

Validation of a Questionnaire to Assess Emotional Impact of Treatment for Type 2 Diabetes (EIDTQ)

Kristina S Boye¹, Louis S Matza², Katelyn N Cutts², Karen G Malley², Karin S Coyne²

¹Eli Lilly and Company, Indianapolis, IN, USA; ²Outcomes Research, Evidera Inc., Wilmington, NC, USA

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METHODS

Study Design

- Patients with T2D treated with a range of medications (oral medications, glucagon-like peptide-1 [GLP-1] receptor agonists, tirzepatide, insulin) were recruited from eight clinical sites in the US.
- All participants completed patient-reported outcome (PRO) measures at visit 1, and approximately one-third of the patients were randomly selected to participate in a second visit 7±2 days later so that test-retest reliability could be assessed for the EIDTQ-Status.

Participants

- Participants were required to meet the following criteria: >18 years of age and a current resident of the US; diagnosed with T2D for at least 6 months; currently prescribed medication for T2D for at least 4 months; previously been treated with a medication for T2D that differs from their current medication; and willing and able to complete the protocol requirements and consent to the study

Measures

- EIDTQ-Status:** A 14-item PRO measure developed to assess the emotional impact of current T2D medications on patients in the past week. Respondents rate the frequency of experiencing each emotion on a 5-point scale ranging from "never" to "almost always."⁹
- Simplicity of Diabetes Treatment Questionnaire:** A 10-item PRO measure developed to assess the simplicity and complexity of a patient's current treatment for T2D. Respondents rate the simplicity or complexity of each treatment attribute on a 5-point scale ranging from "very complex" to "very simple."¹⁰
- Treatment Related Impact Measure – Diabetes (TRIM-D):** A 28-item PRO measure assessing five domains: treatment burden, daily life, diabetes management, compliance, and psychological health.¹¹

- Diabetes Treatment Satisfaction Questionnaire (DTSQ-Status):** PRO measure developed to assess patients' satisfaction with their diabetes treatment.¹²
- Short Form (36) Health Survey (SF-36v2):** Measure of health-related quality of life using a 1-week recall period and norm-based scoring (from the US general population).¹³

Analysis

- Analyses focused on item performance, subscale identification (including exploratory factor analysis), development of a scoring algorithm, internal consistency reliability, test-retest reliability, and construct validity (including convergent and known-groups validity).
- A *t* test was utilized to examine differences in the EIDTQ subscale and total scores for patients taking tirzepatide compared with injectable semaglutide.

RESULTS

Sample Description

- A total of 250 patients living with T2D in the US were recruited (mean age = 59.7 years; 54.4% female). The majority of participants were White (70.8%) or Black (16%).
- Most participants were currently taking oral diabetes medication (70.4%), followed by an injectable GLP-1 (38.4%), insulin (33.2%), and an injectable dual glucose-dependent insulinotropic polypeptide/GLP-1 (24.0%). These categories are not mutually exclusive.

Item Reduction and Subscale Identification

- Item-to-item correlations were examined to identify possible redundancies in the EIDTQ items. All items were found to be strongly correlated (range: -0.13 to 0.78), suggesting no item should be dropped from the measure due to redundancies.
- The Scree plot suggested a two- or three-factor solution. Factor loadings (standardized regression coefficients emerging from the PROMAX rotation) for the three-factor solution ranged from 0.58 to 0.82 for the positive items, 0.76 to 0.87 for the negative items, and 0.61 to 0.86 for the control items with no factor cross-loading for any of the items, supporting the three-factor solution.
- The three-factor solution was further supported by the Cronbach's alpha for the following three subscales demonstrating good internal consistency reliability: positive emotions (eight items; $\alpha = 0.92$), negative emotions (three items; $\alpha = 0.88$), and sense of control over diabetes, eating, and weight (three items; $\alpha = 0.85$). There is also a total score representing overall emotions (all 14 items; $\alpha = 0.77$) (Table 1).
- Scoring is based on a mean of all items within each subscale, transformed to a 0 to 100 scale.

Table 1. EIDTQ-Status Exploratory Factor Analysis (N=250)

EIDTQ-Status	Exploratory Factor Analysis ^a		
	Factor 1	Factor 2	Factor 3
Item 1: Hopeful	0.74631		
Item 2: Optimistic	0.81494		
Item 3: Happy	0.78789		
Item 4: Relieved	0.82178		
Item 5: Self-confident	0.77549		
Item 6: Good about myself	0.73806		
Item 7: Motivated	0.76373		
Item 8: Energetic	0.58380		
Item 9: In control of my diabetes		0.61332	
Item 10: In control of my eating		0.85564	
Item 11: In control of my weight		0.82571	
Item 12: Fearful			0.78833
Item 13: Frustrated			0.76472
Item 14: Worried			0.86671

Abbreviation: EIDTQ = Emotional Impact of Diabetes Treatment Questionnaire

^aFactor 1 is the Positive Emotions subscale; Factor 2 is the Sense of Control Over Diabetes, Eating, and Weight subscale; Factor 3 is the Negative Emotions subscale

Reliability

- The EIDTQ demonstrated good test-retest reliability with intraclass correlation coefficients of 0.85 for the positive emotions subscale, 0.67 for the negative emotions subscale, 0.62 for the control subscale, and 0.88 for the total score.

Validity

- The EIDTQ-Status demonstrated convergent validity via strong, significant correlations (all *P* values <0.0001) with all measures evaluating similar concepts, including the DTSQ-Status treatment satisfaction score, TRIM-D psychologic health subscale score, and SF-36 v2 physical and mental component score. Divergent validity was supported by correlations suggesting no association with body mass index or HbA1c.
- Participants who reported greater emotional health had significantly (all *P* values <0.0001) greater positive emotions, fewer negative emotions, a greater sense of control, and a greater EIDTQ total score than participants who reported fair emotional health or lower (Table 2).

Table 2. Known-Groups Validity: EIDTQ-Status Scores by Overall Rating of Emotional Health Over the Past Week (N=250)

EIDTQ-Status Transformed Scores ^a	Overall Rating of Emotional Health Over the Past Week					Overall <i>F</i> Value	<i>P</i> value	Significant Pairwise Comparisons ^b
	Excellent (N=67) Mean	Very good (N=96) Mean	Good (N=50) Mean	Fair (N=32) Mean	Poor (N=5) Mean			
Positive Emotions	86.60	81.22	76.65	58.83	48.50	21.06***	<0.001	B*, C***, D***, F***, G***, H***, I**
Negative Emotions	83.99	78.42	72.35	62.27	36.50	9.62***	<0.001	C***, D***, F*, G**, I*
Sense of Control Over Diabetes, Eating, and Weight	81.12	75.08	70.70	59.69	36.50	9.89***	<0.001	C***, D***, F*, G**, I*
Total	84.63	79.42	74.35	59.69	43.00	22.89***	<0.001	B**, C***, D***, F***, G***, H***, I***

Abbreviations: EIDTQ = Emotional Impact of Diabetes Treatment Questionnaire; SD = standard deviation; ^a For Emotional Health = Very good, the EIDTQ-Status Negative Emotions score could not be calculated for participant 3021. For Emotional Health = Good, the EIDTQ-Status Negative Emotions score could not be calculated for participant 2041; ^b Scheffé post hoc pairwise comparisons: A: Excellent vs. Very good; B: Excellent vs. Good; C: Excellent vs. Fair; D: Excellent vs. Poor; E: Very good vs. Good; F: Very good vs. Fair; G: Very good vs. Poor; H: Good vs. Fair; I: Good vs. Poor; J: Fair vs. Poor
P*<0.05; *P*<0.01; ****P*<0.001

- Participants who reported that their diabetes medication was simple had higher positive emotions, fewer negative emotions, a greater sense of control, and a greater EIDTQ total score than participants who reported that their medication was complex (Figure 1). The EIDTQ-Status also discriminated among groups of patients categorized based on responses to individual items of the TRIM-D such as item 4a (control of diabetes), 4d (manage weight), and item 7a (feel depressed) (all *P* values <0.0001).

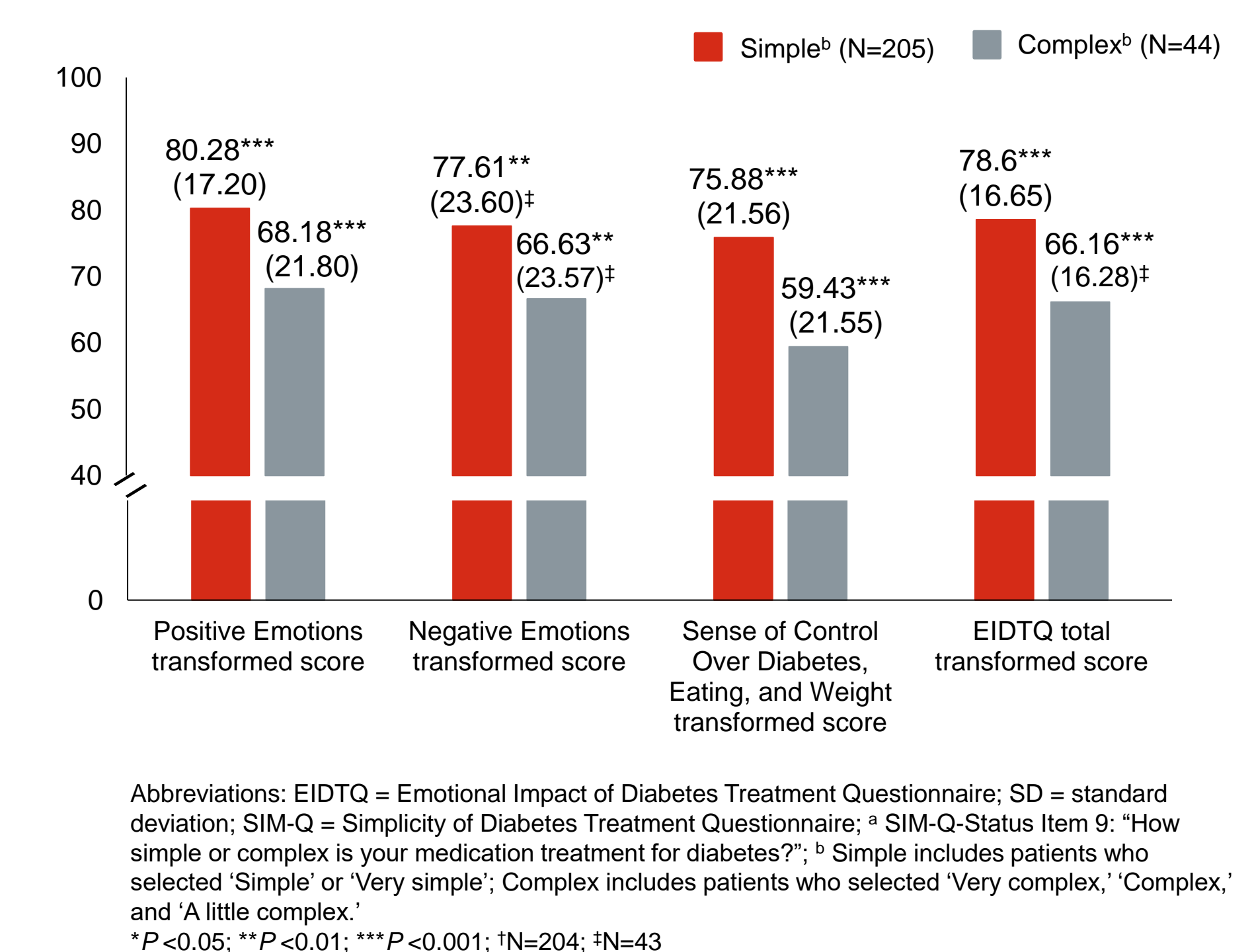
BACKGROUND AND OBJECTIVES

- Type 2 diabetes (T2D) is a chronic illness that has been shown to have a psychological impact on patients.¹ Treatment has the potential to affect psychological aspects such as depression and diabetes-related distress.²⁻⁶
- While two measures have been previously developed to assess psychological adjustment to diabetes and diabetes-related distress,^{7,8} these measures focus on negative emotions.
- As a result, the Emotional Impact of Diabetes Treatment Questionnaire (EIDTQ-Status) was developed based on qualitative research with patients to assess the positive and negative emotional impact of treatment on patients. There is also a second version that allows for comparison between current and previous treatment (EIDTQ-Comparison).⁹
- The purpose of this study was to derive subscales and assess the psychometric properties of the EIDTQ-Status.

CONCLUSION

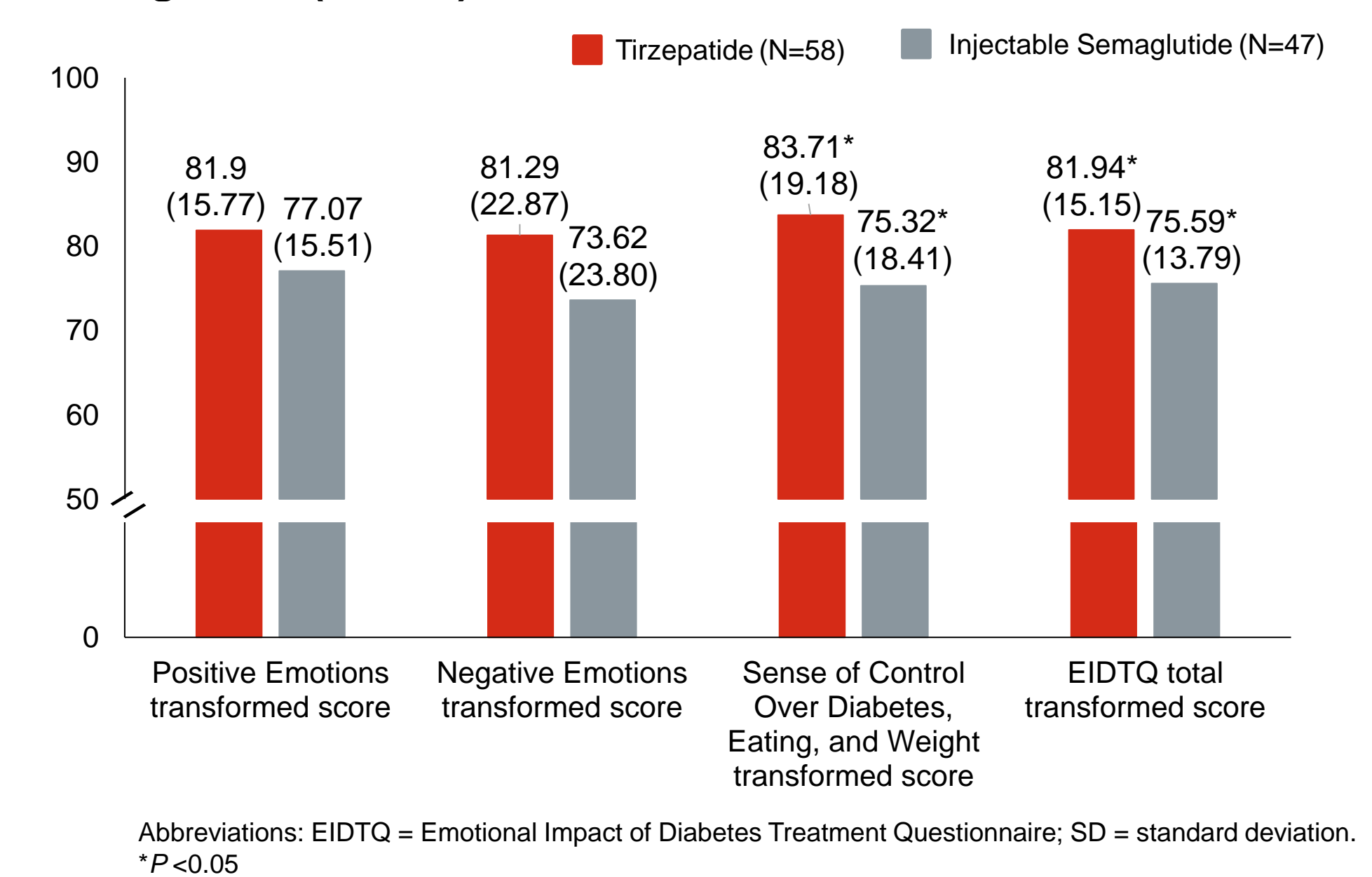
- The EIDTQ-Status had strong factor structure with three subscales and a total score that demonstrated good reliability and validity.
- The EIDTQ-Status may be useful in clinical trials and observational research assessing the emotional impact of treatment for T2D.
- There is preliminary evidence suggesting that the EIDTQ may discriminate among treatments that differ in emotional impact. For example, significant differences were found between tirzepatide and injectable semaglutide.
- Future research will evaluate validity of the comparison version of the EIDTQ. Similar to other instruments focusing on comparison between treatments,¹⁴ this version of the EIDTQ will require data from patients reporting their perceptions of the comparison between two treatments.

Figure 1. Known-Groups Validity: EIDTQ-Status Scores by Simplicity of Medication Treatment for Diabetes^a (N=249)



- Participants treated with tirzepatide had significantly greater mean scores on the sense of control subscale (*P*=0.025) and the total score (*P*=0.028) than participants treated with injectable semaglutide (Figure 2).

Figure 2. EIDTQ-Status Scores by Tirzepatide and Injectable Semaglutide (N=105)



Limitations

- Sample size was somewhat limited for analysis of test-retest reliability and the comparison between treatment groups.

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