Knowledge, Attitude and Practice on Biologicals and Biosimilars among Clinicians in Radiotherapy Department

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Received: 2023-02-09, Revised: 2023-04-24, Accepted: 2023-05-04, Published: 2023-06-30

Abstract

Background: The decoding of human genome helped to design pharmacological agents like Biologicals and Biosimilars which can target the affected etiological aberrations. Biological agents are large complex molecules produced by recombinant techniques in a living system for therapeutic or diagnostic uses and have revolutionized treatment of many diseases. Patent expiry of Biologicals has led to the development of Biosimilars which are similar in efficacy & safety and have no clinically meaningful differences, but are not identical to Biologicals and undergo fewer clinical trials than their reference biologicals. Clinicians' in- depth knowledge of these agents is important to optimize the use of cost-effective & easily accessible options.

Methods: This is a cross sectional observational study conducted between Feb-March 2020 in Radiotherapy/ Chemotherapy Oncology Department of Dr B.R.A.M. Hospital & Pt. J. N. M. Medical College, Raipur, Chhattisgarh, using a self-administered, structured questionnaire consisting of 15-question among 30 clinicians prescribing Biologicals and Biosimilars.

Results: 83.3% of clinicians were familiar with the term 'Biologicals' & 'Biosimilars'. 60% believed that Biosimilars are same as Generic Medicines and have the same potency as Biologicals. 53% assumed that Biologicals & Biosimilars can be switched. 50% were able to explain the difference or similarity between Biologicals and Biosimilars.

Conclusion: The findings reveal that the clinicians had good knowledge about Biologicals and Biosimilars but lacked application of this knowledge in clinical practice. This highlights a need for regular educational initiative to reduce the knowledge deficit & its application in clinical practice. Further, there must be a National Treatment Guidelines on use of Biologicals and Biosimilars.

J Pharm Care 2023; 11(2): 82-92.

Keywords: Biologicals; Biosimilars; Knowledge; Attitude; Practice

Introduction

Biological agents acting as targeted therapy, have transformed treatment for many life-threatening diseases, particularly for chronic diseases involving overactive immune systems and given a new lease on life. Biological products are large-molecule drugs generally made of complex proteins through biotechnology (i.e., recombinant DNA technology, controlled gene expression, or antibody technologies) in a living system, such as a microorganism, plant cell, or animal cell, and used in the prevention, diagnosis, or treatment of cancer and other diseases (1). Complex manufacturing processes and their long development time makes biologicals expensive (2), leading to limited accessibility to patients, particularly in developing countries. Expiry of patents and/or data protection has ushered in an era of 'biosimilars' (3). Biological drugs include therapeutic proteins (such as filgrastim), monoclonal antibodies (such as adalimumab), and vaccines (such as those for influenza and tetanus) (4). Biosimilars that can be used interchangeably with biologicals, undergo fewer clinical trials as compared to their reference products and hence are low-cost alternatives. Use of safe and effective biosimilars has expanded the treatment options and

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increased accessibility to a greater part of the community (2).

World Health Organization (WHO) defines biosimilars as "A bio therapeutic product that is similar in terms of quality, safety and efficacy to an already licensed reference bio therapeutic product"(3). It is a biological product that is highly similar to (in purity, chemical identity and bioactivity) and has no clinically meaningful differences (in potency, efficacy and safety) from an existing FDA-approved reference product or an existing biological medicine. They have the same route of administration, same strength, dosage form and same efficacy and potential side effects (5).

The FDA regulates the manufacturing of biosimilars in terms of quality in accordance with Current Good Manufacturing Practice requirements and follows the same method of manufacturing, processing, packaging, or holding of a drug product. Rigorous clinical assessment is followed to get marketing approval (5).

Indian Scenario

The regulatory authorities developed the first guideline for approval of Biosimilars in July 2012 which were updated in 2016 at par with international guidelines. The regulatory bodies responsible for approval of Biosimilars in India are the Department of Biotechnology (DBT – under the Ministry of Science and Technology), through its Review Committee on Genetic Manipulation (RCGM), and the CDSCO (under the Ministry of Health and Family Welfare) (8).

India is a leading provider of Biosimilars to the world market to the extent of 75% and are also available for use in India (8). In India, the first biosimilar introduced was Biovac™ (hepatitis B vaccine, Wockhardt) in the year 2000 followed by Wepox™ (epoetin alfa) in March 2001. However, the first Biological agent was Humulin developed by Eli lilly & Co. in the 70s and was approved by FDA in 1982 and the first biosimilar agent approved by FDA was Filgrastin-Sndz (Zarxio) in 1991.

All Biosimilars cannot be used interchangeably with Biologicals

For Biosimilars to be used interchangeably, they must be similar to the reference product. Additional information is necessary to confirm that an interchangeable product is expected to produce a similar clinical outcome as the reference product in the patient as outlined by the Biologicals Price Competition and Innovation Act (BPCI) (7). This includes no change in efficacy and safety on switching back and forth between an interchangeable product and a reference product at any time during the course of treatment (5).

Biosimilars are not similar to Generics

Generic drugs have same ingredients as those of branded drugs and are synthesized chemically with a known manufacturing process. The active pharmaceutical ingredients (APIs) in Generic drugs are small molecules, with molecular weight of less than 900 Daltons, mostly non-immunogenic and can be used interchangeably. The generic drugs don't need to repeat clinical trials, but must undergo bioequivalence studies in a relatively small number of volunteers which makes them inexpensive. This takes around 2 years and the impact of a small change in manufacturing process is negligible in terms of potency, safety and efficacy (9).

In comparison to generics, biosimilars are large and complex molecules made from living cells rather than with chemicals, making them naturally variable. Their approval process also requires more clinical studies, which are expensive and time consuming. The manufacturing process of biosimilars is more complex because the manufacturing process of their reference biologicals or originator molecule is not available. Hence, a new cell line needs to be developed till a biosimilar comes in the range of similarity. A minor variation in the manufacturing process may change the final protein structure and function (10).

Biological APIs are high molecular weight proteins (as high as 150,000 Daltons), prepared from living cells and are highly immunogenic. They need special storage and handling facility as they are less stable in comparison to generic drugs. Impurities from the cells, culture media and the purification process can be biologically active, and must undergo comparability exercise, and includes physical-chemical assessments for protein structure, in vitro functional assays, animal tests, and clinical trials for each indication and may require 5 to 9 years before regulatory approval (11).

Patent protection of a Biological agent lasts for 20 years from the date of patent application with 12 years of market exclusivity and 4 years of data exclusivity from the date of FDA approval as per Biological Pricing Competition and Innovation Act (BPCIA) 2009. Many years may lag between patent application and FDA approval to market a drug; therefore, a patent may run out before the exclusivity expires, whereas this act provides 12-year marketing exclusivity protection to the Biosimilar even after patent period expiration. These exclusivity protections are intended to encourage biologic research and development (12).

The high cost of Biologicals, is an important issue in healthcare costs especially in a Low-Middle Income Country like India. Therefore, Biosimilars which cost 20-40% less and are easily available are good alternatives. This study was conducted to assess Clinicians' knowledge, attitude and practice about this new class of drug to identify the gaps, so that future interventions can be targeted to bridge these gaps.

Methods

A cross sectional observational study was conducted by the Department of Pharmacology, Pt. J.N.M. Medical College, Raipur using a data collection tool. This study was conducted between February and March 2020.

The study population consisted of 30 Oncologists of

Department of Radiotherapy at Dr B. R. A. M. Hospital, Raipur who already prescribe Biologicals & Biosimilars in their clinical practice. The purpose of this study was explained, and they were encouraged to answer questions sincerely.

A preformed, semi structured validated questionnaire based on our study objectives was developed with the help of previous literature and reviewed by the faculty members of Department of Pharmacology, Pt. J. N. M. Medical College, Raipur. It was pilot tested among the postgraduate students of the department and subsequently modified. The final questionnaire consisted of 3 parts, dealing with Knowledge, Attitude and Practice respectively with six questions for Knowledge, four for Attitude and five for Practice. All questions were closed-ended, except for question no. 14 and 15 which were open ended. Closed ended questions were framed to be answered as 'Yes', 'No' and 'Don't Know' and it took 15 minutes to fill the questionnaire. Score was awarded as 2 for correct response and zero for incorrect response and 'Don't Know'. The responses were then analysed with Specialty and duration of experience of respondents in the field of oncology.

Statistical Analysis

Statistical analysis was done using descriptive statistics and nonparametric test (Chi square test) for proportionality using IBM SPSS version 20. A p-value <0.05 was considered statistically significant. Reliability of the data was tested using Cronbach's Alpha Reliability Formula.

Results

A total of 30 respondents participated in the study, of which 11 (36.67%) participants were faculty members and 19 (63.33%) were residents pursuing Postgraduate course at Department of Radiotherapy. 70% of the clinicians were male and 30% were female. Among them, 20% had been working in this field for more than 10 years. Age and sex distribution is shown in Figure 1.

In preliminary questioning, most respondents (83.3%) had basic understanding of the definition of biological and biosimilar medicine. However, less familiarity with research and development process was evident as, 60% believed Biosimilars were same as Generics. 73% had the knowledge that Biosimilars are bioequivalent to Biologicals. Knowledge about pricing of Biosimilars was encouraging as 93% believed Biosimilars were cheaper than their Reference Biologicals and 83% understood that Biosimilars can be marketed only after expiry of patent period of their Reference Biologicals as shown in Figure 2.

Figure 1. Age and sex distribution

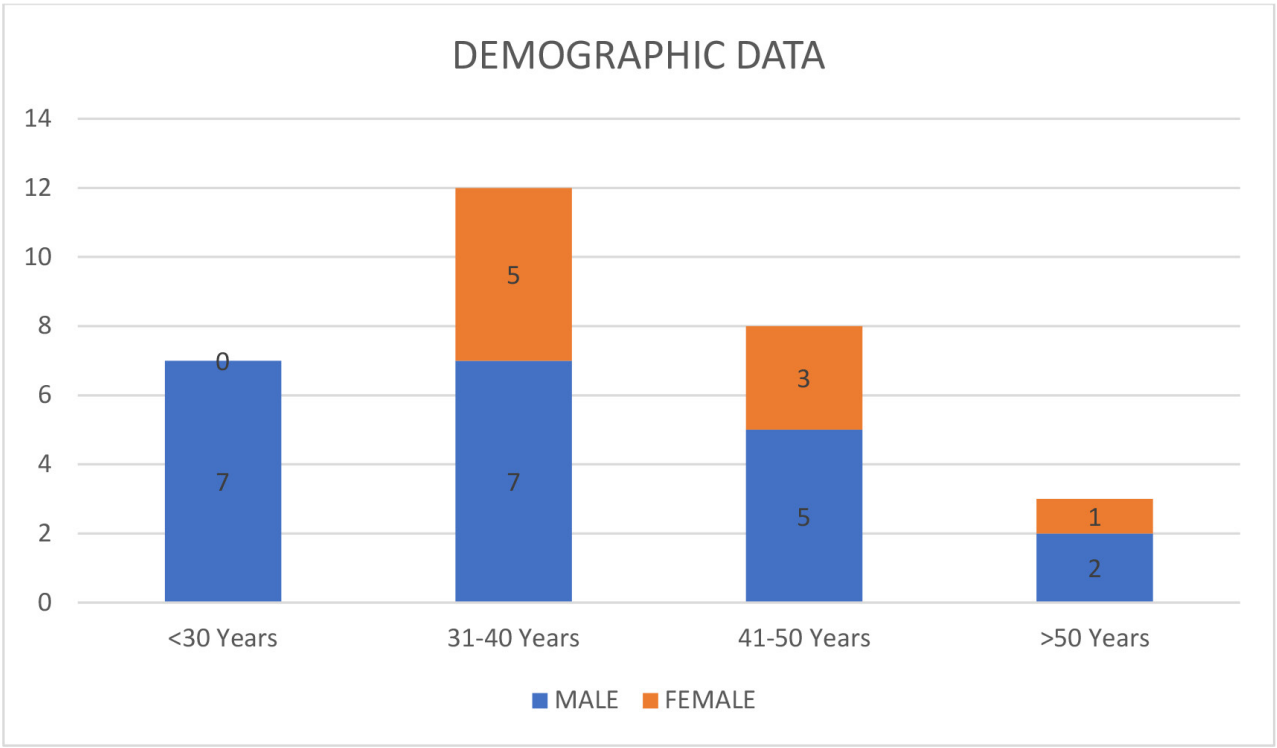


Figure 2. Knowledge About Biologicals and Biosimilars Among Clinicians

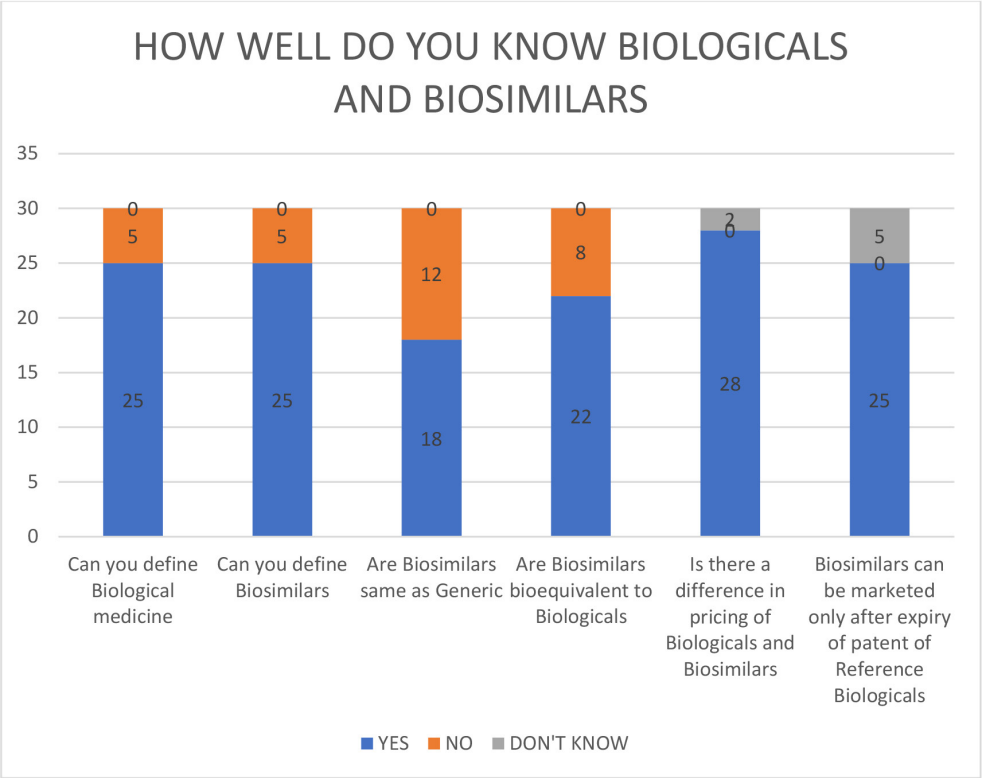


Figure 3. Attitude Towards Biologicals and Biosimilars Among Clinicians

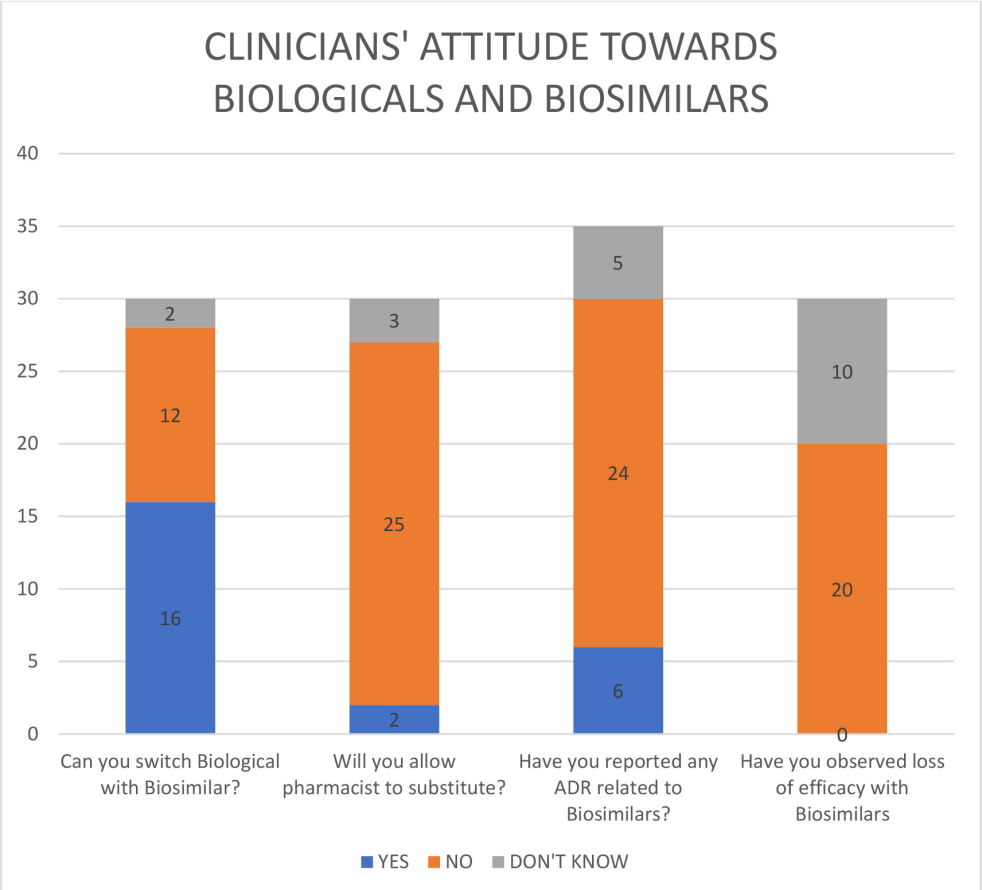
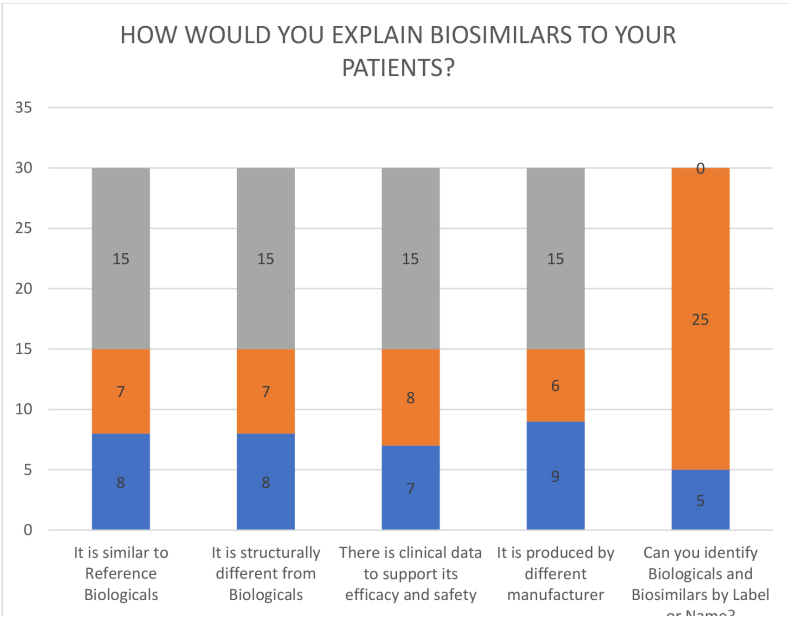


Figure 4. Practice of Biologicals and Biosimilars Among Clinicians



Overall attitude of the respondents (as shown in figure 3) towards Biosimilars was inconclusive as only half (53%) agreed to interchange Biosimilars and Biologicals and 66.67% believed there will be no loss of efficacy while switching to Biosimilars. 83.3% were against Pharmacists substituting the prescribed Biologicals to Biosimilars. Only 20% reported Adverse Drug Reaction due to Biosimilars to the ADR Monitoring Centre, but failed to note the batch number of the suspected Biosimilar which is an important prerequisite.

Table 1.Various Biosimilar terminologies used by different regulatory bodies[6]

Regulatory Bodies	Terminology used for Biosimilars
WHO	Similar Bio therapeutic Product
US-FDA	Follow on Biologicals
Europe-EMA	Biosimilar
India-CDSCO	Similar Biologics
China-NMPA	Copy Biologicals

Table 2. Difference between Biosimilars and Generics

BIOSIMILARS	GENERICS
Biosimilars are highly similar to & has no clinically meaningful differences from the existing FDA approved reference biological product.	Generic drugs are actually the copies of branded drug that have same dose, route, safety & efficacy profile.
There is minor difference in clinically inactive components.	Generic drugs are bioequivalent to an approved brand drug,
Biosimilars are obtained from living organism such mammalian cells bacteria, virus, yeast culture.	Generic drugs are obtained from the clinical synthesis process.
Structure of a Biosimilar is complex & heterogenous.	Structure of a Generic drug is relatively simple & well defined.
It is a large molecule substance, with molecular weight >150,000 Daltons	It has lower molecular weight <900 Daltons
Its manufacturing process is very difficult obtain from the culture process.	Its manufacturing process is relatively simple
Biosimilars are unstable & sensitive to external condition.	It is a stable compound
Due to its Biological source, it is immunologic	It is non immunogenic
It is not Interchangeable with reference product	It can be interchanged with reference product
Biosimilar require one clinical study to compare pharmacokinetics and at least one large randomized clinical trial to demonstrate clinical bioequivalence before approval	No approval for clinical trials required
Biosimilars are costly (nearly 100-200 million)	Low cost
Development takes 8-10 years	Takes 2-3 years for development

Table 3. SPECIALITY vs Level of KNOWLEDGE.

SPECIALTY		LEVEL OF KNOWLEDGE		Total (n=30)	p-Value
		ADEQUATE	INADEQUATE		
Specialized (MD)	Count	11	0	11	0.129
	% Within Specialty	100.0%	0.0%	100.0%	
	% Within Level of Knowledge	44.0%	0.0%	36.7%	
Non-Specialized (MBBS)	Count	14	5	19	
	% Within Specialty	73.7%	26.3%	100.0%	
	% Within Level of Knowledge	56.0%	100.0%	63.3%	
Total	Count	25	5	30	
	% Within Specialty	83.3%	16.7%	100.0%	
	% Within Level of Knowledge	100.0%	100.0%	100.0%	

In the practice habit, counseling the patients regarding their treatment with Biosimilars, only 26.67% could explain structural difference between Biosimilars and their reference, and, described them as similar to their reference biologicals but not totally identical. Only 23% could describe its safety and efficacy with the support of clinical data. 30% explained Biosimilars as the medicine similar to the Biologicals but manufactured by different Pharmaceutical Company. However, more than 83% clinicians were unable to identify the drug as Biosimilar or Biological from the label or name. Most of the clinicians (33%) learnt about Biosimilars through Medical Representatives visiting the Out-Patient Department. 26% read about it in a drug promotional Literature and rest learned about it via CMEs (20%) and Departmental Seminars (20%). Among the most frequently prescribed Biosimilars, Epoetin alpha and Herceptin were leading agents.

Table 4. SPECIALITY vs Level of ATTITUDE

SPECIALTY		LEVEL OF ATTITUDE		Total (n=30)	p-Value
		ADEQUATE	INADEQUATE		
Specialized (MD)	Count	10	1	11	0.372
	% Within Specialty	90.9%	9.1%	100.0%	
	% Within Level of Attitude	41.7%	16.7%	36.7%	
Non-Specialized (MBBS)	Count	14	5	19	
	% Within Specialty	73.7%	26.3%	100.0%	
	% Within Level of Attitude	58.3%	83.3%	63.3%	
Total	Count	24	6	30	
	% Within Specialty	80.0%	20.0%	100.0%	
	% Within Level of Attitude	100.0%	100.0%	100.0%	

Table 5. SPECIALITY vs Level of PRACTICE

SPECIALTY		LEVEL OF PRACTICE		Total (n=30)	p-Value
		ADEQUATE	INADEQUATE		
Specialized (MD)	Count	6	5	11	0.028
	% Within Specialty	54.5%	45.5%	100.0%	
	% Within Level of Practice	75.0%	22.7%	36.7%	
Non-Specialized (MBBS)	Count	2	17	19	
	% Within Specialty	10.5%	89.5%	100.0%	
	% Within Level of Practice	25.0%	77.3%	63.3%	
Total	Count	Count	22	30	
	% within Specialty	% Within Specialty	73.3%	100.0%	
	% Within Level of Practice	% Within Level of Attitude	100.0%	100.0%	

We found that clinicians' educational background, specialty and experience were possible independent factors of their knowledge. Multivariate comparison showed that clinicians with 5 or more years of experience had a better understanding as compared to those with less than 5 years of experience (X2= 14.319, df= 2, p=.0007). The possible impact factor for attitude was years of experience, and clinicians practicing for 5 or more years seemed to have a more positive attitude than those with lesser experience. (X2= 4.661, df= 2, p=.09).

The level of practice was influenced by the educational background. Clinicians with a master's degree had a better practice than those with a bachelor's degree (X2= 6.903, df= 1, p=.0028). Gender did not have a significant impact on the knowledge, attitude and practice amongst the clinicians. Detailed results are shown in the tables in the Appendix.

Table 6. Years of EXPERIENCE vs Level of KNOWLEDGE

Years of EXPERIENCE		LEVEL OF KNOWLEDGE		Total (n=30)	p-Value
		ADEQUATE	INADEQUATE		
5 To 10 Years	Count	20	0	20	
	% Within Years of Experience	100.0%	0.0%	100.0%	
	% Within Level of Knowledge	80.0%	0.0%	66.7%	
Above 10 Years	Count	3	0	3	
	% Within Years of Experience	100.0%	0.0%	100.0%	
	% Within Level of Knowledge	12.0%	0.0%	10.0%	0.00077
Less Than 5 Years	Count	2	5	7	
	% Within Years of Experience	28.6%	71.4%	100.0%	
	% Within Level of Knowledge	8.0%	100.0%	23.3%	
Total	Count	25	5	30	
	% Within Years of Experience	83.3%	16.7%	100.0%	
	% Within Level of Knowledge	100.0%	100.0%	100.0%	

Table 7. Years of EXPERIENCE vs Level of ATTITUDE

Years of EXPERIENCE		LEVEL OF ATTITUDE		Total (n=30)	p-Value
		ADEQUATE	INADEQUATE		
5 To 10 Years	Count	18	2	20	0.09
	% Within Years of Experience	90.0%	10.0%	100.0%	
	% Within Level of Attitude	75.0%	33.3%	66.7%	
Above 10 Years	Count	3	0	3	
	% Within Years of Experience	100.0%	0.0%	100.0%	
	% Within Level of Attitude	12.5%	0.0%	10.0%	
Less Than 5 Years	Count	3	4	7	
	% Within Years of Experience	42.9%	57.1%	100.0%	
	% Within Level of Attitude	12.5%	66.7%	23.3%	
Total	Count	24	6	30	
	% Within Years of Experience	80.0 %	20.0%	100.0%	
	% Within Level of Attitude	100%	100.0%	100.0%	

Table 8. Years of EXPERIENCE vs Level of PRACTICE

YEARS OF EXPERIENCE		LEVEL OF PRACTICE		Total (n=30)	p-Value
		ADEQUATE	INADEQUATE		
5 To 10 Years	Count	6	14	20	0.331
	% Within Years of Experience	30.0%	70.0%	100.0%	
	% Within Level of Practice	75.0%	63.6%	66.7%	
Above 10 Years	Count	2	1	3	
	% Within Years of Experience	66.7%	33.3%	100.0%	
	% Within Level of Practice	25.0%	4.5%	10.0%	
Less Than 5 Years	Count	0	7	7	
	% Within Years of Experience	0.0%	100.0%	100.0%	
	% Within Level of Practice	0.0%	31.8%	23.3%	
Total	Count	8	22	30	
	% Within Years of Experience	26.7%	73.3%	100.0%	
	% Within Level of Practice	100.0%	100.0%	100.0%	

Discussion

Biosimilars are a low-cost alternative to Biologicals and clinicians' knowledge and attitude are important factors towards their use. Most of the clinicians were familiar with the terms Biologicals and Biosimilars similar to other studies as they knew the definition of Biological and Biosimilars (12). But 60% had the opinion that Biosimilars are same as Generic medicines which is incorrect and is similar to Karteev et al., (13). This demonstrates the gap in knowledge as it is well known that Biosimilars are not Generic medicines (10). The clinicians were also familiar with bioequivalence; as 73% respondents felt that Biosimilars were as efficacious and safe as biological which was similar to findings of Shraim et al., (43%) (14). In a study by Chapman et al., (15) from UK, 90% and 95% respondents were of the opinion that Biosimilars and Biologicals were equal in terms of efficacy and safety in contrast to respondents from China as described by Yang Hu et al., (12), where 48% respondents were doubtful about safety and efficacy of Biosimilars.

Though Biosimilars were approved in India as early as in 2000 (insulin) and presently 127 Biosimilars are marketed and used, the level of knowledge lags behind European countries. Biosimilars approval in UK/Europe was in 2006 (Human Growth Hormone) and at present 86 are approved for use (15). In China, as the approval for Biosimilars was delayed until 2014 and at present 18 Biosimilars are approved, and, the level of knowledge was comparatively lower than other countries where Biosimilars were approved earlier (12). Knowledge, and its impact on attitude and practice is not only dependent on the duration of use/ experience but also on explicit knowledge which can be enhanced by educational interventions.

Clinicians had very good knowledge about the price of Biosimilars and Biologicals as 93.3% of them knew that Biosimilars are cheaper than Reference Biologicals. This is consistent with other studies (12, 16). Similarly, the clinicians had knowledge that Biosimilars can be marketed only after expiry of patent of Biologicals which is similar to the findings in other studies (14, 17). The Patent and pricing of Biologicals and Biosimilars is governed by BPCIA 2009. (11, 18). Most Biosimilars follow the wholesale acquisition cost of 3-30% below Biological in USA (19). Alexandria Portelli et al., (20), describes that price of Biosimilars reduce depending on the uptake and prices drop as their use increases. For molecules with higher uptake prices fall by 21.2-59.3%, whereas for those with less uptakes, a smaller reduction 2.4-8.4% was seen. 83% understood the process of research, development and marketing as evident by their knowledge on marketing of Biosimilars after expiry of patent of Reference Biologicals which is similar to a study conducted in the UK (15).

53.3% clinicians were ready to switch between Biologicals and Biosimilars, but 83% were against pharmacist substitution which is similar to the study conducted in Russia (13) showed that 53% of the Physicians had a positive attitude towards interchangeability of Biologicals and Biosimilars, but only 22% allowed substitution by pharmacist. This is in contrast to study findings of Cohen et al., (21) where 67% of US specialists showed faith in the Pharmacists for substitution. FDA considers the

Biosimilars and originator therapeutically interchangeable if the manufacturer has demonstrated no immunologically and clinically significant difference (3,5). To reduce the concerns with switching many randomized control trials have been conducted and they show similar efficacy, safety and immunogenicity between Biosimilars and Biologicals. In a low middle income country like India, switching has wide financial implications. Numbers of scientific societies still have concerns about the practice of switching because of lack of information regarding immunogenicity and side effects. So, there is a need to further evaluate current evidences regarding switching and clarify if multiple back-and-forth switching is acceptable (6, 8). Till date FDA has not granted the 'interchangeable' designation to any Biosimilars agent in Oncology (22), although, the manufacturers may label their drug as interchangeable to any Biosimilars agent. The BPCIA act also approves Biosimilars only if there is no change in efficacy and safety on switching between Biosimilars and Biologicals at any time in the course of treatment (5). In India, interchangeability has not been addressed in CDSCO and Department of Biotechnology Guidelines and is usually interchanged randomly by the prescriber or pharmacist based on the product cost and assumed patient affordability (23).

Multiple challenges exist in reporting ADRs due to Biologicals and are laid down in regulatory guidance document "Good Pharmacovigilance Practices for Biological Medicinal Products" (24). Challenges in Pharmacovigilance are identification and traceability especially where more than one Biosimilar is available. Only 20% clinicians have reported any ADRs to the ADR Monitoring Centre of the Institute but they were unaware about the significance of identifying the manufacturing company (identifiability) and batch number (traceability).

26.7% clinicians could explain about Biosimilars to their patients. As many Biologicals are nearing end of term (Patent), the focus is on shifting to developing Biosimilars and facilitate discussion between clinicians and patients. In a survey of patients and general public, 50% of patients who could be treated with Biologicals had never heard of Biosimilars (25). So, clinicians play a crucial role in shaping patient's perception and should provide appropriate information and advice about the prescribed agents.

It is difficult to identify a Biosimilar or Biological by its label, however the naming convention as per FDA guidelines 2019 update for new originator Biologicals approved after 2019, needs all originator Biologicals and related Biosimilars to bear a non-proprietary name must include a core name with an FDA designated suffix. It is a combination of a core name designated by United States Approved Name (USAN) council and will be same for Biosimilars and Biologicals and a distinguishing suffix attached with a 'hyphen' (-), devoid of meaning and is composed of four lowercase letters of which at least three are distinct, e.g., Nonproprietary name: Infliximab-dyyb, (Remicade-proprietary name) is a biological medicine and its biosimilars are available like Infliximab-axxq, (AVSOLA-a Remicade Biosimilar) (26). However, Epoetin alpha (Epogen/Procrit) a biological agent, and its Biosimilar (Epofer) doesn't have a suffix which makes it difficult to identify. Whereas another biosimilar developed in 2018, Retacrit (Epoetin alpha-epdx) has been provided with a suffix 'epdx'. At present this system of nomenclature of Biosimilars and Biologicals is followed in the US only. Nomenclature of Biosimilars and Biologicals is not addressed by India's CDSCO guidelines 2016 (8). So, the identification of these agents without easily distinguishable product suffix is difficult. Nomenclature with identifiable features of these agents will facilitate prescribing, dispensing, pharmacovigilance, identification of these products by clinicians and patient; minimize inadvertent substitution of products that are not interchangeable.

When clinicians were asked about the sources of information about Biosimilars and Biologicals, pharmaceutical representatives were the foremost source followed by Departmental Seminars and CMEs. This is in contract to a study (17), where the predominant source was scientific literature and self-study, followed by information from Pharmaceutical Representative. In India, clinician's knowledge about new therapeutic options is heavily dependent on Pharmaceutical Organization representatives who provide first-hand information (9). This may be due to increased patient burden and less time for learning initiatives.

Karteev et al., (13) in their study observed that 20% Physicians described Biosimilars as similar but not totally identical to their reference Biologicals, which was similar to our findings (26%). However, 46% physicians who participated in this study13 explained Biosimilars as Biologicals manufactured by different pharmaceutical company, which was less than half of that (20%) in our study. In the study by Guiliani et al., (2), 36.3% participants (Pharmacists and Physicians) were able to identify Biologicals and Biosimilars by their label, and 48% were able to describe safety and efficacy of Biosimilars with the support of clinical data which considerably higher than what we observed in our study (17% and 23%).

Since the questionnaire was self-administered, response bias is likely. Limited number of questions for evaluation of knowledge, attitude and practice may not be adequate. The best way for practice evaluation is achieved by observation. Sample size, though including all the faculty members and Residents pursuing postgraduate course, was relatively smaller.

In this study we concluded that a large proportion of participants had basic knowledge with regards to Biosimilars and Biological medicine. However, their knowledge with regards to research, development and regulatory aspects were relatively low. The results showed that most of the participants showed positive attitude about the substitution of Biologicals with Biosimilars but they were reluctant in having Pharmacists interchange them by their own volition. Better knowledge and perception of Biosimilars is very important for rational prescribing practices to provide viable and effective treatment options to the patients. Continued education

will lead to more informed discussion and decision-making regarding use of Biosimilars, which will help their successful integration in oncology.

Acknowledgement

The authors would like to thank Dr Vivek Choudhary, Professor and Head, Department of Radiotherapy for his encouragement and support for conducting this study. Dr Preeti Raut, Senior Resident, Department of Radiotherapy for her assistance in distribution and collection of samples. The authors would also like to acknowledge Dr Rajesh Hishikar, Dr Ajay Halwai, Dr Shikha Jaiswal, Dr Maya Ramteke, Dr Watsala Singh and Dr Himanshu Sharma for their help in formulating questionnaire and conducting the pilot study prior to the main study. Lastly, the authors would like extend their gratitude to all participants who completed the questionnaire and everyone who provided assistance in hassle-free conducting the survey.

Conflict of interest

The authors declare that they have no conflict of interest in this work.

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PLEASE CITE THIS PAPER AS:

Agrawal M, Mishra S, Nayak G, Aggarwal D, Joshi U. Knowledge, Attitude and Practice on Biologicals and Biosimilars among Clinicians in Radiotherapy Department. J Pharm Care 2023;11(2):82-92.