Characteristics of patients needing basal insulin to be given twice-daily or a second insulin formulation during the first year of the 4-T Trial
Presenter:

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Background and aims: 4-T (Treating to Target in Type 2 diabetes) is a three arm parallel group, open-label randomised trial comparing biphasic, prandial and basal analogue insulin regimens when added to the treatment of patients with type 2 diabetes who had sub-optimal glycaemic control on maximally tolerated doses of metformin and sulfonylureas. We have carried out an exploratory analysis to identify potential differences in the characteristics of trial patients failing to achieve or maintain glycaemic control within pre-specified safety limits over one year on a single insulin formulation.
Materials and methods: Fifty-eight UK and Irish centres randomised 708 patients to twice-daily biphasic insulin (n=235, NovoMix 30), thrice-daily prandial insulin (n=239, NovoRapid), or once-daily basal insulin (n=234, Levemir). Insulin doses were titrated using a predefined algorithm based on self-monitored capillary glucose measurements to achieve fasting and pre-meal targets of 4.0-5.5mmol/l. We compared the characteristics of patients requiring basal insulin twice-daily because of protocol-defined evening hyperglycaemia, with those achieving acceptable values on once-daily basal insulin. We also compared baseline characteristics of patients with HbA1c >10% from 24 weeks (or >8% on two subsequent occasions) up to one year who required a second insulin preparation per protocol, with those achieving lower values on a single insulin preparation.
Results: Of patients allocated to basal insulin, 79 (34%) required it twice-daily. Compared with those requiring basal insulin once-daily, they were older (mean (±SD) 65.0±9.2 vs. 60.4±10.0 years, p=0.002), lighter (80.7±15.7 vs. 87.5±16.5 kg, p=0.006) and had lower triglycerides (median (IQR) 1.2 (1.0-1.7) vs. 1.6 (1.2-2.2), p=0.002). Overall, 73 (10.3%) patients required a second insulin preparation (biphasic insulin 21 (8.9%), prandial insulin 10 (4.2%) basal insulin 42 (17.9%)). Compared with those remaining on a single insulin preparation, they had higher mean HbA1c (9.0±0.7 vs. 8.5±0.8%, p<0.0001), BMI (31.2±4.5 vs. 29.7±4.6 kg/m2, p=0.0089) and higher median triglycerides (1.9 (1.4-2.6) vs. 1.5 (1.1-2.1), p=0.0012).
Conclusion: Patients who required Levemir insulin to be given twice a day were older, lighter and had lower triglycerides. In contrast, those who required two insulin preparations within the first year were more hyperglycaemic, heavier and had higher triglycerides. These differing characteristics may help guide therapy choices when adding insulin to metformin and sulfonylurea therapy in patients with sub-optimal glycaemic control.