



Prescription patterns of traditional Chinese medicine for peptic ulcer disease in Taiwan: A nationwide population-based study



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ABSTRACT

Ethnopharmacological relevance: Peptic ulcer disease is a common digestive disease. There is a lack of large-scale survey on the use of traditional Chinese medicine (TCM) for the treatment of peptic ulcer disease. This study aimed to investigate the utilization of TCM for the treatment of peptic ulcer disease in Taiwan.

Materials and methods: We analyzed a random sample comprised of one million individuals with newly diagnosed peptic ulcer disease between 2001 and 2010 from the National Health Insurance Research Database in Taiwan. Demographic characteristics and TCM usage, including Chinese herbal formulas and the single herbs prescribed for patients with peptic ulcer disease, were analyzed.

Results: A total of 96,624 newly diagnosed subjects with peptic ulcer disease were included. 14,983 (15.5%) patients were TCM users. People residing in highly urbanized areas, younger people and female (compared with male) were more likely to use TCM. With regard to the comorbidities, TCM users had a lower prevalence of coronary artery disease, chronic obstructive lung disease, diabetes mellitus and liver cirrhosis and stroke. The average time between onset of peptic ulcer disease and the first visit to a TCM clinic was 4.7 months. Majority of the patients ($n = 14,449$; 96.4%) received only Chinese herbal remedies. The most frequently prescribed Chinese herbal formula and single herb was Ban-Xia-Xie-Xin-Tang (Pinelliae Decoction to Drain the Epigastrium) and Hai-Piao-Xiao (Os Sepiae), respectively. The core pattern analysis showed that combination of Ban-Xia-Xie-Xin-Tang, Hai-Piao-Xiao (Os Sepiae), Yan-Hu-Suo (Rhizoma Corydalis), Bei-Mu (Bulbus Fritillariae Thunbergii) and Chuan-Lian-Zi (Fructus Toosendan) was most frequently used for peptic ulcer disease.

Conclusions: Our study identified the core prescription patterns of TCM for patients with peptic ulcer disease in Taiwan. Further basic and clinical studies are necessary to elucidate the efficacy and mechanisms.

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1. Introduction

Peptic ulcer disease is a common digestive disorder, including gastric and duodenal ulcers. In the United States, approximately 15 million people have peptic ulcer disease (Torpy et al., 2012). About 12% of males and 10% of females suffered from peptic ulcer disease over their lifetimes (Wang et al., 2012). The prevalence of peptic ulcer disease in asymptomatic subjects is 9.4% in Taiwan (Wang et al., 2011). Two third of the Taiwanese peptic ulcer disease patients had no remarkable symptoms (Lu et al., 2004).

Peptic ulcer disease is an imbalance of aggressive gastric luminal factors and defensive mucosal barrier function. Conventional Western medications for the treatment of peptic ulcer disease include antacids, anti-secretory medications such as H₂-receptor antagonists and proton-pump inhibitors. Although triple or quadruple therapy has been developed for the eradication of *Helicobacter pylori* (Luther et al., 2010), increasing antibiotic resistance and intolerance has made alternative treatments necessary (Malfertheiner et al., 2011). For instance, the primary resistance of amoxicillin, clarithromycin and metronidazole in Taiwan were 2.2%, 7.9%, and 23.7% respectively. The primary levofloxacin resistance even rose from 4.9% in 2000–2007 to 8.3% in 2008–2010 and 13.4% in 2011–2012 in Taiwan (Liou et al., 2015). The use of antibiotics also has an unknown effect on the homeostasis of gut microbiome (Malnick et al., 2014). Other side effects resulting from the conventional medications include constipation and diarrhea (Cohen et al., 2015), impotence (Sabesin, 1993), interference with drug metabolism (Pattichis and Louca, 1995) and parietal cell hypertrophy (Ksiadzyna et al., 2015). These unwanted side effects drive some patients to seek alternative advice. It is necessary to investigate the usage of traditional medicine for the treatment of peptic ulcer disease.

Previous study of traditional Chinese medicine (TCM) have found that Si-Jun-Zi-Tang can inhibit the hypersecretion of hydrogen chloride in the stomach in a rat model of stress-induced peptic ulcers (Chen et al., 2013). Chai-Hu-Gui-Zhi-Tang and can prevent the recurrence of peptic ulcers (Chen et al., 2010) and another formula HZJW can heal peptic ulcer and inhibit *H. pylori* (Xie et al., 2013). Unfortunately, evidence obtained from high-quality clinical studies is very limited (Zhou et al., 2007). Many of the studies neglect stringent evidence based diagnostic and therapeutic criteria (Teschke et al., 2015). Due to the lack of knowledge about the prescription profile of TCM, researchers and doctors have found it difficult to select optimal candidates to explore the potential efficacy and mechanisms of Chinese herbal products targeting peptic ulcer disease.

TCM, which includes acupuncture and moxibustion, Chinese traumatology and Chinese herbal products, has been integrated as an important part of healthcare in Taiwan. It has been used in various diseases such as gynecologic disease (Yen et al., 2015a), atopic dermatitis (Lin et al., 2014), rhinitis (Yen et al., 2015b, 2015c), asthma (Huang et al., 2013), rheumatoid arthritis (Huang et al., 2015) and endocrinologic disorder (Hsu et al., 2014; Yu et al., 2014). The Taiwanese National Health Insurance program, which was established in 1995, also reimburses the above-mentioned TCM services (Huang et al., 2014; Yen et al., 2013). This mandatory insurance program covers approximately 23 million people, comprising 99.89% of the total population in 2010 (BoNH, 2010). Claims data from the National Health Insurance program were de-identified and sent to the National Health Research Institutes to form the National Health Insurance Research Database (NHIRD). This database provides a nationwide population-based claims database with long-term follow-up. The aim of this study is to analyze this comprehensive database and to determine the TCM utilization patterns of newly diagnosed peptic ulcer disease patients in Taiwan. The results of this study should provide valuable information

for further pharmacological studies and clinical trials.

2. Materials and methods

2.1. Data source

This study was designed as a population-based study analyzing a sample of one million subjects randomly selected from the 23 million beneficiaries of the National Health Insurance program in Taiwan. The identification numbers of all individuals were encrypted and transformed to protect the privacy of enrollees. A random number function was used to generate random number and randomly selected the subjects. There is no significant difference in the distribution of age, gender and insured amount between the patients in the randomly selected samples and the original NHIRD. (<http://nhird.nhri.org.tw/en/index.html>). The datasets contain patient's gender and date of birth, all records of clinical visits and hospitalization, prescribed drugs and dosages, including Chinese herbal products, and the major diagnoses coded in the International Classification of Diseases, Ninth Revision, and Clinical Modification (ICD-9-CM) formats. This study was approved by the Research Ethics Committee of the China Medical University and Hospital (CMU-REC-101-012).

2.2. Study subjects

The selection of study subjects from the random sample of one million individuals was represented as Fig. 1. Of the one million randomly selected individuals in the National Health Insurance Program, we identified 176,300 patients with peptic ulcer disease. Patients who were diagnosed as peptic ulcer disease with ICD-9-CM code: 531–534, for more than three times; no matter they are proved by clinical judgment, endoscopy, or *H. pylori* infection, were included. Prevalent cases ($n=79,676$) that had been diagnosed before the end of 2000 were excluded to ensure that all the subjects included were newly diagnosed. Finally, 96,624 study subjects diagnosed as peptic ulcer disease from 2001 to 2008 were included in the study cohort with a follow-up period through 2010. They were further divided into TCM users ($n=14,983$) and non-TCM users ($n=81,641$). TCM users were defined as those who visited TCM clinics. Non-TCM users were defined as those who never visited TCM clinics after the initial diagnosis of peptic ulcer disease.

2.3. Study variables

To determine the key independent variables for utilization of TCM among peptic ulcer disease patients, we selected a series of demographic factors based on previous studies (Huang et al., 2014; Yen et al., 2013). The subjects were categorized into three groups according to age: <20, 20–39, 45–59, and ≥ 60 years. Urbanization levels in Taiwan are divided into four levels as previous described (Yen et al., 2015c). Level 1 indicates the “most urbanized” communities and level 4 indicates the “least urbanized” communities. We also searched the NHIRD database for clinical comorbidities and treatment records related to peptic ulcer disease as independent variables. The comorbidities were identified by ICD-9-CM codes, including 410–414 (coronary artery disease; CAD), 496 (chronic obstructive lung disease; COPD), 250 (diabetes mellitus; DM), 571 (liver cirrhosis) and stroke (430–438). To investigate the financial outcome of TCM in Taiwan, we measured the medical expenditure of outpatient clinic care and hospitalization between patients with and without TCM treatment within the one year after peptic ulcer was diagnosed and calculated in US dollars. The TCM herbal formulas and single herbs reimbursed by

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