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Patient-Reported Outcomes in Adults Initiating Treatment with Tirzepatide or Intensified Conventional Care Early In the Course of T2D: Results After 2 Years of Treatment in SURPASS-EARLY

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Kristina Boye[1], Palash Sharma[1], Arkopal Choudhury[1], Elisa Gomez[1], Suzanne Williamson[2], Vivian Thieu[1]

[1]Eli Lilly and Company, Indianapolis, IN, USA
[2]Greenwich HE&OR Ltd., London, UK

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OBJECTIVE

- We evaluated the HRQoL of adults recently diagnosed with T2D (within 4 years) treated with tirzepatide 15 mg or MTD, or ICC, in SURPASS-EARLY over a 2-year timeframe

CONCLUSIONS

- In addition to the primary findings of improved HbA1c and weight,[1] tirzepatide treatment significantly improved overall physical and psychosocial health and functioning, and weight-related quality of life after 2 years of treatment, specifically the ability to perform daily activities and self-perception, compared with existing treatment options in adults who initiated treatment early in the course of T2D in the SURPASS-EARLY trial
- Although diabetes management focuses on the prevention of complications via control of glucose levels, weight, cardiovascular risk, and cardiorenal damage,[2] improving and maintaining health-related quality of life may be of equal importance to patients

Limitations

- The PROs were administered in a clinical trial setting; therefore, results may not reflect those that may be observed in a real-world setting
- The open-label study design may have influenced participants to over or underestimate their treatment assessments based on their beliefs regarding assigned treatment

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INTRODUCTION

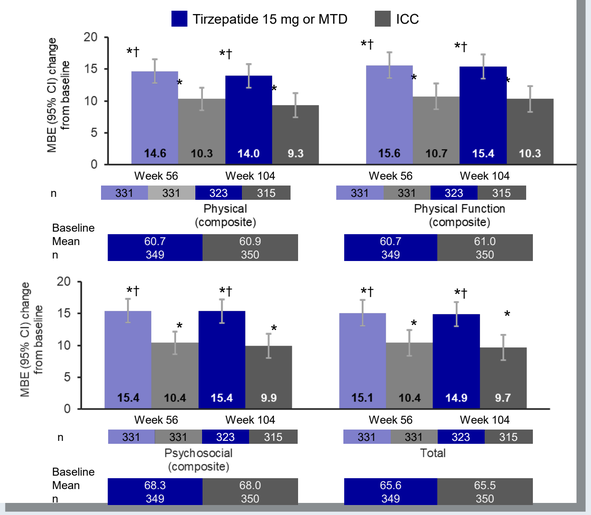
- The UKPDS longitudinal study identified a "legacy effect" in which early glycemic control following the diagnosis of T2D led to long-term improvement in key clinical outcomes[3–5]
- Tirzepatide is a long-acting dual GIP/GLP-1 RA for the treatment of T2D[6] and obesity[7] that has shown greater improvement in glycemic control than GLP-1 RAs in clinical trials of T2D[8,9]
- SURPASS-EARLY was designed to test the hypothesis that initiation of tirzepatide early after T2D diagnosis could establish better and more durable glycemic control than ICC over a 4-year planned study[1]

METHODS – STUDY DESIGN

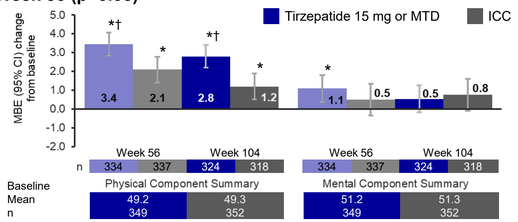
- A Phase 4, randomized, open-label, parallel-group, multicenter, multinational study of the long-term efficacy and safety of tirzepatide vs. ICC
- Adults diagnosed with T2D within the last 4 years, inadequately controlled with diet, exercise, and metformin were randomized (1:1) to tirzepatide 15 mg or MTD, or ICC, for 4 years
- ICC treatments included a range of GLMs approved for the treatment of T2D (except tirzepatide) in accordance with guidelines and local product labels. Dosing was individualized to safely achieve optimal glycemic control (within a non-diabetic range)
- Primary endpoint was change from baseline in HbA1c (%) (non-inferiority) at Week 104; key secondary endpoints included change from baseline in weight (kg) (superiority) at Week 104
- HRQoL was measured at baseline and Weeks 56 and 104 using four PRO measures

KEY RESULTS

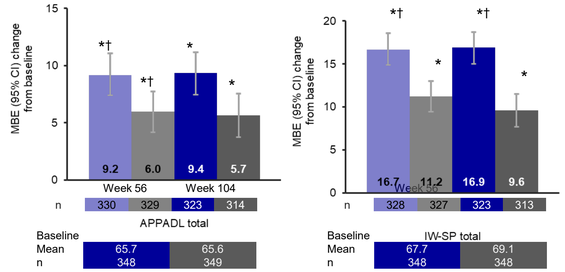
Participants in the tirzepatide 15 mg or MTD group had improved transformed IQWOL-Lite-CT composite and total scores vs. baseline and vs. participants in the ICC group at Weeks 56 and 104 (all p<0.05)



Participants in the tirzepatide 15 mg or MTD group had improved SF-36v2 PCS scores vs. baseline, and vs. participants in the ICC group, at Weeks 56 and 104 (both p<0.05); the SF-36v2 MCS score was only improved vs. baseline in the tirzepatide group at Week 56 (p<0.05)



Participants in the tirzepatide 15 mg or MTD group had improved transformed APPADL and IW-SP total scores vs. baseline and vs. participants in the ICC group at Weeks 56 and 104 (all p<0.05)



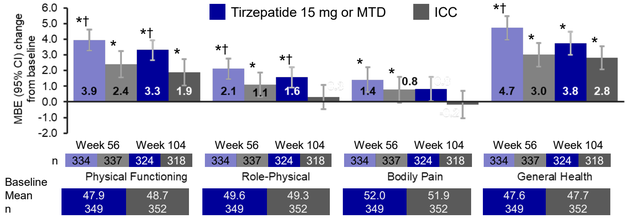
Methods – statistical analyses

- PRO analyses were performed on the randomized population using data prior to treatment discontinuation and without use of rescue medication (efficacy estimand)
- MMRMs assessed changes from baseline to Weeks 56 and 104, for each PRO measure: IWQOL-Lite-CT, SF-36v2, APPADL, and IW-SP
- Only randomized participants with a non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in the analysis
- IWQOL-Lite-CT composite and total, and APPADL and IW-SP total raw scores were transformed to a score from 0–100 and positive changes in scores indicate better outcomes for all PRO measures

Results

- In SURPASS-EARLY, 794 participants were randomized to study treatment (398 to tirzepatide 15 mg or MTD, and 396 to ICC)[1]
- At baseline, mean (SD) age was 53.5 (10.3) years, T2D duration was 2.6 (1.6) years, HbA1c was 7.81 (0.82) %, and BMI was 35.4 (5.5) kg/m^2; 50.6% of participants were male, 81.5% were white, and 45.9% were of Hispanic or Latino ethnicity
- At Week 104, the ICC medications were GLP-1 RAs (85.3%), SGLT-2 inhibitors (16.7%), SUs (3.2%), insulin (2.6%), and DPP4 inhibitors (2.0%)
- Tirzepatide 15 mg or MTD was superior to ICC for change from baseline in HbA1c at Week 104 (ETD –0.79%, 95% CI –0.94, –0.64, p<0.001) and for change from baseline in weight at Week 104 (ETD –9.3, 95% CI –10.8, –7.9, p<0.001)

Tirzepatide 15 mg or MTD improved SF-36v2 Physical Functioning and Role-Physical domain scores vs. baseline and vs. ICC at Weeks 56 and 104; General Health improved vs. baseline and ICC at Week 56 and vs. baseline at Week 104; Bodily Pain improved vs. baseline at Week 56 (all p<0.05)



Participants in the tirzepatide 15 mg or MTD group had improved SF-36v2 Vitality and Mental Health domain scores vs. baseline at Weeks 56 and 104 (all p<0.05), but not vs. participants in the ICC group; improvements in the Social Functioning and Role-Emotional domains were significant vs. baseline at Week 56 but not at Week 104, or vs. ICC at either timepoint

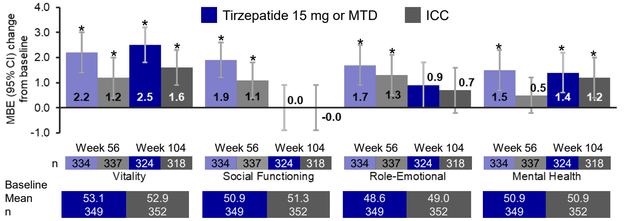


Figure footnotes: **p<0.05 vs. baseline; †p<0.05 vs. ICC. n=number of subjects in the population with value at the specified time point. MMRM included treatment by visit interaction as a fixed effect, and geographic region, baseline HbA1c group (≤8% or >8%), age, and baseline value as covariates. A two-sided alpha-level of 0.05 was used for all statistical comparisons and the endpoints were not adjusted for multiplicity. IWQOL-Lite-CT composite and total scores assessed weight-related functioning (no published MID). SF-36v2 acute form PCS and MCS, and eight domain scores assessed multiple aspects of physical and mental health and functioning (MIDs: PCS, General Health, and Vitality 2 points; MCS, Physical Functioning, Role Physical, Bodily Pain, Social Functioning, and Mental Health 3 points; Role-Emotional 4 points). APPADL total score assessed ability to perform tasks of daily living (MID 6–14 points). IW-SP total score assessed self-perception relating to body weight (MID ≥25 points).*

Abbreviations: APPADL, Ability to Perform Physical Activities of Daily Living; BMI, body mass index; CI, confidence interval; DPP4, dipeptidyl peptidase 4; ETD, estimated treatment difference; GIP, glucose-dependent insulinotropic polypeptide; GLM, glucose-lowering medication; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; HRQoL, health-related quality of life; ICC, intensified conventional care; IWQOL-Lite-CT, Impact of Weight on Quality of Life-Lite-Clinical Trials Version; IW-SP, Impact of Weight on Self-Perceptions; MBE, model-based estimate; MCS, Mental Component Summary; MID, minimally important difference; MMRM, mixed model for repeated measures; MTD, maximum tolerated dose; PRO, patient-reported outcome; PCS, Physical Component Summary; RA, receptor agonist; SD, standard deviation; SF-36v2, 36-item Short Form Health Survey; SGLT-2, sodium glucose co-transporter-2; SU, sulfonylurea; T2D, type 2 diabetes; UKPDS, United Kingdom Prospective Diabetes Study.

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