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CLINICAL EFFECT OF AMOXICILLIN-CLAVULANATE POTASSIUM COMBINED WITH BUDESONIDE SUSPENSION INHALATION IN THE TREATMENT OF CHILDREN WITH SINUSITIS

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Abstract

Objective: To study the clinical efficacy of amoxicillin-clavulanate potassium combined with budesonide suspension inhalation in the treatment of children with sinusitis.

Method: A total of 128 pediatric sinusitis patients admitted to the hospital from December 2018 to April 2020 were selected and divided into two groups according to the order of admission. The control group (n=64) received amoxicillin-clavulanate potassium therapy, and the study group (n=64) received amoxicillin-clavulanate potassium combined with budesonide suspension aerosol inhalation therapy. The improvement of clinical symptoms, curative effect, CT examination results before and after treatment, and adverse reaction rate were evaluated and compared between the two groups.

Result： The subjective scores of clinical symptoms of headache, runny nose, nasal congestion and smelly breathing in the research group were lower than those in the control group ($P<0.05$); the curative effect of the research group was better than that of the control group ($P<0.05$). There was no significant difference in the result scores ($P>0.05$); after treatment, the CT examination results in the study group were lower than those in the control group ($P<0.05$); there was no significant difference in the adverse reaction rates between the two groups ($P>0.05$).

Conclusion： The application of amoxicillin-clavulanate potassium combined with budesonide suspension aerosol inhalation therapy for children with sinusitis has a synergistic effect and has a greater therapeutic advantage. This can effectively relieve the clinical symptoms of children without significantly increasing adverse reactions, suggesting that the combination of the two drugs is safe and has high clinical application value.

Keywords: Pediatric sinusitis; amoxicillin-clavulanate potassium; budesonide suspension; aerosol inhalation;

Introduction

Sinusitis is a common ENT disease, mainly caused by respiratory tract infection, which is more common in children. With the progression of the disease, it can be transformed into chronic sinusitis. If the treatment is not timely or unreasonable, the throat and middle ear tissues may even be involved, which seriously affects the quality of life of children [1]. At present, many clinical advocates use antibiotics, mucus excretion agents, glucocorticoids and other drugs to treat children with sinusitis. Among them, amoxicillin and clavulanate potassium is commonly used in clinical treatment of this disease, but the treatment cycle is long, and long-term use may easily lead to compliance. decline.Some studies have pointed out that the combination of amoxicillin and clavulanate potassium combined with budesonide suspension aerosol inhalation in the treatment of children with sinusitis can achieve ideal efficacy [2]. In order to further explore the clinical application effect of the combination of the two drugs in the treatment of this disease, in view of this, in this study, the application of amoxicillin clavulanate potassium combined with budesonide suspension inhalation in children with sinusitis was studied.

1. Materials and methods

1.1 General information

A total of 128 pediatric sinusitis patients admitted to the hospital from December 2018 to April 2020 were selected and divided into two groups according to the order of admission. In the control group (n=64), there were 36 males and 28 females; aged 3-11 years, with an average age of (7.59±2.80) years; in the research group (n=64), there were 37 males and females, respectively , 27 cases; aged 3-12 years, mean (7.88±3.02) years old. All the children were accompanied by varying degrees of headache, runny nose, nasal congestion, smelly breathing and other clinical symptoms. The baseline data of the two groups were statistically significantly different (P>0.05), which could be used for comparative analysis.Inclusion criteria: (1) All children meet the relevant criteria in "Precision Diagnosis and Treatment of Chronic Rhinosinusitis in Children" [3], and are diagnosed as children with sinusitis by CT examination combined with symptoms; (2) No history of drug allergy (3) All patients and their families have given informed consent, which has been reviewed and approved by the hospital ethics committee.

Exclusion criteria: (1) patients with endocrine system diseases; (2) patients with heart, liver and kidney insufficiency; (3) patients with nasal fibrosis and structural deformities.

1.2 Treatment methods

The control group (n=64) received amoxicillin-clavulanate potassium treatment, that is, the children were given amoxicillin-clavulanate potassium (manufacturer: Chengdu Beite Pharmaceutical Co., Ltd.; approval number: China National Medicine Zhunzi H20023672) 30mg/(kg·d), intravenous infusion, continuous treatment for 3d. Subsequently, amoxicillin and clavulanate potassium dry suspension (manufacturer: Shanghai Haihong Industrial (Group) Chaohu Jinchen Pharmaceutical Co., Ltd.; approval number: China National Medicine Zhunzi H20051654) was given, and children under 7 years old were given once 1 sachet, orally; children aged 7 years and above, 2 sachets at a time, orally, 2 times/d, continuous treatment for 1w.

The study group (n=64) received amoxicillin-clavulanate potassium combined with budesonide suspension atomization inhalation therapy. The dosage of amoxicillin-clavulanate potassium in this group was the same as that in the control group. Then give budesonide suspension (manufacturer: AstraZeneca Pty Ltd; Approval No.: Registration No. H20140475) 1-2 mg/time, aerosol inhalation, 2 times/d, continuous treatment for 1w.

1.3 Observation indicators

To evaluate and compare the improvement of clinical symptoms in the two groups, record the subjective evaluation of the clinical symptoms of headache, runny nose, nasal congestion, and smelly breathing, with a total score of 10 points; the higher the score, the more obvious the symptoms. ②

Curative effect/marked effect: The clinical symptoms of the child's headache, runny nose, nasal congestion, and smelly breathing were completely relieved, and the CT examination results showed that the sinusitis returned to normal; Effective: the child's headache, runny nose, nasal congestion, and smelly breathing The clinical symptoms of odor were gradually relieved, and the CT examination results showed that the sinusitis gradually returned to normal; ineffective: the clinical symptoms of the child's headache, runny nose, nasal congestion, smelly breathing, and CT examination results showed no change. Calculation formula: total effective rate = (the number of markedly effective cases combined with the number of effective cases)/total number of cases × 100%. ③ The CT examination results before and after treatment were scored using the Lund-Mackey scoring method, ranging from 0 to 24; the higher the score, the more severe the disease. ④Adverse reaction rate, record the adverse reaction phenomenon of the children during the treatment period, such as nasal congestion, nasal dryness, nausea and other adverse reactions.

1.4 Statistical methods

Data were included in SPSS22.0 software for analysis, measurement data were expressed as (x±s), t test; count data was expressed as (%), chi-square test, P<0.05 was statistically significant.

2. Results

2.1 Comparison of clinical symptoms improvement between the two groups of children

The subjective scores of clinical symptoms of headache, runny nose, nasal congestion and smelly breathing in the study group were lower than those in the control group (P<0.05). See Table 1 for details.

Table 1 Comparison of the improvement of clinical symptoms in the two groups of children (x±s, points)

Item	n	Headache	Runny nose	Stuffy nose	Smelly breath
Research	64	2.29±0.85	2.63±0.87	2.81±0.90	2.41±0.66
Control	64	4.20±1.12	4.28±1.09	3.77±0.97	3.38±1.00
t	-	10.868	9.465	5.804	6.477
P	-	0.000	0.000	0.000	0.000

2.2 Comparison of curative effect between two groups of children

The total effective rate of the study group was higher than that of the control group (P<0.05). See Table 2 for details.

Table 2 Comparison of curative effect between two groups of patients [n (%)]

Item	n	Effective	Efficient	Invalid	Always valid
Research	64	39（60.94）	20（31.25）	5（7.81）	59（92.19）
Control	64	27（42.19）	21（32.81）	16（25.00）	48（75.00）
x^2	-	7.038	0.056	10.774	10.774
P	-	0.008	0.813	0.001	0.001

2.3 Comparison of CT examination results between the two groups before and after treatment

Before treatment, there was no significant difference in the scores of CT examination results between the two groups (P>0.05); after treatment, the CT examination results scores of the study group were lower than those of the control group (P<0.05). See Table 3 for details.

Table 3 Comparison of CT examination results before and after treatment between the two groups of children (x±s, points)

Item	n	Before treatment	After treatment
Research	64	7.60±1.72	2.63±0.59
Control	64	7.51±1.66	3.92±0.78
t	-	0.301	10.552
P	-	0.764	0.000

2.4 Comparison of adverse reaction rates between the two groups of children

There was no significant difference in the adverse reaction rate between the two groups (P>0.05). See Table 4 for details.

Table 4 Comparison of adverse reaction rates between the two groups [n (%)]

Item	n	Nasal congestion	Dry nasal passages	Nausea	Adverse reaction rate
Research	64	1（1.56）	2（3.13）	1（1.56）	4（6.25）
Control	64	2（3.13）	3（4.69）	0（0.00）	5（7.82）
x^2	-	0.538	0.324	1.572	0.188
P	-	0.463	0.569	0.210	0.664

3. Discussion

Because most children have no nasal hair, and compared with adults, their nasal cavity is shorter, the nasal cavity is rich in blood vessels, and the mucous membrane is soft. They are easily infected by bacteria and induce nasal cavity inflammation, which eventually leads to sinusitis in children [4]. The disease is closely related to environmental factors, and complications such as otitis media and bronchitis may occur with the prolongation of the disease course, which is not conducive to the normal growth and development of children. Antibiotics and glucocorticoids are commonly used in current clinical treatment, and children are instructed to improve immunity and keep warm for prevention.

Amoxicillin-clavulanate potassium is a kind of compound preparation. The main components of this product are amoxicillin and clavulanate potassium [5]. Among them, amoxicillin is a semi-synthetic penicillin broad-spectrum β-lactam antibiotic, which can effectively hinder the synthesis and secretion of bacterial cell membranes, and has a strong ability to penetrate the cell wall, thereby rapidly dissolving bacteria, and can play a good antibacterial and bactericidal agent. effect. Potassium clavulanate can combine with β-lactamase to promote the formation of irreversible conjugates. Although the antibacterial activity is not obvious, it can protect the hydrolysis of amoxicillin by β -lactamase [6].It can be seen that amoxicillin-clavulanate potassium can inhibit the synthesis of bacterial cell walls, and then exert a bactericidal effect. At the same time, it can effectively avoid the destruction of cephalosporins and drug-resistant penicillin, and it can effectively prevent the infection caused by enzyme-resistant bacteria. Has good applicability. Budesonide suspension is a kind of anti-inflammatory corticosteroid drug, the main route of administration is atomization inhalation, and it has become a common drug for clinical treatment of pediatric sinusitis. Compared with dexamethasone, the anti-inflammatory and anti-inflammatory properties of this drug are 980 times higher, and long-term administration will

not affect the growth and development of children [7-8].Budesonide suspension for inhalation can effectively inhibit the inflammatory response of the respiratory tract, has good hydrophilicity, and can be in contact with the mucous membrane after the mucus water-like layer is rapidly dissolved. At the same time, it also has a unique esterification effect, the onset time is short, and the drug lasts for a long time [9]. Through atomization inhalation therapy, the principle of gas jet is used to make tiny droplets suspended in the gas to form an aerosol, which enters the respiratory tract of the child and acts on the inflammation of the nasal mucosa[10-11]. It can effectively promote blood circulation, and is inactivated by first-pass metabolism in the liver without adverse effects on the whole body.In

conclusion, the combined treatment of amoxicillin-clavulanate potassium and budesonide suspension atomization inhalation can significantly improve the nasal inflammation in children with sinusitis, relieve its clinical symptoms, and quickly control the disease without obvious side effects. Its curative effect is better than that of amoxicillin-clavulanate potassium alone.

This study showed that the subjective scores of clinical symptoms of headache, runny nose, nasal congestion, and smelly breathing in the study group were lower than those in the control group. It suggests that the application of amoxicillin-clavulanate potassium plus budesonide suspension aerosol inhalation therapy can effectively relieve the symptoms of children, reduce the pain of treatment, and help improve treatment compliance. The curative effect of the study group was better than that of the control group. It suggests that the application of amoxicillin-clavulanate potassium combined with budesonide suspension aerosol inhalation therapy can effectively control the disease, shorten the treatment cycle, and further improve the clinical treatment effect.Before treatment, there was no significant difference in the scores of CT examination results between the two groups; after treatment, the CT examination results scores of the study group were lower than those of the control group. It suggests that the application of amoxicillin-clavulanate potassium combined with budesonide suspension aerosol inhalation therapy can reduce the severity of the disease and promote the return of the disease to normal. There was no significant difference in the adverse reaction rate between the two groups. It suggests that the application of amoxicillin-clavulanate potassium combined with budesonide suspension aerosol inhalation therapy will not significantly increase adverse reactions such as nasal congestion, nasal dryness, nausea, palpitations, and has high safety.Miao Xiuling[12] conducted a control analysis on 104 cases of children with sinusitis in the study, and divided them into the observation group and the control group. The observation group was treated with antibiotics combined with budesonide suspension nasal aerosol inhalation, and the control group was treated with amoxicillin-clavulanate potassium antibiotics. The results showed that the total effective rate of the observation group was 92.31% higher than that of the control group 76.92%. The symptom scores of the observation group were lower than those of the control group. Conclusions suggest that antibiotics combined with budesonide suspension nasal aerosol inhalation in the treatment of children with sinusitis has high efficacy and safety. This is basically similar to the conclusion of this study.

Conclusion

In conclusion, the application of amoxicillin-clavulanate potassium combined with budesonide suspension aerosol inhalation in the treatment of children with sinusitis has a synergistic effect and has a greater therapeutic advantage. It can effectively relieve the clinical symptoms of children without significantly increasing adverse reactions, suggesting that the combination of the two drugs is safe and has high clinical application value.

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