Contents lists available at ScienceDirect

Journal of Ethnopharmacology

journal homepage: www.elsevier.com/locate/jep

Research Paper

The use of Chinese herbal products and its influence on tamoxifen induced endometrial cancer risk among female breast cancer patients: A population-based study



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A R T I C L E I N F O

Article history: Received 5 March 2014 Received in revised form 30 June 2014 Accepted 6 July 2014 Available online 15 July 2014

Keywords: Tamoxifen Chinese herbal product Herb-drug interaction Breast cancer National Health Insurance Research Database

ABSTRACT

Ethnopharmacological relevance: The increased practice of traditional Chinese medicine (TCM) worldwide has raised concerns regarding herb–drug interactions. The purpose of our study was to analyze the use of Chinese herbal products (CHPs) and to estimate the influence of the use of CHP on tamoxifen induced endometrial cancer risk among female breast cancer patients in Taiwan.

Methods: All patients newly diagnosed with invasive breast cancer receiving tamoxifen treatment from January 1, 1998 to December 31, 2008 were selected from the National Health Insurance Research Database. The usage, frequency of service, and CHPs prescribed among the 20,466 tamoxifen-treated female breast cancer patients were analyzed. The logistic regression method was employed to estimate the odds ratios (ORs) for utilization of CHPs. Cox proportional hazard regression was performed to calculate the hazard ratios (HRs) for subsequent endometrial cancer for CHP non-users and CHP users among female breast cancer patients who had undergone tamoxifen treatment.

Results: More than half of the subjects had ever used a CHP. *Jia-Wei-Xiao-Yao-San* (Augmented Rambling Powder) and *Shu-Jing-Huo-Xue-Tang* (Channel-Coursing Blood-Quickening Decoction) were the two most commonly used CHPs. The HR for the development of endometrial cancer among CHP users was 0.50-fold (95% CI=0.38–0.64) compared to that of CHP non-users.

Conclusion: More than half of the study subjects had ever used a CHP. *Jia-Wei-Xiao-Yao-San* was the most commonly used CHP. Among female breast cancer patients who had undergone tamoxifen therapy, CHP consumption decreased the risk of subsequent endometrial cancer. Exploring potential Chinese herb-tamoxifen interactions and integrating both healthcare approaches are beneficial to the overall health outcomes of tamoxifen-treated female breast cancer patients.

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1. Introduction

Breast cancer survivors reportedly have lower positive psychosocial well-being scores, suffer from greater depression and have more days affected by cancer-related symptoms (Bourque et al., 2009; Ivanauskiene et al., 2014; Koch et al., 2014). The emotional impact of cancer diagnosis and related issues, especially how individuals deal with the uncertainty and body-image problems inherently associated with cancer treatment, can be severe. Tamoxifen is an antagonist of the estrogen receptor present in breast tissue and is currently used for the treatment for estrogen receptor-positive breast cancer (Paik et al., 2004) to prevent breast cancer among women at high risk of breast cancer (Afonso, 2009), and as a means of reducing contralateral (in the opposite breast) cancer in breast cancer sufferers (Swain, 2001). However, tamoxifen not only induces depression, hot flushes, uterine abnormalities (Bonneterre et al., 2000) or/and subsequent endometrial cancer (Nagy et al., 2014), and these involve a complex interaction between cancer-related symptoms and cancer-related mood disorders (Reyes-Gibby et al., 2008). These factors, as well as an increased perception of the risk of breast cancer recurrence







Abbreviations: aHR, adjusted hazard ratio; aOR, adjusted odds ratios; CAM, complementary and alternative medicine; CHP, Chinese herbal products; CI, confidence intervals; DCMP, Department of Chinese Medicine and Pharmacy; ER, estrogen receptor; HR, hazard ratio; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; NHI, National Health Insurance; NHIRD, National Health Insurance Research Database; NHRI, National Health Research Institutes; NT\$, New Taiwan Dollars; OR, odds ratio; TCM, traditional Chinese medicine; WM, Western medicine

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(Lin et al., 2011), may be one of the reason why women with breast cancer often use complementary and alternative medicines (CAMs), including herbs, vitamins, homeopathic remedies and traditional Chinese medicine (Rakovitch et al., 2005; Tagliaferri et al., 2001).

Consisting of a unique group of traditional therapies for various ailments, traditional Chinese medicine (TCM) has been used in Taiwan for hundreds of years and its popularity remains unabated despite the present availability of modern medical care in Taiwan. In addition, one distinguishing feature of the national health care system in Taiwan is the coexistence of modern Western medicine (WM) and TCM, which includes acupuncture, manipulative therapies as well as Chinese herbal products (CHPs). TCM claims in Taiwan have been covered by the National Health Insurance (NHI) system since 1995 (National Health Research Institutes, 2014). TCM remedies are promoted as natural and therefore harmless; as a result these CAMs are also used in Western countries (Liu et al., 2009; Williamson et al., 2013). Nevertheless, information is limited regarding their safety when used in combination with Western drugs such as tamoxifen, especially in terms of herb-drug interactions. Such interactions might involve interference that affects the absorption, metabolism, and clearance of either of Western drug or the CHP. In this context, studies on the prevalence of CHP use and the co-prescription patterns of TCM remedies among tamoxifen-treated breast cancer patients are scant.

Taiwan launched a single-payer National Health Insurance program on March 1, 1995. Individuals in Taiwan are free to choose from care offered by WM clinics or by TCM clinics. With an insured rate of 98% to 99%, the nationwide sample that comprises the NHI research database (NHIRD) is representative of the general population of Taiwan, and should allow a reasonably accurate assessment of the co-utilization of TCM and modern medical resources in Taiwan. Therefore, the NHIRD provides an ideal platform for pharmaco-epidemiological studies (Chen et al., 2013; Lai et al., 2013; Lee et al., 2013). Our study's aim was to describe the demographics and patterns of CHP usage among tamoxifentreated female breast cancer patients from a Taiwanese nationwide cohort and to explore the risk of the occurrence of subsequent endometrial cancer among these individuals. Our findings provide evidence-based information that will help the formulation of appropriate management strategies for drug safety and will help to strengthen the patient-physician relationship during breast cancer care.

2. Materials and methods

2.1. Data resources and study sample

The sample of this study was conducted from the database of approximately more than 23 million people enrolled in the NHI. The data collection began in 1996, but it was more comprehensive after January 1997. Therefore, it was designed as a populationbased study to determine the prevalence of CHP use among tamoxifen-treated breast cancer survivors and to investigate associations between having been prescribed CHP and the occurrence of subsequent endometrial cancer in Taiwan between January 1, 1998 and December 31, 2008. All data were obtained from the NHI reimbursement database and only a small amount of data processing fee is charged by project, either New Taiwan Dollars (NT\$) 500 (£11) per compact disc or New Taiwan Dollars (NT\$) 200 (£4.4) per gigabyte data (Chen et al., 2011). The selection of study period and the amount of data obtained were considered only if research funds subsequently become available. The electronic records of the NHIRD used in this study have encrypted identification numbers for all beneficiaries and the

dataset was transformed and is maintained by the National Health Research Institutes (NHRI) of Taiwan (Department of Chinese Medicine and Pharmacy, 2014; Lee et al., 2010). The NHIRD records contained demographic information, including age and sex, as well as clinical data, which includes all records of clinical visits and hospitalizations together with all information regarding prescribed drugs and dosages, including those for CHPs. The diagnoses used in the NHIRD are coded according to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) (Centers for Disease Control and Prevention, 2014).

The selection of study subjects was performed as follows (Fig. 1). First, subjects under 20 or over 79 years of age (n=8120) were excluded to limit the study sample to the adult cancer patients in Taiwan. Next, we excluded one year, 1997, in order to avoid the inclusion of 22,798 prevalent breast and corpus cancer cases. Furthermore, to control various potential confounding factors, we further excluded 19,586 subjects who had ever used tamoxifen prior to any diagnosis of gynecological cancer or who had a history of hysterectomy (n=3990). Finally, 37,515 tamoxifen-treated female breast cancer patients were included in the study cohort, as shown in Fig. 1. CHP users were identified with tamoxifen-treated female breast cancer patients who have ever been prescribed CHP either before the end of the study or the occurrence of endometrial cancer. No use of CHP was the nonusers, and it included patients who had no record of CHP treatment as well as those who did not ever seek help from TCM. The NHIRD has a unique code that does not include identifying information; therefore, the research that we conducted was exempt to need consent by participates from institutional



Fig. 1. Flowchart showing the recruitment of subjects from the National Health Insurance catastrophic illnesses registry of Taiwan for the years 1998–2008.

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