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Xueshuantong improves therapeutic outcome and quality of life of elderly patients with benign paroxysmal positional vertigo after Epley maneuver

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Abstract

Objective: Benign paroxysmal positional vertigo (BPPV) is a common peripheral vestibular disorder. This study aimed to evaluate the therapeutic effect of *Xueshuantong in* patients with BPPV treated with the Epley maneuver. *Methods:* In this randomized study, 97 patients diagnosed with posterior canal BPPV who met the inclusion and exclusion criteria were allocated to the control group (Epley maneuver) and the experimental group (Epley maneuver plus Xueshuantong). All patients were assessed using the vertigo symptom scale (VSS), Berg balance scale (BBS), dizziness handicap inventory (DHI), and visual analog scale (VAS) before treatment and again on day 14 after treatment. Recurrence rates were assessed during 6-month follow-up period. *Results:* Compared with the control group, the therapeutic outcomes of BPPV were significantly improved in the experimental groups. Significant decrease in VSS (20.8 vs 33.1), total DHI (35.1 vs 46.9), sub DHI and VAS (2.2 vs 7.4) scores and significant increase in BBS scores (55.5 vs 31.8) were observed following Xueshuantong treatment. Xueshuantong treatment also resulted in significantly reduced recurrence rates (81.6% vs. 91.7%; RRR = 11%), with no additional adverse effects.
Conclusions: Post-Epley maneuver treatment with Xueshuantong improves the therapeutic outcomes, reduces the residual dizziness and increases quality of life of elderly patients with BPPV treated with the Epley maneuver.

Keywords: Epley maneuver; benign paroxysmal positional vertigo; therapeutic outcome; quality of life; recurrence rates

INTRODUCTION

Benign paroxysmal positional vertigo (BPPV) is a common peripheral vestibular disease, accounts for 20%–30% of all vertigo diseases. It mostly occurs in middle-aged and elderly people.[1] The clinical manifestations include transient dizziness, a syndrome characterized by short-lived episodes of vertigo associated with rapid changes in head position while picking up objects, standing up from lying, and turning around. BPPV is often accompanied by palpitations, nausea, deafness, and tinnitus, which severely affect quality of life.[2,3] Based on the dislodge of the canalith, BPPV can be divided into mixed, upper semicircular, horizontal, and posterior canal. Among them, posterior canal BPPV is the most common.[4,5]

Various clinical methods have been developed to treat BPPV, such as manual maneuvers, medications, surgery, and the use of a mechanical rotational chair[6-8], of which the Epley (canalith repositioning) maneuver is the most common treatment.[9] The Epley maneuver is a safe and effective treatment for BPPV, particularly posterior canal BPPV. However, the recurrence rate of BPPV after the maneuver is relatively high (36%)[10], and the quality of life of patients is somewhat affected after treatment.[11] In the pharmacological treatment of BPPV and related disorders, the classes of medications proven useful include anticholinergics, antihistamines, benzodiazepines, calcium channel antagonists, and dopamine receptor antagonists. However,

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these medications often have multiple actions and adverse effects.[12] Recently, vitamin D[13,14] and calcium supplementation have been demonstrated to be effective in preventing recurrence of BPPV after canalith repositioning maneuvers, particularly in patients with subnormal serum vitamin D, and Danhong injection (DHI), a traditional Chinese medicine, can effectively reduce residual dizziness after successful repositioning treatment in patients with BPPV.[15] Sodium aescinate has been shown to improve the efficacy of the Epley maneuver for BPPV with few adverse effects. These drugs often reduce vestibular neuritis and improve vestibular function.[16]

Xueshuantong 血栓通 is a herbal medicine formulation, and its active ingredients are saponins extracted from pseudo-ginseng (*Panax notoginseng* (Burk.) F.H. Chen). The main function of this medicine is to promote blood circulation and reduce blood stasis.[17] It is prescribed to treat blood stasis, stroke, hemiplegia, chest pain, central retinal vein occlusion, and complications from cerebral infarction and posterior circulation ischemic vertigo.[18] Therefore, it may be effective as an adjuvant therapy to improve the efficacy of the Epley maneuver for BPPV.

In this study, we investigated the efficacy and safety of Xueshuantong as an adjuvant therapy in combination with the Epley maneuver for BPPV, with a focus on the quality of life of elderly patients.

METHODS

Patients

Patients diagnosed with BPPV based on the 2017 Diagnosis and Treatment Guidelines for BPPV[19,20] at our hospital between June 2019 and February 2021 were enrolled. Patients were included if they had posterior canal BPPV with torsional nystagmus and related symptoms such as tinnitus, headache, fatigue, irritation, numbness and tremor of limbs, insomnia, dreaminess, and were aged between 50 and 70 years. Patients were excluded if they had a history of previously diagnosed BPPV or other peripheral vestibular disorders, cochlear symptoms related to vertigo or dizziness, severe liver and kidney insufficiency, tumor, severe infection, history of craniocerebral surgery and cervical vertebral fracture, mental disorders (including any neurological symptoms or central nervous system disorder), migraine, previous vascular disorders of the central nervous system, psychiatric comorbidities and communication impairments. Patients with abnormal findings in the ear, such as tympanic membrane perforation, cholesteatoma, abnormal intracranial findings from magnetic resonance imaging (MRI), restricted cervical and head movements, and cervical neurological symptoms were excluded. Patients with acute cerebral hemorrhage or allergy to *P. notoginseng* were also excluded. This study was conducted as a single-center, prospective, randomized controlled trial and was performed according to the principles of the Declaration of Helsinki. Informed written consent was obtained from all subjects.

Treatment

The patients were randomized 1:1 into the control group to receive the Epley maneuver and the experimental group to receive Xueshuantong after the Epley maneuver, using a random number table. The Epley maneuver was applied bilaterally in all patients in both groups[21], based on the clinical practice guidelines of BPPV[21,22], and was performed by the same physician. After the canalith repositioning maneuver, debris in all the affected posterior canals were cleared as assessed with the Dix-Hallpike maneuver. Patients in the experimental group were administered Xueshuantong (3 capsules after each meal for seven days) based on the manufacturer's recommendations. Patients in the control group were administered placebo (the same capsules containing 300 mg wheat powder). Xueshuantong capsules were purchased from Zhongsheng Pharmaceutical (Gangzhou, China) (approval no. Z20030017), and contains saponins from *P. notoginseng* as the major active ingredient.

Outcome measures

All patients were evaluated using the vestibular symptoms scale (VSS)[23], Berg Balance Scale (BBS)[24], and dizziness handicap inventory (DHI)[25] on day 1 before treatment and again on day 14 after treatment. VSS assesses balance, dizziness, head dizziness, visual acuity, headache, and nausea with score of 0-10, varying between 0 and 60, with low scores indicating better symptoms. The DHI is a widely used scale to assess the disability of patients with vertigo. It consists of 25 questions and 3 subscales that evaluate physical (DHI-P, 7 items), emotional (DHI-E, 9 items), and functional (DHI-F, 9 items) outcomes of patients. The total DHI score varies between 0 (no disability) and 100 (severe disability).[14] Treatment effects were assessed on day 14

using the Dix-Hallpike test (DHT)[26] and were rated as positive (no dizziness and no evokable nystagmus), or negative (dizziness continued or even deteriorated, nystagmus reappeared). The quality of life of patients after treatment was assessed using a single-item visual analog scale (VAS) ranging from 0 (best) to 10 (worst).[27] Adverse reactions occurred within two weeks of treatment were recorded. Physician performing the maneuver and evaluators were not given information about the interventions and patients during the assessment and were therefore blinded to the received treatment protocol.

Follow-up

To investigate the recurrence rate, all patients were followed-up by telephone interviews at 1, 3, and 6 months after treatment. All patients who reported BPPV symptoms were recalled/readmitted and examined at the same hospital to confirm recurrence. Patient was counted once for the recurrence no matter when the recurrence occurred during the follow-up.

Statistical analysis

Data were analyzed and processed using statistical software (SPSS for Mac v.20.0; SPSS Inc., Chicago, IL, USA). At least 35 patients in each group were determined to be needed to enroll to achieve a power of 85%, allowing for a type I error of 0.05 and effect size of 0.95. Quantitative variables were summarized as mean ±SD, and the independent sample *t*-test was used for comparison; enumeration data were expressed as the number of cases (rate), and the chi-square test was used for comparison. Statistical significance was set at $p < 0.05$.

RESULTS

Demographic characteristics of patients

A total of 162 patients were assessed for inclusion in the study, and 65 patients were excluded owing to secondary BPPV, organ dysfunction, tumor, abnormal findings in the ear, and other reasons. All patients were idiopathic *with* normal neuro-otological examination. Their BPPV lasted 2 to 7 days before treatment. Ninety-seven individuals diagnosed with BPPV who met the inclusion criteria were enrolled and randomized into a control group (n=48) and an experimental group (n=49). A flowchart of patient selection and follow-up is shown in Figure 1. The mean ages of patients in the control and experimental groups were 66.2±4.15 and 66.8±4.75 years, respectively (Table 1). The patients in both groups were similar in terms of age, sex, comorbid diseases (diabetes mellitus, hypertension and coronary artery disease), VSS score, BBS score,

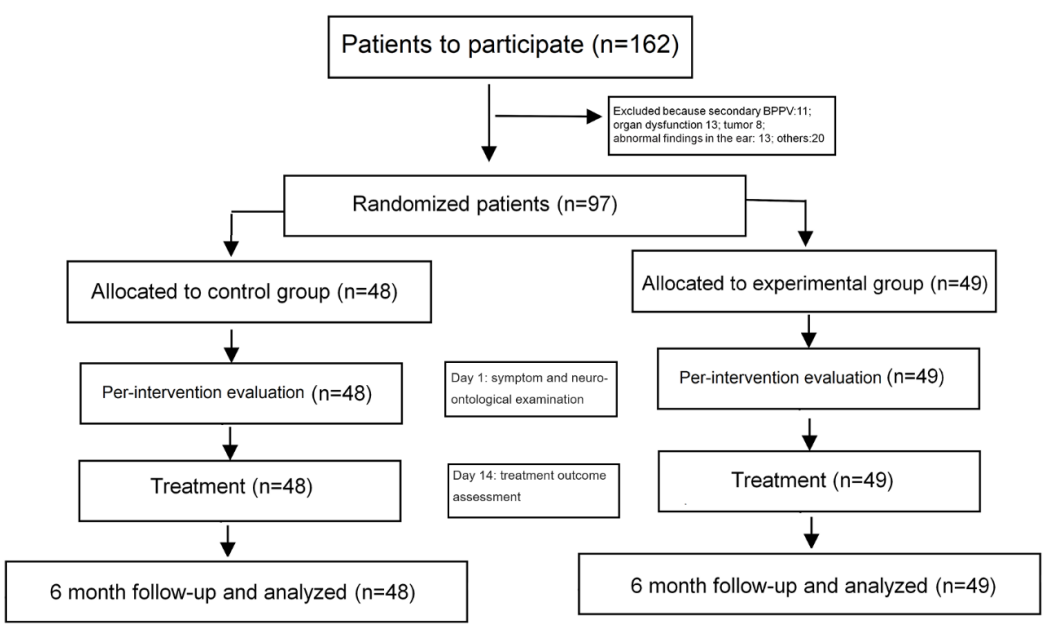

Figure 1. Diagram of parent selection, treatment and analysis

VAS score, and DHI score ($p > 0.05$, Table 1). The female to male ratios were 2 and 2.5 in the control and experimental groups, respectively, and the VAS scores were >7, suggesting that the global quality of life was impaired in the patients before the therapy.

Xueshuantong increases the efficacy of the Epley maneuver

Based on DHT, in the control group, 22.9 % patients were positive (successfully cured where no nystagmus and no dizziness) and 77.1 % patients were negative who experienced limited symptom impvoements, or did not respond to the Epley Maneuver. Meanwhile, in the experimental group, the potive and negative rates were 36.7% and 66.3%, respectively. Statistical analysis showed that compared with the Epley maneuver, *Xueshuantong significnatly increased the positive rate and reduced negative rate* ($p < 0.05$, Table 2).

Xueshuantong improves VSS, DHI, BBS and VAS scores

After treatment, patients in both the control and experimental groups had significantly improved VSS score, total DHI score, sub-DHI score, BBS score, and VAS scores compared to the initial assessments before treatment ($p < 0.01$, Table 3). Furthermore, *Xueshuantong* treatment resulted in a significant improvement in these parameters compared to the Epley maneuver alone ($p < 0.05$, Table 4). The improvement was particularly remarkable in the VAS scores that measured quality of life ($p < 0.000$, Table 4).

Xueshuantong does not increase incidence of adverse reactions

Several possible adverse reactions, including headache, fever, vomiting, and staggering were recorded within two weeks of treatment (Table 5). The total number of adverse reactions was the same in both groups, and these reactions occurred with mild to moderate symptoms 2–5 days after the beginning of treatment and lasted less than two days. All symptoms disppeared spontaneously without medical treatment.

Xueshuantong reduces recuurence rate

To investigate the recurrence rate, all patients were followed up by telephone interviews for up to six months after treatment. Recurrences occurred between the follow-up dates were recorded as recurrence. All patients who reported BPPV symptoms were recalled and examined at the hospital to confirm recurrence. By the end of six month follow up, 91.7% of patients in control group experienced recurrence of BPPV, although the symptoms were less severe as compared

Table 1: Demographics of patients with benign paroxysmal positional vertigo for treatments with the Epley maneuver and Xueshuantong

	Control group (n=48)	Experimental group (n=49)	*P*
Sex, n (F/M)	16/32	14/35	0.514
Age, mean±SD, years	66.2±4.15	66.8±4.75	0.334
Comorbid disease			
DM	29	31	0.434
HT	22	20	0.334
CAD	12	11	0.634
VSS score, mean±SD	33.8±11.11	33.1±9.9	0.324
BBS score, mean±SD	31.5±7.43	31.8±6.43	0.404
VAS score, mean±SD	7.5±1.43	7.4±1.23	0.204
Total DHI score, mean±SD	47.1±15.71	46.9±13.71	0.453
Subscale			0.356
Physical score	14.2±6.53	14.9±4.53	0.456
Emotional score	12.4±5.82	12.1±5.12	0.564
Functional score	20.2±5.11	19.0±5.11	0.544

DM: diabetes mellitus; HT: hypertension; CAD: coronary artery disease; VSS: vestibular symptom scale; BBS: Berg balance scale; DHI: dizziness handicap inventory; VAS: visual analog scale.

Table 2: Therapeutic efficacy of the Epley maneuver alone (control) or in combination with Xueshuantong (experimental) on benign paroxysmal positional vertigo

Group	No. patients treated	Positive		Negative	
		n	%	n	%
Control	48	11	22.9	37	77.1
Experiment	49	18	36.7	31	66.3
P			0.022		0.038

VSS: vestibular symptom scale index, BBS: Berg Balance Scale, DHI: Dizziness Handicap Inventory; VAS: Visual Analog Scale.

Table 3: VSS, DHI, BBS and VAS scores before and after with the Epley maneuver alone (control) or in combination with Xueshuantong (experimental)

	Control			Experiment		
Measures	**Before**	**After**	*P*	**Before**	**After**	**P**
VSS score, mean±SD	33.8±11.11	23.8±5.54	<0.01	33.1±9.9	20.8±4.22	<0.01
BBS score, mean±SD	31.5±7.43	43.5±8.13	<0.01	31.8±6.43	55.5±9.18	<0.01
VAS score, mean±SD	7.5±1.43	4.5±1.23	<0.01	7.4±1.23	2.2±1.23	<0.01
Total DHI score, mean±SD	47.1±15.71	40.1±12.72	<0.01	46.9±13.71	35.1±8.72	<0.01
Subscale						
Physical score	14.2±6.53	13.2±5.51	<0.01	14.9±4.53	12.2±4.11	<0.01
Emotional score	12.4±5.82	10.4±4.81	<0.01	12.1±5.12	8.4±3.21	<0.01
Functional score	20.2±5.11	16.5±4.34	<0.01	19.0±5.11	14.5±3.21	<0.01

VSS: vestibular symptom scale, BBS: Berg Balance Scale, DHI: Dizziness Handicap Inventory; VAS: Visual Analog Scale.

Table 4: VIS, DHI, BBS and VAS scores before and after treatments with the Epley maneuver alone (control) or in combination with Xueshuantong (experimental)

Time	Group	VSS	BBS	VAS	Total DHI score	Physical score	Emotional score	Functional score
Before treatment	Control	33.8±11.11	31.5±7.43	7.5±1.43	47.1±15.71	14.2±6.53	12.4±5.82	20.2±5.11
	Experiment	33.1±9.9	31.8±6.43	7.4±1.23	46.9±13.71	14.9±4.53	12.1±5.12	19.0±5.11
	P	0.321	0.523	0.787	0.681	0.885	0.887	0.723
After treatment	Control	23.8±5.54	43.5±8.13	4.5±1.23	40.1±12.72	13.2±5.51	10.4±4.81	16.5±4.34
	Experiment	20.8±4.22	55.5±9.18	2.2±1.23	35.1±8.72	12.2±4.11	8.4±3.21	14.5±3.21
	P	0.012	0.021	< 0.000	0.017	0.042	0.022	0.032

VSS: vestibular symptom scale, BBS: Berg Balance Scale, DHI: Dizziness Handicap Inventory; VAS: Visual Analog Scale.

Table 5: Adverse reactions in patients with benign paroxysmal positional vertigo after treatment with the Epley maneuver alone (control) or in combination with Xueshuantong (experimental)

Group	No. patients treated	Headache, n (%)		Fever, n (%)		Vomiting, n (%)		Staggering, n (%)		Total, n (%)
Control	48.00	1.00	0.02	1.00	0.02	1.00	0.02	2.00	0.04	5.00
Experiment	49.00	2.00	0.04	1.00	0.02	0.00	0.00	2.00	0.04	5.00

to the initial symptoms. On the other hand, *Xueshuantong treatment significantly reduced* the recurrence rate to 81.6% 6 months after treatment ($p < 0.05$, Table 6). The reduction in recurrence rate was more remarble at one month (relative risk reduction (RRR) =17.5 %) after treatment and decreased at 6 months (RRR = 11%) (Table 6).

DISCUSSION

The outcomes of our study demonstrated that post-Epley maneuver treatment with Xueshuantong significantly improved the therapeutic outcomes and reduced the recurrence rate for elderly patients, but did not increase adverse reactions in BPPV patients. Therefore, Xueshuantong may possibly be useful as an adjunct for posterior canal BPPV treatment in connection with the Epley maneuver to improve their quality of life.

BPPV is the underlying cause for more than one-third of elderly patients who visit neuro-otology clinics with dizziness/vertigo.[28] It induces falls in elderly adults and is responsible for more than 90% of hip fractures and severe head injury.[29] The quality of life of patients with BPPV is compromised, even after therapy.[30] Extensive clinical studies have demonstrated that the Epley maneuver and modified Epley maneuvers are highly effective in the treatment of BPPV and have been considered the gold standard for BPPV treatment.[31] However, there are several side effects related to these methods, such as falling sensations, anxiety, and discomfort.[32] The recurrence rate is relatively high[33] and can be up to 36% for posterior canal BPPV after the treatment.[10]

The pathogenesis of BPPV is complex and can be attributed to aging, migraine, Meniere's disease, infection, trauma, idiopathic paroxysmal hearing loss, sleep habits, osteoporosis, vitamin D deficiency, hyperglycemia, diabetes, chronic head and neck pain, vestibule or semi-vestibule lesions, estrogen deficiency, nervous system diseases, autoimmune diseases, inflammation or rheumatism, and familial or genetic susceptibility.[34] Several classes of drugs have been used in combination with the Epley maneuver to reduce residual dizziness and improve quality of life after successful canalith repositioning procedures, including anticholinergics, antihistamines, benzodiazepines, calcium channel antagonists, and dopamine receptor antagonists.[12] Residual dizziness may be caused by pathological or psychogenic factors such as autonomic dysfunction[35], incomplete canalith repositioning during CRP[36], impaired central adaptation after successful CRP[37], and anxiety/depression.[38] Betastatin, a histamine drug, has been shown to relieve dizziness, probably by inhibiting platelet aggregation and improving blood circulation in the brain and inner ear to relieve dizziness.[39] In addition, anxiolytics such as etizolam significantly reduced functional and emotional subscale scores, as well as the total DHI score.[38]

In the present study, we used Xueshuantong as an adjuvant therapeutic after canalith repositioning with the Epley maneuver for vestibular rehabilitation. Xueshuantong mainly contains saponins, volatile oils, and polyacetylenes[40] and can promote blood circulation and reduce blood stasis.[17,40] It is prescribed to treat blood stasis, stroke, hemiplegia, chest pain, central retinal vein occlusion, and conditions associated with blood coagulation.[41-43] Pharmaceutical studies have shown that Xueshuantong inhibits the activity of angiotensin-converting enzyme[44], prevents the over-activation of the renin-angiotensin system, and ameliorates the activation of the coagulation system by interacting with proteins related to blood coagulation, fibrinolysis, and platelet aggregation.[45] Our work showed that Xueshuantong significantly improved the therapeutic outcomes of the Epley Maneuver, and the improvements in positive rates determined based on DHT were statistically significant between the two groups. Two weeks after the treatments, patients were evaluated for

Table 6: Recurrence of benign paroxysmal positional vertigo after treatment with the Epley maneuver alone or in combination with Xueshuantong

Group	No. patients followed up	BPPV, n (%) on Day 14	Day 30	Day 90	Day 180
Control	48	37 (77.1)	40 (83.3)	42 (87.5)	44 (91.7)
Experiment	49	31 (63.2)	33 (67.3)	37 (75.5)	40 (81.6)
p		<0.01	<0.01	<0.01	<0.01

vestibular symptoms; dizziness-related handicap in physical, emotional, and functional abilities; and quality of life using VSS, DHI, BBS, and VAS scores. Significant reductions in VSS, DHI, and VAS scores and a significant increase in BBS scores were observed in patients receiving Xueshuantong compared to those not receiving Xueshuantong, suggesting that Xueshuantong can improve vestibular symptoms and balance ability, particularly quality of life, and reduce residual dizziness in patients after the Epley Maneuver. It is also noted that the recurrence rates based on the DHT at day 14 were relatively high for both the control and experimental groups. This might be attributed to the old age of patients who might response poorly to the treatment. Previously, it has been shown that younger patients are less likely to express discomfort directly after the Epley maneuver compared with the elderly[46] and the symptoms were significantly reduced in younger patients.[47] On other hand, the elderly patients had relatively poor QoL measures, which are more likely to be positively affected by the treatment, leading to significant improvement after the treatment. It is likely that factors other than age are also responsible for the contradiction between the DixHallpike findings and the other dizziness /QoL measures and more studies are needed to elucidate the difference.

Since Xueshuantong significantly increase the positive rates of the Epley maneuver, it is possible that Xueshuantong has synergy with the Epley maneuver to cure BPPV directly. Previously, a number of reports have shown that Xueshuantong attenuates cervical vertigo due to vertebral artery compression with reduced plasma viscosity, erythrocyte aggregation rate, and blood fibrinogen level.[48] Recently, Xueshuantong has also been shown to reduce posterior circulation ischemic vertigo with reduced whole blood viscosity, platelet adhesion rate, and plasma viscosity when used in combination with betahistine.[18] However, Xueshuantong alone has not been used to treat BPPV. The beneficial effects observed in the present study are likely to result from similar functions in attenuating vertigo[48]; however, further studies are required to elucidate these mechanisms.

In this study, we only treated primary BPPV in order to have less background variations, although recurrent BPPV has the lowest QoL, and would probably benefit most from Xueshuantong. Recurrent BPPV would have complicated history of disease that have led to reduced QoL due to the complications, which could possibly mask the effect of Xueshuantong. Ideally, patients should be stratificated based on the cause and history of BPPV for the treatment to gain more insight on the differential benefit of Xueshuantong. In addition, restrictive inclusion criteria were applied to select patients to maximally ensure that post repositioning symptoms is not confounded by other concurrent vestibular / non-vestibular disorders or inadequate maneuvering. The drawback of these selection is that the results of the paper may not be easy to generalize to all patients with BPPV and more studies are needed for patients of different BPPV to confirm the effect.

Notably, the recurrence rate of BPPV in the experimental group was significantly reduced between Dix Hallpike checks at days 14 and 180 compared to the control, although the rate increased over the period in both groups. However, since Xueshuantong was administered for seven days after the Epley maneuver and the follow-up was 180 days, it remains unclear as how long the Xueshuantong effect would last. Longer or higher doses of Xueshuantong might be beneficial for further reducing recurrence. However, further clinical studies are needed to confirm this hypothesis. In contrast, no additional adverse events were observed after Xueshuantong treatment, indicating that it is safe at the prescribed dose, as reported previously.[17]

Although our study demonstrated the usefulness of Xueshuantong in BPPV treatment, it had several limitations. As a single-center study, the sample size was relatively small and the follow-up time was short. All patients were treated with the same single regime of Xueshuantong, which may not be optimal for individual patients with different types of BPPV and underlying conditions. Furthermore, only otorhinolaryngological and neurological assessments were performed to evaluate the treatment outcome, and no assessment of biochemical factors known to affect BPPV, such as E2, B12, and vitamin D[49,50] was made in this study to provide further mechanistic understanding. These issues should be addressed to further define the best practices for treating BPPV with Xueshuantong. In addition, the effects of priming[51] were not fully addressed in this study. These issues should be addressed to further define the best practices for treating BPPV with Xueshuantong.

In conclusion, to the best of our knowledge, this is the first study in which Xueshuantong was used as adjuvant therapy to the Epley maneuver to treat BPPV. Xueshuantong improves the efficacy of the Epley maneuver in reducing vestibular symptoms

and dizziness-related handicap, and improves quality of life. It also reduced the recurrence of BPPV after the Epley maneuver with no additional side effects. Further studies are needed to define the optimal Xueshuantong scheme for the dose and duration of BPPV management in different patient groups.

DISCLOSURE

Ethics: The study was approved by The Ethics Review Committee of the Nantong First People's Hospital, Nantong. Informed written consent was obtained from the subjects.

Data availability: The datasets used during the current study are available from the corresponding author on reasonable request.

Financial support: None

Conflict of interests: None

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