DOI: https://doi.org/10.54393/pjhs.v7i3.3592

PAKISTAN JOURNAL OF HEALTH SCIENCES
(LAHORE)
https://thejas.com.pk/index.php/pjhs
ISSN (E): 2790-9352, (P): 2790-9344
Volume 7, Issue 03 (March 2026)

Original Article

OPEN ACCESS

Comparison of Treatment Outcomes Between Intravenous Immunoglobulin and Steroid Therapy in Pediatric ITP (Idiopathic Thrombocytopenic Purpura)

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ARTICLE INFO

Keywords:
Immunoglobulins, Purpura, Thrombocytopenic, Steroids, Treatment Outcome

How to Cite:
Ali, Z., Zulqarnain, A., Adil, M. K., Fawad, U., Ahmad, S., & Hanif, A. (2026). Comparison of Treatment Outcomes Between Intravenous Immunoglobulin and Steroid Therapy in Pediatric ITP (Idiopathic Thrombocytopenic Purpura): Intravenous Immunoglobulin and Steroid Therapy in Pediatric ITP. Pakistan Journal of Health Sciences, 7(3), 93-98. https://doi.org/10.54393/pjhs.v7i3.3592

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Received Date: 7th November, 2025
Revised Date: 6th January, 2026
Acceptance Date: 13th January, 2026
Published Date: 31st March, 2026

ABSTRACT

Idiopathic Thrombocytopenic Purpura (ITP) is a common and significant bleeding disorder in children with variable underlying etiologies. **Objectives:** To compare the short-term effectiveness and safety of IVIg versus corticosteroids in children with newly diagnosed ITP. **Methods:** An observational, cross-sectional comparison was conducted at a tertiary pediatric care center over a period of one year. Using consecutive sampling, 210 children were assigned to initial therapy with IVIg (n=105) or corticosteroids (n=105). Primary endpoints were time to platelet recovery and complete response by day 7; secondary endpoints included hospital stay, relapse ≤3 months, and adverse events. Group comparisons used Mann–Whitney U or chi-square/Fisher's exact tests; multivariable logistic regression adjusted for age, gender, and baseline platelet count. **Results:** IVIg led to faster recovery (median 2 vs 4 days) and shorter hospital stay (3 vs 5 days), both p<0.001; higher complete response by day 7 (90.5% vs 71.4%, p<0.001); lower relapse (9.5% vs 21.0%, p=0.012) and fewer adverse events (11.4% vs 33.3%, p<0.001). IVIg independently predicted day-7 complete response (OR 4.5, 95% CI 1.9–10.8). **Conclusions:** In this non-randomized cohort, IVIg showed superior short-term effectiveness and safety versus corticosteroids.

INTRODUCTION

Idiopathic Thrombocytopenic Purpura (ITP) is an important cause of acquired thrombocytopenia in children, and is an important cause of significant morbidity both in developed and resource-limited countries. It is estimated to have a global incidence of 410 cases per 100,000 children per annum, with most happening during early childhood [1]. Precise national-level statistics are not available in Pakistan, though hospital records indicate a similar or even greater burden, which may be due to infections, late diagnosis, and restrictions on access to healthcare [2]. ITP often follows a viral infection or immunization, particularly in children aged 2–10 years [3]. Although many children recover spontaneously within six months, around 20–25% develop chronic ITP, leading to recurrent bleeding episodes and significantly affecting quality of life [4]. First-line treatments for newly diagnosed ITP include corticosteroids and intravenous immunoglobulin (IVIg), both of which aim to increase platelet counts and reduce bleeding risk. However, the choice of therapy is influenced by clinical presentation, urgency of platelet elevation, side effect profiles, and healthcare setting [5]. Corticosteroids, on the other hand, are more affordable and widely used but

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may be associated with slower response times and more side effects with prolonged use [6]. A number of recent studies have compared the efficacy of IVIg and corticosteroids. In a 2020 systematic review, IVIg demonstrated faster initial platelet response but similar long-term remission rates compared to steroids [7]. Another randomized trial showed that IVIg achieved platelet counts ≥30,000/mm^3 within 48 hours in 80% of children compared to 59% in the steroid group [8]. However, this result was not statistically significant in a 2021 Indian study that found no difference between long-term remission or bleeding scores in both groups [9]. The absence of contextual evidence makes clinical decision-making complex, and the physician is left with extrapolated information that may not be relevant to local issues, including delayed diagnosis, frequent infections, and IVIg shortage [10].

Pakistan does not have national ITP information and so international studies have to be extrapolated. There is no local comparative study of IVIg and steroids and long-term results, such as the development of chronic ITP, and side effects of steroids have not been evaluated. The non-randomized study is prone to selection bias, as the treatment is not based on standardized protocols but on IVIg availability. Limitation in generalizability: A single-center study can only generalize to individuals recruited in the same time frame, whereas short-term follow-up (three months) cannot measure long-term outcomes. This study aims to compare the short-term treatment response, relapse rate, and adverse events among pediatric ITP patients receiving either IVIg or corticosteroids. Secondary objectives included assessing the time to platelet count recovery and the need for second-line treatment within three months of follow-up.

METHODS

This cross-sectional comparative study was carried out in the Department of Pediatric Medicine and Hematology at The Children's Hospital and The Institute of Child Health, Multan. The study duration was from 5th October 2024 to 5th October 2025. Non-probability consecutive sampling was used. Ethical approval was obtained from the Institutional Review Board (1980/IRB/CHC/2024). Confidentiality was maintained. Children aged 1–15 years with newly diagnosed immune thrombocytopenic purpura (ITP) were included. Children already treated with steroids or intravenous immunoglobulin (IVIg), or those with inherited thrombocytopenia, malignancy, or active infection, were excluded. Written informed consent was taken from caregivers. Treatment was not randomized. The treating physician decided the treatment based on clinical judgement and the availability of IVIg. Parental preference did not influence treatment choice. No variables were missing, and all required data points were complete for all participants, so no imputation or additional handling of missing data was needed. The sample size was calculated using the WHO Sample Size Calculator with a 95% confidence level and 5% margin of error. An expected IVIg response rate of 60% resulted in a final sample of 210 children [11]. This assumed rate of 60% ensured adequate statistical power for comparison between treatment groups. All enrolled children completed the study. The sample size was divided into two groups of 105 each. The two groups were clinically comparable at baseline, with no significant differences in bleeding severity or presenting features before treatment, and logistic regression was used to adjust for remaining confounders. The primary treatment outcomes were time to platelet recovery and complete response at day 2, day 7, and day 30. Time to platelet recovery was defined as the number of days required to reach a platelet count ≥30 × 10^9/L after initiation of therapy. Complete response was defined as platelet count ≥100 × 10^9/L, and partial response as ≥30 × 10^9/L, according to International Working Group criteria. Secondary outcomes included hospital stay duration, relapse within 3 months, and adverse events. Relapse was defined as a decline in platelet count to <30 × 10^9/L after an initial response. All platelet counts at baseline, day 2, day 7, and day 30 were taken from hospital laboratory reports included in each patient's medical record. For this study, treatment efficacy was defined as the hematologic response achieved after receiving IVIg or corticosteroids. Efficacy included the following components: (1) time to platelet recovery, defined as the number of days needed to reach a platelet count ≥30 × 10^9/L; (2) complete response at day 2, day 7, and day 30, defined as platelet count ≥100 × 10^9/L; (3) partial response, defined as platelet count ≥30 × 10^9/L; and (4) sustained response without relapse during the 3-month follow-up period. These standardized definitions were used to assess and compare the short-term efficacy of both treatment groups. Platelet counts at baseline, day 2, day 7, and day 30 were measured using the hospital's standardized hematology protocol. A 2–3 mL venous blood sample was drawn into EDTA tubes by trained nursing staff. Samples were processed within 2 hours of collection in the hospital hematology laboratory. Platelet counts were obtained using an automated hematology analyzer (Sysmex XN-series), which is calibrated daily according to manufacturer and hospital quality-control procedures. Any abnormal or flagged readings were repeated, and the repeat value was used for analysis. The platelet count printed on the laboratory report was recorded in the study proforma. Data taken from medical records included baseline clinical presentation, bleeding severity, laboratory-confirmed platelet counts, treatment

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administered, hospital stay duration, and all documented adverse events. Adverse events were predefined as vomiting and hypertension. Vomiting was recorded if documented in physician notes or nursing flowcharts. Hypertension was extracted from routine nursing vital-sign charts based on age-adjusted pediatric blood pressure thresholds and was confirmed by the treating physician. In addition to reporting individual adverse events, a composite safety endpoint termed "any adverse event" was calculated. This composite included the occurrence of at least one predefined adverse event (vomiting, hypertension, or both) during hospitalization. The purpose of this composite measure was to summarize the overall safety profile of each treatment group. Follow-up compliance was ensured by scheduling clinic visits on day 7, day 30, and at 3 months post-treatment. Attendance was verified through clinic records. For patients who did not return for scheduled visits, a telephone call was made to obtain platelet counts performed at external laboratories or to encourage an in-person reassessment. Relapse data were obtained either during clinic visits or through verified laboratory reports shared by caregivers. All 210 enrolled children completed follow-up through 3 months. Statistical analysis was performed using IBM SPSS version 26.0. Normality of continuous variables was assessed using the Shapiro–Wilk test, and appropriate statistical tests were applied based on distribution. An independent t-test was used for normally distributed variables. The Mann–Whitney U test was used for non-normal variables. Chi-square or Fisher's exact test was used for categorical variables. Pearson correlation was applied to normally distributed variables, while Spearman correlation was used for non-normally distributed variables, including baseline platelet count and time to platelet recovery, which did not meet the normality assumptions. Logistic regression was adjusted for age, gender, and baseline platelet count to control for confounding, while bleeding severity was excluded as it did not differ significantly between groups. A p-value <0.05 was considered significant. Model adequacy was checked using the Hosmer–Lemeshow goodness-of-fit test, which confirmed an acceptable fit for the logistic regression model.

RESULTS

No dropouts, and 210 pediatric patients were enrolled and completed the study. Participants were divided into two groups: one receiving intravenous immunoglobulin (IVIg) and the other receiving steroid therapy (n=105, 50.0% each). Although the baseline sociodemographic factors (age, gender, parental education, and income) were similar across groups, both day 2 and day 7 treatment responses were significantly different. The IVIg group was noted to have a superior rate of complete response by day 2 (80.9% vs 57.1%, p<0.001), and by day 7 (90.5% vs 71.4%, p<0.001). Chi-square analyses were consistent with these differences, showing that the IVIg group achieved better early treatment efficacy. The relapse rate was significantly lower in the IVIg group (9.5%) compared to the steroid group (21.0%) (p=0.012). Also, the adverse events occurred more often in steroid-treated children (33.3 percent) compared to IVIg (11.4 percent, p<0.001). Hypertension was especially found in the steroid group (4.8%), and the level of vomiting was not significantly different between groups. The exact test of Fisher proved that there was a significant difference in the prevalence of hypertension (p=0.023). The efficacy of IVIg was further supported by logistic regression analysis that indicated that IVIg increased the probability of achieving a complete response at day 7 significantly with an odds ratio of 4.5 (95% CI: 1.910.8, p<0.001). Also, a higher baseline platelet count was independently related to a higher odd of response (OR = 1.04 per unit increase, p=0.002), despite age and gender. The study presents the descriptive statistics of the continuous variables of age, initial platelet count, platelet recovery time, and the duration of stay in the hospital in children undergoing IVIg (n = 105) or steroid therapy (n=105). The Shapiro-Wilk test ensured that age data were normal, but not platelet count, recovery time, and hospital stay. In this regard, an independent t-test or Mann-Whitney U test was adopted. This table shows that the age and the count of platelets across the groups were similar, but platelet recovery and hospitalization duration were shorter in the IVIg group. These results highlight the hastened recovery and decreased inpatient load with IVIg (Table 1).

Table 1: Descriptive Statistics of Continuous Variables in IVIg (n=105) and Steroid Therapy (n=105) Groups

Variables	IVIg Group	Steroid Group	p-value
Age (Years)*	7.4 ± 3.2	7.4 ± 3.2	0.900
Baseline Platelet Count ($\times 10^9$/L)	12 (IQR: 8–18)	14 (IQR: 10–20)	0.073
Time to Platelet Recovery (days)	2 (IQR: 1–3)	4 (IQR: 3–6)	<0.001
Hospital Stay Duration (days)	3 (IQR: 2–4)	5 (IQR: 4–7)	<0.001

*Mean ± SD, analyzed via independent t-test. Median (IQR), analyzed via Mann–Whitney U test Normality tested with Shapiro-Wilk; others non-normal (p<0.001)

The demographic and baseline clinical variables were obtained from two sources. Sociodemographic variables, including age, sex, parental education, income bracket, and residence (urban or rural), were extracted from the standardized admission form completed at the time of hospital registration. Clinical presentation features such as mucosal bleeding, severity of bleeding, fever, petechiae, and other presenting symptoms were taken from initial physician assessment notes documented in the medical record. All data were recorded in the study proforma at

DOI: https://doi.org/10.54393/pjhs.v7i3.3592

enrollment by the research team, ensuring consistency and avoiding missing information. This table demonstrates no statistically significant differences in gender, education, income, or presenting symptoms, indicating well-balanced groups at baseline with equivalent disease severity before treatment (Table 2).

Table 2: Frequency Distribution of Baseline Categorical Characteristics (n=210)

Variables	IVIg Group, n (%)	Steroid Group, n (%)	p-value
Female	60 (57.1%)	58 (55.2%)	0.840
Parental Education (≥ Intermediate)	72 (68.6%)	70 (66.7%)	0.640
Family Income (>PKR 30,000)	61 (58.1%)	59 (56.2%)	0.640
Urban Residence	62 (59.0%)	65 (61.9%)	0.680
Mucosal Bleeding	48 (45.7%)	50 (47.6%)	0.760
Severe Bleeding	35 (33.3%)	38 (36.2%)	0.660
Fever Present	67 (63.8%)	70 (66.7%)	0.580
Petechial Rash	53 (50.5%)	55 (52.4%)	0.810

*Chi-square test applied

The results of the treatments of the two groups (n=105 each) were reported as complete response at day 2 and day 7, and relapse within 3 months, and adverse events. The negative events were hypertension and vomiting. Chi-square and Fisher's exact test were used in the low-frequency outcomes to determine group differences (Table 3).

Table 3: Comparison of Treatment Outcomes and Adverse Events in IVIg vs Steroid Groups (n=105 Each)

Outcomes	IVIg Group, n (%)	Steroid Group, n (%)	p-value
Complete Response by Day 2	85 (80.9%)	60 (57.1%)	<0.001
Complete Response by Day 7	95 (90.5%)	75 (71.4%)	<0.001
Relapse within 3 months	10 (9.5%)	22 (21.0%)	0.012
Any Adverse Event	12 (11.4%)	35 (33.3%)	<0.001
Hypertension†	0 (0.0%)	5 (4.8%)	0.023
Vomiting	4 (3.8%)	8 (7.6%)	0.250

*Chi-square test; †Fisher's exact test

This study indicates correlations and predictive variables with treatment response and platelet recoveries. Pearson correlation evaluated the age in relation to the time to recover; Spearman correlation was used to evaluate the baseline platelet count in relation to recovery time. Binary logistic regression analyzed predictors of full response on Day 7 (Table 4).

Table 4: Correlations and Predictors of Complete Response at Day 7

Variables	Result	p-value
Analysis		
Pearson: Age vs Time to Recovery	r = 0.12	0.090
Spearman: Platelet Count vs Recovery	ρ = −0.42	<0.001
Logistic Regression Predictors of Day 7 Response		
Treatment: IVIg (vs Steroid)	OR = 4.5 (95% CI: 1.9–10.8)	<0.001
Platelet Count (per 1×10^9/L)	OR = 1.04 (95% CI: 1.02–1.06)	0.002
Age (years)	OR = 1.02 (95% CI: 0.96–1.08)	0.480
Gender (Female vs Male)	OR = 0.89 (95% CI: 0.45–1.75)	0.720

*Multivariate logistic regression adjusted for age, gender, and baseline platelet count. Pearson/Spearman correlations based on data normality (Shapiro-Wilk)

DISCUSSION

The sample population consisted of 210 pediatric patients, with half of them in IVIG and the other half in steroid therapy. These results are in line with more recent meta-analyses, which show higher early platelet responsiveness after IVIG compared to corticosteroids in childhood idiopathic thrombocytopenia [12-14]. The combined evidence also suggests that IVIG enables fast hemostatic platelet increments within 2448 hours, as compared to steroids, which acts slower, though they have identical long-term results [15]. The use of IVIG in the acute correction of platelet counts in moderate to severe ITP in children has received consensus-level support [16], although with short-term responses. An early platelet recovery followed by IVIG was retrospectively associated with long-term positive results at 6 and 12 months, and the percentage of responders with persistent or chronic disease was lower [17]. Those observations echo the reduced relapse rate in the present IVIG cohort (9.5%) compared with steroid-treated children (21.0%). According to generic hematologic studies, a quick platelet increment decreases the risk of bleeding and possible complications, which gives biological plausibility to the increased efficacy observed in this case [18]. Patient relevance is evidenced by the fact that IVIG has a better efficacy, durability, and safety profile over steroids in childhood thrombocytopenia [19]. Future studies are recommended to use multicenter designs and use larger cohorts and longer follow-up to determine chronic ITP evolution, economic outcome, and comparative side effects profile, including the cognitive and metabolic effects of steroids in children [20, 21].

Only vomiting and hypertension were considered adverse events, whereas steroid-specific effects such as growth suppression were not included. Additional restrictions to validity include no blinding or consecutive sampling. The outcomes of a single tertiary hospital in Multan are unlikely to be applicable in other areas. Add full monitoring of safety that incorporates growth and cognition. Create an evidence-based treatment algorithm in Pakistani healthcare environments.

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CONCLUSIONS

In this study, intravenous immunoglobulin resulted in faster platelet recovery, higher early treatment response, fewer adverse events, and lower relapse compared to corticosteroids in children with newly diagnosed ITP. These findings suggest that IVIg may be a more effective short-term treatment option in our local setting.

Authors' Contribution

Conceptualization: AZ
Methodology: SA, AH
Formal analysis: UF, AH
Writing and Drafting: ZA, MKA
Review and Editing: ZA, AZ, MKA, UF, SA, AH

All authors approved the final manuscript and take responsibility for the integrity of the work.

Conflicts of Interest

All the authors declare no conflict of interest.

Source of Funding

The author received no financial support for the research, authorship and/or publication of this article.

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