Simvastatin reduced mortality and vascular events in diabetes mellitus


Clinical impact ratings GP/FP/Primary care ★★★★★☆ IM/Ambulatory care ★★★★★☆ Cardiology ★★★★★☆ Endocrine ★★★★★☆

In patients with diabetes mellitus, does simvastatin reduce vascular events?

**METHODS**

**Design:** randomised placebo controlled trial.

**Allocation:** (concealed*)†.

**Blinding:** blinded (participants, clinicians, data collectors, and outcome assessors)*†.

**Follow up period:** mean 4.8 years of follow up.

**Setting:** (69 UK hospitals)*†.

**Patients:** 5963 patients who were 40–80 years of age (mean age 62 y, 70% men); had non-fasting blood total cholesterol levels >3.5 mmol/l, and had a medical history of diabetes mellitus, coronary heart disease, atheromatous disease of non-coronary arteries, or treated hypertension (if also male and >65 y of age). Exclusion criteria included indications or contraindications for statin therapy; myocardial infarction, stroke, or admission for angina in the previous 6 months; chronic liver disease; severe renal disease; and life threatening conditions other than vascular disease or diabetes.

**Intervention:** after a run in phase, compliant patients were allocated to simvastatin, 40 mg/day (n = 2978), or placebo (n = 2985). Patients in each group were also allocated to antioxidants or placebo.

**Outcomes:** coronary events (myocardial infarction or coronary death), stroke, revascularisation, and major vascular events (major coronary events, strokes, and revascularisations).

**Patient follow up:** (~99.5% of patients had complete follow up)*†.

*See glossary.

**MAIN RESULTS**

Analysis was by intention to treat. Patients in the simvastatin group had fewer coronary events, strokes, revascularisation procedures, and major vascular events (table).

**CONCLUSION**

In adults with diabetes mellitus, simvastatin therapy at 40 mg daily reduced vascular events.

Abstract and commentary also appear in ACP Journal Club.

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**Simvastatin (Sim) v placebo in diabetes mellitus at mean 4.8 year follow up***

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Sim</th>
<th>Placebo</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major coronary event</td>
<td>9.4%</td>
<td>13%</td>
<td>26% (14 to 36)</td>
<td>31 (21 to 60)</td>
</tr>
<tr>
<td>Stroke</td>
<td>5.0%</td>
<td>6.5%</td>
<td>23% (4.8 to 37)</td>
<td>69 (38 to 353)</td>
</tr>
<tr>
<td>Revascularisation</td>
<td>8.7%</td>
<td>10%</td>
<td>16% (1.3 to 28)</td>
<td>62 (32 to 770)</td>
</tr>
<tr>
<td>Major vascular event</td>
<td>20%</td>
<td>25%</td>
<td>19% (11 to 27)</td>
<td>21 (15 to 37)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RRR, NNT, and CI calculated from data in article.
†Myocardial infarction or coronary death.
‡Major coronary events, strokes, and revascularizations.