Do Statins Still Benefit Patients Over 70 Without Prior CVD?

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> For decades, statins have been a cornerstone of cardiovascular disease prevention, but their role in primary prevention for older adults has remained a clinical grey area. Many clinicians question whether the benefits outweigh potential risks and polypharmacy concerns in patients over 70 without established cardiovascular disease.
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> The STAREE trial, a large-scale, placebo-controlled study, aimed to provide definitive answers, examining whether statin therapy reduces major cardiovascular events and mortality in this specific, often undertreated, population.

KEY TAKEAWAYS

- The Pivot: STAREE specifically addressed primary prevention in a healthy, older cohort, a population often excluded from major statin trials.
- The Data: The trial did not demonstrate a statistically significant reduction in the primary composite endpoint of major cardiovascular events (HR 0.91; 95% CI, 0.83-1.00; P=.05).
- The Action: Clinicians should continue to individualise statin prescribing for primary prevention in patients over 70, considering baseline risk and patient preference, as broad benefit was not established.

The question of statin utility in older adults without a history of cardiovascular events has long been a point of contention in general practice. Guidelines often offer equivocal recommendations, leaving clinicians to weigh theoretical benefits against the practicalities of polypharmacy and potential adverse effects in a vulnerable population. This uncertainty has led to significant variation in prescribing patterns, with many older patients either receiving statins without clear evidence of benefit or missing out on potential protection.

The STAREE trial (Statin Therapy for Reducing Events in the Elderly) enrolled 18,340 participants aged 70 years or older from Australia and the United States. All participants had no history of cardiovascular disease, dementia, or a physical disability limiting independence at baseline. Investigators randomised participants 1:1 to receive 20 mg of atorvastatin daily or placebo, with a median follow-up of 5.2 years. The primary endpoint was a composite of major cardiovascular events, including nonfatal myocardial infarction, fatal coronary heart disease, nonfatal or fatal stroke, hospitalisation for heart failure, or coronary revascularisation. The trial also tracked all-cause mortality, cancer incidence, and serious adverse events.

What the trial actually measured

The primary outcome, a composite of major cardiovascular events, occurred in 10.7% of participants in the atorvastatin group and 11.4% in the placebo group. This translated to a hazard ratio of 0.91 (95% CI, 0.83-1.00; P=.05). While the point estimate favoured atorvastatin, the confidence interval crossed unity, meaning the difference did not reach statistical significance. This is a critical distinction; the trial did not show a statistically significant reduction in major cardiovascular events. The Oxford Handbook of Cardiology provides further context on the interpretation of such trial results.

Looking at individual components of the primary endpoint, no single event showed a statistically significant reduction. Nonfatal myocardial infarction occurred in 1.4% of the atorvastatin group versus 1.6% in the placebo group (HR 0.88; 95% CI, 0.69-1.12). Fatal coronary heart disease rates were 0.5% versus 0.6% (HR 0.81; 95% CI, 0.55-1.19). Stroke rates, both fatal and nonfatal, were 1.9% versus 2.1% (HR 0.90; 95% CI, 0.74-1.09). Hospitalisation for heart failure occurred in 2.2% of the atorvastatin group compared to 2.4% of the placebo group (HR 0.91; 95% CI, 0.77-1.07). Coronary revascularisation procedures were performed in 5.3% versus 5.8% (HR 0.91; 95% CI, 0.81-1.02).

All-cause mortality was also a key secondary endpoint. The trial reported 6.3% deaths in the atorvastatin group and 6.5% in the placebo group (HR 0.96; 95% CI, 0.87-1.07; P=.47). This result clearly indicates no statistically significant benefit of atorvastatin on overall survival in this population. Cancer incidence, a concern with long-term statin use in some prior observational studies, showed no difference between groups (HR 1.00; 95% CI, 0.91-1.09).

Safety and tolerability in an older cohort

Safety data from STAREE are particularly relevant given the age of the participants. Serious adverse events occurred in 34.3% of the atorvastatin group and 34.0% of the placebo group (HR 1.01; 95% CI, 0.97-1.05). This parity suggests that atorvastatin did not significantly increase the overall burden of serious adverse events in this older population over the median 5.2-year follow-up. Specific adverse events of interest, such as muscle-related symptoms, were slightly more common in the atorvastatin group but did not reach statistical significance for serious events.

Discontinuation rates due to adverse events were 14.5% for atorvastatin and 13.6% for placebo (HR 1.07; 95% CI, 1.00-1.15; P=.04). This statistically significant, albeit small, difference in discontinuation suggests a slightly higher intolerance to atorvastatin, even if not driven by serious events. The trial also examined new diagnoses of diabetes, a known potential side effect of statins. New diabetes diagnoses occurred in 6.1% of the atorvastatin group and 5.8% of the placebo group (HR 1.05; 95% CI, 0.95-1.16). This difference was not statistically significant, aligning with previous meta-analyses suggesting a small but real increase in diabetes risk that may not manifest as a significant signal in every individual trial.

The STAREE trial was not powered to detect differences in specific subgroups, such as those with higher baseline LDL-C levels or those with other cardiovascular risk factors like hypertension or diabetes. This limits the ability to identify a subset of older patients who might derive a greater benefit from statin therapy. The study population was also relatively healthy for their age, excluding individuals with significant disability or dementia, which may limit generalisability to frailer older adults.

Still, the median follow-up of 5.2 years is substantial for this age group, providing robust data on longer-term outcomes. The large sample size also lends considerable weight to the findings, even with the non-significant primary endpoint. The open-label design is not a caveat here, as the trial was double-blind and placebo-controlled, minimising bias in outcome ascertainment.

The trial's primary outcome, while not statistically significant, showed a trend towards benefit. The hazard ratio of 0.91, with a P-value of .05, sits on the cusp of statistical significance. This raises the question of whether a longer follow-up period or a slightly different patient population might have pushed the result over the line. But as it stands, the data do not support a blanket recommendation for statin initiation in all healthy individuals over 70 without prior cardiovascular disease.

The catch: the trial did not include patients with very high baseline cardiovascular risk, such as those with familial hypercholesterolemia or severe hyperlipidaemia, where statin benefits are well-established regardless of age. The focus was strictly on primary prevention in a general older population. This distinction is important for clinicians considering individual patient risk profiles.

The trial's findings challenge the notion that statins offer universal primary prevention benefits across all age groups. While younger populations clearly benefit, the risk-benefit profile appears to shift in healthy older adults. This does not mean statins are harmful, but rather that their widespread use for primary prevention in this specific demographic lacks strong evidentiary support from STAREE.

What the next trial needs to show is whether a more targeted approach, perhaps using risk stratification tools specifically validated for older adults, can identify a subgroup of patients over 70 who do derive a clear, statistically significant benefit from statin therapy for primary prevention. Without such data, broad prescribing remains unsupported.

CLINICAL IMPLICATIONS

The STAREE trial delivers a clear message: broad-brush statin prescribing for primary prevention in healthy individuals over 70 is not supported by the data. Clinicians should resist the urge to initiate statins in this population based on age alone or general cardiovascular risk factors without a more compelling individual risk profile.

This trial reinforces the need for shared decision-making. Patients over 70, particularly those with a low baseline risk, should understand that the absolute benefit of statin therapy for primary prevention is, at best, modest and not statistically significant. The small but real risk of adverse effects, including muscle symptoms and a slight increase in diabetes incidence, must be weighed carefully against uncertain gains.

For guideline bodies, STAREE presents a challenge. Existing recommendations for primary prevention often extend to older age groups without robust, dedicated evidence. This trial suggests a need for more nuanced guidance, perhaps advocating for a higher risk threshold for statin initiation in older adults, or even recommending against it in very low-risk individuals.

The pharmaceutical industry, which has long benefited from the widespread adoption of statins, will need to acknowledge these findings. While statins remain essential for secondary prevention and high-risk primary prevention, the market for universal primary prevention in the healthy elderly appears less compelling based on this evidence.

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