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Analysis of the Clinical Efficacy of Recombinant Human Interferon α2b Nebulization Inhalation in the Treatment of Hand, Foot, and Mouth Disease in Children

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Abstract: This clinical study aimed to explore the therapeutic effect of recombinant human interferon α2b nebulization inhalation in the treatment of hand, foot, and mouth disease in children. Sixty-six patients were selected as the research subjects by the random sampling method and divided into a control group and an observation group. The patients in the control group were treated with ribavirin injection and oral lysine-inositol-vitamin B12 solution, while the patients in the observation group received the treatment of the control group combined with recombinant human interferon α2b nebulization inhalation. The clinical effects of the two groups were compared to determine the clinical efficacy of the two treatment plans. The total effective rates of treatment were 78.79% in the control group and 90.91% in the observation group. The research confirmed that the clinical effect of recombinant human interferon α2b nebulization inhalation in the treatment of hand, foot, and mouth disease in children is remarkable. It can significantly improve the symptoms of children with hand, foot, and mouth disease and is suitable for clinical application and promotion.

Keywords: Nebulization inhalation therapy; Hand, foot and mouth disease in children; Clinical efficacy

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1. Introduction

This clinical study was conducted to evaluate the therapeutic efficacy of recombinant human interferon α2b administered via nebulization inhalation in the treatment of pediatric hand, foot, and mouth disease (HFMD). A total of sixty-six pediatric patients were enrolled through random sampling and allocated into either a control group or an observation group.

The control group received conventional treatment comprising ribavirin injection and oral lysine–inositol–vitamin B12 solution, while the observation group received the same conventional therapy combined with

recombinant human interferon α2b via nebulization inhalation. The primary objective was to compare the clinical outcomes between the two groups and assess the relative efficacy of the two therapeutic regimens. Results demonstrated that the total effective rate was 90.91% in the observation group, significantly higher than the 78.79% observed in the control group. The findings indicate that adjunctive therapy with recombinant human interferon α2b nebulization inhalation yields notable clinical benefits in the treatment of HFMD in children, substantially alleviating symptomatic manifestations and supporting its broader clinical application and promotion.

2. Materials and methods

2.1. General information

Sixty-six children with hand, foot, and mouth disease admitted to the hospital were selected as the research subjects by the random sampling method and divided into a control group and an observation group, with 33 cases in each group (n = 33). In the control group, the age of the children ranged from 1–5 years old, with an average age of (3.18 ± 0.76) years old, including 18 boys and 15 girls. In the observation group, the age ranged from 1–4 years old, with an average age of (3.25 ± 0.71) years old, including 19 boys and 14 girls. There was a small age difference between the control group and the observation group, and there was no statistical significance. Therefore, the two groups were suitable as research subjects. Most of the children included in this study had the following symptoms: acute onset with fever, scattered herpes in the oral mucosa, and maculopapules and herpes on the hands, feet, and buttocks. There might be an inflammatory red halo around the herpes, and the fluid in the blisters was scarce. Some children also had symptoms such as cough, runny nose, and anorexia. At the same time, all children had established medical records in our hospital, and their medical record information and relevant examination results were easily accessible.

2.1.1 Inclusion criteria

The inclusion criteria for this study were as follows.

(1) The children met the clinical diagnostic criteria for hand, foot, and mouth disease in children.
(2) The children could communicate normally and cooperate with doctors to complete the entire treatment process under the guidance of their guardians.
(3) The guardians of the children were informed and consented to this study.

2.1.2. Exclusion criteria

The following children were excluded from this study.

(1) The children currently had other Exanthematous diseases
(2) The children had congenital diseases, abnormal liver and kidney function, autoimmune system diseases, systemic infections, and other diseases
(3) The children were allergic to or had contraindications to the treatment drugs used in this study, such as ribavirin injection, lysine-inositol-vitamin B12 oral solution, and recombinant human interferon α2b; 4. The children had consciousness disorders [1].

2.2. Treatment methods

First, 33 children in the control group were treated with ribavirin injection, with an intravenous drip of 5–10 mg/

(kg.d), and lysine-inositol-vitamin B12 oral solution, with an oral dose of 5 mL per time, three times a day. This treatment plan lasted for one week. The observation group received the treatment of the control group combined with recombinant human interferon α2b nebulization inhalation. The dosages of ribavirin injection and lysine-inositol-vitamin B12 oral solution were the same as those in the control group, and the dosage of recombinant human interferon α2b nebulization inhalation was 0.2 μg per time, twice a day. The treatment plan also lasted for one week. During the medication treatment of the children, doctors should closely observe whether the rashes of the children subsided and whether the overall condition improved. Different from adults, children need more patience and care from doctors during the treatment period. Therefore, doctors should adjust the dosages of the corresponding drugs in a timely manner according to the actual treatment conditions of different children instead of applying a one-size-fits-all approach [2].

2.3. Observation indicators

On the one hand, when the symptoms such as herpes and fever of the children basically disappeared, most of the ulcers healed, and no adverse reactions to the drugs or treatment methods occurred during the treatment period, the clinical treatment effect of the child could be considered "remarkably effective". When the overall treatment effect of the child basically met the expectations, and the symptoms such as herpes, fever, and ulcers were significantly relieved, and the body temperature was normal, the clinical treatment effect of the child could be determined as "effective". When the symptoms such as herpes, fever, and ulcers of the child did not improve or even some adverse reactions occurred, the treatment effect of the child was "ineffective".

The total effective rate of this study was calculated as the number of children with a remarkably effective or effective treatment effect divided by the total number of children participating in the study, multiplied by 100%. On the other hand, 3 mL of venous blood samples of the children were collected, and then the $CD4^+$, $CD8^+$, and $CD4^+/CD8^+$ were measured by a flow cytometer to test the immune function of the children. In addition, doctors also collected 3 mL of venous blood samples from the children and detected the interleukin-6 (IL-6) and C-reactive protein (CRP) of the children through the enzyme-linked immunosorbent assay to determine the levels of inflammatory factors in the children [3].

In addition, all the children in this study were under 5 years old. Therefore, doctors should pay special attention to understanding and collecting information on whether the children had adverse reactions. If adverse reactions occurred, the corresponding drug treatment should be stopped in a timely manner to ensure the physical health of the children. The above observation indicators promoted the scientificity and comprehensiveness of this study to a certain extent, which helped doctors to more accurately understand and master the clinical treatment effect of children with hand, foot, and mouth disease [4].

2.4. Statistical analysis

In this study, SPSS statistical software was used to analyze the data of 66 children, including information such as age, treatment cycle, treatment effect, and presence of adverse reactions. Measurement data were expressed as mean ± standard deviation, and the comparison between the control group and the observation group was performed using the independent *t* - test for samples. Enumeration data were expressed as percentages (%), and the comparison between the two groups was performed using the chi-square test. When $p < 0.05$, it indicated that the difference was statistically significant.

3. Results

After a series of clinical treatments, the total effective rates of the 66 children were 78.79% in the control group and 90.91% in the observation group. The number of children with a "remarkably effective" clinical treatment effect was 39, with 18 in the control group and 21 in the observation group, as shown in **Table 1**. It can be seen that when treating hand, foot, and mouth disease in children, the treatment plan of combining recombinant human interferon α2b nebulization inhalation on the basis of ribavirin injection and oral lysine-inositol-vitamin B12 solution is more conducive to the cure of children. In addition, in this study, the number of children with an "effective" clinical treatment effect was 8 in the control group and 9 in the observation group. The number of children with an "ineffective" clinical treatment effect was 7 in the control group and 3 in the observation group. Therefore, it can be inferred that compared with the treatment plan of simply using ribavirin injection and oral lysine-inositol-vitamin B12 solution, the treatment plan of combining recombinant human interferon α2b nebulization inhalation has obvious therapeutic advantages [5].

Table 1. Comparison of clinical effects between the control group and the observation group

Group	Number of Cases	Markedly Effective	Effective	Ineffective	Total Effective [n (%)]
Control Group	33	18	8	7	26 (78.79)
Observation Group	33	21	9	3	30 (90.91)
χ^2 value					5.714
p value					0.017

In addition, in order to further explore the clinical effect of recombinant human interferon α2b nebulization inhalation in the treatment of hand, foot, and mouth disease in children, this study also compared the inflammatory factor levels before and after treatment between the control group and the observation group. The results showed that there was no statistically significant difference, as shown in **Table 2**. After treatment, the values of C-reactive protein (CRP), a non-specific inflammatory marker, and interleukin-6 (IL-6), an inflammatory mediator that appears earlier than CRP in clinical practice, in both groups were lower than those before treatment, and the values in the observation group were significantly lower than those in the control group [6].

Table 2. Comparison of inflammatory factor levels between the control group and the observation group before and after treatment

Group	Number of Cases	IL-6 (pg/mL)		CRP (mg/L)	
		Before Treatment	After Treatment	Before Treatment	After Treatment
Control Group	33	42.19 ± 6.41	31.67 ± 5.49*	12.43 ± 2.73	9.56 ± 2.11*
Observation Group	33	43.64 ± 6.12	25.43 ± 4.15*	12.38 ± 2.47	7.79 ± 1.94*
t- test		0.94	5.209	0.078	3.547
p-value		0.351	0	0.938	0.001

Note: Compared with before treatment in the same group, *$p < 0.05$

4. Discussion

Hand, foot, and mouth disease (HFMD) in children is an infectious disease caused by enteroviruses, predominantly affecting infants and young children under 5 years of age. Its main manifestations include herpes on the hands, feet, mouth, and other areas, accompanied by systemic symptoms such as fever, cough, and runny nose. HFMD can be transmitted through multiple routes, including the digestive tract, respiratory tract, and close contact. The virus is excreted in the saliva, feces, and urine of infected children, contaminating the surrounding environment. Healthy children who come into contact with such contaminated environments are at high risk of infection. Therefore, poor personal hygiene habits, inadequate protective measures, and close contact with infected children may all lead to HFMD infection in children. Clinically, HFMD in children is classified into mild and severe cases based on severity. Mild cases typically have an acute onset, often with fever, and may be accompanied by runny nose, cough, and loss of appetite; herpes is visible in the mouth, hands, and feet. Severe cases may present with neurological symptoms such as poor mental state, drowsiness, easy fright, headache, and vomiting; respiratory symptoms such as tachypnea, dyspnea, or irregular breathing; and circulatory symptoms such as pale complexion, cold extremities, and cyanosis of fingers (toes). Therefore, both parents and physicians should pay sufficient attention to the prevention and treatment of HFMD in children. To this end, parents and physicians should guide children to maintain good personal hygiene and living habits, and minimize close contact with symptomatic children to effectively prevent HFMD [7].

HFMD is a relatively common infectious disease among children. Children aged 1–5 years have immature immune systems and are highly susceptible to viral attacks, resulting in a high incidence of HFMD. Ribavirin is a broad-spectrum antiviral drug with proven clinical efficacy. It competitively inhibits the activity of membrane proteins such as inosine monophosphate dehydrogenase and further interferes with RNA metabolism. Vitamin B12 enhances immunity by promoting folate absorption and conversion. However, traditional antiviral drugs and symptomatic treatments have limited efficacy in improving clinical symptoms, prompting physicians to explore combination therapies for better outcomes. In the past, interferon was often administered via subcutaneous or intramuscular injection for HFMD, which frequently caused adverse reactions such as fever, chills, and headache in children. In recent years, to improve treatment compliance, nebulization inhalation has been increasingly adopted in pediatric clinics as a more child-friendly approach. Nebulized recombinant human interferon α2b can deliver tiny drug particles to exert potent antiviral effects [8].

As a key immune-protective cytokine, α-interferon helps the body resist viral infections. It binds to membrane receptors to induce antiviral proteins, inhibiting viral replication and enhancing cellular antiviral activity. Additionally, it boosts cellular immunity by accelerating cytotoxic T lymphocyte proliferation, activating natural killer cell activity, and enhancing macrophage phagocytosis, thereby exerting strong antiviral effects. In recent years, recombinant human interferon has been widely used in treating various viral diseases in children, such as viral pneumonia, bronchiolitis, and rotavirus enteritis. This study found that the total effective rate in the observation group was significantly higher than in the control group. Comparisons of immune function and inflammatory factor levels before and after treatment further confirmed that nebulized recombinant human interferon α2b effectively alleviates symptoms and reduces inflammatory responses in children with HFMD [9].

The underlying mechanism is that HFMD is primarily caused by various enteric small RNA viruses, and recombinant human interferon α2b can clear RNA viruses independently of the immune system, with high sensitivity, broad-spectrum activity, and low risk of drug resistance. Nebulization inhalation ensures the drug accumulates at high concentrations in oral and pharyngeal herpes, maximizing local efficacy. Respiratory mucosal

epithelial cells are rich in interferon receptors; upon binding, interferon activates the Janus kinase-signal transducer and activator of transcription pathway, exerting potent antiviral and anti-inflammatory effects. Post-treatment, all indicators in the observation group were significantly better than in the control group ($P < 0.05$), indicating that nebulized recombinant human interferon α2b improves immune function in children with HFMD. HFMD is associated with multiple immune abnormalities, particularly T lymphocyte-mediated inflammatory responses, which play a key role in disease pathogenesis and progression. As a bioactive glycoprotein, recombinant human interferon α2b binds to membrane receptors to reduce intracellular RNA, DNA, and protein synthesis, enhances T cell and natural killer cell activity, regulates immune function, and ultimately strengthens immunity [10].

Through this study, it can be found that recombinant human interferon α2b has certain advantages in the treatment of hand, foot, and mouth disease in children. Firstly, recombinant human interferon α2b can inhibit the replication and transmission of the virus, which has a good effect on the prevention and treatment of hand, foot, and mouth disease in children, can effectively improve the symptoms of the children, and shorten the course of the disease. Secondly, recombinant human interferon α2b also has a certain immunomodulatory effect, which can enhance the immunity of the children and strengthen their antiviral ability. This can prevent the recurrence of hand, foot, and mouth disease and reduce the risk of complications.

In addition, compared with other antiviral drugs, recombinant human interferon α2b has relatively fewer adverse reactions, and its safety can be guaranteed to a certain extent. This makes its treatment of hand, foot, and mouth disease in children more reliable, and also alleviates the worries of parents and doctors about the children's adverse reactions to the drug. However, it should be noted that when using recombinant human interferon α2b to treat hand, foot, and mouth disease in children in clinical practice, it must be carried out under the guidance of doctors to ensure the scientificity and safety of the dosage and course of treatment, so as to prevent adverse reactions in children. At the same time, parents and doctors should also pay close attention to the children's condition after medication, so as to adjust the treatment plan in a timely manner, obtain the best treatment effect, and help the children recover quickly.

5. Conclusion

In summary, advances in science, technology, and medical research have deepened understanding of HFMD, leading to novel treatment strategies based on cutting-edge evidence. These strategies improve clinical efficacy, alleviate symptoms, reduce suffering, and ease parental anxiety. Exploring new HFMD treatments also drives pharmaceutical innovation, warranting greater investment from researchers and clinicians.

Disclosure statement

The author declares no conflict of interest.

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