Continuous Glucose Monitoring Results from the Treating to Target in Type 2 Diabetes (4-T) Trial

Melanie J Davies, Jonathan C Levy, Kerensa I Thorne, Sanjoy K Paul, Julie L Darbyshire, Rury R Holman.

Diabetes (2008): **57**: (Suppl 1): A12

We report the 1-year continuous glucose monitoring (CGM) results from the Treating to Target in Type 2 Diabetes (4-T) trial. 4-T is a randomized, 58-center UK and Irish trial evaluating the addition of biphasic insulin twice daily, prandial insulin aspart three times daily or basal insulin determir once (or twice) daily in type 2 diabetic subjects with HbA1c 7-10% on maximum tolerated metformin and sulfonylurea therapy. Mean 1-year HbA1c in the whole cohort (n=708) was similar in biphasic (7.3%) and prandial (7.2%) groups, but higher in the basal group (7.6%). Respective mean numbers of hypoglycemic events per patient per year were 5.7, 12.0 and 2.3. 112 CGM subjects from 17 centers were monitored for up to 72 hours using the Medtronic Gold CGM System with diary records of meals and hypoglycemia. The primary outcome was the proportion of time glucose values were maintained within 72-99 mg/dl between meals and 72-126 mg/dl for 3 hours after each meal. Biochemical hypoglycemia (<56 mg/dl) was a secondary outcome. Data from 102 profiles (biphasic 33, prandial 31, basal 38) were analysed on an intention to treat basis using a mixed effects logistic model with assumptions of random center effect and autoregressive within patient glucose variability over time and adjustment for meal status. Monitoring time did not differ between groups. Baseline and 1-year HbA1c values were 8.5, 8.5 & 8.4 and 7.1, 7.1 & 7.5 respectively. Results are shown in the table. The proportion of CGM values in target was highest for the prandial group (32.7%) but did not differ between biphasic (24.6%) and basal (24.9%). Mean numbers of biochemical hypoglycemic events per patient per week for all, daytime and night time were (5.5, 6.3, 3.5), (3.4, 3.9, 2.4) and (2.1, 2.3, 1.1) for biphasic, prandial and basal respectively, being significantly lower in the basal than in the other two groups. These CGM results are consistent with those from the main trial showing that subjects in the basal group spent less time within glycemic targets and basal had the a lowest hypoglycemic risk, but biphasic and prandial hypoglycemic risks did not differ.

Results. OR=Odds Ratio, IRR=Incidence Rate Ratio

	Basal vs. Biphasic	Prandial vs. Biphasic	Prandial vs. Basal
	Ratio, p	Ratio, p	Ratio, p
OR for within glycemic targets	1.10, 0.58	1.49, <0.001	1.47, <0.001
IRR for all hypoglycemia	0.64, <0.001	1.14, 0.23	1.78, <0.001
IRR for daytime hypoglycemia	0.71, 0.019	1.14, 0.32	1.62, 0.001
IRR for night time hypoglycemia	0.54, 0.002	1.14, 0.48	2.11, <0.001