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Knowledge and Perceptions of Final-Year Medical Students in Yemeni Universities about Generic Medicines

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ABSTRACT

Objective: To investigate the knowledge and perceptions of final-year medical students in the Yemeni universities about generic medicines.

Methods: A two-month cross-sectional survey was conducted among final-year medical students in three Yemeni universities; Sana'a University, University of Science and Technology and Thamar University in 2013.

Results: One hundred and sixty-five medical students out of 270 responded to the present study, with a response rate of 61.1%. More than 60% of medical students were not introduced to bioequivalence of generic medicines during their undergraduate study, and 80.0% of them had a low desire to inquire about it during their study. In addition, more than 60.0% of them were unaware of the similarity of generic medicines to their brand equivalents in dosage form and dose. More than three-quarters of the medical students incorrectly perceived that generic medicines are inferior in quality (80.0%), less effective (58.0%) and with more side-effects (47.8%) than their brand equivalents. The medical students in the present disagreed about the need for more information on the safety and efficacy of generic medicines.

Conclusions: Yemeni students need to further enhance their awareness and expand their knowledge about the concepts and principles of bioavailability and bioequivalence of generic medicines if they are to contribute appropriately to generic medicine use.

Keywords: Generic medicine, Generic substitution, Bioequivalence, Knowledge, Perception, Medical student, Yemen

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1. Introduction

Utilizing generic medicines in place of their brands has been suggested as one area of health to reduce annual healthcare expenditure without compromising its delivered quality (1–3). Generic medicines are identical, or bioequivalent, to brand medicines in dosage form, safety, efficacy, route of administration, quality and intended medical use (4). Production and manufacturing of generic medicines start after the expiry of the patent on the brand medicine. Registration of generic drugs as new products and their subsequent marketing require bioequivalence studies. These bioequivalence studies of generic medicines are mainly based on maximum plasma concentration (C_{max}) and area under the plasma concentration curve (AUC) from administration to last observed concentration. In Yemen, prior to being introduced to the market, generic medicines have to be approved by the Supreme Board for Drugs & Medical Appliances (5). For generic medicines to be accepted for sale in the Yemeni markets, they must be bioequivalent to the reference product, and hence, their AUC and C_{max} values must be within an acceptance range of 0.80–1.25 of those of the reference product according to the U.S. Pharmacopeia, or these generic medicines have been accepted by two Middle East countries (5).

The attitudes and perceptions of physicians about generic medicines have a great impact on utilizing generic medicines through influencing patients' behaviors towards generic medicines and their prescription rate and use. Information given by prescribing doctors on generic medicines influences patients' acceptance and use of these medicines (2, 6–8). The generic medication prescription rate is improved by physicians (9). In the medicine-use-process, physicians are the key individuals. They initiate the process by

prescribing or ordering medicines and follow their dispensing by pharmacists. However, in most low-income countries, physicians are involved in the dispensing role (10).

Despite being the key individuals in the medicine-use-process, several studies indicated that negative attitudes and perceptions of physicians about generic medicines' safety, quality and efficacy influence generic prescribing (2, 4, 9, 11). Reasons contributing to the negative attitudes and perceptions of physicians about generic medicines are attributed to poor knowledge about the bioequivalence, lack of confidence and misconceptions on generic medicines. Several studies indicated that physicians are unaware of bioequivalence acceptability criteria for generic medicines (4, 12–15). General practitioners, who opposed generic prescribing, showed a poor confidence towards bioequivalence of generic medicines to the innovator brands (12). In Ireland, a fairly low rate of generic prescribing was found compared to England and Northern Ireland. The reliability and quality of generic medicines were the primary concern of Irish prescribers (16) in order to promote cost-effective prescribing of generic medicines. In fact, the misconceptions on generic medicines need to be reconsidered and corrected (13–17). Several studies in Iraq and Australia on medical students' perceptions regarding generic medicines showed that such misconceptions are attributed to misbeliefs that generic medicines are therapeutically identical to their corresponding brand medicines (18–19). The suggested reason leading to such negative perceptions of medical students is that the generic medicine concept is not introduced clearly to those students during their undergraduate study. To overcome this problem, education about the benefits of generic prescribing and substitution should be introduced to future medical students,



prescribers and dispensers (19). Names of generic medicines, cost-containment and medicine pricing policy should be incorporated in course contents of the pharmacy and medical curricula (19). It is noteworthy that local manufacturing facilities cannot meet the domestic demands, addressing only 10% of such needs, while 90% of medicines in the market are imported (20–21). Therefore, it is essential to promote generic medicine concept and practice, which deem necessary to further measure future practitioners' knowledge about generic medicines.

The assessment of final-year medical students' knowledge, attitudes and perceptions about generic medicines may have an important impact on their use. By studying final-year medical students' perspectives in Yemen universities, academics and researchers can formulate more efficient interventions to fill in the knowledge gap about generic medicines and improve their prescribing in the country. To date, no studies have been conducted to assess the medical students' knowledge and perceptions about generic medicines in Sana'a, Yemen. Thus, this study will be a key document for policy makers, legislation, pharmacy and medical colleges/universities and future healthcare providers. The study was conducted to evaluate final-year medical students' knowledge, attitudes and perceptions about generic medicines in Yemen universities.

2. Methods

A two-month cross-sectional survey was conducted among final-year medical students in three Yemeni universities (Sana'a University, the University of Science and Technology and Thamar University) in 2013. The study was approved by the Ethical Committee of the University of Science and Technology. Permission was

also taken from the relevant universities, and informed consent was obtained from the participating respondents. The survey questionnaire was distributed to the students by the coordinators of academic lectures at each respective university. The objectives of the survey were introduced to the students through an explanatory letter annexed to the questionnaire. Anonymity and confidentiality of respondents were ensured.

Data were collected using a pre-tested, structured questionnaire of 22 items. The questionnaire was divided into four sections: section I included four socio-demographic questions about age, sex, nationality, scholarship and university; section II included four knowledge items about the bioequivalence of generic medicines; section III included eight questions to evaluate understanding of brand medicines *versus* generic medicines; and section IV included six questions to evaluate the perceptions of students about current medical and pharmacy education. The last three sections used a five-point Likert scale (5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree and 1 = strongly disagree).

Face validity of the questionnaire was pilot-tested by administering it to a sample of ten students not involved in the core study. The overall Cronbach's alpha value used to ensure internal consistency was 0.80.

The sampling frame of the study included all final-year medical students enrolled in two public and one private universities during the study period. Their number was obtained from the respective lecture coordinators in each university. Descriptive statistics of frequencies and percentages were used to summarize raw data obtained by the questionnaire. Differences between groups were tested by Pearson's chi-



square or Fisher's exact tests, whenever necessary, at a significance level of <0.05.

3. Results

Out of the 270 final-year medical students enrolled in the studied public and private universities, 165 students agreed to participate in the present survey. Therefore, the response rate was 61.1%. Among the respondents, 104 (63.0%) were males and 61 (37.0%) were females, with an average age of 25.6 ± 2.43 years old. Yemeni students represented the majority (79.4%) of the respondents in the study, whereas non-Yemeni students represented only 20.6% (Table 1).

Table 1. General characteristics of the final-year medical students in Yemeni universities (N=165)

Characteristic		n (%)
Mean age (years)		25.6 ±2.43
Sex	Male	104 (63.0)
	Female	61 (37.0)
University	Private	47 (28.5)
	Governmental	118 (71.5)
Nationality	Yemeni	131 (79.4)
	Non-Yemeni	34 (20.6)
Scholarship	Governmental	86 (52.1)
	Private	56 (33.9)
	Other	23 (13.9)

3.1. Students' knowledge about bioequivalence

The responses of the participating students are shown in Table (2). More than 50.0% of them did not consider that generic medicines are therapeutically identical, or equivalent, to the compliant brand medicines, or even to each other. There was a statistically significant difference between the responses to the equivalence of generic medicines according to universities ($p=0.019$). In addition, more than 60.0% of the respondents were not introduced to the issues of bioequivalence of generic medicines

during their study, and more than 80.0% of them did not think of the need for more information about bioequivalence of generic medicines and its methods of testing.

Table 2. Knowledge of the final-year medical students in Yemeni universities about bioequivalence

Statement	No.	SD			D			N			A			SA			p-value			
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)						
All generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to the innovator brand product.	164	16 (9.7)	68 (41.2)	34 (20.6)	68 (41.2)	28 (17.2)	36 (22.0)	10 (6.1)	0.706	0.157	0.191	0.364*	0.019	0.627	0.444	0.240	0.181	0.640*	0.109*	0.113*
All generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to each other.	163	13 (8.0)	72 (44.2)	43 (26.4)	51 (30.9)	25 (15.2)	7 (4.2)	0.444	0.240	0.181	0.640*	0.109*	0.113*	0.444	0.240	0.181	0.640*	0.109*	0.113*	
I have not been introduced to the issues of bioequivalence of generic medicines during my pharmacy education.	165	51 (30.9)	64 (39.8)	15 (9.3)	68 (42.2)	13 (8.1)	1 (0.6)	0.113*	0.109*	0.113*	0.113*	0.109*	0.113*	0.113*	0.109*	0.113*	0.113*	0.109*	0.113*	0.113*
I need more information on how bioequivalence tests are conducted for generic medicines.	161	68 (42.2)	13 (8.1)	1 (0.6)	68 (42.2)	13 (8.1)	1 (0.6)	0.113*	0.109*	0.113*	0.113*	0.109*	0.113*	0.113*	0.109*	0.113*	0.113*	0.109*	0.113*	0.113*

SD, strongly disagree; D, disagree; N, neutral; A, agree; SA, strongly agree. *The test used is Fisher's exact test; n, number of responses



3.2. Students' knowledge about generic versus brand medicines

The responses showed that about a half of the respondents presumed that a generic medicine is not bioequivalent to the corresponding brand medicine. More than 60.0% of the participants were unaware that the generic medicine must be presented in the same dose and dosage form as the brand medicine, with a statistically significant difference in the responses obtained from different universities ($p=0.027$). With regard to quality and efficacy, about 63.0% of the respondents thought that generic medicines are of lower quality (80.0%), are less effective (58.0%) produce more side-effects (47.8%) and adhere to lower safety standards (72.6%) than brand medicines, with a statistically significant difference in the responses to the question about the safety standards between the different universities ($p=0.026$). With respect to the question about the price of generic medicines, 82.6% of the respondents did not believe that generic medicines are less expensive than brand medicines (Table 3).

3.3. Students' perception of the current prescribing education

Table (4) showed the responses of the medical students about the current prescribing education, where a statistically significant difference ($p=0.016$) in the responses related to the respondents' needs for more information on issues pertaining to the safety and efficacy of generic medicines was found. Of the respondents, 46.6% (64/165) felt non-confident enough to prescribe medicines according to generic names instead of their brand medicines. A statistically significant difference ($p=0.036$) was found in the confidence of generic prescribing according to the variable of nationality. About a half of the respondents thought that it is more difficult to recall a medicine's therapeutic class

using its generic compared to the brand name, and 79.4% of them did not believe that pharmacists would give them advice in the future with regard to generic medicines. Approximately 57% of the respondents either disagreed or strongly disagreed that their future prescribing habits will be influenced by their senior colleagues and medical consultants. Moreover, more than a half of the respondents (52.5%) did not believe that advertisements by drug companies will influence their future prescribing patterns. The responses showed that about 45.0% of the respondents considered that their universities do not exert adequate efforts and focus on cost-effective prescribing in their medical curricula, with a statistically significant difference in the responses according to sex.

4. Discussion

Considering the importance of generic medicine use, especially in low- and middle-income countries, the present study is the first study to assess final-year medical students' knowledge and perceptions about generic medicines in Yemeni universities.

The term "generic medicine" has been defined by several public and private health organizations in the world. The World Health Organization defined the 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*' (22). Under the Food and Drug Administration's regulations, a generic medicine must contain identical amounts of the same active ingredients in the same dosage form, safety, strength, route of administration and intended use as a branded medicine (23).



Table 3. Knowledge of the final-year medical students in Yemeni universities about understanding of brand versus generic medicines

Statement	SD		D		N		A		SA		p-value	
	No.	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	Sex	University	Nationality
Generic medicine is bioequivalent to its brand medicine.	160	16 (9.7)	61 (38.1)	38 (23.8)	34 (21.3)	11 (6.9)				0.132	0.039	0.222
Generic medicine must contain the same dose as the brand medicine.	159	49 (30.8)	51 (32.1)	36 (22.6)	18 (11.3)	5 (3.1)				0.68	0.027	0.555*
Generic medicines must be in the same dosage forms (e.g. tablet, capsules) as the brand medicines.	162	33 (20.4)	66 (40.7)	40 (24.7)	19 (11.7)	4 (2.5)				0.762	0.188	0.902*
Generic medicines are of lower quality compared to brand medicine.	158	39 (24.7)	61 (38.6)	35 (22.2)	19 (12.0)	4 (2.5)				0.682	0.146	0.168*
Generic medicines are less effective compared to the brand medicines.	150	33 (22.0)	54 (36.0)	47 (31.3)	12 (8.0)	4 (2.7)				0.436*	0.066*	0.262*
Generic medicines produce more side effects compared to the brand medicines.	159	24 (15.1)	52 (32.7)	52 (32.7)	22 (13.8)	9 (5.7)				0.18	0.418	0.260*
Generic medicines are less expensive than brand medicines.	157	69 (43.9)	61 (38.9)	18 (11.5)	6 (3.8)	3 (1.9)				0.681*	0.077*	0.842*
Brand medicines are required to meet higher safety standards than generic medicines.	164	49 (29.9)	70 (42.7)	29 (17.7)	12 (7.3)	4 (2.4)				0.803*	0.026*	0.592*

SD, strongly disagree; D, disagree; N, neutral; A, agree; SA, strongly agree; *The test used is Fisher's exact test; n, number of responses

Table 4. Perception of the students about current prescribing education

Statement	SD		D		N		A		SA		p-value	
	No.	n (%)	n (%)	n (%)	n (%)	Sex	University	Nationality				
I need more information on the issues pertaining to the safety and efficacy of generic medicines.	162	53 (32.7)	65 (40.1)	24 (14.8)	16 (9.9)	4 (2.5)				0.016	0.275*	0.162*
Up to my knowledge, I am confident with prescription written by generic medicine rather than brand medicine	159	26 (16.4)	48 (30.2)	40 (25.2)	23 (14.5)	8 (5.0)				0.409	0.105	0.036
I find it easier to recall a medicine's therapeutic class using generic rather than brand names.	161	17 (10.6)	61 (37.9)	47 (29.2)	20 (12.4)	16 (9.9)				0.843	0.069	0.452*
I believe that pharmacists are one of the important healthcare professionals to advise me on generic medicines.	160	70 (43.8)	57 (35.6)	21 (13.1)	6 (3.8)	6 (3.8)				0.864*	0.332*	0.234*
I believe that my future prescribing habits will be influenced by my senior colleagues and medical consultants.	156	30 (19.2)	60 (38.5)	37 (23.7)	17 (10.9)	12 (7.7)				0.921	0.718	0.265
I believe that advertisements by drug companies will influence my future prescribing patterns.	162	32 (19.8)	53 (32.7)	39 (24.1)	24 (14.8)	14 (8.6)				0.451	0.609	0.574
I believe that the topic of cost-effective prescribing is well covered in my medical education.	162	27 (16.7)	47 (29.0)	36 (22.2)	29 (17.9)	23 (14.2)				0.027	0.665	0.847

SD, strongly disagree; D, disagree; N, neutral; A, agree; SA, strongly agree; *The test used is Fisher's exact test; n, number of responses



In the present study, only 28.1% of the final-year medical students were aware of the differences between generic and brand medicines and 21.5% of them were aware of the therapeutic bioequivalence to each other. This could be mainly due to the lack of knowledge about these products and their relationship to each other, where 61.8% of the respondents were not introduced to the issues of bioequivalence for generic drugs during their education. Similar findings were reported for Australian and Iraqi final-year medical students (18, 19), where 72.0 and 75.0% of the students did not believe that generic medicines are therapeutically equivalent to their corresponding brand medicines, respectively. Compared to only 8.7% of the respondents in the present study who showed a need for information about the bioequivalence of generic medicines during their medical education, 68.0% and 75.0% of Australian and Iraqi medical students showed such a need, respectively. This is may be due to the lack of importance of generic drugs among students in the Yemeni universities.

As regard to the understanding of students about generic *versus* brand medicines, only 14.4% believed that generic medicines must contain the same dose as the brand medicine. Most of the students agreed that generic medicines are of lower quality (81.3%) and less effective (58.0%) than brand medicines. These findings are in disagreement with those reported among Australian and Iraqi students, where 53.0% and 45.0% of medical students, respectively, believed that both generic and brand medicines have nearly the same dose. However, in both latter studies, students agreed that generic medicines have a lower quality in comparison to brand medicines (93.0% and 68.0%, respectively). When considering the cost of drugs, 82.8% of the students did not expect generic medicines to be cheaper than brand ones. This

is in contrast to the findings from Australia and Iraq, being reported among 2.8 and 6.0% of the students, respectively.

Despite the above-mentioned findings, only 12.4% of the medical students in Yemeni universities showed their need for more information regarding the safety and efficacy of generic medicines, and 28.3% of them felt confident in prescriptions written by generic medicines rather than brand ones. A small proportion of students (7.6%) stated that pharmacists are one of the important healthcare professionals to give advice on generic medicines. This may influence the prescribing patterns of the future practitioners.

Regarding the prescribing education, 45.0% of the students did not believe that the topic of cost-effective prescribing was well covered in their medical education. This is in line with the studies conducted in Australia and Iraq (18, 19). This may have a negative impact on the students' prescription habits while practicing upon graduation.

Overall, there were statistically significant differences between students in different universities regarding the items of questionnaire, and this may reflect the different curricula provided by the three universities involved in the study. However, there was no statistically significant difference between the responses of males and females in the present study. It is noteworthy that a limitation of the present study is that only three out of ten public and private medical schools were included in this study. Thus, there should be further studies involving all universities to provide stronger evidence to the government to adopt the issues of generic medicines in Yemen.



5. Conclusions

This study concludes the lack of knowledge about the bioequivalence and cost of generic medicines among medical students in Yemeni universities. The issues concerning generic medicines should be fully introduced to the medical students during their study to encourage them to start prescribing generic medicines during work practice. In addition, there should be a national strategy towards the use of generic medicines to be adopted by the government in Yemen. This strategy may provide an opportunity to reduce the cost of healthcare and to save money for use in improving access to medicines and other healthcare services in Yemen.

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Authors' Contribution

GQO and AA designed the study; GQO and FAQ contributed to data collection and analysis; GQO, FAQ, MAMA and HAA contributed to data analysis and interpretation of results. GQO drafted the manuscript. GQO, FAQ, MAMA and HAA revised the manuscript. All authors approved the final submission of the manuscript.

Competing interests

The authors declare that they have no competing interests associated with this article.

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