The aim of the study was to investigate changes in clinical outcomes by prior therapy subgroup (n=1057). Prior therapy subgroups used in this analysis are shown in Figure 1. Baseline HbA1c, data are shown in Figure 2. Significant reduction from baseline to end of study (EOS, first visit from week 26–36) in HbA1c, was observed in the overall study population (estimated difference: –1.4% [95% confidence interval, CI: –1.51;–1.29]; p<0.0001). Significant reductions in HbA1c, were also observed in every prior therapy subgroup (Figure 2). Significant reductions in fasting plasma glucose were observed in all prior therapy subgroups, except for the basal-bolus insulin subgroup, in which the observed reduction was nonsignificant (Table 1). There were significant reductions in body weight from baseline to EOS in the OAD, basal insulin and basal-bolus prior therapy subgroups. Observed changes in the other two subgroups were nonsignificant (Table 1; Supplementary Figure 1 at the QR code link). Significant reductions in mean total daily insulin dose were observed from baseline to EOS in the prior premix insulin subgroup (~5.9 units [U] [95% CI: –8.94;–2.90]; p=0.0002) and the prior basal-bolus group (~13.8 U [95% CI: –18.24;–9.27]; p=0.0001). In contrast, a significant increase was observed from baseline to EOS in the prior basal-only subgroup (~11.6 U [95% CI: 8.50;14.71]; p<0.0001).

From the 4 weeks prior to baseline to the 4 weeks prior to EOS or discontinuation, incidence of overall non-severe hypoglycaemia showed significant reductions in the prior OAD, basal and premix insulin subgroups. There were significant reductions in the incidence of nocturnal non-severe hypoglycaemia in the prior basal and premix insulin subgroups in the same period (Table 1). Cases of severe hypoglycaemia, occurring within 26 weeks prior to baseline and 26 weeks prior to EOS, were reported in the prior OAD subgroup only, reflecting its low sample size. There was no significant change in incidence (Table 1).

Table 1: Change from baseline in FPG, body weight and incidence of hypoglycaemia by prior anti-diabetic therapy subgroup

<table>
<thead>
<tr>
<th>Prior anti-diabetic therapy</th>
<th>OADs only n=371</th>
<th>Basal insulin n=230</th>
<th>Premix insulin n=232</th>
<th>Basal-bolus insulin n=137</th>
<th>GLP-1 RA ± insulin n=87</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in FPG, estimated difference (95% CI)</td>
<td>–6.7 mg/dL (-73.90;–61.86); p=0.0001</td>
<td>–40.1 mg/dL (-50.58;–29.71); p&lt;0.0001</td>
<td>–29.8 mg/dL (-43.24;–16.34); p&lt;0.0001</td>
<td>–21.4 mg/dL (-44.12;–3.78); p=0.0633</td>
<td>–31.6 mg/dL (-45.38;–17.77); p=0.0001</td>
</tr>
<tr>
<td>Change in body weight, estimated difference (95% CI)</td>
<td>–1.4 kg (-2.32;–0.49); p=0.0028</td>
<td>–1.1 kg (-2.09;–0.07); p=0.0362</td>
<td>–0.3 kg (-1.28;–0.23); p=0.5653</td>
<td>–1.5 kg (-2.70;–0.33); p=0.0215</td>
<td>–0.3 kg (-1.10;–0.77); p=0.6411</td>
</tr>
<tr>
<td>Severe hypoglycaemia, estimated rate ratio (95% CI)</td>
<td>0.31 (0.04;2.32); p=0.2528</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Definition of ‘nocturnal’ was based on patient’s perception of whether it was night-time. Non-severe hypoglycaemia was defined as an episode with symptoms and/or self-measured blood glucose value ≤3.9 mmol/L that the patient was able to self-treat. Severe hypoglycaemia was defined as per the American Diabetes Association definition as an episode requiring assistance of another person to actively administer carbohydrate, glucagon or take other corrective action.

Conclusions

Across all prior therapy subgroups, treatment with IdegAsp was associated with significant improvement in HbA1c, significant reductions in FPG were observed in all subgroups except basal-bolus insulin, and significant reductions in body weight were observed in the prior basal insulin and basal-bolus insulin subgroups.

A significantly reduced incidence of non-severe hypoglycaemia was observed in certain subgroups.

In prior premix and basal-bolus insulin users, significant reductions in total daily insulin dose were observed after switching to IdegAsp.

The results of this subgroup analysis indicate a variety of benefits associated with switching treatment to IdegAsp in a cohort of real-world patients with T2D with different treatment backgrounds.

References: