United Kingdom Prospective Diabetes Study 17: a 9-year update of a randomized, controlled trial on the effect of improved metabolic control on complications in non–insulin–dependent diabetes mellitus.

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PURPOSE: To report the progress (after 9-year follow-up) of a study designed to determine whether improved glucose control in patients with newly diagnosed non–insulin–dependent diabetes mellitus (NIDDM) is effective in reducing the incidence of clinical complications. DATA SOURCE: A multicenter, randomized, controlled trial of different therapies for NIDDM. After initial diet therapy, 4209 asymptomatic patients who remained hyperglycemic (fasting plasma glucose levels, 6.0 to 15.0 mmol/L) were assigned to either a conventional therapy policy, primarily with diet alone, or to an intensive therapy policy, aiming for fasting plasma glucose levels of less than 6.0 mmol/L, with assignment to primary therapy with sulfonylurea or insulin (which increased insulin supply) or metformin (which enhanced insulin sensitivity). RESULTS: All three modes of pharmacologic therapy in the intensively treated group—sulfonylurea, insulin, and metformin—had similar efficacy in reducing the fasting plasma glucose and glycated hemoglobin levels. Over 9 years, patients assigned to intensive therapy with sulfonylurea or insulin had lower fasting plasma glucose levels (median, 7.3 and 9.0 mmol/L, respectively) than patients assigned to conventional therapy. Regardless of the assigned therapy, however, the fasting plasma glucose and hemoglobin A1c levels increased, and maintaining near–normal glycemia was, in general, not feasible. Even insulin therapy did not achieve the therapeutic goal of near–normal glycemia because of the difficulty in treating marked hyperglycemia and the risk for hypoglycemic episodes. Nine years after the diagnosis of diabetes, 29% of the patients had had a diabetes–related clinical end point, 20% had had a macrovascular complication, and 9% had had a microvascular complication. CONCLUSIONS: A report will be published in 1998 after a median duration from randomization of 11 years (range, 6 to 20 years) with an 81% power at a 1% level of significance of detecting whether the obtained improvement in glucose control causes a 15% decrease or
increase in the incidence of major complications and whether any specific therapy is advantageous or disadvantageous.