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Menière's disease treated by grommet insertion

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ABSTRACT

INTRODUCTION Menière's disease (MD) is an uncommon cause of sudden profound vertigo. A variety of medical and surgical treatments have been used to manage this condition. This study reviewed the outcomes of patients treated with grommet insertion and transtympanic steroid injection.

METHODS Patients diagnosed with MD between 2007 and 2017 were identified, and case notes and audiological data were retrieved for those managed by grommet (ventilation tube) insertion with and without transtympanic steroid injection.

RESULTS Thirty-three patients were identified as being diagnosed with MD. Grommet insertion resulted in cessation or improvement of attacks in 91% of cases. The mean follow-up duration was 33.8 months (median: 29 months). The mean hearing threshold across the low frequencies improved from 57.2dBHL to 49.4dBHL ($p=0.031$). Following the intervention, improved tinnitus was reported in 80% of cases. Twelve patients (36%) reported aural fullness prior to grommet insertion; all reported improved symptoms following the procedure.

CONCLUSIONS Early grommet insertion with transtympanic steroid injection, combined with customised vestibular physiotherapy, may provide an alternative first-line strategy for MD, preventing further true MD attacks. In some patients, it may significantly improve hearing thresholds.

KEYWORDS

Menière's disease – Grommet insertion – Ventilation tube

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Introduction

Menière's disease (MD) is an uncommon cause of vertigo with an estimated incidence of 4.5–8.2 cases per 100,000 per annum.^{1,2} This condition is characterised by spontaneous unpredictable bouts of aural fullness, severe vertigo, hearing loss and roaring tinnitus.³ Sequential pure tone audiometry demonstrating a sensorineural hearing loss and magnetic resonance imaging (MRI) of the internal auditory meatus to exclude central pathology are essential to confirm a clinical diagnosis.

Histological studies have revealed expansion of the scala media with intermittent acute attacks attributed to rupture of Reissner's membrane, and subsequent mixing of perilymph and endolymph.^{4,5} This results in toxic overexcitation of the organ of Corti and vestibular neuroepithelium, with eventual severe sensorineural hearing loss and a reduction in peripheral vestibular function.

As the disease progresses, sensorineural hearing loss worsens in a characteristic stepwise fashion that is associated with profound spells of vertigo.⁶ Patients with end stage disease are prone to spells of dizziness, decompensation (which may be misinterpreted as acute attacks) and sudden drop attacks (Tumarkin attacks).⁷ Severe

sensorineural hearing loss and partial residual vestibular function is often found in a 'burnt out' ear. Symptoms are initially unilateral but may be bilateral.⁸

Grommet (ventilation tube) insertion is a relatively simple procedure that has been advocated by some surgeons in the treatment of MD.⁹ Although the mechanism of action has been attributed to pressure change in the middle ear, tympanometry does not always support the presence of negative middle ear pressure. The aim of this study was to perform a retrospective review of the outcome of patients diagnosed with MD who were treated with grommet insertion only, and of those treated with grommet insertion and transtympanic steroid injection.

Methods

Patients diagnosed with MD between 2007 and 2017 were identified and their case notes reviewed. A diagnosis of MD was made based on each patient fulfilling all four of the following criteria:

- > a history consistent with MD
- > a fluctuating sensorineural hearing loss confirmed by pure tone audiometry
- > normal MRI of the internal auditory meatus

- > a peripheral vestibular deficit confirmed by bithermal caloric testing or suggested by a significant directional preponderance

All patients managed by grommet insertion were identified. All cases were referred to a specialist vestibular physiotherapist for customised vestibular rehabilitation after surgery. Hearing outcomes were assessed by pure tone audiometry before and approximately three months after the procedure. Following the intervention, the frequency and severity of vertiginous episodes was noted, as was the effect of grommet insertion on tinnitus. These patient reported outcome measures were assessed with a value of -1 denoting worsening symptoms, 0 denoting unaltered symptomatology and +1 denoting symptom improvement.

Statistical analysis

The paired t-test was used to compare hearing thresholds following normality assessment with the Kolmogorov-Smirnov test. The Wilcoxon signed-rank test was used for comparison of non-parametric treatment effect outcomes. A *p*-value of <0.05 was considered statistically significant. SPSS® version 24.0 (IBM, New York, US) was employed for data analysis.

Results

A total of 33 patients were identified as being diagnosed with MD. The majority were female (*n*=24, 72.7%). The mean patient age was 46.0 years (standard deviation: 12.4 years). The duration of symptoms exceeded two years in three-quarters of the patients (*n*=24, 72.7%). The mean follow-up duration was 33.8 months (median: 29 months, range: 12–88 months).

The right ear was most commonly affected (*n*=20, 60.8%). A previous or concurrent diagnosis of vestibular (vertiginous) migraine was made in seven cases (21.2%) and treated accordingly. One patient had been previously diagnosed with benign paroxysmal positional vertigo. Three patients (9.1%) had undergone previous grommet insertion for MD prior to referral. Five patients (15.5%) underwent more than one grommet insertion procedure on the same ear; two patients had a total of three insertions and three patients a total of two insertions.

Patients receiving transtympanic steroids had grommet insertion under general anaesthesia, with the ventilation tube inserted into the anteroinferior quadrant of the tympanic membrane. Methylprednisolone (80mg in 2ml) was injected into the middle ear through the tympanic

membrane prior to grommet insertion. The volume of steroid injected was variable and it often spilt into the external auditory canal.

A Shah grommet was the ventilation tube of choice in the majority of cases (*n*=32, 97.0%) and the initial grommet employed in every patient. A Triune tube was used in one patient and a T-tube in a further two patients. Transtympanic steroid injection was performed in 26 patients (78.8%). No adverse effects of grommet insertion or transtympanic steroid injection were reported.

Vertigo

Symptoms of vertigo were resolved or improved following grommet insertion in 30 patients (91.0%). Among these, attacks of MD settled but vestibular migraine and spells of decompensation symptoms persisted.

Two patients (6.1%) reported no change in their symptoms after the intervention. These individuals underwent both grommet insertion and transtympanic steroid injection.

Hearing level

For the entire study cohort, the mean hearing threshold across the low frequencies improved from 57.2dBHL to 49.4dBHL. The treatment effect (expressed as the difference between the mean hearing thresholds before and after treatment) was 7.8dBHL. This was a statistically significant improvement (*p*=0.031). The high frequency hearing thresholds and overall hearing were not significantly altered by the intervention (Table 1).

Subgroup analysis of hearing thresholds for those patients who had grommets and transtympanic steroids showed a sustained significant improvement of the low frequency thresholds with a mean difference of 19.0dBHL (*p*=0.046) (Table 2). Seven patients had grommet insertion alone, with no significant alteration of their hearing thresholds (Table 3).

Five patients underwent grommet insertion on two or more occasions. Pairwise comparisons revealed that the mean difference across the high frequencies and the overall mean difference across all frequencies deteriorated significantly between the second and third insertion (*p*<0.05) with no significant hearing changes for the remaining comparisons (*p*>0.05) (Table 4).

Tinnitus and aural fullness

Fifteen patients (45.5%) reported tinnitus prior to grommet insertion. Of these, 12 (80.0%) felt that the tinnitus

Table 1 Change in mean hearing threshold for entire cohort

| | Before grommet (<i>n</i> =33) | After grommet (+/- steroid) (<i>n</i> =33) | Mean difference | <i>p</i> -value |
|-------------------------|--------------------------------|---|-----------------|-----------------|
| Hearing level | 55.9dBHL (SD: 15.7dBHL) | 52.5dBHL (SD: 20.4dBHL) | 3.4dBHL | 0.240 |
| Low frequencies | 57.2dBHL (SD: 16.1dBHL) | 49.4dBHL (SD: 22.2dBHL) | 7.8dBHL | 0.031 |
| High frequencies | 54.7dBHL (SD: 18.8dBHL) | 55.6dBHL (SD: 20.9dBHL) | -0.9dBHL | 0.757 |
| SD = standard deviation | | | | |

Table 2 Change in mean hearing threshold for patients with grommet insertion and steroid injection

| | Before grommet (n=26) | After grommet (+ steroid) (n=26) | Mean difference | p-value |
|------------------|-------------------------|----------------------------------|-----------------|--------------|
| Hearing level | 56.4dBHL (SD: 16.6dBHL) | 52.3dBHL (SD: 22.3dBHL) | 4.1dBHL | 0.249 |
| Low frequencies | 67.5dBHL (SD: 17.1dBHL) | 48.5dBHL (SD: 24.3dBHL) | 19.0dBHL | 0.046 |
| High frequencies | 55.4dBHL (SD: 19.9dBHL) | 56.1dBHL (SD: 22.4dBHL) | -0.7dBHL | 0.832 |

Table 3 Change in mean hearing threshold for patients with grommet insertion only

| | Before grommet (n=7) | After grommet (no steroid) (n=7) | Mean difference | p-value |
|------------------|-------------------------|----------------------------------|-----------------|---------|
| Hearing level | 54.2dBHL (SD: 12.7dBHL) | 53.3dBHL (SD: 11.9dBHL) | 0.9dBHL | 0.837 |
| Low frequencies | 55.9dBHL (SD: 12.9dBHL) | 52.9dBHL (SD: 13.0dBHL) | 3.0dBHL | 0.340 |
| High frequencies | 52.4dBHL (SD: 14.6dBHL) | 53.8dBHL (SD: 15.6dBHL) | -1.4dBHL | 0.788 |

Table 4 Repeated events analysis: estimated marginal means

| Grommet insertion | Low frequency mean difference | High frequency mean difference | Total threshold difference |
|-------------------|-------------------------------|--------------------------------|----------------------------|
| 1st | 8.0dBHL | -0.4dBHL | 3.8dBHL |
| 2nd | 3.6dBHL | 4.1dBHL | 2.4dBHL |
| 3rd | 0.2dBHL | -5.6dBHL | -3.9dBHL |

improved following the intervention. Of the remaining patients, one had worsening symptoms while two described their symptoms as unchanged. All three received grommets alone.

Twelve patients (36.4%) reported aural fullness prior to treatment. All of these individuals had improved symptoms following the grommet insertion.

When considering the entire study cohort, the treatment effect was positive for all three symptoms, with the effects being statistically significant ($p < 0.01$). This was also the case for the subgroup of patients receiving steroid injection, with significant improvements for all symptoms ($p < 0.01$). For patients who had grommet insertion alone, however, there was no statistically significant improvement in tinnitus ($p = 0.517$) but vertigo attacks and aural fullness did improve significantly ($p = 0.005$ and $p = 0.025$ respectively). Symptoms were improved for the whole cohort while the grommet remained in place, and they recurred during and following grommet extrusion.

Discussion

A variety of medical and surgical treatments have been suggested for the treatment of MD. Medical therapies include betahistine,¹⁰ a histamine analogue that is believed to increase bloodflow to the inner ear, while diuretics such as bendroflumethiazide are thought to reduce the expansion of the endolymph compartment. Cochrane reviews on

both medications have found no good evidence as to their efficacy in reducing the frequency or severity of attacks.^{11,12} Vestibular sedatives (eg prochlorperazine) and antihistamines (eg cyclizine and cinnarizine) are recommended for acute attacks based on their license of use and expert opinion but evidence regarding their efficacy is lacking.¹⁵

Transtympanic interventions include the use of steroid injections such as methylprednisolone¹⁴ and gentamicin ablation.^{15,16} Both interventions reduce the number of vertigo attacks in patients with MD in the six months following treatment. Gentamicin ablation has been a popular method for controlling acute attacks of vertigo in MD patients by destroying vestibular function in the affected ear.¹⁶ However, ablative treatments should be used with caution as this condition may affect both ears in over 40% of cases over a 20-year period.^{7,14} Bilateral vestibular hypofunction is extremely difficult to manage, with many patients wheelchair bound and severely psychologically affected.¹⁷ It could be argued that a 'burnt out' MD ear with reduced vestibular function may be preferential to an inner ear with absent function (as the latter may be more difficult to rehabilitate using vestibular rehabilitation exercises). Furthermore, with increasing life expectancy, more MD patients are likely to survive to develop multilevel vestibulopathy.

Surgical approaches include endolymphatic sac depression, surgical labyrinthectomy and vestibular nerve

section.¹⁸ Tenotomy of the tensor tympani and stapedius tendons for MD has also been described to abolish or reduce attacks.^{19–21} One mechanism, suggested by Loader, is that endocochlear hydrops results in an elevated intracochlear pressure that is displaced on to the ossicular chain.²² This leads to increased rigidity and reduced mobility of the ossicles. Sudden spikes in inner ear pressure and rupture of Reissner's membrane account for the profound and spontaneous bouts of vertigo, hearing loss and tinnitus experienced by patients. Severing the tendons of the stapedius and tensor tympani muscles eliminates the medial force vector of the middle ear ossicles, and this accounts for the improvement in symptoms demonstrated when using this approach.

A curious observation (and one supported by this case series) is that grommet insertion may prevent acute attacks, and partially restore and maintain sensorineural thresholds in the affected ear.⁵ Patients report aural fullness and recurrent attacks on grommet extrusion.

We suggest that grommet insertion may act by a similar mechanism to that proposed previously. Insertion of a ventilation tube could result in a change in tension of the ossicular chain. This limits the forces exerted on the basilar membrane to thresholds below those that result in Reissner's membrane rupture, even though this compartment may be gradually expanding. In our series, grommet insertion resulted in dramatic improvement in sensorineural hearing thresholds and cessation of acute attacks. The sensorineural change is likely to be due to a change in the tension of the middle and hence inner ear, to within a tensile range that supports improved hearing of certain frequencies.^{24,25}

Study limitations

Although the data in this study indicate that grommet insertion is a promising and relatively low risk surgical treatment for MD, our analysis has several limitations. This was a retrospective review, with inherent selection bias. It included only a small number of patients and there was no comparison with a control group. In addition, no dizziness questionnaires were employed. We would therefore recommend a formal prospective case series or randomised controlled trial assessing this approach in the management of MD.

Conclusions

Our findings indicate that early transtympanic steroid injection and grommet insertion, along with customised vestibular physiotherapy, may provide an alternative first-line strategy for the treatment of MD. The results presented imply that this approach prevents attacks and (in some patients) significantly improves hearing thresholds. We suggest a formal prospective case series or randomised

controlled trial is undertaken, comparing this method with other treatment options currently available.

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