An Observational, Cross sectional Study to assess the Prevalence of Heart Failure in Type 2 Diabetes Patients in India

An observational primary data collection study to identify the prevalence and association of heart failure in Type 2 diabetic patients

Study Dates:

First Subject In: 03-Dec-2019

Last Subject In: 27-Feb-2021

Background/Rationale:

As per reported epidemiological and clinical data, heart failure (HF) is a major contributor to cardiovascular (CV) morbidity and mortality in patients with diabetes. The risk associated with developing HF is 2 to 5-fold higher in patients with diabetes. Studies have reported a high prevalence of pre-clinical diastolic dysfunction among subjects with Diabetes Mellitus (DM). Despite control of known CV risk factors, patients with Type 2 diabetes mellitus (T2DM) remain at an elevated risk of developing HF. Around 63-68% of patients with T2DM had evidence of Left Ventricular (LV) dysfunction after 5 years of diagnosis of T2DM. Moreover, during cardiac screening, an undiagnosed heart failure was detected in 28% of patients with diabetes.

However, very few population-based studies have been carried out in India to demonstrate the prevalence of heart failure in Indian diabetic patients. Therefore, this registry aimed at identifying the prevalence of HF in Type 2 diabetic patients and also determine whether there is any association between heart failure and T2DM.

Heart Failure Registry Observational Study Report Synopsis
Study Code: D1843R00300
Version: 1.0
Date: 14-Feb-2022

Objectives:

Primary Objective:

- To determine the prevalence of LV dysfunction and heart failure in T2DM patients.

Secondary Objective:

- To correlate LV dysfunction and heart failure with demographics and comorbidities.

Study design:

This was a cross sectional, observational, multi-centric study which included 621 patients from 27 centres. Data has been captured directly from the patient or from medical records, which was recorded in the Electronic Case Record Form (eCRF) from 27 centres across India. This was a single visit study.

Data source:

Data was captured directly from the patient or from medical records.

Study population and Sample size:

The patients suffering from Type 2 Diabetes Mellitus for 1 year or more visiting Diabetes centre were enrolled in the registry for data collection as per the study protocol. The study enrolled 621 patients from 27 centres.

Inclusion criteria:

1. Both men and women aged ≥ 18 years.

2. Diagnosed with type 2 diabetes (as per ADA Criteria

3. Duration of diabetes for 1 year or more.

4. Willing to provide written informed consent.

Exclusion criteria:

Patients were excluded from the study if they fulfil any of the following criteria:

1. Patients with evidence of coronary artery disease – CAD (based on the clinical expertise of the physician).

2. Patients who were previously diagnosed with heart failure.

3. Patients with evidence of valvular disease based on clinical judgement of the Principal Investigator (PI).

4. Current treatment with digoxin.

5. History or symptoms of peripheral artery disease, chronic obstructive pulmonary disease, and arrhythmias.

6. Patients diagnosed with stage III/IV Chronic Kidney Disease (CKD).

7. Diabetes other than type 2 diabetes mellitus.

Statistical methods:

Data was analysed by using descriptive statistics. Quantitative variables were expressed as mean ± standard deviation. Qualitative variables were expressed as proportion. p value was fixed at 0.05. Correlation between LV dysfunction comorbidities and demographics was assessed by calculating the correlation coefficient (r); correlation was calculated by using the Contingency coefficient.

Results:

Brain Natriuretic Peptide (BNP) test and 2-D electrocardiography (Echo) was performed to analysed the prevalence of LV dysfunction and heart failure in enrolled T2DM patients. The recorded values from tests indicate prevalence around 55% and 10% for LV dysfunction and heart failure respectively in enrolled T2DM patients. The prevalence of patients with HFpEF positive status score was 4% in enrolled T2DM patients. A negligible correlation of LV dysfunction and heart failure was reported with demographics (age and gender) of enrolled T2DM patients. Similar results were reported for correlation of LV dysfunction and heart failure with comorbidities and diabetes duration of enrolled T2DM patients.

Conclusion:

In the present study, the prevalence of LV dysfunction was reported to be high (55%) and that of heart failure was reported to be low (10%) in enrolled T2DM patients. LV dysfunction seems to be more common in T2DM patients.

A negligible correlation of LV dysfunction and heart failure was reported with demographics (age and gender) of T2DM patients. Similar results were reported for correlation of LV dysfunction and heart failure with comorbidities and diabetes duration of enrolled T2DM patients.