Impact of Glucagon-like Peptide-1 Treatments on Patient-Reported Outcomes in Type 2 Diabetes Mellitus

PCR129

Haiyan Sun, MS.[1], Jonathon Briggs, PhD.[2], Zarmina Khankhel, MPH[1]

[1]Genesis Research Group US; [2]Genesis Research Group, UK

Introduction

- Patients with type 2 diabetes mellitus (T2DM) experience substantial impact on health-related quality of life (HRQoL).
- Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are increasingly used in T2DM.

Objective(s)

- **To synthesize data via meta-analysis of emerging evidence of GLP-1 RA impact on patient-reported outcomes (PROs) from key randomized controlled trials.**

Methods

Targeted literature review

- A search of ClinicalTrials.gov clinical trial records conducted in June 2025 for randomized controlled trials (RCTs) evaluating GLP-1 RAs in adults with T2DM.
- Database searches were supplemented by handsearching of publications corresponding to the ClinicalTrials.gov record.
- RCTs were evaluated for inclusion in the targeted literature review based on the criteria in **Table 1**.
- Key study characteristics were extracted from studies meeting the review inclusion criteria and recorded in a standardized workbook, including sample size, population, intervention, comparator, any outcome, PRO outcomes and follow-up period/ reported time points.

Table 1. Targeted literature review inclusion criteria

Criteria	Inclusion criteria	Exclusion criteria
Patient population	Adult patients (≥18 years) with T2DM	Patients receiving GLP-1 RAs for weight management
Intervention(s)	Exenatide, Liraglutide (Victoza), Lixisenatide, Dulaglutide, Semaglutide (Rybelsus), Tirzepatide	Any other intervention
Comparator	Placebo	Any active comparator
Outcomes	Any patient reported outcome or quality of life measure	
Study design	RCT only	Single-arm trials, retrospective studies or SLRs

GLP-1 RAs, Glucagon-like peptide-1 receptor agonists; RCT, randomized controlled trial; T2DM, type 2 diabetes mellitus

Meta-analysis

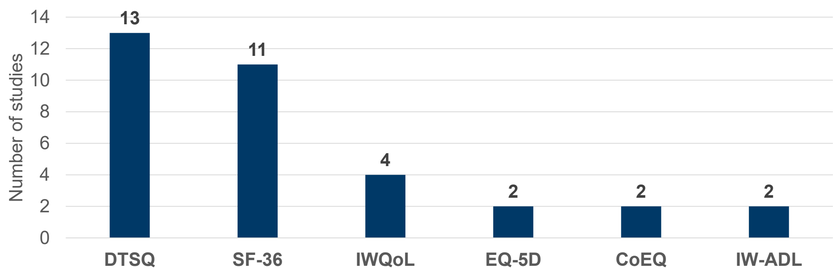
- Random-effects meta-analyses were conducted for outcomes with sufficient data
- Linear mixed-effects models with inverse-variance weighting accounted for between-study variability.
- Heterogeneity was assessed using the I² statistic.
- Study-level estimates were stratified by dose and timepoint.

Results

Targeted literature review

- In total, 58 studies were identified meeting the inclusion criteria of this review (**Table 1**).
- Of these 58 studies, 20 studies reported at least one PRO.
- The most reported general PRO was SF-36 PCS/MCS (n=11 studies) and the most reported disease specific PRO was DTSQ (n=13 studies; **Figure 1**)

Figure 1. PROs reported by number of studies



DTSQ, Diabetes Treatment Satisfaction Questionnaire Status; EQ-5D, EuroQOL-5 dimensions questionnaire; IW-ADL, Impact on Weight Activities of Daily Living; IWQoL, Impact of Weight on Quality of Life; SF-36, short form-36 questionnaire; PRO, patient reported outcomes.

Results

Figure 2. DTSQ a) at 6 months and b) at 12 months

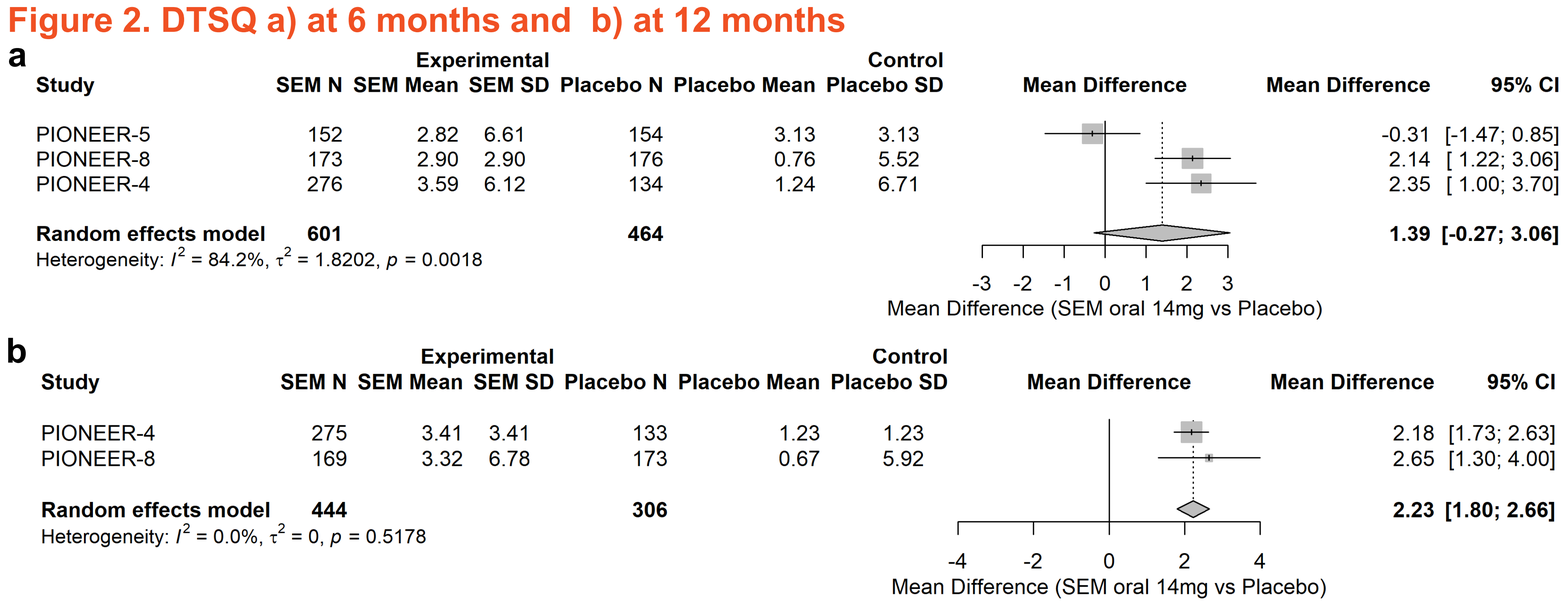
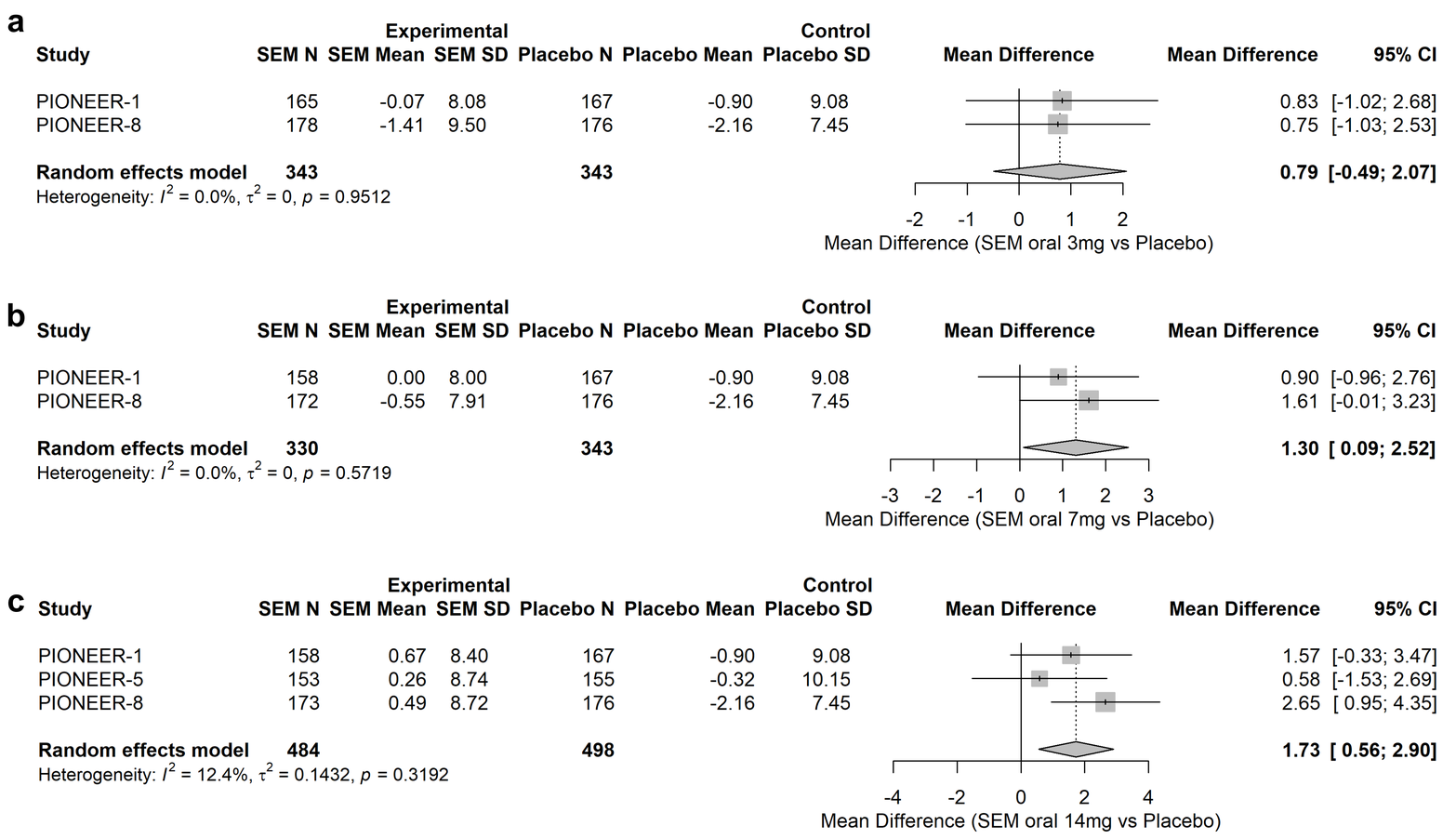


Figure 3. SF-36 MCS at 6months with a) SEM 3mg b) SEM 7mg and c) SEM 14mg



Meta-analysis

- Identified studies were assessed for similarity in patient characteristics, study design, outcomes and timepoints.
- 4 RCTs (PIONEER 1, 4, 5, 8) reported sufficiently comparable PRO data for inclusion; all evaluated oral semaglutide (SEM) versus placebo using diabetes treatment satisfaction questionnaire (DTSQ) and SF-36- physical/ mental component score (PCS/MCS) outcomes

DTSQ

- At 6 months, DTSQ outcomes showed high heterogeneity (**Figure 2a**).
- At 12 months, SEM 14 mg was associated with significant improvement in treatment satisfaction score (**Figure 2b**).

SF-36 –PCS/MCS

- For the SF-36 PCS, 6-month changes were small and non-significant across doses.
- For the MCS, 6-month improvements were dose-dependent and statistically significant at higher SEM doses (**Figure 3a-c**).

Limitations

- The literature review used to gather evidence for synthesis was not systematic and only use one literature database
- A limited number of studies were included in the meta-analysis

Conclusions

- **Key clinical trials in the development of GLP-1 RAs did not consistently report impact on patient quality of life or treatment satisfaction**
- **Although meta-analyses were limited to a small subset of trials and not informed by a systematic literature review, the available evidence suggests oral SEM improves treatment satisfaction and mental health–related quality of life in adults with T2DM**
- **Future research would benefit from standardized collection and reporting of PROs in GLP-1 RA trials to strengthen the evidence base for additional GLP-1s and allow for cross-treatment comparisons.**

References

1. PIONEER-1 (NCT02906930); https://clinicaltrials.gov/study/NCT02906930
2. PIONEER-4 (NCT04923191); https://clinicaltrials.gov/study/NCT04923191
3. PIONEER-5 (NCT04596631); https://clinicaltrials.gov/study/NCT04596631
4. PIONEER-8 (NCT03021187); https://clinicaltrials.gov/study/NCT03021187

Disclosures

This study was conducted by Genesis Research Group.

Contact information:
Zarmina Khankhel: zarmina.khankhel@genesisrg.com

Presented at the ISPOR EU, Nov 9-12, 2025, Glasgow, UK