

Predictive Factors for Response to a Standard Dose of Intravenous Immunoglobulin Therapy in Children with Immune Thrombocytopenia

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ABSTRACT

Objective: Acute immune thrombocytopenic purpura (ITP) is a common acquired bleeding disorder. Intravenous immunoglobulin (IVIG) therapy is commonly given as initial treatment to pediatric patients with ITP. Factors that can predict the response to IVIG have not been fully determined. We retrospectively evaluated whether the clinical and laboratory findings of pediatric patients with ITP at the time of diagnosis could predict the response to IVIG and progression to chronic ITP.

Methods: A total of 45 patients with newly diagnosed ITP who were initially treated with IVIG were evaluated between January 2016 and December 2019. Short-term response was estimated by platelet counts 2 weeks after IVIG, and long-term response was assessed by thrombocytopenia-free survival (TFS). TFS was defined as the probability of survival without treatment failure after initial IVIG, such as relapse, requiring additional therapeutic interventions, or progression to chronic ITP.

Results: In univariate analysis, age ≥ 25 months ($p=0.002$), platelet count $\leq 6.9 \times 10^9/L$ ($p=0.034$), and hemoglobin (Hb) level >12.4 g/dl ($p=0.001$) were considered to be unfavourable factors for short-term response. Univariate analysis of unfavourable factors for long-term response showed that age ≥ 25 months ($p=0.002$), platelet count $\leq 6.9 \times 10^9/L$ ($p=0.034$), and Hb level >12.4 g/dl ($p=0.001$) were significant factors.

Conclusion: These results suggest that in newly diagnosed ITP patients older than 25 months and/or with platelet count $<6.9 \times 10^9/L$, other therapeutic options such as corticosteroids alone or in combination with IVIG may be considered as initial therapy.

INTRODUCTION

Immune thrombocytopenia (ITP) is a rare autoimmune disease identified by the presence of thrombocytopenia (platelet count $<100 \times 10^9/L$ in the peripheral blood) without any other causes associated with thrombocytopenia.^[1] The disease is manifested by thrombocytopenia, and the bone marrow incorporates an elevated number of megakaryocytes.

Immune thrombocytopenia generally presents as signs of bleeding in cutaneous tissues such as petechia, purpura, and ecchymosis in an apparently healthy child. The bleeding does not usually last long and has a good prognosis.^[2,3]

ITP can occur acutely, chronically, or recurrently. Chronic ITP is a clinical picture lasting more than 12 months,

with thrombocyte values $<100 \times 10^9/L$. In almost 20–25% of children newly-diagnosed with ITP, a chronic disease is expected to occur.^[1] Various clinical, therapeutic, laboratory and genetic indicators have been assessed for chronic ITP in the pediatric population.^[4–6] Only 3–5% of children with the disease develop severe bleeding requiring treatment.^[7,8] Close following-up is the key in the management of newly diagnosed ITP as well as the platelet count.^[7,9,10] Intravenous immunoglobulin and steroids are widely used as initial treatments. Intravenous immunoglobulin is mostly the initial treatment for newly-diagnosed ITP patients, as platelet counts increase more rapidly than the steroid therapy, but there is no consensus on predictive factors for IVIG response.^[11–13]

It is known that the psychosocial development of pediatric patients diagnosed with acute and chronic ITP is adversely

affected. Studies involving these children have shown that they are more withdrawn and sensitive than their healthy peers.^[14]

Identifying prognostic factors would help reduce stress and improve the quality of life of both these children and their parents.^[6,15]

Hence, we aimed to determine the predictors for the response to a standard IVIG dose (1 g/kg/day for two consecutive days) when given as initial treatment to children with ITP and chronic ITP progression.

MATERIALS AND METHODS

Patients

The data of children under 18 years of age who had newly diagnosed ITP and underwent IVIG therapy as first-line treatment between January 2016 and December 2019 were examined retrospectively. Patients who were received treatments other than IVIG as the first-line treatment were excluded from the study. The primary ITP was diagnosed through the clinical course, physical examination, and laboratory data, and the cases were determined to develop isolated thrombocytopenia with no cause. The study approval was obtained from the institutional ethics committee, and all study protocols were performed according to the Declaration of Helsinki. A total of 45 patients were included in the analysis. The patients' demographic characteristics are presented in Table 1.

There were 21 male and 24 female patients in the study group, and the mean age at diagnosis was 59.1 months (range; 3–163 months). The ITP onset seasons were January–April with 33.3%, May–August with 33.3%, and Sep-

tember–December with 33.3%. The mean platelet count was found to be $7.78 \times 10^9/L$ at the time of initial diagnosis.

Treatment Response

The definitions from the International Working Group consensus were used to assess the IVIG treatment response. Accordingly, $\geq 100 \times 10^9/L$ platelet count without any other treatment was considered as “complete response (CR),” $\geq 30 \times 10^9/L$ platelet count without any other treatment as “response (R),” and $< 30 \times 10^9/L$ platelet count or the requirement for other treatments as “no response (NR).”

The short-term IVIG response was determined as the results within two weeks after IVIG. The short-term clinical course was divided into two groups: responders (CR+R and with no other treatments within two weeks following IVIG) and non-responders (NR or treatments administered within two weeks following IVIG).

The long-term IVIG response was determined as thrombocytopenia-free survival (TFS). Thrombocytopenia-free survival was specified as the survival probability after IVIG without treatment failure. Treatment failures consisted of additional treatment requirements, relapse, and progression to chronic ITP.

Relapse was defined as a decrease in the patient's platelet count to the NR level.

Chronic ITP was determined as the thrombocytopenia with platelet count less than $100 \times 10^9/L$ lasting more than 12 months after the initiation of the therapy.

IVIG

Immunoglobulin was administered intravenously as the first-line therapy in patients with a platelet level below $10 \times 10^9/L$ or with moderate bleeding findings (extensive purpura or mucosal bleeding), regardless of platelet count, when the initial diagnosis of ITP was made. IVIG was given at a 1 g/kg/day dose for two consecutive days. The parents of all patients provided written informed consent before all treatments were performed.

The product to be used was determined according to the availability of the IVIG preparation in the hospital.

Statistical analysis

IBM SPSS Statistics version 22 program was used for the statistical analysis. The disease onset season for patients and their gender, age, underlying infections, vaccinations, bleeding localization, laboratory data such as serum immunoglobulin G (IgG) level, complete blood cell count, direct coombs status, rheumatological markers were determined as variables for outcome analyses.

The univariate analyses were performed using Fisher's test or t-test between the two patient groups. The Kaplan–Meier method calculated the TFS, and the log-rank test compared the probabilities for different patient groups. For multivariate analysis, variables with low p-values (< 0.1) in univariate analyses were selected. Logistic regression

Table 1. Patients characteristics

No. of patients	45
Age at diagnosis, months, mean (\pm SD)	59.13 (\pm 48.65)
Gender (male/female)	21/24
Onset season (Jan-Apr/May-Aug/Sep-Dec)	15/15/15
Previous infection (yes/no)	12/33
Previous vaccination (yes/no)	2/43
Bleeding types (cutaneous/hematuria/gastrointestinal)	42/2/1
Direct coombs (positive/negative/no check)	3/37/5
Rheumatologic marker positivity (yes/no/no check)	2/31/12
Ig G level (normal range/low/no check)	28/3/2
Peripheral blood at diagnosis	
WBC count, $\times 10^9/L$, median (range)	8.96 (4.6–15.8)
Neutrophil count, $\times 10^9/L$, median (range)	3.94 (0.95–11)
Hb level (g/dL), mean (\pm SD)	11.6 (8.2–14.4)
Platelet counts ($\times 10^9/L$), mean (\pm SD)	7.7 (\pm 5.8)

Jan: January; Apr: April; Aug: August; Sep: September; Dec: December; WBC: White blood cell; Hb: Hemoglobin; SD: Standard deviation.

Table 2. Univariate analysis for short-term IVIG response at 2 weeks

Univariate variables	Responder	Non-responder	p-value
No. of patients (%)	35 (77.7)	10 (22.2)	
Age at diagnosis, m, mean (\pm SD)	44.5 (\pm 7.8)	91.5 (\pm 11.8)	0.09
\geq 25 m, no. of patients (%)	16 (61.5)	10 (38.5)	0.002
<25 m, no. of patients (%)	19 (100)	0 (0)	
Gender (male/female)	16/19	5/5	0.81
Previous infection and vaccination (yes/no/vaccination)	9/24/1	3/7/1	0.93
Onset season; Jan-Apr/May-Aug/Sep-Dec	12/11/12	3/4/3	0.87
WBC counts ($\times 10^9/L$), mean (\pm SD)	8.84 (\pm 2.23)	9.22 (\pm 2.68)	0.61
Neutrophil counts ($\times 10^9/L$), mean (\pm SD)	3.64 (\pm 1.67)	4.59 (\pm 2.33)	0.49
Hb level \leq 12.4 g/dl, no. of patients	28	2	0.001
Hb level >12.4 g/dl, no. of patients	7	8	
Platelet count $\leq 6.9 \times 10^9/L$, no. of patients (%)	18 (66.6)	9 (33.3)	0.034
Platelet count > $6.9 \times 10^9/L$, no. of patients (%)	17 (94.4)	1 (5.5)	

m: Months; Jan: January; Apr: April; Aug: August; Sep: September; Dec: December; WBC: White blood cell; Hb: Hemoglobin; SD: Standard deviation.

Table 3. Multivariate analysis for short-term IVIG response at 2 weeks

Multivariate variables, unfavourable factors	Odds ratio	95% CI	p-value
Age at diagnosis \geq 25 m	1.22	0.57–2.60	0.59
Hb level >12.4 gr/dL	1.75	0.68–4.49	0.23
Platelet counts $\leq 6.9 \times 10^9/L$	1.28	0.59–2.79	0.52

IVIG: Intravenous immunoglobulin; Hb: Hemoglobin; CI: Confidence interval.

models and Cox proportional hazard models assessed the short and long-term treatment responses in multivariate analysis, respectively. The p-value of <0.05 was determined as statistically significant.

RESULTS

Short-term response

Thirty-five (77.8%) of 45 patients were found to be responders (CR+R) within 2 weeks of IVIG administration. In the ROC curve analysis, it was demonstrated that

25-months, $6.9 \times 10^9/L$ platelet count, 12.4 g/dl Hb level at diagnosis were appropriate cut-off values. As presented in Table 2, the univariate analysis indicated that patient age of <25 months ($p=0.002$), platelet count of $>6.9 \times 10^9/L$ ($p=0.034$), and Hb level of ≤ 12.4 g/dL ($p=0.001$) were significantly correlated with the short-term IVIG response. Gender, previous infection, vaccination, the season of onset, IgG level, rheumatological marker status, direct coombs positivity, and bleeding type were not associated with short-term response.

In multivariate analyses, factors that were found to be statistically significant in univariate analyses did not show statistical significance (Table 3).

Long-term response

The long-term response was determined by evaluating TFS. The long-term (1 year) good prognosis rate was found to be 65% (95% CI: 60–82%) with the Kaplan-Meier method.

Patients <25 months were found to have a significantly higher TFS chance (1-year TFS: 94%) than those of ≥ 25 months (1-year TFS: 44%).

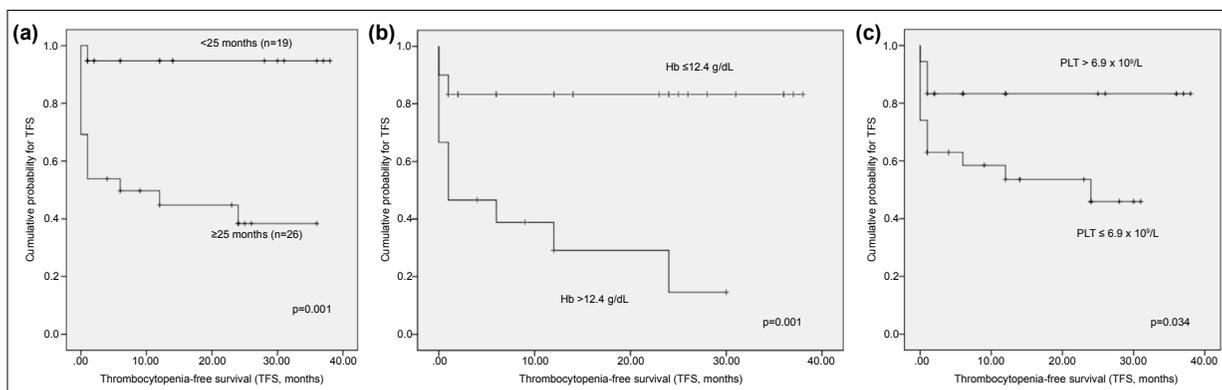


Figure 1. The probability of thrombocytopenia-free survival (TFS) according to age (a), Hb level (b) and platelet count (c) at diagnosis.

Table 4. Multivariate analysis for long-term IVIG response

Multivariate variables, unfavourable factors	Odds ratio	95% CI	p-value
Age at diagnosis ≥ 25 m	0.25	0.025–2.50	0.29
Hb level >12.4 gr/dL	1.03	0.18–5.99	0.97
Platelet counts $\leq 6.9 \times 10^9/L$	2.26	0.23–21.6	0.47

IVIG: Intravenous immunoglobulin; Hb: Hemoglobin; CI: Confidence interval.

TFS was also better in patients with Hb level ≤ 12.4 g/dl than those with Hb level >12.4 (median 31.7 vs. 9.7 months $p=0.001$) and platelet count $>6.9 \times 10^9/L$ than those with platelet count $\leq 6.9 \times 10^9/L$ (median 31.7 vs. 17 months $p=0.03$) (Fig. 1).

The other variables including gender, initial platelet count, the disease onset season, previous infection and vaccination, bleeding type, coombs, rheumatological marker, IgG, white blood cells (WBC), and neutrophil count were not significantly correlated with the IVIG's long-term response.

Patients with platelet count $\geq 140 \times 10^9/L$ at the second week tended to have better TFS than those with platelet counts $<140 \times 10^9/L$ (median 36.1 vs. 26.6 months $p=0.055$), although this difference was not statistically significant.

In multivariate analysis, factors that were found to be statistically significant in univariate analyses did not show statistical significance (Table 4).

Progression to chronic ITP

Chronic ITP developed in nine (20%) patients 1 year after IVIG treatment. None of the children <25 months progressed to chronic ITP, but 9 of 26 patients ≥ 25 months (34%) progressed to chronic ITP ($p=0.01$).

Chronic ITP developed significantly more frequent in patients with Hb level >12.4 g/dl (6 out of 15 patients) than those with Hb level ≤ 12.4 g/dl (3 of 30 patients) ($p=0.042$) and in patients with platelet counts $<140 \times 10^9/L$ (8 of 25 patients) than those with platelet count $\geq 140 \times 10^9/L$ (1 out of 20 patients) ($p=0.03$).

DISCUSSION

Childhood ITP is recognized as a heterogeneous disease with its clinical course and pathophysiology.^[16,17] There is not sufficient information regarding the appropriate treatment planning for these patients in the literature.^[18] Some approaches suggest close follow-up without treatment in patients diagnosed with ITP with no bleeding or with minor bleeding. In order to be able to follow up without treatment with close follow-up, the patient should be able to access the hospital easily, and the patient's family should be well informed about the disease and possible complications.

Lambert emphasized that close follow-up of patients with no treatment in selected patients is a reliable alternative to IVIG treatment.^[19]

On the other hand, IVIG is widely used as the initial treatment of ITP because it causes a more rapid increase in platelet counts than other treatment strategies such as corticosteroids.^[4] In a meta-analysis evaluating first-line treatment modalities in newly diagnosed ITP patients, it was observed that platelet counts were higher at the 48th hour of treatment in patients who received IVIG treatment than those who received anti-D immunoglobulin (anti-D) treatment. In the same meta-analysis, IVIG and anti-D were found to be similar in terms of side effects, and it was stated that anti-D is not recommended in anemic patients since it may trigger hemolysis.^[20]

It was seen in the literature that patients were treated with varying doses of IVIG.^[21–23]

In this study, we attempted to identify factors that may predict the long- and short-term responses to IVIG when children with ITP were given a standard dose of 1 g/kg/d for two consecutive days as first-line therapy.

This study confirmed that advanced age at diagnosis (≥ 25 months) and platelet count of $\leq 6.9 \times 10^9/L$ were adverse predictors for the short-term response, according to Higashide et al.^[21] Unlike previous reports, an Hb level of ≤ 12.4 g/dl was related to positive short- and long-term responses.^[23]

Our study demonstrated that platelet count $<6.9 \times 10^9/L$ and older age at diagnosis (≥ 25 months) were also associated with adverse variables for the long-term response. Besides, many studies have attempted to identify predictive factors for chronic ITP development. Kubota et al.^[24] showed that higher initial platelet count and advanced age were risk factors for chronicity. Donato et al.^[25] found that infants under one year of age had the most favorable prognosis with chronic ITP.

Although there are studies in the literature showing that female patients and patients without a history of infection are more likely to become chronic, such a relationship with chronicity was not shown in our study.^[26]

In this study, advanced age (≥ 25 months) and platelet level of less than $140 \times 10^9/L$ at the second week of initial treatment were associated with chronicity. Unlike previous reports, we identified that higher Hb levels (>12.4 g/dl) were associated with chronicity.

Our study's main limitation was that factors that were found to be statistically significant in univariate analyses were not statistically significant in multivariate analyses. This may be a result of the number of patients enrolled in the study.

CONCLUSION

Based on the literature, we would like to propose that other therapeutic options such as corticosteroids alone or in combination with IVIG can be considered as an initial treatment for patients with ITP with platelet count of $\leq 6.9 \times 10^9/L$ and ≥ 25 months. Further research in a larger patient cohort will be ensured to confirm these findings.

Ethics Committee Approval

This study was approved by the Clinical Research Ethics Committee of Istanbul Health Sciences University Umraniye Training and Research Hospital (date: 18.12.2019, number: B.10.1.TKH.4.34.H.GP.0.01/225).

Informed Consent

Retrospective study.

Peer-review

Internally peer-reviewed.

Authorship Contributions

Concept: Ü.M.Y.; Design: Ü.M.Y., F.T.; Supervision: Ü.M.Y., S.Ç.K.; Materials: Ü.M.Y., F.T., B.Ş.K., F.A.; Data: Ü.M.Y., F.A., B.Ş.K.; Analysis: Ü.M.Y., F.T., B.Ş.K.; Literature search: Ü.M.Y., B.Ş.K., F.A., S.Ç.K.; Writing: Ü.M.Y.; Critical revision: Ü.M.Y., S.Ç.K.

Conflict of Interest

None declared.

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İmmün Trombositopenili Çocuk Hastalarda Standart Dozda Uygulanan İntravenöz İmmünglobulin Tedavisine Yanıtı Belirleyen Faktörler

Amaç: Akut immün trombositopenik purpura (İTP) sık görülen edinsel bir kanama bozukluğudur. İTP'li çocuk hastalarda intravenöz immünglobulin (İVİG) başlangıç tedavisi olarak sıklıkla kullanılır. İVİG'ye yanıtı öngörebilecek faktörler kesin olarak belirlenememiştir. Burada İTP'li çocuk hastaların tanıdaki klinik ve laboratuvar bulgularının İVİG tedavisine olan yanıtları ile kronik İTP gelişmesi arasındaki ilişki incelenmiştir.

Gereç ve Yöntem: Haziran 2016–Aralık 2019 tarihleri arasında başlangıç tedavisi olarak İVİG uygulanan 45 akut İTP tanılı hasta değerlendirilmiştir. Kısa dönem İVİG cevabı; İVİG verildikten iki hafta sonra bakılan trombosit sayısı, uzun dönem yanıt ise trombositopenisiz geçen süre (TFS) olarak belirlenmiştir. TFS, başlangıç tedavisi olarak uygulanan İVİG sonrası relaps, ek tedavi gereksinimi veya kronik İTP'ye progresyon izlenmeden elde edilen sağkalım olarak tanımlanmıştır.

Bulgular: Tek değişkenli analizlerde; hasta yaşının ≥ 25 ay, ($p=0.002$) trombosit sayısının $\leq 6.9 \times 10^9/L$ olması ($p=0.034$) ile hemoglobin (Hb) değerinin > 12.4 g/dL olmasının ($p=0.001$) kısa dönem cevap için olumsuz faktörler olduğu belirlendi. Uzun dönem yanıtta ise yapılan tek değişkenli analizlerde hasta yaşının ≥ 25 ay, ($p=0.002$) trombosit sayısının $\leq 6.9 \times 10^9/L$ olması ($p=0.034$) ile hemoglobin (Hb) değerinin > 12.4 g/dL olmasının ($p=0.001$) İVİG'ye yanıtta olumsuz faktörler olduğu belirlendi.

Sonuç: Çalışmadan elde edilen veriler doğrultusunda yeni tanı almış İTP'li hastalarda yaşı ≥ 25 ay olanlar ile trombosit sayısı $< 6.9 \times 10^9/L$ olan hastaların İVİG'ye yanıtları göz önünde bulundurulduğunda, bu hastaların başlangıç tedavilerinde kortikosteroidler gibi İVİG dışındaki tedavi seçeneklerinin tek başına ya da İVİG ile kombine edilerek kullanılması önerilmektedir.

Anahtar Sözcükler: Çocuk hastalar; İVİG; immün trombositopeni.