

# Statin Underprescribing for Primary Prevention of Cardiovascular Disease among Elderly Diabetic Patients in Saudi Arabia

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## Abstract

**Objectives:** This study aims to assess the rate of statin underprescribing among at-risk elderly diabetic patients in Saudi Arabia, as a primary prevention for cardiovascular disease. **Materials and Methods:** A retrospective cross-sectional data of elderly diabetic patients were obtained from the electronic database of the Academic Tertiary Center in Jeddah, Saudi Arabia. Data were retrieved from January to December 2020. Diabetic patients aged 65–79 with an atherosclerotic cardiovascular disease score of 7.5% and above were included in the study. Descriptive statistics, Chi-square test, and multivariate logistic regression were used to analyze data.  $P < 0.05$  was considered statistically significant. **Results:** A total of 167 patient records were included in this study. The cohort included patients with intermediate risk ( $n = 121$ , 62.5%) and high risk ( $n = 46$ , 27.5%) of developing atherosclerotic cardiovascular disease. The rate of statin underprescribing among the study group was 52.7% ( $n = 88$ ). The predictors of statin use patterns among elderly patients with diabetes and cardiovascular risk were obesity ( $P = 0.045$ ) and smoking ( $P = 0.015$ ). **Conclusion:** Over half of the study group, despite having risk factors, were not taking statin therapy. Clinicians should consider initiating statin therapy for all patients at risk of atherosclerotic cardiovascular disease while optimizing other medications to control blood pressure and glucose.

**Key words:** Cardiovascular events, diabetes mellitus, geriatrics, underprescribing rate, statin therapy

## INTRODUCTION

Diabetes mellitus (DM) remains an important public health concern, with its associated high morbidity, mortality, and economic burden.<sup>[1]</sup> The burden of DM is higher among elderly people aged  $\geq 65$ .<sup>[2]</sup> Appropriate and timely management of DM and its associated cardiovascular risks is particularly crucial for the elderly population owing to likely comorbidities and reduced metabolic organ functions. To this end, the STOP-START criteria were developed to guide clinicians in providing care for this special population.<sup>[2,3]</sup> The STOP-START criteria are evidence-based guidelines used to optimize medication use in elderly patients by identifying potentially inappropriate medications (STOP) and underprescribed therapies (START). These criteria generally aim to minimize inappropriate prescribing (STOP) and ensure that necessary medications are not omitted (START).<sup>[4]</sup> For statin therapy, the STOP criteria suggest discontinuing statins in elderly patients with limited life expectancy, severe frailty, or those in whom the risks outweigh the benefits, such

as those experiencing significant side effects. Conversely, the START criteria recommend initiating statin therapy in geriatric populations with high cardiovascular risk, particularly those with a history of cardiovascular disease (CVD) or diabetes, provided they have a reasonable life expectancy and no contraindications. These STOP-START criteria for statin therapy balance the benefits of cardiovascular protection with the risks associated with polypharmacy and age-related changes in drug metabolism.<sup>[4]</sup>

In Saudi Arabia, the prevalence of DM in men and women aged 60–69 years was estimated to be 49.8% and 43.6%, respectively. However, the prevalence is slightly lower at age  $\geq 70$  years with an estimated 45.8% in men and 40.3% in women.<sup>[5]</sup> The major risk factors associated with DM in this

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population were age, hypertension, dyslipidemia, obesity, and previous history of gestational diabetes.<sup>[5]</sup> Elderly people with DM are prone to developing atherosclerotic cardiovascular disease (ASCVD).<sup>[6]</sup> Given the risk of CVD in the geriatric population with DM, statin therapy is generally recommended as a care component for these patients.<sup>[7]</sup> The 2019 American College of Cardiology/American Heart Association guidelines and 2019 European Society of Cardiology and the European Atherosclerosis Society guidelines recommended statin therapy to prevent cardiovascular events in elderly patients at risk with or without a history of CVD. However, clinical judgment and other patient-specific factors are to be considered when deciding whether to initiate statin therapy for the purpose of primary prevention for CVD in this category of patients.<sup>[8,9]</sup> The National Institute for Health and Care Excellence also recommended adding statin therapy for geriatric patients as a primary preventive measure against cardiovascular events.<sup>[10]</sup> These guidelines suggest that initiating starting therapy in at-risk geriatric populations when appropriate reduces their chances of developing cardiovascular events.

Cardiovascular events are more likely to occur in persons with diabetes because of the substantial increase rate of atherosclerosis. Elderly patients with diabetes benefit from statin use for primary and secondary CVD prevention, regardless of their baseline cholesterol levels, as multiple studies have shown.<sup>[11,12]</sup> Most diabetic patients between the ages of 40 and 75 with ASCVD risk scores of  $\geq 7.5\%$  are strongly advised by clinical recommendations to take statin medication, especially if they smoke or have other cardiovascular risk factors including hypertension.<sup>[12,13]</sup> Although well tolerated, statin medication necessitates routine monitoring for any adverse effects, such as an increase in liver enzymes and myopathy. Overall, lowering the morbidity and mortality linked to CVDs depends critically on the use of statins in the treatment of diabetes.<sup>[12]</sup> However, the rate of statin underprescribing among an elderly population with DM and its associated factors have not been widely studied. Hence, this study aimed to retrospectively assess the rate of statin underprescribing as a primary prevention for CVD among geriatric diabetic patients in an Academic Tertiary Center, in Saudi Arabia.

## MATERIALS AND METHODS

This was a retrospective descriptive study of statin use among elderly diabetic patients at risk of cardiovascular disorder at the Academic Tertiary Center, Jeddah, Saudi Arabia. The data for the study were retrieved from the electronic database of the academic tertiary center, in Jeddah, Saudi Arabia. The data obtained covered the period between January 2020 and December 2020.

This study included patients between the ages of 65–79 years with type 2 DM and a cardiovascular risk score of  $\geq 7.5$ ,

which was assessed using the ASCVD risk estimator calculator.<sup>[14]</sup> The tool estimates the 10-year risk of ASCVD among patients in high-risk groups. This risk estimator tool helps clinicians with the type of lifestyle modification and medications to prevent the risk of cardiovascular events. The ASCVD risk tool categorizes patients as low-risk ( $<5\%$ ), borderline risk (5–7.4%), intermediate risk (7.5–19.9%), and high risk ( $\geq 20\%$ ) which guides the use of statin therapy.<sup>[15]</sup>

Relevant patients' data were gathered during the retrospective review of the electronic database. The data retrieved were the patient's demographic and clinical characteristics and ASCVD risk score. The demographic characteristics included patients' nationality, age, and sex, while the clinical characteristics consisted of blood pressure measurements, presence of coexisting hypertension, heart failure or atrial fibrillation, cholesterol levels, body mass index, blood glucose level, patients on statins, and contraindication for statin use. The relevant data were extracted using a pro forma designed in Microsoft Excel.

The data were coded and entered into IBM Statistical Products and Services Solution version 23 for Windows software. The data were analyzed through descriptive statistics (frequency and percentage) and the Chi-square test. Descriptive statistics were utilized to characterize patients' clinical features. The Chi-square test and Fisher's exact test were employed to identify the factors associated with the underprescribing of statin. The predictors of statin underprescribing among elderly diabetic patients were determined using the multivariate logistic regression.  $P < 0.05$  was considered to be statistically significant.

The study was conducted in compliance with the Helsinki Declaration of 2013 regarding medical research involving human subjects. The patients' data collected were anonymized and assigned study codes. The data were encrypted to ensure utmost confidentiality among the research team and were not shared with any third party. Data storage and handling complied with relevant national laws on data protection.

## RESULTS

### Patient's demographic and clinical characteristics

Table 1 shows the demographic and clinical characteristics of the patients. A total of 167 records of elderly patients with diabetes and ASCVD score of 7.5% and above were included in this study. More than half of the patients were male (87 (52.1%) and non-Saudi nationals ( $n = 89$ , 53.3%). Most of the patients had hypertension ( $n = 138$ , 82.6%). Fewer than 16% of the patients had high cholesterol levels, while about a quarter ( $n = 43$ , 25.7%) were obese. Approximately 11% of the patients were smokers. About a quarter of the patients ( $n = 46$ , 27.5%) had a high risk of developing ASCVD. The rate of statin underprescribing among the study group was 52.7% ( $n = 88/167$ ).

**Table 1: Patients' demographic and clinical characteristics (n=167)**

Variable	Frequency	Percentage
Saudi nationality	78	46.7
Age (years)	72.1±4.1*	
Sex		
Male	87	52.1
Female	80	47.9
Heart failure	8	4.8
Atrial fibrillation	12	7.2
Hypertension	138	82.6
High cholesterol	26	15.6
Obesity	43	25.7
Smoking	19	11.4
Poor glucose control	79	47.3
Contraindication for statin use	9	5.4
Risk of ASCVD		
Intermediate risk	121	72.5
High risk	46	27.5

\*Mean±standard deviation. ASCVD: Atherosclerotic cardiovascular disease

### Predictors of rate of statin underprescribing among elderly patients

Table 2 shows the predictors of statin underprescribing rate among the study participants. The findings of the initial test of association (Chi-square test) demonstrated that hypertension ( $P = 0.044$ ), obesity ( $P = 0.025$ ), smoking ( $P = 0.006$ ), and risk of ASCVD ( $P = 0.046$ ) were significantly associated with the rate of statin underprescribing among the study group. Further, the results of the multivariate logistic regression revealed that obesity ( $P = 0.045$ ) and smoking ( $P = 0.015$ ) significantly predicted the rate of statin underprescribing among elderly patients with diabetes.

## DISCUSSION

In the current study, there was a high rate of statin underprescribing as more than half of the elderly patients with diabetes were not taking statin therapy for the primary prevention of ASCVD. This finding is surprising considering the risk of cardiovascular problems associated with this population. In general, statins are recommended for elderly patients with known cardiovascular risk factors or end-organ damage.<sup>[16,17]</sup> Randomized controlled trials have proven that statin therapy is effective in lowering ASCVD risk in adult diabetic patients.<sup>[12,18]</sup> The rate of statin underprescribing observed in this study was higher compared to those reported in previous studies.<sup>[19,20]</sup> Furthermore, a multicenter prospective cohort study in Italy involving patients aged  $\geq 65$  years found that the potential prescription underprescribing of statin

**Table 2: Predictors of the rate of statin underprescribing among elderly patients with diabetes**

Variable	Statin underprescribing		P-value <sup>a</sup>	P-value <sup>b</sup>
	No	Yes		
Nationality				
Saudi	33 (41.8)	45 (51.1)	0.226	
Sex				
Male	39 (49.4)	48 (54.5)	0.504	
Female	40 (50.6)	40 (45.5)		
Heart failure <sup>c</sup>	2 (2.5)	6 (6.8)	0.195	
Atrial fibrillation <sup>c</sup>	7 (8.9)	5 (5.7)	0.427	
Hypertension	70 (88.6)	68 (77.3)	0.044*	0.332
High cholesterol	12 (15.2)	14 (15.9)	0.898	
Obesity	14 (17.7)	29 (33.0)	0.025*	0.045*
Smoking	15 (19.0)	4 (4.5)	0.006*	0.015*
Poor glucose control <sup>a</sup>	40 (50.6)	39 (44.3)	0.414	
Risk of ASCVD				
Intermediate	63 (79.7)	58 (65.9)	0.046*	0.058
High	16 (20.3)	30 (34.1)		

<sup>a</sup>Chi-square test, <sup>b</sup>Multivariate logistic regression, <sup>c</sup>Fisher's exact test. \*Significant at  $P < 0.05$ . ASCVD: Atherosclerotic cardiovascular disease

among the study group was 6.7%.<sup>[20]</sup> Furthermore, a cross-sectional study in Ethiopia among elderly patients at risk of CVD reported that statin therapy was omitted for 3.16% of the participants.<sup>[19]</sup> The high rate of underprescribing of statin therapy in this present study group could lead to a missed opportunity to prevent serious cardiovascular events. Statins are widely recognized for their role in reducing the risk of cardiovascular events, such as heart attacks and strokes, especially in individuals at high risk, including the elderly. This underprescribing could lead to an increase in preventable cardiovascular events as recommended in the START-STOP criteria, thus potentially impacting morbidity and mortality in this population.<sup>[4]</sup> Studies have shown that statins used for primary prevention reduce both the incidence of cardiovascular events and mortality in elderly patients, similar to their effects in younger populations. Therefore, the high underprescribing rate of statin therapy in this study indicates a significant gap in care as it was only contraindicated in about 5.4% of the patients.

It is commonly known that smoking and obesity increase the risk of cardiovascular disorders.<sup>[21-23]</sup> In this study, obesity and smoking were the predictors of statin using patterns among elderly patients with diabetes and cardiovascular risk. This implies that medical professionals caring for elderly diabetic patients who smoke are more likely to prescribe statins for such patients. Given the increased risk, physicians probably

prioritize prescribing statins in smokers, which effectively lower cholesterol and lower the risk of CVD. On the other hand, physicians are less likely to prescribe it among obese patients. To optimize health outcomes in elderly diabetic patients, this research emphasizes the importance of focused interventions and tailored treatment regimens that consider each patient's unique risk factors.

## Implications for practice

This study's findings emphasize how urgently healthcare professionals must ensure that older diabetes patients receive statin medication for primary prevention of CVD as recommended in current guidelines for clinical practice, except in patients with known contraindications. The main goals should be to prescribe and monitor adherence to statin therapy, provide thorough patient education regarding the advantages of statins in lowering cardiovascular risk, and actively monitor and manage patients who have co-occurring problems such as obesity. Routine evaluations for statin eligibility should be implemented during clinic appointments as a way of closing the observed treatment gap and enhancing cardiovascular outcomes for this susceptible patient population.

## Study limitations

This study provided valuable insight regarding the use of statin therapy for ameliorating the risk of ASCVD in elderly patients with diabetes. However, the study had a few limitations that should be considered while interpreting and applying its findings beyond the study group. First, the study involved the retrospective review of patients' data from a single health facility with small sample size. Hence, there will be limited generalization of the study findings to elderly patients with diabetes to other parts of the country if there are significant variations in clinical practice, patient demographic characteristics, and burden of diabetes. Secondly, owing to the retrospective nature of the study, the factors identified to predict the rate of statin underprescribing among elderly patients with diabetes in this study do not necessarily establish a cause-effect relationship.

## CONCLUSION

The study findings suggest that statin therapy was omitted for more than half of the geriatric patients with DM. These findings underscore the need for targeted interventions ensuring that statin therapy is initiated for all eligible elderly patients with DM as a way of primary prevention of CVD in this vulnerable population.

## ETHICAL CONSENT

The study was granted an Institutional Review Board Approval from King Abdulaziz University (659-18)

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## AUTHORS' CONTRIBUTIONS

The author (S. Alshehri) confirms the sole responsibility for the conception of the study, presenting the results and manuscript preparation.

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