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Outcomes after stroke in patients receiving adjuvant therapy with traditional Chinese medicine: A nationwide matched interventional cohort study

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ABSTRACT

Ethnopharmacological relevance: The use of traditional Chinese medicine (TCM) was high in stroke patients but limited information was available on whether TCM is effective on post-stroke outcomes. The aim of this study is to compare the outcomes of stroke patients with and without receiving adjuvant TCM therapy.

Materials and methods: Using Taiwan's National Health Insurance Research Database, we conducted a nationwide cohort study and selected hospitalized stroke patients receiving routine care with ($n=1734$) and without ($n=1734$) in-hospital adjuvant TCM therapy by propensity score matching procedures. The adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) of poststroke complications and mortality associated with in-hospital adjuvant TCM therapy were calculated. The use of medical resource was also compared between stroke patients with and without adjuvant TCM therapy.

Results: Compared with hospitalized stroke patients receiving routine care alone, hospitalized stroke patients receiving routine care and adjuvant TCM therapy exhibited decreased risks of urinary tract infection (HR 0.82, 95% CI 0.68–1.00), pneumonia (HR 0.60, 95% CI 0.47–0.76), epilepsy (HR 0.67, 95% CI 0.49–0.96), gastrointestinal hemorrhage (HR 0.68, 95% CI 0.47–0.98), and mortality (HR 0.37, 95% CI 0.19–0.70) within 3 months after stroke admission. The corresponding 6-month HRs for urinary tract infection, pneumonia, gastrointestinal hemorrhage, and mortality were 0.83, 0.63, 0.64, and 0.40, respectively. Less use and expenditure of hospitalization were found in those received adjuvant TCM therapy.

Conclusions: Hospitalized stroke patients who received routine care and adjuvant TCM therapy exhibited reduced adverse outcomes after admission within a 6-month follow-up period.

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1. Introduction

Stroke is the second leading cause of death and first leading cause of disability worldwide with the estimation of \$22.8 billion direct medical cost of stroke and annual \$6018 mean expense per person for stroke care in the U.S. in 2009 (Donnan et al., 2008; Go et al., 2013). Medical and neurological complications after stroke may prolong the length of hospital stay, increase medical costs,

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result in worse disability at discharge, and even augment mortality (Ingeman et al., 2011; Katzan et al., 2007; Heuschmann et al., 2004).

After thousands of years of evolution, traditional Chinese medicine (TCM) is now widely applied in Taiwan and in Asian countries (Shih et al., 2010; Ng et al., 2004; Chung et al., 2007; Chang et al., 2011; Ishizaki et al., 2010), and is currently gaining worldwide interest (Chao et al., 2012; Bonafede et al., 2008; Stewart et al., 2001). Our previous study had shown that the use of TCM was higher in stroke patients than in the general population, and has increased consistently in recent years (Liao et al., 2012). In the previous study, we specifically focused on adjuvant TCM therapy for central nervous system damage. We investigated that acupuncture (a form of TCM therapy) was associated with the reduced use of emergency care and incidence of hospitalization in the first year after traumatic brain injury (Shih et al., 2013).

Improving the quality of health care and concurrently maintaining low cost remains a major concern for the Health Promotion Administration and, particularly, policymakers and payers. To reduce the adverse events that occur and the consumption of medical resources for stroke patients, the Department of Health in Taiwan launched a sponsored project of National Health Insurance program in 2006, the Health Policy for Chinese Medicine Adjuvant Therapy in Stroke (Wei, et al., 2011) in which adjuvant TCM therapy and routine care for hospitalized stroke patients were reimbursed. The purpose of this nationwide retrospective cohort study involving comprehensive matched analysis was to compare the outcomes after stroke admission of patients who received in-hospital routine care with adjuvant TCM therapy with those of patients who received in-hospital routine care alone.

2. Methods

2.1. Data sources

The research data were obtained from the reimbursement claim of the universal National Health Insurance program in Taiwan, which was implemented in March 1995, covering more than 99% of 22.6 million Taiwan residents. Taiwan's National Health Research Institute established a National Health Insurance Research Database (NHIRD) recording all beneficiaries' medical services, including patient demographics, primary and secondary diagnoses, procedures, prescriptions and medical expenditures. It also records all inpatient and outpatient utilization of medical services for all beneficiaries. The validity of the Taiwan NHIRD has been evaluated and research articles have been accepted globally for public access (Liao et al., 2012; Shih et al., 2013; Yeh et al., 2013).

2.2. Study design

This nationwide retrospective cohort study used the medical claims from Health Policy for Chinese Medicine Adjuvant Therapy in Stroke. From 173,963 hospitalized stroke patients admitted between Jan 1, 2006 to Dec 31, 2008, we identified 1734 stroke inpatients aged ≥ 20 years who had received in-hospital adjuvant TCM therapy. A propensity score matching procedure was used to identify 1734 stroke inpatients who did not receive in-hospital adjuvant TCM therapy (Shih et al., 2013; Yeh et al., 2013; Austin, 2007). The patients in both cohorts had undergone in-hospital routine care involving conventional regimens and protocols. The 3-month and 6-month adverse outcomes, such as urinary tract infection (UTI), pneumonia, fracture, epilepsy, decubitus ulcer, gastrointestinal hemorrhage, use of medical resources, and mortality, which occurred after stroke admission during the follow-up

period were identified for both cohorts. The 3-month and 6-month complications and mortality observed after the index stroke admission were considered the primary outcomes in this study. The secondary outcomes were the incidence and medical costs of emergency visits and hospitalization after the index stroke admission.

2.3. Adjuvant TCM therapy

There were 26 teaching hospitals participated the program of Health Policy for Chinese Medicine Adjuvant Therapy in Stroke which is a nationwide intervention program conducted by the Ministry of Health and Welfare in Taiwan. All of the hospitalized stroke participants received routine care (in addition to conventional medical treatment, such as neurosurgery, biochemical medication, rehabilitation, and regular body examination) in the neurology ward or in the intensive care unit for no more than 6 months after the initial diagnosis of stroke. TCM physicians visited the hospitalized stroke patients three times per week and prescribed or renewed the regimen. The adjuvant TCM therapy included herb medicine, acupuncture and/or moxibustion, tuina, and providing expertize opinions on nursing care (such as withdrawal of needles, health education, moving patients and replacing clothes) and Chinese medicinal diet therapy. The selection and combination of regimens were determined by TCM physicians' clinical evaluations in accordance with TCM principles. When clinical conditions fluctuated or adverse effects occurred, physicians from both the neurology and TCM departments evaluated the patients and determined a program for further treatment.

2.4. Measures and definitions

According to our previous study (Liao et al., 2012), occupations were classified as blue collar, white collar, or other. We identified income status by defining low-income patients as those qualifying for waived medical copayment, because this status is verified by the Taiwan Bureau of National Health Insurance (Yeh et al., 2013). In accordance with the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), we defined stroke as hemorrhagic (ICD-9-CM 430–432), ischemic (433, 434), or other (ICD-9-CM 435–438), and identified major coexisting medical conditions including hypertension (ICD-9-CM 401–405), chronic obstructive pulmonary diseases (ICD-9-CM 490–496), diabetes mellitus (ICD-9-CM 250), acute myocardial infarction (ICD-9-CM 410), hyperlipidemia (ICD-9-CM 272.9), mental disorder (ICD-9-CM 290–319), and liver cirrhosis (ICD-9-CM 571) recorded in the medical claims during the 24 months prior to the index stroke admission. Renal dialysis (administration code D8, D9) was considered as a pre-stroke functional status. The use of stroke-related medication, such as anticoagulants, anti-platelet agents, and lipid-lowering agents were also considered as potential confounding factors for investigating the effects of adjuvant TCM therapy on post-stroke outcomes. The characteristics of the index stroke admission, such as length of stay, intensive care unit stay, neurosurgery, stroke admission in medical center or not, type of stroke, previous history of stroke were also identified as covariate for the relationship between adjuvant TCM therapy and post-stroke outcomes.

Six major post-stroke complications were considered in this study including UTI (ICD-9-CM 599.0), pneumonia (ICD-9-CM 480–486), fracture (ICD-9-CM 800–829), epilepsy (ICD-9-CM 345), decubitus ulcer (ICD-9-CM 707.0), and gastrointestinal hemorrhage (ICD-9-CM 578).

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