

Full Length Research Paper

Analysis on 72 cases of adverse reactions of Chinese medicine injection

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To provide doctors and patients with the guidelines for reasonable use of Chinese medicine injection through the analysis on the adverse reactions of Chinese medicine injection in use. Statistics and analysis are made on the raw data of 72 patients that is age, allergic history, ADR manifestations and prognosis. It is found that the adverse reactions of Chinese medicine involve organs and systems. They are proportional to age, older patient's internal systems are more sensitive to drugs, coupled with the degradation of immune function, allergic reactions are very easy to occur. Meanwhile, there are many clinical adverse reactions, mostly manifested as rash and pruritus. When using Chinese medicine injections, doctors, patients, manufacturers and even regulatory authorities should take the responsibilities, safely and strictly use or produce them according to the provisions, and establish and perfect the corresponding management system to minimize the occurrence of adverse reactions.

Key words: Chinese medicine injection and adverse reactions.

INTRODUCTION

Along with the gradual deepening of study on traditional Chinese medicine, its formulations get more and more. Chinese medicine injection is made by extracting the active ingredients in traditional Chinese medicine with modern scientific methods, and it has the advantages of fast effect and good efficacy, so its use is more and more frequent. Although there are many advantages in Chinese medicine injection, the adverse reactions occurring in the frequent use also increase (Kunnei et al., 2009).

In this paper, the analysis on the adverse reactions occurring is made and the appropriate measures are taken.

DATA AND METHODS

Data

72 cases of reports selected in the hospital in 2010 are analyzed

according to the ADR relation standard in National ADR Monitoring Center.

Methods

Analysis is made on gender, age, allergic history, adverse drug reactions (ADR) manifestations and prognosis of the patients in the 72 cases of ADR reports.

RESULTS

Among the 72 patients used in the study, 32 were males (44.44%) and 40 were females (55.56%). The ages are mainly distributed in 40~85, as shown in Table 1. The allergic history is shown in Table 2. Drug varieties and their adverse reactions are shown in Table 3.

DISCUSSION

Gender, age and ADR

The data show that the incidence of ADR in female is

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Table 1. Patient age distribution table.

Age (years)	n	Proportion (%)
40~49	8	11.1
50~59	19	26.39
60~69	27	37.5
>70	26	36.1
Total	72	100

Table 2. Allergic history distribution table.

Allergic history	n	Proportion (%)
Yes	18	25
No	30	41.67
Unclear	24	33.33
Total	72	100

Table 3. Distribution table of drug varieties and their adverse reactions.

Drug variety	Adverse reactions
Shenmai Injection	Gastrointestinal reactions, fever, palpitation, short breath, liver function damage and shock
Shenqin Fuzheng Injection	Allergic reactions, thrombocytopenia, rash, eyelid edema and shallow phlebitis (Zhiming and Chunmu, 2011)
Acanthopanax Injection	Rash, dizziness, allergy and shock
Compound Matrine Injection	Pain, fever and digestive tract adverse reactions
Mannatide Injection	Headache, nausea and difficult breathing
Yanhuning Injection	Pruritus, purpura, anhelation, edema and allergy-like reactions
Safflower Injection	Erythema, palpitation, digestive tract adverse reactions and shock
Cinobufotalin Injection	Hyperpyrexia, chill, swelling and venous stimulation
Danhong Injection	Dizziness, suffocation, subcutaneous hemorrhage and gastrointestinal adverse reactions
Cervus and Cucumis Polypeptide Injection	Nausea, vomiting, rash, palpitation and allergic shock

slightly higher than that in male, but almost in balance, indicating that the incidence of ADR has no significant difference in gender. In age, the incidence of ADR in the patients above 60 years old is higher, mainly because of slow metabolism in the elderly, taking many kinds of drugs, enhanced sensitivity of the systems to drugs, and degraded immune function leading to allergic reactions (Zhang et al., 2009).

Clinical manifestation of ADR

The clinical manifestations of ADR are dominantly rash

and pruritus; maybe because skin has rich capillaries, easy for drug gathering, the damage of drugs to skin is increased, so as to cause skin adverse reactions (Wang et al., 2010). Chinese medicine injection, such as Sudden hearing loss (SHL) injection contained chlorogenic acid, is a highly sensitized to antigens, and high allergic reaction is caused by the antigen.

ADR and drug production technology

Chinese medicine injection has more complex ingredients, and most of them are compounds, which

active ingredients can not be clearly identified, the contained protein, polysaccharides, tannins and other macromolecules are antigens and hapten allergens, easy to stimulate the body to produce antibodies or sensitized lymphocytes, so as to cause allergic reactions (Zhang et al., 2006). The technology for the extraction and refining of Chinese medicine injection is very complicated, it should be very cautious in preparation and storage, and if trace of impure ingredients enter the body when using, they will be very likely to cause adverse reactions.

ADR and drug compatibility

Reasonable compatibility of drugs plays an important role in drug use, and improper compatibility can cause many complications and even death. However, many doctors and patients always neglect it and mistakenly believe that drug combination will increase the efficacy of treatment, and this mistaken understanding brings some unnecessary troubles to treatment. According to literature reports, the compatibility of Chinese medicine and western medicine can be discussed in the following aspects: pharmacological incompatibility, for example, cardiac glycosides-containing Chinese medicines, such as *Apocynum venetum*, ginseng, etc, are incompatible with western medicine cardiac glycosides, to prevent cardiac glycoside poisoning; chemical incompatibility, for example, tannin-containing Chinese medicines combined with erythromycin, digoxin and other drugs will make the drug lose the activity and reduce the efficacy (Gai and Zhang, 2004).

Physical incompatibility: the combination of two or more drugs often causes physical changes, for example, ligustrazine combined with salvia, breviscapine, berberine and other injections produces sediment (Ren and Zhang 2007). Others: for example, breviscapine, is incompatible with 10% glucose injection (Xie, 2010).

In Chinese medicine incompatibility, doctors must strictly observe the rules of eighteen incompatibilities and nineteen counteractions. Eighteen incompatibilities mean that Chinese patent drug containing radix *Aconiti kusnezoffii*, *Radix aconiti* and monkshood is incompatible with Chinese patent drug containing rhizoma *bletillae*, radix *ampelopsis*, *pinellia*, *bulbus fritillariae*, *thunberg fritillary bulb* and *trichosanthes kirilowii maxim*; Chinese patent drug containing liquorice is incompatible with Chinese patent drug containing *euphorbia kansui*, *euphorbia*, seaweed and lilac *daphne*; Chinese patent drug containing red peony root, white peony root, radix *glehniae*, *codonopsis pilosula*, *asarum*, *sophora* and radix *scrophulariae* is incompatible with Chinese patent drug containing *veratridine*. Nineteen counteractions mean that Chinese patent drug containing croton is incompatible with Chinese patent drug containing semen

pharbitidis; Chinese patent drug containing radix *curcumae* is incompatible with Chinese patent drug containing clove; Chinese patent drug containing *excrementum pteropi* is incompatible with Chinese patent drug containing ginseng; Chinese patent drug containing *Rhizoma sparganii* is incompatible with Chinese patent drug containing mirabilite; Chinese patent drug containing red halloysite is incompatible with Chinese patent drug containing cinnamon (Chen, 2002). Reasonable drug compatibility can increase the effect of drugs. The combination of Chinese patent medicine injection and western medicine is generally applied currently. According to the relevant literature reports, Shenfu injection is combined with atropine and isoproterenol for the treatment of chronic arrhythmia (Guan et al., 2011; Wang et al., 2003). Shenmai injection is combined with western medicine (Zhang, 2011) and toad venom injection is combined with antibiotics for the treatment of lung infection after lung cancer chemotherapy (Wei et al., 2010). In addition, some Chinese medicine injections are also combined with chemotherapy to treat cancer, for example, compound matrine injection is combined with chemotherapy for the treatment of advanced gastric cancer (Fu et al., 2011; Jianping et al., 2010).

Therefore, reasonable drug compatibility should be discussed.

Preventive measures

Medical personnel should make diagnosis and treatment according to the patient's conditions, timely ask patients whether they have allergic history before drug use, be cautious in drug use for the patients with allergic history, closely observe the reactions after first drug use, and immediately stop drug use when palpitation, cough and other symptoms occur; secondly, we must pay attention to the effects of mutual antagonism between Chinese medicine and western medicine; thirdly, we must pay attention to incompatibility, usage and dosage, skin, mucosa and respiratory system should be observed in intravenous infusion, and syringes used in preparation can not be mixed (Pan et al., 2010). Patients should take the initiative to explain their allergic history, medication history, etc to doctors, because the patients with allergic history are more prone to severe adverse reactions. Drug quality management departments should make uniform quality standards for Chinese medicine injections of same kind and same specification, eliminate the phenomenon of different qualities, to ensure the quality of their preparations, and strict supervision and scientific management should be made to all the links in drug quality; relevant laws and regulations should be continuously established and perfected to make standard and scientific evaluation on the safety and efficacy of the

Chinese medicine injections in the market (Chen and Angela, 2003; Ren et al., 2011). Chinese medicine injection producers should take the responsibilities in preparation and storage processes in strict accordance with the corresponding standards, to ensure high quality of the produced Chinese medicine injections. Only in this way, all the departments can come together to ensure the safe, effective and reasonable drug use.

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