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Research Article

Comparison between Reference Infliximab (Remicade) and its Biosimilar (Remsima) in Patients with Ankylosing Spondylitis: A Field-based Pharmacoeconomic Study

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ABSTRACT

Background: Ankylosing spondylitis is a chronic inflammatory disease that mostly involves the spine and sacroiliac joints. It is associated with a decreased quality of life. Biological medicines such as infliximab and its biosimilar are the mainstay treatments for active ankylosing spondylitis.

Objective: The study objective was to conduct a pharmacoeconomic study comparing the cost-effectiveness of the reference infliximab with its biosimilar in ankylosing spondylitis patients visiting public hospitals.

Subjects and Method: This is a two-center pharmacoeconomic study performed at two large teaching governmental hospitals in Baghdad, Iraq, which supplied infliximab to outpatients with ankylosing spondylitis. The outcome data were obtained from patient's medical records and face-to-face interviews with the patients from December 2021 through April 2022. The Independent T-Test was used to measure the differences in areas of utility, and quality of life, between the two infliximab groups.

Results: The study recruited 62 patients with ankylosing spondylitis who received infliximab (31 received Remicade, and 31 received Remsima) for at least 12 weeks at two public teaching hospitals. The mean age of the patients was 37.85 years and 83.9% were men. In general, both reference infliximab and its biosimilar were successful in increasing the quality of life. Their importation costs were different from 2019 to 2021. The incremental cost-effectiveness ratio of reference infliximab versus biosimilar was $ 40,909/quality-adjusted life year (QALY) according to 2019 pricing. In contrast, in 2021 reference infliximab (Remicade) was less expensive and yielded slightly better quality of life improvement than biosimilar (Remsima) making Remicade more cost-effective (dominant).

Conclusion: Remicade was slightly superior to Remsima in quality of life improvement. However, it was difficult to determine whether the reference or its biosimilar was more cost-effective in 2019 because the health officials did not specify a willingness to pay per quality-adjusted life year. Compared to Remsima, Remicade was more cost-effective in 2021 because it was less expensive and more effective in terms of quality of life improvement.

Introduction

Ankylosing spondylitis (AS) is a lifelong inflammatory disorder that mostly involves the spine and sacroiliac joints (1). It is accompanied by back discomfort and rigidity, which eventually cause joint fusion and deterioration, mainly of the sacroiliac joints, and vertebral ankyloses (1). It's been attributed to a poor quality of life (QoL) (2). AS prevalence varied from 0.09% to 0.30% (3). This condition is related to high socioeconomic expenditure (4). Reducing symptoms, enhancing function, maintaining job capacity, lowering the risk of disease consequences, and avoiding bone destruction are the objectives of treating AS (5).

Patients with active AS are strongly advised to receive treatment with tissue necrosis factor inhibitors (TNFi), such as infliximab (5,6). Due to the complexity of biological pharmaceutical research and production procedures, the costs of these medications are highly expensive, and they place substantial pressure on healthcare systems. Furthermore, the lack of patient access to biological therapies has been a rising concern in various nations (7,8). Numerous reference biological medications are nearing patent expiration, encouraging the creation of so-called "biosimilar" drugs. A biosimilar is defined as "a biotherapeutic product that is equal in quality, safety, and efficacy to an existing approved reference biotherapeutic product" (9). The emergence of biosimilars has resulted in competition in the market and a considerable decline in the net cost of biological medicines (6,10). Remicade is an infliximab biological drug that is made and sold by Janssen Biotech. On the other hand, Remsima is an infliximab biosimilar product that was created by Celltrion Healthcare and is sold by Hikma Pharmaceuticals. In several countries, biosimilar infliximab such as (Remsima) has been authorized for use in all indications approved for reference infliximab (Remicade), including AS (11). The release of the infliximab biosimilar decreased direct medical expenses for both users and payers (12).

In Iraq, the State Company for Marketing Drugs and Medical Appliances (KIMADIA) at the Ministry of Health (MOH) is a governmental company responsible for purchasing and supplying medications, healthcare goods, and tools for governmental healthcare settings across the country (13). The recent shortage of essential drugs in Iraq is mostly due to the limited government funding for KIMADIA (13). Healthcare providers and government decision-makers in Iraq should first get familiar with biosimilars before approving them in Iraqi treatment protocols (14). The majority of pharmacists in Iraqi hospitals had limited expertise with biosimilar pharmaceuticals and were uncertain about the efficiency and safety of these drugs due to this lack of knowledge (15).

For a few years, both the reference and biosimilar infliximab were approved and used in Iraqi public hospitals to treat patients with AS (16). To the best of our knowledge, this is the first pharmacoeconomics study in the Middle East showing the cost-effectiveness of the reference infliximab to its biosimilar in patients with AS from a payer's (MOH) point of view. The study findings could help to assess the effectiveness of biopharmaceutical (Infliximab) medicine in public hospitals (real-world data). The study objective was to conduct a pharmacoeconomic (cost-effectiveness) study comparing the reference infliximab (Remicade) with its biosimilar (Remsima) in AS patients visiting public hospitals.

Subject sand Methods

Study design

This is a two-center pharmacoeconomic study performed at two large teaching governmental hospitals in Baghdad, Iraq (Baghdad Teaching Hospital & Al-Yarmouk Teaching Hospital), which supplied infliximab to outpatients with AS. Data were obtained from patient's medical records and face-to-face interviews with the patients from December 2021 through April 2022.

Patients and settings

This pharmacoeconomic study involved 62 adult patients with AS receiving infliximab therapy and were diagnosed according to the Modified New York Criteria for Ankylosing Spondylitis and Assessment of SpondyloArthritis International Society (ASAS) diagnostic criteria (17,18). Patients with AS who received either Remsima (biosimilar) or Remicade (reference infliximab) at the two participating hospitals were invited to the study. In other words, the inclusion criteria were adult AS patients who had received infliximab for at least 12 weeks. The exclusion criteria included patients with other autoimmune conditions,cognitive impairment preventing them from understanding or completing the questionnaire, and patients who developed antibody responses (immunogenicity) to infliximab and were switched to a different medication.

The infliximab dose was given at around 5 mg/kg as an intravenous induction regimen at 0, 2, and 6 weeks, followed by a maintenance regimen of around 5 mg/kg every 6 weeks thereafter for the treatment of active AS. Rheumatologists decided on the dose and form of infliximab that needed to be administered to each patient.

Data Collection

The researcher used medical records and face-to-face interviews with patients to gather information. At the time of the interview, demographic data (age, gender, weight, height, disease duration, smoking, exercise, and occupation) were gathered. Doses and infliximab therapy duration were gathered from patients' medical records.

The EQ-5D-5L questionnaire was utilized to assess the quality of life. The EQ-5D-5L was selected as the utility outcome due to its homogeneity, patient acceptability, and well-established utility as suggested by Jørgensen et al (19). After getting approval from the European EuroQol Group Foundation, the EQ-5D-5L was used to measure the patient's quality of life (QoL) and convert it to utility. The researchers conducted face-to-face interviews with the AS patients to measure QoL using a validated Arabic version of the EQ-5D-5L. The EQ-5D-5L is a quality-of-life instrument that has been used for a wide range of disease areas. It consists of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and each dimension has five answer levels: no problems, minor, moderate, severe, or extreme problems. The

answers are represented as single-digit numbers between 1 and 5 that indicate the selected severity level for each dimension (20). The health state from the EQ-5D-5L questionnaire was turned into a utility value using the EQ-5D-5L Index Value set for the general population of Zimbabwe (21). The researchers assumed that Zimbabwe has closer living conditions to Iraq than any of the nine countries that have the value index set.

The governmental purchasing (importation) costs of the reference infliximab (Remicade) and its biosimilar (Remsima) were gathered from the KIMADIA website in 2019 and 2021 (22). Thus, the direct cost of infliximab was utilized. The cost-effectiveness study was undertaken from the payer (MOH) viewpoint, which is the only provider of biological therapy for AS in public hospitals. The incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in total costs (incremental cost) of two medications by the difference in the selected measure of health outcome (incremental effect) using the following formula: (ICER = (Cost Remicade - Cost Remsima)/ (Outcome Remicade - Outcome Remsima)) (23). The outcome of the ICER calculation is the additional cost per increased health gain. In this study, the incremental cost-effectiveness ratio (ICER) was computed using the quality-adjusted life year (QALY).

The University of Baghdad College of Pharmacy and the two participating hospitals provided ethical approval for the proposed study. In addition, the patient's verbal consent was obtained before patient recruitment.

Statistical analysis

Descriptive statistics (means, standard deviation, frequencies, and percentages) were conducted for all study items. Data were analyzed using Statistical Package for the Social Sciences (SPSS) software version 25. The independent T-Test was used to measure the differences in utility, and QoL dimensions between the two infliximab groups. A P-value of less than 0.05 was considered statistically significant.

Results

The study recruited 62 patients with AS who received infliximab for at least 12 weeks at two large public teaching hospitals. The patients were classified into two groups based on the type of infliximab: 31 patients received reference infliximab (Remicade), and 31 patients received biosimilar infliximab (Remsima). The demographic and baseline disease characteristics of the two groups were comparable, with a mean age of 37.85 years and a BMI of 27.16. The overwhelming majority of participants were male (83.90%) (Table 1).

There was no significant difference (P-value >0.05) in AS QoL dimensions between the two groups after at least 12 weeks of treatment except for the usual activities dimension which was significantly higher in the Remsima group (Table 2) and (Figure 1). On the other hand, infliximab treatment duration was significantly (P-value <0.05) longer in the Remicade group (37.3 months) compared to the Remsima group (11.8 months) (Table 2).

According to the pricing reported in 2019, Remicade provided somewhat more QALYs, but at a higher cost (Table 3). According to the ICER, to gain one QALY per patient, the MOH needs to pay $ 40,909 (for Remicade). In 2021, Remicade was dominating and more cost-effective than Remsima since the prices had been reduced (Tables 3 & 4). In other words, Remicade produced slightly greater QALYs at a lower cost (Tables 3 & 4) (Figure 2).

Table 1: The characteristics of the participating AS patients

Parameter	All (n=62) Mean ± SD	Remicade (n=31) Mean ± SD	Remsima (n=31) Mean ± SD
Age (Years)	37.85 ± 9.83	38.77 ± 1.67	36.94 ± 1.86
Body mass index (BMI)	27.16 ± 5.38	26.19 ± 0.96	28.12 ± 0.95
Total Dose (mg)	375.81 ± 93.54	370.97 ± 14.06	380.65 ± 19.36
Dose (mg/Kg)	4.82 ± 0.80	4.99 ± 0.11	4.65 ± 0.17
Disease duration (year)	6.30 ± 5.68	8.10 ± 1.14	4.50 ± 0.77
Infliximab treatment duration (months)	24.53 ± 22.73	37.26 ± 4.45	11.81 ± 1.82
	N (%)	**N (%)**	**N (%)**
GENDER			
-Male	52.0(83.90)	26.0(83.90)	26.0(83.90)
-Female	10.0(16.10)	5.0 (16.10)	5.0 (16.10)
Do exercise	23.0 (37.10)	11.0 (35.50)	12.0 (38.70)
Smokers	29.0 (46.8)	10.0(32.30)	19.0(61.30)
Occupation			
-Does not need movement.	35.0(56.50)	15.0(48.40)	20.0(64.50)
-Needs movement	27.0(43.50)	16.0(51.60)	11.0(35.50)
Education level			
-Illiterate or Primary	25.0(40.30)	10.0(32.25)	15.0(48.40)
-Secondary	18.0(29.05)	11.0(35.50)	7.0 (22.60)
-College or above	19.0(30.65)	10.0(32.25)	9.0 (29.00)

Table 2: The difference in the quality-of-life dimensions and utility measures between the two groups before and at least 12 weeks after infliximab treatment

		Before treatment			After at least 14 weeks of treatment.		
QoL dimensions	**Infliximab type**	**N**	**Mean**	**Std. Deviation**	**P-value**	**Mean**	**Std. Deviation**	**P-value**
Mobility limitation	Remicade	31	3.71	1.30	0.686	1.77	.81	.511
	Remsima	31	3.58	1.21		1.94	1.09	
Self-care limitation	Remicade	31	3.55	1.48	0.680	1.39	.67	.097
	Remsima	31	3.39	1.59		1.74	.97	
Limitation of usual activities	Remicade	31	4.00	1.21	0.905	1.97	1.08	.024*
	Remsima	31	4.03	0.88		2.65	1.23	
Pain/ Discomfort	Remicade	31	4.55	0.68	0.410	2.48	.77	.887
	Remsima	31	4.68	0.54		2.52	.10	
Anxiety /Depression	Remicade	31	3.65	1.64	0.542	1.71	.94	.178
	Remsima	31	3.39	1.67		2.10	1.27	
Utility	Remicade	31	0.237	0.242	0.815	.737	.095	.097
	Remsima	31	0.250	0.215		.686	.139	
Utility improvement	Remicade	31				.500	.267	.313
	Remsima	31				.436	.231	
Infliximab duration in months	Remicade	31				37.26	24.77	.000*
	Remsima	31				11.81	10.10	

*Significant (P-value <0.05) according to Independent T-test

Table 3: Cost and benefit of both reference and biosimilar infliximab

Cost and benefit of infliximab			
Cost/Outcome	**Remicade**	**Remsima**	**Difference between Remicade and Remsima**
Cost in 2019 in USD ($)			
• One Vial cost (direct cost)	$ 405	$ 315	$ 90
• Total cost per patient per 1 year	$ 12,150	$ 9,450	$ 2,700
Cost in 2021 in USD ($)			
• One Vial cost (direct cost)	$ 148	$ 200	$ -52
• Total cost per patient per 1 year	$ 4,440	$ 6,000	$ -1560
Mean QALY gained in 1 year (Utility improvement)	0.500	0.436	0.066
No. of visits in 1 year	10	10	

Table 4: The incremental cost-effectiveness ratio (ICER) of Remicade to Remsima

Incremental cost-effectiveness ratio	
	Cost per one QALY
ICER 2019	$ 40,909
ICER 2021	$ -23,636

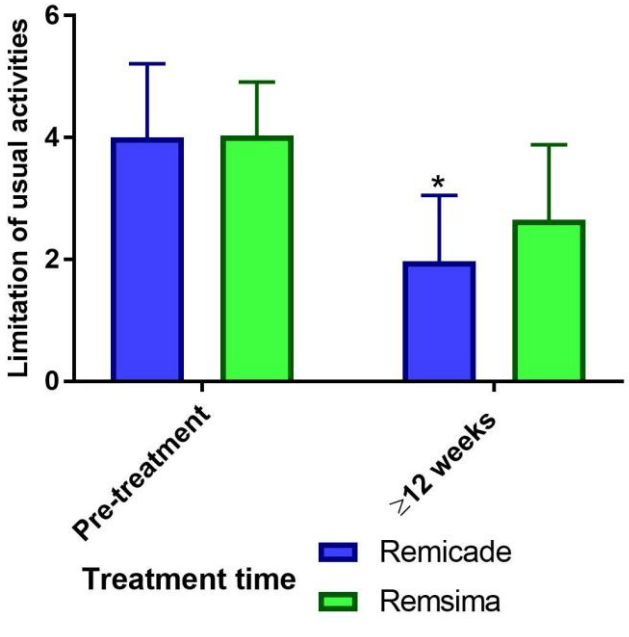

Figure 1: The difference in the limitation of usual activities (QoL) between the two groups before and ≥12 weeks after infliximab treatment

*Significantly (P-value 0.05) lower compared to the level in the Remsima group

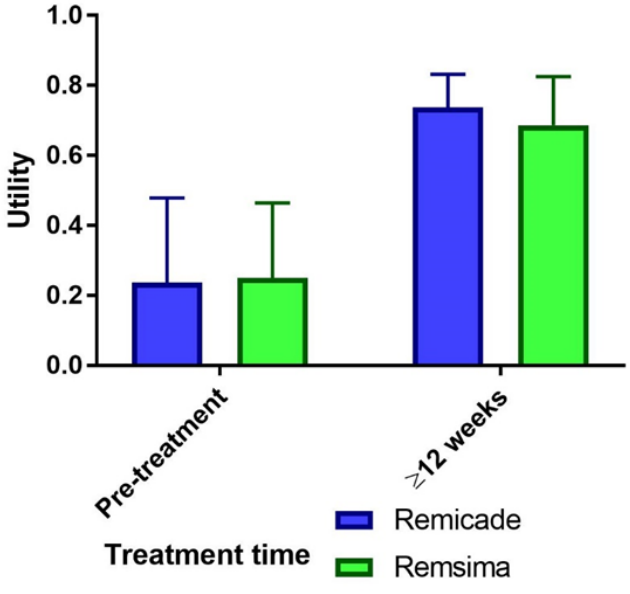

Figure 2: The difference in the utility (QoL) between the two groups before and ≥12 weeks after infliximab treatment

Discussion

The majority of participants were male (83.9%) with a mean age of 37.85 years. According to Nelson et al, men and women have similar AS disease incidence(24). However, in our study, the men-to-woman ratio was significantly higher. This may be because women are more likely to be underdiagnosed than men due to the fact that men have more severe radiographic changes according to Lee et al (25). Nearly half of the participants are smokers (46.8%). There is a strong relationship between smoking and the male gender and the severity of AS according to Kaut et al (26).

Before initiating infliximab medication, the quality of life of all AS. Patients (in both groups) were extremely poor. Rosenbaum et al (27) concluded that AS has a significant negative impact on all quality of life dimensions, with quality of life (QoL) being much below that of the general population. Patients with AS reported substantial improvements in their quality of life after using biological infliximab for at least 12 weeks. Afterwards, the QoL of both groups was assumed to remain fairly steady according to Sengupta, Ray, and Ghosh (28). Han et al (29) and Sengupta, Ray, and Ghosh (28) found that infliximab has been shown to improve the quality of life. Quality of life improved slightly more with Remicade than with Remsima, but the difference between both groups wasn't statistically significant enough to attract attention to it as such.

Because the only cost known at the start of the study was for 2019 and at the end of the study the 2021 price list was published, we took into account both 2019 and 2021 for direct infliximab prices. The prices in 2021 had been redefined and had become lower.

According to the 2019 pricing list published by the KIMADIA website, the total annual cost of infliximab for each patient with ideal body weight (70 kg) for (10 doses of 5mg per kg) of Remicade was $ 12,150 per year, whereas the cost of Remsima was $ 9,450 per year. Remicade had an ICER of $ 40,909 for QALY. While Remicade showed slightly better quality-of-life improvements,

Remicade's price was higher in 2019. As a result, Remicade proved to be more effective, but also more costly. We couldn't decide which was more cost-effective since the Iraqi Ministry of Health (MOH) didn't have a defined willingness to pay per QALY. However, if we assume that the willingness to pay is three times the GDP per person, the Iraqi MOH's willingness to pay may be around $15,000 per QALY according to World Bank Group - International Development, Poverty, & Sustainability n.d. (30). In this situation, Remicade was not more cost-effective than Remsima in 2019.

In 2021 Remicade and Remsima will cost less according to the new pricing list published by KIMADIA. Remicade cost $4,440 for a year's worth of treatment, whereas Remsima cost $6,000. Remicade's cheaper price and slightly better QALY improvements made Remicade more cost-effective in 2021.

There were a few limitations to this study. The study was conducted at two different centers in a single province (Baghdad), and participants were followed for a total of 20 weeks. The sample size of participants was relatively small. We collected the data retrospectively including the QoL baseline since there were few (5) new AS patients who started the infliximab treatment over the five months of the study course.

Conclusion

Remicade was superior to Remsima in 2019, in terms of overall quality of life (QALY. Remicade was not more cost-effective than Remsima in 2019 since a higher cost per QALY was needed. Compared to Remsima, Remicade was more cost-effective in 2021 because it was cheaper and more effective as measured by EQ-5D-5L scores. In general, both infliximab (Remicade) and its biosimilar (Remsima) were successful in increasing patient quality of life (QoL) in AS patients. It was an excellent idea to register and purchase both infliximab's biosimilar and its reference product so that AS patients may continue to receive infliximab at a competitive price and keep infliximab available.

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Conflict of Interest

No conflict of interest

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