

Involving patients with type 2 diabetes, hypertension, and hyperlipidaemia in disease management improved outcomes

Rachmani R, Levi Z, Slavachevski I, et al. *Teaching patients to monitor their risk factors retards the progression of vascular complications in high-risk patients with type 2 diabetes mellitus—a randomized prospective study.* *Diabet Med* 2002;19:385–92.

QUESTION: In patients with type 2 diabetes mellitus, hypertension, and hyperlipidaemia, does involvement in managing their disease improve outcomes?

Design

Randomised (unclear allocation concealment*), unblinded,* controlled trial with 4 years of follow up.

Setting

A hospital diabetes outpatient clinic in Israel.

Patients

141 patients who were 45–70 years age (mean age 57 y, 51% women) with type 2 diabetes, blood pressure >140 mm Hg systolic or >90 mm Hg diastolic, and hyperlipidaemia. Exclusion criteria included diabetes duration >10 years, body mass index (BMI) >35 kg/m², smoking, serum creatinine >176 µmol/l, albumin to creatinine ratio ≥200 mg/g, and history of vascular surgery. Follow up was 91%.

Intervention

Patients were allocated to the participation programme (PP) (n=71) or to standard consultation (SC) (n=70). Patients in the PP group attended a 1 hour teaching session and were given detailed written instructions, and a copy of the structured consultation letter that was sent to their family doctor. They were given responsibility for complying with medications, monitoring treatment effects, requesting treatment changes, and achieving and maintaining target blood pressure, low density lipoprotein cholesterol (LDL C), haemoglobin A_{1c} (HbA_{1c}), and BMI (<25 kg/m² for men and <24 kg/m² for women). These patients had the option to initiate a visit or telephone conversation with a consultant when they needed advice. Patients in the SC group were given annual consultation with structured letters provided to their primary care physician. Patients in both groups received medical care by their primary care physicians.

Main outcome measures

Main outcomes were change in the glomerular filtration rate (GFR) and change in the urinary albumin to creatinine ratio. Secondary outcomes were changes in systolic and diastolic blood pressure, LDL C, and HbA_{1c} concentrations.

Main results

Analysis was by intention to treat. At 4 years, the PP group had a higher mean estimated GFR (98 v 91 ml/min per 1.73 m², p<0.05) and a lower mean urinary albumin to creatinine ratio (44 v 69 mg/g, p<0.05) than the SC group. Fewer patients in the PP group developed

nephropathy (defined as an albumin to creatinine ratio >300 mg/g), new incidences of retinopathy, and cardiovascular events (table). The PP group showed lower mean systolic blood pressure (142 v 148 mm Hg, p<0.05), mean diastolic blood pressure (84 v 88 mm Hg, p<0.05), mean LDL C (114 v 124 mg/dl, p=0.01), and mean HbA_{1c} levels (8.2% v 8.9%, p=0.04) than the SC group.

Conclusion

In patients with type 2 diabetes mellitus, hypertension, and hyperlipidaemia, participation in disease management improved outcomes.

*See glossary.

Patient participation (PP) v standard consultation (SC) for type 2 diabetes, hypertension, and hyperlipidaemia at 4 years†

Outcomes	PP	SC	RRR (95% CI)	NNT (CI)
Nephropathy	0%	6%	100% (8 to 100)	18 (7 to 251)
New retinopathy cases	8%	24%	65% (20 to 85)	6 (4 to 26)
Cardiovascular events	34%	51%	34% (3 to 56)	6 (3 to 80)

†Abbreviations defined in glossary; RRR, NNT, and CI calculated from data in article.

COMMENTARY

The study by Rachmani *et al* adds to the literature on the benefits of actively involving patients in self management. Study participants were selected from a diabetes outpatient clinic in an academic hospital. Although participants were referred from primary care, they were a high risk group with other cardiovascular risk factors. It is possible that the PP may not be similarly effective in primary care centres without academic input.

Participants in the PP group were provided with individualised, detailed instructions. These participants showed clinically and statistically significant improvement in risk factor management, which led to lower blood pressure, HbA_{1c}, and cholesterol concentration. However, interestingly, target concentrations were still not achieved.

This study was not designed to assess such health outcomes as cardiovascular and microvascular events. Other studies, such as the United Kingdom Prospective Diabetes Study¹ and the Heart Protection Study,² have shown that changes in risk factor control (eg, blood glucose, blood pressure, and cholesterol concentrations) result in improved health outcomes.

A worldwide trend exists towards self management of chronic disease. The recent introduction of Medicare funding in the US for diabetes education is an acknowledgment that funding organisations recognise the value of educating patients and building their capacity for self management. This study will help those designing future education programmes for managing diabetes and other chronic diseases.

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- 1 UK Prospective Diabetes Study (UKPDS) Group. Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998;352:837–53.
- 2 Heart Protection Study Collaborative Group. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. *Lancet* 2002;360:7–22.