

RESEARCH ARTICLE

A cross-sectional study to compare knowledge and perception of generic medicine among medical students at a tertiary care center

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ABSTRACT


Background: Prescribing generic medicine is still a debatable issue among prescribers and the issues of bioequivalence, quality, and safety remain problem areas. The perception that generic medicines are inferior to brand medicine can be eradicated by educating medical students who are the future prescribers. **Aim and Objective:** The correct knowledge of generic medicine among students will enhance the prescribing of low cost and effective medicines. Therefore, this study was conducted to analyze the knowledge and perception of generic medicines among undergraduates (UG), interns, and postgraduate (PG) students in a medical teaching institute. **Materials and Methods:** A questionnaire-based cross-sectional study was conducted among 230 medical students (145 UG, 50 interns, and 35 PG) in Uttar Pradesh University of Medical Sciences, Saifai, to assess knowledge and attitude of students for generic medicines. Chi-square test was used to analyze results. **Results:** About 98% of UG and interns and 100% of PG students were aware of generic medicines. Awareness of Jan Aushadhi Scheme is substantially poor in UG students as compared to interns and PG ($P < 0.001$). About 86% of student considered generic medicine of low cost, less effective (30%), poor quality (34%), and having more side effects (38%) as compared to branded medicine. Students believe product bonuses (28%) and advertisement (38%) by pharmaceuticals will alter their prescribing patterns in the future. About 71% of students ($P < 0.001$) consider that it is easier to remember a generic name and 89% of students ($P < 0.001$) wish to have further information regarding generic medicine in their medical curriculum. **Conclusion:** Medical students lack comprehensive knowledge and carry erroneous impressions for generic medicine. There is a need for more emphasis regarding generic medicine in UG medical curriculum. This will augment rational prescribing and cost-effective use of generic medicine in the future.

KEY WORDS: Bioequivalence; Brand Medicine; Cost-Effective; Generic Medicine; Rational Prescribing

INTRODUCTION

Generic medicine, as defined by World Health Organization, is “a pharmaceutical product, usually intended to be interchangeable with an innovator product that is

manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.”^[1] Generic medicine is cheaper and similar to its corresponding brand medicine in terms of dosage form, route, efficacy, safety, and indication for use and quality.^[2] It is estimated that worldwide, drugs worth \$ 150 billion will be off patented in this decade, and generic drugs for the same will be developed by the companies. Increasing medicine and health care costs are a challenge all over the world. The pharmaceutical industry for generic drugs has shown amazing growth in India. In India, government agencies fix the retail price of essential medicines to curb the increasing cost of treatment. A better approach to control the increased

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health-care expense will be the promotion of generic medicine use as compared to controlling the market price of drugs.^[3] The prescription of generic medicines by doctors and more awareness of generic drugs among patients is the need of the hour. Recently, Government of India has also started Jan Aushadhi stores which are offering affordable health care by offering quality medicines at affordable prices.^[4] Escalating health-care costs also necessitates to include knowledge of generic medicine and rational use of medicine in medical curricula being imparted to the medical students during their graduate studies.

Generic medicines need to follow the principle of bioequivalence so that their use is effective and safe. Bioequivalent is defined as two medicinal products are bioequivalent if their bioavailability (rate and extent of availability) after administration in the same molar dose is similar to such a degree that their effects, with respect to both efficacy and safety, are same. When two medicinal products having the same active substance, used in the same amount and dosage form using the same route of administration meet comparable standards, they are said to be pharmaceutically equivalent.^[5] If generic medicine establishes bioequivalence to brand medicine, it precludes performing pre-clinical and clinical testing and the drug can be released in the market. Many doctors do not favor generic medicines and consider them as ineffective, unsafe, and inferior to the corresponding innovator drug. Moreover, generic medicines are criticized for being of poor quality as they are not manufactured following good manufacturing practice guidelines.^[6] On the contrary, many doctors are not unaware of the fact that even generic medicines have to follow strict guidelines of regulatory bodies and have to prove bioequivalence before acquiring approval for product sale.^[7,8]

Prescribing generic medicine is still a debatable issue among prescribers and the issues of bioequivalence, quality, and safety create hindrance in changing their prescribing habit. Studies have shown that it is difficult to alter the established prescribing pattern among health-care professionals.^[9] The belief that generic medicines are of poor quality can be reduced by educating practicing physicians and training students during the graduation phase about drug discovery, development, and regulations.^[10] A potential reason for the lack of adequate knowledge among medical students may be insufficient exposure to the concept of generic medicines during the teaching and training period, which affects their future prescribing practice.^[11] Several studies have been conducted to assess the knowledge and perception of generic medicines among pharmacists, public, and medical professionals.^[12] The previous study conducted in Australia found that more information is required to be delivered to medical students about generic medicines and generic prescribing.^[13] Similarly, study conducted on medical students in Iraq revealed lack of understanding for bioequivalence, quality, and safety of generic medicines.^[14] Further, a comparison between medical

and pharmacy students showed a lack of understanding and modest level of perception about generic medicine.^[15] Hence, medical students need appropriate education and training in prescribing generic medicine so as to influence their future prescribing pattern. Since, medical students will be prescribing drugs in future and will play an important role in promoting generic medicine, this study was carried out to evaluate the knowledge and perception of undergraduates (UG), students undergoing internship, and postgraduate (PG) medical students of a tertiary care institution in India about the generic medicine and generic prescribing.

MATERIALS AND METHODS

This questionnaire-based cross-sectional study was conducted on UG and PG students and students pursuing an internship at UP University of Medical Sciences, Saifai, after attaining approval from the Institutional Ethics Committee. A pre-validated questionnaire from the previous study was modified and used to collect information.^[13] The purpose of the study was explained and written informed consent was obtained from all the participants before being given the questionnaires. The questionnaire comprised four sections where section one consisted of knowledge about generic medicines, and the second section consisted of knowledge about quality, safety, and efficacy of generic medicine versus branded medicine. Third section carried questions related to knowledge and perception of generic equivalents and fourth part consisted of perception of students about generic medicines. Responses such as yes and no were considered as point descriptors. The questionnaire was tested among 145 UGs, 50 interns and 35 PGs students of the institution. Data were collected and analyzed using SPSS IBM version 23. A Chi-square test was used for analysis and $P < 0.05$ was considered statistically significant.

RESULTS

Out of 230 medical students (145 UGs, 50 interns, and 35 PGs), all the students completed the study, a response rate of 100%. The first question asked was whether generic medicine can be considered to be bioequivalent to the brand medicine if the mean area under the curve and the relative mean C_{max} lies within 90% confidence interval. The correct answer was 80–125% and five closely related options were given for response. Among UGs, 29 (20%) answered the question correctly, 35 (24.14%) did not attempt the question; almost two-third of UG students did not know the correct answer. Among interns, 37 (74%) and PG students 19 (54.29%) answered correctly Table 1. Chi-square test showed a statistically significant difference for the knowledge among groups ($P < 0.001$).

Responding to the question on awareness of Jan Aushadhi scheme, 80 UGs (55.17%), 25 interns (50%), and 28 PGs

(80%) answered correctly, with the significant difference among three groups ($P < 0.05$). Response to the question about quality, safety, and efficacy of generic medicine as compared to brand medicine by medical students and interns is shown in Table 2.

A large number of participants were unaware that generic medicine and brand medicine must have the same dosage form, and the difference in response was significant among these groups ($P < 0.0001$). All the participants believed that generic medicines are costly, of substandard quality, and carry more side effects than branded counterparts ($P < 0.0001$). In response to the question assessing knowledge and perception of generic medicines, majority of the students (64%)

believed that all generic product of a particular medicine is therapeutically equivalent to each other ($P < 0.05$), as shown in Table 3. About 89% of medical students responded that they need more understanding on tests and methods used for proving generic medicines as bioequivalent ($P < 0.0001$).

Response to the question on student's perceptions about generic medicines is shown in Table 4. About 54% of students had doubtful view about generic medicines ($P < 0.05$). The majority of the students (91%) said that generic medicines are less safe and efficacious and require more information on efficacy and safety of generics. About 71% of students believed that generic names allow them to remember medicine's therapeutic class as compared to brand name ($P < 0.0001$).

Table 1: Response by students, interns, and postgraduates to the question on bioequivalence and Jan Aushadhi scheme of Government of India

Questions	Options	UG (%) <i>n</i> =145	Intern (%) <i>n</i> =50	PG (%) <i>n</i> =35	Overall %
A generic product is considered to be bioequivalent to the pioneer product if the 90% CI of the mean AUC and the relative mean C_{max} is	80–120	32 (22.07)	2 (4)	5 (14.29)	17
	80–125	29 (20)	37 (74)	19 (54.29)	37*
	90–120	21 (14.48)	8 (16)	4 (11.43)	14.34
	95–100	22 (15.17)	2 (4)	3 (8.57)	12
	95–105	6 (4.14)	2 (4)	4 (11.43)	5.20
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	Yes	UG (%)	Intern (%)	PG (%)	<i>P</i> -value
		80 (55.17)	25 (50)	28 (80)	0.012

* $P < 0.0001$. AUC: Area under the curve, CI: Confidence interval

Table 2: Knowledge of quality, safety, and efficacy of generic medicine versus brand name medicine among medical students

Questions	UG (%) <i>n</i> =145	Intern (%) <i>n</i> =50	PG (%) <i>n</i> =35	<i>P</i> -value
A generic medicine is bioequivalent to a brand name medicine	125 (86.21)	45 (90)	30 (85.71)	0.768054
Generic medicine must be in the same dosage form as the brand name medicine	70 (48.28)	17 (34)	27 (77.14)	0.000412
Generic medicine must be the same dose as the brand name medicine	109 (75.17)	12 (24)	27 (77.14)	0.00001
Generic medicines are of inferior quality to branded medicine	44 (30.44)	14 (28)	20 (57.14)	0.006635
Generic medicines are less effective than brand medicine	40 (27.59)	19 (38)	11 (31.43)	0.382193
Generic medicine produce more side effect than brand medicine	37 (25.52)	27 (54)	5 (14.29)	0.000067
The cost of generic medicine is considerably lower than brand medicine	129 (88.97)	36 (72)	32 (91.43)	0.00734
Brand name medicines are required to meet higher safety standards than the generic brand	63 (43.45)	21 (42)	15 (42.86)	0.983933

Table 3: Knowledge and perception about generic equivalents among undergraduate students, interns, and postgraduate students

Questions	UG (%) <i>n</i> =145	Intern (%) <i>n</i> =50	PG (%) <i>n</i> =35	<i>P</i> -value
All generic product of a particular medicine that is rated as generic equivalent is therapeutically equivalent to the innovator brand product	82 (56.55)	29 (58)	22 (62.86)	0.794359
All generic product of a particular medicine that is rated as generic equivalent is therapeutically equivalent to each other	99 (68.23)	24 (48)	25 (71.43)	0.022768
I have not been introduced to this issue of bioequivalence for generic drugs during my pharmacy education	42 (28.97)	21 (42)	18 (51.43)	0.023238
I need more information on how bioequivalence tests are conducted for generic medicines	137 (94.48)	36 (72)	31 (88.57)	0.000085

Table 4: Perceptions of UG, PG students, and interns about generic medicines

Questions	UG (%)	Intern (%)	PG (%)	P-value
I am skeptical about generic medicines	69 (47.59)	29 (58)	26 (74.29)	0.01
I need more information on the issue pertaining to the safety and efficacy of generic medicines	130 (89.66)	44 (88)	35 (100)	0.32
From the knowledge I have, I am confident in substituting a brand name medicine with a generic brand medicine	79 (54.48)	36 (72)	21 (60)	0.09
It is easier for me to recall a medicine's therapeutic class using generic names rather than brand names	120 (82.76)	19 (38)	25 (71.42)	<0.01
Pharmaceutical companies product bonuses will influence my choice of alternative brands in the future	25 (17.24)	30 (60)	10 (28.57)	<0.01
I believe advertisement by the drug companies will influence my future dispensing pattern	38 (26.21)	34 (68)	15 (42.86)	<0.01
My medical school education covers the topic of cost-effective use of medicines well	111 (76.55)	39 (78)	18 (51.43)	0.001
Hospital budget for drug procurement will affect my future choice of medicines	82 (56.55)	38 (76)	24 (68.57)	0.03
I believe that multinational products are of good quality than local company products	97 (66.9)	37 (74)	30 (85.71)	0.07
I believe we need a standard guideline to medical prescribers on brand name medicine substitution process	131 (90.34)	43 (86)	34 (97.14)	0.22
I believe my medical training curriculum should include a course on rational medicine use	136 (93.79)	44 (88)	32 (91.43)	0.41
I believe my medical training curriculum should include course on national drug policy and essential drug list	137 (94.48)	35 (70)	35 (100)	<0.01
Indian medical council act, regulation, 2002 (amended 2016) states that every physician should prescribe drugs with generic names legibly and preferably in capital letters and ensure that there are a rational prescription and use of drugs	142 (97.93)	27 (54)	35 (100)	<0.01

Students believe product bonuses (28%) and advertisement (38%) by pharmaceuticals will alter their prescribing patterns in the future. About 90% of students responded that national drug policy and essential drug list should be included in their teaching, training curriculum ($P < 0.0001$) and 89% of students were aware that Indian Medical Council mandates that physician should prescribe generic medicines and write the names legibly, in capital letters and ensure that there is a rational use of drugs ($P < 0.0001$). All students agreed that they need more information on bioequivalence, safety, and efficacy and of generic medicines.

DISCUSSION

This study included students at various stages of medical course in a PG medical institute, i.e., UGs, PGs, and interns. Interns (74%) and PGs (54.37%) were more aware of bioequivalence limits as compared to UGs. Most of UGs (94.5%) asked for more information on bioequivalence tests, and 28.9% were unaware of this concept. PG students (80%) were more aware of Jan Aushadhi scheme as compared to others. Most students (UG, 88.9%; intern, 72%; and PG, 91.4%) believed that generic medicines are cheap, but more than one half PG students (57%) responded that generics are of inferior quality. At the same time, one-third of students also regarded generic medicines to be less effective as compared to brand medicine and conversely multinational brand products to be of good quality as compared to local products. Nearly two-third of PGs and one-half of UGs and interns were sceptical of generic medicine, even though most PGs were aware that generic products are therapeutically equivalent to brand products

(62.8%) and that generic equivalents are therapeutically equivalent to each other (71.4%). Most of the students believed that they require more information on the safety and efficacy of generic medicine and were less confident in substituting a brand product with a generic product. However, a generic product name made it easier for them to recall a therapeutic class. More than two-third of students responded that their training curriculum needs to put more emphasis on rational and cost-effective use of medicine, essential drug list, and national drug policy. At the same time, more than 90% of students believe that there should be a standard guideline to substitute brand medicine with generics. On the other hand, an observation regarding interns was their acceptance of change in their prescribing pattern in future *in lieu* of bonuses and advertisement by pharmaceutical companies.

If general practitioners have good knowledge of generic medicines, then they will be self-assured to substitute them with brand medicine and more confident in prescribing generics. Thus, they can contribute to promotion of generic medicine while on the contrary deficient knowledge can generate an un-enthusiastic attitude in prescribing them.^[11] As health-care cost is increasing as a result of the increased cost of medicines, use of generic medicine which is cheap is being endorsed by policy-makers worldwide.^[6] Hence, it is important to educate medical students about cost-effective use of medicine.^[16]

The majority of the students in the present study were not able to select the exact range of bioequivalence required by generic medicine for market approval, 37% of students knew the correct limit, while 24% of UGs did not attempt the question. A similar finding was reported from the previous study where

the majority of final year student were unable to choose the correct range of bioequivalence, 9% had given the correct answer, and 37% of students did not attempt the question.^[14] This manifests lack of knowledge among students of how the tests are conducted for bioequivalence and that students have not been properly educated about the range of bioequivalence required by regulatory agencies. About 80% of PGs in the present study were aware of “Jan Aushadhi” drug stores, a scheme of Government of India when compared to UGs 55% and interns 50%. This difference is possible because PGs have more exposure to routine prescribing and more aware of government schemes than UG students as they are required to implement all the schemes of government. Thus, there is a need for emphasis on training programs and continuing medical education lectures among students to increase awareness regarding generic medicines. Government of India essential medicine schemes should also be included in the curriculum to create awareness among medical students. Overall 91% of students knew that there is a difference between generic and brand medicines and that generic medicine is bioequivalent to brand medicine which was known to 87% of students. Similar findings were reported in an Australian study where 85% of students believed the same^[12] as also by 80% of UGs from another study done in Aruba.^[17] About 66% of the interns and 52% of the UGs in the study were unaware that the dosage form of a generic medicine must be similar to that of brand-name medicine. The finding of the current study is in line with the previous study conducted in UG students in Iraq, where 50% were unaware of this fact.^[14] In India, it is essential that pharmaceutical companies manufacture generic medicine in dosage form similar to that of brand name medicine.^[18] The present study also showed that interns were less aware than UGs that the dose of a generic medicine must be the same as that of corresponding branded medicine. This demonstrates that medical students have poor knowledge and understanding of generic medicines. About 57.14% PGs, 30.44% UGs, and 28% interns in the current study held a strong view that the quality of generic medicine is poor and carry more side effects. Medical student believe that generic medicines are of substandard quality, less efficient, produce more side effects, and less safe as compared to innovator drug, which is also reported in a previous study.^[7] Pharmacy graduates (81.3%) in Australia presumed that benchmark safety standards are not required to be followed for manufacturing generic medicines as required for brand medicines.^[19] Therefore, quality control of generic medicine must be vigorously pursued so that faith of them being equally efficacious can be generated among prescribers and patients. Students from Bangladesh^[20] considered that generic medicine is of inferior quality, and of poor efficacy as seen in the present study, and for the same reason, it seems that 91% of students from the current study responded that information is required as regard efficacy and safety of generics. The poor opinion of generic medicines among medicine students may lead to reduced use of generic medicines by them, and hence there is an urgent requirement of an educational intervention to change their perception and influence their prescribing behavior.^[21]

About 86% of students of the present study agreed that generic medicines are cheaper than innovator drug which is in agreement with a previous study reporting more than 90% of students believing the same.^[17] Hassali *et al.* reported that all students are of opinion that generic equivalents (all generic products of a particular medicine) have the same efficacy as that of brand name medicine.^[19] About 89% of students in the present study needed more information on tests required to conduct bioequivalence for generic medicines, which differed from the previous studies. Differing opinions stated by students from the present study could be as a result of a medical curriculum being followed for teaching is not similar in all countries. UGs were more inquisitive for acquiring knowledge regarding bioequivalence and how to conduct bioequivalence as compared to PGs and interns in the present study.

About 71% of students believed that the generic name of medicine makes it easier for them to remember therapeutic class, which was an encouraging observation. The probable reason for such a response is the widespread use of generic names in medical textbooks, enumeration of generic names of medicines in the classification of therapeutic class and near similar names used for subsequent drugs in a class. A worrisome aspect was revealed in our study where students believe that product bonuses (28%) and advertisement (38%) by pharmaceutical companies will alter their prescribing patterns in the future. A similar observation was reported by Hassali *et al.*, where in a survey more than 50% of the pharmacists used to stock particular brands of generic medicines for higher profits *in lieu* of bonuses by pharmaceutical firms.^[19] This problem is now being stringently dealt with by Medical Council of India (MCI), which has made bonuses by pharmaceutical companies to practitioners a breach of ethical conduct.

About 85.71% of PGs believed that generic and branded medicine from multinational companies is qualitatively better, whereas 74% interns and 67% UGs believed the same. The observation shows that regulatory agencies in India have not been able to generate faith among doctors, probably as a result of various reports of spurious drugs being confiscated across India. The medical training curriculum should lay more emphasis on the essential drug lists, and national drug policy was stated by 92% of students in the current study. This is an encouraging belief and put the onus on medical education teachers to impart the same knowledge and has now been appropriately included in MCI regulated medical curriculum. All PG students believed that Indian Medical Council Act (professional conduct, etiquette, and ethics) regulation, which states that physician, should write generic name of medicines legibly in capital letters and also ensure rational use of drugs in a prescription; 97.93% UGs agreed with PG students while 46% interns did not believe this statement. A large number of students also believed that sharp increase in medical expenses can be curtailed by the use of generic medicine.

Limitation of the Study

The major shortcoming of our study was that the students were enrolled from our institute and the study was conducted by teachers from the institute, this could have biased the responses from students. We can also not rule out the possibility that the students may have discussed the answers among themselves. Since the sample size was small, the result of the study could not be generalized and so does not reflect the opinion of all the students. Furthermore, our study did not analyze the relationship between what is being taught about generic medicine and their responses; this could have elaborated more on the reason for a lack of knowledge about generic medicine. Nonetheless, since most of the students completed the questionnaire, it reflects the interest and urges for knowledge among UG students, interns, and PG students.

CONCLUSION

Medical students lack comprehensive knowledge and carry erroneous impressions for generic medicine. There is insufficient knowledge as regard safety and efficacy of generic medicines among medical students. Lack of knowledge creates a disapproving attitude toward generic medicines among students and health-care professionals, and this will have a cascading effect on the attitude of patients toward the use of generic medicines. It is therefore vital to emphasize on efficacy, safety, bioequivalence, and requirements of regulatory authorities for approval of generic medicine to the medical students and includes these in teaching programs. Rational use of medicines preferably generic medicines also needs to be promoted by educating the students during their training period. This will augment rational prescribing and cost-effective use of generic medicine in the future. Further there is need to put more emphasis on discouraging the erroneous view among medical students about efficacy, safety and side effect of generic medicine so that they are more acceptable.

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