

The Role of Standardized Herbal Formulas in Contemporary Healthcare Delivery

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ABSTRACT: *Scientists, clinicians, and consumers are often concerned about the safety, effectiveness, and consistency of herbal preparations. Their apprehension about these qualities is due to a plethora of unknowns including the complex biochemical heterogeneity of herbs, an apparent dearth of scientific validation, a lack of understanding as to what happens when herbs are combined, raw herb quality and the processing methods used to make the preparations, and potential adulteration. This paper*

addresses these issues by introducing the unique technology now being utilized to produce standardized modern herbal formulations that are safe, efficacious, and of consistent quality. A comprehensive review of the clinical evaluation of four of these modern herbal formulations currently used within the Chinese healthcare system is provided. Biologically active constituents of these formulations that may be associated with their observed pharmacological actions are also discussed.

It is now well known that animals use plants for medicinal purposes and it is unlikely that there was a time when humans did not use herbal medicines.^{1,2} Evidence of the use of plants for medicinal purposes exists from as far back as the Neolithic Era (12,000 B.C.).³ There are also many accounts of medicinal plant use by small communities around the world, who crafted their survival from the resources around them.^{4,6} In modern health care, however, medicinal herb quality is not solely based on ancestral origins and methods of preparation. It is also based on safety, efficacy, and consistency of product.

As an example of recent advancements in the field of modern herbal formula production, this paper introduces the reader to the newest application of traditional Chinese herbology that emphasizes the transformation of empirical knowledge into a discipline that is rooted in modern technology, science, and quality.

PRINCIPLES OF MODERN CHINESE HERBAL QUALITY

The traditions of medicine that developed in China from the pre-historic era are time tested. They survived as a major part of health care provision to the present day and through extraordinary continuity, constitute the most comprehensive clinical strategy for the use of herbal medicines anywhere. Annual U.S. sales of Chinese herbal remedies dispensed by healthcare professionals are estimated at \$30 million.⁷ In China, the over-the-counter (OTC) and prescription herb market is estimated to be \$20 billion annually and accounts for 80% of all medicines that are used.⁸

Empirical knowledge in traditional Chinese medicine has been acquired, continuously enhanced, and passed down through many generations. This has provided a foundation for the innovative technology and science now being used to produce specialized modern herbal formulas that incorporate the following features:

1. **Ease of Application**—Western-like diagnostic and treatment principles are incorporated into the design of the formulas,

making it easier for the clinician to understand and recommend them for specific conditions.

2. **Established Safety and Efficacy**—The safety and usefulness of the formulas has been validated using modern scientific methods. In addition to studying the individual herbs, studies are performed on the actual formulas. These include controlled trials in humans and animals, in vitro studies, safety and toxicity evaluations, and phytochemical analyses.

3. **Ultra-Concentrated Extracts**—Contemporary herbal formulas are first produced according to the traditional methods of individual herb preparation. Then, using sophisticated technology, the herbs are further processed to produce ultra-concentrated extracts, resulting in lower dosing requirements.

4. **Sophisticated Fingerprinting**—The routine measurement of biological markers as well as herbal “fingerprinting” utilizing instrumentation such as fourier transform infrared (FTIR) spectroscopy are performed in order to maintain batch-to-batch consistency. This validates that the right mixture of the proper herbs in the correct proportions was used in order to result in a reproducibly safe and beneficial clinical effect.

5. **Strictly Maintained Quality Control Standards**—Comprehensive standards of quality control are strictly maintained. Every necessary step is taken to ensure that all ingredients are premium, grade A quality as defined in the *Official Chinese Herbal Compendium*. Thorough testing procedures identify each raw herb and ensure it to be free of any adulteration or contamination, including pesticides and heavy metals. The potency of these products through their entire shelf life is guaranteed.

6. **Proven Record of Performance**—These products all have proven records of accomplishment in that they are currently utilized in many clinics and hospitals.

ENSURING AN HERB'S BIOCHEMICAL COMPLEXITY AND REPRODUCIBILITY—A KEY TO EFFICACY

Given that all herbs that are used for medicinal purposes are chemically complex entities, quality issues are of paramount interest to clinicians. Herbs often need to be manufactured by multi-step procedures that can include heat, cold, vacuum, mechanical separation, and sometimes extraction with harsh solvents. As a result, the complement of biologically significant activities will often vary, diminish, or disappear. However, even if the problems of processing the herb are ignored, there still remains the problem of the quality of the herb itself. An herb is biologically defined and even if this definition is adhered to, there is an element of biochemical uncertainty. The active components of a particular dried herb can vary considerably. This is due to factors such as grade used (A, B, C), part used (e.g., root, stem, leaf, root hairs), climate, soil conditions, genetic characteristics, time of harvest, methods of harvest, and drying techniques.

To illustrate the inherent complexity and variability that exists, the part of the herb that is used is a major determining factor in the quality of the finished product. Table 1 shows that the leaves and root hairs of Asian ginseng (*Panax ginseng*) have the highest amount of ginsenosides.⁹ However, the best biologically active Asian ginseng is obtained from the unique combinations of ginsenosides found in the main and lateral roots. For instance, a ratio of Rg1 to Rb1 greater than 0.5 is now accepted as a preferred marker of quality. It is also known that other components found in the main root contribute significantly to the therapeutic activity of Asian ginseng.

Table 1. Content of Ginsenosides in Asian Ginseng (%)⁹

	Rg1	Re	Rf	Rg2	Rb1	Re	Rb2	Rd	Rg1/Rb1	Total
Leaves	1.078	1.524	-	-	-	-	0.553	1.113	-	5.188
Leaf stalks	0.327	0.141	-	-	-	-	0.107	0.765	-	0.765
Stem	0.292	0.070	-	-	-	-	0.397	-	-	0.759
Main root	0.379	0.153	0.092	0.023	0.342	0.190	0.131	0.038	1.11	1.348
Lateral roots	0.406	0.668	0.203	0.090	0.850	0.738	0.434	0.143	0.48	3.532
Root hairs	0.376	1.512	0.150	0.249	1.351	1.349	0.780	0.381	0.28	6.148

One approach to overcome the problem of chemical variation of herbs is to quantify one or more indicator biochemicals to a predefined minimum level. These components may not be solely responsible for the complete spectrum of therapeutic effects of the herb, but rather will act as indicators of consistent quality. However, they should be meaningful indicators of quality. Many common herbal medicines are now quantified for their active components and appropriate dosage ranges are set accordingly. Unfortunately, a major drawback to this approach is that although biochemical indicators can be standardized, this doesn't guarantee that the herbal extract will have reproducible biological activity. In fact, "standardized herbs" produced by different methods, but having equivalent biochemical markers of standardization, can have entirely different profiles of biological activity. For example, when using different manufacturing technologies and plant parts, not all *dong quai* extracts that are standardized to contain 0.2% ligustilides will have the same biological activity.

In any rational approach to incorporating herbs into a clinical practice, what should be of paramount concern to the clinician is: (1) product safety, (2) scientifically and clinically documented efficacy, (3) consistent product with predictable clinical outcome, and (4) a long standing track record of usage that validates safety, efficacy, and consistency.

IS THERE ANY ADVANTAGE IN CHEMICALLY COMPLEX HERBAL PREPARATIONS?

After centuries of empirical use of herbal remedies, Chinese practitioners found that the effects of single herbs change with their herbal environment. Components of herbs that are not active themselves can improve the biological action of the active constituents by affecting stability, solubility, bioavailability, or some other parameter. In pure form, a particular biochemical might have only a fraction of the pharmacological activity that it has in its herb matrix or when combined with other herbs. Scientific inquiry is only beginning to define these biochemical interactions.

Synergy is one example of how an advantage might arise out of biochemical complexity. It applies if the action of a biochemical mixture is greater than the sum of its parts. One study that illustrates synergy was performed to measure the free radical scavenging action of an herbal mixture. The formula studied, *Sheng Mai*, is prepared by first blending the herb parts and then simultaneously extracting them. The study compared the free radical scavenging action of its individual ingredients—Asian ginseng root, ophiopogon root, and schisandra fruit—to the finished decoction. The results demonstrated a net synergistic effect since the finished decoction proved to be a stronger antioxidant than the sum of its individual ingredients.¹⁰

STUDIES ON SELECTED MODERN "TRADITIONAL" HERBAL FORMULAS

The herbal formulas, *Sheng Mai* for heart, *Kuiyangling* for ulcer and stomach, *Yushangling* for soft tissue and bone, and *Xin Qin Ke Li* for sinus problems, exemplify formulas that are in the process of transitioning from a history of clinical empiricism to validation based on formal clinical trials. These preparations, which are manufactured using a complex process that includes standardizing the entire herbal mixture, embody the elements that serve to define "modern herbal formulas."

Sheng Mai—Heart and Circulation Formula

Sheng Mai capsules consist of a highly purified and standardized herbal concentrate of Asian ginseng root (*Panax ginseng*), ophiopogon root (*Ophiopogon japonicus*), and schisandra fruit (*Schisandra chinensis*). According to the theory of traditional Chinese medicine, ginseng can invigorate the primordial energy and invigorate the spleen to benefit the lung, thus promoting the production of nourishing body fluids and tranquilizing the mind. Ophiopogon root can replenish the vital essence to strengthen the stomach and moisten the lung and clear away the "heart fire" to relieve vexation. Schisandra fruit can supplement *qi* and promote the production of nourishing body fluids, tonify the kidney to nourish the heart, and induce astringency.

Among the key active compounds in ginseng are saponins, particularly the ginsenosides, which exert a positive effect on the function of the heart directly or they help treat related conditions.¹¹⁻¹⁶ Some of the mechanisms of action of these ginseng compounds include interference with the absorption of cholesterol of both dietary and endogenous origin,¹⁷⁻¹⁹ inhibition of the 3formation of lipid peroxides in the cardiac muscle¹⁰ and in the liver,²⁰ decreased blood coagulation,²¹⁻²³ and stimulation of the immune system.^{24,25} The ginsenoside Rg3 is a major mediator of the endothelium-dependent relaxation in response to ginsenosides in isolated aorta, possibly via activation of K⁺ channels.^{26,27}

The effectiveness of *Sheng Mai* in preventing and treating various diseases of the heart and circulatory system has been evaluated in several studies. In one study, *Sheng Mai* capsules were used to treat 112 patients with coronary atherosclerosis.²⁸ The patients were randomly separated into two groups: 59 in the treatment group received 500 ml of chrysanthemum tea and 2 *Sheng Mai* capsules, 3 times a day; 53 in the control group received 500 ml of chrysanthemum tea and 3 tablets of red-rooted sage root, 3 times a day. The treatment was continued for 2 weeks. Nitroglycerin was given to patients with severe angina pectoris when necessary.

This study showed the general positive effect of *Sheng Mai* capsules to be 89.3% when evaluated by angina pectoris relief, 80.4% when evaluated by resting electrocardiogram (ECG), and 69.6% when evaluated by dynamic ECG. All evaluations were significantly higher than those in the control group. *Sheng Mai* capsules increased cardiac output, showed a positive effect on arrhythmia, and significantly decreased atrial and ventricular premature contractions. Some authors have reported that *Sheng Mai* capsules lower the concentration of blood lipid peroxides in angina pectoris patients, which may explain one of the mechanisms in which it lessens ischemic lesions and treats angina pectoris.²⁹

The results demonstrate that *Sheng Mai* has a reliable effect on relieving angina pectoris derived from coronary atherosclerosis and a positive effect on the treatment of ischemic heart disease (IHD) and arrhythmias. Only minor side effects were observed.

In a second study, 100 coronary atherosclerosis patients were evaluated.³⁰ The effectiveness of *Sheng Mai* was rated according to the improvement of clinical complaints and signs, oxygen consumption of myocardium, and ECG. Three *Sheng Mai* capsules were given 3 times per day for one week. All other medications were stopped during *Sheng Mai* treatment except for nitroglycerin and dinitrate. Their usage was also used as a parameter for evaluating the effectiveness of *Sheng Mai*, with complete withdrawal or extenuation by more than 50% calculated as effective. Potential adverse reactions were evaluated by including blood and urine routines as well as liver and renal functions, before and after administration.

Following *Sheng Mai* treatment, the general pain-relieving rate among the 100 patients was 91%; the general effective rate on the symptoms of chest distress, shortness of breath, palpitation, dizziness, and tinnitus was greater than 68%; the general withdrawal or extenuation rate of nitroglycerine and dinitrate was greater than 53%; the oxygen consumption of the myocardium was significantly decreased ($p < 0.01$); and the general improvement of ischemia evaluated by ECG was 72%. No significant side effects were observed. Blood and urine routines, liver and renal functions, as well as ECG were all within normal ranges after *Sheng Mai* treatment.

A third study reported the results of using traditional Chinese medicine (*Sheng Mai*) and Western medicine in a combined regime to treat atrial fibrillation caused by rheumatic mitral stenosis.³¹ The data showed that the combined treatment achieved significant therapeutic results. The study included 50 patients with persistent atrial fibrillation caused by rheumatic mitral stenosis, all of which fit the criteria for defibrillation.

The patients were randomly divided into treatment and control

groups. The treatment group received 200 mg *andiantong* (a Western anti-arrhythmia drug) and 2 capsules of *Sheng Mai* 3 times per day. After defibrillation, the dosage of *andiantong* was switched to 200 mg/day, while the dosage for *Sheng Mai* remained the same. The post-defibrillation treatment lasted for 2 weeks. For the control group the dosage and duration of *andiantong* were the same as those in the treatment group, but did not include *Sheng Mai* capsules. One week before treatment, use of digitalis and other anti-arrhythmia medicines was discontinued.

For those who recovered normal sinus rhythm after treatment, the therapy was considered significantly effective. For those with improved symptoms after treatment without defibrillation but where ventricular impulses were controlled within 70-87 minutes, the therapy was considered effective. For those with no obvious changes in syndromes and ventricular rhythm, the therapy was considered not effective. As compared to the *andiantong*-only treatment (control), the positive effect of the combined treatment was significantly greater (Table 2).

Table 2. Comparison of the Positive Effectiveness (%)

Group	Significantly Effective	Effective	Not Effective
Treatment	76.7	23.30	0
Control	45.0	45.0	10

These results indicate that the combination of *Sheng Mai* and *andiantong* is superior to *andiantong* alone and is an ideal therapeutic regime for the treatment of atrial fibrillation caused by rheumatic mitral stenosis, with the features of quicker initiation action and shortened treatment duration.

In summary, studies have indicated that *Sheng Mai* can control arrhythmias, enhance cardiac output, decrease the resistance in coronary arteries, reduce oxygen consumption of myocardium, improve the tolerance of cardiac muscle to ischemic lesions, and shorten the recovery period of ventricular muscle after excitation. These results provide justification for further research to confirm these findings and elaborate the understanding of the clinical application of modern herbal formulas.

***Kuiyangling*—Ulcer and Stomach Formula**

There is a global incidence of stomach and duodenal ulcers as common systemic diseases. According to recent epidemiologic evidence, the rate could be as high as 10% of the population. In hospitalized patients the number of duodenal ulcers is more common than stomach ulcer, the ratio being about 3:1. Although there are many drugs for the treatment of these conditions, the recurrence rate is high. Therefore, seeking a new therapeutic approach that results in a low recurrence rate is an issue of interest.

The herbal approach to the treatment of ulcers should take into account all causative and sustaining factors that are relevant to the individual patient. Rather than being concerned with just inhibiting gastric acid, the herbal approach stresses the importance of factors that protect the mucosa and improve the ability of the body to heal the ulcer. *Kuiyangling* is formulated based on the classical composition of traditional Chinese medicine theory for treating “stomach duct pain” and it is valued for its efficacy and low side-effect profile. The herbal components of *Kuiyangling* are as follows:

- Mucilage and tannin containing herbs including Chinese licorice root (*Glycyrrhiza uralensis*), bletilla root (*Bletilla*

striata), and gambir leaf and stem (*Uncaria gambir*) to enhance mucoprotection.^{32,33}

- Herbs that have been shown to have specific anti-bacterial properties against *Helicobacter pylori*. The isoquinoline alkaloids in corydalis tuber (*Corydalis yanhusuo*) as well as isoflavonoids isolated from licorice provide these properties.³⁴
- Immune-enhancing herbs such as astragalus root (*Astragalus membranaceus*) and licorice are used to help resolve the presence of *H. pylori*. These types of herbs were traditionally used in peptic ulcer disease long before their association to *H. pylori* was recognized.³⁵
- Gently astringent herbs containing tannins assist ulcer healing and boost mucoprotection near the ulcer. Tannins inhibit the viability of infecting microorganisms, check fluid hypersecretion, and neutralize inflammatory proteins.³⁶ Gambir contains the tannins dl-catechin and d-epicatechin and can provide increased protection to gastric mucosa. These tannins are also potent peroxy radical and superoxide anion scavengers.^{37,38}
- Anti-inflammatory herbs such as Chinese licorice and tienchi ginseng root (*Panax pseudoginseng*) to help accelerate the healing process by reducing ulcer inflammation.³⁹⁻⁴⁶
- Anti-spasmodic and carminative herbs to improve gastrointestinal motility. These herbs include corydalis, Chinese licorice, Zhejiang fritillary bulb (*Fritillaria thunbergii*), and Brown's lily bulb (*Lilium brownii*).⁴⁷⁻⁴⁹
- Sepia (cuttlefish shell) to normalize acidity of the stomach.⁵⁰ It appears to decrease the negative effects of acid and pepsin on the mucosa. Additionally, the alkaloid dehydrocorydalin found in corydalis inhibits gastric secretion, thereby further helping to accelerate the healing of the lesion.⁴⁸

An early experimental study showed that *Kuiyangling* exerts a protective effect to the mucous membrane of rats and guinea pigs with chemically induced gastritis and gastric ulcer.⁵¹ The effect of *Kuiyangling* was judged similar to cimetidine. The mechanism of action may be the inhibition of the secretion of pepsin. Both acute and chronic toxicity testing was negative.

In another study, the *H. pylori* in gastric mucosa of chronic atrophic gastritis patients was cultured in vitro and Chinese medicinal herbs were investigated for bacteriostatis.⁵² *H. pylori* was discovered to be sensitive to tienchi ginseng, moderately sensitive to corydalis tuber, and highly sensitive to astragalus root.

In a clinical study utilizing *Kuiyangling* for the treatment of chronic superficial gastritis, 408 patients were evaluated.⁵¹ Diagnosis and outcome were measured by gastroscopy, histology, and symptomatology. The symptomatic effective rate was 90.5%, while therapeutic effect proved by gastroscopy and histology was 81.9% and 72.8%, respectively. No side effects were reported.

In a randomized trial of 425 cases of gastric and duodenal ulcer, *Kuiyangling* was compared to the Western drug Gastridine (Midelid).⁵³ The regimens were given to patients during a 4-week therapeutic course. Gastroscopic examination was used as the index of healing of the ulcer. The rates of complete healing, improvement, and failure of the *Kuiyangling* group and the

Gastridine group are shown in Table 3. In Table 4, the recurrence rate of ulcers after 3-6 months and 1-2 years are shown, with average recurrence rates of 10.9% for the *Kuiyangling* group and 35.3% for the Gastridine group. All results were statistically significant ($p < 0.05$).

Table 3. Comparison of Ulcer Healing

Indication	<i>Kuiyangling</i> (N=325)	Gastridine (N=100)
Complete Healing	95.4%	64.0%
Improvement	3.7%	25.0%
No Change	0.9%	11.0%

Table 4. Comparison of Ulcer Recurrence Rates

	3-6 months	1-2 years	Average Recurrence Rate
<i>Kuiyangling</i> (n=64)	10.9%	0.0%	10.9%
Gastridine (n=34)	23.5%	11.8%	35.3%

The results of this study show that not only was there a higher rate of healing in the *Kuiyangling* group, the average recurrence rate was significantly lower over a 2-year follow-up period.

Yushangling—Bone and Soft Tissue Damage

Yushangling is formulated based on the classical composition of traditional Chinese medicine theory for treating soft tissue and bone injuries. According to this theory, sprains, knocks, falls, and blows to soft tissues, ligaments, tendons, and bones produce a form of congestion referred to as temporary blood stagnation or blood stasis at the site of an injury. When herbs are combined that successfully “move the blood,” the body rebounds more quickly from physical trauma. *Yushangling* is a standardized herbal concentrate that nourishes and “invigorates” the blood, promotes blood circulation, promotes capillary tone, is hemostatic, relaxes muscle, and is anti-inflammatory and analgesic.

The herbs in *Yushangling* reinforce and complement each other's actions. Tienchi ginseng root (*Panax pseudoginseng*), dong quai root (*Angelica sinensis*), safflower flower (*Carthamus tinctorius*) and Sichuan teasel rhizome (*Dipsacus asperoides*) combine to influence circulation. At the same time, traditional use suggests that dong quai also supports digestion; tienchi ginseng influences the liver and possesses the cardiogenic properties associated with the ginseng species; and Sichuan teasel has an affinity for bone. *Xu duan*, Chinese for Sichuan teasel, translates as “bone healing herb.”

In an in vitro study, the effect of the ingredients in *Yushangling* on the synthesis of thromboxane A2 (TXA2) and prostaglandin I2 (PGI2) was studied.⁵⁴ It was found that tienchi ginseng could inhibit the synthesis of TXA2 and decrease the formation of PGI2; safflower significantly inhibited the synthesis of TXA2, but had no effect on the synthesis of PGI2; and Sichuan teasel markedly inhibited the formation of TXA2 and mildly affected the formation of PGI2. These results suggest that through their influence on prostaglandin metabolism, the herbs contained in *Yushangling* promote blood circulation, thus speeding the removal of waste products from the site of injury and promoting healing.

An experimental study on a rat model of inflammatory hyperalgesia identified certain ingredients in *Yushangling* as effective herbal agents in attenuating persistent hindpaw inflammation and hyperalgesia.⁵⁵ These results indicate that some herbal agents may provide alternative approaches to the treatment of persistent inflammatory pain and hyperalgesia.

In another experimental study, the anti-inflammatory effect of *Yushangling* on paw edema, thermal hyperalgesia, and the mRNA increase of neuropeptides in spinal dorsal horn and hypothalamic neurons was investigated using a rat model of peripheral inflammation and hyperalgesia.⁵⁶ The rats that received *Yushangling* 3 days before the injection of CFA into the plantar had significantly less edema and reduced thermal hyperalgesia compared to control rats that received the CFA injection only. The up-regulation of preprodynorphin mRNA in L4-5 dorsal horn neurons 8 hours after CFA injection was also decreased in the *Yushangling* treated rats. Moreover, there was a significant decrease in mRNA level of corticotropin-releasing factor in the paraventricular hypothalamic nucleus in the *Yushangling* treated rats. These data demonstrate that *Yushangling* has anti-inflammatory properties and produces changes in mRNA expression in dorsal horn and hypothalamic neurons, suggesting that *Yushangling* may affect the excitability of neurons through an anti-inflammatory mechanism.

Xin Qin Ke Li—Sinus and Nose Formula

Xin Qin Ke Li is formulated based on the classical composition of traditional Chinese medicine theory for treating conditions of the nose and sinus. It is mainly used to treat cold, allergic rhinitis, acute and chronic rhinitis, nasosinusitis, and other sinus and nose related ailments. It is based on herbs that are traditionally used to disperse cold and relieve pain, expel pathogenic factors from the exterior, strengthen the spleen and replenish the *chi*, expel the pathogenic wind from the body, drain pus, and expel toxins. From the perspective of modern medicine, *Xin Qin Ke Li* is antiseptic, antiviral, and anti-anaphylactic, regulates the immune system, improves the passage of air through the nasal cavities, reduces headache and dizziness, and eliminates pus drainage.

One of the ingredients in this formula is fragrant angelica root (*Angelica dahurica*). It contains a number of naturally occurring furanocoumarins that appear to inhibit nitric oxide (NO) production under tissue-damaging inflammatory conditions.⁵⁷ It is well known that NO production plays an important role in inflammation.

In a blinded clinical study, 690 subjects diagnosed with chronic sinusitis were divided into two groups: Group I subjects (n= 360) were treated with *Xin Qin Ke Li* 1800 mg/3 times per day (subjects under 12 years of age received 900 mg/3 times per day) and Group II subjects (n=330) were given standard sinus medication for a period of 10 days.⁵⁸ The entire group of patients was comprised of 431 males and 259 females between the ages of 8 and 71, with an average age of 37. The shortest symptom period was 3 months and the longest was 32 years.

Table 5 shows the positive effect of the respective treatments on the two groups. “Significant Improvement” means congestion, pus drainage, headache, and the reduced ability to detect odors (hyposmia) has ceased; no pus in nasal meatus; reduction in swelling of turbinates; and normal passage of air through nasal cavity. “Improved” means these symptoms are reduced but not alleviated. “No Effect” means no improvement in any of the symptoms. As Table 5 indicates, those patients in the *Xin Qin Ke Li* group experienced greater improvement in symptoms than those in the sinus medication group.

There are many methods for clinical management of allergic rhinitis in children but satisfactory results are not always attained. In China, Western sinus inflammation medicines have been widely

used in clinical treatment of allergic rhinitis in children because of their low cost. A clinical study on the effect of *Xin Qin Ke Li* was performed to assess its effect compared to sinus medication on 109 children with allergic rhinitis.⁵⁹ One group was treated with *Xin Qin Ke Li* and the other group with sinus inflammation medication. Subjects under 3 years old were given 1250 mg/3 times per day of *Xin Qin Ke Li*, while patients above 3 years were given 2500 mg/

Table 5. *Xin Qin Ke Li* = I Sinus Medication = II

Symptoms & Physical Signs	Total Patients		Significant Improvement		Improved		No Effect		Percentage (%)	
	I	II	I	II	I	II	I	II	I	II
Congestion	360	330	195	99	144	98	21	133	94.17	59.70
Nasal drainage	360	330	172	104	152	96	36	130	90.00	60.61
Headache	280	272	128	78	110	85	42	109	85.00	59.9
Reduced ability to detect odors	156	140	79	38	33	44	44	58	71.79	58.57
Pus drainage	360	330	196	94	131	98	33	138	90.83	58.18
Moderate turbinate swelling	315	293	141	87	111	75	63	131	80.00	55.29
Slight turbinate swelling	305	284	133	90	116	81	56	113	81.64	60.21

3 times per day over a period of 15-30 days. During the period of treatment, no other sinus medication or treatment was given.

From Tables 6 and 7, it can be seen that there was more improvement in symptoms and physical signs and a greater drop in the level of eosinophils in the *Xin Qin Ke Li* group than in the sinus medicine group. The differences in the effectiveness between the two types of medication were statistically significant (p<0.05).

Table 6. Changes in Symptoms

Symptoms	N	Effectiveness			% Total Effectiveness	
		Very Effective	Effective	No Effect		
<i>Xin Qin Ke Li</i>	Congestion	62	42	15	5	91.9
	Itching and sneezing	62	40	18	4	93.5
	Nasal discharge	62	39	16	7	88.7
	Headache and dizziness	48	31	12	5	89.6
Sinus Medicine	Congestion	47	18	15	14	70.2
	Itching and sneezing	47	19	16	12	74.5
	Nasal discharge	47	16	11	20	57.4
	Headache and dizziness	33	11	9	13	60.6

Table 7: Changes in Physical Signs

Sign	N	Improvement		% Improved	
		Improved	No change		
<i>Xin Qin Ke Li</i>	Swollen middle and lower turbinates	62	49	13	79.0
	Presence of eosinophils in nasal discharge	62	58	4	93.5
Sinus Medicine	Swollen middle and lower turbinates	47	28	19	59.6
	Presence of eosinophils in nasal discharge	47	29	18	61.7

According to the clinical observations, *Xin Qin Ke Li* can reduce itchy nose, sneezing, congestion, nasal discharge, headache, and dizziness without side effects for a prolonged period of time. The subjects did not suffer or report any discomfort from taking *Xin Qin Ke Li*. In summary, it appears that the activity of *Xin Qin Ke Li* in reducing nasal and sinus symptoms is very strong, its therapeutic effect very evident, it is very safe, and more effective than Western sinus inflammation medication.

OPTIMIZING EFFICACY

An understanding of the factors that influence bioavailability can lead to more effective use of modern Chinese herbal products. In particular, bowel flora characteristics that optimize the efficacy of many herbal treatments need to be better understood. **Many phytochemicals need to be metabolized by beneficial bacteria in the gut in order to become pharmacologically active.** For example, the bacterial metabolism of tannins results in active biochemicals that have antioxidant properties.⁶⁰ Bowel flora can also have the favorable effect of increasing the physiological benefit of a phytochemical. For example, mucilages can be partially metabolized by beneficial bowel flora into short chain fatty acids. This provides a source of readily absorbed and assimilated nourishment for the mucosal wall. **The bowel factor underlies the importance of a wholesome diet, adequate fiber intake, and the proper use of pre-biotics and probiotics.**

CONCLUSION

The history of herbal treatment is marked by an enormous diversity of local traditions, with much more variety than consistency. However, themes are apparent. These emerge most clearly where local folk practices were systematized in the great written traditions in history. When these are distilled further and then transformed from empirical understanding to the scrutiny of modern science, technology, and quality, we have a rational basis for the development of safe, effective therapies using modern, standardized herbal mixtures.

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