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Research on Features of Peony Using by Zhang Zhongjing in Terms of Medicine Compatibility

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ABSTRACT: Peony is used in 63 prescriptions in books named *Shanghanlun* and *Jingui Yaolue* written by Zhang Zhongjing, with its compatibility features unique in particular. Peony plays the roles of regulating Ying Qi and Wei Qi, relieving spasm and alleviating pain, clearing heat and functioning in anti-diarrhea, nourishing the bowels to relieve constipation, nourishing Yin and the blood as well as being a diuretic by different combinations with others. It has different effect in different dosage. When used as regulating Ying Qi and Wei Qi, the dose is up to 3 *Liang*; when used in relieving spasm to alleviate pain, the dose is up to 6 *Liang*; when used as nourishing Yin and blood for softening liver, the dose is up to 1 *Jin*; when used as a diuretic, the dose is also up to 3 *Liang*. Judging from the dosage form, the amount of decoction is larger than pill and powder, which suggests that the dose of Peony is utterly different when used in different syndrome and compatibility.

KEYWORDS: Zhang Zhongjing; peony; compatibility; regulating Ying Qi and Wei Qi; relieving spasm and alleviating pain; clearing heat and functioning in anti-diarrhea; nourishing the bowels to relieve constipation; nourishing Yin and the blood; diuretic

Shaoyao (Peony) is classified as a "middle grade medicinal herb" in *Shennong's Herbal Classic*, with bitterness as its flavor. Peony can treat bellyache due to pathogenic factor, dredge stagnation of Ying Qi, get rid of hard lump, hernia and cyst, relieve pain, act as diuresis, and tonify Qi[1]. Peony is used in 63 prescriptions in books named *Shanghanlun* and *Jingui Yaolue*, written by Zhang Zhongjing. We can see that Peony was widely used in treating variety of different diseases by Zhang Zhongjing, with the effect significant and compatibility unique in particular. This paper focus on the features of Peony using by Zhang Zhongjing in terms of Peony compatibility.

1 Function of Peony compatibility

1.1 Regulating Ying and Wei

There is the function of regulating Ying and Wei when combine Peony with Guizhi (Cassia Twig). Guizhi Decoction is known as the the crown of all prescriptions as "it plays a role of expelling wind and other pathogenic factors when used for exogenous disease, promoting Qi flow and regulating Yin and Yang when used for internal disease". Cassia Twig, being pungent and warm-natured, can induce sweating to dispel exopathogen and warm the channels to clear obstruction; Peony, cold-natured and sour in flavor, can tonify Yin and contract sweating. Two herbs being used in compatibility can induce sweating to proper degree, balance and regulate Ying and Wei[2]. Therefore, Peony combined with Cassia Twig usually plays role of dispelling pathogenic factors from muscles and regulating Ying and Wei in Guizhi Decoction added with Gegen, Guizhi Decoction added with cassia twig, Inter-decoction of Gui-Ma integrated Decoction, Guizhi Er Mahuang Yi Decoction, Gegen Decoction added with Pinellia ternata, Xiaoqinglong Decoction, etc.

1.2 Relieving spasm to alleviate pain

"Peony can dredge blood vessels, relieve spasm, treat abdominal pain and lumbago"[3] is recorded in *Mingyi Bielu*. "Peony can tonify blood, clear liver-fire, invigorate spleen, nourish liver Yin and cure lumbago due to blood deficiency", is recorded in *Bencao Be-*

iyao. "Peony can remedy abdomen pain of deficiency since the disease is located in the spleen meridian of foot-Taiyin" is recorded in *Tangye Bencao*. It suggests that Peony is one of the vital herbs to cure various kinds of pain. For example, Peony can relieve spasmic gastrocnemius in Shaoyao Gancao Decoction, and it can treat abdominal pain in Zhenwu Decoction, Xiaojianzhong Decoction and Danggui Shaoyao Powder.

1.2.1 Relieving spasmic gastrocnemius

There are just two herbs in Shaoyao Gancao Decoction to treat spasmic astrocnemius caused by Yin-fluid deficiency syndrome. Peony plays the role of nourishing Yin and tonifying blood, when muscles and vessels are supplemented with nutrition, spasm gets relieved. Therefore, these two sour-sweet herbs function together in nourishing Yin, benefiting Qi and nourishing blood, and help cure the spasmic gastrocnemius muscle[4].

1.2.2 Treating abdominal pain

Peony combines with herbs likes Fuzi (Radix Aconiti), Guizhi (Cassia Twig), Wuzhuyu (Evodia Rutaecarpa) and Xixin (Asarum) can warm channel to treat pain caused by coldness. Peony combining with Fuzi (Radix Aconiti) can warm Yang and relieve abdominal pain due to Yang being depleted and water-dampness blocking collaterals. Peony combining with Yitang (Caramel) in Xiaojianzhong Decoction can warm spleen and stomach to relieve spasm and alleviate pain, in addition to that Guizhi (Cassia Twig) warms Yang for dispelling cold, so spleen and stomach Qi and blood are nourished and abdominal pain cured. Danggui (Angelica Sinensis), Peony combining with Chuanxiong (Rhizoma Chuanxiong) in Danggui Shaoyao Powder can nourish liver blood and warm channels to treat various abdominal pain of women. In Dachaihu Decoction, Peony combining with Daihuang (Rheum) can purge excess heat in the stomach meridian of foot-Yangming and nourish liver Yin to treat excess abdominal pain. In Si Ni Powder, Peony combining with Chaihu (Radix Bupleuri) which can lift Yang and alleviate mental depression to contract Yin and nourish blood. These two herbs combining with Zhishi (Fructus Aurantii Immaturus) can activate Qi flowing, regulate Qi and blood to treat abdominal pain caused by liver wood subjugating spleen soil due to Qi stagnation.

1.3 Clearing heat and anti-diarrhea

Zhang Zhongjing is the first person to use Peony combining with Huangqin (Radix Scutellariae) to treat diarrhea, which is believed the representative prescription "ancestor prescription of treating diarrhea", and is named as Huang Qin Decoction which called. The match of the two herbs can contract Yin and nourish blood, clear heat and dampness. Peony combining with Radix Scutellariae in Dachaihu Decoction means the same. "Peony can treat diarrhea, abdominal pain and tenesmus" is recorded in *Bencao Gangmu* written by Li Shizhen. Zhang Yuansu[5] also pointed out that "Peony can treat diarrhea and nourish blood" in *Yixue Qiyuan*.

1.4 Replenishing the vital essence and blood

Peony was used only in purgation before Zhang Zhongjing. For instance Peony was said to "eliminate blood-arthralgia and resolve hard lump" in *Shennong's Herbal Classic*, and to "eliminate blood stasis" in *Mingyi Bielu*. "Danggui Sini Decoction can treat cold hands and feel with too thready pulse to live" said in *Shanghanlun*[6]. In the prescription, Peony combining with Angelica Sinensis can nourish Yin and tonify blood. It combining with Radix Aconiti, Asarum and Mutong (Caulis Akebiae) can clear obstruction in channels and nourish blood. Zhang Zhongjing always used Peony combining with Angelica Sinensis and E' jiao (Donkey-hide Glue) to treat women's diseases, such as consumption diseases, blood deficiency diseases, and puerperal deficiency diseases. Peony combining with Angelica Sinensis in Danggui Powder can contract Yin and nourish blood, consolidate Chong vessel in preventing miscarriage. These two herbs are the preferred durgs in preventing miscarriage. Peony combining with Angelica Sinensis, Donkey-hide Glue and Gandihuang (Rehmannia Glutinosa) in Shuyu Pill can nourish Yin and blood in treating consumptive diseases. In Huangqi Guizhi Wuwu Decoction, Peony combining with Astragalus and Cassia Twig can invigorate Qi

and nourish blood in treating deficiency of Qi, blood, Ying and Wei. In Jiao Ai Decoction, Peony combining with Angelica Sinensis and Rhizoma Chuanxiong can coordinate Chong channel and Ren channel to treat uterine pain during pregnancy and uterine bleeding.

1.5 Nourishing the intestines to relieve constipation

Being sour in flavor and little cold in nature, Peony can relieve constipation since sour herbs help produce body fluid to moisten the bowels. Maziren Pill comes from Xiaochengqi Decoction added with Huomaren (Hemp Seed), Xingren (Almonds) and Peony. Peony combining with Rheum can clear pathogenic heat, and nourish Yin combining with Hemp Seed and Almonds to strengthen spleen and purge lung. The prescription has an effect of nourishing Yin for moistening dryness, purging heat and relaxing the bowels. Just as said in *Benjing Shuzheng*, "Peony is used to nourish Yin and the bowels in Maziren Pill, and then the constipation is eased"[7].

1.6 Diuresis

Bencao Tujing stated that "Zhang Zhongjing always used Peony to treat cold pathogenic diseases, since Peony can regulate cold or hotness, and function in diuresis". It works through the following aspects in Zhen Wu Decoction. ① The flavour of Peony is sour, so Peony can nourish Yin and blood to function diuresis. Zhen Wu Decoction treats difficulty in urinating with cold syndrome due to essence deficiency of Shaoyin but not that with Taiyang disease by nourishing Yin and blood to produce fluid but no removing obstruction. ②Whether or not the urine is obstructed, is closely associated with the catharsis function of liver. *Huangdi Neijing* first pointed out the direct relationship between liver and urine, "enuresis or uroschesis will occur with impairment of the liver" *Miraculous Pivot* says. Wang Kentang and Sun Yikui, two famous physicians in Ming Dynasty, both pointed out that "liver controlling urination" in their books *Nü Ke Zheng Zhi Zhun Sheng* and *Chi Shui Xuan Zhu*. Peony is the key medicine to nourish and smooth liver by invigorating deficiency or restrainting excess, just as Zou Shu said that "the conveyance of heart and dispersion of kidney Qi will be regulated with help of the catharsis of liver Qi"[8], thus leading to urinary excretion. ③With the channel tropism of Peony is spleen channel of foot-Taiyin, Peony can nourish spleen and stomach to be diuretic. Peony combining with Fuling (Poria) and Baizhu (Atractylodes) can invigorate spleen for diuresis, as pathogenic damp is removed. ④Peony plays the role of promoting blood circulation and Poria promoting diuresis[9]. They help the diuretic function and give pathogetic Qi a way out.

2 Dosage and dosage form of Peony in prescriptions

The maximum dose of Peony is 1 *Jin*, while the minimum dose is 1 *Liang* and the common dose is 2 – 4 *Liang*, according to Zhang Zhongjing. When used as regulating Ying and Wei, the dose is 3 *Liang*. For instance, Cassia Twig can disperse Wei Qi by inducing sweating to dispel exopathogen and to restrain Wei Qi, and Peony can tonify blood and reinforce the Ying Qi in Gui Zhi Decoction. Peony combining with Cassia Twig can disperse Wei Qi by inducing sweating to a proper degree. The two herbs have the function of nourishing Yin and Yang, regulating Ying and Wei, which are used in relieving spasm to alleviate pain, with the dose up to 6 *Liang*[10]. "Misusing purgation to treat Taiyang disease, would cause full and pain in abdomen, which belong to the Taiyin disease, Guizhi and Peony Decoction would cure". The dosage of Peony is maximum among all of the herbs in this prescription, since it promotes blood circulation of spleen vein. The combination with Cassia Twig can treat distending pain of abdominal caused by stagnant blockade of spleen blood. When used in nourishing Yin and blood for softening liver, the dose is 1 *Jin*. Large dose of Peony was used in Danggui Shaoyao Powder in nourishing Yin for softening liver, together with Angelica and Rhizoma Chuanxiong to cure abdominal pain caused by liver blood deficiency and malnutrition of channels. Where used as diuresis,

the dose is 3 *Liang*. For instance, Peony works together with others in Zhen Wu Decoction and Si Ni Powder. As to dosage form, the amount of Peony in decoction is larger than that in pill or powder, which suggests that the dose of Peony is utterly different in different syndrome, combination and dosage form in clinical application.

Peony, with multifunction, of complementary and attacking, was used by Zhang Zhongjing skillfully to cure variety of exogenous and internal diseases with different doses to achieve different effect. By analyzing and summing up Peony's usage taught by Zhang Zhongjing, we can learn to use Peony correctly in clinical treatment.

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Investigation and Analysis on Extramarital Sex of Elderly People with AIDS

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ABSTRACT: Objective: To analyze the reasons and discuss the protective measures by investigating the extramarital sex of the elderly people with AIDS group in Daye city, Hubei province. Methods: The data of extramarital sex ratio, living conditions, educational level, marital status, security measures of the elderly AIDS group (≥60 y) from 2009 to 2013 are collected and analyzed. Results: From 2009 to 2013, the infection rate of HIV among the elderly people with AIDS in Daye increased from 25.0% to 51.7%. The rate of the extramarital sex had increased from 70.0% to 77.4%, with the male from 85.7% to 91.7%. The percentage of those who don't use condoms had decreased from 100.0% to 95.8%. Most of these people are married and live in towns or cities, with primary school educational experience. Conclusion: Risky extramarital sex has become the main transmission mode of AIDS among the elderly. Caring for elderly groups, strengthening publicity and education, and popularizing the knowledge of safe sex have become the urgent needs.

KEYWORDS: acquired immunodeficiency syndrome; elderly acquined immunodeficiency syndrome; extramarital sex; Daye Hubei

AIDS is also known as acquired immunodeficienly syndrome. Due to the improved living and health conditions, China's average life expectancy had reached 76 years old by 2011, which was higher than that in other developing countries, and even higher than some of the European countries, according to 2013 *World Health Statistics Report* by WHO. At present, China's elderly population increases to 130 million, accounting for 10.09% of the total population. Population aging is affecting all aspects of human life widely and deeply. In recent years, due to the social development and the limitations of AIDS prevention and controlling work, The number of elderly people with AIDS increased year by year, which is even higher than that in young adult AIDS group in some areas. Among the cases the elderly men mainly suffer from risky extramarital sex, while the elderly women mainly suffer from spousal infections. Risky extramarital sex has become the main infection factor of AIDS among the elderly[1]. At present, the extramarital sex both in urban and in rural areas becomes more and more popular in the process social transformation in our country[2], which is challenging to family life and AIDS prevention work.

1 Materials and methods

1.1 Investigation object

The new onset and confirmed HIV-positive people aged 60 and above from 2009 to 2013 in Daye, Hubei province.

1.2 Investigation contents

The number of annual new onset elderly patients with AIDS, the number of extramarital sex and sex ratio, living conditions, educational level, marital status and security measures are investigated.

1.3 Statistical methods

The data of annual incidence of AIDS patients aged 60 and above, the proportion of those who had extramarital sex ratio, living conditions, educational level, marital status, security measures from 2009 to 2013 are collected and analyzed statistically.

2 Results

2.1 Analysis on incidence and extramarital sex ratio

The incidence increased year by year among people aged 60 and above. The ratio increased from 25.0% in 2009 to 51.7% in 2013. The majority of these patients

have extramarital sex, with the proportion accounting for 70.0% in 2009 and 77.4% in 2013.

2.2 Analysis on gender of extramarital sex participants and their living conditions

Male extramarital sex participants are more in number and most of them inhabit in villages or towns. In 2009, the proportion of men participants accounted for 85.7% and the ratio of women was 14.3%, while in 2013 the former was 91.7% and the latter was 8.3%. People who lived in villages or towns accounted for 100.0% in 2009, while 85.4% in 2013.

2.3 Analysis on educational level and marital status of extramarital sex participants

The educational level of elderly extramarital sex participants was mainly primary school or illiterate. The proportion accounted for 100.0% in 2009, while 89.6% in 2013. Meanwhile, the majority of them were married. In 2009, the proportion of married people accounted for 57.1% and the proportion of divorced or widowed accounted for 42.9%, while in 2013, the former was 70.8%, the latter was 29.2%.

2.4 Analysis on security measures of extramarital sex

Most of the elderly extramarital sex participants didn't use condoms or other security measures, with the ratio 100.0% in 2009, while 95.8% in 2013.

3 Discussion

Elderly AIDS patients are increasing year by year. The main route of transmission of AIDS has changed from blood to sexual transmission, since extramarital sex becomes a major epidemic risk factor and contributes much to its fast growth. Extramarital sex refers to voluntary sexual behavior between men and women outside legal marriage, with basic feature as the opposite sex, extramarital, voluntary and sometimes money[3]. These misbehaviors are usually characterized: being strong concealment, being less likely to be exposed to judicial departments, having potential risk and showing a growing trend[4]. The causes of extramarital sex are various. He Zhanpeng and others[5] classified the causes into nine categories by psychological analysis. They are curiosity, adventure, conquering, compensation, revenge, aggression, coercion, libertinism and animal instinct. The reasons of elderly extramarital sex have their own characteristics.

3.1 Social background

Currently, the social structure is highly differentiated and integrated, in which there is a lack of the uplift of traditional cultural values. It leads to people's behavioral disorder and moral declining. Extramarital sex thus becomes an ethical issues which people face with in the social transition period. On the one hand, individual rights and privacy are used to make excuse for it as legitimacy and rationality. On the other hand, extramarital sex is actually a performance of moral decay and behavior disorder in legal and ethical point of view.

High frequency of extramarital sex usually gets many people involved in rural areas and is becoming villager's tacit "normal" behavior in daily life[6]. As rural to urban migrant population increases, the spiritual life of the elderly and female in rural areas is becoming challenging. The pursuit of "sex" of these lonely people who are left behind in the crowd needs an answer. With the implementation of the family planning policy, contraceptive rate of married women is increasingly, which facilitates extramarital sex and their physical security. Meanwhile, improved medical and health condition and increased private clinics also provide convenience for treatment of sexually transmitted diseases which sometimes due to extramarital sex.

3.2 Physiological needs

A survey suggests that 39.3% of the interviewees explain that sexual demands are the main cause of the extramarital sex. When some couples had disharmonious sexual life, extramarital sex is likely to bring them new and better sexual partners, which diversified their sexual experiences, help them experience greater satisfaction in sexual activities. With the improving of people's living and health condition, more elderly people remain sexually active. It is reported that men at age of 70 still have normal sexual needs. If people, including married people with spouse incompatibility or disharmony, the divorced or widowed people, who are in a long-term depression without regular sex partners, thay

are more likely to satisfy their sexual needs through an extramarital affairs or commercial sexual activities.

3.3 Lack of restriction mechanism

With the disintegration of rural collective system, village administrative power gradually lose control of deviant behavior, and extramarital sex has become private behavior without any structural constraint forces. With the cost of marriage increasing, extramarital sex victims do not tend to disclose or divorce easily and gradually convert it into material compensation, compromise and endurance in order to maintain family unity, which also leads to the cost reduction of infidelity. At the same time, public opinions and moral constraints on extramarital sex are also decelerating. In the past, extramarital sex was always considered as disgraceful and immoral behavior, especially females who were usually humiliated, abused, imprecated and isolated by the public and so on. But with the connection between Chinese and western cultures, extensive mobility of urban and rural population, public opinions and moral standards have also gradually changed, "extramarital affairs" are even considered as a symbol of success and competence of men, which also explain that why men are more likely have extramarital sex to some extent. In addition, most people are indifferent to extramarital sex, which unluckily help with sex release space for those people who have extramarital sex. Further, most of elderly people in rural areas have a low educational level but occupy a dominant position in the family. They are likely to have extramarital sex because of the abscent restraint by family members and healthy recreational activities. Some empty-nesters also become vulnerable population invaded by HIV just because of their spiritual emptiness and lack of care.

3.4 Mentalities of competition, amusement and revenge

In many regions, extramarital sex is not viewed as deviant behavior in violation of social ethics, but is regarded as the embodiment of social status and capability to show off. In many families, if there is infidelity of one spouse, the other will often take corresponding revenge, and find a reasonable excuse for extramarital sex of their own. For the purpose of revenge on society, some people infected with AIDS due to extramarital sex have dangerous extramarital sexual behavior and transmit HIV deliberately. Some rich elderly men in some economically developed areas have much leisure time but lack cultural life, they are spiritually empty and greedy for enjoyment and stimulation, so they are easy to be the sex consumers of special service industry in bathing center. Even in less developed areas, there are sexual transactions with low prices supplied for elderly men.

3.5 Lack of protection knowledge

The cultural level of the old is generally low, mostly with primary education, so the majority of them are lack of knowledge about the dangerous outcome of AIDS and other venereal diseases brought about to society, family and themselves. Some of the elderly are more open-minded than before, and prefer not to use a condom or use it in a wrong way. Many elderly people put emphasis on enjoyment rather than security by thinking they are old and will die whether they are infected or not, when they feel uncomfortable using condoms. Even some people with fluky ideas refuse to use condoms. In addition, in the countryside and the integration area of urban and rural places, the sexual trade is generally being hidden, wide distribution and being mobility. Due to the poor environment and sanitation, without disinfection facilities, condoms and other protection tools or saving money, also, sex participants rarely use or even never use condoms. They are generally old people with lower educational level, and lack of AIDS-related protection knowledge. Therefore, the countryside and the integration of urban and rural places become a hotbed for the spread of AIDS[7].

3.6 Harm of extramarital sex

Extramarital sex will cause double damage both physically and psychologically. Physically, they may suffer from AIDS and other venereal disease. Psychologically, it may produce depression, anxiety and panic over the fear of exposure, spreading to their spouses and being shamful to the family[8]. Extramarital sex brings about negative impact on social values. The increase of extramarital sex will influence the value orientation of those elders who have no extramarital sex

and aggravate the social moral condition. Compared with young groups, the elderly rarely talk to medical or health care personnel about AIDS life or other sexually transmitted diseases. Also, they can seldom received health care education through internet and other media. Meanwhile, the elderly HIV infected patients are often reluctant to accept AIDS related services because of the fear of family's discrimination, thus resulting in spouse and other family members being infected[9,10].

3.7 Preventive measures

Given the status of social morality in our country, the elderly group's demands and the humanistic care. It is hard to put a ban on senile extramarital sex activities. At the same time, according to the requirements of the law of our country and the needs of socialist spiritual civilization, the legalization of sexual transactions also can not be accepted. Considering the severe situation of senile extramarital sex, in order to prevent AIDS and STD better, preventive measures are to be formulated according to the characteristics of the different regions. Firstly, we should get harmfulness of the AIDS and STD widely known, popularize protection measures, encourage free offers of high quality condoms, ban dangerous extramarital sex. Secondly, we need to care for the elderly groups, cultivate their good life style, organize social and cultural activities, promote mutual understanding among elderly people, to meet their demands of making friends. Thirdly, we should strengthen the publicity and education in sex, provide professional advice, to help the elderly couple to maintain good relationship and harmonious sexual life, and help the divorced or widowed elderly to reorganize families. Fourthly, activities of sending health knowledge and care should be organized for remote rural areas elder men. Fifthly, we need to strengthen the management of AIDS patients and eliminate discrimination. In addition to providing free antiretroviral treatment for the elderly patients with AIDS, traditional Chinese medicine treatment can also participate in it as an AIDS pilot project. Besides Chinese medicine treatment, strengthening the ideological and moral education, and helping people with medical care and daily life are also necessary in order to eliminate their thought of revenge on society and prevent transmission of AIDS and other venereal diseases.

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Experience of Professor Jiang Shiqing in Treating Lung Cancer

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ABSTRACT: Lung cancer is a kind of disease with exterior excess and interior deficiency, i. e., lung Qi deficiency and Yin deficiency due to excess of cancer toxin, phlegm toxin, blood stasis toxin accumulation, and should be treated by supplementing Qi and nourishing Yin, detoxification and removing stasis, dissipating phlegm and blood stasis, being the basic symptoms. The treatment for lung cancer should focus on the balance in handling excess and deficiency. At the same time, treatment should be combined syndrome differentiation and disease differentiation, combined with operation, radiotherapy, chemotherapy and other means of treatment. In the early stage of lung cancer, vital Qi is sufficient while pathogenic Qi prevails. The first choice should be an operation combined with TCM therapy, giving priority to eliminating pathogenic factors, supplementing by strengthening healthy Qi; in the middle stage, evil factor becomes deficiency and healthy Qi recovery is made gradually, eliminating pathogenic factors and at the same time, strengthening healthy Qi should be applied in treatment. TCM therapy should take priority over all other cures for the sake of deficiency Qi and organs function to supplementing Qi and nourishing Yin, protecting stomach Qi, namely the digestion, in order to reduce the complications and adverse reaction and to prolong the life time of the patients.

KEYWORDS: Jiang Shiqing; lung cancer; supplementing Qi and nourishing Yin method; detoxification and removing stasis method; treatment of phlegm and blood stasis method

Professor Jiang Shiqing is a famous doctor of Traditional Chinese Medicine in Henan province, being a doctoral tutor, vice president of China Medical Oncology, and chief physician of Third Affiliated Hospital of Henan University of Traditional Chinese Medicine, Professor Jiang has been engaged in TCM oncology clinical work more than 30 years. After treating a large number of cancer patients, he has got unique experience in tumor treatment by unremitting exploration in traditional Chinese medicine theory and practices in the treatment for tumor. The author has learned from professor Jiang for many years. A brief introduction of professor Jiang's unique academic thought and clinical experience in treating lung cancer is to be introduced in this paper.

Lung cancer, also known as primary bronchial lung cancer, is a malignant tumor derived from the bronchial mucosa epithelial. The central type lung cancer grows over the opening in the leaves, segm which type lung cancer ental bronchi, and the bronchial located below segmental bronchi which type lung cancer is called peripheral lung cancer. Lung cancer can be divided into non-small cell lung cancer and small cell lung cancer according to its biological characteristics. Non-small cell lung cancer, including squamous cell carcinoma, adenocarcinoma, large cell carcinoma and adenocarcinoma. According to the world health organization, male lung cancer incidence was 38.46/100 000, with mortality rate as 33.21/100 000, while female incidence was 15.70/100 000, with mortality rate as 13.45/100 000 in China in 2000. Its morbidity and mortality ranked the first place in all kinds of malignant tumor[1]. In ancient TCM literature there was no disease named "lung cancer". It fell into catogeries of "cough", "chest pain", "lung accumulation", "hemoptysis", "rushing respiration", "lung obstructed" and so on. *Yizong Bidu* · *Accumulation* states: "The causes of the formation of accumulation is caused by a lack of health Qi, then the pathogenic Qi occupy the body." *Lingshu* · *Baibingshisheng* states: "The occurrence of

abdominal mass is due to cold pathogen invasion, inverse and upward Qi contributes to it. "*Chongdingyanshijishengfang · Zhengjiajijumen* states:" Abdominal mass can be found a cup-sized bump in the right rib, accompanied by respiratory distress, pulse float and Mao, white color, reversed flow of Qi, back pain, deficiency Qi, forgetfulness, with closed eyes, cold skin and pain like being needling. These symptoms of lung cancer in ancient literature are similar to that of the modern disease called lung cancer. Therefore, it is significant to study the pathogenesis and treatment of lung cancer. "

1 The pathogenesis of lung cancer

1.1 Vital Qi deficiency is the root of onset

Professor Jiang suggests that the reason why people suffer from cancer is associated with deficiency of healthy Qi. So traditional Chinese medicine believes that vital Qi weakness is the intrinsic factor for the formation of cancer, based on which "Yangzhengjizixiao" was put forward by Chinese doctors as a treating principle in Song and Yuan dynasties, which shows the importance of strengthening Qi in the treatment for lung cancer. The occurrence and development of lung cancer will further weaken the vital Qi. It is a process of struggle between vital Qi and pathogen. Pathogen prevails over vital Qi will contribute to the development of cancer, whereas vital Qi prevails pathogen will stifle the disease. So, rising and falling of vital Qi is the key to transformation of lung cancer. In addition, the patients who look for the treatment of traditional Chinese medicine have undergone surgery, radiotherapy, chemotherapy repeatedly, by which the body's vital Qi as well as tumor cells have been injured. Thus vital Qi deficiency is almost along with the whole process of lung cancer. Modern medicine believes that the occurrence and development of malignant tumor are related to the low level on cellular immunity, and the cancer patients who have more active immunity and maintain better immune response ability would be made better prognosis, which holds the same view as traditional Chinese medicine. TCM holds that lung, being a delicate organ, prefers moisture to dryness. If heat-toxicity gets blocked in lung, it can easily consuming Qi and injuring Yin[2].

1.2 Cancer toxin, sputum and blood stasis are the key pathogenesis

Professor Jiang points out that cancer toxin is an important pathogenic factor of lung cancer, which would come from long-term smoking, air pollution, automobile exhaust, asbestos, occupational carcinogenic factor, ionizing radiation, and other factors. Once formed in the body, cancer toxin would in turn act as a pathology product, aggravating further illness, which is difficult to cure. While cancer toxin gets blocked in lung, it can make failure for lung Qi in dispersion and descending, meridian impassability, gasification disorder, abnormal fluid distribution and sputum, abnormal blood distribution and stasis. Then, cancer toxin, sputum and blood stasis twist together, and form masses. Sputum and blood stasis are both the pathogenic products of cancer-invading lung and in turn the pathogenic factors which results in further vital Qi weakness. Therefore, cancer toxin, sputum and blood stasis exist throughout the onset process of lung cancer. Lung cancer is due to deficiency, and from which excess syndrome take place. Early lung cancer, vital Qi is not deficiency, we can choose the operation and cooperate with treatment of traditional Chinese medicine. At this stage, traditional Chinese medicine treatment focus on eliminating pathogen and organ strengthening vital Qi. In lung cancer metaphase, function restoration after surgery, radiotherapy and chemotherapy. At this stage, pathogenic Qi declines and vital Qi gradually recovers, traditional Chinese medicine treatment focus on reinforcement and elimination at the same time. As to late lung cancer, traditional Chinese medicine treatment focus on reducing the complications and adverse reactions, so as to prolong patient survival period.

2 Chinese medicine therapy and medication feature in treating lung cancer

2.1 Tonifying Qi and Yin method

Professor Jiang believes that the development of lung cancer is the result of the whole body's defence function declining. Growth of the tumor inhibits body's immune ability further, and again help with the development of tumor. Being over fifty years of age, human's Yin Qi is half remained, and the body's immune function declines, so the lung cancer mostly occurs to elder-

ly patients. Chinese medicine believes that the lung is a tender organ, preferring moisture to dryness, intolerance of chills and fever, easy to hurt by dry evil[3]. In the process of struggling with lung cancer, most patients suffer surgery, radiotherapy, chemotherapy and others similar to Chinese medicine "purgation method", which damage the body's healthy Qi, hurt the body fluid, and clinical symptoms are Qi and Yin deficiency. Especially in the middle-late stage lung cancer patients, as a result of excessive consumption of the tumor, the lack of nutrition intake, radiation burns, the damage of chemotherapy, etc., fluid loss is much greater. Therefore, for some patients undergoing radiotherapy, chemotherapy, more attention should be paid to the choice of drugs with proper property and flavor, by avoiding warm-dry drugs in treatment, so as not to "add fuel to the flames." Qi tonifying should focus on the spleen and lung, while nourishing Yin should focus on the lung and kidney. Tonifying Qi drugs like Shashen (Adenophora Stricta), Taizishen (Radix Pseudostellariae), Dazao (Jujube) are often used; while nourishing Yin drugs like Maidong (Radix Ophiopogonis), Shihu (Dendrobium), Shengdihuang (Unprocessed Rehmannia Root), Shengbaihe (Born Lily) are commonly used. Lung cancer patients once appearing Qi and Yin pathogenesis, symptoms including cough with little sputum, shortness of breath and tiredness, medicinal pair of Shashen (Adenophora Stricta) and Taizishen (Radix Pseudostellariae) may be used.

2.2 Detoxification and removing stasis method

Professor Jiang suggests, "cancer toxin" a pathological factor which leads to cancer growth and gets human body further injured. When cancer toxin settles in the lungs, Qi stagnation, phlegm accumulation, blood stasis, long-depression and pathological heat production would follow. Lung cancer patients often suffer from searing pain, fever or dysphoria thirst, yellowish and greasy fur, purple-red tongue, rapid pulse and other hot syndrome. Therefore, heat-clearing and detoxifying method is important in the treatment for lung cancer. But clinical practices should follow the principle of avoiding injury the healthy Qi. Medicinals which are frequently used by Professor Jiang in clearing heat and detoxifying are Longkui (Glycoalkaloids), Pugongying (Dandelion), Banbianlian (Chinese Lobelia), Banzhilian (Scutellariae Barbatae), Baihuangsheshecao (Hedyotis Diffusa), Shemei (Duchesnea Indica), Yuxingcao (Herba Houttuyniae), Yiyeyizhihua (Paris Polyphylla), Lufengfang (Nidus Vespae), Jinyinhua (Honeysuckle), Banlangen (Radix Isatidis) and Yeqiaomaigen (Wild Buckwheat Root), etc. Cancer toxin is the rooting cause of lung cancer and may spread to other parts of the body. Cancer toxin is the key factor of the occurrence, recurrence and metastasis of malignant tumor, as the formation of tumor belonging to a process of accumulating over a long period[4,5]. Therefore, drugs which can resolve hard lump slowly and gradually should be used.

2.3 Resolving phlegm and blood stasis method

TCM holds that "spleen problem is the source of producing phlegm, while lung is the storage place of sputum", "Many kinds of diseases are mainly caused by phlegm", and "weird disease often comes from excessive phlegm". Cancer toxin accumulation in the body can disturb the movement of lung Qi, meridian Qi activity, body fluid distribution problems, and phlegm; Qi promoting blood circulation, and Qi stagnation cause blood stasis. When cancer toxin, phlegm and blood stasis take place at the same time, they react to each other and eventually tumor is formed. Phlegm and blood stasis are the pathological product of cancer-toxin invading the lung and causing lung Qi obstruction. They are also the pathogenic causing factors of the vital Qi deficiency. When cancer-toxin accumulation forms, the lung cancer occurs. Drugs commonly used in eliminating sputum and softening hard mass are Xiakucao (Selfheal), Haizao (Seaweed), Kunbu (Kelp), Huangyaozi (Airpotato Yam Rhizome), Shancigu (Pleione Bulbocodioides), Jiegeng (Platycodon Grandiflorum), Tinglizi (Pepperweed Seed), etc., they all have obvious antitumor effect. Commonly used in promoting blood circulation to remove blood stasis drugs such as Ruxiang (Olibanum), Moyao (Myrrh), Yujin (Radix Curcumae), Danshen (Salviae Miltiorrhizae), Chuanxiong (Rhizoma Chuanxiong), Chishao (Radix Paeoniae Rubra), Jixueteng (Spatholobus Suberctu), Honghua (Flos Carthami), etc. Clinical trials suggests that Yiqi Qinghua Paste can improve the level of the expression of mucin

E-calcium, thus increasing the adhesion ability among tumor cells and reducing tumor cell falling off into the surrounding tissue and blood vessels; by lowering the expression of CD44 and CD44v6 level and weakening the heterogeneous adhesion between tumors cells and vascular endothelial cells, between tumors cells and extracellular matrix, the migration of tumor cells would be suppressed, thus playing the role of inhibiting tumor growth and metastasis[6].

3 Summary

Professor Jiang believes that lung cancer is mainly related to Qi deficiency and Yin deficiency. Both Qi and Yin deficiency of lung cancer usually exsit throughout the lung cancer pathogenesis, which brings about pathological changes of phlegm, blood stasis and toxin accumulation, which belong to the excess aspect. Benefiting Qi and nourishing Yin, detoxicating and removing stasis, phlegm and blood stasis elimination method would be the fundamental principle of TCM in treating for middle-late stage lung cancer[7]. How to deal with the relationship between the deficieny and excess would be the key tactis. First of all, benefiting Qi and nourishing Yin, and detoxicating and removing stasis, phlegm and blood stasis method are complementary to each other and can react to each other in human body, in which helping the healthy Qi is fundamental while eliminating pathogenic factor is the purpose. In order to improve the curative effect, both must be taken into account. Treatment with traditional Chinese medicine should combine the conditions of disease and syndrome differentiation. TCM therapy combines with surgery, radiotherapy and chemotherapy would be beeter. The general rules of clinical therapy is giving priority to strengthening healthy Qi and eliminating evil. Strengthening healthy Qi means giving priority to tonifying Qi and Yin. The focus of tonifying Qi is spleen Qi and lung Qi, while the focus of nourishing Yin is lung Qi and kidney Qi. At the same time, the focus of eliminating evil is detoxificating, resolving hard lump and removing phlegm and blood stasis. Treatment should be carried out in stages. For early lung cancer, the evil prevails and the healthy Qi is not in obvious deficiency, traditional Chinese medicine is giving priority to eliminating evil, and strengthening the body health Qi; In the middle stage, evil factor becomes deficiency and healthy Qi recovery is made gradually, eliminating pathogenic factors and at the same time, strengthening healthy Qi should be applied in treatment. TCM therapy should take priority over all other cures for the sake of deficiency Qi and organs function to supplementing Qi and nourishing Yin, protecting stomach Qi namely the digestion, in order to reduce the complications and adverse reaction, to prolong the life time of the patients.

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· Foundation and Theory ·

Study on the Relationship between the Anti-tumor Effect and Toxicity of New Chinese Medicine

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ABSTRACT: Effective ways to develop effective and low toxicity anti-cancer Chinese medicine are as follows: ①By being combined medicine effects and toxicity in the evaluation of new anti-tumor drugs, the anticancer effect of Chinese medicinal material, toxic components and medical material without toxicity is compared and studied. And the scientific method of conserving effect and detoxification (reducing toxicity) is explored. ②By anticancer medicine toxicology experimental animal modeling, the toxicity of anticancer Chinese medicine is evaluated. ③Based on traditional Chinese medicine (TCM) theory with the curative effect as focus, the relationship of anti-cancer effect and toxicity is studied. By animal modeling and multi-target screen modeling are extablished TCM anti-cancer drugs with more effectiveness and less toxicity is developed and the medical mechanism is illustrated.

KEYWORDS: new Chinese medicine; reducing toxicity; "anticancer medicine toxicology experiment animal model"; "effect-toxicity" relationship

Cancer is one of the main injuring chronic diseases for people's health[1]. According to the annual report by National Cancer Registration Center, cancer incidence in nations cancer registry regions was 285.91/100 000 in 2009, ranking the first in city and the second in rural areas as cause of death. Due to the great adverse reactions of western anticancer drugs, the development of Chinese medicines and natural antineoplastic drugs were paid more and more attention of researchers in recent years. The anticancer Chinese medicines have been found toxic, and violent in nature to human body, when toxicity of them are what their therapeutic effect come from. Developing kinds of new anticancer Chinese medicine by which good clinical effect can be achieved and toxicity can be reduced to the least amount has become focus of research. This paper deals with the relationship between new Chinese medicine's anticancer effect and toxicity reducing, aiming at balancing two of them in anticancer practices.

1 Treating with poisonous agents——one of the principle of treating cancer by TCM

The modern term of "cancer" is not found in ancient Chinese medicine classics, however, the terms of "mass", "accumulation", "aggregation", "xuanpi", "expansion", "ye ge" in ancient literature means similar to the modern term for cancer. Cancer is mainly caused by "pathogenic poison" and closely related to zang-fu viscera deficiency and their unbalanced functions, emotional depression and blocked Qi transformation. With external pathogen and improper diet, the Qi stagnation and blood stasis, or accumulating dampness becoming heat or phlegm, or accumulating heat becoming heat-toxicity; when these pathologic products become stagnation or pathogenic poison within body, tumors are induced. Based on clinical practices and modern researches, Professor Zhou Zhongying suggested that "cancer toxin", with characters of infiltration, relapse and flow, is the special pathogenic factor in causing tumors. A variety of pathogenic factors leading to disordering the zang-fu function is its actual pathogenesis[2]. "Cancer toxin" was defined as "formed and continuously neoformative cancer cells or block formed by cancer cells" by Professor Ling Changquan[3]. He believed "cancer toxin" was the core pathogenesis of malignant tumors,

and can be combined with many other pathological factors by diffusion, resulting in further changes. According to these ideas, "treating with poisonous medicinals" has become the common practice of modern TCM clinical treatment for cancer.

"Treating with poisonous medicinals" is a clinical method in treating diseases caused by accumulation of pathogenic poison using drugs with acute toxicity and strong in nature. In other words, it is aimed at injuring or inhibiting in cancer cells and inducing cancer cell apoptosis to kill cancer cells eventually. It is worth noting that cancer are generally higher degree of malignant tumours developing faster, and violent, with serious symptoms, and patients often quickly suffer from progressive weight loss and cachexia. By principle of "strengthening body's immunity power and supporting health energy", TCM treatment choses to strengthening healthy Qi to improve the ability to resist tumor and control the development of it. Therefore, "treating with poisonous medicinals and strengthening body's resistance power can be used simultaneously, and can inhibit cancer toxin and slow down the progress of tumors or even achieve the purposes of controlling and cure of cancer". Professor Zhou Zhongying[2] suggested that "anticancer and detoxification method" should be the main tactics in treatment of tumor being a positive and active treatment measure. By analyzing his clinical practices, we found that anticancer and detoxification medicinals are most frequently used, such as Wugong (Centipede), Zhidannanxing (Rhizoma Arisaematis), Banxia (Pinellia Ternate), etc. These toxic drugs are often used in his prescriptions as principal medicinals. Sun Bingyan[4] believed that "cancer toxin" was the basic cause of cancer's occurrence, development and change. Once the "cancer toxin" accumulating, it may grow and deteriorate fast, which would lead to the deficiency of essence, blood and Yin. So measures like "treating with poisonous medicinals, purgation, removing blood stasis and promoting Qi, resolving phlegm and mass" and other methods based on eliminating pathogenic factors should be adopted in treatment for cancer in order to achieve satisfactory therapeutic effect, with commonly used drugs of "poisonous medicinals" are Banmao (Mylabris), Chansu (Toad Venom), Baipishi (Arsenolite), Lusha (Sal-ammoniae), Liuhuang (Sulfur), Xionghuang (Realgar), Lüfan (Copperas), Chanchu (Toad), Jinqianbaihuashe (Bungarus Parvus), Wugong (Centipede), Quanxie (Scorpion), Fengfang (Nidus Vespae), Huangyaozi (Dioseore Bulbifera), Longkui (Solanum Nigrum), Jixingzi (Semen Impatientis), Banzhilian (Scutellaria Barbata), Sancigu (Pseudobulbus Cremastrae Seu Pleiones), Tubeimu (Bolbostemma Paniculatum) and Langdu (Euphorbia), etc. He emphasizes that when using "poisonous medicinals", the severity of diseases, constitutions of patients, compatibility of medicinals, and methods of taking medicine should be differentiated and treated differently. Professor Liu Weisheng[5] suggested that if "cancer toxin" was deep rooted in body, only in "treating with poisonous medicinals method" should be used to eliminate pathogenic factors. Professor Liu usually uses methods of "heat-clearing and detoxifying, treating with poisonous medicinals, activating blood and dissolving stasis, reducing phlegm and resolving masses" by skillfully using drugs such as Wugong (Centipede), Banzhilian (Scutellaria Barbata), Quanxie (Scorpion), Baihuasheshecao (Hedyotis Diffusa) according to their nature of toxin.

Study of the single medicinal suggests that Banmao (Mylabris), Pishuang (Arsenic) and Shedu (Snake Venom) are typical representatives of "treating with poisonous medicinal" in treating for cancer. Treating malignant tumor with Arsenic in TCM has a long history. *Compendium of Materia Medica* written by Li Shizhen says, "Arsenolite is a kind of hyper-toxic drug, while Arsenic is more toxic than it. Just a little quantity of arsenic can kill mouse or bird and if cat or dog eats them, they will die too." In modern clinical practices, As_2O_3, being the main chemical constituent of Arsenic, is used to cure chronic myeloid leukemia

(CML). Snake and snake venom was also been studied as animal toxin in ancient times, with the antitumor effect has been one application among other. Researches prove that one of the features of snake venom is much stronger in cytotoxicity, in inducing apoptosis and regulating or enhancing immunity, etc. For instance, it is cytotoxic and growth-inhibitory to lung cell line AG-ZY-83a, human gastric carcinoma cell line MG-80, human hepatoma cell Bel-7404 and promyelocytic leukemia cell HL-60[6].

2 Commonly used anticancer but toxic Chinese medicine

83 kinds of toxic Chinese medicine are listed in *China Pharmacopoeia* 2010 *Version*[7]. Among them, there are 10 hyper-toxic ones, 42 toxic ones and 31 hypo-toxic ones, with commonly used ones are Banmao (Mylabris), Quanxie (Scorpion), Wugong (Centipede), Beidougen (Asiatic Moonseed), Tiannanxing (Rhizoma Arisaematis), Banxia (Pinellia Ternate), Langdu (Euphorbia), Wutou (Aconite), Jinqianbaihuashe (Bungarus Parvus), Baiqucai (Celandine), Kuxingren (Bitter Almond), Yadanzi (Khosam), Jixingzi (Semen Impatientis), etc. The toxicity of Huangyaozi (Dioscorea bulbifera L), Binglang (Areca Catechu) and Tenghuang (Gamboge), being not recorded in the Pharmacopoeia, also has been discovered after clinical and toxicological studies.

3 The relation between toxicity and anticancer effect of typical anti-tumor Chinese medicine

3.1 Anti-tumor Chinese medicine in the market

At present, the anti-tumor drugs of TCM with Chinese patent in the market are mainly developed from toxic Chinese medicine. For example, cantharidin comes from mylabris (Banmao). Mylabris being heat in nature and acrid in taste, hyper-toxic can break blood and eliminate mass and phagedena in efficacy. It has been used to cure "mass, stubborn dermatitis, scrofula, excrescence, carbuncle not ulcerated, malignant sore and dead muscles" for more than 2 000 years[8]. It is an anti-tumor Chinese medicine discovered and applied earliest in China. Cantharidin, being an effective anti-tumor component of Mylabris, has intense irritant toxic and can seriously stimulating the urinary system. For another example, Catharanthus is a traditional medicinal plant, being used in the treatment of diabetes, hypertension, malaria, diarrhea and skin diseases. The alkaloid fraction of Catharanthus (such as vinblastine and vincristine) has anticancer effects by inhibiting tubulin assembly, preventing mitotic spindle formation, and lead to the mitotic arresting in metaphase. Although vinblastine has strong neurotoxicity, and may increase the frequency of chromosome abnormalities or even other components of alkaloid fraction of Catharanthus are more toxic than the above two, Catharanthus has been applied in treatment for cancer[9]. Besides, Colchicine has significant anticancer effect with narrow range of treatment dose and liver being the major site of metabolism and toxic target organ. As to the main component of Pishuang (Arsenic) As_2O_3, which has carcinogenic, teratogenic, mutagenic, neurotoxic, and nephrotoxic effect, still has anticancer effect in inhibiting the division and proliferation of endothelial cells and angiogenesis. Last, the main effective component of Tenghuang (Gamboge) is gambogic acid, which can inhibit tumor growth for its cytotoxicity.

3.2 Anti-tumor Chinese medicine in research phase

Early in AD 500 – AD 600, Huangyaozi (Airpotato Yam) had been used in treatment for the diseases which are equivalent to goiter, gastric cancer, colorectal cancer, sore throat, pharyngitis, metrorrhagia in modern medicine and especially in treating for goiter and pleomorphic carcinoma[10]. Pharmacological studies suggest that although Huangyaozi (Airpotato Yam) is a kind of anticancer medicinal, its adverse effects, such as drug induced liver injury, toxic renal lesions, etc. has also been found in clinical applications and animal experi-

ments. Aconitum alkaloids are the toxic and effective components of Chinese medicine Aconitum but there are few studies about its toxicity[11]. They can inhibit neuronal growth in current researches. By studying the effect of aconitum alkaloid to the proliferation cycle of rat retinal neurons and bcl-2 gene expression, Rao Chao-long and others[12] found that aconitum alkaloid can increase the bcl-2 gene expression while it injuries the rat retinal neurons, but the mechanism of its neurotoxicity still needs further research. In recent years, although the toxicity of Rhizoma Arisaematis is obvious (for instance, strong stimulation to mouth, throat and skin and hyper-toxicity to heart, lung and kidney), many research data suggest that the extract of Rhizoma Arisaematis can inhibit experimental tumors like sarcoma S180, hepatic carcinoma and entity type U14 (squamous cell carcinoma) significantly[13].

4 Research method of "effect-toxicity" relation

The treatment for tumor with traditional Chinese medicine has a long history, therefore anti-tumor Chinese medicine is one of the focuses in domestic new drugs developing area. In recent years, the research of extracting effective anti-tumor components or effective parts from Chinese medicine to develop anti-tumor drugs, or composing Chinese herbal compound based on TCM theory are drawing more attention with the development of science and technology. As the existing anticancer toxic herbs are various in kind, the "treating with poisonous medicinal" theory is of great significance new drug development. Since most anti-tumor drugs are often associated with serious adverse reactions, non-clinical trials of anti-tumor drugs are different from others. It's considerable in non-clinical researches of anti-tumor drugs to study seriously and scientifically, with a set of effect-toxicity relation research and development project to support the following clinical trials by reserving effective components of anti-tumor medicinals as much as possible and keeping their efficacy while limiting their toxicity to a minimum degree.

4.1 The relation between "effect" and "toxicity" of anticancer drugs

As a Chinese saying goes, "While water can keep a boat afloat, it can also overturn it". It means everything has two sides, included toxic Chinese medicine. Although it is a toxic drug, efficacy exists in its other side. *Jingyue Quanshu* said that "the toxicity of drugs can treat diseases; because of their four natures and five flavors, where toxicity exists". It should be fully aware that efficacy of anticancer drugs probably just associates with their toxicity, and it may not be the exact efficacy of anticancer new drug of Chinese medicine by screening anticancer drugs in various attenuating ways. Therefore we should treat the relation of "effect-toxicity" in the evaluation of anticancer Chinese medicine as a key issue in new drug researches, by comparing the efficacy and components of toxic drugs with non-toxic ones, thus identifying the coincidence degree between toxicity and efficacy. After this step, further researches can be taken accordingly.

4.2 Study of the relation of "effect-toxicity" of anticancer drugs

Modern pharmacology experiments have demonstrated that toxic component of some Chinese medicinal is just the important what its wide efficacy comes from. The idea "where there is a disease, there are corresponding toxic drugs" in TCM has explained the "effect-toxicity" relation study in early stage. It means "when the diseases are cured using toxic herbs, the patients' body would not be injured by the toxicity at the same time" according to Zhang Jingyue. Our ancestor's recognition of "effect-toxicity" relation tells us that we should focus on the relation between drugs and body. When medicine is used on a disordered body, the toxicity within the medicine will have an obvious effect on the disease itself. When medicine is used on a normal body, human body would get injured by the toxicity. TCM believes "cancer toxin" is the core cause of occurrence and development of cancer and the character

of anticancer drugs is just "treating with poisonous medicinals". So when screening model of animal or multi-targets, study model is to be estatlished. Study of the relation of "effect-toxicity" of anticancer drugs should be based on TCM theory. The "model of cancer toxicological experiment on animal" should be established based on TCM theory too when evaluating the toxicity and efficacy of anticancer Chinese medicine. When its clinical effect is more obvious than toxic injuries, its toxicity should be tolerated[14].

4.3 Research method of conserving effect and detoxification (reducing toxicity)

Generally, the nature and effect of most toxic medicine is strong and easy to get human body injured even when used with small dosage. However, it's worth being noticed that not all toxic Chinese medicinals are anticancer ones and not all toxic components are anticancer ones. Therefore establishing a scientific method of conserving effect and detoxification (reducing toxicity), which is the key step in developing effective, safe and low toxic new anticancer Chinese medicine, efficacy study should be combined with toxicity study, with retaining anticancer efficacy components as the first purpose. According to the characteristics of each anticancer medicinal after crude processing and the decoction pieces after deep processing, based on the physicochemical properties of the main toxicity components in anticancer Chinese medicine modern chromatographic analysis and fingerprint map technique would be used to analyze the change of main toxic or effective components before or after processing under different process conditions.

5 Discussion

Due to the great adverse reactions caused by western medicine anticancer drugs, the development of Chinese medicine and natural antineoplastic drugs has been paid more attention by researchers in recent years. The anticancer Chinese medicine has been found toxic, strong in nature, and fierce in effect. However, the toxicity of it is also found to be related to its therapeutic effect. So cancer is treated with TCM usually by method of "treating with poisonous medicinals". When safety of new drugs is paid much attention, the relation of "effect-toxicity" becomes the focus in anticancer medicine research.

Based on the analysis of cancer pathogenesis, the clinical and experimental study based on "treating with poisonous medicinals" theory, the following three ideas are proposed: ①The method of combinating medicine effects and toxicity in the evaluation of new anti-tumor drugs should be adopted by comparing the clinical effect of original medicinal, its toxic constituents (components) and medical material without toxic constituents. The scientific method of conserving effect and detoxification (reducing toxicity) can be set up. ②Animal screening model and multiple targets model of anticancer medicinal based on TCM theory should be estabished to study the effect-toxicity relation. ③Anticancer drugs would function with effectiveness and little toxic based on TCM theory, in which less toxicity can be tolerated in order to achieve greater curative effect.

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· Clinical Study and Application ·

Clinical Observation of Chinese Medicine Treatment Combined with Concurrent Radiochemotherapy for Non-small Cell Lung Cancer

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ABSTRACT: Objective: To explore and evaluate the clinical effects and safety of Chinese medicine combined with concurrent radiochemotherapy for non-small cell lung cancer. Methods: 166 patients with NSCLC were divided as therapy group and control group randomly and evenly. The patients of control group were cured with concurrent radiochemotherapy including chemotherapy with paclitaxel and cisplatin and radiotherapy with X-ray, while the patients of therapy group were given Chinese medicine Aidi injection in addition to that of control group. The clinical effects, karnofskym (KPS), quality of life (QOL) scores and adverse effects were observed and compared. Results: The total effective rate of the therapy group (86.8%) was significantly higher than that of the control group (71.1%) ($P < 0.05$). The scores of KPS and QOL of therapy group were significantly higher than those of the control group ($P < 0.05$). The incidence rate of adverse effects of the therapy group was lower than that of the control group instead ($P < 0.05$). Conclusion: Chinese medicine combined with concurrent radiochemotherapy has the advantage of better clinical effect when compared with sole concurrent radiochemotherapy. Chinese medicine can significantly lead to a synergistic effect on antitumor treatment and relieve the toxic side effects produced by concurrent radiochemotherapy.

KEYWORDS: non-small cell lung cancer (NSCLC); radiotherapy; chemotherapy; Aidi injection; paclitaxel; cisplatin

Due to the issues of environment pollution and changing lifestyles, the incidence of non-small cell lung cancer (NSCLC), frequently occurred on adults aged 40 – 70 years, has risen prominently. The diagnosis of early stage NSCLC is difficult because its pathogenesis is covert without typical clinical symptoms, and over 80% of the patients are in middle or advanced stage when clinically confirmed, thus they miss the best opportunity for operations and could only rely on chemotherapy or radiotherapy for treatment[1]. However, chemotherapy or radiotherapy has certain adverse reactions on normal cells when they kill cancer cells, and results in great pain on patients. Chinese medicine combined with concurrent radiochemotherapy could positively intervene patients' clinical symptoms and immune functions, hence improve their life quality. This study aims at analyzing the clinical effects and safety of Chinese medicine combining with concurrent radiochemotherapy for NSCLC, and offers scientific theoretical basis for clinical treatment.

1 Materials and methods

1.1 Information

166 study objects were chosen from NSCLC patients in TCM Hospital of Rongshui Miao Nationality Autonomous County, as well as inpatient and outpatient department of oncology in TCM Hospital of Liuzhou, dated from October 2009 to May 2013. All the patients' clinical symptoms and the results of pathological and radiological examinations were in accordance with the diagnostic criteria of NSCLC established by NCCN in 2011[2]. Their tumor lesions could be objectively measured and they underwent kamofsky (KPS) evaluation to assess their physical and health conditions after first admission to hospital. Patients were randomly divided into therapy group and control group by visiting sequence, with 83 patients in therapy group, including 48 male and 35 female, aged (57.8 ± 8.2) years old, 44 cases of adenocarcinoma and 39 cases of squamous cell carcinoma. And with 83 patients in control group, in-

cluding 49 male and 34 female, aged (57.1 ± 10.7) years old, 48 cases of adenocarcinoma and 35 cases of squamous cell carcinoma.

After a detail research on patients, it was sure that two groups had no significant differences on the aspects of sex, age, disease condition, KPS score and various examination indexes ($P > 0.05$), which assure their comparability. This clinical study has been approved by Hospital Ethical Committee, the significance and advantages of using Chinese medicine combined with concurrent radiochemotherapy for NSCLC had been explained to patients and their families in details beforehand. Informed Consent Form were signed by all patients.

1.2 Inclusion criteria[3]

①Patients were enrolled in accordance with the diagnostic criteria of NSCLC established by NCCN in 2011; ②patients with their KPS score of physical and health condition is not lower than 60 points; ③patients with their life-expectancy more than 3 months; ④patients had no severe disease detected in examinations of blood routine, urine routine, electrocardiogram, blood glucose and lipid as well as liver and kidney functions; ⑤patients who stopped receiving other anti-tumor therapies for no less than 1 month and are willing to accept Chinese medicine combined with concurrent radiochemotherapy.

1.3 Exclusion criteria[3]

①Patients with serious combined cardio-cerebrovascular disease, respiratory disease, digestive disease, diabetes, hematologic disease, tumor or patients with primary disease of liver and kidney function deficiency; ② combined patients with respiratory failure, heart failure, myocardial infarction and angina pectoris; ③ patients who were allergic or prohibited with the applied anti-tumor medicine.

1.4 Therapeutic method

Concurrent radiochemotherapy was applied on the control group, with intravenous infusion of 175 mg · m^{-2} paclitaxel injection (product name: Anzatax, Foldin Pharmaceutical Factory of Keding Co., Ltd., Australia; registration number: X20010120). The whole injection process lasted over 3 hours, once in 3 weeks. Meanwhile, intravenous drip injection of 50 mg · m^{-2} Cisplatin (QiLu Pharmaceutical Co., Ltd., number: H37021358) was done once in 3 weeks. In order to avoid tissue necrosis and phlebitis caused by drug exosmosis, the cannulas were accurately placed and well fixed in intravenous infusion. Dexamethasone or Promethazine could be applied for prophylactic use before Paclitaxel injection, to avoid serious allergic reactions. Radiotherapy used linear accelerator to radiate 6MVX ray, targeting at primary tumor, mediastinum, hilar lymph nodes and supraclavicular areas, with 2.0Gy once per day, 5 times a week. When gray unit reached 40 Gy, the targets were only limited to primary tumor and lymph node, with total dose for radiotherapy was about 60 – 70 Gy for 6 weeks therapy.

The therapy group was given Chinese medicine Aidi injection (produced by Guizhou Yibai Pharmaceutical Co., Ltd., number: Z52020236) on the basis of all measures taken on control group. Intravenous infusion was done once a day with medicine dissolved into saline. Two groups' clinical effects and adverse reactions were observed.

On the basis of anti-tumor treatments such as Chinese medicine and radiochemotherapy, we offered appropriate psychological and daily life care to all patients according to their specific conditions, and encouraged them to accept the treatments with positive attitude and to cultivate healthy living habits. To avoid being overwork, to quit cigarette and alcohol, and to maintain a positive mind are all helpful in conquering disease.

1.5 Efficiency criteria

Serial evaluations on patients' recovery were made based on their clinical symptoms (such as coughing, fatigue, bloody sputum, fever, dyspnea and chest pain), tumor condition and radiological examination (such as X-ray, CT, MRI and abdominal ultrasound), as well as KPS score. Patients' qualities of life were evaluated on the aspects of appetite, spirit, sleeping condition, fatigue, pain, understanding and cooperation from family

and friends, self-recognition and attitude as well as adverse reactions of therapy. The better the recovery was, the higher the score would be[4]. Clinical effect was marked by four standards: markedly effective, effective, ineffective and dead. Markedly effective: obvious improvements on various clinical symptoms; KPS score was not lower than 80; QOL score 46 – 60. Effective: fine improvements on clinical symptoms; KPS score 60 – 80, QOL score 31 – 45. Ineffective or dead: no obvious improvement on clinical symptoms; KPS score was lower than 60; QOL score lower than 30.

1.6 Statistical analysis

SPSS 16.0 was used to perform statistical analysis. Measurement data was marked by mean value ± standard deviation ($\bar{x} \pm s$), with t as the tester, while enumeration data was marked by case (percentage), with "χ^2" as the tester. $P < 0.05$ was considered to be statistically significant.

2 Results

2.1 Comparison of clinical effects of two groups

See Table 1.

Table 1 Comparison of clinical effects of two groups Cases (%)

Groups	n	Effectual	Effective	Ineffective or dead	Effective rate
Control	83	33(39.8)	26(31.3)	24(28.9)	59(71.1)
Therapy	83	54(65.1)	18(21.7)	11(13.2)	72(86.8)
χ^2		17.73	3.78	22.15	13.88
P		<0.05	<0.05	<0.05	<0.05

2.2 Comparison of KPS score and QOL score of two groups before and after treatment

See Table 2.

Table 2 Comparison of KPS score and QOL score of two groups ($\bar{x} \pm s$, points)

Groups	KPS score		QOL score	
	Before	After	Before	After
Control	63.4 ± 7.5	81.3 ± 11.5	32.3 ± 7.5	46.3 ± 11.2
Therapy	62.9 ± 6.8	94.5 ± 10.9	31.8 ± 6.7	56.4 ± 10.5
t	0.12	8.45	0.18	5.38
P	>0.05	<0.05	>0.05	<0.05

2.3 Comparison of adverse reactions of the two groups

Patients in both groups underwent examinations on blood routine, urine routine, electrolyte, blood glucose, liver and kidney functions during administration. In the control group, 8 cases (9.6%) of allergy appeared, along with 58 cases (69.9%) of myelosuppression, with prominent decrease on leukocyte, platelet, hemoglobin and neutrophil, 46 cases (55.4%) of gastrointestinal reaction like nausea and vomiting, 48 cases (57.8%) of radiation esophagitis and 36 cases (43.4%) of radiation pneumonitis. In the therapy group, 3 cases (3.6%) of allergy were observed, along with 35 cases (42.2%) of myelosuppression, with prominent decrease on leukocyte, platelet, hemoglobin and neutrophil, 27 cases (32.5%) of gastrointestinal reaction like nausea and vomiting, 28 cases (33.7%) of radiation esophagitis and 20 cases (24.1%) of radiation pneumonitis. The data above illustrated that the adverse reaction rate of the control group was obviously higher than that of therapy group ($P < 0.05$), which suggests that Chinese medicine with concurrent radiochemotherapy could significantly reduce the adverse reactions caused by radiochemotherapy.

3 Discussion

The early stage of NSCLC is difficult to be spotted for its lack of typical clinical symptoms, and the majority of patients is in middle or advanced stage when clinically proved to have NSCLC, thus they miss the best opportunity for operations and have to choose chemotherapy or radiotherapy in treatment. Sole radiotherapy or chemotherapy has limitations. Chemotherapy could exterminate metastatic cancer cells that come from afar, but its effect on local lesion is far from satisfaction, while radiotherapy could control local cancer cells to the largest extent, but it fails in exterminating micro cancer cells in metastasis. As a result, concurrent radiochemotherapy is the most effective treatment for advanced NSCLC in practice. On one hand, chemotherapy could increase the sensitivity of local tumor lesion towards radiotherapy, and radiotherapy could increase the cytotoxicity of chemotherapeutic drug to a certain degree, improve its effectiveness on local tumor, eliminate the possibility of tumor cells' accelerated repopulation

afterward, and hence increase the survival rate of patients[5]. On the other hand, chemotherapy could exterminate existed micro metastatic lesions and reduce the metastasis rate of tumor lesion, while radiotherapy could improve the effect of chemotherapy on local primary lesions[6]. Chemotherapy and radiotherapy could cooperatively control primary lesions and the metastasis of micro lesions; as a result they could shorten the treatment cycle of NSCLC, accelerate patients' recovery and improve their qualities of life.

Concurrent radiochemotherapy has significant clinical effects on NSCLC. However, it would incur adverse reactions, such as fever, gastrointestinal reaction like nausea and vomiting, myelosuppression, radiation esophagitis, radiation pneumonitis and radiodermatitis during the elimination of tumor cells. When serious adverse reactions happen, patients have to stop receiving treatment. Therefore, how to reduce the side effects and increases its clinical effects of concurrent radiochemotherapy for NSCLC has become a hotspot in study of oncology home and abroad.

By far, traditional Chinese medicine diagnosis is usually clinically separated from western medicine diagnosis. Chemotherapy and radiotherapy are classified as western therapies, and few doctors would prefer to choose integrated methods to improve treatment effects. In recent years, more and more clinical studies have proved the effectiveness and safety of integrated therapy, and valuable experiences and references have been offered for integrated clinical therapy of NSCLC. Western medication emphasizes on exterminating tumor cells on targeted lesions, or reducing the influence range of tumor, in the purpose of prolonging patients' lives and improving their qualities of life, while Chinese medication focuses on human's immunity, as well as, harmony of blood and Qi within human body, to improve the basic physiological functions and nutritious status. This study aims at offering better scheme for clinical NSCLC treatment by means of TCM combined with concurrent radiochemotherapy, in the hope of improving therapy effects, patients' qualities of life and lessening adverse reactions and in this way enhancing the comprehensive clinical diagnosis and curing level of the hospital.

The main compositions of Aidi injection are extracts of Banmao (Mylabris), Renshen (Ginseng), Huangqi (Astragalus) and Ciwujia(Acanthopanax Senticosus), which are refined and processed with modern formulation technology. They have prominent effects on heat-clearing, detoxifying and removing blood stasis, and are frequently used in treatment for primary liver cancer, lung cancer, rectal cancer, malignant lymphoma and gynecologic malignant tumor. The main components of these Chinese medicines are nor cantharidin, ginsenoside, astragalus saponin and acanthopanax senticosus polysaccharide. Nor cantharidin can not only induce the apoptosis of tumor cells, but also accelerate the splitting of marrow stem cells and increase leukocytes without causing myelosuppression[7]. Ginsenoside and astragalus saponin could greatly activate cell viability, improve immune and anti-fatigue functions, strengthen the influence of marrow stromal cells and hematopoietic stimulating factors, recover the marrow hematopoietic function and significantly relief myelosuppression caused by radiochemotherapy. Acanthopanax senticosus polysaccharide can strengthen specific and non specific immune functions in cells, increase immunoglobulin and antibodies, improve immunity and have anti-tumor effects[8-10]. These Chinese medicines cooperatively exterminate tumor cells, meanwhile prominently relief the side effects caused by radiochemotherapy, improve patients' immunities and qualities of life, such as leading to better sleeping, appetite and physical condition, and help patients to build up better physical and spiritual conditions when receiving radiochemotherapy.

The result of this clinical study illustrates that the clinical effects of Chinese medicine Aidi injection combined with concurrent radiochemotherapy for NSCLC is significantly superior to sole radiochemotherapy, since it can improve patients' health conditions physically and mentally, enhance short-term and long-term effects of therapy and the quality of patients' life by reducing the adverse reactions caused by radiochemotherapy.

This integrated method has obvious synergistic effect with low rate of adverse reaction and gains high satisfaction among patients and their families.

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· Clinical Study and Application ·

Clinical Research on Shengmai Injection Combining with Ambroxol Hydrochloride in Preventing Acute Radiation Pneumonitis

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ABSTRACT: Objective: To observe the effect of Shengmai injection combining with ambroxol hydrochloride in preventing acute radiation pneumonitis. Methods: 64 old chest tumor patients treated by three dimensional conformal radiotherapy were randomly divided into control group and treatment group. Patients in control group simply received radiation therapy, and those of treatment group were given ambroxol hydrochloride combining with Shengmai injection at the beginning of radiotheropy. The pathogenesis of acute radioactive pneumonia of two groups was compared. Results: The acute radioactive pneumonia incidence of treatment group was significantly lower than that of the control group ($P < 0.05$). The time of acute radioactive pneumonia in treatment group was obviously delayed, significantly ($P < 0.05$). Conclusion: The treatment of Shengmai injection combining with ambroxol hydrochloride has significant effect on preventing acute radiation pneumonitis.

KEYWORDS: acute radiation pneumonitis; ambroxol hydrochloride; Shengmai injection

The incidence of radiation pneumonitis in elder patients received thoracic radiotherapy is higher, with acute radiation pneumonitis or chronic pulmonary fibrosis as the main outcome, which seriously affect the prognosis and quality of patients' life. Because of the wide variety of medical disorders in elder patients, the use of glucocorticoids and antibiotics is somewhat restricted. The treatment of Shengmai injection combining with ambroxol hydrochloride has achieved a significant benefit in preventing acute radiation pneumonitis. We report it as follows.

1 Materials and methods

1.1 Information

64 elder patients who accepted thoracic radiotherapy in Affiliated Hospital of North Sichuan Medical College from September 2011 to September 2012 were selected to participate the experiment. All of them had no serious complication diseases (such as heart, liver, kidney and other organ dysfunction) and their score of karnofsky performance status (KPS) were not less than 70. All the patients were randomly divided into the control group (31 cases with 18 males and 13 females) and the treatment group (33 cases with 21 males and 12 females). In the control group, there were 10 cases of lung cancer, 19 cases of esophageal cancer, 2 cases of non-Hodgkin's lymphoma. Among them, 24 cases of patients were 60 – 69 years old, 7 cases of patients were older than or equal to 70 years old. In the treatment group, there were 10 cases of lung cancer, 22 cases of esophageal cancer, 1 case of non-Hodgkin's lymphoma. 29 cases of patients were 60 – 69 years old, 4 cases of patients were older than or equal to 70 years old. The two groups' differences of general information (gender, age, pathological type, etc.) had no statistical significance ($P > 0.05$).

1.2 Therapeutic method

All patients were treated with three-dimensional conformal radiotherapy irradiation [(1.8 – 2.0) Gy/f, 5 f/w × (5 – 7) w, DT (50 – 66) Gy]. People in the treatment group accepted supportive treatment of ambroxol hydrochloride injection (Chapter One Suzhou Pharmaceutical Co., Ltd.) and Shengmai injection (Ya'an Sanjiu Pharmaceutical Co., Ltd.) during radiotherapy. Patients in the control group were given sole radiotherapy.

1.3 Diagnostic criteria

The acute radiation pneumonitis, based on US Radia-

tion Therapy Oncology Group Standards, was divided into 5 levels (Grade 0: no change; Grade Ⅰ: mild dry, cough or difficulty in breathing after overwork; Grade Ⅱ: persistent cough, require narcotic antitussive agents, difficulty in breathing after minor labor, no dyspnea at rest; Grade Ⅲ: severe cough, narcotic antitussive no relief, dyspnea at rest, clinical manifestations of acute pneumonia or radiographic changes, needing intermittent oxygen or hormone treatment; Grade Ⅳ: severe breathing difficulties, being in need of continuous oxygen).

1.4 Observational index

All patients were respectively accepted chest CT examination at the beginning of radiotherapy, the fourth week during treatment, and the first month and the third months after treatment. The incidence, occurrence time and grading of acute radiation pneumonitis were recorded.

1.5 Statistical analysis

SPSS 19.0 was used for statistical analysis. Measurement data was marked by mean value ± standard deviation ($\bar{x} \pm s$), while t was the tester; then we used χ^2 test for analysis of enumeration data. The ordinal date was analyzed by rank-sum test, and $P < 0.05$ was considered to be statistically significant.

2 Results

2.1 Comparison the incidence and occurrence time of acute radiation pneumonitis of the two groups

There were 14 cases of patients with acute radiation pneumonitis in the treatment group and 21 cases in the control group, with the incidence of 42.42% and 67.74% respectively, and the difference was significant ($\chi^2 = 4.135$, $P = 0.042 < 0.05$). The occurrence time of acute radiation pneumonitisin in the treament group was (72.43 ± 7.99) days, which were statistically different in comparison with the control group (52.29 ± 5.76) days ($t = 2.097$, $P = 0.0437 < 0.05$).

2.2 Comparison the grading of acute radiation pneumonitis of the two groups

Table 1.

Table 1 Comparison the grading of acute radiation pneumonitis of the two groups Cases

Groups	n	Grading of acute radiation pneumonitis						
		Grade Ⅰ	Incidence of Grade Ⅰ (/%)	Grade Ⅱ	Incidence of Grade Ⅱ (/%)	Grade Ⅲ	Grade Ⅳ	Incidence of Grade Ⅲ - Ⅳ (/%)
Control group	31	4	19.5	10	47.62	6	1	33.33
Treatment group	33	7	50.0 *	6	42.86 *	1	0	7.14 *

Note: Compared with the control group, * $P > 0.05$

3 Discussion

Radiation pneumonitis is a common complication of thoracic radiotherapy, especially for elder patients. Doctors believe that the main mechanism of radiation pneumonitis include two aspects[1-3]. ① According to the classic pulmonary vascular endothelial cells and alveolar type Ⅱ cell damage theory, endothelial cells of lung capillary blood can be damaged by radiotherapy and the permeability of these cells will be increased which resulting pulmonary interstitial edema and inflammation cell infiltration. With the advance of the dose, the permeability of alveolar type Ⅱ cells can be also increased which resulting cell necrosis. If the decomposed products go into the alveolar space, the lung damnification will be aggravated and finally progress to acute radiation pneumonitis (acute phase of radiation pneumonitis). If the disease continues, the alveolar wall will be damaged and many substances such as cellulose, serum proteins will leak into alveolar wall and alveolar space, finally induce radiation pulmonary fibrosis (chronic phase of radiation pneumonitis). ②Cytokines theory: with further study, scholars have found that the classic theory could not explain all the events in the development of radiation pneumonitis. There are many cytokines which guide and sustain the entire process of lung radioactive damage. For example[4], tumor necrosis factor, transforming growth factor β1, platelet derived growth factor, interleukin 1, insulin-like growth factor 1, etc. become the focus of studies recently. In traditional Chinese medicine, radiation pneumonitis is called "pulmonary flaccidity". Radiation with heat toxin can damage the pulmonary vessels, consume the body fluid and blood, finally result in Yin and fluid de-

ficiency and lung heat blood stasis[5-7].

In this research, there are two reasons for choosing the combination therapy of ambroxol hydrochloride and Shengmai injection. In the first place, ambroxol hydrochloride can stimulate the synthesis and secretion of lung alveolar surfactant in type Ⅱ penumonocyte, increase the swing of respiratory cilia which help discharge sputum, promote the englobement effect of macrophages[8-10]. In the second place, Shengmai injection is developed from traditional medicine " Shengmaisan", which contains many commponents such as Renshen (Ginseng), Maidong (Lilyturf Root), Wuweizi (Fructus Schizandrae), et al. Renshen (Ginseng) plus Maidong (Lilyturf Root) can supplement Qi and nourish Yin; Wuweizi (Fructus Schizandrae) can astring the lung to stop cough. The combination of the three can supply body's fluids and reinforce Qi[11-13].

Previous studies of Chinese medicine treatment of radiation pneumonitis mainly focused on curative analysis of single drug (ambroxol hydrochloride or Shengmai injection). In this research, we used the above two drugs in the prevention of radiation pneumonitis. It is found that the combination therapy can significantly reduce the incidence of radiation pneumonitis happening to elder patients and can also delay the occurrence time. It is believed that the combination of Chinese and western medicine has broad prospects and deserves further study.

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· Clinical Study and Application ·

Clinical Research on Psychosomatic Treatment for Combined Allergic Rhinitis and Asthma Syndrome

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ABSTRACT: Objective: To observe the clinical curative effect of psychosomatic treatment for combined allergic rhinitis and asthma syndrome (CARAS). Methods: 62 Patients were selected with the Hamilton anxiety scale (HAMA) and Hamilton depression scale (HAMD). They were randomly divided into study group and control group. The control group was treated with Chinese medicine decoction and budesonide aerosol nasal spray, and the study group was given psychological treatment in addition to the treatment of the control group. The course of treatment lasted 4 weeks. Asthma control test (ACT) score, rhinitis symptoms score, HAMA score and HAMD score of the two groups before and after treatment were compared. Results: ACT score, rhinitis symptoms score, HAMA score, HAMD score of the two groups were improved significantly after treatment ($P < 0.05$), with those of the study group were improved more significantly ($P < 0.01$). Except the ACT score, the data of the study group and the control group, the other three items of comparison suggested statistical differences ($P < 0.05$). Conclusion: Psychosomatic treatment for combined allergic rhinitis and asthma syndrome (CARAS) has marked clinical curative effect.

KEYWORDS: combined allergic rhinitis and asthma syndrome; psychosomatic treatment; budesonide aerosol

Allergic rhinitis (AR) and bronchial asthma (BA) are common respiratory allergic disease. Clinically, the two diseases often occurred successively or simultaneously, being one of the world's sharp rising incidence diseases. The World Allergy Organization (WAO) named them as a new medical diagnostic terminology, i. e., combined allergic rhinitis and asthma syndrome (CARAS), by stressing that for the upper respiratory and lower respiratory disease joint diagnosis and combined therapy should be practiced. However, clinically CARAS is often characterized by repeated outbreak and being hard to cure. In recent years, with the establishment of the new medical model of "biological-psychological-society", a lot of research on the roles of psychological and emotional playing in the occurrence, development and prognosis of AR and BA were carried out. It is believed that AR and BA are both psychosomatic diseases. One study suggests that both anxiety and depression are psychological factors which have closely related to allergic diseases[1]. Therefore this paper discusses the medical tactics and effectiveness of the combining therapy of the upper and lower respiratory, and psychological adjuvant therapy. It is believed that physical and mental treatment can improve the curative effect for AR and BA.

1 Materials and methods

1.1 Information

From September 2012 to October 2013, 85 cases of patients of acute exacerbation of CARAS in mild and moderate degree treated in The Third People's Hospital of Zhengzhou City were selected, and Hamilton anxiety scale (HAMA) and Hamilton depression scale (HAMD) were used to evaluate the patients. 62 cases of patients in accordance with criteria were selected and randomly divided into study group and control group with 31 cases in each group. In the control group, 18 male cases, 13 female cases; the age ranged

from 18 to 63(37.6 ± 12.3) years old; course of 2 to 35(11.2 ± 6.5) years. In the study group, 16 male cases, 15 female cases; the age ranged from 18 to 65 (38.5 ± 12.6); course of 3 to 34(11.5 ± 6.2) years. There was no statistically significant difference of the two groups($P > 0.05$).

1.2 Inclusive criteria

All the patients met the diagnosis standard of allergic rhinitis and bronchial asthma[2,3], and conformed to anxiety and depression judgment criteria of HAMA and HAMD scale[4].

1.3 Exclusion criteria

Patients with severe asthma and requiring breathing machine; secondary anxiety patients with other body diseases; pregnant women and nursing mothers.

1.4 Therapeutic methods

31 cases in the control group were treated with nasal inhalation budesonide aerosol, 200 μg each time, twice a day. At the same time self-made Chinese medicine decoction was used, with composition of Mahuang (Ephedra) 5 g, Xingren (Almond) 10 g, Houpu (Magnolia Officinalis) 10 g, Huangqi (Astragalus Root) 20 g, Fangfeng (Radix Sileris) 15g, Baizhu (Rhizoma Atractylodis Macrocephalae) 15 g, Baishao (White Peony Root) 15 g, Fuling (Poria Cocos) 15 g, Jiangcan (Stiff Silkworm) 10 g, Chantui (Periostracum Cicada) 10 g, Chuanxiong (Rhizoma Chuanxiong) 10 g, Taoren (Peach Seed) 10 g, Gancao (Liquorice) 10 g. 300 mL of decoction was taken, twice a day, namely, 150 mL in the morning and another 150 mL in the evening. The study group was treated with psychological treatment based on that of the control group, including relaxation training, mood guidance, health education, etc. once in 1 h. The period of treatment of both groups is 2 weeks. The treatmetn lasted 2 courses.

1.5 Obvervational index

1.5.1 Asthma control test

25-mark system asthma control test scale[5] reported by 2005 USA Thoracic Society was used to evaluate the degree of asthma. 25 points means complete control of asthma; 20 – 24 points means well control, and below 20 points means uncontrolled asthma.

1.5.2 Allergic rhinitis symptom scores

Symptoms such as sneezing, cleaning stuff, nose blocking and itchy nose were scored based on allergic rhinitis guidelines[2] before and after treatment.

1.5.3 Psychology index

Evaluation of HAMA and HAMD scales before and after treatment, was carried out and the form were filled with guidance of professional personnel.

1.6 Statistical methods

SPSS 18.0 software was used for statistical analysis. Measurement data was marked by mean value ± standard deviation, with t as the test. Counting data was marked by case (percentage) with "χ^2" as the tester. $P < 0.05$ was considered to be statistically significant.

2 Results

2.1 Comparison of ACT score of two groups

See Table 1.

Table 1 Comparison of ACT score of two groups before and after treatment ($\bar{x} \pm s$, points)

Groups	n	Before treatment	After treatment	P
Control	31	15.67 ± 5.03	20.94 ± 2.87	< 0.05
Study	31	15.72 ± 4.81	22.65 ± 3.43	< 0.01
P		> 0.05	> 0.05	

2.2 Comparison of rhinitis symptom scores of two groups

See Table 2.

Table 2 Comparison of rhinitis symptom scores of two groups ($\bar{x} \pm s$, points)

Groups	n	Before treatment	After treatment	P
Control	31	1.73 ± 0.89	0.85 ± 0.25	< 0.05
Study	31	1.75 ± 0.86	0.31 ± 0.24	< 0.01
P		> 0.05	< 0.05	

2.3 Comparison of HAMA and HAMD scales of two groups

See Table 3, 4.

Table 3 Comparison of HAMA scale of two groups before and after treatment ($\bar{x} \pm s$, points)

Groups	n	Before treatment	After treatment	P
Control	31	26.38 ± 2.59	20.56 ± 2.62	< 0.05
Study	31	25.97 ± 7.53	12.21 ± 6.39	< 0.01
P		> 0.05	< 0.01	

Table 4 Comparison of HAMD scale of two groups before and after treatment ($\bar{x} \pm s$, points)

Groups	*n*	Before treatment	After treatment	*P*
Control	31	25.97 ± 7.98	20.78 ± 6.39	<0.05
Study	31	26.31 ± 1.58	10.51 ± 2.53	<0.01
P		>0.05	<0.01	

3 Discussion

Both AR and BA are type I allergic diseases, based on the the same pathological changes, with different clinical manifestations of eithor the upper or lower respiratory tract[6]. Therefore, CARAS is considered to be "one airway, one disease", and the correlation with emotional and psychological factors of the two diseases have been confirmed. According to a survey, nearly 68% of BA patients have different degree of anxiety symptoms, while 66% of BA patients are with depressive symptoms[7]. In 2011, a retrospective study on the relationship between AR and bad feelings suggested that subjects who suffer from both anxiety-depression and AR symptoms accounted for 99.9% and 97.1% respectively[8]. Psychological research has confirmed that when people are excessively anxiety depression, or under mental stress, their brain and endocrine system would run in disorder, and harmful substances would be released from nerve system, which can increase bronchial airway resistance and immunity imbalance, causing allergy aggravation[9].

As a highly efficient local anti-inflammatory glucocorticoid, Budesonide can control CARAS inflammation of the upper and lower airway in patients, by directly inhibiting the release and downgoing of inflammatory substances such as histamine, leukotriene and prostaglandins by nasal secretion with nasal inhalation route, so as to prevent and reduce the bronchospasm, thus reducing airway hyperresponsiveness, improving the nasal and pulmonary ventilation function[10]. Beginning with regulating the wind, phlegm, blood stasis, deficiency, feeling abnormal[11], traditional Chinese medicine treatment by syndrome differentiation, overall modulation also achieve significant results. So this study combined traditional Chinese and western medicine, treatment both symptoms and root causes, in order to further improve the curative effect.

In traditional Chinese medicine CARAS belongs to "bi-qiu" and "asthma syndrome", being recurrent, refractory lingering with patients. Its basic pathogenesis is lung Qi deficiency, exogenous pathogenic wind, wind phlegm obstruction lung. At the same time, because of the long course of disease, accumulation of phlegm and blood stasis syndrome can be seen as "long illness often leading to stasis". In view of the above pathogenesis characteristics, the author created a traditional Chinese prescription, in order to achieve "dispersing lung Qi and invigorating spleen, dispelling wind-phlegm, relieving blood stasis and asthma". In the prescription, Mahuang, Xingren, and Houpu for dispersing lung Qi and relieving asthma. Combining with Huangqi, Baizhu, and Fangfeng, replenishing and restoring lung Qi and dispelling the wind can be achieved. Xinyi, Xixin, Baizhi are used for warming nasal orifices. When combined with Chenpi, Banxia, and Fuling, invigorating spleen to eliminate dampness would realized. Jiangcan, Chantui, Chuanxiong, Taoren are used for dispelling wind, removing blood stasis and dredging collaterals, while Gancao is used to reconcile the medicine. The combination of Baishao and Gancao would have the function of relieving spasm. In treating both symptoms and root causes, not only the lung and spleen get better, but also wind and disperse blood stasis are cured, thus reducing CARAS related symptoms, and reducing the recurrence. This study adopted the method of psychological therapy such as relaxation training, cognitive therapy, emotional adjustment, group psychotherapy according to patients' different mental state. Results suggasted that drug treatment with psychological therapy can significantly eliminate patient's anxiety and depression, so as to help with the control of CARAS. Research suggests that psychological therapy can adjust and improve CARAS patients endocrine dysfunction and all kinds of abnormal hormone secretion, reduce inflammatory mediator release through cerebral cortex benign

stimulation and stability neuroendocrine system regulating function, improve the lung function through cerebral cortex benign stimulation, stability neuroendocrine system regulating function, so as to promote clinical symptom control. At the same time, psychological therapy are beneficial to ease the psychological stress, reduce the vagus nerve tension and increase immunity, reduce susceptibility to allergic reaction, so as to decrease the number of attacks for CARAS, speed up the recovery.

At present, there is insufficient study and practice in clinical diagnosis and treatment for CARAS, especially the insufficient recognition of mental disorders in patients with CARAS, this study combined drug and psychological treatment, help doctors establish the concept of mind and body being a whole unit, so that the illness can be comprehensively and effectively controlled. This requires clinicians have knowledge of psychosomatic medicine and skills of offering, synchronization therapy of physiological and psychological problem in clinical practices, so as to avoid incomplete diagnosis insufficient treatment, and eventually better curative effect can be achieved.

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· Chinese Pharmacy and Preparation ·

Modern Research and Application Characteristics Analysis of Platycodon Grandiflorum

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ABSTRACT: Jiegeng (Platycodon Grandiflorum) contains triterpenoid saponins, polysaccharides and other useful ingredients. Being a kind of Chinese medicine herb, it plays the role of removing phlegm, relieving cough, anti-inflammation, immunomodulation, antitumor, liver protection, regulating blood fat, antidiabetics, antiobesity, fatigue resistance and other pharmacological effects. Jiegeng (Platycodon Grandiflorum) contained diet and other application in curing diabetes, cardio-cerebrovascular disease will be the focus of research in the future.

KEYWORDS: platycodon grandiflorum; chemical composition; pharmacology; diet; clinical application

Jiegeng (Platycodon grandiflorum), is the dry roots of Platycodon grandiflorum plants. Being neutral in nature and sweet, acrid and bitter in flavor with tiny odor, and with meridian tropism in lung and stomach. It can release stagnated lung-Qi, soothe the sore throat, be an expectorant, get rid of pus and so on. Platycodon grandiflorum mainly contains triterpenoid saponins, flavonoids, phenolic compounds, fatty acids, inorganic elements, volatile oil contents, etc. Being a medicinal and edible herb, Platycodon grandiflorum performs extensive pharmacological tasks such as eliminating phlegm, preventing cough, liver protection, anti-inflammation, anticancer, lowering blood sugar, lowering blood pressure, immune regulation and so on. This paper summarizes and analyzes the modern researches on Platycodon grandiflorum to explore ways of its utilization in medicine.

1 Chemical compositions of Platycodon grandiflorum

Triterpenoid saponins are the main active ingredients in Platycodon grandiflorum[1], including Platycodon grandiflorum acid Class A, Class B and Polygala acid Class E, etc. Polysaccharides ingredients are Platycodonis Polysaccharides (PPS), which includes PPS80-I and PPS80-II[2,3]. Platycodon grandiflorum is rich in fatty acids with small amount of fatty oils like linoleic acid (42.79%) and 19 kinds of saturated fatty acids[4]. In addition, Platycodon grandiflorum also contains Fe, Mn, Co, Zn, Cr, Mg, Ca, Sr, Li and other trace elements. The total amino acid content of Platycodon grandiflorum is up to 15.01%[5].

2 Pharmacological effects of Platycodon grandiflorum

2.1 Expelling phlegm, relieving cough and anti-inflammation

Anesthetized dogs airway mucus secretion can significantly increase after taking in 1 $g \cdot kg^{-1}$ Platycodon grandiflorum decoction; functioning similar to chloride. To anesthetized cats, Platycodon grandiflorum decoction also has significant expectorant effect lasting over 7 hours[6]. Research[7] suggests that Platycodon grandiflorum root as well as the root bark, stems, leaves, flowers and fruits all work well being on expectorant, cough latency and cough times of mice were observed with ammonia in experiment. Mouse's tracheal phenol red secretion was used to evaluate whether the cough latency increased significantly and the frequency of cough significantly reduced or not. Compared with the blank control group, the tracheal phenol red secretion increased significantly in high and middle dose groups of mice after intaking Platycodon grandiflorum water extract. The study suggests that Platycodon grandiflorum has marked effect in relieving cough. Besides, the inhibitory function of platycodin of different dosage on

carrageenan acute inflammation and cotton induced chronic inflammation suggests that platycodin capsules work well in anti-inflammation, relieving cough, anti-asthma and expelling phlegm[8].

2.2 Hepatoprotective effect

Platycodon grandiflorum has anti-lipid peroxidation and anti-liver fibrosis effects, which can promote liver injury recovery, and improve hepatic microcirculation to protect liver cells.

Platycodon grandiflorum water extract can inhibit liver inflammation and activate hepatic stellate cells to reduce the carbon tetrachloride-induced liver fibrosis. In addition, Platycodon grandiflorum water extract can stop hepatic drug metabolizing enzyme in activating paracetamol, thus protecting liver damage caused by paracetamol. Platycodon grandiflorum also has a protective effect on liver by removing toxicity caused by peroxide tert-butyl alcohol[9].

2.3 Blood lipid regulation

Wistar rats were fed with high fat food to establish hyperlipidemia rats model. Medicines of normal saline, positive drug and platycodin solution were given by gavage. Tail vein blood was collected to detect the triglycerides (TG) level, total cholesterol (TC) level, low density lipoprotein cholesterol (LDL-C) level as well as high density lipoprotein cholesterol (HDL-C) level, apolipoprotein AI (APOAI) levels and apolipoprotein B level. The significantly regulating effect of platycodin on serum index suggests that platycodin, with functions of lowering blood fat, is an ideal natural product of improving the function of cardiovascular physiolog[10]. Platycodon is polysaccharide also has an effect of significantly reducing the serum total cholesterol and serum triacylglycerol to achieve and lipid-lowering purpose[11].

2.4 Improvement in diabetes mellitus

Using streptozotocin intraperitoneal injection with high-energy feed method to establish the diabetic rats models. With 2.8 $g \cdot kg^{-1}$ of Platycodon grandiflorum water extraction and alcohol precipitation supernatant dilution, Glucobay and pure water to rats used in gavage experiment. The sugar tolerance, the serum insulin levels (NS), insulin sensitivity index (ISI) and the morphological changes of pancreatic tissue in rats were observed. Results suggest that, compared with the model group, high dose drug group rats' glucose tolerance level, NS and ISI levels were increased, while the severity of pancreatic injury was reduced significantly, which confirms that Platycodon grandiflorum water extraction and alcohol precipitation of the supernatant part can effectively improve the glucose tolerance level of diabetic model rats by improving insulin sensitivity and repairing some of the damage to the pancreas[12]. Platycodon grandiflorum can also effectively inhibit the vascular complications of diabetes by lowering blood glucose and H_2O_2 damage to vascular endothelial cells, and reducing the formation of protein glycosylation[13].

2.5 Anti-tumor effect and immune regulation

Studies proved that platycodin D (PD) can affect the proliferation and apoptosis of human breast cancer cell-7 (Michigan Cancer Foundation 7, MCF-7). PD can up-regulating B cell leukemia-2 associated X protein (Bcl 2 Assaciated X protein, Bax) expression, and regulate down B expression in leukemia cell line-2. It can also activate proteolytic enzymes-9 and through death receptor mediated apoptosis pathway induce breast cancer cell apoptosis[14]. PD also can regulate the expression of cell cycle protein D1, avian myelocytomatosis viral oncogene and cyclin dependent kinase (cyclin/dependent kinase-6, CDK-6) to get cell arrested in G1 phase thus inducing cell apoptosis to inhibit the proliferation of human colon cancer cell[15]. In recent years, it was found that polysaccharide also has anti-tumor effect. Platycodon's polysaccharide can up-regulate the expression of pro-apoptotic factor Bax gene and down-regulating expression of anti-apoptotic factor Bcl-2, as well as up-regulating mitochondrial dependent caspase-3, then activate the apoptosis signal pathway, finally induce the apoptosis of human colorectal cancer cell line HT-29[16]. Giving mice cervical cancer solid tumor model polysaccharide by gavage for 15 days, it was found that polysaccharide could significantly inhibit the growth of mice cervical cancer U14 solid tumor[17]. Polysaccharide can obviously increase the thymus index and spleen index of cyclophosphamide induced immunosuppressed mice, increase the content of interleukin-2 and tumor necrosis factor-α in serum, with dose dependent manner, which suggests that poly-

saccharide has immunomodulatory effects on cyclophosphamide induced immunosuppressed mice[18].

2.6 Anti-obesity and anti-fatigue

Platycodin D can inhibit the accumulation of triglyceride in mouse embryonic fibroblasts, indicating that PD plays an anti-adipogenesis role. Its mechanism is relavant to transcription factors′ positive regulation and negative regulation of peroxisome proliferator activated receptor C[19,20]. The ethanol extract of Platycodon grandiflorum can hence the liver glycogen and muscle glycogen reserves, prolonging the time of pole climbing and swimming, and delaying the body fatigue[21].

3 Clinical compatibility application of Platycodon grandiflorum

Platycodon grandiflorum can release stagnated lung-Qi, relieve asthma and soothe the sore throat, being an important medicine in treatment for throat and respiratory system diseases. The compatibility of Platycodon grandiflorum, Ziwan (Aster) and Baibu (Stemonae) can treat exogenous cough, excessive phlegm and itching in throat. The compatibility of the medicinal with Mahuang (Ephedra), and Guizhi (Cassia Twig) or Qianghuo (Notopterygium), and Fangfeng (Windproof) can treat cold cough. The compatibility with Sangye (Mulberry Leaf) and Juhua (Chrysanthemum) can have therapeutic efficacy on coughing due to wind-heat. The compatibility of Platycodon grandiflorum, Gancao (Licorice) and Niubangzi (Fructus Arctii) can cure sore throat and aphonia caused by external factors attacking lungs. The compatibility of Platycodon grandiflorum, Mabo (Puffball) and Shegan (Rhizoma Belamcandae) can clear the heat and toxicity to relive sore throat, which can be used to treat sore throat and toxic heat congestion. Platycodon root with Shengdihuang (Unprocessed Rehmannia Root), Maidong (Ophiopogon) and Gancao (Licorice) can cure acute tonsillitis. The compatibility of this medicinal with Yuxingcao (Herba Houttuyniae) can be used in treatment of lung abscess or pneumonia along with fever, coughing, spitting putrid purulent sputum. Platycodon grandiflorum can also treat acute or chronic tracheitis when being matched with Huangqin (Scutellaria Baicalensis), Xingren (Almond), Zhimu (Anemarrhenae) and Yuanzhi (Polygala Root).

Platycodon grandiflorum, besides curing respiratory system diseases, has also been used to treat diseases of other systems. The compatibility with Platycodon grandiflorum and Zhike (Fructus aurantii) can regulate Qi activities in treating full chest without pain and functional abdominal bloating. Platycodon grandiflorum with Banxia (Pinellia), Chenpi (Dried Orange Peel) has curative effect on flatulence affected by cold. Cangzhu Jiegeng Tang (including Atractylodes rhizome, white Atractylodes rhizome, Platycodi Radix, etc.) is used to treat children′s viral and lienteric enteritis. Platycodon grandiflorum can be used with Daihuang (Rhubarb) to treat antipsychotic drug induced urination difficulty. The major founction of Platycodon grandiflorum matching Huangqi (Astragalus), Renshen (Ginseng) and others can cure heart-Qi deficiency and fatigue[22]. Platycodon grandiflorum can also be used for oral diseases. For example, Platycodon grandif matches Huixiang (Fennel), when being burnt and crushed, can cure smelly rotten gums, with external application. When matching Gancao (Licorice), Platycodon grandiflorum can treat aphtha. With founctions of pus drainage and removing stasis, Platycodon grandiflorum is commonly used in surgery. For instance, in Runfei Huayan Tang, Platycodon grandiflorum is used to treat sores of wind-heat type. Decoctions pieces of Platycodon root, Danggui (Angelica) and Rhizoma ligustici wallichii can be prepared and used in cream to clean for skin rash in treating chloasma. Besides, 30 g Platycodon grandiflorum after ground into fine powder and taken with yellow rice wine can cure sprain and contusion.

4 Diet aids researches of Platycodon grandiflorum

Platycodon grandiflorum, as an edible traditional Chinese medicine food, has been eaten in China for a long history, such as that in Platycodon grandiflorum pickles. There are many types of processed products made of Platycodon grandiflorum, such as that in quick-frozen Platycodon grandiflorum, Platycodon grandiflorum Pisi, Platycodon grandiflorum pickles. Modern research has found that Platycodon grandiflorum plays a wide range of pharmacological roles and can be con-

sumed regularly for health care.

Platycodon grandiflorum seedlings are rich in nutrition with variety of nutrients. Carotene and vitamin are rich in it, which can help strengthening people's immunity, curing illnesses, making skin emollient, and building body. For example, fried Platycodon grandiflorum seedlings and fungus Platycodon grandiflorum seedlings are suitable for exogenous cough, sore throat, lung pain, full chest of hypochondriac and other illnesses. The compatibility of Platycodon grandiflorum with cucumber and carrot cut into shreds, has effects of heat-clearing, detoxifying, and diffusing lung-Qi. Platycodon grandiflorum, lily flowers and black fungus can be made to compatible Xuan flower assorted dish, in which, Platycodon grandiflorum benefits the five internal organs, moistens lung and clears heat from throat, thus playing several therapeutic efficacies such as detoxification, expectorant, anti-inflammatory and so on.

In addition, diet aids of Platycodon grandiflorum can also be made in soup or tea. Jiegeng Donggua Soup with Wax Gourd 150 g, Xingren (Almond) 10 g, Platycodon grandiflorum 9 g, Gancao (Licorice) 6 g, soup is made dispell wind and heat from the body to prevent cough by ventilating lung, being applicable to the acute bronchitis patients with wind attacking lung. Platycodon grandiflorum matches Dangshen (Radix Codonopsis), beans, pork loin as compatibility to be used to make soup can get kidney nourished, dryness moistend, benefit Qi replenished and saliva produced, being suitable for dryness and heat consuming Yin or both Qi and Yin deficiency with symptoms of cough, shortness of breath, thirst and wanting to drink, or dried mouth tending to drink a lot. Jiegeng digupi stews with lung: platycodon grandiflorum 6 money (18 g), half piece of Digupi (Cortex Lycii Radicis), American ginseng 4 money (12 g), Ziwan (Radix Asteris) 4 money (12 g), appropriate amount Almond, 1 piece of pork lung, 2 slices Ginger. This soup can cure Qi-dificiency, chronic cough, phlegm and moisten lung. Jiegeng Gancao Tea: Platycodon grandiflorum and Gancao (Liquorice) with equal amounts, ground into powder (10 g per bag), and get ready for tea. It can eliminate phlegm and stop cough as well as regulate lung-Qi. In book of *Ming Yi Bie Lu*, it was recorded that Platycodon grandiflorum can clear heat, cold and wind weakness of human body. There is a compatibility of Platycodon grandiflorum and Houpu (Magnolia Bark), Fangfeng (Windproof), Baizhi (Angelica Dahurica), which is used to devolope Tusu wine, with effects of removing pathogenic wind and dampness, regulating Qi and eliminating bloating, strengthening spleen and stomach, relieving dyspepsia, is suitable for patients with rheumatoid embolism.

5 Prospects of the study and application of Platycodon grandiflorum

In recent years, with the improvement of people's living standard, health care products are more and more popular. Platycodon grandiflorum, being a medicinal as well as an edible plant without adverse reactions, can be used inhealth care and has been used in people's daily life. A lot of experimental studies and clinical applications of traditional Chinese medicine suggested that Platycodon grandiflorum has wide range of curative effects, has great development potential. Cardiovascular and cerebrovascular diseases, being number one killer disease for human, have been great threats especially to the elderly. Diabetes patient's quality of life seriously because of various complications. According to the reports[23], Platycodon grandiflorum's regulation function to macrophages is the basic mechanism for anti-inflammation, and pathogenic microorganism resistance. In addtion, macrophages are important factors involved in atherosclerosis and some enzyme which can cause inflammation in macrophages have direct relationship with insulin resistance and type 2 diabetes. So far, study on Platycodon grandiflorum in treatment for cardiovascular and cerebrovascular diseases is rarely reported, and the mechanism of it on diabetes is not clear enough. Therefore, future researches of Platycodon grandiflorum in prevention and treatment for cardiovascular disease and diabetes will have great prospects and social benefits.

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Research on the Quality Standard of Medicated Leaven

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ABSTRACT: Objective: To establish the quality standards of Medicated leaven. Methods: National Medicated leaven formulation, drug dosage ratio, fermentation process and product quality were analyzed. Results: Because of different medicated leaven composition, dosage ratio, fermentation process, and quality control standard and sensory judgment, it was hard to achieve identical quality standard. Conclusion: Establishment of identical national standards is urgently needed to ensure ideal clinical therapeutic effect of Medicated leaven.
KEYWORDS: medicated leaven; quality standard; prescription and dosage ratio; fermentation process

Medicated leaven is a fermentation manufactured product which is made of wheat bran, wheat flour, almond and red bean flour, mixed with squeezed liquid or decoction of fresh Qinghao (Artemisia Apiacea), fresh Laliao (Red-knees Herb) and fresh Cangercao (Xanthium Sibiricum Grass). It plays a role in tonifying spleen and stomach and helping with digestion[1,2]. It is used in curing spleen and stomach weakness, food stagnation, thoracic abdominal distention, children dyspepsia, being a commonly used drug to improve digestion in clinical practices. Decoction slices of it can be divided into the following kinds[3], namely, Medicated leaven, baked Medicated leaven, bran baked fried Medicated leaven, coked Medicated leaven and Medicated leaven charcoal. It is often used with Jiaoshanzha (Coked Hawthorn) and Jiaomaiya (Caramel Malt), which become a commonly known medicinal group as "charred triplet" in clinic. However, without a unified quality standard, production process, when the production of Medicated leaven massively floods the market, the clinical curative effect of Medicated leaven would be seriously challenged. This paper, analyzes the prescriptions of Medicated leaven, the fermentation process, quality and processed products of it to explore the quality standard evaluation system of Medicated leaven.

1 Analysis of Medicated leaven prescription composition

1.1 Recorded Medicated leaven's prescription and the dosage ratio in China[2]

The processing standards of the traditional Chinese medicine Medicated leaven are recorded not only in *Drug Standards* by China Ministry of Health (for traditional Chinese medicine Prescription Drugs, the 19th section) and *Nationwide Chinese Medicine Processing Standard* but also are recorded in each provincal processing standards or Chinese medicinal standards. Its prescription includes flour, wheat bran, almond, rice bean, fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass, but the dosage ratio of each crude drug is different. Sometimes, dried Artemisia Apiacea, Red-knees Herb, Xanthium Sibiricum Grass are use with dose being 1/3 of the fresh ones. Sometimes, Gancaofen (Licorice Powder), Jiuqu (Distiller's Yeast) and Hongdoukou (Fructus Galangae) are added into the prescription. The composition of Medicated leaven recorded in some of national standards can be seen in Table 1.

There are 7 cases of standards using full Flour in 17 volume standards, 1 full Wheat Bran, 7 cases of 20% – 34% Wheat Bran, and 2 cases of 50% Wheat Bran.

The dosage of Almond and Red Bean accounting for less than 3% exists in 5 cases, 4% – 6% exists in 11 cases, and 10% exists in 1 case. The dosage of fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass accounting for 1% in 1 case, 4% – 6% in 8 cases, 6% – 8% in 5 cases, and 15% – 20% in 3 cases.

Table 1 Prescription drug composition analysis of Medicated leaven across the country

	Wheat bran (/%)	Flour (/%)	Almond (/%)	Red bean (/%)	Fresh Artemisia Apiacea(/%)	Fresh Red-knees Herb(/%)	Fresh Xanthium Sibiricum Grass(/%)
The drug standards of the ministry of health (traditional Chinese medicine prescription preparation) the 19th copy	33	67	1.3	1.3	6.7	6.7	6.7
The national traditional Chinese medicine processing standards for the 1988 edition	0	100	4	4	7	7	7
Shanghai traditional Chinese medicine processing standards for the 1994 edition	29	71	2.6	2.1	5.7	5.7	2.6
Beijing traditional Chinese medicine standard for the 1998 edition	0	100	4	4	7	7	7
Sichuan province traditional Chinese medicine standard for the 1987 edition	30	70	3	3	20	20	20
Jilin province traditional Chinese medicine standard for the 1986 edition	0	100	10	10	4	4	4
Hunan province traditional Chinese medicine processing standards for the 1983 edition	100	0	3	3	5	5	5
Jiangxi province traditional Chinese medicine processing standards for the 1999 edition	20	80	4.8	4.8	8	8	8
Hubei Wenbang	33	67	2	1.25	17	17	17
Jiangsu province traditional Chinese medicine pieces processing standards for the 1980 edition	50	50	6	6	5	5	5
Shandong province traditional Chinese medicine pieces processing standards for the1990 edition	20	80	5	5	5	5	5
Gansu province traditional Chinese medicine standard for the 2009 edition	0	100	4	4	15	15	15
Guangxi Zhuang autonomous region traditional Chinese medicine pieces processing standards for the 2007 edition	24	76	4.8	4.8	4.8	4.8	4.8
Anhui province traditional Chinese medicine pieces processing standards for the 2005 edition	0	100	4	4	7	7	7
Zhejiang province traditional Chinese medicine processing standards for the 1986 edition	50	50	4.5	4.5	5	5	5
Ningxia Hui autonomous region traditional Chinese medicine standards for the 1993 edition	0	100	4	4	1	1	1
Heilongjiang province traditional Chinese medicine standard for the 2004 edition	0	100	4	4	4	4	4

Remark: Hunan plus 2% Distiller's Yeast, Jiangxi plus 4.8% Licorice Powder, Hubei Wenbang plus 1.25% Fructus Galangae

Note: the total amount of wheat bran and flour in prescription are 100, other drugs account for percentage of the total of wheat bran and flour.

1.2 Suggestion of Medicated leaven's standard prescription

Li Zhongzi said in *The Understanding of* the *Nature of Drugs of Lei Gong's Processing Drugs*: *on* 6th June in Chinese lunar calendar, 2.5 kg flour were needed, a bowl of Xanthium Sibiricum Grass and natural juice, a

bowl of wild natural juice, a bowl of Artemisia Apiacea natural juice, peeled Almond five taels, peeled ripe Red Bean four taels, all made into yeast and dried for future use. And Zhang Lu said in *Benjing Fengyuan*: in summer, using white flour 2.5 kg, added with a bowl of Artemisia Apiacea natural juice, a bowl of Xanthium Sibiricum natural juice, a bowl of Wild Liao natural juice, Almond mash four taels, Red Bean two taels, all being boiled, ground and made into yeast, then get it dried. When used, get it backed. In both record the drug composition and the different dosage ratio of Medicated leaven, while the dosage of Almond was 5% to 6.25% and the dosage of the rice bean was 2.5% to 5%. According to current drug standard and the above mentioned records, it is suggested to make and other medicinals like this: 33 kg of Wheat Bran, 67 kg of Flour, 4 kg of Almond, 4 kg of Red Bean, 6 – 7 kg of fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass, respectively.

2 Fermentation processing techniques of Medicated leaven

2.1 Fermentation processing techniques of Medicated leaven in various regions in China

Ground bitter Almond and the Red Bean into coarse powder and get the latter boiled. Chop fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass. Mix Flour, bean paste and bitter Almond powder withall of them, add water and knead them into coarse particles, with a degree in water content that gripped as dough, and thrown as small particles, press it in wooden model, then wrap it with cotton cloth or hemp fimble leaf, put it in a wooden or bamboo basket to get fermented, wait for yellowish-white mildew appearing on the surface, remove out, cut and get it dried.

Add water to fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass for juicing, boil Red Bean, ground bitter Almond into coarse powder, add them in Bran and Wheat Powder. Stir and compress the material into 1.5 – 2.0 cm^3 block shape, heap in bamboo basket, use straw to cover it, put to ferment, when yellowish-white mildew on the surface produced, remove and dry the material for use.

Take raw Almond and Red bean, boil them and get them mashed, mix the mash with White Flour. Ground Artemisia Apiacea, Red-knees Herb, Xanthium Sibiricum Grass are made into decoction and add it to the mixed powder prepared before hand. Mix them well and knead them into clump with cloth wrapped, put it in the model to form a block, get it out, cover it tightly with hemp fimble leaf, put into basket and covered with wet sacks. When it ferments naturally, and yellowish-white mildew is on the surface, and then be frangrant, take it out and dry it into medicine.

Take raw Almond and Red bean to get them boiled, mashed. Then mixed them with White Flour. Ground Artemisia Apiacea, Red-knees Herb, Xanthium Sibiricum Grass into powder, medicinals, mix all of them well and with with cloth wrapping it, make it into cube in a model. Get it out, cover it tightly with hemp fimble leaf, put it in basket and cover with wet sacks. Get it ferments naturally. When yellowish-white mildew is on the surface, and then be frangrant, take it out to dry as medicine.

2.2 Advice on Medicated leaven's fermentation technique

By comprehensive analysis it is found no specifisic indications in these fermentation processing: whether the Wheat Bran and Flour need to insects killing and sterilizing, what is the best amount or concentration of the squeezed juice or dried juice of fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass, whether cutting before fermenting or not, what is the best fermentation temperature and the number of days of fermentation.

Based on our research, the best processing technique is as the followings: Grind Ground bitter Almond into coarse powder, then Red Bean trituration, chop fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass or smash the dried one into powder. Mix them with into Flour, Wheat Bran (sterilized) and bitter Almond powder. Adding about 40 kg of water to form coarse particles.

Take fresh Artemisia Apiacea, fresh Red-knees Herb, fresh Xanthium Sibiricum Grass and juice them or make the dried materials of the three into concentration (about 40 kg) by boiling. Boil red bean, grind the

bitter almond into powder, add Bran and Wheat Powder into the mixture of all above mentioned materials, stir, knead it into coarse particles, press it in wooden model, then wrap it with cotton cloth or hemp fimble leaf. Put all the blocks in a wooden or bamboo basket, there should be gaps between them, fermenting between 30 ℃ – 37 ℃, for 5 – 7 days, when yellowish-white mildew is on the surface, get it out, cut and dry it for future use.

3 The quality standards of Medicated leaven[3,4]

3.1 Characters

3.1.1 Smell

Being fragrant, without mildewy and stinking smell.

3.1.2 Appearance

There are yellowish-white hyphae and a few black spores on the surface, with the rims of the blocks is bright yellow. The expansion part of the yellow conidium handle can be seen with a magnifying glass. Sometimes black spores exist among the yellow ones.

3.1.3 Internal

Being solid block in shape and can be removed as a whole. There are hyphae and immature spores observed with a magnifying glass.

3.2 Powder microscopic characteristics

Powder is yellowish-white or yellowish brown, notglandular unicellular, 19 – 1 513 μm long, xylem nucellus residual cells are rectangular or polygonal, walls are thicker, nucellus are residual inside, layered textures are faintly visible, starch grains are 35 – 68 μm in diameter, umbilical points are stellate or fissuring, obvious grain layer, palisade cells are yellowish brown, walls thicken from inside to outside, cell cavity contains red brown material there is a belt of radiance to the outer side view.

4 Discussion

Medicated leaven is a common medicine to improve the digestion in clinical practices. There are crude, fired Medicated leaven, bran fried Medicated leaven, focal Medicated leaven and Medicated leaven carbon formulas, with the effect according to different processing methods. The crude Medicated leaven can tonify spleen and stimulate appetite, being divergent. It is more often used to treat cold dyspepsia. Bran fried one is mainly to activate spleen and stomach to enhance indigestion, food stagnation, borborygmus diarrhoea, etc. After being coked the power for digestion has been improved, so it can treat dyspepsia diarrhea. There are many Medicated leaven's modern processing techniques with different and digestive enzyme control indexes. The author noticed the following related factors.

When experimental materials in, the prescription coming from different sources, the results would be different. Wang Haiyang and others[5] studied the influence of different processing technigues of Medicated leaven had on the amylase activity. Wang Qiuhong and others[6] carried out the antimicrobial activity research of Medicated leaven, also with the tested samples different in some aspects.

Digestive enzymes are adopted as quantitative indexes in studys. However, whether it is reasonable, raw Medicated leaven being preferred in clinical practices. Different processed Medicated leavens have different functions. Bran fried medicated leaven and coke medicated leaven are often used to tonify spleen and stomach in helping digestion in traditional Chinese medicine. Although the digestive enzymes of medicated leaven had reduced a lot in fried one and coked one, the function of digestion and stopping diarrhea is more obvious. Nan Yunsheng and others[7], Zhang Lurong and others[8] verified that bran fried product and coked product could better promote the secretion function of the stomach and strengthen the promoting function of the stomach, and the two medicines were superior to other products in the product character and yield. They are better in tonifying spleen and helping digestion. Zhang Yanling and others[9], by one dimensional infrared spectrum and second derivative spectrum analysis, found that the three kinds of medicated leaven containe similar chemical compositions, but not totally the same. They all contained the chemical composition of double bond or benzene ring structure. Both Medicated leaven and coked Medicated leaven contain esters, acids and ketones, but fired medicated leaven only contain ester composition. In addition, the raw medicated leaven may contain calcium oxalate, while fried Medicated leaven

and coked Medicated leaven contain less or no calcium oxalate, which suggested that Medicated leaven's compositions change after processing. Wang Qiuhong and others[6] found that bran fried Medicated leaven's ethyl acetate extracted parts has a strong antibacterial effect, with the minimum inhibitory concentration is 0.64 g · L^{-1} and minimum bactericidal concentration is 0.65 g · L^{-1}. It is found bran fried medicated leaven has activated antibacterial and bactericidal power, which could be one of the mechanisms in treating dyspepsia and diarrhea.

Both flour and wheat bran are used as raw materials is favorable, inorder to get betler produat in adhesiveness, and fermentation effect. Gao Hui and others[10] found when the ratio of wheat bran and flour is 0% – 75%, there is no significant difference between amylase and protease activity, considering the viscosity of the block, the degree of difficulty of stirring and the economy of raw materials, the proportion of wheat bran and flour should be 25 : 75. They also found that the activity of enzyme fermented for 7 days is the largest, and there exists significant differences compared with 5 days' fermentation sample. Therefore, it is suggested that the fermentation time should be 7 days, with the proportion of wheat bran and flour as 33 : 67, and fermentation days 5 – 7 days.

In formulating the national standards of Medicated leaven, both the basic theory of traditional Chinese medicine and clinical practices of traditional Chinese medicine, should be studied systemetically.

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· Acupuncture and Massage ·

Clinical Therapeutic Effect of the Needling Method of Regulating Defence-Qi and Invigorating Brain for Insomnia

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ABSTRACT: Objective: To observe the clinical therapeutic effect of the needling method of regulating defence-Qi and invigorating brain for insomnia. Methods: 200 patients with insomnia were randomly divided into experimental group and control group ($n = 100$). The control group was treated by needling on Sishencong (EX-HN1), Shenmen (HT7) and Sanyinjiao (SP6), while the experimental group was treated with needling method aiming at regulating defence-Qi and invigorating brain, with Baihui (GV20), Dazhui (GV14), Shenmai (BL62), Zhaohai (KI6) and ear points Yuanzhong, Shenmen selected. Both groups were treated once a day for 15 days. Pittsburgh sleep quality index (PSQI) score was used before and after the treatment. Results: The total effective rate of the control group was 65.0%, while the experimental group was 89.0% ($P < 0.01$), which suggested significant differences between the two groups. The PSQI scores before and after treatment was -9.15 ± 5.68 in the experimental group and -5.64 ± 5.73 in the control group, which also means significant differences between the two groups ($P < 0.01$). Conclusion: The clinical therapeutic effect of the needling method of regulating defence-Qi and invigorating brain for insomnia is better than the ordinary way.

KEYWORDS: insomnia; regulating defence-Qi and invigorating brain; Sishencong (EX-HN1); Shenmen (HT7); Baihui (GV20); Dazhui (GV14); clinical research

As the society rhythm speeding up and people's work and life pressure increasing, insomnia is becoming a common phenomenon. A survey by WHO in 2007 suggested that nearly 27% of 25 916 persons had different levels of sleep problems[1]. Another investigation carried out by Chinese Sleep Research Society found that the rate of sleep disorder was 38.4%[2].

Long-term insomnia is harmful physically and mentally, and leads to many kinds of health problems. At present, carried out by using medical treatment for insomnia sedative drugs, which usually generate resistance, addiction and dependence, withdrawal reaction, and cause liver and kidney damage. Luckily acupuncture treatment for insomnia can achieve better curative effect, being quicker, safer and more reliable[3]. In recent years, the author adopted the needling method of regulating defence-Qi and invigorating brain for insomnia observed satisfactory curative effects. Now we report the result as follows.

1 Materials and methods

1.1 Information

There were 200 patients who came from acupuncture clinics of the Third Affiliated Hospital of Henan University of Traditional Chinese Medicine from March 2010 to November 2014. Of 100 cases in the control group 11 cases fell off, and the percent of pass was 89.0%. Of 100 cases of the control group, 8 cases fell off, and the percent of pass was 92.0%. The number of the tested cases met the requirement of experiment.

1.2 Comparable analysis

There were 52 males and 48 females in the control group, while in the test group, there were 53 males and 47 females. The average age in the control group was (39.90 ± 13.40) years old, while that in the test group was (39.46 ± 12.69), $P > 0.05$ in t test. The data of the two groups have no significant differene statistically in gender and age.

Illness conditions: There were 48 cases of mild illness, 23 moderate cases, and 29 severe cases in the control group, and 49 mild cases, 23 moderate cases, 28 cases of severe illness in the test group. By χ^2 test, $P > 0.05$, illness conditions of the two group were comparable.

Pittsburgh sleep quality index (PSQI) total points of

the two groups are: 6 points to 24 points in the two groups, with the average score was (17.42 ± 4.11) in the control group, and (18.25 ± 3.81) points in the test group. $P > 0.05$ in t test, PSQI total score of two groups had comparability basis.

1.3 Diagnostic criteria

1.3.1 Western medicine diagnostic criteria

By referring to the diagnostic criteria of Chinese classification of mental illness scheme Chinese *Psychiatric Classification and Diagnostic Criteria* (*CCMD-3*)[4], diagnose was made.

1.3.2 Diagnostic criteria of TCM

The diagnosis made by referring to the *Clinical Guiding Principle about New Chinese Medicine* issued by the National Ministry of Health in 1993[5]. The *Diagnosis-Standard of Curative Effect* of *Traditional Chinese Medicine Curative Selection Effect* issued by the State Administration of Traditional Chinese Medicine in 1994[6].

1.4 Selection

1.4.1 Inclusion criteria[7]

Case inclusion criteria: the typical symptoms of insomnia of more than 28 days in course; meeting the diagnostic criteria of TCM; 18 – 65 years old; following the doctor's advice; signing the informed consent.

1.4.2 Exclusion criteria

According to the *Clinical Guiding Principle about New Chinese Medicine*[5] (insomnia), the exclusion criteria are: ① the systemic disease: pain, fever, cough, operation, etc., as well as the external environment factor causing insomnia. ② Pregnant or breast-feeding women. ③With severe primary disease of cardiovascular, lung, liver, kidney and hematopoietic system. ④ Psychiatric patients. ⑤Patients who do not conform to the standard or can't take medicine according to the requirements; or the curative effect cannot be judged or curative effect and safety cannot be judged due to in complete data.

1.4.3 Eliminating criteria

①Patients who didn't receive the treatment according to the experimental scheme. ②Patients who use other therapy or medication. ③Patients who had poor obedience and the judgment was difficult to make.

1.4.4 Falling off criteria

①Patients who quitted the treatment in the process, or can't stick to it. ②Patients who couldn't cooperate in the treatment.

1.4.5 Discontinuing criteria

①Patients got fainting or can't tolerate the acupuncture treatment. ②patierts suffered from other diseases, and affected the test result.

1.5 Curative Effect criteria

Curative effect evaluation was made according to *The Diagnosis Standard in Curative Effect of Traditional Chinese Medicine*[6]. Healing: returning to normal condition or sleep time more than 6h, deep sleep, full of energy after sleep; markedly: the quality of sleep is significantly better, the sleep time increases by more than 3 hours, sleep depth increases; effective: symptoms have been alleviated, and the sleep time increases less than 3 hours; invalid: no obvious improvement or even worse.

1.6 Statistical analysis

Balance inspection: use χ^2 test, t test or rank-sum to make balance inspection of the two groups; use t test clinical effect analysis to compare the date before and after the treatment; use rank-sum test, t test and CMH to compare the curative effect of the two groups; use SAS statistical software package to analyze the date. Test statistics and their corresponding P values are given by relevant test, if $P < 0.05$, the difference is statistically significant.

1.7 Therapeutic method

1.7.1 Acupoint selection

①The control group: Sishencong (EX-HN1), Shenmen (HT7) and Sanyinjiao (SP6). Deficiency of heart and spleen syndrome: addition Xinshu (BL15), Pishu (BL20); disharmony of heart and liver syndrome: addition Xinshu (BL15), Shenshu (BL23); ascending of liver Qi syndrome: addition Ganshu (BL18), Taichong (LR3); disharmony of spleen and stomach syndome: addition Weishu (BL23), Zusanli (ST36). ② The test group: Baihui (GV20), Dazhui (GV14), Shenmai (BL62), Zhaohai (KI6) and ear points Yuanzhong, Shenmen. The matching points of the different types were same as the control group.

1.7.2 Operation

(1) The control group: To achieve convenience in acupuncture, the supine or prone position were used. After the routine disinfection of the skin, choosing

points according to the diagnostic result. After Qi obtained, lifting, thrusting, twirling and rotating method were used, and the method of supplementation or draining was decided by deficiency or excess. Retaining the needle for 30 minutes, with the needle being operated every 10 minutes. Acupuncture was giving in the afternoon once a day, with 15 days being a course of treatment.

(2) The experimental group: ① The treatment process was the same as that to the control group, with different selection of acupuncture points. ② After acupuncture, pressed the ear points with cowherb seed (a kind of Chinese medicine), once every 3 days, and patients needed to press the points 10 – 15 minutes each time, twice a day.

1.7.3 Observation method

(1) Using PSQI score to record sleeping time, level of sleep condition and state of mind after sleep. The specialist was responsible for inquiring the condition to score. The patients obtain 0, 1, 2, 3 points according the mild, moderate or severe degree of their illness.

(2) Recording time: 1 week and 2 weeks before and after the treatment; tracking the well-healed patients condition 7 days after the treatment; treatment of each group lasted for 15 days.

2 Results

2.1 Comparison the curative effect of insomnia in the two groups

See Table 1.

Table 1 Curative effect comparison of insomnia patients in the two groups

Groups	*n*	Healing	Marked	Effectiveness	Invalid	Total effective rate	CMH
Control	100	0	12	53	35	65.0	20.01
Treatment	100	0	29	60	11	89.0	

According to the Table 1, compared with two groups' total effective rate by the CMH chi-square and ITT analysis suggests that there is significant differences between the two groups ($P = 0.00 < 0.01$), with the curative effect of the treatment group better than the control group.

2.2 Comparison the PSQI total score of insomnia in the two groups

See Table 2.

Table 2 Comparison the PSQI total score of insomnia patients in the two groups ($\bar{x} \pm s$)

Groups	*n*	Before treatment	After treatment	D-value	*t*
Control	100	17.42 ± 4.11	11.78 ± 5.40	-5.64 ± 5.73	-9.85
Treatment	100	18.25 ± 3.81	9.10 ± 4.44	-9.15 ± 5.68	-16.12

Table 2 suggests that the PSQI scores of the two groups have significant differences before and after the treatment by *t* test and ITT analysis ($P = 0.00 < 0.01$).

2.3 Follow-up

30 days after treatment, two groups were compared in sleep time, cough or drowsiness (times/week), the physical recovery, the improvement of syndrome. It was found that all data had significant differences ($P < 0.05$), with the curative effect of the treatment superior to the control group. Compared with the date in waking up easily at night, the times of early awakening between the two groups (times/week), and times of going to the toilet at night, $P > 0.05$, there were no significant differences in curative effect between the two groups by ITT analysis and PP analysis.

2.4 Safety evaluation

During the experiment, if there were any adverse medical events, whether it was related to the experimental treatments or not, they were all judged as adverse events. We truthfully filled them in the table of adverse events, including the time of occurrence, severity, duration, measures and the outcome. Adverse events were recorded in the designated table of CRF[8].

Safety evaluation standard: level 1: security: without any adverse reaction; level 2: safer: if there were any adverse reaction, no treatment needed; level 3: there are security issues and moderate adverse reaction, with some treatment needed; level 4: treatment stops because of adverse reactions.

Two groups of this study had no adverse events, and both of the safety assessments were conformed as level 1, which suggests that acupuncture treatment is safe and feasible.

3 Typical case

Wang (female, 17 years old, student) came to the clinic on September 29, 2014. Chief symptoms: shallow sleep with much dream for two months, and the symp-

toms had aggravated for 1 week. History of present illness: patients had poor quality of sleep at night with shallow sleep and much dream, because of study pressure for 2 months. She had the feeling of hallucinations, tension, fear and irritability for one week. She had ever taken olanzapine and sertraline hydrochloride but found no effect. We could see the symptoms like that: anenergia, poor appetite, normal urine and excrement, red tongue with thin yellow fur, string-like pulse. Physical examination: there was no obvious tenderness in occipitalia and top head. Diagnosis: western medicine diagnosis: insomnia, TCM diagnosis: insomnia (excessive rising of liver-yang type). Therapeutic principle: regulating defence-Qi, invigorating brain and reducing liver fire. Selected Points: Baihui (GV20), Dazhui (GV14), Shenmai (BL62), Zhaohai (KI6) and Taichong (LR3). Retaining needle for 40 minutes, and the patient felt needle cover the entire head. She felt better after acupuncture. In subsequent visit on October 7, 2014, her sleep quality got improved, and the symptoms of fear and irritability alleviated. After we continued the method for another 10 days, the symptoms disappeared.

4 Conclusion

The clinical practices of needling in regulating defence-Qi and invigorating brain is based on the theory of eight extra meridians, with points of Baihui (GV20), Dazhui (GV14), Shenmai (BL62), Zhaohai (KI6) and ear points Yuanzhong, Shenmen selected in treatment, combining with pressing ear points to regulate defence-Qi and invigorating brain. Acupuncture treatment has the effect of the coordination of Yin and Yang without side effect[9].

Acupuncture treatment for insomnia combining with the methods of ear points and massage are being explored in clinical treatment. The occurrence of insomnia is closely related to the deficiency of heart and spleen, liver depression. Therefore, the treatment should be carried out based on the theory of holism. There isn't a unified evaluation criteria according to domestic literature. So it is an important task of traditional Chinese medicine to establish certain standard of diagnosis and treatment for the disease. In this may, the level of diagnosis and treatment for insomnia with traditional therapy of traditional Chinese medicine also can be achieved.

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· Acupuncture and Massage ·

Observation of Combination Therapy of Surrounding Acupuncture and Suspended Moxibustion on the Anesthesia Area in Treating Cesarean Postpartum Urinary Retention

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ABSTRACT: Objective: To observe the clinical efficacy of surrounding acupuncture and suspended moxibustion on the anesthesia area in treating cesarean postpartum urinary retention. Methods: 128 cases of cesarean postpartum urinary retention patients were randomly divided into treatment group and control group. The treatment group was treated with combination therapy of surrounding acupuncture and suspended moxibustion on the anesthesia area, and the control group received acupuncture treatment only. Results: The cure rate of treatment group was 96.9%, and that of control group was 81.0%. The difference between the two groups was significant. This suggested that the results of acupuncture and moxibustion co-treatment of surrounding acupuncture and suspended moxibustion on the anesthesia area was more effective in cesarean postpartum urinary retention treatment than the sole acupuncture tharapy. Conclusion: Surrounding acupuncture and suspended moxibustion on the anesthesia area can exert marked therapeutic effects on cesarean postpartum urinary retention in clinical treatment.

KEYWORDS: cesarean postpartum urinary retention; surrounding acupuncture; suspended moxibustion, anesthesia area

With the improvement of living standards, more and more pregnant women choose cesarean manner to give birth. They believe cesarean section bring less pain, thus leading to the high cesarean section rate. However, when the indwelling urinary catheter are pull out after cesarean section, some patients prone to suffer the urinary retention. That is to say they could not micturate of their free will or with difficultly, which finally cause urine retention in the bladder, which is one of the common complications in obstetrics. Without out proper treatment, it would result in weak uterine contraction, the severe vaginal bleeding and the increasing incidence of urinary system infection, which may bring severe pain to puerperae. The author used the surrounding acupuncture and suspended moxibustion on the anesthesia area to treat 65 patients with cesarean postpartum urinary retention from March 2009 to March 2013. All data would be compared to those of other 63 patients treated with sole acupuncture and the results are reported as follows.

1 Materials and methods

1.1 Basic information

128 patients from obstetrics or gynecology department of The Second Affiliated Hospital of Guangxi Science and Technology University Medical College. There were 98 unipara and 30 multipara among them. All the patients went through cesarean postpartum urinary retention and were randomly divided into treatment group ($n = 65$) and control group ($n = 63$). In the treatment group, there were 48 unipara and 17 multipara, from 20 to 39 (28.02 ± 2.63) years old, with course of disease for 6 to 9 hours. While in the control group, there were 50 unipara and 13 multipara, from 21 to 41 (27.08 ± 1.89) years old, with course of disease for 7 to 10 hours. There were no statistically significant differences in general data comparing between the two groups ($P > 0.05$). All the patients with organic obstruction in urinary system and acute inflammation in bladder or urethra were excluded. Patients were well informed and consent forms were signed.

1.2 Therapeutic method

1.2.1 Treatment group

The prescription of acupoints: in the narcotic region of cesarean section.

Methods: ① Surrounding acupuncture: patients lay down in prone position, after sterilization, about 0.3 cm around the pinhole of anesthetization, with acupuncture

needle(0.25 mm × 25 mm, brand: Hwato, produced by Medical Supplies Factory of Suzhou, Jiangsu province, H type, standard number: GB20241994). Stabing into the skin with 15° angle. The point of the needle were toward the center of pinhole for anesthetization. Each acupuncture point was 1 cm apart. Twirling the needle to bring about the desired sensation. The retention of needle lasted for 30 min, once a day. ② Suspended moxibustion: two moxa stick were lighted, hung over the center of anesthesia area, about 2 – 3 cm away from the skin[1]. The patients feel warm with redden skin around the area, once a day.

1.2.2 Control group

Patients lay down in supine position. The prescription of acupoints were Guanyuan (CV4), Zhongji (CV3), Baihui (GV20) and bilateral Sanyinjiao (SP6), Taixi (KI3). After sterilization, we used acupuncture needle[0.25 mm × (25 – 40) mm] to prick vertical into Guanyuan (CV4) and Zhongji (CV3) about 1 inch, entwisting the needle slightly in one direction, to make the patients feel swelling, tension and anaesthesia in lower abdomen. Then prick Sanyinjiao (SP6) with mild reinforcing-reducing method, Taixi (KI3) with reducing method following reinforcing method. Finally, we used 1.5 inch acupuncture needle to stab into Baihui(GV20) with 15° under the surface of skin. Twirled the needle heavily to bring about the desired sensation. The retention of needle lasted for 30 min, once a day.

1.3 Efficiency criteria

Based on disease diagnosis and treatment standard of TCM, curative effect would be divided into being cured and invalid. Being cured: self-urination more than twice after treatment, and there was no recidivism in 24 h during observation. Invalid: without self-urination after treatment, and the patients needed urine catheterization or indwelling catheter.

1.4 Statistical analysis

Using SPSS 19.0 software package for statistical analysis. Measurement data using t test, count data by chi-square test. Differences were statistically significant when $P < 0.05$.

2 Results

The outcome of two kinds of treatment were compared. There were statistically significant differences between the two groups ($\chi^2 = 8.377$, $P = 0.004 < 0.05$). See Table 1.

Table 1 Curative effect comparison of cesarean postpartum urinary retention between the two groups Cases

Groups	n	Cure	Invalid	Cure rate(/%)
Control	63	51	12	81.0
Treatment	65	63	2	96.9

3 Discussion

There are various causes for cesarean postpartum urinary retention. ①puerperae are not used to micturating on bed; ②puerperae feel pain in abdominal incision or worry that incision would be torn when get out of bed to urinate, so they dare not put forth their strength to micturate; ③some puerperae suffer from bladder sphincter muscle spasm due to psychological stress, which also give rise to urinary retention[2]. Most cases of cesarean postpartum urinary retention caused by psychological factors could be relieved with guidance and nursing offered by medical workers. However, during birth process, cases like bladder being mucosal edema, congestion under the pressure, reduced bladder muscle tension, the decreasing sensibility to internal pressure or the pain in the perineum wound, inability to urinate, etc. may also contribute to cesarean postpartum urinary retention. Once this happens, we should take a certain treatment action to relieve the related symptoms. But the application of anesthetics in cesarean section could lead to urinary retention by poor bladder detrusor contractility, which is usually neglected[3]. In recent years, spinal canal anesthesia is one of the most popular anesthesia methods used in cesarean section. That is also the case in our hospital. Either thoracic segments or lumbar segments nerve for anesthesia plane can be used, and the anesthesia area is clearly visible after operation. When stupefacient is injected into skin and its period of validity being extended the recovery of neurological function would be postponed, which would incur the decline of sensibility to internal pressure[4] and then uroschesis occurred. Cao Zeyi[5] agreeed that lumbar nerve anesthesia is one of the reasons for cesarean postpartum urinary retention. In traditional Chinese medicine, it is considered that cesarean postpartum uri-

nary retention is closed related to kidney deficiency, disturbance of Qi movement in bladder and dampness-heat pouring down after operation. The etiology and pathogenesis of the disease could be bladder Qi transformation dysfunction and abnormality systolic function[6]. In *Fu Qingzhu's Obstetrics and Gynecology*, it is stated that puerperal always suffer from deficiency and blood stasis in syndrome. Therapeutical principle focused on tonifying deficiency, resolving stasis and dredging collaterals. Based on this principle, we could apply acupuncture combining moxibustion to cure[7]. By acupuncture on Sanyinjiao (SP6), Guanyuan (CV4), Zhongji (CV3), Taixi (KI3), Baihui (GV20), etc. to dredge channels and activate collaterals. Moxibustion on Guanyuan (CV4) and Shenque (CV8) can also bring about certain therapeutic effect. For example, in our study, cure rate in the control group was up to 81.0%. But the author explored a mew wary. Now that the remaining anesthesia efficacy and disorder of local nerve function are blamed for cesarean postpartum urinary retention, the key to cure might be to stimulate anesthesia part and activate low neural function. So the new therapy is selecting local acupoints. Since subcutaneous area belongs to collateral disease in TCM theory and the lesions is mainly on the superficial, we should choose shallow needling method. We are familiar with the "surrounding acupuncture", which is the equivalent of the ancient "centro-square needling", meaning a shallow needling method. *Miraculous Pivot* says: Centro-square needling has the ability of dredging meridians, activating blood, resolving stasis and activating lower neural function. In this study, we mainly used surrounding acupuncture combining with suspended moxibustion on the anesthesia area in treating cesarean postpartum urinary retention. Surrounding acupuncture can directly cure the disease, dredge collaterals and relieve pain. Moxibustion can drive pathogenic Qi out, warm and dredge the meridian, promote the movement of Qi and blood and dissipate stasis[8]. *New Compilation of Materia Medica* points out that folium artemisiae argyi can dredge all meridians and cure many diseases. In 1950s, some scholars considered that moxibustion is a physical process and it has a thermogenetic effect, adjusting the function of the nervous system through stimulating the skin receptors. Modern research confirmed that moxibustion could diminish inflammation, inhibit edema, decrease nervous excitement, and could also adjust the self-discipline movement of capillaries, improve microcirculation morphology and hemodynamic status, increase blood oxygen supply in nidus organization and accelerate the metabolism of body fluid in cooperating with acupuncture. In this way, the meridian Qi and restore the circulation of Qi and blood are significantly stimulated[9]. Therefore, we consider surrounding acupuncture combined suspended moxibustion have better impact on dredging the meridian, dissipating stasis as well as adjusting the function of the nervous system. The study also proved the obvious curative effect in treating cesarean postpartum urinary retention with the cure rate 96.9%. Shallow needling method and the prescription of acupionts are used at the same time, which works directly on the focal location and plays a role in dredging collaterals and relieving pain. It also fully exhibits the outstanding features of local moxibustion. With help of thermogenetic effect, moxibustion stimulates the Qi of meridian, improves the movement of Qi and blood. The curative effect of this method is better than before as well as simple and practicable, which also can save medical resources.

4 Conclusion

Traditional Chinese medicine considered that the etiology of cesarean postpartum urinary retention is closely related to kidney deficiency, disturbance of Qi movement in bladder and dampness-heat pouring down after operation. It is caused by bladder Qi transformation dysfunction and systolic function abnormality. Disease in bladder is also closely related to the function of lung, spleen and kidney system. The disease is susceptible to deficiency and stasis. But it still rare to attribute cesarean postpartum urinary retention to the application of anesthetic in lumbar nerve.

In traditional Chinese medicine, the treatment for cesarean postpartum urinary retention could be concluded as follws: in case of Qi deficiency treating by tonifying and elevating Qi; in case of kidney deficiency, warming and tonifying kidney Yang to promote dieresis; in case of blood stasis, activating blood and resolving stasis.

Therapies mainly concentrate on invigorating spleen, tonifying kidney, resolving stasis, dredging collaterals and regulating water passage throughout the whole body. Prescription of selecting points are usually Piyu (BL20), Shenyu (BL23), Pangguangyu (BL28), Zhongji (CV3), Guanyuan (CV4), Shenque (CV8), Xuehai (SP10), Zhibian (BL54), etc. However, there is no study about selecting acupoint on local anesthesia area, nor the application of combination therapy of surrounding acupuncture and suspended moxibustion.

So the author considered it is an innovation to put forward that the application of the anesthetic is one of the reasons for cesarean postpartum urinary retention. Furthermore, combination therapy of surrounding acupuncture and suspended moxibustion on the anesthesia area in treating cesarean postpartum urinary retention is a quite new clinic treatment. This method is also simple, cheap, and safe in clinical practices, with better curative effect.

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