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RESEARCH ARTICLE

A study of knowledge, attitude, and practice on generic drugs among teaching faculties at a tertiary care teaching hospital in South Gujarat, India

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ABSTRACT

Background: The practice of generic medicines prescribing, dispensing, and substitution in developing countries has been controversial among doctors, particularly due to issues on quality, safety, and efficacy. These controversies are as a result of country to country differences in drug policies and laws as well as individualized knowledge and attitudes of healthcare professionals related to generic medicines. Moreover, generic medicines in the past have been criticized for being substandard mainly due to poor adherence with good manufacturing practice guidelines. **Aims and Objectives:** The aim of this study is to evaluate and compare knowledge, attitude, and practice of generic drugs among teaching faculties in a tertiary care teaching hospital. **Materials and Methods:** A cross-sectional study was carried out using a questionnaire in a tertiary care teaching hospital in south Gujarat. The questionnaire was designed to assess the knowledge, attitude, and practice about generic drugs. The medical teachers working in the institute during the study period were included. The data were analyzed by MS Excel. Responses were calculated in percentage. **Results:** Of all participants, 54% were male and majority and 83% were postgraduate degree holders. It was known to 61.8% faculties that generic drug contains the same active substance(s) as the innovator drug, while 63.2% knew that it is used at the same dose(s) to treat the same disease(s) as the innovator drug. Among faculties, 72% believed the fact that generic drug manufacturers need to conduct bioequivalence studies to show equivalence between the generic and innovator drug. Most of the faculties (75%) did not agree that generic drugs are more costly than their innovator counterpart. Among faculties, 59% had not ever switch a patient on innovator drug to available generic drugs. Only 2% were not in favor of supporting generic drug prescribing. **Conclusion:** Although a good percentage of medical faculties had knowledge about generic medicines, there was gap on knowledge and perception toward generic and brand drugs. Hence, mass awareness programs seemed to be necessary to fill this gap and that would increase the use of generic drugs which ultimately would reduce healthcare expenditure.

KEY WORDS: Generic Medicine; Knowledge; Attitude; Practice

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INTRODUCTION

Nowadays, irrational use of drugs is increasing due to a variety of factors like lack of knowledge among the patients, doctors, commercial approach by the doctors while prescribing, pressures on the doctors by the patients, money making approach by the pharmaceutical companies, and

lack of implementation of stringent laws and regulations to restrain such activities.[1] Hence, there is an overall increase in healthcare expenditure throughout the world. A report by the World Health Organization shows that nearly 80% of total health care expenses are shared by out-of-pocket payments.[2] In developing country with limited resources like India, substitution with generics for brand-name drugs might be an alternative way to reduce drug expenditure and hence decrease in overall healthcare cost. The US Food and Drug Administration (FDA) defines generic drug as "a drug product that should have the same active ingredient, strength, dosage form, route of administration, quality, performance, characteristics and intended use as the brand-name drug".[3] As per global market trend, it is estimated that approximately $150 billion worth of drugs will be off-patented during the period 2010–2017, which will serve as a platform for pharmaceutical companies to develop generic drugs. The pharmaceutical industry in India has shown a remarkable growth which in turn has raised the economy of India.[4] However, the practice of generic medicines prescribing, dispensing and substitution in developing countries has been controversial among doctors, particularly due to issues on quality, safety, and efficacy. These controversies are as a result of country to country differences in drug policies and laws as well as individualized knowledge and attitudes of healthcare professionals related to generic medicines.[5] Moreover, generic medicines in the past have been criticized for being substandard mainly due to poor adherence with good manufacturing practice guidelines.[6] For getting approval from the regulatory body for generic medicine, the manufacturer must prove bioequivalence of generic drugs. Many doctors may not be familiar with this rigorous regulation.[7] Some studies in India and abroad reported that the experience and attitude toward generic drugs are not uniform among physicians across countries.[7-9] Therefore, the present study was undertaken with the objective to evaluate knowledge, attitude, and practices of medical faculties of our institute regarding the use of generic drugs which may help in recognizing possible barriers to mass scale use of generic medicines and to propose the methods of promoting the use of generic medicines.

MATERIALS AND METHOD

Setting

The study was carried out involving teaching faculties (clinical, paraclinical, and non-clinical) of a tertiary care teaching hospital in South Gujarat, India. The study was initiated after the Institutional Ethics Committee approval.

Study Design

The present study was a cross-sectional, prospective, questionnaire-based study. The questionnaire designed for the study comprised four sections: Section A of demographic data of participants such as name, sex, age, and qualification, Section B contains 10 questions related to knowledge, Section C of 10 questions related to attitude, and Section D of 5 questions, of which 4 were structured and 1 were open, related to practice of generic medicines. Prior written informed consent was obtained from the participants who wanted to participate in the study.

Sample Size and Data Collection

Pilot study was done on 10 teaching faculties. There were a total of 125 questionnaires distributed among the teaching faculties. one day was given for returning the filled questionnaires. Of which 110 had returned the questionnaires.

Statistical Analysis

Data were analyzed by MS Excel. Responses were calculated in percentage.

Response Rate

There were a total of 125 questionnaires distributed among the medical faculties and 110 responded (response rate is 88%).

RESULTS

Demographic Characteristics

The demographic details of the participants have been summarized in Table 1.

Of all participants, 54% were male and 46% were female, 66% (male and female) were from 31 years to 40 years age category, and 83% of participants were postgraduate degree holders.

Knowledge

Results showed that 76.5% of faculties knew that generic drug can be used in place of innovator (patented) drug. Only 13.2% of faculties agreed that generic drugs can only

Table 1: Demographic details of the participants (*n*=110)

Characteristics	Factors	Frequency (%)
Gender	Female	50 (46)
	Male	60 (54)
Age (years)	≤30	23 (25)
	31–40	60 (66)
	41–50	6 (7)
	50–60	11 (12)
Qualification	MBBS	25 (27)
	PG (MD/MS/Diploma)	75 (83)

be marketed after the expiry date of innovator drug; 61.8% of faculties knew that generic drug contains the same active substance(s) as the innovator drug, while 63.2% knew that it is used at the same dose(s) to treat the same disease(s) as the innovator drug. Among study participants, only 26.4% knew that generic drug manufacturers need not to repeat the preclinical studies and clinical trials required for the innovator drugs; 72% faculties believed the fact that generic drug manufacturers need to conduct bioequivalence studies to show equivalence between the generic and innovator drug. Most of the faculties (75%) know that innovator drugs are more costly than their generic substitute. Only 29.4% faculties aware of Indian Medical Council states that every physician should, as far as possible, prescribe a drug with generic names. 79.4 % faculties aware of Jan Aushadhi scheme by the Government of India to set up generic stores across the country. Only 22.1% of participants knew that patients or pharmacists are not legally empowered to sell or purchase generic drugs over prescribed innovator drugs. Knowledge-related questions and their responses are summarized in Table 2.

Attitude

There were 10 questions related to attitude of participants for generic drug prescribing. Majority of the participants were disagree with generic drugs that are not as safe as innovator medicine (50%) and generic drugs are not as effective as innovator medicines (42.6%). Among faculties, 42.6% of 'faculties disagreed or did not agree with generic drugs which have longer duration of action as compared to innovator drug, whereas 45.6% were neutral in this regard. Only 23.5% of participants were agree that innovator drug is made in modern manufacturing facilities and generic drugs are often made in substandard manufacturing facilities, but 45.5% were neutral in this regard. There were a good number of participants (63.2%) who did not agree that generic drugs cost less because they are inferior to innovator (patented) drugs. 88.2% faculties gave the opinion that there should be a training program to increase the awareness regarding generic drugs among doctors and patients. 86.7% faculties said that there should be a generic medicine store at every government hospital. Only 29.4% faculties said that there should be a law which bounds doctors to compulsory prescribe generic medicines when they are available and 28% were neutral in this regard. Only 26.5% of participants said that medical insurance company should give preference to generic drugs over innovator drugs while reimbursement of insurance. Majority of participants (82.3%) gave opinion that patients should be legally given freedom to choose generic or innovator drug. Attitude-related questions and their responses are summarized in Table 3.

Practice

In practice-related questionnaire, 35% of faculties prescribed innovator drugs and almost equal % of faculties (34%) did not prescribe innovator drugs when generic drugs are available. Of this 34%, only 12% had mentioned the reason of cost-effectiveness with generic drugs, and of 35%, only 6% had mentioned the reason of less efficacy with generic drugs. Among all participants, 59% said that they had not ever switch a patient on innovator drug to available generic drugs. Majority of faculties (82%) did not ever read any article on comparison of safety and efficacy of generic versus innovator drugs. Maximum number of participants (76%) supported prescribing generic drugs but not in all cases, whereas 22% supported prescribing generic drugs in all cases where generic is available. Only 2% were not in favor of supporting generic drug prescribing. While recording the opinion of all faculties about the ways to improve prescribing generic medicine over innovator drug, maximum (23.6%) suggested way

Table 2: Generic medicine knowledge-related questions and frequency (%) of responses

Questions	Yes (%)	No (%)	Don't know (%)
Can generic drug be used in place of innovator (patented) drug?	84 (76.5)	8 (7.3)	18 (16.2)
Can generic drugs only be marketed after the expiry date of innovator (patented) drug?	15 (13.2)	60 (54.4)	35 (32.4)
Does a generic drug contain the same active substance (s) as the innovator (patented) drug?	68 (61.8)	16 (14.7)	26 (23.5)
Is a generic drug can be used at the same dose (s) to treat the same disease (s) as the innovator (patented) drug?	69 (63.2)	10 (8.8)	31 (28)
Does a generic drug manufacturer need to repeat the preclinical studies and clinical trials for generic drugs?	74 (67.6)	29 (26.4)	7 (6)
Does generic drug manufacturer need to conduct bioavailability and bioequivalence studies to demonstrate equivalence between generic and innovator (patented) drug?	79 (72)	18 (16.2)	13 (11.8)
Are generic drugs costlier than innovator (patented) drug?	2 (1.5)	82 (75)	26 (23.5)
Is there any law in India which states that every physician should, as far as possible, prescribe drugs with generic names?	31 (29.4)	47 (42.6)	32 (28)
Are you aware of the scheme of Government of India called Aushadhi whose purpose is to set up generic drug stores around the country?	87 (79.4)	16 (114.7)	7 (5.9)
Is patient or pharmacist legally empowered to purchase or sell generic drugs in place of prescribed innovator (patented) drug?	54 (48.5)	24 (22.1)	32 (29.4)

was for training/awareness about generic drugs, followed by availability of generic drugs in government and private pharmacies (12.5%), improvement in safety and efficacy of generic drugs as innovator drugs (12%), need more research to compare generic and innovator drugs (8%), strict rules and regulations should be there to insure the quality of generic drugs (7%,) and least (1.5%) considered that patient freedom to choose among generic and innovator drugs. Practice-related questions and their responses are summarized in Tables 4-6.

DISCUSSION

In the present study, the majority of medical faculties had a considerable amount of knowledge about generic drugs, but this was not translated into their percentage of prescribing generic drugs. Similar studies were done on physicians, pharmacists, interns, and postgraduates which showed similar results as in our study.[10,11]

The results in this study showed that most of the medical faculties were aware that generic drugs are substitute of innovator drugs. However, very few of them know that it can be prescribed after the expiry of the patent of innovator medicine till it is protected by patent law and doctor can only prescribe innovator medicine.[12] Most of the participating faculties were aware about the generic drug that contains the same active substance(s) and can be used at the same dose(s) to treat the same disease(s) as the innovator drug. Regulatory requirements by government mentioned generic medicines need not be passed from preclinical studies and clinical trials, but they must be passed from bioavailability and bioequivalence studies.[13] Some studies conducted between 1996 and 2007 were evaluated by the US FDA which showed no significant difference in bioavailability between branded and generic drugs.[14] One another study conducted in India showed that both branded and branded-generic versions of the five "paired" medicines had identical quality and they fulfilled all the criteria prescribed by the statutory standards.[15] Most of the faculties were aware about these regulatory requirements of bioequivalence between generic and innovator drugs. However, a majority of them were unaware about the fact that a generic manufacturers need not repeat the preclinical studies and clinical trials for generic drugs.

Over the years, India has developed a strong capability in producing quality generic and branded drugs in the most of the therapeutic categories. However, still there are overburdened healthcare expenses on poor people in the country. Accordingly, our Government has taken some important steps to enable a key objective of ensuring availability of quality medicines at affordable prices to all.

Table 3: Generic medicine attitude-related questions and frequency of responses (*n*=110)

Questions	Agree (%)	Disagree (%)	Neutral (%)
Generic drugs are not as safe as innovator (patented) drug	10 (8.8)	55 (50)	45 (41.2)
Generic drugs are not as effective as innovator (patented) drug	13 (11.8)	47 (42.6)	50 (45.6)
Generic drugs have longer duration of action in comparison to innovator (patented) drug	13 (11.8)	52 (47)	45 (41.2)
Innovator (patented) drug is made in modern manufacturing facilities and generic drugs are often made in substandard manufacturing facilities	26 (23.5)	34 (31)	50 (45.5)
Generic drugs cost less because they are inferior to innovator (patented) drug	18 (16.2)	69 (63.2)	23 (20.6)
Give your opinion about there should be a training program to increase the awareness regarding generic drugs among doctors and patients	97 (88.2)	3 (3)	10 (8.8)
Do you think that there should be a generic medicine store at every government hospital?	95 (86.7)	8 (7.3)	7 (6)
What is your opinion about "there should be a law which bounds doctor to compulsory prescribe generic drugs?"	32 (29.4)	47 (42.6)	31 (28)
Do you think that medical insurance company should give preference to generic drugs over innovator (patented) drugs while reimbursement of insurance?	29 (26.5)	39 (35.3)	42 (38.2)
What is your opinion about patients should be legally given freedom to choose generic or innovator (patented) drug?	91 (82.3)	3 (3)	16 (14.7)

Table 4: Generic medicine practice-related questions and frequency of responses (*n*=110)

Questions	Yes (%)	No (%)	NA/No response
Do you prescribe innovator (patented) drug when generic drug available?	39 (35)	40 (36)	31 (29)
Reason/s	Efficacy: 1 As and when required: 1	Economic: 4	
Have you ever switch a patient on innovator (patented) drug to available generic drugs?	24 (22)	65 (59)	21 (19)
Have you ever read any article on comparison of safety and efficacy of generic versus innovator (patented) drugs?	13 (12)	90 (82)	7 (6)

As a part of this objective, Indian Government has started a project named Jan Aushadhi in November 2008 which helps in all the ways to set up generic medicine store. However, it has not been reached anywhere to desired objectives. Hence, new plan was released during August 2013 with a new target to set up 3000 generic medicine stores all over India by the end of 2016–2017. Until now, 2149 Jan Aushadhi stores were opened all over India and in which total 757 generic drugs are made available. Moreover, Government had issued guidelines for starting generic medicine store.[16] In our study, a good number of faculties were aware about such initiative. In India, patients or pharmacists are not legally empowered to sell or purchase generic medicine in place of branded medicines, respectively.[17] However, a very few faculties were aware in this regard. Moreover, they have given their opinion that patient should have freedom to choose generic or innovator drugs of their choice. In the US, a national survey of 1891 physicians in 7 speciality areas indicated that approximately 4 of 10 physicians sometimes or often prescribe a brand-name drug to a patient when a generic drug is available because the patient requested for it.[18]

In India, the cost of generic drugs has been found to be up to 91% less than that of the innovator drugs.[19] Hence, widespread use of generic drugs can reduce overall healthcare cost as well as reduce the use of innovator drugs that can lead to reduce the cost of innovator drugs by creating competition. However, as generic drugs need not to pass from the large and costly clinical trials and no need to pay for costly advertising, promotion and marketing; adding to this the competition among multiple generic companies, ultimately lead to lower cost of generic drugs, may raise doubt about their efficacy, safety and quality.[20] However, in our study, most of the participants believed in safety, efficacy, and quality of generic drugs as compared to innovator drugs. In one systemic review, meta-analysis of 38 Randomized clinical trials (RCTs) was done which compared generic and branded name drugs used to treat Cardio vascular diseases. Among these RCTs, they observed that there was no evidence of the superiority of innovator to generic drugs and concluded that it is reasonable for physicians and patients rely on FDA bioequivalency rating to judge clinical equivalence.[21] As in point of fact, there are no sufficient proofs that generic drugs are less safe and less effective than their innovator counterparts. In this study, majority of faculties disagree about the statement that generic drugs are often made in substandard facilities and many of them do not agree that generic drugs cost less as they are inferior to innovator drugs.

In developing country like India, doctors as well as patients have less awareness about generic medicines, so participants agreed with that there should be some training programs for doctors and patients about generic medicines. Owing to the unavailability of drugs in the public hospitals, medicine costs continue to account for a large share of all out-of-pocket health expenses incurred by general public, and thus, availability and affordability are the major concern in India. Hence, the government should start generic medicine stores in every government hospitals. In our study, majority of faculties agreed in this regard. Even though the majority of the faculties having trust in generic drugs, they do not agree to abide a law in which doctor has to compulsory prescribe generic drugs.

In countries like the US and UK, among all medicines reimbursed under medical insurance, majority of the drugs are generics. According to one report of 2014 in the US, generic drugs saved 214 billion dollars and from this 51% saved from commercially insured patients by medical insurance.[22] However, the participants in our study do not agree that our medical insurance companies should give preference to generic drugs over innovator drugs while reimbursement of insurance. In India, if insurance companies make such policy to promote generic drugs, then it would be benefited by both patients as well as insurance companies and there would be a great help to reduce overall healthcare expenditure.

Table 5: Statement expressing the opinion about prescribing generic drugs over innovator (patented) drugs

Questions	Frequency (%)
I support prescribing generic drugs in all cases where generic is available	24 (22)
I support prescribing generic drugs but not in all cases	84 (76.5)
I do not support prescribing generic drugs	2 (1.5)

Table 6: The ways to improve prescribing generic medicine over innovator (patented) drug

Questions	Frequency (%)
Availability of drugs in Government and private pharmacies	14 (12.5)
Improvement in quality of generic drugs as innovator drugs	6 (5.6)
Patients' freedom to choose the generic or innovator drug	2 (1.5)
Awareness/training about generic drugs for patients and medical practitioners	26 (23.6)
Safety and/or efficacy of generic should be improved	5 (4)
Rules and regulations	8 (7)
Research for comparison of both generic and patented drugs	9 (8)
No response	40 (36)

In India, generic substitution is legally not allowed, so patients' awareness about generics is limited and patients do not want to change from prescribed innovator to generic drug. In this study, maximum participants gave the opinion that legally patients should be given freedom to choose generic or innovator drugs. Hence, patient can choose the drugs according to their affordability. Moreover, although the majority of faculties were found to have a greater trust, good knowledge, and good attitude for generic drugs, overall response rates were low in terms of prescribing generic drugs and majority of them have never switch a patient on innovator drug to available generic counterpart.

Maximum numbers of faculties have never read an article which compares safety and efficacy of generic versus innovator drugs, which indicates that there is a huge need of awareness programs on various aspects of generic drugs to build confidence among doctors as well as patients. Majority of participants expressed that they support prescribing generic drugs but not in all cases.

Regarding their opinion for the ways to improve prescribing generic drugs over innovator drugs, awareness/training program about generic drugs was the most common one, followed by availability of generic drugs in government and private pharmacies; safety, efficacy, and quality check of generic drugs; legislative regulatory steps for quality control of generic drugs; and performing more clinical research/studies comparing generic and innovator drugs. Hence, it shows that there is a great need to conduct mass awareness program for doctors, pharmacists, and patients that would clear the doubts or myths about generic drugs and that ultimately would increase the use of generic drugs.

CONCLUSION

Although a good percentage of faculties had good knowledge and attitude regarding generic drugs, this was not reflected in prescription rates, which is showing the gap between knowledge with attitude and practice. Major concern was awareness, which should be increased through regular training program such as continued medical education and workshops. Particularly, doctors should educate early right from their undergraduate career about the generic drugs. Moreover, the National Generic Medicine guidelines should be circulated among doctors or should be made available on the internet. It helps to build up confidence in them as they always remain aware of information of generic drugs they desire to prescribe, which ultimately leads to an increase in generic drugs prescribing.[23] The Government should reform policy by which pharmacists and patients are legally empowered to sell or purchase generic medicine, respectively, in place of costly innovator medicines. As a part of the promotion of generic drug usage, the Government has been already launched Jan Aushadhi scheme. However, there should raise public awareness regarding this scheme, so maximum patients can avail the affordable medical treatment. Furthermore, more research on generic drugs should be done and results should be widely published that ultimately would increase awareness and usage of generics.

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