AMERICAN JOURNAL OF BIOMEDICINE AND PHARMACY
https://biojournals.us/index.php/AJBP
ISSN: 2997-7177

Article

Atorvastatin-Associated Myopathy: A Clinical Study in Thi-Qar Province, Iraq

Alyaa abdalrazaq abass[1]

Citation: Abass, A. A., Atorvastatin-Associated Myopathy: A Clinical Study in Thi-Qar Province, Iraq. American Journal of Biomedicine and Pharmacy 2026, 3(9), 52-58.

Received: 10th Jan 2026
Revised: 17th Feb 2026
Accepted: 20th Mar 2026
Published: 3rd Sept 2026

1. Assist. Lecturer, pharmacognosy department, college of pharmacy, Thi-Qar university, Iraq
Correspondance: alyaaabdalrazzq@utq.edu.iq

Abstract:; Statins are lipid-lowering agents broadly prescribed to reduce cardiovascular events; atorvastatin is one of the most used drugs due to its high efficacy. Patients who take statins had muscle related outcomes, an increased risk of cardiovascular events are the most significant causes of statin discontinuation.

This study aims to provide a comprehensive overview of the dual impact of statins, particularly atorvastatin, in the context of cardiovascular therapy and risk of muscle related side effects within Nasiriyah city.

The study is a cross-sectional study was managed at al-Nasiriyah teaching hospital /Nasiriyah Heart Hospital / Specialized Center for Diabetes and Endocrinology in Thi-Qar.

The results indicate that higher statin doses are significantly associated with increased BMI, elevated creatinine, with certain risk factors (older age, gender, smokes, and vitamin D deficiency) that greater incidence of myopathy. The risk of developing myopathy increases with higher doses of the drug and in individuals with certain risk factors, Concomitant use of other medications that affect statin metabolism.

Keywords: statin, atorvastatin, myopathy, Coronary artery disease, Iraq.

Introduction

The most common cause of morbidity and mortality in developed countries is coronary artery disease (CAD), elevation of low-density lipoprotein cholesterol concentration (LDL-C), is one of the most important risk factors for CAD and effective reduction of its levels was shown to diminish morbidity and mortality that associated with CAD and the progress of atherosclerosis[1].

Statins are competitive inhibitors of the 3-hydroxy-3-methylglutaryl coenzyme A (HMG CoA) reductase, which is an endoplasmic reticulum (ER) enzyme, which plays a crucial role the in synthesis of endogenous cholesterol.[2] statins primarily target the liver because hepatic cholesterol synthesis , the liver serves as the primary therapeutic target organ of statins , so the cholesterol intracellular levels in the hepatocytes decreases LDL-C receptors on their surface are upregulated and consequently LDL-C hepatic uptake and catabolism rises.

Statins are the main treatment for hypercholesterolemia and the cornerstone of atherosclerotic cardiovascular disease prevention. Many patients taking statins report muscle related signs, an increased risk of cardiovascular events are the most significant causes of statin discontinuation, so it is critical to identify patients who are statin intolerant to avoid unwarranted discontinuation of statins beneficial treatment.[3].

Different statins work in slightly different ways in your body and there are 7 types available in the U.S., if levels of LDL cholesterol are very high or have other risk factor for cardiovascular diseases, more powerful statins will typically be prescribed, there are classified according to strength from strongest to mildest: Rosuvastatin, atorvastatin, pitavastatin, simvastatin, lovastatin pravastatin, fluvastatin.[4].

Atorvastatin is the most known example of statins, is a safe and effective 3-hydroxy-3-methyl-glutaryl-CoA (HMG-COA) reductase inhibitor, it is the most type of statin that decreases low density lipoprotein (LDL), and total cholesterol levels .Also It was the first statin indicated to lower triglycerides(TG) in patients with isolated hypertriglyceridemia, it has a good safety profile in common with other statins ,it has many additional effects as non-lipid lowering effects including improving the endothelial function, diminishing platelet aggregation and antiproliferative actions on smooth muscle, furthermore it has anti-inflammatory effects and plasma glucose levels reduction[5].

The common side effects of statin are including Headache, dizziness, fatigue, low blood platelet count and nausea. However, the most imperative adverse effects are liver and muscle toxicity [6] the most powerful statins can cause diverse side effects, most of them tend to wear off after weeks or months of statin use.[7].

Myopathy is a major side effect of statins that leads to statin intolerance and discontinuation, the main objective was to estimate the incidence of myopathy in patients receiving statins, in addition we identified some risk factors associated with statin induced myopathy.[8].

Myopathy is separated into three different types based on toxicity: myalgia, myositis and rhabdomyolysis, firstly myalgia which states as generalized muscles pain, there may be a small rise in the creatine kinase(ck) enzyme, which is related to muscle damage.[9].

Myositis can be described as muscle pain tenderness or weakness and a higher level of creatine kinase in bloodstream. another type of extreme life-threatening myopathy is rhabdomyolysis, it's caused significant creatine kinase (ck) elevations up to 10 times greater than normal values and muscle breakdown, in some cases it can be lethal due to acute renal failure(ARF) but rhabdomyolysis still rare in occurrence, less than 1 person per 100,000 per year in patients who took statins.[10].

The study purpose is to evaluate the relationship between atorvastatin therapy and the occurrence of myopathy in 'Nasiriyah-Thi-Qar' patients, with an emphasis on determining its occurrence, identifying associated risk factors, and exploring the underlying factors contributing to atorvastatin-induced muscle-related adverse effects, while also evaluating the influence of concomitant medications and patient medical history on these outcomes.

Methodology

Between October 2024 and June 2025 across sectional observational study was carried out, the study was conducted at '[al-Nasiriya teaching hospital / Nasiriyah heart hospital / specialized center

for Diabetes and Endocrinology/Thi-Qar governorate /Iraq]. Ethical and scientific committee of the faculty of pharmacy/Thi-Qar university in addition to the scientific committee of research of a Thi-Qar health directorate approved this study.'

Participants were evaluated at baseline on the day of enrollment using a semi-structured questionnaire, the inclusion criteria of the study were patients >18 years of either gender, patients or relatives of patients who can be able to communicate and agreeable to participate in this study, patients who take statin drug (atorvastatin). also, patients with chronic kidney disease, diabetes mellitus, hypertension, renal disease, and hepatic diseases. Exclusion criteria were

Patients who were <18 years or children, HIV, human immunodeficiency virus (HIV). excluded Patients who rejected to participate, or cognitive (physical or mental state) deficits patients and breastfeeding or pregnant females.

One ninety (91) patients were recruited in the present study, they all approved with data collection used. The data collected from patients from their file in hospital and the laboratory analysis.

In this study the statistical analysis used were created using Microsoft Excel 2016 version and SPSS 2023 version, the p value of (>0.05) is reflected as statistically significant.

Estimation of BMI which is the most used indicator of obesity in population studies was calculated as: Weight (Kg) / height2(m)2 [11].

Results

Nine one (91) patients were included in this study, about (21) patients from both genders aged between (61-70 years), half of them (46) were male, (45) were female, other sociodemographic Characteristic considering patients like BMI, smoking is involved in table 1.

1-Distribution of study sample according to sociodemographic characteristic (n= 91), regarding age distribution, the majority of male participants were aged between 51-60 years , whereas the largest group of females was within the 61-70 years category, the mean age was higher in males (63.96 ± 16.26 years) compared to females (56.67 + 18.63 years), and the difference approached statistical significance (p = 0.050), indicating a potential age-related variation between genders in this study , all information's shown in table 1 .

The distribution of body mass index (BMI) that was shown in table (1) among patients, categorized into four groups: underweight (≤18.4), normal weight (18.5–24.9), and overweight (25.0–39.9) and obese patients. These data indicate that a significant majority of individuals fall within the overweight category. Also, smoking based on table (1) provided, we can see the distribution of smoking status among the participants where 27.47% (25 individuals) are smokers and 72.53% (66 individuals) are non- smokers, there is significant relationship.

Table 1: Distribution of study sample according to sociodemographic characteristic (n= 91)

Variable	**Categories**	Female	**Male**	**F**	**%**	**P value**
Age (years)	20-30 years	7	1	8	8.8 %	
	31-40 years	3	1	4	4.4%	
	41-50 years	6	8	14	15.4%	
	51-60 years	7	12	19	20.9%	
	61-70 years	13	8	21	23.1%	
	71-80 years	7	7	14	15.4%	
	81-90 years	1	6	7	7.7%	
	>90 years	1	3	4	4.4%	
	Mean + SD	56.67±18.63	63.96 ±16.26			p = 0.050
Gender		49.45%	50.55%	91		
Body mass index (BMI)(kg/m^2)	Underweight (≤ 18.4)	2	2	4	4.4%	
	Normal (18.5 - 24.9)	10	16	26	28.6%	
	Overweigh (25.0 - 39.9)	33	28	61	67.0%	0.410
	Obese (≥ 40.0)	0	0	0	0%	

	Mean +SD	25.98 ±4.675	27.27±4.6881			0.191
Smoking	Yes	3	22	25	27.5%	0.000
	No	42	24	66	72.5%	
Alcohol	Yes	0	2	2	2.2%	0.157
	No	45	44	89	97.8%	
Note: n= number of samples, F= frequency, %=percentage, p value < or = 0.05 significant.						

2-The data presented in table 2 provides insights into the distribution of statin usage, discontinuation, and associated symptoms among the study participants (n=91). The most prescribed dose of Atorvastatin was 40 mg, used by 49.5% of the sample, followed by 20 mg (34.1%). Only a small percentage of patients were on 10 mg (4.4%) or 80 mg (12.1%), these results indicating preference for moderate dosing in clinical practice. A significant majority of participants (93.4%) reported taking their statin at night. Moreover, 90.1% of participants used statins consistently without interruption, which reflects good adherence.

Table2: Distribution of study sample according to atorvastatin drug uses and discontinuation (n= 91)

Variable	Categories	F	%	P value
Statin dosage (Atorvastatin)	10 mg/tab	4	4.4%	0.483
	20 mg /tab	31	34.1%	
	40 mg/tab	45	49.5%	
	80 mg/tab	11	12.1%	
Time use	Morning	6	6.6%	0.097
	Night	85	93.4%	
Time to discontinuation (TTD)	Constant	82	90.1%	0.160
	1 week	1	1.1%	
	1 month	2	2.2%	
	3 months	5	5.5%	
	4 months	1	1.1%	
The symptoms of myopathy	No pain	15	16.5%	0.095
	Mild pain	44	48.4%	
	Severe pain	32	35.2%	
Note: n= number of samples, F= frequency, %=percentage, p value < or = 0.05 significant.				

3- In table 3, a significant positive correlation was observed between statin dosage and BMI($r = 0.301$, $p = 0.004$), proposing that individuals with higher BMI values were more likely to receive higher doses of statins. The strongest correlation was detected between statin dosage and myopathy ($r= 0.645$, $p < 0.001$), representing a significant and strong relationship. This suggests that increased statin dosage is strongly associated with a higher risk of developing myopathy, which is a known adverse effect of statin therapy. elevated creatinine, and greater incidence of myopathy. These findings highlight the need for individualized statin therapy, balancing therapeutic benefits with potential side effects, particularly in patients with higher BMI or existing renal concerns.

Table 3: Correlations of statin dose with other variables of study sample (n= 91)

	Correlation coefficient	Statin dosage	BMI	TTD	Creatinine

BMI	Spearman's rho	0.301			
	P value	0.004			
TTD	Spearman's rho	- 0.186	- 0.039		
	P value	.0780	.7140		
Creatinine	Spearman's rho	0.474	0.159	- 0.253	
	P value	.0000	.1310	.0160	
Myopathy	Spearman's rho	0.645	0.174	- 0.195	0.672
	P value	.0000	.1000	.0640	.0000
Note: **. Correlation is significant at the 0.01 level (2-tailed): *. Correlation is significant at the 0.05 level (2-tailed).					

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Discussion:

Statins are widely prescribed for prevention of cardiovascular diseases and the hypercholesterolemia management. However, one of the most recognized adverse effects of statin therapy is statin-associated myopathy which includes a variety of muscle related symptoms ranging from mild myalgia to severe rhabdomyolysis Myopathy occurs in approximately 5-10% of patients on statins depending on the population and method of detection.[12].

1- Regarding age distribution, in table 1, the majority of male participants were aged between 51-60 years , whereas the largest group of females was within the 61-70 years category, the mean age was higher in males (63.96 + 16.26 years) compared to females (56.67 +18.63 years), and the difference approached statistical significance (p= 0.050), indicating a potential age-related variation between genders in the study distribution, age related variation between genders plays a significant role in the risk of developing myopathy from statins.

Older individuals, particularly those above the age of 65, are at higher risk due to age related physiological changes, decreased muscle mass, and which can increase the chances of drug interactions. Additionally age-related decline in liver and kidney function can affect the metabolism and clearance of statins further increasing the risk. The results of this study was consistent with studies of.[13],[14].

There is correlation between gender difference and the effects of atorvastatin which those females (49.45%) may be more prone to statin induced myopathy compared to males (50.55%), this could be due to differences in muscle mass, drug metabolism, and hormonal influences. Women generally have lower muscle mass, which may increase their susceptibility to muscle-related side effects, women tend to have higher plasma concentrations of atorvastatin due to difference in body fat distribution and liver enzyme activity, atorvastatin, may have a greater risk of muscle- related side effects in women due to slower clearance, this balance allows for a more accurate comparison of how statins affect both genders differently given the potential for increased statin related myopathy in females, clinicians should consider gender specific factors when prescribing statins, these results of study is consistent with studies.[15],[16].

The distribution of body mass index (BMI) that was shown in table (1) among patients, the data indicates that a significant majority of individuals fall within the overweight category. Statins are commonly prescribed to manage cholesterol levels, particularly in individuals with cardiovascular risk factors such as obesity. Given that 67% of the population are overweight, these groups are more likely to be prescribed statins, due to the link between obesity and cardiovascular risk. As a result, the risk of myopathy may also be higher in this group, either due to higher statin exposure or the presence of comorbidities like diabetes, which also contribute to muscle-related side effects.[17].

Smoking based on table (1) provided, we can see the distribution of smoking status among the participants where 27.47% (25 individuals) are smokers and 72.53% (66 individuals) are non- smokers. The data shows a significant difference in the proportion of smokers and non-smokers within the study population; this is an important observation when analyzing the risk of statin induced myopathy. Smoking may exacerbate the risk of myopathy through several mechanisms. It contributes to oxidative stress and inflammation; this result is consistent with studies [18],[19],[20].

The frequency of alcohol use among individuals likely within a population being treated with statins and possibly experiencing myopathy. It shows that only 2.2 % (2 individuals) reported alcohol

use while 97.8% (89 individuals) did not, this distribution indicates that alcohol use is very uncommon in this sample group , since alcohol is known to potentially increase the risk of muscle related side effects such as myopathy when combined with statin therapy , Alcohol may exacerbate this risk but in this case the impact of alcohol appears minimal due to its very limited use among the participants this results were consistent with studies[21],[22],[23],[24].

2-Dose-dependent effects on statin therapy shown in table (2), we notice that the (40) mg dose is the most frequently prescribed, followed by 20 mg, and fewer patients are on the highest dose of 80 mg. This important when considering the dose-dependent relationship between statins and myopathy, therefore, patients on 40 mg are more likely to experience myopathy compared to those on lower doses, this results consistent with study of Abd T, Jacobson T [25].

The distribution of statin usage time with a significant preference for nighttime administration (93.41%) compared to morning use (6.59%), this difference is relevant when considering the potential impact of statin timing on both efficacy and side effects including the risk of myopathy, the timing of statin administration is commonly taken at night to get their maximum effect when due to the body's natural cholesterol synthesis peaking during sleep. Many guidelines recommend taking statins in the evening particularly those with short half-lives, these results were consistent with studies [26],[27],[28].

A significant majority of patients (90.11%) continue in taking statins consistently without discontinuation, a small percentage (ranging from 1.1% to 5.49%) discontinue treatment at various intervals such as one week, one month, three months, or four months , this pattern suggests that while statin associated myopathy may lead to treatment discontinuation it affects only a small subset of patients , the higher discontinuation rate at three months (5.49%) might indicate a delayed onset of muscle-related symptoms in some individuals. However, the fact that most patients continue therapy suggests that either the symptoms are tolerable or that alternative strategies help mitigate adverse effects early discontinuation might be linked to acute intolerance or patient perception of side effects continuous use suggests that most patients do not experience severe adverse effects or receive proper management strategies, this result of study is consistent with studies.[29],[30].

3- The strongest correlation was observed between statin dosage and myopathy ($r= 0.645$, $p <0.001$), indicating a significant and strong relationship as elicited in table 3. This suggests that increased statin dosage is strongly associated with a higher risk of developing myopathy, which is a known adverse effect of statin therapy. The development of statin-induced myopathy is closely linked to both the type and dose of statin used; these results emphasize the importance of careful dose adjustment and monitoring for muscle-related symptoms during statin treatment. This study is consistent with studies.[31],[32],[33],[34].

Higher statin doses are a statistically significantly positive correlation associated with increased BMI, elevated creatinine. These findings highlight the need for individualized statin therapy, balancing therapeutic benefits with potential side effects, particularly in patients with higher BMI or existing renal Concerns.[35] Higher BMI values were more likely to receive higher doses of statins. This may expose clinical practice, where obesity is often associated with increased cardiovascular risk, provoking higher statin prescriptions. These results of study are consistent with studies.[36],[37].

The correlation was found between statin dosage and creatinine levels ($r= 0.474$, $p < 0.001$)is moderately positive , which may suggest a potential dose-related effect of statins on renal function. Higher doses of statins may impact kidney function. This finding associates consistent with some previous studies, creatinine levels were also significantly correlated with myopathy ($r =0.672$, $p < 0.001$), further accompanying the link between muscle side effects and renal function [38],[39].

higher statin doses are significantly associated with elevated creatinine and greater occurrence of myopathy. These outcomes highlight the need for statin therapy, therapeutic benefits balancing with prospective side effects, especially in patients with existing renal concerns or higher BMI. This study results is consistent with studies.[40].

Conclusion

A known side effect of statins is myopathy, including atorvastatin. The risk of myopathy developing rises with higher doses of the drug and in patients with certain factors (e.g., BMI, older age, renal impairment). Female gender, advanced age, extreme body mass index, renal impairment, and are associated with a higher incidence of statin-induced muscle symptoms. The sociodemographic profile of the study proposes a population that may be susceptible to statin-induced myopathy, particularly

due to BMI and age factors. Atorvastatin remains a vital cornerstone in the primary and secondary prevention of atherosclerotic cardiovascular disease, yet its therapeutic efficacy is frequently constrained by statin-associated muscle symptoms. This cross-sectional clinical investigation in Thi-Qar Province demonstrates that atorvastatin-induced myopathy is a significant, dose-dependent clinical issue among Iraqi patients. The strong positive correlation between higher atorvastatin dosages (particularly 40 mg and 80 mg daily) and the incidence and severity of myopathy underscores the critical need for vigilant dose optimization in routine clinical practice. The findings emphasize that statin intolerance and muscle toxicity do not occur uniformly across patient populations but are heavily mediated by specific sociodemographic and physiological risk factors. Advanced age, female gender, elevated Body Mass Index (BMI), and concurrent renal impairment (evidenced by elevated serum creatinine levels) represent major vulnerability markers for developing severe muscle-related side effects. Furthermore, lifestyle variables such as active smoking exacerbate this risk through additive oxidative stress and vascular pathways. Recognizing this high-risk patient profile is essential for preventing unwarranted drug discontinuation, which directly exposes patients to heightened cardiovascular events.

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