Research Paper

Study on the application of integrated Orem behavior care model in early diabetic retinopathy intervention with Yijing soup

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ABSTRACT

Objective: To investigate the impact of the Orem integrated self-care model on patients 'self-care deficits in the early stage of type 2 diabetic retinopathy treated with Yijing Decoction. Methods: This study is a prospective randomized controlled trial involving 48 patients (96 eyes) with early-stage type 2 diabetic retinopathy (aged 45-60 years). These patients were randomly divided into two groups: Group A (control group) received Yijing Decoction under the Orem self-care model, and Group B (control group) received Yijing Decoction alone. Both groups underwent examinations of visual acuity, fundus fluorescein angiography, fundus photography, and changes in TCM syndrome at baseline, one day before treatment, and at 3 days, 7 days, 14 days, 1 month, and 3 months post-treatment. The sample mean and standard deviation of general data were analyzed using independent samples T-tests, and the effectiveness (changes in visual acuity before and after treatment) was evaluated using chi-square tests. Results: Before treatment, there was no statistically significant difference in the general data between the two groups. After treatment, Group A showed significantly better corrected vision and TCM syndrome efficacy index compared to Group B, with all differences being statistically significant (P<0.05). Conclusion: The Orem integrated self-care model can compensate for patients' self-care deficiencies, enhance their self-care abilities, and improve the efficacy of Yijing Decoction in treating early-stage type 2 diabetic retinopathy.

INTRODUCTION

Diabetes mellitus (DM) is the fourth leading cause of health threats, following cardiovascular disease, cancer, and chronic respiratory diseases, with its incidence rate rapidly increasing. By 2015, the number of people with DM worldwide had surpassed 400 million [1]. In China, the prevalence of DM is 11.6%, making it the country with the highest number of patients [2]. Diabetic retinopathy (DR) is one of the most common vascular complications of

DM, with the incidence rate increasing as the disease progresses. In the United States, the incidence of DR in type 1 DM patients within the first 5 years of the disease is 44.4%, rising to 56% after 7 years, and reaching 98% after 15 years. In China, a 2013 report indicated that among patients diagnosed with DM for the first time, the incidence of DR was 30.6%, and this rate increased to 54% after 10-19 years.

Diabetic retinopathy (DR) is an irreversible eye disease that ranks first among the four leading causes of blindness worldwide. It is a long-term condition, predominantly affecting middle-aged and elderly individuals, who often lack effective self-management skills. Currently, DR has become one of the most serious health issues affecting the physical and mental well-being of the Chinese population. Therefore, using the Orem integrated self-care model for nursing intervention can help prevent or address the development of self-care deficiencies in patients and provide support to those whose self-care needs cannot be met. This approach aims to compensate for the patient's self-care deficiencies, encourage their initiative, and enhance their self-care abilities. Additionally, it involves using Yijing Decoction to intervene early in diabetic retinopathy microvascular damage. Research on the integrated self-care model for early-stage DR is a crucial topic in blindness prevention and treatment, as it is vital for delaying the progression of DR, improving quality of life, and reducing social economic losses.

Traditional Chinese medicine (TCM) has certain advantages in the early treatment of diabetic retinopathy (DR). DM is categorized under TCM as 'Xiaoke disease,' where TCM believes that DM is fundamentally due to yin deficiency and is marked by dry heat [3]. DR often develops after DM has been present for more than five years. As DM progresses, dry heat depletes qi and injures body fluids, leading to further pathological changes: yin deficiency with insufficient body fluids fails to carry blood, or qi deficiency weakens the circulation of blood, causing blood stasis. In severe cases, it can lead to qi failing to control blood, resulting in retinal hemorrhage, exudation, and edema. The progression of the disease often results in both qi and yin deficiency, and this deficiency also leads to blood stasis. Therefore, treating DR should focus on tonifying qi, nourishing yin, and resolving stasis.

Yijing Decoction (originally named Jia Wei Bu Yang Huan Wu Decoction) is a traditional Chinese medicine developed by Professor Jin Weil, a renowned TCM practitioner in Fujian Province. Based on extensive clinical observations of patient symptoms and the exploration of disease mechanisms, he integrated the holistic diagnostic thinking of TCM and made adjustments to Bu Yang Huan Wu Decoction. This formula is designed to effectively prevent and treat DR [4]. It addresses the pathological characteristics of DR, which involve both qi and yin deficiency with stasis. Building on the qi-tonifying, blood-activating, and meridian-connecting effects of Bu Yang Huan Wu Decoction, it removes earthworms and adds ingredients such as yam, poria, atractylodes, raw rehmannia, and scrophularia, all of which work together to tonify qi, nourish yin, activate blood, and improve vision. Early clinical studies have shown that Yijing Decoction has demonstrated good therapeutic effects for DR, improving retinal microcirculation, reducing macular edema, and regulating VEGF levels. However, the specific mechanisms by which Yijing Decoction intervenes in DR require further research to expand its development and application prospects.

Therefore, discussing the integration of Orem's behavior nursing model combined with Yijing soup for early intervention of diabetic retinopathy microvascular damage will undoubtedly help to fundamentally change the patient's behavior pattern, prevent DR, save the patient's visual function, and improve the quality of life of patients.

DATA AND METHODS

1. Method

1.1 Empirical method

Using a prospective randomized controlled double-blind study method, 293 patients who received DR treatment at the Ophthalmology Outpatient Department of the First Affiliated Hospital of Nanchang University from March 2021 to March 2022 were selected. The patients 'medical histories were reviewed, and comprehensive fundus examinations were conducted. Ultimately, 48 patients (96

eyes) were selected to meet the experimental criteria. Among these, 36 males (72 eyes) and 12 females (24 eyes) were included, with an age range of 45-60 years and a disease duration of 5-15 years. Important non-experimental factors, such as age and disease duration, were considered, and the patients were randomly divided into two groups, A and B, based on the principle of the smallest imbalance index: each group consisted of 24 cases (96 eyes), with 3 cases per segment, totaling 8 segments. Each segment was assigned a random number from 1 to 6 for sorting, with those numbered 1-3 placed in Group A and guided by the Orem self-care model, taking Yijing Decoction orally once daily; those numbered 4-6 placed in Group B, taking Yijing Decoction orally once daily. Both groups used antidiabetic drugs and insulin to strictly control blood glucose levels. The power analysis was performed using G*Power 3.1.9.7, with an effect size of 0.5 (large effect size), a=0.05, a total sample size of 96, and degrees of freedom = 1, yielding a power of 99.84%. All research methods involved in this study adhered to the Declaration of Helsinki, complied with medical ethics principles, and were approved by the hospital's medical ethics committee. All participants provided informed consent to be included in the study and signed the informed consent form.

1.2 Yijing soup formula and decoction and oral method

Formula: raw astragalus 15g, yam 15g, Atractylodes 9g, peach kernel 5g, safflower 5g, angelica 9g, Chuanxiong 6g, red peony 10g, poria 15g, raw ground-fruit 15g, and xuan Shen 15g.

Boiling and oral administration: the above formula was decocted into 50mL original decoction, diluted with drinking water and administered by gastric infusion once a day.

2. General information

Before treatment, all participants had their systolic and diastolic blood pressure, serum total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and hemoglobin A1c (HbA1c) levels measured. One day before treatment and at 3 days, 7 days, 14 days, 1 month, and 3 months after treatment, the participants 'visual acuity (BCVA), fundus examination, fundus fluorescein angiography (FFA), fundus photography, and TCM syndrome scores were assessed. The patients' self-care ability was evaluated using the Barthel scale (a measure of a person's ability to perform activities independently) at 3 days, 7 days, 14 days, 1 month, and 3 months post-treatment.

3. Research subjects

3.1 Inclusion criteria for type 2 DR

(1) DM was diagnosed according to the 1997 American Diabetes Association (ADA) diagnostic criteria

(2) Type 2 DM patients with basically stable blood glucose control on the basis of physical therapy or drug therapy (fasting was measured three times within 2 weeks

The postprandial 2h blood glucose and the blood glucose one day before the third test) were fasting blood glucose ≤7.8 mmol·L-1, 2h after meal

Blood glucose was less than or equal to 11.1 mmol·L-1.

（3） Simple (non-proliferative) DR with BCVA and FFA compliance in patients aged 45-60 years with a disease course of 5-15 years: <20 retinal hemorrhages in any quadrant; <2 quadrants of retinal venous beaded changes or <1 quadrant of significant retinal microvascular abnormalities.

(4) Patients are willing to cooperate and can have regular follow-up according to the requirements.

3.2 Exclusion criteria

(1) Those with allergy history, who cannot accept FFA examination, those with history of internal eye and kidney surgery, trauma;

(2) Patients with ocular diseases such as corneal lesions, uveitis, retinal lesions (non-DM fundus changes), optic neuropathy;

(3) Patients with severe primary diseases such as cardiovascular, liver, kidney and hematopoietic system;

(4) Those with proliferative changes of diabetic retinopathy;

(5) Pregnant and lactating women, patients with abnormal liver function, dementia, various mental illness patients and unwilling to cooperate.

(6) Patients and their families are unwilling to cooperate and cannot be examined regularly as required;

(7) Patients who are participating in other clinical research projects.

4. Evaluation indicators and statistical analysis

4.1 Clinical Efficacy Evaluation Indicators: If the corrected

visual acuity improves by at least 2 lines on the International Standard Visual Acuity Chart, or if there is no improvement or a decrease of less than 2 lines, the treatment is considered effective; otherwise, it is deemed ineffective. For fundus photography and FFA, if the microaneurysms and hemorrhages in the fundus images are completely absorbed, reduced, or not enlarged, if exudation is reduced or not enlarged, and if the sodium fluorescein leakage area is reduced or not enlarged, the treatment is considered effective. If at least two of the following criteria are met—vision, fundus changes, and FFA—the treatment is considered effective in this study.

4.2 TCM Differential Diagnosis and Scoring Criteria: The basic pathogenesis of DR evolves into the transformation characteristics of qi and yin deficiency, liver and kidney deficiency, and yin-yang deficiency, which is divided into early, middle, and late stages. In the early stage (qi and yin deficiency), the main symptoms include blurred vision, dry eyes, and floating black spots in front of the eyes; secondary symptoms include fatigue, shortness of breath, reluctance to speak, dry mouth and throat, spontaneous sweating, dry or loose stools, a swollen, tender tongue with dark purple color or ecchymosis, and a deep, fine, and weak pulse [5]. A diagnosis can be made if one or more of the main symptoms are present, and at least one of the secondary symptoms is present. For the TCM symptom scoring criteria, see reference [6].

4.3 Efficacy criteria of TCM syndromes: Efficacy index (n) = (pre-treatment score-post-treatment score)/ pre-treatment score *100%. If n is greater than or equal to 30%, the treatment is considered effective; otherwise, it is considered ineffective.

4.4 Data statistics and analysis: Data were entered into Excel, and statistical analysis was performed using SPSS27. For general data, the sample mean and standard deviation values were analyzed, and independent samples T-test analysis was conducted. The effectiveness (changes in visual acuity before and after treatment and changes in TCM syndrome efficacy index) was analyzed by chi-square test, with $p<0.05$ indicating statistically significant differences.

BEAR FRUIT

1. General information comparison

Before treatment, there was no significant difference in age, disease course, gender, systolic blood pressure, diastolic blood pressure, TG, TC, LDL-C, HDL-C and HbA1c between the two groups (all $p> 0.05$, see Table 1).

Table 1. Comparison of general conditions before treatment in the two groups

general run of things	A group	B group	Statistical analysis	
			t price	p price
average age (y)	52.6±15.6	53.5±16.2	0.515	> 0.05
Mean duration of diabetes (a)	10.2±7.8	10.35±7.2	-0.322	> 0.05
Man: Woman	3:1	3:1	0.651	> 0.05
Systolic pressure (mmHg)	136±15.2	132±16.4	0.458	> 0.05
Diastolic blood pressure (mmHg)	82±7.8	80±7.1	0.312	> 0.05
TG (mmol/L)	1..92±0.25	2.12±0.12	-0.532	> 0.05
TC (mmol/L)	6.52±2.12	6.71±2.87	-0.212	> 0.05

LDL-C（mmol/L）	4.12±1.20	3.82±1.56	0.272	> 0.05
HDL-C（mmol/L）	1.12±0.56	1.24±0.43	-0.192	> 0.05
HbA1c（%）	9.23±3.35	8.71±3.87	0.819	> 0.05

2．The clinical efficacy of the two groups was compared with that of TCM syndrome

The comparison of the number of patients with improved corrected vision and the number of patients with effective TCM syndrome efficacy index after treatment showed that Group A had an 87.50% clinical efficacy rate and a 75.00% TCM syndrome efficacy rate, while Group B had an 70.83% clinical efficacy rate and a 54.17% TCM syndrome efficacy rate. The chi-square test analysis revealed that under the Orem self-care model intervention, Group A patients showed significantly better clinical efficacy (χ 2=4.0421, p=0.0444) and TCM syndrome efficacy (χ 2=4.5541, p=0.0328) after taking Yijing Decoction compared to Group B, with the difference being statistically significant (p<0.05, see Table 2).

Table 2. Comparison of corrected vision after treatment in two groups

Group	Clinical effects				Efficacy of Traditional Chinese medicine syndrome			
	Number of eyes	valid	of no avail	effective percentage (%)	Number of eyes	valid	of no avail	effective percentage (%)
A group	48	42	6	87.50	48	36	12	75.00
B group	48	34	14	70.83	48	26	22	54.17
amount to	96	76	20	79.17	96	62	34	64.58
χ^2	4.0421				4.5541			
p	0.0444				0.0328			

Diabetic retinopathy (DR) is one of the most common and severe microvascular complications of diabetes, as well as one of the leading causes of blindness. The incidence and prevalence of DR have been increasing annually due to changes in dietary habits and lifestyle, which not only prolongs the course of diabetes and increases the social and economic burden but also raises the risk of vision loss and exacerbates the social and psychological burden. DR has a long course, predominantly affecting middle-aged and elderly individuals, with significant visual impairment and limited short-term effectiveness of anti-VEGF treatments. Long-term and frequent anti-VEGF treatments can increase the economic and psychological burden on patients and

reduce their adherence to regular injections. A study on the factors influencing delayed medical consultation among DR patients found that patients from different regions, with varying economic conditions and educational levels, have differing perceptions of the severity of DR and the optimal timing for treatment, with most having insufficient awareness. Poor self-management skills, poor compliance with surgical treatments, and a lack of emotional support during long-term treatment are all contributing factors to delayed medical consultation. In addition to the impact of patients' own cognitive abilities, DR can also lead to cognitive impairments, which worsen over time, resulting in mental sluggishness, reduced information processing, attention, and executive function. The pathogenesis of DR may involve damage to the blood-retinal barrier, similar to damage to the blood-brain barrier, vascular endothelial cell dysfunction, and increased serum neurogenic lipase levels. Among these, serum neurogenic lipase is considered a sensitive marker of neuronal damage. In short, DR has become one of the increasingly serious diseases affecting the physical and mental health of Chinese people. However, DR patients lack effective self-management methods.

Traditional Chinese medicine (TCM) is a distinct medical system from Western medicine, making significant contributions to the diagnosis and treatment of diabetes and its complications. Diabetic retinopathy (DR) falls under TCM categories such as 'dim vision,' 'cloudy eyes,' 'sudden blindness,' and 'blood flooding the pupil.' Currently, effective traditional Chinese medicines for treating DR include barbary wolfberry seeds, raw rehmannia, Cornus officinalis, Salvia miltiorrhiza, and Astragalus membranaceus. Traditional Chinese patent medicines include Compound Danshen Drops, Qimeng Granules, Shuangdan Mingmu Capsules, and Tongluo Mingmu Capsules. Yijing Decoction, developed by Professor Jin Wei from the Affiliated People's Hospital of Fujian University of Traditional Chinese Medicine, is an effective formula designed based on years of clinical observation of patient symptoms, exploration of disease mechanisms, and integration of TCM holistic diagnostic thinking. Yijing Decoction can inhibit the expression of inflammatory factors such as COX-2, PGE2, and VEGF in the retina of DR patients, regulate the expression of matrix metalloproteinases 2, 3, and 9 (MMP-2, MMP-3, MMP-9), type IV collagen (CIV), and laminin (LN), intervene in high-sugar-mediated basement membrane remodeling, inhibit damage to the inner blood-retinal barrier (iBRB), improve the microvascular circulation in the eye of DR patients, and thus intervene in the progression of DR [4,10,11]. Despite its significant role in the treatment of DR, patients' lack of awareness, cognitive barriers, and poor compliance may still limit the effectiveness of Yijing Decoction.

Nursing plays a crucial role in the treatment of diseases. DR nursing aims to alleviate patients 'negative emotions during treatment and provide long-term emotional support and psychological encouragement. Traditional nursing interventions typically focus on preoperative preparation and postoperative recovery. This short-term care model for perioperative patients is no longer suitable for the long-term management of chronic diseases. New nursing models, such as Orem self-care,

high-quality care, systematic care, evidence-based care, continuous care, and traditional Chinese medicine care, can better support patients' long-term self-management [12]. Research on new nursing models has shown that nursing interventions based on health behavior change theory can improve patients' disease awareness and self-management skills [13]. Providing enhanced nursing interventions (such as psychological counseling, health education, dietary control education, and specialized nursing) to DR patients can effectively improve their compliance and quality of life [14].

Orem's self-care theory posits that individuals have the capacity to take purposeful actions to meet their daily living needs. When an individual's self-care ability falls below their therapeutic self-care needs due to illness, nursing care becomes necessary. Based on the varying levels of self-care needs and abilities among patients, Orem has developed three types of nursing compensation systems: total compensation system, partial compensation system, and support education system. The total compensation system is designed for patients who have completely lost their self-care abilities, where nursing staff must provide full care for the patient's daily activities. The partial compensation system is suitable for patients with some self-care abilities, where nursing staff work with the patient's family to manage the patient's daily activities. The support education system is a supplementary form of compensatory care, where nursing staff need to understand the patient and their family's comprehension abilities, introduce disease knowledge and success stories to boost the patient's confidence in treatment, and develop personalized dietary plans to help alleviate negative emotions. Research by Lin Zhiliang et al. shows [15] that the Orem self-care model significantly improves the quality of life for patients with DR. Studies by Chen Chunmei et al. indicate [16] that the Orem self-care model can enhance the quality of life for patients with DR. Li Xiaoyuan's research findings [17] show that Orem nursing intervention can restore visual function and improve the quality of life for patients. These conclusions align with our research results. Integrating Orem's integrated self-care behavior model with Yijing Decoction for the treatment of DR can indirectly or directly prevent the occurrence and development of self-care deficits, delay the progression of DR, and improve the quality of life for patients.

CONCLUSION

The deficiency in self-management skills can reduce the prognosis of diabetic retinopathy. The Orem integrated self-care model can compensate for patients' self-care deficiencies, enhance their initiative, and improve their self-care abilities. By integrating the Orem self-care model with Yijing Decoction, early-stage type 2 diabetic retinopathy can be effectively managed, reducing microvascular damage and delaying its impact on visual function. Additionally, this approach deepens the study of nursing models, providing a theoretical foundation for the clinical application of the Orem integrated self-care model. This not only offers a new nursing model and experimental basis for the early prevention and treatment of DR but also lays the groundwork for the broader application of traditional Chinese medicine, enhancing modern medical nursing

concepts and improving nursing methods.

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AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

The study methods and protocols were approved by the Medical Ethics Committee of the First Affiliated Hospital of Nanchang University (Nanchang, China) and followed the principles of the Declaration of Helsinki. All subjects were notified of the objectives and content of the study and latent risks, and then provided written informed consent to participate.

PATIENT CONSENT FOR PUBLICATION

Not applicable.

COMPETING INTERESTS

This study did not receive any industrial support. The authors have no competing interests to declare regarding this study.

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