

Role of Intratympanic Steroids in the Management of Meniere's Disease—A Review of 151 Cases

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Abstract

Objective: To assess the outcomes of hearing and vertigo in patients with Meniere's disease who were treated with intratympanic methylprednisolone. **Study Design:** Retrospective study. **Setting:** Tertiary referral hospital. **Methods:** In our study with 151 patients [191 ears] were diagnosed as Menieres as per 1995 AAO-HNS guidelines. As an office based procedure these patients were treated with intratympanic methyl prednisolone. **Results:** There was a 98.6% improvement in the vertigo control rate, a 73.82% improvement in hearing and 29.31% had a definitive improvement in tinnitus. **Conclusion:** We conclude from our study that intratympanic steroid injection significantly controls vertigo, tinnitus and improves hearing in Meniere's disease with minimal complications. Hence, it can be tried as a first line treatment for patients with Meniere's disease.

Keywords

Meniere's, Intratympanic Steroids, Methyl Prednisolone

1. Introduction

Meneire's disease is first described by Prosper Meniere, as inner ear disorder characterised by vertigo, hearing loss, tinnitus and aural fullness. The pathogenesis of the disease is not understood but other etiological factors attributed to Meneire's disease are autoimmune, viral infection like varicella zoster, herpes simplex virus and cytomegalovirus, or as a consequence of other inner ear disorders like infectious labrynthitis, noise induced hearing loss or vestibular schwannoma [1].

The disease is diagnosed clinically by low frequency hearing loss, episodic vertigo lasting for more than 20

minutes, tinnitus and aural fullness. The disease is unilateral in majority of cases and bilateral in 30% cases [2].

There are many modalities of treatment like lifestyle modification, antiviral, steroids, endolymphatic sac decompression and vestibular nerve section [3] but evidence regarding their efficacy is scarce.

Intratympanic steroid injection is a promising modality for treating patients with Meniere's disease. As the disease is immune mediated, studies suggest treatment with intratympanic steroids improve the function of normal stria vascularis [4], protects the inner ear and reverses the hearing loss [5].

In our study we used intratympanic methyl prednisolone as the first line of treatment in patients with Meniere's disease, the rationale being higher concentrations of the drug reaching the inner ear [6].

The advantage of intratympanic steroids is that the drug acts locally in the inner ear with no systemic absorption. Intratympanic steroids have minimal complications like transient pain, giddiness, otitis media and persistent perforation [6] as compared to systemic steroids.

This is a prospective study done in a tertiary referral centre. We included 151 patients with 191 ears receiving intratympanic steroids.

2. Materials and Methods

The aim of the study is to assess the clinical efficacy of intratympanic methyl prednisolone injections in Meniere's disease.

The study was conducted in the department of ENT and head and neck surgery in a tertiary care hospital from December 2009 to June 2015. The study was conducted with the approval of institute's ethical committee.

A total of 151 patients were included in the study and 191 ears received intratympanic steroids. The AAO-HNS guidelines were used for diagnosing patients with Meniere's disease. Detailed history was taken from the patients regarding hearing loss, vertigo, tinnitus and aural fullness. Hearing loss was assessed and quantified with audiometric testing. Tinnitus was graded with tinnitus handicap index inventory of Newmann and Mc Combe [7] [8]. The AAO-HNS criteria were used to quantify the control of vertigo: the number of definite spells of vertigo during the 6 months previous to treatment with intratympanic methylprednisolone was compared with the number of episodes 6 months after treatment. The AAO-HNS Functional Level Scale (FLS) were used to reflect how the disease affects the patient's activities. The FLS is a 6-point scale that evaluates the patient's overall function or current status, and it offers an objective measure of the patient's state at any given time.

Other causes of vertigo and hearing loss were ruled out by performing audiometry, Dix Hallpike Manoeuvre (to rule out BPPV) and magnetic resonance imaging of brain with gadolinium contrast (to rule out other retrocochlear lesions). Hearing loss was assessed and quantified with audiometric testing. Electrocochleography was not performed as the investigation was not available in the area where the study was being conducted. Other vestibular tests like Vestibular evoked myogenic potential [VEMP] and caloric tests were not performed. All the patients met the AAO-HNS criteria of Definite Meniere's category.

2.1. Inclusion Criteria

Patients diagnosed as definite Meniere's disease as per 1995 AAO-HNS guidelines.

2.2. Exclusion Criteria

- 1) Patients below the age of 18 years and above 80 years.
- 2) Patients with acute infections of the external auditory canal.
- 3) Patients with Chronic ear disease presenting with vertigo.
- 4) Neurologically unstable patients.
- 5) Patients with coagulopathies.

The procedure was performed as a day care procedure. Patients' consent was taken before starting the procedure. Patients were made to lie down in a semi reclined position. The ear was anaesthetised by instilling 4% lignocaine drops in the ear for ten minutes. With the help of a 0° Karl Storz endoscope a nick was made in the anterosuperior quadrant of tympanic membrane. A mixture of 0.3 ml of injection methyl prednisolone and 0.1 ml of 2% xylocaine was injected into the middle ear through another site in the anterosuperior quadrant of the tympanic membrane.

All patients received four doses of intratympanic steroids with a gap of four days in between the doses. After seven days of completion of the treatment, repeat audiometric testing and grading of tinnitus and vertigo were

done. In eleven patients there was subjective improvement of the symptoms but did not have complete relief. These patients received further doses of ITS until there was no further improvement. Three patients did not have complete relief from vertigo and they received intratympanic gentamycin. Patients were followed up for a period of one year post intervention. Only 16 patients who underwent the procedure in 2015 have a follow up of 6 months. The therapy was deemed successful when the patients had complete relief of the most debilitating symptom, vertigo and did not require any further therapy.

2.3. Data Analysis

The data was analysed using ANOVA and t test.

2.4. Results and Observations

A total of 191 ears diagnosed as Meniere's received ITS. Out of these, 93 were right ears and 98 were left ears. There were 104 male and 47 female patients with the sex ratio being 2.2. The mean age was 45 years; the age range was 18 - 76 years. In 111 patients the disease was unilateral while in 40 ears the disease was bilateral.

Out of the 191 ears, 180 ears received four doses, one ear received eight doses, one ear received 10 doses and nine ears received 12 doses.

2.4.1. Improvement in Vertigo

The mean episodes of vertigo in last 6 months reduced from 3.8 to 0.06 post therapy. The functional vertigo grading is reported in [Table 1](#). Patients in all grades had relief of vertigo except in grade 5 where it got reduced to a higher grade [3 and 4].

2.4.2. PTA Score

In 141 ears the mean PTA scores improved. Among these, 30 ears had improvement of greater than 20 db and 111 ears had improvement ranging from 5 - 20 db.

In 47 ears the mean PTA remained the same and in three ears, the mean PTA score decreased.

The mean PTA before and after ITS was 55.88 and 47.25 respectively

2.4.3. SDS Scores

In 117 ears SDS scores improved, it remained the same in 66 ears and in eight ears it decreased. The mean SDS score before and after ITS, was 56.20 and 64 respectively.

2.4.4. THI Grade

134 cases had same THI grade post intervention but patients reported subjective improvement. In 56 patients the grade reduced to a lower one. In one patient the THI grade increased by 1 grade. The mean THI grade pre ITS was 0.91 and post ITS was 0.49.

Complications: In three patients there was worsening of hearing. None of the patients had any other major complications. Few patients had transient ear pain and vertigo which subsided with medical treatment.

Table 1. Functional vertigo grading results as per 1995 AAO-HNS Criteria.

Grade	Pre its [number of patients]	Post its [number of patients]
0	0	148
1	106	0
2	22	0
3	19	1
4	1	2
5	3	0
6	0	0

3. Discussion

We performed our study on patients diagnosed with Meniere's disease as per 1995 AAO-HNS committee guidelines [9]. All patients met the criteria of Definite Meniere's disease. Methyl prednisolone 125mg with 2% xylocaine was chosen as the drug for all patients. Intratympanic methyl prednisolone attains a higher concentration in perilymph with minimal systemic absorption. A study compared the perilymph and plasma concentration of methyl prednisolone after administering intratympanic methyl prednisolone 125 mg, intravenous methyl prednisolone 1 mg/kg and intravenous infusion of methyl prednisolone 10 mg/kg. The median perilymph concentration of methyl prednisolone was 126 fold higher after intratympanic administration as compared to intravenous methyl prednisolone 1 mg/kg and 33 folds higher as compared to intravenous infusion of methyl prednisolone 10 mg/kg. The plasma concentration of methyl prednisolone was 16 fold lower after intratympanic methyl prednisolone than after IV administration of methyl prednisolone 1 mg/kg and 136 fold lower compared to IV infusion of methyl prednisolone 10 mg/kg. Thus systemic absorption of intratympanic methyl prednisolone was much lower [10].

Four doses of intratympanic methyl prednisolone were given with an interval of four days between the doses. The interval of four days between the doses prevents permanent perforation of the tympanic membrane. The drug dosage was 0.3 ml of methyl prednisolone with 0.1 ml of 2% lidocaine. Lidocaine was added to reduce the pain perceived by the patients due to methyl prednisolone. Barrs *et al.* in their study reported reduction in the pain after adding 0.1 ml of lidocaine [11]. There is no consensus in the literature regarding appropriate dosing and duration of treatment [12]. Martin Sanz E *et al.* compared the efficacy of daily and weekly intratympanic steroids and, found not many differences in the outcome [13].

The male:female ratio was 2.2:1 which is slightly higher compared to a recent study which quotes the ratio to be 1.89:1 [14].

The mean age in our study was 45 years which is concordant with other studies which state that the occurrence of Meniere's disease increases with increasing age [14].

In our study 26% of patients had bilateral affection as compared to the literature which states it to be 30% [2].

In our study, the intra tympanic therapy was deemed successful when the patients had complete relief of the most debilitating symptom-vertigo and did not require any further therapy. Vertigo control rate was 98.01% [148 patients]. Jackson and Silverstein *et al.* found that control of vertigo with intratympanic steroids was excellent-rivalling other prominent surgical treatments and concluded that intratympanic therapy can become the most prominent first line treatment for Meniere's disease [15].

In our study improvement in hearing was seen in 73.82% [141 ears] out of which 16.2% [30 patients] had improvement which was more than 20 db and the rest had improvement which was less than 20 db. In 24.06% [47 patients] the mean PTA remained the same and 1.5% [three patients] the mean PTA scores decreased. Lu L *et al.* have studied the efficacy of intratympanic steroids in 10 patients and have reported improvement in hearing by more than 30 db in 1 patient and in between 15 - 30 db in 4 patients and less than 15 db in four patients. Hearing worsened only in 1 patient [16].

A study done by Hillman *et al.* found improvement in PTA by 40%, no change in 56% and worsening in 4% of the patients [17]. The mean PTA scores before and after intratympanic methyl prednisolone in our study was 55.88 and 47.25 respectively and the improvement was statistically significant. She W *et al.* investigated the long term efficacy of intra tympanic steroids. The PTA average in their study was 53 db before intratympanic steroids and 50 db at six months and 52 db at 24 months after intratympanic steroids [18].

There is no conclusive evidence in the literature with regards to the minimum amount of improvement in the average PTA patients with Meniere's disease.

In our study, the mean SDS before and after was 56.20 and 64.0 with an overall improvement by eight percent. This suggests that patients not only had an improvement in hearing but also could discriminate sounds clearly.

In our study 29.31% [56 patients] had a definitive improvement in tinnitus. Chen. Y *et al.* have reported an improvement in tinnitus by 41% [19]. Silverstein *et al.* have used intratympanic depomedrol 80 mg and found improvement in tinnitus in 47% of patients [20].

In 70.15% [134 patients], the THI grade remained the same but the scores reduced. In one patient there was worsening of tinnitus.

Advantages of the therapy include relative ease of administration. It can be given as an office based treatment, it is cost effective and obviates the need of surgical therapy.

The drawback in our study was objective vestibular assessment and electrocochleography was not done. Also 0.1 ml of xylocaine was added to the reconstituted injection methyl prednisolone to reduce the pain, but the effects of xylocaine on Meniere's cannot be quantified.

None of the patients in our study had any serious complications confirming the safety of the therapy. A study done by Phillips *et al* reported no complications [21].

4. Conclusion

We conclude from our study that intratympanic steroid injection significantly controls vertigo, tinnitus and improves hearing in Meniere's disease with minimal complications. Hence, it can be tried as a first line treatment for patients with Meniere's disease.

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