



# A Randomised Controlled Trial Comparing Intratympanic Gentamicin with Methylprednisolone in Meniere's Disease with Good Hearing

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## Abstract

A randomized prospective parallel group trial was done to compare the efficacy of intratympanic low dose gentamicin with methylprednisolone in treating intractable unilateral Meniere's disease with serviceable hearing. Study Design: Randomised prospective parallel group trial. Setting: Tertiary care centre in South India. Subjects and methods: Forty patients with unilateral Meniere's disease and serviceable hearing with vertigo following 6 months of conservative therapy were enrolled between November 2018 and March 2020. Twenty patients were administered with one dose of intratympanic Gentamicin (40 mg/ml) and the other half were given intratympanic Methylprednisolone (40 mg/ml, 4 injections given on alternate days). Pure tone audiogram, speech discrimination score, number of vertigo episodes, dizziness handicap inventory, tinnitus handicap inventory and functional scores were compared before treatment, 3 months later and up to 24 months. There was no significant difference between the two treatments with regard to short term as well as long term DHI scores, THI scores, Functional level score and average pure tone audiogram of patients. In patients with unilateral Meniere's disease who have good hearing, one dose of Gentamicin had equivalent effect to that of four doses of Methylprednisolone in vertigo and tinnitus control, hearing preservation and quality of life.

**Keywords** Meniere's disease · Intratympanic Gentamicin · Intratympanic Methyl Prednisolone · Serviceable hearing

## Introduction

Meniere's disease (MD) is a clinical disorder of the inner ear characterized by spontaneous attacks of vertigo, fluctuating sensorineural hearing loss, tinnitus, and aural fullness. The prevalence of MD is approximately 34–190 per 100 000 [1]. If the cause of the disease is unknown, the term Meniere's disease is applied. When the disease is secondary to a known cause, the term Meniere's syndrome is used [2]. The disease may occur in children but is more common in adulthood with peak incidence in 40 to 60 years of age [3]. A slight

female preponderance has been reported with up to 1.3 times more women affected than men [4]. The disease may become bilateral with age and duration of MD. There is no universally accepted theory on the underlying pathophysiology of this disorder. It is assumed that endolymphatic hydrops is the pathologic feature based on histopathologic studies [5]. Aetiology is multifactorial which include anatomic, genetic, immunologic, viral, vascular, metabolic, and psychological factors [6]. Regardless of aetiology, treatment of Meniere's disease is focused in reducing the frequency and severity of attacks. In 2015 after a consensus between 5 neurotological societies the diagnostic criteria for MD have been published [1]. Although now there is a consensus on the diagnostic criteria current literature lacks consensus on appropriate management. Significant control of symptoms is accomplished with Betahistine, diuretics and diet restriction of caffeine and excessive salt in about two third of the patients [7]. An ablative approach is recommended when medical management is unable to control the recurrent symptoms. In the past three decades, the advent of less invasive procedures like intratympanic injections has changed the approach to refractory MD [7]. From the 1990s onward intratympanic

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gentamicin (ITG) became popular. Its local delivery to the inner ear is now considered an effective treatment for vestibular symptoms [7]. Studies have shown that the use of intratympanic gentamicin carries a distinct risk of inducing hearing loss and post-treatment disequilibrium [8]. At present no consensus exists on the best dosing schedule to minimize hearing damage. This is particularly apparent regarding intractable Meniere's disease with reasonably good hearing. In the last decade, studies have demonstrated the immunological abnormalities in Meniere's disease and the use of steroids to decrease this inflammation [9]. Intratympanic (IT) steroids can control vertigo attacks with minimized risk of hearing loss and post-treatment disequilibrium avoiding the systemic side effects [7]. There have been many studies published in the English literature comparing the use of both intratympanic gentamicin and steroids for the control of Meniere's disease. These have mostly been in patients who had poor hearing with intractable Meniere's disease [7–9, 11–13, 16, 18, 19].

In our study we objectively compared a single dose intratympanic gentamicin (ITG) with 4 doses of intratympanic methylprednisolone (ITMP) in patients with intractable unilateral MD who had serviceable hearing. The aim of our study was to develop a guide to treatment protocols for future patients based on the evidence and to document the side effects that may arise from this treatment.

## Materials and Methods

A randomized prospective parallel group trial was conducted in the otology and audio vestibular unit of our tertiary care referral hospital between November 2018 and March 2020. Adult patients with unilateral Meniere's disease who fulfilled the ICVD 2015 diagnostic criteria for definite Meniere's disease and having a pure tone average of 50 dB or less (at 500, 1000, 2000, 3000 Hz) in the affected ear, with no improvement in vertigo following 6 months of medical therapy (Betahistine 48 mg) and with no evidence of retro cochlear disease were enrolled in the study. Patients with other otological disorders, allergies to the proposed drugs, who had previous intratympanic injections and those who were unable to come for follow up following the intervention were excluded from the study. The proposal for the study was evaluated and cleared by the Institutional ethics review board (IRB min no: 10592). The study was registered under the Clinical trials registry of India (CTRI/2018/12/016650). Patients were recruited in the study after obtaining a written consent.

Consecutive patients who fulfilled the inclusion criteria were explained about the nature of this disease, the study conducted, with respect to the methodology, the desired effects, and the side effects of the drugs in a language they

understood. An information sheet describing the above was also provided to the patient. Once they understood the procedure and were willing to undergo the treatment and come for follow up, a formal written consent was taken. The patients who were enrolled in the study underwent a full otological evaluation which included a detailed history, audio-vestibular evaluation, pure tone audiogram (PTA) with impedance testing, speech discrimination score (SDS), caloric testing, blood tests along with a magnetic resonance imaging (MRI) of the brain with contrast or an auditory brainstem response (ABR) test if the examination suggested a retro cochlear lesion. The dizziness handicap inventory (DHI) score, number of vertigo episodes per month, tinnitus handicap inventory (THI) score and Functional level (FL) score were also assessed. The patients were then randomized into one of the two groups: A) the group receiving intratympanic gentamicin 40 mg/1 ml with a buffer- 1 injection, ITG or B) the group receiving intratympanic methylprednisolone 40 mg/ml- 4 injections, ITMP.

The patients were allocated equally to both arms using a block randomization technique. The randomization schedule was generated using STATA 13.1 I/C software by the statistician. Allocation concealment was done by sealed envelope method.

## Procedure

The patient was made to lie down in the supine position with head on a pillow with the affected ear facing upwards. After filling the ear with a topical anesthetic agent (10% Lignocaine spray) for ten minutes, the pinna and external auditory canal were cleaned using a solution of Povidone Iodine which was then suctioned out using a sterile suction tip. The principal investigator/ co investigators then injected the drug through the tympanic membrane of the affected ear. The ITG Group received 0.6 ml of Gentamicin (40 mg/ml) buffered with 0.4 ml of sodium bicarbonate and the ITMP Group, 1 ml of Methylprednisolone (40 mg/ml). This was taken in a 2 cc syringe and injected under microscope guidance using a 25-gauge lumbar puncture needle. Around 0.5–0.8 ml of drug was injected into the middle ear through the postero-inferior quadrant of the tympanic membrane. Patients were advised to lie in this position for 20 min with the injected ear uppermost without swallowing and talking, following which they went home and could continue with their daily activities. If the drug was Gentamicin, the procedure was completed with a single injection, while with Methyl prednisolone, the same procedure was repeated on every alternate day for a total of 4 injections. All patients were asked to continue Betahistine 48 mg tablet once daily for three more months (first review). Patients were reviewed after 3 months by a co-investigator who was blinded to the injections received and were assessed using the DHI score, THI

and FL score. Patients also underwent a repeat pure tone audiogram and speech discrimination score. The number of vertigo episodes and side effects if any were documented. The same was repeated for all patients, at regular intervals for a period ranging from 24 to 48 months.

## Statistical Methods

For normally distributed variables, the mean and standard deviation and non-normally distributed variables, the median (IQR) were reported. For categorical data, the number and percentage were presented.

Non-parametric Wilcoxon signed rank test was performed to assess pre and post assessment at 3 months and 24 months for the following variables: DHI Emotional, DHI functional, DHI Physical, DHI Total, FL score, number of vertigo episodes, PTA, SDS and the THI score. The histogram with summary values and Shapiro–Wilk test were used to test the hypothesis of normal distribution. The t-test and the non-parametric Mann Whitney test were performed to find the difference between two groups on the study variables. The Chi-square and Fisher's exact test (less cell frequency) were performed to find association between categorical variables. Repeated Measures ANOVA was performed to assess the change over time between two groups on the study variables. All tests were two-sided at  $\alpha=0.05$  level of significance. Statistical Package for Social Sciences (SPSS) software Version 21.0 (Armonk, NY: IBM Corp) was used for the analysis.

## Results

Forty patients with intractable Meniere's disease who fulfilled the inclusion criteria were recruited for the study during this period.

Twenty patients (11 men and 9 women) were treated with ITMP, and twenty patients (12 men and 8 women) were treated with ITG. The mean age in the ITMP group was 49.05 years (SD: 10.52 years) while the mean age in the ITG group was 44.55 years (SD: 11.64 years). Table 1 shows the clinical characteristics of both groups.

The duration of follow up ranged from 24 to 60 months (mean being 42 months) in both the groups. In ITMP group, 18 out of 20 patients had stopped medications while 2 patients were on tablet Betahistine 48 mg once daily during their last follow up. In ITG group, 15 out of 20 patients had stopped medications while 2 patients were on tablet Betahistine 48 mg, 1 patient was on Betahistine at a reduced dose and 2 patients were taking other medications for concomitant vestibular migraine.

None of the patients in either group had any major immediate side effects. 7 out of 20 patients who received ITMP

**Table 1** Comparison of treatment groups

		Methylprednisolone	Gentamicin
Side affected	Left	12	9
	Right	8	11
Duration of symptoms	<1 year	3	3
	1–5 years	12	11
	>5 years	5	6

had mild pain during the injection which subsided with oral analgesics. At their last follow up, 3 patients in the ITMP group and 2 patients in the ITG group had developed imbalance.

## Vertigo

Within the ITMP group, there was significant improvement in the total DHI score post injection at 3 months as well as in the long term, along with a statistically significant improvement in each of the subcomponent scores of DHI viz, DHI physical, functional, and emotional scores (Table 2).

Within the ITG group also, there was significant improvement in the total DHI score post injection at 3 months as well as in the long term, along with a statistically significant improvement in each of the subcomponent scores of DHI (Table 2).

However, between the two groups, there was no significant difference in the DHI total score as well as in the DHI physical, functional, and emotional scores post injection at 3 months as well as in the long term (Tables 3 and 4).

At their last follow up, of the 20 patients in ITMP group, 11 had achieved class A control, 6 class B and 3 class C. In the ITG group, 13 patients had achieved class A control, 5 class B and 2 class C.

## Tinnitus

There was a significant decrease in THI score after ITMP and ITG at both 3 months as well as in the long term. (Table 2) However, the difference in THI scores between the 2 groups was not statistically significant at both 3 months as well as in the long term (Tables 3 and 4).

## Hearing Loss

The results of the hearing thresholds prior to and post-intervention in both groups is summarised in Table 5.

In the ITMP group, the median 4 frequency average PTA before treatment was 38.3dBHL while it was 41.65 dBHL after 3 months and 49.50 dBHL at the end of the

**Table 2** Comparison of DHI, THI and functional level score outcome measures pre and post injection within the two treatment groups ITG and ITMP

Title	Group	n	Median	P value	
DHI total	ITG	Pre	20	29	
		Post 3 months	20	4	0.001
		Post 2 years	20	0	<0.001
	ITMP	Pre	20	33	
		Post 3 months	20	11	<0.001
		Post 2 years	20	0	<0.001
DHI physical	ITG	Pre	20	6	
		Post 3 months	20	0	0.008
		Post 2 years	20	0	0.001
	ITMP	Pre	20	8	
		Post 3 months	20	0	0.002
		Post 2 years	20	0	0.001
DHI functional	ITG	Pre	20	12	
		Post 3 months	20	1	0.002
		Post 2 years	20	0	<0.001
	ITMP	Pre	20	18	
		Post 3 months	20	5	0.001
		Post 2 years	20	0	<0.001
DHI emotional	ITG	Pre	20	12	
		Post 3 months	20	2	0.003
		Post 2 years	20	0	<0.001
	ITMP	Pre	20	8	
		Post 3 months	20	4	0.004
		Post 2 years	20	0	0.002
THS	ITG	Pre	20	26	
		Post 3 months	20	11	<0.001
		Post 2 years	20	7	<0.001
	ITMP	Pre	20	22	
		Post 3 months	20	4	0.005
		Post 2 years	20	3	0.001
Functional level score	ITG	Pre	20	3	
		Post 3 months	20	1.5	<0.001
		Post 2 years	20	1	<0.001
	ITMP	Pre	20	3	
		Post 3 months	20	2	<0.001
		Post 2 years	20	1	<0.001

**Table 3** Comparison of SDS, DHI, THS, and functional level outcome measures at 3 months between ITG and ITMP groups

Title	Group	n	Median	P value
SDS	ITG	20	78	0.446
	ITMP	20	82.50	
DHI total	ITG	20	4	0.251
	ITMP	20	11	
DHI physical	ITG	20	0	0.569
	ITMP	20	0	
DHI functional	ITG	20	1	0.205
	ITMP	20	5	
DHI emotional	ITG	20	2	0.703
	ITMP	20	4	
THS	ITG	20	11	0.138
	ITMP	20	4	
Functional level score	ITG	20	1.5	0.098
	ITMP	20	2	

**Table 4** Comparison of SDS, DHI, THS and functional level score outcome measures at the end of the study between ITG and ITMP groups

Title	Group	n	Median	P value
SDS	ITG	20	77.50	0.816
	ITMP	20	80.00	
DHI total	ITG	20	0	0.647
	ITMP	20	0	
DHI physical	ITG	20	0	0.907
	ITMP	20	0	
DHI functional	ITG	20	0	0.745
	ITMP	20	0	
DHI emotional	ITG	20	0	0.513
	ITMP	20	0	
THS	ITG	20	7	0.385
	ITMP	20	3	
Functional score	ITG	20	1	0.892
	ITMP	20	1	

study. This difference was not statistically significant (Table 5).

In the ITG group, the median 4 frequency average PTA before treatment was 45.63dBHL while it was 43.75dBHL after 3 months and 46.50 dBHL at the end of the study. However, this difference was also not statistically significant (Table 5).

There was also no significant difference in the PTA before and after treatment, at 3 months as well as in the long term

at 500, 1000, 2000 and 3000 Hz between the two groups (Tables 6 and 7).

The median speech discrimination score (SDS) of patients who received ITMP was 92.5% before treatment, 82.5% three months post injection and 80% at the end of the study. There was significant decrease in SDS before and after treatment with ITMP post 3 months as well as in the long term (Table 8).

The median speech discrimination score of patients who received ITG was 85% before treatment and it was 78% three months post injection and 77.5% at the end of the study. There was no significant difference in SDS before and after

**Table 5** Comparison of PTA outcome measures pre and post injection within two treatment groups, ITG and ITMP (Wilcoxon signed ranks test)

			n	Median PTA	P value
PTA at 500 Hz	ITG	Pre	20	50	
		Post 3 months	20	50	0.705
		Post 2 years	20	50	0.659
	ITMP	Pre	20	45	
		Post 3 months	20	50	0.441
		Post 2 years	20	50	0.092
PTA at 1000 Hz	ITG	Pre	20	50	
		Post 3 months	20	50	0.842
		Post 2 years	20	50	0.515
	ITMP	Pre	20	32.5	
		Post 3 months	20	42.5	0.360
		Post 2 years	20	47.5	0.076
PTA at 2000 Hz	ITG	Pre	20	47.5	
		Post 3 months	20	40	0.752
		Post 2 years	20	42.50	0.070
	ITMP	Pre	20	35	
		Post 3 months	20	37.50	0.473
		Post 2 years	20	50	0.042
PTA at 3000 Hz	ITG	Pre	20	47.5	
		Post 3 months	20	40	0.773
		Post 2 years	20	50	0.009
	ITMP	Pre	20	42.50	
		Post 3 months	20	42.50	0.661
		Post 2 years	20	50	0.054
Average PTA	ITG	Pre	20	45.625	
		Post 3 months	20	43.750	0.687
		Post 2 years	20	46.50	0.151
	ITMP	pre	20	38.3	
		Post 3 months	20	41.650	0.506
		Post 2 years	20	49.50	0.079

**Table 6** Comparison of SDS outcome measures pre and post injection within 2 treatment groups, ITG and ITMP

Group		n	Median SDS	P value
ITG	Pre	20	85.00	
	Post 3 months	20	78.00	0.096
	Post 2 years	20	77.50	0.116
ITMP	Pre	20	92.50	
	Post 3 months	20	82.50	0.002
	Post 2 years	20	80.00	0.001

treatment with ITG post 3 months as well as in the long term (Table 8).

**Table 7** Comparison of PTA outcome measures post 3 months between ITG and ITMP groups (MANN WHITNEY TEST)

Title	Group	n	Median	P value
PTA at 500 Hz	ITG	20	50	0.901
	ITMP	20	50	
PTA at 1000 Hz	ITG	20	50	0.343
	ITMP	20	42.50	
PTA at 2000 Hz	ITG	20	40	0.360
	ITMP	20	37.50	
PTA at 3000Hz	ITG	20	40	0.913
	ITMP	20	42.50	
Average PTA	ITG	20	43.750	0.507
	ITMP	20	41.650	

**Table 8** Comparison of PTA outcome measures at the end of the study between ITG and ITMP groups

Title	Group	N	Median	P value
PTA at 500 Hz	ITG	20	50	0.923
	ITMP	20	50	
PTA at 1000 Hz	ITG	20	50	0.604
	ITMP	20	47.50	
PTA at 2000 Hz	ITG	20	42.50	0.631

There was no significant difference in SDS before and after treatment between the groups post 3 months as well as in the long term (Tables 3 and 4).

**Functional Level**

In both the groups, the improvement in functional level score was found to be statistically significant at both 3 months and at the end of the study (Table 2). However, between the groups there was no significant difference in the functional level score post injection at 3 months as well as at the end of the study (Tables 3 and 4).

**Discussion**

Meniere’s disease is a debilitating disease often developing at an age when an individual is likely to be employed and raising a family. This disease affects the patient and their families in many ways, including psychosocially and financially [10]. There is no cure for the disease but the goal of any treatment is to reduce the frequency and severity of the vertigo attacks, reduce or eliminate hearing loss and tinnitus associated with attacks, minimize disability and prevent disease progression, particularly hearing loss and imbalance.



Both intratympanic Methylprednisolone and intratympanic Gentamicin have been useful in patients with Meniere's disease. But there are no standardised protocols describing the use and duration of these intratympanic injections, more so in patients with good hearing. In this study intratympanic Methylprednisolone injections were given as four doses on alternate days, whereas intratympanic Gentamicin was given as a single dose for patients with unilateral Meniere's disease whose hearing was serviceable. We compared the number of vertigo episodes, dizziness handicap inventory, tinnitus handicap inventory, functional scale scores, pure tone audiogram and speech discrimination score in patients with unilateral Meniere's disease who received ITMP and ITG before and after treatment. Few studies have assessed the outcomes comparing these two drugs. According to Patel et al., both methylprednisolone and Gentamicin give significant relief from vertigo episodes. In their study 60 patients with unilateral Meniere's disease received either intratympanic Methylprednisolone (62.5 mg/ml) or Gentamicin (40 mg/ml), 2 injections 2 weeks apart and patients were followed up for 2 years. The degree of hearing loss in these patients was not mentioned [11]. They found no difference between the 2 treatment options when these patients were followed up for 70 months [12]. In the study by Thomas L et al., 22 patients with unilateral intractable MD with non-serviceable hearing were recruited to receive 4 injections of either intratympanic Methylprednisolone (40 mg/ml) or Gentamicin (40 mg/ml) on alternate days and were followed up for 48 months. Both ITMP and ITG were found to be effective in controlling the symptoms with regards to vertigo control, DHI score and THI score post 3 months injection while ITG showed better improvement in total DHI score, DHI functional and emotional score, better functional level scale and vertigo control rate than ITMP in the long term with no significant worsening of hearing [13]. Casani et al. used a low dose Gentamicin protocol and found better vertigo control when compared with intratympanic Dexamethasone (93.5% vs 61%) and it was associated with a very low incidence of hearing impairment (12.5%) [7].

In our study, out of the 20 patients in the ITMP group, 11 achieved class A control, 6 class B and 3 class C. In the ITG group, 13 patients achieved class A control, 5 class B and 2 class C. The Dizziness Handicap Inventory (DHI) was used to assess the impact of dizziness on quality of life. It addresses physical, emotional, and functional aspects of the patient and thus gives a detailed and broader evaluation of the impact of dizziness [14]. In this study we found that in both ITMP and ITG group, there was significant improvement in the total DHI score post injection at 3 months as well as long term, along with a statistically significant improvement in each of the subcomponent scores of DHI viz, DHI physical, functional and emotional scores. However, between the two groups, there was no significant difference in the

DHI total score as well as in the DHI physical, functional, and emotional scores post injection at 3 months as well as long term. Patel et al. and Harcourt et al. also found no difference between these two treatments with regard to the long term DHI scores [11, 12].

Tinnitus was another disabling symptom after vertigo for most of the patients included in our study. Tinnitus handicap inventory was used to determine the degree of distress suffered by our patients. This self-report 25-item THI contains questions relating to the functional, emotional, and catastrophic reactions to tinnitus [15]. In our study there was significant decrease in tinnitus handicap inventory score after ITMP and ITG at both 3 months as well as in the long term. However, the difference in THI scores between the 2 groups was not statistically significant at both 3 months as well as in the long term. In the meta-analysis done by Zhang et al. the overall improvement rate in tinnitus was 50% after intratympanic Gentamicin using different treatment protocols [16].

Functional level scale introduced by AAO-HNS in 1995 was used to assess the effects of episodic vertigo on daily activities [17]. In our study both the groups showed improvement in functional level score which was statistically significant at both 3 months and at the end of the study. However, between the groups there was no significant difference in the functional level score post injection at 3 months as well as at the end of the study.

Hearing loss is a known side effect of Gentamicin. Studies have shown that low doses of Gentamicin cause minimal side effects, mainly hearing loss and post-treatment imbalance [18].

Flanagan et al. reported 21.4% of hearing loss and 81.3% of vertigo control after a single injection of Gentamicin while Casani et al. reported 12% of hearing loss and 81% vertigo control after a maximum of 2 doses of Gentamicin [7, 19]. We used a single injection of Gentamicin in our study protocol vs 4 injections of Methylprednisolone to mitigate the effects of Gentamicin on hearing levels. In the ITMP group of our study, the median 4 frequency average PTA before treatment was 38.3dBHL while it was 41.65 dBHL post 3 months and 49.50 dBHL at the end of the study. This difference was not statistically significant post 3 months as well as in the long term while in the ITG group, the median 4 frequency average PTA before treatment was 45.63dBHL while it was 43.75dBHL post 3 months and 46.50dBHL at the end of the study. However, this difference was also not statistically significant post 3 months as well as in the long term. There was also no significant difference in PTA before and after treatment post 3 months as well as in the long term at 500, 1000 Hz, 2000 and 3000 Hz between the two groups. In fact, there was a significant deterioration of SDS after treatment, in the ITMP group compared to the SDS pretreatment. We propose that this could be attributed to the normal

progression of disease; however, conversely could low dose gentamicin have a protective effect on disease progression? This has to be studied further.

## Limitations

Recruitment of a larger study group was limited, since many of our patients were from different regions of our country and could not come for follow up with us. The doses of the injections were different in both the arms, hence blinding of patients to the drug was impossible, however post treatment assessment was blinded.

## Conclusion

In patients with unilateral Meniere's disease who have good hearing, we found that one dose of Gentamicin had equivalent effect to that of four doses of Methylprednisolone in vertigo and tinnitus control, hearing preservation as well as quality of life. There was no difference between these two treatments with regard to short term as well as long term DHI scores, THI scores, Functional level score and average pure tone audiogram of patients. Both these treatment options gave good results in the management of intractable vertigo in unilateral Meniere's disease with serviceable hearing.

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