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Improved Mental And Psychosocial Patient-Reported Outcomes Among People With Obesity Treated With Tirzepatide: Results From SURMOUNT-1 Study

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Background: Living with obesity negatively impacts a person's mental health and psychosocial function, leading to impaired health-related quality of life (HRQoL). Tirzepatide resulted in clinically sustained reductions in body weight among participants with obesity in SURMOUNT-1, a Phase 3 randomized clinical trial. To determine the impact of tirzepatide treatment on mental health and psychosocial function, changes in HRQoL were assessed in SURMOUNT-1 using the Short Form 36 health survey version 2 acute form (SF-36v2) and the Impact of Weight on Quality of Life-Lite Clinical Trials Version

(IWQOL-Lite-CT). **Methods:** A total of 2,539 participants were included in the study (tirzepatide 5 mg, N=630; 10 mg, N=636; 15 mg, N=630; placebo, N=643). The SF-36v2 (36 items) and IWQOL-Lite-CT (20 items) were collected at both baseline and endpoint of primary treatment period (week 72 or early discontinuation, where last observation was carried forward (LOCF)). The SF-36v2 assesses eight domains of HRQoL including role-emotional and mental health, and yields two additional summary scores, including the Mental Component Summary (MCS) score. SF-36v2 scores are norm-based with mean (SD) 50 (10). IWQOL-Lite-CT assesses three primary composites, including 13-item psychosocial composite score. IWQOL-Lite-CT composite scores were transformed to a scale of 0 to 100. Higher scores of both SF-36v2 and IWQOL-Lite-CT indicates better levels of health and psychosocial function. Estimated mean change from baseline to week 72 for SF-36v2 (norm-based) and IWQOL-Lite-CT composite (transformed) scores were analyzed using an analysis of covariance (ANCOVA) model. **Results:** Mean scores at baseline for tirzepatide 5, 10, 15 mg doses and placebo for SF-36v2 role-emotional were 50.7, 51.0, 50.5, and 50.8, respectively, and for mental health were 53.4, 54.0, 53.4, and 53.4, respectively. Mean MCS scores at baseline for tirzepatide 5, 10, 15 mg doses and placebo were 53.3, 53.8, 53.4, and 53.5, respectively. Mean scores at baseline for tirzepatide 5, 10, 15 mg doses and placebo for IWQOL-Lite-CT psychosocial composite score were 64.3, 62.1, 63.2, and 63.2, respectively. All doses of tirzepatide showed significant improvements at week 72 compared to placebo for both SF-36v2 and IWQOL-Lite-CT scores ($p < 0.05$). Estimated mean change from baseline to week 72 with tirzepatide 5, 10, 15 mg doses versus placebo were as follows: SF-36v2 role-emotional scores, 1.7, 1.3, and 1.8, versus 0.3 ($p < 0.05$); SF-36v2 mental health scores 0.8, 0.8, and 1.1, versus -0.2 ($p < 0.05$); SF-36v2 MCS scores were 0.7, 0.4, and 0.7 versus -0.5 ($p < 0.05$); IWQOL-Lite-CT psychosocial scores 19.6, 22.1, and 23.6 versus 11.0 ($p < 0.001$). **Conclusion:** In SURMOUNT-1, tirzepatide demonstrated statistically significant improvements in patient-reported mental health and psychosocial function as assessed by SF-36v2 and IWQOL-Lite-CT, compared to placebo.

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