



MENIETT

Low Pressure Pulse Generator

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Meniere's Syndrome

- Classic symptoms: episodic vertigo, tinnitus and hearing loss with sensation of fullness.
 - Generally affects people in the 20 – 50 year age range.
 - No gender differences.
 - Normally unilateral, but bilateral in about 15% of cases.
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Meniere's Treatments

- Lifestyle: low salt diet; avoidance of caffeine, smoking, alcohol; maintaining regular eating/sleeping schedule.
 - Medical: diuretics, anti-vertigo drugs, anti-emetic drugs.
 - Surgical: chemical ablation, endolymphatic shunt or decompression surgery, singular neurectomy, labyrinthectomy, VIIIth nerve resection.
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What is the Meniett?

- Non-invasive, non-destructive, portable, patient administered device.
 - Delivers intermittent low-pressure pulses via a tympanostomy tube to the ME.
 - Pressure pulses act on the round window membrane, resulting in perilymph displacement.
 - Perilymph displacement acts on endolymph, resulting in reduction of endolymphatic pressure—relieving symptoms.
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FDA Approved? Safe? Cost?

- Received US FDA approval in 1999 (has been used in Europe since 1997).
 - No study has shown deleterious effects.
 - Pressure pulses are weak (less than 20 cm H₂O scale)—about the pressure felt in the ear when under 6-7” water.
 - Treatment is not painful. Unit costs \$3500.
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Who is a candidate?

- Patients with Meniere's diagnosis for whom lifestyle/medical management has failed and who would otherwise be surgical candidates.
 - Patient must be motivated and able to self-administer several short (~ 5 min) treatments per day with the device.
 - No contraindications for tympanostomy tube placement and capable of following a "dry ear" protocol.
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Treatment Plan

- Most patients advised to use the device 3 times per day—nearly equally spaced over the 24 hour span.
 - Treatment should continue until symptoms are reduced to the extent treatment is unnecessary; thereafter, as needed.
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DEMO

- Place device on a level surface.
 - Select appropriate probe tip
 - Seal and hold in EAC
 - Keep head upright.
 - Press start button

 - Protocol: Leak test (30 sec), treatment (60 sec), rest (40 sec), treatment (60 sec), rest (40 sec), treatment (60 sec).
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Evidence of Efficacy

- Good evidence is hard to come by, but there are a number of clinical series and studies with varied methodological weaknesses that, in aggregate, tend to show benefit from the treatment.
 - A large, well-controlled, double-blinded study is needed to definitively answer this question.
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Our Experience

- HNS at our facility started recommending the device in mid to late 2004.
 - We agreed to order and instruct the patient in the use of the device.
 - To date we have treated 8 patients: 7 males and 1 female. Patient selection is done by HNS staff. The patient is then consulted to us for ultimate determination for candidacy.
 - We declined to fit one patient who was referred. HNS concurred based on our recommendation.
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Our Experience (Cont.)

- Ours has been a clinical rather than a research protocol, but we are happy to share our observations.
 - The candidate is queried re: frequency/severity of symptoms and this is recorded as baseline.
 - We wait at least one month after the tympanostomy tube is placed. During that time, the device is ordered/received.
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Our Experience (Cont.)

- Patient is scheduled for Audiology clinic visit.
 - We determine what effect (if any) tympanostomy tube placement itself has had on symptoms.
 - Device operation described and patient able to demonstrate use.
 - Patient follow-up typically done by telephone contact.
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Summary

- 9 patients referred, 8 devices dispensed.
 - 7 male, 1 female:
 - 62 y.o. m Used one year. Total resolution. D/C Meniett.
 - 58 y.o. m Used one year. No improvement.
 - 37 y.o. m Sxs. Improved
 - 42 y.o. m Sxs-free
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Summary (Cont.)

- 46 y.o. m Sx eliminated
 - 41 y.o. m Insufficient trial
 - 59 y.o. m Improved? Died
 - 45 y.o. m Unknown (spotty
 compliance)
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Outcomes?

- Total resolution: 3 (37.5%)
 - Partial resolution: 2 (25%)
 - No change: 1 (12.5%)
 - Can't judge: 2 (25%)
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Case Study #1

- MS: 62 y.o. male
 - Multiple med. probs incl. AD Menieres
 - 2002- tx HCTZ, then PET placement, d/c HCTZ after PE tube with some improvement, later, sxs worsened.
 - 1/04 started HCTZ BID.
 - 7/04 PET extruded and replaced. Next day, severe attack and tinnitus started. Attacks about every other day.
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Case #1 (Cont.)

- Trial prednisone for worsening sx's.
 - HNS discussed options of Meniett, intratympanic gentamycin and endolymphatic shunt surgery. Patient elected Meniett.
 - 9/04 Meniett dispensed. Continuing with HCTZ. Baseline: small daily attacks with a big one ~weekly.
 - 11/04 reported improved symptoms (improved vertigo, 4 minors/wk, no majors in a month, no fullness, occasional tinnitus).
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Case #1 (Cont.)

- 1/05. Reported only one attack in 2 months.
 - 2/06. Used as instructed. Hasn't been using Meniett for ~5 months. Is not having episodes any more. He is continuing the HCTZ.
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Case #2

- PP: 58 y.o. male. Meniere's dx 1994. Daily attacks. Severe tinnitus X 34 yrs; classic Migraines X 7 yrs.
 - Had endolymphatic shunt surgery in 1997. Tinnitus and vertigo have gotten progressively worse since surgery. HCTZ 12.5 mg/day.
 - 10/04 HCTZ doubled. Daily attacks w/slight improvement in severity. Option of Meniett vs. IT gent. Opted for Meniett
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Case #2 (Cont.)

- 10/04 PET placement AS
 - 11/5/04 Vertigo worse since PET placement. Sleeps ~ 18 hours/day.
 - 12/9/04 Meniett dispensed. Baseline: daily minor, 3 majors per week.
 - 6/05 Still having about 3 attacks per week, but less severe. Continues w/HCTZ, low salt diet.
 - 12/05 PET extruded. 2/06 Pt felt No improvement after one year use.
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Case #3

- GC: 37 y.o. male w/o classic Menieres sxs but does have fluctuating HL A.S., constant tinnitus, near-constant “strange feeling in head as if things are not entirely right with balance, vision, etc.” Attacks infrequent (~ once/3 mos). W/bad attack, he stays home and sleeps for a couple days. Thinks brought on by prolonged inadequate sleep.
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Case #3 (Cont.)

- 12/04 Meniett dispensed.
 - 1/27/05: no change in sx's. Continues w/HCTZ and low salt diet.
 - 4/28/05 Attacks less frequent than previously. Using 2 times/day. Continues with HCTZ. Had noted vague sx's of vertigo when he didn't use device for a 3 day period.
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Case #3 (Cont.)

- 10/6/05. Meniett being used. PET in place. No episodes of vertigo since last visit.
 - 2/06. Uses Meniett once/day 6 days/wk. He thinks the benefits have been fairly subtle and he had had no attacks since July-Aug
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Case #4

- JD: 42 y.o. male.
 - 10/28/04 Menieres sxs X 4 years (vertigo, fullness, fluctuating hearing), but for past year daily dysequilibrium though not vertigo—other sxs unchanged. HCTZ started (25 mg BID) and potassium; low salt diet.
 - 12/2/04 No change in dysequilibrium. Also now has loud tinnitus. Sxs worse A.D.
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Case #4 (Cont.)

- 1/21/05 PET placed AD.
 - 2/14/05. Meniett dispensed. Baseline: minor (1.5 – 2 minute) attacks daily with big (30-40 minute) attacks every one to two weeks.
 - 4/28/05 Pt doing well with no bad attacks, only occasional minor. Using Meniett 4X/day. PET extruded and to be replaced only if attacks resume.
 - 5/19/05. Doing well w/o Meniett.
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Case #4 (Cont.)

- 7/19/05. Frequent lightheadedness w/one vertigo episode/wk. Constant tinnitus.
- 8/25/05 Worsening sx's. Constant lightheaded w/3 episodes of vertigo/wk. PET replaced AD and resumed meniett use.
 - 10/14/04 Ongoing lightheadedness, but no major episodes since PET replaced. Continues HCTZ.
 - 3/22/06. Patient uses Meniett daily X2. He has been entirely symptom-free for 4-5 months. Happy camper.
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Case #5

- AD: 78 y.o. male with Menieres tx w/ meclizine BID. Has minor attacks every 1-2 wks and “full blown” 1Xmonth—lasting 1-2 days.
 - 4/22/05 PET placed A.D.
 - 5/31/05. Pt. presented for Meniett. Has had no attacks since PET placement. Age/mental status makes prognosis for successful use doubtful. Lives in Mexico. Did not recommend or issue Meniett.
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Case #5 (Cont.)

- 11/15/05. Had another attack last month. Currently with sinus infection. PET extruded. Pt. desired to clear up sinus infection before considering replacement of PET.
 - 1/3/06. Sinus infection somewhat improved, but continues foul smelling drainage.
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Case #6

- FP: 46 y.o. male w/Menieres since 1999. Had been tx w HCTZ prn, valium, chlorpromazine and low salt diet. AS fullness prior to attacks. Was able to avert attacks by taking valium at onset of fullness from 2000 until 4/9/05.
 - 4/9/05 He went to mountains, had AS fullness, HL, vertigo, vomiting. Has had several similar attacks since.
 - Rx for HCTZ, valium and chlorpromazine. On low salt diet.
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Case #6 (Cont.)

- 4/26/05. Pt. now taking valium daily to avert attacks
 - 5/05 PET place A.S.
 - 7/21/05. Sxs improved with PET (3-4 episodes in two months vs. 3/wk prior). Also, severity of attacks diminished.
 - 7/26/05. Meniett dispensed. Baseline: weekly mild attack (~2 hrs) with bad attack 1X/2 mos, lasting 12-14 hrs; and bedridden.
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Case #6 (Cont.)

- 10/25/05. Meniett no longer effective b/c PET extruded. Sched. for re-insertion.
 - When PE tube was replaced, he said it was a “miracle device.” It stopped the vertigo and fullness completely and was using it 1X/day.
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Case #7

- NL: 41 y.o. male with 3-4 month h/o lightheadedness/imbalance fairly constant. Also, with episodic vertigo, nausea X 3 (longest 1.5 days), tinnitus and fullness A.D. Has been taking meclizine 1 X day for past month.
 - 11/3/04 Put on trial of HCTZ and low salt diet.
 - 1/13/05. Some help w/dysequilibrium but episodic vertigo continues.
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Case #7 (Cont.)

- 3/11/05. Sxs unchanged.
 - 5/24/05. Daily dysequilibrium and now weekly attacks of vertigo
 - 7/15/05. PET placed A.D.
 - 8/18/05. Sxs. not improved with PET. In fact, somewhat worse.
 - 8/25/05 PET extruded and replaced.
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Case #7 (Cont.)

- 9/19/05. Meniett dispensed. Baseline: 3-4 minor attacks/week ~ 15 mins; 3-12 major attacks/month ~7-8 hours up to 2 days.
 - 10/25/05. Non-patent AD PET. Meds given to clear.
 - 12/27/05. Meniett judged by patient to be ineffective. PET is in process of extruding. Pt does not want tube replaced. Used Meniett 3-4 weeks w/o noticeable benefit.
 - 3/23/06 Device was returned.
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Case #8

- CS: 59 y.o. female c/o vertigo/pressure/hearing loss A.D. Also has conductive component, (Otoscl.?). Had prior stapedectomy A.S.
 - 9/22/05. Trial HCTZ and potassium.
 - 10/5/05. Pt reported adverse reactions to HCTZ and potassium taken 9/22 to 9/25.
 - 10/21/05. PET placed.
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Case #8 (Cont.)

- 11/8/05. Partial reduction of sx's. Prior to PET she was symptomatic ~75% of time (dizzy on and off throughout day and fearful of falling). Post PET placement, sx's present about one third of time and bouts don't last as long.
 - 12/1/05. Meniett dispensed. Baseline: 1 5-10 min episode per day if not up and about. If active, 3-4 episodes/day.
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Case #8 (Cont.)

- 3/05 Patient left phone message, saying Meniett was “working.” No info on any further improvement with use of device.
 - Lost to follow-up. Died 3/21/06.
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Case #9

- KB: 45 y.o. male presented for second opinion. Had been treated for 2 yrs for Menieres with HCTZ without effect. Has had about 50 episodes over the past 2 years, often associated with fullness and tinnitus A.D. Episodes last ~1 minute and are associated with nausea.
 - 12/14/05 Increased HCTZ to 25 mg BID and continue low salt diet.
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Case #9 (Cont.)

- 1/11/05. Since increasing HCTZ, has had one episode during which he was incapacitated and one episode of fullness only.
 - 1/24/05. 1-2 min episodes of vertigo/nausea (last one 20 days ago vs. 6 episodes in November).
 - 5/12/05. Sxs stable on medical treatment.
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Case #9 (Cont.)

- 12/15/05. Still having several attacks per week.
 - 1/6/06. PET placement A.D. followed by 3 weeks asymptomatic.
 - 1/27/06 Had episode yesterday and again this morning. Meniett dispensed. Prior to PET placement, was averaging about 1 per week.
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Case #9 (Cont.)

- 3/06 Reported sx's less pronounced at beginning of Meniett use, less compliant with Meniett use and now is starting to be more compliant with treatment regimen.
 - Current sx's, 3-4 times per day, 3-4 days per week. It has been about 10 days since last episode. Insufficient compliance time to determine benefit yet. Will continue to follow.
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Comments/Observations?
