

Meniere's Disease: Causes and Treatments

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Prosper Ménière

Described patients with severe spinning
vertigo in 1861.

Was the first to identify vertigo as having an
origin in the inner ear.

Meniere's Disease

Episodic *vertigo* lasting hours – spinning, nausea, vomiting, diaphoresis

Hearing loss - typically fluctuating in early phases of disease

Tinnitus - often increasing before or during attack

Aural Pressure

Attacks are random and unpredictable - frequent, rare or clustered

Patient feels perfectly fine between attacks

Fluid Spaces of the Inner Ear

Perilymph

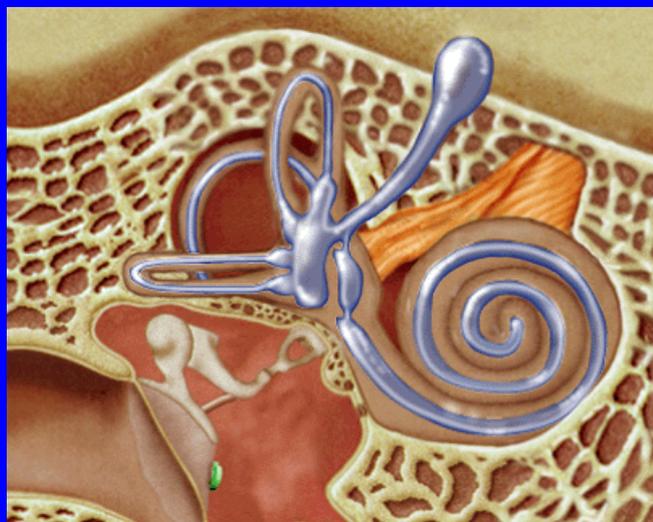
Surrounds membranes of the inner ear

Contiguous with CSF

Endolymph

Unique high K^+ content

Fills membranes of the inner ear

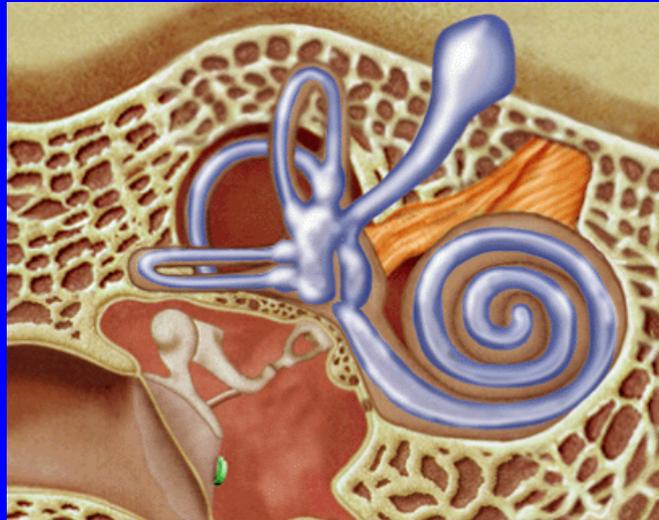


Pathology of Meniere's

Slow rate of turnover of endolymph is normal.

Meniere's caused by under reabsorption of endolymph

Root cause of unknown but multiple anomalies of the endolymphatic sac and duct are reported



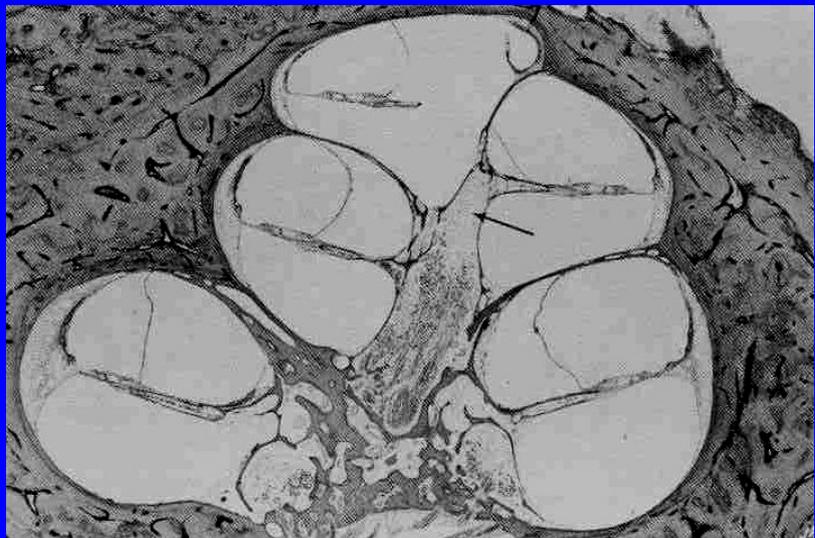
Pathology of Meniere's

Dilation of the endolymphatic spaces (hydrops)

13/13 Meniere's patents had hydrops

13/19 temporal bones with hydrops had Meniere's

Rauch et al 1989



Pathophysiology of Attacks

Ruptures of membranous labyrinth

Mixing of high K^+ endolymph with perilymph bathing the 8th nerve fibers.

Direction changing nystagmus during attack – first excitatory and second inhibitory.

Underlying cause?

Autoimmune

Viral

Variable Patterns of Meniere's

Fluctuating
Hearing loss
Alone

Vestibular
Attacks Alone



Cochlear
Meniere's

Typical
Meniere's

Vestibular
Meniere's

Difficulties in Studying Meniere's

High individual variability

Individual attacks unpredictable

Severity of individual attacks variable

Course of disease unpredictable with clusters of attacks and periods of remission common

Disease eventually burns out, usually with severe hearing loss

Meniere's: Medical Management

Dietary Management

Salt restriction

Caffeine

Nicotine

Chocolate

Diuretics

Exercise and general conditioning

Meniere's: Success of Medical Management

60 – 80% of patients need no further treatment

Surgical Management of Meniere's

Restorative

Attempt to restore the normal physiology of the endolymphatic space.

Destructive

Prevent abnormal nerve impulses from reaching the brain.

Surgical Management of Meniere's

Restorative

Endolymphatic sac surgery

Destructive

Chemical labyrinthectomy

Surgical labyrinthectomy

Vestibular nerve section

Endolymphatic Sac Surgery

Rationale:

Place drainage tube in the endolymphatic sac.

Advantages:

Straight forward, low complication rate,
low risk to hearing

Disadvantages:

May not work as theoretically designed
Failure rate of 30%



Vestibular Nerve Section

Rationale:

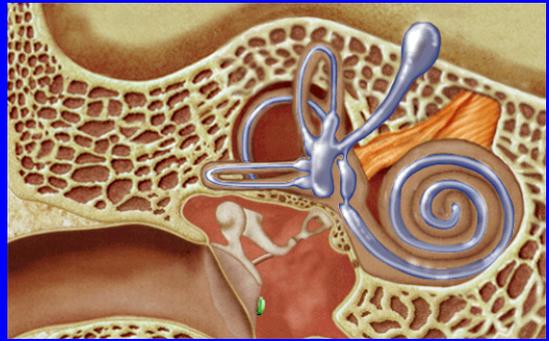
Divide vestibular nerve
between inner ear and
brainstem

Advantages:

High success rate (>95%)
Hearing preserved

Disadvantages:

Craniotomy
Facial nerve at small risk



Labyrinthectomy: Chemical or Surgical

Rationale:

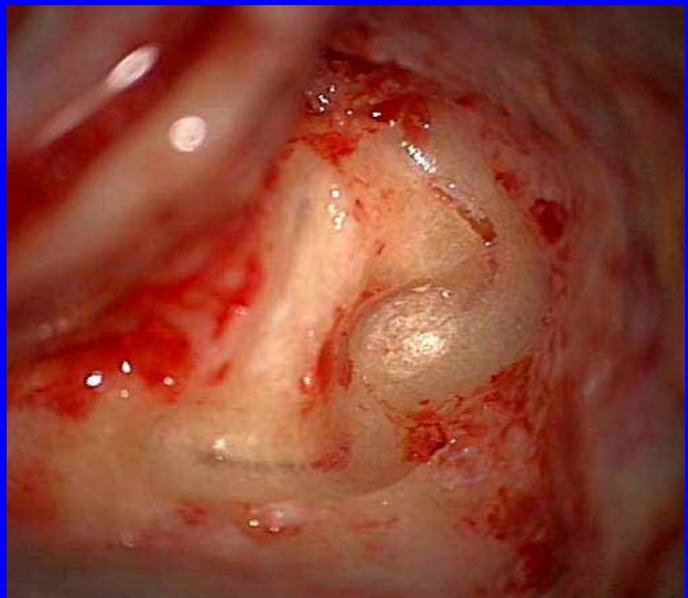
Destroy inner ear
preventing abnormal nerve
impulses from
reaching the brainstem

Advantages:

High success rate
(>95%)

Disadvantages:

Hearing lost



Chemical Labyrinthectomy

Schuknecht (1957) – intratympanic streptomycin

Lange (1976) – intratympanic gentamicin

Daily injections until caloric response abolished

High rates of sensorineural hearing loss.

Low Dose Aminoglycosides

Single dose of intratympanic gentamicin adequate to control vertigo in most patients with hearing commensurate with natural history of Meniere's.

Harner et al 2001

Treatment Protocol

Intratympanic aminoglycosides must be considered with just as much seriousness as a surgical procedure.

There is the same risk of chronic disequilibrium as after labyrinthectomy.

Treatment Protocol

Topical anesthesia with concentrated phenol
Anterior and posterior pinpoint myringotomy
Bicarbonate buffered gentamicin
Middle ear filled, approx 0.4 ml
Patient retained supine for 45 minutes

Results: Vertigo and Hearing

n = 34

Complete control of vertigo (Class A) – 90%

Hearing

Improved - 15%

Unchanged - 68%

Worse - 17%

(Profound hearing loss – 3%)

Wu & Minor, 2003

Intermediate Alternative

Medtronic
XOMED
Meniett® Low-Pressure
Pulse Generator



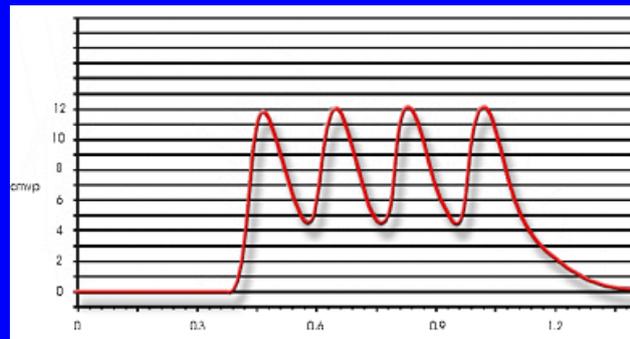


Meniett™

Low Pressure Pulses

Max Pressure - 12 cm wc

Frequency - 6 Hz

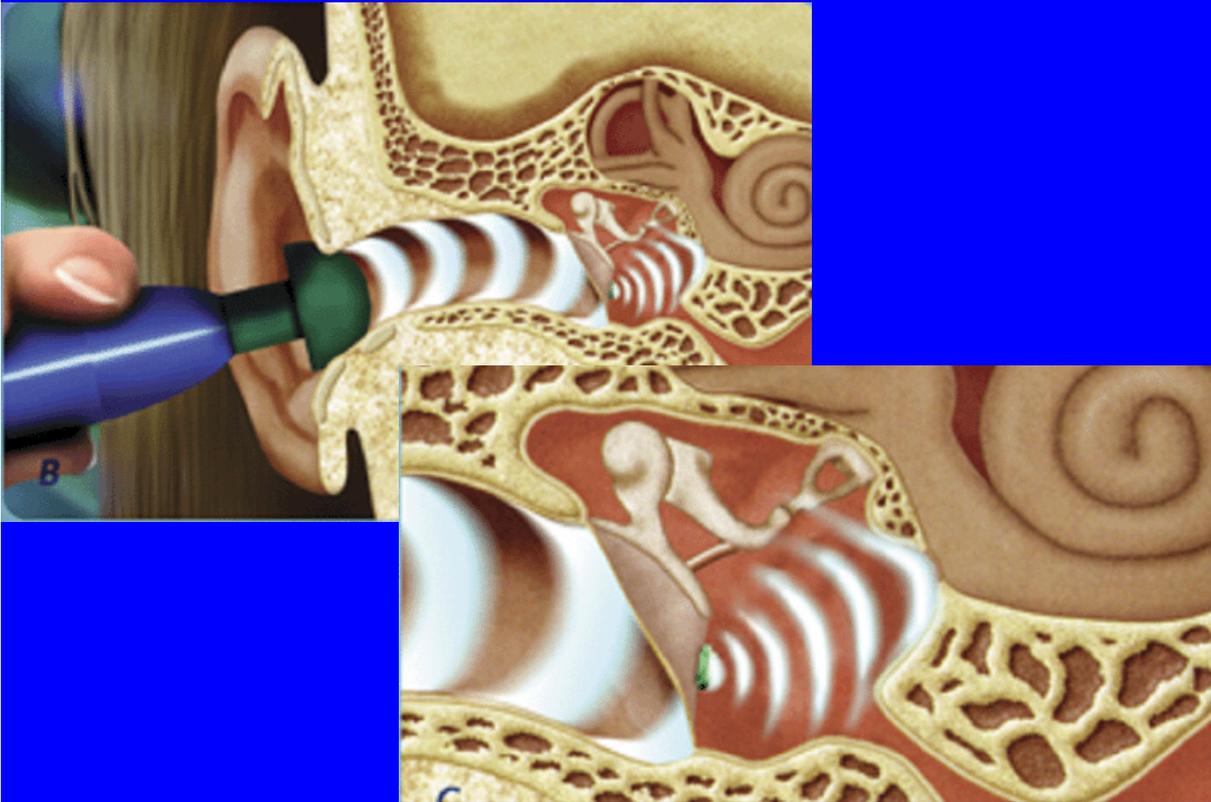


Proposed Mechanisms of Physiologic Effect

A pressure-generating device delivers a complex series of low pressure pulses. The pressure pulses are transmitted to the inner ear.

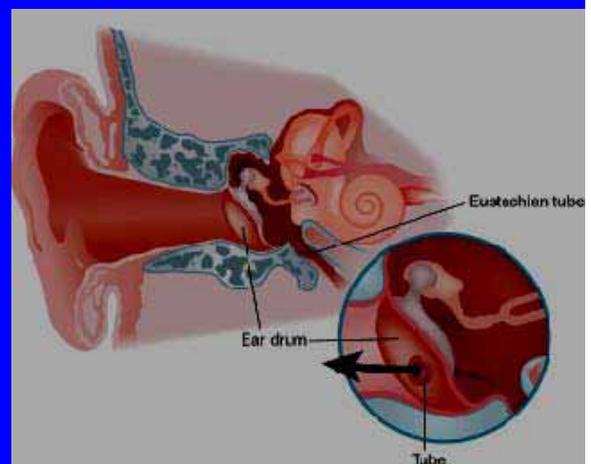
The pressure pulses cause displacement of the perilymphatic fluid and stimulates flow of the endolymph

Meniett™ Treatment



Myringotomy Tube

Allows pressure equalization across tympanic membrane.
Required if Meniett is to work.
Placed under local topical anesthesia in office.



Initial Investigations

Evaluation of pressure treatments in patients with Ménière's Disease:

- 1975 Effects of a hypobaric pressure chamber in patients.
- 1980 Control of vertigo and improvement of cochlear function in patients with advanced long-standing symptoms.
- 1987 Improvement in cochlear selectivity and control of vertigo in patients with well defined inner ear symptoms.
- 1987 Improvement of bone conducted thresholds in patients with advanced sensorineural hearing losses due to Meniere's Disease.
- 1995 Improvement in electrocochleograms in patients with definite Ménière's Disease.

Clinical Studies

Safety and Efficacy studies using the Meniett™ in patients with Ménière's Disease:

- 1997 Densert et al: Improvement of cochlear electric potentials (TTECoG) immediately after exposure to low pressure pulses. Prospective, randomized, placebo controlled study.
- 1998 Odkvist et al: Improvement of vertigo and functionality after short term pressure treatment. Prospective, randomized, placebo controlled study.
- 2001 Densert & Sass: A two year follow up - Control of vertigo, significant improvement in functionality, and conserving effect on hearing levels in patients with refractory forms of Ménière's Disease (AAO-HNS criteria for reporting and evaluation of therapies).

Control of Symptoms in Patients with Ménière's Disease Using Middle Ear Pressure Applications, a Two-Years Follow Up.

B. Densert & K. Sass. In publication, Acta Otolaryngol (Stockh), 2001;Vol. 5

Methods:

37 definite Ménière's patients, Stage 2-4 according to the AAO criteria.

31 patients had failed to respond to medical treatment.

Ventilation tubes placed 2-4 weeks prior to the start of treatment.

Results:

19 patients were free from vertigo spells, (Class A).

15 patients had a significant decrease in frequency of vertigo spells, (Class B).

3 patients did not respond to pressure treatment (8%).

Functionality improved by at least 2 levels for all 34 patients who responded to treatment.

The 34 patients who responded to treatment did not resume their intake of diuretics or other medications.

No side effects or adverse events related to the pressure treatment during the 2 years.

Meniett Randomized Trial, 2004

Randomized, placebo-controlled, double-blind
multicenter trial

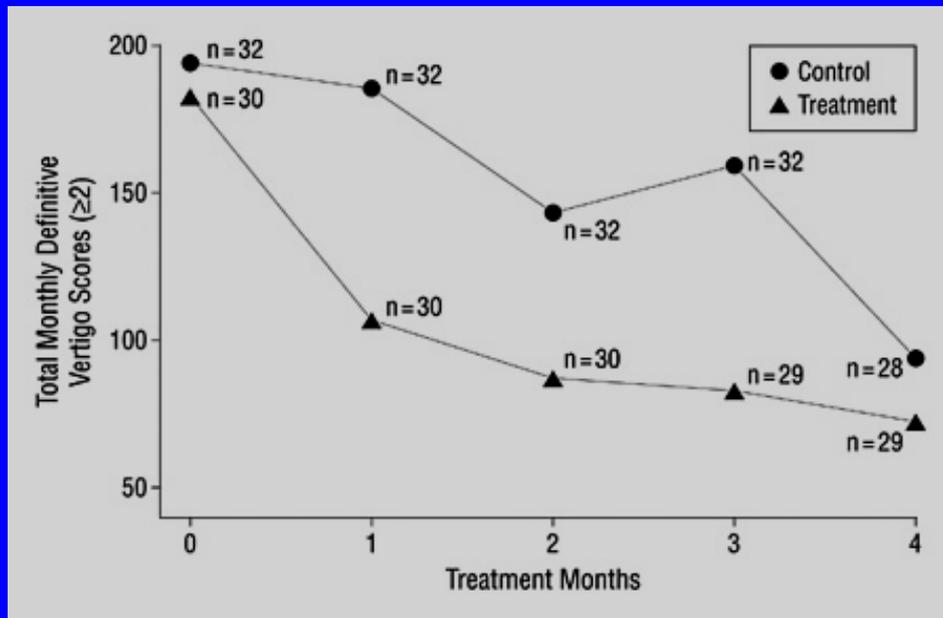
4 months duration

62 evaluable patients

Outcome measures: vertigo, daily activity,
and hearing.

Gates, et al. *Arch Otolaryngology*, June 2004

Meniett Randomized Trial, 2004



Gates, et al. *Arch Otolaryngology*, June 2004

Meniett Randomized Trial, 2004

Treatment group had significantly less vertigo

Fewer days of definitive vertigo

Fewer days lost from work

Outcome did not differ by age, gender,
laterality, duration of symptoms

Tympanostomy tube alone had no effect

No effect on hearing

Gates, et al. *Arch Otolaryngology*, June 2004

Treatment Plan

Diagnosis of Ménière's Disease confirmed and medical evaluation completed

Medical therapy trial failed

In-office placement of ventilation tube

Patient training in-office with the **Meniett™**

Patient administered treatment 3-5 times/day, 5 min.

Treatments continue until remission and, thereafter, depending on duration and severity of symptoms

Importance of Daily Use

Success is highly based upon treatment regimen of 3-5 times per day

It only takes 5 minutes per treatment

Certain people respond immediately, others respond in 4-6 weeks

Emory 2 & 3 Year Results

2/2002 – 2/2004

21 patients prescribed and obtained Meniett

Emory 2 Year Results

| | Year 2 |
|----------------------|--------|
| Original Cohort | 23 |
| Lost to Follow-up | 2 |
| Evaluable | 21 |
| Failed | 6 |
| Failed % | 29% |
| Asymptomatic | 4 |
| Using | 11 |
| Using/Asymptomatic % | 71% |

Emory 3 Year Results

| | Year 2 | Year 3 |
|----------------------|--------|--------|
| Original Cohort | 23 | 23 |
| Lost to Follow-up | 2 | 4 |
| Evaluable | 21 | 19 |
| Failed | 6 | 7 |
| Failed % | 29% | 37% |
| Asymptomatic | 4 | 4 |
| Using | 11 | 8 |
| Using/Asymptomatic % | 71% | 63% |

Ménière's Patients Particularly Suited for Pressure Treatment

Intense vestibular and cochlear symptoms
Patients who have failed medical treatment
Bilateral Ménière's Disease
Affection of the remaining ear
>65 years
Juvenile Ménière's Disease

Treatment Protocol

