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Real-world experience with romiplostim in the management of primary immune thrombocytopenia in Iraqi adult patients

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Abstract:

BACKGROUND: Low platelet counts resulting from increased platelet breakdown and poor platelet generation are the hallmarks of immune thrombocytopenia (ITP), an autoimmune illness. Romiplostim increases platelet counts in the majority of patients and lowers bleeding risk in those with ITP.

OBJECTIVES: To evaluate the median dose of romiplostim required to maintain platelet counts ≥50 × 10^9/L and to assess platelet response rates among adult Iraqi patients with primary ITP.

MATERIALS AND METHODS: The cross-sectional study looked at 200 patients' ages ≥14 years who had primary ITP that failed 1st line treatment. They were treated at Baghdad Medical City from May 2022 to December 2023. Medical records were used to get the information. Romiplostim (Nplate®, Amgen Inc., Thousand Oaks, CA, USA) was injected subcutaneously once a week. The dose started at 1 μg/kg and was increased by 1 μg/kg each time to keep the platelet numbers between 50 and 200 × 10^9/L (maximum 10 μg/kg).

RESULTS: Among 200 patients (60% female), the median age was 38 years and the median treatment duration was 4 months. The median weekly dosage of romiplostim was 250 μg and the median baseline platelet count was 19 × 10^9/L, which significantly increased to 138 × 10^9/L after romiplostim therapy (P = 0.011). A total of 73.5% of patients achieved a platelet response ≥ 50 × 10^9/L. There was no significant difference in response between patients aged ≥ 60 years and those < 60 years (P = 0.25).

CONCLUSIONS: Romiplostim has a robust and persistent platelet response in adult patients with refractory ITP and good safety. Its effectiveness as a second-line treatment was confirmed by its age-neutral response.

Keywords:

Immune thrombocytopenia, romiplostim, thrombopoietin receptor agonist

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Introduction

Immune thrombocytopenia (ITP) is a long-lasting autoimmune disease that causes the immune system to destroy the platelets and make it harder for platelets to be made. Most patients respond to first-line treatments such as corticosteroids and intravenous immunoglobulin at first, but many of them have to switch to second-line treatments because they get worse.[1]

Thrombopoietin receptor agonists (TPO-RAs) have profoundly transformed the treatment paradigm of ITP by enhancing platelet formation and diminishing the necessity for prolonged immunosuppressive medication. The U.S. Food and Drug Administration and the European Medicines Agency have authorized eltrombopag,

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romiplostim, and avatrombopag for the treatment of ITP patients who do not respond to first-line therapy.[2]

Randomized controlled studies, including patients with chronic ITP, have shown that TPO-RAs work for 70%–90% of patients and that about 50%–60% of those individuals keep responding.[3]

Romiplostim is a peptibody that has a peptide that binds to the thrombopoietin receptor and an IgG1 Fc domain. It is given as a weekly subcutaneous injection, starting at 1 μg/kg and going up to 10 μg/kg dependent on how well the platelets respond.[4] Romiplostim is effective in raising platelet counts in people with refractory ITP, but it does not provide a complete cure. However, treatment-free remission has been seen in a specific cohort of individuals after extended exposure.[5,6]

So yet, there are no accurate clinical predictions of how well TPO-RAs will work, and the results of treatment may be different for each person. Moreover, real-world data assessing platelet response patterns and the impact of patient-related parameters, such as age, are still insufficient.

This study aimed to assess the median romiplostim dosage and platelet response in adult Iraqi patients with primary ITP, as well as to ascertain the impact of age on treatment efficacy.

Materials and Methods

Study design and participants

This retrospective cross-sectional study was performed at Baghdad Medical City, Hematology and Transplantation Center, from May 2022 to December 2023. Data were acquired from the patients' medical records and treatment documentation.

The study includes 200 patients aged 14 years and older with a confirmed diagnosis of primary ITP. The diagnosis of ITP was based on clinical evaluation, laboratory findings, and bone marrow examination when indicated.

Inclusion criteria

- Patients aged ≥14 years diagnosed with primary ITP
- Patients who received romiplostim therapy for at least three consecutive weeks
- Availability of complete medical records and follow-up data.

Exclusion criteria

- Patients with secondary causes of thrombocytopenia (e.g., drug-induced, systemic lupus erythematosus, infections, and malignancy)
- Patients who discontinued treatment before completing three doses of romiplostim
- Patients with incomplete or missing data.

Treatment protocol

Romiplostim (Nplate®, Amgen Inc., Thousand Oaks, CA, USA) was administered through subcutaneous injection weekly. The initial dosage was 1 μg/kg/week, increased to achieved response which is defined as platelet count ≥50×10^9/L (aiming to maintain it within range of 50–200 × 10^9/L), with a maximum allowable dose is 10 μg/kg.

Ethical considerations

The study protocol was reviewed and approved by the Institutional Review Board of Hematology and Transplant Center, according to ethical approval No. 15 at February 8, 2022. All procedures were conducted in accordance with the ethical standards of the responsible committee on human experimentation and with the Declaration of Helsinki (2000 revision).

Verbal consent was obtained from all adult participants and from parents or legal guardians of participants under 18 years of age. Confidentiality of all patient data was maintained throughout the study.

Statistical analysis

IBM SPSS version 23 software (IBM Corp., Armonk, NY, USA) was used to analyze the data. Frequency and percentage were used to describe the categorical variables, whereas mean ± standard deviation or median (range) were used for the continuous variables. The Chi-square test for the categorical variables and the Student's *t*-test for the continuous data were used to compare the groups.

Statistical significance was established at a $P < 0.05$. Where appropriate, 95% confidence intervals were computed for the data.

Results

A total of 200 individuals were enrolled, with the treatment for ITP switched to romiplostim due to inadequate response to previous medication, which was the primary reason for therapy transition among all patients. The median age of patients was 38.0 years (interquartile range: 27–52) [Table 1]. Women made up 60% of the cases, which form the majority.

The median weekly dosage of romiplostim was 250 μg, a range: 60–975 μg. The median duration of treatment was 4 months (range: 3–83 months) and the median number of injections was 12. The treatment characteristics are summarized in Table 2. The analytic outcomes for platelet response before and after treatment are shown

in Table 3, which shows a significant difference between pre- and last-on treatment level ($P = 0.011$).

The overall platelet response of at least 50×10^9/L at the last on-treatment assessment was attained in 147 out of 200 patients (73.5%). When stratified by age, 26 out of 29 patients with age ≥60 years achieved this response (89.7%) and this response was similar to patients under the age of 60 years without significant difference ($P = 0.25$). Platelet response according to age and overall platelet response are summarized in Tables 4 and 5.

Discussion

This observational study aimed to describe the population of adult patients with ITP who received romiplostim in routine clinical practice at a single center in Iraq. Two hundred adult patients with refractory ITP were enrolled in the study; most of them (73%) responded satisfactorily following romiplostim, with platelet levels above 50×10^9/L, which was maintained throughout the study period. The response rate in this study aligns with results from Jumaa *et al*.,[7] who reported a 75% response rate in Iraqi patients, and with Cooper *et al*.[8] and Cines *et al*.,[9] who reported 75.5% and 87%, respectively. Similarly, Shirasugi *et al*. demonstrated a 95% response rate in Japanese patients during an 11-week randomized Phase III clinical trial.[10] The median weekly dose (250 μg, ≈3.5 μg/kg) in this study is comparable to that reported in previous trials, which showed median doses between 2 and 3 μg/kg,[8,11,12] with a starting dose of 1 μg/kg with Romiplostim, to meet the target platelet counts, which can be raised to a maximum of 10 μg/kg/week in compliance with the European label requirements.[13]

Table 1: Baseline demographics and patient characteristics

Parameter	Value, *n* (%)
Age (years), median (IQR)	38 (27–52)
Age ≥60 years	29 (14.5)
Sex	
Male	80 (40)
Female	120 (60)

IQR=Interquartile range

Table 2: Median dosage and treatment duration of Romiplostim

Parameter	Value
Dosage per week (μg)	
Mean±SD	264±134.8
Median (range)	250 (60–975)
Duration of treatment with romiplostim (months), median (range)	4 (3–83)
Number of injections, median (range)	12 (3–83)

SD=Standard deviation

Table 3: Analytical platelet response after romiplostim therapy

PLT count	Mean±SD (median)	*P*
At baseline treatment (×10⁹/L)	25±33.9 (19)	0.011
Last-on treatment (×10⁹/L)	174±143.6 (138)	

SD=Standard deviation, PLT=Platelet

Table 4: Response to romiplostim according to age group

Age (years)	Responders/total	*P*
≥60	26/29	0.25
<60	121/174	

Table 5: Overall response posttreatment with romiplostim

Response category	*n* (%)
PLT count ≥50×10⁹/L	147 (73.5)
PLT count <50×10⁹/L	53 (26.5)

PLT=Platelet

The current study, with its median treatment duration of 16 weeks, still aligns well with the results of more stringent trials, further supporting romiplostim as a reliable treatment option. Different ITP studies may employ different definitions of platelet response, but the platelet count criterion of $\geq 50 \times 10^9$/L used in this investigation has been used in all prior trials with romiplostim and other ITP treatments.[11,12,14,15] Importantly, no significant difference was observed between older (≥60 years) and younger patients ($P = 0.25$), suggesting that romiplostim is equally effective across age groups.[16,17] This finding is consistent with studies by Michel *et al*.[16] and Palandri *et al*.[17]

This study found that romiplostim is an effective treatment for refractory ITP in the clinical settings. When treatment choices are limited in refractory cases, maintaining platelet levels lower the risk of bleeding. Its consistent response over the course of the study points to a potential function in managing ITP over the long run.

However, this study has limitations as a retrospective single-center analysis; it is limited by potential data incompleteness and inability to assess long-term safety outcomes in addition to insufficient recording for the reasons of treatment discontinuation for all the participants. Future prospective studies are needed to address these aspects more accurately.

Conclusions

Romiplostim showed a significant and prolonged improvement in platelet count in adult patients with refractory ITP, accompanied by an acceptable safety profile. The response was uniform across age demographics, reinforcing its significance as an effective second-line treatment. Additional prospective studies

are necessary to assess the long-term outcomes and determinants of sustained remission. However, the determinants of persistent outcomes and sustained remission in Iraqi patients further prospective multicenter trials are required.

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Conflicts of interest
There are no conflicts of interest.

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