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.

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

and 52 were significantly greater in the group treated with IDegLira than in those treated with IDeg or liraglutide ($P < .0001$, all).

The decrease in FGP was similar in the IDegLira and IDeg groups (–3.6 mmol/L) and significantly lower when compared with the liraglutide group (–1.75 mmol/L) at 26 weeks ($P < .001$). These decreases were maintained at 52 weeks, when FPG was 5.7, 6.0, and 7.3 mmol/L, respectively. At both 26 and 52 weeks, confirmed hypoglycemia was lowest with liraglutide and highest with IDeg, although rates were low overall. There was a slight increase in weight with IDeg, a decrease with liraglutide, and a slight but significant decrease with IDegLira when compared with either treatment ($P < .001$).

The rates of nausea in patients receiving IDeg and IDegLira were generally lower than they were for liraglutide. Other adverse events were similar across groups, and those for patients taking IDegLira were as expected for the individual components.

In conclusion, the DUAL I study showed that IDegLira was associated with significantly greater reductions in HbA_{1c}, significantly lower risk of hypoglycemia, and no weight gain as compared with IDeg at 52 weeks. When compared with liraglutide, IDegLira had greater reductions in HbA_{1c} and FPG while resulting in fewer GI adverse events. These data provide further support for the long-term safety and sustainability of the glucose-lowering effect of IDegLira.

Once Weekly Exenatide Is Safe and Effective for Long-term T2DM Treatment

Written by Lynne Lederman

Patients with type 2 diabetes mellitus (T2DM) require long-term treatment with a hypoglycemic agent, but these agents can be difficult in terms of patient adherence. Eric J. Klein, MD, Capital Clinical Research Center, Olympia, Washington, USA, presented 6-year follow-up data on the efficacy of a once-weekly formulation of exenatide. The phase 3 Effects of Exenatide Long-Acting Release on Glucose Control and Safety in Subjects With Type 2 Diabetes Mellitus [DURATION-1; NCT00308139] is the longest assessment of a glucagon-like peptide–1 receptor agonist reported to date [MacConell L et al. *Diabetes Metab Syndr Obes.* 2013].

Inclusion criteria for DURATION-1 included T2DM (treated with either diet and exercise or oral antidiabetic agents), HbA_{1c} 7.1% to 11.0%, fasting plasma glucose (FPG) < 16 mmol/L, and body mass index 25 to 45 kg/m^2 [Taylor L et al. *BMC Endocr.* 2011; Buse JB et al. *Diabetes Care.* 2010; Drucker DJ et al. *Lancet.* 2008]. Patients were randomly assigned 1:1 to weekly or twice-daily exenatide. At the end of 30 weeks, patients could continue on the extension trial with weekly exenatide. According to Dr Klein, there were no differences in the baseline characteristics between the intention-to-treat (ITT) population and the 6-year completer population.

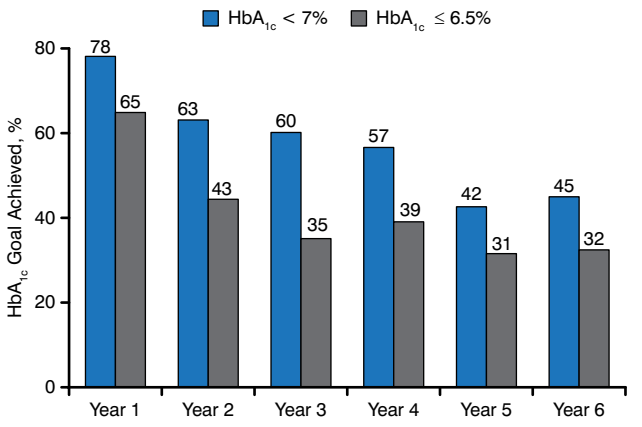
Efficacy data were reported for the population that completed 6 years of follow-up (n = 127). Safety data reported for the ITT population (n = 295) included all individuals who received ≥ 1 dose of exenatide. Drug discontinuation over 6 years of follow-up occurred in 59% of the ITT population (n = 175).

At year 1, the HbA_{1c} level had dropped by 2.2%. The HbA_{1c} level increased over the next 5 years, but at the end of the study the least squares (LS) mean change was –1.6%. The HbA_{1c} level over the entire 6 years was significantly lower than baseline ($P < .05$). The percentages of patients whose HbA_{1c} levels were < 7% or ≤ 6.5% during the course of the study are shown in Figure 1.

FGP decreased by 2.7 mmol/L in the first year. Over the next 5 years, FPG increased but remained lower at study end (–1.6 mmol/L). FPG over the entire 6 years was significantly lower than at baseline ($P < .05$). With regard to weight, patients lost 4.7 kg the first year, regained some weight over the next 2 years, and lost weight again in years 4, 5, and 6. At year 6, the LS mean weight loss was 4.3 kg. Differences from baseline were significantly lower at each year of follow-up except for year 4. There was a decrease in blood pressure after the first year of treatment, but this difference was not sustained over the course of the study.

There were no incremental safety findings, including

Figure 1. Patients Whose HbA_{1c} Levels Were < 7% or ≤ 6.5% Over Time



Six-year completer population (n = 127).

Reproduced with permission from EJ Klein, MD.