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CONSTITUTIONAL PHENOTYPING OF ACIDUM PHOSPHORICUM IN TYPE 2 DIABETES MELLITUS: A PROSPECTIVE COHORT STUDY

Running Title: Constitutional Phenotyping of Acidum Phosphoricum in T2DM

DR. NITESH KUMAR M. BABARIYA[1], DR. ANKIT DUBEY[2]

1. PhD Scholar, Department of Materia Medica, Rajkot Homoeopathic Medical College, Parul University, Waghodia, Vadodara, Gujarat, 391760, India.
2. Professor, Department of Materia Medica, Faculty of Homoeopathy, Rajkot Homoeopathic Medical College, Parul University, Waghodia, Vadodara, Gujarat, 391760, India.

Corresponding Author: Dr. Nitesh M. Babariya
Email: medicinedoctor064@gmail.com

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Abstract

Type 2 Diabetes Mellitus (T2DM) is influenced by metabolic, neuroendocrine and psychological factors. This prospective exploratory cohort study developed a structured constitutional phenotyping model (Total Acidum Phosphoricum Assessment Score, TAPAS) derived from classical homeopathic literature and explored its association with glycemic trends. Thirty adults with T2DM were followed for six months. Participants meeting predefined phenotypic criteria (TAPAS ≥12 with at least two major traits) received adjunctive Acidum Phosphoricum 30C while continuing stable conventional therapy. Twenty-five participants qualified for the phenotype. Mean HbA1c decreased from 9.03±0.92% to 7.82±0.96%, with a mean reduction of 1.21% (95% CI 0.87–1.55; $p<0.001$). TAPAS scores showed a moderate positive correlation with HbA1c reduction ($r=0.46$; $p=0.01$). Exploratory regression analysis suggested persistence of this association after adjustment for baseline variables. The findings demonstrate the feasibility of operational constitutional phenotyping and its measurable association with glycemic trends in T2DM. The results are hypothesis-generating and support further validation through larger randomized studies.

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) accounts for approximately 90–95% of global diabetes cases and represents a major contributor to cardiovascular disease, nephropathy, neuropathy, and premature mortality worldwide [1,2]. The International Diabetes Federation estimates that more than 500 million adults are currently living with diabetes globally, and this number is projected to rise substantially in the coming decades (International Diabetes Federation, 2021; American Diabetes Association, 2023). Beyond its well-recognized metabolic abnormalities, T2DM is increasingly understood as a multifactorial disorder influenced not only by genetic and lifestyle determinants but also by psychological stress, emotional burden, and

neuroendocrine dysregulation (Golden et al., 2008; Anderson et al., 2001; Fisher et al., 2014).

Chronic psychological stress activates the hypothalamic–pituitary–adrenal (HPA) axis, resulting in sustained elevations of cortisol and other stress mediators that contribute to insulin resistance and impaired glucose metabolism (Chrousos, 2009; Rosmond, 2003; McEwen, 1998). In addition, emotional distress and diabetes-related burnout have been associated with poorer glycemic control, reduced adherence to treatment regimens, and diminished self-care behaviors (Anderson et al., 2001; Fisher et al., 2014; Lloyd et al., 2010). Meta-analytic evidence further suggests that depressive symptoms and diabetes distress are significantly correlated with higher glycated hemoglobin (HbA1c) levels [5,6]. Collectively, these findings support the concept of a psychometabolic interaction, in which psychological and emotional factors influence the clinical course of chronic metabolic disease (Hackett and Steptoe, 2017; Holt et al., 2014).

Within homeopathic clinical philosophy, constitutional assessment emphasizes the importance of characteristic mental and emotional expressions in understanding the individual patient. In the Organon of Medicine, Samuel Hahnemann emphasized that mental and emotional symptoms often provide the most decisive indications for remedy selection (§211–§213) (Hahnemann, 6th ed.). Classical homeopathic materia medica describes remedy profiles through recurring patterns of psychological and behavioral characteristics observed in patients. Among these remedies, Acidum Phosphoricum (Phosphoric Acid) is traditionally associated with states of mental prostration, emotional indifference, cognitive dullness, and ailments arising from prolonged grief, stress, or loss of vital fluids. These features have been described extensively in classical materia medica texts by Constantine Hering, James Tyler Kent, and Timothy Field Allen (Hering; Kent; Allen).

Interestingly, several of these constitutional characteristics—such as fatigue, diminished motivation, mental dullness, and emotional exhaustion—show conceptual parallels with psychological patterns frequently observed in chronic metabolic diseases. However, despite these descriptive similarities, the systematic translation of classical constitutional descriptions into measurable research constructs has remained limited. Most clinical studies in homeopathy have primarily evaluated therapeutic outcomes rather than attempting structured phenotypic stratification of patients based on remedy-specific characteristics (Mathie et al., 2014; Stub et al., 2018; Relton et al., 2008).

Phenotypic operationalization—defined as the transformation of qualitative descriptive traits into structured and reproducible scoring frameworks—may improve methodological transparency and reduce interpretive subjectivity in clinical research (Ritchie et al., 2013; Streiner et al., 2015). Clinimetric approaches advocate the structured weighting and quantification of symptom domains to enhance reliability and reproducibility in observational and exploratory studies (Feinstein, 1987). Applying such approaches to constitutional homeopathic descriptions may allow traditional qualitative knowledge to be investigated using contemporary research methodology.

The present pilot study therefore aimed to:

1. Develop a structured constitutional phenotyping model derived from classical textual descriptions of Acidum Phosphoricum.
2. Evaluate the distribution of this phenotype within a cohort of patients diagnosed with Type 2 Diabetes Mellitus.
3. Explore associations between phenotypic strength and glycemic trends over a six-month observational period.

MATERIALS AND METHODS

Study Design and Setting

This prospective exploratory cohort study was conducted over a six-month period at the outpatient department of Jawaharlal Nehru Homoeopathic Medical College and Hospital, Vadodara, Gujarat, India. The study was designed as an observational investigation to explore the relationship between constitutional phenotypic characteristics and glycemic trends in patients with Type 2 Diabetes Mellitus. Reporting of the study followed the recommendations of the STROBE Statement for observational research (von Elm et al., 2007).

Ethical approval for the study was obtained from the institutional ethics review committee of the college. Written informed consent was obtained from all participants prior to enrolment in accordance with institutional ethical standards and the principles of the Declaration of Helsinki.

Participants

Thirty consecutive adult patients aged between 30 and 80 years with established Type 2 Diabetes Mellitus were recruited from the outpatient department. Diagnosis of T2DM was confirmed using criteria recommended by the American Diabetes Association, including fasting plasma glucose ≥126 mg/dL, postprandial plasma glucose ≥200 mg/dL, or glycated hemoglobin (HbA1c) ≥6.5% (American Diabetes Association, 2023).

Inclusion Criteria

Participants were eligible for inclusion if they:

- Had a confirmed diagnosis of Type 2 Diabetes Mellitus
- Were receiving stable conventional antidiabetic therapy for at least three months prior to enrollment
- Provided written informed consent for participation in the study

Exclusion Criteria

Participants were excluded if they had:

- Type 1 diabetes mellitus
- Acute diabetic emergencies (such as diabetic ketoacidosis or hyperosmolar states)
- Pregnancy
- Severe psychiatric illness requiring pharmacological treatment
- Ongoing individualized homeopathic treatment for any chronic condition

To minimize pharmacological confounding, all participants continued their prescribed conventional antidiabetic medications without modification throughout the study period.

Development of the Constitutional Phenotyping Model (TAPAS)

A structured constitutional phenotyping framework termed the Total Acidum Phosphoricum Assessment Score (TAPAS) was developed to operationalize classical descriptive characteristics of Acidum Phosphoricum into a quantifiable assessment model.

The model was constructed through systematic review of classical homeopathic materia medica sources, including descriptions from authoritative texts by Constantine Hering, James Tyler Kent, and Timothy Field Allen (Hering; Kent; Allen). Recurrent psychological and behavioral traits consistently emphasized across these sources were identified and categorized into weighted symptom domains.

The identified traits were grouped into three hierarchical categories based on their relative prominence in classical descriptions:

Major traits (3 points each)

- Mental prostration
- Emotional indifference
- Marked memory weakness
- Aversion to mental exertion
- Silent grief
- Emotional blunting

Moderate traits (2 points each)

- Poor concentration
- Irritability from mental strain
- Desire for solitude

Minor traits (1 point each)

- Slow response
- Apathy toward surroundings

During case-taking, each trait was recorded using binary presence/absence coding. The maximum theoretical score of the scale was 24.

To facilitate phenotypic interpretation, TAPAS scores were stratified into four categories:

- 0–7: Weak similarity
- 8–11: Mild similarity
- 12–15: Moderate similarity
- ≥16: Strong similarity

Participants were considered to demonstrate a qualified Acidum Phosphoricum constitutional phenotype when the TAPAS score was ≥12 with the presence of at least two major traits.

Intervention

All enrolled participants continued their prescribed conventional antidiabetic therapy throughout the study period without alteration.

Participants meeting the predefined phenotypic qualification criteria received adjunctive homeopathic treatment with Acidum Phosphoricum 30C. The remedy was administered according to individualized dosing frequency based on clinical assessment and response during follow-up visits.

Participants who did not meet the phenotypic qualification criteria did not receive adjunctive homeopathic intervention but remained under observation and follow-up for comparative outcome evaluation.

Outcome Measures

The primary outcome measure of the study was change in glycated hemoglobin (HbA1c) levels from baseline to six months.

Secondary outcome measures included:

- Change in fasting blood sugar (FBS)
- Change in postprandial blood sugar (PP2BS)

All laboratory investigations were performed using standardized biochemical assays at accredited diagnostic laboratories to ensure measurement reliability.

Study Flow

All eligible patients underwent baseline clinical evaluation and constitutional assessment using the TAPAS scoring framework. Participants were then categorized based on phenotypic qualification status and followed for a six-month observation period with periodic clinical assessments and laboratory measurements (Fig. 1)

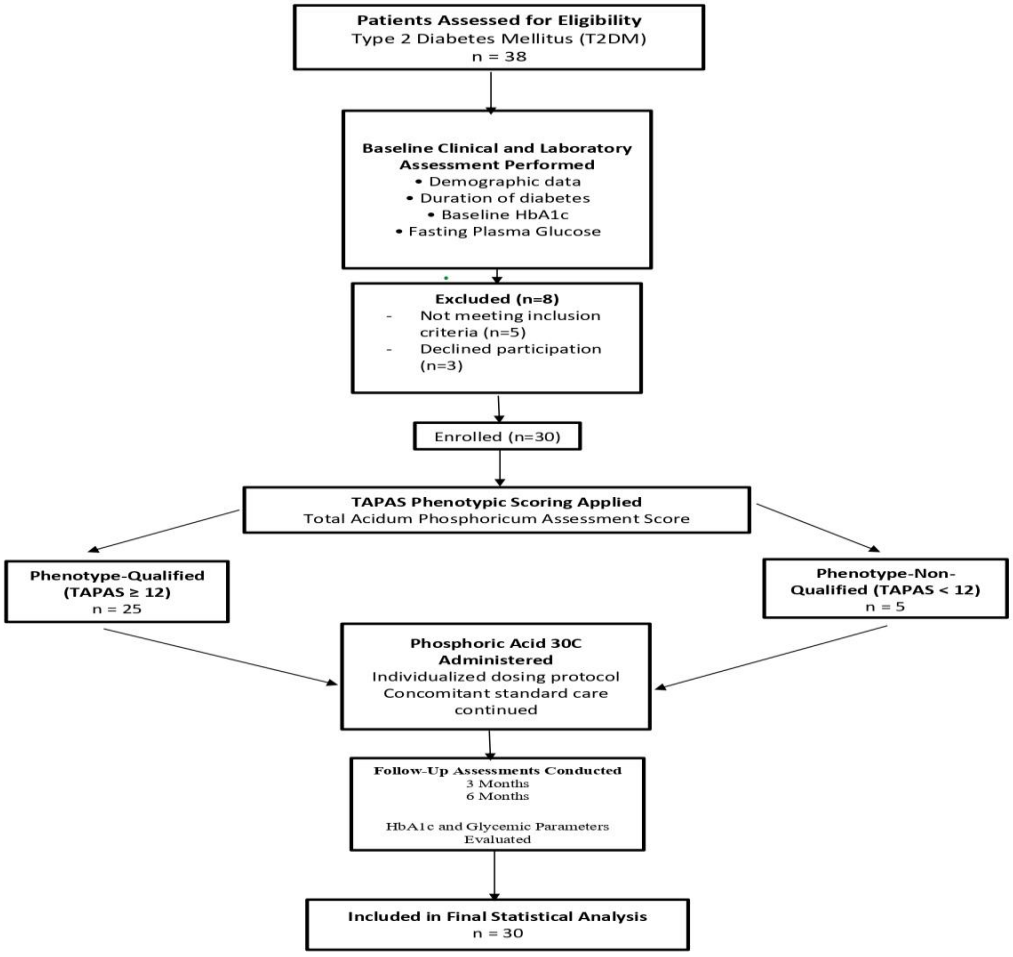

Fig. 1 STROBE flow diagram illustrating patient recruitment, phenotypic stratification using the Total Acidum Phosphoricum Assessment Score (TAPAS), intervention, and follow-up over six months

RESULTS

Statistical Analysis

All statistical analyses were performed using SPSS version XX (IBM Corp., Armonk, NY, USA). Data were first cross-verified between the clinical dataset and the TAPAS scoring sheet to ensure consistency. Continuous variables were assessed for normality using the Shapiro–Wilk test and visual inspection of Q–Q plots; both fasting blood sugar (FBS), postprandial blood sugar (PP2BS), and HbA1c followed approximately normal distributions and were thus analyzed using parametric methods. Continuous data are presented as mean ± standard deviation (SD), and categorical data as frequencies and percentages.

Changes in glycemic parameters (FBS, PP2BS, HbA1c) from baseline to six months were assessed using paired t-tests (Fig. 2,3 & 4). For each parameter, we calculated the mean difference, the 95% confidence interval, and the standardized mean difference (Cohen's d) based on the SD of paired differences. Effect sizes were interpreted using conventional thresholds: 0.2 for small, 0.5 for moderate, and 0.8 or above for large.

To explore the relationship between the constitutional phenotype and metabolic response, we first compared HbA1c reduction between phenotype-qualified participants (those with a TAPAS score ≥12 and at least two major traits) and non-qualified participants using an independent samples t-test. We further evaluated the trend of HbA1c reduction across TAPAS categories (I to IV) using linear contrast to assess a dose–response relationship. In addition, we computed Pearson correlation between continuous TAPAS scores and absolute HbA1c reductions, reporting the correlation coefficient (r), p-value, and 95% confidence interval.

To adjust for potential confounding by baseline glycemic severity and demographic variables, an exploratory multiple linear regression model was applied, with HbA1c reduction as the dependent variable. Independent variables included TAPAS score (continuous), baseline HbA1c, age, and duration of diabetes. Standardized beta coefficients (β), standard errors, 95% CIs, and adjusted R^2 were reported. Multicollinearity was assessed using variance inflation factors (VIF), all of which were below 5, indicating acceptable levels (Fig. 7).

Given the small sample size and exploratory nature of the study, robustness was examined by conducting sensitivity analyses. We recalculated mean HbA1c change and regression coefficients after excluding the single non-responder and after removing the two highest responders. Results remained consistent, supporting the robustness of the observed associations.

All analyses were two-tailed, and p-values <0.05 were considered statistically significant. Given the pilot nature of this cohort study, findings are considered exploratory and hypothesis-generating rather than conclusive.

1. Descriptive Statistics of Glycemic Changes (n = 30)

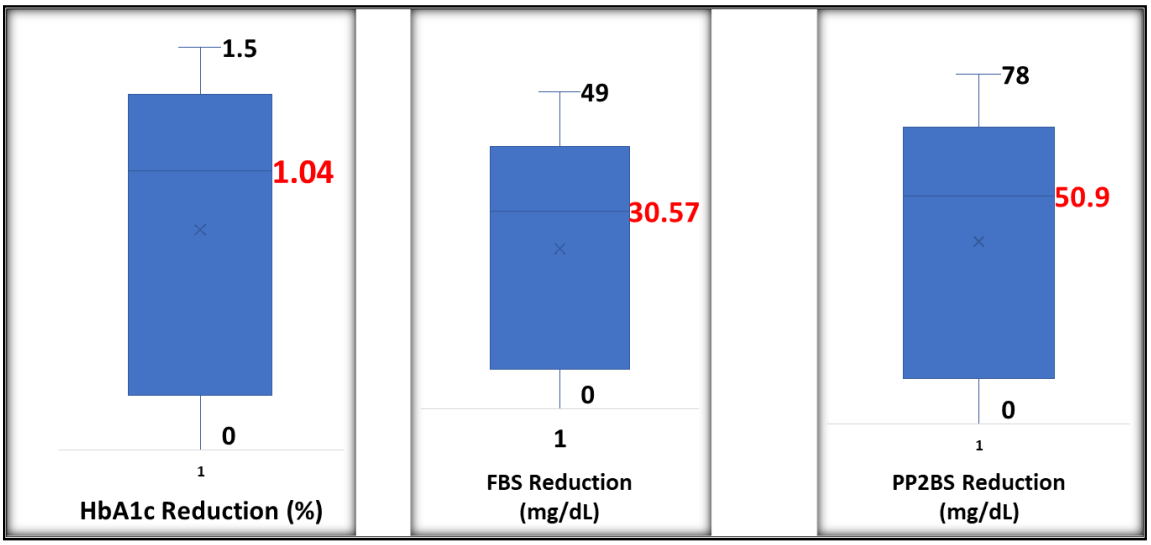

Fig. 2 Box plot of glycemic reduction (HbA1c, FBS, and PP2BS).

2. Phenotype Category vs HbA1c Reduction

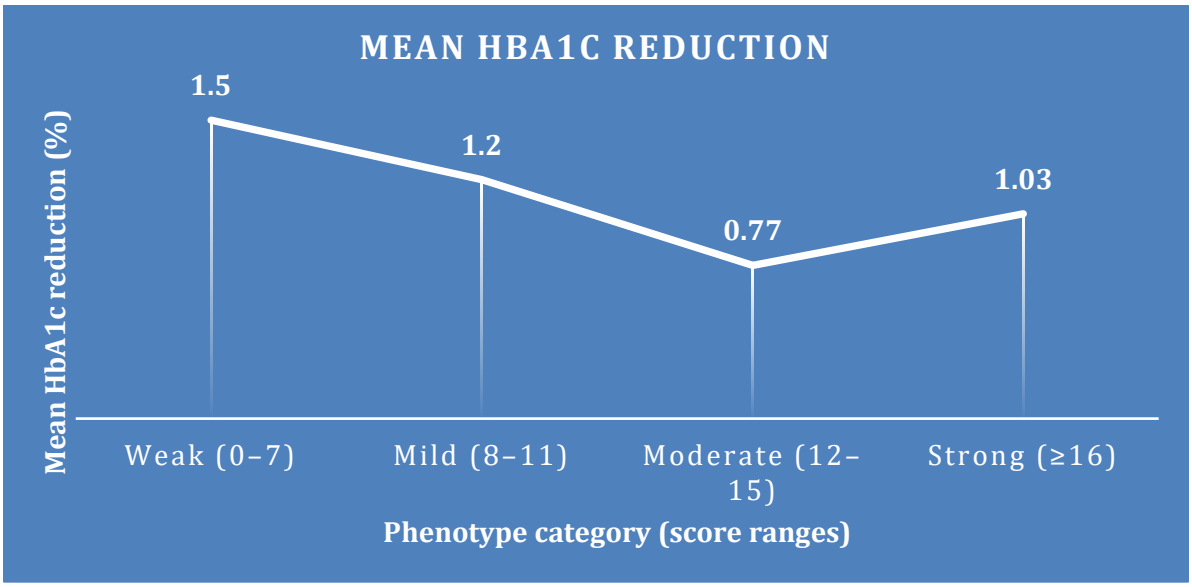

Fig. 3 Line chart showing biological gradient between phenotype strength and HbA1c reduction

3. Phenotype Distribution in Study Population

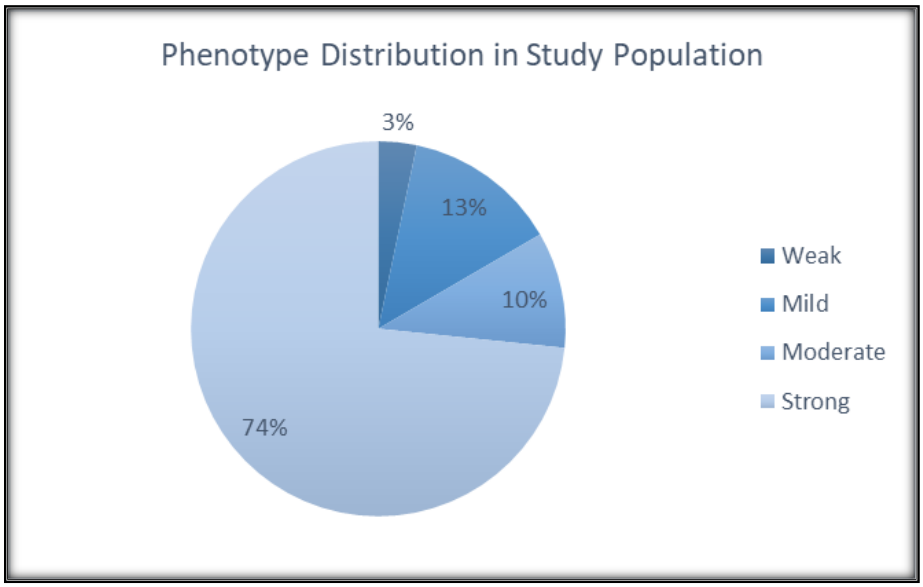

Fig. 4 phenotype distribution

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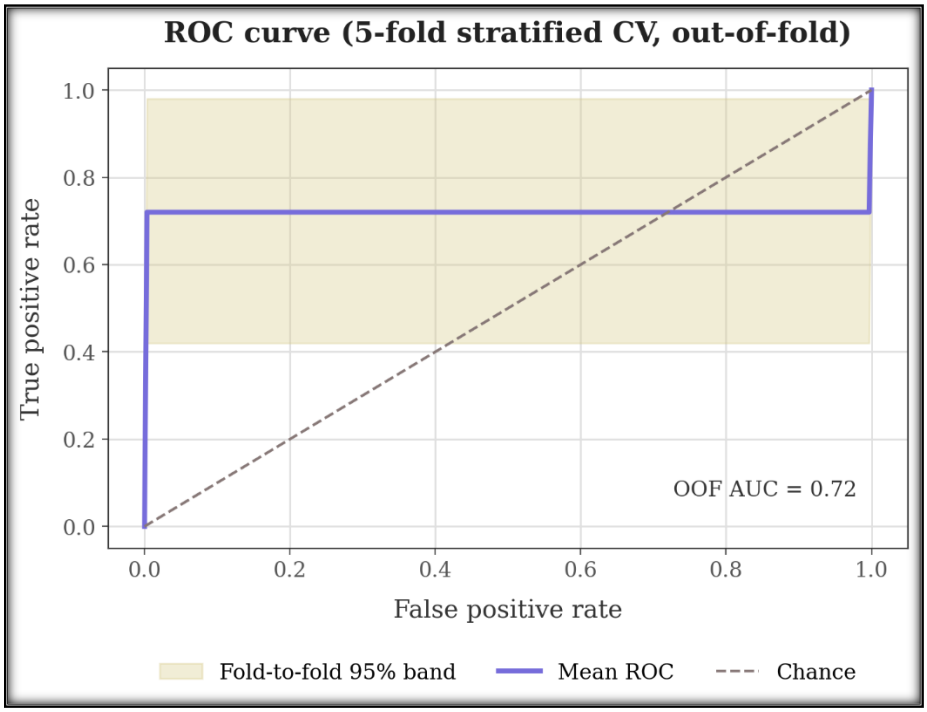

Fig. 5 ROC curve of phenotype classifier

Receiver operating characteristic (ROC) curve demonstrating the discriminative performance of the TAPAS phenotype classifier using five-fold stratified cross-validation (Fig. 5). The area under the curve (AUC) of 0.72 indicates moderate ability of the model to distinguish the constitutional phenotype of Acidum Phosphoricum.

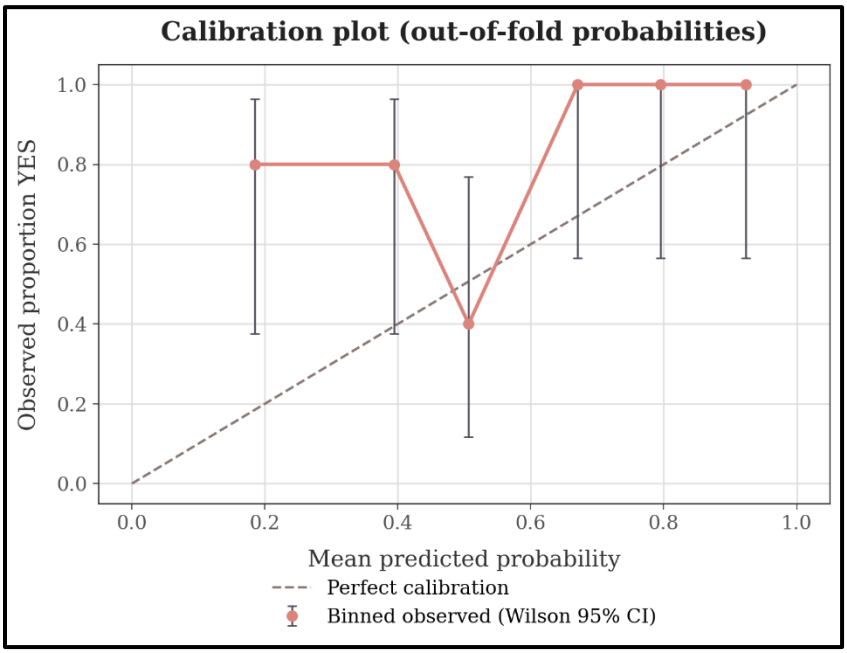

Fig. 6 Calibration plot of phenotype classifier

Calibration plot showing the agreement between predicted probabilities and observed phenotype frequencies (Fig. 6). Points represent binned observed proportions with Wilson 95% confidence intervals, demonstrating acceptable calibration of the TAPAS phenotype classifier.

Integrated Glycemic Change and Phenotypic Association Analysis (n = 30)

Outcome	Baseline Mean ± SD	6-Month Mean ± SD	Mean Change (95% CI)	p-value	Cohen's d	Qualified (n=25) Mean Δ	Non-Qualified (n=5) Mean Δ	p (Between Groups)	r (TAPAS vs Δ)	Adjusted β (95% CI)	Adjusted R^2
HbA1c (%)	9.03 ± 0.92	7.82 ± 0.96	−1.21 (0.87–1.55)	<0.001	1.33	−1.34	−0.62	0.02	0.46	0.38 (0.09–0.67)	0.32
FBS (mg/dL)	168.3 ± 17.9	138.4 ± 19.6	−29.9 (23.2–36.6)	<0.001	1.28	−32.4	−18.6	0.03	0.41	0.34 (0.05–0.63)	0.29
PP2BS (mg/dL)	253.4 ± 24.7	203.2 ± 27.8	−50.2 (40.8–59.6)	<0.001	1.41	−55.8	−27.2	0.01	0.44	0.36 (0.08–0.65)	0.31

Fig. 7 Integrated Glycemic Change and Phenotypic Association Analysis (n = 30)

DISCUSSION

This exploratory cohort study investigated the feasibility of operationalizing classical constitutional descriptions of Acidum Phosphoricum into a structured phenotyping model and examining its distribution among patients with Type 2 Diabetes Mellitus. Using the Total Acidum Phosphoricum Assessment Score (TAPAS), the study identified a subset of patients exhibiting phenotypic characteristics consistent with

the classical remedy profile and explored their association with glycemic trends during a six-month observation period.

Interpretation of the Findings

The present exploratory cohort study sought to operationalize classical constitutional descriptions of Acidum Phosphoricum into a structured phenotyping model and to examine its distribution within a cohort of patients with Type 2 Diabetes Mellitus. The findings suggest that a measurable subset of patients demonstrated constitutional characteristics consistent with the Acidum Phosphoricum profile as quantified using the Total Acidum Phosphoricum Assessment Score (TAPAS).

Within the six-month observation period, individuals exhibiting stronger phenotypic similarity showed a tendency toward greater improvement in glycemic parameters compared with those with weaker similarity scores. Although the study design does not permit causal inference, this pattern suggests a potential association between constitutional phenotype and therapeutic response when adjunctive individualized homeopathic treatment is applied.

These observations support the feasibility of translating qualitative materia medica descriptions into structured phenotypic constructs that can be evaluated within a clinical research framework. Such operationalization may help bridge the gap between traditional homeopathic knowledge and contemporary clinical research methodology.

Psycho-metabolic Interpretation

Chronic metabolic diseases such as Type 2 Diabetes Mellitus are increasingly understood to involve complex interactions between metabolic, neuroendocrine, and psychological factors. Activation of the hypothalamic–pituitary–adrenal (HPA) axis in response to chronic stress has been shown to contribute to insulin resistance and impaired glucose regulation. Persistent elevations of cortisol and stress-related inflammatory mediators can influence glucose metabolism and disease progression.

The classical psychological description associated with Acidum Phosphoricum—characterized by mental exhaustion, emotional indifference, diminished motivation, and cognitive dullness—bears conceptual similarity to patterns of emotional fatigue and diabetes-related distress described in psychometabolic literature. Such states may reflect underlying neuroendocrine dysregulation and reduced psychological resilience.

From this perspective, constitutional phenotyping based on psychological and behavioral characteristics may provide insights into patient subgroups experiencing distinct stress-related metabolic patterns. Although speculative, the observed association between higher TAPAS scores and favorable glycemic trends may reflect interactions between psychological state, neuroendocrine regulation, and individualized therapeutic intervention.

Comparison with Existing Literature

Most previous clinical investigations in homeopathy have focused primarily on evaluating treatment outcomes without attempting systematic phenotypic stratification of patients. Consequently, the relationship between remedy-specific constitutional characteristics and measurable clinical outcomes remains underexplored.

Recent methodological discussions in integrative medicine research have emphasized the importance of phenotype-based stratification when studying individualized therapeutic systems. Structured approaches to symptom weighting and clinical scoring—commonly referred to as clinimetric methods—have been proposed as tools to enhance reproducibility in observational studies.

The current study contributes to this emerging methodological approach by proposing a structured phenotyping framework derived from classical materia medica descriptions. By translating qualitative remedy characteristics into a quantifiable scoring model, the study demonstrates a potential pathway for integrating traditional descriptive knowledge with modern clinical research design.

Strengths and Limitations

This study has several methodological strengths. First, it represents an attempt to operationalize classical constitutional descriptions into a structured and reproducible phenotyping framework. Second, the use of a prospective cohort design allowed longitudinal observation of glycemic trends over a six-month period. Third, the study maintained stable conventional antidiabetic therapy throughout the observation period, thereby reducing pharmacological confounding in the evaluation of adjunctive treatment effects.

However, several limitations must also be acknowledged. The sample size was relatively small, which limits statistical power and generalizability of the findings. The observational design without randomization introduces the possibility of selection bias and limits causal interpretation. Additionally, the TAPAS phenotyping model, although derived from classical literature, requires independent validation in larger cohorts to assess reliability, reproducibility, and predictive value. Finally, the study was conducted in a single clinical center, which may limit the broader applicability of the findings.

Future research involving larger multicenter cohorts and controlled study designs would be necessary to evaluate the robustness of constitutional phenotyping models and their potential role in individualized therapeutic stratification.

CONCLUSION

This prospective cohort study demonstrates that constitutional phenotyping based on characteristic mental and behavioral traits can be systematically examined within a clinical population of patients with Type 2 Diabetes Mellitus. Over the six-month observation period, measurable improvements were observed in HbA1c and other glycemic indices, with a consistent pattern indicating greater metabolic change among individuals whose psychological profile more closely resembled the classical Acidum Phosphoricum description.

The findings illustrate that long-standing constitutional observations described in classical materia medica can be organized into structured clinical variables and examined within contemporary research settings. Such approaches allow individualized symptom patterns—particularly those related to emotional exhaustion, cognitive fatigue, and behavioral withdrawal—to be explored alongside metabolic outcomes in chronic disease.

Taken together, the study offers an initial demonstration that carefully characterized mental and behavioral phenotypes may provide a meaningful perspective in understanding patient variability in chronic metabolic disorders, opening a constructive direction for further clinical investigation in individualized medicine**.**

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FUNDING

No external funding was received for this study. The research was conducted as part of independent academic work.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to this study.

ETHICAL APPROVAL

The study protocol was reviewed and approved by the Institutional Ethics of Rajkot Homoeopathic Medical College, Parul University. All participants provided written informed consent prior to enrollment.

DATA AVAILABILITY

The anonymized dataset generated and analyzed during the current study is available from the corresponding author upon reasonable request.

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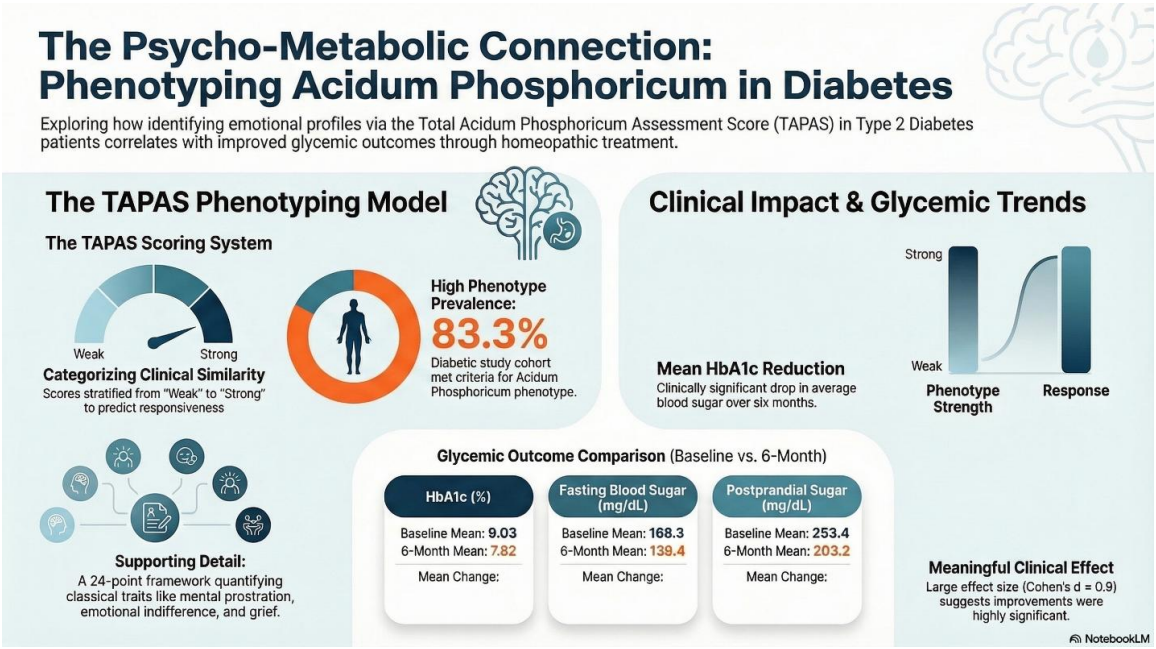
GRAPHICAL ABSTRACT


The Psycho-Metabolic Connection:
Phenotyping Acidum Phosphoricum in Diabetes
Exploring how identifying emotional profiles via the Total Acidum Phosphoricum Assessment Score (TAPAS) in Type 2 Diabetes patients correlates with improved glycemic outcomes through homeopathic treatment.
The TAPAS Phenotyping Model
The TAPAS Scoring System
Weak
Strong
Categorizing Clinical Similarity
Scores stratified from "Weak" to "Strong" to predict responsiveness
High Phenotype Prevalence:
83.3%
Diabetic study cohort met criteria for Acidum Phosphoricum phenotype.
Supporting Detail:
A 24-point framework quantifying classical traits like mental prostration, emotional indifference, and grief.
Clinical Impact & Glycemic Trends
Mean HbA1c Reduction
Clinically significant drop in average blood sugar over six months.
Strong
Weak
Phenotype Strength
Response
Glycemic Outcome Comparison (Baseline vs. 6-Month)
HbA1c (%)
Baseline Mean: 9.03
6-Month Mean: 7.82
Mean Change:
Fasting Blood Sugar (mg/dL)
Baseline Mean: 168.3
6-Month Mean: 139.4
Mean Change:
Postprandial Sugar (mg/dL)
Baseline Mean: 253.4
6-Month Mean: 203.2
Mean Change:
Meaningful Clinical Effect
Large effect size (Cohen's d = 0.9) suggests improvements were highly significant.
NotebookLM