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ORIGINAL ARTICLE

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Treatment satisfaction and time in range after 16 weeks of treatment with iGlarLixi in insulin-naive adults with suboptimally controlled type 2 diabetes

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Abstract

Aims: In Soli-CGM, treatment with iGlarLixi (insulin glargine 100 U/mL and lixisenatide 33 μg/mL) in insulin-naive adults with suboptimally controlled type 2 diabetes (T2D; haemoglobin A1c 9%–13% on ≥2 oral antihyperglycaemic agents (OADs) ± glucagon-like peptide-1 receptor agonist (GLP-1 RA) therapy) increased time in range (TIR; primary endpoint) from 26.4% at baseline to 52.7% at Week 16. This exploratory analysis examined the impact of treatment with iGlarLixi on patient-reported treatment satisfaction.

Materials and Methods: Soli-CGM was a single-arm, 16-week, multicentre, interventional, open-label, phase 4 study using blinded continuous glucose monitoring (CGM; FreeStyle Libre Pro) to assess glycaemic metrics ($N = 124$). CGM data were collected for a 2-week period before initiation of iGlarLixi, and after treatment with iGlarLixi (Weeks 14–16). Treatment satisfaction was assessed using the Diabetes Medication Treatment Satisfaction Tool (DM-SAT, which comprises four domains: well-being, medical control, lifestyle and convenience), at baseline and end-of-treatment. Association of TIR and overall satisfaction (sum of all items) was also assessed.

Results: Overall, 118 (95.9%) and 107 (87.0%) participants completed the DM-SAT at baseline and Week 16, respectively. Mean overall score increased by 0.18, from 0.59 (baseline) to 0.78 (Week 16). A trend in improvement in score was observed in all domains. Improvement in TIR had a positive, but weak, trend of association with improvement in overall treatment satisfaction (mean $r = 0.14$).

Conclusions: In people with T2D suboptimally controlled on ≥2 OADs ± GLP-1 RA, 16 weeks' treatment with iGlarLixi resulted in a trend of improvement in treatment satisfaction.

KEYWORDS

continuous glucose monitoring (CGM), fixed-ratio combination, Patient Reported Outcomes, type 2 diabetes

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1 | INTRODUCTION

Type 2 diabetes (T2D) is a progressive disease,[1] and despite advances in treatment, many people fail to achieve and/or maintain glycaemic control.[2] In a retrospective study in people initiating either basal insulin or glucagon-like peptide-1 receptor agonists (GLP-1 RA; specifically, exenatide, liraglutide, lixisenatide, albiglutide or dulaglutide), in individuals with glycated haemoglobin A1c (HbA1c) ≥9%, the likelihood of reaching glycaemic control (HbA1c ≤7%) with either therapy alone was <25%, which was lower than that in people with a baseline HbA1c of 7%–8% (40%–60%).[3] For individuals with high HbA1c, compared with sequential administration, simultaneous administration of basal insulin and a GLP-1 RA increases the likelihood of achieving target levels.[4] The American Association of Clinical Endocrinology 2023 guidelines recommend that if HbA1c is >10% and/or glucose is >300 mg/dL with symptomatic hyperglycaemia, basal insulin therapy should be initiated, either with or without a GLP-1 RA.[5] The American Diabetes Association 2024 guidelines recommend that for adults with T2D, if insulin is used, combination therapy with a GLP-1 RA (which could include a dual glucose-dependent insulinotropic polypeptide and GLP-1 RA) is recommended for greater glycaemic effectiveness as well as beneficial effects on weight and hypoglycaemia risk.[6] Therefore, in people with high HbA1c, fixed-ratio combination (FRC) therapies, such as iGlarLixi (insulin glargine 100 U/mL and lixisenatide 33 µg/mL) or IDegLira (insulin degludec 100 U/mL and liraglutide 3.6 mg/mL) may be appropriate treatment options.

Continuous glucose monitoring (CGM) provides a more comprehensive assessment of glycaemic status[7,8] than does self-monitored blood glucose or HbA1c.[9,10] Data from previous CGM studies show that in people with an HbA1c >9%, time in range (TIR) is <40%,[11] well below the target of ≥70%.[12] Soli-CGM was a prospective study conducted in the United States, which was designed to use CGM metrics (specifically TIR) to assess the impact of treatment with iGlarLixi in a racially and ethnically diverse population of insulin-naive adults with suboptimally controlled T2D (HbA1c 9%–13%) despite treatment with ≥2 oral antihyperglycaemic drugs (OADs) ± GLP-1 RA.[13] The results demonstrated that initiation of and treatment with iGlarLixi for 16 weeks significantly increased the proportion of TIR, from 26.4% at baseline to 52.7%.[13] Other measures of glycaemic control that were also improved after 16 weeks of treatment with iGlarLixi included time above range, time in tight range, maximum postprandial glucose exposure in the 4 hours after breakfast, and HbA1c levels. Time below range remained within the recommended target levels of <4% for <70 mg/dL and <1% for <54 mg/dL,[12] however, it did show an increase as expected when initiating insulin therapy.[9]

It is well documented that improved treatment satisfaction is associated with improved medication persistence and adherence.[14] As such, alongside assessment of clinical measures of glycaemic improvement, to assess the relatable benefit to people with T2D, it is important to investigate impact on treatment satisfaction. Treatment satisfaction is a patient-reported outcome (PRO) that incorporates both the expectations and actual experience of study participants, and translates findings into a measure of satisfaction, thus differentiating these data from measures such as quality of life (QoL).[15] However, evidence regarding the impact of FRCs on treatment satisfaction in people with T2D is limited, and there are no studies examining the association of treatment satisfaction with CGM metrics in this population.

Results of a study that used the Diabetes Treatment Satisfaction Questionnaire (DTSQ) to assess treatment satisfaction in people switching from multiple daily insulin injections to IDegLira revealed that scores improved after 6 months of treatment with IDegLira.[16] Similarly, a subanalysis of the SoliMix trial, which compared the efficacy and safety of iGlarLixi versus biphasic insulin aspart 30/70 (BIAsp 30) in people with T2D, was conducted to assess PROs using Treatment-Related Impact Measure Diabetes (TRIM-D; which measures treatment impact) and Global Treatment Effectiveness Evaluation (GTEE; which measures effectiveness of a treatment) questionnaires.[17] Compared with people who received BIAsp 30, those who received iGlarLixi demonstrated a greater improvement from baseline in total TRIM-D score, and in each TRIM-D domain, with the largest reported difference being in the diabetes management and treatment burden domains.[17] While these surveys provide good evidence of treatment outcomes relating to perceived improvements in QoL for people with T2D, it is important to note that there are limitations. For example, the DTSQ measures overall treatment satisfaction well but does not place this within the context of multiple medications where regimen complexity and treatment burden may become important.[18] By comparison, the Diabetes Medication Treatment Satisfaction Tool (DM-SAT) has been demonstrated to perform well in assessing treatment experience within the domains of convenience, lifestyle, well-being and medical control and has also been demonstrated to have associations with treatment complexity, self-rated glucose control, Mean Opinion Score Health Worries Scale score and HbA1c.[18] In addition, the DM-SAT does not have a ceiling effect, which occurs when responses are skewed to a value they cannot exceed, as observed with other measures of treatment satisfaction associated with T2D, including the DTSQ, DTSQ status version, Diabetes Medication System Rating Questionnaire (DMSRQ), DMSRQ-short form, Diabetes Tablet Treatment Questionnaire, Perceptions About Medications for Diabetes, and Satisfaction with Oral Anti-Diabetic Agent Scale.[15] This exploratory analysis of the Soli-CGM study was performed to examine the impact of iGlarLixi on patient-reported treatment satisfaction using DM-SAT, and to examine the association of treatment satisfaction with TIR.

2 | METHODS

2.1 | Study design, participants, and dosing

Soli-CGM (ClinicalTrials.gov identifier: NCT05114590) was a single-arm, 16-week, multicentre, interventional, open-label phase 4 study using blinded CGM (FreeStyle Libre Pro) to assess the impact of iGlarLixi on CGM metrics. The study was conducted from January 2022 to April 2023 with a duration of approximately 22 weeks. The study was performed in accordance with the ethical principles of the Declaration

of Helsinki, International Council for Harmonisation, Good Clinical Practice and all applicable regulations. Institutional review boards/ethics committees at each study site approved the protocol. All participants provided written informed consent.

The study has been described in full previously.[13] Briefly, participants were aged ≥18 years and had T2D diagnosed ≥6 months before the baseline period. T2D was suboptimally controlled (HbA1c of 9%–13%) despite treatment with ≥2 OADs ± GLP-1 RAs (stable doses for 3 months before the screening period). Site recruitment efforts were made to ensure that the study population represented the diversity of the US patient population with T2D. Participants were excluded if they had a diagnosis of type 1 diabetes or any other type of diabetes, were being treated with meglitinides (owing to a high risk of hypoglycaemia) or had a body mass index >40 kg/m^2 during the screening period. Individuals who had previously received any insulin therapy and those who had used weight loss agents within 12 weeks of the screening visit were also excluded.

Following screening, the blinded CGM device was applied to the back of the upper arm, and 14 days of baseline data were collected during the run-in period. The first dose of iGlarLixi was administered >7 (±2) days after the last weekly GLP-1 RA dose, or on the morning following the last dose of daily GLP-1 RA/dipeptidyl peptidase-4 inhibitor, to allow a washout period. iGlarLixi was dose-titrated between Weeks 1 and 12 with the goal of achieving a self-monitored fasting plasma glucose of 80–100 mg/dL while minimising the risk of hypoglycaemia and hyperglycaemia. The maximum daily dose could not exceed 60 units of insulin glargine (corresponding to 20 μg of lixisenatide). The CGM device was applied for another 14 days at the end of the treatment period. TIR was measured as the proportion of time spent with a blood glucose range of 70 to 180 mg/dL, and values at Week 16 were compared with those from baseline.

2.2 | DM-SAT assessment

The DM-SAT is a 16-item measure with four domains assessing well-being (3 items), medical control (3 items), lifestyle (5 items) and convenience (5 items).[18] Participants were asked to complete the questionnaire in a quiet place, independently of the investigator or site staff, and without any help from friends or relatives. The DM-SAT was completed at the baseline visit (before background therapies were stopped or dose-reduced) and again at the end of the treatment period. Individual questions were scored 0 (not at all satisfied), 1–3 (not too satisfied), 4–6 (somewhat satisfied), 7–9 (very satisfied) or 10 (extremely satisfied). The overall score of the DM-SAT was calculated by dividing the sum of the scores obtained for all 16 questions by the maximal possible score for the questionnaire (160) to provide a score of between 0 and 1, representing overall satisfaction. Similarly, to calculate the total score for each domain, the sum of the scores obtained for all questions within the domain was divided by the maximum possible score for that domain (well-being = 30; medical control = 30; lifestyle = 50; and convenience = 50), to provide a score of between 0 and 1. If there were more than 25% missing items for a domain, the domain was treated as missing. There was no reverse score as this is not applicable to DM-SAT survey items.

2.3 | Statistical analysis

Changes in DM-SAT scores from baseline to week 16 were assessed using the efficacy analysis set (all enrolled participants who received ≥1 dose of iGlarLixi and had evaluable CGM data at baseline) and were reported descriptively as mean, standard deviation (SD) and associated 95% confidence intervals (CI) for overall score, for each question, and for each of the four domains. Association of TIR with overall satisfaction (sum of all items), and with the individual domains of well-being, medical control, lifestyle and convenience, was assessed using Pearson correlation coefficient (*r* value).[19] As an exploratory analysis, all results were considered descriptive.

3 | RESULTS

3.1 | Baseline demographics and clinical characteristics

Of the 124 people who were enrolled in the study, 123 initiated iGlarLixi, and 111 (89.5%) completed the 16-week treatment period. The full study period, as specified per protocol, was completed by 110 (88.7%) participants. Participants had a mean age of 55.6 years, 58.9% were male and 70.2% were of Hispanic or Latino ethnicity. The population had a mean baseline HbA1c of 10.2% and a mean T2D duration of 10.6 years. Most participants were receiving metformin and/or a sulfonylurea (Table S1).[13] Of the 123 participants who initiated iGlarLixi, 118 (95.9%) completed the DM-SAT at baseline and 107 (87.0%) completed the DM-SAT at Week 16.

3.2 | DM-SAT results

3.2.1 | Overall assessment

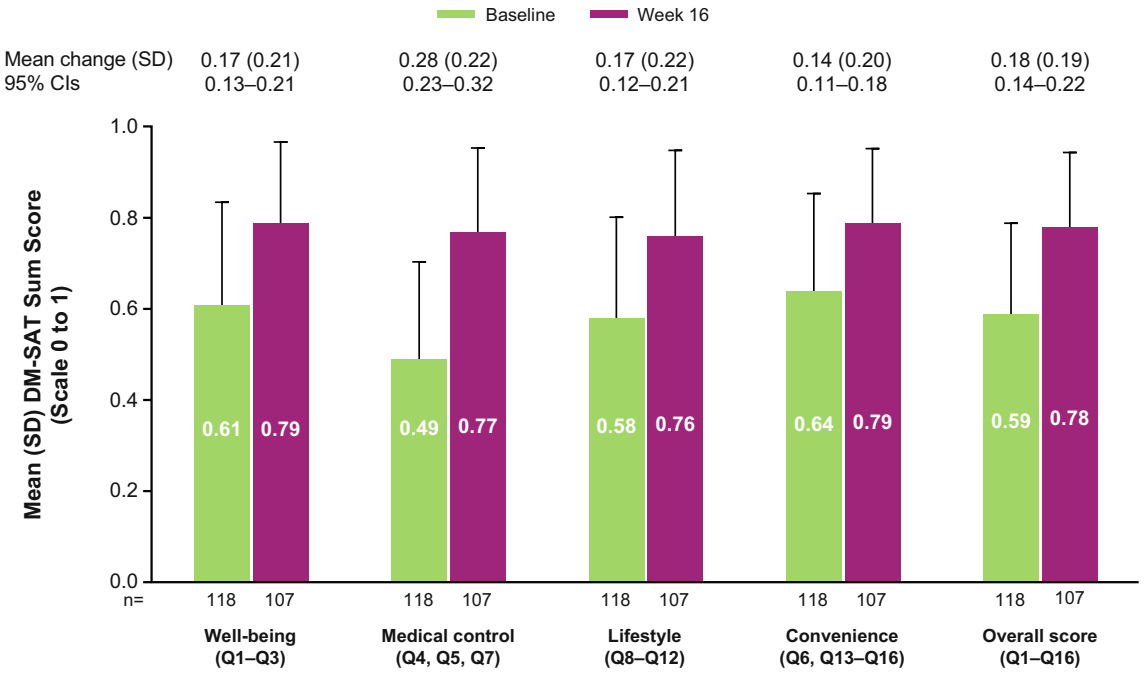
The mean (SD) overall score improved from 0.59 (0.20) at baseline to 0.78 (0.16) at Week 16, for a mean (SD) change of 0.18 (0.19) (Figure 1).

3.2.2 | Well-being domain

The mean (SD) score improved from 0.61 (0.22) at baseline to 0.79 (0.18) at Week 16 (mean change [SD], 0.17 [0.21]; Figure 1). For each question within the domain (Q1–Q3), scores ranged from 5.7 to 6.4 at baseline and rose to between 7.5 and 8.2 at Week 16 (Figure 2).

3.2.3 | Medical control domain

The mean (SD) score improved from 0.49 (0.21) at baseline to 0.77 (0.18) at Week 16 (mean change [SD], 0.28 [0.22]; Figure 1). Scores for each question within the domain (Q4, Q5 and Q7) increased from a range of 4.8 to 5.0 at baseline to between 7.6 and 7.9 at Week 16 (Figure 3).



Baseline, [n] r	[100] −0.04	[100] −0.12	[100] 0.00	[100] −0.04	[100] −0.04
Week 16, [n] r	[99] 0.13	[99] 0.18	[99] 0.17	[99] 0.08	[99] 0.15
Mean change from baseline, [n] r (95% CI)	[99] 0.07 (–0.13 to 0.26)	[99] 0.24 (0.04 to 0.41)	[99] 0.13 (–0.07 to 0.32)	[99] 0.08 (–0.12 to 0.28)	[99] 0.14 (–0.06 to 0.33)

FIGURE 1 Change from baseline to Week 16 in DM-SAT domain and overall scores and correlation of TIR (70–180 mg/dL), and patient satisfaction from baseline to Week 16. $n = 106$ for all change from baseline data. Higher scores indicate an improvement in DM-SAT domain. CI, confidence interval; DM-SAT, diabetes medication satisfaction tool; *n*, number of participants; Q, question; SD, standard deviation; TIR, time in range.

3.2.4 | Lifestyle domain

At baseline, the mean (SD) score was 0.58 (0.22), which increased to 0.76 (0.19) at Week 16 (mean change [SD], 0.17 [0.22]; Figure 1). For each question within the domain (Q8–Q12), scores at baseline ranged from 5.6 to 5.9 and rose to between 7.5 and 7.7 at Week 16 (Figure 4).

3.2.5 | Convenience domain

The mean (SD) score improved from 0.64 (0.21) at baseline to 0.79 (0.16) at Week 16 (mean change [SD], 0.14 [0.20]; Figure 1). All individual question scores within the domain (Q6 and Q13–Q16) increased from a range of 6.1 to 6.7 at baseline to between 7.6 and 8.2 at Week 16 (Figure 5).

3.2.6 | Correlation with TIR

TIR improvements had a positive but weak association with improvements in overall mean (95% CI) treatment satisfaction ($r = 0.14$ [−0.06 to 0.33]; $n = 99$), and in all four DM-SAT domains: well-being ($n = 99$, $r = 0.07$ [−0.13 to 0.26]), medical control ($n = 99$, $r = 0.24$ [0.04 to 0.41]), lifestyle ($n = 99$, $r = 0.13$ [−0.07 to 0.32]), and convenience ($n = 99$, $r = 0.08$ [−0.12 to 0.28]); Figure 1).

4 | DISCUSSION

This analysis was designed to investigate the relationship between treatment satisfaction and TIR in people with T2D that was suboptimally controlled on ≥2 OADs ± GLP-1 RA, who initiated the FRC therapy iGlarLixi and completed 16 weeks of treatment. The findings of the primary analysis of the Soli-CGM study demonstrated that the introduction of iGlarLixi exhibited a statistically and clinically significant improvement in TIR between baseline and Week 16.[13] TIR doubled, from 26.4% at baseline to 52.7% at Week 16.[13] The results of this exploratory analysis of the Soli-CGM study showed a parallel trend in improvement in the DM-SAT overall score as well as a trend in the improvement in scores for all individual domains of the DM-SAT (well-being, medical control, lifestyle and convenience). However, the trend of improvement in treatment satisfaction was only weakly associated with improvement in TIR.

Of the four domains, the largest increase in treatment satisfaction was in the medical control domain. This may be expected as questions

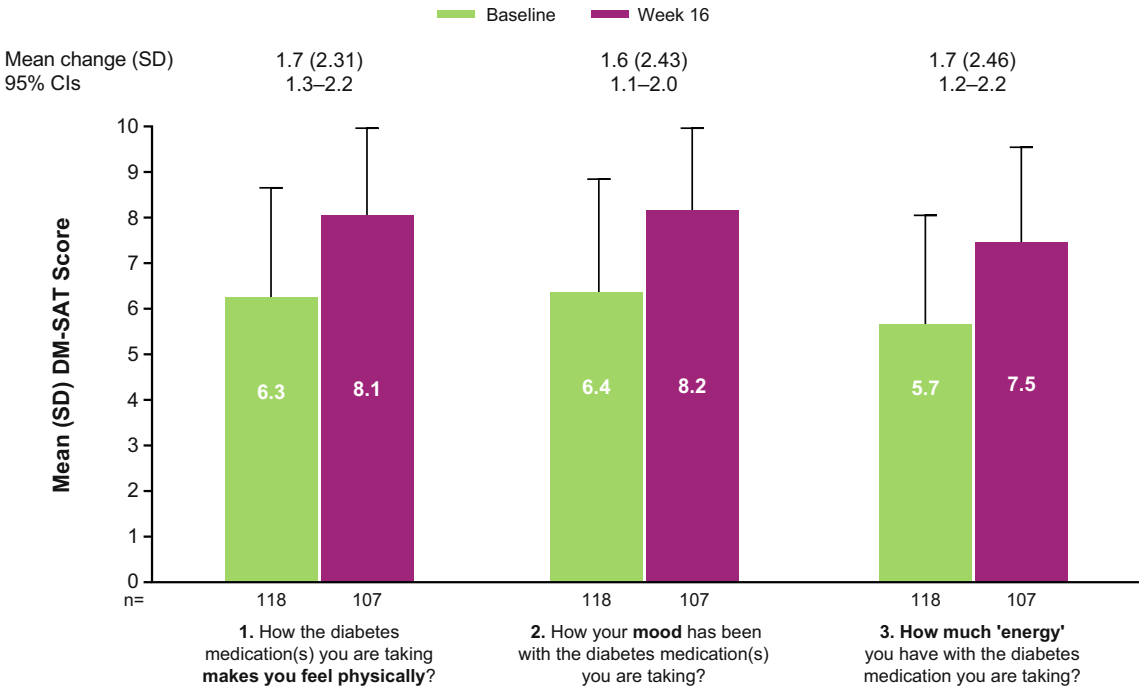


FIGURE 2 Change from baseline to Week 16 in DM-SAT well-being domain (Q1–Q3) scores. $n = 106$ for all change from baseline data. Higher scores indicate an improvement in DM-SAT domain. CI, confidence interval; DM-SAT, diabetes medication satisfaction tool; Q, question; SD, standard deviation.

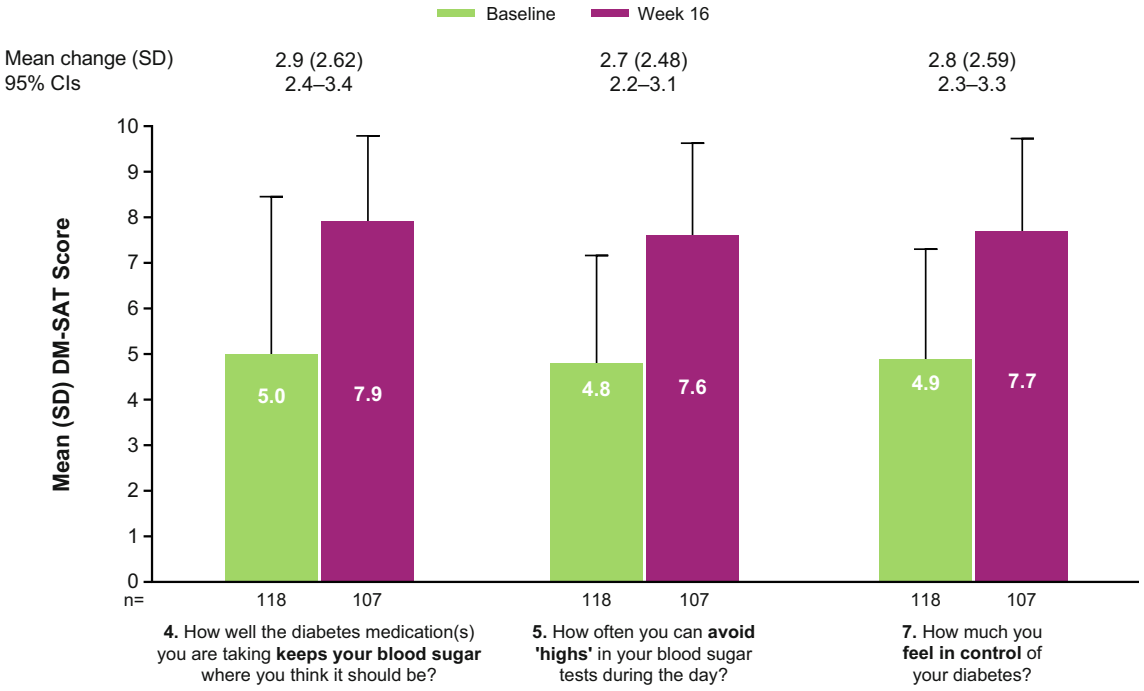


FIGURE 3 Change from baseline to Week 16 in DM-SAT medical control domain (Q4, Q5, Q7) scores. $n = 106$ for all change from baseline data. Higher scores indicate an improvement in DM-SAT domain. CI, confidence interval; DM-SAT, diabetes medication satisfaction tool; Q, question; SD, standard deviation.

in this domain closely relate to glycaemic control. Indeed, the question with the largest overall improvement in mean score (from 5.0 at baseline to 7.9 at Week 16) was in the medical control domain ("How well did the diabetes medication(s) you are taking keep your blood sugar where you think it should be?"). In comparison, scores were lower for questions in the lifestyle domain, which encompasses topics such as

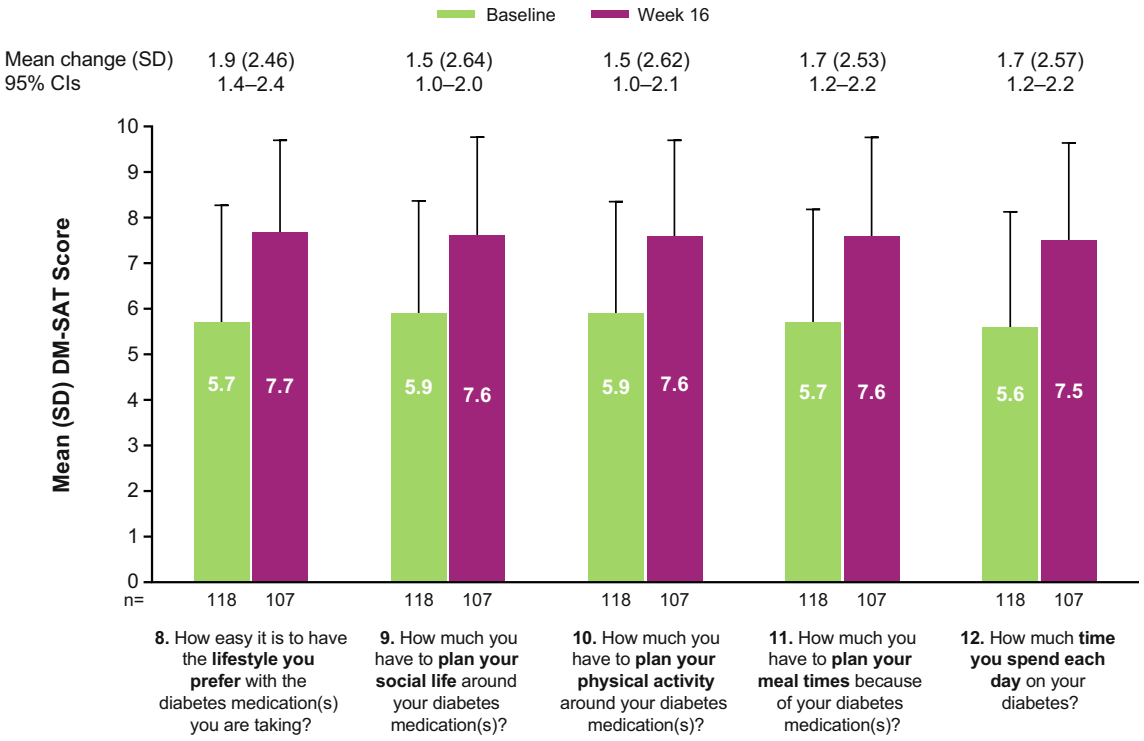


FIGURE 4 Change from baseline to Week 16 in DM-SAT lifestyle domain (Q8–Q12) scores. $n = 106$ for all change from baseline data. Higher scores indicate an improvement in DM-SAT domain. CI, confidence interval; DM-SAT, diabetes medication satisfaction tool; Q, question; SD, standard deviation.

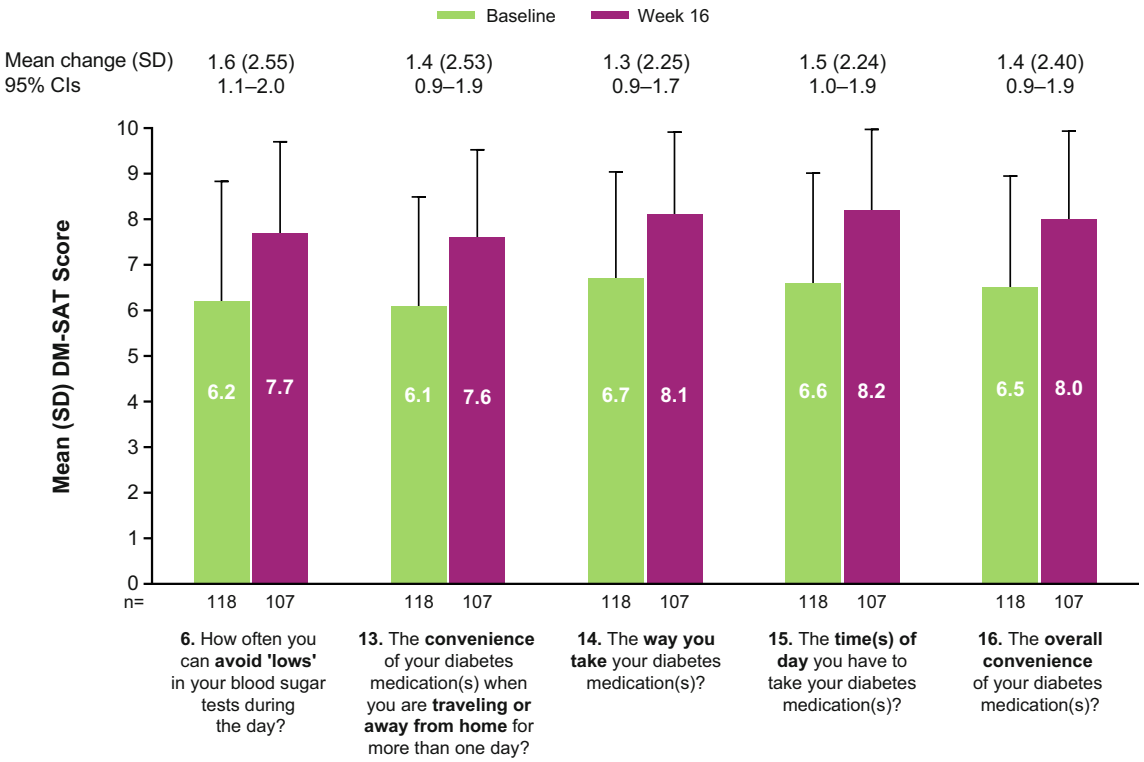


FIGURE 5 Change from baseline to Week 16 in DM-SAT convenience domain (Q6, Q13–Q16) scores. $n = 106$ for all change from baseline data. Higher scores indicate an improvement in DM-SAT domain. CI, confidence interval; DM-SAT, diabetes medication satisfaction tool; Q, question; SD, standard deviation.

planning activities or meals around taking diabetes medications, and similarly for the convenience domain, where questions relate to the number of times a day a person takes their medication, or the convenience of taking medication when travelling. Notably, despite the Soli-CGM cohort having their treatment intensified to include iGlarLixi, an injectable therapy, most participants reported an improvement in convenience and lifestyle. This could possibly be related to a dose reduction or discontinuation of previous therapy, or to improvement in glycaemic control, resulting in improved health. However, it is important to note that at baseline, many participants were receiving treatment that was not guideline compliant. For instance, approximately 70% of participants were receiving sulfonylureas, which are associated with a risk for hypoglycaemia. Additionally, only 8% of participants were receiving a GLP-1 RA despite having HbA1c of >9%.

Positive but weak associations with improvement in TIR and improvement in overall mean treatment satisfaction, and between improvement in TIR and in all DM-SAT domain scores was observed. Improvement in the medical control domain score had the strongest association with improved TIR of the four DM-SAT domains. These findings are consistent with other literature, which report that the correlation between PROs and CGM metrics is limited despite marked improvements in both measures.[20]

Ethnic minorities are disproportionately affected by T2D,[21,22] for instance, in the US, incidence and prevalence of T2D are higher in the Hispanic/Latino population compared with the non-Hispanic White population across all age groups.[21] Despite this, ethnic minorities remain underrepresented in clinical studies,[23] which makes it difficult to extrapolate efficacy and safety outcomes. An important factor in the Soli-CGM study is that it represents an ethnic population that is disproportionately affected by T2D and also had very high HbA1c (9%–13%).

Several other studies have reported on the impact of FRCs on PROs. The BEYOND trial demonstrated that switching to an FRC or to a basal insulin plus sodium-glucose cotransporter-2 inhibitor from a basal-bolus insulin regimen resulted in increased DTSQ scores compared with those for participants remaining on basal-bolus insulin.[24] In a subanalysis of the SoliMix study,[25] initiation of iGlarLixi, compared with BIAsp30, was associated with greater improvement in TRIM-D scores, and the GTEE indicated that a greater proportion of both people with T2D and their physicians perceived a complete or marked improvement of diabetes control with iGlarLixi.[17] Studies have demonstrated an association between IDegLira and improvements in DTSQ scores among people who switched to IDegLira from multiple daily insulin, basal insulin + OADs, or OADs alone.[16,26] The results of these studies, together with those from the Soli-CGM analysis, indicate that the improved glycaemic control observed with FRCs translates into meaningful improvements in treatment satisfaction in people with T2D.

The Soli-CGM study had several limitations. It was a single-arm study, and as such, it is difficult to draw comparisons with other studies owing to the lack of a control arm. As the population had such a high baseline HbA1c, the improvements in glycaemic control, and therefore treatment satisfaction, may have been further improved with longer treatment/follow-up. It should also be noted that introducing any new treatment, or indeed, any positive feeling a participant may have from being involved in a clinical study, may lead to the perception of improvement, which could possibly skew results. Additionally, the DM-SAT was only provided in English, however, individual sites assessed participants to ensure they could read English at enrolment. The DM-SAT is also limited by the subjective nature of the questions used to assess treatment satisfaction, which is common in this type of tool. This may result in some people under- or over-estimating any changes in their treatment satisfaction over the study period.

In conclusion, in people with T2D suboptimally controlled on ≥2 OADs ± GLP-1 RA, 16 weeks of treatment with iGlarLixi resulted in a trend for improvement in treatment satisfaction. A trend for improvement was observed in the DM-SAT overall score as well as in all four domains (well-being, medical control, lifestyle and convenience). There was a weak trend of an association of improvement in DM-SAT scores with improvement with TIR, therefore, no strong conclusion can be made regarding this association. However, this analysis does show that when people with T2D have an elevated HbA1c, they can recognize improvements in their own well-being, even if they do not achieve their TIR targets. This is important, as people who are satisfied with their treatment are more likely to keep taking it as recommended.[14] These findings emphasize the benefits of treating people with very suboptimally controlled T2D with appropriate therapies to reduce their HbA1c. Further research is needed to better understand the correlation between improvements in glycaemic control and PROs.

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CONFLICT OF INTEREST STATEMENT

VNS reports receiving fees from Ascensia, Dexcom, Diabetes Care, Embecta, Genomelink, Insulet, LumosFit, Novo Nordisk, Sanofi and Tandem Diabetes Care for speaking, consulting or advising services. TD and LM are employees of, and may hold stocks/shares in, Sanofi. AR is an employee of Ividata, contracted by Sanofi. WHP reports receiving fees from Abbott Diabetes, Bigfoot, Dexcom, Eli Lilly, Embecta, Insulet, Novo Nordisk, Sanofi and Vertex for consulting, and research support from Abbott Diabetes and Dexcom.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.16251.

DATA AVAILABILITY STATEMENT

Qualified researchers may request access to patient-level data and related documents [including, e.g., the clinical study report, study

protocol with any amendments, blank case report form, statistical analysis plan and dataset specifications]. Patient-level data will be anonymised, and study documents will be redacted to protect the privacy of trial participants. Further details on Sanofi's data sharing criteria, eligible studies, and process for requesting access can be found at https://vivli.org/.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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