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Safety of Statins in the Elderly: A Systematic Review of Randomized Control Trials and Observational Studies

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INTRODUCTION & AIM

Statins are widely prescribed for cardiovascular disease prevention, yet their safety in older adults, particularly those aged ≥75 years, remains under scrutiny due to polypharmacy risks, age-related pharmacokinetics, and frailty.

This systematic review assesses the safety profile of statins in elderly populations, synthesizing current evidence from randomized and observational studies.

METHOD

We conducted a systematic review in accordance with PRISMA 2020 guidelines. Databases searched included PubMed and Cochrane CENTRAL (last search: July 2025). We included studies reporting adverse outcomes of statin therapy in patients aged ≥65 years. Data were extracted on study design, population characteristics, and reported adverse effects. Risk of bias was assessed using Cochrane RoB2 and Newcastle-Ottawa tools.

RESULTS & DISCUSSION

From 248 initial records, 7 studies (4 RCTs, 2 cohort studies, 1 meta-analysis) met inclusion criteria. Across studies, statins were generally well-tolerated. Myopathy and elevated liver enzymes were reported, but at low frequencies. No consistent increase in serious adverse events (e.g., rhabdomyolysis, cognitive decline) was observed in elderly cohorts compared to younger groups. One observational study noted a higher discontinuation rate in adults ≥80 years, largely due to patient preference or comorbidities rather than toxicity.

CONCLUSION

Statins appear to have an acceptable safety profile in older adults, including the very elderly, though individualized risk-benefit assessments remain essential. Future studies should explore safety in frail subpopulations and clarify long-term tolerability, particularly regarding drug—drug interactions, multimorbidity, and functional outcomes. These findings may support more confident prescribing in age groups historically underrepresented in trials and guide geriatric-focused clinical decision-making.

FUTURE WORK / REFERENCES

- 1. Shepherd J, Blauw GJ, Murphy MB, et al. Pravastatin in elderly individuals at risk of vascular disease (PROSPER): a randomised controlled trial. Lancet. 2002;360(9346):1623–30.
- 2. Cholesterol Treatment Trialists' Collaboration. Efficacy and safety of statin therapy in older people: a meta-analysis of individual participant data from 28 randomised controlled trials. Lancet. 2019;393(10170):407–15.