ELSEVIER

Blood 142 (2023) 1213–1214

The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

311.DISORDERS OF PLATELET NUMBER OR FUNCTION: CLINICAL AND EPIDEMIOLOGICAL

The Combination of Intravenous Immunoglobulin (IVIG) and Low Does Recombinant Human Thrombopoietin (rhTPO) for the Management of Corticosteroid/IVIG Monotherapy-Resistant Immune Thrombocytopenia in Pregnancy

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Introduction

Primary immune thrombocytopenia (ITP) is a common autoimmune disease characterized by a low platelet count resulting from antibody-mediated platelet destruction and insufficient platelet production. ITP, with a prevalence of 1 in 1000-10 000 pregnancies, accounts for approximately 3% of all causes of thrombocytopenia in pregnancy and is reported to be the most common cause of thrombocytopenia in the first and early second trimesters. It has been revealed that severe ITP is associated with devastating outcomes. It remains a challenge to manage pregnant patients with ITP. First-line treatment options in pregnant ITP patients currently include corticosteroids and intravenous immunoglobulin (IVIg). However, previous studies reported that the response rate of pregnant ITP patients to corticosteroids was less than 40% and that to IVIg was 38-56%, which was lower than that of nonpregnant ITP patients. The second-line treatment options are limited for pregnant ITP patients. Recombinant human thrombopoietin (rhTPO), a full-length and glycosylated TPO with a molecular weight of 90 000 Daltons developed by 3SBIO (Shenyang, China), has also been approved by the China State Food and Drug Administration as a second-line option for nonpregnant ITP patients. It cannot cross the placenta theoretically with such a large molecular weight, and thus, it has an apparent theoretical advantage over the two TPO mimetics since it would not impact the fetus. A study investigating the application of rhTPO in pregnancy suggested that rhTPO was a potentially effective and well-tolerated treatment option for ITP patients during pregnancy. It might be explained that the development of ITP was associated with increased platelet destruction and impaired platelet production, and the combination of IVIg and TPO mimetics impacts these two targets since IVIg could reduce platelet destruction, whereas TPO mimetics could increase platelet production. Therefore, we conducted a monocenter, single-arm, open-label study to investigate the efficacy and safety of low-dose rhTPO plus IVIg in pregnant corticosteroid/IVIg monotherapy-resistant ITP patients.

Methods

This study was registered at www.clinicaltrials.gov as NCT05634824.The following criteria were considered: patients have a diagnosis of primary ITP before or first onset during pregnancy; patients ≥ 18 years; patients complicated with bleeding manifestations and/or have a platelet count < 30 × 10^9/L and failed to respond to initial treatment of corticosteroids or intravenous immunoglobulin (IVIg) monotherapy or relapsed during the tapering or discontinuation of corticosteroids. For those patients, the initial combination therapy consisted of rhTPO at an initial dose of 150 U/kg once daily subcutaneously for 28 days and IVIg 400 mg/kg per day for 5 days. If the platelet count was in the range of 30 to 50 × 10^9/L, the combination

therapy was repeated. To reduce the risk for thrombocytosis, patients received maintenance therapy consisting of rhTPO at a dose of 150 U/kg per day if the platelet count rose above 50 × 10^9/L, and treatment was discontinued when platelet counts exceeded 100 × 10^9/L. After delivery, the treatment consisted of rhTPO 150 U/kg per day, and the dose was maintained if the platelet count exceeded 30 × 10^9/L. In addition, IVIg 400 mg/kg per day for 5 days was added if the platelet count could not be maintained above 30 × 10^9/L. If patients did not achieve a count of 30 × 10^9/L within 4 weeks, treatment was also discontinued.

Results

The study included 19 patients with thrombocytopenia during pregnancy who were admitted to Peking University People's Hospital from December 1, 2022, to May 30, 2023, all of whom had failed hormone and IVIG treatment. The median age of those patients was 34 years old (range 20 to 42 years old), and the median platelet count before treatment was 13×10^9/L (range 1-30×10^9/L). The four-week response rate was 63.2% (12/19), and the median response time was 7.5 days (range 5 to 35 days). There were no treatment-related adverse reactions.

Conclusions

Low-dose rhTPO plus IVIg in pregnant corticosteroid/IVIg monotherapy-resistant ITP patients is effective and safe. These findings suggest that IVIg plus low-dose rhTPO may represent a potential combination therapy for pregnant patients with ITP.

Disclosures No relevant conflicts of interest to declare.

https://doi.org/10.1182/blood-2023-185453