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Efficacy of Pulsatilla in the treatment of Chronic Suppurative Otitis Media

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Abstract:
Chronic suppurative otitis media, also known as chronic otitis media, is a stage of ear disease in which there is an on-going chronic infection of the middle ear without an intact tympanic membrane. This disease is a chronic inflammation of the middle ear and mastoid cavity. The characteristic presentation is chronic or persistent otorrhoea over 2 to 6 weeks through a perforated tympanic membrane. When dysfunction of the Eustachian tube occurs, the pressure equilibration in the middle ear is impaired, and the middle ear aeration is perturbed, resulting in the classic symptoms of chronic suppurative otitis media. The study is done to access the efficacy of Pulsatilla in the treatment of chronic suppurative otitis media in reducing the symptoms. The findings of the present study suggest that homoeopathic treatment may have a beneficial role in the management of symptoms associated with Chronic Suppurative Otitis Media (CSOM). The statistical analysis revealed a highly significant improvement, with a p-value of less than 0.0001, indicating that the observed changes were statistically significant.

Keywords: Chronic suppurative otitis media, Pulsatilla, Homoeopathy, Discharge.

Introduction:

Chronic suppurative otitis media (CSOM) is a common cause of hearing impairment and disability. Occasionally it can lead to fatal intracranial infections and acute mastoiditis, especially in developing countries.

CSOM is usually a complication of persistent AOM, but the risk factors for CSOM vary in different settings. Frequent upper respiratory tract infections and poor socioeconomic conditions (overcrowded housing and poor hygiene and nutrition) are often associated with the development of CSOM. In developed countries and advantaged populations, previous insertion of tympanostomy tubes is now probably the single most important aetiological factor. Of those children with tympanostomy tubes in place, a history of recurrent AOM, older siblings, and attendance at child care centres all increase the risk of developing CSOM. In developing countries and disadvantaged populations, poverty, overcrowding, family history, exposure to smoke, and being Indigenous are important. Improvement in housing, hygiene, and nutrition in Maori children was associated with a halving of the prevalence of CSOM between 1978 and 1987 (see also review on acute otitis media).

Aims and objectives:

1. To study the clinical manifestation of chronic suppurative otitis media.
2. To find the efficacy of different potencies of Pusatilla in the treatment in chronic suppurative otitis media.

Review of Literature:

Chronic suppurative otitis media is a persistent, chronically draining (> 6 weeks), suppurative perforation of the tympanic membrane. Symptoms include painless otorrhea with conductive hearing loss. Complications include development of aural polyps, cholesteatoma, and other infections.

Chronic suppurative otitis media can result from acute otitis media, eustachian tube obstruction, mechanical trauma, thermal or chemical burns, blast injuries, or iatrogenic causes (eg, after tympanostomy tube placement). Risk is increased in patients with craniofacial abnormalities (eg, Down syndrome, cri du chat syndrome, cleft lip and/or cleft palate, 22q11.2 deletion [also called velocardiofacial syndrome, Shprintzen syndrome, Shprintzen-Goldberg syndrome, and DiGeorge syndrome]).

Chronic suppurative otitis media may be exacerbated after an upper respiratory infection or by water entering the middle ear through a tympanic membrane perforation during bathing or swimming. Chronic exposure to air pollution and poor hygiene related to living in a low-resource community can also exacerbate symptoms.

Diagnosis of chronic suppurative otitis media is usually clinical. Samples of the discharge are cultured.

When cholesteatoma or other complications are suspected (as in a febrile patient or one with vertigo or otalgia), CT or MRI is done. These tests may show intratemporal or intracranial processes (eg, labyrinthitis, ossicular or temporal erosion, abscesses). If patients have persistent or recurrent granulation tissue, biopsies should be done to exclude a neoplasm.

Management

The choice of treatment should be individualized according to the clinical findings, presence of complications, hearing status, and overall condition of the patient. Appropriate management aims to control infection, achieve a dry and safe ear, improve hearing where possible, and prevent complications.

Role of Homoeopathy

Homoeopathy has been used by some practitioners as a complementary or alternative approach in the management of chronic ear conditions. Various homoeopathic medicines have traditionally been prescribed based on the individual symptom picture, constitutional characteristics, and associated complaints of the patient. However, the evidence regarding the effectiveness of homoeopathy in CSOM remains limited, and further well-designed clinical research is required to establish its efficacy and clinical role.

The present study was therefore undertaken to evaluate the effect of homoeopathic treatment on the symptoms of **Chronic Suppurative Otitis Media (CSOM)** and to assess the changes observed following treatment using appropriate clinical and statistical methods.

Methodology:

This study was conducted in the outpatient department of Father Muller Homoeopathic Medical College and in peripheral centres.

Study design

Inclusion Criteria:

- Both sexes
- Paediatric age group 5-15 years

- Diagnosed cases of CSOM

Exclusion criteria:

- Cases other than CSOM
- Patients with other system of treatment.

SAMPLE SIZE

According to Cochran's formula,

$n = Z^2 (p) q / d^2$ { Where , n = Sample size

Z = 1.96

p = prevalence

q = 1 – p }

If d = 10 % and

prevalence (p) = 8%

q = (1 – 0.11) = 0.89

Then ,

$n = (1.96)^2 \times 0.11 \times 0.89 / (0.10)^2$

= 0.376 / 0.01

= 29.6 ~ 30.

Research protocol

Thirty diagnosed cases of CSOM were included in the study based on the diagnostic criteria like ear pain, reduced hearing and fluid leaking if the ear drum bursts.

The present study was conducted as a **prospective observational study** using purposive sampling. Institutional Ethical Committee clearance was obtained prior to commencement of the study. Written informed consent was obtained from the participants, and an assent form was obtained where applicable. Patients who fulfilled the predefined inclusion and exclusion criteria were enrolled in the study. The **Ear Outcome Survey-16 (EOS-16)** was used as an assessment tool to evaluate the clinical outcomes and changes in symptoms during the study period.

Scoring criteria Ear Outcome Survey-16 (EOS-16) is taken before and after the study in each cases.

Ear Outcome Survey-16 (EOS-16©) v1.1

Name: Date:

Personal ID:

Below is a list of the symptoms and problems associated with ear disorders. With the help of the survey, we will find their occurrence and impact on your Quality of Life.

Select the level of difficulty that best describes your problems over THE LAST THREE MONTHS. If you have symptoms in both ears, answer the questions about the ear with more severe symptoms. If you answer the survey for a post-treatment control visit, please answer for the treated ear.	No problem	Mild problem	Moderate problem	Severe problem	Very severe problem
1. I have had pain in my ear.	0	1	2	3	4
2. I have had an itch in my ear.	0	1	2	3	4
3. I have felt pressure in my ear.	0	1	2	3	4
4. I have felt moisture in my ear.	0	1	2	3	4
5. I have heard a buzzing or ringing sound in my ear (tinnitus).	0	1	2	3	4
6. I have experienced dizziness or disequilibrium.	0	1	2	3	4
7. My hearing has worsened.	0	1	2	3	4
8. I have had problems hearing because of background noise.	0	1	2	3	4
9. I have had difficulty locating the direction of a sound.	0	1	2	3	4
10. Protecting my ear from water has restricted my life.	0	1	2	3	4
11. Because of ear problems, I face challenges in my daily activities / at school / at work.	0	1	2	3	4
12. Symptoms related to my ears limit my hobbies.	0	1	2	3	4
13. I fear that the symptoms related to my ears will worsen in the future.	0	1	2	3	4
14. I feel like my ear problems have negatively affected my quality of life.	0	1	2	3	4
Select the option that best describes your situation. Answer the questions for the PREVIOUS THREE MONTHS.	I haven't	Once	Twice	3-4 times	Over 4 times
15. I have consulted a doctor because of my ear problems.	0	1	2	3	4
16. I have used antibiotic ear drops (as prescribed).	0	1	2	3	4

Overall score:_____

There were no controls used in the study and all the patients were treated on the outpatient basis. Since the clinical history and examination findings were sufficient to arrive at a diagnosis and carried out when needed to rule out any associated systematic manifestations.
Pulsatilla in different potencies were prescribed according to the demand of the case.
Duration of study was for 3 months.

Research Hypothesis:

- Is there any difference between the score taken before the treatment and after the treatment
- **Null hypothesis:** Homoeopathic remedies are not effective in CSOM
- **Alternative hypothesis:** Homoeopathic remedies are effective in CSOM

Assessment of effectiveness were done with the follow up based on following criteria.

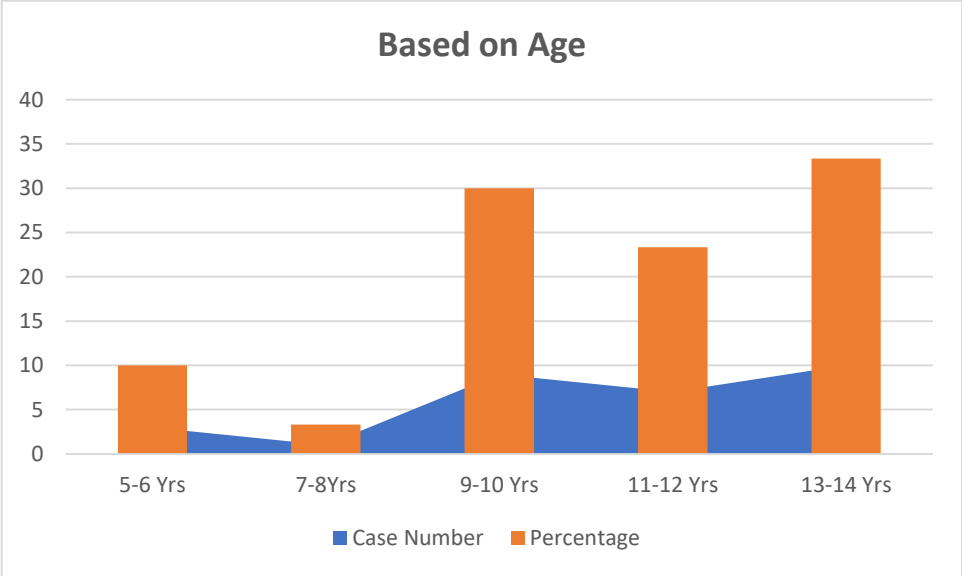
1. Clinical assessment: disappearance of symptoms, improvement of general health.
2. A scoring chart was formulated to assess the efficacy of the treatment.
3. After the collection of sufficient data, the values are statistically evaluated by using "paired t" test.

Result:

Thirty diagnosed cases of Chronic suppurative otitis media was included in the study. All these thirty cases were observed from three months to 6 months. Scoring criteria is taken before and after the study in each case. The following results are obtained from this study.

TABLE 1.1: Based on Age

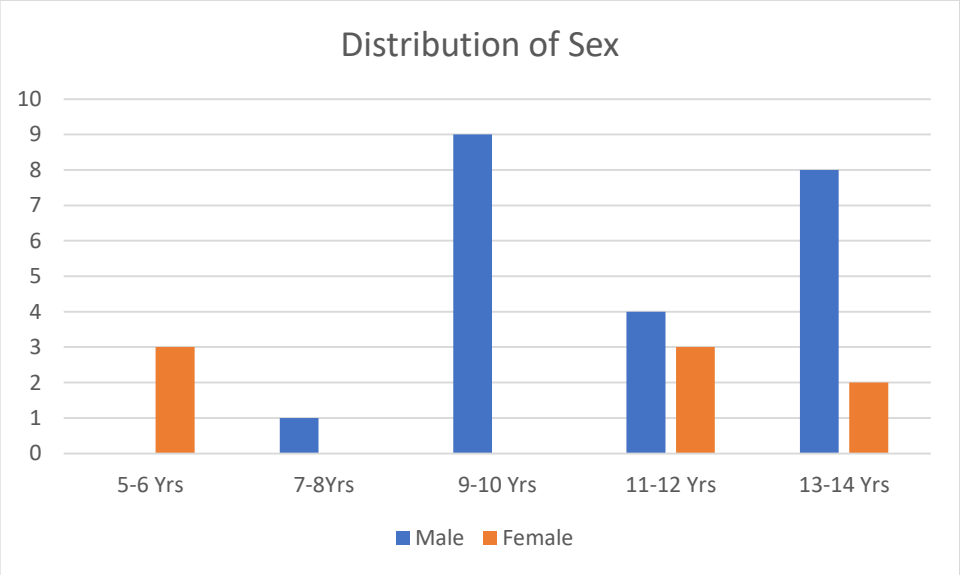
Age	Case Number	Percentage
5-6 Yrs	3	10
7-8Yrs	1	3.33
9-10 Yrs	9	30
11-12 Yrs	7	23.33
13-14 Yrs	10	33.34



GRAPH 2.1: Diagrammatic representation of age group

Table 1.2: Distribution of Sex

Age group	Male	Female
5-6 Yrs	0	3
7-8Yrs	1	0
9-10 Yrs	9	0
11-12 Yrs	4	3
13-14 Yrs	8	2



GRAPH 2.2: Diagrammatic representation according to Sex

TABLE 1.3: Distribution of Potency

Potency	No of Cases	Percentage
30	1	3.33
200	23	76.68
1M	5	16.66
0/1	1	3.33

GRAPH 2.3: Diagrammatic Representation of Potency used

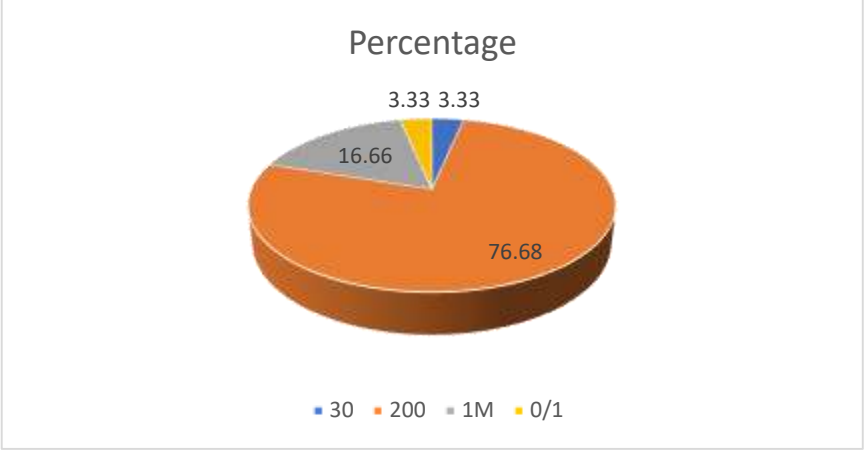


Table 1.4: Treatment Outcome

Treatment Outcome	No of Cases	Percentage
Improved	28	93.33
Not improved	2	6.67

GRAPH 2.4: Diagrammatic Representation of Outcome of Treatment

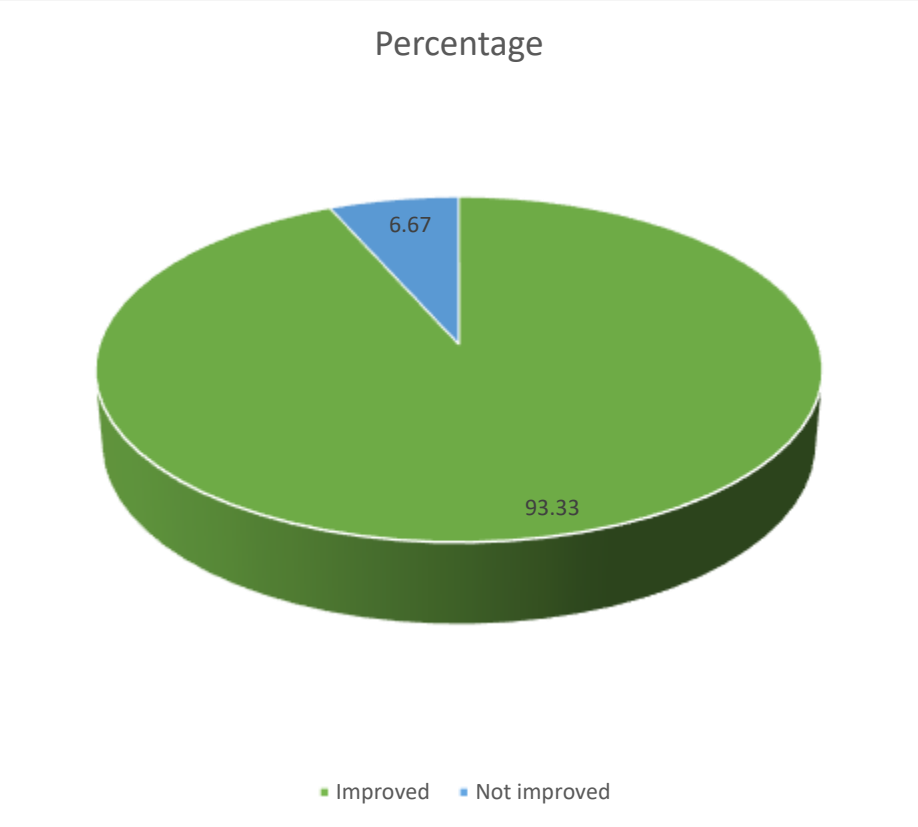


Table 1.5: Ear Outcome Survey-16 (EOS-16)

CASE NO	Scoring before treatment	Scoring after treatment
1	34	12
2	42	5
3	32	4
4	51	4
5	45	4
6	42	1
7	51	2
8	41	1
9	30	3
10	38	1
11	40	2
12	51	4
13	42	5

14	39	2
15	42	3
16	41	2
17	44	2
18	52	3
19	50	4
20	52	10
21	39	4
22	34	4
23	45	5
24	50	3
25	60	8
26	49	3
27	42	4
28	31	2
29	42	4
30	50	5

Statistical analysis

Paired t test results

Confidence interval:

The mean of Before minus After equals 8.13.

95% confidence interval of this difference: From 7.25 to 9.01

Intermediate values used in calculations:

t = 18.8793

df = 29

standard error of difference = 0.431

1.7: Review of data:

Group	Before	After
Mean	11.37	3.23
SD	1.77	1.99
SEM	0.32	0.36
N	30	30

P value:

The two-tailed P value is less than 0.0001.

By conventional criteria, we can see this difference, it is statistically significant.

When compare with the table value:

This critical ratio, t follows a distribution with n-1(29) degree of freedom. The 5% level is 2.045 and 1% level is 2.756 for 29 degrees of freedom. Since the calculated value is 18.87 is more than the table value at 5% and 1% level.

Since the P value is less than 0.0001 by conventional criteria, here we can see the difference which is statistically significant and reject null hypothesis.

Discussion:

The present study was undertaken to evaluate the effect of homoeopathic treatment on the symptoms of Chronic Suppurative Otitis Media (CSOM) and to assess the clinical outcomes following treatment through appropriate clinical evaluation and statistical analysis. The study aimed to determine the extent of symptomatic improvement and analyse the statistical significance of the observed changes, thereby exploring the potential role of homoeopathic treatment in the management of CSOM.

The findings of the present study suggest that homoeopathic treatment may have a beneficial role in the management of symptoms associated with Chronic Suppurative Otitis Media (CSOM). The statistical analysis revealed a highly significant improvement, with a p-value of less than 0.0001, indicating that the observed changes were statistically significant. Consequently, the null hypothesis was rejected, suggesting that the improvement observed following treatment was unlikely to be due to chance alone.

The results indicate the potential of homoeopathic medicines in alleviating the symptoms associated with CSOM. However, statistical significance alone does not establish clinical efficacy or causation. The findings should therefore be interpreted with caution. Further research involving larger sample sizes, appropriate control groups, longer follow-up periods, and well-defined outcome measures is necessary to validate the observations and provide stronger evidence regarding the role of homoeopathy in the management of CSOM.

Conclusion:

The findings of this study suggest that homoeopathic treatment have a beneficial role in reducing the symptoms associated with Chronic Suppurative Otitis Media (CSOM). The statistical analysis demonstrated a **p-value of <0.0001**, indicating that the observed difference was highly statistically significant according to conventional criteria. Consequently, the null hypothesis was rejected.

Based on the findings of the present study, homoeopathic medicine appears to be effective in reducing the symptoms of CSOM. However, further well-designed studies with larger sample sizes and appropriate controls are warranted to substantiate these findings and establish the role of homoeopathy in the management of CSOM.

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References:

1. https://www.msdmanuals.com/professional/ear-nose-and-throat-disorders/middle-ear-and-tympanic-membrane-disorders/otitis-media-chronic suppurative? ruleredirectid=743
2. https://www.google.com/search?q=prevalence+of+chronic+suppurative+otitis+media&rlz=1C1SQJL_enIN858IN858&oq=prevalence+of+chronic+suppurative+otitis+media&gs_lcrp=EgZjaHJvbWUyCQgAEEUYORiABDIICAEQABgWGB4yDQgCEAAYhgMYgAQYigUyDQgDEAAYhgMYgAQYigUyDQgEEAAYhgMYgAQYigUyDQgFEAAYhgMYgAQYigUyCggGEAAYgAQYogQyCgg

HEAAYgAQYogQyCggIEAAYgAQYogQyCggJEAAYgAQYogTSAQkxNDkxNmowajmoAgCwAgA&sourceid=chrome&ie=UTF-8

3. Hughe Richard L.R.C.S. *A Manual of pharmacodynamics*. Sixth Edition: DelhiB Jain publishers (P) Ltd; 1999; p .779
4. Murphy Robin ND, *Lotus Materia Medica* 1400 homoeopathic and herbal remedies. 3rd Edition: Delhi, B Jain Publishers (P) Ltd; 2004; p. 1660.
5. Chaudhary N.M, *A Study on Materia Medica* (An ideal text book for Homoeo students), Reprint Edition: Delhi, B Jain Publishers (P) Ltd; 1999; p. 630.
6. Boericke William, M.D, *Pocket manual of Homoeopathic Materia Medica and Repertory and a chapter on Rare and Uncommon Remedies*: Delhi Jain Publishers PVT Ltd, 1991; p. 554
7. Clarke Henry John MD, *Clarke a Dictionary of Practical Materia Medica*. vol- III Delhi, B Jain Publishers (P) Ltd; 1995; P. 990-93.
8. Journal of Otology, Volume 16, Issue 2, 2021, pp. 65-70 Dario A. Yacovino, …, Timothy C. Hain
9. Journal of Otology, Volume 16, Issue 1, 2021, pp. 6-11 Pedro Salvador, …, Rui Fonseca