



A NON-RANDOMIZED SINGLE-BLIND CLINICAL STUDY TO OBSERVE THE EFFECTS OF HOMOEOPATHIC MEDICINES IN PATIENTS WITH ACUTE AND RECURRENT TONSILLITIS

Dr. Haimanti Das*

Post Graduate Scholar from Department of Homoeopathic Materia Medica, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune, Maharashtra. *Corresponding Author

Dr. Arun Bhargav Jadhav

Head of Institute, PG Guide, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune, Maharashtra.

ABSTRACT

BACKGROUND- Tonsillitis is one of the most common URTI in children hampering daily lives and studies. Studies show that the prevalence of tonsillitis rises by 70-90% during puberty. Homoeopathy can be used in tonsillitis, however not much researches have been done regarding this. This study was aimed to investigate whether homoeopathic medicines have effect in the treatment of patients with acute and recurrent tonsillitis.

METHOD- It is a non-randomized, single blind clinical study conducted at the outpatient department of Bharati Vidyapeeth (Deemed to be University) Homoeopathic College & Research Centre, Pune. Total 33 patients (Male & Female) belonging to the age group of 03-17 years were enrolled in this study. Out of which, 03 patients dropped out and 30 patients completed their follow up. Tonsil size was checked according to the Brodsky grading scale and intensity of symptoms was recorded.

RESULT- The final outcome was reduction in tonsil size and symptomatic relief in acute tonsillitis as well as decrease in the frequency of the episodes in patients with recurrent tonsillitis after 10-12 weeks of outpatient care. Analysis was done using Student paired "t" test and one sample "t" test. A significant reduction was observed in the tonsil size after treatment & the patients showed symptomatic relief as well. Mean reduction in intensity of symptoms in acute tonsillitis was 84.06 ± 17.05 , in recurrent tonsillitis was 63.21 ± 12.34 and total was 74.33 ± 18.18 after completion of study.

CONCLUSION- Homoeopathic medicines produced significant effect in reduction of acute and recurrent tonsillitis. Further studies with larger sample size and control group can provide a greater resource for proving that homeopathic medicines have an effect in the treatment of acute and recurrent tonsillitis.

KEYWORDS : Tonsillitis, children, homoeopathy

INTRODUCTION

Tonsils are an important defense system which protects us against any pathogen which could be inhaled or ingested. They act as the first line of immunological barrier by protecting against outer threats. The palatine or faucial tonsils are located in the lateral oropharynx between the palatoglossal arch anteriorly and the palatopharyngeal arch posteriorly, which are known as the palatine arches or pillars. They are made of lymphatic tissues and along with the lingual tonsil, tubal tonsil and nasopharyngeal tonsil are components of the Waldeyer's ring. In normal state, they look pink in colour.^[1]

Tonsillitis is the inflammation of the tonsils. It is most commonly caused by a viral infection. It can also be caused by a bacterial infection. Acute tonsillitis is a clinical diagnosis done on the basis of clinical features and history. In case of recurrent tonsillitis, frequency is difficult to determine because of the lack of agreement on a measurement criteria. The most recent criteria used to define recurrent tonsillitis is that the patients should have 5 or more episodes of true tonsillitis in a year, with history of symptoms for minimum of 1 year, and episodes that are disabling and prevent normal functioning.^[2]

Various grading scores or scales are used to categorize tonsillitis based on the size of the tonsils. Brodsky Grading Scale is one of the standardized classifications of tonsil size where the tonsils sizes are divided into 5 grades where grades 0-2 indicate normal tonsil size, grade 3 and 4 indicate tonsillitis, grade 4 correlates to kissing tonsils or airway obstruction. Grading of tonsil size in this manner is helpful in understanding the prognosis of the patient during clinical examination.^[3]

Infection of tonsils in children is very common especially from pre-school to mid-teenage ages, although it can sometimes affect adults as well.^[2] Tonsillitis is a common affection in children in India. Tonsillitis is a common condition encountered in the ENT out-patient department of every

hospital. In India, 1 out of every 10 children visiting the ENT OPD, suffer from acute tonsillitis.^[4] It is seen in around 9-17% of children aged 3-11 years. At puberty, prevalence rises to 70-90%. Tonsillitis most commonly affects the pre-school ages and the mid-teenage years of children.

Yet, there is no specific treatment for tonsillitis in modern medicine.^[2] Their treatment for tonsillitis mainly consists of management of pain by administration of antibiotics, fluid supplements and rest. If oral antibiotics fail then intravenous antibiotics are given in a hospital. However the medicines given for tonsillitis, such as Paracetamol and ibuprofen in itself are known to cause many harmful side-effects and can be harmful especially for children.

And in cases of recurrent tonsillitis which doesn't respond to the above treatments surgical removal of tonsils is often done. According to the Paradise Criteria for tonsillectomy, if a patient is having 7 or more episodes of episodes in a year along with sore throat plus accompanying symptoms, then the patient can be referred for tonsillectomy. Tonsillectomy is one of the most frequently performed surgical procedures for recurrent tonsillitis even though there are no solid studies to show if tonsillectomy is really beneficial.^{[2][5]}

The most common symptoms of tonsillitis include –

- Sore throat that is aggravated when swallowing,
- Enlarged or congested tonsils,
- Tender lymph nodes on the side of the neck,
- Referred pain to the ears,
- Odynophagia and dysphagia,
- Loss of appetite,
- High temperature above 38 °c,
- Coughing and hoarseness of voice,
- Headache, malaise, fatigue and lethargy to do any work,
- Increased irritability, etc.

Tonsillitis also affects very young children and it becomes very difficult to diagnose these cases as these children are not able

to describe their symptoms or how they are feeling. In these cases, it becomes extremely difficult to diagnose the intensity of tonsillitis; apart from the signs of tonsillitis, children may also present with symptoms such as

- Drooling which could be due to difficulty or pain during swallowing,
- Nausea and vomiting,
- Refusal to eat due to odynophagia,
- Unusual fussiness, unwillingness to play or study,
- Increased crying and irritability,
- Disturbed sleep, etc.

In Aphorisms 72 and 73 of Organon of Medicine, Dr. Hahnemann has discussed the acute diseases in details with its definition and its various types such as individual, sporadic, epidemic and endemic. In Aphorism 72, he has given the definition of acute disease which he describes as the abnormal derangement of vital force due to some exciting factors which he describes as various external factors such as insufficient nutrition, heat, cold, changes in weather, etc and which runs its course quickly, within a short period of time. In Aphorism 73, he continues about acute diseases as well as acute exacerbations of chronic diseases which he denotes to be nothing but the "transient explosion of latent Psora" which goes away by acute treatment but unless given constitutional medicine for, will return again in a matter of time.^[6]

According to these aphorisms and various other principles laid down in the Organon of Medicine, it can be concluded that Acute tonsillitis will fall under the category of individual acute diseases and Recurrent tonsillitis will fall under the category of acute exacerbation of chronic diseases as the episodes present as acute disease but it runs with repeated attacks for years. There is a wide range of medicines recorded in various Materia Medica books for tonsillitis which can help in these cases. Thus, Homoeopathic mode of treatment can be used as a more effective, safe and inexpensive method of treatment in cases of acute and recurrent tonsillitis. The selection of dose of the similar medicine further depends on the stage of the disease, susceptibility of the person, age, sex and other various factors. It not only helps treating patient of his present complaints but by correcting his immunity and susceptibility improves his health and reduces chances of health derangements too. By putting the most common symptoms of tonsillitis in various repertories, some medicines such as Belladonna, Hepar Sulphuris, Ailanthus, Baryta Carb, Baryta Mur, Silicea, Merc Sol, etc come up repeatedly in highest grade in those repertories which can be used for the treatment of these patients. Similarly, these remedies can also be correlated from various books of Materia Medica where the symptoms are noted down in details. In various clinical Materia Medica books, tonsillitis is noted down as a clinical diagnosis in many medicines such as Baryta Carb, Calcarea carb, etc. Recurrent tonsillitis has also been noted under specific remedies under symptoms such as "tendency to repeated attacks of tonsillitis".^{[7][8][9][10]}

Thus, more effective modes of treatment are needed to cure tonsillitis and homoeopathy can act as a safe and effective way to cure tonsillitis, as there are numerous medicines given in our Materia Medica textbooks specifically for tonsillitis which has been used for many years.

METHODOLOGY

Theoretical study: Theoretical study of this topic was done from various books, Homoeopathic journals, research journals, researches and authentic internet search through websites, Google scholar, Pubmed, etc.

Clinical study: 30 patients with acute and recurrent tonsillitis of both sexes, of age group 3-17 years were enrolled in the study.

Case definition: Cases presenting with complaints of acute and recurrent tonsillitis of both sexes involving age group from 03-17 years.

Study setting: This study was conducted at outpatient department of Bharati Vidyapeeth Deemed University Homoeopathic College & Research Centre, Katraj, Pune. It is a non-randomized, single blind clinical study to see the effect of homoeopathic medicines in patients with acute and recurrent tonsillitis in the age group of 03-17 years.

- Allocation: Non-randomised
- End point classification: Effectiveness.
- Masking: Single blind
- Mode of intervention : Oral

Intervention: Medicine was administered to all patients in 30 size globule half an hour before meal orally on tongue, no water intake for at least 15 – 20 min. Drug was stored in Bharati Vidyapeeth Homoeopathic Hospital pharmacy, Katraj, Pune as per the rules of Pharmacopoeia (HPI), under appropriate temperature. Log no. & batch no. was maintained. In cases where medicine was not necessary, only placebo was prescribed, in the form of sugar of milk globules. Sampling procedure: Patients were enrolled in this study from Bharati Vidyapeeth Homoeopathic Hospital, peripheral OPD, Various rural & urban camp series, OPD and IPD from 2020-2021 (Approximately 52 weeks). Total 33 Cases (male & female) age groups of 03-17 years were selected based on inclusion and exclusion criteria and those who wanted to participate willingly in research.

Case taking was done according to the standard case taking proforma as per homoeopathic principles. Medical history, physical examination (including vital signs, systemic examination) was recorded on a case form. No study participants were included who are in a direct relationship with or dependent on, the sponsor or research team (students, employee of the institution, close relatives).

Follow up:

Each case was followed up for approx 3 months in cases of recurrent tonsillitis and 2 weeks in cases of acute tonsillitis.

- All the patients were duly followed up and details of the symptomatic and clinical changes were recorded and prognoses were studied.
- Follow up differed from patient to patient.
- Standard Follow-up was prepared giving details.
- It was based on Homoeopathic principles.

Criteria for assessment:

| | |
|-----------------------|--|
| Marked improvement: | When there is more than 75% disappearance of the symptoms. |
| Moderate improvement: | When the patient has symptomatic relief with 50-75% reduction of the complaints. |
| Mild improvement: | When the patient has symptomatic relief with less than 50% reduction of the complaints. |
| No improvement: | No response seen after treatment. |
| Worse: | Aggravation of subjective and objective symptoms. |
| Dropped out: | The patient opts out of the study or attending physician does not want to keep the patient under study for any valid reason. |

Parameter used:

Brodsky Grading Scale.

Inclusion Criteria:

- Cases from the age group of 03 – 17 yrs.
- Patients irrespective of ethnic group, socio-economic

status and gender will be considered.

- The ability to give informed consent & comply with study procedures and Legal capacity.

Exclusion criteria: -

- Cases presenting with any gross pathology such as Stage IV tonsillitis (kissing tonsils), Quincy, Tonsillar exudates, etc.
- Cases of acute and recurrent tonsillitis complicated with sleep apnoea, air-way obstruction, etc.
- Patient without written consent.

Outcome Measures:-

The primary outcome measure is the score of the Brodsky Grading Scale after the period of the study. These were compared with the initial values, and the difference analyzed using statistical tests, to find the efficacy or otherwise, of the treatment. The statistical analyses were conducted separately for acute and recurrent tonsillitis as well as combined by using the one sample test and the student paired "t" test respectively. These tests helped to establish whether the changes observed before and after treatment were significant or not.

OBSERVATION AND RESULTS

Total 30 patients (n=30) were selected from the age group of 03-17 years, out of which 16 patients had acute tonsillitis (n₁=16) and 14 patients had recurrent tonsillitis (n₂=14). The highest percentage of patients belonged to the age group of 10-15 years (36.67%) and the lowest from the age group of 3-5 years (6.67%) indicating that children between the age of 10-15 years might be affected the most. 12 participants were male (40%) & 18 were female (60%). Mean reduction in intensity of symptoms in acute tonsillitis was 84.06± 17.05, in recurrent tonsillitis was 63.21±12.34 and total was 74.33± 18.18. Combined P value was 0.000 which is very small.

Table 1: Distribution according to demographic variables (n=30)

| Demographic variables | F | % | |
|-----------------------|---------------|----|--------|
| Age | 3- 5 years | 2 | 6.67% |
| | 5 - 10 years | 8 | 26.67% |
| | 10 -15 years | 11 | 36.67% |
| | 15 – 17 years | 9 | 30.00% |
| Gender | Male | 12 | 40% |
| | Female | 18 | 60% |

f:Frequency

Table 2: Distribution according to diagnosis

| Diagnosis | F | % |
|-----------------------|----|--------|
| Acute Tonsillitis | 16 | 53.33% |
| Recurrent Tonsillitis | 14 | 46.67% |

The data was statistically analyzed by using one sample test which showed significant reduction in the intensity of symptoms. For acute tonsillitis (n₁=16) average reduction in intensity of symptoms was 84.06± 17.05. Test statistic value was 7.99 and p-value was 0.000 which is very small. For recurrent tonsillitis (n₂=14) average reduction in intensity of symptoms was 63.21±12.34. Test statistic value was 4.01 and p-value 0.001 which is very small. For all patients (n=30) average reduction in intensity of symptoms was 74.33± 18.18. Test statistic value was 7.33 and p-value was 0.000 which is very small, it suggests that we reject H₀ and accept H₁ that is, Homoeopathic medicines have effect in the treatment of patients with acute and recurrent tonsillitis.

Table 4 shows before and after scaling of tonsil size by Brodsky Grading Scale which shows marked reduction in tonsil size from 100% being size 3 before treatment to reduction to size 1(60%), size 2(33.33%) and size 0(6.67%) after treatment.

Table 5 shows the reduction in number of episodes during the treatment in recurrent tonsillitis with a mean difference of 2.000± 1.109 and p-value 0.000 which is highly significant indicating that homoeopathic medicines have effect in reduction of episodes. Paired t test was used.

Table 3: Average reduction in intensity of symptoms pre & post treatment

| DIAGNOSIS | Mean ± SD | T-value | p-value | Decision |
|-----------------------------|-------------|---------|---------|-----------------------|
| Acute Tonsillitis(N=16) | 84.06±17.05 | 7.99 | 0.000** | Reject H ₀ |
| Recurrent Tonsillitis(N=14) | 63.21±12.34 | 4.01 | 0.001** | Reject H ₀ |
| Total (n=30) | 74.33±18.18 | 7.33 | 0.000** | Reject H ₀ |

Test used: One sample t-test, **: Highly Significant Difference, T-value: Test Statistic value

Table 4: Distribution of patients according to Brodsky Grading Scaling pre & post treatment

| DIAGNOSIS | Brodsky Grading Scale | Before Treatment | | After Treatment | |
|------------------------------|-----------------------|------------------|---------|-----------------|--------|
| | | F | % | F | % |
| ACUTE TONSILLITIS (n=16) | Size 0 | 0 | 0.00% | 2 | 12.50% |
| | Size 1 | 0 | 0.00% | 13 | 81.25% |
| | Size 2 | 0 | 0.00% | 1 | 6.25% |
| | Size 3 | 16 | 100.00% | 0 | 0.00% |
| RECURRENT TONSILLITIS (n=14) | Size 0 | 0 | 0.00% | 0 | 0.00% |
| | Size 1 | 0 | 0.00% | 5 | 35.71% |
| | Size 2 | 0 | 0.00% | 9 | 64.29% |
| | Size 3 | 14 | 100.00% | 0 | 0.00% |
| Total (n=30) | Size 0 | 0 | 0.00% | 2 | 6.67% |
| | Size 1 | 0 | 0.00% | 18 | 60.00% |
| | Size 2 | 0 | 0.00% | 10 | 33.33% |
| | Size 3 | 30 | 100.00% | 0 | 0.00% |

Table 5: Descriptive statistics of no. of episodes score before and during treatment

| No. of episodes | Mean ± SD | T-value | p-value | Decision |
|-----------------------------|--------------|----------------------------------|---------|-----------------------|
| 3 Months Before Treatment | 3.143± 0.949 | 6.75 | 0.000** | Reject H ₀ |
| During Treatment (3 Months) | 1.143± 0.535 | | | |
| Difference | 2.000± 1.109 | Difference is Highly Significant | | |

Test used: Paired t-test, **: Highly Significant Difference, T-value: Test Statistic value, n=14

DISCUSSION

Tonsillitis is one of the most common URTIs in children hampering daily functioning and studies. Recent studies show that the prevalence of tonsillitis rises by 70-90% during puberty. Tonsillitis is a very common diagnosis in hospitals in India, almost 1 in every 10 patient in a pediatric OPD is of tonsillitis.¹⁴ Homoeopathy can be used in tonsillitis, both acute and recurrent. However more evidence based data need to be collected through researches for strengthening the role of homoeopathy in cases of acute and recurrent tonsillitis. This study was primarily aimed to investigate whether homoeopathic medicines have any effect in the treatment of patients with acute and recurrent tonsillitis. For this study, 30 patients were enrolled belonging to the age group of 03-17 years, of both sexes. Out of which 16 patients had acute tonsillitis and the rest 14 had recurrent tonsillitis. Prescription was done on the basis of acute totality and constitutional totality respectively. The most common remedies prescribed in the first prescription were Belladonna 30, Hepar Sulph 30, Merc Sol 30, Belladonna 200, Merc sol 200, etc. The patients showed positive results; statistical analysis was done by students paired 't' test and one sample 't' test due to small sample size. There was overall improvement in the patients of

both acute as well as recurrent tonsillitis and the null hypothesis was rejected. Tonsil size grading was done before and after treatment using Brodsky Grading Scale which showed great reduction in tonsils size especially in the patients with acute tonsillitis and moderate reduction in size in recurrent tonsillitis. For recurrent tonsillitis, the frequency of episodes was also considered and compared 3 months before and after the treatment which showed great reduction in the number of episodes overall. During the study period, none of the patients were referred for tonsillectomy and no adverse effects were noted.

CONCLUSION

From the above observations, it can be concluded that homeopathic medicines have effect in the treatment of patients with acute and recurrent tonsillitis. Homeopathic medicines can be used to treat acute tonsillitis and it also helps to reduce the intensity and frequency of number of episodes in cases of recurrent tonsillitis. The results have showed that prescriptions made on the basis of acute totality in acute tonsillitis and constitutional totality in cases of recurrent tonsillitis can work to reduce the size of the tonsils as well as provide general improvement.

However, since it is a small sample study over a shorter period of time, further research needs to be done in the future considering large sample size & extending the duration of the study.

CONFLICT OF INTEREST

The authors have no conflict of interest among them regarding the research.

SOURCE OF FUNDING

The funds used in this research work were sponsored by author, Dr. Haimanti Das.

ACKNOWLEDGEMENT

Authors are thankful to Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Research Centre for providing the facilities necessary for the research. Author would like to extend their gratitude to Dr. Arun B Jadhav, Principal and PG Guide for their unmatched and relentless guidance during the project.

REFERENCES

1. Meegalla N, Downs BW. Anatomy, Head and Neck, Palatine Tonsil (Faucial Tonsils). StatPearls [Internet]. 2019 Feb 20.
2. Georgalas CC, Tolley NS, Narula A. Tonsillitis. *BMJ clinical evidence*. 2014;2014.
3. Ng SK, Lee DL, Li AM, Wing YK, Tong MC. Reproducibility of clinical grading of tonsillar size. *Archives of Otolaryngology-Head & Neck Surgery*. 2010 Feb 15;136(2):159-62.
4. Mahajan, G.D. Ingale, M. Study of common bacterial isolates in acute tonsillitis in India. *Indian Journal of Basic and Applied Medical Research*. 2017;Otorhinolaryngology (Special issue)
5. Randel A. AAO-HNS guidelines for tonsillectomy in children and adolescents. *American family physician*. 2011 Sep 1;84(5):566-73.
6. Hahnemann CF. *Organon of Medicine*; translated from the 5th ed. with an appendix by RE Dudgeon, with addition and alterations as per 6th ed. Translated by William Boericke, and introduction by James Krauss. Low Price ed. New Delhi: B. Jain Publishers (P) Ltd. 2002;31:166-7.
7. Clarke JH. *A dictionary of practical materia medica*. homoeopathic publishing Company; 1902.
8. Farrington EA. *Clinical materia medica*. In *Clinical Materia Medica* 1975 (pp. 826-826).
9. Barthel H. *Synthetic repertory*. B. Jain Publishers; 1974.
10. Murphy R. *Homoeopathic Medical Repertory* (1ind Ed.). B. Jain Publishers; 1998.