ORIGINAL ARTICLE

Pharmacists' Awareness and Perceptions of Biosimilars in Saudi Arabia

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Abstract

Objective: The current study aimed to evaluate practicing pharmacists' awareness and perceptions about biosimilars in Saudi Arabia. **Materials and Methods:** A cross-sectional study was performed using a pre-validated and self-administered research tool by convenience sampling method. Registered pharmacists were approached to participate in the study. Descriptive and inferential statistics were performed using the Statistical Package for the Social Sciences version 24.0. $P < 0.05$ was considered statistically significant. **Results:** Out of 319 pharmacists, 34.79% were familiar and 12.87% were very much familiar with the biosimilars. Around 33.22% were aware of the approval pathway and regulatory issues associated with prescribing biosimilars. The majority of the respondents (>60%) had good awareness and positive perception toward biosimilars. **Conclusion:** This study concluded an appropriate awareness and positive perception toward biosimilars among pharmacists in Saudi Arabia. Statistically non-significant association regarding biosimilars' perception and awareness was observed between male and female pharmacists.

Key words: Biosimilars, community, hospital, pharmacists, Saudi Arabia

INTRODUCTION

Biosimilars are the novel medicines that have become a huge part of biological remedies used by numerous health-care professionals (HCPs) in the management of various diseases such as cancer, rheumatoid arthritis, colitis, diabetes mellitus, Crohn's disease, anemia, immunologic diseases, osteoporosis, and other diseases.[1-3] The European Medicines Agency states that biosimilarity demonstrates a high similarity profile in terms of biological activity, structure, safety, efficacy, and immunogenicity to the original medication.[4,5] However, some HCPs and health-care organizations believe that biosimilar medications are complex proteins and as a result, these medications will never be an identical duplicate of the original drug because of their high molecular weight, heterogeneous nature, and batch-to-batch complexity and variability. Regarding the future market acquisition of the biosimilars, various factors are significantly important to understand, that is, pricing and cost-effectiveness, prescription rules and prescribing patterns, dispensing techniques, and trust regarding safety and efficacy among the patients.[6,7]

At present, not only prescribers but also other HCPs are involved in their distribution, dispensing, application, and usage among the general public. In some countries, biosimilars are relatively new such as the United States and numerous developing countries. On the other hand, in most of the developed counties such as European Union, biosimilars have been safely and effectively utilized since 2006. In several other countries, they are often used to treat

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various chronic and life-threatening diseases as substitutes of numerous biologic and chemical molecules including insulin, erythropoietin, recombinant human growth hormone, follitropin, filgrastim, etanercept, and infliximab.[3-9] In the near future, plentiful biosimilars will be ready to enter the health-care sector of several countries. They are very likely expected to offer advanced pharmaceutical care to the patients suffering from various life-threatening diseases which are difficult to treat including autoimmune disorders, cancer, endocrine diseases, gastrointestinal disorders, anemia, and many more. Biosimilars are often considered as cheaper alternative therapeutic products because they offer a cost-effective alternative to the existing expensive chemical and biological drugs.[10-14]

For an apt usage of the biosimilars, a better understanding and complete awareness of biosimilars among HCPs especially pharmacists are crucial and it is also expected that all HCPs will entail themselves to attain an in-depth understanding of the biosimilars prior offering to their patients. The same way as they did in the late 1980s when the concept of the generic drugs was first evolved and all of the HCPs were required to clearly understand them before prescribing and dispensing to their patients.[3,11-15] Similarly, in the literature, it is reported that pharmacists could play a significant role in supervising the introduction of biosimilars into the health-care systems.[16,17] In light of the growing need of availability of biosimilars in Saudi Arabia, this study aimed to identify pharmacists' familiarity, awareness, and perceptions toward the appropriate use of biosimilars in Saudi Arabia.

MATERIALS AND METHODS

Study type and study participants

A cross-sectional study was conducted among registered pharmacists using a newly developed and validated research instrument. The convenience sampling technique was used to select study participants.

Study instrument and data collection

Data were collected in June–August 2019, using a research instrument that was developed after an extensive literature review and consultations with content experts. The questionnaire consisted of three diverse parts. The first part included demographic characteristics of the study pharmacists, that is, gender, specialty, experience, and working setup. The second part included questions regarding the familiarity of the pharmacists toward biosimilars in Saudi Arabia. The third part included statements regarding pharmacists' awareness and perceptions toward biosimilars. The research was approved from the ethics committee of the concerned department; however, the participation was voluntary.

Inclusion and exclusion criteria

For inclusion criteria, pharmacists which were registered in Saudi Arabia and signed written consent were included in the study. For exclusion criteria, non-registered pharmacists, pharmacy technicians, and those who refused to sign the consent forms were excluded from the study.

Statistical analysis

Data analyses and calculations were carried out using Statistical Package for the Social Sciences version 24.0 and Microsoft Excel (Microsoft Corp., Redmond, WA, USA). Means and standard deviations were calculated for the continuous variables, whereas the frequencies and percentages were presented for the categorical variables. The correlation and association among male and female pharmacists regarding familiarity, awareness and perceptions about biosimilars were determined using the Spearman correlation coefficient. $P < 0.05$ was considered statistically significant.

RESULTS

Demographic characteristics of the pharmacists

There were a total of 319 pharmacists of various specialties from various regions of the country participated in the study. Out of the total 319 pharmacists, there were 111 female and 208 male pharmacists. About 41% of them were working in community pharmacies, 34% were working in hospital pharmacies, and 25% were working in other settings. Only 44.05% of the participants had more than 5 years' experience. Figure 1 represents the specialties of the pharmacists practicing at various setups and Figure 2 shows experience levels among the studied pharmacists.

Awareness of the pharmacists with biosimilars

Out of 319 pharmacists, around 34.79% were familiar and 12.87% were very much familiar with the biosimilars.

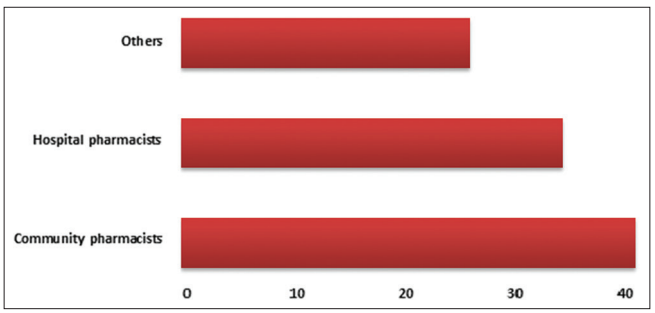

Figure 1: Specialties of the pharmacists working in different setups

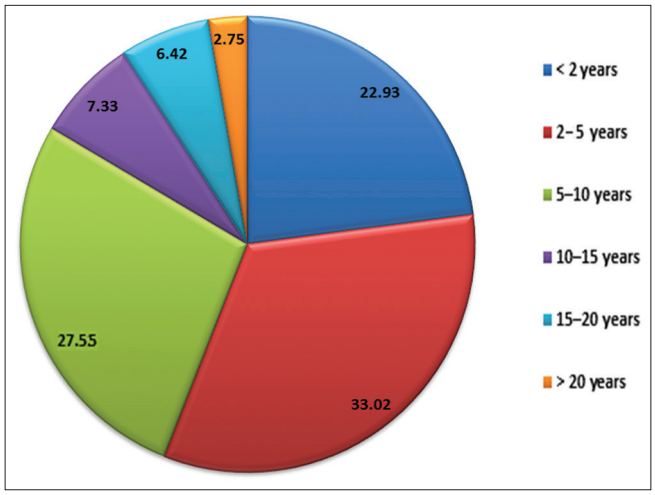

Figure 2: Experience of the studied pharmacists

Table 1: Awareness of the pharmacists about biosimilars in Saudi Arabia

Items	*n* (%)
How much are you familiar with the biosimilars?	
Not familiar	50 (15.67)
Somewhat familiar	117 (36.67)
Familiar	111 (34.79)
Very familiar	41 (12.87)
Are you aware of the approval pathway and regulatory issues associated with prescribing biosimilars in Saudi Arabia?	
Not at all	108 (33.85)
Somewhat	105 (32.93)
Very well	106 (33.22)

Moreover, only 33.22% were aware of the approval pathway and regulatory issues associated with prescribing biosimilars in Saudi Arabia. Table 1 represents the familiarity and awareness of the pharmacists with biosimilars.

Pharmacists' perception of biosimilars

A total of 77.74% pharmacists showed positive perception and were exceedingly agree to implement the usage of the biosimilars whereas only 6.58% disagreed. The majority of the study pharmacists, that is, 65.20% also showed a positive perception regarding the interchange ability and their substitution from a reference biological or chemical product by the pharmacists. The pharmacists' perception of biosimilars is shown in Table 2.

Table 3 illustrates the findings of the correlation analysis matrix for the male and female pharmacists regarding their perceptions about biosimilars. Statistically, a non-significant association ($P > 0.05$) was observed.

DISCUSSION

This study aimed to identify pharmacists' familiarity, awareness, and perceptions regarding the usage of biosimilars in clinical practice in Saudi Arabia. The results highlighted that approximately 50% of the pharmacists in the current study were familiar with biosimilars and around 34% were aware of the approval pathway and regulatory issues associated with biosimilars in Saudi Arabia. These findings were quite useful regarding the biosimilars availability in the Saudi Arabian health-care system. Two studies also reported that the majority of the participated pharmacists had good familiarity with biosimilars.[5,18] Similar to two previous studies, the reason could be that the study populations, the pharmacy curricula, and market availability, and the resources regarding the biosimilars were different among these studies.[19,20]

More than 60% of the study pharmacists perceived positive about the interchangeability of chemical and biological substitutes of the biosimilars. More than 60% of the study participants were in favor of the change of a biological medicinal substitute and chemical substitute to an alike biosimilar by the pharmacists. Moreover, around 10% were of the view that this change must be consulted with the concerned physician. Similar results were reported by another study that the substitution must be done after proper consultation of a prescriber.[18] This findings might raise the need for continuous updation of the medical and the pharmacy curricula to keep up with the latest information and the latest resources regarding the available biosimilars in the local market.[21,22]

Recently, the United State Food and Drug Administration had finalized its protocols regarding biosimilars which ultimately allowed pharmacists to routinely dispense therapeutically equivalent and cheaper alternatives.[23,24] In our study results, the majority of the pharmacists advocated the concept that even if pharmacists are allowed to dispense biosimilars, a rationale and scientifically justified approach should be followed for the interchangeability and substitution of the biosimilars. The majority of the hospital and community pharmacists were profoundly interested in the introduction of biosimilars in Saudi Arabian clinical practice. Another interesting finding observed in the current study was that the majority of the study participants had positive perceptions regarding efficacy and safety perspective of the biosimilars and they were agreed that biosimilars should be tried and tested before their usage among the patients. Regarding the cost-effectiveness of the biosimilars, our study found that 55.48% of the pharmacists believed that the biosimilars for numerous diseases are cheaper than the medicinal products so they could play a key role in controlling health-care costs of a populace.

In terms of the association between the two genders' perception (male and female) with the familiarity of the biosimilars and awareness with their approval and regulatory issues, self-perspectives toward general information of the

Table 2: Pharmacists perception toward biosimilar medications

No.	Items	No (%)	Neutral (%)	Yes (%)
1	I am in favor of the implementation of usage of the biosimilars	21 (6.58)	50 (15.68)	248 (77.74)
2	Biosimilars are tried and tested in terms of efficacy and safety before their availability in the market	15 (4.71)	38 (11.91)	266 (83.38)
3	Biosimilars information is of greater concern for the pharmacists	29 (9.10)	132 (41.37)	158 (49.53)
4	I favor the substitution of a reference biological medicinal product to its biosimilar by a pharmacist	35 (10.97)	76 (23.83)	208 (65.20)
5	I favor the substitution of a reference chemical medicinal product to its generic product by a pharmacist	36 (11.28)	64 (20.06)	219 (68.66)
6	Prescribing biosimilar helps in reducing healthcare costs	41 (12.85)	101 (31.67)	177 (55.48)
7	Biosimilars are safer medicines to use	18 (5.64)	46 (14.43)	255 (79.93)
8	Biosimilars should be named alike to their parent molecules	38 (11.91)	114 (35.73)	167 (52.36)
9	Biosimilars should be prepared considering local market needs and stakeholders policy	26 (8.15)	140 (43.89)	153 (47.96)

Table 3: Association of awareness and perception among male and female pharmacists regarding biosimilars

No.	Items	*P*-value
1	Familiar with biosimilars	0.061
2	Aware of the approval pathway and regulatory issues of biosimilars	0.182
3	Biosimilars information is important for the pharmacists	0.245
4	Local market demands and stakeholders policies should be considered before biosimilars production	0.342

*Correlation is significant at 0.05 level (two-tailed)

biosimilars, and local market demands and stakeholders' policies regarding biosimilars, statistically, a non-significant association ($P > 0.05$) was observed. This finding suggested that both of the genders, that is, male and female pharmacists working as hospital pharmacists, community pharmacists or in any other setup in Saudi Arabia were familiar with the biosimilars and were quite comfortable to dispense them in near future in Saudi Arabia.

Undeniably pharmacists' awareness of biosimilars is vital but patients' understanding and awareness of biosimilars are also of great importance to get an optimum pharmacotherapy.[25,26] Inappropriate use of biosimilars among patients may result in nocebo effects which could be minimized or prevented by better patient counseling. Moreover, nocebo effects may impact patients' overall quality of life, medication adherence, and treatment progression if patients and HCPs are not very-well aware of biosimilars.[27,28] Similarly, all of the biosimilar producing companies are also required to be extra efficient in the entire process of biosimilar production, that is, quality control, research, and development and distribution to gain patients' trust and satisfaction and maintain their biosimilar sustainability for a longer-term.[29,30]

CONCLUSION

The use of biosimilars for optimum patient care needs special attention from the HCPs especially pharmacists due to the numerous concerns relating to their dose, efficacy, and safety. The findings of our study have important implications for pharmacists awareness and perceptions regarding the uptake of biosimilar drugs. The present study shows that many pharmacists are in favor of the implementation of biosimilar medicines and are convinced of their cost savings aspects.

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