

The Treatment of COVID-19 with Chinese Medicine

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Read the Material and Answer the Questions (*This exam material with questions is provided by professor Xinjun Wang from NJUCM the 6th of April 2020*)

Diagnosis and Treatment Protocol for COVID-19 (Trial Version 7)

Traditional Chinese Medicine (TCM) Treatment

The COVID-19 belongs to plague in TCM with the etiology of epidemic factor exposure. Different regions can refer to the following plans for syndrome differentiation and treatment, according to the disease, local climate characteristics and different constitutions. Prescriptions which exceed maximum dose according to pharmacopoeia should be used under the guidance of a physician.

1. Medical Observation Period

1.1. Clinical manifestation: fatigue with gastrointestinal discomfort.

Recommended Chinese patent medicine: Huoxiang Zhengqi Capsule (Pill, Liquid, Oral Liquid).

1.2. Clinical manifestation: fatigue with fever.

Recommended Chinese patent medicines: Jinhua Qinggan Granule, Lianhua Qingwen Capsule (Granule), Shufeng Jiedu Capsule (Granule).

2. Clinical Treatment Period (Confirmed Cases)

2.1. Qingfei Paidu Decoction.

Scope of application: in accordance with the clinical observations of doctors in various locations, it is suitable for mild, moderate and severe cases, and can be used reasonably with the consideration of the actual conditions of critically ill patients.

The basic formula: Ma Huang (Ephedrae Herba) 9g, Zhi Gan Cao (Glycyrrhizae Radix) 6g, Xing Ren (Armeniacae Semen) 9g, Sheng Shi Gao (Gypsum Fibrosum) (decocted first) 15-30g, Gui Zhi (Cinnamomi Ramulus) 9g, Ze Xie (Alismatis Rhizoma) 9g, Zhu Ling (Polyporus) 9g, Bai Zhu (Atractylodis Macrocephalae Rhizoma) 9g, Fu Ling (Poria) 15g, Chai Hu (Bupleuri Radix) 16g, Huang Qin (Scutellariae Radix) 6g, Jiang Ban Xia (Pinellinae Rhizoma Praeparatum) 9g, Sheng Jiang (Zingiberis Rhizoma Recens) 9g, Zi Wan (Asteris Radix) 9g, Kuan Dong Hua (Farfarae Flos) 9g, She Gan (Belamcandae Rhizoma) 9g, Xi Xin (Asari Radix Et Rhizoma) 6g, Shan Yao (Dioscoreae Rhizoma) 12g, Zhi Shi (Aurantii Fructus Immaturus) 6g, Chen Pi (Citri Reticulatae Pericarpium) 6g, Huo Xiang (Pogostemonis Herba) 9g.

Administration: traditional Chinese herbal pieces in decoction. One package per day. Take warm twice (40 minutes after meal in the morning and evening). One course of treatment is for three packages.

If possible, half bowl of rice soup after taking the decoction is advised. For the patients with dry tongue due to fluid depletion, one bowl of rice soup is suggested. Note: If no fever, the dosage of gypsum should be reduced. In case with fever or high fever, the amount of gypsum can be increased. If the symptoms improve but not totally recovered, continue the second course of treatment. If the patient has a special condition or other underlying diseases, the formula can be modified according to the actual situation in the second course. If the symptoms disappear, the drug should be discontinued.

Reference: The General Office of the National Health Commission of the people's Republic of China. The Office of the National Administration of Traditional Chinese Medicine 'Notice on Recommending the Use of Qingfei Paidu Decoction in Pneumonia Treated with Integrated Chinese and Western Medicine for the COVID-19 Infection' (National Administration of Traditional Chinese Medicine Office Medical Letter [2020] No.22).

Questions

The patients in clinical treatment period (confirmed cases), should take Qingfei Paidu Decoction. However, the patients in medical observation period, whether confirmed COVID-19 or not, should take Chinese patent medicines.

1. Is it scientific?
2. Is it reasonable?
3. Is it ethical?
4. Is it legal?

Answers

1. Is It Scientific?

This question firstly requires some explanation. What is the exact meaning of 'scientific'? According to the Cambridge Dictionary 'scientific' means: 1. relating to science, or using the organized methods of science and 2. careful and using a system or method¹. According to Oxford Learner's Dictionaries it means: 1. involving science; connected with science or 2. (of a way of doing something or thinking) careful and logical². This implies there are some nuances in how the word 'scientific' and the question 'Is it scientific?' can be interpreted.

Unfortunately, from Western biomedical viewpoint, Chinese medicine is generally considered as a pseudoscience³ (while Chinese medicine is very systematically, methodologically and logically). Western medicine and Chinese medicine are based on different philosophies and principles. In the Western way of thinking scientific relates with measurements. For Chinese medicine it is necessary to be studied from this biomedical way to get a serious place in the Western medical world. This is not an easy task as Chinese medicine thinks in principles of Qi, Yin and Yang and they have to be converted into biomedical terms to be understood by the Western world. Measuring Chinese medical principles is a challenge that way for the future! Regarding the efficacy and safety of Chinese herbal formulas measuring is definitely possible yet. Measurements or not: Chinese medicine has served the Chinese people for centuries and the Chinese government supports its use highly. Let's focus now on scientific and COVID-19.

COVID-19 (also called SARS-CoV-2) is a new type of coronavirus that caused an outbreak of pneumonia in China last December 2019 and has resulted in a pandemic disease. No anti-virus drugs or vaccines are available yet. At this moment 85% of COVID-19 infected patients in China are receiving Chinese Medicine (TCM) beside Western conventional therapies⁴. Herbal formulas that are used concern among others: Qingfei Paidu Decoction and the patent formulas Huoxiang Zhengqi Capsule (Pill, Liquid, Oral liquid), Jinhua Qinggan Granule, Lianhua Qingwen Capsule (Granule) and Shufeng Jiedu Capsule (Granule).

The treatment of COVID-19 with mentioned herbal formulas performed in Chinese hospitals are in an experimental stage. Many clinical trials are performed yet to examine the efficacy and safety in the use of these Chinese herbal formulas in the treatment of COVID-19. We may say this is 'scientific' as it is a part of a scientific process, it is relating to science and organized methods of science as RCT's and CCT's are used. Research is developing but all is still in an early stage. Some positive effects regarding the use of Qingfei Paidu Decoction and Lianhua Qingwen are seen yet (Yang et al., 2020)⁵.

Regarding scientific viewpoint we can state that the use of patent formulas is more scientific as the dosages that are given are the same and the quality can be controlled well. Using a decoction is the most traditional form of preparing herbs in Chinese medicine but it can have some disadvantages, such as the difficulties in ensuring quality control of the herbal ingredients and the requirement to consume a large volume of unpleasant tasting medicine⁶. The last-mentioned disadvantage can give problems when a patient is very ill and has trouble drinking. The way of preparing the decoction has influence on the effects of it and the total amount of the liquid. With patent formulas there is the same dosage so you measure the same 'thing' while of course there can be difference in the quality of the ingredients but more control is possible and that's why for scientific research the patents are more preferable/reliable.

Important regarding the question if it is scientific it is necessary that the clinical trials - that are being performed yet - are done properly to enhance its scientific value. This implies certain requirements for the research methods regarding planning, performance, documentation, analysis and publication. Due to the early stage of research regarding COVID-19 and the efficacy and safety of Chinese medicine, information is limited at this moment.

The overall plan for all procedures involved in a study consists of:

- Question to be answered: The question should be clearly defined (including primary and secondary objectives). It must specify the group of patients, the area, the disease, the condition, perhaps also the intervention and what endpoint is to be determined with which method at what point in time. Comparisons, between two groups, or before and after the intervention. How are the patients randomized? What kind of blinding is used (double, single, open)?
At this moment - as mentioned above - 85 % of COVID-19 infected patients in China are receiving Chinese medicine. No information is available about the control groups (if present) in the review of Yang et al. (2020).
- Study population: Yang et al. (2020) do mention the sample size of researches that are done yet. Some have a clearly small sample size (such as 60 or 72 patients) which decreases the power of the study, may lead to sample size bias and bringing the risk that real differences will not be identified. Other studies have a sample size of for example 400, 300 and respectively 348 patients, which give more power to the study.
- Type of study: Research on primary data or research on secondary data. The ongoing clinical trials that are performed in the hospitals yet in China concern research on primary data as they are focused on answering questions and achieving new knowledge about the effects of Chinese herbal formulas on COVID-19.
The study of Yang et al. (2020) concerns the analysis of secondary data and it mentions the amount of 303 ongoing clinical trials (on the 1st of March 2020) aiming to evaluate the efficacy and safety of treatments for COVID-19 patients. Yang et al. provided positive results (a report of National Administration of Traditional Chinese Medicine, up to February 5th, 2020) about a study with 214 COVID-19 patients who were treated with *Qingfei Paidu Decoction* in Shanxi, Hebei, Heilongjiang and Shaanxi Provinces with an overall effective rate of $\geq 90\%$. Among them, the symptoms of majority of patients ($\geq 60\%$) were markedly improved, while illness of others (30%) was stabilized⁷. After that, 701 COVID-19 patients were treated with *Qing Fei Pai Du Tang* in 10 provinces in China. The result showed that 130 patients (18.5%) were completely cured after treatment. The treatment also resulted in the disappearance of characteristic symptoms of COVID-19 such as fever and cough in 51 patients (7.27%). In addition, symptom improvement or stabilization were observed in 268 patients (38.2%), and in 212 patients (30.2%), respectively⁸.
Regarding *Lianhua Qingwen Capsule* is mentioned by Yang et al. (2020) that research from Yao et al.⁹ and Lu et al.¹⁰ showed this patent could 'markedly relieve major symptoms such as fever and cough and had the capacity to promote the recovery'.
No further information about these trials is available yet to examine the scientific value of the researches itself.
- Unit of observation/analysis: Patients with and without confirmed COVID-19. Patients in clinical treatment with COVID-19 (confirmed cases) should take *Qingfei Paidu Decoction* but the patients in medical observation period (whether confirmed COVID-19 or not) should take Chinese patent formulas. The research regarding the patients in medical observation is scientifically seen reducing the power of the studies (= selection bias) as it is not known which patient has COVID-19 or not so you can't examine the effects from the patents on COVID-19 clearly as also patients without COVID-19 are included.
- Measuring technique: Not enough information about the measuring techniques and measurement plan is available yet.
- Calculation of the sample size: Information about the types of tests is not available.

At this moment no/not enough information is available about the performance, documentation, analysis and publication of the studies as many studies are being performed yet. An important aspect of research analysis is, for example, the P-value, which indicates if the results of the study are statistically significant. We simply need to know a P-value to assess the scientific value of a study.

COVID-19 patients do get acupuncture or other characteristic therapy of TCM as well (such as moxibustion) in the Chinese hospitals (= treatment bias). To examine the pure effects on the Chinese herbal formulas itself on COVID-19 it is important not to combine its use with acupuncture treatment (or a control group with patients that don't get acupuncture should be integrated). Of course, it's logical from human viewpoint that all is done yet to save/improve the patient's life but it can bias scientific research.

Regarding the current trials related with COVID-19 and Chinese herbal formulas: these should be reported according the CONSORT-CHM Formulas 2017 to guarantee the quality of the clinical experiment design.

2. Is It Reasonable?

The CONSORT-CHM Formulas 2017 includes the item 'Generalizability. Item 21: Discussion of how the formula works on different TCM Patterns or diseases'. The example given there says: 'In TCM, syndromes are the foundations for therapeutic principles, and the same method of treatment can be applied to patients with the same syndrome, no matter what disease, as defined in Western terms, they have'. This implies that the use of the mentioned patent herbal formulas is reasonable as they have been tested scientifically on efficacy and safety in the past on certain syndromes and diseases. (See appendix for composition mentioned patent herbal formulas)

Research examples from these patent herbal formulas and its effects are:

- Huoxiang Zhengqi Soft Capsule and gastric motility and gastrointestinal hormones in functional dyspepsia patients with Spleen-deficiency with predominant Dampness¹¹
- Jinhua Qinggan Granule and influenza of Wind-Heat affecting Fei syndrome¹² (this granule is developed during the 2009 H1N1 influenza pandemic; clinical notes: COVID-19 is not the same as influenza: they have similarities (both cause respiratory diseases, transmission by contact, droplets and fomites) but also differences such as speed of transmission and reproductive number¹³)
- Lianhua Qingwen Capsule and influenza¹⁴
- Shufeng Jiedu Capsule and influenza (Wind-Heat cold)¹⁵.

The Qingfei Paidu Decoction is an extended combination specifically made for COVID-19. It is based mainly on herbs derived from four classical formulas that originate from the Shang Han Lun, compiled by physician Zhang Zhongjing around 200 CE: Ma Xing Shi Gan Tang, She Gan Ma Huang Tang, Xiao Chai Hu Tang and Wu Ling San¹⁶. The herbs used in Qingfei Paidu Decoction have shown their value during centuries (= have stand the test of time) which makes it reasonable they are given yet.

Research examples from these classical formulas and its effects are:

- Ma Xing Shi Gan Tang and its mechanism that inhibits the entry of influenza virus¹⁷
- She Gan Ma Huang Tang and asthma¹⁸
- Xiao Chai Hu Tang and enhancement macrophages¹⁹
- Wu Ling San and edema²⁰.

From my own viewpoint it might be reasonable to help the COVID-19 patient in the clinic with all that is in the power of Chinese medicine as the clinical signs and symptoms can change from mild into severe in a very short time. To prevent such an urgent condition, you should do all that is within reach especially when no anti-virus drugs and vaccines are available. This virus can cause severe damage to the lungs with possibly long-term problems as a result. Figures show the comparable low death rate in China compared with other countries related with the amount of COVID-19 infected people (beside that there is a big bias in information provided in statistics yet as in many countries people are not tested consequently due to lack of test material²¹). Despite some information bias the numbers of death in China still are low compared with other countries based on the number of inhabitants per country. Reason enough to combine western treatments with Chinese herbal formulas.

This pandemic has resulted in totally disrupted societies with adverse effects on health, economy and social life with stress due to fear to be contaminated, having no or less income as certain professions may not work and elderly people may not have contact with their family as they belong to a vulnerable group. So, what is reasonable for countries where Chinese herbal medicine is not accepted: doing

nothing as justice doesn't allow you to treat or do anything possible? This consideration connects with the ethical and legal aspects of it.

3. Is It Ethical?

The COVID-19 concerns a new virus and so many things are not known yet such as all its characteristic features and its effects but knowledge is increasing rapidly. From Western viewpoint there are currently no specific anti-virus drugs or vaccines available. The Western treatment consists of supportive care and non-specific treatment. As the virus infection can develop very quickly the patient's health condition can deteriorate extremely fast with emergency admission on the intensive care. Chinese Medicine has shown its value, having experience for centuries with pandemic and endemic diseases. So, its use might be seen as an urgent tool to benefit patients and save their lives. Doing nothing might end up in fatal ending of the patient's life.

'Moral' is the set of values and norms that is important to a person or group. 'Ethics' is systematic thinking about that morality. So: ethics studies and analyzes morality. You analyze this by ordering and assessing values and arguments. This assessment can result in a trade-off about what is right to do. Ethics is not only a thinking discipline, it is also a practical activity. It can help practice further. Ultimately, this revolves around the question: "What is morally good to do in this situation?"²²

However: ethics in health care are different in countries depending on norms and values, legislation and the standard of living. The four principles of health care ethics (of Beauchamp & Childress) are²³:

- **Autonomy:** In medicine, autonomy refers to the right of the patient to retain control over his or her body. A health care professional can suggest or advise, but any actions that attempt to persuade or coerce the patient into making a choice are violations of this principle. In the end, the patient must be allowed to make his or her own decisions – whether or not the medical provider believes these choices are in that patient's best interests – independently and according to his or her personal values and beliefs.
- **Beneficence:** This principle states that health care providers must do all they can to benefit the patient in each situation. All procedures and treatments recommended must be with the intention to do the most good for the patient. To ensure beneficence, medical practitioners must develop and maintain a high level of skill and knowledge, make sure that they are trained in the most current and best medical practices, and must consider their patients' individual circumstances; what is good for one patient will not necessary benefit another.
- **Non-maleficence:** Non-maleficence is probably the best known of the four principles. In short, it means, "to do no harm." This principle is intended to be the end goal for all of a practitioner's decisions, and means that medical providers must consider whether other people or society could be harmed by a decision made, even if it is made for the benefit of an individual patient.
- **Justice:** The principle of justice states that there should be an element of fairness in all medical decisions: fairness in decisions that burden and benefit, as well as equal distribution of scarce resources and new treatments, and for medical practitioners to uphold applicable laws and legislation when making choices.

The treatments in China with Chinese herbal formulas are ethical when these four aspects are met. China has an advantageous position seen from 'justice viewpoint' as the government supports TCM highly. In many other countries 'justice' may be a problem (see: Is it legal?).

When people participate a clinical trial to support scientific research they must be informed that they are part of a trial and should sign a consent form.

4. Is It Legal?

In China the use of these mentioned herbal formulas (Qingfei Paidu Decoction and the Chinese patent medicines) is legal as its use is recommended in the 'Diagnosis and Treatment Protocol for COVID-19 (Trial Version 7)' by the National Administration Office of Traditional Chinese Medicine. The National Administration Office of Traditional Chinese Medicine is a state administration of the People's Republic of China under the jurisdiction of the National Health Commission, responsible for the regulation of Traditional Chinese Medicine. The National Health Commission is a cabinet-level executive department of the State Council, responsible for formulating health policies in Mainland

China. In China more than 3100 TCM physicians were dispatched to Hubei province and they fully participated in the whole rescue process²⁴.

In many countries in Europe, the USA and Australia all Chinese medicine / acupuncture private clinics and practices are closed at the moment because of the lockdown policy regarding the protection of the people against contamination with COVID-19. This makes - unfortunately - clear that Chinese medicine is not integrated in these societies and for sure not integrated with the Western treatments given in the 'regular' / academic hospitals. To give face-to-face treatments in private clinics and practices is forbidden currently and according the Dutch Acupuncture Association (NVA) even prosecutable. A 'safe' distance from 1.5 meters is required at the moment, which makes face-to-face treatments impossible. Only in hospitals, nursing homes and home care face-to-face treatments are allowed with the use of special protection materials such as FFP2 and FFP3 mouth masks, medical gloves etc. (though, a big problem in the Netherlands is the shortage of protecting materials whereby health workers in nursing homes and home care work unprotected with many contaminations as a consequence). Online consultations (by phone, Skype, WhatsApp) are permitted but to diagnose the clinical signs and symptoms according Chinese medicine principles it is not possible to perform all needed diagnostics such as pulse and tongue diagnostics. Of course, you can examine the tongue with a photo but the image might be influenced by the available light.

Another problem is the possible use of Qingfei Paidu Decoction as it contains Ma Huang (Herba Ephedrae). In many countries the use of Ma Huang is forbidden as it contains Ephedrine, which can be a doping material (beside that it can be medically used to treat for example nose and lung disorders prescribed by a physician). If Ephedrine is processed, 1 gram of Ephedrine can extract 0.75 gram of Methamphetamine, which is criminal and a form of specific hard drugs (ATS = Amphetamine-Type Stimulants).

In the USA Ma Huang is forbidden and Xi Xin (Radix Et Rhizoma Asari) as well whereby the official Qingfei Paidu Decoction is not available for legal commercial purchase²⁵. Xi Xin is also forbidden in countries such as Canada, the UK, Taiwan, Germany, Switzerland and the Netherlands as it contains AA (= aristolochic acid)²⁶. There may be concluded that the use of Qingfei Paidu Decoction legally is not allowed yet in many countries outside Asia.

Jinhua Qinggan Granule and Lianhua Qingwen Capsule (Granule) both contain Ma Huang as well so the same problem applies to these patent herbal formulas.

The question may be: can legislation be changed now (and how fast) if the governments of these countries want to support the Western treatments that are given currently with Chinese herbal formulas? Thereby Chinese medicine can be integrated with Western medicine, which may lead to a more adequate treatment of COVID-19. The effects of lockdowns are tremendously on the economics and the quality of life of people. When Chinese medicine can support to achieve quicker results of recovery of COVID-19 patients it might be reason enough to change legislation as yet it is a missed chance not to be able to combine the best of two worlds in many countries. Trials of high scientific value in China may be an important condition to get legislation changed world-wide!

Appendix Composition Patent Herbal Formulas Used for COVID-19

Huoxiang Zhengqi Capsule (Pill, Liquid, Oral Liquid)²⁷:

Huo Xiang (Herba Pogostemonis), Huo Po (Cortex Magnoliae Officinalis), Zi Su Ye (Folium Perillae), Fu Ling (Poria), Bai Zhu (Rhizoma Atractylodis Macrocephalae), Da Fu Pi (Pericarpium Arecae), Jie Geng (Radix Platycodi), Ban Xia (Rhizoma Pinelliae Praeparatum), Da Zao (Fructus Jujube), Bai Zhi (Radix Angelicae Dahuricae), Chen Pi (Pericarpium Citri Reticulatae), Zhi Gan Cao (Radix Et Rhizoma Glycyrrhizae), Sheng Jiang (Rhizoma Zingiberis Recens).

Jinhua Qinggan Granule²⁸:

Jin Yin Hua (Flos Loniceræ Japonicæ), Shi Gao (Gypsum Fibrosum), Ma Huang (Herba Ephedrae), Xing Ren (Semen Armeniacæ Amarum), Huang Qin (Radix Scutellariae), Lian Qiao (Fructus Forsythiae), Zhe Bei Mu (Bulbus Fritillariae Thunbergii), Zhi Mu (Rhizoma Anemarrhenae), Niu Bang Zi (Fructus Arctii), Qing Hao (Herba Artemisiae Annuae), Bo He Nao (Mentholum), Gan Cao (Radix Et Rhizoma Glycyrrhizae).

Lianhua Qingwen Capsule (Granule)²⁹:

Lian Qiao (Fructus Forsythiae), Jin Yin Hua (Flos Loniceræ Japonicæ), Ma Huang (Herba Ephedrae), Xing Ren (Semen Armeniacæ Amarum), Shi Gao (Gypsum Fibrosum), Ban Lan Gen (Radix Isatidis), Mian Ma Guan Zhong (Rhizoma Dryopteridis Crassirhizomatis), Yu Xing Cao (Herba Houttuyniae), Huo Xiang (Herba Pogostemonis), Da Huang (Radix Et Rhizoma Rhei), Hong Jing Tian (Radix Et Rhizoma Rhodiolae Crenulatae), Bo He Nao (Mentholum), Gan Cao (Radix Et Rhizoma Glycyrrhizae).

Shufeng Jiedu Capsule (Granule)³⁰:

Hu Zhang (Rhizoma Et Polygoni Cuspidati), Lian Qiao (Fructus Forsythiae), Ban Lan Gen (Radix Isatidis), Chai Hu (Radix Bupleuri), Bai Jiang Cao (Herba Patriniae), Ma Bian Cao (Herba Verbenae), Lu Gen (Rhizoma Phragmitis), Gan Cao (Radix Et Rhizoma Glycyrrhizae).

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