

Characteristics and Application Analysis of Traditional Chinese Medicine Containing Sophora Japonica

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Abstract. Purposes: To sum up the characteristics of Chinese medicine with Sophora Japonica and provide reference for the research, development and utilization of the Chinese medicine of Sophora japonica in the future. Methods: The author sums up the forms, functions, indications, usage, dosage and contraindications of the proprietary Chinese medicine containing Sophora Japonica in the Chinese Pharmacopoeia and the Ministerial standards. In addition, we will inquire about the clinical application of proprietary Chinese medicine containing Sophora japonica in the China National Knowledge Infrastructure (CNKI). Results: The proprietary Chinese medicine containing Sophora Japonica was widely used in the treatment of various diseases in clinic, but it was taken orally and without any external use of Chinese patent medicine. Moreover, in most of the proprietary Chinese medicine, Sophora japonica was used as a supplement; In addition, the causes of adverse reactions were not analyzed, and the safety of the drugs needed to be further analyzed. Conclusions: To make clear the role of Sophora japonica in proprietary Chinese medicine, we can develop the Chinese medicine new dosage forms of Sophora japonica; The Chinese medicine is made up of a variety of single herbs, some are toxic drugs, when an adverse reaction occurs, We should analyze the specific causes and avoid the occurrence of adverse reactions. In addition, Sophora japonica is a traditional herbal medicine and food in China; we can expand the application in other areas and explore the pharmacological and toxicological pathology.

1. Introduction

Sophora japonica is the dried flower and bud of *Sophora japonica* L.. It is one of the traditional Chinese medicines with a long history. It can be used as medicine and ornamental. Chinese medicine thinks *Sophora japonica* tastes bitter and has a slight cold. Liver meridian and large intestine meridian; It has the effect of cooling blood, stopping bleeding, clearing liver and purging fire. In addition to eating value, *Sophora japonica* also contains rutin, quercetin, fatty acids, polysaccharide and other chemical composition, with anti-inflammatory, hemostasis, reduce blood pressure, coronary artery expansion and other pharmacological effects, it was widely used in clinical research. *Sophora japonica* proprietary Chinese medicine in clinical is widely used in the treatment of stroke, hemorrhoids blood in the stool, dizziness, headache. In order to further explore the effect of *Sophora japonica* in proprietary Chinese medicine, the direction and focus of future research, this article on Chinese Pharmacopoeia, People's Republic of China Ministry of Health Drug Standards (Chinese medicine proprietary Chinese medicine 1 ~ 20) (hereinafter referred to as ministerial standards) included the efficacy of Chinese medicine with *Sophora japonica* and the application and characteristics of *Sophora japonica* proprietary Chinese medicines were analyzed and summarized, so as to provide reference value for the development and utilization of *Sophora japonica* proprietary Chinese medicines.



2. Analysis of Proprietary Chinese Medicines Containing Sophora Japonica in the Chinese Pharmacopoeia and the Ministerial Standards[1]

In the 2015 edition of the Chinese Pharmacopoeia, a total of 20 prescriptions containing *Sophora japonica* was searched, the ministerial standards contain 18 kinds. Excluding the two books are included in the 7 species, there are 31 kinds of Chinese medicine with *Sophora japonica*; Formulations are capsules, granules, tablets, pills, etc., see Table 1; There are only 9 Chinese medicine with *Sophora japonica* as the main medicine, in most of the proprietary Chinese medicine, *Sophora japonica* was used as a supplement. Capsules, granules, tablets in the way to add boiling water to the medicine; In the pills, *Sophora japonica* was ground into fine powder, plus honey made of honey pill.

In the above proprietary Chinese medicine, the methods of *Sophora japonica* are mostly decocted with water, accounting for 71% of the total; In the pills, *Sophora japonica* research powder and honey made of honey pill, accounting for 22.6% of the total. In the Chinese Pharmacopoeia and the ministerial standards, the proprietary Chinese medicines containing *Sophora japonica* are orally taken and there is no proprietary Chinese medicine for external use, but the query *Sophora japonica* related literature, there are has the record of *Sophora japonica* charcoal nasal plug in treatment of epistaxis, *Sophora* pollen add sesame oil into a paste with the treatment of burn and scald records; Therefore, if the *Sophora japonica* in the topical treatment of disease was researched, which can develop new proprietary Chinese medicine and more formulations, has broad prospects.

Table 1. The distribution of drug dosage form of *Sophora japonica* in proprietary Chinese medicine

| Dosage form | Capsule | Granule | Tablet | Pill | Paste | Teabag |
|----------------|---------|---------|--------|------|-------|--------|
| Number | 7 | 5 | 10 | 7 | 1 | 1 |
| Percentage (%) | 22.6 | 16.1 | 32.3 | 22.6 | 3.2 | 3.2 |

3. With *Sophora Japonica* Statutory Proprietary Chinese Medicine Indications, *Sophora Japonica* Efficacy and Representative Drugs

With *Sophora japonica* Chinese medicine according to its efficacy and function indications can be divided into five categories, respectively, superficies-relieving formula, heat-clearing formula, sedative and tranquilizing prescriptions, blood stasis removing agent and blood regulating agent. *Sophora japonica* as a heat and cooling blood antidote, with *Sophora japonica* Chinese medicine for the treatment of internal hemorrhoids, external hemorrhoids, For example, Diyu Huaijiao pills is commonly used in traditional Chinese medicine in the treatment of hemorrhoids and anal fistula at present, It has the effect of expelling wind, cooling blood, Purging Heat and moistening dryness. It can clear viscera, heat and large intestine fire; 6 kinds of heat-clearing formulas, accounting for 25.8% of all, it has the effect of clearing away heat and cooling blood, nourishing blood and stopping bleeding. There also has superficies-relieving formula and sedative and tranquilizing prescriptions, see Table 2.

From Table 2 can be seen, most of the *Sophora japonica* proprietary Chinese medicines are the blood regulating agent, the main effect of cooling blood to stop bleeding, activating blood circulation to remove stasis, clinically used for the treatment of hemorrhoids, blood in the stool; *Sophora japonica* in the proprietary Chinese medicine to play its role in cooling blood and hemostasis. In addition, *Sophora japonica* can also be used for Superficies-relieving formula and Sedative and tranquilizing prescriptions, clear liver heat, treatment of stroke.

Table 2. Efficacy, indications and representative drug analysis of Chinese medicine containing *Sophora japonica*

| Classification | Efficacy | Representative drug | Number |
|--|--|--------------------------|--------|
| Superficies-relieving formula | Resolving phlegm and strengthening the brain, dispelling wind and activating meridians and collaterals | XingnaoZaizao capsules | 2 |
| Heat-clearing formula | Clearing away heat and cooling blood and nourishing blood to stop bleeding | Qinggan Jiangya Capsules | 8 |
| Sedative and tranquilizing prescriptions | Tonify liver and kidney, promoting intelligence and calming the nerves | Tianzhi particles | 1 |
| Blood stasis removing agent | Regulating qi to relieve pain and activating blood circulation to remove stasis | Xinning tablets | 6 |
| Blood regulating agent | Dispelling wind and cooling blood, Purging Heat and moistening dryness | DiyuHuaijiao pills | 14 |

4. Application and Characteristics Analysis of the Proprietary Chinese Medicine Containing *Sophora Japonica*

4.1. Clinical Application and Adverse Reactions of the Proprietary Chinese Medicine Containing *Sophora japonica*

The author searched the name of Chinese herbal medicine containing *Sophora japonica* in CNKI and retrieved it for nearly ten years (2007 -2017), with 408 related periodicals (excluding the doctoral and master's thesis). In the 408 journals, there are 239 articles that belong to the clinical research and treatment of diseases, accounting for 58.6% of the total relevant literature; A total of 52 articles were used in laboratory studies, accounting for 12.7% of the total; There are 78 articles concerning the determination of chemical active ingredients in Chinese patent medicines, accounting for 19.1%; There are 33 related articles about the preparation process, quality standard, pharmacological effect and so on. Of the 239 articles on clinical use, 111 were combined with other medicines, accounting for 46.4% of the total, and 128 (53.6%) were used alone for clinical treatment. Another 5 adverse reactions reported, which all are XueshuanXinmaoning tablets (capsules) of the adverse reactions, mainly were rash, allergies, digestive system toxicity, bradycardia, excessive use of thrombosis of the heart caused by acute diarrhea.

Table 3. Overview of clinical treatment of disease literature

| Disease | Cerebral infarction | Vascular dementia | Coronary heart disease, angina | Hypertension | Glomerular nephritis | Hemorrhoids and blood in the stool | Other |
|----------------|---------------------|-------------------|--------------------------------|--------------|----------------------|------------------------------------|-------|
| Number | 54 | 79 | 42 | 20 | 15 | 9 | 20 |
| Percentage (%) | 22.6 | 33.1 | 17.5 | 8.4 | 6.3 | 3.7 | 8.4 |

In 239 articles containing *Sophora japonica* proprietary Chinese medicine clinical application literatures, involving a variety of diseases. Including cerebral infarction, vascular dementia (cognitive impairment), coronary heart disease, angina[2], hypertension, glomerular nephritis, hemorrhoids and

blood in the stool; There are 219 articles dealing with the treatment of the above diseases, accounting for 91.6% of the total. The remaining articles deals with the treatment of diabetic complication,, ventricular premature beats, depression and other diseases[3], a total of 20 articles, accounting for 8.4% of the total, see Table 3.

4.2. Clinical Application Analysis

The proprietary Chinese medicine containing *Sophora japonica* is used in clinic for the treatment of vascular dementia (cognitive impairment), cerebral infarction, coronary heart disease, angina, hypertension and other diseases.

4.2.1. Vascular Dementia. In the treatment of vascular dementia in 79 papers, combined with Western medicine treatment of 36 papers, accounting for 45.6%; For example, the compound preparation of Tianzhi granules is TianmaGoutengyin plus *Sophora japonica* refined, Prescription of *Sophora japonica* and gardenia and other drugs together, playing the effect of clearing down the liver-fire, nourishing liver and kidney. For the TCM syndrome of deficiency of liver-yin and kidney-yin, excessive rising of liver-yang related dizziness, irritability, insomnia, soreness and weakness of waist and knees and other symptoms have a significant effect. Clinical Tianzhi granules combined with donepezil for hyperactivity of liver Yang Syndrome in patients with vascular dementia symptoms improved significantly better than the single use of two drugs [4].

4.2.2. Cerebral infarction. Acute cerebral infarction belongs to the category of "stroke", mainly due to stagnation of blood stasis and the end of cerebral venous obstruction. In the 54 papers of clinical treatment of cerebral infarction, the combination of drugs accounted for 42.6%. For example, XingnaoZaizao capsules is the AngongNiu Huang pills by scientific extraction and refined from the new Chinese medicine preparations. It is composed of 36 kinds of medicinal materials. In the prescription, warm medicinal herbs are 15 flavors, 15 flavors of cold herbs, neutral medicinal materials are 6 flavors. *Sophora japonica* in the prescription, mainly play the role of clearing away heat and purging fire, with the compatibility of various drugs, a total of phlegm, wind dispelling the vitality of the work. For the confusion, mouth salivation, cerebral thrombosis recovery and so on, the effect is significant. Studies have shown that XingnaoZaizao capsules can inhibit the blood vessels due to vascular obstruction and local blood stasis formation of thrombus, which suggesting that the drug has inhibited the role of thrombosis in vivo [5-6].

4.2.3. Cardiovascular Disease. The main pathogenesis of coronary heart disease and angina in TCM is qi stagnation and blood stasis. Promoting blood circulation to dissipate blood stasis and relieving pain through the pulse, which is one of the important treatment methods for coronary heart disease and angina. There are 42 clinical studies on the treatment of coronary heart disease and angina in CNKI, including 28 drugs alone and 14 drugs in combination. For example, Xining tablet is based on the basic pathogenesis of "qi deficiency blood stasis", from the theory of "deficiency" and "stasis", which can be used to invigorating qi and activating blood circulation, activating meridians to stop pain. From the angle of traditional Chinese medicine theory, this medicine pays attention to the difference between the true and the false of Chinese medicine and the five elements (viscera), the treatment of phlegm from the spleen, dual therapy of Qi and blood [7]. In clinical research, the treatment of angina and coronary heart disease with XueshuanXinmaining tablets combined with Ginkgo leaf extract and dipyridamole can significantly improve the symptoms of chest pain, chest tightness and heart palpitations, and also reduce the number of attacks of angina [8-9].

There also has literatures suggests that for patients with sleep disorders (liver kidney yin deficiency, hyperactivity of liver fire syndrome) in the elderly patients with hypertension by Qinggan Jiangya capsules combined with amlodipine treatment not only can effectively improve the sleep status of patients, improve the quality of life, and non dipper blood pressure also get better control [10].

4.2.4. Hemorrhoids and blood in the stool. *Sophora japonica* bitter, slightly cold, good clear large intestine of the fiery, especially to the digestive tract hemorrhage hemorrhoids, blood in the stool is

good for the treatment of blood in the stool commonly used drugs. In the Chinese Pharmacopoeia and the ministerial standards in the query with the Sophora Chinese medicine 31 kinds, of which 14 kinds of proprietary Chinese medicine for the treatment of hemorrhoids and blood in the blood. For example, clinical oral Diyu Huaijiao pills can clear heat and drain dampness, regulate qi and activate blood, detumescence and relieve pain, it can combine with Mayinglong hemorrhoids ointment (bolt) playing the effect of clear away heat and toxic material, detumescence and relieve pain, the treatment of mixed hemorrhoids curative effect; Zanglian pills and Sihongdan has a good hemostatic effect, which can be used for the treatment of hemorrhoids, hematochezia and other diseases [11-12].

4.2.5. Other. Chinese medicine containing Sophora japonica can also treat glomerular nephritis, hyperlipidemia, diabetes complications, ventricular premature beat, and depression and so on, mostly for combination therapy. For example, Xinmaitong tablets combined with mecobalamine has obvious effect on lowering blood pressure and blood fat, nourishing heart and activating blood circulation to dissipate blood stasis; It has definite curative effect on hyperlipidemia and hypertension and has certain curative effect on improving the peripheral circulation of diabetic patients [13]. Tianzhi granules could relieve the Deanxit caused insomnia and transient discomfort and other adverse reactions, depression after stroke with Deanxit in the treatment of clinical use of Tianzhi granules have significant effect [14]. In addition, laboratory studies have shown that total flavonoids of Sophora japonica has a good therapeutic effect on streptozotocin diabetic rat model, which can significantly decrease serum glucose and leptin levels, serum insulin levels and C-peptide levels are significantly increased [15].

4.3. Adverse Reactions Analysis

5 adverse reactions in the search on CNKI reports are all Xueshuan Xinmaoning tablets (capsules)[16]. Xueshuan Xinmaining in the Chinese Pharmacopoeia note "pregnant women should avoid". The adverse reaction is "unclear" in the specification. We found that few reports related to acute diarrhea, bradycardia and allergic reaction etc.. There are a large number of medicinal herbs in the prescription, some of which are poisonous. For example, leech is a kind of insect medicine, containing animal heterologous protein, there is a rash after the patient took [17]; Venenum Bufonis is a kind of animal protein, It has strong sensitization, which can lead to immune reaction, induce platelet destruction and allergic dermatitis [18]; In addition, musk and borneol have adverse reactions reported; therefore, the safety of this drug needs further systematic analysis.

As can be seen, the traditional Chinese medicine is not only used alone in clinical application, and Chinese medicine combined with Western medicine can not only increase the curative effect, but also can reduce the side effects of Western medicine. Which can give full play to the advantages of Chinese and Western medicine respectively? But we need to distinguish disease dialectical and select the appropriate medicine, according to the patient's physical condition, and the characteristics of the order of priority, choose appropriate drugs.

5. Results

As early as in the Huangdineijing, there has the records of the pill, powder, ointment, Dan and other Chinese medicine forms, then gradually developed. Although the traditional Chinese medicine research is still not perfect, but we are still in a dominant position. Sophora japonica as traditional Chinese medicine tastes fragrant sweet, rich in vitamins and minerals, but also clearing away heat and toxic material, cooling blood and moistening lung, lowering blood pressure and prevention of stroke. The Sophora japonica proprietary Chinese medicines in the Chinese Pharmacopoeia and the ministerial Standard included only 30 kinds, but in clinical can be used to treat a variety of diseases.

There are some problems in the development of Chinese herbal medicine. For example, the Chinese Pharmacopoeia and the ministerial standards included in the Sophora japonica Chinese medicine are oral medication, without Sophora japonica topical proprietary Chinese medicine; In clinical applications are also taken orally, no external treatment of disease research literature. And in the existing proprietary Chinese medicine, Sophora japonica is used as a supplement. In addition, the causes of adverse reactions were not analyzed, and the safety of the drugs needed to be further analyzed.

Study on the active components of modern Chinese medicine containing *Sophora japonica* has gradually increased. There are 78 articles involving the determination of chemical composition, laboratory studies have 52 articles, it can be seen that modern research is gradually deepening. The pharmacological activities of *Sophora japonica* are various, the chemical composition is complex, and the modern new technology is developing rapidly. Therefore, the traditional Chinese medicine containing *Sophora japonica* can be gradually developed. To make clear the role of *Sophora japonica* in proprietary Chinese medicine, we can develop the Chinese medicine new dosage forms of *Sophora japonica*; The Chinese medicine is made up of a certain proportion of the drug, which involves a variety of single herbs, some are toxic drugs, When an adverse reaction occurs, We should analyze the specific causes and avoid the occurrence of adverse reactions. In addition, *Sophora japonica* is a traditional herbal medicine and food in China, we can expand the application in the field of food and explore the pharmacological and toxicological pathology, etc., which can better serve the people, promote the modernization of Chinese medicine.

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7. References

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