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Research Article:

Disease Activity and Safety of Altebrel in Iraqi Rheumatoid Arthritis: A Retrospective Study

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Abstract

Background: Rheumatoid arthritis (RA) is a chronic inflammatory disease whose global burden is rising. Etanercept biosimilars and intended copies broaden access in low-income settings, but real-world evidence from Iraq and about Altebrel are scarce. **Objective:** To evaluate disease activity at assessment, safety, and predictors of moderate/high disease activity among Iraqi adults with rheumatoid arthritis treated with Altebrel in routine practice. **Methods:** This was a single-center retrospective observational study with cross-sectional disease activity assessment and retrospective laboratory comparison (medical record review) of adults with RA who were biologic-naïve or previous biologic users who had switched to Altebrel. Retrospectively collected data included demographics (age, sex), clinical characteristics (disease duration, body mass index, smoking status), treatment variables (methotrexate use, prior biologic use), adherence (refill-based), laboratory parameters (CRP, ESR, urea, creatinine, liver enzymes), and DAS28 at assessment. Associations between adherence and Disease Activity Score in 28 joints (DAS28) were explored with Spearman's correlation. Multivariable logistic regression estimated predictors of moderate/high disease activity (DAS28 ≥ 3.2). **Results:** One hundred patients (80 % female; mean age 48 ± 11 years) were analyzed. DAS28 at assessment was higher in previous biologic users than in biologic-naïve patients (median 4.34 vs 3.73; p=0.048). Age independently predicted moderate/high disease activity (odds ratio 1.07 per year; 95% confidence interval 1.01–1.14); adherence, smoking, methotrexate use, and marital status were not significant. Urea levels declined modestly after Altebrel (median 5.1 (3.9 - 6.6) to 4.4 (3.3 - 5.2) mmol/L, p=0.027), whereas creatinine and liver enzymes remained stable. **Conclusions:** In this Iraqi cohort, Altebrel therapy achieved moderate disease control with no major short-term safety concerns. Older age—but not adherence, smoking or marital status—predicted higher disease activity. These findings support the real-world use of Altebrel and highlight the need for treat-to-target strategies and prospective studies in the region.

1. Introduction

Rheumatoid arthritis (RA) is a systemic autoimmune disease characterized by chronic synovial inflammation leading to joint destruction, disability and reduced quality of life (1). The global burden of RA continues to rise; in the Middle East and North Africa (MENA) region, the age-standardized point prevalence and incidence increased by 28.3 % and 25.2 %, respectively, between 1990 and 2019 (2). In Iraq, early surveys suggested a prevalence of around 1 % of adults (3). Modern management emphasizes early diagnosis and a treat-to-target strategy, aiming for remission or low disease activity. The 2022 European League Against Rheumatism (EULAR) update recommends initial therapy with methotrexate (MTX) plus glucocorticoids and addition of a biological disease modifying antirheumatic drugs (bDMARD) within three to six months if response is inadequate (4).

Tumor necrosis factor inhibitors (TNFi) such as etanercept revolutionized RA therapy. Patents have expired, stimulating the development of biosimilars and intended copies, which improve access in resource-limited settings (5). Etanercept biosimilars, including GP2015, have demonstrated similar efficacy and treatment persistence to the reference product in real-world studies (6). Altebrel is an intended copy of etanercept produced for use in Iraq;

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however, published data on its clinical outcomes, adherence and safety are lacking (7). Furthermore, factors such as age, sex, smoking, MTX use, and marital status may influence disease activity and adherence in RA but remain understudied in Middle Eastern populations.
This study aimed to evaluate the disease activity outcomes, safety, and predictors of moderate/high disease activity at assessment with Altebrel in Iraqi patients with RA treated in routine clinical practice at a single rheumatology center in Mosul, Iraq. The findings will inform clinicians about real-world outcomes of this intended copy and guide future research and policy.

2. Materials and Methods

2.1. Study design and setting

This was a single-center retrospective observational study with cross-sectional disease activity assessment and retrospective laboratory comparison. Disease Activity Score in 28 joints (DAS28) was assessed at the patient visit, and laboratory parameters were compared between pre-treatment baseline and the assessment time. The study was conducted at the rheumatology clinic of a tertiary hospital in Mosul, Nineveh province, Iraq. The clinic serves a broad catchment area, facilitating convenient sample selection and maintains comprehensive electronic medical records. Data were extracted from the patients' clinic records for visits and laboratory results recorded between October 1, 2025 and January 25, 2026. Ethical approval was obtained from the Pharmaceutical Research Ethics Committee at the College of Pharmacy, University of Mosul (Ref. No.: PREC-25-4-12) and permission was granted by the Iraqi Ministry of Health (Ref. No.: 43887). This study was a retrospective review of existing clinical records, so the ethics committee approved the use of de-identified data. Patient identifiers were removed before analysis, and the data were handled confidentially.

2.2. Participants

Adults (aged ≥18 years) with a diagnosis of RA according to the 2010 ACR/EULAR criteria who had received at least three doses of Altebrel were eligible, to ensure adequate initial exposure for clinical response assessment, consistent with prior real-world TNFi studies evaluating early treatment outcomes. Patients were included regardless of whether they were biologic-naïve or previous biologic user. Patients were excluded if the DAS28 data at assessment were missing. A total of 100 patients met the inclusion criteria and were included in the study; the cohort was predominantly female (80%) and married (90%), with a mean age of 48.0 ± 10.8 years and median disease duration of seven years (IQR 3.0–14.0). Current smokers comprised 14% of the sample.

2.3. Data collection

Retrospective patients' data were extracted from their records, including age, sex, marital status, smoking status (non-smoker or current/ex-smoker), body mass index (BMI), RA disease duration, co-medication (MTX, corticosteroids, and NSAIDs) and previous biologic use (biologic naïve vs previous biologic user). Adherence was estimated from pharmacy refill records using refill dates and days' supply (8). For each patient, we summed the days' supply across available refills and divided it by the number of days between the first refill date and the assessment visit (inclusive). To avoid inflation from early refills, values above 1.0 were truncated to 1.0 (9). Good adherence was defined as ≥80 %, moderate (60–79 %) or poor (<60 %) (10). Disease activity at assessment was assessed using the DAS28 (calculated from tender and swollen joint counts, patient global assessment and ESR). Baseline DAS28 values were not consistently available in the medical records and were therefore not included in the analysis. Laboratory parameters included CRP, ESR, urea, creatinine, SGPT and SGOT measured before starting Altebrel (baseline) and at the time of disease activity assessment. CRP values were only quantitatively recorded for positive results, while negative results were documented qualitatively in the medical records. Responders were defined as patients in remission or low disease activity at assessment (DAS28 < 3.2), while non-responders had DAS28 ≥ 3.2, in accordance with established DAS28 thresholds (4). Adverse events were identified from documented clinic notes and hospital records during the period of Altebrel use up to the assessment visit.

2.4. Statistical analysis

Descriptive statistics were summarized and presented as mean ± standard deviation (SD) or median with interquartile range (IQR) for continuous variables and frequencies with percentages for categorical variables. The Shapiro–Wilk test assessed the normality of continuous variables. Comparisons between biologic-naïve and previous biologic users using Student's t- test for normally distributed variables and Mann–Whitney U test for non-normal variables. Differences across adherence categories were evaluated using Kruskal–Wallis tests. Spearman's correlation assessed the association between adherence (as a continuous percentage) and DAS28 score (4).
To identify predictors of moderate/high disease activity (DAS28 ≥ 3.2), a multivariable logistic regression model was constructed. Covariates included age, sex, BMI, RA duration, previous biologic use, adherence proportion, smoking status, MTX use and marital status. Odds ratios (ORs) with 95 % confidence intervals (CIs) were reported. Model fit was examined using pseudo-R^2 and likelihood ratio tests. Statistical significance was defined as $p<0.05$. Alongside p-values, we reported effect sizes to reflect the size of the observed differences. Cohen's d was used for mean differences in continuous outcomes (about 0.2, 0.5, and 0.8 were considered small, moderate, and large effects) (11). For Mann–Whitney comparisons, we reported the rank-biserial effect size (r); values around 0.10, 0.30, and 0.50 were taken as small, moderate, and large, and the sign only indicates the direction based on group order (12). For associations between categorical variables, we used Cramér's V, interpreted roughly as 0.10 (small), 0.30 (moderate), and 0.50 (large). Analyses were performed using SPSS v26 (IBM Corp., Armonk, NY, USA).

3. Results

3.1. Baseline characteristics

More than half of previous biologic users had switched to Altebrel (55 %), and 62 % concomitantly received MTX. Adherence was good in 67 % of patients. Baseline demographics and clinical characteristics are presented in **Table 1**. Age and BMI were normally distributed; disease duration, ESR and liver enzymes were skewed.

Table 1. Baseline demographics and clinical characteristics of the study population (n = 100)

Characteristic	Value
Age (years)	48.0 ± 10.8
Sex, n (%)	
Female	80 (80.0 %)
Male	20 (20.0 %)
BMI (kg/m²)	30.2 ± 5.9
Disease duration (years)	7.0 (3.0–14.0)
Smoking status, n (%)	
Non-smoker	86 (86.0 %)
Current/ex-smoker	14 (14.0 %)
Previous biologic use, n (%)	
Biologic naïve	45 (45.0 %)
Previous biologic users	55 (55.0 %)

Variables are presented as mean ± SD for normally distributed data and median (inter quartile range) for non-normally distributed data.

3.2. Clinical outcomes

3.2.1. Disease activity and inflammatory markers by previous biologic use

The median DAS28 at assessment was 3.73 (IQR 2.77–4.40). Patients who had previously received a biologic had higher DAS28 at assessment than biologic-naïve patients (median 4.34 vs 3.73; p = 0.048), with a moderate rank-based effect size (rank-biserial r = 0.48). CRP and ESR at assessment did not differ between groups and the effect sizes were small (**Table 2**).

3.2.2. Baseline versus at assessment changes in inflammatory and laboratory parameters

Wilcoxon signed rank tests were used to assess paired changes because ESR and liver enzymes were non normally distributed. ESR decreased from a median of 33.0 (IQR 23.0–44.0) mm/hr at baseline to 28.0 (17.5–41.5) mm/hr at assessment (p = 0.026). Urea declined from 5.1 (3.9–6.6) to 4.4 (3.3–5.2) mmol/L (p = 0.027). Creatinine, SGPT and SGOT did not change significantly (all p > 0.05) (**Table 3**).

3.3. Adherence and its association with outcomes

Adherence (mean ± SD = 0.85 ± 0.13) was recorded as a continuous proportion and categorized as good (≥80 %), moderate (60–79 %) or poor (<60 %). Spearman correlation coefficients showed no significant association between adherence proportion and DAS28 at assessment (ρ = −0.09; p = 0.389), CRP (ρ = −0.07; p = 0.661) or ESR (ρ = −0.17; p = 0.094). Kruskal–Wallis tests comparing outcomes across adherence categories found no significant differences in DAS28, CRP or ESR at assessment (all p > 0.05) (**Table 4**). The generally high adherence levels with limited variability in this cohort may have reduced the ability to detect a statistically significant association, and therefore the absence of association should not be interpreted as lack of clinical relevance.

3.4. Predictors of treatment response

Univariate analyses compared responders (remission or low disease activity, n = 27) with non responders (n = 73). Responders were younger (mean age 44.1 ± 11.0 vs 49.5 ± 10.4 years; p = 0.026) and more likely to be male (37.0 % vs 13.7 %; p = 0.021) or current/ex smokers (29.6 % vs 8.2 %; p = 0.016). BMI, disease duration, prior biologic use and adherence did not differ significantly between groups (**Table 5**).
A multivariable logistic regression model including age, sex, BMI, RA duration, previous biologic use, adherence, smoking status, methotrexate use and marital status identified age as the only independent predictor of moderate/high disease activity (DAS28 >= 3.2). Each additional year of age increased the odds of moderate/high disease activity by 7% (odds ratio 1.07; 95% CI 1.01-1.14; p = 0.019). Other factors were not significant (**Table 6**).

3.5. Safety

Adverse events were infrequent. Injection site reactions occurred in 6 % of patients; no serious infections or malignancies were reported. One patient (1 %) developed transient elevation of liver enzymes. One patient (1%) had a transient renal laboratory abnormality documented in the record, without persistent impairment.

Table 2. Disease activity and inflammatory markers at assessment by previous biologic use status

Variable	Group	N	Mean ± SD	Median (IQR)
DAS28 at assessment	Biologic naïve	45	3.66 ± 1.11	3.73 (2.77–4.40)
	Previous biologic users	55	4.33 ± 1.11	4.34 (3.43–5.22)
CRP at assessment (mg/L)*	Biologic naïve	20	7.47 ± 5.18	6.00 (6.00–9.00)
	Previous biologic users	26	8.65 ± 6.60	6.00 (6.00–12.00)
ESR at assessment (mm/hr)	Biologic naïve	45	26.58 ± 16.27	23.0 (14.0–39.0)
	Previous biologic users	55	30.55 ± 17.71	30.0 (19.0–42.0)

** CRP values were available only for patients with a recorded positive result (n=46); negative results were recorded qualitatively in the chart and were not quantified.*

Table 3. Changes in inflammatory and laboratory parameters before and after Altebrel (n=100)

Parameter	Baseline median (IQR)	At assessment median (IQR)	p-value	Effect size (*rank-biserial r*)
ESR (mm/hr)	33.0 (23.0–44.0)	28.0 (17.5–41.5)	**0.026**	0.21
Urea (mmol/L)	5.1 (3.9–6.6)	4.4 (3.3–5.2)	**0.027**	0.20
Creatinine (µmol/L)	61.0 (53.0–71.0)	62.0 (55.0–69.0)	0.905	0.03
SGPT (U/L)	19.0 (15.0–25.0)	20.0 (16.0–24.0)	0.684	0.05
SGOT (U/L)	19.0 (16.2–22.0)	20.0 (17.0–23.0)	0.274	0.15

Table 4. DAS28 at assessment outcomes by adherence category (n=100)

Outcome	Good (n = 67) median (IQR)	Moderate (n = 20) median (IQR)	Poor (n = 13) median (IQR)	H statistic	p-value
DAS28 at assessment	4.06 (3.06–4.73)	4.01 (2.89–4.57)	5.11 (4.45–5.46)	4.03	0.133
CRP at assessment (mg/L)	8.00 (5.50–12.0)	7.00 (6.00–11.0)	7.00 (6.00–8.00)	0.24	0.886
ESR at assessment (mm/hr)	29.0 (14.0–39.5)	31.5 (17.0–42.3)	30.0 (25.0–38.5)	1.35	0.509

Table 5. Univariate predictors of treatment response
Comparison between responders (remission/low disease activity) and non-responders.

Variable	Responders (n = 27)	Non-responders (n = 73)	p-value	Effect size
Age (years)	44.1 ± 11.0	49.5 ± 10.4	**0.026**	0.51 (Cohen's *d*)
BMI (kg/m²)	29.3 ± 5.4	30.5 ± 6.1	0.355	0.21 (Cohen's *d*)
Disease duration (yr)	5.0 (2.0–12.0)	8.0 (3.0–14.0)	0.166	0.14 (*rank-biserial r*)
Male sex	10 (37.0 %)	10 (13.7 %)	**0.021**	0.23 (Cramér's V)
Smoker/ex-smoker	8 (29.6 %)	6 (8.2 %)	**0.016**	0.24 (Cramér's V)
Biologic naïve	16 (59.3 %)	29 (39.7 %)	0.129	0.15 (Cramér's V)
Good adherence	20 (74.1 %)	51 (69.9 %)	0.732	0.08 (Cramér's V)

Table 6. Predictors of moderate/high disease activity (DAS28 ≥ 3.2) in multivariable logistic regression

Predictor	Coefficient	Odds ratio (95 % CI)	p-value
Previous biologic use	0.41	1.50 (0.47–4.85)	0.49
Adherence (proportion)	−3.92	0.02 (0.00–2.09)	0.10
RA duration (years)	0.03	1.03 (0.94–1.13)	0.51
Age (years)	**0.07**	**1.07 (1.01–1.14)**	**0.019**
Female sex	1.46	4.31 (0.86–21.66)	0.076
BMI (kg/m²)	0.01	1.01 (0.91–1.12)	0.84
Smoking status (current)	−0.20	0.82 (0.13–5.28)	0.84
Methotrexate use	0.00	1.00 (0.33–3.04)	0.99
Marital status (single)	−0.21	0.81 (0.10–6.66)	0.85

4. Discussion

This single-center retrospective observational study with cross-sectional disease activity assessment and retrospective laboratory comparison provides the first real-world evaluation of Altebrel, an etanercept intended copy, in Iraqi RA patients. We observed moderate disease activity (median DAS28 ≈ 3.7) in patients receiving Altebrel. Previous biologic users had slightly higher disease activity than those starting biological therapy. This difference may reflect more refractory disease, prior treatment failure, or delayed disease control among patients requiring switching, although detailed reasons for switching were not consistently available in the records.

Logistic regression identified age as the only independent predictor of moderate/high disease activity, with a 7 % increase in odds per year of age. Notably, adherence percentage, smoking status, MTX use and marital status were not associated with DAS28 at assessment. Safety analyses demonstrated a modest reduction in urea and stable creatinine and liver enzymes, suggesting good renal and hepatic tolerability.

Our findings complement data from Europe and North America demonstrating equivalent efficacy and persistence of etanercept biosimilars and intended copies compared with the originator (13, 14). Carballo and colleagues showed that etanercept and its biosimilar GP2015 achieved comparable reductions in DAS28-CRP and similar drug survival at 52 weeks (6). Although we lacked baseline disease activity, the moderate DAS28 scores and absence of adverse hepatic or renal effects align with this literature. While we found no association between smoking and disease activity, this contrasts with observational registry studies reporting poorer clinical response to TNF inhibitors among smokers; this could be due to the small number of current smokers in our sample (15, 16). Similarly, in this cross-sectional RA analysis, neither concomitant methotrexate (MTX) use nor marital status was associated with disease activity. While MTX co-therapy has been reported to improve biologic persistence in some real-world cohorts and reviews, the influence of individual covariates on outcomes is heterogeneous across settings and models. Our findings add to this literature by suggesting no independent association of MTX use or marital status with

disease activity in our population (17-19). Age-related differences may reflect cumulative joint damage, comorbidities and immunosenescence.

The moderate disease control observed highlights the importance of rigorous treat-to-target strategies in Iraqi clinical practice. EULAR recommends initiating MTX with short-term glucocorticoids and adding a bDMARD such as etanercept within 3–6 months if response is inadequate (4). Our data suggest that older patients may require closer monitoring and possibly earlier escalation of therapy. In multivariable analysis, adherence was not independently associated with disease activity. This should not be interpreted as evidence that adherence is unimportant; rather, adherence levels in our cohort were generally high with limited variability, which may have reduced our ability to detect an association (i.e., restricted range and limited power) (20). Patient education and adherence support, therefore, remain key components of care in RA (21).

Strengths of this study include the evaluation of a locally produced intended copy in a real-world cohort, inclusion of both biologic-naïve and previous biologic users, assessment of adherence and safety, and comprehensive multivariable analyses. The study also addresses a gap in regional data for RA management.

Limitations must be acknowledged. The retrospective observational design precluded causal inference and prevented assessment of changes from baseline; indeed, baseline DAS28 and CRP were unavailable. Sample size was moderate, and some subgroups (e.g., smokers, single individuals) were small, reducing statistical power. As a single-center study, generalizability to other Iraqi settings may be limited. The single-center design may also introduce selection bias, as the study population may not fully represent all RA patients across different healthcare settings in Iraq. Finally, socio-economic factors and comorbidities were not captured.

Prospective longitudinal studies are needed to compare Altebrel with originator etanercept and other biosimilars, including baseline and follow-up disease activity, patient-reported outcomes and radiographic progression. Larger cohorts would allow investigation of adherence determinants and the impact of socio-economic status, education and psychological factors. Pharmacovigilance registries will be crucial to monitor long-term safety.

5. Conclusion

In this single-center retrospective observational study with cross-sectional disease activity assessment and retrospective laboratory comparison conducted at a rheumatology center in Mosul, Iraq, Altebrel therapy achieved moderate disease control with an acceptable observed safety profile within the study period. Older age was associated with higher disease activity at assessment, whereas adherence, smoking status, MTX use and marital status were not. These findings support the continued use of Altebrel as a cost-effective TNFi option in Iraq and underscore the need for treat-to-target strategies, vigilant monitoring of older patients and prospective comparative studies.

6. Conflict of Interest

The authors have no conflicts to declare.

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نشاط المرض وسلامة دواء ألتبريل في علاج التهاب المفاصل الروماتويدي لدى العراقيين: دراسة استرجاعية

الخلاصة

المقدمة: يُعدّ التهاب المفاصل الروماتويدي مرضًا التهابيًا مزمنًا يتزايد انتشاره عالميًا. تُساهم البدائل الحيوية للإيتانيرسيبت والنسخ المُستهدفة في توسيع نطاق الوصول إلى العلاج في البلدان منخفضة الدخل، إلا أن الأدلة الواقعية من العراق حول دواء ألتبريل لا تزال شحيحة.**الهدف:** تقييم نشاط المرض عند التشخيص، وسلامة الدواء، والعوامل المُتنبئة بنشاط المرض المتوسط/العالي لدى البالغين العراقيين المصابين بالتهاب المفاصل الروماتويدي والذين يتلقون علاج ألتبريل في الممارسة السريرية الروتينية. **طرق العمل:** دراسة رصدية استرجاعية أحادية المركز، شملت تقييمًا مقطعيًا لنشاط المرض ومقارنةً استرجاعية للنتائج المختبرية (مراجعة السجلات الطبية) لدى البالغين المصابين بالتهاب المفاصل الروماتويدي، سواءً كانوا لم يتلقوا علاجًا بيولوجيًا من قبل أو كانوا يستخدمونه سابقًا ثم تحولوا إلى ألتبريل. شملت البيانات التي جُمعت بأثر رجعي المعلومات الديموغرافية (العمر، الجنس)، والخصائص السريرية (مدة المرض، مؤشر كتلة الجسم، حالة التدخين)، ومتغيرات العلاج (استخدام الميثوتريكسات، استخدام العلاجات البيولوجية سابقًا)، والالتزام بالعلاج (بناءً على تجديد الوصفة الطبية)، والتحاليل المخبرية (بروتين سي التفاعلي، سرعة ترسب الدم، اليوريا، الكرياتينين، إنزيمات الكبد)، ومؤشر نشاط المرض في 28 مفصلًا (DAS28) عند التقييم. وتم استكشاف العلاقة بين الالتزام بالعلاج ومؤشر نشاط المرض في 28 مفصلًا (DAS28) باستخدام معامل ارتباط سبيرمان. وقدّر تحليل الانحدار اللوجستي متعدد المتغيرات مؤشرات التنبؤ بنشاط المرض المتوسط/العالي.(DAS28 ≥ 3.2) **النتائج:** تم تحليل بيانات مئة مريض (80% إناث؛ متوسط العمر 48 ± 11 سنة). كان مؤشر DAS28 عند التقييم أعلى لدى المرضى الذين سبق لهم استخدام العلاجات البيولوجية مقارنةً بالمرضى الذين لم يسبق لهم استخدامها (الوسيط 4.34 مقابل 3.73؛ p=0.048). تنبأ العمر بشكل مستقل بنشاط مرضي متوسط/مرتفع (نسبة الأرجحية 1.07 لكل سنة؛ فاصل الثقة 95% 1.01-1.14)؛ بينما لم يكن الالتزام بالعلاج، والتدخين، واستخدام الميثوتريكسات، والحالة الاجتماعية عوامل ذات دلالة إحصائية. انخفضت مستويات اليوريا بشكل طفيف بعد تناول دواء ألتبريل (المتوسط 5.1 (3.9 - 6.6) إلى 4.4 (3.3 - 5.2) مليمول/لتر، p=0.027)، في حين بقيت مستويات الكرياتينين وإنزيمات الكبد مستقرة. في هذه المجموعة العراقية، حقق علاج ألتبريل سيطرة متوسطة على المرض دون أي مخاوف كبيرة تتعلق بالسلامة على المدى القصير. تنبأ التقدم في السن - وليس الالتزام بالعلاج، أو التدخين، أو الحالة الاجتماعية - بنشاط مرضي أعلى. **الاستنتاج:** تدعم هذه النتائج استخدام ألتبريل في الواقع العملي، وتؤكد على الحاجة إلى استراتيجيات علاجية موجهة نحو الهدف، ودراسات مستقبلية في المنطقة.

الكلمات المفتاحية: الالتزام بالعلاج؛ إيتانيرسيبت؛ العراق؛ التهاب المفاصل الروماتويدي مثبط عامل نخر الورم