

The impact of adjunct dapagliflozin on treatment satisfaction in type 1 diabetes mellitus

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Introduction

- The Dapagliflozin Evaluation in Patients With Inadequately Controlled Type 1 Diabetes (DEPICT) clinical trial programme, showed that among patients with type 1 diabetes mellitus (T1DM) inadequately controlled by insulin alone, adjunct dapagliflozin reduced body weight and improved glycaemic control versus placebo, without increased risk of hypoglycaemia¹⁻³.
- The incidence and related fear of hypoglycaemia and weight gain are among factors that negatively influence patient-reported outcomes, such as quality of life and treatment satisfaction⁴⁻⁵.
- Treatment satisfaction for people with T1DM is particularly important due to its links to treatment adherence, glycaemic control and reduced risk of future T1DM-related complications⁶.
- This study aimed to assess the impact of dapagliflozin (10 mg or 5 mg) on patient-reported treatment satisfaction from DEPICT clinical trial data.

Methods

- The DEPICT clinical trial programme consisted of two similarly designed trials: DEPICT-1 (NCT02268214) and DEPICT-2 (NCT02460978).
- In the trials, patient treatment satisfaction was measured at study baseline and weeks 24 and 52 following baseline, via the Diabetes Treatment Satisfaction Questionnaire (DTSQ) total score.
- DTSQ is a widely used instrument for the assessment of treatment satisfaction (1) and perceived burden of hyper- and hypoglycaemia (2). The DTSQ total score refers to the sum of responses to six questions related to the first factor; higher scores indicate higher treatment satisfaction and the maximum total score is 36⁵.
- A 3-point increase in DTSQ total score is considered a clinically meaningful improvement in treatment satisfaction for patients⁷.
- All participants in DEPICT-1 and DEPICT-2 were eligible for inclusion in the analysis.
- Absolute DTSQ total scores were statistically summarised at each study timepoint (baseline, week 24, week 52), stratified by study arm.
- A responder analysis was undertaken, where response was defined as at least a 3-point increase in DTSQ total score from baseline. Responder rates (i.e. the percentage of patients achieving the defined increase) were evaluated at week 24 and week 52, for each study arm.
- The statistical significance of observed differences between groups was assessed using a Z-test of proportions.

Results

- Table 1 summarises the baseline characteristics of the pooled DEPICT-1 and DEPICT-2 study population. Demographics and other baseline characteristics were similar across study arms, including baseline insulin dosage and method of administration.
- In total, 1,591 patients were considered for inclusion in the analysis, with low levels of missing data at each time point.

Table 1. Summary of baseline characteristics and DTSQ total score in the DEPICT population, by study arm

	Dapagliflozin 5 mg (n = 529)	Dapagliflozin 10 mg (n = 530)	Placebo (n = 532)
Baseline characteristics			
Age (years)	42.3	42.5	42.9
Male (%)	43.2	47.4	47.2
Duration of T1DM (years)	19.5	19.7	20.1
BMI (kg/m ²)	27.8	28.0	28.1
HbA1c (%)	8.5	8.5	8.5
Total baseline insulin (IU)	0.74	0.72	0.72
Total baseline insulin (IU/kg)	60.1	59.1	59.8
Mode of insulin administration (%):			
Multiple daily injections	64.3	64.8	64.9
Continuous subcutaneous infusion	35.7	35.2	35.1
Baseline DTSQ total score			
N	491	493	477
Mean (SD)	29.0 (5.5)	29.2 (5.5)	29.1 (5.2)
Median (min, max)	30 (5, 36)	30 (4, 36)	30 (10, 36)

BMI: body mass index; IU: insulin units; SD: standard deviation; T1DM: type 1 diabetes mellitus.
n: number of subjects in each study arm; N: number of subjects in each study arm with baseline and at least one other post-baseline value

- Across arms, 92% of the study population had records of DTSQ total score at study baseline and at least one other timepoint (week 24 or 52). In these patients, average DTSQ total scores at baseline were similar across arms (Table 1).
- By contrast, mean DTSQ total scores were higher among dapagliflozin-treated patients at both week 24 and week 52 compared to placebo.
- Figure 1 presents the mean and associated 95% confidence interval for DTSQ total score at each study timepoint.
- Larger increases from baseline were observed for dapagliflozin versus placebo across elements of the DTSQ total score (Figure 2).

Figure 1: Summary of DTSQ total scores over the DEPICT study period, by study arm

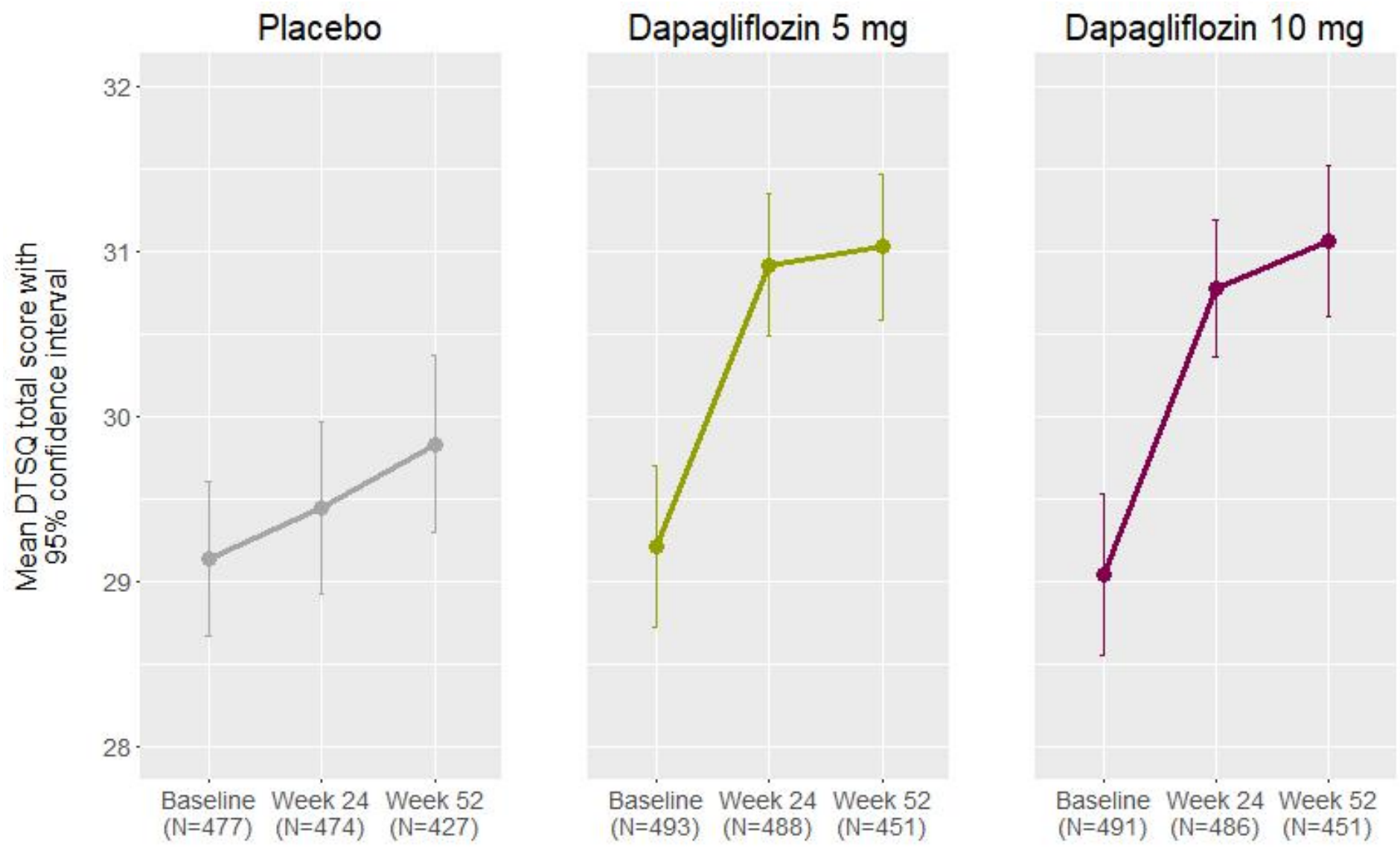
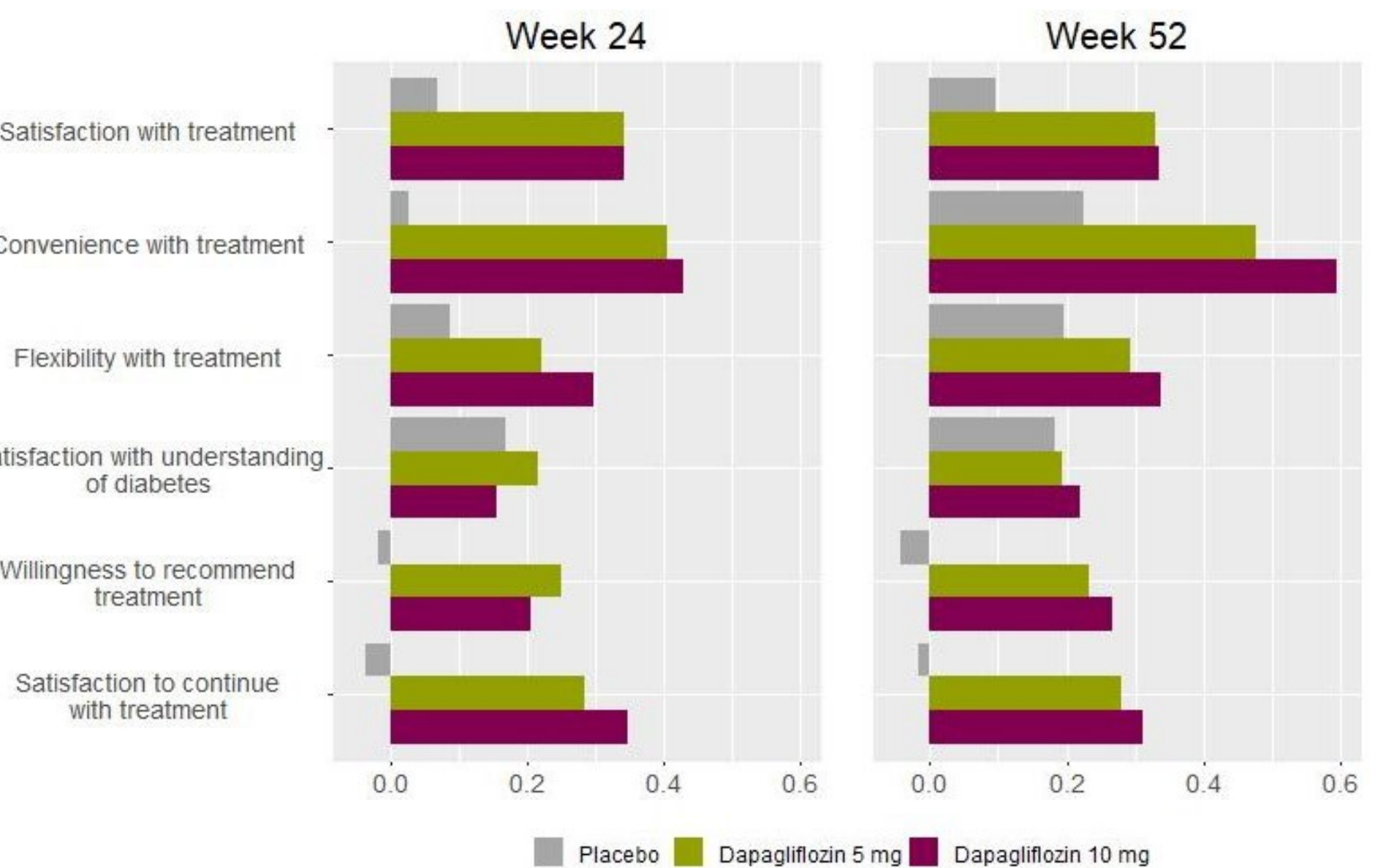


Figure 2: Mean change from baseline for each component of the DTSQ total score, by study arm



- For placebo, 28% of patients achieved at least a 3-point increase in DTSQ total score at 24 weeks, increasing to 32% at 52 weeks. Response rates were 9%–10% higher for dapagliflozin 10 mg and 5%–11% higher for dapagliflozin 5 mg (Figure 3).
- Between group differences in response rate were statistically significant for both doses of dapagliflozin at week 24. At week 52, only the observed difference between dapagliflozin 10 mg and placebo was significant at the 5% level (Table 2).

Figure 3: Percentage of patients achieving ≥3-point increase in DTSQ total score

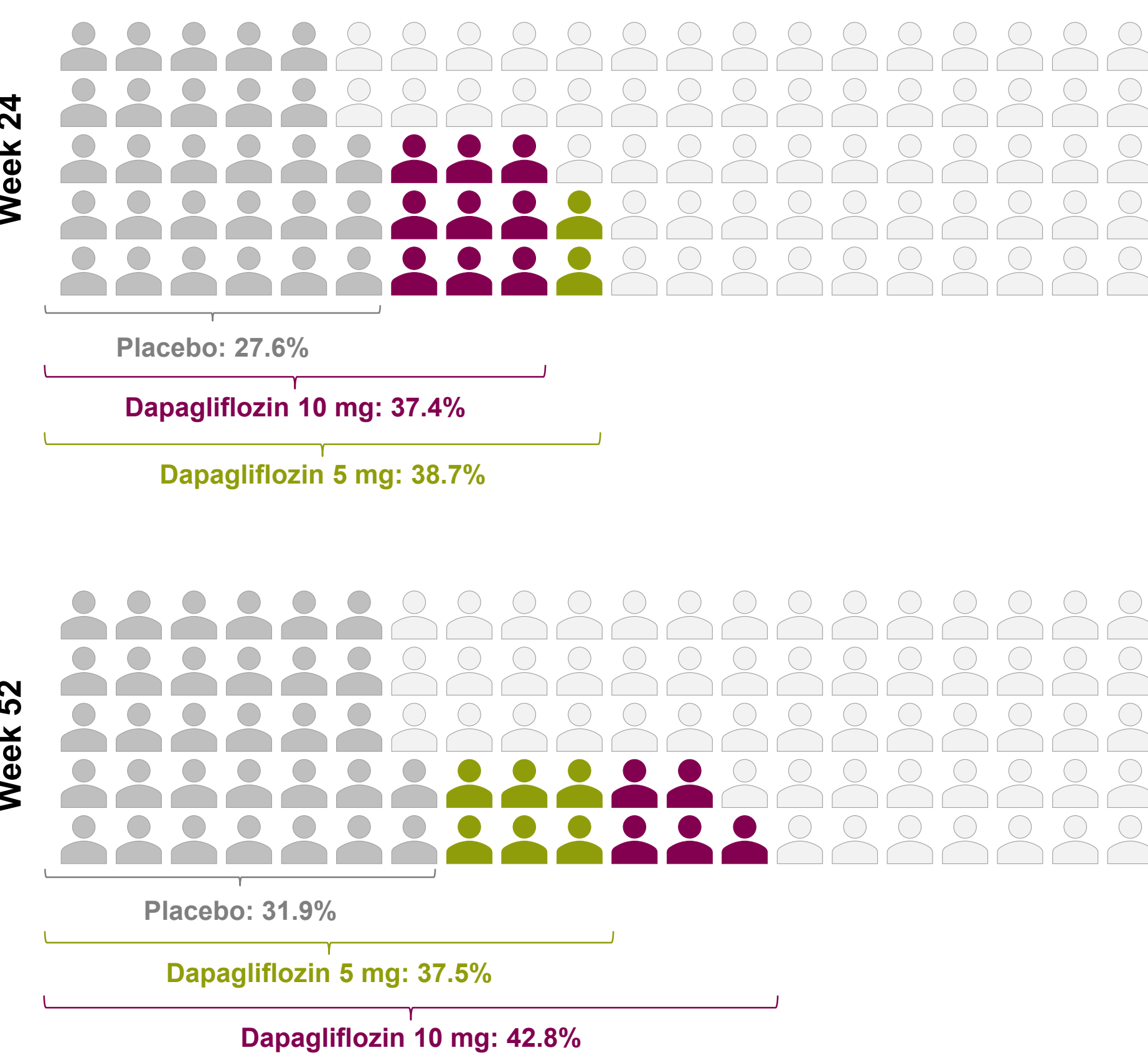


Table 2. Statistical analysis of between-group differences in response rate (≥3-point increase in DTSQ total score)

		Dapagliflozin 5 mg (n = 529)	Dapagliflozin 10 mg (n = 530)
Week 24	Difference versus placebo	9.81	11.09
	95% CI	3.71 to 15.91	4.98 to 17.21
	p-value*	0.002	< 0.001
Week 52	Difference versus placebo	10.94	5.62
	95% CI	4.36 to 17.53	−0.89 to 12.13
	p-value*	0.001	0.093

CI: confidence interval
* p-value based on Z-test of proportions

Conclusions

- The results of this study demonstrated that compared to placebo, treatment with dapagliflozin was associated with an improvement in diabetes treatment satisfaction, as measured by the DTSQ total score.
- Together with improvements in glycaemic control and weight and without increased risk of hypoglycaemia, improvements in patient-reported outcomes support the role of dapagliflozin in T1DM management.

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