United Kingdom Prospective Diabetes Study (UKPDS). 13: Relative efficacy of randomly allocated diet, sulphonylurea, insulin, or metformin in patients with newly diagnosed non-insulin dependent diabetes followed for three years.

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OBJECTIVE--To assess the relative efficacy of treatments for non-insulin dependent diabetes over three years from diagnosis. DESIGN--Multicentre, randomised, controlled trial allocating patients to treatment with diet alone or additional chlorpropamide, glibenclamide, insulin, or metformin (if obese) to achieve fasting plasma glucose concentrations < or = 6 mmol/l. SETTING--Outpatient diabetic clinics in 15 British hospitals. SUBJECTS--2520 subjects who, after a three month dietary run in period, had fasting plasma glucose concentrations of 6.1-14.9 mmol/l but no hyperglycaemic symptoms. MAIN OUTCOME MEASURES--Fasting plasma glucose, glycated haemoglobin, and fasting plasma insulin concentrations; body weight; compliance; and hypoglycaemia. RESULTS--Median fasting plasma glucose concentrations were significantly lower at three years in patients allocated to chlorpropamide, glibenclamide, or insulin rather than diet alone (7.0, 7.6, 7.4, and 9.0 mmol/l respectively; $P < 0.001$) with lower mean glycated haemoglobin values (6.8%, 6.9%, 7.0%, and 7.6%, respectively; $P < 0.001$). Mean body weight increased significantly with chlorpropamide, glibenclamide, and insulin but not diet (by 3.5, 4.8, 4.8, and 1.7 kg; $P < 0.001$). A similar pattern was seen for mean fasting plasma insulin concentration (by 0.9, 1.2, 2.4, and -0.1 mU/l; $P < 0.001$). In obese subjects metformin was as effective as the other drugs with no change in mean body weight and significant reduction in mean fasting plasma insulin concentration (-2.5 mU/l; $P < 0.001$). More hypoglycaemic episodes occurred with sulphonylurea or insulin than with diet or metformin. CONCLUSION--The drugs had similar glucose lowering efficacy, although most patients remained hyperglycaemic. Long term follow up is required to determine the risk-benefit ratio of the glycaemic improvement, side effects, changes in body weight, and plasma insulin concentration.