An intensive, target driven intervention reduced cardiovascular and microvascular events in patients with type 2 diabetes and microalbuminuria


QUESTION: In patients with type 2 diabetes and microalbuminuria, what is the effect of a target driven, long term, intensive, multifactorial intervention compared with conventional treatment on cardiovascular and microvascular disease?

Design
Randomised [allocation concealed]*, blinded [data collectors and outcome assessors]*, controlled trial with mean follow up of 7.8 years (the Steno-2 Study).

Setting
A diabetes centre in Denmark.

Outcomes (mean 7.8 y follow up)

<table>
<thead>
<tr>
<th>Outcomes (mean 7.8 y follow up)</th>
<th>Intensive</th>
<th>Conventional</th>
<th>Adjusted HR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite endpoint‡</td>
<td>24%</td>
<td>44%</td>
<td>0.47 (0.22 to 0.74)</td>
<td>5 (3 to 19)</td>
</tr>
<tr>
<td>Diabetic nephropathy</td>
<td>20%</td>
<td>39%</td>
<td>48% (15 to 69)</td>
<td>6 (4 to 22)</td>
</tr>
<tr>
<td>Retinopathy (developed or progressed)</td>
<td>48%</td>
<td>64%</td>
<td>25% (1.5 to 44)</td>
<td>7 (4 to 125)</td>
</tr>
<tr>
<td>Autonomic neuropathy</td>
<td>30%</td>
<td>54%</td>
<td>44% (18 to 63)</td>
<td>5 (3 to 12)</td>
</tr>
</tbody>
</table>

HR = hazard ratio. Other abbreviations defined in glossary; RRR, NNT, and CI calculated from data provided by author. HR adjusted for baseline characteristics.

‡Composite endpoint of various cardiovascular events.

COMMENTARY
With the rising incidence of diabetes creating a health and economic burden, research on the prevention of diabetes related morbidity and mortality is applicable to all practitioners.1 The findings of the United Kingdom Prospective Diabetes Study showed that stringent glycaemic control improved outcomes and highlighted the need for interventions to modify the risk of complications.2 In the Steno-2 study, a multifactorial approach (medications and behaviour modification of diet, exercise, and smoking) was used to modify risk factors associated with diabetes. The sustained improvement in the intensive therapy group over 7.8 years of follow up enhances the value of the study findings.

Improvements in fat and carbohydrate intake and reductions in HbA1c, serum triglyceride and cholesterol concentrations, systolic and diastolic blood pressure, and albumin excretion rate were found, but interventions to improve body mass index and increase exercise had little effect. Little information was provided on the behaviourally directed therapies such as the smoking cessation or exercise programme,3 and one is left with the sense that this was a secondary aspect of the management. However, the researchers emphasise that education, motivation, and individualised plans were part of the overall strategy. Patients in the intensive therapy group were seen a mean of 4 times per year at a diabetes centre compared with those in the conventional group who were seen by their general practitioner. However, without a clear understanding of what occurred during these visits, it is difficult to determine the relative importance of interventions directed toward self management of lifestyle versus pharmacological treatments. It is possible that additional gains may result from lifestyle interventions of the same intensity as the pharmacological ones reported in the Steno-2 study. Such investigations are needed.

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