

## Original Research Article

### Utility of Repertory of the Homoeopathic Materia Medica by J.T.Kent (Kent's repertory) in the treatment of Chronic Suppurative Otitis Media- A prospective observational study.

#### Abstract

##### **Background**

Chronic Suppurative Otitis Media is a long standing infection of middle ear with intermittent or persistent otorrhoea through perforated tympanic membrane for more than 6 weeks duration. It is more prevalent in developing nation than developed countries. In India the overall prevalence rate of CSOM was found to be 6%. In present scenario indiscriminate, haphazard use of antibiotics and the poor follow up of the patients have resulted in the persistence of low grade infections in middle ear and development of multiple resistant strain of bacteria. Homoeopathy can offers an alternative option for treatment of CSOM. So the aim of this study was to find out the efficacy of homoeopathic constitutional medicine in the management of CSOM with the help of Repertory of the Homoeopathic Materia Medica by J.T.Kent.

##### **Methods:**

A prospective, single-arm, non-randomised, open-label, observational study was conducted on 30 patients diagnosed with CSOM at the Outpatient Department of National Institute of Homoeopathy, Kolkata. The Chronic Otitis Media Outcome Test (COMOT 15) score was the primary outcome measure. The outcome measure was obtained at baseline and 6 months after treatment. The intention to treat population was statistically analysed in the end.

##### **Result:**

The maximum number of patients belonged to age group of 11 to 20 years (n = 8; 27%) and 41–50 years (n = 8; 27%). Male: female ratio was 1:2. Compared to baseline, COMOT 15 scores have been reduced significantly over 6 months ( $51.2 \pm 6.42$  vs.  $26.93 \pm 13.24$ ; mean difference:  $24.27 \pm 12.95$  [95% confidence interval (CI): 19.54, 28.99];  $t = 10.26$ ;  $P < 0.0001$ ; Student's t-test. The most frequently indicated medicines were Pulsatilla nigricans (n= 5; 16.66%) and Mercurius solubilis (n= 5; 16.66%).

##### **Conclusion:**

Homoeopathic medicines seemed to have a potential effect in the treatment of chronic suppurative otitis media with the help of Repertory of the Homoeopathic Materia Medica by J.T.Kent. To generalized the result more studies like randomised controlled trials should be undertaken.

##### **Keywords:**

## **Introduction**

"WHO defines CSOM as a chronic inflammation of the middle ear and mastoid cavity. CSOM presents with recurrent ear discharges or otorrhoea through a perforated tympanic membrane. Generally, patients with tympanic perforation who continue to discharge mucoid material for period of 6 weeks to 3 months are recognized as CSOM cases. The WHO definition requires only 2 weeks of otorrhoea, but otolaryngologists tend to adopt a longer duration, e.g. more than 3 months of active disease".<sup>1</sup>

The incidence of CSOM is higher in developing country especially in the lower socioeconomic strata of society because of improper hygiene and lack of health education.

"In India the overall prevalence rate of CSOM was found around 6%. The older age group were having a slightly higher prevalence rate (1.5%) than the younger age group (0.7%)".<sup>2</sup>

"Globally CSOM-related hearing impairment was having the prevalence of 30.82 per ten-thousand. The prevalence increases with age, with 9.34 per ten thousand in the first year of life and a highest around 45.05 per ten-thousand in the age group of 65–74 years".<sup>3</sup> According to WHO survey, in India 77% population of CSOM affected with mild to moderate conductive hearing impairment ranging from 30 dB to 60 dB. Along with hearing impairment CSOM may also results in other life threatening complications, it accounts for thousands of deaths and millions of **Disability Adjusted Life Years (DALYs)** worldwide.<sup>4</sup> "Commonly encountered IC (intracranial) complications of CSOM are brain abscess, meningitis and lateral sinus thrombophlebitis and EC (extra cranial) complications are mastoid abscess followed by labyrinthitis and facial nerve palsy".<sup>5</sup>

Various bacteriological studies of ear discharge have shown multiple organism involvement including aerobic, anaerobic and fungi. Most common etiological agents were Aerobes esp. *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Other important organisms were *Klebsella*,  $\beta$ - Hemolytic streptococci, *Proteus*, *E. coli*, and *Candida albicans*.<sup>6, 7, 8</sup>

There are several factors which predispose the occurrence of CSOM such as- Eustachian tube malfunction<sup>9, 10</sup>, Previous history of Acute Otitis Media<sup>11</sup>, Atopic conditions<sup>12, 13</sup>, Low parental education level, low parental income, malnutrition, overcrowding, lack of clean water and sanitation<sup>14, 15</sup> and Individuals with cleft palate or Down's syndrome<sup>16</sup>

Previous research studies have revealed the role of Homeopathic Medicines as a Clinical Alternative for Symptomatic Care in the cases of Acute Otitis Media<sup>17, 18, 19</sup> Upper Respiratory Infections<sup>20, 21, 22</sup> and CSOM<sup>23, 24</sup> However, more research is needed to prove the effectiveness of homoeopathic medicines.

Hence present study is conducted to explore the effect of Homoeopathic medicines in the cases of CSOM. 'Repertory of the Homoeopathic Materia Medica by J. T. Kent' (Kent's Repertory) was selected for study purpose. Kent's Repertory was offered to "the profession as a general repertory of Homoeopathic Materia Medica. It is a compilation of all the useful symptoms recorded in the fundamental works of our Materia Medica and on other hand clinical matters have been given a place when it was observed to be consistent with the nature of remedy"<sup>25</sup>.

### **Aim and objectives**

To find out the efficacy of homoeopathic constitutional medicine in the management of CSOM with the help of Repertory of the Homoeopathic Materia Medica by J.T.Kent with respect to-

- Primary objective- To observe the response of chronic otitis media outcome test (COMOT 15) scores of the CSOM patients after homoeopathic treatment.
- Secondary objective- To find out effective group of medicines with their indication.

### **Methods**

**Study design and setting-** A prospective, single-arm, non-randomised, open-label, observational study was conducted on 30 adults diagnosed with CSOM at the Outpatient Department of National Institute of Homoeopathy, Kolkata. The study was conducted according to Declaration of Helsinki<sup>26</sup> and Good Clinical Practice in India. The study was approved by the Ethical Committee of the institution (F.No.5-023/NIH/PG/Ethical comm. 2009/Vol-II/1281(A/S), dated 01 January 2016). Prior to enrolment of the patients a written information sheet (Bengali) was provided to the patients detailing objective, method, risk, benefits and confidentiality issues. Written consent was obtained from every patient.

**Trial registration-** The trial could not be registered to Clinical Trials Registry of India.

### **Inclusion criteria and Exclusion criteria**

Individuals of either of the sexes, of all age group, who had safe variety of CSOM (tubotympanic type or mucosal disease), having no unstable psychiatric illness or other life threatening systemic disease were enrolled. Patients having unsafe variety of CSOM (atticoantral type or bony disease) with development of cholesteatoma in the pars flaccida and posterosuperior portion of the pars tensa, with local destruction of bone, having Acute otitis media and who had not given consent were excluded. All the cases were diagnosed on the basis of X-ray mastoid, pure tone audiometry and clinical assessment. Case taking was done for each patient in accordance with the standardized homoeopathic format.

### **Intervention and follow-up-**

All cases were repertorised with the help of “Repertory of the Homoeopathic material medica by J. T. Kent” using RADAR 10 software. A suitable homoeopathic medicine was administered in centesimal scale. The drugs identified for the trial were procured from a GMP compliant pharmaceutical firm approved by the Council. Medicines were dispensed in sugar globules of standard size 30. Repetition was done depending on the individual requirement of the cases. Each patient enrolled was intervened at least for a period of 3 months, and follow-up was conducted at least once a month or earlier, as required by the patient.

### Outcome assessment

The assessment of the outcome of the treatment was done by considering the improvement of the patient in general level and using a scoring scale. A COMOT 15 scoring scale comprising of 15 most prominent symptoms for HR-QOL of CSOM was used in this study. It consists of three subscales categorized as ear symptoms (OS=questions 1-6), hearing function (HF=questions 7-9), and mental health (PB= questions 10-13). Additionally, 2 more questions were asked related to general evaluation of impacts of Chronic otitis media and frequency of doctor visits related to **Chronic otitis media. COMOT 15** is 6 point scale from 0 to 5, 0= no issue at all and 5= problem as bad as it can be. The patients having COMOT 15 scores between 15- 75 have been included in this study.<sup>27</sup> [Table-1]

**Table-1: Chronic Otitis Media Outcome Test - 15(COMOT-15)**

S N	Symptoms	No issue at all	Very mild issue	Mild or slight issue	Moderate issue	Severe issue	Problem as bad as it can be
1	Discharge from the ear	0	1	2	3	4	5
2	Earache	0	1	2	3	4	5
3	Ear pressure/fullness of the ear	0	1	2	3	4	5
4	Tinnitus (ringing in the ear)	0	1	2	3	4	5
5	Headache	0	1	2	3	4	5
6	Hearing loss	0	1	2	3	4	5
7	I have difficulties to understand someone speaking from a larger distance	0	1	2	3	4	5
8	I have difficulties to understand something in a	0	1	2	3	4	5

	noisy surrounding area						
9	I have difficulties to understand when people are speaking simultaneously	0	1	2	3	4	5
10	My hearing loss makes me feel depressive /sad	0	1	2	3	4	5
11	Because of my hearing loss I fear to misunderstand other people	0	1	2	3	4	5
12	My hearing loss does cause embarrassing situations	0	1	2	3	4	5
13	I am scared that my ear problems will increase in the future	0	1	2	3	4	5
14	Overall assessment of the impact the ear disease on quality of life	0	1	2	3	4	5
15	Frequency of doctor visits for problems with my ear(s)	0	1	2	3	4	5

### **Statistical technique and data analysis**

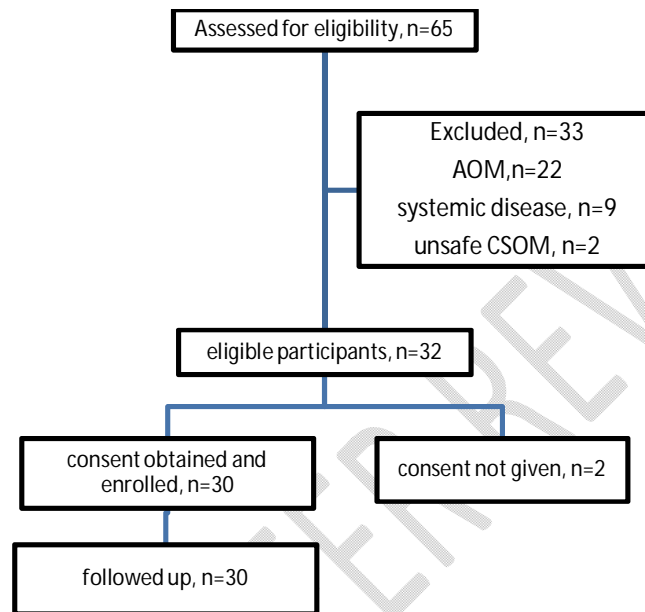
As the data collected through 'COMOT 15' score scale were quantitative in nature, sample size was 30 and same sample was evaluated before and after treatment. Paired "t" test was used for analyzing the changes that occurred in the values of COMOT 15 score in each patient as a result of the intervention.  $P < 0.05$  considered statistically significant.

### **Results**

#### **Study flow design**

A total of 65 patients were preliminarily screened on the basis of entry criterion of occurrence of discharge from ear. Out of 65 patients, 22 had AOM, 9 patients had associated systemic disease, 2 patients had unsafe variety of CSOM (like ear polyp, cholesteatoma) and 2 did not give consent. Hence, only 30 patients could be enrolled in the study after screening them according to the inclusion and exclusion criteria [Figure 1].

**Figure 1: Study flow design**



**Baseline characteristics**

In this study Patients belonged to varying age group from 11 to 60 years The maximum number of patients were from the age group of 11 to 20 years (n = 8; 27%) and 31–40 years (n = 8; 27%). Male: female ratio was 1:2. Further, 63.3% (n= 19) cases of CSOM were found to be associated with URTI, Maximum association was seen with allergic rhinitis i.e. 36.6 % (n=11) followed by pharyngitis 11 % (n=4) and Tonsillitis 11 % (n=4). 67% (n=20) of cases were presented with hearing impairment. The mean COMOT 15 score was 51.2, with 56.7% (n = 17) having a score less than 51.2 and 43.3% (n=13) having scores more than 51.2. None of the patients had score above 63 [Table 2].

**Table 2: Baseline features of the patients (n=30)**

Features	n (%)
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Age groups	
• 11-20	8 (27)
• 21-30	6 (20)
• 31-40	8 (27)
• 41-50	4 (13)
• 51-60	4 (13)
Gender	
• Male	10 (33)
• Female	20 (67)
Economic status	
• Lower	17 (56.6)
• Middle	13 (43.3)
• Upper	0 (0)
Habitat	
• Urban	9 (30)
• Rural	21 (70)
Associated URTI	
• Allergic rhinitis	11(36.6)
• Tonsillitis	4 (11)
• Pharyngitis	4 (11)
• Absent	11 (36.6)
Hearing impairment	
• Present	20 (67)
• Absent	10 (33)

### Pre post comparison-

Among 30 patients only one patient had an increase of score after treatment. The mean COMOT 15 score at baseline was  $51.2 \pm 6.42$  and at end of the treatment was reduced to  $26.93 \pm 13.24$ . The mean reduction in scores was  $24.27 \pm 12.95$ , 95% confidence interval [CI] = 19.54, 28.99,  $P < 0.001$ , student's t- test reduced significantly after 6 months of treatment. [Table -3]

**Table -3 :Comparison of outcome measures at baseline and after 6 months by paired t-test**

Outcome	Mean $\pm$ SD			t <sub>30</sub> - test	P value
	Baseline	6 months	Changes 0-6 ( 95% CI)		
COMOT 15	51.2 $\pm$ 6.42	26.93 $\pm$ 13.24	24.27 $\pm$ 12.95 (19.54, 28.99)	10.26	< 0.001

COMOT 15: chronic otitis media outcome test 15, SD: Standard deviation, CI: Confidence interval

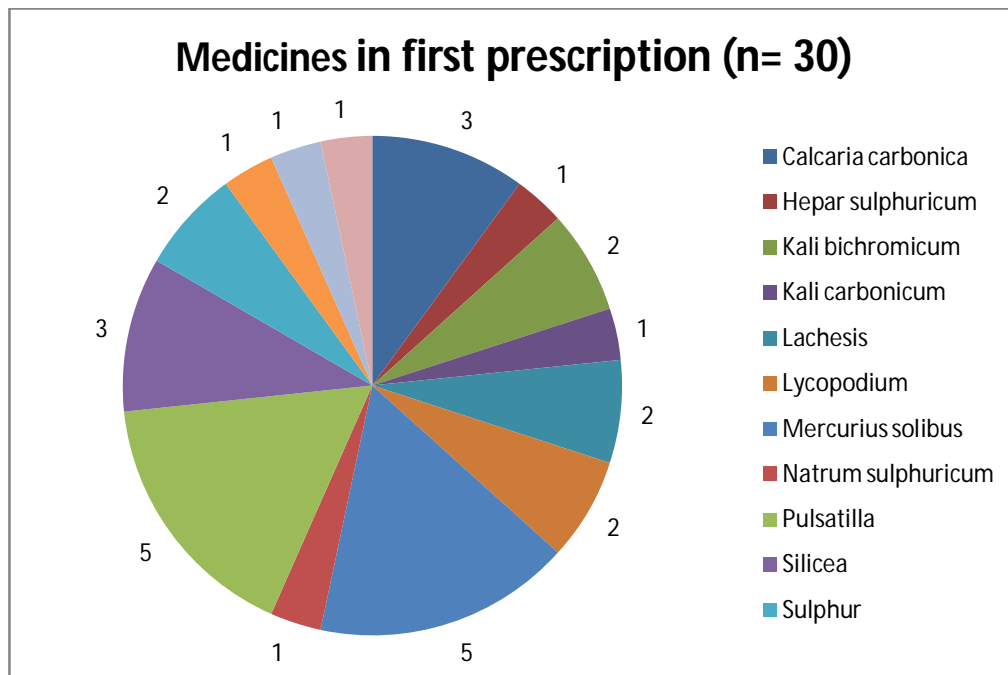
### Homeopathic medicine used

Among all 30 patients Pulsatilla nigricans (n= 5; 16.66%) and Mercurius solubilis (n= 5; 16.66%) were commonly prescribed, followed by Calcarea carbonica (n= 3; 10%), Silicea terra (n= 3; 10%), Lycopodium clavatum(n=2; 6%), Kalium bichromicum(n=2; 6%), Lachesis mutus(n=2; 6%) and Sulphur(n=2; 6%). Other medicines namely Tellurium, Kalium Carbonica, Hepar Sulphuricum, Natrium Sulphuricum, Thuja occidentalis, and Tuberculinum were prescribed to single patient (n=1; 3.3%)[ Table-4, Figure-2]. Out of these 14 medicines 3 medicines namely Pulsatilla nigricans, Lycopodium clavatum and Thuja occidentalis were from plant source and 9 medicines namely Mercurius solubilis, Calcarea carbonica, Silicea terra, Kalium bichromicum, Tellurium, Kalium Carbonica, Sulphur, Hepar Sulphuricum, Natrium Sulphuricum were from mineral source and rest 2 medicines Lachesis mutus and Tuberculinum were Nosodes. These medicines were procured from a GMP compliant pharmaceutical firm approved by the Council. The medicines were prescribed in different potencies as per the susceptibility of the individual patient and according to Organon of Medicine. Medicines were changed as per the demand of each case, when there was no such marked improvement or totality of symptoms has changed. According to principals of Homoeopathy (§245) Every perceptibly progressive and strikingly increasing amelioration in a transient (acute) or persistent (chronic) disease, is a condition which, as long as it lasts, completely precludes every repetition of the administration of any medicine whatsoever<sup>28</sup>. Hence placebo was prescribed as long as improvement continued.

**Table 4:- Medicine in first prescription (n=30)**

MEDICINES	n (%)
Calcarea carbonica	3 (10)
Hepar sulphuricum	1 (3.3)
Kali bichromicum	2 (6.6)
Kali carbonicum	1 (3.3)
Lachesis	2 (6.6)
Lycopodium	2 (6.6)
Mercurius solibus	5(16.66)
Natrum sulphuricum	1 (3.3)
Pulsatilla	5(16.66)
Silicea	3 (10)
Sulphur	2 (6.6)
Tellurim	1 (3.3)
Thuja	1 (3.3)
Tuberculinum	1 (3.3)

**Figure : 2 Medicine in first prescription (n=30)**



## Discussion

A prospective, single-arm, non-randomised, open-label, observational study was conducted on 30 adults diagnosed with CSOM at the Outpatient Department of National Institute of Homoeopathy, Kolkata. This study aims to reflect the efficacy of homoeopathic constitutional medicine in the management of CSOM with the help of Repertory of the Homoeopathic Materia Medica by J.T.Kent.

Previous research studies have revealed the role of Homeopathic Medicines in the treatment of Otitis Media<sup>20,21,22,23,24</sup>. However, these existing studies lack in proper prevalidated scoring scales. Hence this study was conducted using a reliable and valid scoring scale for assessment and Kent's repertory for proper repertorization of all cases.

There was a significant decrease in the COMOT 15 score after treatment with individualized homoeopathic medicines and P- value was statistically significant (P value < 0.001). This observation indicates that the Homoeopathic medicines are effective in the treatment of CSOM by using Kent's repertory.

There were several medicines found to be effective in treatment of CSOM. Out of which Pulsatilla nigricans and Mercurius solubilis were commonly prescribed, followed by Calcarea carbonica and Silicea terra. Several other medicines were also administered with variable outcome like Lycopodium clavatum, Kalium bichromicum, Thuja occidentalis, Lachesis mutus, Tellurium, Kalium Carbonica, Sulphur, Hepar Sulphuricum, Natrium Sulphuricum And Tuberculinum.

It has been well established that in India 77% population of CSOM affected with hearing Impairment. The current study also presented the same result, 67% of cases were found to be affected with hearing impairment. This study also provided evidence of association of CSOM with upper respiratory tract infection in 63.3% cases (Maximum association was seen with allergic rhinitis, 36.6%).

The study had its limitation in terms of small sample size, absence of control group, and lack of laboratory evidence of improvement in all cases.

## **Conclusion**

This prospective observational study has revealed promising treatment effect of homoeopathic medicines in chronic suppurative otitis media with the help of Repertory of the Homoeopathic Materia Medica by J.T.Kent. More studies like randomised placebo-controlled design with enhanced methodological rigor and longer follow-up are warranted to draw strong evidence.

## **Consent**

As per international standard or university standard, patient(s) written consent has been collected and preserved by the author(s).

## **Ethical Approval**

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

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