

Systematic Review

Systematic Review and Meta-Analysis of Meniett Therapy for Meniere's Disease

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Objectives/Hypothesis: To perform a systematic review and meta-analysis of micropressure treatment for Meniere's disease (MD).

Data Sources: Medline, Ovid, Web of Science, and Cochrane Library search of the literature from January 1996 to December 2012.

Review Methods: Systematic literature review followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Inclusion criteria required definitive diagnosis of unilateral MD, treatment with Meniett device, vertigo control results, and hearing results before and after treatment. Randomized controlled trials and other types of case-control studies were included. Improvements in vertigo, American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) functional score, and pure tone average (PTA) were assessed. Funnel plots were used to detect bias and Q test was used to assess for heterogeneity. Random effects model was used for meta-analysis. T test was used to assess for significance.

Results: Of 113 abstracts screened, 18 studies met criteria for review and 12 were used for meta-analysis. Eight studies reported hearing evaluation and the improvement in PTA after Meniett treatment was significant ($P = 0.0085$). Data could not be combined for AAO-HNS functional score due to heterogeneity. However, there was a trend toward improvement. Of six studies reporting frequency of vertigo, Meniett treatment significantly reduced frequency of vertigo ($P < .0001$).

Limitations: Much of the data used in the analysis was derived from retrospective or level 4 studies. The average follow-up was only 5 months, and there were low number of patients in the treatment and control groups.

Conclusion: The Meniett device is a safe, nondestructive treatment for patients' refractory to medical therapy for MD.

Key Words: Meniett device; micropressure treatment; Meniere's disease; vertigo; middle ear pressure treatment.

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INTRODUCTION

Meniere's disease (MD) is a chronic idiopathic inner-ear disorder defined by recurrent vertigo attacks lasting more than 20 minutes, fluctuant low-frequency hearing loss, aural fullness, and/or tinnitus. Endolymphatic hydrops may represent the histological inner ear/cochlear findings in most patients. The vertigo attacks may arrive without warning and can be debilitating. Over time, in some patients MD can lead to progressive hearing loss and chronic disequilibrium. In early stages, the hearing may fluctuate, but eventually the disease can lead to severe to profound hearing loss in some cases.¹

A variety of medical and surgical treatments have been developed to treat or control the symptoms. No cure exists for MD. Treatment can be divided into non-destructive and destructive procedures. Nondestructive methods aim to reduce the symptoms of MD through dietary restrictions as well as through the use of diuretics. Surgical decompression of the endolymphatic sac, considered a nondestructive treatment, is effective in about 60% to 70% of patients.^{1–4} Transtympanic steroid injection has also been shown to be an effective, nondestructive treatment for MD.⁵ Destructive procedures include surgical or chemical labyrinthectomy and vestibular nerve section.^{2,6}

During the 1970s, while searching for a more effective and nondestructive method, Inglestadt et al. observed that some patients reported improvement with pressure changes in a pressure chamber.⁷ Densert et al. showed that manipulation of the middle ear pressure influences inner ear pressure.⁸ Later, improvement in vertigo and hearing in patients with MD were described after application of positive pressure to the middle ear. In addition, the cochlear electric potentials were noted to improve after application of middle ear pressure.⁹ These reports eventually led to the development of the Meniett device (Medtronic Xomed Surgical Products, Jacksonville, FL).

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The Meniett device emits a repeated .6 second pulse of pressure at a range from 0- to 20-cm H₂O at 6 Hz. Treatment consists of three to four cycles of a 5-minute treatment sequence. It is noninvasive and only requires placement of a short-term ventilation tube to allow transmission of pressure pulses through the external auditory canal and into the middle ear. Although the Food and Drug Administration approved the device for use in patients with Meniere's disease in 2002, Meniett therapy is rarely recommended in the United States.³ We were not sure whether this is due to a lack of efficacy or because of the lack of information about the device that is available to practicing otolaryngologists.

With this in mind, a preliminary, brief review of the literature was performed. The goal was to determine the effectiveness of the Meniett device and to determine if it would be a viable alternative to destructive procedures for patients who are no longer helped by more conservative medical treatments. The preliminary review of the literature indicated that there were few studies on the use of the Meniett device, and the number of patients in each study was small as well. As a result, it was decided that using the statistical technique of meta-analysis would help better to integrate the results from the selected studies. Subsequently, we performed a systematic evaluation of the literature and meta-analysis of the available studies to determine the efficacy of Meniett therapy for unilateral Meniere's disease.

MATERIALS AND METHODS

A literature search using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines was performed independently by two authors (S.A. AND R.S.) to identify all studies that examined the Meniett device as a therapy for patients with MD.¹⁰ The subject headings "Meniett," "middle ear pressure treatment," "micropressure treatment," "positive pressure pulse treatment," "transtympanic pressure," and "Meniere's disease" were entered into PubMed and Ovid search engines in different combinations. The Cochrane database was also searched for relevant studies. Search was limited to English language human studies published between January 1996 and December 2012.

Inclusion criteria included randomized controlled trials (RCTs) and all other study types; case reports and review articles were excluded. Further inclusion criteria included: patients with definitive diagnosis of MD using, when possible, the 1995 American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) criteria;¹¹ patients who failed conventional conservative therapy (dietary modification and diuretics); and patients who had not received surgical intervention or invasive procedures, including any transtympanic steroids or gentamicin for MD. Only studies containing a clear description of vertigo control results and hearing pretreatment and posttreatment were included. For the studies with controls, age and sex-matched controls were preferred when possible.

The publications' abstracts were reviewed, and those fulfilling the criteria were obtained and their references then reviewed to identify any relevant articles. The outcome measures examined included: the effect on hearing using pure tone average (PTA), the effect on vertigo control as defined by the reduction of the frequency of vertigo (freq. vertigo), and the improvement in the AAO-HNS functional level (fxn level). Some studies did not use these outcome measures; therefore, they

were not used in further analysis. A few studies used similar reporting measures that could be combined. These provided a greater pooled number of cases for statistical analysis. The mean, standard deviation, and range were recorded for each parameter (PTA, freq. vertigo, fxn level). However, due to the low number of studies, we included all studies that fulfilled our search criteria and contained a clear description of treatment duration, follow-up, vertigo control, and hearing measures. Each selected article was assigned a level of evidence by two of the authors (S.A., R.S.) using guidelines published by the Oxford University Centre for Evidence-Based Medicine (CEBM) (<http://www.cebm.net>). Any dispute in the assignment of the levels was resolved after discussion and mutual agreement.

Statistical Analysis

A meta-analysis was performed by comparing the PTA before and after Meniett treatment—the reduction in the frequency of vertigo and improvement in AAO-HNS functional level after treatment with the Meniett device. Funnel plots were applied as a visual aid to detect publication bias, and Egger tests were conducted to test for significance of the asymmetry. Due to the small number of studies and missing values for covariates, it was not applicable to investigate the source of heterogeneity or to do meta-regression. However, Q statistics was utilized for assessing heterogeneity and then used to identify a subset of studies that could be selected to pool overall effects. This analysis was performed for evaluating each set of initial studies by looking at the effects on PTA, the effects on the frequency of vertigo, and the effects on the AAO functional score. Random effects model was applied to estimate the overall effects by using DerSimonian-Laird (DSL) as well as restricted maximum likelihood (REML). A *t* test was used to assess if the pooled effect size was significantly different from zero. Forest plots were created to easily capture the information. The statistical analyses were obtained by using SAS 9.2 and R.

RESULTS

Figure 1 shows the flow chart of the search results. Of 113 studies identified, 18 studies met criteria for a thorough review.^{12–29} Table I and Table II provide the characteristics of the 18 studies (type of study, number of patients, PTA before and after Meniett treatment, vertigo scores before and after treatment). These studies included 436 subjects in the experimental arm and 157 subjects in the control arm. However, only 12 studies were able to be combined for meta-analysis, totaling 241 subjects in the experimental group and 72 subjects in the control group. The average duration of Meniett treatment was 7.3 months for the 11 studies where duration was clearly noted. Overall level of evidence is grade C due to a majority of level 4 studies with only two level 1b and one level 3b studies.

Of the 18 studies, four were randomized controlled trials, six were prospective nonrandomized studies, six were retrospective studies, and two studies were difficult to discern the type—and therefore were labeled as unknown. Only one of the four RCTs could be combined with other studies to analyze the effect on vertigo. Two of the other RCTs used the number of sick days before and after treatment as a measure that was common between them.^{13,16} Because of the lack of using similar measures for reporting vertigo results (frequency of

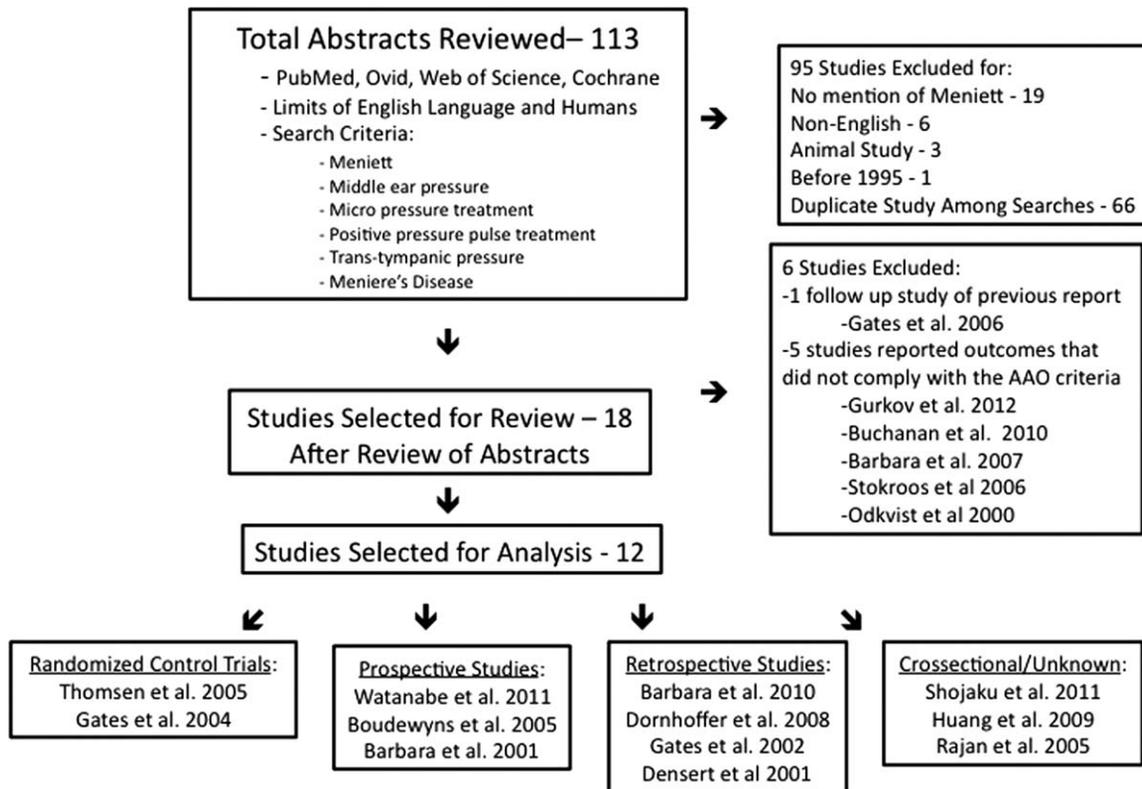


Fig. 1. Flow chart of study selection for review and meta-analysis.

TABLE I.
aSummary of Studies Using the Meniett Device for the Treatment of Meniere's Disease.

Author (year)	Design/Level of Evidence*	No. Patients Treatment/C	Duration Treatment (months)	Pretreatment PTA(db)(SD) (range)	Posttreatment PTA(db) Mean (SD) (range)
Gates (2004)	RCT/1b	30/32	4	56.1(19.7) (11.7–101.7)	51.9 (23.4)
Odkvist (2000)	RCT/1b	31/25	.5		
Thomsen (2005)	RCT/1b	20/20	2		
Gurkov (2012)	RCT/1b	37/31	4		
Watanabe (2011)	Prosp/NC//4	15/NC	9.2	58.8(23.1)	52.4(28.0)
Boudewyns (2005)	Prosp/NC//4	12/NC	2	63.7(36.9–79.4)	65.0(35.0–83.1)
Barbara (2001)	Prosp/w/C//3b	18/20	.67		
Rajan (2005)	Cxnl case Study/4	18/NC	18	48.8(25–70)	44.6(12–70)
Huang (2009)	Cxnl case Study/4	18/NC	2	47.4(13.7)	39.1 (17.8)
Barbara (2007)	Unknown/4	36/NC	2		
Gates (2002)	Retrospective./4	10/NC	8	34.1(12.1)	50.8(22.2)
Dornhoffer (2008)	Retrospective./4	12/NC	Variable		
Buchanan (2010)	Retrospective./4	30/NC	1–1.5		
Shojaku (2011)	Unknown/4	28/NC	3		
Gates (2006)	Retrospective/3b	29/29	24		
Densert (2001)	Retrospective/4	37/NC	24	51.6 (2.97)	47.5 (6.57)
Stokroos (2006)	Prospective/4	32/NC	Unknown		
Barbara (2010)	Retrospective/4	23/NC	1	51.9(17.9)	60(20.8)

*Level of evidence according to the Centre for Evidence-based Medicine at the University of Oxford (<http://www.cebm.net>).

C = control; Cxnl = cross-sectional; db = decibel; NC = no control; PTA = pure tone average; Prosp = prospective; RCT = randomized controlled trial; SD = standard deviation.

TABLE II.
Vertigo Scores Before and After Treatment With the Meniett Device.

Author	AAO fxnl Score Pretreatment (SD or range)	AAO fxnl Score Posttreatment (SD or range)	Frequency of Vertigo Pretreatment (SD or range)	Frequency of Vertigo Posttreatment (SD or range)
Thomsen (2005)	4.2 (1.1)	2.4 (1.1)	9.6 (6.7)	1.9 (4.1)
Watanabe (2011)			15.1 (13.5)	1.4 (2.4)
Boudewyns (2005)	3 (3–4.2)	4.0 (3–5)	10 (4–19)	3 (1.5–4.5)
Barbara (2001)			9.22 (7.96)	1.67 (2.25)
Rajan (2005)	4.1 (1.3)	2.4 (1.1)		
Huang (2009)	5.4 (.8)	1.4 (.6)	42.3 (13.7)	5.9 (7.6)
Gates (2002)	4.3 (1.0)	1.3 (.71)		
Dornhoffer (2008)	4.56 (.966)	1.56 (1.58)	20.7 (15.1)	3.0 (6.52)
Shojaku (2011)			2.6 (2.0)	0.4 (0.8)
Densert (2001)			2.88 (1.60)	0.25 (0.27)

AAO fxnl = American Academy of Otolaryngology functional score; SD = standard deviation.

vertigo; AAO-HNS functional score); these studies could not be combined with the others. However, both studies showed a significant improvement in vertigo scores after Meniett treatment (follow-up was 4 months). Another RCT used a visual analog scale to describe the effects of Meniett treatment on vertigo.¹⁴ No other studies used this measure; thus, it was not used for the meta-analysis. This study also showed improvement in reported vertigo, but follow-up was only 2 weeks.

Nine studies reported PTA before and after Meniett treatment,^{12,13,17,18,20–22,24,25} eight studies reported frequency of vertigo before and after treatment,^{15,17–19,21–23,25} and seven studies reported the AAO-HNS functional score before and after treatment.^{12,15,18,20–22,25} Egger tests for all three study sets showed that there was no significant publication biases among these studies for PTA ($P = 0.33$), AAO-HNS function score ($P = 0.48$), and frequency of vertigo ($P = 0.07$). Given the high heterogeneity among these studies, further subset analysis was performed within homogeneous studies obtained using Q statistics. For the PTA analysis, one of the nine studies was found to be significantly heterogeneous from the others; therefore, it was not used for further analysis.²² In evaluating the effect on

frequency of vertigo, two of the studies had significant heterogeneity and were not used in subset analysis.^{17,18} Finally, for the effect on AAO-HNS functional score, it was not possible to subset for homogeneity; thus, the pooled estimation was deemed inadequate for conclusions without adjusting for any covariates. Three studies were not used because they did not use the selected reporting measures of vertigo.^{27–29} Another study was a long-term follow-up of a previously reported study; thus, it was not used in the meta-analysis.²⁶ However, it did show long-term benefits in patients who completed the study (67% had Class A or B results using the AAO-HNS classification; 24% had Class F or dropouts who required surgical treatment during follow-up).

For the evaluation of the effect of micropressure treatment on hearing, nine studies reported PTA measurement pre-device application and post-device application.^{12,13,17,18,20–22,24,25} For the subset analysis, after eliminating one study the homogeneity statistic ($Q = 6.83$; P value = 0.45) indicated that the studies were homogeneous; therefore, the pooled estimation would be appropriate. A random effects model was calculated because it was determined to be more appropriate in

TABLE III.
Analysis of the Effect of Meniett Treatment on PTA and Frequency of Vertigo.

A. PTA				
Method		Difference of PTA	Standard Error	P Value
Random	DSL	–3.74	1.03	0.0085
Random	REML	–3.74	1.03	0.0085
B. Frequency of Vertigo				
Method		Difference in Frequency	Standard Error	P Value
Random	DSL	–2.59	0.20	<0.0001
Random	REML	–2.59	0.20	<0.0001

DSL = DerSimonian & Laird; freq = frequency of vertigo; PTA = pure tone average; REML = restricted maximum likelihood.

Forest Plot (DerSimonian & Laird Analysis)

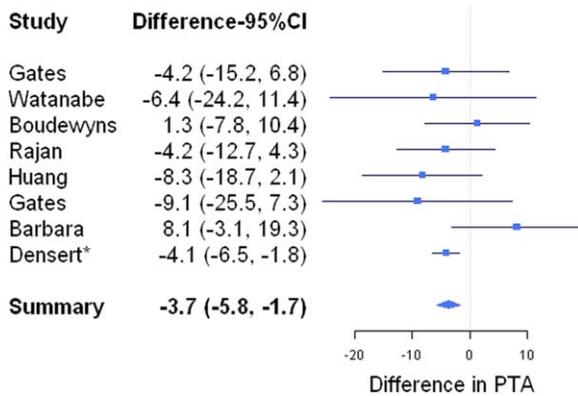


Fig. 2. Difference in PTA before and after Meniett device application. PTA = pure tone average. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

this setting due to the small number of studies, low number of patients, and little information about the covariates. The difference in PTA pretreatment and post-treatment was significant (Table III, part A). The forest plot (Fig. 2) of the difference in PTA after treatment showed a tendency for improvement ($P = 0.0082$).

Seven studies examined the effect of Meniett therapy on improvement in AAO-HNS functional level.^{12,15,18,20–22,25} Combining the studies led to a total of 127 patients in the experimental group and only 20 in the control group. It was not possible to subset for homogeneity, so a meta-analysis could not be performed. However, a trend toward improvement was observed in AAO-HNS functional score with Meniett treatment in all but one of the studies (Fig. 3).

Eight studies reported the effect on frequency of vertigo after Meniett treatment.^{15,17–19,21–23,25} After eliminating two studies due to increased risk of bias, six studies were combined for a total of 133 patients in the treatment group and 40 in the control group. The studies were homogeneous ($Q = 3.44$; $P = 0.63$) and could be combined. The random effects model (DSL, REML) indicated that Meniett treatment significantly reduced the frequency of vertigo (Table III, part B). The forest plot (Fig. 4) illustrates that all studies showed improvement in the frequency of vertigo after treatment with the Meniett device.

DISCUSSION

Meta-analysis of the six studies reporting frequency of vertigo after treatment suggests that the Meniett device reduces frequency of vertigo in patients with active Meniere's disease who failed conventional treatments. Excellent short-term results were found in the control of vertigo with the Meniett device. There was also a trend toward improvement in the AAO-HNS functional score, but any conclusions must take into consideration that these studies could not reach the required homogeneity. In addition, of the eight studies analyzed for the effect on hearing, analysis indicated that the Meniett device does significantly improve hearing. Previously,

Forest Plot (DerSimonian & Laird Analysis)

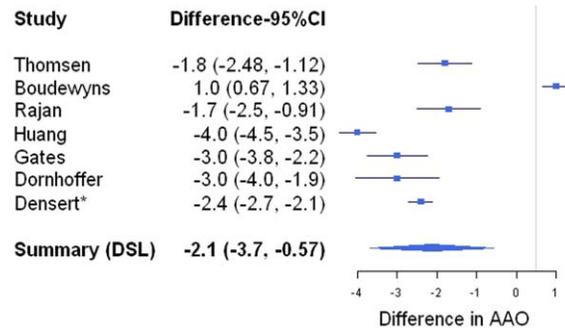


Fig. 3. Difference in AAO-HNS function before and after Meniett device application. AAO = American Academy of Otolaryngology-Head and Neck Surgery functional score. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

only one of four RCTs had reported a statistically significant improvement in hearing levels.¹⁴ Odqvist et al.¹⁴ found an improvement in low frequency hearing (500Hz and 1kHz) after treatment with the Meniett device. No such improvement was noted in the control group. Taken as a whole, there were no reported complications, and all studies reported that the treatment is safe.

Overall, the various studies reported either complete resolution or significant control of vertigo in 60% to 100% of patients treated.^{13,17,20–22,29} Some of the studies had short follow-up duration (around 2 months), but some were up to 4 years after treatment.^{17,21,22} Most of the RCTs could not be combined due to the use of non-standardized metrics used to report vertigo. This lack of using recommended measures of vertigo is one of the main limitations in allowing for the combination of patients in these well-conducted studies. Only one of the RCTs could be used along with the other studies in our evaluation of the effect of Meniett on vertigo.¹⁵ However, one of the other RCTs was used for analyzing effects on PTA.¹³

Forest Plot (DerSimonian & Laird Analysis)

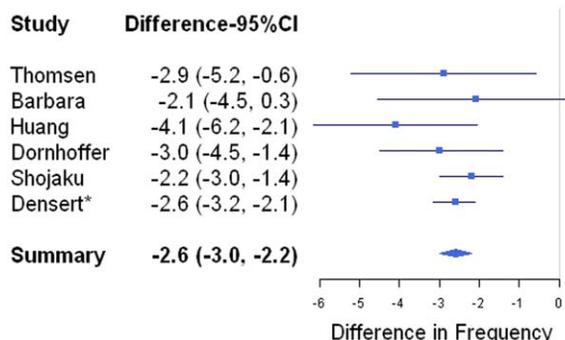


Fig. 4. Difference in frequency of vertigo before and after Meniett device application. Frequency = frequency of vertigo. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

In general, the results of meta-analysis may depend more on inclusion criteria and not necessarily on the data. However, by applying strict criteria and accounting for heterogeneity and publication bias, a good attempt can be made to reduce some of these weaknesses. Meniere's disease is a cyclical disorder. Its natural history is one of recurrence and remissions; therefore, a good study should take into account the reporting guidelines for the treatment of vertigo (Committee on Hearing and Equilibrium, 1995).¹¹ In addition, a control group should be included to differentiate true treatment effects from spontaneous improvements. One of the limitations of this study is that a major source of the data is based on retrospective and cross-sectional studies. There is a lack of level 1 and 2 studies; in fact, only two RCT studies were used for the final statistical analysis. Only five studies in the present report utilized a control group. Four of these were RCTs (Table I), and only two of these could be used for the meta-analysis. Another was a prospective study without randomization. The follow-up average was 5 months, which is substantially shorter than the recommended follow-up of 2 years by AAO-HNS 1995 guidelines.¹¹ Two studies (one included in the meta-analysis) had a 2-year follow-up.^{25,26} Both showed excellent control of vertigo with the Meniett device. The other limitations of this analysis include the low number of patients in the treatment and control groups and not using the recommended measures of reporting results. This prevented combining all of the studies for a more robust analysis and a more solid statistical evidence on which to base our conclusions.

CONCLUSION

This meta-analysis and review of the literature suggests that the Meniett device is effective in relieving symptoms and functional deficits due to vertigo in patients with Meniere's disease. It also has a significant favorable effect on hearing. Overall, in the small number of studies evaluated, it has been shown to be a safe and effective nondestructive alternative for patients who are refractory to initial medical therapy. Otolaryngologists have an option to use this device prior to recommending more destructive treatments. However, these conclusions must be interpreted with caution due to the limitations of this analysis. Future research in this area should utilize a RCT with a long-term follow-up and AAO-HNS reporting guidelines for MD in order to overcome some of the weaknesses found in the literature.

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