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Research Article

Latent TB Prevention using Homoeopathic Medicine "Tuberculinum" (Nosode) in High Potency: A Pilot Study

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Abstract

Background: Latent Tuberculosis Infection (LTBI) represents a significant reservoir for future active TB cases, particularly in pediatric populations where the risk of progression is higher. Traditional prophylactic treatments often face challenges regarding side effects and compliance. This pilot study explores the preventive potential of the homoeopathic nosode, Tuberculinum, in high potency for children with clinical and radiological evidence of latent infection. Since the Homoeopathic medicines corrects the underlying physical and mental pathologies through the vital force, particularly when taken for prolonged time so as to keep the Vital Force activated ,hence the achieved benefit is often permanent as per the Doctrine of Recuperation of Cancer(here TUBERCULOSIS) prophylaxis.

Objective: To evaluate the efficacy of high-potency Tuberculinum in managing pediatric cases of latent TB and preventing the progression to active, sputum-positive disease.

Methodology: A pilot study was conducted involving 20 children under the age of 12. Inclusion criteria focused on subjects who were serologically negative but demonstrated infectivity through positive Mantoux tests and characteristic findings on Chest X-ray. The cohort was categorized into four clinical groups:

- Enlarged Mesenteric Lymph Nodes
- Enlarged Cervical Lymph Nodes
- Non-cavitary Lung TB (Sputum Negative)
- Close contacts of active TB-positive cases

All cases were treated with individualized high-potency doses of Tuberculinum (Nosode) and monitored for clinical improvement and radiological resolution.

Results: Preliminary observations indicate a favorable response to high-potency Tuberculinum. Subjects showed a reduction in lymphadenopathy and stabilization of radiological markers without progression to active sputum-positive status. The treatment was well-tolerated, with no reported adverse effects during the study period.

Conclusion: The results of this pilot study suggest that Tuberculinum in high potency may serve as a viable complementary approach for latent TB prevention in children. These findings warrant further large-scale, randomized controlled trials to establish standardized protocols for homoeopathicprophylaxis in TB-burdened regions.

More Information

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Keywords: Latent tuberculosis; Homoeopathy; Tuberculinum; Nosode; Pediatric TB; Mantoux test; Preventive medicine

Introduction

Impact of tuberculosis

Tuberculosis (TB) remains one of the most significant public health challenges in India, which bears approximately 25% to 27% of the global TB burden [1]. In the pediatric population, the impact is particularly severe; it is estimated that over 3.42 lakh children under the age of 14 contract the disease annually in India [2]. While the National Tuberculosis Elimination Programme (NTEP) has made strides toward the goal of elimination by 2025, children remain a vulnerable and often under-detected group. This is largely due to the paucibacillary nature of pediatric TB—where low bacterial loads make traditional sputum-based diagnosis difficult—leading to significant gaps in case notification and a high risk of progression from latent infection to active disease [3].

The etiology and clinical presentation of childhood TB vary significantly from adult forms, often manifesting in diverse and non-specific ways [4]. While *Mycobacterium tuberculosis* is the primary causative agent, the disease in children frequently presents as extra-pulmonary tuberculosis (EPTB) or disseminated forms rather than the classic cavitary pulmonary TB seen in adults [2]. Common etiologies include lymphatic involvement, such as cervical and mesenteric lymphadenopathy, as well as primary pulmonary complexes that may remain sputum-negative. Furthermore, children in close contact with active TB cases face a high risk of Latent TB Infection (LTBI) [12,16], where the bacteria remain dormant but the patient remains "infective" as indicated by a positive Mantoux test or radiological changes [5]. These varying presentations necessitate a high index of clinical suspicion and explore the need for effective preventive interventions to halt the progression of the disease [6].

Homeopathy

Homeopathy is a safe and natural holistic healing system [11,14,15] that is easily administered and low cost [7-9]. The World Health Organization suggests it is especially useful for "areas where the infrastructure, equipment, and drugs needed for conventional medicine cannot be provided" [10]. In the management of complex infectious diseases like tuberculosis, homeopathy focuses on the individual's susceptibility and the underlying miasmatic influence. William Boericke's *Pocket Manual of Homoeopathic Materia Medica* [13] identifies Tuberculinum [19] as a profound nosode for individuals with a "tubercular diathesis"—those who are physically frail, prone to rapid emaciation, and highly sensitive to environmental changes. Boericke describes the remedy as essential for cases where there is a strong family history of the disease or when symptoms are persistently "changing" and "shifting," indicating a deep constitutional imbalance.

In pediatric cases, particularly those involving the latent stages of TB, *Tuberculinum* acts as a powerful anti-miasmatic agent. Boericke highlights its specific affinity for the respiratory system and the glandular system, making it highly relevant for the cervical and mesenteric lymphadenopathy frequently observed in children. By addressing the "taint" of the infection before it manifests as active, sputum-positive disease, the remedy seeks to fortify the body's innate immunity. When used in high potency as a preventive or intercurrent measure, it aims to resolve localized glandular swellings and improve the patient's "recuperative powers," thereby halting the progression of the tubercular process in its incipient stage.

Since the Homoeopathic medicines corrects the underlying physical and mental pathologies through the vital force, particularly when taken for prolonged time so as to keep the Vital Force activated ,hence the achieved benefit is often permanent as per the Doctrine of Recuperation of Cancer (here TUBERCULOSIS) prophylaxis [11].

Homoeopathy, with its emerging connection to nanoscience, offers a promising complementary approach in the management of infectious diseases. Its ability to reduce complications, accelerate recovery, and integrate with modern scientific paradigms underscores its potential as a valuable component of holistic healthcare strategies in developing countries [19].

Study setting

The present clinical study was conducted across two distinct healthcare facilities in Agra, Uttar Pradesh, providing a diverse patient base from both semi-urban and urban populations. These settings were chosen for their established infrastructure in diagnostic radiology and their long-standing history of providing integrated or specialized pediatric care.

Saran Ashram Hospital, Dayalbagh, Agra: Saran Ashram Hospital is a premier charitable institution established in 1927, known for its integrated medical approach combining Modern Medicine, Homeopathy, and Ayurveda. Located in the serene environment of Dayalbagh, it serves as a significant hub for patients seeking alternative and complementary therapies. The hospital's specialized Homeopathy Department and its focus on "Service of Mankind" provided an ideal environment for observing the long-term effects of Tuberculinum in children, supported by on-site diagnostic facilities including X-ray and pathology for the required Mantoux testing.

Siddharth Hospital, Delhi Gate, Agra: Situated in the heart of the city near Delhi Gate, Siddharth Hospital is a wellestablished multispecialty center with a strong focus on Pediatrics and General Medicine. This setting provided access to a more urban demographic, including children who had been in close contact with active TB cases. The hospital's expertise in managing infectious diseases and its robust diagnostic wing ensured precise screening of subjects—facilitating the identification of cases that were serologically negative but radiologically and clinically positive for latent infection.

Methods

Participants

The study population consisted of 20 children under the age of 12 who met the criteria for latent tuberculosis infection (LTBI). These participants were characterized by a state of "clinical infectivity" despite being serologically negative and sputumnegative, meaning they did not harbor a contagious active pulmonary infection but showed clear internal evidence of the disease. Specifically, all selected participants tested positive on the Mantoux (Tuberculin) Skin Test and exhibited diagnostic findings on Chest X-rays. The cohort was composed of four clinical subgroups: those with enlarged mesenteric lymph nodes (abdominal involvement), those with cervical lymphadenopathy (neck swelling), cases of non-cavitary lung TB (radiological lung changes without positive sputum), and asymptomatic children who were in close contact with active TB-positive household members.

Study design

This pilot study utilized a pre-post clinical intervention design over a period of one year to evaluate the efficacy of homoeopathic medicine Tuberculinum in children with latent TB. The design focused on the transition from clinical/radiological positivity to resolution, with systematic monitoring at three-month intervals.

Diagnostic baseline and follow-up: Prior to the initial homoeopathic consultation, each child underwent a rigorous diagnostic screening to establish a baseline. This included:

1. Two Mantoux (TST) tests and two Chest X-rays (taken four weeks apart) to confirm the persistence of latent infection and rule out transient inflammatory changes.

2. Serological testing and Sputum microscopy to confirm the "Sputum Negative/Seronegative" status required for inclusion.

Treatment protocol

Following the baseline assessment, participants received an initial homoeopathic consultation where a high-potency dose of Tuberculinum (Nosode) was administered based on constitutional requirements. The study followed a structured timeline:

Intervention: homoeopathic medicines were administered in a cyclical (2 doses of 1M potency 6 Months apart) manner as per the specific requirements of the high-potency protocol.

Follow-ups: Clinical evaluations were conducted at three-month intervals to monitor changes in lymph node size, weight gain, and general vitality [17,18].

Final assessment: At the conclusion of the 6-month study period, a final diagnostic test was performed, including a repeat Chest X-ray, Mantoux test, and, where applicable, Ultrasonography (USG) for mesenteric lymph nodes to objectively measure the resolution of the initial findings.

The Intervention

The therapeutic intervention followed the classical homoeopathic principle of individualization, tailored to the specific miasmatic and constitutional presentation of each child. While Tuberculinum (Nosode) served as the primary intercurrent or curative agent due to the latent TB diagnosis, the final prescription was determined by the homeopath through a comprehensive repertorization of the "total composite of symptoms" obtained during the initial consultation. This approach ensured that the medicine matched the unique physical and general characteristics of the child, such as their thermal preferences, appetite, and specific location of lymphadenopathy.

For the purpose of this study, the medicine was administered in high potency (1M) at specific intervals, though for certain cases requiring consistent stimulation, a protocol of 200c potency taken fortnightly in water was adopted.

Adherence was strictly monitored to ensure the validity of the pilot study:

Administration: For children dosing was supervised by the Professional Homoeopath to ensure the "dose" method was followed correctly.

Dosing gaps: In alignment with management protocols, children did not take the medicines before the supervisors direction. Proper dosing gap was maintained.

Follow-ups: Participants attended follow-up consultations at 3-month intervals. During these visits, we assessed the child's progress, evaluated changes in lymph node size and radiological markers, and determined if the potency needed adjustment or if the remedy required changing based on the evolving symptom picture.

Outcome measurement

The primary objective of this study was to measure the resolution of latent tubercular indicators through standardized clinical and radiological assessments. To ensure accuracy, the following diagnostic protocols were strictly followed:

Radiological assessment: Change in the status of Lung Parenchyma and Hilar Lymphadenopathy was evaluated via Chest X-rays (Postero-Anterior view). These were interpreted by a senior radiologist at the respective hospital settings (Saran Ashram or Siddharth Hospital). Any signs of calcification, reduction in infiltrates, or resolution of hilar shadows were documented.

Lymphatic evaluation: For participants with Cervical Lymphadenopathy, progress was measured via clinical

palpation and measurement of node diameter. For those with Mesenteric Lymphadenopathy, specialized Ultrasonography (USG) of the Abdomen was conducted to monitor the reduction in the size and number of enlarged mesenteric nodes.

Immune response (Mantoux test): The Tuberculin Skin Test (TST) was repeated at the end of the one-year study period to observe changes in the induration size (measured in millimeters) as an indicator of the body's immune response to the *Mycobacterium tuberculosis* antigen.

Clinical and systematic monitoring: General health indicators, including weight gain, appetite improvement, and the cessation of recurrent low-grade fever, were systematically recorded at each three-month follow-up.

Contact history tracking: For the "Close Contact" subgroup, participants were monitored for the appearance of any secondary symptoms to ensure that no progression from latent to active TB occurred during the intervention period.

Qualitative reports: Reports from parents and caregivers regarding the child's energy levels and susceptibility to common colds were collated by the research team during consultations to provide a holistic view of the child's recovery.

Analysis

The assessment of treatment efficacy for latent TB focused on the quantitative and qualitative regression of clinical and radiological markers over the 06-month study period. Data analysis was conducted as follows:

Radiological and lymphatic analysis: Change in the size and density of lymph nodes (Cervical and Mesenteric) and hilar shadows on Chest X-ray/USG was compared from baseline to the one-year mark. Improvement was defined as a reduction of 25% or more in the diameter of the largest involved node or the complete resolution of pulmonary infiltrates.

Mantoux (TST) quantification: The induration size was measured in millimeters (mm). A reduction in the diameter of the induration by 5 mm or more at the end of the study compared to the baseline average was considered a significant immunological improvement.

Baseline protocols: Baseline scores consisted of the average of two initial readings (X-ray/USG and Mantoux) taken prior to the start of treatment. In cases where only one baseline set was available, those single test results were utilized for comparison.

Data consistency: Where the final 06-month follow-up data was unavailable due to participant attrition or logistical issues, the most recent 6-month or 9-month follow-up data was carried forward for analysis (Last Observation Carried Forward - LOCF).

Clinical vorrelation: Descriptive changes in constitutional health—such as a body weight increase of >10% or a marked reduction in the frequency of recurrent respiratory infections—were compared alongside the objective radiological data to determine the overall success of the Tuberculinum intervention.

Statistical analysis

Statistical analysis was performed to evaluate the efficacy of high-potency

Tuberculinum by comparing clinical and immunological markers before and after the 6-month intervention period. Continuous variables—specifically Mantoux skin test induration diameter (mm) and lymph node dimensions (mm)—were analyzed using a Paired Samples t-test to evaluate the significance of changes from baseline to posttreatment. For all analyses, statistical significance was set a priori at $p < 0.05$. In addition to hypothesis testing, Cohen's d was calculated to determine the standardized effect size, representing the magnitude of the clinical intervention. All statistical computations were conducted using standard open-source statistical software (Jamovi/JASP environment).

Statistical and objective improvements: The clinical and immunological metrics showed highly significant improvements from baseline to the 6-month post-intervention follow-up across all evaluated parameters.

1. Immunological response (Mantoux test induration)

For the entire cohort ($n = 20$), the mean Mantoux test induration diameter decreased significantly from a highly reactive baseline mean of 16.40 mm (± 3.20mm) to a posttreatment mean of 11.15 mm(± 3.10 mm).

I. t-statistic: $t(19) = 11.23$

II. p - value: $p < 0.001$

III. Effect size: Cohen's d = 2.51

This indicates a statistically robust reduction in the localized immune hypersensitivity to the Mycobacterium tuberculosis antigen, carrying an exceptionally large effect size.

2. Glandular and lymphatic resolution

Objective regression of localized lymphadenopathy was confirmed mathematically within the respective clinical subgroups:

- **Cervical Lymphadenopathy Subgroup ($n = 5$):** The mean diameter of the involved cervical lymph nodes decreased significantly from a baseline of 14.20 mm (± 2.28 mm) to 9.00 mm(± 1.58 mm) post-treatment ($t(4) = 5.92$, $p = 0.004$, Cohen's d = 2.65). This constitutes an average reduction of 36.6%, easily exceeding the study's defined improvement threshold of ≥25%.

- **Mesenteric Lymphadenopathy Subgroup (n = 6):** Ultrasonographic monitoring of the abdominal group demonstrated a highly significant reduction in mesenteric node short-axis diameter, decreasing from a baseline mean of 12.00 mm (±2.00 mm) to 7.50 mm (±1.38 mm) post-treatment (t(5) = 7.30, p < 0.001, Cohen's d = 2.98). This represents a definitive 37.5% mean structural reduction.

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Results

Baseline characteristics

Following the initial screening at Saran Ashram Hospital and Siddharth Hospital, a total of 25 children fulfilling the study inclusion criteria were identified. During the enrollment phase, three cases were excluded as the parents opted for conventional prophylactic treatment (ATT), and two cases were lost to follow-up immediately after the first screening. This left a final cohort of 20 participants who complied with the diagnostic testing and completed the six-month homoeopathic treatment protocol.

Of the 20 participants, all were under the age of 12. The distribution across the four clinical categories was as follows:

Enlarged mesenteric lymph nodes: 6 cases (30%)

Enlarged cervical lymph nodes: 5 cases (25%)

Non-cavitary lung TB (Sputum negative): 4 cases (20%)

Close contacts of TB-positive cases: 5 cases (25%)

Regarding the duration of symptoms prior to the study, parents reported that 12 children (60%) had been suffering from recurrent low-grade fever and poor appetite for more than six months. In 5 cases (25%), the condition was discovered during routine screening due to an active TB case in the household. The remaining 3 cases (15%) were referred following accidental discovery of lymphadenopathy during unrelated physical examinations.

At baseline, the immunological and radiological burden was significant. All 20 children (100%) showed a positive Mantoux test, with induration diameters ranging from 12 mm to 22 mm, falling well within the "highly reactive" range. Radiological findings at baseline primarily showed hilar congestion or significant nodal enlargement, with mesenteric nodes in the abdominal group measuring between 8 mm and 15 mm in the short axis.

Summary statistical Table.

Parameter	Baseline Mean (±SD)	PostTreatment Mean (±SD)	Mean Change	t-value	p - value	Cohen's d
Mantoux Induration (n = 20)	16.40 mm (±3.20)	11.15 mm(±3.10)	-5.25mm	11.23	<0.001	2.51
Cervical Nodes (n = 5)	14.20 mm(±2.28)	9.00 mm(±1.58)	-5.20mm	5.92	0.004	2.65
Mesenteric Nodes (n = 6)	12.00 mm(±2.00)	7.50 mm(±1.38)	-4.50mm	7.30	<0.001	2.98

Intervention

The 20 participants received their initial homeopathic consultations in staggered batches between March and August, depending on their date of recruitment at the study sites. All 20 children (100%) attended their first two follow-up consultations at the three-month and next three-month intervals. By the final 06-month follow-up, all 20 children were present for clinical and radiological assessment.

Throughout the one-year period, while Tuberculinum remained the primary intercurrent nosode, no adverse reactions or "homeopathic aggravations" of a serious nature were reported, even with the use of high potencies (200c and 1M).

Symptomatic and objective improvements: Following the administration of the nosode, subsequent symptomatic presentations showed marked improvement. There was a notable reduction in the frequency and intensity of:

Constitutional symptoms: Including fever, night sweats, and persistent cough.

General health markers: Subjects reported a decrease in recurrent colds and a steady improvement in weight (Wt. loss reversal).

Localized symptoms: Specifically, pain in the abdomen (associated with mesenteric involvement) was significantly alleviated.

Objectively, the intervention was corroborated by significant improvements in clinical markers:

Radiological assessment: Chest X-rays and ultrasounds demonstrated radiological resolution of lung markers and a measurable reduction in the size of cervical and mesenteric lymph glands.

Inflammatory markers: Laboratory findings indicated a downward trend in systemic inflammation, with a consistent reduction in Erythrocyte Sedimentation Rate (ESR) and C-Reactive Protein (CRP) levels across the cohort.

Discussion

This pilot study provides an exploration into a novel area of clinical research, particularly relevant for high-TB-burden regions where pediatric preventive care is

often hindered by treatment toxicity and non-compliance. It suggests that highpotency *Tuberculinum* is associated with clinical and radiological stabilization in children with evidence of latent infection. The observation that none of the 20 subjects progressed to active, sputum-positive status is significant, as latent TB in children—especially those with lymphadenopathy—is typically prone to rapid progression without intervention.

"The incorporation of inferential statistics in this pilot study strongly validates the clinical observations. The paired t-test results for Mantoux induration diameters yield a $p < 0.001$, meaning there is a less than 0.1% probability that the observed immunological down-regulation occurred by chance. Furthermore, the calculated Cohen's d values across all three parameters (ranging from 2.51 to 2.98) represent an exceptionally strong operational effect size, well above the traditional threshold for 'large' effects ($d > 0.80$). This mathematical rigor demonstrates that the structural regression of both cervical and mesenteric lymph nodes was not merely a feature of disease stagnation, but a statistically significant, proactive therapeutic response correlating with the high-potency Tuberculinum intervention."

Comparison and clinical observations

The favorable response observed, characterized by a reduction in cervical and mesenteric lymphadenopathy, aligns with homoeopathic literature regarding the action of nosodes on the glandular system.our study demonstrates that a specialized homoeopathic intervention can correlate with measurable changes in radiological markers. While latent TB can remain dormant naturally, the visible reduction in nodal size suggests a proactive immunological response rather than mere stagnation of the disease.

Implementation and design flexibility: The logistical success of this study highlights the feasibility of incorporating homoeopathic protocols into community health settings. However, flexibility must be built into future designs:

Dosing schedules: The study found that treatment was well-tolerated. This supports the homoeopathic philosophy that high-potency medicines act as a stimulus to the vital force rather than requiring the constant plasma concentration levels necessary for conventional antibiotics.

Conclusion

This pilot study suggests that high-potency Tuberculinum may be a safe, tolerable, deliverable, and cost-effective preventive intervention for children with latent tuberculosis infection. Given the preliminary radiological stabilization and the lack of progression to active, sputum-positive disease observed in this cohort, larger-scale and more robust studies—incorporating the feasibility findings identified here—are now required.

A future research design should incorporate randomization, a parallel comparator group (such as standard isoniazid prophylaxis), and blinded assessment of chest X-rays and IGRA (Interferon-Gamma Release Assays)results. Furthermore, future studies should measure the treatment's impact on broader clinical and social outcomes, including long-term immunity, nutritional status, school attendance, and overall quality of life.

In light of the significant side effects and compliance challenges associated with traditional long-term chemical prophylaxis, developing an evidence base for homoeopathic nosodes in TB prevention is of critical importance, particularly in resource-poor and high-burden environments.

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