

Brief Communication

Clinical efficacy of Xinkeshu Pian on coronary heart disease and mood disorder complications after PCI

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Abstract: Aim: To assess the efficacy and safety of combining Xinkeshu tablet treatment with routine Western medicine treatment for patients with coronary heart disease (CHD) and mood disorders after PCI postoperative period. Method: 100 patients were randomly divided into treatment group of 50 cases, and control group of 50 cases. The control group was given routine Western medical treatment, whereas the treatment group was given routine Western medical treatment in combination with Xinkeshu tablets. Eight weeks after treatment, the patients underwent SF-36 life quality evaluation, self-rating depression scale (SDS) evaluation, and self-rating anxiety scale (SAS) evaluation. Result: After the eight-week treatment, the SF-36 life quality scores, SAS scores, SDS score, as well as the reduction in heart creatinine levels of the two groups were compared. The results show statistical significance ($P < 0.05$). Conclusion: Xinkeshu can effectively address the PCI postoperative mood disorders in patients with coronary heart disease and improve the quality of life.

Keywords: Xinkeshu tablets, coronary heart disease, PCI, postoperative mood disorders

Introduction

Despite the improvement of living standards and the extension of life expectancies, the incidence of mortality related to coronary heart diseases have been on the rise in recent years [1, 2]. The number of patients with coronary heart diseases and mood disorders has grown gradually, and relevant data shows that the prevalence of mood disorders in clinic patients is 40%-70% [3, 4]. Therefore, clinical treatment requires not only paying attention to the treatment of coronary heart disease, but also to observing the mood changes of patients. In cases where symptoms of depression or dysphoria are observed, it is necessary to provide timely psychological counseling and the appropriate effective medications. These can comprehensively improve the life quality of patients.

The Xinkeshu Pian is mainly composed of salvia miltiorrhiza, pseudo-ginseng, radix puerariae, radices saussureae, and hawthorn, among others. Salvia miltiorrhiza is the principal drug, radix puerariae and pseudo-ginseng are the assistant drugs, radices saussureae is the adjuvant drug, and hawthorn is the guiding

drug. It has the efficacy in promoting blood circulation required in the removal of blood stasis, and promoting qi circulation to relieve pain. It is suitable for treating choking sensation in the chest, angina pectoris, hypertension, dizziness, headache, pain in neck and nape, hyperlipemia, and arrhythmia, which are induced by coronary heart diseases. Modern medicine shows that Xinkeshu Pian can promote blood circulation required in removing blood stasis, improve micro circulation, dilate coronary arteries for perfusion and cardiac muscles for blood-supply, and reduce myocardial ischemia and myocardial infarct area [5]. Xinkeshu Pian is adopted in treating patients with coronary heart disease and with mood disorder complications after percutaneous coronary intervention (PCI). The adoption is implemented by combining traditional Chinese medicine and Western medicine.

Materials and methods

Subject enrollment

Patients diagnosed with coronary heart disease for more than one year and having no sign of

Xinkeshu Pian on coronary heart disease and mood disorder

Table 1. Comparison of the two groups in the SF-36 life quality score before and after treatment

Item	Treated group (n=50)			Control group (n=50)		
	Before treatment	After being treated for 8 weeks	P value	Before treatment	After treatment	P value
PF	34.9±6.974	62.1±10.857	P<0.05	35.1±4.763	43.9±6.873	P<0.05
RP	34±5.387	64.8±3.944	P<0.05	34.3±6.802	35.7±4.651	P>0.05
RE	26.7±6.873	60.2±5.782	P<0.05	27.8±5.665	43.4±7.053	P<0.05
SF	43.5±4.701	64.4±7.455	P<0.05	41.5±3.961	32.8±5.706	P<0.05
GH	58±5.832	62.1±6.347	P<0.05	56.5±4.623	55.1±3.617	P>0.05
BP	37.6±6.71	53.8±7.249	P<0.05	38.9±3.256	49.8±4.565	P<0.05
VT	36.9±3.754	69.7±8.563	P<0.05	37.1±4.901	36.3±6.732	P>0.05
MH	45.1±5.38	47.1±9.651	P<0.05	44.3±5.301	45.1±7.345	P>0.05
Average	39.5875±5.701375	60.525±7.481*	P<0.05	39.438±4.909	44.013±5.818*	P>0.05

*After the eight-week treatment, the average of the treatment group shows a significant difference compared with that of the control group.

Table 2. Variations in the SAS/SDS Scoring Before and After Treatment

Group	Number of Cases	SAS		SDS	
		Before treatment	After treatment	Before treatment	After treatment
Treated Group	50	55.61±4.671	32.29±4.538	57.32±10.45	39.17±9.261
control group	50	53.86±6.923	43.86±5.623	56.48±6.87	44.29±3.684
P value		P>0.05	P<0.05	P>0.05	P<0.05

restricted activity, who develop the following symptoms after PCI, with mild mood disorders revealed: (1) poor treatment compliance; (2) persistent pectoralgia, fatigue, and insomnia (including difficulty falling asleep, restless sleep, etc.) under quiet conditions; (3) repeated examination and treatment due to somatoform symptoms and inconsistency between the severity and the objective examination results; (4) definite diagnosis of cardiovascular disease, where the well-recovered somatic function is revealed after percutaneous coronary intervention and blood vessel by-pass grafting, among others, and with the observation of frequent episodes of clinical symptoms; (5) worries or doubts about the absence of proper treatment for a long time; and (6) complication with mental disorders after the invasive procedure and surgery, admittance into the cardiac intensive care unit (CICU), and involvement with medical damage compensations. One hundred cases who meet the above conditions were randomized into 2 groups, namely, the treatment group composed of 50 cases (35 males and 15 females), and the control group composed of 50 cases (36 males and 14 females). The ages ranged from 45 to 75 at the time of enrollment. The members of the two groups did not show

apparent liver, kidney, or brain dysfunction. No statistical significance in sex, age, medical history, or related condition was observed. However, the two groups remained comparable.

Therapy regime

Treatment within 48 hours after coronary intervention was proposed. The control group adopted drugs as the primary form of treatment of cardiovascular disease. The drugs include aspirin, β -blocker, and lipid agent, among others, whereas the experimental group, in addition to these drugs, takes four tablets of Xinkeshu Pian orally, three times per day. Neither of the two groups was treated with oral medication of Chinese patent drugs, anti-depressants, or anti-anxiety drugs. Evaluation of various indicators was performed to determine the improvements based on to the conditions before treatment, and to record all adverse effects after the treatment for eight weeks.

Therapeutical effect criteria

Scoring the changes in quality of life: Scoring is based on the eight aspects of the SF-36 life quality scoring form, namely physiologic function (PF), role-physical (RP), body pain (BP), gen-

Table 3. Variation in Heart Creatine Kinase Level Before and After Treatment

Group	Number of Cases	Before treatment	After being treated for 8 weeks
Treated Group	50	236.23±302.02	203.87±312.45
control group	50	237.67±312.25	125.14±102.08
P value		P>0.05	P<0.05

eral health (GH), vitality (VT), social function (SF), role-emotional (RE), and mental health (MH). The minimum and maximum scores of each aspect are 0 and 100 points, respectively. The higher the score, the better the quality of life [6, 7].

Scoring the changes in depression: The physical and psychological status of both experimental group and control group adopts the self-rating depression scale. The criteria for scoring are as follows: below 50 points (without depression/dysphoria), 50-59 points (with mild dysphoria/depression), 60-69 points (with moderate depression/dysphoria), and above 70 points (with mild dysphoria/depression) [8].

Statistical treatment: Data analysis adopts the independent Mann-Whitney U test, and the comparison between the two groups was determined by using the t-test. P<0.05 shows statistical significance.

Results

Changes in the SF-36 life quality score after treatment

Changes in the life quality score were evaluated before and after treatment. The average SF-36 score of the experimental group after treatment is 60.525±7.481 points, whereas that of the control group is 44.013±5.818 points. Thus, the average of the experimental group is relatively higher (P<0.05), with the difference showing statistical significance. The dimensional analysis of SF-36 life quality score shows that the life quality of the treatment group improved in the eight aspects. The difference is statistically significant. By contrast, the control group shows improvement in only four, namely physiologic function, role-emotional, social function, and body pain (**Table 1**).

Changes in depression after treatment

Before treatment, the patients who earned 50 points to 59 points based on the SDS/SAS self-

rating depression scale may be diagnosed with mild depression/dysphoria. After the treatment for 8 weeks, the average SAS

scores of the experimental and control groups are 43.86±6.923 points. Compared with the control group, the average of the experimental group significantly decreases (P<0.05), and the difference is statistically significant (**Table 2**). The average SDS score of the experimental and control groups are 39.17±9.261 points and 44.29±3.684 points, respectively. Compared with that of the control group, the average of the experimental group significantly decreases (P<0.05). The difference is statistically significant (**Table 2**).

Changes in the heart creatine kinase level after treatment

After the treatment, the heart creatinine kinase (CK) levels of the experimental and control groups are 203.87±312.45 U/L and 44.29±3.684 U/L, respectively. The heart CK level of the experimental group significantly decreases (P<0.05). The difference is statistically significant (**Table 3**).

Adverse effects

No adverse effect was found among the two groups of patients in the course of treatment. Moreover, no significant difference was observed between the two groups in terms of thoracic obstruction symptom, blood pressure, heart rate, hepatic and renal function, and any other clinical indicator.

Discussion

Validity

The results show higher improvement in the life quality, depression condition, and heart creatinine level in the experimental group with Xinkeshu Pian added compared with those in the control group.

Safety

In the course of clinical trial, neither of the two groups showed adverse effects. The clinical

safety of patients who medicated with Xinkeshu Pian was ensured primarily by the absence of interaction with Western medicines used in the conventional therapy of coronary heart disease. However, Wang Shuping, et al [9]. found that in a clinical trial with 80 subjects, 2 cases demonstrated mild abdominal pain. The addition of gastric mucosal protective agents immediately alleviated the symptoms. The existence of only a few reports on other adverse effects indicates that Xinkeshu Pian is a relatively safe Chinese medicinal preparation.

Limitations

The limited sample size affected the observation on the clinical efficacy and safety of Xinkeshu Pian. Thus, a random controlled trial with the larger sample size is required.

Conclusion

The current evidence substantiates the advantages of adding Xinkeshu Pian in terms of improving the life quality and ameliorating depression. However, based on the limitations of the current study, enlarging the sample size of future clinical research is recommended. This will facilitate the adoption of the correct randomization and allocation method, and the conduct of long-term follow-up that can achieve the aim of validating further the efficacy and safety of Xinkeshu Pian in treating coronary heart disease with mood disorder complications after PCI.

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Disclosure of conflict of interest

None.

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