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Original Article

A survey and analysis of using traditional Chinese medicine during pregnancy

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Abstract: Background: The usage of Traditional Chinese Medicine (TCM) during pregnancy is very common for Chinese people. However, there are only a few studies relevant to the usage of TCM during pregnancy-providing very little knowledge on the benefits or harmful effects of these medicines to pregnant women or the fetus. Objectives: The purpose of this study is to survey the current situation of TCM usage during pregnancy, and to explore the factors that affect the use of TCM. Methods: Data was collected from pregnant patients who delivered in our hospital, from March 2012 to August 2012. All patients who agreed to join this study were asked to fill-up a questionnaire. Results: 1,010 patients were willing to participate in this study. 11.2% (113, 1,010) of patients used at least one kind of TCM during pregnancy. The average TCM usage is 2.1 species. The most commonly used drugs are Antai pill (39 cases, 34.5%), Xiaochaihu granules (31 cases, 27.4%), and Shengxuening tablets (23 cases, 20.4%). Patients who smoke during pregnancy (OR=1.8, 95% CI: 0.7~5.1), drink during pregnancy (OR=1.6, 95% CI: 0.4~6.1), have been hospitalized during pregnancy (OR=4.8, 95% CI: 2.9~7.9), have pregnancy complications (OR=2.7, 95% CI: 1.5~4.9) and those who are infertile (OR=2.6, 95% CI: 1.4~4.8) have higher chances of using TCM during pregnancy. Conclusions: Pregnant women commonly use TCM during pregnancy. Pregnant women who smoke, drink, hospitalized during pregnancy, experience pregnancy complications and infertility are more likely to use TCM.

Keywords: TCM, pregnancy, Chinese people

Introduction

In China, TCM is a traditional method of treatment; and it is a phenomenon that TCM has been commonly used by pregnant women. However, until today, the benefits or harmful effects of TCM in pregnant women or the fetus is still unknown. Even though we know that TCM is commonly used, we still do not know the proportion of pregnant women, who use TCM, and the factors that affects TCM usage. Studies have shown that 40%-90% of pregnant women use at least one kind of TCM during pregnancy [1-3]. As we all know, the improper use of these drugs can be harmful to the fetus, affect the growth of the fetus, or cause the fetus to be teratogenic. TCM has a broad range of medicines, but most of its effects on the fetus is still unclear. Studies have also shown that most pregnant women use TCM by themselves [4]. Although this phenomenon is common during clinical treatments, there are only a few studies in China relevant to TCM usage during pregnancy. The purpose of this study is to have a preliminary understanding and analyze the factors that affect the use of TCM during pregnancy. This was achieved by collecting patient's data by means of questionnaires, which the participants completed after delivery; clinical information was also recorded from the patient's medical records. We hope this study would benefit doctors that carry out clinical counseling and prenatal care services.

Materials and methods

From March 2012 to August 2012, pregnant patients, who delivered at the obstetric department of the First Affiliated Hospital of Sun Yat-sen University, participated in this study. All participants signed an informed consent and were asked to complete a Chinese questionnaire. The questionnaire included the patient's age, education, average monthly income, marital

Table 1. Comparison of the basic information of the two groups

Basic information		Research group n=113	Control group n=897	t/X^2 value	*P* value
Age (yr, mean ± SD)		30.6±4.6	29.9±3.8	-1.833	0.067
Marriage (n, %)	Yes	110 (97.3)	881 (98.2)	0.423	0.521
	Other	3 (2.7)	16 (1.8)		
Regular prenatal care (n, %)	Yes	90 (79.6)	782 (87.2)	4.828	0.028
	No	23 (20.4)	115 (12.8)		
Primipara (n, %)	Yes	91 (80.5)	753 (83.9)	0.852	0.356
	No	22 (19.5)	144 (16.1)		
Income (RMB, n, %)	≥10000	67 (59.3)	532 (59.3)	15.187	<0.001
	5000-10000	33 (29.2)	332 (37.0)		
	<5000	13 (11.5)	33 (3.7)		
BMI (kg/m^2, n, %)	18.5-24.9	42 (37.2)	316 (35.2)	1.144	0.564
	25-29.9	57 (50.4)	493 (55.0)		
	≥30	14 (12.4)	88 (9.8)		
Education (yr, n, %)	≤9	1 (0.9)	3 (0.3)	2.274	0.321
	≤12	28 (24.8)	179 (20.0)		
	>12	84 (74.3)	715 (79.7)		
Alcohol consumption (n, %)	Yes	5 (4.4)	26 (2.9)	0.786	0.375
	No	108 (95.6)	871 (97.1)		
Smoking history (n, %)	Yes	3 (2.7)	20 (2.2)	0.082	0.775
	No	110 (97.3)	877 (97.8)		
Diseases before/during pregnancy (n, %)	Yes	48 (42.5)	284 (31.7)	5.321	0.021
	No	65 (57.5)	613 (68.3)		
Pregnancy complications (n, %)	Yes	68 (60.2)	422 (37.0)	6.928	0.008
	No	45 (39.8)	475 (63.0)		
Hospitalization (n, %)	Yes	36 (31.9)	88 (9.8)	45.297	<0.001
	No	77 (68.1)	809 (90.2)		
Infertility (n, %)		20 (17.7)	78 (8.7)	9.285	0.002

status, smoking habits during pregnancy, alcohol consumption during pregnancy, and TCM usage (excluding medicinal food). At the same time, we also reviewed and recorded information from the patient's maternal medical records, such as parity, body mass index (BMI), prenatal care, infertility history, pregnancy complications, hospitalization during pregnancy or before delivery, TCM usage during pregnancy [5, 6], etc.

The participants were divided into two groups, patients who used at least one kind of TCM during pregnancy were classified as the research group, and patients who did not used any kind of TCM were classified as the control group. A general comparison was done between the two groups, analyzing the factors that affect pregnant patients, who used any kind of TCM for treatment.

The two groups were compared based on general situations, such as the patient's age, education level, average monthly income, marital status, parity, birth, smoking habits during pregnancy, drinking consumption during pregnancy, BMI, diseases before or during pregnancy (such as anemia, diabetes mellitus, hypertension, heart disease, acute appendicitis, etc.), pregnancy complications (such as polyhydramnios, premature membrane rupture, placental abruption, placenta previa, etc.), infertility history, hospitalization before delivery, etc. The relationships between these factors and the use of TCM during pregnancy will also be analyzed.

The collected datas was entered to the SPSS19.0 software for statistical analysis. The count data, describing its frequency, and the

Table 2. Factors in using traditional Chinese medicine during pregnancy

Factors		Adjusted OR (95% CI)	*P* value
Income	≥10000	-	-
	<10000	1.1 (0.7, 1.6)	0.452
Parity	0	-	-
	≥1	1.0 (0.5, 1.8)	0.513
Marriage	Yes	-	-
	Other	0.9 (0.2, 3.8)	0.764
Prenatal care	Yes	-	-
	No	1.3 (0.7, 2.5)	0.414
Education	≥12 years	-	-
	<12 years	1.2 (0.6, 2.1)	0.382
Alcohol Consumption		1.6 (0.4, 6.1)	0.043
Smoking History		1.8 (0.7, 5.1)	0.034
Diseases before/during pregnancy		2.7 (1.5, 4.9)	0.287
Pregnancy complications		0.4 (0.2, 0.7)	<0.001
Hospitalization		4.8 (2.9, 7.9)	0.032
Infertility		2.6 (1.4, 4.8)	0.015

rate differences between the groups were compared using the chi-square test; mean ± standard deviation (x±s) was used for normally distributed measurement data. Factors relevant to TCM usage were analyzed by multiple regression analysis to estimate odds ratios (ORs) and the 95% confidence intervals (CIs). P<0.05 was considered statistically significant.

Results

1,822 pregnant women delivered at our hospital from March 2012 to August 2012. 1,010 patients were willing to complete the questionnaires.

The characteristics of the two groups that we interviewed are summarized in **Table 1**. The average age of the female patients was 30.0± 2.6 years old (18 to 45 years old), which was included in analyzing the 1,010 cases. 11.2% of patients used at least one kind of TCM during pregnancy. Among the patients, 35 cases (30.8%) used only one kind of TCM, and 62 cases (54.9%) used two kinds of TCMs. The most common kinds of TCMs used during pregnancy are Antai pill (39 cases, 34.5%), Xiaochaihu granules (31 cases, 27.4%), and Shengxuening tablets (23 cases, 20.4%). Regular prenatal care, high income, diseases before or during pregnancy, pregnancy complications, hospitalization history and infertility history data values were significantly higher than the control group (X^2 values were 4.828, 15.187, 5.321, 6.928, 45.297 and 9.285, respectively, P<0.05). But other data values, such as marital status, BMI, parity, education, smoking, and alcohol consumption during pregnancy showed no significant difference between the two groups.

The risk factors affecting TCM usage during pregnancy are shown in **Table 2**. After adjusting all other variables, such as age, parity, education level, marital status, BMI, smoking, drinking, disease before or at pregnancy, pregnancy complications, hospitalization, infertility history, and regular prenatal care; multiple regression analysis was used to process the data. Pregnant women with factors, such as smoking during pregnancy (OR 1.8, 95% CI: 0.7~5.1), alcohol consumption during pregnancy (OR 1.6, 95% CI: 0.4~6.1), hospitalization during pregnancy (OR 4.8, 95% CI: 2.9~7.9), pregnancy complications (OR 2.7, 95% CI: 1.5~4.9) and infertility (OR 2.6, 95% CI: 1.4~4.8), would most likely use TCM during pregnancy. However, factors, such as parity, age, education level, income, and pregnancy complications did not show any effects with the use of TCM during pregnancy.

Discussion

China has a very large population, and most Chinese people use TCM for treatment; specially, during pregnancy-which has a relatively high usage rate. Furthermore, China has yet to create standards that can fully and correctly evaluate the impact of TCM usage on pregnant women. Many pregnant women use TCMs themselves, instead of consulting medical specialists; because most of them thought that TCM only had minimal adverse effects during pregnancy-on the account of natural treatment. However, the physiological characteristics of pregnant women are different from ordinary people, and TCM could also harm the fetus and the mother, through the placenta barrier.

Due to ethical issues, most clinical trials excluded pregnant women; hence, available information relevant to evaluating of TCM usage during

pregnancy is very rare. It is also difficult to identify the potential toxic effects of TCM on the fetus; and even if TCM could potentially cause harmful effects to the mother or the fetus, it is still difficult to find [7]. Further, even though animal experiments did not show any harmful effects to the animal fetus-concluding that no adverse effects could occur on the human fetus-various studies revealed that the adverse effects on the human fetus of most of these drugs came from single case reports or small case series reports [8].

The results of this study showed that 11.2% (113/1,010) of the participants used one or more kinds of TCM during pregnancy. Other studies reported that the proportion of TCM usage during pregnancy ranged from 7%-96%, depending on the TCM classification standard or standards used in conducting different medical studies [9-14]. Chuang CH et al. [12] interviewed 24,200 cases during the period of 2005-2006, and found that 33.6% respondents used at least one kind of TCM during pregnancy, such as pearl powder, berberine, etc. In a study conducted by Byrne M et al. [13], 48 cases of antenatal inpatients were interviewed and showed that 56% of the respondents used at least one kind of TCM, such as tea, ginger, etc. However, the research of Westfall RE [14] interviewed 27 women in the 3rd trimester and the results showed that 96% of respondents used TCM during pregnancy; 50% of which used TCMs to treat nausea and other reactions during the 1st trimester, such as ginger, garlic, etc. This study showed that the reasons for TCM usage during pregnancy were mainly to treat acute upper respiratory tract infections and miscarriage. The most commonly used kinds of TCMs are Antai pill (39 cases, 34.5%), Xiaochaihu granules (31 cases, 27.4%), and Shengxuening tablets (23 cases, 20.4%). The TCM criterion for this research did not include ginger, garlic and spices and the like, since these plants are widely used for food seasoning in China.

The results of this study revealed that pregnant women who had factors, such as smoking during pregnancy (OR 1.8, 95% CI: 0.7~5.1), alcohol consumption during pregnancy (OR 1.6, 95% CI: 0.4~6.1), hospitalization history during pregnancy (OR 4.8, 95% CI: 2.9~7.9), pregnancy complications (OR 2.7, 95% CI: 1.5~4.9) and infertility (OR 2.6, 95% CI: 1.4~4.8), most likely to used TCM during pregnancy-which was slightly different from previous studies. Chuang CH et al. [12] investigated the use of TCM during pregnancy and discovered that people who had a high level of education, threatened abortion, chronic diseases and primipara, most likely used TCM. However, the study of Forster DA [15] revealed that patients who are older, had high education, English language literate, nonsmokers and primipara, most likely to used herbs during pregnancy. Ong CO et al. [16] found that people with low education and low income, most likely used TCM during pregnancy.

Due to the increasing popularity of scientific medical knowledge, people now have a better understanding and knowledge of medication. However, due to various cultural backgrounds, pregnant women are susceptible to influence by others, in their choice of drugs. Moreover, most TCMs do not contain instructions for pregnant woman or the fetus. As we all know, most TCMs were only used on the basis of traditional experience most of the medicines did not have any user instructions. Some of these medicines, which are commonly used during pregnancy, contained ingredients, such as radix bupleuri, coptis, radix isatidis, etc. These ingredients could promote uterine contractions and even lead to abortion. But then again, the utilization of TCMs during pregnancy was high, and most of the TCM users self-treated themselves with these medicines or used these medicines at their own will-without any knowledge of its safety precautions. Therefore, TCM must be recommended by professional doctors, and pregnant women must not use TCMs by themselves. The safe usage of TCM during pregnancy needs to be improved.

At present, foreign scholars are now studying the impact of TCM on animal fetal in animal experiments. Wang CC et al. [17] and other studies found that reproductive toxicity occurred in pregnant mice after using these common medicines, and researchers recommended that TCM should be used with extreme caution for pregnant women. But in China, only a few studies conducted animal experiments relevant to the usage of TCM during pregnancy.

The composition and roles of TCM are very complex, and the reproductive safety precautions of most TCMs are still unknown. Most

of these medicines did not undergo rigorous reproductive toxicology studies, nor are there any reproductive toxicity regulations to secure the safe usage of TCMs in humans. In using TCMs during pregnancy, we should not only consider its therapeutic effects, but we must also consider the impact of these drugs on the growth and development of the fetus or the newly born baby. To promote and regulate the safe use of TCMs during pregnancy, a reasonable and effective evaluation of safe TCM usage should be the subject of a much-needed research.

Disclosure of conflict of interest

None.

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