

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

Rachmani R, Levi Z, Slavachevski I, Avin M, Ravid M. 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 hyperlipidemia, does involvement in managing their disease improve outcomes?

DESIGN

Randomized (unclear allocation concealment*), unblinded,* controlled trial with 4-year follow-up.

SETTING

A hospital diabetes outpatient clinic in Israel.

PATIENTS

141 patients who were 45 to 70 years of age (mean age 57 y, 51% women) with type 2 diabetes, blood pressure > 140 mm Hg systolic or > 90 mm Hg diastolic, and hyperlipidemia. 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 program (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), hemoglobin A_{1c} (HbA_{1c}), and BMI (< 25 kg/m² for men, < 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. All patients 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} levels.

MAIN RESULTS

Analysis was by intention to treat. At 4 years, the PP group had a higher mean estimated GFR (98 vs 91 mL/min per 1.73 m²,

P < 0.05) and a lower mean urinary albumin-to-creatinine ratio (44 vs 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 vs 148 mm Hg, *P* < 0.05), mean diastolic blood pressure (84 vs 88 mm Hg, *P* < 0.05), mean LDL-C (114 vs 124 mg/dL, *P* = 0.01), and mean HbA_{1c} levels (8.2% vs 8.9%, *P* = 0.04) than the SC group.

CONCLUSION

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

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*See Glossary.

Patient participation (PP) vs standard consultation (SC) for type 2 diabetes, hypertension, and hyperlipidemia 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 and colleagues 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 program may not be similarly effective in primary care centers without academic input.

Participants in the PP group were provided with individualized, detailed instructions. These participants showed clinically and statistically significant improvement in risk factor management, which led to lower blood pressure, HbA_{1c}, and cholesterol levels. Interestingly, target levels 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 Study (1) and the Heart Protection Study (2), have shown that changes in risk factor control (e.g., blood glucose, blood pressure, and cholesterol levels) result in improved health outcomes.

A worldwide trend exists toward self-management of chronic disease. The recent introduction of Medicare funding in the United States for diabetes education is an acknowledgment that funding organizations recognize the value of educating patients and building their capacity for self-management. This study will help those designing future education programs for managing diabetes and other chronic diseases.

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References

1. UK Prospective Diabetes Study (UKPDS) Group. *Lancet.* 1998;352:837-53.
2. Heart Protection Study Collaborative Group. *Lancet.* 2002;360:7-22.