

“AN OBSERVATIONAL STUDY PROTOCOL FOR THE PREVALENCE OF NON-INSULIN DEPENDENT DIABETES MELLITUS IN DIFFERENT TYPES OF PRAKRUTI IN WARDHA CITY”

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ABSTRACT:

Background: *Prakruti* is the morphological, physiological, and psychological basic traits, manifested in the intrauterine life and is said to be unchangeable throughout life. Noninsulin dependent diabetes mellitus (NIDDM) is taxonomically adjacent to *Madhumeha* in Ayurveda; The present study is focused to observe the prevalence of NIDDM in different *Prakruti*. **Aim:** To observe the prevalence of non-insulin dependent diabetes mellitus in different *Prakruti* in the population of Wardha city. **Objectives:** To compare *Prakruti* wise blood sugar level and Urine sugar in the population of Wardha city and to create awareness in the population of Wardha city regarding non-insulin dependent diabetes mellitus and its relation with *Prakruti*. **Methodology:** NIDDM participants with proper consent will be interviewed by a well prepared and structured questionnaire regarding the *Prakruti*. And blood, urine investigation will be done. The values of investigation will be correlated with respective the *Prakruti* and the list of dos, don'ts will be provided to the participants for their diet and workout concerning their *Prakruti*. **Discussion:** Personalized medicine is the need of today's era, so to develop the treatment pattern and template to reduce the disease burden of diabetes as well the awareness is the parallel arm to lessen worldwide problems.

Keywords: *Madhumeha*, *Prakruti* and Diabetes mellitus, NIDDM

INTRODUCTION

Prakruti is a unique combination of the morphological, physiological, and psychological basic traits. It is manifested in the intrauterine life according to the *Beeja* (genetic) and *Dosha* (body humours viz. *Vata*, *Pitta* and *Kapha*) influence and remain to be constant throughout life (1). Ayurveda gives utmost importance to personalized therapy under “*Purusham Purusham Vikshya*” (personalized medicine) principle. Genetic and intrauterine influences make, every individual a distinct entity. Hence, a person has the physiological and pathological variations accordingly. *Prakruti* of each person determines the response differently when exposed to the similar stimuli. The variability in resistance to diseases, different natural course of disease and diverse therapeutic responses needs to be explored for *Prakruti* (2). Noninsulin dependent diabetes mellitus (NIDDM) is taxonomically adjacent to *Madhumeha* in Ayurveda; *Prakruti* types exhibited striking differences to biochemical and hematological parameters, even at genome-wide expression levels. The present study was focused to observe the prevalence of NIDDM in different *Prakruti*.

Rationale of the study

Prakruti is a notable basic construct of Ayurved epistemology. Fundamentally, it may explain the biological variability that is observed in different individuals. Modern medicine also accepting the concept of personalized medicine as a treatment pattern for the individual patient. As the percentage of DM is more in urban areas, the *Prakruti* analysis survey is indeed for the generation of awareness and suitable *Ahar-Vihar* (diet & exercise) in regards to their *Prakruti* in the patients of non-insulin dependent diabetes mellitus to avoid expected complications and destructive further changes in the body.

Material & Methods:

Study Design

A cross-sectional observational study using survey strategy in the form questioner based personal interview of the individual meeting to eligibility criteria of the research. The primary aim of the study is to determine the prevalence of non-insulin dependent diabetes mellitus in different *Prakruti* of individuals located in Wardha city. In addition, as secondary objectives are aimed to compare *Prakruti* wise blood sugar level and Urine sugar in the located population and to create awareness in the population regarding non-insulin dependent diabetes mellitus and its relation with *Prakruti*.

Setting

The study will be conducted at two hospitals named as Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H) and Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha. The cross-sectional survey will be conducted for six months for that approval is taken from the institutional ethical committee. Data will be collected by personal interviews and blood & urine sugar investigations. All the subjects will be personally interviewed based on the *Prakruti* questionnaire. *Prakruti* Questionnaires will help to identify the prevalence of non-insulin dependent diabetes mellitus according to *Prakruti*. Before the investigation and interview, the informed consent of the participants will be taken.

Participants

The patient suffering from non-insulin dependent diabetes mellitus (ICD – 10 Criteria E11) between the age group 35-70 years, irrespective of gender, and who are willing to enroll in the study. The patient will be selected by investigating the blood sugar level. The patients' known case of diabetes of either sex having fasting blood sugar level $>/ 126$ mg/dL and postprandial blood sugar $>/ 200$ mg/dL. The patients other than NIDDM and having any major life-threatening disorder will be excluded from the study.

Recruitment

By using simple random sampling, all eligible participants will be informed in advance about the nature of the study and the required time for the completion of the questionnaire. Proper informed consent will be taken from the patients in their known language (Marathi / Hindi /English). The participation of the patient will be voluntary and not any financial assistance will be given. The questionnaire will be filled by the intern students during the interview of the participants. All the essential information will be recorded like name, address, affiliation, phone number, and email address for further assistance, if required. If the participants have any questions regarding research or study, that will be answered by investigating researchers.

Data Collection

For the development of the *Prakruti* survey questionnaire, the literature search and review regarding *Prakruti* analysis was carried out, and depending upon that information the questionnaire was prepared. The answers will be recorded in the questionnaire by marking the appropriate answer with the help of intern students. The blood and urine investigation will be recorded in a special structured case proforma. After completion of the survey procedure, the participants *Prakruti* will be analyzed, and concerning to their *Prakruti* the list of Do's and Don'ts (*Ahar and Vihar*) will be provided.

Sample size

Considering 8% prevalence of non-insulin dependent diabetes in Wardha city according to population survey conducted by government (3) and statistical data regarding diabetes in Wardha region (4), a sample size of 500 participants (complete questionnaires) is required (95% confidence interval). Expecting a 10% incomplete questionnaire or technical difficulty, at least 550 participants will be surveyed to achieve the target of 550 complete questionnaires.

Data extraction, management, and statistical methods

Manual data entry will be done in an excel sheet from marked answers in the completed *Prakruti* survey questionnaire and case record form. All the data will be analyzed with the help of statistical experts by using the Chi-square test to assess the association between categorical variables and the relation between *Prakruti* and variation in glucose level in Blood and Urine. In windows, SPSS software will be used for all statistical analyses.

Discussion

The World Health Organization (WHO) projected that there the population living with diabetes will be 300 million by 2025 (5). There is a need for prevention and control type-2 diabetes by changing lifestyle and dietary patterns (6). The modern medicine researcher also searching about personalized medicine by clinical validation and reliability of clarity for the interpretation (7). *Prakruti* is a unique amalgamation decided at the time of fertilization and cannot be changed throughout life, so taking advantage of this factor this survey study is planned to search Type-2 diabetes concerning the *Prakruti*. In this survey study, one can calculate the glucose level pattern in the blood and urine concerning *Prakruti*, which ultimately helps to decide the diet (*Ahar*) and workout (*Vihar*) of the patients. Diabetes is included in the list of lifestyle disorder and government taken so many initiatives for the awareness about seriousness and facts of the diabetes (8) and in one of the research study the researcher find out the need for conducting large scale diabetes awareness and education programs for the Indian population to reduce the disease burden (9). Thus, in the study after interviewing the participants for the awareness of the disease- do's and don'ts list concerning to their *Prakruti* will be provided. So, this survey study can generate certain guidelines to treat Type-2 diabetes and a template that any researcher can use in the future for the betterment of human beings. Rathi et al conducted nerve conduction studies of peripheral motor and sensory nerves in the subjects with prediabetes (10). Gaidhane et al and Khatib et al conducted some systematic reviews on effects of electronic media on diet, exercise and substance abuse among adolescents (11-12). Ray et al studied effects of alirocumab on cardiovascular and metabolic outcomes after acute coronary syndrome in patients with or without diabetes (13). . Gaidhane et al reported about perceptions of primary care doctors towards type 2 diabetes mellitus and challenges for care at primary care level in India(14). Gondivkar et al assessed gustatory function in patients with diabetes mellitus type 2 (15). Khatib et al suggested M-HEALTH intervention for type II diabetes mellitus patients in Indian rural areas (16). Kambale et al studied effect of Insulin on wound healing (17).

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