Diabetes Kongress 2021 DDG

Channel 6, Donnerstag, 13.05.2021, 08:30 Uhr

Hier scannen um das vollständige e-Poster oder diese zusammenfassenden Folien herunterzuladen

e-Poster Zusammenfassung

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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Disclosures

Conget – Received a fee from Sanofi-Aventis for coordination of the OneCARE study, and received lecturing and consulting fees from Medtronic, Bayer, GlaxoSmithKline, Eli Lilly, Novo Nordisk, Sanofi-Aventis, Novartis, AstraZeneca and MSD. **E. Delgado** – Received unrestricted research support from AstraZeneca, Novo Nordisk, Sanofi, Pfizer, and Roche, and has received consulting fees and/or honoraria for membership on advisory boards and speaker's bureau from AstraZeneca, Novo Nordisk, Eli Lilly, Sanofi, GlaxoSmithKline, Pfizer, Almirall, Novartis, Abbott Laboratories, Esteve, and MSD. **M.Á. Mangas** – Received consulting fees and/or honoraria for training activities, courses or advisory meetings: Sanofi, Novo Nordisk, Eli Lilly, AstraZeneca, Boehringer Ingelheim, Esteve, Janssen, Abbot, and has received honoraria for participation as a Researcher in clinical trials: Sanofi, Novo Nordisk, AstraZeneca, GlaxoSmithKline, Millendo Therapeutics. **C. Morales** – Clinical Trials: Novo Nordisk, Sanofi, AstraZeneca, Pfizer, Lilly, Merck, Lexicon, FPS, Hanmi, Janssen, Boehringer Ingelheim, Takeda, Roche, Theracos, LeeGanz. Advisory board: Novo Nordisk, Eli Lilly, MSD, Boehringer Ingelheim, AstraZeneca, Sanofi, Abbott. Speaker: Sanofi, Novo Nordisk, AstraZeneca, Roche, Eli Lilly, Boehringer Ingelheim, MSD, Ferrer Pharma, Janssen, Abbot. **J. Caro** – Reports no disclosures. **M. Gimenez** – Received lecturing and consulting fees from Medtronic, Eli Lilly, Novo Nordisk, Sanofi-Aventis, AstraZeneca and MSD**. M. Borrell** – Sanofi employee.

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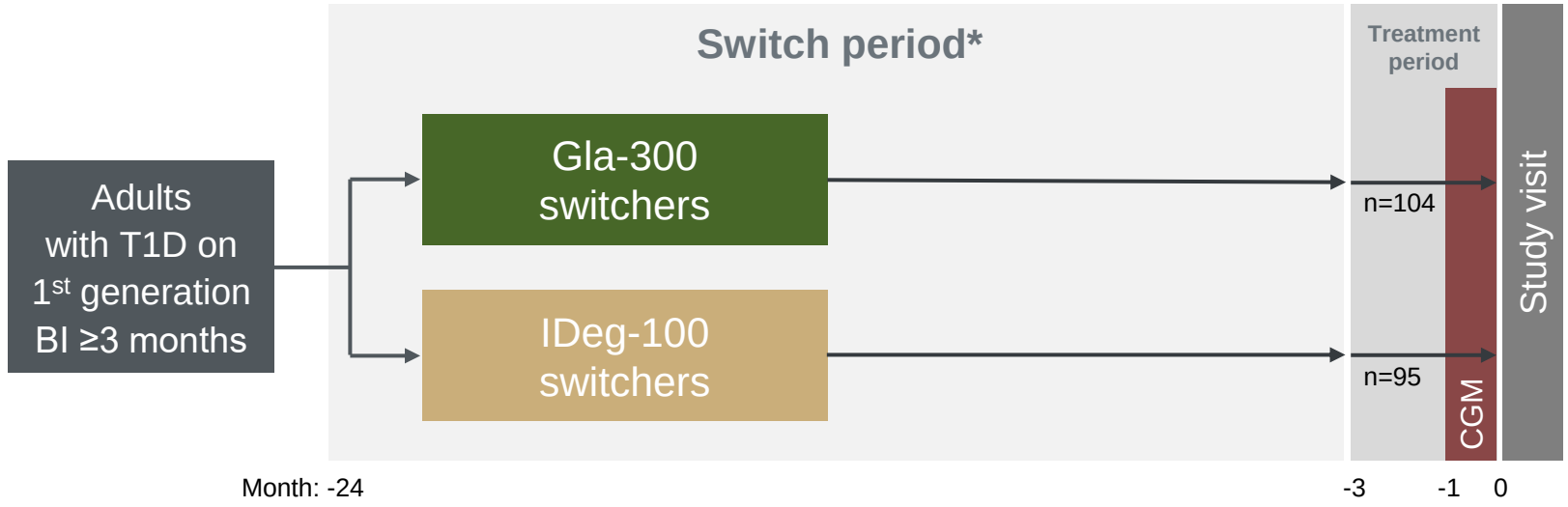
Introduction

- Less than one-third of people with T1D achieve glycaemic targets[1]

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

Study design



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

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.

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.
1. Miller KM, *et al*. *Diabetes Care* 2015;38:971–8.

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

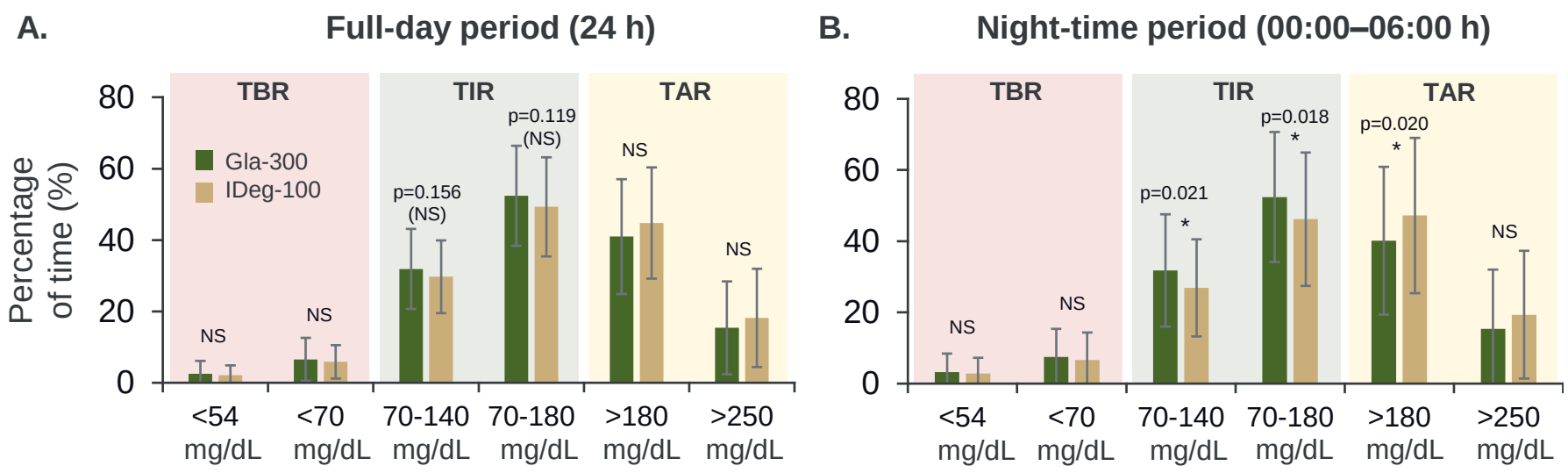
- 220 people met the inclusion criteria for the study; 104 participants received Gla-300, 95 received IDeg-100.
  - 21 people were excluded from the analysis due to insufficient CGM / FGM data (<14 days or <70% of the time)
- Participants had a relatively long duration of diagnosed T1D (mean of 18.4 years overall); this was shorter for the Gla-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 Gla-300 vs 27.4% in IDeg-100; p=0.0241)

Results – Effectiveness from CGM

- 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



- Mean glucose curves were statistically significantly smoother for the Gla-300 vs IDeg-100 group at night

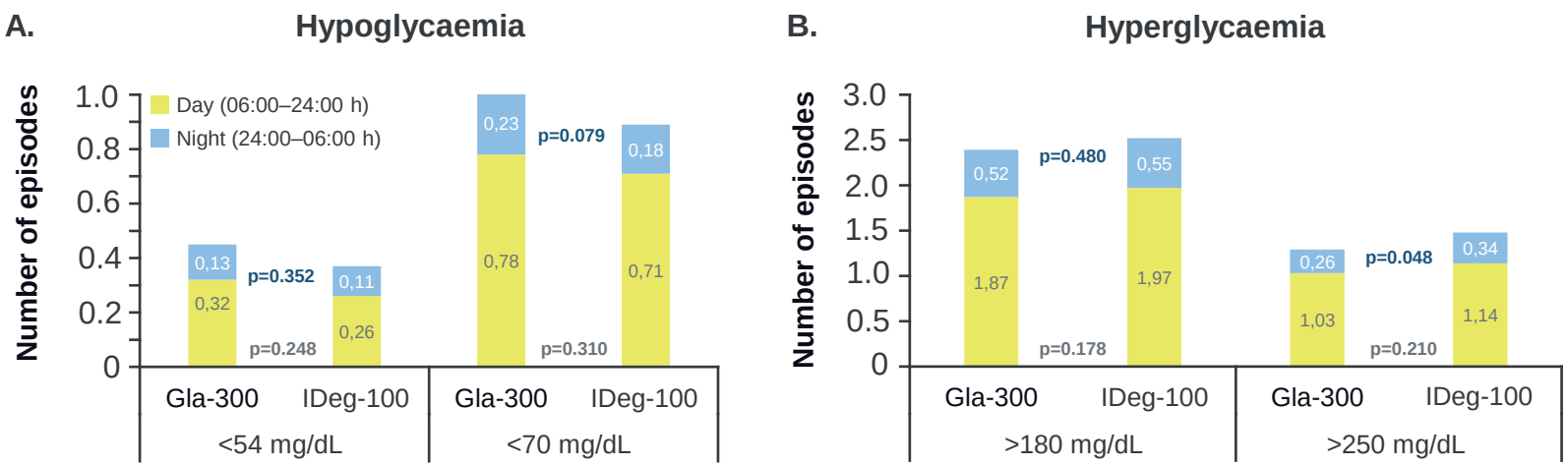
Gla-300, insulin glargine 300 U/mL; IDeg-100, insulin degludec 100 U/mL; NS, not significant; TAR, time above range; TBR, time below range; TIR, time in range

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

Average number of episodes/d in hypoglycaemia and hyperglycaemia



- 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

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[1]

- 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

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

1. Kawaguchi Y, *et al. J Diabetes Investig* 2019;10:343–51.