

Safety of Custom Traditional Chinese Herbal Medicine Practice at Cleveland Clinic

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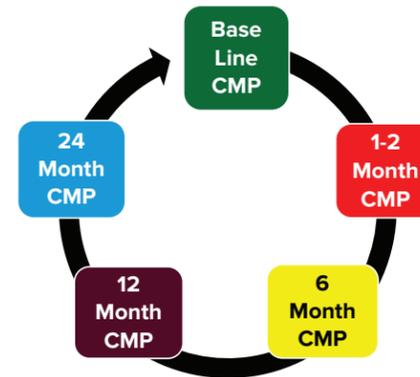
AIM

To evaluate the safety of Traditional Chinese Herbal Medicine (TCHM) as practiced at the Cleveland Clinic Center for Integrative and Lifestyle Medicine (CILM):

- Outpatient facility
- Most vigorously tested herbs
- Custom prescriptions for each patient
- No diagnosis limitation admission

TCHM AT CILM

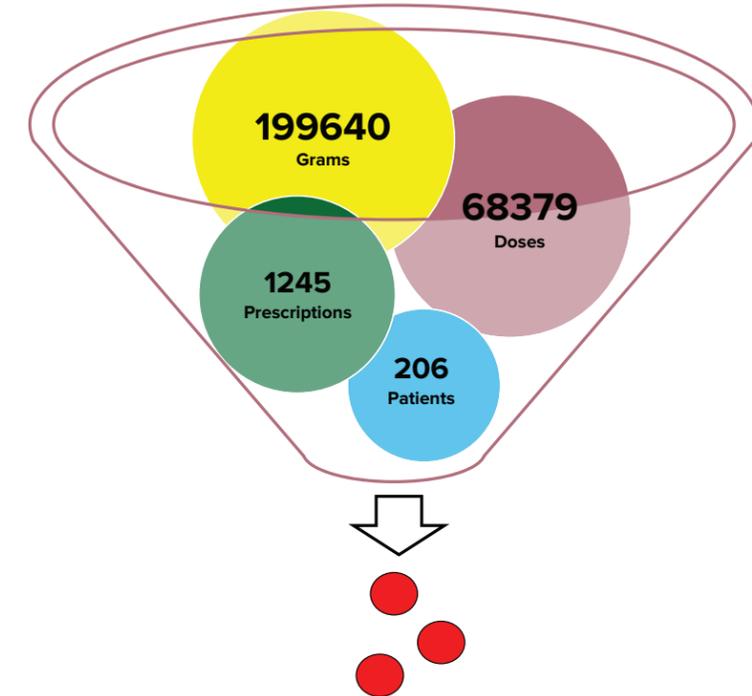
- Under supervision of a physician, licensed Chinese Herbalists prescribe custom herbal formulas based on TCHM diagnosis
- Patients re-evaluated in person on an as-needed basis
- Detailed treatment plan, progress, adverse events and hospitalizations are documented in the patient's medical record
- A complete metabolic panel (CMP) is ordered at baseline, 1-2 months, 6 months, 12 months and 24 months of herbal intake



METHODS

- Review of medical records of patients referred to TCHM clinic from June 1, 2014 to June 1, 2016
- Exclusion criteria:
 - Patients younger than 12 years old
 - Patients on Heparin, Warfarin or Coumadin
 - Patients on Interferon or active chemotherapy
 - Patients with liver or kidney failure
 - Patients with a liver or kidney transplant
- Safety was evaluated using CMP results with emphasis on kidney and liver functions

24 MONTHS DATA



3 Mild Adverse Events

- CMP did not detect any changes caused by herbs
- Patients reported three cases of mild adverse events which included anxiety, nausea and pruritus, that equals 1.46% rate of occurrence
- All events were reported to The State of Ohio Medical Board according to Ohio law but none required FDA reporting

CONCLUSIONS

- This chart review illustrates TCHM as practiced at Cleveland Clinic CILM is likely to be safe
- A prospective, well-controlled trial which includes a larger cohort monitored over a longer period of time is warranted

FDA COMPLIANT TCHM LABEL

FDA Disclaimer → These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Custom intake directions → Take 3 level spoons with warm water 3 times a day. Separate by 1 hour from the rest of your meds and supplements

Allergy warning → **Allergy Warning:** This herb prescription contains Shen Qu potential Gluten and Tree Nuts and Wheat allergen, and Tao Ren (Peach Kernel (persical)), which is a potential Tree Nuts allergen.

Prescription # → Prescription # 17852365

Prescription and Expiration Date → Prescribed: 12/21/16
Filled: 12/21/16
Discard after: 12/21/17

Pharmacy Address → Manufactured & distributed by CRANE HERB PHARMACY, Mashpee, MA 02649 (508) 539-1700 www.CraneHerb.com

CUSTOM CLINIC NAME → Jane Doe 12/21/2016

Dosage: 3 gm 3 times per day for 14 days

Herbal Supplement Facts

| Latin Binomial | Part | Pin Yin | Amount Per Serving | % Daily Value |
|-------------------------------|--------|-----------------|--------------------|---------------|
| Rehmanniae Radix (cooked) | Root | Shu Di Huang | 401 mg* | |
| Angelicae Sinensis Radix | Root | Dang Gui (Shen) | 374 mg* | |
| Paeoniae Lactiflorae Radix | Root | Bai Shao | 365 mg* | |
| Corydalis Yanhusuo Rhizoma | Stem | Yan Hu Suo | 243 mg* | |
| Cyperus Rotundus Rhizoma | Stem | Xiang Fu | 243 mg* | |
| Pericarpae Saman | Seed | Tao Ren | 243 mg* | |
| Cyathulae Officinalis Radix | Root | Niu Xi (Chuan) | 243 mg* | |
| Carthami Tricoloris Flos | Flower | Hong Hua | 243 mg* | |
| Chuanxiong rhizoma | Root | Chuan Xiong | 243 mg* | |
| Massa Medicata Fermentata | Leaven | Shen Ou | 160 mg* | |
| Citri Reticulatae Pericarpium | Peel | Chen Pi (Ju Pi) | 160 mg* | |
| Glycyrrhizae Uralensis Radix | Root | Gan Cao | 81 mg* | |

Latin binomial, Plant part, PinYin, Dosage →

Prescriber → Ms. Jane Doe, 33 Main St, Cleveland Clinic - Wellness, 1950 Richmond Road - TR201, Lyndhurst, OH 44124, 216-986-4325

Manufacturer, Concentration, Carrier = Inactive ingredient → KPC 5:1 concentrated water-extract granule, Carrier: non-GMO Potato starch, *Daily Value not established

All TCHM formulas are custom compounded from concentrated 5:1 water-decocted extract granules manufactured according to ISO/TC249 international standards, ISO/IEC 17025:2005 testing lab and FDA GMP Title 21 CFR 111

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AIM:

The goal of this study is to evaluate the safety of Traditional Chinese Herbal Medicine (TCHM) practice at CC CILM.

METHODS:

Patients >12 years old, with a variety of health complaints, not taking anticoagulants or receiving active chemotherapy, with normal liver enzymes and creatinine were qualified to receive TCHM.

Patients' electronic medical records (EMR) were reviewed. Under the supervision of a physician, a licensed Chinese Herbalist prescribed herbal formulas based on TCM diagnosis.

TCHM intake was separated by 2 hours from existing medications and supplements. Concurrent use of multiple supplements and < 5 pharmaceutical drugs was allowed.

Herbal granules manufactured by Kaiser Pharmaceutical Company (Taiwan) and compounded by Crane Herb Pharmacy (USA) were used.

RESULTS:

Over 24 months, 206 patients received 1245 prescriptions, totaling 68,379 doses and 199,640 grams.

Patients were re-evaluated in person on an as-needed basis. Detailed treatment progress, adverse event and hospitalizations were documented in the patient's EMR. In the event of any unusual symptom or allergic reaction, patients were instructed to contact a provider.

A complete metabolic panel (CMP) collected at a baseline, 4-8 weeks and 6 months of herbal intake was used to evaluate safety.

CMP results did not detect changes that could be attributed to herbs. Patients reported three cases (1.5%) of mild adverse effects which includes anxiety, nausea and pruritus. All events were reported to The State of Ohio Medical Board according to Ohio law but none required FDA reporting.

CONCLUSION:

This study illustrates THCM as practiced at CC CILM is likely to be safe. This includes TCHM formulas compounded from concentrated 5:1 water-decocted extract granules manufactured according to ISO/IEC 17025:2005 testing lab international standards, compounded according to FDA regulation Title 21 CFR 111., and prescribed according to TCM principles by a licensed Chinese Herbalist.

A prospective, well-controlled trial which includes a larger cohort monitored over a longer period of time is warranted.