

Efficacy of Golden Dendrobium tablets on clearing and smoothing laryngopharynx*

YU Hong^{1,2}, QU Yan^{2,4}, CHEN Xing-qi^{1,3,4}

(1. Inmol Laboratory of Biotechnology, Kunming 650106, China;

2. Laboratory of Ecological Genetics, School of Life Science, Yunnan University, Kunming 650091, China;

3. Laboratory of Systematic and Evolutionary Botany, Institute of Botany, Chinese Academy of Sciences, Beijing 100093, China;

4. Xiyuan Hospital of China Academy of Traditional Chinese Medicine, Beijing 100021, China)

Abstract: The aim of the present paper is to assess the efficacy of Golden Dendrobium tablets mainly refined from the stems of *Dendrobium nobile* Lindl. in resolving the symptoms of the patients with chronic pharyngitis and to investigate their safety for patients' health. Randomised controlled trial and self-contrast test were used. Altogether 40 patients with chronic pharyngitis in Xiyuan Hospital, aged 18—65, were randomly assigned to take Golden Dendrobium tablets for fifteen days. Before and after the experimental medicine-taking test, blood regulation, urine regulation and blood biochemical indexes, coupled with clinical symptoms and features of examinations on laryngopharynx were measured for a comparative analysis. It is obvious that Golden Dendrobium tablets can improve clinical symptoms and features of laryngopharynx in 31 subjects after 15-day medicine-taking experiment (at an efficacy rate of 77.5%). No distinct changes were found in blood regulation, urine regulation and blood biochemical indexes. All data before and after medicine-taking experiment were recorded for comparison on patients under self-contrast test. The dramatic clinical response suggests that Golden Dendrobium tablets be effective in the treatment of chronic pharyngitis and is free of adverse effect on patient's health.

Key words: Golden Dendrobium tablets; chronic pharyngitis; body medicine-taking experiment; clearing and smoothing laryngopharynx

CLC number: TS 218 **Document code:** A **Article ID:** 0258 - 7971(2005)05 - 0440 - 06

Chronic pharyngitis, a chronic inflammation of the pharyngeal mucous membrane and submucous lymphoid tissues, is often caused by un-thorough treatment of acute pharyngitis or repeated occurrences of upper respiratory tract infection, and caused by a high-dusty environment. Alternatively, the patient has a poor diet; for instance, eating too much high protein foods, those with a high fat or grease content or at high-salt levels, or spicy foods. The accumulation of these kinds of foods in the stomach and intestines causes the rise of inflamed toxins. The patient shows signs of irritableness, and

so causing the "Qi" of the liver to stagnate, the stasis of the blood and inflammation around the liver. Clinically it manifests itself as a dryness, feeling of thirst, itching, or soreness of the throat. In addition, when coughing, there is a feeling of a foreign body or obstruction in the throat. In TCM it belongs to the category of "hou bi", or inflammation of throat^[1]. The chronic pharyngitis is reported to be increasingly prevalent worldwide. In the pharynx catalogue, chronic pharyngitis has a high incidence, reaching 20%^[2]. The treatment for chronic pharyngitis depends on the understanding of the following causes.

* Received date: 2005 - 06 - 02

Foundation item: This research is supported by Modern Science and Technology Industrialized Base of Yunnan Chines Medicine.

Chinese medicine considers that ,for the type of dryness of the lung mainly due to “ yin ” deficiency and accumulation of food in the stomach and intestines , the therapeutic principle should be: “ nourishing yin ”, “ moistening dryness ”, and “ purging ‘ pathogenic fire ’ to relieve sore throat ”, and “ removing accumulation of food ”; while for the type of stasis of “ Qi ” and stagnation of phlegm , the therapeutic principle should be: “ promoting circulation of Qi ”, “ alleviating mental distress ” and “ reducing phlegm to remove masses ”. In curing the diseases , Chinese traditional medical science is first to adjust different systems of our body to correct all imbalances inside. In this way all the illness will be cured at the same time. It does not affect any normal systems but flexibly suit the specific needs of the patients , body , and is free of adverse effect and low costs. The Golden Dendrobium tablets we developed are mainly extracted by the stems of *Dendrobium nobile* Lindl.

Dendrobium is a large orchid genus of over 1 400 species , ranging from tropical and subtropical Asia to Oceania. Some 70 species of this genus are found in China , of which as many as 48 species occur in Yunnan. Some species are used medically in China , such as *D. nobile*^[4] , *D. officinale*^[4-6] and *D. tosaense*^[5]. The functional compositions are mainly aldaldoid and mucopolysaccharide in *Dendrobium nobile*^[2]. Dating back to more than 1 500 years ago , *Dendrobium tosaense* was first recorded in 《Shen Nong Ben Cao Jing》 (The Materia Medica of the Mythical Emperor) and ever listed as a top grade tonic in all Chinese traditional medical writings. The Golden Dendrobium Tablets are developed by Yunnan Inmol Laboratory of Biotechnology. It is a pure

hygienical food composed of multiple nature components. One of the main components is refined from the stems *D. nobile* which has long been a drug in the traditional Chinese medicine , used for the treatment of chronic pharyngitis disease , recorded in 《Compendium of Materia Medica》 written by Li Shi-zhen in the Ming Dynasty. *Dendrobium nobile* is effective in promoting the production of body fluid , nourishing the stomach and moving the bowels , and then removing intense heat from the throat , strengthening the muscles , replenishing vital essence and prolonging the life. So the Golden Dendrobium tablets are expected to nourish “ yin ”, “ moisten dryness ”, purge “ pathogenic fire ”, and relieve sore throat , and also to remove accumulation of food , promote circulation of “ Qi ”, alleviate mental distress and reduce phlegm to remove masses.

Although *Dendrobium nobile* has been used in Chinese traditional medicine to cure chronic pharyngitis , no special study has been made to identify its efficacy and safety scientifically. This is what we aim at in the present study.

1 Materials and methods

1.1 Experimental Samples Golden Dendrobium tablets (500 mg/ tablet × 12 tablets/ board × 200 boards , 12 mm diameter/ tablet) are provided by Yunnan Inmol Laboratory of Biotechnology. Table 1 lists the main components and contents in Golden Dendrobium tablets.

1.2 Participating Practices Our study was conducted in 2002 in Xiyuan Hospital (XYH) of China Academy of Traditional Chinese Medicine (CA TCM) .

Tab. 1 Main ingredients in Golden Dendrobium tablets

Main components	Contents/ (mg/ tablet)	Main components	Content/ (mg/ tablet)
ssucrose	240.00	lactose	213.00
Green Tea Polyphenols	5.75	citric acid	10.00
Stevioside	0.25	menthe - camphor	1.00
<i>Dendrobium nobile</i> Extracts (powder)	30.00		

1.3 Patients Selection of Patients: The patients who fulfil all the following criteria were selected and included: age between 18 and 65; having medical history of itching, dryness, soreness of the throat, being unable to clear sputum, giving hacking cough, usually cross-occurrence; clinical features of diffuse dark redness of laryngopharynx, edema of the pharyngeal mucous membrane, hyperplasia of lymphoid follicles of retropharyngeal wall, attachment of exudates; absence of severe incidence of heart, liver and lungs complications. Volunteers checked with one or more symptoms mentioned above and qualified with physical examination were allowed to be under the observation of medicine-taking test. Patients were excluded from enrollment if they had history (and/or clinical evidence) of: clinical symptoms caused by some latent pathological changes in the oropharynx, nasopharynx, throat, nose, larynx, oesophagus, cervical part or the whole body and any other pre-existing severe diseases which might influence the clinical course. anyone whose age is above 65 or under 18, women in the period of pregnancy or lactation or anyone allergic to Golden Dendrobium Tablets. anyone who has something wrong with blood vessels, heart, liver, kidney, hematopoiesis system or has severe idiopath or psychopath. anyone who is not qualified by the standard of patient selection, or not willing to take medicine according to prescript, being unable to measure the efficacy or whose efficacy or safety measurement being influenced due to lack of information.

1.4 Methods Forty patients with chronic pharyngitis were randomly assigned to use Golden Dendrobium tablets for 15 days. The dosage was one tablet, six times daily. No other treatment was allowed. Before and after 15-day experimental medicine-taking test, the patients were examined involving two aspects: One is efficacy measurement which includes clinical symptoms and features of examination on laryngopharynx and blood regulation; another is safety observation by measuring urine regulation and blood biochemical indexes. Analysis was

in intention to treat and compare the degree of the total amount of pain relief.

1.5 Efficacy measurement Clinical symptoms of examination on laryngopharynx include itching, dryness, soreness of the throat, hacking cough, dry and coarse throat. Chronic pharyngitis is classified by the symptoms of severity. Severe symptom is given three scores, moderate two scores and mild one score. Before and after experimental medicine-taking test, the integral statistics value and symptom-improved rate were recorded.

Clinical features of examination on laryngopharynx includes diffuse dark redness of laryngopharynx, follicles hyperplasia of retropharyngeal wall, edema of the pharyngeal mucous membrane, exudates. (chronic pharyngitis is classified by the symptoms of severity. mild is the first grade, moderate the second grade and severe the third grade) and features-improved rate was also recorded.

Clinical symptoms and features integral statistical analysis: Data are expressed as mean standard deviation (SD). Data recorded before and after medicine-taking test will be used for comparison between patients under self-contrast test. A P value < 0.05 denotes the presence of a significant statistical difference.

1.6 Safety observation Blood regulation check includes red blood cell (RBC) counts, hemoglobin, white blood cell (WBC) counts and classification.

Biochemical index assays blood-lipid (including TC and TG), TP, ALB, function of heart, liver and kidney (including AST, ALT, urine, and CRE), and GLU, all being evaluated in order to assure medicine safety.

In addition, Abdomen B-supersonic wave, cardiogram, and chest X-ray were also conducted.

1.7 Graded Standard Results are graded according to procedures and measurement on efficacy of health food:

Significant efficacy (2-Grade): clearly resolving clinical symptoms and alleviating clinical features on laryngopharynx;

Clearly efficacy (1-Grade): alleviating clinical

symptoms and clinical features on laryngopharynx ;

Inefficacy efficacy : no change in clinical symptoms and features.

1.8 Apparatus and Reagent Blood Cell Calculator (F - 820 Type) ; Fully Ten-items urine cell analyzer made in German Boehringer Mannheim GmbH ;

Olympus full-automated biochemistry analyzer made in Japan (Type AU600) ;

Biochemical reagent boxes made in Zhongsheng Corp.

2 Results

2.1 General Information A total of 40 patients (16 males , 24 females , mean age : 47.55 ± 13.93 ; range : 18 — 65 ; mean disease duration 8.23 ± 6.39 year : 19 cases for 1 — 5 year ; 14 cases for 6 — 10 year ; 7 cases for above 10 years ; the shortest disease

duration is 1 year and the longest 20 years) were choosed to take randomised controlled trial.

2.2 Results and analysis on efficacy During observations on 40 patients receiving treatment with Golden Dendrobium Tablets , no case was graded as significant efficacy (clearly resolving clinical symptoms and alleviating laryngopharynx clinical features) ; 31 cases were graded as clearly efficacy (alleviating clinical symptoms and laryngopharynx clinical features) ; 9 cases were inefficacy (no change on clinical symptoms and features) . Physicians judged the clinical efficacy to be good or excellent (100 %) . Clinical evidence were given on March 2002 by Xiyuan Hospital (XYH) of China Academy of Traditional Chinese Medicine (CATCM) . (See Table 2 below for details) .

The clinical symptoms and features of the patients are shown in Table 3 and Table 4.

Tab. 2 Data for grading Golden Dendrobium tablets efficacy

Cases	Significant Efficacy	Clearly efficacy	Inefficacy	Total efficacy rate/ %
40	0 (0.0 %)	31 (77.5 %)	9 (22.5 %)	77.50

Tab. 3 Main clinical features improved statistic

Symptoms	Cases	Significant Efficacy	Clearly efficacy	Inefficacy	Improvement rate/ %
Sore throat	27	1	17	9	66.77
Itching throat	37	6	20	11	70.27
Hacking cough	22	6	16	0	100.00
Dry and coarse throat	31	4	27	0	100.00

Tab. 4 Main clinical features on pharynx improved statistic

Features on Pharynx	Cases	Significant improvement	Clearly efficacy	inefficacy	Improvement rate/ %
Diffuse dark redness of laryngopharynx	26	2	24	0	100.00
Follicles hyperplasia of retropharyngeal wall	7	0	7	0	100.00
Edema of the pharyngeal mucous membrane	23	21	21	0	100.00
Exudates	11	10	10	0	100.00

Integral statistics of clinical symptoms and features are respectively shown in Table 5 and Table 6. Comparison of main symptom improvements between before and after medicine-taking trial.

Blood and urine regulation measurement before and after medicine - taking experiments were shown in Table 7.

Analysis: In before and after medicine-taking

experiments, all blood and urine regulations indexes did not differ significantly and are all within normal range.

2.3 Results and analysis on safety observation

Observation results on blood safety index before and after medicine - taking experiment are shown in Table 8.

Tab. 5 Integral statistical of clinical symptoms (mean \pm SD. $P < 0.01$)

Cases	Before medicine-taking	After medicine-taking	Balance (difference)
40	5.50 \pm 1.71	2.68 \pm 1.82	2.82 \pm 1.41

Tab. 6 Integral statistical of clinical features (mean \pm SD. $P < 0.01$)

Cases	Before medicine-taking	After medicine-taking	Balance (difference)
40	3.88 \pm 1.52	2.08 \pm 1.49	1.80 \pm 1.38

Tab. 7 Comparison of blood and urine regulation safety indexes change

Items	Before medicine-taking trial	After medicine-taking trial
HGB/ (g L^{-1})	22.83 \pm 10.72	23.13 \pm 9.12
RBC/ (10^{12}L^{-1})	26.70 \pm 5.68	26.08 \pm 5.36
WBC/ (10^9L^{-1})	5.56 \pm 1.01	5.56 \pm 0.76
Emiction normal measurement	Normal	Normal

Tab. 8 Comparison of blood safety indexes change (mean \pm SD)

Items	Before medicine-taking experiment	After medicine-taking experiment
ALU/ (U L^{-1})	22.83 \pm 10.72	23.13 \pm 9.12
AST/ (U L^{-1})	26.70 \pm 5.68	26.08 \pm 5.36
UREA/ (mmol L^{-1})	5.56 \pm 1.01	5.56 \pm 0.76
CRE/ ($\mu\text{mol} \text{L}^{-1}$)	92.05 \pm 11.28	89.18 \pm 6.99
TC/ (mmol L^{-1})	4.67 \pm 0.74	4.77 \pm 0.69
TG/ (mmol L^{-1})	1.54 \pm 0.92	1.48 \pm 0.80
GLU (mmol/L)	5.10 \pm 0.98	5.23 \pm 0.88

Analysis: In before and after medicine-taking experiments, all biochemical indexes of blood measurement did not differ significantly and are all within normal range.

3 Discussion

Our study showed that Golden Dendrobium tablets can effectively minimise or eliminate main symptoms of chronic pharyngitis such as itching,

dryness, soreness of the throat, and furthermore, can improve the clinical features such as diffuse dark redness of laryngopharynx, and follicles hyperplasia of retropharyngeal wall. Our study also demonstrated that before and after Golden Dendrobium tablets-taking experiments, blood-lipid (including TC and TG), TP, ALB, function of heart, liver and kidney (including AST, ALT, urine, and CRE), and GLU indexes were all within normal range. In addition, during the experiment no allergic nor other negative reaction to Golden Dendrobium tablets had been found. All above information provides the theoretical basis for the efficacy and safety of Golden Dendrobium tablets in the clinical application. In conclusion, Golden Dendrobium tablets in the treatment for chronic pharyngitis can accelerate the resolution of symptoms of patients and effectively clear and smooth laryngopharynx, and are also free of toxic and adverse effects of treatment. With good taste, it could be taken for a long time to avoid the recurrences of symptoms.

4 Suggestions

Due to self-contrast limitation, more clinical evidences could not be provided to prove Golden Dendrobium tablets superior to other medicines for curing chronic pharyngitis. We suggest that more com-

parisons be made between different types of chronic pharyngitis^[3], different medicinal treatment, especially Chinese traditional medicine products of various brands, and on their efficacy and safety. In doing so, it may be easier to give more persuasive proofs for efficacy of Golden Dendrobium tablets and its superiority to other brands of same kind of medicines, because dendrobiums have been used for curing chronic pharyngitis in ancient China for over two thousands of years.

References :

- [1] Jiangsu New Medical College. Dictionary of chinese traditional and herb medicines [M]. Shanghai: Shanghai Scientific and Technologic Press, 1987.
- [2] XIAO Shi-zhi. Pharyngology [M]. Shanghai: Shanghai Scientific and Technologic Press, 1979.
- [3] LI Kang-ti. Clinical studies on 64 cases of chronic pharyngitis treated with ganlu qingyan mixture [J]. Acta universitatis scientiae Medicinae Chongqing, 1996, 1: 60-63.
- [4] CHEN Sing-chi, TSI Zhan-huo, LUO Yr-bo. Native orchids of China in colour [M]. Beijing: Science Press, 1999.
- [5] TSI Zhan-huo. Dendrobium in flora reipublicae popularis sinicae [M]. Beijing: Science Press, 1999.
- [6] BAO Xue-sheng, SHUN Qing-sheng, CHEN Li-zuan. The medicinal plants of dendrobium (Shi Hu) in China [M]. Shanghai: Fudan University Press, 2001.

金石斛含片清咽润喉功效的研究*

虞 泓^{1,2}, 屈 燕^{2,4}, 陈心启^{1,3,4}

(1. 云南茂英生物技术实验室, 云南 昆明 650106; 2. 云南大学 生命科学学院 生态遗传学实验室, 云南 昆明 650091; 3. 中国科学院 植物研究所 植物系统与进化实验室, 北京 100093; 4. 中国中医研究院 西苑医院, 北京 100021)

摘要:评价由金钗石斛提取物等多种成分精制而成的健康食品金石斛含片对于改善慢性咽炎患者咽部症状及体征的功效及其对患者健康状况的影响。采用自身对照的方法, 结合咽部检查、尿常规、血常规及血生化指标的测定, 随机选取 40 例年龄在 18~65 岁的慢性咽炎患者在西苑医院进行金石斛含片清咽润喉功效的人体试食试验, 所有数据在试验前后进行记录和对比分析。受试者在连续含服金石斛含片 15 d 后, 咽部症状改善明显, 31 例有效, 有效率为 77.5%; 血常规、尿常规、血生化无明显改变。显著的临床试验结果表明金石斛含片能有效改善慢性咽炎患者咽部症状及体征并且对患者的身体健康状况无任何副作用。

关键词:金石斛含片; 慢性咽炎; 人体试食试验; 清咽润喉

* 作者简介: 虞 泓(1962-), 教授, 博士生导师, 主要从事药用植物引种驯化、遗传育种、GAP、化学和生物指纹图谱研究。