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Analysis on 102 cases of adverse reactions caused by amoxicillin

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To analyze the reports of adverse reactions caused by amoxicillin and explore its occurrence rules and characteristics. To collect the cases of adverse reactions caused by amoxicillin in the past five years in the hospital and make the statistical analysis. In the reports of the 102 cases of adverse reactions, the clinical manifestations were mainly skin and its accessory damage and systemic damage. Allergic reaction is the most common clinical manifestation of the adverse reactions caused by amoxicillin, and physicians should pay attention to patient's history of drug allergy and make close observation at the first drug use, which has important significance in prevention of the adverse reactions caused by amoxicillin.

Key words: Amoxicillin, adverse reactions, preventive measures.

INTRODUCTION

Amoxicillin is a β-lactam antibiotic, and oral dosage which form has good absorption, easy use and broad spectrum used for respiratory tract infection, urinary tract infection, ear, nose, throat, skin and soft tissue infections, and typhoid fever. While recognizing the efficacy of this drug, people neglect its adverse reactions. This paper collects and analyses the statistics on the cases of adverse reactions caused by this antibiotic in the past five years in our hospital.

DATA AND METHODS

Epidemiological analysis of the survey showed that the incidence of adverse reactions was 21.93% (the ADRs center of Beijing in China), which has attracted our attention (Qi-ping Liu et al., 2001). 102 cases of adverse reactions caused by amoxicillin were collected from outpatients and some inpatients with age of 50 days – 80 years old in our hospital in 2005-2010. Classification was made according to the adverse reaction types specified by WHO Adverse Drug Reaction Monitoring Center. Statistics and analysis were also made on age, gender, primary diseases, drug usage, clinical manifestations of adverse reactions and prognosis, and the relevant characteristics of adverse reaction occurrence was discussed.

RESULTS

Age and gender

In 43 males and 59 females with an age range of 50 days-80 years old, 18 cases have past drug allergy history, 20 cases have no drug allergy history, and the other 64 cases have unknown drug allergy history, as shown in Table 1. Primary diseases are shown in Table 2.

Drug usage, adverse reactions and clinical manifestations

Amoxicillin has better gastrointestinal absorption, so most

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Table 1. Distribution of ages and gender.

Age	Male	Female	Total
<20	14	12	26
20-39	11	19	30
40-59	10	18	28
60-79	5	6	11
>80	3	4	7
Total	43	59	102

Table 2. Distribution of primary diseases.

Primary disease	n	Proportion (%)
Endocarditis	12	11.76
Gastritis	23	22.54
Peptic ulcer	9	8.82
Acute tonsillitis	28	27.45
Breast lobule hyperplasia	16	15.69
Influenza	8	7.84
Others	6	5.88
Total	102	100

patients orally take this drug. Some patients also choose injection, as the efficacy comes faster. In addition, amoxicillin is often combined with other drugs, such as Chinese patent drugs, antibacterial drugs, antipyretic and analgesic drugs, digestive system drugs, respiratory system drugs, vitamin drugs, etc. There are 25 cases of patients with rational use of drugs (Table 3). The listed items have no obvious incompatibility with the amoxicillin (Xiao-yun et al., 2007). Different types of adverse reactions and clinical manifestations are shown in Table 4.

Prognosis of adverse reactions caused by amoxicillin

The adverse reactions caused by amoxicillin were relieved or the intensity decreased after stopping the drug administration, by symptomatic antiallergic and other kinds of treatments. Only few cases of allergic shock died after rescue.

DISCUSSION

Relationship between ages and gender and adverse reactions

It can be seen from the statistical result that the ages of patients with adverse reactions caused by amoxicillin are widely distributed, but mainly at the ages of 20-60 years old. For gender, female is slightly higher than male, probably because the incidence of gynecological inflammation in female is higher.

Relationship between primary diseases and adverse reactions

For the types of primary diseases, the patients generally suffer from respiratory tract infection, gastrointestinal tract infection, urinary tract infection, etc, which are related with pyogenic streptococcus, pneumococcus, hemophilus influenzae, Escherichia coli, pneumobacillus and other Gram-positive and Gram-negative bacteria, indicating that amoxicillin has high antibacterial activity against Gram-positive and Gram-negative bacteria (Ju-fang et al., 1999) .

Relationship between drug combination and adverse reactions

Rational drug combination therapy can increase efficacy. For example, amoxicillin combined with lincomycin and erythromycin has better efficacy in treatment of endocarditis. In addition, amoxicillin combined with omeprazole can effectively remove *Helicobacter pylori* (Kucers et al., 2010). But, mis-combination will cause serious adverse reactions. A related literature reports that administration of gentamicin sulfate, houttuynia cordata injection and amoxicillin for a patient with acute enteritis caused papules and limb convulsion, and excluding the allergy to other drugs, the patient was accurately diagnosed as allergy to amoxicillin. After a patient with duodenal ulcer orally took amoxicillin and Losec, low platelet level occurred (Qi-ping, 2003). After treatment of peptic ulcer with the combination of clarithromycin, omeprazole and amoxicillin, nausea, vomiting, diarrhea, constipation and other adverse reactions occurred (Yun-jian, 2010). After combination therapy of amoxicillin and potassium clavulanate, liver toxic reaction, hemorrhagic enteritis, abscess and child tooth pigmentation also occurred (Zhong-shan et al., 2004; Garcia et al. 2003).

Therefore, drug combination should be used with caution, medical care staff should make surveys before drug use and carefully ask allergy history and family history. Patients should also cooperate actively and tell the disease conditions and drug taking.

Clinical manifestations of adverse reactions

It can be seen from Table 4 that the clinical manifestations of adverse reactions caused by amoxicillin is firstly observed on the skin and secondly in the digestive

Table 3. Combination therapy in 25 cases of amoxicillin adverse reactions.

Class of drugs	Combined drug
Antimicrobial agents	Metronidazole tablets, Gentamicin injection, Amikacin injection , Cephradine injection
Antipyretic and analgesic	Paracetamol tablets, Aspirin tablets, Quike capsule
Chinese patent medicines	Small children-speed efficiency flu tablets, LingCao coral buccal tablet, Compound Liquorice Tablets, Isatidis granules, Changyanning Tablet, anti-cold and heat-clearing electuary, detoxicating tablet of cow-bezoar, jizhi syrup, Voiceless pill, tablet for treating common cold, cholagogic tablet, Wenweishu granules, Breast Mass Resolving Tablet, Shuanghuanglian oral liquor, Houttuynia cordata injection, Powerful VC yinqiao tablets
Digestive System Drugs	Losec capsules, Omeprazole, Lansoprazole tablets, Famotidine tablets
Respiratory medicine	Aminophylline tablets
Vitamins	Vitamin B 6 tablets

Patients with more than two kinds of medication, so the combined number of drugs is greater than 25.

Table 4. Types and clinical manifestations of adverse reactions.

Adverse reaction type	Clinical manifestations	n	Proportion (%)
Skin	Drug rash, drug fever, herpes, exfoliative dermatitis	25	24.5
Digestive system	Nausea, vomiting, abdominal pain, watery stool	15	14.7
Nervous system	Exciting, dysphoria, tinnitus, deafness	5	4.9
Blood system	Thrombocytopenia, allergic purpura	4	3.92
Urinary system	Frequent urination, hematuria, proteinuria, acute interstitial nephritis	7	6.86
Respiratory system	Difficult breathing, asthma, laryngeal edema	10	9.8
Systemic damage	Death caused by shock, allergic shock, syncope	17	16.67
Others	Lymph node enlargement, hemianopia, toe vein thrombosis	19	18.63
Total		102	100

organs. Additionally, some literatures report some rare adverse reactions, such as severe tinnitus, death caused by allergy, hemianopia, allergic shock complicated with hypoglycemic coma, hematuria (Jin-lan, 2010), toe vein thrombosis (Jun and Yu-ming, 2007), etc. Therefore, physicians or patients should be cautious in drug use, physicians should use drugs after completely learning about patient's conditions, and patients should carefully read the instructions before drug use and learn about drug application scope and adverse reactions after drug use.

Reasons for adverse reaction increase and the preventive measures

The reasons for adverse reaction increase are mainly as follows. First, patients buy and abuse antibiotics. As people's cultural level rising, the ability to accept new things is strong, but people know little about drugs, especially antibiotics, even though some are "illiterate". Many people mistakenly believe that more expensive drug is better. Second, drug stores improperly sell antibiotics, antibiotics supervision in China is not strict, and they can be bought in drug stores easily, which provides chances for antibiotic abuse. Third, medical care staff should strengthen the training for rational use of antibiotics, to improve their identification of indications for antibiotic use and ability for correct use of antibiotics. Fourth, economic factors also contribute to this problem, and free medical care system reform is urgent (Guang-ping, 2010; Ju-fang and Hui-ying, 1995; Kunin et al., 1990). The use of antibiotics should follow certain principles, thus it can effectively prevent the occurrence

of adverse reactions. First, patients diagnosed as bacterial infection can use antibiotics; second, to determine infectious agents and choose antibiotics according to the pathogenic species; third, drugs should be rationally chosen according to characteristics of drug effects, and those which can be used alone should not be used in combination, to reach the goal of good efficacy and little side effect; fourth, treatment options should be determined according to patient's condition, pathogen species and the characteristics of drug effects, and particularly the elderly and children should be cautious to use drugs. The tissues and organs of the elderly show degenerative changes in physiology, and immune function decreases, once they are infected, drugs will be metabolized slowly and more accumulated in body, thus causing adverse reactions, so the elderly should choose the antibiotics with low toxicity and good bactericidal effects. For children, their organs have not yet been developed well, especially liver and kidney function, and drugs are easily accumulate in the body, so they should choose the antibiotics with low liver toxicity and low kidney toxicity and that are easy to monitor by the plasma concentration (Niehols, 1995; Zhi-hui, 2010; Ji-ping et al., 2000). Only when stopping drug misuse and mastering drug use principles, we can ensure safe, rational and effective drug use and reduce the occurrence of adverse reactions.

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