied being proposed/recommended by a physician or a pharmacist to replace or substitute a branded drug with a generic drug. Several other studies also show similar results.[12,13,23] This shows that the perception of the primary care physicians and pharmacists regarding generic use is poor and they usually prefer to prescribe branded drugs. Literature shows poor knowledge of the primary care physician regarding the Food and Drug Administration standards for bioequivalence for generics which can further hamper the prescribing habits.[24] The patients do have a high degree of trust in their treating physicians and patient perception to great extent relies on their physician advice as this study shows 71.4% followed the recommendation when advised. Hence, improving the impression of generics among the primary care physicians would definitely have a positive impact on the prescribing and use of generics.[25]

This study showed that approximately 61% of patients said that they trust the efficacy of generics. Studies by Choulera *et al.* (42.25%), Jangra *et al.* (52.2%), and Das *et al.* (93%) reported varied results regarding the perception of the efficacy of generics among patients.[12,15,19] In this study, about 60% of patients agreed that generic drugs are as effective as branded ones. Similar results were reported by Tripathi and Bhattacharya (61%) and Pettersen *et al.* (62%), whereas Jangra *et al.* (34.7%) and George *et al.* (28%) reported a comparatively lesser proportion of patients who believed that generic medicines have lower quality than branded medicines.[13,19,26,27] A systematic review by Colgan *et al.* reported that 25.1% (95% CI, 24.2% to 26.0%) laypersons considered generic medicines were of inferior quality and 35.6% (95%

Table 3: Factors affecting knowledge of generics drugs in patients included in the study

Variables	OR	95% CI	*P*
Age Group (Years)			
≤25	1.00		
25-35	5.30	1.27-22.18	0.022
35-45	2.34	0.73-7.51	0.152
45-55	3.16	1.05-9.56	0.041
55-65	1.29	0.47-3.60	0. 617
>65	1.56	0.57-4.28	0.384
Gender			
Male	1.00		
Female	0.92	0.44-1.94	0.836
Locality			
Rural	1.00		
Urban	1.16	0.65-2.08	0.618
Disease			
Chronic	1.00		
Acute	0.90	0.49-1.65	0.742
Marital Status			
Married	1.00		
Unmarried	0.76	0.26-2.20	0.615
Education Qualification			
No formal education	1.00		
Primary	8.01	2.73-23.54	<0.001
Secondary	6.19	2.56-14.99	<0.001
Higher Secondary	3.07	1.28-7.39	0.012
Graduation	0.926	0.31-2.77	0.891
Family Income (INR)/Month			
≤10000	1.00		
10000-20000	2.66	0.77-9.09	0.119
20000-30000	1.43	0.40-5.10	0.579
>30000	1.70	0.36-7.89	0.500
Occupation			
Daily Labourer	1.0		
Self-employed	5.75	0.68-48.47	0.108
Government Job	1.95	0.40-9.39	0.404
Private Job	2.13	0.36-12.74	0.407
House-Wife	1.40	0.23-8.59	0.715
Not Working	2.16	0.42-11.00	0.356
Student	2.21	0.43-11.40	0.342
Others	0.53	0.59-4.81	0.532

CI, 34.8% to 36.4%) considered generics as less effective as compared to branded medication.[23]

17% of patients believed generics medications are more prone to cause adverse drug reactions (ADRs). Choulera *et al.* reported 5.63% of patients informed that there can be always associated ADRs with generic medicines.[12] Das *et al.* reported no significant difference in reported ADRs between generic and branded medicine users.[15] George *et al.* reported that about 30% of patients and Pettersen *et al.* (56%) think generic and branded drugs are equally safe.[26,27] However, the reports of Colgan *et al.* 18.8% (CI, 17.8% to 19.8%) were consistent with our study.[23]

This study reported that almost half (49.7%) of the patients were willing to use generics. The study results were consistent with those of Jangra *et al.* (50%) and Choulera *et al.* (40.85%).[12,19]

A majority of the patients denied (74.2%) regarding substitution or replacement of a branded drug with a generic one. The result was contrary to the one reported by the systematic review by Colgan *et al.* (34.0%; 95% CI, 33.2% to 34.9%).[23] The majority of the studies included in the systematic review are from western countries where the awareness and acceptance of the generic medicines are better than the Indian subcontinent which might be a reason for better acceptance of generic acceptance as compared to our study.[16,17,18,23]

It was also worth praising that generics have started building trust among our community, the majority (90%) who used generics after using branded drugs were satisfied with the generics, and the majority (66.7%) participants were ready to switch brand with generics if it is recommended by their primary care physician. The finding was consistent with that of Jangra *et al.* (88%).[19]

Conclusion

It can be concluded that the awareness about the generic drugs in patients visiting the primary care physician is low and efforts need to be taken to improve the patients understanding about the use of generic drugs so that they can inquire doctors about the same which will enhance prescription of generic drugs. As the young age and education were positively associated with the awareness of generic drugs, more awareness needs to be generated in the old age people and people with low literacy.

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Conflicts of interest

There are no conflicts of interest.

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