

THE MENIERE'S TREATMENT LADDER (part two)

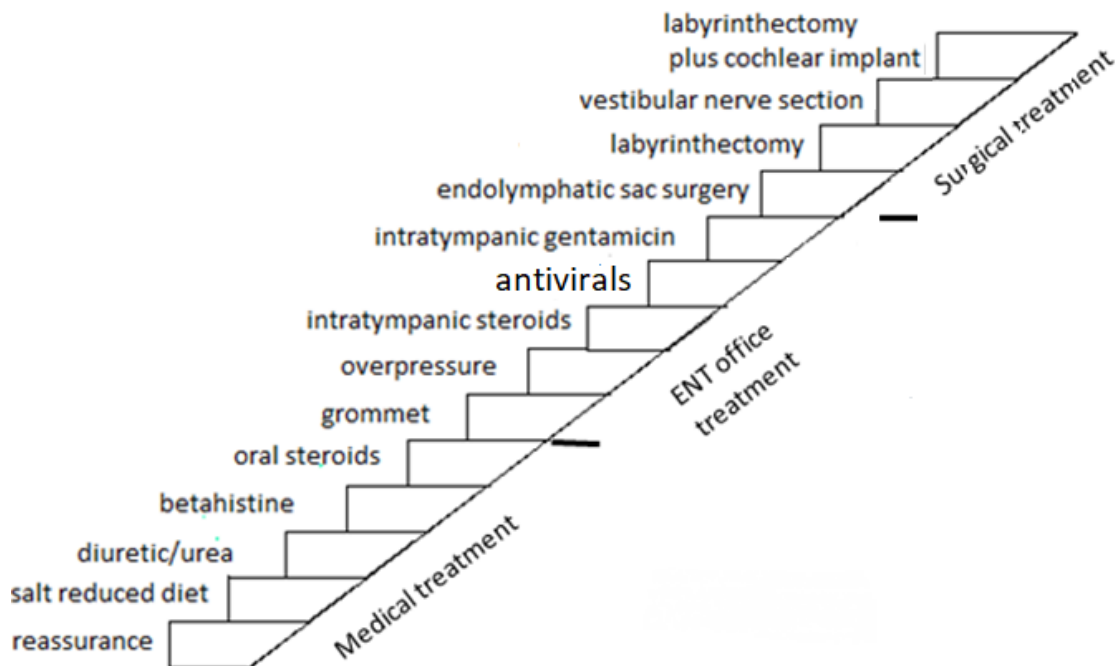
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I introduced the Meniere's treatment ladder in part 1 and explained the first four steps, covering reassurance, the low salt diet, use of diuretics/urea and betahistine.

The ladder climbs from the most benign therapies to the most radical surgery.

In this instalment I will cover the next five steps; oral steroids, grommets overpressure and intratympanic therapies.

The final 4 steps, which look at surgical treatment will be continued in part 3.



CI - cochlear Implant
VI - Vestibular Implant

STEP FIVE - Oral Steroids

In Australia, the usual steroids prescribed are prednisone or prednisolone which can be swallowed (oral medication). Steroids reduce inflammation and are given for various conditions including facial palsy and sudden hearing loss. The use of steroids for the treatment of Meniere's Disease (MD) is based on the concept that an inflammatory process results in the formation of excess fluid within the

membranous labyrinth (endolymphatic hydrops), and fluctuations in the endolymph level cause the attacks of vertigo and other symptoms. The inflammation may result from a reduced immunological response to a virus or to an auto-immune response. (Auto-immune diseases such as asthma, rheumatic arthritis are when the body falsely recognises its own tissues as foreign and mounts an immunological attack on them). Steroids have been shown to be effective in treating most auto-immune diseases.

Some support for an auto-immune theory is the finding that HLA (human leucocytic antigen) deficiencies are found in some MD sufferers. This deficit is related to an abnormality on chromosome 6 and this probably accounts for MD occurring in family members.

The Cochrane database⁽¹⁾ has given support to the use of intratympanic steroids so it is hoped that giving the steroids orally will have the same effect. The usual dosage is 60-80mg daily for 5-7 days and then a tailing off dosage. Some clinicians prefer to tail off very slowly and a maintenance dose of around 10- 20mg daily for some weeks. Usually the steroids are given when there is a cluster of attacks of vertigo occurring.

A study by well-respected researchers⁽²⁾ in Los Angeles failed to show any improvement in hearing levels after oral steroids and the Cochrane database review was also inconclusive. Nevertheless many physicians do believe anecdotally that oral steroids help to halt a series of attacks.

The problem with oral steroids is that they affect the entire body and can cause significant side effects. The most serious side effect is bleeding in the stomach and oral steroids should be stopped immediately if significant indigestion occurs. Oral steroids can also adversely affect blood sugar levels in diabetics. Steroids may alter the body's defence against infections and long term use leads to weight gain and fluid retention. The advantage of intratympanic administration of steroids is that a larger dose is received into the inner ear and virtually none of the steroid leaks into the rest of the body.

STEP SIX - grommets

Over 70 years ago, Professor Tumarkin in Liverpool, England championed the value of grommets to stop Meniere's attacks.

Grommets are tiny tubes inserted into the eardrum to equalise the pressure within the middle ear cleft. The concept is that pressure fluctuations within the middle ear can be transmitted to the inner ear and excessive pressure changes can increase the formation of endolymph causing attacks of vertigo. It is also suspected that the feeling of aural fullness is due to an increased sensitivity within the middle ear.

Short term grommets can usually be inserted using local anaesthetic in the ENT surgeon's office unless there is a narrow ear canal. If there is a benefit, the grommets can be exchanged for longer staying T tube grommets.

There is a risk of infection especially if contaminated water enters the ear. Swimming in public pools is unwise and swimming in the sea only possible if ear plugs fit effectively. Wax can sometimes block the grommet making it ineffective. There is always a risk of a permanent perforation of the ear drum after the grommet extrudes, especially if a long stay grommet is inserted.

The Cochrane database review states that there is insufficient evidence that grommets are beneficial although there are some compelling studies. Montandon and co-workers⁽³⁾ reported a series of 28 patients in which 82% benefitted with a marked reduction in the vertigo attacks. No placebo group was possible.

STEP SEVEN - Overpressure (The Meniett device)

The Meniett device delivers small calibrated pulses of pressure through a grommet into the middle ear cleft to 'milk away' endolymphatic hydrops.

In Sweden, where MD is a common disorder, studies were undertaken using hyperbaric chambers. These are the decompression chambers into which a diver is placed after a diving accident when 'bends' has occurred. Hyperbaric oxygen chambers are used to force oxygen into poorly healing tissues. It was found when a MD sufferer was placed into a hyperbaric chamber, there was often a temporary improvement in symptoms with less fullness in the ear and better hearing. Too great a pressure could actually cause an attack of vertigo to occur so the pressure change had to be very carefully monitored.

In 1980, Barbara Densert and her husband Ove Densert began a series of studies to develop the low pressure unit which became commercialized in 1999 as the Meniett™ device. The concept is that these small pressure pulses gently squeeze the endolymph compartment and disperse the excess fluid either to the endolymphatic duct or back into blood vessels. A number of prototype devices were trialed in Sweden and eventually this work led to the commercial development of a machine which is available in Australia and which has been the subject of several scientific trials.

To use the machine, a grommet must be inserted initially into the ear drum to allow the pressure pulses to pass through to the middle ear. The MD sufferer is then asked to wait about a week to ensure the grommet is stable.

The Meniett™ machine should be placed on a level surface. The user must be sitting in an upright position (not lying down). The ear piece is then held in the ear canal and a button to commence the programme is pressed. There are some simple lights on the machine to indicate the progress. The machine is designed to deliver small pressure pulses in a safe manner. First it checks that an airtight seal has been achieved. Then the machine calculates the middle ear pressure, applies a static pressure of 10 cm H₂O and then applies pulses of 15 cm H₂O. A series of four pulses is presented three times with a gap of 4 seconds, there is then a period of 45 seconds without pulses. This paradigm is repeated three times so the entire

treatment period is about 3 minutes. It is recommended that while the MD is active, the machine is used at least 3 times a day.

Gates and co-workers⁽⁴⁾ have conducted a controlled trial of 67 patients involving 4 centres in the USA which was carefully designed and showed a positive outcome for the patients when using the device.

Despite this the Cochrane Data base⁽⁵⁾ remains uncommitted and suggests that further evidence is needed before they can endorse the treatment.

In conclusion: the Meniett™ device is a mechanical means of controlling the excess endolymph in MD sufferers. It is not expected to be an absolute means of controlling MD. The results can be expected to equal the results seen with salt reduction or the use of diuretics. The advantage is that the treatment can be combined with the other methods of fluid reduction. There are few disadvantages other than those of having a grommet permanently in the ear. Unfortunately the device is expensive and costs over \$5000 although the company (Medtronic) will lease the device so individuals can trial it at a lesser cost. Some costs are refunded by some private health insurers on special request but those without private health have to purchase the device for themselves as Medicare does not cover this item.

STEPS 8 & 9 – Intratympanic therapies

Two medications which are most commonly delivered by intratympanic injection have both been studied and found to have proven benefit. These medications are intratympanic steroids⁽⁶⁾ and intratympanic gentamicin⁽⁷⁾.

The method for delivery of intratympanic medications requires the patient to lie on a couch and the ear is examined using an operating microscope. The tympanic membrane (eardrum) in the affected ear is anaesthetised. I use a tiny droplet of phenol but other ENT specialists may prefer to use an analgesic ointment. Often the patient is asked to check the labelling to ensure the correct medication is drawn up into a small syringe. Using a long intrathecal needle the medication is delivered through the eardrum into the middle ear cleft. The patient feels little pain but feels the ear is filling up with fluid and some may pass down the Eustachian tube into the throat. The patient then keeps lying down for at least 5 minutes so that the medication can perfuse from the middle ear into the inner ear. There is usually no feeling of dizziness and the patient can go home within a few minutes. The ear should be kept dry for 2 days to prevent infection and the patient should not keep squeezing air up into the ear from the back of the throat so the small perforation caused by the needle can close.

Intratympanic steroids

Usually 2ml of 40mg/ml of dexamethasone is drawn into the syringe but less than half will fill the middle ear cleft. The amount of steroid entering the inner ear is unknown and variable. The steroid solution will pass along the basal coil of the

cochlear before it is removed by the blood vessels within the ear. Some steroid will also pass up the spiral ligament into the vestibular portion of the inner ear. Steroid injections have a powerful anti-inflammatory effect and have been used in other branches of medicine: for example, to treat inflamed joints. It is suspected that recurrences of Meniere's symptoms have an inflammatory basis. The intratympanic steroids can halt a series of attacks and have been shown to help preserve hearing. There are minimal risks involved for the patient. Complications of treatment are exceedingly rare. It is important that the tip of the needle is placed safely through the eardrum without disrupting any of the ear bones. The possibility of a persistent perforation or infection is also very rare.

Intratympanic gentamicin

The concept is that the affected ear has a faulty vestibular output which suddenly flares up causing attacks of vertigo. It can be likened to a faulty engine on an aeroplane which suddenly flares up spinning the plane around. Surgery can be performed to totally destroy the output of the faulty vestibular labyrinth (labyrinthectomy and vestibular nerve section). However, it needs to be considered that Meniere's disease will eventually 'burn out' and the attacks of vertigo will peter out and eventually cease. After 'burn out', approximately 40% of the balance function remains in the ear which is useful to prevent unsteadiness especially for those who develop bilateral disease and older persons. The adage is 'don't offer therapies which make the outcome worse than the natural outcome of the condition'. The problem is that it can take years of distressing vertigo before the eventual 'burn out' occurs. Gentamicin is a vestibular toxic medication which destroys vestibular function. Several intratympanic doses can be given to completely destroy all the balance function of the ear without the need for surgery. However a major advantage of intratympanic gentamicin is that it is possible to give only limited amounts intratympanically to reduce the balance in the ear sufficiently to reduce the severity of the attacks so that the patient can retain some balance function while waiting for 'burn out' to occur. Balance function in the affected ear is gradually lost as the disease progresses. It is hoped that there is little difference in the amount of residual balance function after limited gentamicin treatment compared to the amount of balance remaining after the natural 'burn out' of the disease, although several distressing years are avoided.

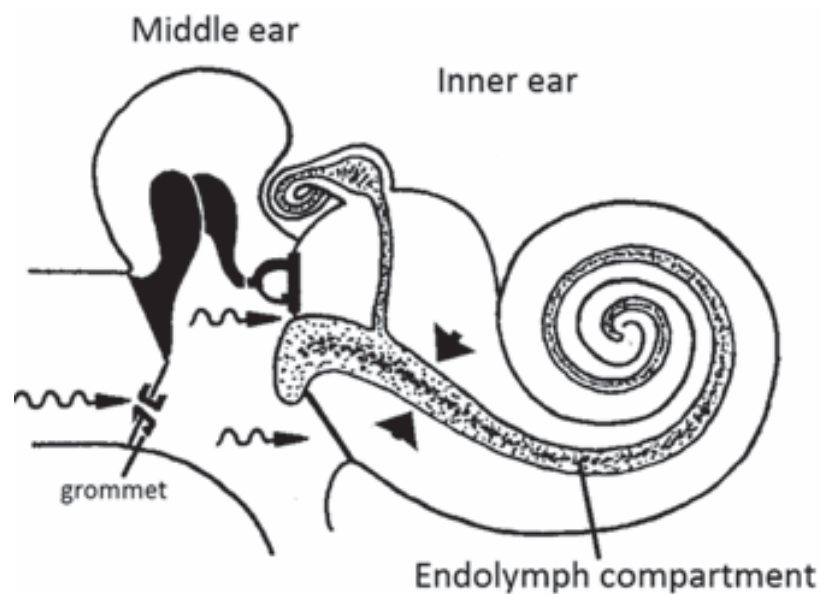
There is no immediate feeling of dizziness, but usually 2-3 days later the patient may feel some unsteadiness. The unsteadiness will increase if further intratympanic injections are given, especially when the goal is to destroy all the faulty vestibular function in the affected ear. Often a balance test is performed 6 weeks after the last dose to discover the effectiveness of the treatment.

There are the same possible complications as already mentioned for intratympanic steroid therapy. In some patients (5-10%) the gentamicin has little or no effect on the inner ear and sometimes the tympanic membrane is lifted surgically to find out why the medication did not perfuse into the inner ear. Sometimes there are fibrous

adhesions blocking the windows of the inner ear and a pledget of gelatine foam is soaked in gentamicin and applied directly. This can have a marked effect losing a lot of inner ear balance function after just one application. Rarely, intratympanic delivery of gentamicin can have a similar effect (1%). There is a risk to the hearing if several applications are given and typically some of the high frequency hearing can be lost.

Vestibular physiotherapy has a major role in re-establishing balance after gentamicin therapy. Again using the aeroplane analogy, the pilot has to relearn the controls after losing the output of one of the engines.

It is expected that other medications will become available which can be applied by the intratympanic route. For example, trials of OTO-104 are being done in the US and EU by a commercial company called Otonomy. This is steroid gel which is placed into the round window niche and it is hoped that it will have a longer lasting effect.



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