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AN INTEGRATIVE REVIEW OF THE EVIDENCE ON THE MEDICATION VERTIGOHEEL

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Introduction. Vertigoheel is multicomponent homeopathically produced medication that used for the bioregulatorytherapy of dizziness of various origins, including dizziness associated with motion sickness.

Objective: to review the scientific literature on the efficiency of using Vertigoheel to treat dizziness.

Material and methods. The available data on Vertigoheelwere analyzed using an integrative approach, i.e. mixed methods. The analysis includedboth the determination of the level of evidence, by applying a hierarchical grading system, and the assessment of the data by non-hierarchicalmethods.

Results. Eleven works, including 1 review, 2clinical trials, 7 observationalstudies, and one basic researchstudies were analyzed.

Conclusion. Studies on Vertigoheel comprise are a multifaceted and diverse evidence-base that increases every year. The integrative approach isof value in the context of individualized medical care.

Key words: bioregulatory therapy, dizziness, integrative approach, evidence base.

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INTRODUCTION

Vertigoheel is a homeopathic medicinal product that is applied according to bioregulatory principles derived from a homotoxicological approach and, therefore, also called an *antihomotoxic preparation*. It is multicomponent and has been shown to have a multitarget action in the endothelial vascular network. Vertigoheel is used for dizziness of various origins, including dizziness associated with motion sickness.

The data for this review was obtained via a search of the literature using the search term «Vertigoheel» in the title and/or abstract and/or keywords of the article. In addition to this, available studies were requested from, and made available by, Biologische Heilmittel Heel.

The main objective of this study was to obtain an overview of the evidence on the use of Vertigoheel for its main registered indication, as stated above.

METHODS

This review applied an integrative, «mixed methods» approach with regard to the available data on Vertigoheel. This involved grading the level of evidence using one of the classical hierarchical evidence grading systems and complementing this by a non-hierarchical assessment of the available data.

For determining the level of evidence of each of the identified studies, the OCEBM 2011 Levels of Evidence schedule1 for treatment benefits was used.

Figure 1. Evidence Mosaic

For the nonhierarchical evidence classification, the evidence mosaic categories as depicted in Figure 1 were used. In the «evidence mosaic» [2] approach, use is made of the metaphor that different research methods, each with their strengths and weaknesses, contribute to a «mosaic» of evidence.

RESULTS

Studies on all types of vertigo were included. Eleven studies were identified, consisting of one review paper by Schneider [3]; two clinical trials by Weiser (1998) [4] and Issing [5] respectively; seven observational studies by Wolschner [6], Strösser [7], Rabe [8], Seeger-Schellerhoff [9], Sedláček [10], Weiser (2000) [11], and Klopp [12] and one basic research study by Heinle [13].

The main characteristics of the Vertigoheel studies as well as the evidence grading in accordance with the OCEBM Levels of Evidence Schedule are summarized in the Table.

The Table illustrates that treatment benefits of Vertigoheel are supported by the following levels of evidence: one review paper was graded as level-1 evidence; two clinical trials, level-2 evidence; seven observational studies, level-3 evidence, and one basic research study, level-5 evidence.

The level-1 evidence was provided by a meta-analysis [3] of four of the vailable studies. The two

SUMMARY OF THE MAIN CHARACTERISTICS OF THE INCLUDED VERTIGOHEEL STUDIES AND EVIDENCE GRADINGA

Study design	First author (year)	Objective	OCEBM evidence level treatment benefits
Prospective reference-controlled cohort study	Wolschner (2001) [6]	To investigate the effectiveness and tolerability of Vertigoheel compared to dimenhydrinate in the treatment of dizziness	3
Prospective reference-controlled cohort study	Strösser (2002) [7]	To investigate the effectiveness and tolerability of Vertigoheel compared with dimenhydrinate in the treatment of nonvestibular vertigo	3
Prospective reference-controlled cohort study	Rabe (2003) [8]	To investigate the effectiveness and tolerability of Vertigoheel compared with dimenhydrinate in the treatment of cardiovascular vertigo	3
Prospective comparative cohort study	Weiser (2000) [11]	To compare the effectiveness and tolerability of Vertigoheel with betahistine in regular therapy	3
Prospective comparative cohort study	Klopp (2005) [12]	To compare the action of Vertigoheel on markers of microcirculatory function with untreated controls	3
Prospective cohort study	Seeger-Schellerhoff (2009) [9]	To investigate the effectiveness and tolerability of Vertigoheel for the treatment of vertigo in elderly hypertensive subjects in a general practice setting	3
Prospective cohort study	Sedláček (2011) [10]	To examine the clinical use of Vertigoheel in the management of patients with transient ischemic attack (TIA)	3
Randomized, double-blind, controlled clinical trial	Weiser (1998) [4]	To compare the efficacy and safety of Vertigoheel with betahistine hydrochloride in the treatment of patients with vertigo of various origins	2
Prospective randomized, double-blinded, parallel group study	Issing (2005) [5]	To demonstrate that Vertigoheel is noninferior to phytotherapy with *Ginkgo biloba* in elderly patients with atherosclerosis-related vertigo.	2
Meta-analysis of studies with active controls	Schneider (2005) [3]	To demonstrate noninferiority of Vertigoheel to active control in a meta-analysis of 4 available clinical studies comparing Vertigoheel with usual therapies (betahistine, *Ginkgo biloba* extract, dimenhydrinate)	1
Basic research, *in vitro*	Heinle (2010) [13]	To test the hypothesis that Vertigoheel has vasodilatory effects via the stimulation of adenylate and/or guanylate cyclase pathways	5

trials that provide level-2 evidence were included in this meta-analysis, complemented by two of the reference-controlled noninterventional studies by Weiser [11] and Wolschner [6]. This meta-analysis confirmed that Vertigoheel was noninferior to active comparator products with regard to changes in the frequency, duration, and intensity of vertigo attacks.

The available clinical trial data is supplemented by seven observational studies (level-3 evidence) that further support the effectiveness and safety of Vertigoheel in various types of vertigo, including vestibular and circulation-related vertigo. One study in patients with vestibular vertigo suggested a possible influence of Vertigoheel on the subcutaneous microcirculation [12]. Another observational study indicated that Vertigoheel is also active in specific subpopulations, such as hypertensive patients older than 50 years of age [9]. The basic research study provides support for mechanism-based reasoning of an action on microcirculation via a variety of pathways [13].

Using the OCEBM Levels of Evidence Schedule, there is some of the highest level-1 and level-2 evidence supporting the efficacy of this product. In addition, there is a considerable body of level-3 evidence supporting the effectiveness and safety of the use of Vertigoheel in daily practice in a broad mix of vertigo patients. Some level-5 evidence is available that supports the biological plausibility of a possible action on microcirculation mediated via vasorelaxant properties of Vertigoheel's ingredients. The Vertigoheel evidence mosaic categories are visualized in Figure 2.

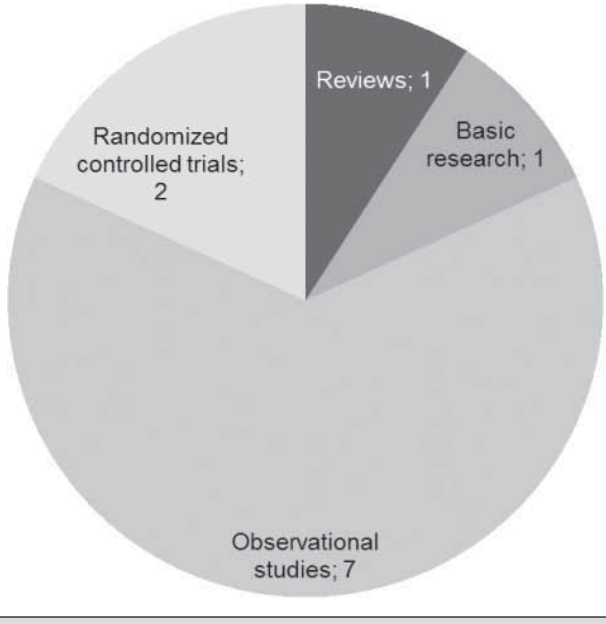

Figure 2. Vertigoheel Evidence Mosaic Chart

Figure 2 illustrates that the evidence base of Vertigoheel is supported by a broad mix of data. Added value is provided by coherence between data from the different sources. For instance, noninferiority to *Ginkgo biloba* in the trial by Issing et al [5] in patients with atherosclerosis-related vertigo suggests that improved circulation, a well-established effect of *Ginkgo biloba*, plays a possible role in Vertigoheel's efficacy. This is further supported by the observational study by Seeger-Schellerhoff et al [9], which demonstrates that Vertigoheel is associated with clinically relevant symptomatic improvements in hypertensive patients older than 50 years of age, a subpopulation in which problems with circulation are more likely to play a role in the vertigo pathogenesis. The establishment by Klopp et al [12] of objective changes in the microcirculation of patients treated with Vertigoheel is consistent with the available clinical data. The in-vitro study by Heinle [13], which in isolation does not provide strong evidence, makes sense if seen in conjunction with the above-mentioned evidence. Therefore, looking at these different sources of evidence in a more integrative manner can provide added value. Synergy is created when the available evidence fits well in a mosaic of evidence which points to a coherent and consistent pattern in the available data; this is where «the whole becomes more than the sum of the parts». The Table in conjunction with Figure 2 illustrates that such synergies are available in the evidence base of Vertigoheel.

DISCUSSION

The review of the data on Vertigoheel indicates that there is convincing evidence that Vertigoheel is effective and safe in the treatment of different types of vertigo in heterogeneous, including the elderly, patient populations.

Vertigoheel appears to act as a multicomponent drug via multiple pathways, making not only the mode of action, but also the relative safety compared to single-component, single-target drugs biologically plausible.

Whilst high-level evidence on Vertigoheel in the management of vertigo is available, some weaknesses and areas of improvement in the evidence base are worth mentioning. The trial evidence of Vertigoheel could be further strengthened by a placebo-controlled clinical trial. The observational study by Klopp et al

[12] on microcirculatory function has a relatively low number of subjects, and the identification and selection of the control group are not well described; therefore, some caution with regard to the comparisons made is in place.

Whilst promising preclinical data is available that supports a possible action of Vertigoheel on the microcirculation, this evidence is still preliminary and it does not exclude the possible involvement of other, yet to be confirmed, modes of action of Vertigoheel, such as central compensation in some types of vertigo.

The available data on Vertigoheel suggest that there is a growing and multi-faceted evidence base for this product. In our opinion, obtaining such an integrative, multifaceted perspective on the available evidence provides significant added value as a source for informing individualized patient care.

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ИНТЕГРАТИВНЫЙ ОБЗОР ДОКАЗАТЕЛЬНОЙ БАЗЫ ДЛЯ ПРЕПАРАТА «ВЕРТИГОХЕЛЬ»

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РЕЗЮМЕ

Введение. «Вертигохель» – многокомпонентный препарат, произведенный по гомеопатической технологии. Препарат предназначен для биорегуляционной терапии головокружений различного генеза.

Цель публикации – обзор литературы, в которой представлены данные об эффективности и безопасности препарата «Вертигохель» для лечения головокружений.

Материал и методы. Доступные данные по препарату «Вертигохель» анализировали с использованием интегративного подхода, т.е. смешанных методов. Анализ включал как определение уровня доказательности с помощью иерархической системы классификации, так и оценку данных неиерархическими методами.

Результаты. Проанализированы 11 работ, в том числе: 1 обзор, 2 клинических исследования, 7 исследований и 1 фундаментальное исследование.

Вывод. Доказательная база препарата «Вертигохель» многогранна и разнообразна, причем ее данные пополняются каждый год. Интегративный подход имеет ключевое значение в плане персонализированной терапии.

Ключевые слова: биорегуляционная терапия, головокружение, интегративный подход, база доказательств.

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