The Glycaemic Optimisation Outcomes in Diabetes (GOOD) feasibility study: early use of combination therapies and insulin in general practice.

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**Background and Aims:** The UKPDS showed that improved blood glucose control in type 2 diabetic patients reduced the risk of complications and that earlier, more aggressive, combination therapy is needed to combat progressively declining beta-cell function in patients. The Glycaemic Optimisation Outcomes in Diabetes (GOOD) feasibility study has evaluated the early use of six randomly allocated oral hypoglycaemic agent (OHA) combinations, with added basal insulin if necessary, to determine whether near normoglycaemia can be obtained in a community setting.

**Materials and Methods:** Patients with type 2 diabetes, aged 40 to 75 years, with HbA1C 6.2 to 10.0 % on diet or oral monotherapy, were recruited from 7 general practices. Basal glucose was optimised with a thiazolidinedione, biguanide or sulphonylurea and prandial glucose targeted simultaneously with a prandial glucose regulator, alpha-glucosidase inhibitor or rapid-acting insulin. Therapy was adjusted aiming for capillary plasma glucose values fasting <6.0 mmol/L and 2-hour post-prandial <8.0 mmol/L. Isophane and/or lispro insulin was added where glucose targets were not attained with maximal OHA therapy.

**Results:** 60 patients were recruited, 65% male, with mean (SD) age 61.0 (8.2) years, BMI 29.8 (5.3) kg/m², HbA1C 7.5 (0.9)% and median (IQR) diabetes duration 3 (1 to 5) years. 41 patients completed the study. The mean number of therapies required to attain normoglycaemia was 2.4. 50% of patients required 3 therapies, 30% 2 and 10% monotherapy at 1 year. 24 (59%) patients received (59%) additional isophane and 5 lispro insulin to achieve glucose targets. The overall mean HbA1c reduction was -0.8% at 1 year with a reduction of -1.2% in protocol-adherent patients. Only 5 episodes of significant hypoglycaemia occurred.

**Conclusion:** A structured approach to glucose optimisation with earlier use of combination OHAs and insulin can successfully achieve a mean HbA1c reduction of -0.8% in a community setting over 1 year. The methodology developed in this study will be used in a large, multicentre trial examining the degree to which different OHAs can improve cardiovascular outcomes in type 2 diabetes.