INFLUENCE OF ANTIVERTIGO DRUGS ON POSTURAL BALANCE AND HEALTH-RELATED QUALITY OF LIFE OF INDIVIDUALS WITH DIZZINESS COMPLAINTS

Influência do tratamento com fármacos antivertiginosos sobre o equilíbrio postural e qualidade de vida de indivíduos com queixas de tontura

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ABSTRACT

Purpose: this study aimed to identify the influence of antivertigo drugs on the health-related quality of life and balance in adults and elder individuals with dizziness complaints. **Methods:** 51 individuals with dizziness complaints were enrolled at this cross-sectional study. The sample was divided into two groups according to chronic use of antivertigo drugs (medicated group, n=25 or non-medicated group, n=26). Information regarding vertigo-related symptoms, health-related quality of life (through *Dizziness Handicap Inventory*), dizziness intensity (measured by dizziness visual analogue scale) and postural balance (using a force platform) were assessed in all subjects recruited. **Results:** a moderate intensity of dizziness was observed (Mean: 4.6 ± 2.8) as well as negative impact on health-related quality of life (Mean: 47.3 ± 22.4) at this sample. When medicated and non-medicated groups were compared, no statistically differences were observed concerning dizziness intensity (p=0.74) and health-related quality of life (p=0.79). Similar results were observed regarding balance parameters (Unpaired t test, p > 0.05). However, after including the time duration of antivertigo drugs' use as a covariable of this study, a worse balance in different balance tasks was observed at the medicated group (ANCOVA, p<0.05). **Conclusion**: no beneffits concerning the symptoms or health-related quality of life were observed after chronic treatment with anti-vertigo drugs. On the other hand, worse balance control was observed in medicated group.

KEYWORDS: Dizziness; Quality of Life; Postural Balance; Medicines; Rehabilitation

INTRODUCTION

Dizziness, vertigo and postural instability are frequent symptoms in vestibular disorders and affect not only functional capacity, but also individuals' health-related quality of life (HRQoL) of both genders and different age range[1,2]. These symptoms result from unilateral peripheral dysfunction of the vestibular system or from the vestibular portion of the eighth brain nerve[3,4], usually with unknown etiology[5].

The peripheral vestibular system is located in the inner ear and its primary function is to assist in the maintenance of postural balance. Balance can be defined as the ability to maintain a stable position of the body based on the location of mass center and gravity during static and dynamic positions, such as gait patterns[6,7]. It is a complex process, involving the reception and integration of sensory stimuli (vestibular, visual and proprioceptive), in harmony with the central nervous system (CNS) and the

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Conflict of interest: non-existent

musculoskeletal, for the planning and execution of body movements[3,7.]

It is estimated that vestibular symptoms affect 5 to 10% of the population and the most common symptom appears after 65 years of age[8]. In adults, the prevalence is of 5% and the incidence of 1.4%, rates increase with the aging process and can be two to three times more frequent in woman[9,10]. Vestibular dysfunctions are present in 49.4% of seniors - 60 to 69 years old, rising to 84.8% in people over 80 years old[11].

The intensity and duration of clinical manifestations that follow vestibular disorders often compromise social activities, family relations and labor causing physical, financial and psychological limitations, such as loss of self-confidence, depression, as well as giving rise to decreased concentration and physical performance[12]. In absolute figures, there is a considerable portion of the population predisposed to functional limitations arising from vestibular dysfunction, which leads to lower HRQoL indexes[9,11]. It is noteworthy that postural control is also damaged in individuals with vestibular disorders[13,14].

Among most common treatment options for vestibular symptoms are drug treatment, repositioning maneuvers and vestibular rehabilitation. Regardless of the method applied, the goal is to control symptoms, reduce functional deficits and improve HRQoL of patients[2]. The pharmacological treatment with anti-vertigo drugs is the main approach for vestibular disorders amongst calcium channel blockers, anti-histamine drugs, antidopaminergic drugs and / or benzodiazepines[4,14].

On the other hand, due to high prevalence of dizziness complaints from patients, the appropriate course of action would be forwarding the patient for otorhinolaryngology care[15,16], once it is known that anti-vertigo drugs should be carefully used and for the shortest amount of time as possible[4,17].

Most importantly, the use of a single therapy mode may not be enough to complete resolution of vestibular complaints, as the pharmacological treatment can only provide temporary symptoms relief, but not the central compensation from the CNS-mediated mechanisms of neuroplasticity[18,19].

To date no study evaluating the clinical-functional impact of the use of anti-vertigo drugs on HRQoL and postural balance of adults of different age range. Moreover, the influence of the treatment duration with anti-vertigo drugs' on the same variables is not known. It is worth mentioning the limitations in the diagnosing criteria by clinical research and especially the methodological biases and qualitative approaches according to the current symptom of each individual[18,20]. In such case, the inclusion of quantitative measure, especially regarding postural balance, considered one of the main factors of falls among the elderly, becomes necessary to better clinical decision making.

The aim of this study was to evaluate the influence of anti-vertigo drugs treatment on health related quality of life and postural balance in older adults with dizziness complaints.

■ METHODS

This research is a descriptive, comparative cross-sectional study, with a quantitative approach, developed in the premises of a Physical Therapy Clinic of a higher education institution in Londrina-PR, from March 2012 to November 2013. The study was approved by the Ethics in Research Committee (Protocol no. 177.276/12) and all participants signed a written informed consent.

A convenience sample of individuals with complaints of dizziness was selected for the study, sent from different medical services in Londrina and region. Individuals were selected based on the following eligibility criteria described below: a) inclusion criteria - individuals of both genders, over 18 years old, with chronic vestibular dysfunction characterized by complaints of dizziness and / or balance disorders and / or other nonspecific feelings of dizziness which have been present for at least three months, forwarded by a doctor, with higher scores or equal to one point on the Visual Analogue Scale (VAS) Dizziness and / or bigger or equal to 16 points in the Dizziness Handicap Inventory (DHI). b) Exclusion criteria - individuals with visual and / or severe hearing impairment (detected during air and bone tonal threshold search), inability to understand and meet the simple verbal commands and / or inability to adopt the requested positions, due to orthopedic disorders and / or injuries of the nervous system that resulted in motor deficit and / or additional sensory, and / or peripheral vestibular, such as the benign paroxysmal positional vertigo (BPPV), identified from the patients records and showed the presence of positional nystagmus after Dix-Hallpike maneuver.

The study included 51 patients with chronic vestibular dysfunction, aged 20 to 83 years old. As for their current occupation, 14 (27.4%) were retired, 13 (25.6%) managed household activities, seven (13.7%) were teachers. The remaining functional and clinical data are shown in Table 1.

Table 1 – Clinical data of the sample (n= 51)

Variables	Categorias	Absolute Frequency (n)	Relative Frequency (%)
Gender	Female	43	84.3%
	Male	08	15.7%
Age range	20 – 40 years old	09	17.6%
	41 – 60 years old	20	39.3%
	> 60 years old or	22	43.1%
Symptoms' Period	< 1 year	15	29.4%
	1- 10 years	25	49.0%
	> 10 years	11	21.6%
Main Complaint	Dizziness	32	62.7%
	Dizziness and Tinnitus	11	21.6%
	Dizziness and Heavy head	08	15.7%
Period of Dizziness	Anytime	26	51.0%
	Morning/Afternoon	17	33.3%
	noite/madrugada	08	15.7%
Frequency of Dizziness	Daily	27	52.9%
	Weekly	11	21.6%
	Monthlyl/Sporadic	13	25.5%
Dizziness' duration	Seconds/Minutes	21	41.2%
	Hours/Days	30	58.8%
Dizziness' characteristics	Unbalance and Vertigo	16	31.4%
	Vertigo	12	23.5%
	Unbalance	19	37.3%
	Unbalance and Obscured vision	04	7,8%
Associated symptoms	Yes	49	96.1%
	no	02	3.9%

Initially, patients with complaints of dizziness were evaluated in the institution's Speech Therapy department for a hearing diagnostic assessment, which consisted of audiological anamnesis and pure tone audiometry. Afterwards, participants were evaluated by performing the diagnostic Dix-Hallpike maneuver in order to rule out recurrent symptoms due to BPPV. When the result was positive, the individual was treated through Epley, Semont or Brandt-Daroff maneuvers, according to the type of positional nystagmus on Dix-Hallpike by a specialized speech therapist. However, when the result of the diagnostic Dix-Hallpike was negative, the individual was referred to the physiotherapy department, and a physiotherapy assessment was conducted as described below: data collection was performed by a specialist physiotherapist, using a protocol which consisted of the following assessment tools: a) participant identification form, with personal data, anamnesis, additional otoneurological exams, medical history, use and treatment duration with anti-vertigo drugs, use of other medications and major complaints; b) evaluation form of vertigo symptoms, assessed through an interview, in order to find out about the following variables: clinical course of time (over one year), dizziness features, dizziness duration, frequency of dizziness and associated neurovegetative symptoms[19,20]. c) Dizziness Handicap Inventory Questionnaire (DHI) in order to evaluate the effects caused by dizziness on HRQoL. Used in many countries, this questionnaire was translated and adapted to the country's cultural background to use with the Brazilian population in 2007.

It consists of 25 questions that analyze the occurrence of damage on the physical aspects (seven questions), nine functional questions and nine emotional questions about daily activities of the individuals assessed. For each question, there are three possible answers: "yes" (four points), "sometimes" (two points) and "No" (zero). The maximum possible score is 100 points, and the

higher the value, the worse the perception of the individual's HRQoL. The rating was established by dysfunction established by Yorke et al.[21] as follows: mild (16 to 34 points), moderate impairment (36 to 52 points) and severe impairment (over 54 points); c) Dizziness Visual Analog Scale (VAS), indicating the intensity of vertigo symptoms, that varies on a numerical scale from zero to ten, where zero indicates the absence of dizziness and ten, the worst dizziness intensity[19].

This tool consists of a graphic-visual way to determine by self-report the intensity of dizziness during the evaluation; d) stabilometry to assess postural balance - the participants were evaluated on a force platform called BIOMEC400 (EMG System - Brazil, *SP Ltda*.), with data sampled at 100 Hz[22]. Center of pressure variables were used (COP in cm^2) and average speed of oscillation COP (VEL in cm / s) in both movement directions: anterior-posterior (A/P) and medio-lateral (M/L). Participants were evaluated in the standing position, barefoot, loose and relaxed upper limbs beside the body, with the head positioned horizontally at ground level, and eyes directed to a fixed target on the wall, at the same eye level, at a distance of 2.5 meters (for tests with eyes open) [22]. A protocol standardized by researchers was followed in four different conditions described below: 1) bipedal support with aligned feet with eyes open (BEO); 2) bipedal support, aligned feet with head rotation to the right and to the left, following audible feedback, using a metronome (BHR); 3) bipedal support in the position of semi-Tanden (right foot forward to the left foot or the other way around, according to participant's preference, with a slight space between feet and eyes open (STEO); and 4) eyes closed (STEC).

In each position, the patient should remain on the force platform for 30 seconds. Two samples were taken for testing, with an interval of 30 seconds between them. The order of positions was achieved through simple drawing lots made by the individual himself, before the tests began.

To meet study objectives, participants were divided into two groups: 1) medicated Group (MG), formed by subjects undertaking anti-vertigo drugs; 2) non-medicated group (NG), formed by subjects who did not use anti-vertigo medication. Anti-vertigo drugs used were: Betahistine dihydrochloride (8, 16 or 24 mg), dimenhydrinate (100 mg), Flunarizine (10 mg) and Ginkgobiloba extract (EGb 761) (40 mg).

Data were descriptively and analytically analyzed, in the Statistical Package for Social Sciences (SPSS) program, version 18.0 (Serial number: 180012). Categorical variables related to dizziness characteristics were presented by absolute and relative frequencies. To investigate the association between these variables and the use of anti-vertigo drugs, the *Chi* Square test was used.

In order to verify the data normality of numerical variables of the study, the Shapiro-Wilk test was used. For comparison between the GM and GN groups, we used the Student t test for independent samples, as the normality assumption was granted for groups. Finally, the ANCOVA test was performed to compare groups in order to reduce the error variance and adjust the average covariables "time of use of anti-vertigo medication" for all subjects in a fixed amount. A confidence interval of 95% and a significance level of 5% (p <0.05) was set for all tests.

■ RESULTS

Health-Related Quality of Life and dizziness intensity

The results from the DHI questionnaire analysis showed that vestibular symptoms caused negative impact on HRQoL of the participants, with a minimum of 16 and maximum of 96 points (Table 2). According to the standard stratification by Yorke et al.[21], 19 (37.2%) presented mild dysfunction, 13 (25.6%) had moderate impairment and 19 (37.2%) serious dysfunction. Apparently, the distribution of total scores and dimensions were similar in both groups.

Table 2 – Clinical and functional data, Dizziness Handicap Inventory (DHI) global and domains and Dizziness Visual Analogue Scale for global sample, for the medicated (MG) and non-medicated (NG) groups

Variables	Total (n=51) Mean ± SD	MG (n= 25) Mean ± SD	NG (n= 26) Mean ± SD	p (Unpaired t Test)	p (Ancova)
Age (years)	56.1±14.4	54.3±12.5	57.7±15.8	0.32	–
Symptoms' duration (years)	8.1±11.26	10.1±12.9	6.4±9.49	0.19	–
DHI total	47.4±22.4	46.6±23.4	48.1±21.9	0.79	0.39
DHI – Physical Aspects	17.2±6.4	16.6±6.9	17.7±5.9	0.89	0.33
DHI – Functional Aspects	17.9±9.6	17.4±9.7	18.3±9.6	0.86	0.40
DHI –	12.5±8.9	12.6±9.1	12.3±8.8	0.63	0.52
Dizziness Visual Analogue Scale	4.6±2.8	4.8±2.9	4.4±2.7	0.74	0.41

Notes: DHI – Dizziness Handicap Inventory; MG – Medicated Group; NG – Non-medicated Group; SD – Standard Deviation.

Dizziness EVA revealed that on the assessment day, the intensity of dizziness was moderate for most participants – the values: minimum (zero) and maximum (ten) were reported (Table 2). However, even when the score on this scale was zero, which denotes the absence of symptoms, the participant was included in the study to present scores greater than 16 points in DHI.

Postural Balance

In stabilometry, the permanence time was 30 seconds in all tests for 47 (92.2%) participants. Only four participants (7.8%) failed to complete the total time, especially in STEC and BHR tests, due to discomfort caused by the presence of symptoms at the time of testing. For those ones, the total permanence time was taken into consideration when processing the data (Table 3).

Table 3 – Stabilometric parameters for total sample, for the medicated and non-medicated groups

Variables	Total (n=51) Mean ± DP	MG (n= 25) Mean ± DP	NG (n= 26) Mean ± DP	p (Unpaired t Test)	p (Ancova)
BEO					
COP area (cm^2)	4.19±10.83	6.03±15.37	2.56±3.37	0.18	0.004*
VEL A/P (cm/s)	0.91±0.39	0.85±0.38	0.95±0.39	0.50	η =0.12
VEL M/L (cm/s)	0.65±0.32	0.66±0.41	0.64±0.21	0.82	
BHR					
COP area (cm^2)	3.63±2,57	4.41±3.10	2.94±1.77	0.77	0.004*
VEL A/P (cm/s)	1.20±0,37	1.18±0.30	1.22±0.43	0.47	η =0.24
VEL M/L (cm/s)	0.86±0,26	0.90±0.25	0.83±0.26	0.62	
STEO					
COP area (cm^2)	5.94±5.47	7.49±7.15	4.57±2.87	0.03*	<0.001*
VEL A/P (cm/s)	1.59±1.42	1.63±0.64	1.55±0.50	0.69	η =0.43
VEL M/L (cm/s)	1.42±0.50	1.40±0.44	1.44±0.55	0.78	
STEC					
COP area (cm^2)	9.66±8.61	11.49±11.03	8.04±5.42	0.09	<0.001*
VEL A/P (cm/s)	2.29±0.98	2.27±0.94	2.31±1.04	0.86	η =0.46
VEL M/L (cm/s)	2.17±0.90	2.07±0.77	2.26±1.01	0.40	

Notes: MG – Medicated Group; NG – Non-medicated Group; COP area – Center of Pressure Area; VEL – average Speed (Velocity); BEO – Bipedal support with Eyes Open; BHR – Bipedal support with Head Rotation; STEO – Semi-Tanden position with Eyes Open; STEC – Semi-Tanden position with Eyes Closed; A/P – antero-posterior; M/L – medial-lateral; η - effect size.

Comparison of clinical and functional variables concerning drug treatment, using the t test for independent samples

In the comparison between the GM and GN groups, there was no statistically significant difference in the DHI, dizziness VAS and the parameters analyzed in the four stabilometry tests. The significance values are described in Tables 2 and 3.

There was no association between the use of medication and categorical variables of the study: main complaint (p = 0.46), a period of crisis (p = 0.42), frequency of crisis (p = 0.53), characterization of crisis (p = 0.24), duration of crisis (p = 0.68) and associated neurovegetative symptoms (p = 0.15).

Comparison of clinical and functional variables in relation to drug treatment using a covariate "time of use of anti-vertigo medication"

Considering the time of use of anti-vertigo drugs as a covariate, no statistically significant differences were found between the GM and GN groups on total DHI and physical, functional and emotional aspects as well as dizziness VAS (Table 2). On the other hand, the value of COP area in the three test conditions on force platform was significantly influenced by the use of anti-vertigo drug (BEO: p = 0.004; BHR: p = 0.004; STEO: p = <0.001; STEC:

p = <0.001), after accounting for the effect of anti-vertigo drugs usage time as a covariate (table 3).

◼ DISCUSSION

There was a higher proportion of female subjects (84.3%) who reported dizziness complaints. According to Neuhauser and Lempert[9], dizziness is more frequent in women, with a ratio of 2:1, due to the association of vestibular disease, hormone and metabolic disorders and also women's bigger concern to seek medical advice in relation to men.

HRQoL proved to be impaired for all participants, with a total score greater than 16 points at DHI. According to Yorke et al.[21], this value indicates that dizziness has a negative impact on the daily life of individuals -scores higher than 10 points demonstrate the need for an evaluation of dysfunction patients by an expert.

The scores of the total DHI and its three areas were similar to those found in other baseline studies, such as Santos et al.[18], Hansson and Magnusson[23], Bayat et al.[24], Giray et al.[25], Patatas, Ganança and Ganança[26], Nishino, Granato and Campos[27], Morettin, Mariotto and Costa Filho[28] and Albera et al.[29]. It should be noted here that in studies where some form of treatment to minimize the vestibular symptoms was used, there was an improvement

in the HRQoL, with significant decreases in DHI questionnaire scores.

No statistically difference between the use or not of anti-vertigo drugs was observed with respect to the DHI (total and all domains) and EVA dizziness, when medication duration was assessed as a covariance with ANCOVA test. Therefore, one may assume that the pharmacological treatment with anti-vertigo drugs is not efficient for symptoms' relief. Santos et al.[18] reported in their study that the use of anti-vertigo medication was not associated with worse or better HRQoL when compared to subjects who did not use them. The assumption of the authors is that in chronic phase of decompensated vestibular disorders, pharmacotherapy alone did not have much effect related to the aspects investigated. These results could be explained by the sample characteristics sample in this study, composed primarily by individuals in the chronic phase of the disease (disease duration greater than one year), who only then turned to a non-drug treatment for the problem. Similarly, Meldrum et al.[30] suggest that the use of anti-vertigo medication should be done in the acute phase of vestibular dysfunction, and in chronic stages, the most suitable therapeutic approach is vestibular rehabilitation.

Still, poor performance in daily activities of patients with vestibular diseases can also occur by influences of impairment in postural control, since it may cause anxiety and fear, as well as difficulties in gait and orientation[24]. It is expected that individuals with complaints of dizziness show worse performance in tests on the force platform, especially in situations of vestibular stress, such as the conditions of closed eyes and unstable surface[31]. This occurs when one of the sensory components that interfere with postural control is faulty, for instance, the vestibular system, and as a result unpleasant reactions and symptoms may be present in everyday life[32].

The absence of a control group without vestibular complaints hindered this analysis to this study, since no studies that used similar stabilometric assessment methods were found. Bastos, Lima and Oliveira[5] made this comparison between individuals with and without vestibular complaints and found a different behavior between the two groups. The results obtained by individuals with complaints were considered abnormal when compared to subjects without complaints, showing that the vestibular dysfunction causes damage on postural control of individuals. Quitschal et al.[31] also described the occurrence of impaired postural control in patients with unilateral vestibular hypofunction, and observed changes in weight distribution and synchronization of postural sway right / left fingers / heels, predisposing these individuals to an increased risk of falls .

In analyzing the stabilometric parameters of postural balance in BOE, BHR, STEO and STEC tests using the ANCOVA test, a statistically significant difference in favor of natural gas was found. That is, besides not providing symptom improvement for GM, the use of anti-vertigo drugs negatively affected the performance on postural balance tests. Analyzing the values of the effect in these tests, it is clear that the use of these drugs at this stage of the disease can promote deleterious effect on the long-term balance. According to Soto and Vega[2], Singh and Singh[17]e Hain and Uddin[33] it is important to know the mechanism of action of drugs used in the treatment of vestibular dysfunction so that the indication is beneficial.

Inadequate drug use may worsen the symptoms presented by the patients with such disorder. Still, the duration of use of anti-vertigo medication should be carefully evaluated, because if used for prolonged periods, it can slow the central clearing/compensation that naturally occur by the SNC[34].

It is expected that the findings of this study may serve to clinical practice to alert health professionals, especially in primary care, in what refers to the appointment / prescription of anti-vertigo drugs, since the use of such drugs has not been associated with clinical improvement of patients with vestibular disorders in the chronic phase of the disease, and it may also predispose to the risk of side-effects when the use is prolonged and uncontrolled.

■ CONCLUSION

Vestibular symptoms had a negative impact on HRQoL of patients with vestibular complaints who make use or not of anti-vertigo drugs. However postural balance has worsened in individuals under-using such drugs.

RESUMO

Objetivo: avaliar a influência do tratamento com fármacos antivertiginosos sobre a qualidade de vida e o equilíbrio postural de adultos e idosos com queixas de tontura. **Métodos:** estudo transversal, com amostra de 51 indivíduos portadores de queixas de tontura, divididos em dois grupos, de acordo com o uso (grupo medicado, n=25) ou não (grupo não medicado, n=26) de fármacos antivertiginosos. Foram coletadas informações sobre: caracterização dos sintomas (ficha elaborada pelos pesquisadores), autopercepção de qualidade de vida (*Dizziness Handicap Inventory),* intensidade de tontura (escala visual analógica de tontura) e equilíbrio postural (plataforma de força). **Resultados:** verificou--se intensidade moderada de tontura (Média: 4,6 ± 2,8) e impacto negativo das vestibulopatias sobre a qualidade de vida (Média: 47,3 ± 22,4) na amostra total. Quando comparados os dois grupos, não houve diferença estatisticamente significante na intensidade da tontura (p=0,74) ou qualidade de vida (p=0,79), e também, nos parâmetros da estabilometria, em quatro tarefas (teste t independente, p>0,05). Contudo, após a inclusão do tempo de utilização de fármacos antivertiginosos como uma covariável do estudo, foi verificado pior desempenho nas diferentes tarefas da estabilometria no grupo medicado (ANCOVA, p<0,05). **Conclusão:** o uso de fármacos antivertiginosos não melhora a qualidade de vida de indivíduos com queixas de tontura e o equilíbrio postural esteve alterado no grupo medicado.

DESCRITORES: Tontura; Qualidade de Vida; Equilíbrio Postural; Fármacos; Reabilitação

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