



**STUDY TO EVALUATE ON COMPLIANCES WITH THE ADA GUIDELINES FOR STATIN THERAPY AMONG PATIENTS OF TYPE II DIABETES MELLITUS NON CARDIAC VARIANT IN A TERTIARY CARE TEACHING HOSPITAL, KARNATAKA, SOUTH INDIA. – A STANDARD BASED CLINICAL AUDIT**

**General Medicine**

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**ABSTRACT**

**Background:** - Based on the recent update of the 2019 American Diabetes Association guidelines for medical care in Diabetes Mellitus patients, initiation of Statin therapy is now a recommended for all patients with risk factors and patient aged more than 40yrs even without risk factors.

**Aim & Objectives:-** To improve the care being provided to patients with Diabetes mellitus within the organization

**Methods:** - It was Retrospective, analytical, standard based clinical audit of patient care. The study setting was a tertiary care, teaching hospital in Mysuru city. All the patients were screened for usage of statins and their intensity in different age group and tabulated. The data was analysed and results were interpreted and concluded.

**Results:-** Out of 32 patients there were 20 male patients and 12 Female. Majority of patient were 40 years and above. Out of 32 patients, 24 patients had risk factors. 3 out of 6 diabetic patients in the age group <40 years with risk factors and received statin therapy. 4 out of 6 diabetic patients with no risk factors aged more than 40 years received statin therapy. 15 out of 18 diabetic patients with Atherosclerotic Cardiovascular Disease risk factors with age of 40 and above received Statin therapy.

**Conclusion:** - In conclusion, this audit shows there is a gap between guidelines and clinical practice in the provision of statin therapy diabetes care. Overall, statin use is beneficial and should be recommended in diabetic patients to target their increased Cardiovascular Disease risk. The quality of care was found to be suboptimal; however, by motivating the primary care doctors via combinations of health care professional education, audit and peer review, the quality of diabetes care in study setting could be improved.

**KEYWORDS**

Diabetes Mellitus, clinical Audit, statins, Quality.

**INTRODUCTION:-**

Diabetes mellitus (DM) is one of the common chronic illnesses worldwide. In recent years, there has been a global increase in the incidence of type 2 Diabetes Mellitus. In year 2000, 171 million people suffered from diabetes globally. It is estimated that the number would double by the year 2030. The increase in incidence of DM in developing countries follows the trend of population growth, aging, urbanization and lifestyle changes.

Diabetes Mellitus is a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both.(1)

Diabetes mellitus has become one of the major public health issues worldwide.(2) It is associated with significant morbidity such as coronary heart disease, stroke and nephropathy leading to increased mortality and healthcare cost to the patient and the community. There is increasing evidence along with good glycemic control, control of cardiovascular risk factors prevent or delay complications of Diabetes Mellitus.(3) This in turn would restore quality of life.

The use of statins for primary and secondary prevention in patients with diabetes is well established and supported by robust data from randomized, controlled trials and national guidelines. It has been proved that statins are effective for primary or secondary CVD prophylaxis. Optimization of the lipid-lowering therapy among Type 2 Diabetes Mellitus patients has been considered as one of the significant approaches to decrease the overall CVD burden. Reports have highlighted the underutilization of statins in clinical practice and the suboptimal dosage adherence to guideline recommendations. (4) Apart from acting on diabetic dyslipidemia, statins were shown to exert beneficial effects on several diabetic complications as well as other cardiovascular (CVD) risk predictors such as endothelial dysfunction, inflammation, oxidative stress, chronic kidney disease (CKD), non-

alcoholic fatty liver disease (NAFLD), metabolic syndrome, obstructive sleep apnea syndrome (OSAS) and hyperuricemia.(5)

The new 2017 American Diabetes Association (ADA) Standards of Medical Care in Diabetes contains recommendations for the management of diabetes and its complications.(6) The American Diabetes Association statement has been updated based on the recent evidence regarding diabetes care and reiterates the focus on the control of traditional modifiable cardiovascular disease (CVD) risk factors through lifestyle and pharmacological interventions. These ADA evidenced-based recommendations for using pharmacological agents to treat risk factors are useful for minimizing CVD risk, taking into consideration the risk-benefit of treatments.(7)

Audit provides the opportunity for clinicians to monitor and modify their own service delivery through the collection of local and timely information. National Institute for Clinical Excellence (NICE), UK has defined audit as “a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change”.(8) Clinical audit is a strategy that allows for gauging the quality of care on current practice of a particular medical condition. Clinical audit in General medicine practice is being introduced in many countries as a quality improvement tool.

Primary care doctors have an important and challenging task in providing quality management to patients with type II Diabetes Mellitus.(9) Therefore, this standard based clinical audit was conducted to estimate the volume of diabetic patients who are receiving statins as per American Diabetes Association guidelines in our tertiary care teaching hospital, to emphasize the clinical benefits of statins in diabetic population and to sensitize the need for adherence to standard treatment guidelines in prescribing statin medications. A Standard based Audit is a cycle involving defining standards, collecting data to measure current practice against these standards and implementing necessary changes.(10)

**AIM & OBJECTIVES:**

**AIM:** - To improve the care being provided to patients with Diabetes mellitus within the organization by comparing practice against the set norms.

**OBJECTIVES:-**

- To ensure that Patients with Type 2 Diabetes mellitus were prescribed statins as per the requirement in accordance with ADA guidelines.
- To create the awareness among clinicians to Optimize lipid-lowering therapy in T2DM patients which decreases the overall Cardiovascular Disease burden as per American Diabetes Association guidelines

**MATERIALS & METHODS:-**

The audit was conducted in the following steps

**Study Type:-** It was Retrospective, analytical, descriptive and standard based clinical audit of patient care. Clearance from the ethical committee of the institution was obtained; patient anonymity was maintained by coding the data.

**Study Area:** - The study setting was a tertiary care, teaching hospital in Mysuru city.

**Inclusion Criteria:** All patients diagnosed with type II Diabetes Mellitus aged 18 years and above, who got admitted for different clinical conditions in general medicine ward between April 1st to May 15th 2019 included in this audit.

**Exclusion Criteria:** Patients with type I Diabetes Mellitus and gestational Diabetes Mellitus were excluded from this audit. Patients with Cardiovascular disease, cerebrovascular disease, Hepatocellular dysfunction were also excluded. Paediatric age group are also excluded.

**Study Tool:** - A standard structured pro forma was used to document the secondary data of the patients.

**Data Collection:** - Data was collected retrospectively from patient's clinical case records admitted during April 1<sup>st</sup> to May 15<sup>th</sup> by a team comprising of representatives from General medicine department and quality assurance department. A total of 32 patients were selected. The following data were recorded from each patient's case record:-

- Gender
- Age
- Presence or absence of atherosclerotic cardiovascular risk factors (LDL cholesterol  $\geq$  100 mg/dL, Hypertension, smoking, chronic kidney disease, Albuminuria, Family history of premature atherosclerotic CVD).
- Statin therapy received or not received.

All the patients were screened for usage of statins and their intensity in different age group and tabulated. The data was analysed and results were interpreted and concluded

**Statistical Analysis:** - This study involves a review of patient data; hence, the statistical analysis is descriptive. Categorical data are expressed as numbers and percentages. Microsoft Excel was used for statistical analysis

**RESULTS:-**

A total of 32 medical records of patients with type II Diabetes Mellitus which fulfilled the criteria were reviewed. The demographic characteristics are presented in Tables 1 and 2. The majority (62.5%) of the patients were males and rest were females and Most (75%) of the patients were in the age group of 40years and above. Presence or absence of Atherosclerotic Cardiovascular Risk factors among patients were summarized in table no.3 and approximately 75% of the patients had those Risk factors. The statin therapy prescribed for patients of diabetes care are summarised in Tables No.s 4 and 5.

**Table no.1:- Gender wise Distribution of patients**

Gender of patients	No. of patients n =32	Percentage
Males	20	62.5%
females	12	37.5%

**Table no.2:- Age wise Distribution of patients**

Age range of patients	No. of patients n =32	Percentage
Less than 40yrs	8	25%
40yrs and above	24	75%

**Table no.3:- Distribution of Patients according to the Presence or absence of Risk factors**

ASCVD Risk Factors	No. of patients (N = 32)	Percentage
Present	24	75%
Absent	8	25%

**Table no.4. Distribution of patients without risk factors who received statin therapy according to age ranges**

AGE	No. of patients	Who actually need	Who actually received
Less than 40yrs	2	0	0
40yrs and above	6	6	4

**Table no.5:- Distribution of patients with risk factors who received statin therapy according to age ranges**

AGE	No. of patients	Who actually need	Who actually received
Less than 40yrs	6	6	3
40yrs and above	18	18	15

**DISCUSSION:-**

Guidelines for Statin Therapy in Diabetes

The classification of diabetes as a CHD risk equivalent has had implications for CVD prevention strategies. Joint American Heart Association and American Diabetes Association (ADA) guidelines recommend adding a statin to lifestyle changes regardless of baseline lipid levels in patients with diabetes who are more than 40 years of age with or without risk factors. For patients less than 40 years of age who have multiple CVD risk factors, guidelines suggest consideration of a statin in addition to lifestyle therapy. For adults with diabetes who have CVD risk factors, there are uniform recommendations for targeting an LDL cholesterol of < 100 mg/dl with an optional goal of < 70 mg/dl using higher-potency statins.(11)

In this Audit, Among 6 patients of Type II diabetes Mellitus who were in the age group of 40yrs and above but did not had any cardiovascular risk factors, only 4 patients has received statin therapy and two patients did not receive the statin therapy (Table No.4).

In the present audit, prescription practice of Statin therapy was marginally suboptimal. Among 6 diabetes patients who had risk factors and were in the age group less than 40 years, only 3 patients has received statin therapy (Table No.5). The majority of the patients in this present audit i.e., 15 out of 18 patients who were in the age group of 40yrs and above and with presence of Atherosclerotic Cardiovascular Disease risk factors were received statin therapy. (Table No.5). However, majority of patients received moderate intensity statins irrespective of risk stratification. The possible reason for this under prescription of statin therapy in those patients could be due to lack of awareness of recent updated standards of American Diabetes Association guidelines.

This study has several strengths. First, we have conducted this audit to improve the quality of care rendered to diabetic patients in view of preventing complications at this medical college, hospital. To our knowledge, such domain has not been analyzed by experts of the field in this hospital. Second, the paucity of literature also warranted this study. On the other hand, there have been a few limitations as well. First, the current study catered only indoor patients. To evaluate the actual quality of services it should have included OPD services. Second, in this audit, the retrospective nature of data collection was limited by the accuracy of the data obtained from medical records, with the possibility of undocumented of statin therapy prescribing practices. Third, the findings emerging out of the current study cannot be generalized or extrapolated to all other hospitals of India.

The immense potential of clinical audit can be utilized only when open mindedness and innovativeness are encouraged and evidence based work culture is cultivated.

**CONCLUSION:-**

The importance of quality assurance and quality control is rapidly gaining popularity in practice of general medicine as the scope for clinical audit and other quality improvement tools in the vast and burgeoning field of general medicine is endless. This study emphasizes the need for adherence to standard treatment guidelines while delivering optimal healthcare to the patients of diabetes mellitus. In conclusion, this audit shows there is a gap between guidelines and

clinical practice in the provision of statin therapy in diabetes care. Overall, statin use is beneficial and should be recommended in diabetic patients to target their increased Cardiovascular Disease risk. The quality of care was found to be suboptimal; however, by motivating the primary care doctors via combinations of health care professional education, audit and peer review, the quality of diabetes care in study setting could be improved.

#### **RECOMMENDATIONS:-**

Reports have highlighted the underutilization of statins in clinical practice and the suboptimal care to guideline recommendations. Adherence to clinical guidelines that recommend statins for Type 2 Diabetes Mellitus patients as the main CVD prophylaxis treatment may help in achieving better clinical outcomes among patients with Type II Diabetes Mellitus. It is desirable to have further research in this area, so as to adopt such principles into the day-to-day clinical practice of general medicine. We can address these by incorporating the suitable remedial measures. All clinical departments should audit the quality of their service, and the results should be shared and published

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**Conflict of interest:** - None declared

**Ethical approval:** - The study was approved by the institutional Ethical committee.

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