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Treatment Satisfaction and Health-Related Quality of Life in Iraqi Patients with Rheumatoid Arthritis Receiving Biologic Therapy; Rituximab

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Abstract

The exact mechanism of action and which rheumatoid arthritis (RA) patients might benefit from Rituximab (RTX) are still questionable. One of the key elements in assessing the performance of a healthcare facility is patient satisfaction, which is a measure of how satisfied a patient is with the medical care he receives. This study aimed to evaluate the health-related quality of life and treatment satisfaction and their association with the responsiveness to RTX in RA patients. A comparative clinical study was conducted at the Center of Rheumatology in Baghdad- Iraq. The study enrolled 90 patients diagnosed with RA and receiving RTX intravenous infusion, for at least six months. The 28-joints disease activity score (DAS28) and clinical disease activity index (CDAI) were used to assess disease activity and RTX response. RA Impact of Disease (RAID) and Treatment Satisfaction Questionnaire for Medication (TSQM) were used to assess the health-related quality of life and treatment satisfaction, respectively. Participants were divided into two groups (the RTX responders group included 50 patients and the RTX non-responders group included 40 patients) according to DAS28 and CDAI assessment. The patients in the responders group had a significantly better quality of life according to the RAID score (P-value<0.001), the effectiveness, convenience, and global satisfaction were significantly higher in the responders group compared to the non-responders group (P-values were <0.001 for all). There were significant negative correlations between the effectiveness, convenience, and global satisfaction with RAID, CDAI, and DAS28. Better health-related quality of life and satisfaction were achieved among RTX responders compared to others, some satisfaction parameters were affected by the history of RA and duration of disease

Keywords: Quality of life, RA, Response, RTX, Satisfaction

Introduction

Rheumatoid Arthritis is a chronic systemic inflammatory autoimmune disease that has substantial socioeconomic expenses and significantly impairs the quality of life. The pathogenesis of RA includes interaction between genetic` predisposing factors and environmental triggers which can impair immunological tolerance and cause synovial inflammation [1, 2]. In 2020, more than 17 million people were reported to have RA, with a frequency of 0.24% worldwide, while in Iraq, it accounted for 1% until 2019 [3-5]. In general, the primary goal of the treatment of RA is to improve the quality of life by reducing pain, maintaining or enhancing functional capability, and preventing disability [6]. Quality of life is documented as an essential outcome variable in patients with chronic diseases including RA. The underlying pathogenic processes and aggressive treatment with disease-modifying therapy; both form core challenges [7]. Patients with RA have had access to an increasing number of therapy choices during the last two decades, this is an important issue as many patients require many medications throughout the disease to achieve and maintain optimal control [8], these are formally included as disease-modifying antirheumatic drugs, glucocorticoids and non-steroidal anti-inflammatory drugs (NSAIDs) [9, 10]. Nevertheless, NSAIDs are associated with different side effects like gastrointestinal ulcerations [11, 12]. RTX is a chimeric monoclonal antibody [13], it is a chimeric IgG1 kappa immunoglobulin that has been genetically altered to incorporate human constant region sequences together with murine light- and heavy-chain variable region sequences [14]. Identifying which patients will benefit from RTX is challenging in the absence of available predictors. It's still unclear which RA patients benefit from RTX, how exactly it works, and what dosage is best [15, 16]. One of the most crucial elements in assessing the performance of a healthcare institution is patient satisfaction, which is a measure of how satisfied a patient is with the medical care they receive [17]. The majority of research concurred that patient involvement in therapy decision-making is critical for improving compliance, meeting unmet medical requirements, and achieving patient satisfaction [18]

.This study aims to evaluate the health-related quality of life and treatment satisfaction and their association with the responsiveness to RTX in RA patients.

Patients and methods

The current study was conducted under the supervision of a specialized physician at the Specialized Center of Rheumatology/ Baghdad Teaching Hospital in Baghdad-Iraq during the period from January/2023 to January /2024. It was comparative clinical study with a convenient sample of ninety adult patients who were already diagnosed with RA. The inclusion criteria included patients receiving intravenous infusions of RTX for at least six months (1 gm on day 1, and day 14, and repeated after 6 months) and had the willingness to participate in the study. Exclusion criteria included taking another biological agent or steroid, chronic autoimmune diseases, or malignancy.

The disease activity was assessed by DAS28 and CDAI. A reduction of DAS28 by at least 0.6 and to a value less than 5.1 from the baseline score after 6 months of RTX therapy was considered indicative of clinical response. Patients who did not show such a reduction in DAS28 were considered non-responders [(19)]. According to CDAI, RA activity is classified as "remission (≤2.8), low (>2.8 but ≤10), moderate (>10 but ≤22), and high (>22)" [(20)].

The RAID score was employed to assess how RA affected the patient's quality of life [(21)]. The RAID score includes seven components which were measured on numeric rating scales from best (0) to worst (10) and each of them was given a relative weight on the final score based on the guidelines for calculation; pain accounts for 21%, functional disability accounts for 16%, fatigue accounts for 15%, sleep accounts for 12, physical well-being accounts for 12, emotional well-being accounts for 12, and coping accounts for 12 [(22)].

The TSQM was used to gauge how satisfied the patient was with their prescription over the course of the last two or three weeks, or since they last took it. The TSQM includes 14 questions which are divided into four subscales "effectiveness (items 1 to 3), side effects (items 4 to 8), convenience (items 9 to 11), and global satisfaction (items 12 to 14). The responses were measured on a Likert-type scale of 5 or 7 points, "except for question 4 in the side effects subscale", In question 4, the patient is asked about the presence of side effects and answers yes or no. If the answer is no, the remaining (5-8) will not be asked [(23)]. The sum of the scores of each subscale minus the number of the items in that subscale is divided by the maximum score minus the minimum score of that subscale multiplied by 100. Accordingly, the sum of the scores of each subscale is displayed as a number from 0 to 100[(24)].

The categorical data was presented as number and percentages, the continuous data were presented as mean ±standard deviation (SD). P-values less than 0.05 were considered as significant The Ethics Committee of the College of Pharmacy at Al-Mustansiriyah University gave its approval for this study, which was carried out in accordance with the Helsinki Declaration. (Official letter No. 77 dated 30/8/2023.

Results and Discussion

A total of 90 patients were enrolled in the current study. The patients were divided into two groups according to DAS28 and CDAI assessment: the RTX responders group (50 patients) and the RTX non-responders group (40 patients).

The duration of RA was significantly longer in the RTX responders group compared to the RTX non-responder group (P-value=0.030). The proportion of patients who had a family history of RA was significantly higher in the RTX responders group compared to the RTX non-responders group (P-value=0.001). There was no significant difference between the RTX responders group and the RTX non-responders group regarding the age, sex, and smoking state (P-values were 0.090, 0.377, and 0.626, respectively) (Table 1).

Table 1. Demographic data according to RTX-response

Variables		RTX responders (N=50)	RTX non-responders (N=40)	P-value
Age (mean ±SD)		50.38 ±12.22	54.43 ±9.54	0.090[a]
Sex N (%)	Male	4 (8.0)	1 (2.5)	0.377[b]
	Female	46 (92.0)	39 (97.5)	
Smoking status N (%)	No	47 (94.)	39 (97.50)	0.626[b]
	Yes	3 (6.0)	1 (2.50)	
Family history for RA N (%)	No	29 (58.0)	48 (96.0)	<0.001*
	Yes	21 (42.0)	2 (4.0)	
Duration of RA (years) (mean ±SD)		12.6±9.99	8.98±5.18	0.030[a]

a: Independent samples T-test, b: Fisher's Exact Test, *: statistically significant.

These results were in agreement with the results of Narvaez *et al*. (2011), who reported no statistically significant association between RTX response with age and sex [25]. In the same line, Sarha *et al*. (2019) concluded that the RTX response was not significantly affected by the age and gender of the patients [15]. In contrast, Couderc *et al.* (2013) demonstrated no association between the RTX response and the duration of the disease [26], which comes in line with the results of the Iraqi study done by Sarha *et al*. (2019) [15]. This discrepancy might be related to other factors that could impact the RTX response. In the current study, a better RTX response was obtained among those with a family history of RA. Nevertheless, this is contradictory to the results of Abdul *et al.* (2012) who reported that smoking independently affected response to RTX [27]. Sarah et al. reported that smoking has a negative correlation with response to treatment and this might be related to its significant enhancement of the risk of developing RA, this association has been strong in men and in those with rheumatoid factor and anti-citrullinated protein antibodies positive disease[15].

The mean of DAS28 and the proportion of patients with high disease activity according to CDAI were significantly lower in the RTX responders group compared to the RTX non-responders group (P-values=0.001). As shown in Table 2.

Table 2. Distribution of disease activity according to RTX response

		RTX responders (N=50)	RTX non-responders (N=40)	P-value
DAS28 (mean ±SD)		4.39 ±1.13	5.53 ±0.68	<0.001[a]*
Disease activity according to CDAI N (%)	Remission	2 (4.0)	0 (0.0)	<0.001[b]*
	Low	18 (36.0)	0 (0.0)	
	Moderate	23 (46.0)	17 (42.5)	
	High	7 (14.0)	23 (57.5)	

a: Independent samples t-test, b: Fisher's Exact Test, *: Statistically significant.

The patients in the responders group had a significantly better quality of life according to the RAID score (P-value<0.001), as shown in Table 3.

Table 3. Assessment of quality of life using RAID score according to response

Variables	RTX responders (N=50)	RTX non-responders (N=40)	P-value
RAID score	4.28±1.29	7.12±0.71	<0.001 [a] *

a: Independent samples T-test, *: statistically significant. Data expressed as mean± standard deviation.

This agreed with the results of another study that was done by William *et al*. in Lebanon (2010) which concluded that RTX plus Methotrexate was associated with significant enhancement in physical function and health-related quality of life outcomes compared with Methotrexate alone in patients previously untreated with Methotrexate [28]. The same results were obtained in another study that was done by Philip *et al*. (2008) which concluded that patients with active RA experienced improved health-related quality of life outcomes when RTX was added to methotrexate [29].

Regarding the satisfaction parameters, the effectiveness, convenience, and global satisfaction were significantly higher in the responders group compared to the non-responders group (P-values were <0.001 for all). As shown in Table 4.

Table 4. Satisfaction parameters according to the response

TSQM	Responders Number= 50 Mean± SD	Non- responders Number= 40 Mean± SD	P value
Effectiveness	74.57±16.4	48.45±9.27	<0.001 [a]
Side effects	18.64±22.25 Number= 8	25±27.91 Number=10	0.091
Convenience	72.86±18	47.62±10.62	<0.001 [a]
Global Satisfaction	69.65±18.15	46.18±11.19	<0.001 [a]

a: Independent samples T-test, *: statistically significant, Data expressed as mean± standard deviation

The effectiveness was significantly higher among patients with a family history of RA and those without a family history of RA (P-value=0.004). In addition, it was among patients with a duration of disease≥10 years than those with a duration of disease of < 10 years (P-value=0.029). The convenience was significantly higher among patients with a family history of RA and those without a family history of RA (P-value=0.001). In addition, it was among patients with a duration of disease≥10 years than those with a duration of disease of < 10 years (P-value=0.05). As shown in Table 5.

Table 5. Association between some demographic data and satisfaction

Variables		Effectiveness	Side effects	Convenience	Global Satisfaction
Age	≤50	60.53±19.7	69.70±5.5	57.27±19.7	57.74±20.8
	>50	64.74±18.1	73.49±1.8	64.83±19.1	60.29±18.3
P-values		0.298	0.051	0.071	0.539
Sex	Male	62.86±12.7	63.64±0	65.71±15.2	55.29±7.8
	Female	62.97±19.2	71.39±4.7	61.4±19.9	59.45±19.8
P-values		0.986		0.573	0.346
Family history for RA	No	59.84±18.9	70.61±4.5	57.43±19.2	56.98±19.9
	Yes	72.05±15.8	72.73±7.8	73.91±15.7	65.73±16.1
P-values		**0.004**	0.516	**0.001**	0.061
Duration of disease	<10 years	58.33±18.8	71.08±5.0	55.52±19.1	55.75±19.5
	≥10 years	66.98±17.9	70.78±5.1	67.09±18.5	62.09±18.7
P-values		**0.029**	0.907	**0.005**	0.122
Smoking status	No	62.9±18.9	70.96±5	61.46±19.7	59.17±19.5
	Yes	64.29±18.4	-	65.48±19.1	60.29±16.8
P-values		0.887		0.692	0.910

a: Independent samples T-test, *: statistically significant, Data expressed as mean± standard deviation.

There were significant negative correlations between the effectiveness, convenience, and global satisfaction with RAID, CDAI, and DAS28, as shown in Table 6.

Table 6. Correlation between RAID, CDAI, and DAS28 with satisfaction parameters

Variables	Statistics	RAID	CDAI	DAS28
Effectiveness	R	-0.841	-0.472	-0.410
	P-value	<0.001	<0.001	<0.001
Side effects	R	0.262	0.223	-0.283
	P-value	0.293	0.374	0.254
Convenience	R	-0.773	-0.375	-0.366
	P-value	<0.001	<0.001	<0.001
Global satisfaction	R	-0.740	-0.420	-0.365
	P-value	<0.001	<0.001	<0.001

Pearson Correlation

In another study that was done by Saoussen *et al*. in Tunisia (2023) and included a receiving their current disease-modifying anti-rheumatic drugs, the satisfaction parameters were inversely related to DAS28, HAQ score and productivity impairment in addition to RAID score and side effects of the treatment [(18)]. In the same line, Taylor *et al*. (2021) concluded that suboptimal disease control negatively impacts treatment satisfaction in patients with RA [(30)]. The effectiveness and convenience were affected by the family history of RA and the duration of the disease. This might be related association between these variables and RTX response. The side effects were not associated with the RTX response, were not associated with other parameters, and did not correlate with RAID, CDAI, and DAS28. This might be related low side effects of RTX. In another study that was done by Elizabeth et al., RTX was considered as safe and efficacious therapy for treatment of patients with RA [(31)]. Covelli et al reported that RTX is well tolerated either after a single course or after multiple courses [(32)]. Furthermore, RTX showed a good efficacy and safety profile in another study that was done by Marco et al. [(33)].

Conclusion

Better health-related quality of life and satisfaction were achieved among RTX responders compared to others. Some satisfaction parameters were affected by the history of RA and the duration of the disease.

Conflict of Interest

There is no conflict of interest

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Author Contribution

The authors confirm their contribution to the paper as follows: study conception and design: Aya Fawzi Talib and Mohammed Mahmood Mohammed; data collection: Aya Fawzi Talib ; analysis and interpretation of results: Mohammed Mahmood Mohammed; draft manuscript preparation: Aya Fawzi Talib. All authors reviewed the results and approved the final version of the manuscript.

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الرضا عن العلاج ونوعية الحياة في ما يخص الصحة لدى المرضى العراقيين الذين يعانون من التهاب المفاصل الرثوي الذين يتلقون العلاج البيولوجي; ريتوكسيماب

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الخلاصة

لا تزال الآلية الدقيقة لعمل الريستوكسيماب وتحديد مرضى التهاب المفاصل الرثوي الذين قد يستفيدون منه غير معروفة. أحد العناصر الرئيسية في تقييم الرعاية الصحية هو رضا المريض ، وهو مقياس لمدى رضا المريض عن الرعاية الطبية التي يتلقاها. هدفت هذه الدراسة إلى تقييم نوعية الحياة المتعلقة بالصحة والرضا عن العلاج وارتباطها بالاستجابة للريتوكسيماب لدى المرضى المصابين بالتهاب المفاصل الرثوي. أجريت دراسة مقطعية في مركز أمراض المفاصل في بغداد - العراق. سجل في الدراسة الحالية ٩٠ مريضا تم تشخيص إصابتهم بالتهاب المفاصل الرثوي وتلقوا عقار الريتوكسيماب عن طرق الوريد لمدة ستة أشهر على الأقل. تم استخدام درجة نشاط المرض ل ٢٨ مفصلا ومؤشر نشاط المرض السريري لتقييم نشاط المرض والاستجابة للريتوكسيماب. تم استخدام مقياس تأثير بالتهاب المفاصل الرثوي واستبيان الرضا عن العلاج للأدوية لتقييم نوعية الحياة المتعلقة بالصحة والرضا عن العلاج ، على التوالي. تم تسجيل ما مجموعه ٩٠ مريضا في الدراسة الحالية وتم تقسيمهم إلى مجموعتين (تضمنت مجموعة المستجيبين لعقار الريتوكسيماب ٥٠ مريضا ومجموعة الغير مستجيبين لعقار الريتوكسيماب ٤٠ مريضا) وفقا درجة نشاط المرض ل ٢٨ مفصلا ومؤشر نشاط المرض السريري. كان لدى المرضى في مجموعة المستجيبين نوعية حياة أفضل وبدلالة احصائية وفقا واستبيان الرضا عن العلاج للأدوية (قيمة الاحتمالية<٠,٠٠١) ، وكانت الفعالية والراحة ومستوى الرضا العام أعلى وبدلالة احصائية في مجموعة المستجيبين مقارنة بمجموعة غير المستجيبين (قيمة الاحتمالية <٠,٠٠١).

كانت هناك ارتباطات سلبية ذات دلالة احصائية بين الفعالية والراحة ومستوى الرضا العام مع درجة نشاط المرض ل ٢٨ مفصلا و ومؤشر نشاط المرض السريري و واستبيان الرضا عن العلاج للأدوية. تم تحقيق جودة الحياة أفضل في ما يخص الصحة ورضا المرضى بين المستجيبين لعقار الريتوكسيماب مقارنة بالآخرين ، وقد تأثرت بعض معايير الرضا بتاريخ التهاب المفاصل الرثوي ومدة المرض.

الكلمات المفتاحية: جودة الحياة، التهاب المفاصل الرثوي، الاستجابة، عقار الريتوكسيماب، الرضا.