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Awareness and Knowledge of Biosimilars Among Rheumatologists and Patients

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ABSTRACT

Background: Biosimilars offer cost-effective alternatives to biologics in rheumatology; however, their adoption remains hindered by physician hesitancy and patient misconceptions. Despite increasing clinical use, knowledge gaps persist, affecting prescribing behaviors and treatment adherence. **Objective**: This study aimed to assess awareness, perceptions, and barriers to biosimilar adoption among rheumatologists and patients, identifying key factors influencing acceptance. **Methods**: A cross-sectional survey was conducted among 22 rheumatologists and 66 patients in clinical rheumatology settings. Structured questionnaires evaluated demographic characteristics, familiarity with biosimilars, prescribing patterns, and patient acceptance. Data were analyzed using SPSS v25, employing chi-square tests and t-tests to assess statistical significance, with p-values <0.05 considered significant. **Results**: Among rheumatologists, 80% (n=18, p=0.021) were very familiar with biosimilars, and 75% (n=16, p=0.017) had received formal education, yet only 70% (n=15, p=0.015) had prescribed them. Among patients, 60% (n=40, p=0.003) rated their biosimilar knowledge as poor, and 55% (n=36, p=0.006) were unsure about their safety and efficacy. A significant gap in physician-patient communication was observed, with 65% (n=43, p=0.008) of patients never discussing biosimilars with their rheumatologist. **Conclusion**: Rheumatologists demonstrated strong biosimilar knowledge, yet prescribing reluctance persisted, while patients exhibited significant uncertainty and reliance on non-medical information. Targeted education and structured communication strategies are essential to improve biosimilar adoption, ensuring cost-effective and evidence-based treatment.

Keywords
Biosimilars, Rheumatology, Biologic Therapy, Patient Education, Physician Awareness, Drug Substitution, Immunotherapy,

INTRODUCTION

Biosimilars have emerged as a cost-effective alternative to biologics for the treatment of immune-mediated diseases, including rheumatic disorders. Despite their potential benefits in increasing patient access and reducing healthcare costs, their adoption remains suboptimal due to concerns about safety, efficacy, and limited awareness among healthcare providers and patients (1-3). Rheumatologists

generally demonstrate a higher level of understanding of biosimilars, yet they often express reluctance in switching stable patients from reference biologics due to concerns about nonmedical switching and interchangeability (4). In contrast, patient awareness remains limited, with many individuals relying solely on their physician's recommendations without fully understanding biosimilar therapies (5).

Several studies have investigated physicians' perceptions of biosimilars across different regions. In the United States, rheumatologists display a good understanding of biosimilars but remain hesitant to switch stable patients, citing a need for further education (6). Similarly, physicians in Russia exhibit a positive attitude toward biosimilars but lack knowledge distinguishing biosimilars from generic drugs, indicating the necessity for additional educational initiatives (7-9). In Asian countries, despite strong biosimilar knowledge among physicians (68%), availability remains limited, and further support through education and regulatory clarity is needed to improve biosimilar prescribing (10).

One of the most significant barriers to biosimilar adoption is the concern regarding efficacy and safety. Studies indicate that healthcare providers often express apprehensions about switching patients from originator biologics to biosimilars, fearing loss of efficacy and potential adverse reactions (11). A systematic review further highlights that healthcare professionals' hesitancy stems from a lack of clear national guidelines and concerns regarding pharmacist-led substitution (12). Additionally, providers often report insufficient education about biosimilars, reinforcing the need for clinician-directed training programs to enhance biosimilar confidence and prescribing behavior (13).

Patient knowledge about biosimilars remains significantly lower than that of physicians. In a French national survey, only 43% of rheumatic disease patients were aware of biosimilars, with many reporting that they were not informed before being prescribed a biosimilar (14). In Romania, half of the surveyed patients were unaware of biosimilars, even though some were already receiving them as treatment (15). Similarly, in the United States, a survey found that 66% of patients with immune-mediated conditions had no prior knowledge of biosimilars before being provided with a definition, with major concerns including side effects, long-term safety, and lack of information (16).

However, education appears to play a crucial role in improving patient acceptance of biosimilars. Studies indicate that when patients receive clear information from their rheumatologists or nurse specialists, their satisfaction and confidence in biosimilar switching increase (17-19). In a European study, structured education by healthcare providers significantly reduced patient concerns about biosimilar use (20). Likewise, in Australia, most rheumatoid arthritis patients were willing to accept biosimilars if recommended by their rheumatologist, despite initial unfamiliarity (21-23). These findings highlight the importance of physician-led patient education in fostering biosimilar acceptance.

Beyond physician and patient awareness, systemic factors also impact biosimilar uptake. In Latin America, barriers to biosimilar adoption include inconsistent regulatory guidelines and limited pharmacovigilance systems, leading to uncertainty among healthcare professionals (24). In Taiwan, knowledge gaps among healthcare providers, including rheumatologists and pharmacists, further hinder biosimilar use, with many professionals expressing low confidence in their efficacy and safety (25). Furthermore, the nocebo effect—where negative expectations influence patient experiences—has been cited as a major obstacle to biosimilar adoption. Studies suggest that careful communication about biosimilars' equivalency to reference products can help mitigate this effect (26-27). Additionally, shared decision-making between physicians and patients has been identified as a key factor in successful biosimilar implementation, as seen in real-world data from Colorado, USA (28-31). This study aimed to evaluate biosimilar awareness, prescribing behavior, and adoption challenges among rheumatologists and patients while assessing the impact of education on acceptance and regional differences in uptake.

MATERIALS AND METHODS

A cross-sectional survey was conducted to assess the awareness and knowledge of biosimilars among rheumatologists and patients. The study sample comprised 22 rheumatologists and 66 patients diagnosed with rheumatic diseases. Participants were selected using a non-probability convenience sampling method from outpatient rheumatology clinics and hospitals. Rheumatologists were required to have at least one year of clinical experience in managing patients with biologic therapies, while patients were included if they had been prescribed or were aware of biologic or biosimilar treatments. Individuals with cognitive impairments or those unwilling to participate were excluded.

The survey was developed based on validated questionnaires used in previous studies assessing biosimilar awareness and knowledge (32). It consisted of two separate sections tailored for rheumatologists and patients, covering demographic characteristics, knowledge about biosimilars, perceptions of safety and efficacy, and willingness to prescribe or switch to biosimilars. Rheumatologists' responses included their level of familiarity with biosimilars, prescribing practices, and perceived barriers to prescribing. Patients' responses assessed their awareness, sources of information, and factors influencing their acceptance of biosimilars.

Data were collected through structured, self-administered questionnaires distributed in both paper and electronic formats. Participants provided informed consent before completing the survey, ensuring voluntary participation. Ethical approval was obtained from the institutional review board, and the study adhered to the ethical principles of the Declaration of Helsinki. Confidentiality and anonymity of the participants were maintained throughout the study.

Descriptive statistics, including frequencies and percentages, were used to summarize categorical variables, while means and standard deviations were reported for continuous variables. Comparisons between groups were performed using chi-square tests for categorical data and independent t-tests for continuous variables, as appropriate. A p-value of <0.05 was considered statistically significant. Statistical analyses were conducted using SPSS version 25.

RESULTS

The study surveyed 22 rheumatologists and 66 patients, assessing their demographics, awareness, perceptions, and preferences regarding biosimilars. The results demonstrate a significant gap in knowledge and acceptance between healthcare providers and patients, with p-values indicating statistical significance in many variables. The age distribution among rheumatologists showed that the majority (45%) were between 40-49 years (n=10, p=0.032), whereas most patients were in the 50-59 years age group (35%, n=23, p=0.004). The gender distribution showed a predominance of male rheumatologists (70%) (n=15, p=0.027) and female patients (65%) (n=43, p=0.015).

Regarding professional experience, 50% of rheumatologists (n=11, p=0.041) had 11-20 years of practice, indicating a relatively experienced sample. Among patients, the highest education level recorded was bachelor's degree (50%) (n=33, p=0.008), which may impact their health literacy and ability to understand biosimilar treatment options. The majority of rheumatologists practiced in hospital-based settings (60%) (n=13, p=0.022), whereas both groups predominantly resided in urban areas—70% among doctors (n=15, p=0.039) and 67% among patients (n=44, p=0.021), reflecting accessibility to specialized healthcare facilities.

Biosimilar awareness was significantly higher among rheumatologists compared to patients. 80% of doctors (n=18, p=0.021) reported being very familiar with biosimilars, while 60% of patients (n=40, p=0.003) rated their familiarity as not very good. Furthermore, 75% of rheumatologists (n=16, p=0.017) had received formal education on biosimilars, which contrasts with patients' responses showing 50% (n=33, p=0.002) had no understanding of biosimilars. Confidence levels also showed a major discrepancy, with 65% of rheumatologists (n=14, p=0.029) expressing high confidence in explaining biosimilars to patients. However, when examining patients' first exposure to biosimilar information, 50% (n=33, p=0.014) cited the Internet and social media as their primary source rather than healthcare professionals, highlighting an information gap that may contribute to patient hesitancy.

When evaluating perceptions of biosimilars, 85% of rheumatologists (n=19, p=0.018) expressed confidence in the safety and efficacy of biosimilars,

Table 1: Demographics of Rheumatologists and Patients

Variable	Response/Category	Frequency (%)	P-Value
Age (Doctors)	40-49	10 (45%)	0.032
Age (Patients)	50-59	23 (35%)	0.004
Gender (Doctors)	Male	15 (70%)	0.027
Gender (Patients)	Female	43 (65%)	0.015
Years in Practice (Doctors)	11-20 years	11 (50%)	0.041
Highest Education (Patients)	Bachelor's degree	33 (50%)	0.008
Practice Setting (Doctors)	Hospital-based	13 (60%)	0.022
Geographic Location (Doctors)	Urban	15 (70%)	0.039
Geographic Location (Patients)	Urban	44 (67%)	0.021

Table 2: Awareness and Knowledge of Biosimilars

Variable	Response/Category	Frequency (%)	P-Value
Familiarity with Biosimilars (Doctors)	Very familiar	18 (80%)	0.021
Familiarity with Biosimilars (Patients)	Not very good	40 (60%)	0.003
Formal Education on Biosimilars (Doctors)	Yes	16 (75%)	0.017
Confidence in Explaining Biosimilars (Doctors)	Very confident	14 (65%)	0.029
Understanding of Biosimilars (Patients)	No understanding	33 (50%)	0.002
First Source of Information (Patients)	Internet/Social Media	33 (50%)	0.014

Table 3: Perceptions, Barriers, and Preferences Regarding Biosimilars

Variable	Response/Category	Frequency (%)	P-Value
Belief in Safety and Efficacy (Doctors)	Yes	19 (85%)	0.018
Belief in Safety and Efficacy (Patients)	Unsure	36 (55%)	0.006
Have Prescribed Biosimilars? (Doctors)	Yes	15 (70%)	0.015
Willingness to Switch (Patients)	Unsure	33 (50%)	0.005
Concerns About Biosimilars (Patients)	Fear of side effects	40 (60%)	0.002
Importance of Cost (Patients)	Very important	46 (70%)	0.011
Have Discussed Biosimilars with Rheumatologist? (Patients)	No	43 (65%)	0.008

Table 4: Additional Information Needed by Patients

Variable	Response/Category	Frequency (%)	P-Value
Preferred Additional Information (Patients)	Data on long-term safety/efficacy	40 (60%)	0.009
Open Comments on Biosimilars (Patients)	Concerns about safety and lack of information	-	-

whereas 55% of patients (n=36, p=0.006) remained unsure. Despite this confidence among doctors, only 70% (n=15, p=0.015) reported prescribing biosimilars, indicating remaining reservations about widespread adoption. Patient acceptance of biosimilars also showed uncertainty, with 50% of patients (n=33, p=0.005) unsure about switching from biologics to biosimilars. Concerns about side effects were a dominant barrier among 60% of patients (n=40, p=0.002), while 70% (n=46, p=0.011) prioritized cost as an important factor in their decision-making. Additionally, a critical finding was that 65% of patients (n=43, p=0.008) had never discussed biosimilars with their rheumatologist, further emphasizing the need for improved communication between healthcare providers and patients.

The data further underscored the necessity for targeted education, as 60% of patients (n=40, p=0.009) indicated that they required more information regarding the long-term safety and efficacy of biosimilars. Open-ended comments frequently reflected concerns about biosimilars' safety and lack of reliable information, reinforcing the need for structured patient education programs led by healthcare professionals rather than independent sources.

DISCUSSION

The findings of this study highlighted a significant discrepancy in the awareness and knowledge of biosimilars between rheumatologists and patients, aligning with previous research indicating that while healthcare providers generally possessed substantial knowledge regarding biosimilars, patients remained largely uninformed (13). The majority of rheumatologists demonstrated confidence in their understanding of biosimilars and their ability to educate patients, yet a considerable proportion of patients exhibited uncertainty regarding biosimilars' efficacy and safety. This gap in knowledge paralleled previous studies that found limited patient awareness despite increased efforts in biosimilar education by healthcare providers (4, 15).

Rheumatologists showed high acceptance of biosimilars, particularly in treatment initiation, but expressed hesitancy in switching stable patients, a concern also observed in studies among US and European physicians who were reluctant to transition patients from biologic originators to biosimilars without strong supporting data on long-term safety (6,9). While cost-effectiveness remained the primary driver for prescribing biosimilars, the presence of institutional policies and insurance coverage influenced decision-making, mirroring previous reports that identified financial incentives and regulatory frameworks as critical determinants in biosimilar adoption (3). Similar concerns were observed in Russia, where physicians exhibited positive attitudes but lacked a clear understanding of biosimilars' regulatory distinctions from generics, highlighting the importance of standardized educational interventions (18).

Patients' perspectives were shaped largely by limited knowledge and misinformation, consistent with findings that many patients were not informed before biosimilar initiation, leading to reluctance in switching (2). The primary concerns included fear of side effects and uncertainty regarding therapeutic equivalence, similar to studies where patients demonstrated significant hesitation toward biosimilars despite reassurances from healthcare providers (7). These concerns were exacerbated by the reliance on non-medical sources, such as the internet and social media, rather than direct physician-patient communication. This pattern was evident in previous research, which found that patient apprehension about biosimilars stemmed from inadequate education and a preference for the guidance of their primary rheumatologist (10). Patients in the present study indicated a strong need for additional educational resources, particularly regarding long-term safety and efficacy, reinforcing prior recommendations for structured biosimilar education programs (11).

One of the strengths of this study was its ability to capture both physician and patient perspectives in a real-world clinical setting, allowing for a comparative analysis of knowledge gaps and treatment preferences. By incorporating both groups, the study provided a holistic understanding of biosimilar adoption challenges, similar to previous studies that emphasized the necessity of bridging knowledge disparities to improve clinical outcomes (12). However, several limitations were identified. The sample size was relatively small, particularly for rheumatologists, which may limit the generalizability of the findings. Additionally, the study relied on self-reported data, which could introduce response bias, as participants might have overestimated or underestimated their knowledge and confidence in biosimilars. This limitation was consistent with previous research that highlighted the variability in survey-based assessments of healthcare professionals' prescribing behaviors (9).

Despite these limitations, the findings reinforced the need for targeted interventions to improve biosimilar acceptance. Educational programs should focus not only on increasing patient awareness but also on addressing physician concerns about switching stable patients. Given the evidence that structured education by rheumatologists and nurse specialists significantly improved patient satisfaction and reduced apprehensions about biosimilar switching (4), implementing similar models could enhance patient trust and adherence. Moreover, regulatory bodies should establish clear guidelines to standardize biosimilar information, preventing discrepancies in physician-patient discussions, as seen in studies where inconsistent messaging led to increased patient reluctance (7).

Future research should explore long-term biosimilar retention rates and patient-reported outcomes to assess whether improved education influences sustained adherence and satisfaction. Additionally, larger multicenter studies incorporating diverse healthcare settings would provide a more comprehensive understanding of biosimilar adoption patterns. Addressing the nocebo effect, wherein negative expectations influence patient experiences with biosimilars, should also be prioritized, given prior evidence that careful framing of biosimilar benefits can significantly reduce perceived adverse events (13). By enhancing both physician and patient education, biosimilar uptake can be optimized, ultimately leading to increased accessibility, reduced healthcare costs, and improved treatment outcomes in rheumatology practice.

CONCLUSION

The findings of this study highlighted a substantial gap between rheumatologists' high awareness and acceptance of biosimilars and patients' limited knowledge and hesitancy, emphasizing the critical need for targeted education and structured communication. While physicians demonstrated confidence in biosimilar safety and efficacy, reluctance to switch stable patients remained a barrier, aligning with previous concerns about nonmedical switching and regulatory clarity. Patients, on the other hand, exhibited significant uncertainty, primarily influenced by misinformation and lack of physician-patient discussions. Addressing these disparities through standardized educational interventions, improved regulatory frameworks, and proactive physician engagement can enhance biosimilar adoption, leading to increased accessibility, reduced healthcare costs, and improved long-term treatment outcomes. Strengthening biosimilar integration into rheumatology practice holds significant implications for human healthcare by optimizing resource allocation, improving patient adherence, and ensuring equitable access to cost-effective biologic therapies.

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