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Analysis of Adverse Reactions of Azithromycin in Pediatric Clinical Application

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Abstract: Objective: this study mainly discusses the adverse reactions of azithromycin in the clinical treatment of pediatrics. **Methods:** 400 cases of children with infectious diseases treated in our hospital from March 2020 to December 2021 were selected as the main subjects of the study, and were arbitrarily divided into the observation group and the control group, with 200 cases in each group. The children in the observation group were divided into intravenous drip group (91 cases) and oral group (109 cases) according to the medication. Children in the control group were treated with antibiotics other than azithromycin, and children in the observation group were treated with azithromycin. The children in the intravenous drip group were treated with azithromycin intravenous drip, and the children in the oral group were treated with azithromycin extended-release tablets. Comparison of adverse reactions between the observation group and the control group, intravenous drip group and oral group. **Results:** The incidence of adverse reactions in the observation group was much higher than that in the control group (19.0%, 10.5%, respectively), and the difference was statistically significant ($P < 0.05$). Gastrointestinal reactions, followed by allergic symptoms, were the most common among the children in both groups. The incidence of adverse reactions was 18.68% in the intravenous drip group and 19.27% in the oral group, which was not significant ($P > 0.05$). **Conclusion:** azithromycin has many adverse reactions in pediatric use. When applying azithromycin in clinical medicine, the scope of application should be strictly grasped, and drug monitoring and observation should be improved during the medication period, so that adverse reactions can be detected as soon as possible, and then solved by symptomatic treatment.

Keywords: Azithromycin; Adverse reaction; Clinical analysis

Introduction

Azithromycin is classified as a macrolide, which has very good bacteriostatic effect on gram-negative bacilli and anaerobic bacilli, and also has the effect of eliminating Mycoplasma and Mycoplasma pneumoniae. Its antibacterial effect is very great, and it has become the most common medicine for clinical treatment. Since then, erythromycin is often used in the treatment of neonatal pneumonia, but it takes a long time to treat and has many adverse reactions, which can easily lead to continuous illness, and the birth of azithromycin greatly improves the therapeutic effect. However, along with the wide application of azithromycin, it has caused many adverse

reactions in young children. Whether taken internally or injected, many children have different degrees of adverse drug reactions after taking the drug, which is not beneficial to the recovery of the child's condition. The significance of this study is to contemporary the adverse reactions of azithromycin in pediatric clinical medicine in order to improve the safety of clinical medication[1].

1. Data and Methods

1.1 General Information

In this study, 400 cases of children with infectious diseases treated in our hospital from March 2020 to December 2021 were mainly selected as the study subjects. Inclusion indicators: ① out-of-hospital infections; ② eligible for azithromycin; ③ age 3~14 years old. Exclusion indexes: ① children with systemic infection; ② patients with congenital diseases, autoimmune diseases, key human organ function problems and other diseases; ③ children with serious infection. The children were arbitrarily divided into an observation group and a control group, with 200 cases in each group. The control group contained 102 male and 98 female children. The ages ranged from 3 to 12 years, with a mean value of (7.9±2.1) years. There were 144 respiratory infections, 45 skin and soft tissue infections, and 11 urinary infections. In the observation group 105 children were male and 95 were female. Age ranged from 3 to 14 years, mean value (8.0±2.2) years. There were 148 cases of respiratory infections, 44 cases of skin and soft tissue infections, and 8 cases of urinary system infections.There was no significant difference in the general data of the two groups ($P > 0.05$), and they were comparable. The children in the observation group were divided into the intravenous drip group (91 cases) and the oral group (109 cases) according to the type of medication. There were 48 male and 43 female children in the intravenous group. Age ranged from 3 to 13 years with a mean value of (7.9±2.0) years. 70 cases had respiratory infections, 17 cases had skin and soft tissue infections, and 4 cases had urinary tract infections. Disease classification: mild 65 cases, moderate 26 cases. There were 57 male and 52 female children in the oral group. The mean age was (8.1±2.3) years.78 respiratory tract infections, 27 skin and soft tissue infections and 4 urinary tract infections. Disease classification: 71 cases of mild and 38 cases of moderate. The general data information between intravenous drip group and oral did not have significant differences($P > 0.05$), with comparative [2].

1.2 Methods

Children in the control group were treated with antibiotics other than azithromycin, and cephalosporin antibiotics and quinolones were used according to the patient's condition.

Children in the observation group were given azithromycin for treatment. ① The intravenous group applied injection azithromycin (Zhejiang Asia-Pacific Pharmaceutical Co., Ltd, SFDA approval number H20063284, specification number: 0.25g), and the amount of use was controlled according to the age and weight of the children, which was usually 0.01-0.50g. ② The oral group was given azithromycin extended-release tablets for treatment. Commonly used drugs for azithromycin tablets (Zhejiang Yongning Pharmaceutical Co., Ltd, SFDA approval number H20066924, specification number: 0.125g), the use of the amount of weight control according to the age of the child, usually 0.25 ~ 0.50g. After taking the medicine should be highly concerned about the child's condition, analyze whether there is any adverse reaction, and make a good record, including the type of adverse reaction, the length of time the medicine is given, the way to cut off the medicine and so on. It is also necessary to do a good job of pharmacological supervision when taking medication, strict management of medication, avoiding adverse reactions as much as possible, and ensuring drug safety.

1.3 Observation Indicators

Compare the status of adverse reactions between the observation group and the control group, the intravenous group and the oral group. Adverse reactions include gastrointestinal reactions, liver damage, allergic symptoms and convulsions [3].

1.4 Statistical Methods

In order to ensure the reasonableness of the data, SPSS18.0 applied statistical software to carry out statistical analysis of the data, (χ±s) represents the measurement data, line t-test, the comparison of count data using the χ^2 test, with $P < 0.05$ represents the difference is statistically significant.

2. Results

2.1 Comparison of Adverse Reactions in the Observation Group and the Control Group

The incidence of adverse reactions in the observation group was 19.0%, much higher than the 10.5% in the control group, and the difference was statistically significant.The most common reaction in the two groups was gastrointestinal reaction, followed by allergic symptoms. The specific data are shown in **Table 1**.

Table 1. Comparison of the occurrence of adverse reactions in the observation group as well as the control group [*n* (%)]

Group	Number of cases	Gastrointestinal tract	Reaction Liver injury	Allergic reaction	Convulsions	Total
Observation group	200	23(11.5)	4(2.0)	11(5.5)	0	38(19.0)a
Control group	200	10(5.0)	2(1.0)	6(3.0)	3(1.5)	21(10.5)
χ^2						5.746
P						0.017

Note: Compared with the control group, $^aP < 0.05$

2.2 Comparison of the Adverse Reactions in the Intravenous Group and the Oral Group

The incidence of adverse reactions in the Intravenous group was 18.68% and the incidence of adverse reactions in the oral group was 19.27%, the difference was not statistically significant ($P > 0.05$). Specific data are shown in **Table 2**.

Table 2. Comparison of the occurrence of adverse reactions in the IV group as well as in the oral group [*n* (%)]

Group	Number of cases	Gastrointestinal tract	Reaction Liver injury	Convulsions	Total
Intravenous group	91	10(10.99)	2(2.20)	5(5.49)	17(18.68)a
Oral group	109	13(11.93)	2(1.83)	6(5.50)	21(19.27)
χ^2					0.011
P					0.916

3. Discussion

3.1 Azithromycin Characteristics

Azithromycin is frequently used in hospitals in China. Azithromycin can treat acute pharyngitis and acute tonsillitis, and doctors will determine whether to apply azithromycin according to the patient's condition. An in-depth analysis of Azithromycin reveals that it can treat lung infections caused by pneumococcus and Mycoplasma pneumoniae, and it can be used to treat urinary tract infections and cervical inflammation caused by a number of pathogens. There are a number of dermatologists who are able to apply Azithromycin on a patient-by-patient basis. Azithromycin itself is categorized as an azathioprine anti-inflammatory drug. Azithromycin enters the body and fuses with the more sensitive small molecule water, affecting the entire process of protein production in the more sensitive small molecule water without destroying the more sensitive small nucleic acid. The human body has multiple procedural defenses that together form a sanitary and epidemiological management system. The bacterium formed by the various bacterial and viral complexes of streptococci is essential for defense against disease, and azithromycin promotes the stable functioning of its own protective system. This organism together with Azithromycin produces some reflective enzymes with the level of the person's own immune system, but some of the final results formed by the reflection of germs with Azithromycin are not yet clear. However, the author azithromycin role is to manipulate chlamydia and mycoplasma, and at the same time a kind of cyclic lactone anti-inflammatory drug, which makes azithromycin become the best choice of medicine for the treatment of these kinds of diseases at present[4].

3.2 Azithromycin Pharmacology

Azithromycin has no adverse effects and has its own endocyclic effects such as hematopoietic function and no genotoxicity[5]. It has been used clinically for

many years without mutagenic effects, but the toxic components in the mother increase with the number of applications. No abnormalities have been seen in children, but the efficacy of non-reproductive toxicity has not been determined. Renal failure in some patients is likely to cause other negative effects. Thus, clinical use of azithromycin is not recommended if there are any problems with the hepatobiliary judgment system[6].

Azithromycin is an azathioprine anti-inflammatory drug, which has an important effect on protein synthesis in cells, and has good efficacy in diseases caused by Chlamydia, Mycoplasma, and Gramnegative bacteria. Azithromycin can be metabolized through the body's hepatobiliary system, and its antibacterial concentration value can still be maintained for about 72 hours after stopping the drug. Azithromycin is mainly used to treat acute pharyngolaryngitis, acute bronchitis and other conditions in pediatric clinics. Accompanied by the increase of azithromycin use and frequency, the incidence of clinical side effects is still rising, which has caused great concern [7].

In the paper, the incidence of adverse reactions of azithromycin in the treatment of pediatric infectious diseases was discussed in all aspects. The relevant data can be shown that the incidence of adverse reactions in the observation group was 19.0%, much higher than the incidence of adverse reactions in children in the control group of 10.5%, and the difference was statistically significant ($P < 0.05$); and the most common adverse reactions in the two groups of children were gastrointestinal adverse reactions, followed by allergic adverse reactions. In addition to this, there were more patients with upper respiratory tract infections in this study, and gastrointestinal disturbances caused by respiratory diseases were also taken into account. Allergic reactions are usually anaphylactic rashes, and the cause of dissection may be an immediate allergic adverse reaction caused by human immunoglobulin E (IgE), or the release of substances caused by drug-irritating histiocytes or parabasic neutrophils, which may cause allergic adverse reactions. Because allergic adverse reactions to azithromycin generally develop very rapidly, it is important to take a medical history, family history, and history of adverse reactions before administering the medication, and to carry out skin tests if needed. In the event of a more severe allergic reaction, the medication needs to be discontinued immediately so that the safety of the child can be effectively ensured. Apart from gastrointestinal and allergic reactions, there are also very few babies who have adverse reactions of liver damage. The liver is an important excretory system for azithromycin, and more than 50% of the drug is excreted as a prototype according to the common bile duct within 48 hours. Clinical studies have demonstrated that the concentration of azithromycin in the liver can reach 25-200 times the plasma concentration, but adverse reactions caused by azithromycin are underreported. In this study, liver damage occurred in only 4 patients, and the liver function will become better soon after symptomatic treatment of hepatoprotective therapy. The incidence of adverse reactions in the children in the IV group and the children in the oral group was found to be non-significant ($P > 0.05$) in this study. It is best to apply azithromycin by all means may result in relatively high adverse effects. Because azithromycin causes more adverse reactions in clinical children's infectious diseases, in order to ensure the safety of medication, the author believes that it is necessary to improve the monitoring and observation of drugs in all the medication links, first of all, from the following aspects: ① First of all, it is necessary to rigorously grasp the relevant requirements for the use of medication as well as the conditions of azithromycin before treatment, the first through the bacterial culture, based on the conclusion of the drug sensitivity test to select the azithromycin. However, the efficacy and safety of internal azithromycin for 2-year-olds has not been determined, and the safety of injected azithromycin for 16-year-olds has not been determined, so children and teenagers need to be careful when using azithromycin. ② Supervision of operation methods. When azithromycin is applied to children and adolescents, internal administration is preferred. Since azithromycin is a highly effective antimicrobial, it should be taken only once a day, and it is strictly prohibited to take it several times a day [8]. Clinical medical investigations have shown that blindly following the trend of elevating the intake of azithromycin and increasing the duration of dosing cause important reasons for more serious adverse reactions. Therefore, the authors believe that the detection and management methods should be strictly upgraded, azithromycin

should be applied according to the instructions for use, and the number of rounds of observation should be upgraded by strictly and comprehensively observing during the dosage period. In order to detect the signs of adverse reactions at an early stage, symptomatic treatment can be solved and the generation of adverse reactions can be reduced. ③ Supervision and management of synergistic use of drugs. When Azithromycin needs to be used in combination with other drugs, the following matters need to be paid attention to. Azithromycin can not be shared with lincomycin, aluminum, magnesium and other antacids [9], in order to prevent the enhancement of the chances of adverse reactions, thereby jeopardizing the metallurgical effect of children. In addition, the two drugs should be used more than 2 hours apart to prevent the occurrence of adverse reactions [10].

Conclusion

In conclusion, all possibilities of errors in the daily operation of hospitals need to be highly emphasized. Azithromycin, despite its use to date, has amply demonstrated its clinical utility as well as its significant value. However, due to the high number of uses, it is easy for adverse drug reactions to occur, which can lead to a certain degree of harm to the child's condition. Therefore, different prescriptions should be prescribed according to the actual situation of patients in pediatrics. And when applying azithromycin in clinical medicine, the scope of application should be strictly grasped, and the monitoring and observation of drugs should be improved during the period of medication, so that the adverse reactions can be found as soon as possible, and then the symptomatic treatment can be solved.

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