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The Therapy Based on Traditional Chinese Medicine for Otolithiasis

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Abstract

Background: Otolithiasis (also named benign paroxysmal positional vertigo, BPPV) is one of the most common illness for hospital visits. Residual dizziness and recurrence after reduction are problems for the treating BPPV with Western medicine. Traditional Chinese medicine (TCM) has shown obvious superiority in the treating BPPV. Here, we explore the curative effect of the theory of dizziness of TCM in treating BPPV. **Methods:** 183 BPPV patients were randomly divided into 3 groups: Reset group (RG) 61 cases, Traditional Chinese Medicine group (TG) 61 cases, and Reset plus Traditional Chinese medicine group (R+TG) 61 cases. RG received machine reset. TG was given the therapy based on the theory of dizziness of TCM. R+TG received machine reset plus the therapy of TCM. All patients, before and on 1th day, 7th day, and 14th day of treatment, were evaluated with the dizziness handicap inventory (DHI) for the physical (P), functional (F) and emotional (E) state. The efficacy of the different therapy in the treatment of mild, moderate, and severe BPPV has been observed. Follow up for 6 months, we record and compare the ratio of patients with residual dizziness and the recurrence of BPPV for the three groups. Serum levels of vitamin D, estrogen, and calcium and phosphorus ions were detected and compared between the groups of BPPV patients, dizziness non-BPPV patients, and non-dizziness patients. **Results:** The DHI score of the three groups, compared with which before treatment, RG ($p < 0.05$), TG ($p < 0.01$), and R+TG ($p < 0.01$), decreased significantly on the 7th day of treatment; R+TG decreased more significantly than RG ($p < 0.05$). The DHI scores of the three groups, on the 14th day of treatment, were significantly lower than those before treatment ($p < 0.01$). On the 7th day of treatment, compared with the same period of RG, the score of item E of TG and R+TG, decreased significantly ($p < 0.05$). Patients of mild BPPV responded well to the three kinds of the therapy; For the patients of moderate BPPV, on the 7th day of treatment, assessed by DHI, the effect showed significant improve for RG ($p < 0.05$), TG ($p < 0.01$) and R+TG ($p < 0.01$). For the patients of severe BPPV, on the 7th day of treatment, the effect of RG, assessed with DHI, showed no improvement ($p > 0.05$), while TG ($p < 0.05$) and RG+TG ($p < 0.01$) showed effective. The incidence of residual dizziness between the three groups show significantly different on the 2nd week ($x^2 = 7.635$, $p = 0.022$) and the 1th month ($x^2 = 7.502$, $p = 0.023$) of treatment; The incidence of RG was higher than those of TG and R+TG. The recurrence rates of BPPV of the three groups were significantly different on the end of 2nd month ($x^2 = 8.528$, $p = 0.014$), 4th month ($x^2 = 13.287$, $p = 0.001$), and 6th month ($x^2 = 12.587$, $p = 0.002$) of treatment. The recurrence rates of TG and R+TG were lower than that of RG. There was no significant difference in recurrence rate and residual dizziness occurrence rate between TG and R+TG. There were differences in serum vitamin D and estrogen levels between the group of BPPV patients, dizziness non-BPPV patients, and non-dizziness patients; There was no difference in calcium and phosphorus ion levels between the three groups. **Conclusions:** Compared with therapy of RG, TG and R+TG showed more effective in treating BPPV; They can significantly improve patient's bad mood, reduce the proportion of residual dizziness, and reduce the recurrence rate. TCM and TCM plus reset have better efficacy in treating moderate and severe BPPV. The specificity of abnormal changes in serum vitamin D and estrogen for BPPV patients needs be further study.

1 Introduction

Otolithiasis, also known as benign paroxysmal positional dizziness (BPPV), is due to the otoliths from the utricle shed into the semicircular canal, and the patient of BPPV has transient dizziness with nystagmus when the head position changes. Dizziness refers to the hallucination or illusion that the patient feels the surrounding environment rotates or moves when there is no body movement; Otolithiasis is one of the most common diseases with dizziness, and is the most common peripheral vestibular disease [1]. Otolith reduction is recommended by the Guidelines for the treating BPPV; After successful reduction, 61.2% of patients still had residual dizziness; The recurrence rate of patients with otolithiasis after reduction is between 20% and 50% [2]. Non-specific persistent dizziness, fluttering, unsteady walking, etc. constitute residual symptoms after otolith reset; Western medicine, using drugs to improve inner ear circulation, showed no effective for residual dizziness [3]. Residual dizziness and recurrence are problems in the treatment of BPPV. We, using "dizziness" related theory of TCM to treat BPPV, compare the effect of TCM with simple reset and TCM plus reset.

2 Materials and methods

2.1 Diagnosis criteria

Patients suffered from BPPV, who were treated at the East Branch of the First Affiliated Hospital of Sun Yat-sen University from January 2020 to August 2022, were selected. According to the Otorhinolaryngology Branch of the Chinese Medical Association, the diagnostic criteria for BPPV were formulated [4]; All patients were confirmed diagnosis with vestibular function instrument examination. Diagnosis of TCM: in line with the "dizziness" syndrome in the diagnosis and treatment guidelines for common diseases of internal medicine of TCM [5]; TCM syndrome differentiation and treatment classification: (1) Deficiency of Qi and blood, (2) Insufficiency of kidney essence, (3) Accumulation of phlegm turbidity, (4) Blood stasis blocking collaterals, (5) Hyperactivity of liver yang.

2.2 Inclusion, exclusion and dropout criteria

Inclusion criteria: (1) Aged 16-80 years old; (2) Meeting the diagnostic criteria of BPPV of western medicine and "dizziness" of TCM; (3) Not receiving relevant treatment for the disease; (4) Complete data and compliance better, be able to accept regular follow-up; (5)Voluntarily participate in the study. Exclusion criteria: (1) Cerebrovascular disease, traumatic dizziness; (2) Secondary peripheral dizziness, such as vestibular paroxysmal syndrome, vestibular neuritis, etc.; (3) Suspected otolithiasis does not be confirmed diagnosis with vestibular function instrument examination; (4) Insufficiency of important organs, pregnancy, breastfeeding; (5) Incomplete clinical data; (6) Unable to cooperate with vestibular function examination and assessment. Dropout criteria: Those who have poor compliance, fail to receive treatment as required, or withdraw from the program voluntarily.

2.3 Treatment grouping method

This observation project is a randomized parallel controlled design. Among the 183 BPPV patients, there were 74 males (40.43%) and 109 females (59.56%), aged (50.47 ± 19.68) years old; There were 131 cases (71.59%) of posterior semicircular canal lesions, 47 cases (25.68%) of horizontal semicircular canal lesions, and 5 cases (2.73%) of anterior semicircular canal lesions.There were 58 cases (31.69%) with hypertension, 35 cases (19.13%) with diabetes, and 21 cases (11.48%) with insomnia. According to the TCM syndrome classification of 183 patients with dizziness, deficiency of qi and blood accounted for 30.4%, accumulation of phlegm turbidity accounted for 15.5%, insufficiency of kidney essence 26.4%, blood stasis blocking collaterals 24.3%, and hyperactivity of liver yang accounted for 3.4%. 183 patients of otolithiasis were randomly

divided into reset group (RG), traditional Chinese medicine group (TG) and reset plus traditional Chinese medicine group (R+TG) according to the random numbers generated by SPSS. There were no significant statistical differences between the three groups in terms of age, gender, affected semicircular canals, underlying diseases, and TCM syndrome types.

RG: These group received machine reset treatment. The machine reset uses the G-Force diagnosis and treatment system from CHINA MEDICAL. The patient wears an infrared ophthalmoscope and is fixed on a 360° rotatable reduction chair. Three-dimensionally rotate the reset chair to induce nystagmus, then we record the nystagmus parameters, judge whether there is otolithiasis, judge the involved semicircular canal, and reset it.

TG: These group received therapy of TCM. TCM syndrome differentiation treatment was given on the day of diagnosis; And the course of treatment was 2 weeks. Treatment is performed by doctors with a master's degree or above. Treatment plan: Qi and blood deficiency syndrome, pathogenesis: Deficiency of Qi and blood, brain loss nourishment. Treating method: nourishing qi and blood, invigorating the spleen and stomach. Qishen Yiqi Dropping Pills (Tasly Pharmaceutical Group Co., Ltd., batch No. Z20030139), 1 bag tid; or/and Dengzhan Shengmai Capsules (Yunnan Biological Valley Pharmaceutical Co., Ltd., batch No. Z20026439), 2 capsules, tid. Internal accumulation of phlegm turbidity syndrome, pathogenesis: internal accumulation of phlegm turbidity disturbs the organ of equilibration. Treating method: Dampness and phlegm resolving, invigorating the spleen and harmonizing the stomach. Tiandan Tongluo Capsules (Shandong Phoenix Pharmaceutical Co., Ltd., batch No. Z20010029), 5 capsules, tid; or/and Naoshuantong Capsules (Guangdong South China Pharmaceutical Group Co., Ltd.,batch No. Z20040093), 3 capsules, tid. Kidney Essence Deficiency Syndrome, pathogenesis: Deficiency of Kidney Essence, unable to transform qi, and lack of nourishment of the brain. Treating method: tonify the kidney and essence, nourish the brain. Peiyuan Tongnao Capsules (Henan Lingrui Pharmaceutical Co., Ltd., batch No. Z20000022), 3 capsules, tid; or/and Compound Ginkgo Tongmai Oral Liquid (Hunan Butian Pharmaceutical Co., Ltd., batch No. B20020924), 1 ampoule tid. Syndrome of blood stasis blocking collaterals, pathogenesis: obstruction of collaterals by blood stasis, poor flow of Qi and blood. Treating method: Promoting blood circulation to remove collaterals obstruction. Tongxinluo (Shijiazhuang Yiling Pharmaceutical Co., Ltd.,batch No. Z19980015), 3 capsules, tid; or/and Compound Xueshuantong Capsules (Guangdong Zhongsheng Pharmaceutical Co., Ltd., batch No. Z20030017), 3 capsules, tid. Syndrome of hyperactivity of liver yang, pathogenesis: hyperactivity of liver yang, disturbing the organ of equilibration. Treating method: Calming the liver and suppressing yang. Qiangli Dingxuan Tablets (Shaanxi Hanwang Pharmaceutical Co., Ltd., batch No. Z61020139), 5 capsules, tid; or/and Quantianma Capsules (Shanghai Shikangte Pharmaceutical Co., Ltd., batch No. Z20003249), 4 capsules, tid.

Multiple pathological syndrome types, for example: deficiency of Qi and blood combined with deficiency of kidney essence, should be treated with Qishen Yiqi Dropping Pills or/and Dengzhan Shengmai Capsules, together with Peiyuan Tongnao Capsules or/and Compound Ginkgo Tongmai Oral Liquid.

R+TG: These group received therapy of machine reset plus TCM syndrome differentiation treatment.

The complications maintains the original treatment.

2.4 Observation indicators

Clinical symptoms are scored with dizziness handicap inventory (DHI) scale [6]; The score involves

conditions of body: physical (P), emotion (E) and function (F) with 25 items; Each item has options of "yes", "sometimes" and "none" with 4, 2, and 0 points respectively; The total score is 100. The higher the score, the more serious the disease. BPPV is graded according to the DHI score: less than or equal to 30 points is mild, between 31 and 60 points is moderate, and greater than 60 points is severe.The DHI scale was evaluated before treatment, on the 1th day, the 7th and 14th days of the treatment. Follow-up observation is given within 6 months after treatment. We record and compare the occurrence rate of patients with residual dizziness for the three groups; We record and compare the recurrence rate of BPPV for the three groups.

2.5 Observation of serum vitamin D, estrogen, calcium and phosphorus ion levels of the BPPV patients

61 BPPV patients were selected as the BPPV group. 61 patients, who had dizziness attack and were excluded from BPPV with vestibular function instrument examination, were selected as dizziness non-BPPV group. 61 patients without dizziness symptoms were selected as the non-dizziness group. The non-dizziness group was originally a group of persons planing for a health check-up; However, system medical examination results display that these group are suffered from more or less health problems, such as vision problems, sleep disorders, abnormal blood glucose or lipids and so on. So we named this group as non-dizziness group. Patients of the three groups had no gynecological and thyroid diseases, and did not take estrogen, calcium and phosphorus drugs.The age, sex, menopausal ratio and other basic information showed no difference between the three groups. From 7:30 to 9:00 in the morning, the fasting venous blood of the patients of the three groups were drawn and submitted for clinical examination. And vitamin D, estrogen, and calcium phosphorus ion levels are compared between the three groups.

2.6 Adverse reactions

Observe if the patients of RG, TG or R+TG have dizziness, aggravated dizziness, or other discomfort during the treatment.

2.7 Statistical methods

Normally distributed measurement data are expressed as mean ± standard deviation, and skewed distribution data are expressed as median ± interquartile range. One-way analysis of variance or Kruskal-Wallis rank sum test was used to compare measurement data among multiple groups; Pairwise comparison among multiple groups: LSD-t test and Bonferroni method were used for normal distribution, and Bonferroni method was used to correct ρ value for skewed distribution, and then grouped Wilcoxon test was used. The enumeration data is represented by n (case), the chi-square test is used for the comparison of multiple groups, and the Bonferroni method is used for the comparison of two-two rates among multiple groups; SPSS19.0 software (SPSS, Chicago, IL, USA) was used for statistical processing of data, all statistical tests were two-sided, and a ρ value less than 0.05 was considered statistically significant.

3 Results

3.1 Comparison of DHI scores before and after the treatment between the three groups

The total score of DHI, P, F and E scores were evaluated for the RG, TG or R+TG before and on the 1th day, 7th day, and 14th day of the treatment.

On the first day of the treatment, the total score of DHI of the TG ($\rho < 0.05$) and R+TG ($\rho < 0.05$), compared with which before treatment, decreased significantly. On the 7th day of treatment, compared with which before treatment, the total score of DHI of RG ($\rho < 0.05$), the TG ($\rho < 0.01$) and the R+TG ($\rho < 0.01$) decreased significantly. Compared with which of

the RG, the reduction in the R+TG was more significant ($p < 0.05$). On the 14th day of treatment, compared with which before treatment, the total score of DHI of all the three groups($p < 0.01$) decreased significantly . See Figure 1A for details.

On the first day of the treatment, the P score of only the R+TG ($p < 0.05$), compared with which before treatment, decrease significantly. On the 7th day of treatment, compared with which before treatment, the P score of the RG ($p < 0.05$), the TG ($p < 0.05$) and the R+TG ($p < 0.01$) all showed significant decrease. Compared with which of the RG, the reduction of the R+TG showed more obviously ($p < 0.05$). On the 14th day of treatment, compared with which before treatment, the P scores of the three groups all showed significantly reduced ($p < 0.01$). See Figure 1B for details.

On the first day of the treatment, compared with which before treatment, the F score of the RG ($p < 0.05$), the TG ($p < 0.05$), the R+TG ($p < 0.01$) decreased significantly. On the 7th day of treatment, compared with which before treatment, the F score of the RG ($p < 0.05$), the TG ($p < 0.01$) and the R+TG ($p < 0.01$) all showed significant decreased; Compared with the RG, the reduction of the R+TG was more obvious ($p < 0.05$). On the 14th day of treatment, compared with which before treatment, the scores of all the three groups showed significantly reduced ($p < 0.01$). See Figure 1C for details.

On the first day of the treatment, compared with which before treatment, the E score of the TG ($p < 0.05$) and the R+TG ($p < 0.05$), decreased significantly. On the 7th day of treatment, compared with which before treatment, of all the RG ($p < 0.05$), the TG ($p < 0.05$) and the R+TG ($p < 0.01$) showed significant decrease. Compared with which of the RG, the E score of the TG ($p < 0.05$) and R+TG ($p < 0.05$) decreased more significantly. On the 14th day of treatment, compared with which before treatment, the E scores of all the three groups showed significantly reduced ($p < 0.01$). See Figure 1D for details.

3.2 Comparison of DHI scores before and after treatment between mild, moderate and severe BPPV groups

The DHI total scores of the mild, moderate and severe BPPV groups were compared before and on the 1th day, 7th day, and 14th day of the treatment.

On the first day of the treatment, compared with which before treatment, the total score DHI of mild group of the RG ($p < 0.05$), the TG group ($p < 0.01$) and the R+TG ($p < 0.01$), all decreased significantly; On the 7th and 14th day of treatment, compared with before treatment, the total score DHI of all the three BPPV groups decreased significantly ($p < 0.01$).See Figure 2A for details.

On the first day of the treatment, compared with which before treatment, the total DHI score of moderate BPPV group of the TG ($p < 0.05$) and the R+TG ($p < 0.05$) decreased significantly; On the 7th day of treatment,the total DHI score of the RG ($p < 0.05$), the TG ($p < 0.01$) and the R+TG ($p < 0.01$) decreased significantly; On the 14th day of treatment, compared with before treatment, the total DHI score of all the three groups decreased significantly ($p < 0.01$). See Figure 2B for details.

On the first day of the treatment, compared with which before treatment, the total DHI score of severe BPPV group of the R+TG ($p < 0.05$) decreased significantly; On the 7th day of treatment, the total DHI score of severe BPPV group of the the TG ($p < 0.05$) and the R+TG ($p < 0.01$) decreased significantly. On the 14th day of treatment, compared with before treatment, the RG ($p < 0.05$), the total DHI score of severe BPPV group of the TG ($p < 0.01$) and the R+TG ($p < 0.01$) all showed significant reductions. See Figure 2C for details.

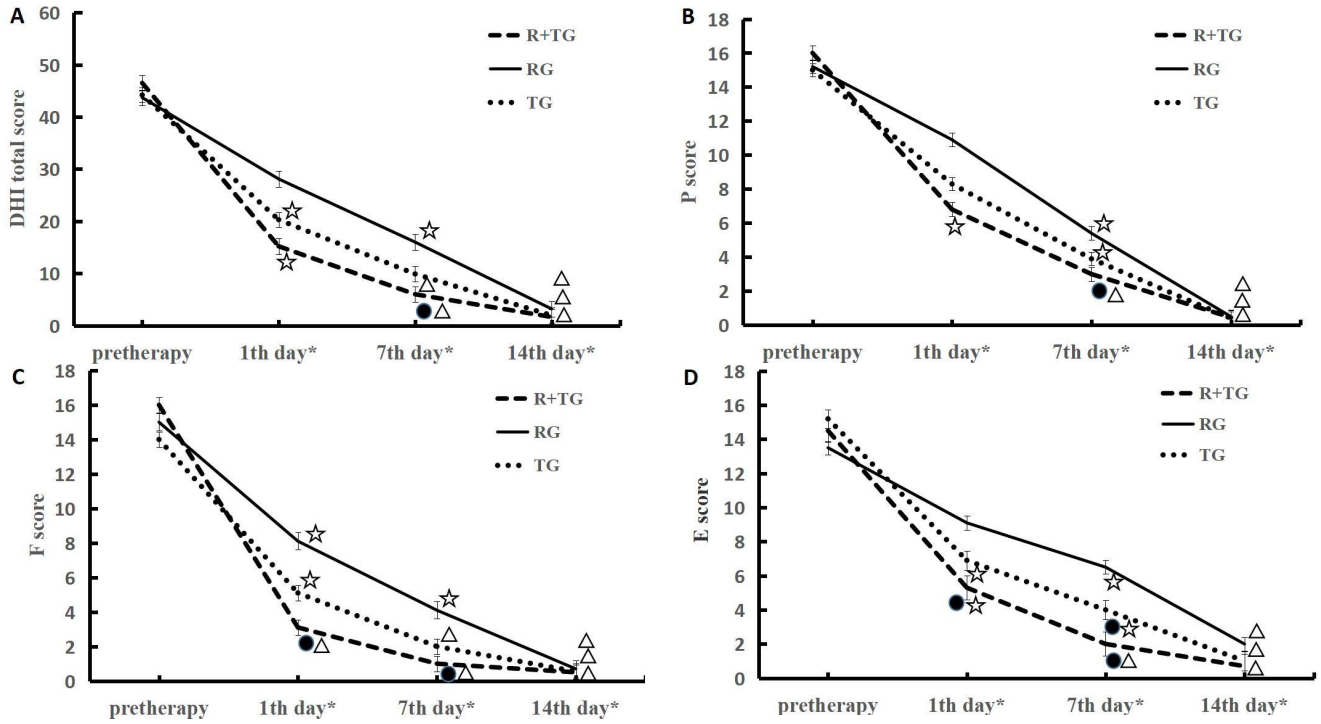

Figure 1 Comparison of DHI, P, F and E scores in the three groups before and after treatment. (A) The total score of DHI in the three groups before and after treatment; (B) The score of P in the three groups before and after treatment; (C) The score of F in the three groups before and after treatment; (D) The score of E in the three groups before and after treatment. Compared with which before treatment, ☆: $p < 0.05$, △: $p < 0.01$; Compared with the reset group at the same period, ●: $p < 0.05$. P: physical, F:function, E: emotion; *: post-therapy.

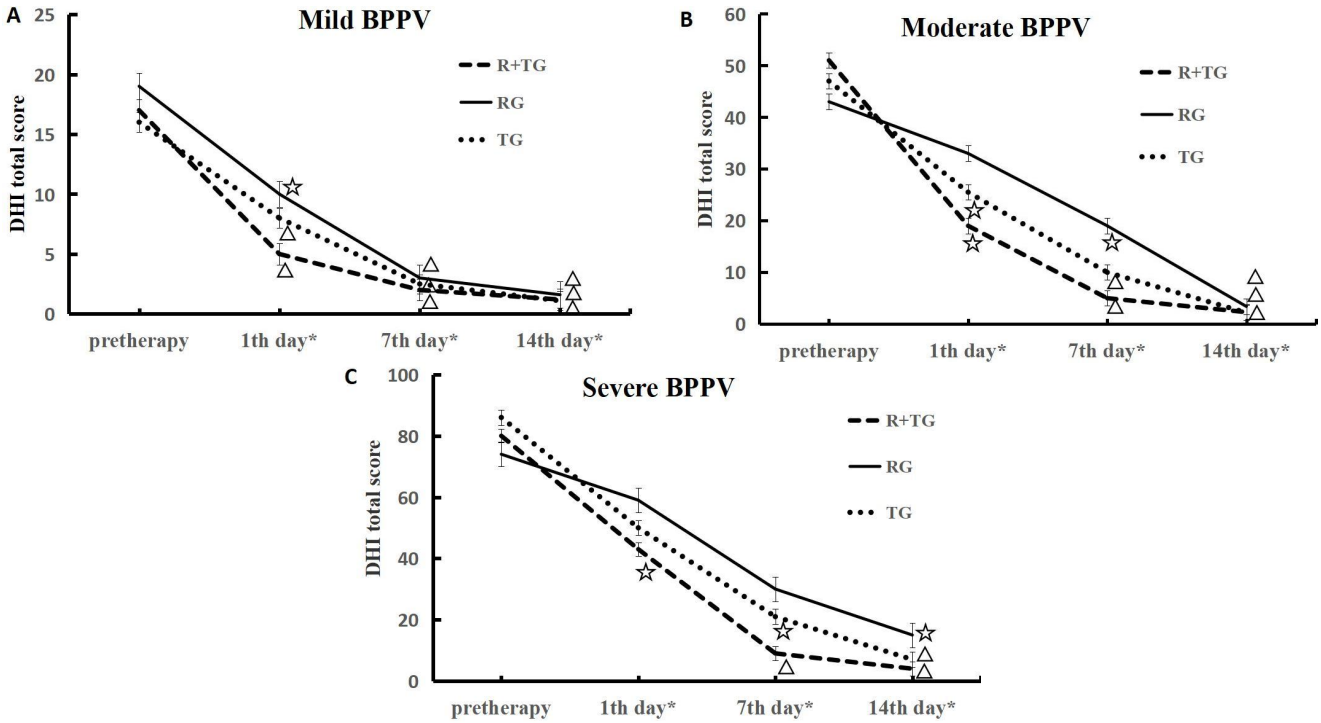

Figure 2 Comparison of DHI scores of mild, moderate and severe BPPV groups before and after treatment. (A) The change of DHI total score for mild BPPV groups; (B) The change of DHI total score for moderate BPPV groups; (C) The change of DHI total score for severe BPPV groups. Compared with before treatment, ☆: $p < 0.05$, △: $p < 0.01$.

3.3 Recurrence of otolith after treatment in three groups

After treatment, the three groups of RG, TG and R+TG were followed up for 6 months to observe the recurrence of BPPV; After treatment, in the end of 2nd, 4th and 6th month, there were significant differences among the threegroups. Compared with the RG, the recurrence rate of the TG and the R+TG was significantly lower ($p < 0.05$). See Table 1 for details.

3.4 Persistence of dizziness symptoms in three groups of RG, TG and R+TG after treatment

Follow-up observation is given within 6 months after treatment. While in the end of 2nd week and 1th month, there are significant differences among the three groups for the number of persistence of dizziness; Compared with the RG, the cases of dizziness of the TG and the R+TG were significantly reduced ($p < 0.05$). See Table 2 for details.

3.5 Comparison of serum estrogen, vitamin D, calcium and phosphorus ion levels among three groups

Among the BBPV, dizziness non-BBPV, and non-dizziness group, the estrogen levels of the dizziness non-BBPV group was the lowest and showed different from the BPPV group ($p < 0.05$). Vitamin D level of the three groups were all lower than the normal value (normal value ≥ 30 ng/mL); The BPPV group was the lowest level and was lower than non-dizziness group ($p < 0.05$). There was no difference for the serum calcium and phosphorus ion levels between the three groups (Table 3).

Table 1 Number of recurrent cases of otolithiasis in 3 groups (cases).

Group	Number of cases	1th month recurrence	2nd month recurrence	4th month recurrence	6th month recurrence
RG	61	4	12	19	21
TG	61	2	3	7	8
R+TG	61	1	4	5	7
X^2		2.068	8.528	13.287	12.587
p		0.356	0.014	0.001	0.002

Table 2 Number of cases of persistent dizziness symptoms in the 3 groups (cases).

Group	Cases	2nd week	1th month	3th month
RG	61	19	13	7
TG	61	9	4	3
R+TG	61	8	5	2
X^2		7.635	7.502	3.725
p		0.022	0.023	0.155

Table 3 Comparison of the indicators among the 3 groups (mean ± standard deviation, median ± interquartile range).

	BBPV group	Dizziness non-BBPV group	Non-dizziness group	p
Estrogen (pg/mL)	22.81 ± 21.5	13.11 ± 12.5°	33.64 ± 31.5	0.007
Vitamin D (ng/mL)	20.56 ± 6.75	24.38 ± 7.36	29.85 ± 18.3°	0.026
Calcium (mmol/L)	2.39 ± 0.05	2.36 ± 0.17	2.41 ± 0.11	0.31
Phosphorus (mmol/L)	1.07 ± 0.21	1.12 ± 0.20	1.21 ± 0.18	0.177

Note: ◊: Compared with the BPPV group, $p < 0.05$.

3.6 Adverse reactions and dropout of patients in the 3 groups during treatment

None of the 183 BPPV patients shedding during 14 days of treatment ; These may be related to the serious condition of the patients and the short course of treatment.

During the reset treatment, nearly half of the RG patients experienced nausea, dizziness, or aggravation of suchsymptoms; Among the RG, within 14 days, 5 patients had to repeat the reset at intervals of more than 24 hours due to residual symptoms or obvious dizziness. In the RG, BPPV symptoms of 2 patients recurred in the second week of treatment; In the TG, the symptoms of all patients showed a gradual remission, and no aggravation or other discomfort occurred in the patients.

4 Discussion

Otolithiasis is basically not life-threatening; But when the symptoms are severe, it can bring fear and a sense of near-death to the patients. So far, there is no objective evaluation for dizziness symptoms; The symptoms of patients with otolithiasis can be quantified with the DHI scale, which is a widely accepted evaluating index for dizziness symptoms by clinicians [7]. Here, we used the DHI scale to effectively evaluate the dynamic changes in symptoms for patients of BPPV. In this paper, the three kinds of therapy all show significant effects after 2 weeks of treatment. However, nearly half of the patients experienced obvious discomfort, or the dizziness fluctuated during the reset treatment; Individual patients need repeated resets. After one week of treatment, the score DHI showed that the emotional distress of the TG and the R+TG alleviate better than RG. For the long-term effect of treatment, from the points of the frequency of residual dizziness and the proportion of disease recurrence, the therapy of the RG is not so well. This showed the advantages of TCM. Otolith reset is the recommended in the guide treatment for BPPV. After reduction, most of the patients' were relieved from dizziness; However the recurrence is about 7%~50% [8]. The recurrence affects the living quality of the patients; It is reported that 72.6% of the recurrent patients are accompanied with other diseases [9]. 48.6% of recurrent patients of these groups are complicated with one or more other diseases. Through our clinical data, we recorded the direct cause of recurrence of BPPV: staying up late and insomnia (23.6%), more contact with mobile phones and other electronic products (22.3%), fatigue (18.1%), improper diet (10.3%), catch cold (8.3%), and others (17.4%) [10]. It is significance to explore more effective therapy to short the duration of residual dizziness and reduce recurrence rate for BPPV. From the perspective of TCM, the recurrence of BPPV is the the recurrence of qi and blood deficiency, phlegm turbidity, insufficient kidney essence, hyperactivity of liver yang, and blood stasis obstruction. The patients of TG and R+TG show significantly reduction of the recurrence rate; There was no difference between the R+TG and the TG in reducing the recurrence rate; It is suggested that reduction the recurrence rate of BPPV is mainly the effect of TCM. After being resetted, most the patients of BPPV disappeared from severe dizziness, but 61.2% of them continued to have residual dizziness. Otolithiasis causes vestibular balance disorder for a period of time. Residual dizziness affects patients' quality of life. There is no reliable method for treating residual dizziness with Western medicine [3]. Factors causing residual dizziness: After reduction, there are still a small amount of otoliths in the semicircular canal [11]; And the structure of the otolith membrane of the utriculus was partially changed and is dysfunction [12]. This study showed that, 2 weeks and 1 month after treatment, the incidence of residual dizziness of the TG and R+TG was lower than those of the RG. This suggested TCM has a definite and significant effect on residual dizziness. For mild, moderate, and severe

type of BPPV, we have observed that the efficacy of the TG is still better than that of the RG. The R+TG show the best effect. For patients suffered from severe BPPV, the symptoms of the RG is poorly relieved after reset; Most patients of the RG experience worsening symptoms during the process of reduction. During the treatment of severe BPPV, there was no worsening of symptoms in the TG; While The R+TG group showed best therapeutic effect. The concept of "dizziness" of TCM first appeared in the The Yellow Emperors Internal Classic. "Dizziness" refers to blurred vision or dizziness, and the feeling of the environment rotation. The patient with mild symptoms can be relieved by closing their eyes; While severe cases are accompanied with panic, sweating, nausea and vomiting.There is no BPPV in TCM, and the syndromes of "dizziness" in TCM are consistent with the symptoms of BPPV; So it is considered that BPPV belongs to the category of “dizziness” of TCM. The syndromes of "dizziness" in TCM are based on deficiency, with phlegm and blood stasis, and mixed with deficiency and excess. The etiology are the dysfunction of the liver, spleen, kidney and other viscera [13,14]; The interaction of multiple pathological factors leads to the disorder of the balance of yin and yang in the body and causes diseases. Individualized treated with TCM syndrome differentiation can effectively improve the function of viscera, remove phlegm, increase blood circulation in the inner ear, and improve the curative effect [15]. In view of the above theories of TCM, through decades of practice, we explored a simple and effective treatment for BPPV. We choose the Chinese patent medicine that have the ability to treat the corresponding TCM syndromes, which is used to treat BPPV. For example, Qishen Yiqi Dropping Pills have the effect of supplementing qi and nourishing blood, activating blood and unblocking pulse [16], which is used to treat BPPV of deficiency of qi and blood syndrome; Tongxinluo capsules have the effect of removing blood stasis, unblocking collaterals and smoothing qi and blood [17], and is used for BPPV of blood stasis blocking collaterals syndrome; and so on; Our treatment scheme is simple to operate, easy to repeat, and has definite curative effect. Serum estrogen, vitamin D and calcium levels are believed to be related to BPPV [18]. We selected three groups of patients, namely BPPV group, dizziness non-BPPV group and non-dizziness group. The dizziness non-BPPV group was selected to observe if the changes of serum estrogen, vitamin D and calcium are BPPV specific. We found that the level of estrogen in patients with vestibular dysfunction and non-BPPV decreased more significantly. The average level of vitamin D in the three groups were all lower than normal; And the BPPV group showed the most significant decrease. The levels of calcium and phosphorus ions in the three groups are all within the normal range, and there is no difference between the three groups. Our results suggest that if serum estrogen and vitamin D level abnormalities being the specific indicators of BPPV is worth further discussion. Compared with only reset, TCM dizziness theory can improve the curative effect, reduce the recurrence and shorten the time of residual dizziness for BPPV patients. Therapy with syndrome differentiation and reset can relieve the dizziness more quickly, especially for patients suffered from severe BPPV.

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Conflicts of Interest

All authors declare that the research was conducted in the absence of any commercial or fnancial

relationships that could be construed as a potential confict of interest.

Author Contributions

S.C. and J.J. conceptualized the trial with support from co-authors. S.C., J.J. and Y.N. participated in creating the study design. J.J. made the first draft of the manuscript. J.J., Y.L. and Y.W. participated in creating the statistical analysis plan. All authors reviewed and revised the manuscript critically for important intellectual content. All authors reviewed the final manuscript as submitted. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate

Ethics approval was obtained from IEC for Clinical and Animal Trials of the the First Affiliated Hospital of Sun Yat-Sen University Hospital (No. 2022-654). All Chinese patent medicine used in the trial is a marketed drug approved by China National Medical Products Administration. All participants will sign a written informed consent prior to inclusion and will be managed exclusively by a trained clinician during the study. The study will follow the Declaration of Helsink, participants can make the decision to withdraw from the trial at any time, and all data that may reveal personal privacy will be hidden.

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Not applicable.

Availability of Data and Materials

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding authors.

Supplementary Materials

Not applicable.

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