

# The Efficacy of Arlevert Therapy for Vertigo and Tinnitus

M. Novotný,\* R. Kostrica,\* and Z. Círek†

\*Department of Otolaryngology, University Hospital, Brno–Bohunice, and

†Ear, Nose and Throat Clinic Plzen, Czech Republic

**Abstract:** We were interested in determining the efficacy of Arlevert therapy in vertigo and tinnitus patients, especially as it compared to the efficacy of the drug's two component agents, dimenhydrinate and cinnarizine. We conducted a comparative, randomized, double blind, multicenter, parallel group study involving a group of patients ( $n = 122$ ) with vertigo and tinnitus of peripheral or central origin. The three test groups, nearly equal in size, were administered three times daily for 4 weeks one of the three agents being evaluated. To evaluate therapeutic success, we studied patients' vertigo symptoms, concomitant vegetative symptoms, CCG parameters, and electronystagmographic and audiometric parameters. We also obtained subjective assessments of outcomes from the test patients. Our results led us to conclude that Arlevert is more effective than either of its component drugs alone in treating vertigo and tinnitus. The drug also was well tolerated.

**Keywords:** Arlevert therapy (cinnarizine and dimenhydrinate); tinnitus; vertigo

Owing to the modernization and far-reaching industrialization of our everyday lives, the number of so called civilization's diseases has increased. Vertigo and tinnitus of both peripheral and central origin are high on the list of such diseases. Fa. Henning Arzneimittel GmbH and Co. (Flörsheim am M., Germany) is introducing in the Czech market its new preparation, Arlevert. This agent is formed from two components—cinnarizine and dimenhydrinate—each of which has a high antivertiginous influence. The aim of this study is to inform readers about Arlevert and its two components, about its efficacy and tolerability, and about how the two components compare to each other.

## MATERIAL AND METHODS

Two Czech ear, nose, and throat clinics in Brno and Plzen are participating in a clinical trial with three in-

ternational study groups. The trial is a comparative, randomized, double blind, multicenter, parallel group study. We composed a group of patients ( $n = 122$ ) with vertigo and tinnitus of peripheral or central origin, excluding Meniere's disease and BPPV.

Patient distribution among the groups is as follows: group A (Arlevert), 40 patients (32.8%); group D (dimenhydrinate), 41 (33.6%); and group C (cinnarizine), 41 patients (33.6%). The mean age of patients in group A is 56.83 years, in group D is 51.51 years, and in group C is 50.21 years. The gender distribution in group A is 19 male and 44 female patients; in group D, 16 male and 25 female; and in group C, 20 male and 20 female. Test medication was administered three times daily for 4 weeks in the following doses: group A, one tablet composed of 20 g cinnarizine and 40 mg dimenhydrinate; group D, one 40-mg dimenhydrinate tablet; and group C, one 20-mg cinnarizine tablet.

The evaluative methods used were as follows: vestibulo-spinal test, ([CCG]); nystagmus tests, Frenzel glasses and electronystagmography (to study spontaneous nystagmus, positional nystagmus, OPKN, and caloric test by Claussen). Threshold audiometry also was performed. For evaluation of therapeutic success, we studied patients' vertigo symptoms (dystasia, unsteadiness while

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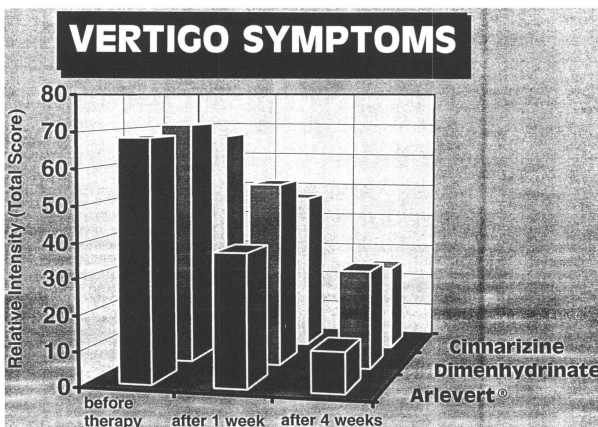
Reprint requests: M. Novotný, M.D., Ph.D., University Hospital, I. P. Pavlova 6. 775 20 Olomouc, Czech Republic. This study was presented at the Twenty-Fifth Ordinary Scientific Congress of the Neurootological and Equilibriometric Society, March 19–22, 1998, Bad Kissingen, Germany.

walking, staggering, rotary sensations, tendency to fall, lift sensations, and scotodinia), concomitant vegetative symptoms (nausea, vomiting, sweating, tachycardia, tinnitus, and impaired hearing), CCG parameters, and electronystagmographic (ENG) and audiometric parameters. We also studied factors that give rise to vertigo, including change of position, bowing, rising from bed, and driving by car or other motor vehicle.

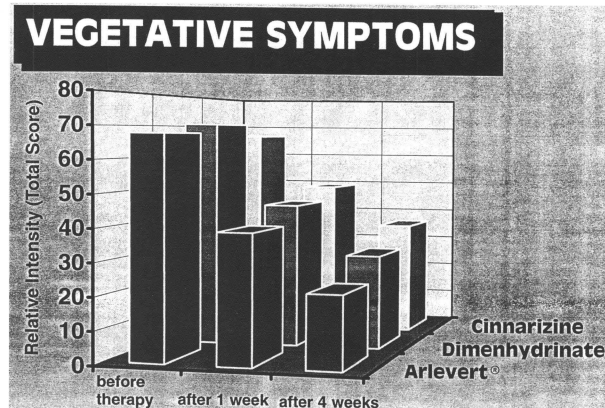
**RESULTS**

Figure 1 displays a subjective assessment of patients' vertigo symptoms, obtained before and after the first and fourth weeks of therapy. The best results are in group A, followed by C and, finally, D. Vegetative symptoms were assessed on the same schedule, and here too the best results were observed in group A, though group D patients fared better than those in group C in this evaluation (Fig. 2). Especially as regards tinnitus, group A patients benefited most, followed by group D and then group C patients (Fig. 3). Both tinnitus and impaired hearing improved during the course of the 4-week study, though no significant differences were noted in the responses to the three medications.

The mean ENG frequency for all patients began within the normal range (20–60 beats) and showed little change during the study. Differences among the three medications were not significant. For only those patients (very few) whose initial frequencies exceeded 60 beats per 30 seconds before treatment, the frequencies climbed after 1 week of therapy to near-normal range and, during second to fourth weeks, changed very little. Statistically, no differences were noted among the three



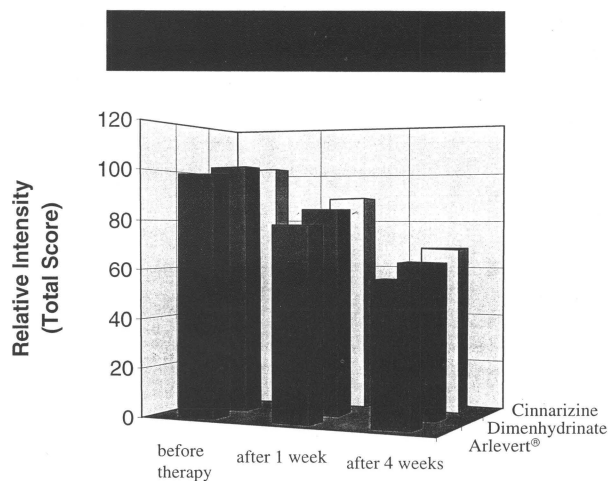
**Figure 1.** Subjective assessment of patients' vertigo symptoms, obtained before and after the first and fourth weeks of therapy. The best results are seen in the Arlevert patients, followed by those treated with cinnarizine and, finally, by those receiving dimenhydrinate.



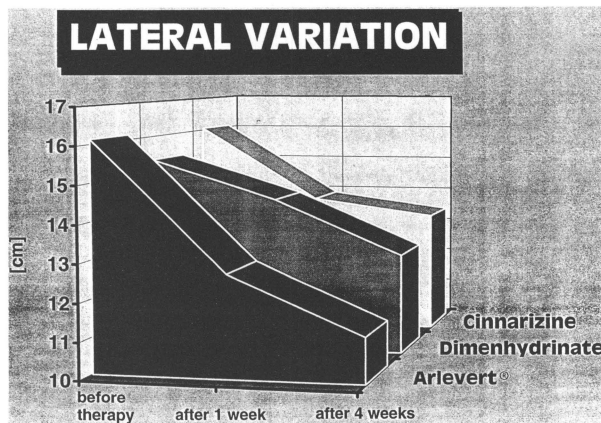
**Figure 2.** Vegetative symptoms were improved most among the patients receiving Arlevert, though dimenhydrinate patients fared better than did those receiving cinnarizine in this evaluation.

medications. The final audiometric results showed very little or no change during the course of study for all three medications.

Figure 4 depicts the CCG results: Group A patients fared better than group D patients, who in turn were better off than were those in group C. In Table 1, statistical evaluations (Kruskal-Wallis test) of vertigo symptoms, vegetative symptoms, and CCG parameters after 4 weeks therapy are presented. Here Arlevert is compared to dimenhydrinate alone and to cinnarizine alone. We can conclude from this comparison that Arlevert is significantly more effective than is either dimenhydrinate or cinnarizine alone, the difference between Arlevert and cinnarizine being highly significant ( $p < .01$ ). Pa-



**Figure 3.** Especially as regards tinnitus, Arlevert patients benefited most, followed by dimenhydrinate and then cinnarizine patients.



**Figure 4.** CCG results in the three test groups. Arlevert patients fared better than did dimenhydrinate patients and, in turn, were better off than were cinnarizine patients.

tients' judgment of their tolerance for these three preparations was very good or good in all cases. No side effects were noted.

**DISCUSSION**

In this study are presented the results of subjective observations of our patients and objective tests including CCG, ENG, and audiologic assessments. From these statistical evaluations, we are able to summarize that Arlevert produced the best results, followed by dimenhydrinate and then cinnarizine. On the basis of our findings, we suggest that in Arlevert, the various properties of dimenhydrinate (e.g., peripheral depressant action at the labyrinth, especially to the otoliths [1], and very strong antivertiginous and antiemetic influences [2]) and of cinnarizine (e.g., sedative action on the vestibular labyrinth, as a calcium entry blocker, and antivasoconstrictor properties) have been successfully employed [3–5]. Thus, we have observed very good results in treatment of vertigo and tinnitus, not only that of peripheral origin but also that of central origin [6–9]. The small effects in threshold audiometric and ENG results can be explained by the fact that the majority of our patients had suffered hearing loss for 3–5 or more years and so could not be expected to exhibit very marked changes in these tests. Among the “fresh” cases, patients (only a few in this group, and most young) usually recovered

**Table 1.** Comparison of Arlevert and Its Separate Component Drugs: Statistical Significance Levels (as Determined by Kruskal-Wallis Test)

	Vertigo Symptoms	Vegetative Symptoms	Lateral Variation
Arlevert vs. dimenhydrinate	SS	S	S
Arlevert vs. cinnarizine	SS	SS	SS

S =  $p \leq .05$ ; SS =  $p \leq .01$ .

considerably—to the physiological level in both audiometric threshold and ENG tests.

**CONCLUSIONS**

From this study, we conclude that Arlevert has good antivertiginous and antiemetic properties. It proved to be effective therapy for patients with vertigo or tinnitus of peripheral vestibular or central origin. Our statistical evaluations show Arlevert to be more effective than either of its constituent drugs (dimenhydrinate and cinnarizine) used separately. Finally, Arlevert was well tolerated by the patients in our study.

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