EFFECTIVENESS OF CINNARIZINE AND/OR POSTURAL RESTRICTION AS AN ADJUVANT MEASURES ON THE THERAPEUTIC EFFECTS OF CANALITH REPOSITIONING PROCEDURE IN TREATING UNILATERAL PC-BPPV

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Submitted: 15/4/2015; Accepted: 30/8/2015; Published: 1/6/2016

ABSTRACT

Background

Posterior Canal Benign Paroxysmal Positional Vertigo (PC-BPPV) is by far the most common cause of vertigo, to establish the diagnosis the Dix-Hallpike maneuver (DX) is the definitive part of the physical examination. First-line therapy is organized around Canalith Repositioning Procedure (CRP). Further treatment options include: many otolaryngologists had routinely prescribed post-maneuver postural restriction and/or vestibular suppressants the latter as an adjuvant treatment for this disorder.

Pateints and Methods

A prospective double blinded randomized interventional controlled study conducted on 109 patients diagnosed as having canalithiasis unilateral PC-BPPV. Enrolled patients were received CRP as an initial standard treatment then randomly assigned in to four groups of treatments. Two different scales of vertigo symptoms assessment were used before & after the procedure: 1- Dizziness Handicap Inventory (DHI). 2- Vertigo Symptom Scale - Short Form (SF).

Results

DHI 1, SF 1 (1 week post-CRP) and DHI 3, SF 3 (3 months post-CRP) didn't show significant differences across the groups, P value: 0.487, 0.933, 0.979 and 0.145 respectively ($P > 0.05$). The mean ranks of DHI 2 and SF 2 (1month post-CRP) in G3 in compare with other groups are lower in both scales. The mean ranks of DHI 2 in Groups 1, 2, 3 and 4 are 59.78, 53.33, 29.39 and 42.1 respectively and in addition these ranks for SF 2 are 53.5, 57.07, 29.95 and 45.48 respectively.

Conclusion

Cinnarizine as adjuvant therapy didn't enhance the therapeutic effect of CRP. Adjuvant postural restriction enhances the therapeutic effect of CRP by facilitating symptoms resolution within one month (medium term effect).

Keywords: *Posterior canal BPPV, Canalith Repositioning Procedure, Cinnarizine, Postural restriction, Vestibular suppressants.*

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https://doi.org/10.17656/jsmc.10083

INTRODUCTION

Vestibular vertigo accounts for a considerable percentage of personal and health care burden. This suggest that diagnosis and treatment of frequent vestibular conditions are important issues in primary care [(1)]. Of all the inner ear disorders that can cause dizziness or vertigo, Benign Paroxysmal Positional Vertigo (BPPV) is by far the most common. In a large dizziness clinic (Royal Victoria Hospital - Montreal), BPPV was the cause of vertigo in about 17% of patients. The vast majority of all BPPV cases are of the posterior canal variant. The pathophysiology that causes most posterior canal BPPV (PC-BPPV) cases is thought to be canalithiasis. This is probably because most free-floating endolymph debris tends to gravitate to the posterior canal [(2)]. The exact mechanism by which free-floating debris leads to paroxysmal vertigo and nystagmus is un-known, but presumably the movement of the debris causes alterations in endolymphatic pressure and thus cupular deflection [(3)]. Both cupulolithiasis and canalolithasis are potentially valid mechanisms of (BPPV). However, canalolithiasis is the most likely mechanism of BPPV, which is usually characterized by nystagmus of short duration and long latency. A vibratory stimulus was able to detach the otoconia from the utricle, suggesting that mechanical insult could be a possible etiology of BPPV [(4)].

The diagnosis of BPPV is usually suggested on history. Patients describe sudden, severe attacks of horizontal or vertical vertigo, or both, precipitated by certain head positions and movements. The Dix-Hallpike maneuver (DX) is the definitive part of the physical examination to establish the diagnosis of BPPV [(2)]. Figure 1-A shows maneuvering of the head in the plane of the posterior semicircular canal in this test triggers nystagmus and vertigo in patients by inducing movement of the debris [(5)]. PC involvement is proved from the type of the visually observed paroxysmal positioning nystagmus, which is beating towards the undermost and affected ear, with a torsional component clockwise when following leftward movement, or counterclockwise, when following rightward movement. Typically an upbeating nystagmus component is superimposed, resulting in a mixed torsional-vertical eye movement [(6)]. In most cases the BPPV symptoms spontaneously abate within a few weeks, however, in up to 30% of untreated cases the symptoms may persist for months, resulting in significant disability and frustration for the patient [(7)].

First-line therapy for BPPV is organized around Canalith Repositioning Procedure (CRP). In cases of canalithiasis, the gravity is used to move canalith debris out of the affected semicircular canal and into the vestibule. For PC-BPPV the maneuver developed by Epley (Figure 1) is particularly effective. The maneuver is repeated until no nystagmus is elicited & is effective in more than 90% of cases in eliminating BPPV [(8)].

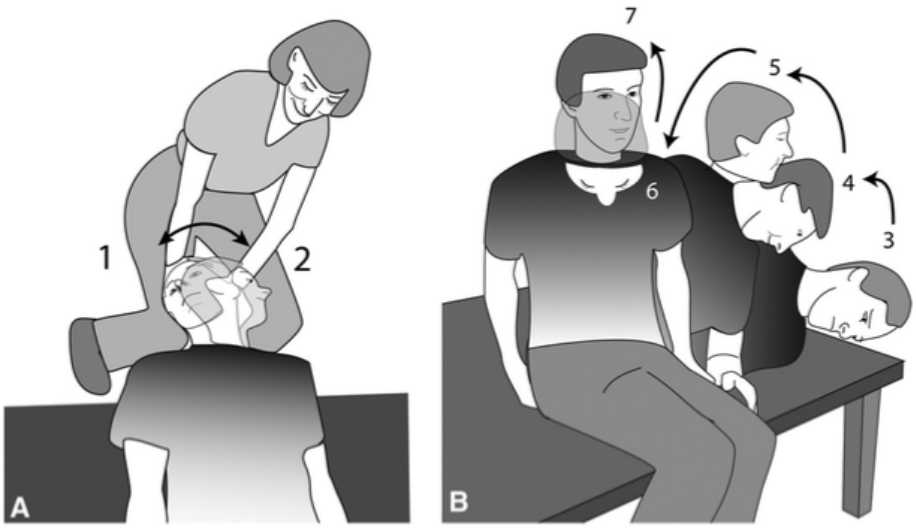

Figure 1: CRP. A: 1- DX, 2- head turned 90 degrees contralaterally, B: 3- torso and head turned 30 degrees further contralaterally 4- sit up, head turned contralaterally. The head is maintained in each position for 10 seconds after vertigo ceased or for at least 30 seconds if no vertigo is elicited [(9)].

The symptoms of vertigo due to many different underlying etiologies are commonly treated with medications. Several categories of vestibular suppressant medications are in common use. There is no evidence in the literature to suggest that any of these vestibular suppressant medications are effective as a definitive, primary treatment for BPPV, or as a substitute for repositioning maneuvers [10]. Many safe and efficient anti-vertigo drugs are currently available. Clinical experience has shown that 12.5 mg of cinnarizine (CIN) three times daily (TID) may be useful in vertigo control [11]. In a short questionnaire survey conducted in a major otolaryngology–Head and neck center in this locality, among 21 otolaryngologists who answered the questions about treatment of BPPV, 16 of them were selected labyrinthine sedative as an adjuvant therapy after CRP and 11 of them specifically preferred cinnarizine with or without postural restriction.

Part of the treatment protocol for BPPV includes post-maneuver prohibitions. An extensive variety of patient limitations is recommended and utilized to prevent the loose debris from returning to the semicircular canals following treatment. Such instructions may include remaining supine, keeping the head erect, sleeping at a 45º angle, refraining from lying on the pathologic side, and even wearing a cervical collar to prevent head movements [12].

To prevent debris from re-entering the canal, the patient is usually advised to avoid head and trunk movement, use a cervical collar, and sleep in a semi seated position for two days. The patient is also instructed to avoid sleeping over the affected ear for the next five days following the repositioning maneuver [13].

Two patient-reported scales have been widely used to comprehensively evaluate patients with vestibular-balance symptoms: 1- the Dizziness Handicap Inventory (DHI) 2- Vertigo Symptom Scale (VSS). The DHI evaluates handicaps due to dizziness in daily life. VSS was developed to measure symptom frequency over 1 month, with the main goal of assessing therapeutic effect, and this has been used in clinical trials [14].

In virtue of overpresciption of labrynthine sedatives with or without postural restriction by otolaryngologists as an adjuvant therapy after standard treatment (CRP) in BPPV. This randomized interventional controlled study was conducted to evaluate the benefit of prescribing cinnarizine and postural restriction as an adjuvant therapies for this clinical condition via assessment of short (1 week), medium (1 month) and long (3 months) term efficacy of Cinnarizine and/or postural restriction as post-CRP measures on therapeutic effect of CRP in patients with unilateral PC-BPPV.

PATIENTS AND METHODS

This study was carried out according to the ethical regulation established by Scientific Affairs and Postgraduate Studies of University of Sulaimani, with approval number: N536, in accordance with the Helsinki declaration ethical principles for medical research involving human subjects.

A prospective double blinded randomized interventional controlled study conducted in Sulaimani teaching hospital from October 2013 to February 2015, on 109 patients diagnosed as having canalithiasis unilateral PC-BPPV (classical history, reported vertigo on DX and characteristic paroxysmal positioning mixed upbeating geotropic, torsional, fatigable, reversible and reactivated nystagmus with latency >10sec., duration < 1 min.). Eye movements and nystagmus were analysed and printed by software using the medical diagnostic device VNG ULMER version C4-13 Rev A. To avoid inclusion of false positive cases pure tone audiometry and vestibular tests for spontaneous nystagmus, saccade, smooth pursuit, positional, head shake and caloric tests were implemented.

Inclusion criteria

1. Age above 18.

2. Normal range of mobility in the neck and back.

3. Unilateral PC-BPPV according to known clinical criteria.

4. Normal range of hearing & tympanic membrane.

5. Normal eyes and extra ocular muscles.

Exclusion criteria

1. History of chronic ear problems and surgery

2. Neurological, orthopedic and connective tissue disorders that may interfere with the tests and treatments.

3. Patients on vestibular suppressants or ototoxic medication.

4. Other co-existed causes of vertigo.

5. Cases having mystagmus with latency less than 10 sec. and duration more than one minute (PC-BPPV of cupulolithiasis type).

6. Positive horizontal head roll maneuver and multiple canals BPPV.

7. Patients exhibiting difficulties to answer the questions in the vertigo assessment scales.

Two different forms: DHI and SF were used as a vertigo assessment scale covering different aspects of daily activity, complaints, intensity, frequency and psychological impact of the vertigo, high scores indicates severity of the symptoms. DHI is the most widely used and accepted self reported measurement of patients with dizziness. It has been translated into fourteen languages [15]. Permission for translation to Kurdish language was taken from Professor Jacobson Gary P. as one of the developers of DHI [16].

Enrolled patients were received initial standard treatment inform of modified Eply canalith repositioning procedure (CRP). This maneuver was repeated until no nystagmus elicited, then they were randomly assigned to four groups:

1- Group1 (G1), 31 patients: no further treatments neither instructions (control group).

2-Group2 (G2), 27 patients: asked to take 25mg CIN tablet after meal TID for one week.

3-Group3 (G3), 26 patients: asked to follow postural restriction for one week.

4-Group4 (G4), 25 patients: asked to take CIN tablets and follow postural restriction for 1 week as both G 2 and 3 were instructed.

Patients in each of the above groups were subjected to DX and evaluations by asking them to select their suitable answers in both forms in four different sessions (time): the first was pre-CRP session (DHI and SF Baselines) when they were selected for the study before receiving CRP followed by three post-CRP sessions: first (DHI 1, SF 1) at one week, second (DHI 2, SF 2) at one month and the last or third (DHI 3, SF 3) session at three months (or according to a suitable schedule). Patients in post-CRP sessions with positive DX were received further CRP until no nystagmus elicited.

Patient Instructions: patients in both G3 and 4 were instructed to sleep sitting up position wearing soft foam cervical collar for the first two nights. For the following 5 consecutive days they were asked not to lie on the symptomatic side and avoid sudden and excessive movement of the head especially in rostral-caudal (anterior-posterior) axis [17].

The therapeutic effect of CRP as a treatment and CIN and/or postural restriction as post-treatment measure for patients with unilateral PC-BPPV were analyzed by multiple comparisons using Nonparametric independent samples (Kruskal-Wallis test) in Statistical Package for Social Sciences (SPSS) version 21 for Windows.

RESULTS

Out of 109 enrolled patients the gender distribution was 65 Females 59.6% and 44 Males 40.4%; the range of age was 18-81 years with mean of 53.1 with standard deviation 15.6. The main symptoms associated with positional vertigo were nausea 60% followed by nausea plus vomiting 25%; the onset of consultation after initial vertigo was 1-14 days with mean of 5.06 with std. Deviation 3.58 (Figure 2 and 3).

As the scores of DHI and SF scales are directly proportional with the severity of the disease. This study strongly supported the effectiveness of CRP as a treatment of unilateral PC-BPPV in all Groups & post-CPR sessions, owing to the means of post-CPR scores: DHI 1 (21.56), DHI 2 (9.87), DHI 3 (4.29) and SF 1 (7.91), SF 2 (3.51), SF 3 (1.53) showed remarkable declining, if we compare them with means of pre-CPR DHI baseline (43.01) and SF baseline (14.08) scores respectively (Table 1).

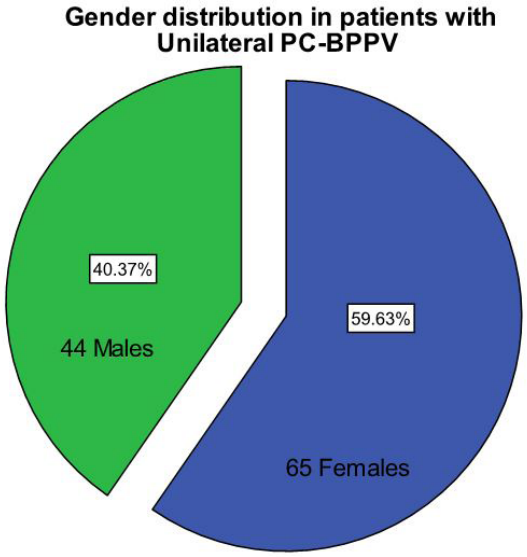

Figure 2. Gender distribution in patients with PC-BPPV

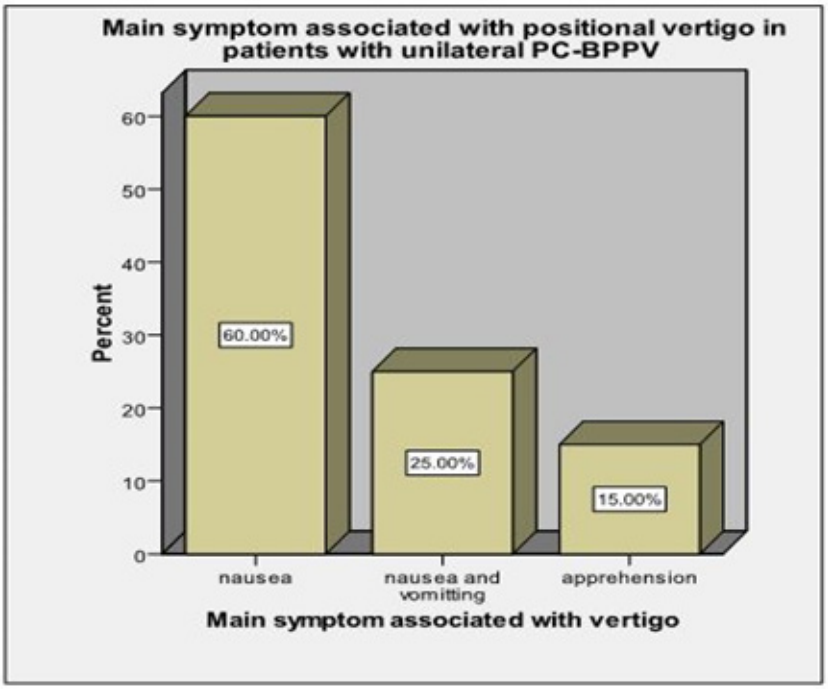

Figure 3. Main symptom associated with positional vertigo in patients with PC-BPPV.

Table 1. Age, Duration of vertigo and means of DHI and SF scores at pre and post-CRP sessions in 4 different Groups of patients: Group1, 2, 3 and 4 (no further treatment), (CIN for 1 week), (postural restriction for 1 week) and (both CIN + postural restriction for 1 week) respectively.

Case Summaries a,b

Groups		Age / years	vertigo/ days	DHI Baseline	DHI 1	DHI 2	DHI 3	SF Baseline	SF 1	SF 2	SF 3
G1	N	31	31	31	31	27	25	31	31	27	26
	Mean	58.87	6.32	45.42	21.68	11.19	4.00	14.71	7.97	3.93	1.15
	Std. Deviation	15.656	4.045	12.819	6.891	5.299	6.429	3.570	2.470	2.688	2.327
G2	N	27	27	27	27	23	21	27	27	23	21
	Mean	51.59	4.63	41.41	20.52	10.96	4.67	15.59	7.74	4.04	1.95
	Std. Deviation	13.706	2.884	8.409	7.371	6.263	7.439	3.041	2.314	2.364	2.711
G3	N	26	26	26	26	22	19	26	26	22	20
	Mean	52.46	4.27	42.15	22.38	7.00	4.84	13.73	7.88	2.45	1.55
	Std. Deviation	15.042	3.244	8.177	7.311	6.810	8.335	2.255	2.389	2.110	2.460
G4	N	25	25	25	25	21	18	25	25	21	19
	Mean	48.24	4.76	42.64	21.68	10.00	3.67	12.04	8.04	3.48	1.58
	Std. Deviation	16.808	3.778	8.655	7.931	7.797	6.481	1.925	2.541	2.337	2.388
Total	N	109	109	109	109	93	83	109	109	93	86
	Mean	53.10	5.06	43.01	21.56	9.87	4.29	14.08	7.91	3.51	1.53
	Std. Deviation	15.626	3.582	9.864	7.284	6.625	7.055	3.074	2.398	2.443	2.443

a. G1 (no further treatment),G2 (CIN for 1 week),G3 (postural restriction for 1 week) and G4 (both CIN + postural restriction for 1 week).

b. DHI and SF baselines (pre-CRP), DHI 1 and SF 1 (1 week post-CRP), DHI 2 and SF 2 (1 month post-CRP), DHI 3 and SF 3 (3 months post-CRP).

This descent in the scores continues as the time passes in consecutive post-CRP sessions, i.e., strong after 1 week (DHI 1 and SF 1 with mean differences 21.45 and 6.17 respectively), stronger after 1 month (DHI 2 and SF 2 with mean differences of 33.14, 10.56 respectively) and strongest after 3 months (DHI 3 SF 3 with mean difference of 38.72 and 12.55 respectively), the P values < 0.05, in these comparisons (Table 2).

Being the design of this study is based on 4 different independent groups using more than one nonparametric testes (DHI and SF), i.e., their data not assumed to follow the normal distribution, therefore Kruskal-Wallis 1-way ANOVA, was selected for analysis between groups which revealed: overall DHI 1, DHI 3, SF 1 and SF 3 namely (1 week and 3 months post-CRP) didn't show significant differences across groups, P value: 0.487, 0.933, 0.979 & 0.145 respectively ($P > 0.05$), indicating that there is no significant change in the distribution of vertigo evaluation scales across categories of different post-CRP measures (no further treatment, cinnarizine and/or postural restriction) in one week and 3months post-CRP sessions so the null hypothesis that the medians and the distribution of the DHI and SF scores across categories groups are the same was retained (Table 3).

For multiple comparison in both DHI 2 and SF 2 in addition to previously mentioned test both Jonckheere-Terpstra for k samples (test for ordered alternatives) and Median test k samples (to compare median across groups) were added for analysis in which they clearly

manifest the effectiveness of postral restriction (G3) over other three post-CRP measures in decreasing the mean ranks of both scales after one month post-CRP: Groups1, 2, 3 and 4 with DHI 2 mean rank of 59.78, 53.33, 29.39 and 42.1 respectively and SF 2 mean ranks of 53.5, 57.07, 29.95 and 45.48 respectively.

As it is obvious the mean ranks of G3 in both scales are lower than other Groups (Bold Data) influencing Asymptotic significances (except median test for SF 2) with P value incase of DHI 2: 0.000, 0.025, and 0.001 and incase of SF 2: 0.002, 0.437 and 0.043 for Kruskal, Median and Konckheere testes respectively (Table 3 and Figures 4 and 5). The scores of these patients (G3) also showed lower median rank than those of G4 (both CIN + postural restriction) DHI 2: 29.39, SF 2: 29.95 and DHI 2: 42.1, SF 2: 45.48 for G3 and G4 respectively, but these differences were not statistically significant.

Table 2. Mean and mean differences between pre-CRP and three post-CRP scores of DHI and SF scales.

	Test Value	t	df	Sig. (2-tailed)	Mean	Mean Difference	95% Confidence interval of the difference	
							Lower	Upper
DHI 1	Mean of DHI Baseline = 43.01	-30.743	108	0.000	22	-21.450	-22.82	-20.07
DHI 2		-48.236	92	0.000	9.9	-33.139	-34.50	-31.17
DHI 3		-50.004	82	0.000	4.29	-38.721	-40.26	-37.18
SF 1	Mean of SF Baseline = 14.08	-26.869	108	0.000	7.91	-6.172	-6.63	-5.72
SF 2		-41.737	92	0.000	3.5	-10.575	-11.08	-10.07
SF 3		-47.617	85	0.000	2	-12.545	-13.07	-12.02

Table 3. Multiple comparison for Asymptotic significance (A. Sig.) across grand means (GM) and mean ranks (MR) of DHI & SF scores in three Post-CPR sessions across 4 Different Groups using three Independent Samples Tests.

			Kruskal-Wallis Test				Median Test				Jonckheere-Terpstra Test			
Score	Total	Gs	MR	TS	DF	A. Sig.	TS	DF	GM	A. Sig.	TS	SE	STS	A. Sig.
DHI 1	109	G1	55.65	2.437	3	0.487	.595	3	20.000	0.898	2,341.500	182.245	.653	0.514
		G2	47.2											
		G3	59.19											
		G4	58.26											
DHI 2	93	G1	59.78	18.002	3	0.000	9.351	3	8.000	0.025	1,153.500	142.915	-3.2	0.001
		G2	53.33											
		G3	29.39											
		G4	42.10											
DHI 3	83	G1	42.78	.433	3	0.933	.866	3	2.000	0.834	1,225.500	116.922	-0.50	0.615
		G2	44.05											
		G3	41.03											
		G4	39.56											
SF1	109	G1	56.37	.194	3	.979	.478	3	7.000	0.924	2,214.500	179.611	-.045	0.964
		G2	52.89											
		G3	55.15											
		G4	55.42											
SF2	93	G1	53.50	14.486	3	0.002	2.716	3	3.000	0.437	1,331.000	140.953	-2.025	0.043
		G2	57.07											
		G3	29.95											
		G4	45.48											
SF3	86	G1	35.37	5.400	3	0.145	6.092	3	1.000	0.107	1,546.000	121.597	1.369	0.171
		G2	50.74											
		G3	43.75											
		G4	46.37											

Test Statistic (TS), Degree of Freedom (DF), Slandered Error (SE) & Slandered Test Statistic (STS) with Multiple comparison for Asymptotic significance (A. Sig.) across grand means (GM) and mean ranks (MR) of DHI and SF scores in three post-CRP sessions across 4 Different Groups using three Independent Samples Tests

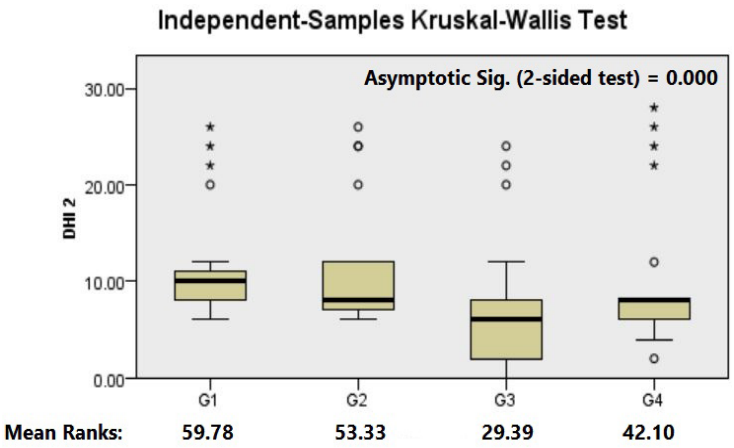

Figure 4. Mean ranks differences for DHI2 across 4 different Groups.

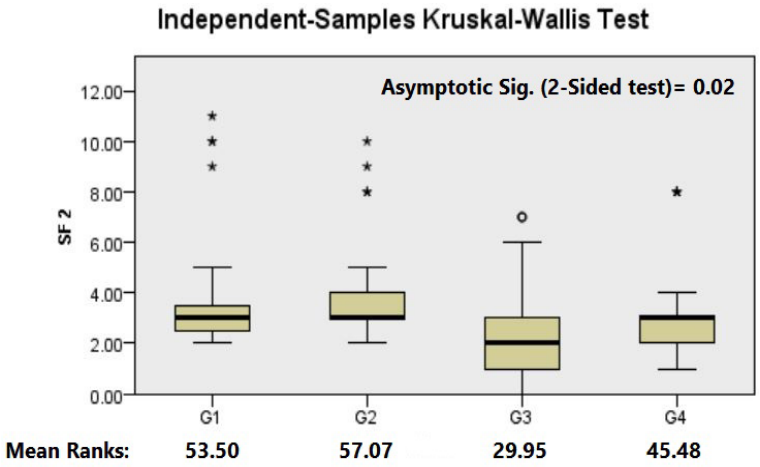

Figure 5. Mean ranks differences for SF2 across 4 different Groups.

DISCUSSION

In this study PC-BPPV causes moderate degree of handicap, the mean scores of DHI was 43.01 (< 52) while in Vereeck L, et al. (2007) the degree for the same disorder was mild (< 36), their pre-treatment DHI score was 31.5 [18]. This distance between the scores may be due to the alteration in subjective description for symptoms between peoples, which depends on many factors like region, gender, and socio-economic status.

The transparent decrease in the post-treatment scores in present study clarifies the effectiveness of CRP. Table 2 showed and replicated the efficacy of this repositioning procedure in majority of patients. This procedure have proved and remained as a 'gold standard' treatment for this disorder by achieving symptomatic relief after a single or short-term application [19-22]. Some patients of Group1 who received CRP alone showed positive DX and high scores in post-CRP evaluation scales in consecutive sessions but in spite of this, there were significant decrease in the mean of these post-CRP scores DHI 1, 2 and 3 and SF 1, 2 and 3 in comparison with their pre-CRP scores, the least mean difference between pre and post-treatment DHI 1 was 21.45 (Table 2) and this is a true change because it is more than 18 it indicates that satisfactory test-retest change has been demonstrated [16], confirming the effectiveness of the procedure alone in providing fast and long-lasting treatment in most patients who report complete symptoms resolution [23, 24].

Cinnarizine is a selective calcium channel blocker that has been used to prevent and treat vertigo. Several studies confirmed that this medication alone or in combination is an effective and well-tolerated option showing marked efficacy in the treatment of vestibular vertigo by decreasing the incidence of moderate and sever vertigo episodes [11, 25-28]. These objectives were supported by Kim, M. B., et al. (2014) who stated: after one-week follow-up, he concluded that: vestibular suppressants significantly reduced residual symptoms compared to both placebo and no medication after CRPs [29].

These conclusions were not replicated in our analysis, since multiple comparisons for scores of G3 in all post-CRP sessions (first, second and third) didn't disclose any significant differences across the other three groups including the control one (Table 3), we couldn't find any statistically significant data to support the effectiveness of cinnarizine with or without postural restriction as a post-CRP adjuvant therapy in enhancing the therapeutic effect of CRP.

In his study, even Kim, M. B., et al. who in favor of adjuvant vestibular suppressants couldn't notice significant reduction in DHI score compared with the control group.

Cinnarizine as a vestibular suppressant may interfere and delay the process of vestibular compensation. This process helps majority of patients with peripheral vestibular disorder to learn to function almost normally within few weeks or months and in most cases the BPPV symptoms spontaneously abate within few weeks.

Despite an improved understanding of vestibular neurochemistry, we lack a clear understanding of the mechanisms subserving vestibular compensation and the exact effect of commonly used drugs have on the vestibular system [30].

The lack of data in the present study to support effectiveness of postural restriction in group 3 and 4 over control group in first and third post-CRP sessions (1 week and 3 months) is inconsistence with several studies that concluded: post-maneuver restrictions do not add to the success of the treatment of BPPV and there is no reason to submit patients to these impractical instructions, even though most recent control studies state that there is no significant effect of post-maneuver postural restrictions on both treatment and recurrence rates [13, 31-34].

While in this study postural restriction was effective in decreasing frequency and intensity of vertigo particularly in the second post-CRP session (1 month), demonstrated a significant decrease in the mean rank of both DHI 2 and SF 2 scores in Gruop 3 (Table3) in comparison with that of (Group1, 2 and 4) patients, P value < 0.05.

Over all we concluded from these statistics that postural restriction has only a medium term effect (1 month) and it facilitate and promote therapeutic effect of CRP within the range of one month in the treatment of PC-BPPV. Such conclusion is in accordance with argue of the authors, who advocate such postural restrictions, that the period without head movements would facilitate the absorption or adhesion of otoconia to the utriculus otolithic membrane [13]. Burak et al. also concluded that: postural restriction enhances the therapeutic effect of the CRP in the treatment of PC-BPPV and should be applied in resistant cases, but they couldn't demonstrate the long-term efficacy of postural restriction in preventing BPPV recurrence [35].

Within 3 months follow-up in patients with unilateral PC-BPPV we conclude that CRP is an effective standard treatment, post-CRP adjuvant cinnarizine did not enhance the therapeutic effect of CRP, postural restriction enhance the therapeutic effect of CRP, by facilitating symptoms resolution within one month (medium term effect) and the effect of these post interventional adjuvant measures on recurrence of the disorder cannot be assessed in this study, it needs larger sample size and longer follow-up period.

Limitations of the study

• For the sake of the genuine answering and not haphazard dictation in dizzy patients we included only 2 evaluation forms to assess the symptoms, The European Evaluation of Vertigo scale (EEV) and Vestibular Disorders Activities of Daily Living scale (VDAL) were not included.

• The obedience of some patients regarding instruction was incomplete across all groups. Patients from G1&2 were conservative with their movement and avoiding to sleep on the symptomatic side. Few patients from G2 didn't take the tablets regularly. On the other hand several patients from Group 3 and 4 with supposed postural restriction reported difficulty to follow instructions completely.

• In spite the effort to arrange a suitable schedule for the patients to return for assessments still there were missing patients in the last 2 sessions especially the 3 month post-treatment follow-up.

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