Transtympanic Micropressure Applications as a Treatment of Meniere's Disease

Description

Transtympanic micropressure treatment for Meniere's disease involves use of a hand-held air pressure generator that delivers intermittent complex pressure pulses. For this device to be used, a conventional ventilation tube is surgically placed in the eardrum. Patients then place an ear-cuff in the external ear canal and treat themselves for 3 minutes, 3 times daily. Treatment is continued for as long as patients find themselves in a period of attacks of vertigo.

Background

Meniere's disease is an idiopathic disorder of the inner ear characterized by episodes of vertigo, fluctuating hearing loss, tinnitus, and ear pressure. The vertigo attacks are often unpredictable and incapacitating and may prevent activities of daily living. Therapy is symptomatic in nature and does not address the underlying pathophysiology. Although the pathophysiology of Meniere's disease is not precisely known, it is thought to be related to a disturbance in the pressure/volume relationship of the endolymph within the inner ear. Conservative therapy includes a low sodium diet and diuretics to reduce fluid accumulation (i.e., hydrops) and pharmacologic therapy to reduce vestibular symptoms. Persons who do not respond to these conservative measures may receive gentamicin drops in the ear, as a technique of chemical labyrinthectomy to ablate vestibular function on the affected side. No therapy is available to restore hearing loss.

There has been interest in developing a more physiologic approach to treatment by applying local pressure treatment to restore the underlying fluid homeostasis. Researchers have noted that symptoms of Meniere's disease improve with fluctuations in ambient pressure, and patients with acute vertigo have been successfully treated in hyperbaric chambers. It is hypothesized that the application of low-frequency, low-amplitude pressure pulse to the middle ear functions to evacuate endolymphatic fluids from the inner ear, thus relieving vertigo.
Regulatory Status

In 1999, the Meniett device (Medtronic, Minneapolis, MN) received clearance to market through a U.S. Food and Drug Administration (FDA) 510(k) process specifically as a symptomatic treatment of Meniere's disease.

Related Policies

None

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Transtympanic micropressure applications as a treatment of Meniere's disease are considered not medically necessary.

Rationale

Literature Review

Data submitted to the U.S. Food and Drug Administration (FDA) as part of the FDA-approval process consisted of a case series of 20 patients. Other case series have also been published in the peer-reviewed literature. (1-8) These case series are inadequate to form conclusions due to the lack of a control group, and they will not be discussed further in this review. The remaining literature review will focus on three randomized, controlled trials (RCTs) that have been published.

The first RCT was published in 2004, by Gates and colleagues. This trial reported the 4-month results of a randomized multi-institutional study that enrolled 67 patients with active unilateral Meniere’s disease refractory to a 3-month trial of medical management. (9) All patients underwent tympanostomy, and patients were additionally randomly assigned to either a sham device or a Meniett device. Outcomes were assessed using symptom report cards that focused on the severity and frequency of vertigo. The total number of days of definitive vertigo for all the participants was reported at each month. While an analysis of variance (ANOVA) showed that over the entire 4-month trial, there was a significant difference in the total number of episodes of vertigo in the treatment group compared to the control group, the difference between the groups is most apparent at 1 month, while at 4 months the treatment effect had disappeared almost entirely. Similarly, overall, there was a significant decrease in the frequency of vertigo in the treatment group, but again this difference was most apparent at the 1-month interval and almost disappeared at 4 months. This study is limited by a number of methodologic issues related to the statistical analysis of the data. In particular, repeated-
measures ANOVA, which was the primary method used to analyze these data, assumes normal distribution, equal variances and covariances, and equal variances over time (compound symmetry or the so-called sphericity assumption); whether these assumptions were met is unclear from the report. There are a number of "outlier" patients. These outliers would result in the data not being "normally distributed" and also could be influential in the marginally significant p values noted in the study. It is unclear that the "interim power analysis" performed was preplanned or that the trial was intended as an adaptive group sequential design. Whether consideration was given to protecting the type I error rate is also unclear. Given these concerns, results from this trial do not allow drawing conclusions about the impact of this device on patient outcomes.

In 2006, Gates and colleagues reported a 2-year open-label follow-up of patients from this randomized trial. (9,10) At the end of the randomized phase of the study, 61 of 67 patients from both the control and active treatment arms were treated openly with the Meniett device; 3 were subsequently lost to follow-up or excluded due to concurrent health problems. Vertigo episodes were reported on a daily symptom diary (44 patients) or by a structured telephone interview (17 patients). Of the 58 patients followed up for 2 years, 14 (24%) dropped out to seek alternative surgical treatment, 5 (9%) showed little or no improvement, and 39 (67%) reported being in remission or substantially improved. Patients who went into remission had an 80% probability of remaining in remission for the 2 years. This assessment is limited, however, by the lack of a control group followed up over the same period.

A 2005 multicenter, double-blind, placebo-controlled trial with 63 patients compared micropressure devices with ventilation tubes and sham pressure devices. (11) This trial reported an improvement in functionality (American Academy of Otolaryngology–Head and Neck Surgery [AAO-HNS] criteria) and a trend (p=0.09) toward a reduction in episodes of vertigo for the active treatment group compared with controls. The frequency of attacks decreased from 10.5 to 4.0 in the placebo group and from 9.6 to 1.9 in the active group. There were no changes in secondary outcome measures (patient’s perception of tinnitus, aural pressure, and hearing). In addition to a marginal improvement in efficacy over placebo, this study is limited by the high dropout rate (37%), lack of intent-to-treat analysis, and short (2-month) monitoring period.

In 2012, Gurkov et al. reported a randomized double-blind sham-controlled trial with the Meniett device. (12) After a 4-week baseline period, 74 patients underwent ventilation tube placement and were monitored for another 4 weeks. Patients were then randomized to 16 weeks of active or sham treatment (5 minutes, 3 times daily). The primary outcomes were subjective vertigo score, number of definitive vertigo days, and number of sick days as recorded on a daily log over the last 4 weeks of treatment. Sixty-eight patients (92%) completed the study. The cumulative vertigo score decreased by 6.5 in the active group and by 1.19 in the sham group (p=0.048). The number of vertigo days decreased by 2.42 in the active treatment group and by 0.42 in the sham group (p=0.102), and the number of sick days decreased by 2.32 in the active treatment group and increased by 0.58 days in the sham group (p=0.041). There was no significant difference between groups in the vertigo-free days, activity score, hearing level, or slow phase velocity. This double-blind sham-controlled study
shows a modest improvement in 2 of 5 subjective measures, but not in objective outcome measures, with the Meniett device. It is also limited by the relatively short (4-month) follow-up period.

Practice Guidelines and Position Statements

In 2012, the American Academy of Otolaryngology-Head and Neck Surgery updated their position statement on the use of transtympanic micropressure: “We find that there is convincing and well-controlled medical evidence to support the use of micropressure therapy (such as the Meniett device) in certain cases of Meniere’s disease. Micropressure therapy is best used as a second level therapy when medical treatment has failed. The device represents a largely non-surgical therapy that should be available as one of the many treatments for Meniere’s disease.” (13) No supporting evidence was provided.

In 2012, guidance from the United Kingdom’s National Institute for Clinical Excellence (NICE) concluded that current evidence on the safety of micropressure therapy for refractory Meniere’s disease is inadequate in quantity. Although there is some evidence of efficacy, it is based on limited numbers of patients. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit, or research. (14)

Summary

Currently 3 randomized controlled trials of the Meniett device have been published. Results of the 2 most recent trials show a marginal improvement at short-term follow-up in some subjective outcome measures when compared with insertion of ventilation tubes and use of a sham device. Other primary and secondary outcome measures, including objective measures, were not improved. Analysis of these data on a per-patient level, i.e., by reporting the percent of responders who achieve a minimal clinically important difference on each outcome measure, would allow greater certainty on whether improvements with this device are clinically significant. At this time, the scientific evidence does not permit conclusions concerning the effect of this technology on health outcomes. Therefore, it is considered not medically necessary.

Medicare National Coverage

There is no national coverage determination.

References


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<tr>
<td></td>
<td>September 2012</td>
<td>New Policy</td>
<td>Policy updated with literature review, policy statement unchanged. Several references added.</td>
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<td>December 2013</td>
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Keywords

Meniere's disease
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This policy was approved by the FEP Pharmacy and Medical Policy Committee on December 6, 2013 and is effective January 15, 2014.

Signature on File
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