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 ≤ 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.