International Journal of Research in Medical Sciences
Gupta R et al. Int J Res Med Sci. 2018 Apr;6(4):1362-1367
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20181297

Original Research Article

A study on assessment of awareness on generic drugs among doctors in a tertiary care teaching hospital in north India

Rohini Gupta[1]*, Apoorva Malhotra[2], Pavan Malhotra[2]

[1]Department of of Pharmacology and Therapeutics, Government Medical College, Jammu, J & K, India
[2]Department of of Pharmacology and Therapeutics, ASCOMS and H, Sidhra, Jammu, J & K, India

Received: 03 February 2018
Accepted: 06 March 2018

***Correspondence:**
Dr. Rohini Gupta,
E-mail: rohinigupta299@ymail.com

ABSTRACT

Background: The assessment of doctors' perceptions and understanding about generic medicines may help in recognizing the key areas which may act as hurdle to mass scale use of generics. The primary objective of this study was to explore the knowledge, attitude, and practice (KAP) of doctors toward generic medicines.
Methods: A cross-sectional study was carried out using a pretested questionnaire in a tertiary care teaching hospital of Jammu (J and K). The questionnaire was designed to assess the KAP about generic medicines. The doctors working in this institute during the study period were included. Data was compiled and analysed using online website, http://www.graphpad.com. P-values of < 0.05 were considered to indicate statistical significance.
Results: A 62.9% doctors agreed to the fact that generic medicines were intended to be interchangeable with a branded drug (p=0.0139). Among the doctors, 77.5% were aware that generic drug manufacturers need to conduct studies to show bioequivalence between the generic medicine and their branded counterparts (p =0.0001). 88.8% of the doctors agreed that importance of generic medicines should be taught in early part of internship. 80.9% doctors did not think that switching a patient from a brand-name to generic drug may change the outcome of the therapy (p <0.0001).
Conclusion: The present study showed that a good percentage of doctors were well aware of generic medicines' usage. However due to concerns expressed by a certain fraction of participants, further work is needed on how interventions for medical professionals and for the public can lead to increase in the awareness and acceptability of generic medicines.

Keywords: Attitude, Generic medicines, Knowledge, Practice

INTRODUCTION

The rising health-care expenses remain a serious concern for the health-care system worldwide. One of the major components of this increased cost of healthcare related expenses is cost of medicines. Medicines consume major chunk of total money spent on healthcare[1].

As reported by the WHO, in many developing countries out-of-pocket expenses may go up to as high as 80% of total health-care expenditures.[2] Therefore it will be a fruitful exercise to reduce these expenditures to minimum possible levels without affecting quality of health care.

As we aim to cater high-quality health-care system to the masses with limited available resources, increased usage of generic medicines can improve affordability of the health care without compromising the quality.[3] A generic drug is identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. On expiration of the originator product's patent term

protection, other manufacturing companies may file submissions to regulatory authorities for approval to market generic versions of the originator medicine. Generic drugs may be marketed under the non-propriety name or as a branded generic. Branded generic drugs have names derived from a combination of the manufacturer's name and the non-proprietary name. This enables the manufacturer to market the product in a way similar to the proprietary product.[4] Once generic version of the innovator medicine is launched, the price of that medicine decreases substantially, which gives greater access to the larger number of patients.[5]

Promotion of generic medicine is very important for India as well as other developing countries for their healthcare policy. Even though various agencies are promoting generic medicines, they are still under-utilized. Recently government has taken many steps to reduce healthcare cost. Government of India has also started Jan aushadhi stores which are offering affordable health care by offering quality medicines at affordable price.[6]

Thus, promotion of cheaper generic drugs instead of the more expensive branded equivalents could prove beneficial in controlling the total health expenditure. Generic drugs are cheaper in comparison to branded drugs because there is no need to make investments in research and development (R and D) as in the case of new drugs.[7]

However, doctor's viewpoint about generic medicines may pose a decisive hurdle to large-scale usage, culminating in increased health-care expenses. Physicians may favour branded medicines on various accounts. Many doctors may believe that generic medicines are not as effective and safe as their brand-name counterparts. Moreover, generic medicines in the past have been denounced for being below standard mainly due to poor adherence with Good Manufacturing Practice (GMP) guidelines.[8] Many doctors may not be familiar with the rigorous regulations imposed by the regulatory body for proving bioequivalence before a generic medicine is granted approval.[9] Moreover, the practice of bribing doctors by pharmaceutical companies to create more and more prescriptions is not recent in the country as well as world over. The unethical promotional practices being adopted by the companies make the essential medicines unaffordable to common man.[10]

Therefore it is important to know the attitudes and perceptions of physicians regarding use of generics.[11,12] Many studies have shown that compliance of patients on generic drugs was far more better as compared to their brand name counterparts.[13,14] Hence the present study was planned with the intentions to evaluate knowledge, attitude and practices of physicians regarding use of generic medicines and to identify the key areas, which may act as hurdle to mass scale use of generics and provide recommendations to reduce the same.

METHODS

It was a cross-sectional, prospective, questionnaire-based observational study. The study was conducted at Acharaya Shri Chandra College of Medical Sciences and Hospital (ASCOMS and H), Sidhra, Jammu, J and K, India for a period of 1 month in March 2017.

The study was initiated after taking approval from Institutional Ethics Committee (IEC). Doctors (Faculty) of various departments working at the hospital during the study period were included in the study to assess the extent of knowledge, attitude and practice of generic drugs whereas the doctors who were not willing to participate in the study were excluded. Pre-validated self-administered questionnaire was used to collect the data from the respondents.[15,16]

The purpose of the study was explained and written informed consent was obtained from all the participants before being given the questionnaires. The questionnaire designed for this study comprised of 24 questions related to the KAP of generic medicines and about demographic details of the participants. The questionnaire contained eight questions pertaining to knowledge of generic medicine, nine questions eliciting participants' attitude towards generic medicine, and seven questions related to practice of generic medicine.

Data analysis

Data was compiled and analysed using online website, http://www.graphpad.com. P-values of <0.05 were considered to indicate statistical significance.

RESULTS

Demographic characteristics

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

Table 1: Demographic details of the participants (n=89).

Factors		
	Frequency (%)	
Gender	Male	52 (58.4)
	Female	37 (41.6)
Age (years)	<30	13 (14.6)
	30-40	31 (34.8)
	41-50	23 (25.8)
	51-60	15 (16.9)
	>60	7 (7.9)
	Mean age=41.85±11.47	
Qualification	Graduate 21 (23.6)	
	Postgraduate 68 (76.4)	

Knowledge

The knowledge related questions and frequency of response of the participants is shown in Table 2. It is evident from the table that 62.9% doctors agreed that generic medicines were intended to be interchangeably with branded drug (p=0.0139). An 56.2% of the doctors were aware that generic medicines were only marketed after the expiry of the patent period of the innovator drug (p=0.2458); 89.9% doctors had knowledge that composition, dose and indications of generic medicines were same as the branded counterparts (p<0.0001). Among the study participants 58.4% were aware that repetition of preclinical and clinical studies wasn't required for manufacturing generic medicines (p=0.1123). An 88.8% of the participants believed that generic medicines were an important tool to reduce the overall health expenditure (p<0.0001). A 77.75% were aware that generic drug manufacturers need to conduct bioequivalence studies (p<0.0001). An 80.9% of doctors were aware that drugs with generic names should be prescribed by every physician as stated in the Indian Medical council Act (Professional conduct, Etiquette and Ethics) Regulations, 2002 (p<0.0001). An 67.4% participants told that they were aware regarding the Jan Aushadhi Scheme (p=0.0008).

Table 2: Knowledge-related questions and frequency (%) of responses.

Questions	Yes (%)	No (%)	p value
Generic drugs are usually intended to be interchangeably	56(62.9)	33(37.1)	0.0139
Generics only marketed after expiring of patent of innovator drug.	50(56.2)	39(43.8)	0.2458
Composition, dose and indications of generic medicines are same as branded medicine.	80(89.9)	9(10.1)	<0.0001
Preclinical and clinical studies should be repeated for manufacture of generic medicine.	52(58.4)	37(41.6)	0.1123
Overall health expenditure can be reduced by prescribing generic medicines.	79(88.8)	10(11.2)	<0.0001
Generic medicines manufacturers need to conduct bioequivalence studies.	69(77.5)	20(22.5)	<0.0001
Awareness of Indian medical Regulation Act,2002	72(80.9)	17(19.1)	<0.0001
Awareness about 'Jan Aushadhi Scheme' by Govt. of India.	60(67.4)	29(32.6)	0.0008

Table 3: Attitude-related questions and frequency (%) of responses.

Questions	Yes (%)	No (%)	p value
Generics are not as safe as branded drugs.	22(24.7)	67(75.3)	<0.0001
Generics take longer time to act in the body.	11(12.4)	78(87.6)	<0.0001
Generics are often made in substandard facilities as compared to brand name drugs.	32(36.0)	57(64.0)	0.0073
Generic drugs cost less because they are inferior to brand-name drugs.	9(10.1)	80(89.9)	<0.0001
Do you think that there should be a training program to increase the awareness regarding generic drugs among doctors and patients?	83(93.3)	6(6.7)	<0.0001
Do you think that there should be a generic medicine store in every hospital?	82(92.1)	7(7.9)	<0.0001
Generics are meant only for poor.	0(0)	89(100)	<0.0001
Importance of generics should be taught in early part of internship.	79(88.8)	10(11.2)	<0.0001
Quality testing of generics should be made more vigorous.	77(86.5)	12(13.5)	<0.0001

Attitude

From the Table 3 showing the response of the participants towards the use of generic drugs, it is found that 75.3% of the doctors were of the view that generic medicines were safe as that of branded drugs (p<0.0001). 87.6% of the doctors did not agree that generic medicines used to take longer time to act in the body (p<0.0001). 64% of the participants denied that generic medicines were often made in substandard facilities as compared to brand name drugs (p=0.0073). Another 89.9% doctors did not agree that generic drugs cost less because they are inferior to brand name drugs (p<0.0001). An 93.3% agreed that there should be training program to increase the awareness regarding generic drugs among doctors and patients (p<0.0001). An 92.1% doctors said that there should be a generic medicine store in every hospital (p<0.0001). None of the doctors were of the view that generics are meant only for poor. An 88.8% of the doctors agreed that importance of generics should be taught in early part of internship (p<0.0001). An 86.5% of the participants were of the view that quality testing of

generic medicines should be made more vigorous (p<0.0001).

Practice

The practice related questions and the responses of the participants are summarized in Table 4. 86.5% of the doctors said that they prescribed generic medicines (p <0.0001). 27% of the participants did not read any article on comparison of safety and efficacy of generic versus brand name medicines (p <0.0001). A majority 80.9% of the doctors did not think that switching a patient from a brand name to generic medicines might change the outcome of therapy. Most of the doctors 87.6 % said that medical representatives did not influence their prescription. Another 88.8% of the doctors were not comfortable if pharmacists changed branded drugs prescribed by them (p <0.0001). 19.1% of the doctors prescribed branded drugs because their names were easy to memorize (p <0.0001).64% of the doctors said that the demand of the patient did not influence their prescription (p= 0.0073).

Table 4: Practice-related questions and frequency (%) of responses.

Questions	Yes (%)	No (%)	p value
Do you prescribe generic medicines?	77(86.5)	12(13.5)	<0.0001
Have you any time read any article on comparison of safety and efficacy of generic vs brand name medicines.	65(73)	24(27)	<0.0001
Switching a patient from a brand name to generics may change the outcome of therapy.	17(19.1)	72(80.9)	<0.0001
Do medical representatives influence your prescription?	11(12.4)	78(87.6)	<0.0001
Are you comfortable if pharmacists change branded drugs prescribed by you	10(11.2)	79(88.8)	<0.0001
You prescribe branded drugs because their names are easy to memorize.	17(19.1)	72(80.9)	<0.0001
Patients demands influence your prescription.	32(36)	57(64)	0.0073

DISCUSSION

According to the present analysis, good percentage of doctors had knowledge about generic medicines and they had good attitude about the efficacy, safety, and quality of generic medicines; majority of them said that they prescribe generic medicines. These findings are similar to that of Bhattachargee P et al.[15] Majority of the participants had knowledge that generic medicines are intended to be interchangeable with a branded drug which is in accordance with finding of Davit BM et al.[17] Significantly high number of doctors about 77.5% of the participants were aware that generic drug manufacturers need to conduct bioequivalence studies which is contrary to the finding (63.2%) of Badwaik RT et al.[18]

Significantly high number of doctors agreed that generic drugs are an important tool for reducing overall health expenditure. Indeed, lower price is the major boon for generic drugs. In Indian context, the cost of generic drugs has been found to be up to 91% less than that of the innovator medicine.[5] Hence, widespread use of generic drugs has the potential to reduce the price of other brand-name drugs by creating more competition. But the fact that generic drugs need not have to go through the large and costly clinical trials that are required for approval of innovator medicines, ultimately leading to lower price of generics, may raise doubt about their efficacy, safety, and quality.[19] But in this study, majority of physicians were found to be comfortable with the efficacy and safety of generic medications in spite of knowing that generic drug manufacturer need not repeat the preclinical and clinical studies required for originator medicines. As a matter of fact there are no ample proofs that generic drugs are less safe or less effective than their brand-name counterparts. Moreover, when a generic-drug product is granted approval, it has fulfilled strict regulations required by the regulatory body with respect to identity, strength, quality, purity, and potency.

The regulatory body appraises the manufacturer's compliance to the GMP guidelines before the drug is marketed, and the manufacturer need to give detailed information about the facilities it uses for production, packaging, labelling, among others, of the generic drug.[19,20] In this study, majority of doctors did not agree that generic drugs are made in substandard manufacturing facility. Majority of the doctors were found to have a greater trust in generic drugs and they prescribed them to a greater degree.

In the present study, about 92.1% of the participants have a view that every hospital should have a generic medicine store and patient should have the liberty to choose generic medicines over branded drugs. Interestingly, there should be a training programme among doctors and patients to increase the awareness regarding generic medicines. Also, most of the participants believe that in early part of internship importance of generic medicines should be taught. In this study majority believe that quality testing of generic medicines should be made more vigorous which is similar to the finding of another

study.[18] About 67.4% of participants were aware of Jan Aushadhi scheme of Govt. of India whose purpose is to set up generic drug stores around the country which is contrary to the finding of Badwaik RT et al.[18]

A major chunk of participants believe that they prescribe branded drugs because their names are easy to memorize which is similar to the finding of another study.[18] Therefore, generic medicine guidelines should be disseminated to the physicians so that they feel more assured about its usage, ultimately leading to an increase in prescribing generic medicine.[21] However, most of the participants think that switching a patient from a brand name drug to generic drug does not change the outcome of the therapy which is similar to the finding of another study.[16] The assumptions about the decreased quality of generics could be eliminated by continuing medical education of physicians about drug discovery, development, and regulations.[10,22]

The major limitation of this study is the small sample size. Hence, findings of this study cannot be generalized. Another limitation is that we have only analyzed the doctor's perception and understanding about generic medicines. It would be appropriate to also know the opinion and level of understanding of pharmacists and patients about generic medicines.

CONCLUSION

Although good percentage of doctors had good knowledge and attitude about generic medicines but there was a meaningful proportion who expressed concerns about them. Further work is needed on how interventions for medical professionals and for the public can lead to increase in the awareness and acceptability of generic medicines.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Bakthavathsalam G. Generic drugs: cost effective alternative to branded drug, Health Administrator. 2006;19:16-19.
2. 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;61:80-3.
3. Jamshed SQ, Ibrahim MIM, Hassali MA, Masood I, Low BY, Shafie AA, et al. Perception and attitude of general practitioners regarding generic medicines in Karachi, Pakistan: a questionnaire-based study. Southern Med Rev. 2012;5(1):22-30.
4. King DR, Kanavos P. Encouraging the use of generic medicines: implications for transition economics. Croat Med J. 2002;43(4):462-469.
5. Lopes Gde L. Cost comparison and economic implications of commonly used originator and generic chemotherapy drugs in India. Ann Oncol. 2013;24(Suppl 5):v13-6.
6. Bhowmick S. India's Cheap Generic Drug Effort Hits roadblock. Available at http://www.indiaspend .com/sectors/indias-cheap-generic-drug-effort-hits-early-roadblocks.
7. Dadhich A, Upadhyaya M. A review: exploring branded generic drugs by Indian pharmaceutical multinational companies as a new prospect. Pharmacophore. 2011;2(6):271-5.
8. King DR, Kanavos P. Encouraging the use of generic medicines: implications for transition economies. Croat Med J. 2002;43:462-9.
9. Steinman MA, Chren MM, Landefeld CS. What's in a name? Use of brand versus generic drug names in United States outpatient practice. J Gen Intern Med. 2007;22:645-8.
10. Singhal GL, Kotwani A, Nanda A. Jan aushadhi stores in India and quality of medicines therein. Int J Pharmacy Pharm Sci. 2011;3(1):204-7.
11. James H, Handu SS, Al Khaja KA, Otoom S, Sequeira RP. Evaluation of the knowledge, attitude and practice of self-medication among first-year medical students. Medical principles practice. 2006;15(4):270-5.
12. Sontakke SD, Bajait CS, Pimpalkhute SA, Jaiswal KM, Jaiswal SR. Comparative study of evaluation of self-medication practices in first and third year medical students. Int J Biol Med Res. 2011;2(2):561-4.
13. Shrank WH, Hoang T, Ettner SL, Glassman PA, Nair K, DeLapp D, et al. The implications of choice: prescribing generic or preferred pharmaceuticals improves medication adherence for chronic conditions. Archives Inter Med. 2006;166(3):332-7.
14. Briesacher BA, Andrade SE, Fouayzi H, Chan KA. Medication adherence and the use of generic drug therapies. Am J managed care. 2009;15(7):450.
15. Bhattacharjee P, Das L, Ghosh R, Das UK, Chakraborty M. Knowledge, attitude and practice of generic medicines among doctors in a tertiary care teaching hospital of Tripura, India. Int J Basic Clin Pharmacol. 2017;6:1287-92.
16. 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. National J Physiology, Pharm Pharmacol. 2015;5(1):39-44.
17. 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 Pharm. 2009;43:1583-97.

18. Badwaik RT, Chopade SS, Mahajan HM, Honrao R. Prescribers Views on Generic Medicines: A Study on Knowledge, Attitude and Practice. J Cont Med A Dent. 2015;3(2):27-32.
19. Lewek P, Kardas P. Generic drugs: the benefits and risks of making the switch. J Fam Pract. 2010;59:634-4.
20. Gupta PB. Survey of pharmacists: impact of the generic drug scandal and implications for marketing generic drugs. Health Mark Q. 1996;13:109-20.
21. Shrank WH, Liberman JN, Fischer MA, Girdish C, Brennan TA, Choudhry NK. Physician perceptions about generic drugs. Ann Pharmacother. 2011;45:31-8.
22. Sharrad AK, Hassali MA, Shafie AA. Generic medicines: perception of physicians in Basrah, Iraq. AMJ. 2009;1(8):58-64.

Cite this article as: Gupta R, Malhotra A, Malhotra P. A study on assessment of awareness on generic drugs among doctors in a tertiary care teaching hospital in north India. Int J Res Med Sci 2018;6:1362-7.