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Efficacy and Safety Analysis of Recombinant Human Interferon Alpha-2b Combined with Hydroxyurea Tablets in the Treatment of MPN

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Abstract

Objective: To explore the efficacy and safety of recombinant human interferon alpha-2b combined with hydroxyurea tablets in the treatment of myeloproliferative neoplasms (MPN). **Methods:** The study included 90 patients admitted between January 2019 and August 2024, all diagnosed with MPN. Patients were randomly divided into a control group and an observation group, each consisting of 45 patients. The control group received hydroxyurea tablets, while the observation group received recombinant human interferon alpha-2b combined with hydroxyurea tablets. Clinical treatment outcomes, changes in blood parameters (hemoglobin [HGB], platelet count [PLT]), and adverse reactions were compared between the two groups. **Results:** The total clinical effectiveness rate was higher in the observation group than in the control group ($P < 0.05$). After treatment, HGB and PLT levels were lower in the observation group compared to the control group ($P < 0.05$). There was no significant difference in the incidence of adverse reactions between the two groups ($P > 0.05$). **Conclusion:** Recombinant human interferon alpha-2b combined with hydroxyurea tablets improves clinical treatment outcomes and HGB and PLT levels in MPN patients, demonstrating high safety.

Keywords

Recombinant human interferon alpha-2b; hydroxyurea tablets; MPN; efficacy; safety

Myeloproliferative neoplasms (MPNs) are a heterogeneous group of blood disorders, primarily including polycythemia vera (PV), essential thrombocythemia (ET), and primary and secondary myelofibrosis (MF). MPN patients not only face the risk of thrombosis but also have a risk of transforming into acute myeloid leukemia (AML) within the first 10 years after diagnosis. Additionally, the risk of lymphoproliferative diseases and solid tumors is significantly increased in MPN patients. Hydroxyurea tablets, an antimetabolic and nonalkylating myelosuppressive agent, are the most commonly used cytoreductive therapy for MPNs. Although hydroxyurea tablets effectively reduce the incidence of thrombosis and improve survival rates in elderly ET and PV patients, their interference with DNA synthesis raises concerns about their potential mutagenic and leukemogenic potential. This study aims to investigate the efficacy and safety of recombinant human interferon alpha-2b combined with hydroxyurea tablets in the treatment of MPNs. The findings are reported herein.

1. Data and Methods

1.1 General Information

The study included 90 patients admitted from January 2019 to August 2024, all diagnosed with myeloproliferative neoplasm (MPN) after examination. Patients were randomly divided into a control group and an observation group, each consisting of 45 cases, using a random number table method. The study was approved by the hospital's medical ethics committee. There were no significant differences between the two groups' general data (P > 0.05), indicating comparable baseline characteristics. The control group comprised 21 males and 24 females, with ages ranging from 30 to 82 years, averaging 66.27 ± 5.34 years, and disease duration ranging from 0.5 to 6 years, averaging 3.36 ± 0.69 years. The observation group included 23 males and 22 females, with ages ranging from 29 to 83 years, averaging 65.87 ± 5.21 years, and disease duration ranging from 0.5 to 7 years, averaging 3.48 ± 0.71 years. Inclusion criteria: confirmed MPN diagnosis through bone marrow cytology; complete medical records; signed informed consent by the patient or their family. Exclusion criteria: presence of significant organ dysfunction such as heart, liver, or kidney failure, or mental illness; allergy to recombinant human interferon alpha-2b or hydroxyurea tablets; pregnant or lactating women.

1.2 Methods

The control group received hydroxyurea tablet treatment. Hydroxyurea tablets (National Medicine Approval No. H43022021; specification: 0.5 grams) produced by Hunan Dongting Pharmaceutical Co., Ltd., were administered orally at a dose of 0.5 grams once daily for a continuous treatment period of 12 weeks.

The observation group received treatment with recombinant human interferon alpha-2b combined with hydroxyurea tablets. Recombinant human interferon alpha-2b (National Drug Approval Number S20030012; specification: 1 million IU/bottle), produced by Shanghai Huaxin Biotechnology Co., Ltd., was administered intramuscularly at a dose of 1.5 million IU per session, three times a week, with one course lasting six weeks, and continued for two courses.

1.3 Observation Indicators

(1) Overall clinical effectiveness rate: Significant improvement: Over 60% increase in white blood cell count and hemoglobin levels, with nearly complete or total disappearance of related clinical symptoms and signs; Effective: Improvement in white blood cell count and hemoglobin levels between 30% and 60%, showing significant progress in related clinical symptoms and signs; Ineffective: No increase or less than 30% increase in white blood cell count and hemoglobin levels, with no change in related clinical symptoms and signs. Overall effectiveness rate = (number of significant improvements + number of effective cases) / total number of cases × 100%

(2) Changes in blood parameters. Blood samples were collected before and after treatment to test hemoglobin (HGB) and platelet count (PLT).

(3) Incidence of adverse reactions. Adverse reactions include loss of appetite, headache, proteinuria, mild thrombocytopenia, and muscle pain.

1.4 Statistical Analysis

Data were analyzed using SPSS 26.0 software, with $P<0.05$ indicating statistically significant differences. Count metrics (overall clinical efficacy rate and incidence of adverse reactions) were expressed as number/percentage (n/%), and analyzed using the chi-square test. Measurement metrics (HGB and PLT levels) were expressed as mean ± standard deviation ($\bar{x} \pm s$) and analyzed using the t-test. $P<0.05$ indicated statistically significant differences.

2. Results

2.1 Compare the Overall Effective Rates of Treatment Between Two Groups

The clinical treatment total effective rate in the observation group was higher than that in the control group ($P < 0.05$) (see Table 1).

Table 1. Comparison of the overall effective rates of clinical treatment between the two groups (n, %)

Grouping	Number of cases	Effective	Moderately effective	Ineffective	Overall effectiveness rate
Observation group	45	18 (40.00)	26 (57.78)	1 (2.22)	44 (97.78)
Control group	45	10 (22.22)	29 (64.44)	6 (13.33)	39 (86.67)
χ^2	-				3.873
P	-				0.049

2.2 Comparison of Blood Profile Changes Between the Two Groups

Before treatment, there was no significant difference between the two groups in terms of HGB and PLT indicators ($P > 0.05$). After treatment, both HGB and PLT levels decreased in both groups, but the observation group had lower levels than the control group ($P < 0.05$) (see Table 2).

Table 2. Comparison of the changes in blood counts between the two groups ($\bar{x} \pm s$)

Grouping	Number of cases	HGB（g/L）		PLT（109/L）	
		Before treatment	After treatment	Before treatment	After treatment
Observation group	45	199.56±24.95	150.53±22.54*	457.36±31.53	323.02±27.68*
Control group	45	198.41±25.19	169.27±23.37*	455.29±33.65	364.93±29.78*
t	-	0.218	3.872	0.301	6.915
P	-	0.828	0.000	0.764	0.000

Note: *P < 0.05 compared to before treatment.

2.3 Comparison of adverse reaction rates between two groups

There was no significant difference in the incidence of adverse reactions between the two groups ($P > 0.05$), as shown in Table 3.

Table 3. Comparison of the incidence rates of adverse reactions (n, %) between the two groups

Grouping	Number of cases	loss of appetite	headache	proteinuria	Mild thrombocytopenia	Muscle soreness	Overall incidence rate
Observation group	45	1（2.22）	1（2.22）	1（2.22）	0（0.00）	2（4.44）	5（11.11）
Control group	45	2（4.44）	1（2.22）	1（2.22）	1（2.22）	2（4.44）	7（15.56）
χ^2	-						0.385
P	-						0.535

3. Discussion

Myeloproliferative neoplasms (MPN) are a group of clonal proliferative diseases originating from hematopoietic stem cells in the bone marrow, which have the potential for multilineage differentiation. Patients may experience symptoms such as fatigue, weight loss, night sweats, and bone pain [1]. The treatment methods for MPN primarily include drug therapy, radiotherapy, surgery, and stem cell transplantation, with drug therapy being the most commonly used method [2]. Previously, clinical practice often involved using therapies like leukapheresis, phlebotomy, or hydroxyurea to alleviate patient symptoms, but these treatments were ineffective in preventing disease progression and could also cause various adverse reactions [3]. Interferons are a class of proteins with antiviral, antiproliferative, and immunomodulatory effects. In some cases, long-term use of recombinant human interferon alpha-2b may lead to complete remission of the disease [4].

This study found that the clinical treatment total effective rate in the observation group was higher than in the control group ($P<0.05$). After treatment, the HGB and PLT levels in the observation group were lower than those in the control group ($P<0.05$). Recombinant human interferon alpha-2b works by binding to specific receptors on cell surfaces, activating intracellular signaling pathways, thereby inhibiting tumor cell proliferation and differentiation [5]. In the treatment of MPN, recombinant human interferon alpha-2b can suppress proliferating cells in the bone marrow abnormally, reduce white blood cell and platelet counts, decrease the risk of thrombosis, and improve clinical symptoms. The study also showed no significant difference in adverse reaction rates between the two groups ($P>0.05$). Recombinant human interferon alpha-2b primarily targets the immune system, regulating immune function to inhibit tumor cell proliferation and differentiation, making its side effects relatively mild and often reversible. Its safety has been validated through extensive clinical trials and practical applications.

In summary, the combination of recombinant human interferon alpha-2b and hydroxyurea tablets improves clinical treatment outcomes for MPN patients, enhances HGB and PLT levels, and demonstrates high safety.

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