

Sulfonylurea inadequacy: efficacy of addition of insulin over 6 years in patients with type 2 diabetes in the U.K. Prospective Diabetes Study (UKPDS 57).

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OBJECTIVE: To evaluate the efficacy of the addition of insulin when maximal sulfonylurea therapy is inadequate in individuals with type 2 diabetes. **RESEARCH DESIGN AND METHODS:** Glycemic control, hypoglycemia, and body weight were monitored over 6 years in 826 patients with newly diagnosed type 2 diabetes in 8 of 23 U.K. Prospective Diabetes Study (UKPDS) centers that used a modified protocol. Patients were randomly allocated to a conventional glucose control policy, primarily with diet (n = 242) or an intensive policy with insulin alone (n = 245), as in the main study. However, for patients randomized to an intensive policy with sulfonylurea (n = 339), insulin was added automatically if the fasting plasma glucose remained >108 mg/dl (6.0 mmol/l) despite maximal sulfonylurea doses. **RESULTS:** Over 6 years, approximately 53% of patients allocated to treatment with sulfonylurea required additional insulin therapy. Median HbA(1c) in the sulfonylurea +/- insulin group was significantly lower (6.6%, interquartile range [IQR] 6.0-7.6) than in the group taking insulin alone (7.1%, IQR 6.2-8.0; P = 0.0066), and significantly more patients in the sulfonylurea +/- insulin group had an HbA(1c) <7% (47 vs. 35%, respectively; P = 0.011). Weight gain was similar in the intensive therapy groups, but major hypoglycemia occurred less frequently over all in the sulfonylurea (+/- insulin) group compared with the insulin alone group (1.6 vs. 3.2% per annum, respectively; P = 0.017). **CONCLUSIONS:** Early addition of insulin when maximal sulfonylurea therapy is inadequate can significantly improve glycemic control without promoting increased hypoglycemia or weight gain.