Oral Semaglutide vs Sitagliptin: Efficacy by Baseline HbA1c and Baseline OAD in PIONEER 3

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Methods

• POISE 3 was a randomized, double-blind, placebo-controlled, parallel-group, investigator-initiated, multinational trial in patients with T2D.

• Patients were randomized to receive once-daily oral semaglutide 7 mg, 14 mg, or placebo. Patients were randomized to either sitagliptin or placebo at improving glycemic control and reducing body weight after 26 weeks.

• This exploratory analysis of POISE 3 investigated baseline HbA1c (HbA1c) and baseline oral antidiabetic drug (OAD) with an effect on the glycemic efficacy of oral semaglutide vs sitagliptin.

• For the binary endpoint, missing values of HbA1c were imputed from patients with the same HbA1c level from the same treatment arm of the on-treatment analysis.

• The results were combined using Rubin’s rule.

• Baseline demographics and disease characteristics were similar across all baseline HbA1c and background OAD subgroups (Figure 1).

• Patients achieving HbA1c <7.0% were statistically significantly greater at receiving 14 mg semaglutide vs placebo.

• The exploratory analysis was based on the trial product analysis, including patients with baseline HbA1c ≥9.0% who were treated with semaglutide 14 mg at baseline.

Funding statement

This trial was sponsored by Novo Nordisk and is registered with ClinicalTrials.gov (NCT01773250).

Results

1. Baseline characteristics

1.1. Baseline demographics and disease characteristics

Table 1: Baseline demographics and disease characteristics by subgroup

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Weight</th>
<th>Height</th>
<th>Age</th>
<th>Sex (M/F)</th>
<th>BMI</th>
<th>Diabetes duration</th>
<th>HbA1c</th>
<th>Baseline OAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>100</td>
<td>70.4</td>
<td>1.76</td>
<td>6</td>
<td>54/46</td>
<td>28.1</td>
<td>5.6</td>
<td>7.1</td>
<td>Metformin</td>
</tr>
<tr>
<td>7 mg</td>
<td>100</td>
<td>70.4</td>
<td>1.76</td>
<td>6</td>
<td>54/46</td>
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<td>Metformin</td>
</tr>
</tbody>
</table>

1.2. Change from baseline in HbA1c

Figure 2: Change from baseline in HbA1c at week 26. A, By baseline HbA1c. B, By baseline OAD.

2. Patients achieving HbA1c <7.0%

3. Safety

4. Discussion

5. Conclusion

References

2. The authors acknowledge the John M. Denzil and Mary E. Denzil Ericksen Fellowship for medical writing assistance.

Figure 1: Baseline demographics and disease characteristics by subgroup. HbA1c, glycated hemoglobin; SU, sulfonylurea; T2D, type 2 diabetes.