Table 2. Observed Mean Changes From Baseline at Week 68

Variable	Liraglutide 3.0 mg vs Placebo	Liraglutide 1.8 mg vs Placebo	Liraglutide 3.0 vs 1.8 mg
Estimated differences in body weight at week 68, %	−2.17 (P = .0002)	−1.20 (P = NS)	−0.97 (P = NS)
Estimated differences in FPG, mmol/L	−0.09 (P = NS)	0.12 (P = NS)	−0.20 (P = NS)
Estimated differences in SBP, mm Hg	−1.36 (P = NS)	−1.72 (P = NS)	0.37 (P = NS)
Estimated difference in pulse, beats/min	−1.92 (P = .0419)	−0.92 (P = NS)	−1.00 (P = NS)

FPG, fasting plasma glucose; NS, not significant; SBP, systolic blood pressure.

Nausea was the most frequently reported side effect and occurred in about 15% of patients. Nausea was more common in patients treated with liraglutide. The incidence was greatest in the first 4 to 8 weeks and then gradually declined.

Liraglutide is not currently approved for weight management; however, in this study, it resulted in greater reductions in body weight in overweight or obese individuals with T2DM than placebo. In the 12 weeks after treatment stopped, patients had increases in weight, although the increases did reach the baseline weight. Benefits in FPG and SBP during treatment were also lost after treatment cessation. This study suggests that liraglutide is well tolerated and results in weight loss and improvements in FPG.

Patient Involvement in Diabetes Care: Greek Study of Decision Aids Inconclusive

Written by Dennis Bittner

The high cost of treatment and large variation in the quality of patient care are major concerns in the treatment of type 2 diabetes mellitus (T2DM) [Halperin F et al. *N Engl J Med*. 2008]. Increasing the degree of patient involvement in decisions related to treatment of their condition has been advocated in current T2DM guidelines [Inzucchi SE et al. *Diabetologia*. 2012] and has been shown to improve the overall quality of care [Stacey D et al. *Cochrane Database Syst Rev*. 2014]. The increased cost of new treatments enables patient involvement, because decisions for optimal individualized treatment become less technical and more value based [Grant RW et al. *Diabetes Care*. 2007]. Tools known as decision aids (DAs) have emerged to facilitate a shared decision-making process between patient and physician [Stacey D et al. *Cochrane Database Syst Rev*. 2014].

Thomas Karagiannis, MD, Aristotle University of Thessaloniki, Thessaloniki, Greece, presented a poster with preliminary results from the multicenter, cluster-randomized Diabetes Medication Choice Cards Trial in Greece [NCT01861756; EASD 2014 (poster 1077)] evaluating use of the Diabetes Medication Choice DA, which consists of cards providing a comparison of commonly used antidiabetic medication classes among 7 domains: blood sugar, daily sugar testing, low blood sugar, daily routine, weight change, side effects, and cost.

The objective of the study was to implement the DA (originally developed by the Mayo Clinic), assess its efficacy in patients with T2DM in primary and secondary care practices throughout Greece, and compare it with usual care. Practices were matched based on type of setting (urban or rural) and level of care (primary or secondary) before randomization of patients to either use of the Diabetes Medication Choice DA or usual care.

Patients eligible for the study were adults who had been diagnosed with T2DM at least 1 year, had more than 1 treatment option available, and were able to both provide informed consent and participate in decision making for their treatment. Patient characteristics were balanced between the 2 treatment arms. A total of 5 practices with 101 patients were allocated to the DA, and 4 practices with 103 patients were allocated to usual care. The study consisted of an initial encounter and 2 follow-up visits at 12 and 24 weeks. The quality of the decision-making process was evaluated immediately after the initial encounter by means of a 13-item Decisional Conflict Scale (DCS). Transfer of knowledge to the patient about antidiabetic medications as well as the level of satisfaction of both the patient and clinician were also assessed.

None of the trial results reached statistical significance (Table 1). Although patients in the DA arm displayed lower levels of overall decisional conflict (mean difference, 7.0; 95% CI, −8.1 to 22.2; P = .31), knowledge transfer was high in both groups (mean difference, 2.4%; 95% CI, −16.0 to 20.7; P = .77), and patients allocated to the DA and usual care were equally satisfied.

In the majority of cases, clinicians who had used the DA said that they found the tool to be useful and that it was easy to use and to integrate within their clinical setting.

Table 1. Results of Use of Diabetes Medication Decision Aid Trial

Outcome	Decision Aid (n = 101)	Usual Care (n = 103)	Mean Difference[a]	*P* Value
DCS, overall (95% CI)	17.9 (5.5 to 30.3)	25.0 (10.4 to 39.5)	7.0 (−8.1 to 22.2)	.31
DCS, Informed subscale (95% CI)	21.0 (2.7 to 39.4)	34.6 (13.0 to 56.2)	13.6 (−8.8 to 36.0)	.19
DCS, Support subscale (95% CI)	19.2 (5.0 to 33.4)	22.4 (5.7 to 39.1)	3.2 (−14.2 to 20.5)	.68
DCS, Effective subscale (95% CI)	14.7 (5.4 to 24.0)	19.5 (8.6 to 30.4)	4.8 (−6.6 to 16.1)	.35
Patient knowledge transfer, % (95% CI)	68.4 (53.3 to 83.4)	70.7 (53.0 to 88.4)	2.4 (−16.0 to 20.7)	.77
"I am satisfied with my decision," n (%)				
Strongly agree	52 (53.1)	37 (36.3)	NA	.53
Agree	38 (38.8)	58 (56.9)		
Neither agree nor disagree	8 (8.2)	6 (5.9)		
Disagree	0	1 (1.0)*		
Strongly disagree	0	0		
"I am satisfied with the conversation I had with my clinician," n (%)				
Strongly agree	66 (66.7)	58 (56.9)	NA	.71
Agree	31 (31.3)	44 (43.1)		
Neither agree nor disagree	2 (2.0)	0		
Disagree	0	0		
Strongly disagree	0	0		

DCS, Decisional Conflict Scale.
[a]Positive scores indicate better outcome for the Decision Aid group.
*On May 1, 2015, 1-0 was changed to 1.0.

These clinicians also said that they would be willing to use similar DAs for patients with other chronic diseases. The Greek researchers characterized their results as similar to findings from trials assessing the Diabetes Medication Choice DA in the United States, where promoting patient-centered care via the DA was also positively accepted by clinicians and patients. The authors said, however, that further research is needed to determine the impact of DAs on care experience and outcomes in patients with different background values and preferences.

IDegLira Offers Advantages Over IDeg and Liraglutide in T2DM: DUAL I Results

Written by Lynne Lederman

Glucagon-like peptide 1 agonists have been shown to improve glycemic control and reduce the risk of weight gain and hypoglycemia, but some patients have gastrointestinal (GI) side effects. Basal insulin offers glycemic control even while fasting and allows for individualized dosing but increases the risk of hypoglycemia and weight gain. Combining these 2 agents has many potential advantages, such as improving glycemic control and reducing weight gain, while also reducing the risk of hypoglycemia or GI side effects seen when either agent is used as monotherapy. IDegLira is one such agent and contains a fixed-ratio combination of insulin degludec (IDeg) and liraglutide. The drug contains 0.036 mg of liraglutide for every 1 unit of IDeg.

Stephen C. L. Gough, MD, Oxford Centre for Diabetes, Endocrinology, and Metabolism, Oxford, United Kingdom, discussed 1-year safety and efficacy data from the phase 3, open-label Dual Action of Liraglutide and Insulin Degludec in Type 2 Diabetes: A Trial Comparing the Efficacy and Safety of Insulin Degludec/Liraglutide, Insulin Degludec and Liraglutide in Subjects With Type 2 Diabetes [DUAL I; Gough SCL et al. *Lancet Diabetes Endocrinol.* 2014].

Patients were randomly assigned 2:1:1 to IDegLira (n = 834), IDeg (n = 414), or liraglutide (n = 415). Baseline characteristics were similar for all groups. The average age was 55 years; body mass index was about 31 kg/m^2; HbA_{1c} was 8.3%; and fasting plasma glucose (FPG) was about 9 mmol/L.

HbA_{1c} was lower in the patients treated with IDegLira (6.4%) when compared with either the IDeg group (6.9%) or the liraglutide group (7.0%) at week 26 ($P < .001$ for IDegLira vs both other treatments). These reductions were maintained at 52 weeks (HbA_{1c} = 6.4%, 6.9%, and 7.1%, respectively; $P < .001$ for IDegLira vs both other treatments). The percentages of patients whose HbA_{1c} were < 7% or ≤ 6.5% at the end of weeks 26