Similar variability of fasting and 24-h self-measured plasma glucose (SMPG) with insulin glargine 300 U/mL (Gla-300) vs insulin degludec 100 U/mL (IDeg-100) in insulin-naïve adults with T2DM: the randomized BRIGHT trial

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ABSTRACT

Objective: To compare glycemic variability of Gla-300 and IDeg-100 using variability of 24-h self-measured plasma glucose (SMPG), based on 8-point SMPG profiles, and variability of fasting SMPG.

Methods: BRIGHT (NCT02738151) was a multicenter, open-label, parallel-group, randomized, 24-week actively controlled study in insulin-naïve adults with T2DM. 

- Two studies comparing the PK/PD properties of Gla-300 and IDeg-100 are second-generation basal insulins, with improved pharmacodynamic (PD) and pharmacokinetic (PK) properties compared with the first-generation basal insulin, insulin glargine 100 U/mL (Gla-100).
- Variability of 24-h SMPG was assessed as the mean coefficient of variation (CV; calculated as: [standard deviation (SD)/mean] × 100) over 7 days prior to baseline and the visits at 2, 4, 12, and 20, and 24. 
- A mixed model of repeated measures was used to assess the change in variability of 24-h and fasting SMPG, with fixed categorical effects of treatment group, visit, treatment-by-visit interaction; and randomization stratum of saxagliptin/modified use (Yes/No) and HbA1c (<8 %) at baseline. 

Results: Baseline characteristics were comparable in both treatment groups (Table 1).

- Glycemic variability was similar between treatment groups at baseline. 
- Similar increases in mean fasting SMPG variability were seen in both treatment groups from baseline to week 24, with a mean change of 1.22% (0.7% for Gla-300 and 0.7% for IDeg-100, respectively). Least squares (LS) mean difference between treatment groups was –0.48% (–1.22 to 0.98) (Figure 2).

Conclusion: Similar variability in 24-h SMPG and fasting SMPG was observed with Gla-300 and IDeg-100 over the 24-week treatment period.

Table 1: Baseline characteristics (randomized population) 

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Gla-300 (N=442)</th>
<th>IDeg-100 (N=433)</th>
<th>Total (N=875)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>59.7 ± 9.6</td>
<td>59.4 ± 9.7</td>
<td>59.5 ± 9.6</td>
</tr>
<tr>
<td>Gender, % (male/female)</td>
<td>45.7/54.3</td>
<td>46.1/53.9</td>
<td>46.0/54.0</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>31.7 ± 4.3</td>
<td>31.3 ± 4.4</td>
<td>31.5 ± 4.4</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>8.71 ± 0.83</td>
<td>8.57 ± 0.80</td>
<td>8.64 ± 0.82</td>
</tr>
<tr>
<td>Fasting SMPG, mg/dL</td>
<td>109.6 ± 28.8</td>
<td>108.3 ± 28.4</td>
<td>108.9 ± 28.6</td>
</tr>
</tbody>
</table>

DISCUSSION

The present analysis indicates that the differences in glycemic variability between Gla-300 and IDeg-100 reported in previous PK/PD studies do not translate into meaningful clinical differences in variability of 24-h and fasting SMPG.

- Glycemic variability was similar between treatment groups at baseline. 
- As expected in these previously insulin-naïve participants, a slight increase in within-day and day-to-day variability was observed after insulin initiation and titration, for both basal insulins.
- Despite Gla-300 showing within-day and day-to-day plasma glucose variability as low as that of IDeg-100, Gla-300 provided similar increases in plasma glucose variability as IDeg-100 due to the hypoglycemia during the 0–12 week active titration period.
- Gla-300 or IDeg-100 are both suitable treatment options for people with T2DM, with similar glycemic variability, they may be equally effective in reducing the risk of complications associated with hypo- and hyperglycemia.

CONCLUSION

Similar variability in 24-h SMPG and fasting SMPG was observed with Gla-300 and IDeg-100 over the 24-week treatment period.

REFERENCES


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