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Analysis of Adverse Reactions and Drug Safety Evaluation of β-lactam Antibacterial Drugs

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Abstract: *Objective:* To explore the changes in inflammatory indicators before and after treatment with β-lactam antibacterial drugs to evaluate the antibacterial effect of the drugs, summarize the characteristics of adverse reactions caused by them, and analyze their drug safety characteristics. *Methods:* A retrospective analysis was conducted on 11 cases of adverse reactions to β-lactam antibacterial drugs admitted from 2022 to 2024, and the clinical data of the patients were collected, and the inflammatory indicators before and after treatment, adverse reaction manifestations and recovery conditions were analyzed. *Results:* The 11 patients were aged between 6 and 77 years old, mainly middle-aged and elderly people; the diseases included 3 cases of pneumonia, 4 cases of bronchitis, 1 case of tonsillitis, 1 case of respiratory tract infection, 1 case of pulmonary infection, and 2 cases of soft tissue infection. Among the types of medication, oxacillin sodium for injection was used the most (7 cases), followed by cefuroxime sodium (2 cases), amoxicillin sodium and clavulanate potassium (1 case), and ceftazidime (1 case). After treatment, the patient's white blood cell count, neutrophil ratio, and C-reactive protein all decreased ($p < 0.05$). The main adverse reactions were skin rash (2 cases), nausea and vomiting (4 cases), and chest tightness and fatigue (3 cases). Most of them appeared within 1 hour of taking the drug, and all returned to normal after standardized treatment. *Conclusion:* β-lactam antibacterial drugs can effectively reduce inflammatory indicators in clinical use, but it is necessary to be alert to adverse reactions such as rash and gastrointestinal reactions. Clinical medication needs to pay attention to the antibacterial efficacy of drugs while strengthening the prevention of adverse reactions to improve medication safety.

Keywords: β-lactam antibacterial drugs; Adverse reactions; Drug safety evaluation

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1. Introduction

β-lactam antibacterial drugs are commonly used basic drugs in the clinical treatment of bacterial infections. These drugs are widely used in the treatment of respiratory tract infections such as pneumonia and bronchitis, as well as soft tissue infections [1]. As the use of these drugs increases, there are more and more reports about their adverse reactions, especially problems such as rash, gastrointestinal discomfort, and allergic reactions, which are currently receiving more attention [2]. β-lactam drugs can exert antibacterial effects by inhibiting the synthesis of bacterial cell walls. This study retrospectively analyzed 11 cases of adverse reaction cases of β-lactam antibacterial drugs, and collected clinical data such as the age distribution of patients, types of infectious diseases involved, types of β-lactam antibacterial drugs, and adverse reaction

manifestations. The purpose was to explore the characteristics of adverse reactions of β-lactam drugs, provide a more comprehensive reference for rational clinical use of drugs, and ensure the safety of treatment.

2. Materials and methods

2.1. General information

Among the 11 patients, the youngest was 6 years old and the oldest was 77 years old, with a wide age range. Among them, 10 were middle-aged and elderly patients (≥ 45 years old), accounting for 90.91%, and only one was a 6-year-old child. The diseases involved included 3 cases of pneumonia, 4 cases of bronchitis, 1 case of tonsillitis, 1 case of respiratory tract infection, 1 case of pulmonary infection, and 2 cases of soft tissue infection. Inclusion criteria: Patients who were treated with β-lactam antibacterial drugs in our hospital from 2022 to 2024 and had adverse reactions while taking the drugs, and who had complete medical records and clear clinical information.

2.2. Method

This study used a retrospective study to search for cases with adverse reactions to β-lactam antibacterial drugs recorded in the hospital's electronic medical record system from January 1, 2022 to December 31, 2024. In accordance with the diagnostic standards of the "Adverse Drug Reaction Reporting and Monitoring Management Measures", 11 eligible cases were screened out. The study collected clinical data such as patient age, gender, underlying diseases, and infection types, and also recorded in detail the specific types, administration routes, dosages, and duration of β-lactam antibacterial drugs used.

Statistics on the time of occurrence of adverse reactions, specific manifestations, treatment measures, and outcomes of patients: In these 11 cases of adverse reactions to β-lactam antibacterial drugs, the first step after confirming the adverse reactions was to immediately stop the relevant antibacterial drugs to prevent further worsening of symptoms. For allergic reactions, such as a 56-year-old patient with soft tissue infection who developed rash, palpitation, and chest tightness after using oxacillin sodium for injection, and a 6-year-old patient with bronchitis who developed rash and itching after using ceftazidime for injection, an anti-allergic regimen of intramuscular epinephrine, intravenous dexamethasone, and intramuscular injection of promethazine was quickly given to stabilize the immune system; for gastrointestinal reactions, such as a 47-year-old patient with bronchitis who used oxacillin for injection Nausea after sodium, a 49-year-old patient with pulmonary infection experienced diarrhea after using cefuroxime sodium for injection, and a 77-year-old patient with acute bronchitis experienced nausea and abdominal discomfort after using amoxicillin sodium and clavulanate potassium for injection. Measures were taken to stop the infusion, monitor vital signs, and use metoclopramide for antiemetics and omeprazole to protect the stomach. In the face of chills and fever symptoms, such as a 41-year-old pneumonia patient after using oxacillin sodium for injection. If chills or fever occur, intramuscular injection of promethazine, intravenous infusion of methylprednisolone, and oral acetaminophen are used for cooling and anti-inflammatory treatment; when the patient develops circulatory symptoms such as dizziness, chest tightness, and fatigue, for example, a 20-year-old patient with soft tissue infection developed dizziness, chest tightness, asthma, fatigue, and numbness of both hands after half of the infusion of cefuroxime sodium for injection, and a 68-year-old patient with tonsillitis developed chest tightness after using oxacillin sodium for injection. , fatigue, cold sweats, etc., maintain stable vital signs by immediately stopping infusion, opening intravenous channels for rehydration, bed rest, oxygen inhalation, etc.; for the vomiting, blurred vision and accompanying drop in blood pressure that occurred when a 73-year-old patient with bronchitis used oxacillin sodium for injection, after stopping the drug, rapid intravenous infusion of sodium chloride was given to expand the volume, and dexamethasone was used to increase blood pressure, and continued observation until the symptoms improved. In addition, follow-up visits were conducted for all patients to ensure that the symptoms completely disappeared and there were no sequelae, so as to ensure the health and safety of the patients. In terms of monitoring inflammatory indicators, the study collected laboratory test data before patients took medication and after their condition stabilized. White blood cell count (WBC) and neutrophil

proportion (NEU%) were measured by a fully automatic blood cell analyzer, and C-reactive protein (CRP) was detected by an immunoturbidimetric method.

2.3. Statistical methods

The data were processed with SPSS22.0 software, and the measurement data were subjected to *t* test. $p < 0.05$ indicated that the difference was significant.

3. Results

3.1. Types of diseases

The disease types of the 11 patients included 3 cases of pneumonia, 4 cases of bronchitis, 1 case of tonsillitis, 1 case of respiratory tract infection, 1 case of pulmonary infection, and 2 cases of soft tissue infection. See **Table 1**.

Table 1. Disease types [n (%)]

Disease type	n	Percentage (%)
Pneumonia	3	27.27
Bronchitis	4	36.36
Tonsillitis	1	9.09
Respiratory tract infection	1	9.09
Lung infection	1	9.09
Soft tissue infection	2	9.09
Total	11	100.00

3.2. Types of medication

Among the types of medications used by the 11 patients, oxacillin sodium for injection was the most used (7 cases), followed by cefuroxime sodium (2 cases), amoxicillin sodium and clavulanate potassium (1 case), and ceftazidime (1 case). See **Table 2**.

Table 2. Medication types [n (%)]

Drug name	n	Percentage (%)
Oxacillin sodium for injection	7	63.64
Cefuroxime sodium	2	18.18
Amoxicillin sodium clavulanate potassium	1	9.09
Ceftazidime	1	9.09
Total	11	100.00

3.3. Changes in inflammatory indicators before and after treatment

After treatment, all inflammatory indicators were reduced, $p < 0.05$, see **Table 3**.

Table 3. Comparison of inflammatory indicators before and after treatment ($\bar{x} \pm s$)

Time	White blood cell count WBC ($\times 10^9$/L)	Neutrophil proportion NEU% (%)	C-reactive protein CRP (mg/L)
Before treatment	12.00 ± 1.50	80.00 ± 3.50	50.00 ± 8.50
After treatment	8.50 ± 1.20	65.00 ± 2.80	15.00 ± 3.20
t	6.043	11.099	12.781
p	0.000	0.000	0.000

3.4. Types of adverse reactions

The main adverse reactions were skin rash (2 cases), nausea and vomiting (4 cases), and chest tightness and fatigue (3 cases). Most of them appeared within 1 hour of taking the drug, and all returned to normal after standardized treatment. As shown in **Table 4**.

Table 4. Types of adverse reactions [n (%)]

Type of adverse reaction	n	Percentage (%)
Rash	2	18.18
Nausea and vomiting	4	36.36
Chest tightness and fatigue	3	27.27
Other	2	18.18
Total	11	100.00

4. Discussion

As the basic drugs for clinical anti-infective treatment, β-lactam antibacterial drugs are widely used in various bacterial infectious diseases due to their broad antibacterial spectrum and strong bactericidal ability. Their antibacterial mechanism is mainly achieved by inhibiting bacterial cell wall synthesis [3]. However, with the increasing frequency of clinical use, there are also many adverse reaction problems with this type of drugs. Therefore, a deep understanding of the adverse reaction characteristics and medication safety caused by β-lactam antibacterial drugs is of great practical significance for optimizing clinical medication strategies and ensuring patient treatment safety.

Judging from the 11 adverse reaction cases included this time, respiratory infectious diseases accounted for a relatively large proportion, including a total of 9 cases of pneumonia, bronchitis, respiratory tract infection, pulmonary infection and tonsillitis. This is related to the high clinical incidence of respiratory diseases. The respiratory mucosa, as the body's first line of defense against pathogens, can easily cause inflammation after being invaded by viruses and bacteria. β-lactam antibacterial drugs have become a common drug for the treatment of respiratory tract infections due to their broad antibacterial spectrum and precise efficacy, which also increases the risk of exposure to a certain extent [4]. In addition, 2 patients with soft tissue infections also experienced adverse reactions. Soft tissue infections are mostly caused by pathogens such as Staphylococcus aureus. Drugs such as oxacillin sodium among β-lactams are highly targeted against such pathogens, so they are used more frequently. Changes in inflammatory indicators are an important basis for evaluating the therapeutic effect of β-lactam antibiotics. During the treatment process of the 11 patients in this study, as the medication progressed, the inflammatory indicators decreased significantly. This situation shows that this type of drugs effectively controls the infection and also reduces the body's inflammatory response. Judging from the significant

improvement in inflammatory indicators in all patients after treatment, the effectiveness of β-lactam antibacterial drugs in the treatment of pulmonary infections can be intuitively reflected. The 11 adverse reaction cases included in this study had a large age gap, ranging from 6 to 77 years old, and they were mainly middle-aged and elderly patients. In the middle-aged and elderly people, due to the gradual decline in the functions of various organs in the body, especially the physiological decline in liver and kidney functions, drug metabolism and excretion capabilities decrease, which prolongs the half-life of the drug in the body and the blood drug concentration easily exceeds the safe range, thereby increasing the risk of adverse reactions.

In terms of types of drugs used, oxacillin sodium for injection was used in the most cases, with 7 cases. Oxacillin sodium is an enzyme-resistant penicillin drug with good antibacterial activity against penicillinase-producing Staphylococcus aureus. It is commonly used to treat gram-positive bacterial infections in the respiratory tract, soft tissue and other parts of the body. This drug is widely used, on the one hand because of its targeted therapeutic effect on common pathogenic bacteria, and on the other hand because clinicians pay more attention to Staphylococcus infections. Cefuroxime sodium is a second-generation cephalosporin with antibacterial activity against Gram-positive bacteria and some Gram-negative bacteria, and is suitable for treating infections in the respiratory tract, urinary tract and other parts of the body; amoxicillin sodium and clavulanate potassium use β-lactamase inhibitors clavulanic acid and amoxicillin. The combination expands the antibacterial spectrum and enhances the antibacterial effect against enzyme-producing bacteria; ceftazidime is a third-generation cephalosporin that has strong antibacterial activity against Gram-negative bacteria, especially *Pseudomonas aeruginosa*, and is often used to treat patients with severe infections or immunodeficiency. Different varieties of β-lactam antibacterial drugs have different chemical structures, which makes their antibacterial spectrum, pharmacokinetics and adverse reaction characteristics different. For example, the β-lactam ring structure of penicillin is relatively unstable and prone to degradation, and the products produced by degradation may become haptens, thereby triggering allergic reactions in the body; allergic reactions to cephalosporins are slightly lower than those of penicillin, but there is still a risk of cross-allergy, especially varieties with side chain structures similar to penicillin; compound preparations containing enzyme inhibitors may increase the occurrence of gastrointestinal and other adverse reactions due to their more complex ingredients [5,6].

The adverse reactions in this case were diverse but relatively concentrated. The main symptoms are rash, nausea and vomiting, chest tightness and fatigue, etc., and most of them occur within 1 hour of taking the drug, which is an immediate adverse reaction. The main mechanism of rash is that drugs act as haptens and bind to proteins in the body to form antigens, which stimulate the body's immune system and trigger allergic reactions. The occurrence of gastrointestinal reactions such as nausea and vomiting may be caused by drugs directly stimulating the gastrointestinal mucosa and affecting the function of gastrointestinal mucosal cells; it may also be caused by affecting the normal peristaltic rhythm of the gastrointestinal tract, resulting in delayed gastrointestinal emptying; in addition, drugs may also stimulate the trigger zone of emetic chemoreceptors, causing central vomiting. The occurrence of chest tightness and fatigue symptoms may be related to the effects of drugs on the cardiovascular system, such as causing arrhythmia, changes in myocardial contractility, or triggering the body's systemic stress response, affecting nervous system function, causing fatigue, dizziness and other symptoms. Some patients may experience multiple adverse reactions at the same time, which indicates that the body response caused by the drug is relatively complex and may involve dysfunction of multiple systems. Timely identification of these adverse reactions and taking measures such as drug withdrawal and symptomatic treatment can effectively control the development of symptoms and promote patient recovery. For example, for patients with rash, allergenic drugs should be stopped promptly and treated with antihistamine drugs; for patients with gastrointestinal reactions, antiemetic drugs and gastric mucosal protective agents can be used to relieve symptoms; for patients with chest tightness and fatigue, vital signs need to be closely monitored, and corresponding supportive treatment should be provided if necessary [7,8].

In terms of drug safety, although β-lactam antibacterial drugs can effectively control infections, the existence of adverse reactions reminds them to be cautious in clinical application. Before taking medication, you must ask the patient in detail about his drug allergy history and underlying disease history, and then conduct necessary skin allergy tests. This can

reduce the risk of severe allergic reactions. If the patient has a history of allergy to penicillin or cephalosporin, alternative drugs or desensitization treatment must be carefully selected depending on the type and severity of the allergic reaction. When taking medication, it is necessary to strengthen the observation of the patient's symptoms and signs, especially in the early stages of medication, which will help to detect adverse reactions in time. At the same time, the dosage and dosage interval should be adjusted according to the patient's liver and kidney function, which can reduce toxic reactions caused by drug accumulation. For patients with hepatic insufficiency, the metabolic pathway and first-pass effect of the drug in the liver must be considered; for patients with renal insufficiency, the dose must be adjusted based on creatinine clearance, and blood drug concentration must be monitored if necessary. In addition, rational selection of the route of administration is also critical. Although intravenous administration can quickly reach effective blood concentrations, adverse reactions occur relatively quickly; oral administration is more suitable for patients with milder conditions and better compliance [9,10].

In summary, β-lactam antibacterial drugs have good antibacterial effects in clinical anti-infection treatment and can effectively reduce inflammatory indicators and control infection. However, it is also necessary to pay attention to its adverse reaction characteristics, strengthen medication safety management, and minimize the occurrence of adverse reactions while ensuring the therapeutic effect.

About the author

Yang Jihua (1976-) Han nationality, native of Nanjing, Jiangsu Province, with a bachelor's degree and currently holds the title of deputy director pharmacist of the community.

Disclosure statement

The author declares no conflict of interest.

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