

Knowledge and attitude of MBBS undergraduate students for use of generic medicines at a tertiary care hospital

Aruna Gurung¹, Ujwala P. Gawali^{2,*}

¹Assistant Professor, ²Professor and Head, Dept. of Pharmacology, Dr. V.M. Govt. Medical College, Solapur, Maharashtra, India

***Corresponding Author:**

Email: ujwalapgawali@gmail.com

Abstract

Introduction: The cost incurred on medicine is one of the major concerning components of health expenditure. Prescription of generic drugs, can reduce the costs without reducing the quality of treatment. Hence this study is being taken to explore knowledge and attitude of MBBS undergraduate students for use of generic medicine, who are the future prescriber of generic medicines.

Materials and Methods: A questionnaire based cross-sectional, observational study was carried out in II, III and final year MBBS students of Dr. V.M. Govt. Medical College Solapur, from 1st March 2018 to 31st May 2018. A 20 item multiple choice questionnaire consisting of knowledge (10) and attitude (10) was distributed to the participants.

Result: 45.62% agreed that generic medicines are usually intended to be interchangeable with the innovator drugs. Among the participants, 73.73% were aware that generic drug manufacturers need to conduct studies to show bioequivalence between the generic medicine and their branded counterparts. Majority of the participants (66.36%) were of the view that generic medicines were as safe as that of branded drugs. 93.55% of the participants agreed that importance of generic medicines should be taught in early part of the MBBS period.

Conclusion: The present study showed that participants had good amount of knowledge and positive attitude regarding generic medicines. In order to provide safe and effective treatment to the community and decrease the cost of healthcare delivery system, the number of generic medicine prescription should be increased. Hence, workshops and CME on generic medicines should be organized and more time should be dedicated to generic medicine lectures during the MBBS period.

Keywords: Generic medicines, MBBS students, Knowledge, Attitude.

Introduction

World Health Organization (WHO) reports that nearly 80% of total health care expenses are shared by out-of-pocket payments. The Indian Government spends just 1.2 percent of the GDP on the health sector, which is amongst the lowest in the world.¹ The cost incurred on medicine is one of the major concerning components of health expenditure. Prescription of generic drugs, when clinically appropriate can reduce the costs without reducing quality.²

A brand name drug is a medicine that is discovered, developed and marketed by a pharmaceutical company. The brand name manufacturers are rewarded for this investment with a patent—a time during which no other manufacturer can produce the drug. The price set by the brand name manufacturer depends on the money spent in research and development. Once patent expires, the generic drug companies are free to manufacture and sell the drug provided that the generic version of the new drugs is bioequivalent to the innovator brand name drugs. The US Food and Drug Administration (FDA) and European regulations consider the products to be bioequivalent if the mean maximum concentration achieved, the time at which that concentration is achieved, and the area under the concentration–time curve for the generic product falls within 80%–125% of the innovator or branded product, when administered under a fed or fasting state.³

Hence we can infer that generic drugs are efficacious, safe and are of same quality as their brand counterparts, but various studies have shown low prescription of generic medicines in India.⁴ Even though the Government of India had undertaken schemes like the Pradhan Mantri Bhartiya Jan Aushadhi Pari Yojana Kendra (PMBJPK) campaign to provide generic drugs to the patients still the rate of generic medicine prescription has not increased much.⁵ Recently, CDSCO (central Drug standard Control Organization) has also issued an order to provide a shelf or rack for generic medicines in every retail shops across the country hoping to increase the utilization of generic medicines.⁶

But still the major role for generic medicine prescription lies in the hands of the prescribers. The prescribers may have wrong notion that the generic medicines are not as effective and safe as their brand-name counterparts which have led to lower confidence in prescribing generic medicines. Moreover, generic medicines in the past have been denounced for being below standard mainly due to poor adherence with Good Manufacturing Practice (GMP) guidelines.⁷ The scenario has now changed but still 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.⁸

Therefore, a better understanding of generic medicines during the early years of doctors training may change the perception and bring a revolution in the

field of generic drug usage. Despite being a prolific prescriber of the future MBBS students are least explored groups. Hence this study is being taken to explore knowledge and attitude of MBBS undergraduate students for use of generic medicine at a tertiary care hospital of Solapur, Maharashtra, India.

Aims and Objectives

To assess the knowledge and attitude of generic medicines among MBBS students in a tertiary care teaching hospital of Solapur, India.

Materials and Methods

A questionnaire based cross-sectional, observational, study was carried out in II, III and final year MBBS students of Dr. V.M. Govt. Medical College Solapur, Maharashtra from 1st March 2018 to 31st May 2018 after taking approval from the Institutional Ethics Committee. Those who were willing to participate were included in the study. A 20 item multiple choice questionnaire consisting of knowledge (10) and attitude (10) was prepared and validated for the study. A written informed consent was obtained from the participants before starting the study. The time provided for solving the questionnaire was 30 minutes. Any clarification needed in understanding the questionnaire was provided.

Data Analysis

The data was filled in Microsoft excel sheet and percentage were calculated.

Results

A total of 217 M.B.B.S students participated in the study. Response rate was 100%.

Knowledge about generic medicines

211 (97.24%) participants had heard about generic medicines, but only 110 (50.69%) of the participants knew that generic name of the drug and generic drugs are different.

About 99 (45.62%) of the participants agreed that generic medicines were intended to be interchanged with the brand name drugs. Among the participants 122 (56.23%) were aware that generic medicine contains the same active substances as the innovator medicine and it is used at the same doses to treat the same diseases. Only 41(18%) of the participants were aware that repeat repetition of preclinical and clinical studies were not required for manufacturing the generic medicine while majority [137 (63.13%)] of the participants thought that the preclinical and clinical tests are required. 193 (88.94%) believed that generic medicines were important tool for reducing the overall health care expenditure. 160 (73.73%) were aware that bioequivalence studies must be conducted by the generic drug manufacturers. Many participants had misconception about the manufacturing process of generic medicine as 100 (46.08%) thought that generic medicine are manufactured in substandard facilities and brand name drugs are made in modern manufacturing facilities. 142 (65.44%) participants knew that according to the Indian Medical Council Act (Professional conduct, Etiquette and Ethics) Regulations 2002, every physician should prescribe as far as possible, drug with generic name. About 143 (65.9%) of the participants were aware about Jan Aushadi scheme of the government of India whose purpose is to set up generic drug stores around the country. Knowledge related questionnaire and their responses have been summarised in (Table 1).

Table 1: Knowledge of MBBS undergraduate students towards the use of generic medicines

S. No.	Knowledge based Questionnaire	Yes (%)	No (%)	Don't Know (%)
1	Have you heard about generic medicines?	211(97.24)	6(2.76)	0
2	Generic medicines and generic name of the drugs are same and can be used interchangeably.	61(28.11)	110(50.69)	46(21.2)
3	Generic medicines are usually intended to be interchangeable with its innovator drug (newly developed drug)?	99(45.62)	58(26.73)	60(27.65)
4	A generic medicine contains the same active substance(s) as the innovator medicine, and it is used at the same dose(s) to treat the same disease(s) as the innovator medicine.	122(56.23)	51(23.5)	44(20.27)
5	Generic medicines manufacturer need to repeat the preclinical and clinical studies required for originator medicine	137(63.13)	41(18.9)	39(17.97)
6	Generic medicine are an important tool for reducing an overall health expenditure	193(88.94)	13(5.99)	11(5.07)
7	Generic medicines manufacturers need to conduct bioequivalence studies to demonstrate equivalence between the generic medicine and the innovator medicine.	160(73.73)	25(11.53)	32(14.74)
8	Brand name drugs are made in modern manufacturing facilities, and generic medicines are often made in substandard facilities.	100(46.08)	88(40.56)	29(13.36)
9	Indian Medical Council Act(Professional conduct, Etiquette and Ethics) Regulations,2002 states that every physician should, as far as possible, prescribe drugs with generic names	142(65.44)	32(14.74)	43(19.82)

Overall knowledge about generic medicine is 60.32%

Attitude towards generic medicines

Majority of the participants [144 (66.36%)] were of the view that generic medicines were as safe as that of branded drugs. 133 (61.29%) participants felt that generic drugs are as effective as the innovator drugs. 91 (41.94%) of the participants agreed that the onset of action of generic drug is same as that of the innovator drug. Almost all the participants [199 (91.71%)] believed that there should be a generic drug store in every hospital. 162 (74.65%) of the participants agreed that prescribing generic medicine should be made compulsory in a tertiary care hospital.

Majority of the participants [187 (86.18%)] thinks that the patient should have liberty to choose generic medicine over brand name drugs. Almost half of the participants [113 (52.07%)] felt that incentives should be paid to the doctors for prescribing generics. 203 (93.55%) of the participants agreed that the importance of generics should be taught in early part of doctors training. 200 (92.17%) believed that confidence should be built in patients to use more generics. Almost all the participants [207 (95.39%)] thinks that a national level generic online reference should be made available. Attitude based questionnaire and their responses have been summarised in (Table 2).

Table 2: Attitude of the MBBS students towards the use of generic medicines

S. No	Attitude based questionnaire	Yes	No	Don't Know
1	Generics are not safe as innovator drugs.	32(14.75)	144(66.36)	41(18.89)
2	Generics are not effective as innovator drugs.	42(19.36)	133(61.29)	42(19.35)
3	Generics have slower onset of action compared to innovator drugs.	60(27.65)	91(41.94)	66(30.41)
4	Do you think there should be generic drug store in every hospital?	199(91.71)	16(7.37)	2(0.92)
5	Prescribing of generic medicines should be made compulsory in a tertiary care hospital.	162(74.65)	55(25.35)	0(%)
6	Patient should have liberty to choose generic medicine over brand drugs.	187(86.18)	30(13.82)	0(%)
7	Incentives should be paid to the doctors for prescribing generics.	113(52.07)	104(47.93)	0(%)
8	Importance of generics should be taught in early part of doctors training.	203(93.55)	14(6.45)	0(%)
9	Confidence should be built in patients to use more generics.	200(92.17)	17(7.83)	0(%)
10	National level generic online reference should be made available	207(95.39)	10(4.61)	0(%)

Discussion

Cost of prescription is an important concern and it accounts for major health care expenditure that attributes to most of the health care systems in the world. Around one third of the global population encounter difficulties in accessing medicines due to high price, whereas 50% of the Indians are facing this problem.¹ Prescription of generic drugs may bring down the cost of health care system. Since MBBS students are the future prolific prescriber of the drugs, a better understanding of generic medicines in them may change the perception and bring a revolution in the field of generic drug usage. Hence to assess the knowledge and attitude of MBBS students about generic medicines this study was conducted.

In our study majority of the participant had a good knowledge and good attitude about the efficacy, safety and quality of generic medicine. The participating students were aware that the generic medicines contain the same active component as the innovator drugs and hence can be used interchangeably. The findings were similar to that of Todkar et al.¹

Majority of the participants had less knowledge about the fact that repeat preclinical and clinical test are not needed for marketing the generic medicines but many (73.73%) participants knew that bioequivalence studies are essential and should be performed by the generic marketing company. Similar findings were also noted by Badwik et al.⁴

Another interesting observation was that the participants were quite aware (88.94%) regarding the reduction in overall health expenditure by the use of generic medicine. It has been seen that on an average, the cost of a generic drug is about 20-80% lower than that of brand name drugs. Hence a good knowledge regarding the cost reduction by use of generic drug was seen in our study.

Around 46.08% thought that generic medicines are often made in substandard facilities and brand name drugs are made in modern manufacturing facilities. This misconception amongst the participants might be due to the lower cost of the generic medicine. The low cost of generic medicine is because the generic manufacturers are not needed to repeat the costly preclinical and clinical trials and multiple generic companies are often approved to market the single product which creates competition in the market place.

These facts should be taught to the MBBS students by continuing the medical education about drug discovery, development, and regulations early in their course.

About 65.44% participants knew that Indian Medical Council Act (Professional conduct, Etiquette and Ethics) Regulations 2002, states that every physician should as far as possible prescribe drugs with generic names. Prescribing drugs in generic names will reduce the confusion among patients and medication errors. Similarly in the study conducted by Badwik et al

68% participants knew about the Indian Medical Council Act Regulation 2002.⁴

Around 65.9% of the participants knew about the Jan Aushadi Scheme whose purpose is to set up generic drug stores around the country. Since the aim of the Jan aushadi Scheme is to make the generic medicine available to the patients Government agencies must make it a point to organize various programs on a mass scale to increase its awareness.⁵

Regarding the attitude, 66.36% of the participants were of the opinion that generic medicine is as safe as brand name drugs. Around 61.29% thought that generic medicines are effective as brand name drugs. But 60% believed that brand name drugs have faster onset of action compared to the generic drugs. Other studies have shown a higher percentage of participants who believed that generic medicines are as safe and as effective as brand name drugs and less percentage of participants who believed that generic drugs have same onset of action as compared to the innovator drugs.^{2,9}

Majority of the participants thinks that a generic drug store should be established by every hospital and prescription of generic medicine should be made compulsory in a tertiary care hospital. Opening of generic drug stores will be a great support to the sale of generic drugs in domestic market and thus would benefit consumers. Also making the prescription of generic medicine compulsory, may change the behaviour and beliefs of prescribers towards generic substitution.

The participants also think that patient should have the liberty to choose generic medicine over brand name drugs. Since the patient comes from different economic background a cafeteria approach should be made to minimize the economic constraints and thus improve the compliance of the patient. Other studies have also shown similar findings.²

Almost 52.07% of the participants think that incentive should be paid to the doctors for prescribing generic medicine. But almost all the participants thinks that teaching the importance of generic medicine in early part of training and building the confidence of patients in using generic medicine may be more fruitful. Hence educating the prescribers and the patient about generic medicine may in the long run benefit the generic drug prescription.

Conclusion

The present study shows that participants had good amount of knowledge and positive attitude regarding generic medicines. In order to provide safe and effective treatment to the community and decrease the cost of healthcare delivery system, the number of generic medicine prescription should be increased.

Hence, workshops and CME on generic medicines should be organized and more time should be dedicated to generic medicine lectures during the MBBS period.

Conflict of Interest: Non declared

Source of Support: Nil

Ethical Permission: Obtained

References

1. Todkar SL, Tiwari SA, Ghongane BB. A Study of Knowledge, Attitude and Practice of Generic Drugs among General Practitioners of Pune Region. *IOSR-JDMS*. 2017;16:1-9.
2. Bhattacharjee P, Das L, Ghosh R, Das UK, Chakraborty M. 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.
3. FDA. Therapeutic Equivalence of Generic Drugs: Letter to Health Practitioners. Available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm073182.ht>. Accessed on August 06, 2018.
4. 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;3:27-32.
5. "Jan Aushadhi: An Initiative of Government of India | Generic Medicine Campaign Improving Access to Medicines". *janaushadhi.gov.in*. Accessed on August 06, 2018.
6. CDSCO. Letter regarding providing a separate shelf/rack for generic medicine in retail shops visible to the consumers. Available at [cdsco.nic.in /forms /list.aspx ?lid =2028 &Id=31](http://cdsco.nic.in/forms/list.aspx?lid=2028&Id=31). Accessed on August 06, 2018.
7. King DR, Kanavos P. Encouraging the use of generic medicines: implications for transition economies. *Croat Med J*. 2002;43:462-9.
8. 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.
9. Gupta SK, Nayak RP, Vidyarthi SK. Study on the Knowledge, Attitude, and Practice of Generic Medicine among the doctors in a tertiary care teaching hospital in South India. *NJJP*. 2015;5:39-44.