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Review article

MEDICAL SPECIALISTS' KNOWLEDGE AND PERCEPTIONS OF BIOLOGICS AND BIOSIMILARS: A LITERATURE REVIEW

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Abstract

Introduction: Newly developed biological medicines offer essential treatment for many acute and chronic conditions. In addition, the increasing availability of biosimilar drugs improve access to vital biologic treatments. Medical specialists prescribe biological medicines, thus the adoption of these products in the market heavily relies on their readiness to prescribe, and integrate them into clinical practice, which depends on their knowledge, perspectives, and beliefs.

Aim: To review the scientific literature regarding knowledge and perceptions related to the use of originator biologics and biosimilars, along with the need for additional education on this topic.

Material and methods: A literature search was conducted using journal databases, such as PubMed, Cochrane Library, and Scopus, with carefully selected search terms, and applying the inclusion criteria that match the aim of the study.

Results: The majority of studies meeting the specified criteria were carried out in Europe and the USA, primarily in the form of brief surveys. Studies show that most of the medical specialists are familiar with the biologic medicines, however their measured knowledge was less extensive than their self-assessed knowledge. In general, a larger percentage of those who were surveyed expressed the need for additional education.

Conclusions: Medical specialists' knowledge and opinions towards biologics in general are highly variable, with a general observation that there is a need of increasing the knowledge in the field. Therefore, education is a key prerequisite for better understanding the differences among originator biologics and biosimilars, which will support their inclusion into treatment plans.

Keywords: biologicals, biosimilars, medical specialists, knowledge

Introduction

Biological medicines (biologics) have revolutionized modern healthcare, significantly improving outcomes for severe and life-threatening conditions like diabetes, numerous cancers,

autoimmune disorders (such as rheumatoid arthritis, Crohn's disease, multiple sclerosis, and severe psoriasis), as well as rare diseases[1]. In addition to treating diseases, they are also important in improving the quality of life of patients. Their use in contemporary disease treatment has become of great significance in the last decades, especially in modern societies.

A biological drug is defined as any drug that contains an active substance, a biological substance or a substance obtained by a procedure involving biological systems[2]. Strict regulatory rules exist in order to assess the quality, safety and efficacy of biological medicines, especially regarding immunological reactions that may occur during their use. Occurrence of immunogenicity is a possibility, given that these medicinal compounds come from living systems, and may change biological processes and/or produce allergic reactions leading to clinical repercussions.

Biosimilars are newer addition to biologic drugs scene, containing a version of the active substance of a previously approved original biological medicine (also known as originator or reference medicine). They emerge as competing products for an originator (reference) biologic product when their patent protection or marketing exclusivity has lapsed. The active substance of the biosimilar is comparable to the active substance of the reference biological medicine. However, their similarity to the reference biological medicine must be demonstrated in terms of quality, biological activity, safety and efficacy based on comparative studies. Their dosage and use should be the same as for the reference biological drug.

The heterogeneous nature, high molecular weight, batch-to-batch variability and complexity of many biological substances make it impossible for a different manufacturer to produce an exact copy of the biological medicine; therefore, generics of biological medicines are not feasible. On the other hand, a generic approval of drugs containing chemically synthesized medicines is possible once an identical chemical structure for the active substance has been confirmed and bioequivalence to the reference product has been demonstrated[3].

Owing to the inherent differences between biological and chemical substances, the abbreviated regulatory pathway used for generics is not suitable for biological substances manufactured by different producers. Therefore, biosimilar manufacturers are required to demonstrate, by way of a comprehensive comparability exercise, that the biosimilar is similar in quality, safety and efficacy to the reference medicine. The variability associated with biological drugs manufacturing make it more challenging to reproduce the exact molecular structure, even among batches of the same product, and is a subject to strict control by manufacturers and regulatory authorities[4].

After the approval of the first biosimilar in the EU in 2006, the number of these drugs on the market is constantly increasing. Until 2020, biosimilars occupied 1% of the total biologics market worldwide[5]. According to this report, the biosimilar market is expected to peak in Europe in the next 10 years, due to the anticipated loss of exclusivity of many originators, especially in the fields of oncology (29%), followed by blood and lymphatic conditions (21%)[6].

The introduction of biosimilars fosters greater competition between manufacturers, reduces prices, and facilitates patients' access to expensive medicines. Because the biosimilar approval process is abbreviated, they offer reduced-cost treatments and have become more available to patients, compared to originator biologic products. The adoption of biosimilars could lead to healthcare cost savings and improved patient access to expensive biologic therapies[7].

Although the benefits of the introduction of biosimilar drugs are established, there is still a reservation regarding their use. Most of the available data on manufactured products is disseminated to medical specialists through manufacturers' representatives. However, this source of information is rarely sufficient to encourage the prescription of these drugs, especially

biosimilars. Although considerable efforts have been made by manufacturers, governments, and representative organisations, the uptake of biosimilars still faces numerous barriers[8].

Extensive studies have been conducted in order to elaborate the facilitating factors and barriers affecting biosimilar uptake, but mostly focusing on specific factors such as medical specialists' knowledge and confidence regarding the biosimilars, patients' knowledge and confidence in biosimilars, and policies that limit their uptake[9]. The knowledge remains to be the main pillar in the healthcare profession, providing professionals with reliable information on medicines in general, but especially in biologicals. Medical specialists have the main role in patient care, thus their appropriate knowledge is of utmost importance, as well as the appropriate access to accurate information about these medicines: what they are, what scientific rules support their development, marketing authorization and safety monitoring. The primary objective of this literature review was to assess and evaluate the reported knowledge of medical specialists and their perception/opinion of originator biologics and biosimilars.

Material and methods

A comprehensive literature search was conducted using relevant databases, including PubMed, Scopus and Cochrane Library, with the following search terms: biological, biosimilar, survey, questionnaire, knowledge, and education. The generated results were subjected to selection of original scientific articles that provide surveys conducted among physicians. Some of the studies include pharmacists and nurses, but only questionaries from physicians were subject to evaluation. Studies involving questionnaires administered to patients and pharmaceutical companies were not subject to evaluation.

Sixty-one study were identified in the literature. After selection of studies that met the required criteria, a total of 13 officially published studies were selected, and subjected to evaluation. The selected studies were conducted in many countries worldwide over the past decade.

Results

A total of 13 studies was chosen for inclusion in the analysis and for evaluation. These studies included different medical specialists: 7 studies involved oncologists, 5 dermatologists, 10 rheumatologists, 2 gastroenterologists; 1 haematologist and in 6 studies the specific field of surveyed medical specialists was not defined.

Each of the 13 selected studies was thoroughly reviewed, and the following information was extracted: general information (authors, year, and country of publication), study objective and included sample, methods and results regarding the assessed knowledge and opinion for biologic originator and biosimilar drugs. The evaluation of the reviewed articles was set to topics that concerned medical specialists: (1) self-rated knowledge of biosimilars, (2) evaluated knowledge of biosimilars, (3) opinions regarding the advantages and disadvantages of biosimilars, (4) identified need for further education.

Evaluation of the knowledge and opinions toward original biological and biosimilar medicines among medical specialists

Many of the studies included self-rated assessment of the knowledge on original biologics and biosimilars, resulting in wide variation in medical specialists' self-rated knowledge.

The study by Gibofsky *et al*. aimed at evaluating the knowledge of rheumatologists on biologics in general[10]. In this study, 38% of physicians self-reported that they were extremely,

and 36% were moderately familiar with the FDA's definition of a biosimilar. Regarding the treatment initiation with biosimilars, 66% of rheumatologists would prefer to initiate biosimilar treatment for a naive patient. Physicians (71%) answered that biosimilars were not automatically interchangeable with originator biologic medicine, which is in line with current recommendations[4]. Most of the medical specialists (60%) were hesitant to switch the therapy from originator to its biosimilar.

Van Overbeeke *et al*. evaluated both self-assessed and measured knowledge using a survey among rheumatologists, including patients diagnosed with rheumatoid arthritis. Rheumatologists more often than patients expressed concerns about potential differences in quality between originators and biosimilars (60% of rheumatologist *vs*. 40% of patients), safety (64% of rheumatologists *vs*. 28% of patients), and price (92% of rheumatologists *vs*. 74% of patients). This study revealed a variation in medical specialists'opinions on interchangeability and extrapolation of indication. This is in line with a conclusion that majority of studies state that the progression of usage of biosimilars mainly depends on the opinion of the medical specialists[11].

The study by Kellner *et al*. aimed to assess the awareness and acceptance of biosimilars by rheumatologists, and was conducted in 11 European countries[12]. Their results showed that rheumatologists had little knowledge and lacked available information about biosimilar drugs, because only 48% correctly identified the definition of a biosimilar, and 52% of rheumatologists defined that biosimilars were the equivalent of generics for originator biologic. Regarding the prescribing, many rheumatologists prefer to start these treatments with biologic-naive patients or those who have stopped responding to their original biologic therapy. However, in the questionary intended for self-assessed knowledge, 65% of rheumatologists claimed familiarity with biosimilars, even though their knowledge of biologics development processes was insufficient. This survey also measured knowledge, with 48% of respondents correctly identifying the EMA biosimilar definition, 16% incorrectly defined biosimilars as an equivalent of generics for biologics, and 36% defined biosimilars as similar biologics, having the same mechanism of action as the originator.

Knowledge gaps identified through market research studies with US rheumatologists were identified as contributing factors to the limited adoption of infliximab biosimilars in the USA as noted by Oskouei *et al*., discussing the factors that impact the implementation of biosimilars by healthcare providers[13,14].

An assessment of the knowledge on biologicals among dermatologists was conducted in USA by Barsell *et al*. Their study showed that only 37% of dermatologists were aware that a biosimilar was highly similar to a reference biological product, whereas 26% incorrectly described biosimilars as a generic of a known biologic. Ten percent of dermatologists stated they did not know the definition of biosimilar[15].

Varying results were found when the knowledge of oncologists was assessed. Peipert *et al*. examined the measured knowledge among oncologists, and evaluated the opinions regarding the biosimilar efficacy between the oncologists from university hospitals and oncologists from private hospitals or private practices. Half of the respondents (52%) correctly answered that biosimilars were not the same as generic medicines. Less than half (40%) oncologists reported that their institution provided education about biosimilars. One of the conclusions of this study was that the oncologists from university hospitals (36%) were more concerned about biosimilar efficacy than from community/private hospitals (28%). All respondents (99%) reported that information related to safety and efficacy was important for considering using the biosimilars[16].

The survey conducted by Giuliani *et al*. aimed to assess the knowledge gaps regarding biosimilar development, clinical trial design, endpoint selection, and the requirements for

extrapolation of indications for administration of biosimilars. Among the oncologists surveyed, 49% reported actively using biosimilars in their clinical practice, with most rating their general knowledge of biologics and biosimilars as average to very high. Regarding the surveyed opinion about interchangeability, i.e. switching from originator to biosimilar medicine, most of them mentioned the potential of increased risk due to immunogenicity as a main concern[17].

Cook *et al*. conducted a survey among US oncologists in order to evaluate their opinions related to three topics: clinician understanding, prescription preferences and patient involvement in the use of biosimilars[18]. 74% of respondents could not give an appropriate definition of a biosimilar, and 40.3% considered the biosimilar the same as a generic drug. This study also surveyed the opinion of medical specialists regarding the involvement of pharmacists, especially in the decision regarding the substitution of originator to biosimilar and received split opinions of clinicians. Only 13% of participants considered that pharmacists should be involved in the therapy decision-making regarding biologics. However, they thought that decision was not possible to be made by the pharmacists alone. In a study conducted in China, where 76.70% of HCPs showed knowledge about biosimilars, there was general acceptance of biosimilars and interchangeability, but insecurity regarding efficacy, safety and immunogenicity[19].

Ismailov *et al*. conducted a survey in oncologists that was aimed to assess the knowledge and opinions related to definition, regulation and interchangeability of biologic medicines. More than 90% of respondents identified and correctly distinguished biosimilars from originators, stating that safety and efficacy were the most important factors in their decision to prescribe a biosimilar. Most of respondents were interested in sharing their knowledge with colleagues and patients[20].

Other reviewed studies involved various medical specialists, but retrieved similar results, that can be summarized as follows:

- The vast majority of respondents across all specialties have heard about biosimilars, but their actual knowledge of the fundamentals of biosimilars is low[21];
- Chapman *et al*. consider that the guidance from National Institute for Health and Care Excellence and well-made pharmacovigilance studies on biosimilars are also important factors for increasing the use of biosimilars[22];
- The survey findings indicate that the majority of participants demonstrate good knowledge of the biosimilars regulation. Major concerns raised regarding biosimilars were mainly about their pharmaceutical quality, safety (especially immunogenicity), efficacy (particularly in extrapolated indications) and interchangeability with the originator product[23];
- There is an overall lack of biosimilar familiarity in U.S. and European healthcare settings accompanied with concerns about biosimilar safety, efficacy, extrapolation, and interchangeability[16];
- Medical specialists have greater concerns about safety and efficacy when switching patients to biosimilars than when starting biosimilars in biological naive patients.

Reviewed data reflect lack of understanding of what defines a biologic in a survey conducted in the Spanish Society of Physicians[24]. The definition of biosimilar was not known by 58% of those that responded, and 73% were unaware that the management of biosimilars and generics was not comparable. Most of those that responded (84%) were not aware that the studies required for the approval of biosimilars are different from reference biological medicines, whereas in an earlier study conducted in Germany, Italy and Spain, only 23% of survey respondents expressed complete or good knowledge about scientific principle of biosimilars[25].

It is interesting to note that countries that have different policy for registration and prescription of biologics/biosimilars, such as Russia, are still holding the position that a drug needs to be prescribed by its international non-proprietary name (thus holding the risk of unintended switching of original biologics with a biosimilar, and *vice-versa*). They show openness to learn more about the difference of these two entities of biologics. This is in line with the results obtained from an online survey, where 80% of survey respondents from different specialties showed lack of understanding of biosimilars[26].

When it comes to the investigation of the same topic in Asian countries, a recent survey report by Poon *et al.*, which included hospital pharmacists and medical specialists (oncologists and rheumatologists) in Taiwan, revealed that 86% of participants had given (recognised) the correct definition of biosimilars, and only 26.6% of respondents knew the exact difference between biosimilars and originators. Rheumatologists showed higher confidence in their knowledge, however higher acceptance of switching from originator to biosimilar was shown by the pharmacists. Generally, knowledge and confidence for biosimilars was low when it comes to safety and efficacy, and the respondents have concerns regarding these products[27]. In another recent study, the perceptions and beliefs among dermatologists, gastroenterologists and rheumatologists regarding biosimilars was analyzed by Thongpooswan *et al*. This study included medical specialists from Hong Kong, Pakistan, Taiwan, India, Singapore and Thailand and revealed that 68% of prescribing physicians reported to have good knowledge of biosimilars, once again concluding that knowledge is a crucial factor for enhancing access of patients to biologics[28].

Discussion

Considering that medical specialists hold a key role in the acceptance and prescribing of biologics, both originators and biosimilars, many of the performed studies involve surveying these professionals, with some studies involving also patients' and pharmacists' opinions who not covered by this review. The results of the studies show that medical specialists' knowledge of originator biologics and biosimilars varies widely, even when not specifying how the surveys were designed (measured knowledge *vs*. self- assessment). In general, the disparity between measured knowledge and self-assessed knowledge is a common finding in studies involving medical specialists' understanding of biologics, especially biosimilars. The evaluation in the studies was conducted through administered questionnaires, that allow deeper assessment of both self-assessed and measured knowledge related to definition, regulatory and clinical practice, including the opinions related to biologic originator and biosimilar medicines.

Most of the participants in the surveys reported that they used multiple sources of information about biologic medicines. Despite that, in general, their knowledge was not always in line with this statement. Most of the participants answered that a biosimilar was the same as a generic medicine. A variation is present also in the perception of biosimilars and their uptake. Specifically, respondents generally showed a preference for originator products over biosimilars and would prescribe biosimilars mainly for biologic-naive patients[23].

This literature review found that medical specialists' knowledge of biosimilars in many cases was inadequate, which may contribute to low incidence of prescribing and uptake of biosimilars. Therefore, educational activities provided by academia and medical societies, in addition to the information provided by companies, are vital in order to improve the knowledge among medical specialists, which would enable comprehensive utilisation of biologics including biosimilar drugs in clinical practice, as noted also by Sidikou *et al*.[29]. Studies performed in countries with high usage of biologics, such as USA, Canada and EU, show that medical

specialists' lack of knowledge about biosimilar drugs can contribute to concerns about their safety and efficacy.

In this context, just recently, Rieger *et al.* conducted a study to identify the barriers to the uptake of biosimilar medicines, aligning with many previously obtained findings: general lack of knowledge about biosimilars, as well as concerns related to their safety and efficacy[30].

Regarding the fact that biologics market is constantly growing, provision of adequate basic knowledge, as well as up-to-date insights on specific medicines is essential in order to completely use the benefits that these innovative therapies have to offer. Furthermore, innovative biological therapies are increasingly present in treatment guidelines based on evidence-based medicine, including our country[31].

Our study aimed to summarize the findings of the published research, and while many results lead to similar conclusions, certain limitations remain. The data presented in the selected studies were received using different study designs, different questionnaires, and there was no registered use of one single protocol for their retrieval. Therefore, we analyzed only selected topics of interest that aligned with the aims of the study previously elaborated.

Conclusion

Based on the findings of this literature review, it can be concluded that the lack of adequate knowledge and perception of originator biologics and biosimilarsis is still an important issue, even after nearly two decades of presence of biosimilars on the market. This conclusion highlights the need for continuous education regarding this topic. This was confirmed in different countries worldwide, thus highlighting the global significance of this issue.

Therefore, action is needed on fostering access to education and provision of educational initiatives for medical specialists, as well as other healthcare workers that relate to this topic. In this line, education and national recommendations and policies for switching and substitution of biologic medicines are needed to support the decisions that are made during prescribing and/or switching from- and to- biosimilars and to provide healthcare professionals with clear guidelines about the process.

Although many studies have tried to evaluate medical specialists' knowledge and perceptions regarding biologics, the emergence of new research, interventions and experience in using these medicines, suggests that further evaluation of progress about this topic, including different medical disciplines, particularly with qualitative research methods, will continue in the future.

Conflict of interest statement. None declared

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