National Journal of Physiology, Pharmacy and Pharmacology

RESEARCH ARTICLE

Study of medical student's perspectives about prescribing generic medicine at tertiary care teaching hospital

Nilesh Chavda[1], Niravkumar M Patel[1], Kirtida Tandel[1], Jatin V Dhanani[1], Priti Solanky[2]

[1]Department of Pharmacology, Gujarat Medical Education and Research Society Medical College, Valsad, Gujarat, India, [2]Department of Preventive and Social Medicine, Gujarat Medical Education and Research Society Medical College, Valsad, Gujarat, India

Correspondence to: Niravkumar M Patel, E-mail: niravpharma16@gmail.com

Received: July 13, 2016; **Accepted:** August 13, 2016

ABSTRACT

Background: Health-care expenses are booming nowadays. India is one of the biggest generic medicine manufacturers in all over the world still generic medicines are less prescribed in India. In the USA, 86% prescriptions contain generic medicines which saved 1.5 trillion dollars of USA consumers in the past decade. Less knowledge of generic medicine is correlated to less prescribing. Previously, studies were carried out on pharmacist and general practitioner to assess knowledge, attitude, and practice of generic medicine among them. Such study was not done on MBBS students who will be future doctors. **Aims and Objectives:** This study was planned with the aim of assessing knowledge, attitude, and practice of medical students toward generic medicines. **Materials and Methods:** This was a questioner-based cross-sectional survey kind of study. This preformed and pre-evaluated questioner was given to third semester of second year MBBS students. Questioner contains 10 items for knowledge, 10 items for attitude, and 2 items for practice. These are multiple choice kind of questions. Data were analyzed by MS Excel. **Results:** In this study, 110 students participated. Only 14.55% of students said that generic drugs only be marketed after expiry of patent of innovator drug. Only 27.27% of students said that generic drug manufacturer need not to repeat the preclinical studies and clinical trials as required by innovator medicines. Most of the students (65.45%) know that innovator drugs are more costly than their generic substitute. Only 23.64% of students were aware about the Government of India scheme called Jan Aushadhi whose sole purpose to set up generic drug stores in the country. Just 30.91% of participants know that patients or pharmacists are not legally empowered to sell or purchase generic medicines over innovator medicine. There were a good number of participants (54.55%) not agree with Generic drugs cost less because they are inferior to innovator (patented) drug. About 88.18% of students gave the opinion that there should be a training program to increase the awareness regarding generic drugs among doctors and patients. Nearly 81.82% of students gave the opinion that there should be a generic medicine store at every government hospital. 80% of participants had not read any article regarding the comparison of safety and efficacy of generic versus innovator (patented) drugs. **Conclusion:** This study showed that medical students having good knowledge, attitude about safety, efficacy, and cost of generic medicines. Students know less about government scheme such as Jan Aushadhi. They also support that patients and pharmacist are legally empowered to sell or purchase generic medicine in place of costly innovator medicines. Students also agree with there should be some change in policy by medical insurance company to improve generic drugs prescribing.

KEY WORDS: Generic Medicine; Innovator (Patented) Drug; Jan Aushadhi

Access this article online	
Website: www.njppp.com	Quick Response code
DOI: 10.5455/njppp.2017.7.07199160820171	

INTRODUCTION

Generic drug is identical to a brand name drug in dosage form, safety, strengths, route of administration, quality, performance characteristics, and intended uses. When new drug is generated, the innovator company spends billions of dollars in research and development. Hence, this innovator

company was given patent protection for certain period of time in that time period that company exclusively can sell this new drug. Due to such large expenditure in new drug development, new drugs are costly. However, when patent of a new drug expires, any pharmaceutical company can make a generic version of that new drug. For that, the company has to file abbreviated new drug application to food and drug administration (FDA). It will not require rigorous animal studies and clinical research. Drugs to be marketed as generic medicines should pass from bioavailability and bioequivalence studies. To meet this standard, the FDA requires a demonstration that the 90% confidence intervals for brand-to-generic ratios of the active ingredient's maximum serum concentration (Cmax) and area under the serum concentration over time curve - area under curve (AUC) fall within 0.80-1.25. Generic medicines also require continuous pharmacovigilance study as required by other medicine after marketing. Moreover, Innovator Company had already done the marketing of the new drug, so generic medicine will require less expenditure on marketing. Due to this reasons, generic medicines are cheaper in cost as compare to branded medicines.[1,2]

Health-care expenses are booming nowadays which is out of reach for poor needy people of developing country like India.[3] From this total health-care cost, major portion goes to pharmaceutical expenditure. One solution suggested for this is to promote the use of generic drugs in place of branded drugs. Data said generic drugs save 8-10 billion dollars a year of consumers at retail pharmacies even more billions can be saved when hospital starts using generic medicines. It was noted that 8 out of 10 prescriptions are filled in the USA of generic medicines.[4] In the USA, 86% prescriptions contain generic medicines which saved 1.5 trillion dollars of USA consumers in the past decade.[5] In India, the Medical Council of India (MCI) has taken various steps to increase generic prescribing. In the year 2012, MCI issued circular mentioning every physician as far as possible prescribe drugs with generic names.[6] After all, India is one of biggest generic medicine manufacturers country, but in India itself, generic medicines are less prescribed in comparison to branded medicines.

Previously, studies were carried out on pharmacist and general practitioner to assess knowledge, attitude, and practice of generic medicine among them.[3,7,8] Such study was not done on MBBS students who will be future doctors. Hence, we planned this study with the aim of assessing knowledge, attitude, and practice of medical students toward generic medicines.

MATERIALS AND METHODS

This was a cross-sectional observational study. The study participants were students who were studying in third semester of second year MBBS at our college. This was a questioner-based study which comprised of four sections. Section A contains demographic data of participants, Section B contains 10 questions related to knowledge, Section C of 10 questions related to attitude, and Section D of 2 questions related to practice of generic medicines. All the questions were multiple-choice questions. The study was started after permission of the institutional ethics committee and head of the department. Prior written informed consent was obtained from the participants who want to participate in the study. A pilot study was done on 10 students. There were 110 students who want to participate in the study. Investigator had given questioner to students and recollected after 20 min. Data were analyzed by MS Excel.

RESULTS

In the present study, 110 students were given consent for participation in the study. From this, 50 (45.45%) were males, and 60 (54.55%) were females. Students were studying in the fifth semester of MBBS, and mean age of participants were 19.65 years.

The results showed that 80.91% of students know that generic medicine can be used in place of innovator drug. Only 14.55% of students said that generic drugs only be marketed after expiry of patent of innovator drug. From all participants, 70% knows that generic drug contains same active substance as the innovator drug and 43.73% mentioned that generic drug should be used at the same dose to treat the same disease as innovator medicine. Only 27.27% of students said generic drug manufacturer need not to repeat the preclinical studies and clinical trials as required by innovator medicines. That is one of the reasons why generic drugs are cheaper as compare to innovator drugs. About 60% of students know that generic drug manufacturer should only do bioavailability and bioequivalence studies to demonstrate equivalence between generic and innovator drug. Most of the students (65.45%) know that innovator drugs are more costly than their generic substitute. Only 26.36% of students know that there was a law made by MCI for doctors that every physician as far as possible prescribes a drug with generic names only. Only 23.64% of students were aware about the Government of India scheme called Jan Aushadhi whose sole purpose to set up generic drug stores in the country. Just 30.91% of participants know that patients of pharmacists are not legally empowered to sell or purchase generic medicines over innovator medicine (Table 1).

There were 10 questions related to attitude of participants for generic drug prescribing. Most of the participants disagree that generic drugs are not as effective as innovator medicine (58.18%) and generic drugs are not as safe as innovator medicines (65.45%). Only 30.91% of students disagree with generic drugs have longer duration of action as compare to innovator medicine. Only 30.91% of participants were not agreeing with innovator (patented) drug is made in modern manufacturing facilities and generic drugs are often made

in substandard manufacturing facilities. There were a good number of participants (54.55%) not agree with generic drugs cost less because they are inferior to innovator (patented) drug. Nearly 88.18% of students gave the opinion that there should be a training program to increase the awareness regarding generic drugs among doctors and patients. 81.82% of students gave the opinion that there should be a generic medicine store at every government hospital. Only half of students (49.55%) said that there should be a law which bounds doctors to compulsory prescribe generic medicines when they are available. 40.91% of participants said that medical insurance company should give preference to generic drugs over innovator (patented) drugs while reimbursement of insurance. Majority of participants (64.55%) gave opinion that patients should be legally given freedom to choose generic or innovator (patented) drug (Table 2).

There were few questions related to the practice of generic medicine. 80% of participants had not read any article regarding the comparison of safety and efficacy of generic versus innovator (patented) drugs. 61.82% of students denied prescribing generic medicines over innovator medicines (Table 3).

DISCUSSION

Doctors are professionally responsible for safe, effective, and affordable drugs for patients. For that good knowledge, positive attitude and quality practice of generic medicine are very essential. Hence, this study was planned to assess knowledge, attitude, and practice of generic medicine among second year MBBS students. Similar studies were done on pharmacists and doctors which showed similar results as in our study.[3,7,8]

The results of this study showed that most of the students were aware that generic medicines are substitute of innovator medicines. However, very few know that it can be prescribed after expiry of patent of innovator medicine till it is protected by patent law and doctor can only prescribe innovator medicine.[1]

Most of students were aware that generic medicines have same active drugs and can be used at same doses/for same clinical conditions as their counterpart innovator medicines. Regulatory requirements by government mentioned that generic medicines should not be passed from stringent clinical trials, but they should be passed from bioavailability and bioequivalence studies. In one review, generic medicine approved by FDA between 1996 and 2007 showed only 4.4% difference of average Cmax and 3.6% difference of AUC values between generic and branded medicines, and 98% of these values differed by <10%.[9] Most of the students were not aware about these regulatory requirements. Due to generic drugs have not passed from these clinical trials, there were savings of billions of rupees. Moreover, innovator drugs were already in the market, so generic medicines will require less marketing. Hence, generic medicines are less costly than innovator medicines.[10]

To promote generic medicines availability, the Government of India started Jan Aushadhi scheme which helps in every way to set up generic medicine stores. Moreover, in the year 2016-2017, the Government of India planned to set up 3000 generic medicine stores all over India.[11] The government had issued guidelines for starting generic medicine store.[12] However, in our study, only very few students were aware about such initiative. In India, patients or pharmacists are not legally empowered to sell or purchase generic medicine

Table 1: Generic medicine knowledge related questions and frequency of responses (*n*=110)

Questions	*n* (%)		
	Yes	No	Do not know
1. Can generic drug be used in place of innovator (patented) drug?	89 (80.91)	13 (11.82)	8 (7.27)
2. Can generic drugs only be marketed after the expiry date of innovator (patented) drug?	16 (14.55)	71 (64.55)	23 (20.91)
3. Does a generic drug contain the same active substance(s) as the innovator (patented) drug?	77 (70)	15 (13.64)	18 (16.36)
4. Is a generic drug can be used at the same dose(s) to treat the same disease(s) as the innovator (patented) drug?	48 (43.73)	31 (28.18)	31 (28.18)
5. Does a generic drug manufacturer need to repeat the preclinical studies and clinical trials for generic drugs?	47 (42.73)	30 (27.27)	33 (30)
6. Does generic drug manufacturer need to conduct bioavailability and bioequivalence studies to demonstrate equivalence between generic and innovator (patented) drug?	66 (60)	22 (20)	22 (20)
7. Are generic drugs costlier than innovator (patented) drug?	7 (6.36)	72 (65.45)	31 (28.18)
8. Is there any law in India which states that every physician should, as far as possible, prescribe drugs with generic names?	29 (26.36)	25 (22.73)	56 (50.91)
9. Are you aware of the scheme of Government of India called Jan Aushadhi whose purpose is to set up generic drug stores around the country?	26 (23.64)	35 (31.82)	49 (44.55)
10. Is patient or pharmacist legally empowered to purchase or sell generic drugs in place of prescribed innovator (patented) drug?	42 (38.18)	34 (30.91)	34 (30.91)

Table 2: Generic medicine attitude-related questions and frequency of responses (*n*=110)

Questions	*n* (%)		
	Agree	Disagree	Neutral
1. Generic drugs are not as safe as innovator (patented) drug	21 (19.09)	72 (65.45)	17 (15.45)
2. Generic drugs are not as effective as innovator (patented) drug	11 (10)	64 (58.18)	35 (31.82)
3. Generic drugs have longer duration of action in comparison to innovator (patented) drug	26 (23.64)	34 (30.91)	50 (45.45)
4. Innovator (patented) drug are made in modern manufacturing facilities, and generic drugs are often made in substandard manufacturing facilities	42 (38.18)	34 (30.91)	34 (30.91)
5. Generic drugs cost less because they are inferior to innovator (patented) drug	35 (31.82)	60 (54.55)	15 (13.64)
6. Give your opinion about there should be a training program to increase the awareness regarding generic drugs among doctors and patients	97 (88.18)	3 (2.73)	10 (9.09)
7. Do you think that there should be a generic medicine store at every government hospital?	90 (81.82)	8 (7.27)	12 (10.91)
8. What is your opinion about "there should be a law which bounds doctor to compulsory prescribes generic drugs"?	54 (49.09)	18 (16.36)	38 (34.55)
9. Do you think that medical insurance company should give preference to generic drugs over innovator (patented) drugs while reimbursement of insurance?	45 (40.91)	13 (11.82)	52 (47.27)
10. What is your opinion about patients should be legally given freedom to choose generic or innovator (patented) drug?	71 (64.55)	20 (18.18)	19 (17.27)

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

Question	*n* (%)		
	Yes	No	
1. Have you ever read any article on comparison of safety and efficacy of generic versus innovator (patented) drugs?	22 (20)	88 (80)	
Question	***n* (%)**		
	A	**B**	**C**
2. What is your opinion about prescribing generic drugs over innovator (patented) drug?	39 (35.45)	68 (61.82)	3 (2.73)

in place of branded medicines.[13] A good number of students aware about it and gave opinion that this community should be empowered to purchase or sell generic medicines in place of branded medicines. If such reforms happen, then it will be a great boon to patients that they can have right to purchase less costly generic medicines. Nowadays, in the era of internet, there are websites available on which people can see medicine prices and different brands as well as can place an order online.[14] Hence, patients can compare the cost of medicines and choose medicines according to their affordability.

Generic drugs have same safety, efficacy, and duration of action as their counterpart innovator medicines. Generic drugs should be manufactured by same standard technique as innovator medicines.[10] Previously, doctor's perception about generic medicine is that they are less effective, less safe, and substandard as compare to innovator medicines.[7,15] In our study, most of participants were gave opinion that generic and innovator medicines both same in safety, effectiveness, and manufacturing standards. In India, doctors as well as patients have little less awareness about generic medicines so participants agree with there should be some training session for doctors and patients about awareness of generic medicines. The government hospitals are providing safe, affordable, and effective health-care services to poor and needy patients. Hence, government should take initiative in starting generic drug stores in every government hospitals in India.

In foreign country like the US, generic medicines are more prescribed in comparison to innovator medicines. In this country, health-care facilities are quiet costly, so most of the people have medical insurance. These medical insurance companies time-to-time issue a medicines list, which is used to reimbursed under insurance. This list is mainly containing generic medicine over innovator medicines. According to one report, generic drugs savings in the US in 2014 are 214 billion dollars from this 51% savings from commercially insured patients by medical insurance.[16] The participants in this study also agree that our insurance company should have such policy to promote generic medicine. It is good for patients as well as insurance company.

There are various studies done to promote generic drugs prescribing. In one study, color-coded formulary was given to the physicians which increase 3.3% increase in generic prescribing.[17] In another study, quality information about cost effective and rational use of medicines prepared by university expert were given to physicians and that increase prescribing of generic medicines.[18] The studies done in Michigan and new york showed financial incentive given by medical insurance company for prescribing generic medicine also significantly increase generic prescribing and cost saving by patients as well as insurance company.[19,20] Such kind of information supplying program to physician as well as financial incentive program can be implemented by medical insurance company and employers of doctors can change the scenario of generic medicine prescribing.[21]

This study showed that very few participants have read article about comparing generic medicine to innovator medicines. Hence, there is a great need to improve awareness about generic medicine among patients as well as doctors. Similar results in other study done on general practitioners also.[7]

This study is done on MBBS students, but better study can be planned with patients, lay persons, pharmacists, and medical as well as other branch practitioners.

CONCLUSION

In the developing country, promoting generic drug prescribing in place of innovator medicines can save a significant amount of money. This study showed that medical students having good knowledge, attitude about safety, efficacy, and cost of generic medicines. Students know less about government scheme such as Jan Aushadhi. They also support that patients and pharmacist are legally empowered to sell or purchase generic medicine in place of costly innovator medicines. Students also agree that there should be some change in policy by medical insurance company to improve generic drugs prescribing. Students are very less aware about research article comparing generic medicines to innovator medicines. Hence, awareness session about generic drugs can be planned for pharmacist, patients, and doctors.

REFERENCES

1. Facts about Generic Drugs Infographic; 2016. Available from: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm305896.htm. [Last cited on 2016 Jul 13].
2. Buehler G. History of Bioquivalence for Critical Dose Drugs; 2010. Available from: http://www.fda.gov/downloads/%20AdvisoryCommittees//UCM209319.pdf. [Last accessed on 2015 Jan 27].
3. Jamshed SQ, Hassali MA, Ibrahim MI, Babar ZU. Knowledge attitude and perception of dispensing doctors regarding generic medicines in Karachi, Pakistan: A qualitative study. J Pak Med Assoc. 2011;61(1):80-3.
4. United States Government Accountability Office. SAVINGS An Economical Analysis of Generic Drug Usage in the U.S, GPhA. Washington, DC: United States Government Accountability Office; 2011. p1.
5. Generic Pharmaceutical Association and IMS Institute for Healthcare Informatics. Generic Drug Savings in the U.S; 2013. Available from: http://www.gphaonline.org/media/cms/%20GPhA_Generic_Cost_Savings_2014_IMS_presentation.pdf. [Last accessed on 2015 Jan 27].
6. MCI Circular No. MCI-211(2)(Gen.)/2012-ethics/145183 dated 22/11/2012.
7. Gupta SK, Nayak RP, Vidyarthi SK. A study on the knowledge, attitude, and practice of generic medicines among the doctors in a tertiary care teaching hospital in South India. Natl J Physiol Pharm Pharmacol. 2015;5:39-44.
8. Awaisu A, Kheir N, Ibrahim MI, El-Hajj M, Hazi H, Khudair N, et al. Knowledge, attitudes, and practices of community pharmacists on generic medicines in Qatar. Int J Clin Pharm. 2014;36(2):394-404.
9. Davit BM, Nwakama PE, Buehler GJ, Conner DP, Haidar SH, Patel DT, et al. Comparing generic and innovator drugs: A review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43(10):1583-97.
10. Guidelines for Bioavailability and Bioequivalence Studies, CDSCO. Directorate General of Health Services. New Delhi: Ministry of Health & Family Welfare, Government of India; 2015.
11. 3,000 Generic Drug Stores, Dialysis Centres to Come Up: Jaitley. The Hindu: Mobile Edition; 2016. Available from: http://www.m.thehindu.com/news/national/3000-new-drug-stores-to-come-up-jaitley/article8295815.ece. [Last cited on 2016 Jul 13].
12. Aushadhi J. An Initiative of Government of India, Generic Medicine Campaign Improving Access to Medicines; 2016. Available from: http://www.janaushadhi.gov.in/Guidelines.html. [Last cited on 2016 Jul 13].
13. Hassali MA, Shafie AA, Jamshed S, Ibrahim MI, Awaisu A. Consumers' views on generic medicines: A review of the literature. Int J Pharm Pract. 2009;17(2):79-88.
14. Indian Online Pharmacy. Buy Medicines Online, Fast Delivery; 2016. Available from: http://www.netmeds.com. [Last cited on 2016 Jul 13].
15. King DR, Kanavos P. Encouraging the use of generic medicines: Implications for transition economies. Croat Med J. 2002;43:462-9.
16. Generic Drugs Savings in the US Report. 7th ed. AAM; 2015.
17. Fischer MA, Vogeli C, Stedman M, Ferris T, Brookhart MA, Weissman JS. Effect of electronic prescribing with formulary decision support on medication use and cost. Arch Intern Med. 2008;168(22):2433-9.
18. O'Brien MA, Rogers S, Jamtvedt G, Oxman AD, Odgaard-Jensen J, Kristoffersen DT, et al. Educational outreach visits: Effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2007;4:CD000409.
19. Fuhrmans V. Doctors Paid to Prescribe Generic Pills; 2008. Available from: http://www.online.wsj.com/%20news/articles/SB120114138064112219. [Last accessed on 2015 Jan 27].
20. Insurers Pay Doctors to Push Generic Drugs. Available from: http://www.nysun.com/business/insurers-pay-doctors-to-push-generic-drugs/81992. [Last accessed on 2015 Jan 27].
21. Sarpatwari A, Choudhry NK, Avorn J, Kesselheim AS. Paying physicians to prescribe generic drugs and follow-on biologics in the United States. PLoS Med. DOI: 10.1371.

How to cite this article: Chavda N, Patel NM, Tandel K, Dhanani JV, Solanky P. Study of medical student's perspectives about prescribing generic medicine at tertiary care teaching hospital. Natl J Physiol Pharm Pharmacol 2017;7(10):1116-1120.

Source of Support: Nil, **Conflict of Interest:** None declared.