

# Efficacy of Low-Dose Rituximab in Primary Immune Thrombocytopenia

Ben Niu, Lan Li\*

Department of Hematology, Shaanxi Provincial People's Hospital, Xi'an 710068, Shaanxi Province, China

\*Corresponding author: Lan Li, lilanlanxin@163.com

**Copyright:** © 2023 Author(s). This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY 4.0), permitting distribution and reproduction in any medium, provided the original work is cited.

**Abstract:** *Objective:* To explore the effect of low-dose rituximab in primary immune thrombocytopenia. *Methods:* From January 2022 to January 2023, 60 patients with primary immune thrombocytopenia were randomly divided into two groups. The control group was treated with standard doses of rituximab, and the observation group was treated with low doses of rituximab. Rituximab was used for treatment, and the clinical curative effect of the two groups was observed. *Results:* Before treatment, there was no statistically significant difference in platelet count (PLT), anti-GPIIb/IIIa antibody, and anti-GPIb/IX antibody between the two groups ( $P > 0.05$ ). After treatment, the PLT of the two groups increased significantly. Antibodies were all decreased, and there was no significant difference between the two groups ( $P > 0.05$ ). The incidence of adverse reactions in the observation group was 13.33%, and that in the control group was 40.00%. The adverse reactions in the observation group were significantly lower than the control group ( $P < 0.05$ ). *Conclusion:* In the clinical treatment of primary immune thrombocytopenia, low-dose rituximab can control the progression of the disease, improve blood routine indicators, and have fewer adverse reactions.

**Keywords:** Rituximab; Primary; Immune thrombocytopenia

**Online publication:** July 20, 2023

## 1. Introduction

Primary immune thrombocytopenia (formerly idiopathic thrombocytopenia purpura, ITP) is an autoimmune disease, and the main clinical symptoms of this disease are thrombocytopenia and bleeding. When treating ITP, the traditional treatment plan can achieve certain effects, but there are still a small number of patients who found the treatment being ineffective<sup>[1]</sup>. After continuous clinical practice and research, rituximab is gradually used in the clinical treatment of immune thrombocytopenia. This drug belongs to a human-mouse chimeric CD20 monoclonal antibody, which can eliminate B cells. Currently, rituximab is used as second-line therapy. In order to explore the therapeutic effect of low-dose rituximab on ITP, 60 patients were selected in this study and divided into two groups. The results are as follows.

## 2. Materials and methods

### 2.1. General information

During the period from January 2022 to January 2023, 60 patients with ITP were selected from the Shaanxi Provincial People's Hospital, and randomly divided into two groups, with 30 cases in both groups; the observation group had 16 males and 14 females, aged 20–75 years, with an average age of  $42.2 \pm 5.3$  years old; the control group had 15 males and 15 females, aged 20–75 years, with an average age of  $42.3 \pm 5.6$  years old. This study was approved by the ethics committee of the Shaanxi Provincial People's Hospital,

all patients or family members signed the informed consent form, and there was no difference in the basic information of the two groups of patients ( $P > 0.05$ ).

## 2.2. Methods

Before treatment, the patients in the two groups received an intramuscular injection of 12.5 mg diphenhydramine, and an intravenous infusion of 10 mg dexamethasone to prevent allergic reactions. Patients in the control group were treated with a standard dose of rituximab, 375 mg/m<sup>2</sup>, by intravenous infusion at a rate of 50 mg/h, once a week. The observation group received a small dose of rituximab, 100 mg/m<sup>2</sup>, by intravenous infusion at a rate of 50 mg/h, once a week. The treatment period for both groups was 4 weeks.

## 2.3. Observation effect

Before and after treatment, relevant blood routine indicators such as platelet count (PLT), anti-GPIIb/IIIa antibody, and anti-GPIb/IX antibody were detected in the two groups. The adverse reactions of the two groups of patients, mainly pulmonary infection, bleeding reaction, allergic reaction, and infusion reaction, as well as the statistical incidence, were observed.

## 2.4. Statistical methods

The statistical processing of the data adopts SPSS 21.0 version software, the measurement data is expressed in the form of mean  $\pm$  standard deviation (SD) and the test value is  $t$ . The count data is expressed in the form of %, and the test value is  $\chi^2$ . When the  $P$  value is less than 0.05, there is a statistical difference.

## 3. Results

### 3.1. Comparison of blood routine indicators related to patients

Before treatment, the PLT, anti-GPIIb/IIIa antibody, and anti-GPIb/IX antibody of the two groups were not statistically significant ( $P > 0.05$ ). After treatment, the PLT of the two groups was significantly increased ( $P < 0.0001$ ), the specific antibodies were all significantly reduced ( $P < 0.0001$ ), and there was no statistically significant difference between the two groups ( $P > 0.05$ ). See **Table 1**.

**Table 1.** Comparison of blood routine indicators related to patients

Group	Sample sizes	PLT ( $\times 10^9/L$ )		Anti-GPIIb/IIIa antibody		Anti-GPIb/IX antibody	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	30	26.36 $\pm$ 8.12	86.05 $\pm$ 13.11*	0.48 $\pm$ 0.03	0.36 $\pm$ 0.05*	0.43 $\pm$ 0.05	0.37 $\pm$ 0.06*
Control group	30	26.17 $\pm$ 9.31	86.12 $\pm$ 13.25*	0.47 $\pm$ 0.05	0.35 $\pm$ 0.04*	0.42 $\pm$ 0.05	0.36 $\pm$ 0.04*
$t$ -value		0.084	0.021	0.939	0.856	0.775	0.760
$P$ value		0.933	0.984	0.352	0.396	0.442	0.451

Note: \*  $P < 0.0001$  when compared to before treatment.

### 3.2. Comparison of adverse reactions between the two groups of patients

The incidence of adverse reactions in the observation group was 13.33%, and that in the control group was 40.00%. The adverse reactions in the observation group were significantly fewer than the control group ( $P < 0.05$ ), see **Table 2** for details.

**Table 2.** Comparison of adverse reactions between the two groups [n (%)]

Group	Number of cases	Lung infection	Bleeding reaction	Allergic reaction	Infusion reaction	Incidence rate
Observation group	30	1	1	1	1	4 (13.33)
Control group	30	2	2	4	4	12 (40.00)
$\chi^2$ value						5.4545
<i>P</i> value						0.020

#### 4. Discussion

Immune thrombocytopenia is a disease of the immune system leading to severe conditions. Its pathogenesis is relatively complicated, and the cause of the disease is ambiguous. When patients develop the disease, the obvious feature included a significant decrease in platelets and an abnormal increase in bone marrow megakaryocytes. If the patients are not accurately diagnosed and given effective treatment, the disease will be progressive [2]. As the condition worsens, the patients will experience gastrointestinal bleeding, which directly endangers their life. The common treatment of immune thrombocytopenia is the usage of glucocorticoids, and some patients require splenectomy. However, the effect of conventional treatment is not ideal [3-6].

Rituximab is a new type of therapeutic drug called a monoclonal antibody, which specifically binds to CD20 protein on the surface of B cells. Under the influence of complement-dependent and antibody-dependent cytotoxicity, it can induce apoptosis of B cells, and B cells that produce antibodies will also be effectively eliminated [7,8]. In the treatment of immune thrombocytopenia, rituximab can increase the number of platelets and improve clinical symptoms. In the clinical treatment of ITP, standard doses of rituximab (375 mg/m<sup>2</sup>) can be used. Smaller doses can also be considered because the number of B cells in ITP patients is significantly lesser than that of lymphoma patients, and the use of standard doses of drugs may easily damage normal B cells, further leading to a decline in immune function and an increase in the possibility of infection. Moreover, conventional treatment methods cost more money. Small doses of rituximab can save the costs of treatment and are relatively safe [9,10].

In this study, the PLT, anti-GPIIb/IIIa antibody, and anti-GPIb/IX antibody of the two groups before treatment were not statistically significant ( $P > 0.05$ ). However, after treatment, the PLT of the two groups was significantly increased, the specific antibodies were all lower, and there was no statistically significant difference between the two groups ( $P > 0.05$ ). The incidence rates of adverse reactions in the observation and control groups were 13.33% and 40.00%, respectively. The adverse reactions in the observation group were significantly lesser as compared to the control group ( $P < 0.05$ ).

In summary, when treating ITP, the use of low-dose rituximab can effectively increase the number of platelets, improve various clinical symptoms, and have relatively fewer adverse reactions. Its safety is high, and this treatment method is worthy of clinical promotion.

#### Disclosure statement

The authors declare no conflict of interest.

#### References

- [1] Liu C, Luan L, 2019, The Effect of Glucocorticoid Combined with Low-Dose Rituximab Injection in the Treatment of Refractory Primary Immune Thrombocytopenia. *China Contemporary Medicine*, 26(30): 68-70 + 74.

- [2] Yan L, Zhang J, Ding X, 2021, Effect Analysis of Low-Dose Rituximab Combined with Prednisone Acetate Tablets in the Treatment of Primary Immune Thrombocytopenia. *Clinical Medicine Engineering*, 28(11): 1505–1506.
- [3] Zhang Y, Du J, 2021, Clinical Curative Effect Analysis of Low-Dose and Standard-Dose Rituximab on Elderly Patients with Chronic Refractory Primary Immune Thrombocytopenia. *Shanxi Medical Journal*, 50(1): 56–58.
- [4] Hu X, Luo Y. Comparison of the Effect of Standard-Dose and Low-Dose Rituximab in the Treatment of Primary Immune Thrombocytopenia. *Chinese and Foreign Medical Research*, 19(2): 30–32.
- [5] Hu X, Bao G, Wang H, et al, 2020, Efficacy of Low-Dose Rituximab and Cyclosporine in the Treatment of Refractory Primary Immune Thrombocytopenia and Safety Analysis. *Chinese Medicine and Clinic*, 20(20): 3476–3478.
- [6] Li J, Chen L, Jiang G, et al, 2021, Efficacy and Safety Analysis of Low-Dose Rituximab in the Treatment of Refractory Thrombocytopenia Secondary to Systemic Lupus Erythematosus. *Jilin Medicine*, 42(4): 966–969.
- [7] Zhu X, Ma J, Gu H, et al, 2021, Analysis of Clinical Characteristics of Primary Chronic Refractory Immune Thrombocytopenia in Children in a Single Center. *Journal of Clinical Hematology*, 34(11): 781–784.
- [8] Zhang Y, Du J, 2021, Clinical Curative Effect Analysis of Low-Dose and Standard-Dose Rituximab on Elderly Patients with Chronic Refractory Primary Immune Thrombocytopenia. *Shanxi Medical Journal*, 50(1): 56–58.
- [9] Yan L, Zhang J, Ding X, 2021, Effect Analysis of Low-Dose Rituximab Combined with Prednisone Acetate Tablets in the Treatment of Primary Immune Thrombocytopenia. *Clinical Medicine Engineering*, 28(11): 1505–1506.
- [10] Zhu X, Ma J, Chen Z, et al, 2022, Comparison of the Efficacy and Safety of Two Small Doses of Rituximab in the Second-Line Treatment of Children with Primary Immune Thrombocytopenia. *Chinese Journal of Pediatrics*, 60(11): 1185–1190.

**Publisher's note**

Bio-Byword Scientific Publishing remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.