

**Gates GA, Green JD, Tucci DL, Telian SA. The Effects of Transtympanic Micropressure Treatment in People With Unilateral Meniere's Disease. Arch Otolaryngol Head Neck Surg 2004;130:718-725.**

Design: Randomized clinical trial

Population/sample size/setting:

- 67 patients (42 women, 25 men, mean age 49) with active Meniere's disease in 4 study centers sponsored by manufacturer of Meniett Device
- Eligible if at least 2 disruptive attacks of vertigo for past 2 months despite 3 months of low-sodium diet, documented low-frequency sensorineural hearing loss, functionality level 2 to 4 (able to work, drive, engage in most essential activities but with various degrees of limitation, where functional level scale of 5 and 6 signify inability to work), normal auditory brainstem responses, abnormal electrocochleogram (ECoG) in affected ear
- Exclusion criteria not stated
- Vestibular status measured with bithermal caloric test, with 30% or more of canal weakness classified as abnormal

Main outcome measures:

- Randomized to Meniett device (n=34) or identical appearing sealed device (n=33) with similar clicking sound and light operation
- All had tympanostomy tubes placed for 2 weeks prior to administration of treatment/control device; tube placement did not affect vertigo symptoms
- Vertigo frequency, severity, and activity level (sick days/canceled activity due to vertigo) recorded by self-report diaries at baseline and at 1, 2, 3, and 4 months of treatment
- 62 of 67 randomized completed 4 months of treatment; usage data downloaded from devices showed no difference in usage between Meniett and placebo groups (median number of applications/day=2.6)
- Both Meniett and placebo groups experienced declines in vertigo frequency, with repeated measures ANOVA showing greater decline in Meniett than in placebo group
- Greater reduction in proportion of vertigo days seen in patients with higher proportion of vertigo days at baseline; with greater Meniett treatment effect observed at higher levels of baseline vertigo
- Canal weakness associated with treatment response, with treatment advantage at lower levels of canal weakness and no treatment advantage at higher levels
- Both groups had fewer sick days over time, with greater improvement in Meniett treatment group sick days
- No significant difference in hearing scores during study for either group

Authors' conclusions:

- Meniett device likely to be effective for pts with established Meniere's disease, reduced vestibular function, and high levels of vertigo despite adequate medical therapy, provided they can tolerate tympanostomy tubes

Comments:

- Although frequency of vertigo and number of sick days decreased more rapidly in treatment group than in control group, Table 3 shows that treatment and control groups are equal at 4 months in both measures of outcome
- Table 4 shows regression model with  $R^2$  of 0.214, which means that treatment group, baseline vertigo, and canal weakness collectively account for only 21% of variation in proportion of days with vertigo
- Text of article and Figure 3 indicate two interaction effects: canal weakness/treatment response and baseline vertigo/treatment response, but regression model in Table 4 does not mention whether an interaction term was entered into regression equation

Assessment: Adequate for some evidence that the portable low-intensity alternating-pressure generator reduces vertigo in patients with Ménière's disease