

Stunning Herbal Formula Wins Recognition in the Western Medical Community

By Jake Paul Fratkin, OMD, LAc

Dr. Xiumin Li, a TCM doctor originally from Beijing, has assembled a research team at Mt. Sinai School of Medicine in New York that has created an effective Chinese herbal formula for the treatment of asthma. Her results, done with the collaboration of Dr. Hugh Sampson in the department of allergy and immunology, are generating significant and favorable reviews in the Western medical community for the use of Chinese herbs as an effective alternative to steroid use.

An Oct. 18, 2005 press release from Decision News Media stated, "An oral combination of three Chinese herbs could be as effective as conventional medicines at alleviating asthma symptoms but without such severe side effects, report Chinese and American researchers."¹ The release refers to a double-blind, placebo-controlled study published in the September 2005 issue of the *Journal of Allergy and Clinical Immunology*. The research was performed on 91 adults at the Waifeng Asthma Hospital in China, under the direction of Drs. Li and Sampson. An herbal pill was administered to subjects with moderate to severe "persistent asthma" over a four-week duration. Forty-six patients were given 12 capsules of the herbal formula per day, plus a placebo similar in appearance to prednisone. A control group of 45 people were given 20 mg of Prednisone a day, plus 12 capsules of placebo herbal capsules. The researchers measured lung function as well as serum cortisol, cytokine and IgE levels before and after treatment. Subjects were also monitored for side-effects of both treatments.

Results showed a "slightly better" effect on lung function with the prednisone, but the results of the herbal formula were quite impressive. While also beneficial to lung function, the herbal formula showed no adverse effects on adrenal function, and had a more beneficial effect on TH1 and TH2 cytokine levels. Prednisone patients also experienced gastric discomfort and weight gain not seen in the herbal group.

Because continued prednisone therapy is so widespread among pediatric asthma patients, with serious medical consequences, the opportunity of developing safe treatments for asthma is a welcomed event in the Western medical community.

The same press release reported, "'Taken together, the findings of this study show that ASHMI (the herbal formula) is effective and well-tolerated in nonsteroid-dependent patients with moderate-severe persistent asthma,' wrote the researchers. They said that the mechanisms underlying its 'remarkable' effects are largely unknown but that they are likely to be the result of synergistic or additive effects of the complex nature of its constituents."²

For the study, a three-herb formula was used as a concentrated extract. The formula was labeled ASHMI (for Antiasthma Herbal Medicine Intervention Formula) and produced by Weifeng Pharmaceutical Factory in China. For a daily dosage, 32 grams of raw herbs were concentrated down to 3.6 grams, and given in 12 capsules. The following herbs were used:

- *ling zhi* (ganoderma lucidum) 20 g
- *ku shen* (radix sophorae flavascentis), 9 g
- *gan cao* (radix glycyrrhizae), 3 g

From a traditional background in TCM, it would be hard to predict the success of this formula, as it is, for treatment and control of asthma. It's a very small formula, lacking in herbs that are commonly found in classical or modern asthma prescriptions. One can see, however, that the three herbs could be of benefit. *Ling zhi* has immune-enhancing effects, and at this dosage, one can accept that the cytokine levels moved towards normalization. *Ku shen* reduces heat in the lung (in addition to its strong antimicrobial effects), which could prove important in relaxing bronchial spasm. Most asthma is thought, both in TCM and Western medicine, to be the consequence of allergic inflammation, and the cooling properties of *ku shen* reduce that. The use of a small amount of *gan cao* helps to harmonize *ling zhi* with *ku shen*. The idea of "harmonization" here, in traditional herbal medicine, is to be able to take two distinctive or opposing herbal effects and allow them to present together, in this case *ling zhi* and *ku shen*. In addition, *gan cao* has the effect of regulating and enhancing adrenal function.

The deeper question is, why these three herbs? I talked at length with Brian Schofield, a colleague in Dr. Li's research who works at Johns Hopkins University, and conducted a short interview with Dr. Li.

Dr. Xiumin Li trained as a TCM herbalist in Beijing, and worked in the pediatrics department at the Sino-Japan Friendship Hospital in Beijing. She also received a master's degree in China in medical research. In the United States, she pursued postgraduate studies at Johns Hopkins University and refined her skills as a researcher. She achieved a position at the department of allergy and immunology at Mt. Sinai School of Medicine, working in close association with its director, Dr. Hugh Sampson.

In China, she was well aware of traditional herbal formulas for asthma, and wanted to discover, by research, which herbs actually had an affect on immunological and inflammatory response. To do this, she started with a successful asthma formula used at her Beijing hospital, which she called MSSN-002. This formula contained the following ingredients:

- *su zi* (fructus perillae frutescentis), 9 g
- *ting li zi* (semen lepidii), 9 g
- *xing ren* (semen pruni armeniacae), 9 g
- *huang qin* (radix scutellariae baicalensis), 9 g
- *ku shen* (radix sophorae flavascentis), 9 g
- *dang gui* (radix angelicae sinensis), 9 g
- *bai shao* (radix paeoniae lactiflorae), 9 g
- *ge gen* (radix puerariae), 9 g
- *jie geng* (radix platycodi grandiflori), 6 g
- *zhen zhu mu* (concha margaritifera), 6 g
- *ling zhi* (ganoderma lucidum), 6 g
- *gan cao* (radix glycyrrhizae), 6 g
- *da zao* (fructus ziziphi jujubae), 5 pieces
- *sheng jiang* (rhizoma zingiberis officinalis), 6 g

Dr. Li first tested the complete formula, and performed the research on mice (the standard lab animal these days) by inducing asthmatic reactions to allergic antigens. After administering the herbal formula, she evaluated various components of immune response and inflammatory reaction, including TH2-type cytokine release, airway inflammation, mast cell degranulation, release of histamine, tryptase, leukotrienes, and others.³ The researchers also tested the effect on the lymphocytes thought to be ultimately responsible for asthma.

With the idea of creating a small formula that might meet FDA approval for distribution to conventional Western medical practitioners, Dr. Li set about the laborious and painstaking task of evaluating each herb, as well as synergistic combinations of small groups of herbs, and their effect on the known physiological parameters of allergic asthma. After several years, she was able to hone in on three herbs that were found to have a definite and positive effect.

Schofield expressed it to me this way. "We hypothesized that not all herbs in MSSM-002 were necessary to produce beneficial effects on allergic asthma, and began testing the effects of each herb in our animal model of asthma. We found that some had little or no effect, whereas others were very effective. We therefore eliminated the herbs with little effect. By a process of elimination and recombination, we found that a combination of *ling zhi*, *ku shen* and *gan cao* was as effective as the 14-herb formula."⁴

The fact that she could prove its efficacy in human trials following her studies on mice opened the doors for the Western medical community to seriously look at her work. The next step is for human trials to be duplicated in the U.S., which is currently underway. A change in U.S. patent law now allows a patent to exist for herbal formulas when the application is based on solid western scientific validation.

Now that she has concluded her studies on ASHMI for bronchial asthma, Dr. Li's current project (with Dr. Sampson) involves applying her research skills for an herbal formula to treat food allergies, particularly the potentially fatal peanut allergy. For this, she is using the traditional formula *wu mei san* with the addition of *ling zhi*. Due to FDA concerns, she removed from the original formula aconite (*fu zi*) and asarum (*xi xin*). The formula used is the following:

- *ling zhi* (*ganoderma lucidum*), 28.17%
- *wu mei* (*fructus pruni mume*), 28.17%
- *huang lian* (*rhizoma coptidis*), 8.46%
- *ren shen* (*radix ginseng*), 8.45%
- *huang bai* (*cortex phellodendri*), 5.63%
- *gan jiang* (*rhizoma zingiberis officinalis*), 8.45%
- *dang gui* (*radix angelicae sinensis*), 8.45%
- *gui zhi* (*ramulus cinnamomi cassiae*), 2.81%
- *chuan jiao* (*pericarpium zanthoxyli bungeanum*), 1.41%

The National Institutes of Health has given Dr. Li a grant to pursue this study. She has already completed her animal studies. The results are extremely promising, showing that the formula completely blocks anaphylactic reaction due to peanuts in mice.⁵ It remains to be seen if she will try to reduce the formula based on the research protocol she applied to MSSN-002.

For traditional TCM herbalists, I think we can look at Dr. Li's three-herb combination for asthma, as well as working with the original MSSN-02 hospital formula. The same holds true for her modified *wu mei san* formula for food allergies. The validation of the efficacy of these formulas should encourage practitioners in choosing or creating herbal formulas for asthma and food allergy.

Dr. Xiumin Li should be recognized and honored as a pioneer in introducing Chinese herbal medicine into the American mainstream of scientific medicine, and for using the scientific method to analyze the efficacy of traditional formulas. Her name is one to remember, because it is certain she will become famous in both traditional Chinese medicine as well as Western scientific medicine.

References

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