INTENSIFY: effectiveness of insulin degludec/iraglutide (IDegLira) in a real-world T2DM population in the UAE

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INTENSIFY

Aim

To investigate the effect of IDegLira when used according to routine clinical practice in the linked Arab Emirate (UAE) in a real-world population of patients with type 2 diabetes mellitus (T2DM), inadequately controlled on basal insulin (BI) or glucagon-like peptide-1 receptor agonists (GLP-1 RAs) with or without oral antidiabetic drugs (OADs).

The primary objective was to evaluate the effect of IDegLira on glycemic control. Secondary objectives were to investigate the effect of IDegLira on treatment on other clinical parameters. Safety and patients’ treatment preferences were also investigated.

Introduction

In patients with T2DM who have inadequate glycemic control, combining a GLP-1 RA with BI offers an effective treatment-intensification strategy.

IDegLira (Novo Nordisk) is a fixed-ratio combination of insulin degludec and iraglutide.

IDegLira was launched in the UAE in 2018 for use with OADs, when these medicines (alone or in combination with GLP-1 RAs or BI) do not provide adequate glycemic control.

To date, however, there have been no real-world studies on IDegLira in the UAE.

Methods

Study design

INTENSIFY was a non-interventional, prospective, open-label, real-world study conducted at 31 sites in the UAE between January 2019 and December 2020 (Figure 1).

Throughout the study, visit frequency followed the local standard of care.

Inclusion criteria

Patients with T2DM were eligible if they met key inclusion criteria:

- Age ≥18 years
- Treated with BI or GLP-1 RA x OADs (except DegLira)
- Decision to switch to IDegLira already made by physician
- Available and documented hemoglobin A1c (HbA1c) value ≤12 weeks prior to initiation of IDegLira treatment.

Endpoints

Study endpoints are summarized in Figure 2.

Analysis

Study endpoints were analyzed in the full analysis set (FAS), which comprised all eligible patients who provided informed consent and initiated treatment with IDegLira.

Results

Patients

Of 263 patients comprising the FAS, 234 (88.1%) completed the study.

Among the 263 patients in the FAS, 204 (77.6%) and (57.2%) patients had previously received BI ± OADs and GLP-1 RA ± OADs, respectively.

At baseline, mean HbA1c, was 9.2% (Table 1).

Of 26 patients who discontinued treatment, only one minority discontinued due to adverse events (AEs) [Gl−1 RA] or insufficient glycemic control (28) [17].

Among patients who switched from BI + OADs, previous mean (standard deviation) (SD) insulin dose was 30.1±14.0IU/day.

The most common concurrent antidiabetic medications in both patient subgroups were biguanides (76.2% and 86.9% of patients in the BI ± OADs and GLP-1 RA ± OADs groups, respectively) and sodium glucose co-transporter 2 inhibitors (58.2% and 64.9%, respectively).

HbA1c changes were evaluated in patients who switched from BI to BI ± OADs and those who switched from GLP-1 RA ± OADs.

Table 1: Baseline demographic and clinical characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BI ± OADs (n=234)</th>
<th>GLP-1 RA ± OADs (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>65 (15.4)</td>
<td>65 (16.3)</td>
</tr>
<tr>
<td>Male, %</td>
<td>137 (58.4)</td>
<td>22 (75.9)</td>
</tr>
<tr>
<td>Body weight, kg</td>
<td>98.4 (16.8)</td>
<td>98.4 (15.8)</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>9.2 (1.1)</td>
<td>7.5 (0.7)</td>
</tr>
<tr>
<td>EPG, mg/dL</td>
<td>206 (92)</td>
<td>206 (92)</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Concomitant</td>
<td>32 (13.7)</td>
<td>19 (66.7)</td>
</tr>
<tr>
<td>Primary drug</td>
<td>25 (10.8)</td>
<td>0</td>
</tr>
</tbody>
</table>

Change in HbA1c

- Switching to IDegLira was associated with significant reductions in HbA1c, (Figure 3).
- Mean (standard error [SE]) reductions from baseline of -0.83 (0.14) and -1.29% (0.12), respectively, in patients previously treated with BI ± OADs and GLP-1 RA ± OADs (both p<0.0001).

Change in fasting plasma glucose (FPG)

- There were also significant reductions in FPG, with mean (SE) changes from baseline of -39.48 mg/dL (7.75) in the BI ± OADs subgroup and -66.76 mg/dL (5.65) in the GLP-1 RA ± OADs subgroup (both p<0.0001).

Change in body weight

- A significant reduction in body weight was achieved in patients who switched from BI ± OADs, with an estimated mean (SD) change from baseline of -1.05 (0.25) kg (p<0.0001).

Gastrointestinal adverse events

- No major or severe adverse gastrointestinal events were reported in the study.

Hypoglycemic episodes

The estimated incidence of non-severe, non-serious, and non-serious nocturnal hypoglycemic episodes was numerically lower within 8 weeks prior to end of study or discontinuation versus 4 weeks prior to IDegLira initiation (Figure 4).

Conclusions

- Treatment with IDegLira significantly reduced HbA1c from baseline in patients previously treated with BI ± OADs (both SD). This reduction was greater in previous GLP-1 RA ± OAD users.

IDegLira was also well tolerated with no unexpected safety findings.

- Gastrointestinal and metabolic AEs were the most frequent safety events, but reported rates were very low (1% and 7 events overall, respectively).

- These AEs occurred more frequently in patients who switched from BI ± OADs versus those who switched from GLP-1 RA ± OADs; gastrointestinal AEs, 1% versus 1%; metabolic AEs, 7% versus 0%.

- Most patients (88%) preferred IDegLira over previous treatments and were willing to continue treatment with IDegLira.

References: