

Evaluation of outcome of Homoeopathic treatment in probable Ménière's Disease- Case Series

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Abstract:

Ménière's disease is considered as an idiopathic syndrome in which the patients present with symptoms like vertigo which is typically rotatory in nature, tinnitus and hearing impairment. Of all symptoms, the vertigo episodes are the most incapacitating. Aim of the present case series was to observe the treatment outcome of the symptoms 'vertigo' and 'tinnitus' after 2 years of Homoeopathic treatment. 16 cases were identified during 2017, and followed-up for 2 years at National Homeopathy Research Institute in Mental Health [NHRIMH] Kottayam, Kerala. Diagnosis was based on the Diagnostic criteria jointly formulated by a committee of experts, issued during 2015. Scoring was done for the symptoms 'vertigo' and 'tinnitus'. After 2 years of Homoeopathic treatment, patients reported with clinically relevant improvement, as per the reporting guidelines. The medicines found to be useful in the management of Probable Ménière's disease were *Pulsatilla nigricans*, *Causticum* and *Calcarea carbonica*.

Keywords: Homoeopathy, Ménière's disease, Tinnitus, Vertigo.

Received: 27.07.2020

Revised: 02.09.2020

Accepted: 20.09.2020

Quick Response code



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Introduction:

Meniere's disease is considered as an idiopathic syndrome in which the patients present with symptoms like vertigo which is typically rotatory in nature, tinnitus and hearing impairment.^[1,2] Vertigo is the most incapacitating symptom in Ménière's disease and it may last up to 24 hours in Probable Ménière's disease.^[1] It is the commonest cause of otogenic vertigo. Tinnitus is a troublesome symptom, and it increases during the episode of vertigo. Audiometry shows sensorineural hearing loss.^[2] According to a cross sectional data analysis older persons and females have greater tendency for Ménière's disease.^[3] There is no gold standard test for the diagnosis of Ménière's disease.^[1] So the diagnosis of Ménière's disease is made clinically based on the 'Diagnostic criteria for Ménière's disease, jointly formulated by a committee of experts.^[4] This will improve the quality of clinical data obtained from patients. As per this criterion Ménière's disease can be divided into two categories – Definitive Ménière's disease and Probable Ménière's disease. In definitive Ménière's disease there will be two or more spontaneous episodes of vertigo lasting 20 minutes to 12 hours, low to medium frequency sensorineural hearing loss and fluctuating aural symptoms like fullness of the affected ear. Probable Ménière's disease is a broader concept when there are two or more episodes of vertigo or dizziness lasting up to 24 hours and fluctuating aural symptoms in the affected ear.^[4]

International Consensus [ICON] on treatment of Ménière's disease recommends lifestyle change, Vestibular rehabilitation and Psychotherapy. In

Conventional medicine the first line treatment is medical management by diuretics and betahistine. When it fails the second line treatment is intratympanic injection of steroids. The third line treatment could be either the endolymphatic sac surgery or intratympanic injection of Gentamicin. The last option is the destructive surgical treatment labyrinthectomy.^[5]

There was significant direct and indirect cost for Ménière's disease, with loss of earnings as per a multi data approach study.^[6] The extent of disability caused by Ménière's disease is evident from the fact that it is one of the diagnoses which can be used for reimbursement purpose as per ICD-10-CM 2020.^[7] So it is the need of hour to develop a cost effective treatment protocol for Ménière's disease. During the period January 2017 to January 2020, 31 new cases of Ménière's disease [ICD-10-CM H81.09] were registered in the ENT OPD of National Homoeopathy Research Institute in Mental Health [NHRIMH] Kottayam, Kerala. This is apart from the number of cases reported with peripheral vertigo [H81.3] and tinnitus [H93.1]. This reflects the need for highlighting the effectiveness of Homoeopathic treatment in the management of Ménière's disease and for future research in this subject.

Previous studies on the treatment of Meniere's disease by Homoeopathic medicines were reported by Romer,R and Jack.R.A during 1987 and 1988 respectively. They were observational case series study and Romer noted that 8 patients were relieved of vertigo but not tinnitus.^[8,9] In a randomized double blind controlled clinical study by Michael Weiser et al.; it was statistically proven

that the Homoeopathic medicine was equivalent to betahistine in reduction of vertigo attacks. ^[10]

Like these previous studies, the present case series also attempts to highlight the effectiveness of Homoeopathic medicines in the management of Ménière's disease.

Methodology:

This case series was done at NHRIMH Kottayam, Kerala during the year 2017-2019, under the ENT OPD. The cases which presented with symptoms of Ménière's disease were referred to the ENT consultant who diagnosed the case according to the guidelines mentioned in the Diagnostic criteria. ^[4]

The case taking was done in a 'Pre-structured Ménière's disease case recording Performa, which documented the frequency and intensity of vertigo, tinnitus, hearing impairment and the comments by ENT consultant. Socio-demographic features like age, gender, occupation; and presence of any other illness, other medications taken, were all recorded in the case recording Performa. [Table -1]The outcome parameters were recorded as part of the routine clinical care.

Baseline scores were recorded for the symptom 'vertigo' by calculating the average number of vertigo episodes for the past 6 months before initiating the therapy, and for the symptom 'tinnitus', using the Tinnitus Functional Index [TFI]. Clinical assessment of vertigo and tinnitus with respect to its intensity and frequency, hearing impairment and VAS [Visual Analogue Scale] were recorded during the follow-up visits.

As per the outcome reporting guideline any treatment for vertigo in Ménière's

disease can be evaluated 2 years after treatment started. ^[1] At that follow-up visit, the frequency of vertigo over the last six months has to be reported. Cases with other vestibular disorders which had similar presentations of Ménière's disease like Vestibular Schwannoma and Benign Paroxysmal Positional vertigo were excluded by the ENT consultant.

After Homoeopathic treatment for 2 years, the average number of vertigo spells per month for the last six months [X] (18-24 months) of Homoeopathic treatment was calculated. The average number of vertigo spells per month for the 6 months before therapy [Y] was calculated at the baseline level. Numerical value was calculated as $X/Y \times 100$, and categorized accordingly ^[1] [Table -2].

The intensity and severity of tinnitus was assessed using the TFI which consists of 25 items, the maximum mark of each item is 10. ^[11] This divided by the number of questions for which the respondents provided valid answers provided the respondents overall TFI score. The before and after TFI scores were compared at the end of the study. [Table-3]

Informed consent was obtained from patients for publication of the treatment outcome.

Statistical Analysis:

The statistical Analysis was carried out using IBM SPSS version 20.0. The TFI scores of 16 cases at baseline and end of the study are shown in Table No. 3. TFI score at the end, for case no.15 was not available. The difference between the TFI scores at baseline and end of the study was assessed for normality by using Shaipro-Wilks Test. Wilcoxon Signed rank test was used to compare changes in TFI Score. ^[12]

Table -1: Socio-demographic data and health information:

Case no.	Age	Gender	Occupation	Marital status	Duration of illness	Comorbidities	Other medications, if any
1	52	M	Business	Married	3 years	HTN	Antihypertensive, Vertin
2	65	M	Business	Married	1.5 years	DMT2, HTN, Fistula in ano	Antidiabetics, Antihypertensive
3	66	M	Retired bank employee	Married	6 months	Nil	Nil
4	54	M	Business	Married	10 years	Asthma	Bronchodilators
5	50	F	House wife	Married	6 months	Nil	Nil
6	61	M	Business	Married	3 years	DMT2, HTN	Antidiabetics, Antihypertensive
7	52	F	House wife	Married	18 years	Varicose vein, GERD, Hemorrhoids, Renal calculi	Nil
8	66	M	Farmer	Married	5 years	DMT2, HTN	Antidiabetics, Antihypertensive
9	34	M	Auto driver	Married	5 years	Nil	Nil
10	30	M	Nurse	Unmarried	3 Years	Nil	Nil
11	63	M	Retired Govt. servant	Married	19 years	HTN	Antihypertensive
12	37	F	Teacher	Married	3 years	Nil	Nil
13	56	M	Retired Bus conductor	Married	2 years	Nil	Nil
14	69	M	Business	Married	2 years	DMT2, HTN, DLP	Antidiabetics, Antihypertensive
15	53	M	Waiter	Married	15 years	Generalized Anxiety disorder	Nil
16	63	F	House wife	Married	3 years	Nil	Nil

M- Male, F-Female, HTN-hypertension, DMT2 – Diabetes mellitus Type 2, GERD – Gastro Esophageal reflux Disease, DLP- Dyslipidaemia

Table 2: Vertigo score at baseline and at end of study:

Case no.	X	Y	Numerical value[X/Y×100]	Category
1	0	8	0	A
2	2	2	100	D
3	0	2	0	A
4	0	4	0	A
5	0	4	0	A
6	0	12	0	A
7	0	3	0	A
8	0	8	0	A
9	0	12	0	A
10	0	12	0	A
11	0	8	0	A
12	0	5	0	A
13	0	4	0	A
14	0	12	0	A
15	-	12	-	F
16	0	5	0	A

Numerical value = $X/Y \times 100$, where X is the average number of definitive spells per month for the 6 months 18-24 months after therapy and Y is the average number of definitive spells per month for the 6 months before therapy. Category A - complete control of vertigo spells. Category D - Numerical value between 81-120, No improvement. Category F - Secondary treatment initiated due to disability from vertigo.^[1]

Table 3: Tinnitus functional Index score at baseline and at end of study:

Case no.	TFI at baseline	TFI at the end of the study	Interpretation of scores
1	72.63	63.1	No clinically meaningful reduction
2	71.05	71.05	No change
3	69.47	68.42	No clinically meaningful reduction
4	68.42	68.42	No change
5	50	0	Cured
6	71.05	58.95	Clinically meaningful reduction
7	50	0	Cured
8	52.63	0	Cured
9	41.57	0	Cured
10	43.68	0	Cured
11	67.89	44.21	Clinically meaningful reduction
12	64.74	55.26	No clinically meaningful reduction
13	61.58	28.95	Clinically meaningful reduction
14	43.16	0	Cured
15	71.05	-	Secondary treatment initiated due to disability
16	43.16	0	Cured

TFI – Tinnitus Functional Index. Clinically meaningful reduction means a 13-point reduction between baseline TFI score and TFI score at end of the study.^[1]

Table 4: Reporting guideline for vertigo:

Numerical value	Class
0	A
1-40	B
41-80	C
81-120	D
>120	E
Secondary treatment initiated due to disability from vertigo	F

Table taken from copyright publication: Scott-Brown's Otorhinolaryngology Head and Neck Surgery, 8thEd. Numerical value = $X/Y \times 100$, where X is the average number of definitive spells per month for the 6 months 18-24 months after therapy and Y is the average number of definitive spells per month for the 6 months before therapy.^[1]

Result:

Out of the 16 cases, 7 cases had complete control of vertigo episodes [Category A] and TFI score became 0; 4 cases had complete control of vertigo episodes and clinically meaningful reduction in TFI score [13-point reduction between the before and after treatment score]; 3 cases had complete control of vertigo episodes but there was no clinically meaningful

reduction in TFI score after 2 years of Homeopathic treatment. 2 cases had no improvement for either vertigo or tinnitus [Table 2 & 3] and were classified under category D and category F respectively as per the guidelines [Table 4].

Shaiprow- Wilks Test showed a significant departure from normality. The median score reduced from 61.58 to 28.95. There

was statistically significant change in TFI scores at baseline and end.

Most improvements were seen in patients being treated with *Pulsatilla nigricans* [4 cases], *Causticum* [4 cases] and *Calcarea carbonica* [3 cases].

Homoeopathic Treatment:

Homoeopathic medicines were given for all the diagnosed cases by the Homoeopathic physician attending the ENT OPD. All the 16 cases which reported in the OPD were on conventional medicine for Ménière's disease, and they were having episodes of vertigo and tinnitus at frequent intervals. The conventional medicines were tapered and discontinued during the subsequent visit.

Selection of medicine:

Homoeopathic medicines were selected on the basis of totality of symptoms, thermal reaction and constitution of the patient after referring to Homeopathic Materia Medica and Repertory [13, 14]. After analyzing the case records and the medicines prescribed in each case, it was found that different constitutional medicines were indicated in those 16 cases and patients had improvement for their symptoms with these medicines. Commonly indicated medicines were *Pulsatilla nigricans* (*Puls.*), *Causticum* (*Caust.*), *Calcarea carbonica* (*Cal. Carb.*), *Conium maculatum* (*Con.*), *Natrum muriaticum* (*Nat. mur.*) and *Sulphur* (*Sulph.*) [Table-5]. *Pulsatilla nigricans* gave relief in 4 cases, *Causticum* in 4 cases, *Calcarea carbonica* in 3 cases, *Sulphur* in 1 case, *Natrum muriaticum* in 1 case and *Conium maculatum* in 1 case.

Pulsatilla nigricans in increasing potencies were prescribed for 6 cases at certain points of their treatment period and it relieved vertigo and tinnitus in 4 out of 5 cases (80%).

Causticum in increasing potencies was prescribed in 4 cases, and vertigo was relieved completely in all the 4 cases [100%]. In 2 out of the 4 cases (50%), the TFI score was nil after treatment, whereas in 2 cases there was no reduction in TFI scores.

Calcarea carbonica in increasing potencies was prescribed in 3 cases, and vertigo was nil [100%] after treatment in these cases. In 1 case TFI score was 0 after treatment, and in 2 cases there was a clinically meaningful reduction in TFI score (100%).

Sulphur was prescribed in 1 case starting with the 30th potency, and potency was raised up to 1M. Vertigo was nil after treatment, but tinnitus remained as such.

Natrum muriaticum was prescribed in 1 case starting with the 200th potency, and potency was raised up to 1M. Vertigo was relieved completely after treatment, but there was no clinically meaningful reduction in TFI scores.

Conium maculatum in 30 & 200 potencies were prescribed initially for 7 cases. Vertigo and tinnitus were completely relieved only in 1 case. In 2 cases the intensity of vertigo was reduced, but there was no complete relief. In 4 cases there was no relief either for vertigo or tinnitus. So for the rest 6 patients, cases were retaken and Individualized Homoeopathic medicines were prescribed, with relief for the symptom.

Chininum sulphuricum (*Chin.Sulph.*) 30 was prescribed in 3 cases, at varying

periods of treatment, but there was no relief. Individualized Homoeopathic medicines were prescribed in these 3 cases with relief for symptoms.

Selection of Potency:

Potency of medicine was selected based on the fundamental principles of Homoeopathy mentioned in Organon of Medicine. [15] Treatment was started with 30th or 200th centesimal scale potency, according to the susceptibility of the patient. In some cases the potency was gradually raised to 1M or 10 M depending upon the symptomatology.

Dosage and Repetition of Medicine:

Dosage and repetition of medicine was according to the basic principles mentioned in Kent's Philosophy, H.A Roberts and Stuart Close [16, 17, 18]. More severe the symptoms, more frequent were the repetitions.

Medicine dispensing:

4 globules of number 40 pills medicated with the prescribed medicine were given as doses in Saccharum lactose. Medicines were dispensed from the Pharmacy of NHRIMH Kottayam, as per the Prescription of the Physician.

Follow-up:

Follow-up of the cases were done at 2 weeks interval or earlier according to the severity of vertigo. Once the vertigo spells were reduced significantly, follow-up was

done at 1 month interval. If there was no relief with the initial prescription, case was retaken, and the most similar remedy was prescribed. Out of the 15 cases, 7 cases discontinued treatment after relief for their symptoms and 8 cases are still under follow-up for the symptom tinnitus. All the cases which discontinued treatment were contacted over telephone, and information regarding their symptoms were collected and recorded periodically up to 2 years.

Outcome:

The treatment outcome was calculated for two variables – 'vertigo' and 'tinnitus'. For assessment of the symptom vertigo, 'Numerical value' for vertigo was calculated and the cases were divided into five categories [A, B, C, D, E and F]; where A denotes the complete control of spells and F denotes 'secondary treatment' initiated due to disability from vertigo. [1][Table-4]

For assessment of the Improvement for the symptom 'tinnitus' the TFI scoring sheet was used. The TFI score ranges between 0-100. TFI score of 0 after treatment indicates complete cure. The reduction in TFI score was considered as clinically meaningful reduction only if there is a 13 point reduction from baseline score after treatment. [1] Audiometry is one of the treatment outcomes in Ménière's disease. Since the present case series is on Probable Ménière's disease, it was not repeated at the end of the study.

Table 5: List of medicines prescribed with their Indications:

Sl no	Name of medicine	Symptom totality of the patient indicating the medicine prescribed
1	<i>Pulsatilla nigricans</i>	<p><i>Auditory symptoms</i>-Ringing in ears, tinnitus, buzzing .Vertigo, turning as if in a circle. Vertigo on stooping. Vertigo with nausea and vomiting. Vertigo aggravation rising from lying position in the morning.</p> <p><i>General symptoms</i>-Mind- Sympathetic. Company desires, weep easily. Fear of darkness, grief</p> <p>Thirst-Reduced.</p> <p>Appetite-wanting.</p> <p>Urine-Pain in urethra after micturition. Burning during micturition, renal calculi.</p> <p>Incontinence of urine aggravation night</p> <p>Stool-Constipation with hard stool.</p> <p>Thermal Reaction-Hot patient.</p> <p><i>Particular symptoms</i></p> <p>Respiration-breathing difficulty during night time.</p> <p>Head-Frontal headache aggravation afternoon.</p> <p>Stomach-Heartburn, belching after every food. Sour eructation.</p> <p>Rectum-Constipation with hard stool.</p> <p>Extremities-Varicosities with edema of the ankles aggravation evening. Aching in leg and knees. Pain in the heels</p> <p>Back-Pain on back aggravation standing.</p> <p>Female-Prolapsed uterus with incontinence of urine.</p>
2	<i>Causticum</i>	<p><i>Auditory symptoms</i> -Vertigo lying down. Whirling sensation of the head. Roaring and ringing in the ears. Hearing impaired.</p> <p><i>General symptoms</i></p> <p>Thirst-Thirsty.</p> <p>Appetite-Increased.</p> <p>Thermal Reaction-Chilly patient.</p> <p><i>Particular symptoms</i></p> <p>Face-Pain over face aggravation cold.</p> <p>Eyes-Swollen eyes from exposure to cold.</p> <p>Nose-Epistaxis in the morning, left nostrils. Chronic sneezing aggravation from cold.</p> <p>Throat-Hoarseness of voice from cold exposure.</p> <p>Stomach-Acid dyspepsia with heart urn.</p> <p>Back-Dull pain in nape of neck aggravation from cold air.</p> <p>Skin-Warts over face.</p>
3	<i>Calcarea carbonica</i>	<p><i>Auditory symptoms</i> -Vertigo as if everything were turned around them. Perversion of hearing. Roaring noises in the ear and stopped feeling. Throbbing and cracking in ears. Vertigo as if everything was turning around them.</p> <p><i>General symptoms</i></p> <p>Aversion to company .Weakness of memory.</p> <p>Desire-Egg, sweet, milk and salt.</p> <p>Sleep-Sleeplessness</p> <p>Stool-Constipated, unsatisfactory stool with hemorrhoids.</p> <p>Urine-Sugar in urine.</p> <p>Thermal Reaction-Chilly patient.</p> <p><i>Particulars</i></p> <p>Head-Headache from sun exposure.</p> <p>Eye-dimness of vision during vertigo.</p> <p>Nose-Sneezing aggravation wet weather.</p> <p>Throat-Hoarseness, scraped feeling of throat and hawking up of mucus aggravation wet weather.</p> <p>Respiratory-Cough on becoming cold. Want of breath on least exercise.</p> <p>Stomach-Nausea, vomiting, heart burn, eructation, belching.</p> <p>Rectum-Hemorrhoids with constipation, flatulence.</p> <p>Urethra-burning in urethra after micturition.</p> <p>Extremities-Numbness of hand and fingers aggravation from cold.</p>

4	<i>Conium maculatum</i>	<p><i>Auditory symptoms</i> -Tinnitus, deafness. Vertigo aggravation bending. Vertigo from motion. Vertigo with vomiting.</p> <p><i>General symptoms</i> Anxiety about trifles, depressed .Religious. Thermal Reaction-chilly patient.</p> <p><i>Particulars</i> Nose-Sneezing. Rectum-Hemorrhoid with stitching pain in anus.</p>
5	<i>Natrum muriaticum</i>	<p><i>Auditory symptoms</i>-Vertigo and nausea. Hearing impaired, recurrent headache. Hair falling. Buzzing sounds in the ear.</p> <p><i>General symptoms</i> Anxiety and depression .Sensitive. Thermal Reaction -Hot patient.</p> <p><i>Particulars</i> Head- Migraine. Throat-Thyroid affections. Rectum - Flatulence. Extremities-Pain in shoulder, pain in hips.</p>
6.	<i>Sulphur</i>	<p><i>Auditory symptoms</i>-Buzzing and whizzing noises in ear. Hearing impaired with Vertigo.</p> <p><i>General symptoms</i> Anxiety. Desire-Sweets.</p> <p><i>Particulars</i> Nose-Sneezing in the morning. Rectum-Stool, constipated. Insufficient and ineffectual urging.</p>

Table 6: Homoeopathic treatment outcome after 2 years of follow-up:

Case no.	Vertigo category after treatment	TFI score after treatment	Medicines found to be useful	Treatment outcome
1	A	63.15	<i>Causticum</i> 1M, 10 M	Vertigo nil Tinnitus – no clinically relevant improvement
2	D	71.5	<i>Pulsatilla nigricans</i> 30, 200, 1M	No improvement
3	A	68.42	<i>Sulphur</i> 30, 200,1M	Vertigo nil Tinnitus – no clinically relevant improvement
4	A	68.42	<i>Causticum</i> 200,	Vertigo nil Tinnitus – no improvement
5	A	0	<i>Pulsatilla nigricans</i> 30	Vertigo nil Tinnitus nil Cured
6	A	58.95	<i>Calcarea carbonicum</i> 200, 1M	Vertigo nil Tinnitus – clinically relevant improvement
7	A	0	<i>Pulsatilla nigricans</i> 30,200	Vertigo nil Tinnitus nil Cured
8	A	0	<i>Calcarea carbonica</i> 200	Vertigo nil Tinnitus nil Cured
9	A	0	<i>Causticum</i> 200,1M	Vertigo nil Tinnitus nil Cured
10	A	0	<i>Pulsatilla nigricans</i> 200, 1M	Vertigo nil Tinnitus nil Cured

11	A	44.21	<i>Calcarea carbonica</i> 30,1M	Vertigo nil Tinnitus– clinically relevant improvement
12	A	55.26	<i>Natrum muriaticum</i> 200	Vertigo nil Tinnitus – clinically relevant improvement
13	A	28.95	<i>Pulsatilla nigricans</i> 30	Vertigo nil Tinnitus – clinically relevant improvement
14	A	0	<i>Conium maculatum</i> 200	Vertigo nil Tinnitus nil Cured
15	F	-	<i>Nux vomica</i> 30	Secondary treatment initiated due to disability
16	A	0	<i>Causticum</i> 200	Vertigo nil Tinnitus nil Cured

A – Complete control of vertigo episodes. Category D - Numerical value between 81-120; no improvement. Category F - Secondary treatment initiated due to disability from vertigo. ^[1] TFI – Tinnitus Functional Index.

Discussion:

16 cases diagnosed as Probable Ménière's disease by the ENT consultant during the year 2017, were followed-up for 2 years, up to 2019. The cases were diagnosed as per the Diagnostic criteria ^[4] and available Audiometry reports. Age group of the patients ranged from 30 to 75, with 4 females and 12 males.

All the cases presented with rotatory vertigo of more than 2 definite episodes which lasted more than 20 minutes. Evaluation of the treatment outcome after a particular therapy could be done only after 2 years of treatment as the cases will be having recurrence of the vertigo episodes. So the Homoeopathic treatment was aimed at reducing or completely stopping the episodes of vertigo.

All of them had fluctuating aural symptoms like tinnitus, or a feeling of discomfort or fullness in one or both the ear. The respondents overall TFI score ranges from 0-100. The TFI score of the patients in the present case series ranged from 41 to 73, with 9 cases having scores above 60 and the rest of cases between 40 and 60.

Hearing impairment was assessed clinically in all the cases by the ENT consultant. Tuning fork test was done in most of the cases and the patients were advised Audiometry for further confirmation of the diagnosis. But only few patients reported with results of Audiometry. So the effectiveness of Homoeopathic medicines in the management of hearing impairment couldn't be assessed.

All the cases were on conventional medicine for Ménière's disease, during their first visit. Individualized Homoeopathic medicines based on the general symptoms were prescribed for each case. 14 out of the 16 cases were able to either discontinue or taper the usage of conventional medicine, within the first month of Homoeopathic treatment.

There was improvement in the frequency and intensity of vertigo within the first month of Homoeopathic treatment. There was a complete absence of vertigo spell within the first 12 months of treatment in 14 cases. One case discontinued treatment as the vertigo was severe and took secondary treatment. One case is still on conventional medicine for vertigo as the

attacks were not controlled with Homoeopathic medicines.

The intensity of tinnitus was relieved only gradually compared to that of vertigo. In all the 7 cases in which the TFI score became 0 after treatment, the baseline TFI score was between 40 and 53. There was a significant change in TFI score in 3 patients where the TFI score ranged from 61 to 68. There was no significant change in 5 cases and in all these cases the baseline score was above 64. In 2 out of the 5 cases with no change, the TFI score before and after treatment remained the same.

In 14 cases, all the indicated medicines proved to be useful in reducing the vertigo episodes, but with regard to the symptom tinnitus the intensity came down gradually during the course of treatment and it was not relieved completely as compared to the symptom vertigo. So the potency was raised or specific medicines for tinnitus were prescribed, if there was no relief even after raising the potency. *Pulsatilla nigricans*, *Causticum*, *Calcarea carbonica* and *Conium Maculatum* relieved tinnitus to varying degrees, but with *Sulphur* and *Natrum muriaticum* there was no improvement. The cases which are having tinnitus are still under follow-up in ENT OPD.

During the analysis it was observed that *Conium maculatum* was prescribed as an acute remedy during the definitive spells of vertigo, and the medicine relieved the intensity of vertigo in 3 out of 7 cases. In 4 cases there was no relief after *Conium maculatum*, and 2 cases improved with individualized Homeopathic medicine which was prescribed after *Conium maculatum* failed.

Chininum sulphuricum 30 was prescribed as an acute remedy for tinnitus in 3 cases, but it was not found to be effective.

Thus after 2 years there were no vertigo episodes and tinnitus in 7 cases; 7 cases reported with relief for vertigo episode alone and 3 cases reported with improvement in tinnitus along with relief for vertigo episodes [Table 6].

Conclusion:

14 out of 16 patients reported with clinically relevant improvement for the symptoms vertigo and tinnitus in Probable Ménière's disease after Homoeopathic treatment. The evaluation of the outcome was done after 2 years of treatment as per the outcome reporting guidelines.

Strength and limitations of the study:

The present case series indicates that Homoeopathic treatment can produce clinically relevant improvement for symptoms vertigo and tinnitus in Probable Ménière's disease. But further Case reports, Clinical trials and Case control studies are required for the confirmation of the results. The cause of Ménière's disease is mainly idiopathic although hydrops of Endolymphatic sac is the pathological change present in the inner ear. Recently the use of delayed MRI after intra tympanic injection of Gadolinium has enabled the clinician to demonstrate the endolymphatic hydrops in vivo, but this technique is not recommended by the ENT Surgeons for diagnostic purposes. So the diagnosis is mainly based on the Diagnostic criteria proposed and published by the Expert committee in 2015. The most important challenge in diagnosing the cases was to exclude other vestibular

causes for Ménière's disease. This is done by an ENT physician through further Investigations. So in this case series diagnosis of the cases by the ENT physician was one of the strengths of this study. The outcome reporting was done with respect to the symptom 'vertigo' and 'tinnitus' according to the reporting guideline in ScottBrown for 'vertigo' by calculating the Numerical value and by the TFI score. Other outcomes like Dizziness Handicap Inventory, Ménière's disease outcome questionnaire, Electronystagmography, hearing loss assessment through Audiometry, Tympanometry, if assessed would have further added to the evidence. Randomized control trials with conventional medicine in the other arm will further enhance the quality of study with regard to its efficacy over conventional system and the unique benefits of Homeopathic treatment if any. Hearing impairment is an important symptom in Ménière's disease which could be recorded objectively with Audiometry. Although most of the cases had gone for Audiometry at baseline, it was not repeated at the end of the study, so the effectiveness of Homoeopathic medicines in the management of hearing impairment could not be assessed systematically. Only the frequency of vertigo was assessed during the study period. Inclusion of a valid scale for assessing the intensity of vertigo and extent of disability caused by Meneire's disease would have further added to the evidence. The percentage of patients improved with Individualized Homoeopathic medicines and specific medicines mentioned in the Homoeopathic

literature could not be studied separately due to the less number of cases.

Future Directions:

Ménière's disease is a clinical condition which restricts the personal and social life of a person to a great extent. With every subsequent attack of vertigo there is a subjective decrease in hearing ability. A systematic prospective clinical trial should be done to study the utility of Homeopathic medicine in reducing the intensity and frequency of vertigo and tinnitus as well as to study the improvement in Hearing ability

Declaration of patient consent:

The authors declare that they have obtained written informed consent from each patient for publication of this case series. The patients were informed that all their personal information will be strictly confidential.

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- Conflict of interest:** Author declares that there is no conflict of interest.
- Guarantor:** Corresponding author is guarantor of this article and its contents.
- Source of support:** None
- How to cite this article:**
Vinita ER Divya B, Resmy R. Evaluation of outcome of Homoeopathic treatment in probable Ménière's Disease- Case Series. *Int. J. AYUSH CaRe*. 2020; 4(3):176-188.