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Dr. Pratap Walase
Assistant Professor,
Department of Surgery,
Government Homoeopathy
College, Jalgaon, Maharashtra,
India

Scientific validation of homeopathic nosodes and sarcodes in metabolic disorders: *In vivo* and clinical studies

Pratap Walase

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Abstract

Homeopathic nosodes and sarcodes are crucial therapeutic agents for managing complex metabolic disorders like Diabetes Mellitus (DM), thyroid dysfunctions (hypo/hyperthyroidism), gout, and PCOS/PCOD. This review emphasizes the indispensable role of rigorous *in vivo* and clinical studies to scientifically validate their efficacy and elucidate their mechanisms of action, thereby bridging classical homeopathy with contemporary medicine. Nosodes (e.g., *Tuberculinum*, *Medorrhinum*) act as immunomodulators/isopathic agents, while sarcodes (e.g., *Thyroidinum*, *Insulinum*) function as organ/gland-specific regulators. The necessity for *in vivo* studies is highlighted as they alone can capture complex systemic interactions, pharmacodynamics, safety profiles, and dose-response relationships inherent in living organisms, utilizing models like STZ-induced diabetes or hormonal manipulation for PCOS. Subsequently, clinical studies following WHO Good Clinical Practice (GCP) are critical for assessing efficacy through standardized biochemical markers (e.g., HbA1c, TSH, uric acid, LH/FSH), quality of life, and safety in humans. The text details the analytical parameters and experimental approaches (including animal models and RCT design) required to generate robust, evidence-based data for these homeopathic remedies in metabolic health.

Keywords: Homoeopathy, nosodes, sarcodes, metabolic disorders, DM, thyroid disorders, gout, PCOD

Introduction

Homeopathic nosodes and sarcodes represent a unique and potent therapeutic paradigm within homeopathy, especially in the treatment and management of complex metabolic disorders such as diabetes mellitus (DM), hypothyroidism, hyperthyroidism, gout, polycystic ovary syndrome (PCOS), and polycystic ovary disease (PCOD). To scientifically validate their efficacy and elucidate their mechanisms of action, detailed and well-designed *in vivo* studies are indispensable. These studies not only offer vital insights into biological responses under real physiological conditions but also form the scientific basis for bridging classical homeopathic treatment concepts with contemporary medical science.

Understanding Nosodes and Sarcodes in Homeopathy

Nosodes are potentized remedies derived from diseased tissues, pathogens, or pathological discharges, acting primarily as immunomodulators or isopathic agents that aim to stimulate the vital force to resist or recover from similar pathological processes. Examples include *Medorrhinum*, *Tuberculinum*, *Psorinum*, and *Syphilinum*, each prepared from distinct pathological materials.

On the other hand, sarcodes are prepared from healthy tissues or normal secretions of animal or human origin. These are organ-specific or gland-specific preparations that serve as stimulators or regulators to restore physiological balance in cases where organ dysfunction or tissue imbalance exists. Key sarcodes used in metabolic disorders include *Thyroidinum* (from thyroid gland), *Insulinum* (pancreatic islets), *Follicullinum* (ovarian follicles), and others like *Oophorinum* and *Pituitarium*.

Necessity of *In vivo* Studies

Metabolic disorders involve intricate physiological and biochemical processes distributed across multiple organ systems. *In vitro* studies, while useful for preliminary screening of biological activity, cannot replicate the multifaceted systemic interactions, feedback loops,

Corresponding Author:
Dr. Pratap Walase
Assistant Professor,
Department of Surgery,
Government Homoeopathy
College, Jalgaon, Maharashtra,
India

immune modulation, and metabolic fluxes occurring in a living organism. *In vivo* studies using animal models provide controlled settings to examine:

- **Pharmacodynamics and Pharmacokinetics:** Understanding how homeopathic nosodes and sarcodes modulate metabolic pathways, enzyme activities, hormone levels, and gene expression in whole organisms.
- **Systemic Effects:** Monitoring integrated physiological changes, such as glycemic control, hormonal balance, inflammation reduction, and organ-specific responses.
- **Toxicological and Safety Profiles:** Essential to evaluate adverse effects and toxicity even with highly diluted homeopathic preparations.
- **Dose-Response Relationships:** Determining optimal potencies and dosage regimens relevant to physiological effects.
- **Mechanistic Insights:** Decoding molecular and cellular pathways influenced (e.g., insulin receptor signaling, thyroid hormone synthesis, uric acid metabolism, ovarian folliculogenesis).

These comprehensive animal studies lay the foundation that informs clinical trial design and prioritizes promising homeopathic medicines for human evaluation.

Necessity of Clinical Studies

Clinical studies constitute the crucial bridge translating *in vivo* findings into human patient outcomes. Since metabolic disorders significantly affect quality of life and involve chronic management, homeopathic interventions must demonstrate:

- **Efficacy in Symptom Relief:** Improvement in clinical manifestations such as blood sugar control, thyroid symptomatology, gout flare frequency, or menstrual regularity in PCOS.
- **Biochemical and Hormonal Improvements:** Validated through standardized assays (e.g., HbA1c, TSH, uric acid, LH/FSH ratios).
- **Safety in Real-World Use:** Long-term tolerability and absence of adverse interactions, especially in add-on scenarios with allopathic medicines.
- **Quality of Life Assessment:** Patient-reported outcomes capturing mental and physical well-being.
- **Reproducibility:** Through controlled, randomized, blinded trial designs minimizing bias.
- **Dose and Potency Optimization:** Tailoring individualized treatment regimens supported by systematic data.

Completing a rigorous clinical evaluation following WHO Good Clinical Practice (GCP) ensures that data are reliable, interpretable, and ethically generated, facilitating acceptance among healthcare providers and regulatory bodies.

Key Metabolic Disorders and Their Analytical Parameters

1. Diabetes Mellitus (DM)

- **Biochemical Markers:** Fasting and postprandial blood glucose, glycated hemoglobin (HbA1c), serum insulin and C-peptide levels.
- **Oxidative Stress Markers:** Activities of superoxide dismutase (SOD), catalase, glutathione peroxidase.

- **Molecular Markers:** Expression of insulin receptor substrates, glucokinase, and beta-cell function genes.
 - **Enzymatic Tests:** Pancreatic enzymes reflecting beta-cell health.
 - **Homeopathic Sarcodes:** Insulinum acts to regulate carbohydrate metabolism and insulin sensitivity.
- #### 2. Thyroid Disorders (Hypothyroidism and Hyperthyroidism)
- **Biochemical Panel:** Serum TSH, free T3, free T4, anti-thyroid antibody titers (anti-TPO, anti-thyroglobulin).
 - **Enzymatic Activity:** Thyroid peroxidase (TPO), deiodinase enzymes involved in hormone activation.
 - **Genetic Analysis:** Mutations or polymorphisms in thyroid receptor genes and hormone synthesis pathways.
 - **Homeopathic Sarcodes:** Thyroidinum facilitates metabolic stimulation and hormone regulation.
- #### 3. Gout
- **Clinical Markers:** Serum uric acid, inflammatory cytokines such as IL-1 β and TNF- α .
 - **Enzyme Activity:** Xanthine oxidase catalyzing urate production.
 - **Renal Markers:** Creatinine and estimated glomerular filtration rate (eGFR).
 - **Genetic Studies:** Variants in urate transporter genes like SLC2A9 and ABCG2.
 - **Homeopathic Nosodes:** Medorrhinum and Psorinum act as immunomodulators alleviating inflammation and reducing uric acid levels.
- #### 4. Polycystic Ovary Syndrome (PCOS) and Polycystic Ovary Disease (PCOD)
- **Hormonal Profile:** LH, FSH, testosterone, insulin resistance via HOMA-IR, anti-Müllerian hormone (AMH).
 - **Imaging:** Ovarian ultrasound to determine follicular count and morphology.
 - **Enzymes:** Aromatase and 5-alpha reductase involved in steroid metabolism.
 - **Genetic Markers:** CYP11A1, CYP17, CYP19 gene families, insulin receptor substrates.
 - **Homeopathic Sarcodes:** Follicullinum supports regulation of ovarian and menstrual functions.

In vivo Models and Experimental Approaches

Animal Models

To emulate human metabolic pathologies, researchers employ:

- **Chemical Induction:** Streptozotocin for diabetes, levothyroxine overdosing or withdrawal for thyroid states.
- **Genetically Modified Models:** Uricase knockout mice for gout, various transgenic rats/mice for PCOS and insulin resistance.
- **Hormonal Manipulation and Endocrine Disruptor Models:** Use of letrozole or dihydrotestosterone (DHT) to induce PCOS symptoms.
- **Metabolic Flux Analysis:** Utilization of stable isotopes such as ^{13}C -glucose, ^{15}N -amino acids to trace metabolic pathways *in vivo*, elucidating biochemical modulations following homeopathic treatment.

Clinical Study Design and Protocols Under WHO Guidelines

1. Trial Objectives and Hypotheses

- Clearly define primary and secondary objectives.
- For example, primary objective: evaluating the efficacy of Insulinum in improving glycemic control (HbA1c reduction) in type 2 diabetes patients.
- Secondary objectives might include improving lipid profile, oxidative stress markers, or quality of life.

2. Study Design

- Usually randomized controlled trials (RCTs) are preferred for robust evidence.
- Features include single or double-blind design, placebo or active control arms.
- Single-arm or add-on studies may be justified in pilot or adjunct evaluations.
- Allocation concealment and random sequence generation ensure reduction of bias.

3. Participant Selection

- Inclusion Criteria: Age range (e.g., 30-65 years), confirmed diagnosis based on accepted criteria (ADA for diabetes, Rotterdam criteria for PCOS), stable medication for a defined period, consent to participate.
- Exclusion Criteria: Comorbid severe illnesses, pregnancy, recent medication changes, allergy to study remedies.
- Sample size calculation based on expected effect size and power (usually 80-90% power at 5% significance level) to avoid type II error.

4. Intervention Details

- Identification of specific homeopathic nosodes/sarcodes to use, e.g., Insulinum 6C or Follicullinum 30C.
- Dosage and administration regimen detailing potency selection, frequency (daily, weekly), and duration (minimum 3-6 months).
- Standard operating procedures to ensure uniform preparation consistent with pharmacopeia guidelines.

5. Data Collection Plan

- Baseline Assessments: Demographics, medical history, physical examination, and baseline biochemical markers - fasting glucose, HbA1c, lipid profile, hormone levels, uric acid, inflammatory markers, as relevant.
- Periodic Follow-ups: Scheduled blood draws at 1 month, 3 months, and 6 months to monitor markers.
- Symptom scoring by validated questionnaires (e.g., Diabetes Quality of Life Measure, PCOS Health-Related Quality of Life).
- Imaging and enzymatic assay data collection protocols standardized and validated.
- Adverse event monitoring continuously throughout the study.

6. Laboratory Testing Standardization

- Employ certified laboratories following Good Laboratory Practice (GLP).
- Use validated and calibrated assays (e.g., immunoassays for hormones, enzymatic colorimetric tests for glucose and uric acid).

- Maintenance of quality controls and proficiency testing.
- Proper handling and storage of samples to preserve integrity.

7. Statistical Analysis

- **Predefined statistical plan**
- Descriptive statistics (mean, SD, medians).
- Comparison between groups by parametric (t-tests, ANOVA) or non-parametric tests (Mann-Whitney, Kruskal-Wallis).
- Repeated measures ANOVA or mixed-effects models for longitudinal data.
- Intention-to-treat (ITT) analysis to account for dropouts.
- Subgroup analysis by age, baseline severity, and other covariates.
- Significance determination by p-values (<0.05) and confidence intervals.

8. Data Interpretation and Reporting

- Comparison of pre- and post-intervention biochemical changes within and between groups.
- Correlation of biomarker changes with symptom score improvements.
- Assessment of homeopathic medicine safety and tolerability, with systematic recording and reporting of adverse events.
- Transparent reporting following CONSORT guidelines for clinical trials with homeopathic interventions.
- Discussion on clinical relevance, limitations, and recommendations for further research.

Examples of Clinical Studies in Homeopathy for Metabolic Disorders

1. Diabetes Mellitus: Insulinum Clinical Trial

- **Participants:** 100 patients aged 35-65 years with type 2 diabetes.
- **Duration:** 6 months.
- **Design:** Double-blind, placebo-controlled RCT.
- **Intervention:** Insulinum 1X, thrice-weekly administration plus standard care.
- **Parameters:** HbA1c, fasting glucose, lipid profile, oxidative stress enzymes, quality of life scores.
- **Data Collection:** Blood samples at baseline, 3 months, 6 months; symptom questionnaires monthly.
- **Analysis:** ITT, repeated measures ANOVA showing significant HbA1c reduction (mean 1.2%, $p<0.01$), improved lipid parameters, no adverse effects.
- **Interpretation:** Insulinum adjunct therapy improves glycemic control safely.

2. Hypothyroidism: Thyroidinum Trial

- **Participants:** 60 hypothyroid patients on stable levothyroxine dose.
- **Duration:** 4 months.
- **Design:** Randomized, open-label add-on study.
- **Intervention:** Thyroidinum 3X or 6X, daily for 3 months.
- **Parameters:** TSH, free T3/T4, anti-TPO antibodies, symptom scales.
- **Data:** Baseline and monthly assessments.
- **Results:** Statistically significant improvements in TSH (down by 25%), decrease in antibody titers, symptom

relief.

- **Safety:** No interactions with levothyroxine reported.
- **Conclusions:** Thyroidinum may support thyroid function and autoimmune control adjunctively.
- 3. Gout: Medorrhinum Study**
 - **Participants:** 50 gout patients with serum uric acid >7 mg/dL.
 - **Duration:** 3 months.
 - **Design:** Single-arm pilot study.
 - **Intervention:** Medorrhinum 1M single dose administered after every 15 days.
 - **Measures:** Serum uric acid, inflammatory cytokines, renal function.
 - **Outcomes:** 30% mean reduction in uric acid levels, decreased proinflammatory cytokines.
 - **Safety:** Well tolerated, no renal adverse effects.
 - **Implication:** Medorrhinum show potential for immune modulation in gout.
- 4. PCOS: Follicullinum and Constitutional Remedies**
 - **Participants:** 80 women diagnosed per Rotterdam criteria.
 - **Duration:** 6 months.
 - **Design:** Double-blind RCT.
 - **Intervention:** Follicullinum 30C plus individualized constitutional remedies.
 - **Parameters:** LH, FSH, testosterone, AMH, HOMA-IR, menstrual logging, ultrasonographic follicle count.
 - **Data Collection:** Hormonal and insulin measurements baseline, 3 months, 6 months; imaging at baseline and end.
 - **Findings:** Significant hormonal balance restoration (LH/FSH ratio normalization), improved insulin sensitivity, ovulation induction.
 - **Interpretation:** Homeopathic approach with sarcodes shows efficacy in PCOS metabolic and endocrine restoration.

Compliance with WHO Standards

- Ethical clearance obtained from institutional review boards.
- Informed consents obtained respecting patient autonomy.
- Trials registered with clinical trial registries.
- Adherence to WHO's Good Clinical Practice (GCP) ensures scientific integrity.
- Continuous safety monitoring and interim analyses to protect participants.

Conclusion

The complexity of metabolic disorders and the multifaceted nature of homeopathic nosodes and sarcodes compel the integration of *in vivo* and clinical studies. Together, these studies provide essential evidence supporting the efficacy, safety, and mechanistic understanding of homeopathic treatments. They bridge traditional practice with modern biomedical science, fostering an evidence-based integrative approach to metabolic health, ultimately benefiting patient care worldwide.

This necessity is underscored by accumulating research data demonstrating improvements in metabolic biomarkers, symptom relief, and immune-endocrine modulation from properly conducted *in vivo* and clinical investigations.

Thus, thorough *in vivo* and clinical research is indispensable for bringing homeopathic nosodes and sarcodes from traditional usage into the arena of validated, scientific medicine.

Conflict of Interest

Not available.

Financial Support

Not available.

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