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Effects of empagliflozin, diet, or both on physical activity and sedentary behaviour in people with type 2 diabetes: analyses from the SEESAW trial

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Abstract:

Background and aims: Empagliflozin lowers glucose and body weight in people with type 2 diabetes (T2D) by promoting glucosuria. However, weight loss (WL) is less than predicted by modelling glucose excretion. We report exploratory analyses of changes in physical activity/sedentary behaviour after initiating empagliflozin, diet-induced WL (DIWL), or both, in people with T2D enrolled in a recent placebo-controlled trial.

Materials and methods: 68 adults with T2D (65% male; median (IQR) age 63 (57 – 69) y, BMI 31 (29 – 35) kg/m², HbA1c 6.9 (6.5 – 7.1) %), were randomised (1:1:1:1) to placebo (PLA), empagliflozin 25mg/day (EMPA), placebo plus DIWL (DIET), or empagliflozin 25mg/day plus DIWL (EMPA+DIET) for 24 wk. DIET and EMPA+DIET were supported to lower energy intake by 1500kJ/day. Mean WL at 24 wk was 0.4, 2.2, 1.9 and 5.7 kg in each group, whilst HbA1c was reduced in EMPA and EMPA+DIET only (mean change ~0.4% in each). No compensatory changes in appetite or appetite-related hormones (trial primary research question) were apparent. Participants wore a hip-worn accelerometer for 7 d at 0, 6, 12 and 24 wk, to assess total ambulatory activity (steps/day), time spent sedentary, and time in light- (LIPA) and moderate to vigorous-intensity physical activity (MVPA). Generalised estimating equations (GEE) explored differences between groups across follow-up, with pairwise comparisons of each group vs PLA. Generalised linear models (GLM) compared each group vs PLA at 6, 12 and 24 wk. Models were adjusted for baseline, BMI, age and accelerometer wear time. Statistical significance was deemed $p < 0.05$.

Results: Valid accelerometer data were available for 68, 58, 62 and 58 individuals at 0, 6, 12 and 24 wk. Baseline activity/sedentary time were similar between groups (full cohort; steps 4965 (3867 – 7729) per day, sedentary time 582 (529 – 656) min/day, LIPA 267 (221 – 328) min/day, MVPA 18 (9 – 32) min/day). GEE modelling revealed a difference in daily steps between groups across follow-up ($p = 0.046$), with steps significantly lower in EMPA vs PLA (Table). GLM suggested that this was primarily driven by a reduction in steps at 6 wk. Sedentary time, LIPA and MVPA were unchanged.

Conclusion: Alongside improvements in glycaemic control and weight loss, we observed a reduction in overall physical activity volume, measured by daily steps, after initiation of

empagliflozin in people with T2D. Whether reduced physical activity-related energy expenditure contributes to the less-than-modelled WL with empagliflozin warrants further investigation.

Table – Daily steps at baseline, 6, 12 and 24 weeks in placebo, empagliflozin, placebo plus diet-induced weight loss and empagliflozin plus diet-induced weight loss groups.

	Baseline (median (IQR))	Absolute change from baseline (mean ± SD)			Generalised estimating equations	Generalised linear models		
		6 weeks	12 weeks	24 weeks	Difference vs PLA (coefficient [95%CI]) ^a	Difference vs PLA (coefficient [95%CI])		
					-	6 weeks	12 weeks	24 weeks
PLA	5126 (3640 – 7198)	1036 ± 1834	201 ± 1480	303 ± 2180	-	-	-	-
EMPA	5077 (4494 – 7912)	-550 ± 1655	14 ± 1987	-633 ± 1522	-818 [-1593, -44] ^b	-1411 [-2580, -241] ^c	-167 [-1144, 810]	-800 [-2047, 447]
DIET	4747 (3611 – 7261)	652 ± 972	1085 ± 1461	1005 ± 726	238 [-595, 1071]	-318 [-1607, 971]	507 [-532, 1546]	604 [-698, 1906]
EMPA+DIET	5170 (3797 – 8533)	562 ± 1866	302 ± 1942	775 ± 2291	98 [-679, 875]	-437 [-1580, 707]	50 [-922, 1023]	574 [-695, 1843]

All models adjusted for baseline value, BMI, age and accelerometer wear time; ^a overall main effect of group $p = 0.046$; ^b pairwise comparison $p = 0.038$; ^c pairwise comparison $p = 0.018$.

Abbreviations: DIET - placebo plus diet-induced weight loss group; EMPA - empagliflozin 25mg once daily group; EMPA+DIET - empagliflozin 25 mg once daily plus diet-induced weight loss group; PLA - placebo group.

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