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Impact of Statin Intolerance on Functional Capacity and Quality of Life in Patients with Cardiovascular Comorbidities

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ABSTRACT

Background: Long-term statin therapy is essential in managing cardiovascular risk but may lead to muscle-related adverse effects, contributing to functional limitations and diminished quality of life. This study explores the functional impact of statin intolerance among patients with cardiovascular comorbidities.

Objective: To assess the effect of statin intolerance-associated muscle symptoms on physical functioning and perceived quality of life in patients on long-term statin therapy.

Methods: An observational cross-sectional study was conducted among 110 patients aged 30 to 80 years on statins for at least one year. Data on muscle-related symptoms, occupation type, functional limitations, and biochemical markers were collected. Functional limitation was inferred from the site and severity of muscle pain, physical performance status, and change in activity patterns.

Results: Among 110 patients, 56 (51%) reported muscle-related complaints. Of these, 55 (98.2%) experienced pain in the hip flexors, thighs, or calves, and 43 (76.7%) had pain in the shoulders or proximal upper limbs. Pain was more common during movement (61.8%) than palpation (20%). Patients reporting pain had significantly greater physical limitation, especially in moderate and heavy occupation categories. Pain symptoms were exacerbated by exertion in 48% of cases. Elevated CK levels were found in 24.5% of symptomatic patients. Approximately 68% of symptomatic patients reported reduced mobility, 43% had difficulty performing household chores, and 21% had partially withdrawn from previously routine activities. Nearly 18% of affected individuals reported symptoms of low mood, anxiety, or social withdrawal secondary to physical limitation.

Conclusion: Statin intolerance, particularly muscle-related symptoms, significantly impairs functional capacity and may adversely affect quality of life in patients with cardiovascular comorbidities. Clinical recognition and individualized statin management may help preserve function and enhance patient wellbeing.

Keywords: Statin intolerance, functional limitation, quality of life, cardiovascular disease, muscle symptoms, psychosocial impact

ORIGINAL RESEARCH ARTICLE

INTRODUCTION

Statins remain the cornerstone of lipid-lowering therapy and play a pivotal role in the secondary prevention of atherosclerotic cardiovascular disease. However, a subset of patients experience adverse effects, the most prevalent of which are statin-associated muscle symptoms (SAMS). These may range from mild myalgias to severe rhabdomyolysis but are most commonly characterized by diffuse muscle pain and fatigue that may not correlate with biochemical derangements.

While the clinical literature predominantly focuses on the biochemical markers and cardiovascular outcomes of statin therapy, limited attention has been given to the real-world implications of SAMS on physical functioning. Functional limitations induced by muscle symptoms can substantially impair mobility, reduce independence, and alter daily living patterns. This burden may be particularly pronounced among individuals with existing cardiovascular comorbidities, for whom physical activity is both preventive and therapeutic.

Additionally, the chronic nature of these symptoms may have downstream psychosocial consequences. Functional impairment can diminish one's role in occupational, domestic, and social environments, contributing to psychological stress and impaired wellbeing. This study aims to fill a gap in the literature by exploring how statin intolerance impacts functional status and perceived quality of life in patients with cardiovascular risk factors in a real-world Indian cohort.

MATERIALS AND METHODS

Study Design and Setting: This was a cross-sectional observational study conducted at the Department of Pharmacology, Gandhi Medical College, Bhopal, between May, 2023 and December, 2024.

Participants: Adults aged 30–80 years on statin therapy (Atorvastatin or Rosuvastatin) for at least one year were eligible. Patients with known neuromuscular disorders, recent trauma, or acute medical illness were excluded.

Sampling and Data Collection: A total of 110 patients were recruited. A structured questionnaire was administered to collect demographic details, statin type and duration, presence and characteristics of muscle symptoms, and daily activity impact. Occupation was categorized as sedentary, moderate, or heavy work. Symptoms were evaluated using a modified SAMS-CI scale.

Functional Assessment: Patients were asked about limitations in walking, stair climbing, household tasks, occupational productivity, and social engagement. Responses were graded on a 4-point Likert scale (no difficulty to severe limitation). Physical performance was further inferred from pain during movement vs. rest, and whether symptoms limited routine activity.

Biochemical Evaluation: Creatine kinase (CK), AST, ALT, fasting blood sugar (FBS), and postprandial sugar (PPS) levels were recorded. Elevated CK (>195 U/L in males, >170 U/L in females) was considered supportive of SAMS.

Ethical Considerations: The study was approved by the Institutional Ethics Committee of Gandhi Medical College. Informed consent was obtained from all participants.

RESULTS

Demographics: Mean age of participants was 58 years; 58.1% were female. 82.7% were on Atorvastatin and 17.2% on Rosuvastatin. Duration of statin use was 1–3 years in 20%, 3–5 years in 46.3%, and over 5 years in 33.6%.

FIGURE: 1

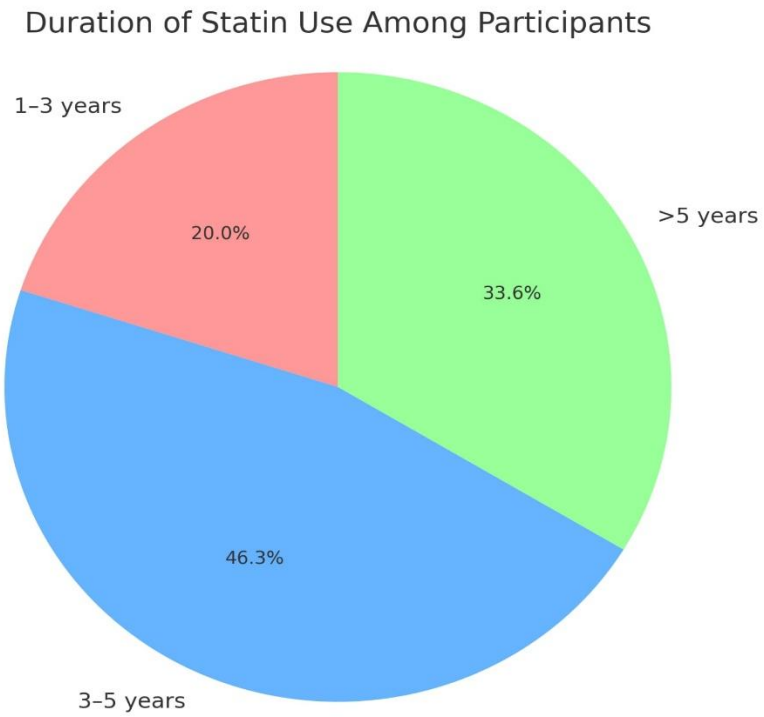
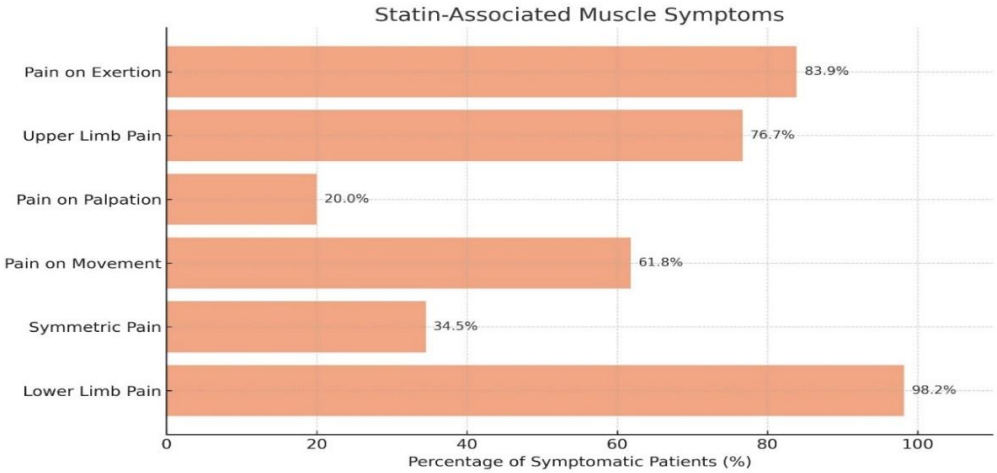


TABLE 1: ASSOCIATION BETWEEN DURATION OF STATIN USE AND MUSCLE SYMPTOMS

Duration of Statin Use	Symptomatic (n = 56) n (%)	Asymptomatic (n = 54) n (%)	p-value
1–3 years	6 (10.7%)	16 (29.6%)	
3–5 years	23 (41.1%)	28 (51.9%)	
>5 years	27 (48.2%)	10 (18.5%)	**0.001**

Occupation Distribution: 50% were sedentary workers, 46.3% moderate, and 3.6% heavy workers.
Muscle Symptoms: 56 patients (51%) reported muscle-related symptoms. Pain localization included hip flexors/thighs/calves in 98.2% and shoulder/proximal arms in 76.7%. 61.8% had pain on movement; 20% on palpation. Pain was bilateral in 34.5%.

FIGURE 2:



Exertional Worsening: 47% of symptomatic patients reported worsening symptoms with exertion or prolonged standing.

Functional Limitation:
68% of symptomatic patients reported limitation in walking or stair climbing.
43% found difficulty in household tasks.
21% avoided or withdrew from routine activities.
10% experienced job performance decline or had to switch to less demanding tasks.

Biochemical Correlates:
Elevated CK in 24.5%
Elevated AST/ALT in 11.8% and 19% respectively
17.2% had new-onset elevated FBS

FIGURE 3:

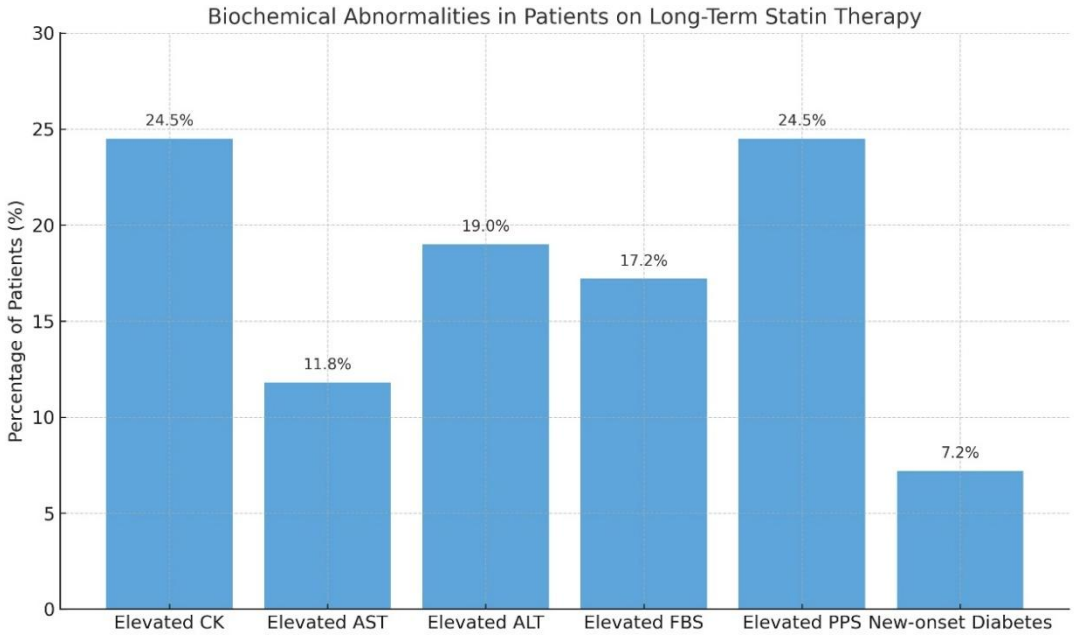


TABLE 2: COMPARISON OF BIOCHEMICAL PARAMETERS IN SYMPTOMATIC VS ASYMPTOMATIC PATIENTS ON LONG-TERM STATIN THERAPY

Parameter	Symptomatic (n = 56) Mean ± SD	Asymptomatic (n = 54) Mean ± SD	p-value
CK (U/L)	198 ± 82	148 ± 60	0.003
AST (U/L)	45 ± 12	36 ± 11	0.012
ALT (U/L)	52 ± 18	44 ± 15	0.045
FBS (mg/dL)	112 ± 20	98 ± 17	0.009
PPS (mg/dL)	165 ± 25	142 ± 21	0.006

Psychosocial Impact:
18% of symptomatic patients reported persistent low mood or irritability.
7% described social withdrawal due to perceived physical disability.

DISCUSSION
Statin-associated muscle symptoms are a major cause of treatment discontinuation and non-adherence, yet their broader impact on patient function and psychosocial wellbeing remains underreported. In our study, nearly half of the patients experienced muscle symptoms, with significant impact on mobility and routine activity. This aligns with prior studies estimating SAMS prevalence between 10–29% in observational cohorts [1,2].

Our findings emphasize that functional limitation is not merely a byproduct of aging or comorbidity but can be directly attributable to statin intolerance. Patients with moderate or heavy occupational demands were disproportionately affected. Importantly, physical limitations extended into domestic and social roles, compromising quality of life. Similar trends were reported in a European survey where SAMS was linked to work absenteeism and decreased physical activity [3,4].

The observed psychosocial consequences—including withdrawal from social activities and depressive symptoms—suggest a bi-directional relationship between physical impairment and mental health. This has implications for recovery-oriented care models, which advocate for holistic wellbeing. While psychiatric diagnosis was not an endpoint of this study, our findings underscore the importance of multidisciplinary support, including counseling and rehabilitation for affected patients [5–7].

TABLE 3: ASSOCIATION BETWEEN MUSCLE SYMPTOMS AND PSYCHOLOGICAL DISTRESS IN STATIN USERS

Psychological Measure (Self-Reported)*	Symptomatic (n = 56),n (%)	Asymptomatic (n = 54),n (%)	p-value
Mood changes / irritability	22 (39.3%)	8 (14.8%)	0.004
Sleep disturbances (insomnia/fatigue)	26 (46.4%)	10 (18.5%)	0.001
Health-related anxiety / somatic focus	18 (32.1%)	6 (11.1%)	0.006

These symptoms may reflect a biopsychosocial interplay between chronic statin use and patient-perceived health. Patients with symptoms may be more sensitive to bodily sensations, suggesting an overlap with somatoform or health-anxiety tendencies. Highlights the importance of psychiatric screening and psychoeducation as part of statin therapy rehabilitation.
Clinicians must not overlook mild or moderate SAMS, especially when symptoms interfere with physical functioning. Objective tools like CK are useful but not definitive; hence, patient-reported outcome measures should be integrated into routine care. Therapeutic alternatives such as dose reduction, statin switching, non-statin lipid-lowering therapies, or periodic drug holidays may be considered in conjunction with functional rehabilitation strategies [8–10].

CONCLUSION
Statin intolerance significantly affects not just cardiovascular outcomes but the lived physical and psychosocial experience of patients. Muscle-related symptoms, even when not life-threatening, can impair function, reduce independence, and diminish quality of life. This study highlights the importance of incorporating functional assessments and patient-centered care in managing statin intolerance. Interdisciplinary collaboration—including pharmacological management and rehabilitation—is critical to preserve health and wellbeing in this population.

Conflict of Interest: None declared
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Ethical Clearance: Approved by Institutional Ethics Committee, Gandhi Medical College, Bhopal.

REFERENCES

1. Stroes ES, et al. Statin-associated muscle symptoms: impact on statin therapy—European Atherosclerosis Society Consensus. Eur Heart J. 2015;36(17):1012–1022.
2. Parker BA, et al. Effect of statins on skeletal muscle function. Circulation. 2013;127(1):96–103.
3. Banach M, et al. Statin intolerance—an attempt at a unified definition. Position paper from International Lipid Expert Panel. Arch Med Sci. 2015;11(1):1–23.
4. Liew SM, et al. Prevalence and predictors of statin use among elderly in primary care. BMC Fam Pract. 2020;21(1):34.
5. McHorney CA, et al. Adherence to statin therapy: Patient-reported symptoms, health beliefs, and daily functioning. Clin Ther. 2007;29(4):742–752.
6. Cohen JD, et al. Underutilization of statins in high-risk patients. Am J Cardiol. 2012;110(10):1458–1464.
7. Mace R, et al. Managing muscle symptoms in statin-treated patients: Role of physical rehabilitation. J Clin Lipidol. 2021;15(1):88–95.
8. Bruckert E, et al. Mild to moderate muscular symptoms with high-dosage statin therapy in hyperlipidemic patients—the PRIMO study. Cardiovasc Drugs Ther. 2005;19(6):403–414.
9. Mancini GB, et al. Diagnosis, prevention, and management of statin adverse effects. Can J Cardiol. 2011;27(5):635–662.
10. Rabar S, et al. Lipid modification and cardiovascular risk: NICE guidelines. Br J Gen Pract. 2014;64(627):E123–E125.