Effectiveness and safety of Gla-300 vs IDeg-100 evaluated with continuous glucose monitoring profile in adults with type 1 diabetes in routine clinical practice in Spain: OneCARE study

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Introduction

- Less than one-third of people with T1D achieve glycaemic targets¹

- Real-world CGM evidence for the effectiveness of the second-generation BI analogues in T1D is lacking

Objective

To compare the effectiveness and safety of Gla-300 vs IDeg-100, as measured by CGM / FGM in routine clinical practice, in adults with T1D.

Study design

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- Primary endpoint: percentage of time in range (TIR) (70–180 mg/dL) over 14 consecutive days using CGM / FGM

BI, basal insulin; CGM, continuous glucose monitoring; FGM, flash glucose monitoring; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; T1D, type 1 diabetes

*The switch to Gla-300 or IDeg-100 could occur at any time during this period.

Study design and methods

- observational, retrospective cohort, cross-sectional, multicentre study in Spain, including adults with T1D who had switched from a first-generation BI analogue (insulin glargine 100 U/mL or detemir) to either Gla-300 or IDeg-100 within 24 months of the study visit

- CGM / FGM was performed using the Freestyle Libre® device (Abbott), and data from 14 days of consecutive use were analysed

- Primary endpoint: percentage of time in range (TIR) (70–180 mg/dL) over 14 consecutive days using CGM / FGM

- Secondary endpoints included:
  - TBR, percentage of time below range for glucose ranges <54 mg/dL, <70 mg/dL
  - TIR, time in range for glucose ranges 70-140 mg/dL
  - TAR, time above range for glucose ranges >180 mg/dL, >250 mg/dL
  - glycaemic variability, excursions and safety (hyperglycaemia / hypoglycaemia) by CGM / FGM
  - effectiveness and safety through patient history
  - patient satisfaction and physician outcomes
Inclusion and exclusion criteria, statistical considerations

• Inclusion criteria:
  - adults diagnosed with T1D at least 3 years prior to study enrolment
  - switched from ≥3 months of treatment with a basal-bolus insulin treatment (first-generation BI) to Gla-300 or IDeg-100 within the previous 24 months
  - HbA1c ≥7.5% before the switch
  - maintained current treatment ≥3 months

• Exclusion criteria:
  - use of insulin pump, intermediate acting insulin (NPH) or premixed prior or after the switch

• Statistical considerations:
  TIR, TAR and TBR were analysed using an ANCOVA model with treatment group as the fixed effect and baseline glucose level as the covariate

• Sample size calculation showed 214 participants (107 per treatment group) was suitable to address the primary endpoint, considering a minimum difference to detect of 3.3%, with a significance level of 0.05, a statistical power of 0.80 and a standard deviation (SD) of 8.6
Patient characteristics

• 220 people met the inclusion criteria for the study; 104 participants received Glα-300, 95 received IDeg-100.
  - 21 people were excluded from the analysis due to insufficient CGM / FGM data (<14 days or <70% of the time)
• Participants had a relatively long duration of diagnosed T1D (mean of 18.4 years overall); this was shorter for the Glα-300 group than the IDeg-100 group (16.8 ± 10.2 vs 20.2 ± 10.5 years; p=0.0218)
• Diabetic retinopathy was the only comorbidity showing a difference between the two groups (14.4% in Glα-300 vs 27.4% in IDeg-100; p=0.0241)
• There were no significant differences in TIR, TAR or TBR between the treatment groups during the full-day period

• Differences favouring Gla-300 were observed during the night for TIR (both 70–140 and 70–180 mg/dL ranges) and TAR (>180 mg/dL)

**Percentage of time at glucose target levels for different periods during 24 hours**

**A. Full-day period (24 h)**

- TBR
- TIR
- TAR

**B. Night-time period (00:00–06:00 h)**

- TBR
- TIR
- TAR

**Results – Effectiveness from CGM**

Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; NS, not significant; TAR, time above range; TBR, time below range; TIR, time in range
Results – Safety from CGM / FGM and other outcomes

- There were no statistically significant differences between treatment groups in the number of hypoglycaemic episodes.

- The average number of night-time hyperglycaemic episodes per day >250 mg/dL was lower with Gla-300 vs IDeg-100.

- The main reasons for the physician to change BI were poor glycaemic control and frequent hypoglycaemic episodes.

- A higher number of patient-reported hypoglycaemic episodes was seen in all participants before the switch vs after (p=0.0003), with no difference between treatment groups.

- Satisfaction with treatment using the DTSQs did not show a difference between treatment groups; the mean global score was 27.8 points, reflecting high treatment satisfaction.

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**Average number of episodes/d in hypoglycaemia and hyperglycaemia**

**A. Hypoglycaemia**

<table>
<thead>
<tr>
<th></th>
<th>Gla-300</th>
<th>IDeg-100</th>
<th>Gla-300</th>
<th>IDeg-100</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;54 mg/dL</td>
<td>0.13</td>
<td>0.32</td>
<td>0.23</td>
<td>0.31</td>
</tr>
<tr>
<td>p</td>
<td>0.352</td>
<td>0.248</td>
<td>0.073</td>
<td>0.310</td>
</tr>
<tr>
<td>&lt;70 mg/dL</td>
<td>0.11</td>
<td>0.26</td>
<td>0.78</td>
<td>0.71</td>
</tr>
<tr>
<td><strong>Number of episodes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**B. Hyperglycaemia**

<table>
<thead>
<tr>
<th></th>
<th>Gla-300</th>
<th>IDeg-100</th>
<th>Gla-300</th>
<th>IDeg-100</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;180 mg/dL</td>
<td>1.87</td>
<td>1.78</td>
<td>0.25</td>
<td>0.24</td>
</tr>
<tr>
<td>p</td>
<td>0.480</td>
<td>0.178</td>
<td>0.048</td>
<td>0.210</td>
</tr>
<tr>
<td>&gt;250 mg/dL</td>
<td>0.52</td>
<td>0.55</td>
<td>1.00</td>
<td>1.14</td>
</tr>
<tr>
<td><strong>Number of episodes</strong></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

BI, basal insulin; DTSQs, Diabetes Treatment Satisfaction Questionnaire (status version); Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL.
Conclusion

- The OneCARE study from Spain provides the first real-world CGM / FGM evidence for the use of second-generation BI analogues in adults with T1D

- The effectiveness of Gla-300 in adults with T1D, when looking at the full-day TIR 70–180 mg/dL, was similar to that of IDeg-100, which mirrors results found in T2D

- TIR results (70–140 and 70–180 mg/dL) favoured Gla-300 for the night-time period, as did TAR >180 mg/dL
  - This coincided with fewer night-time hyperglycaemic episodes per day >250 mg/dL

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Conclusion

- The results of the OneCARE study show that in a real-world setting in adults with T1D, the effectiveness and safety of Gla-300 was generally similar to IDeg-100 in those switching from first-generation BI analogues.
- People on Gla-300 spent more time in target glucose range at night compared with IDeg-100.

BI, basal insulin; CGM, continuous glucose monitoring; Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; T1D, type 1 diabetes; T2D, type 2 diabetes; TAR, time above range; TIR, time in range