Knowledge, Attitude and Perception of Community Pharmacists about Generic Medicines: A Pilot Observational Study

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ABSTRACT

Background: Healthcare expenses are increasing at an alarming rate. Companies usually increase the cost of their brands to compensate drug development process. But it is very difficult for the poor to afford such expensive medicines. Here, generic drugs come into play to act as the best substitute for various brands after patent expiry. Community pharmacist plays a major role in promoting generic drug utilization and performs generic substitution wherever possible to reduce healthcare expenditures.

Objectives: To assess knowledge, attitude, and perception of community pharmacists towards generic drugs.

Methods: This study was conducted in Jalandhar city of Punjab, India. A total of 60 community pharmacists were involved in this observational study. A questionnaire was designed which consisted of total 25 objective-type questions and divided into three sections. The pharmacists' responses were recorded and analyzed using SPSS (Statistical package for social sciences) version 16.

Result: Out of 60 participants, most pharmacists (90%) were male and Diploma in Pharmacy holder. The mean (±SD) knowledge score was 6.4 (±3.7). The majority (46.7%) of participants agreed that generic drug substitution is a good practice. But some participants had a wrong perception about the quality of generic drugs; around 30% agreed that generic drugs are cheaper due to inferior quality.

Conclusion: Overall, participants have basic knowledge and a positive attitude towards generic drugs. However, some participants have misconceptions about the quality of generic drugs. Therefore, pharmacists must have in-depth information to promote generic drug utilization and substitution to reduce healthcare expenses.

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Introduction

The major concern about healthcare services around the globe is increasing the cost of medical facilities.^[1] For instance, pharmaceutical products account the second-highest proportion in terms of cost in healthcare sector.^[2] It might be due to a plethora of reasons, firstly there is an increase in the count of sufferers from infectious diseases, fatal disease like cancer owing to lifestyle modifications and a rise in risk factors. Secondly, to compensate for the cost of various modern medical treatments and drug discovery processes, especially for branded drug products. [3] It is very difficult for poor people to afford healthcare facilities especially in developing nations. To root out this problem, generic medicines came into play to provide cost-effective drug therapy to the patients. Pharmacists act as a link between patients and the healthcare facilities whereas pharmacy practice principle plays a very important role in improving the healthcare sector. [4] Past few years, the pharmacist's role has been reached to the horizon; instead of compounding and dispensing, they are also involved in providing effective drug therapy at low prices due to the big generic medicines market.^[5]

Generic medicines are therapeutically equivalent to branded ones in composition and efficacy, but they are sold in the market after the innovator's patent expires. Generic drugs have the same API, strength, dose, route of administration, indication and effectiveness as branded products and differ in composition of excipients (flavoring agent, etc.), shape, color, packaging, storage conditions, and labeling. [6] For the generic drug approval process, ANDA (abbreviated new drug application) is submitted to the FDA for manufacturing and marketing license. Unlike

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NDA (New drug application), it includes bioequivalence study to compare safety and efficacy with branded drugs and other documentation is similar to NDA excluding preclinical and clinical studies. Generic medicines must release the API at the same rate and extent as branded drug products; there should be no significant difference.

Generic drug products are the best alternative to branded medicines at a very reasonable cost and help in reducing healthcare monetary expenses. [7] Moreover, healthcare providers are free to do the generic substitution, a cost-effective strategy to provide medical services to patients. [8]

The utilization trend of generic medicines has been increased around the globe. In many countries, pharmacists have the right to substitute the branded versions with comparable generic medicines if available. [9] Community pharmacies are the primary source of healthcare facilities, especially for the rural population. So, the pharmacist must have adequate knowledge

regarding generic medicines to provide cost-effective medicines as well as helps to reduce healthcare expenditures. Insufficient or misleading information among healthcare providers about generic medicines would result into lack of confidence on dispensing generic versions, which ultimately increases the healthcare cost. As a result, customers might get the wrong perception about the quality of generic drug products. [10] Generic medicines play a crucial role in healthcare care sector without compromising the quality of drug products. Hence, it is very important to assess community pharmacists' knowledge, attitude, and perception about generic drug products to promote the use of generic versions of drugs at lower price. Besides that, it also helps policymakers fill the gaps by implementing needful regulations to provide reasonable medical care facilities. [10]

METHODS

Study Design and Setting

This community-based cross-sectional study was conducted in the community pharmacy located in Jalandhar city of Punjab, India from January to April 2021. A total of 72 community pharmacists invited to participate in the study. Participants were selected by convenience sampling methods.

Study Description and Tool

A self-administered questionnaire was designed after extensively reviewing previous articles related to knowledge, attitude and practice of community pharmacist regarding generic medicine.^[4,10-12] The questionnaire was prepared in English. It consisted of 25 questions, divided into three sections. The first section of the questionnaire consisted of sociodemographic characteristics of the participants such as age, gender, qualification, experience and number of prescriptions dispensed daily. In the second section ten knowledge-based questions were asked to assess the knowledge regarding generic medicines and three options were given to the participants to give their responses. These include 'Correct, Incorrect and Don't know'. [13] To analyze the knowledge of pharmacist scoring was done, one point was given for the right answer and zero for wrong and 'don't know'. The score range was 0 to 10, highest score implies respondent have enough knowledge about generic drugs. [10] The third section comprised of total 10 questions to analyze the attitude and perceptions of community pharmacist regarding generic substitution, quality, cost and effectiveness of generic versions of drugs. Participants had to respond on a 5- point Likert scale where, 1 represent strongly agree and 5 indicated strongly disagree. [4,10]

Questionnaire Development

Pretesting of the questionnaire was done by distributing the questionnaire among 5 community pharmacists located in Jalandhar city. Based on the results of this, the questionnaire was modified to ensure simplicity and understandability. The data of these 5 participants were not included in the final analysis. Content validity of the questionnaire was done by 4 experienced pharmacists. Few questions were modified and revised version of the questionnaire was used for collection of data.

Ethical Statement

The study protocol was approved by the Institutional Ethics Committee of Lovely Professional University. Verbal informed consent was taken from all the participants.

Data Analysis

The statistical analysis was done by using statistical package for social sciences (SPSS) version 16. Categorical data were presented as frequency (percentage). The descriptive analysis was done by using mean and standard deviation.

RESULT

Demographic Details of Participated Community Pharmacists

Questionnaire was distributed to 72 pharmacists, out of them only 60 were participated in the study. The majority 54(90%) of participants were male, whereas female pharmacists accounted only one-tenth 6 (10%) of the total participants. The mean age of participant was 36.7 years. Higher proportions of pharmacists were between the age group of 20 to 30 years. Around 62% of participants were Diploma holder in pharmacy, whereas only 3(5%) were PharmD background, nearly half of them had been working for more than 10 years in the community pharmacy. Majority of Pharmacy (38.3%) were dispensing about 1 to 20 prescriptions per day. The details demography data of community pharmacy were represented in the Table 1.

Table 1: Demographic details of community pharmacists

| Table 11 bernegrapine details of community pharmacists | | | | | |
|--|------------|--|--|--|--|
| Demographic details No. (%) | | | | | |
| Gender | | | | | |
| Male | 54 (90) | | | | |
| Female | 6 (10) | | | | |
| Age | | | | | |
| 20–30 | 26 (43.33) | | | | |
| 31–40 | 11 (18.33) | | | | |
| 41–50 | 17 (28.33) | | | | |
| >50 6(10) | | | | | |
| Qualification | | | | | |
| B. Pharmacy | 20 (33.3) | | | | |
| D. Pharmacy | 37 (61.7) | | | | |
| Pharm. D | 3(5) | | | | |
| Working experience (in years) | | | | | |
| <1 11 | (18.3) | | | | |
| 1–5 11 | (18.3) | | | | |
| 5–10 | 12 (20) | | | | |
| >10 | 26 (43.3) | | | | |
| Number of prescriptions dispensed per day | | | | | |
| 1–20 | 23 (38.3) | | | | |
| 20–40 | 14 (23.3) | | | | |
| 40–60 | 11 (18.3) | | | | |
| >60 | 12 (20) | | | | |

Knowledge of Participated Community Pharmacists Regarding Generic Medicines

The mean (SD) knowledge score of the participants was 6.4 (3.77). Out of 60 participants only 2 (3.34%) have obtained 10 out of 10 knowledge score, whereas only one participant had got 2 scores which was the lowest score obtained so far. Around 84% of the participants gave the correct answer to item 1 in Table 2. More than half (58.5%) of the pharmacists know that generic versions cannot be marketed before the patent expiration of branded drugs. Nearly half of the participants 49 (81.7%) replied correctly to item 9 in Table 2 "Generic and branded drugs must have the same API (active pharmaceutical ingredient), dose and dosage form". Surprisingly, about 72% of pharmacists responded "A medicine may have more than one generic name" which was purely an incorrect statement. As per amendment made in drug and cosmetic act, bioequivalence studies are mandatory for generic drugs, but around 39% of the participants don't know about it. The details knowledge of pharmacist was presented in Table 2.

Attitude and Perception of Participated Community Pharmacists Regarding Generic Medicines

It was observed that more than half of the participants 34 (56.6.3%), one half was disagreed and other half was strongly disagreed that generic drugs are cheaper due to inferior quality. In contrast, the same proportion (28.3%) of participants were agreed to the same question. The response to item 2 in Table 3 was almost neutral as same (28.3%, 26.7%) percentile of pharmacists disagreed and agreed, respectively. Nearly half 28 (46.7%) of the participants find easy to dispense medicines by generic names. The majority (46.7%) of participants were in agreement with the following statement, "Generic substitution is a good practice and must be followed in India as far as possible to reduce healthcare expenditures". Out of 60 participants,

only 9 strongly agreed about prescribing the drugs solely by generic names. None of the participants strongly disagreed with the patient awareness about generic substitution, but still two (3.3%) disagreed and the rest of them were in strong agreement, agreement and neutral. Detailed responses of each Likert scale point for each question is presented in Table 3.

Discussion

To the best of our knowledge, no study has been conducted, especially in Northern region of India regarding assessment of community pharmacist knowledge, attitude and perception regarding generic medicines.

This study reveals that community pharmacists have average knowledge regarding generic drugs. The knowledge score is similar to the previous studies in Qatar and Palestine that were 6.8 and 5.91, respectively. [10,14] Around 83.3% of the participants know that generic medicines are bioequivalent to branded drugs, but the percentile was quite less in other related studies conducted in Eastern Ethiopia and Saudi Arabia. [4,12] In addition to this, 22% of participating pharmacists had given correct answers under the knowledge section in another study.^[14] On the other hand, in the current study, only 3.34% has replied correctly to all knowledge-based questions. It was observed that majority (38.3%) of participants has given response as 'Do not know' in technical questions related to bioequivalence studies. A good illustration of the statement mentioned above is that community pharmacists are well-known with basic information of generic versions, whereas technical knowledge was lacking. In another similar study, got the same response to the same question but proportion was only 6%, which is very low compared to the current survey.^[13]

The majority of participating pharmacists had a positive attitude towards generic drug substitution; similarly, other

Table 2: Representing knowledge-based data of community pharmacists on generic medicines

| | Correct | Incorrect | Don't know |
|--|-----------|-----------|------------|
| Knowledge of community pharmacists on generic medicines | no. (%) | no. (%) | no. (%) |
| Generic drugs are pharmaceutically as well as therapeutically bioequivalent to brand name medicines (T) | 50 (83.3) | 8 (13.3) | 2 (3.3) |
| A generic medicine can be marketed before the patent expiration of branded drugs (F) | 20 (33.3) | 35 (58.3) | 5 (8.3) |
| Generic drugs can be used interchangeably with branded drugs if they are not bioequivalent (F) | 14 (23.3) | 33 (55) | 13 (21.7) |
| Generic and branded drugs must have same API (active pharmaceutical ingredient), dose and dosage form (T) | 49 (81.7) | 6 (10) | 5 (8.3) |
| It may be possible that generic and branded drugs have different therapeutic uses (F) | 10 (16.7) | 43 (71.7) | 7 (11.7) |
| Clinical and non-clinical study is mandatory for generic drug approval (F) | 29 (48.3) | 23 (38.3) | 8 (13.3) |
| A medicine may have more than one generic name (F) | 43 (71.7) | 14 (23.3) | 3 (5) |
| Generic drugs are available at lower price than branded drugs (T) | 57 (95) | 3 (5) | 0 |
| Generic and brand name drugs have different excipients (like flavoring agent, sweetening agent etc.) (T) | 48 (80) | 7 (11.7) | 5 (8.3) |
| As per amendment made in drug and cosmetic act, bioequivalence studies are mandatory for generic drugs (T) | 31 (51.7) | 6 (10) | 23 (38.3) |

T = True F = False

Table 3: Representing attitude and perception-based data of community pharmacists on generic medicines

| · | | | | • | |
|--|---------------------------|------------------|--------------------|------------------------------|---------------------|
| Attitude and perception of community pharmacists on generic medicines | Strongly agree no. (%) | Agree no. (%) | Neutral no. (%) | Strongly disagree no. (%) | Disagree no. (%) |
| Generic drugs are cheaper than brand name drugs due to low quality (F) | 3 (5.0) | 17 (28.3) | 6 (10) | 17 (28.3) | 17 (28.3) |
| Generic drugs take more time to give response (F) | 3 (5.0) | 16 (26.7) | 14 (23.3) | 10 (16.7) | 17 (28.3) |
| It is easy to dispense medications by generic name | 11 (18.3) | 28 (46.7) | 10 (16.7) | 2 (3.3) | 9 (15.0) |
| Generic substitution is a good practice and must be followed in India as far as possible to reduce healthcare expenditures | 16 (26.7) | 28 (46.7) | 7 (11.7) | 1 (1.7) | 8 (13.3) |
| There must be strict regulations by the government in India about prescribing the drugs solely by generic name | 9 (15.0) | 36 (60.0) | 13 (21.7) | 0 | 2 (3.3) |
| If prescribed brand name medicine is not available, I would prefer to do generic substitution except for narrow therapeutic index drugs | 11 (18.3) | 35 (58.3) | 10 (16.7) | 3(5.0) | 1 (1.7) |
| I am in favor of promoting generic drugs utilization as far as possible | 14 (23.3) | 33 (55.0) | 10 (16.7) | 0 | 3 (5.0) |
| Generally, I would like to dispense generic drugs for minor ailments without consulting the physician | 6 (10.0) | 21 (35.0) | 7 (11.7) | 7(11.7) | 19 (31.7) |
| At least each community should have one generic drug store | 14 (23.3) | 32 (53.3) | 9 (15.0) | 3(5.0) | 2 (3.3) |
| Patients must be aware of generic versions to support generic substitution in India | 22 (36.7) | 27 (45.0) | 9 (15.0) | 0 | 2 (3.3) |

studies showed that more than half of the participants believed it was a good practice. [11,14] In contrast, a study had revealed that 80% of participants do not support generic substitution, which implies that they might have misconceptions regarding the quality and safety of generic drugs. [11] As evidence, the study mentioned above also showed that 30% of participants agreed that generic medicines possess the inferior quality to branded drugs. Also, In the current study, 5% pharmacists strongly agreed, and 28.3% agreed that generic drugs are cheaper due to low quality. In addition to this, sixteen participants had the wrong perception that generic drugs take more time to respond, but it was noticed that in another study, two-fifths of the pharmacists had opposite opinions. [4]

Further, it was observed that 45% of community pharmacists do generic substitution without consulting physician except for medicines having narrow therapeutic windows. Similarly, 64.5% of pharmacists agreed to the above statement in Palestine. Therefore, it perceives that the community pharmacists favor generic drug substitution, hence, paved the way in reducing healthcare expenses. To succeed in any field, public support is the crucial part of any government project or initiative, and the same is applicable here also. To support generic drug utilization awareness in public, it is very important to eliminate wrong perceptions about generic drugs' quality, safety, and efficacy. Pharmacists are directly involved in dispensing drugs, so they should create awareness among the public regarding generic drugs. The current study has shown a positive involvement of participating pharmacists (81.7%, both strongly agreed and

agreed) towards public awareness and promoting generic substitution in India. Not only in India, but a study from Saudi Arabia also reported that enough information should be given to patients about generic medicines.

Conclusion

Overall, community pharmacists have superficial knowledge regarding generic drugs. However, they should have in-depth information regarding generic versions. It could be possible only by conducting such studies to assess pharmacists' knowledge, attitude, and perception so that government would take initiatives by making certain policies to create awareness among public and community pharmacists to promote generic drug utilization. From this study, it seems that community pharmacists have poor technical knowledge about the regulatory process of generic drugs. Therefore, community pharmacists should have sufficient knowledge regarding generic drugs. As a consequence, they can promote generic substitution. If they have enough knowledge, they would be able to convince the patient about generic medicines, which helps reduce the healthcare expenses.

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