Original Article

Use of Traditional Chinese Medicine in Chinese Patients with Coronary Heart Disease^{*}

GUO Xiang Yu, LIU Jing, LIU Jun, LI Hong Juan, QI Yue, QIN Lan Ping, WANG Miao, and ZHAO Dong[#]

Beijing Anzhen Hospital, Capital Medical University, Beijing Institute of Heart, Lung & Blood Vessel Diseases, Beijing 100029, China

Abstract

Objective To study the use of traditional Chinese medicine (TCM) or both TCM and guideline-recommended Western medicine (WM) in Chinese patients with coronary heart disease (CHD).

Methods A cross-sectional nationwide survey of 2803 CHD outpatients was completed by collecting information, including general demographic data, disease history, and use of drugs (including TCM and WM).

Results Of the 2712 CHD outpatients with complete drug treatment data, only 3.1% received TCM without any WM for CHD, 30.0% received both TCM and WM recommended by current CHD guidelines, and 66.9% received only WM. Patients with a longer history of CHD or with a history of stroke, were more likely to use TCM. However, 90.6% of CHD patients who used TCM also used certain WM. Furthermore, patients who used more types of TCM tended to use much less WM recommended by current guidelines.

Conclusion A substantial proportion of Chinese CHD outpatients use both TCM and WM for secondary prevention of CHD. It is important to assess the effect of combined TCM and WM on major clinical outcomes in Chinese CHD patients.

Key words: Traditional Chinese medicine; Coronary heart disease; Guidelines

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INTRODUCTION

oronary heart disease (CHD) is one of the major causes of death in China^[1]. It was reported that the morbidity and mortality of CHD in Chinese populations will increase remarkably in the next 20 years because of aging and increasing risk factors for CHD^[2-3]. A recent study reported that the number of CHD patients will increase by 3.3 times from 2010 to 2030 and is at the highest risk for recurrent CHD events and death^[4]. It

is critically important to reduce their risk of recurrent events and death^[5-7]. Traditional Chinese medicine (TCM) is widely used in prevention and treatment of many diseases in China. However, few studies are available on use of TCM in secondary prevention of CHD. Therefore, information on use of TCM in CHD outpatients was provided, association between use of TCM and guideline-recommended Western medicine (WM) was analyzed, patients who are more likely to take TCM were observed in this cross-sectional study.

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[#]Corresponding author: ZHAO Dong, professor, MD and Ph.D. Tel: 86-10-64456524. Fax:86-10-64419738. E-mail: deezhao@vip.sina.com

Biographical note of the first author: GUO Xiang Yu, male, born in 1968, Ph.D candidate, associated professor, majoring in cardiovascular pharmacoepidemiology.

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SUBJECTS AND METHODS

Study Subjects

Subjects were selected from hospitals in mainland China. Multistage non-randomized sampling was used in this study. Fifty-seven cities or regions were selected according to their economic levels, from which 32 second class hospitals and 32 third class hospitals were chosen. Fifty consecutive CHD outpatients were selected from each hospital from March 15 to June 15, 2006, with their history of acute coronary syndrome (ACS) recorded.

Those with a past history of ACS (codes I20.0 and I21-I22 in the International Classification of Diseases, tenth version) and their age≥18 years were included in this study. The following patients were excluded from this study, including those with acute cardiovascular disease (ACD), acute stroke, needing to be hospitalized or discharged from hospitals in less than 28 days, those with renal failure requiring dialysis or on any drug treatment or with severe potentially life-threatening diseases such as cancer, and those who refused to participate in this survey. The study was approved by the Ethics Committee of Beijing Anzhen Hospital, Capital Medical University, China.

Definitions

TCM for Treatment of CHD TCM refers to pharmaceutical products (including Chinese crude decoction pieces, and Chinese patent drugs. medicines) used for preventing and treating diseases. Crude forms and decoction pieces or injection forms of TCM were excluded because few were prescribed in out-patient settings. The name and dose of each TCM were recorded in detail. TCM was prescribed for CHD according to its indications approved by State Food and Drug Administration of China (SFDA) or the guidelines of clinical applications in National Traditional Chinese Medicine Formulary. Main types of TCM covered are blood-activating agents, stasisremoving agents, Qi-tonifying agents, Qi-regulating agents, heat-clearing agents, dampness-draining agents, phlegm-resolving agents and blood-tonifying agents. TCM treatment was defined as patients who received TCM before the survey or the prescription of TCM.

Guideline-recommended Western Drugs The 4 major medications, recommended by the CHD secondary prevention guidelines, include anti-platelet drugs (aspirin/clopidogrel), β-blockers,

statins, and angiotensin-converting enzyme inhibitor (ACEI)/angiotensin II receptor blocker (ARB).

Data Collection

A uniform case report form was designed and used in this study. Patients who visited the outpatient department of a collaborating hospital and met the inclusion criteria in this study were interviewed by a trained physician or a cardiologist. The questionnaire was completed by the physician to collect data about socioeconomic status, disease history, risk factors, previous medications and current prescriptions of TCM and WM. To validate the data, a similar questionnaire was completed by the patients. The quality of data input was controlled. The data were validated with double entry methods and checked for logic errors. Ten percent of cases were followed up by telephone. If there was any inconsistency, the data were double checked and verified by local researchers. The effect of TCM or WM on CHD was then assayed.

Statistical Analysis

Continuous variables were expressed as mean \pm SD and differences were tested by Student's *t* test or one-way analysis of variance. Difference in categorical variables was detected by χ^2 test. Multivariate analysis was performed with a logistic regression model.

All data analyses were carried out by SPSS 13.0 software for Windows (SPSS, Chicago, IL) with *P*<0.05 considered to be statistically significant.

RESULTS

A total of 2712 CHD patients (1871 males and 841 females) aged 64.9±10.4 years with complete medical data were enrolled in this study. Of them, 905 (33.4%) had a history of recurrent ACS.

Use of TCM

Of the 2712 CHD patients, 33.1% (897) used TCM for CHD. Of the 897 patients who used TCM, 90% used one TCM preparation and 10% used two or more TCM preparations. The main types of TCM used by the patients included Danshen preparation (with the main components being Salvia miltiorrhiza, Radix notoginseng, and Borneol) and Tongxinluo (with main components being ginseng, leeches, and scorpions). The rates of CHD patients who used TCM are shown in Table 1. Females, elderly patients, patients with a longer CHD history or with a history of stroke were more likely to use TCM than those

with a history of percutaneous coronary intervention (PCI) and those who visited third class hospitals.

		n	WM Only %(n)(1)	TCM Only %(<i>n</i>)(2)	TCM+WM %(n)(3)	TCM %(n)(2)+(3)
Gender	Men	1871	68.3(1278) [†]	2.7(50)	29.0(543)	31.7(593) [†]
	Women	841	63.9(537)	4.0(34)	32.1(270)	36.1(304)
Age (years)	<55	498	72.5(361) [‡]	2.8(14)	24.7(123)	27.5(137) [‡]
	55-64	792	67.2(532)	2.5(20)	30.3(240)	32.8(260)
	65-74	943	67.0(632)	3.4(32)	29.6(279)	33.0(311)
	≥75	479	60.5(290)	3.8(18)	35.7(171)	39.5(189)
Education	Low	1435	66.1(948)	3.8(54)	30.2(433)	33.9(487)
	Medium	746	67.6(504)	2.3(17)	30.2(225)	32.4(242)
	High	531	68.4(363)	2.4(13)	29.2(155)	31.6(168)
Monthly income	< 800	798	63.4(506)	4.3(34) [‡]	32.3(258) ⁺	36.6(292) [‡]
(RMB:Yuan)	800- 1200	1000	65.5(655)	3.4(34)	31.1(311)	34.5(345)
	≥ 1200	914	71.6(654)	1.8(16)	26.7(244)	28.4(260)
Reimbursement	< 30%	686	67.3(462)	3.4(23)	29.3(201)	32.7(224)
Proportion	30%-80%	1812	67.1(1216)	3.1(57)	29.7(539)	32.9(596)
	≥ 80%	214	64.0(137)	1.9(4)	34.1(73)	36.0(77)
Time of CHD	<=1 year	1085	73.9(802)	3.6(39)	22.5(244) [‡]	26.1(283) [‡]
diagnosis	1-5 years	899	64.0(575)	2.8(25)	33.3(299)	36.0(324)
	6-10 years	419	62.3(261)	2.6(11)	35.1(147)	37.7(158)
	>10 years	309	57.3(177)	2.9(9)	39.8(123)	42.7(132)
Recurrent ACS	Yes	905	66.0(597)	2.4(22)	31.6(286)	34.0(308)
	No	1807	67.4(1218)	3.4(62)	29.2(527)	32.6(589)
PCI history	Yes	755	79.2(598) [‡]	1.1(8) [‡]	19.7(149) [‡]	20.8(157) [‡]
	No	1957	62.2(1217)	3.9(76)	33.9(664)	37.8(740)
Stroke history	Yes	290	57.6(167)	3.1(9)	39.3(114) [‡]	42.4(123) [‡]
	No	2422	68.0(1648)	3.1(75)	28.9(699)	32.0(774)
Hypertension	Yes	1599	68.6(763)	4.4(49)	27.0(301) [‡]	31.4(350)
history	No	1113	65.8(1052)	2.2(35)	32.0(512)	34.2(547)
Hypercholesterolemia	Yes	852	67.0(571)	1.2(10)	31.8(271)	33.0(281)
history	No	1860	66.9(1244)	4.0(74)	29.1(542)	33.1(616)
Hospital level	Secondary	1320	61.4(810) [‡]	3.9(52)	34.7(458) [‡]	38.6(510) [‡]
	Tertiary	1392	72.2(1005)	2.3(32)	25.5(355)	27.8(387)
Total		2712	66.9(1815)	3.1(84)	30.0(813)	33.1(897)

Table 1. Rate of CHD Patients Who Used TCM and WM

Note. ${}^{\dagger}P < 0.05$, ${}^{\dagger}P < 0.01$. TCM: traditional Chinese medicine, WM: western medicine; CHD: coronary heart disease, PCI: percutaneous coronary intervention, ACS: acute coronary syndrome.

Characteristics of CHD patients who were more likely to use TCM were further identified by multivariate logistic regression analysis, which showed that the likelihood of using TCM was significantly associated with the years of CHD, history of stroke and PCI, level of hospitals the patients visited (Table 2). Furthermore, patients with CHD diagnosed for over 10 years were more likely to use TCM than those with a history of CHD less than 1 year (OR=2.01, 95% CI: 1.54-2.64). In addition, patients with a history of stroke tended to use TCM (OR=1.50, 95% CI: 1.54-2.64). The rate of CHD patients who used TCM was 1.37-fold higher in second-class hospitals than in third-class hospitals.

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Factors	R Coofficients	OP	95% CI of OR		D.Volue
Factors	p coencients	UK	Lower	Upper	P value
Time of CHD diagnosis					
<=1 year		1.00			
1-5 years	0.48	1.61	1.26	2.06	<0.001
5-10 years	0.53	1.71	1.40	2.08	<0.001
>10 years	0.70	2.01	1.54	2.64	<0.001
PCI history					
Yes		1.00			
No	0.84	2.32	1.89	2.85	<0.001
Stroke history					
No		1.00			
Yes	0.40	1.50	1.15	1.94	0.002
Hospital level					
Tertiary hospital		1.00			
Secondary hospital	0.31	1.37	1.16	1.62	<0.001

Note. OR: odds ratio, CI: confidence interval; TCM: traditional Chinese medicine; CHD: coronary heart disease; PCI: percutaneous coronary intervention.

TCM and WM Treatment Patterns

Of the CHD patients in this study, 3.1% used TCM only, and 30.0% used both TCM and WM, indicating that 90% CHD patients who used TCM also used WM. The proportion of patients who used both TCM and WM or only TCM for CHD was 19.7%-39.8% and 1.1%-4.4%, respectively (Table 1).

The mean number of drugs used for CHD in this study was 3.8±1.3 (range 1-8). The number of drugs was greater in CHD patients who used both TCM and WM than in those who used only WM or TCM 1.1±0.4, (4.4±1.3 and 3.7±1.1 vs P<0.05). Furthermore, the higher the number of TCM was used, the fewer the number of WM was used. The proportion of patients who used two or more TCM preparations was 15.3%, 31.0%, 49.4%, and 41.3% lower than that of those who used anti-platelet drugs, β -blockers, statins and ACEI/ARB (Table 3).

DISCUSSION

The application of TCM in secondary prevention of CHD, its prescription patterns and association with the use of guideline-recommended WM was studied based on a representative sample of CHD outpatients in mainland China. The results showed that (1) a considerable number of CHD patients used TCM as their regular treatment, especially those with a longer CHD history or with a history of stroke, (2) most CHD patients who used TCM also received all or some of guideline-recommended WM, and (3) patients who used TCM had a lower rate of using guideline-recommended WM. It was reported that the diversities of economic development in different areas and the difference in hospital levels should be considered in the study design and patient selection^[8-9]. Therefore, this study demonstrated the

No. of TCM Intake	Total	WM [%(<i>n</i>)]					
	TOtal	Aspirin/clopidogrel	β-blockers	Statins	ACEI/ARB		
0	1815	87.8(1594)	66.1(1199)	63.7(1156)	64.4(1169)		
1	807	81.4(657)	54.3(438)	44.0(355)	52.9(427)		
≥2	90	74.4(67)	45.6(41)	32.2(29)	37.8(34)		
Total	2712	85.5(2318) [‡]	61.9(1678) [‡]	56.8(1540) [‡]	60.1(1630) [‡]		

Table 3. Rate of Patients Who Used TCM and WM

Note. [‡]*P*<0.01, TCM: traditional Chinese medicine, WM: western medicine, ACEI: angiotensin-converting enzyme inhibitor, ARB: angiotensin II receptor blockers.

use of TCM in CHD outpatients who visited third or second class hospitals in China and highlighted the association between use of TCM and guideline-recommended WM.

Non-guideline-recommended TCM is prescribed for many CHD patients due to the following reasons. (1) TCM, a complex medical science, reflects traditional Chinese culture and philosophical principles, embodies rich dialectical thought, places the human body into a large system for observation and adjusts humans to remain in a healthy state^[10-12]. Chinese people have a preference for the TCM culture, and some of them (including Western-trained doctors) consider TCM to be natural, green, nontoxic, effective and cheap^[13-17]. (2) Although clinical TCM trials should be further improved^[18-20], increasing clinical TCM studies have revealed its efficacy in some medical treatment. For example, compound Danshen dripping pills. Tongxinluo, and Shexiang Baoxin pills can lower blood lipids and blood viscosity, and improve micro-circulation, protect against oxidation, resist apoptosis, and endothelial function^[21-22]. It was reported that CHD patients receiving long-term TCM have a significantly lower risk of sudden death, myocardial infarction and death, fewer demands for surgery or intervention, and fewer or milder side effects^[23].

Both TCM and guideline-recommended WM were prescribed for CHD patients in this study. In China, the integration of Chinese and WM (ICWM) has been explored for many years^[24-27]. Some studies showed the potential benefits of combined TCM and WM on alleviating clinical symptoms, reducing post-PCI restenosis, enhancing quality of life and improving post-PCI myocardial perfusion in CHD patients^[28-34]. A prospective study of 5284 CHD patients showed that ICWM is an independent protective factor and reduces the risk of major adverse cardiac events by 31%^[35], which, to some

extent, can explain why a substantially proportion of physicians prefer to use both TCM and WM. As the use of WM increases, the incidence of its adverse reactions (AR) also increases, especially in senior CHD patients. Toxic and side effects can reduce the compliance of patients^[36-39]. Consequently, some doctors are likely to use TCM instead of guideline-recommended WM because patients and doctors in China believe that TCM is not toxic and has no AR^[13-17]. In fact, it is difficult to prove that TCM is safer than WM in treatment of CHD, and particular attention needs to be paid to the use of "TCM + all four guideline-recommended drugs". Large scale, rigorously designed, and randomized double-blind control clinical trials are needed to verify and support the effect of TCM on CHD and to answer the questions whether the use of "TCM + all four guideline-recommended drugs" is better than guideline-recommended medication sole and whether it has additional value to inpatients. Additionally, when TCM is used in combination with WM, it is important to understand the nature and pharmacological effects of various chemical constituents in TCM. This is because the interaction between TCM and WM is similar to drug-drug interactions in terms of their effects on absorption, metabolism, distribution, and excretion. and potential interactions between TCM and some WM for cardiovascular disease may lead to adverse effects^[40-41]. For example, a recent study showed that Danshen can result in additive anti-platelet effects and a risk of bleeding. The concurrent use of ginkgo with anti-platelet agents increased the risk of bleeding. It was reported that TCM is used for hyphema, subphrenic hematoma and intracranial hemorrhage, and ginkgo can reduce the effect of antihypertensive drugs by interacting with the cytochrome P450 system^[42-44].

Multivariate logistic regression analysis revealed that patients with a history of stroke were more

likely to use TCM. Since effective therapeutic strategy is needed for prevention of brain injury in patients with cerebral ischemia, TCM may be used in limiting neurological damage associated with stroke^[45-46]. Interestingly, the rate of patients with a longer CHD history who used TCM was significantly higher, which needs to be further studied.

There are two notable limitations in this study. (1) Hospitals below the second class were not included, which may lead to underestimation of the use of TCM at primary hospitals and rural clinics. (2) Cross-sectional data and classification of TCM used in this study were not in detail according to the TCM theories, a direct comparison of the effectiveness between combined used of TCM and WM and single use of WM is questionable, which is another reason why long-term follow-up is important.

In conclusion, although TCM is not yet listed in CHD prevention and treatment guidelines in China, it is still taken by many Chinese patients. Among TCM users, the addition of WM is common. Use of TCM may decrease the use of WM. The main problems of ICWM for treatment of CHD are how to adhere to the principle of evidence-based medicine, determine advantages of ICWM and objectively assess the effects, with the primary outcome as the goal of observation.

Appendix: Participating Hospitals and Their Chief Investigators

Beijing Anzhen Hospital (ZHAO Dong), Beijing

Beijing Luhe Hospital (GUO Jin Cheng), Beijing

The Second Hospital of Tianjin Medical University (LI Guang Ping), Tianjin

Tianjin Benchen Hospital (LI Guang Shun), Tianjin

The Affiliated Hospital of Hebei University (LIU Ke Ye), Baoding

Huailai County TCM Hospital (NIU Jian Zhong), Huailai County

The Third Hospital of Shijiazhuang (Luo Da Yong), Shijiazhuang

The Second Hospital of Shanxi Medical University (YANG Zhi Ming), Taiyuan

541 Hospital in Yun City (WANG Cai Ping), Yun City

The First Affiliated Hospital of Baotou Medical College (GUO Xiao Ling), Baotou

Linhe Central Hospital (HUO Ping), Linhe

Shenyang Red Cross Hospital (YAN Zhong Zheng), Shenyang

The Third Hospital of Liaoyang (LIU Ri Hui), Liaoyang

The First Hospital of Jilin University (ZHAO Xue Zhong), Changchun

The Second People's Hospital of Jilin City (ZHUANG Yuan Qing), Jilin

The First Clinical College of Harbin Medical University (LI Wei Min), Harbin

Harbin Boiler Company Hospital (WANG Li Ping), Harbin

Xinhua Hospital Shanghai Jiaotong University Medical College (CHEN Shu Yan), Shanghai

Shanghai Shibei Hospital (WANG Bin), Shanghai

The Affiliated Hospital of Xuzhou Medical College (XIA Yong), Xuzhou

Nanjing Gangkou Hospital (CAI Wei), Nanjing

The First Affiliated Hospital of Zhejiang University (ZHU Jian Hua), Hangzhou

The First People's Hospital of Pinghu (FANG Fang), Pinghu

The First Affiliated Hospital of Anhui Medical University (XU Yan), Hefei

The People's Hospital of Mingguang City (WU Xiang Ming), Mingguang

Fujian Medical College Xiehe Hospital (CHEN Liang Long), Fuzhou

The First Hospital of Putian (LIN Shou Xue), Putian

The First Hospital of Nanchang University (ZHANG Yang Long), Nanchang

Municipal Hospital of Shangrao City (LU Xi), Shangrao

The Affiliated Hospital of Medical College Qingdao University (CAI Shang Lang), Qingdao

The First People's Hospital of Tancheng (ZHAO Feng Long), Tancheng

The First Affiliated Hospital of Zhengzhou University (HUANG Zhen Wen), Zhengzhou

The People's Hospital of Jun County (LI Jian Min), Jun County

Wuhan Union Hospital (CHENG Pei), Wuhan

Yiling Hospital of Yichang City (QU Ke Yi), Yichang

Hunan Provincial People's Hospital (OU Bo Qing), Changsha

The Fourth People's Hospital of Yongzhou City (QIN Jian Ming), Yongzhou

Guangdong Provincial People's Hospital (ZHOU Ying Ling), Guangzhou

The Second People's Hospital of Foshan City (XUN Jian), Foshan

The People's Hospital of Hechi City (TANG Xiu Ge), Hechi

The Second People's Hospital of Beihai City (HUANG Yong Kang), Beihai

The People's Hospital of Haikou City (CHEN Mo Shui), Haikou

The People's Hospital of Sanya City (WEI Di Xiong), Sanya

The Second Hospital of Chongqing Medical University (GAO Da Zhong), Chongqing

The Second People's Hospital of Banan District Chongqing (WU Yun), Chongqing

Huaxi Hospital of Sichuan University (CHEN Xiao Ping), Chengdu

Shifang People's Hospital (LIN Liang Cai), Shifang The Affiliated Hospital of Guiyang Medical College (WU Li Rong), Guiyang

The People's Hospital of Liupanshui City (LIN Jin Hong), Liupanshui

The First Affiliated Hospital of Kuming Medical College (Guo Tao), Kuming

Yunnan Chuxiong Hospital (WEN Shao Chang), Chuxiong

Tibet Autonomous Region People's Hospital (Gesangluobu), Lhasa

Lhasa People's Hospital (Suolanglaicuo), Lhasa

The First Affiliated Hospital, Medical School of Xi'an Jiaotong University (MA Ai Qun), Xi'an

The Second Hospital of Xi'an (MENG Jian Jiang), Xi'an

The Second People's Hospital of Lanzhou City (QIAO Xiao Min), Lanzhou

General Hospital of Gansu Construction Company (CHEN Yuan), Lanzhou

Qinghai Provincial People's Hospital (ZHOU Bai Li), Xining

Qinghai Transportation Hospital (ZHAO Shu Ping), Xining

The Affiliated Hospital of Ningxia Medical College (LIU Xiao Fang), Yinchuan

The People's Hospital of Pingluo County (TIAN Wei Ning), Pingluo County

The People's Hospital of Xinjiang Uygur Autonomous Region (LI Nan Fang), Urumchi

Hami Prefecture Hospital of Xinjiang (LIN Tao), Hami Prefecture

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