
Non-Interventional Study Report Synopsis

NIS Name/Code D1843R00282

Edition Number 1.0

Date 09 Jun 2020

Indian Phenotype Registry

A Non-interventional nationwide registry to identify Indian Phenotype characteristics in Diabetes Mellitus patients in India

Study dates:**First Subject in:** 11 Dec 2017**Last Subject Last Visit:** 08 Aug 2019

NIS REPORT SYNOPSIS

Indian Phenotype Registry

A Non-interventional nationwide registry to identify Indian Phenotype characteristics in Diabetes Mellitus patients in India

Background/Rationale:

Diabetes mellitus (DM) is a chronic and progressive disease imposing huge health and economic burden worldwide. Currently there are 415 million patients with Diabetes worldwide which is estimated to increase to 642 million by 2040 as per the International Diabetes federation (IDF) 2016 data. Similarly, in India also at present there are 67 million patients which will rise to 100 million by 2030.(1) Obesity is most commonly associated comorbidity in diabetic patients which further impacts various metabolic parameters in this chronic metabolic disorder. Insulin resistance linked with visceral obesity is believed to play vital role in disease progression in diabetes mellitus patients.(2) Obesity defined by Body Mass Index (BMI) categories is different in India compare to western counterparts. There are data which suggest that at lower BMI level Indian diabetes mellitus patients have higher fat content including visceral fat. This phenomenon is termed as Y-Y paradox.(3)

Currently availability of nationwide data on diabetes mellitus patients is very limited. It will be useful to identify key characteristics of Indian phenotype in diabetes mellitus. This will help to address specific unmet needs unique to Indian population and choose an appropriate treatment strategy for improved long term outcome. This registry aims to create nationwide data on diabetes mellitus patient population to define key characteristics of Indian phenotype

Objectives and Hypotheses:

Primary Objective

To evaluate total body fat content across various BMI categories in the study population

Secondary Objectives

1. To analyse different characteristics of diabetes mellitus patient in study population
2. To correlate Glycated Haemoglobin (HbA1C) level with various BMI categories
3. To record associated comorbidities in study population
4. To record ongoing glucose lowering drugs in study population

Methods:

Study design:

This was a non-interventional, multicentre, descriptive, cross-sectional study. Approximately 50000 patients, 50 at each sites were planned to be enrolled, the study recruited 38849 patients at 845 sites.

Study Population:

Inclusion Criteria

1. Male or female patients with 18 years and above.
2. Patients who provide written informed consent.
3. Patients with previously diagnosed with diabetes mellitus
4. HbA1C report available within past 03 months

Exclusion Criteria

None

Exposure:

This was a non-interventional, cross-sectional study and aimed to capture the data from patients who visited study centre as a part of their routine clinical care visit. The study did not aim to expose patients to any other intervention

Outcomes:

Patient Characteristics:

- Age, gender

- Co-morbidities defined by diagnosis coding (Hypertension, Dyslipidaemia, CKD, CVD, Heart Failure, Stroke/TIA, Neuropathy, Retinopathy and/or Other).
- Duration of diabetes mellitus
- Drug prescriptions and treatment patterns by class of molecules
- History of tobacco use
- Weight and/or BMI records
- HbA1C value records
- Total Body fat content (By Omron Body fat analyser)

Sample Size Estimations:

All analyses were descriptive. There were 38849 patients in the registry to describe variables as mentioned in above section.

Statistical Analysis:

The patient characteristics and variables were described using frequency and percentage distributions for categorical variables. For example, proportion of patients falling above/below certain weight/BMI and HbA1c thresholds were derived. Continuous and count variables were described using mean (\pm standard deviation [SD], median (quartiles) and 95% confidence intervals (95% CI).

Results: A total of 38849 subjects were enrolled. 55.6 % of the subjects were males. 16890 (43.5 %) subjects were in Pre-Obese category (25-29.9 Kg/m²) with 32.1 mean body fat. More than 30 % of subjects with diabetes mellitus were in age group 60 and above years. Maximum percentage of subjects (43.5 %) was in overweight category. 14707 subjects were in $\leq 7.49\%$ HbA1C category, out of which more than 40 % of subjects were in Pre-Obese category. The most prevalent comorbidity reported was hypertension with 71.1 % of subjects. Majority of subjects (86.9 %) were taking metformin for management of diabetes mellitus.

Conclusion: Our study provided the largest data nationwide on key characteristics of diabetes mellitus patient population. In our study, most of the diabetic patients were classified in pre-obese category based on their body fat content and no correlation could be established between HbA1c and BMI category. The most common comorbidity was hypertension in Indian DM patients.