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A survey exploring the knowledge and perceptions of senior medical students in Nepal toward generic medicines

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Abstract

Background: The accurate knowledge of generic medicine issues among future prescribers will enhance the prescribing of cost-effective medicines. This study aimed to explore the knowledge and perception of senior medical students about the generic medicines.

Methodology: A cross-sectional study was conducted among 237 senior medical students (final year students and interns) using a validated self-administered questionnaire. The collected data were analyzed using Statistical Package for the Social Sciences version 20 for windows and comparison of difference was done using linear by linear association. A p value of less than 0.05 was taken as statistically significant.

Results: The average age (standard deviation) of the respondents was 23.54 (1.39) years. Almost 5% of respondents correctly answered the question regarding the regulatory limits for bioequivalence. Almost two-thirds of respondents correctly agreed that generic medicine is bioequivalent to a brand-name medicine, and 79.3% and 72.5% of respondents correctly agreed that the medicine should be present in the same dosage form and same dose, respectively, as the brand-name medicines. However, almost half of the respondents had impression that brand-name medicines are required to meet higher safety standard than generic medicines. Almost 90% of respondents felt that advertisement by the drug companies would influence the use of brand-name medicine and they need more information about generic medicine.

Conclusion: This study highlights the negative perception and knowledge deficit among the respondents. The students' responses to almost all the statements were almost similar to the respondents' academic year (final year students and interns), gender and nationality.

Keywords

Generic medicines, generic prescribing, generic substitution, medical students

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Introduction

Reducing constantly increasing medicine and health care costs is a challenge all over the world. In Southeast Asian countries like Nepal and India, government bodies fix the ceiling and retail price of essential medicines and try to check the raising medicine cost.[1,2] Recently, the Department of Drug Administration (DDA), drug controlling authority of government of Nepal, has fixed the maximum retail price of few medicines by reducing their market price.[1,3] However, the implementation of the cost has become challenge and doubtful.[3]

Promotion of the use of generic medicine could be a better strategy to control the escalating medicine than the strategy of controlling retail price of medicines. The World Health Organization (WHO) defines a generic medicine as "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."[4] Generic medicine is cheaper but is identical to its

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corresponding innovator medicine in terms of quality, efficacy, safety, therapeutic use, dosage form, strength and route of administration, and quality.[5] The presence of more generic medicines in pharmaceutical market also makes the market competitive, which ultimately plays an important role in lowering the prices of other medicines including generic equivalents.[6] Hence, promotion of generic medicines could help to reduce the escalating health care (especially medicine) cost significantly[6,7] and ultimately improve medicine accessibility.[6]

The generic medicine prescribing and generic substitution require changing existing prescribing behavior which is difficult and contentious issue even in developed countries. Several countries around the world have their own policies to promote generic medicine.[6] Knowledge and perception of prescribers plays a very vital role in promotion of generic medicine prescribing and use.[6] Hence, the medical students could be informed and educated about the benefits of generic prescribing at medical school. The authors of this article think that the students with good knowledge about generic medicine would practice and advocate for generic prescriptions/generic substitution.

As a future doctor/prescriber and health policy makers, the medical doctors have very important role in implementation and promotion of generic medicine. Studies conducted among Australian medical students had shown knowledge deficits about the generic medicines.[8] Knowledge and perceptions about generic medicines among medical students has not been previously studied in Nepal. Hence, the study was carried out to (1) explore the knowledge and perception of final year medical students and interns about the generic medicine and generic prescribing and (2) compare differences of scores in knowledge and perceptions (if any) among different subgroups of respondents.

Methodology

Study design and procedure

The present cross-sectional study was conducted from 22 August to 30 September 2015 using a validated questionnaire. All the senior undergraduate medical students (final year students and interns (students undergoing residential rotational internship)) of Manipal College of Medical Sciences (MCOMS) willing to participate in the study were included in the study. The MCOMS is an international private medical school in Nepal and admits students mainly from Nepal, India, Sri Lanka and Maldives to the undergraduate medical course (MBBS). The course is of five-and-a-half years' duration including 1-year compulsory residential rotating internship.[9] The questionnaires were distributed to the respondents and they were asked to return back after filling the questionnaire by themselves.

Study tool

The validated questionnaire from previous study[8] was used to collect information. Three faculty members of the department checked the validity of the questionnaire and their feedback and comments were modified in the final version of the tool to be clearer to the respondents. The respondents' agreement with a set of statements was noted using the normal 5-point Likert scale (Strongly agree, Agree, Neutral, Disagree and Strongly disagree with the statements). The questionnaire consisted of three parts. The first part obtained demographic data of the respondents, for example, age, gender, nationality and year of medical study (e.g. final year or internship). The second part of the questionnaire, which included a multiple-choice question and six statements, measured respondents' knowledge toward generic medicine. The multiple-choice question regarding the regulatory limits for bioequivalence was provided with six options out of which one was correct. The third part of the questionnaire included six statements and measured perception toward issues pertaining generic medicine utilization. The questionnaire was tested among 10 third-year students of the institution. The data of the pilot study were not included in the final analysis. Cronbach's alpha was calculated to be 0.712, indicating a good level of internal consistency.

Ethical considerations

The study was approved by the Institutional Review Committee (IRC), MCOMS, Pokhara vide notification MEMG/IRC/GA (i). The respondents were invited for voluntary participation (could withdraw from the study at any time without giving any reason) in the study. They were informed about the objectives of the study, its importance and benefits were explained. They were explained that the participation was voluntary and the participants were assured about the confidentiality of the data. A written informed consent was obtained from all respondents prior administration of the questionnaire.

Data analysis

The collected data were entered into and analyzed using SPSS (Statistical Package for the Social Sciences) version 20 for windows. Comparison of difference according to gender, year of medical study (e.g. final year or internship) and nationality was done using linear by linear association. The data were skewed and the expected frequencies in some cell/s in most of the cross tables (chi-square test) were less than 5 (some were having expected frequency less than 1) so linear by linear association. For this study data, a p value of less than 0.05 was taken as statistically significant.

Results

Of 272 senior medical students (final year students and interns), 237 responded to the study with response rate of 87.1%. More number of respondents were female, of Nepalese nationality, and of age 23 years (Table 1). The average age (standard deviation (SD)) of the respondents was 23.54 (1.39) years. Table 1 shows the demographic characteristics of the final year students and interns.

Table 1. Respondents' demographic characteristics.

Characteristics		Final year students, n = 120 (%)	Interns, n = 117 (%)	Total, n = 237 (%)
Gender	Female	52 (43.3)	68 (58.1)	120 (50.6)
	Male	68 (56.7)	49 (41.9)	117 (49.4)
Age in years	21	9 (7.5)	0 (0.0)	9 (3.8)
	22	36 (30.0)	6 (5.1)	42 (17.7)
	23	42 (35.0)	31 (26.5)	73 (30.8)
	24	18 (15.0)	46 (39.3)	64 (27.0)
	25	12 (10.0)	22 (18.8)	34 (14.4)
	26	2 (1.7)	8 (6.8)	10 (4.2)
	>26	1 (0.8)	4 (3.4)	5 (2.1)
Nationality	Nepalese	63 (52.5)	78 (66.7)	141 (59.5)
	Indian	41 (34.2)	37 (31.6)	78 (32.9)
	Sri Lankan	16 (13.3)	2 (1.7)	18 (7.6)

Table 2. Knowledge of respondents toward bioequivalence.

Response	Final year students, n (%)	Interns, n (%)	Total, n (%)
80%–120%	7 (5.8)	5 (4.3)	12 (5.1)
80%–125%	9 (7.5)	2 (1.7)	11 (4.6)
90%–120%	24 (20.0)	23 (19.7)	47 (19.8)
95%–100%	5 (4.2)	3 (2.6)	8 (3.4)
95%–105%	4 (3.3)	3 (2.6)	7 (3.0)
I don't know	71 (59.2)	81 (69.2)	152 (64.1)
Total	120 (100)	117 (100)	237 (100)

The first question of the questionnaire was "The regulatory limits applied are that 90% confidence intervals for the log ratios (generic product: brand name product) of the areas under the plasma drug concentration versus time curves and the maximum plasma drug concentrations must fall between," six options (mentioned in Table 2) were given, with the correct answer being 80%–125%. The respondents were asked to check one of the options. The following explanatory statement was printed prior to the first question:

> In pharmacology, the term bioavailability refers to the rate (how fast) and the extent (how much) to which an active ingredient is absorbed and becomes available at the site of drug action. Most of the drug regulatory agency around the world considers a generic product to be bioequivalent if its bioavailability is within an allowable range compared with the currently marketed brand product.

The statement was given to ensure a common understanding of the concept of bioequivalence among the respondents. Eleven (4.6%), 9 final year students and 2 interns only, answered the question correctly. Almost two-thirds of respondents (71 final year students and 81 interns) said that they do not know the correct answer, while others (31.2%) answered the question incorrectly (Table 2). Linear by linear association showed that there was no significant difference in the knowledge according to the respondents' year of medical study (e.g. final year or internship), gender and nationality.

Responses to other individual statements measuring knowledge toward generic medicines and perceptions toward issues pertaining generic medicine utilization are presented in Tables 3 and 4.

Almost two-thirds (64.1%) of respondents correctly agreed that a generic medicine is bioequivalent to a brand-name medicine. They also correctly agreed that the medicine should be present in the same dosage form (79.3%) and in the same dose (72.5%) as the brand-name medicine. In contrary to the above impression, 110 (46.4%) respondents had impression that the brand-name medicines are required to meet higher safety standards than generic medicines and only 28.3% correctly disagreed that brand-name medicines are required to meet higher safety standard than generic medicine (Table 3). Almost 17% of respondents have a wrong impression that that the generic medicine causes more side effects compared to brand-name medicines while 25% of respondents were neutral to the question. Similarly, 39 respondents (16.5%) thought that generic medicines are less effective compared to brand-name medicines.

More than 88% of respondents felt that they need more information on the issue pertaining to safety and efficacy of generic medicines (Table 4). A similar proportion of respondents believed that advertisement by the drug companies would influence the use of brand-name medicines. Almost one-half of respondents perceive that their future prescribing habits would be affected by the hospital budget for drug procurement.

There was no significant difference in the knowledge and perception according to the respondents' gender, nationality and year of medical study (Tables 3 and 4).

Discussion

Generic medicines are encouraged by most policy makers around the world to make the medicine affordable and more accessible and to decrease the cost of the health care system.[6,7] Medical prescribers are one of the most important stakeholders that have influential role in promotion and the use of generic medicines. Medical prescribers having good knowledge regarding generic medicines could be confident in prescribing and substituting generic medicines. In contrary, the lack of knowledge about generic medicine helps to generate negative attitude in them.[8] As a future medical prescribers and health policy makers, the medical students should know about the generic medicines and bioequivalence from the very beginning of medical course. Unfortunately, this study on overall knowledge and perception about generic medicine among senior medical student showed that the respondents' knowledge was not optimum and there are scopes of improvement.

Table 3. Knowledge of senior medical students about generic medicines and its association with gender, academic year (final year students and interns) and nationality.

Questionnaire statements/questions	Response to the statements					Linear by linear association (p values)		
	SA, n (%)	A, n (%)	N, n (%)	D, n (%)	SD, n (%)	Academic year	Gender	Nationality
A generic medicine is bioequivalent to a brand-name medicine	42 (17.7)	110 (46.4)	39 (16.5)	36 (15.2)	10 (4.2)	0.821	0.407	0.312
A generic medicine must be in the same dosage form as the brand-name medicine	73 (30.8)	115 (48.5)	23 (9.7)	24 (10.1)	2 (0.8)	0.216	0.677	0.049
A generic medicine must contain the same dose as the brand-name medicines	72 (30.4)	100 (42.2)	26 (11.0)	35 (14.8)	4 (1.7)	0.925	0.171	0.976
Generic medicines are less effective compared to brand-name medicines	13 (5.5)	26 (11.0)	55 (23.2)	100 (42.2)	43 (18.1)	0.535	0.824	0.815
Generic medicines produce more side effects compared to brand-name medicines	7 (3.0)	32 (13.50)	62 (26.2)	103 (43.5)	33 (13.9)	0.378	0.821	0.931
Brand-name medicines are required to meet higher safety standards than generic medicines	24 (10.1)	86 (36.3)	60 (25.3)	49 (20.7)	18 (7.6)	0.798	0.427	0.074

SA: strongly agree; A: agree; N: neutral; D: disagree; SD: strongly disagree.

Table 4. Perception of senior medical students about generic medicines and its association with gender, academic year (final year students and interns) and nationality.

Questionnaire statements/questions	Response to the statements					Linear by linear association (p values)		
	SA, n (%)	A, n (%)	N, n (%)	D, n (%)	SD, n (%)	Academic year	Gender	Nationality
I believe we need a standard guideline to medical prescribers on brand-name medicine substitution process	113 (47.7)	112 (47.3)	10 (4.2)	2 (0.8)	0 (0.0)	0.001	0.979	0.371
In my opinion, quality use of generic medicines among patients can be achieved if medical prescribers work together	98 (41.4)	118 (49.8)	18 (7.6)	2 (0.8)	1 (0.4)	0.855	0.086	0.070
I think patient should be given enough information about generic medicines in order to make sure they really understand about the medicines they take	96 (40.5)	109 (46.0)	26 (11.0)	5 (2.1)	1 (0.4)	0.751	0.166	0.453
I believe advertisement by the drug companies will influence use of brand-name medicines	74 (31.2)	120 (50.6)	36 (15.2)	6 (2.5)	1 (18.1)	0.435	0.692	0.229
I need more information on the issues pertaining to the safety and efficacy of generic medicines	86 (36.3)	124 (52.3)	24 (10.1)	3 (1.3)	0 (0.0)	0.405	0.613	0.051
Hospital budget for drug procurement will affect my future choice of medicines	31 (13.1)	87 (36.7)	75 (31.6)	30 (12.7)	14 (5.9)	0.393	0.393	0.005

SA: strongly agree; A: agree; N: neutral; D: disagree; SD: strongly disagree.

Majority of the respondents were unable to select the correct bioequivalence limits allowed for approval of generic medicines. That a higher proportion of respondents did not attempt to select a range medical students, this might be due to lack of understanding of the complex concepts of bioequivalence testing. This concept is also not included in their medical curriculum and briefly the concept is mentioned in Pharmacology in the first year of the course.[10]

In our study, almost 65% of respondents believed that a generic medicine was bioequivalent to the corresponding brand-name medicine while in studies from Australia more than 85% of medical students[8] and 86.1% pharmacy graduates[11] believed the same. Similarly, in this study

almost more than 70% of respondents thought that a generic medicine must be in same dose and dosage form (e.g. tablet, capsule) as the corresponding brand-name medicine which is higher than the knowledge of medical students[8] but less than the pharmacy graduates[11] in Australia.

Almost 50% of the respondents of our study thought that brand-name medicines are required to meet higher safety standards than generic medicines. However, all the medicines marketed in Nepal, generic or brand-name medicines, have to meet the same quality standards.[12] Generic medicines in Australia are also required to meet the same quality standards as brand-name medicines,[13] but 81.3% of pharmacy graduates in Australia were under impression that generic medicines need to meet lower safety standards than brand-name medicines.[11] Generic substitution is not allowed in public and/or private sector facilities in Nepal.[14] Furthermore, 17% of the respondents thought generic medicines are less effective and produce more side effects compared to brand-name medicines while almost one-quarter had neural opinion (neither agreeing nor disagreeing) to the statements. Less positive attitude toward safety and efficacy of generic medicine and no provision for generic substitution may hinder the use of generic medicines.

More than 80% of respondents either agreed or strongly agreed that they would like to have more information pertaining to the safety and efficacy of generic medicines while the percentage was 54.4 among pre-registrants pharmacy graduates in Australia.[11] The perception among our respondents might be due to deficiency of knowledge about generic medicine or might be a hawthorn effect (general tendency to show willingness to acquire more information when it is offered).

Almost 82% of respondents thought that they would be influenced for brand-name medicine prescribing by pharmaceutical company advertisement. Pharmaceutical companies' drug information are biased toward brand-name medicines which may create a negative attitude toward generic medicine. The drug regulatory body of country should take initiative to provide the medical prescribers with evidence-based information about generic medicines and their therapeutic equivalence with their counterpart original brands.[15] This finding suggests that the medical students need to be trained on how to evaluate drug promotional materials of pharmaceutical company.[16] The drug regulatory body should also monitor and audit drug information provided by pharmaceutical sales. In Nepal, preapproval for medicines advertisements is required and the approval is given only to non-prescription medicines. No legal provisions exist for advertising and promotion of prescription medicines by the pharmaceutical company to medical prescriber.[14]

Strength and limitations of the study

The high response rate and good sample size could be considered as strength of the study. The respondents were requested to complete the questionnaire independently without consultation with others, but discussion between the respondents could not be entirely ruled out. This might be considered as limitation of the study.

Conclusion

The students' responses to almost all the statements (questions) were similar (no statistically significant difference) to the respondents' academic year (final year students vs interns), gender and nationality. It was found that the respondents' and all the subgroups of respondents' overall knowledge about the generic medicine was deficient. The perception of the respondents' toward generic medicine was also not positive. Hence, the issue needs to be addressed by educators and the state (through Ministry of Health and Population and DDA, Nepal) before promoting the use of generic medicines and brand-name medicine substitution in the country.

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Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Ethical approval

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Informed consent

Written informed consent was obtained from all subjects before the study.

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