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**Quality of Life in
Vertigo Patients:
A Double-Blind
Comparative Study
of a Homeopathic
Medication**

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Abstract

Quality-of-life issues and accurate observation of symptoms can be essential in selecting individually appropriate pharmaceutical therapy for vertigo. For this reason, the present study compares the effects of Vertigoheel and betahistine not only with regard to the frequency, duration, and intensity of vertigo attacks but also with regard to quality of life in patients with vertigos of varying etiology.

The double-blind study included a total of 119 patients from 15 practices. Treatment was administered three times daily for six weeks and consisted of either 15 drops of Vertigoheel or 6 mg of betahistine. Quality of life was assessed by means of two psychometric tests, the SF-36 Health Survey and a vertigo-specific questionnaire. Quality of life (measured in terms of both physical and psychological well-being) improved significantly during therapy with Vertigoheel, which proved to be equivalent to betahistine therapy.

Keywords: Vertigoheel, betahistine, vertigo, clinical study, quality of life

Introduction

Nearly 10% of all patients seen by physicians in family practice name dizziness as one of the symptoms of their health problem (1). Primary-care physicians often wonder whether an initial physical examination and a few simple, common tests of coordination can adequately pinpoint the cause of this condition or whether the patient will have to be referred to a specialist for further examination. In most cases, targeted tests of coordination can indeed determine the exact etiology and severity of the vertigo. If needed, more extensive examination may include nystagmus analysis, electronystagmography, or posturography (2).

A patient who fears sudden attacks of vertigo may avoid physical exertion and psychological stress and withdraw from social activities. Because such avoidance is often associated with depressive loss of self-esteem that affects the patient's subsequent behavior, therapeutic measures target both the frequency and the severity of the attacks in order to improve the patient's quality of life and thus his or her subjectively perceived state of health.

The findings of various research groups, however, reveal that patients' overall clinical pictures involve more than just the objectively determined degree of severity of their vertigo. In the process of subjective evaluation and care of individual vertigo patients, physicians repeatedly find that even when they observe and document similar clinical conditions and functional limitations in patients, substantial differences are evident in these patients' behavior and subjective perceptions of health. Depending on personality, life situation, and individual values the burden of

suffering that the basic ailment imposes on individual vertigo patients varies significantly (3). Therefore, assessment of a patient's total situation must include not only technologically measurable and quantifiable symptoms but also the patient's subjective perception of the severity of his or her illness as it impacts quality of life. This perspective has reopened the discussion on a number of pharmacological therapies, including not only antivertigo drugs but also antihistamines and hemorheological medications; increasingly, their therapeutic value is being considered from additional perspectives. This basic approach was given special consideration in the current clinical trial of Vertigoheel (drops) versus betahistine in patients with vertigos of varying etiology.

COMMENTARY

A randomized double-blind study by Weiser et al. comparing the efficacy of Vertigoheel and betahistine was published in *Arch Otolaryngol Head Neck* 1998. While that first paper focussed on efficacy and tolerance of the two medications, this second article adds the parameter of quality of life and is therefore more than just an afterthought to the first. Taken together, these two papers provide an example of evidence-based medicine. This procedure should become the accepted standard because it demonstrates how quality control can be implemented in biological medicine. The results of this study, by confirming the equivalence of the antihomotoxic medication and the allopathic drug in improving quality of life, also document the cost effectiveness and lack of adverse effects of antihomotoxic therapy for mild forms of vertigo.

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Criteria

Question 1:

In general, would you say your health is:

Scale:

excellent; very good; good; fair; poor

Question 2:

Compared to one year ago, how would you rate your health in general now?

Scale:

much better now than one year ago; somewhat better now than one year ago; about the same as one year ago; somewhat worse than one year ago; much worse than one year ago.

Question 3:

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

- a. Vigorous activities such as running, lifting heavy objects, participating in strenuous sports
- b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
- c. Lifting or carrying groceries
- d. Climbing several flights of stairs
- e. Climbing one flight of stairs
- f. Bending, kneeling, or stooping
- g. Walking more than a mile
- h. Walking several hundred yards
- i. Walking one hundred yards
- j. Bathing or dressing yourself

Scale:

yes, limited a lot; yes, limited a little; no, not limited at all

Question 4:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

- a. Cut down on the amount of time you spent on work or other activities
- b. Accomplished less than you would like
- c. Were limited in the kind of work or other activities
- d. Had difficulty performing the work or other activities (for example, it took extra effort)

Scale:

yes, no

Question 5:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

- a. Cut down on the amount of time you spent on work or other activities
- b. Accomplished less than you would like
- c. Did work or activities less carefully than usual

Scale:

yes, no

Question 6:

During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or circle of acquaintances?

Scale:

Not at all; slightly; moderately; quite a bit; extremely

Question 7:

How much bodily pain have you had during the past 4 weeks?

Scale:

none; very mild; mild; moderate; severe; very severe

Question 8:

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Scale:

not at all; a little bit; moderately; quite a bit; extremely

Question 9:

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

- a. Did you feel full of life?
- b. Have you been very nervous?
- c. Have you felt so down in the dumps that nothing could cheer you up?
- d. Have you felt calm and peaceful?
- e. Did you have a lot of energy?
- f. Have you felt downhearted and depressed?
- g. Did you feel worn out?
- h. Have you been happy?
- i. Did you feel tired?

Scale:

all of the time; most of the time; some of the time; a little of the time; none of the time

Question 10:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

Scale:

all of the time; most of the time; some of the time; a little of the time; none of the time

Question 11:

How TRUE or FALSE is each of the following statements for you?

- a. I seem to get sick a little easier than other people
- b. I am as healthy as anybody I know
- c. I expect my health to get worse
- d. My health is excellent

Scale:

definitely true; mostly true; don't know; mostly false; definitely false

Tab. 1: The SF-36 Health Survey for evaluating quality of life (German version).

Vertigoheel, manufactured by Biologische Heilmittel Heel GmbH of Baden-Baden, is a homeopathic medication containing the ingredients Ambra 6X, Cocculus 4X, Conium 3X, and Petroleum 8X. Several studies have confirmed the efficacy of this combination in treating vertigos of varying etiology (4-6, 12). In the present study, the antivertigo drug betahistine, an H₃ receptor antagonist, served as the reference substance. This drug has been widely tested in clinical studies; available data on it are abundant and include direct comparisons to other reference substances

(antivertigo drugs, calcium antagonists, neuroleptics, and placebos) (7-11).

The results of the present study were first published in 1998 in a paper that focussed on assessing the effects of Vertigoheel and betahistine on the frequency, duration, and intensity of vertigo attacks and only briefly discussed the results of psychometric testing (12). For reasons mentioned above, however, a more detailed investigation of patients' subjective state of health and the issue of quality of life is of particular interest. The purpose of the pre-

sent paper is to convey the results of the study's psychometric assessments of quality of life and to investigate this aspect of the performance of Vertigoheel and betahistine in a direct comparison test.

Methods

Design of the Study

For the purpose of daily comparison of the efficacy of Vertigoheel and betahistine against vertigo over a treatment period of six weeks, the study was conceived as a multicentric, randomized, double-blind

Criteria

Category 1:
direct symptoms of vertigo

Question:

How would you rate the severity of the following symptoms in any vertigo attacks you had since your last visit?

- a. rotating sensation
- b. swaying sensation
- c. sensation of being elevated
- d. everything goes black
- e. everything gets blurry
- f. general unsteadiness
- g. disturbed coordination

Scale:

nonexistent; slight; moderate; severe; very severe

Category 2:
intensity of vertigo attacks during specific activities

Question:

Since your last visit, how bad have your attacks of vertigo been when you

- a. turned your head?
- b. bent over?
- c. stood up?
- d. lay down?

Scale:

no sensation of vertigo; very mild; moderate; severe; very severe

Category 3:
symptoms associated with vertigo

Question:

Since your last visit, how often have you experienced the following symptoms in connection with attacks of vertigo?

- a. physical weakness and exhaustion
- b. difficulty in seeing
- c. difficulty in hearing
- d. tinnitus
- e. headache
- f. palpitations
- g. trembling limbs
- h. gastrointestinal disturbances
- i. nausea
- j. a feeling of heaviness and pressure in your head
- k. an empty feeling in various body parts or organs
- l. general mental exhaustion
- m. light-headedness
- n. difficulty in concentrating
- o. restless sleep or insomnia
- p. nervousness
- q. fatigue
- r. forgetfulness
- s. anxiety

Scale:

never; seldom; sometimes; often; very often

Category 4:
limitations on daily activities

Question:

How true is each of the following statements about how you have been since your last visit?

- a. I was afraid of falling
- b. I was afraid that my illness would get worse
- c. I had trouble with fast movements
- d. I had trouble driving or using public transportation (bus/train)
- e. I had trouble getting up from a lying position
- f. I had trouble standing up from a sitting position
- g. I had trouble reading
- h. It was hard for me to climb stairs
- i. It was hard for me to go down stairs
- j. It was hard for me to move around in the dark
- k. It was hard for me to leave the house/apartment
- l. It was hard for me to look down
- m. It was hard for me to do housework

Scale:

not true at all; a little bit true; moderately true; mostly true; very true

Tab. 2: Vertigo-specific questionnaire for evaluating quality of life

clinical test comparing parallel groups. The double-dummy technique with corresponding placebos was implemented to maintain the double-blind procedure (for details, see (12)). Each patient kept a daily record of frequency, duration, and intensity of vertigo attacks and assessed these primary variables using a four or five-point rating system. To assess quality of life, each patient completed the SF-36 Health Survey and a vertigo-specific questionnaire (see Tables 1 and 2) on the first and last days of treatment (visits 1 and 6).

Patient Demographics

Patients with acute or chronic vertigos of varying etiology (including Menière's disease and vasomotor disturbances) were included in the study. Excluded, for example, were patients with vertigo caused by autonomic dysregulation, tumors, or consumption of caffeine, nicotine, or alcohol. Concomitant treatment with other anti-vertigo drugs was not permitted during

the study. The duration of treatment for each patient was six weeks; the dosage was 3x15 drops of Vertigoheel or 3x6 mg of betahistine per day (for details, see (12)).

The criteria targeted in assessing efficacy were:

- frequency, duration, and intensity of the vertigo attacks (patient diaries)
- vertigo-specific symptoms (vertigo-specific questionnaire)
- quality of life (normed SF-36 questionnaire)
- general efficacy ratings by patients and physicians.

Quality-of-Life Questionnaire

The SF-36 Health Survey is a general instrument for assessing health-related quality of life; it is not illness-specific (13). This psychometric test was originally developed for use in English-speaking countries, but meanwhile the normed

German version has also performed well in terms of its scale structure and reliability in several series of tests on healthy and ill individuals. The SF-36 questionnaire consists of 11 questions and 36 subquestions in these 8 categories: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health (Table 1).

Where needed, scores for individual questions were transposed so that high scores uniformly reflected positive assessments of quality of life. Scores in each category were then totaled and converted into a score on a scale of 0 to 100 (converted score = 100 x [actual total score - lowest score] / range). Thus a score of 0 corresponds to the lowest quality of life and a score of 100 to the highest quality of life. For each of the two treatment groups, average values were calculated for the total score in each category at visit 1 and visit 6 and for the difference between visit

Category	Vertigoheel				Betahistine			
	V1	V6	Diff.	Statistics	V1	V6	Diff.	Statistics
1. Direct symptoms of vertigo	58.5	87.1	+28.6	P<0.001	64.4	90.2	+25.8	P<0.001
2. Intensity of vertigo attacks during specific activities	53.6	82.9	+29.3	P<0.001	58.4	87.1	+28.7	P<0.001
3. Symptoms associated with vertigo	65.2	84.2	+19.0	P<0.001	72.8	89.6	+16.8	P<0.001
4. Limitations on daily activities	47.9	59.7	+11.8	P<0.001	49.7	62.2	+12.5	P<0.001

Tab. 3: Vertigo-specific questionnaire. V1 = score at beginning of treatment; V6 = score after six weeks of treatment; Diff. = difference; Statistics: Wilcoxon-Pratt test (2-tailed)

6 and visit 1. In this scoring system, positive differences correspond to increases in quality of life. Mann-Whitney statistics and the left boundaries of the 90% confidence interval served as standards of relevance for differences that appeared over the course of treatment.

Vertigo-Specific Questionnaire

This self-assessment questionnaire for evaluating the course of the illness consists of four categories of questions. The first category deals with the severity or intensity of sensations contributing to vertigo, the second with activities that trigger vertigo, the third with related symptoms, and the fourth with other physical and

emotional concomitant phenomena (Table 2). Individual questions were scored from 0 to 4, with 0 representing a total absence and 4 great severity of the symptom in question. After transposing each individual score (4 - original score), total scores were calculated for each category and converted to a scale of 0 to 100 (converted score = [actual total score/highest possible total score] x 100) for easier comparison. In each treatment group, average scores were calculated for each visit and for the difference between final and initial status (visit 6 and visit 1). In this scoring system, positive differences correspond to improvements in health. Here, too, Mann-Whitney statistics and the left boundaries

of the 90% confidence interval served as standards of relevance for differences appearing over the course of treatment.

Results

Vertigo Attacks

In total, 119 patients (59 in the Vertigoheel group and 60 in the betahistine group) from 15 licensed family practices participated in the study. (Due to protocol violations, 14 of these 119 patients were excluded from statistical analysis of efficacy.) The two treatment groups were equivalent in terms of demography and patients' medical histories. Statistical evaluation revealed significant and clinically relevant reductions in the frequency, duration, and intensity of vertigo attacks (the primary criteria) in both groups during the six-week treatment period. The reductions were statistically equivalent in the two groups (for details, see (12)).

Quality of Life

The recorded data confirm that at the beginning of treatment, all patients had experienced often considerable declines in their quality of life. Such declines were especially evident in the "vitality" and "role-emotional" areas (in the mental health summary measure) and in the "role-physical" and "general health" areas (in the physical health summary measure). The significant and clinically relevant reduction in vertigo attacks (in terms of duration, intensity, and frequency) that was documented during the six-week treatment period was paralleled by improvement in quality of life in both treatment groups. Statistically, the

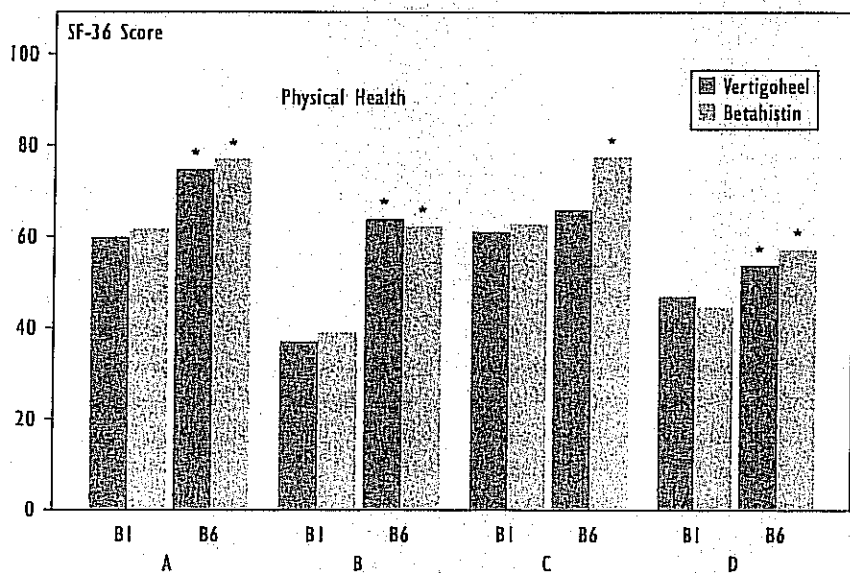


Fig. 1: The influence of Vertigoheel and betahistine on quality of life (summary measure: physical health) in patients with vertigo. V1 = initial score (beginning of treatment); V6 = final score (after six weeks of treatment); A = physical functioning; B = role-physical; C = bodily pain; D = general health. *Wilcoxon-Pratt test (2-tailed; P<0.05)

improvement in quality of life was equivalent in the two groups (Figures 1 and 2).

Vertigo-Specific Questionnaire

In the psychometric test of vertigo symptoms, significant improvement in all items was observed in both treatment groups and corresponded to positive change in quality of life. For example, subjective vertigo-related impairments (palpitations, gastrointestinal symptoms, light-headedness, nervousness, or sleep disorders) decreased significantly under both treatment protocols, and the decreases were equivalent in the two treatment groups (Table 3).

Evaluation of Therapy

Assessments of the efficacy of the therapies by both physicians and patients corroborated the results of the psychometric tests. A majority of the physicians and patients rated the efficacy of therapy as "very good" (= complete freedom from symptoms) or "good" (= obvious improvement). According to the physicians' ratings, symptomatic improvement was achieved in 94% of the Vertigoheel patients and 83% of the betahistine patients (for details, see (12)).

Discussion

The purpose of this study was to compare the efficacy of Vertigoheel (drops) to that of betahistine in outpatients with vertigos of varying etiology during a six-week treatment period. In addition to the primary criteria (frequency, duration, and intensity of vertigo attacks) the study also recorded the effect of therapy on quality of life as measured by the SF-36 Health Survey and a vertigo-specific questionnaire. The antivertigo drug betahistine served as a recognized reference substance whose efficacy in suppressing typical vertigo symptoms and improving patients' sense of well-being had already been documented by clinical studies (7, 8, 11). In both treatment groups, significant and clinically relevant reductions in vertigo attacks occurred over the course of the six-week treatment period. Clinically relevant reductions in subjective symptoms were also apparent in both groups

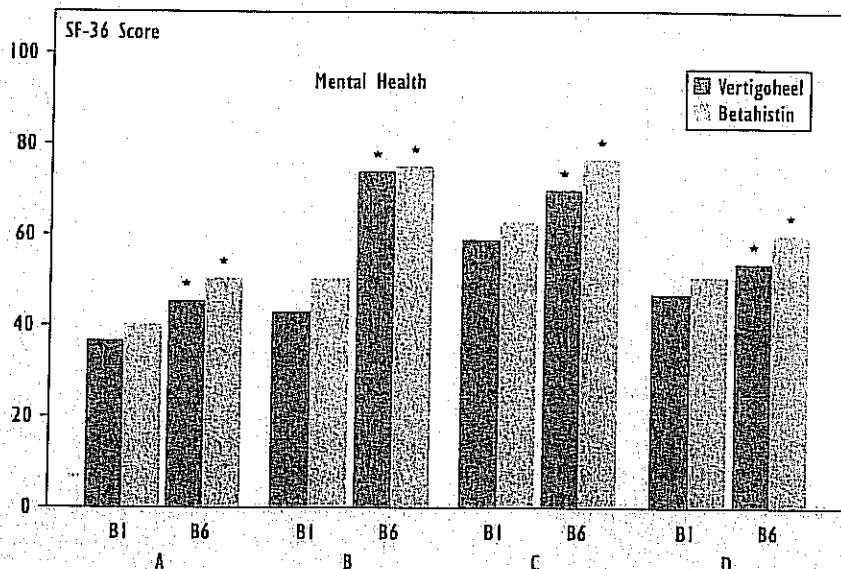


Fig. 2: The influence of Vertigoheel and betahistine on quality of life (summary measure: mental health) in patients with vertigo. V1 = initial score (beginning of treatment); V6 = final score (after six weeks of treatment); A = vitality; B = role-emotional; C = social functioning; D = general mental health. *Wilcoxon-Pratt test (2-tailed; P<0.05)

and corresponded to improvements in health-related quality of life. The changes in individual symptoms (severity of the vertigo and the intensity of sensations contributing to it) in the vertigo-specific scoring system revealed significant trends toward higher scores. In some instances, the average improvements amounted to nearly 50% of pretreatment scores.

A great deal of concentrated scientific effort has gone into developing and applying standard international guidelines for documenting and assessing quality of life in individuals with specific illnesses. The example of the SF-36 survey administered in the present study very clearly demonstrates both the immensity of the preparatory work involved in developing qualitative procedures internationally suited to assessing health-related quality of life and the substantial effort required for methodologically adequate conversion of a test instrument for use in other languages. Success on the international level, however, facilitates analysis of multinational clinical studies and research on international issues of health and health economics. In England, public health facilities have already begun

to implement psychometric procedures to help determine the need for suitable therapies and quantify the effects of therapies (14).

The present study approaches the assessment of quality of life from the perspectives of both mental and physical health. The participating patients became more contented and took more initiative; they felt more capable of climbing stairs, driving, or moving about in the dark, for example, without fear or recourse to outside assistance. They experienced significantly fewer limitations on both domestic and recreational activities than at the beginning of treatment, and their sense of being able to perform various tasks well increased significantly. Because they felt less constrained by psychological problems, their social behavior also normalized.

In a study of postcoronary patients in the rehabilitation phase, Denollet et al. demonstrated that social integration and activation of social contacts, as expressions of quality of life, are significant for prognosis (15). In the first two to five years after their heart attacks, the patients

belonging to Denollet's Type D ("distressed personality"), which is characterized by severe depression and social alienation, had a mortality rate four times that of the patient group as a whole.

In summary, the results of the present study demonstrate that treating vertigo patients with Vertigoheel produces obvious improvement in both physical and mental health (as expressions of quality of life) and that the effects of Vertigoheel are comparable to those of betahistine. Furthermore, the safety of both forms of therapy is confirmed.

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