

Comparative Effectiveness of rhTPO and TPO Receptor Agonists in Severe, Refractory Immune Thrombocytopenia during Pregnancy: A Retrospective Analysis

Yuan Hu

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

Shuhuan Feng

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

Lilan Chen

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

Siying Chen

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

Meng Jiang

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

Shibin Hong

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

Chuan Wang

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

Ning Zhang

ningning1723@126.com

Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine

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Abstract

Objective

To evaluate the efficacy and safety of recombinant human thrombopoietin (rhTPO), thrombopoietin receptor agonists (TPO-RAs), and their combination in pregnant patients with refractory severe immune thrombocytopenia (ITP) (platelet count $< 30 \times 10^9/L$, unresponsive to first-line corticosteroids/intravenous immunoglobulin [IVIG]).

Methods

This retrospective study enrolled 28 pregnant patients with severe ITP. Patients were assigned to three groups: rhTPO monotherapy ($n = 16$), TPO-RA monotherapy (eltrombopag, hetrombopag, or avatrombopag; $n = 3$), or combined rhTPO + TPO-RA therapy ($n = 9$). Efficacy (complete/partial/no response) was assessed 2 weeks post-treatment per standardized criteria. Safety (maternal adverse events, neonatal outcomes) and obstetric outcomes (gestational age at delivery, mode of delivery, postpartum hemorrhage) were analyzed.

Results

TPO-RA monotherapy achieved a 100% response rate (1 CR, 2 PR); rhTPO monotherapy had a 25% response rate (2 CR, 2 PR); combined therapy showed 0% response. No serious maternal adverse events occurred except 1 case of mild eltrombopag-related liver function impairment (resolved after switching to hetrombopag). Excluding 3 second-trimester medical inductions for treatment failure, 25 singleton live births were recorded, with only 1 neonate having thrombocytopenia (no severe neonatal complications).

Conclusion

TPO-RAs exhibit a favorable safety profile and promising efficacy in patients with refractory severe ITP, whereas rhTPO demonstrates a suboptimal response. Combined rhTPO + TPO-RAs therapy showed no responses, likely due to selection bias; thus, it is not routinely recommended, and sequential therapy (e.g., TPO-RA after rhTPO failure) may be a more rational approach. This study provides valuable insights for clinical decision-making in the absence of standardized second-line guidelines for gestational ITP, though large multicenter validation is needed.

Introduction

Primary immune thrombocytopenia (ITP) is an acquired autoimmune bleeding disorder characterized by isolated thrombocytopenia (platelet count $< 100 \times 10^9/L$) resulting from immune-mediated platelet destruction and impaired platelet production. It accounts for one-third of pregnancy-related bleeding

disorders, with a higher prevalence in women of childbearing age, and is the leading cause of platelet count $< 50 \times 10^9/L$ in early pregnancy [1,2]. Pregnancy often exacerbates thrombocytopenia—over one-third of pregnant patients with ITP require intervention before delivery, and those with platelet counts $< 20 \times 10^9/L$ face life-threatening risks of spontaneous bleeding, postpartum hemorrhage, and placental abruption [3–5].

Corticosteroids and intravenous immunoglobulin (IVIG) are first-line therapies, but their response rates in pregnant patients (38%-40%) are significantly lower than in non-pregnant populations [6]. While platelet-stimulating agents (e.g., rhTPO, TPO-RAs) have revolutionized adult ITP management [7,8], evidence for second-line therapies in gestational ITP remains scarce, with no standardized guidelines for refractory cases (platelet count $< 30 \times 10^9/L$) [9].

rhTPO, a recombinant form of endogenous TPO with 99% structural homology to native TPO, is approved for refractory ITP in China [7]. Animal studies have confirmed its non-teratogenicity, and it is unlikely to cross the placenta [16]. Kong et al. [16] reported a 74.2% response rate in 31 refractory pregnant patients with no serious adverse events, but other studies show variable response rates (25%-51.5%), requiring further validation [18]. TPO-RAs (eltrombopag, romiplostim, hetrombopag, avatrombopag) activate TPO receptors via non-competitive binding [8]. Though effective in non-pregnant patients, they lack gestational approval due to placental transfer concerns and limited safety data [19,20]. A meta-analysis of 45 pregnant patients found an 86.7% response rate and favorable maternal safety, with neonatal thrombocytopenia in one-third of cases [20].

Given this unmet clinical need, we retrospectively analyzed 28 patients with refractory severe gestational ITP at a tertiary maternity critical care center to evaluate the efficacy and safety of rhTPO, TPO-RAs, and their combination, providing real-world evidence for clinical decision-making.

Materials and Methods

Study population

This single-center retrospective cohort study was conducted at Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine, a tertiary general hospital with a specialized obstetric critical care unit that undertakes approximately 5,500 deliveries yearly and serves as a regional referral center for high-risk pregnancies. We retrospectively analyzed 28 pregnant patients with severe refractory immune thrombocytopenia (ITP) admitted to the hospital's Department of Obstetrics and Gynecology from September 2018 to September 2025, all of whom received multidisciplinary management by obstetricians, hematologists, anesthesiologists, and neonatologists. Inclusion criteria: (1) Diagnosis of primary ITP confirmed by hematology specialists, meeting the following criteria: at least two consecutive blood routine tests showing thrombocytopenia ($< 100 \times 10^9/L$); normal peripheral blood smear morphology; no splenomegaly; bone marrow aspiration showing increased or normal megakaryocytes with maturation arrest; (2) Refractory to first-line therapy (corticosteroids and/or IVIG, defined as no

response or transient response with platelet count returning to baseline within 1 week); (3) Platelet count $< 30 \times 10^9/L$ during treatment; (4) Regular prenatal care and complete clinical data; (5) Written informed consent obtained after full explanation of risks and benefits. Exclusion criteria: (1) Secondary thrombocytopenia (autoimmune diseases, infections, myelodysplastic syndromes, malignant hematologic diseases, etc.); (2) Platelet consumptive disorders (e.g., disseminated intravascular coagulation); (3) Drug-induced thrombocytopenia; (4) Congenital thrombocytopenia; (5) Gestational thrombocytopenia; (6) Pregnancy-associated hypertensive disorders, thrombotic microangiopathy, or acute fatty liver of pregnancy; (7) Severe hepatic/renal dysfunction; (8) Irregular prenatal care or incomplete clinical data.

Treatment regimens

First-line therapy: Corticosteroids (oral prednisone $0.25\text{--}0.50 \text{ mg}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$) and/or IVIG ($400 \text{ mg}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$ for 5 consecutive days). Patients who failed first-line therapy received second-line treatment as follows:

rhTPO monotherapy: Subcutaneous injection of $300 \text{ U}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$ for 14 consecutive days;

TPO-RA monotherapy: Oral eltrombopag ($25\text{--}75 \text{ mg qd}$), hetrombopag (5 mg qd), or avatrombopag ($20\text{--}60 \text{ mg qd}$);

Combined therapy: rhTPO ($300 \text{ U}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$ for 14 days) plus TPO-RA (oral, same dosage as monotherapy), with rhTPO discontinued after 2 weeks if no response, and TPO-RA continued until delivery if clinically indicated.

Treatment initiation timing was determined by gestational age, platelet count, and bleeding status: second trimester (14–27 weeks) or third trimester (≥ 28 weeks). All patients received treatment under close monitoring of platelet counts (twice weekly) and bleeding symptoms.

Efficacy and Safety Assessment

Efficacy assessment: Performed after 2 weeks of treatment, using standardized criteria [4,20]: Complete response (CR): Platelet count $\geq 100 \times 10^9/L$ with no bleeding symptoms; Partial response (PR): Platelet count $(30\text{--}99) \times 10^9/L$, at least doubling from baseline, with no bleeding symptoms; No response (NR): Platelet count $< 30 \times 10^9/L$, less than doubling from baseline, or persistent bleeding symptoms. Overall response rate (ORR) = $(\text{CR} + \text{PR})/\text{total number of patients} \times 100\%$.

Safety assessment: Maternal adverse events (e.g., thromboembolism, liver/kidney dysfunction, injection site reactions) were recorded throughout treatment and the perinatal period. Neonatal outcomes included birth weight, Apgar scores (1 and 5 minutes), platelet count within 72 hours of birth, and complications (e.g., thrombocytopenia, bleeding, congenital anomalies).

Statistical analysis

SPSS 25.0 statistical software was used for data analysis. Continuous variables were expressed as mean $\pm$ standard deviation or median (interquartile range) based on distribution, and categorical variables as N (%). Comparisons between groups were performed using the χ^2 test or Fisher's exact test for categorical data, and t-test or Mann-Whitney U test for continuous data. A two-sided $P < 0.05$ was considered statistically significant.

Results

Baseline Clinical Characteristics

The baseline characteristics of the 28 enrolled patients are summarized in Table 1. The mean age was 31.14 ± 5.23 years, with 20 patients (71.43%) aged < 35 years and 19 (67.86%) primiparas. Fifteen patients (53.57%) had a normal BMI (18.5–23.9), and 12 (42.86%) were overweight (BMI > 23.9). Nineteen patients (67.86%) had gestational complications or comorbidities, including gestational diabetes, preeclampsia, fetal growth restriction, hypothyroidism, epilepsy, and HBV carrier status.

Table 1
Baseline characteristics of 28 pregnant patients with severe refractory ITP

Characteristics	N (%)
Maternal age < 35	20 (71.43)
Primipara	19 (67.86)
ITP diagnosis before pregnancy	20 (71.43)
Gestational complication/comorbidity	19 (67.86)
Gestational age at first thrombocytopenia detection < 14 weeks	18 (64.29)
BMI	
<18.5	1 (3.57)
18.5–23.9	15 (53.57)
>23.9	12 (42.86)
Minimum platelet count during pregnancy ($\times 10^9/L$)	
< 10	12 (42.86)
10–20	13 (46.43)
20–30	3 (10.71)
Concurrent anemia	25 (89.29)
Leukopenia ($< 3.5 \times 10^9/L$)	12 (42.86)
Abnormal immune indicators	6 (21.43)
Bleeding tendency	26 (92.86)
Platelet antibody	
Positive	11 (39.29)
Negative	10 (35.71)
Not tested	7 (25.00)

Twenty patients (71.43%) were diagnosed with ITP before pregnancy, and 8 (28.57%) were newly diagnosed during pregnancy. Thrombocytopenia was first detected in the first trimester (< 14 weeks) in 18 patients (64.29%), and in the second/third trimester (≥ 14 weeks) in 10 (35.71%). The median gestational age at first thrombocytopenia detection was 12 (8–24) weeks. During pregnancy, 12 patients (42.86%) had a minimum platelet count $< 10 \times 10^9/L$, and 13 (46.43%) had a minimum platelet count of $10\text{--}20 \times 10^9/L$. Twenty-five patients (89.29%) had concurrent anemia, 12 (42.86%) had leukopenia ($< 3.5 \times 10^9/L$), and 6 (21.43%) had abnormal immune indicators (antinuclear antibody titer 1:80 – 1:160).

Platelet antibodies were positive in 11 patients (39.29%), negative in 10 (35.71%), and not tested in 7 (25.00%). Twenty-six patients (92.86%) had bleeding tendencies, mainly presenting as petechiae, gingival bleeding, or epistaxis, with no life-threatening bleeding events.

Treatment Details and Timing

All 28 patients failed first-line therapy: 26 (92.86%) were refractory to corticosteroids, and 25 (89.29%) to IVIG (3 patients had a transient response to IVIG but relapsed within 1 week). The timing of second-line treatment initiation was as follows: 11 patients (39.29%) in the second trimester (14–27 weeks) and 17 (60.71%) in the third trimester (≥ 28 weeks), with a median treatment initiation gestational age of 24 (16–32) weeks.

Treatment regimens and outcomes are summarized in Table 2 and Fig. 1. Of note, treatment allocation was not randomized but based on physician discretion and drug availability, leading to baseline imbalances across groups.

Table 2
Treatment regimens and efficacy outcomes

Treatment regimen	CR, N(%)	PR, N(%)	NR, N(%)	Total	ORR, %
rhTPO monotherapy	2 (12.50)	2 (12.50)	12 (75.00)	16	25
TPO-RA monotherapy	1 (33.33)	2 (66.67)	0 (0.00)	3	100
rhTPO + TPO-RA combination	0 (0.00)	0 (0.00)	9 (100.00)	9	0
CR = complete response; PR = partial response; ORR = overall response rate; NR = no response. TPO-RA includes eltrombopag, hetrombopag, and avatrombopag.					

1. rhTPO monotherapy (n = 16): Treatment duration was 14 days for 11 patients, and adjusted to 7–10 days for 5 patients due to clinical considerations. Four patients (25.0%) responded (2 CR, 2 PR), and 12 (75.0%) showed no response.
2. TPO-RA monotherapy (n = 3): One patient received hetrombopag (5 mg qd) from the second trimester, one received avatrombopag (40 mg qd) from 28 weeks, and one received avatrombopag (60 mg qd) throughout pregnancy (pre-pregnancy initiation). All 3 patients responded (1 CR, 2 PR), with an ORR of 100%.
3. Combined rhTPO + TPO-RA therapy (n = 9): rhTPO was administered for 14 days, and TPO-RA (eltrombopag in 5 patients, avatrombopag in 4) was continued for a median of 6 (1–18) weeks. All 9 patients showed no response, and rhTPO was discontinued after 2 weeks as per protocol.

Safety Outcomes

No serious maternal adverse events were observed. One patient treated with eltrombopag developed mild transaminase elevation (ALT 86 U/L, normal range < 40 U/L) at 4 weeks of treatment, which resolved within 2 weeks after switching to hetrombopag. No thromboembolic events, severe infections, or other organ dysfunction were reported.

Delivery and Neonatal Outcomes

Delivery outcomes are shown in Table 3. Three patients (3/28, 10.71%) underwent medical induction in the second trimester due to persistent severe thrombocytopenia and no treatment response. The remaining 25 patients (25/28, 89.29%) delivered by cesarean section, with 2 (7.14%) term deliveries (≥ 37 weeks), 21 (75.00%) preterm deliveries (28–36 weeks), and 2 (7.14%) late preterm deliveries (26–28 weeks). All cesarean sections were performed under general anesthesia due to thrombocytopenia-related anesthesia safety concerns. Perioperative platelet transfusion was administered in 24 patients (85.71%), with no postpartum hemorrhage or placental infarction reported.

Table 3
Delivery outcomes of patients enrolled in the study

Delivery outcomes	N (%)
Gestational age at termination of pregnancy	
< 26 weeks	3 (10.71)
≥ 26 and < 28 weeks	2 (7.14)
≥ 28 and < 37 weeks	21 (75)
≥ 37 weeks	2(7.14)
Terminating pregnancy	
Medical abortion	3 (10.71)
Caesarean section	25 (89.29)
Postpartum hemorrhage	0 (0.00)
Infarction of placenta	0 (0.00)
Perioperative platelet transfusion	24 (85.71)

Neonatal outcomes are summarized in Table 4. Among 25 singleton live births, 22 (88.00%) had a birth weight ≥ 1000 g, and 19 (76.00%) were admitted to the neonatal intensive care unit (NICU) due to prematurity or low birth weight. The 1-minute Apgar score was 8–10 in 22 neonates (88.00%), 4–7 in 2 (8.00%), and 3 in 1 (4.00%); the 5-minute Apgar score was 8–10 in 24 neonates (96.00%) and 7 in 1 (4.00%). Only 1 neonate (4.00%) had a platelet count < $100 \times 10^9/L$ ($85 \times 10^9/L$) within 72 hours of birth, with no bleeding symptoms and spontaneous recovery by 2 weeks of age. No other neonatal

complications (e.g., intracranial hemorrhage, congenital anomalies, developmental delay) were observed.

Table 4
Neonatal Conditions of patients enrolled in the study

Neonatal outcomes (N = 25)	N (%)
Neonatal weight (≥ 1000g)	22 (88.00)
Apgar score-1minute	
0–3	1 (4.00)
4–7	2 (8.00)
8–10	22 (88.00)
Apgar score-5minute	
0–3	0 (0.00)
4–7	1 (4.00)
8–10	24 (96.00)
Neonatal thrombocytopenia	1 (4.00)
Admission to NICU	19 (76.00)

Literature review

To systematically contextualize our findings within the existing literature, we conducted a comprehensive literature search using PubMed, Web of Science, and Embase databases. The search employed the following keywords and their combinations: “immune thrombocytopenia”, “ITP”, “pregnancy”, “gestational”, “recombinant human thrombopoietin”, “rhTPO”, “thrombopoietin receptor agonist”, “TPO-RA”, “eltrombopag”, “romiplostim”, “hetrombopag”, “avatrombopag”, and “refractory”. Articles were limited to those published in English. We identified five potentially relevant studies, from which four key studies were selected for detailed comparison based on the following criteria: 1) focus on second-line treatment (rhTPO or TPO-RAs) for immune thrombocytopenia during pregnancy; 2) reporting of efficacy and safety outcomes; 3) availability of comparable data (e.g., response rates, maternal/neonatal safety). Our retrospective analysis (Renji Hospital) was compared with these selected studies, revealing similarities and differences in efficacy, safety profiles, and therapeutic approaches, as summarized in the following Table S1.

Discussion

Pregnancy-associated ITP remains a clinical challenge, especially for patients refractory to first-line therapy, due to the lack of standardized second-line treatment guidelines. This study from a tertiary

maternity critical care center provides valuable real-world evidence on the efficacy and safety of rhTPO, TPO-RAs, and their combination in 28 patients with severe refractory gestational ITP (platelet count < $30 \times 10^9/L$).

Our findings reveal distinct efficacy profiles between rhTPO and TPO-RAs. TPO-RA monotherapy achieved a 100% response rate, consistent with Rottenstreich et al.'s meta-analysis (86.7% ORR in 45 pregnant patients) [20] and Michel et al.'s 77% response rate in 17 pregnancies [19], confirming the promising efficacy of TPO-RAs. This is attributed to their non-competitive binding to TPO receptors, directly activating megakaryocyte proliferation [8]. Notably, our study includes hetrombopag and avatrombopag, expanding the available gestational TPO-RA options with favorable non-pregnant safety profiles.

In contrast, rhTPO monotherapy showed a suboptimal 25% ORR, lower than prior reports (50%-74.2%) [16,17,18]. This discrepancy may stem from the more severe disease in our cohort (71.43% pre-pregnancy ITP, 42.86% with platelet counts < $10 \times 10^9/L$) and later rhTPO initiation (median 24 weeks). Lin et al. [18] noted higher responses with treatment before 28 weeks, suggesting earlier intervention may be beneficial. The lower response rate in our study also underscores the need for personalized treatment selection based on disease severity and gestational age.

A key finding of this study is the 0% response rate to combined rhTPO and TPO-RA therapy. Although pharmacologically these agents might be expected to act synergistically [8], the null response likely reflects negative selection bias rather than true antagonism. Treatment allocation was non-randomized; patients receiving combination therapy had more refractory disease characteristics than those receiving TPO-RA monotherapy. Moreover, the TPO-RA monotherapy group was very small ($n = 3$), precluding valid efficacy comparisons. The continued lack of response after a median of 6 weeks of TPO-RA in the combination group suggests intrinsic resistance to both agents. Therefore, combined rhTPO and TPO-RA is not routinely recommended for refractory gestational ITP; sequential therapy (e.g., TPO-RA after rhTPO failure) may be a more rational approach.

Consistent with previous studies [16,19,20], platelet-stimulating agents showed favorable safety in our cohort. No thromboembolic events were observed, despite the hypercoagulable state of pregnancy. This may be attributed to close monitoring of platelet counts and avoidance of excessive thrombocytosis (targeting platelet counts $30-100 \times 10^9/L$). The only adverse event was mild liver function impairment in an eltrombopag-treated patient, which resolved after switching to hetrombopag—consistent with reports of eltrombopag-related hepatotoxicity and the better safety profile of hetrombopag [20,23].

Neonatal safety is a critical concern for gestational drug use. Only 1 neonate (4.00%) had thrombocytopenia, lower than the 29%-34% reported in previous studies [16,20]. This difference may be due to the low transplacental transfer of rhTPO (molecular weight 90 kDa, exceeding the placental barrier threshold of 5 kDa) and limited exposure to TPO-RA in the third trimester [16,20]. No severe neonatal complications (e.g., intracranial hemorrhage, congenital anomalies) were observed, confirming

the relative safety of these agents for fetal development. However, long-term neonatal follow-up is needed to rule out potential late effects.

This study adds to the limited evidence for second-line treatment of gestational refractory ITP. TPO-RA monotherapy is preferred for severe refractory cases, while rhTPO may be considered as a second-line agent; combined therapy is not recommended due to lack of observed efficacy in this heavily refractory cohort, likely driven by selection bias. The 100% cesarean section rate and general anesthesia use reflect a conservative approach for severe thrombocytopenia, though international guidelines prioritize obstetric indications over platelet count for delivery mode [21,22]. Perioperative platelet transfusion was administered in most patients (consistent with guidelines for cesarean section with platelet counts $< 50 \times 10^9/L$ [22]) to ensure hemostasis.

This study has several limitations: (1) Retrospective single-center design with small sample size (potential selection bias); (2) Lack of a control group (e.g., other second-line therapies or supportive care); (3) Limited long-term maternal/neonatal follow-up; (4) No analysis of response predictors (e.g., baseline mean platelet volume, platelet-lymphocyte ratio) [18]. Future multicenter prospective trials with larger samples, comparative designs, and long-term follow-up are needed to validate these findings and identify predictors of response.

In conclusion, this retrospective study from a tertiary maternity critical care center shows that TPO-RAs have promising efficacy and favorable safety in pregnant patients with severe refractory ITP, while rhTPO exhibits suboptimal response. Combined rhTPO and TPO-RA therapy showed no responses in this cohort, likely due to negative

selection bias; therefore, it is not routinely recommended, and sequential therapy may be more rational. These findings provide valuable real-world evidence for clinical decision-making amid the lack of standardized guidelines. Given the complexity of gestational ITP management, a multidisciplinary approach (involving obstetricians, hematologists, anesthesiologists) is essential to balance maternal and fetal safety. Large-sample, multicenter prospective studies are needed to further validate the efficacy and safety of platelet-stimulating agents and inform evidence-based second-line treatment guidelines for gestational refractory ITP.

Abbreviations

rhTPO

recombinant human thrombopoietin

TPO-RAs

thrombopoietin receptor agonists

ITP

refractory severe immune thrombocytopenia

IVIg

intravenous immunoglobulin

CR
Complete response
PR
Partial response
NR
No response
ORR
Overall response rate

Declarations

Ethical Approval and Consent to participate

This observational retrospective cohort study was approved and informed consent was waived by the Ethics Committee on Human Research of Renji Hospital, Shanghai Jiao Tong University, Shanghai, China (Approval number:LY2023-199-C).

Consent for publication

Not applicable.

Competing interests

The authors declared that they have no conflicting interest.

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Author Contribution

Conceived and designed the study: CW, NZ; Collected data: YH, SH F, LL C; Analyzed data: LL C, YH, MJ; Figures preparation: YH, SB H; Interpreted the results: YH, SY C; Contributed to the writing of the manuscript: YH, SH F, SB H, CW, NZ. The author(s) read and approved the final manuscript.

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Data Availability

Data available with restricted access: The data supporting the findings of this study contain sensitive patient information and are subject to access restrictions, so they are not publicly available. Researchers who wish to access the data may contact the corresponding author Ning Zhang to apply for data sharing upon reasonable request. The contact email for the corresponding author is ningning1723@126.com.

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Figures

Platelet Count Before and After Treatment

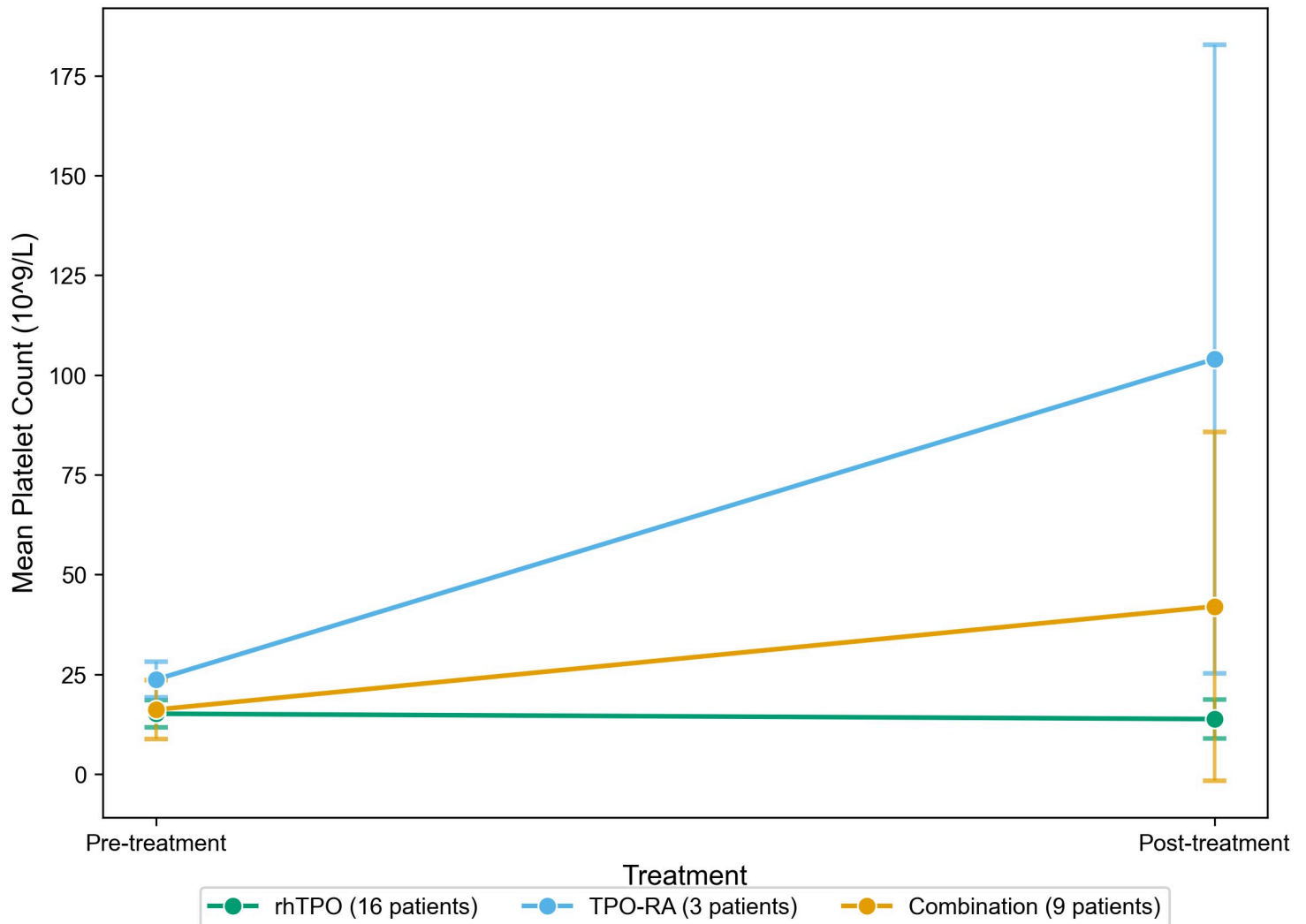


Figure 1

Platelet count changes before and after treatment.

Supplementary Files

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- [TableS1.docx](#)