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## RESEARCH ARTICLE

### INVESTIGATING THE IMPACT OF USING SIMVASTATIN PRESCRIPTION IN PATIENTS WITH DIABETES TYPE 2: A CROSS-SECTIONAL STUDY AT HERA GENERAL HOSPITAL MAKKAH

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#### ABSTRACT

**Introduction:** Diabetes mellitus is considered an epidemic disease in the gulf countries. Its prevalence in Saudi Arabia is becoming the highest in the world affecting around 30% of adults (1), (3). Indeed, diabetes is associated with an elevated risk of cardiovascular disease (CVD). Therefore, management of diabetic dyslipidemia, a well-recognized and modifiable risk factor, is an essential factor in the multifactorial approach to prevent CVD in individuals with type 2 diabetes (4). Several meta-analyses studies have clearly shown the benefits of statin therapy (3). **Aims:** To assess the results of the prescription of simvastatin for patients with type 2 diabetes. **Methods:** A cross-sectional study of 168 diabetic patients was conducted in Hera General Hospital. Data were retrieved from medical records from January 2018 until December 2018. Data analysis was performed using Excelsoftwares. **Results:** Most of the sample population (95%) was older than 40 years old. Nearly all patients (97%) were on statin treatment. The treatment goal for LDL-c <2.5 mmol/l was achieved in 42 (21%) patients. Diabetic men were more likely than diabetic women to be given a prescription for a statin (P<0.05). **Conclusion:** Data from 2018 elucidate that diabetic patients at HGH were associated with a statin prescription. However, only a small proportion of patients with diabetes reaches the LDL-c treatment target. These results emphasize the need for better monitoring, better utilization of available medication and for new treatment options for a better quality of life.

## INTRODUCTION

Statins, otherwise called HMG-CoA reductase inhibitors, are a class of lipid-lowering prescriptions (Miettinen, 1982). Statins can aggressively repress 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, bringing about a viable decline of low-thickness lipoprotein (LDL) cholesterol levels, and their utilization has been demonstrated to diminish major cardiovascular occasions in both essential and optional counteractive action (Cholesterol Treatment Trialists, 2010) This is huge in light of the fact that most coursing cholesterol originates from interior production as opposed to the eating routine. At the point when the liver can never again produce cholesterol, dimensions of cholesterol in the blood will fall. Cholesterol production seems to happen for the most part around evening time, (Miettinen, 1982) so statins with short half-lives are generally taken during the evening to amplify their impact. Studies have demonstrated more noteworthy LDL

and complete cholesterol decreases in the short-acting simvastatin taken around evening time as opposed to the morning (Saito *et al.*, 1991; Wallace, 2003). In diabetic patients, essential avoidance with statins is suggested or ought to be considered in about all  $\geq 40$  years old, with the force of treatment relying upon the of other cardiovascular hazard factors and end-organ harm ( Reiner, *et al.*, 2011; Perk, 2012; About diabetes, 2014). Statin treatment ought to be added to way of life treatment, paying little respect to pattern lipid levels, for diabetic patients.

- The essential objective is a LDL cholesterol <100 mg/dl (<2.6 mmol/l) (An); a lower LDL cholesterol objective of 70 mg/dl (1.8 mmol/l), utilizing a high portion of a statin, is a choice.
- Without CVD who are beyond 40 one years old and have at least one other CVD chance factor. The

essential objective is a LDL cholesterol <100 mg/dl (<2.6 mmol/l).

- Statin treatment ought to be considered notwithstanding way of life treatment if LDL cholesterol remains >100 mg/dl or in people with various CVD hazard factors. On the off chance that medicate treated patients don't achieve the above focuses on maximal endured statin treatment, a decrease in LDL cholesterol of >40% from benchmark is an elective helpful objective (Reiner, 2011; Perk *et al.*, 2012; About diabetes, 2014).

The following statistics are very clear clarifying that there is a solid relationship between cardiovascular sickness (CVD) and diabetes:

- At least 68 percent of individuals age 65 or more established with diabetes die from some type of coronary illness; and 16% die from stroke (About diabetes, 2014).
- Adults with diabetes are two to four times more likely to die from coronary illness than grown-ups without diabetes.
- The American Heart Association believes diabetes to be one of the seven noteworthy controllable hazard factors for cardiovascular sickness. Diabetes mellitus (DM) is a gathering of metabolic issue in which there are high glucose levels over a delayed period (Archived from the original on 26 August 2013. Retrieved 2/3/2019) Symptoms of high glucose incorporate regular urination, expanded thirst, and expanded appetite. Whenever left untreated, diabetes can cause numerous complications (Kitabchi, 2009). Intense complications can incorporate diabetic ketoacidosis, hyperosmolar hyperglycemic state, or even death (Wilson, 1998). Serious long-term complications incorporate cardiovascular disorders, stroke, chronic kidney illness, foot ulcers, and harm to the eyes (9). Over time, high blood glucose from diabetes can harm veins and nerves that control heart and veins. The longer you have diabetes, the higher the odds that you will have coronary illness. Individuals with diabetes will in general develop coronary illness at a more youthful age than individuals without diabetes.

An extensive collection of epidemiological information reports that diabetes is an autonomous hazard factor for CVD in both males and females (Wilson, 1998; McGill, 1998; Brezinka, 1994). Women with diabetes appear to lose the majority of their natural security against creating CVD (Wilson, 1998; Geiss, 1995). CVDs are recorded as the reason for death in ≈65% of people with diabetes (Stone *et al.*, 1989). Diabetes acts as an independent risk factor for several forms of CVD. To exacerbate the situation, when patients with diabetes develop clinical CVD, they sustain apoor prognosis for survival than do CVD patients without diabetes (Singer, 1989; Smith *et al.*, 1984; Muhlestein, 2003). Diabetes is a prime risk factor for cardiovascular illness (CVD). Vascular diseases incorporate retinopathy and nephropathy, fringe peripheral vascular disease (PVD), stroke, and coronary artery disease (CAD). Diabetes additionally influences the heart muscle, causing both systolic and diastolic heart disturbances. The etiology of this excess cardiovascular morbidity and mortality is not completely clear. Evidence suggests that although hyperglycemia, the hallmark of diabetes, contributes to myocardial damage after ischemic events, it is clearly not the

only factor, because both pre-diabetes and the presence of the metabolic syndrome, even in normoglycemic patients, increase the risk of most types of CVD (Thrainsdottir, 2005; Nielson, 2005; The DECODE Study Group, 1999; Estimation of cardiovascular risk in an individual patient without known cardiovascular disease., 2010). The Framingham criteria used to estimate 10-years risk of coronary heart disease (CHD) in individuals who are free of known CHD. Which include age range, hypertension treatment, systolic blood pressure, total cholesterol, HDL and smoking status according to gender (WHO, 2013).

**Aim:** Our main aim was to investigate the impact of simvastatins use in type-II diabetes patients.

## METHODS

A cross-sectional study was conducted in Hera General Hospital. Data were retrieved from medical records from January 2018 until December 2018. The study was conducted at Hera General Hospital – Makkah. Sample size were about 168 diabetic patients type 2. Data was collected from medical case records. Inclusion criteria included Diabetics type 2 Male and female adult patients under treatment with simvastatin. Exclusion criteria was all other types of diabetes, children, old age and other types of stat in medications. Data analysis was performed using Excel software 2018. Values were expressed as means ± SD unless otherwise indicated. General linear models were used in the analysis. t-test with a Bonferroni correction for multiple comparisons was used as a post hoc test. All the tests were two-tailed with the significance level set at  $P < 0.05$ . Ethical approval was obtained from Umm Al-Qura University IRB commity UQU- COP-EA-#143913.

## RESULTS

### Age data from the study population:

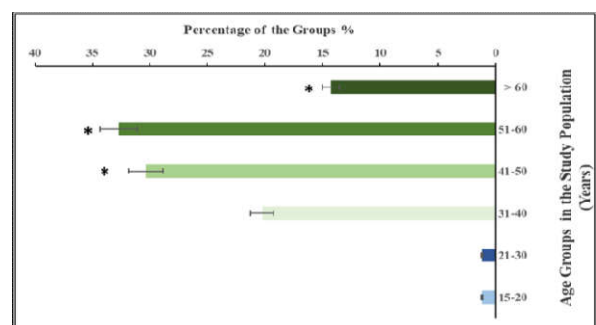


Figure 1. Chart representing the percentage of all age-groups in the study population. (n=168); t-test ( $P < 0.05$ ); \*95% > than 40 years old.

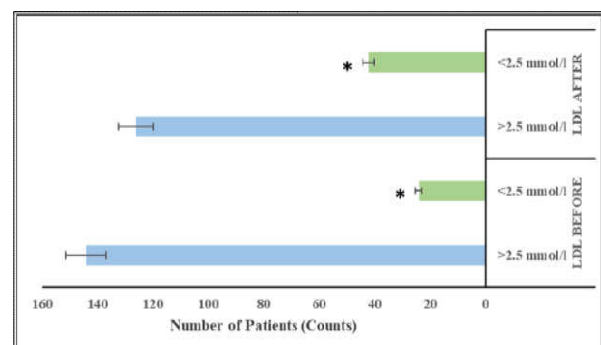


Figure 2. Chart representing the number of patients in counts for LDL levels before and after simvastatin therapy. (n=168); t-test ( $P < 0.05$ ); \*LDL <2.5 mmol/l vs. >2.5 mmol/l

- Most of the sample population (95%) was older than 40 years old (Figure1),
- And nearly all patients (97%) were on simvastatin 20mg/day treatment.
- LDL-C values before and after simvastatin treatment
- The treatment goal for LDL-c <2.5 mmol/l was achieved in only 42 (21%) of the patients (Figure2).
- Cholesterol values before and after simvastatin treatment

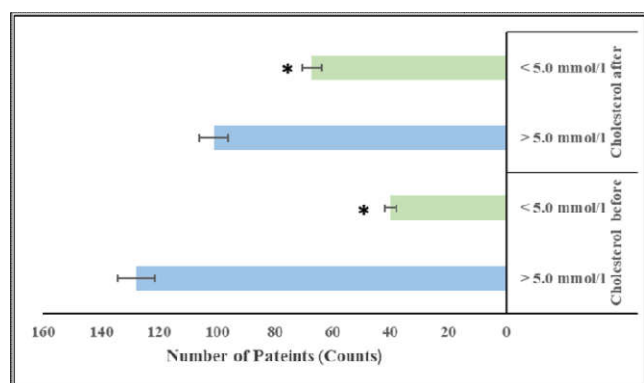


Figure 3. Chart representing the number of patients in counts for cholesterol levels before and after simvastatin therapy. (n=168); t-test ( $P < 0.05$ ); \* Cholesterol before <5.0 mmol/l vs. Cholesterol after < 5.0 mmol/l

For Cholesterol levels around 67 (45%) patients reached the desirable level of < 5.0 mmol/l (Figure.3).

- Male to female ratio using simvastatin
- Diabetic men were more likely than diabetic women to be given a prescription for a statin ( $P < 0.05$ ).

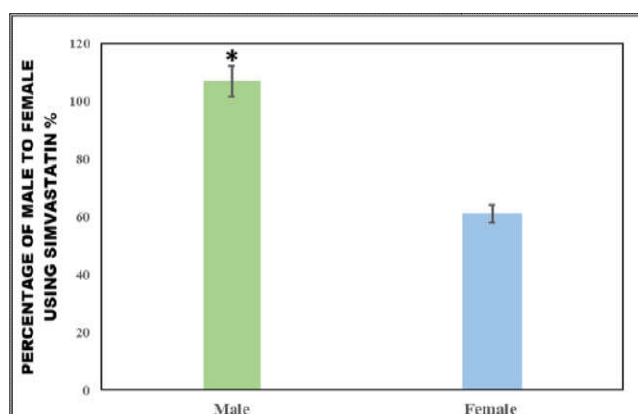


Figure 4. Chart representing percentage of Male to female patients using simvastatin 20 mg/day. (n=168); t-test ( $P < 0.05$ ); \*Male vs. Female

## DISCUSSION

In spite of the importance of the impact of statin therapy for achieving therapeutic goals, there are limited reports about the impact of statin therapy and its associated factors. Thus, our investigation was the first of its type to be done in Makkah, Saudi Arabia. Our main aim in this study was to investigate the impact of simvastatin use in type-II diabetes patients at Haraa General Hospital (HGH) in Makkah Al-Mukarramah. Most of the sample population (95%) was older than 40 years old, And nearly all patients (97%) were on simvastatin 20mg/day

treatment as shown in (Figure 1). Moreover, diabetic men were more likely than diabetic women to be given a prescription for simvastatin ( $P < 0.05$ , Figure 4). Our results from this study revealed that according to the obtained data from medical case records, more than three fourth of patients with diabetes were not adherent to their statin therapy. This was very clear in their lipid profiles. As shown in (Figure 2) the treatment goal for LDL-c <2.5 mmol/l was achieved in only 42 (21%) of the patients and the majority of the patient did not achieve this result. Moreover, their Cholesterol levels were only achieved to the desirable levels of < 5.0 mmol/l in only 67 (45%) patients (Figure 3). Unfortunately, one of the constraints that we were not able to know the HDL-c and triglycerides values as they were missing from the records. Inadequate adherence can be laid at many doors. Poly-pharmacy is common among patients with type 2 diabetes, which implies to the prescription of oral hypoglycemic, antihypertensive and lipid lowering medications for an individual. It is also a growing barrier to adherence and attainment of therapeutic goal (Kitabchi, 2009). In addition, limited time spent during clinic visits contributes to inadequate attention to multiple aspects of this care (Wilson, 1998). It is important to expand attention to the most vital reasons for non-adherence (Wilson, 1998). Along these lines the advancement of intercessions, for example, asking polls might be valuable to improve adherence and to bring down cholesterol proportion by clarifying the significance of treatment and way of life alterations. There was one previous study that additionally exhibited an improvement of wellbeing by decreased cholesterol levels which diminishes heart diseases and related results in patients with type 2 diabetes by including clinical drug specialist in the multidisciplinary group. Therefore, more examinations will be expected to assess the impacts of various medications (Wilson, 1998).

Endorsing satisfactory measure of statins between doctors visits is another answer for improve adherence and personal satisfaction. This makes patients certain about having enough accessible prescriptions to use before doctors visit. In addition, tolerant instruction and better communications of patient and human health services group will have the huge impact on improving personal satisfaction. Another factor could impact on personal satisfaction was financial position including patients salary. Despite the fact that due to our nearby culture, we could not assess this factor yet but a recent cohort study demonstrated a diminished personal satisfaction with diminishing salary in patients with built up cardiovascular sickness particularly among men matured 40-64 years (McGill, 1998). There is discussion that expanded medicine adherence is related with decreased social insurance costs especially during the years quickly following the beginning of diabetes. Therefore, drug adherence can improve human quality of life results (Brezinka, 1994).

In this manner, instruction in regards to statin treatment and way of life changes, adherence is important to improve personal satisfaction especially with low financial levels. In this study we were most able to calculate or measure the risk score us in the estimated Framingham score which is utilized to evaluate multiyear cardiovascular hazard. Results of a similar study did this and they found that Framingham is useful for both the individual patient and for the clinician in helping decide whether lifestyle modification and preventive medical treatment, and for patient education, by identifying men and women at increased risk for future cardiovascular events (Brezinka, 1994).

## Conclusion

Data from 2018 elucidate that type 2 diabetic patients treatments at HGH were associated with simvastatin prescriptions. However, only a small proportion of patients with diabetes reaches the LDL-c treatment target. These results emphasize the need for better monitoring, better utilization of available medication and for new treatment options for a better quality of life.

## Recommendations

- Check the adherence and compliance of statin therapy in each diabetic patients.
- Educational interventions to increase the dose or add another statin therapy to reach the desired LDL-C goal.
- Use the Framingham Risk Score to estimate the 10-year cardiovascular risk of an individual.
- To increase the awareness among patients about statin therapy and lifestyle modifications.

## Limitations

### Limitations of this study include

- Laboratory results as HDL-c and triglycerides were missing.
- Some errors were detected in entries at the pharmacy, especially quantities of issued medicines and some double entries.

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