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Synopsis of the original article ***Efficacy and safety of oral semaglutide by subgroups of patient characteristics in the PIONEER phase 3 programme***

Aroda VR, et al. Diabetes Obes Metab. 2022;24:1338–50.
doi: 10.1111/dom.14710

Synopsis created and reviewed by Novo Nordisk

Aims

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To evaluate the efficacy and safety of oral semaglutide versus comparators by patient characteristic subgroups in patients with type 2 diabetes.

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Methods

Endpoints were assessed for oral semaglutide (7 mg, 14 mg and flex) or comparators across all baseline subgroups

Endpoints

- Change from baseline in HbA_{1c}
- Change from baseline in body weight
- Achievement of HbA_{1c} <7.0%

Subgroups

- Age
- Race
- Ethnicity
- Diabetes duration
- Body mass index
- HbA_{1c}

Treatment differences were analysed using a mixed model for repeated measurements for continuous variables and a logistic regression model for the binary endpoint

Pooled safety data were analysed descriptively

Flex, flexible dosing.

Results

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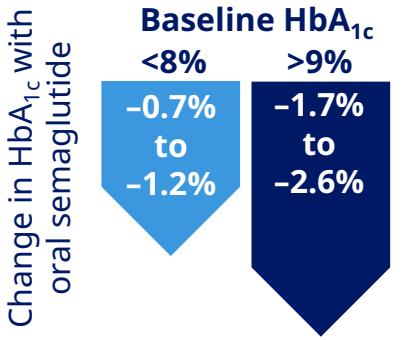
Changes from baseline in HbA_{1c} and body weight, and the odds of achieving HbA_{1c} <7.0% versus comparators (n=2077) across most subgroups were:

- Greater with oral semaglutide 14 mg/flex (n=1934)
- Higher or similar with oral semaglutide 7 mg (n=823)

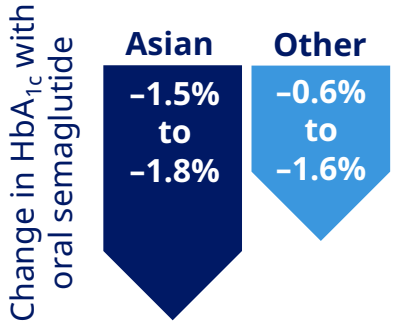
Changes in HbA_{1c} with oral semaglutide 14 mg/flex were greater for patients with higher baseline HbA_{1c}



Overall incidence of adverse events with oral semaglutide was similar to comparators and consistent across subgroups

More gastrointestinal adverse events were observed with oral semaglutide, versus comparators, across subgroups

In some trials, Asian patients experienced greater HbA_{1c} reductions with oral semaglutide 14 mg/flex than other racial populations



Flex, flexible dosing.

Conclusions

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Oral semaglutide demonstrated consistently greater HbA_{1c} and body weight reductions across a range of patient characteristics

Greater HbA_{1c} reductions were seen at higher baseline HbA_{1c} levels

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