Simultaneous versus Sequential Initiation of Lixisenatide and Basal Insulin for Type 2 Diabetes: Subgroup Analysis of a Japanese Post-Marketing Surveillance Study of Lixisenatide (PRANDIAL)

Supplementary Material

Authors: Hideaki Kaneto[a], Mike Baxter[b, c], Yoko Takahashi[d], Yasuo Terauchi[e]

Affiliations:

[a]Kawasaki Medical School, Kawasaki, Japan

[b]Medical Affairs, Sanofi, Reading, UK

[c]Swansea University, Swansea, Wales, UK

[d]Sanofi K.K. General Medicine Medical Department, Tokyo, Japan

[e]Department of Endocrinology and Metabolism, Yokohama City University, Kanazawa-ku, Yokohama, Japan

Corresponding author: Yoko Takahashi

Email: Yoko.Takahashi@sanofi.com

Supplementary Table S1 Post-prandial plasma glucose (PPG) levels according to timing of basal insulin (BI) relative to initiation of lixisenatide (Lixi) treatment in a subgroup of patients with PPG data

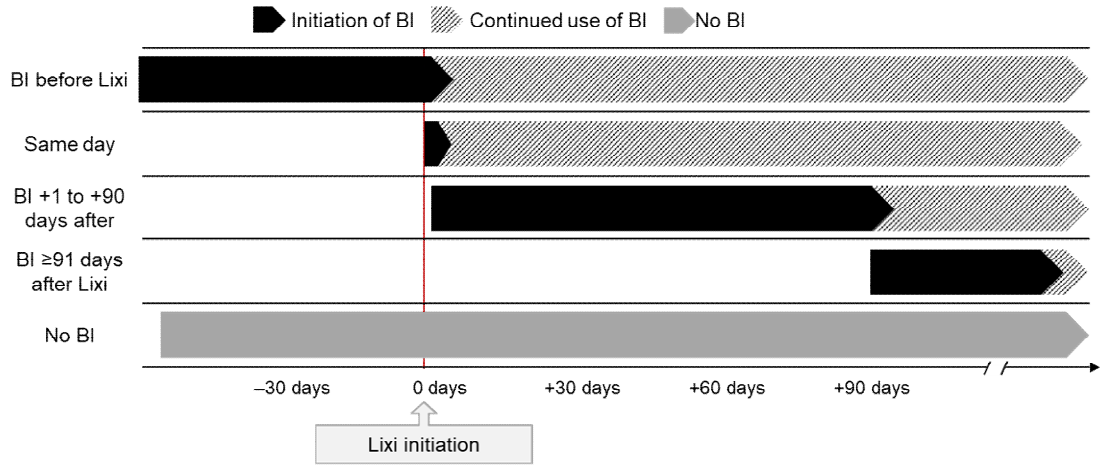
PPG level, mean ± SD (mg/dL)[a]	All (*n* = 250)	BI timing subgroups				
		Before Lixi (*n* = 103)	Same day (*n* = 41)	+1 to +90 days after Lixi (*n* = 5)	≥91 days after Lixi (*n* = 20)	No BI (*n* = 81)
Baseline	213.8 ± 91.8	223.0 ± 101.3	230.9 ± 83.2	152.6 ± 28.3	204.1 ± 76.2	199.7 ± 86.8
Change from baseline at Week 24	−56.0 ± 96.4	−53.5 ± 98.0	−90.3 ± 97.0	55.6 ± 99.0	−30.8 ± 80.5	−55.0 ± 91.5
Change from baseline at Week 156	−51.2 ± 93.7	−52.0 ± 104.7	−62.0 ± 87.1	−18.2 ± 11.4	−36.5 ± 74.8	−50.5 ± 89.6
p-value[b]	**<0.0001**	**<0.0001**	**<0.0001**	**0.0236**	**0.0422**	**<0.0001**

[a]PPG values are an aggregate of postprandial blood glucose measurements with timing at 1h (0.5–1.4h) after a meal, 2h (1.5–2.4h) after a meal, postprandial (other), or at an unknown time point at the time of data collection

[b]*p*-values derived from paired t-test comparing change from baseline with baseline value. Significant p-values are shown in bold

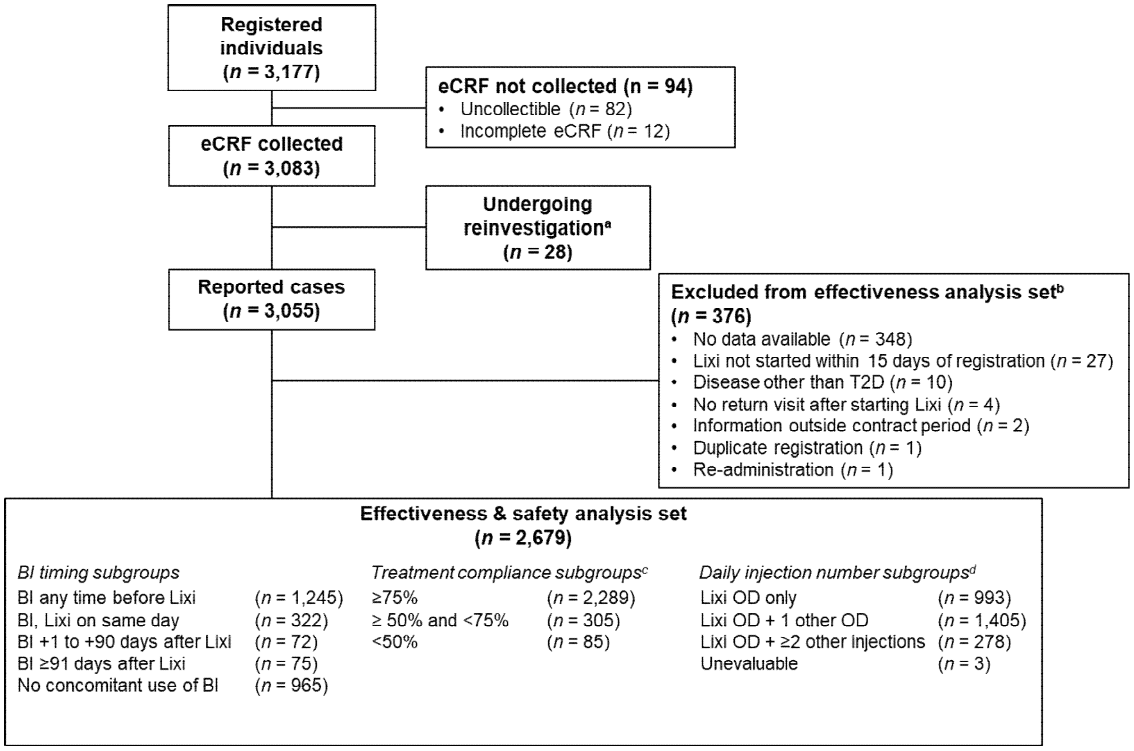
BI basal insulin, *h* hour, *Lixi* lixisenatide, *PPG* postprandial plasma glucose, *SD* standard deviation

Supplementary Fig. S1 Subgroups of study participants receiving concomitant lixisenatide and basal insulin according to the time interval between the start of lixisenatide and basal insulin administration



BI basal insulin, *Lixi* lixisenatide

Supplementary Fig. S2 Study participant disposition and subgroups



[a]During data extraction for this analysis, additional enquiries were required for 28 cases where data were missing or appeared incorrect, therefore these cases were excluded

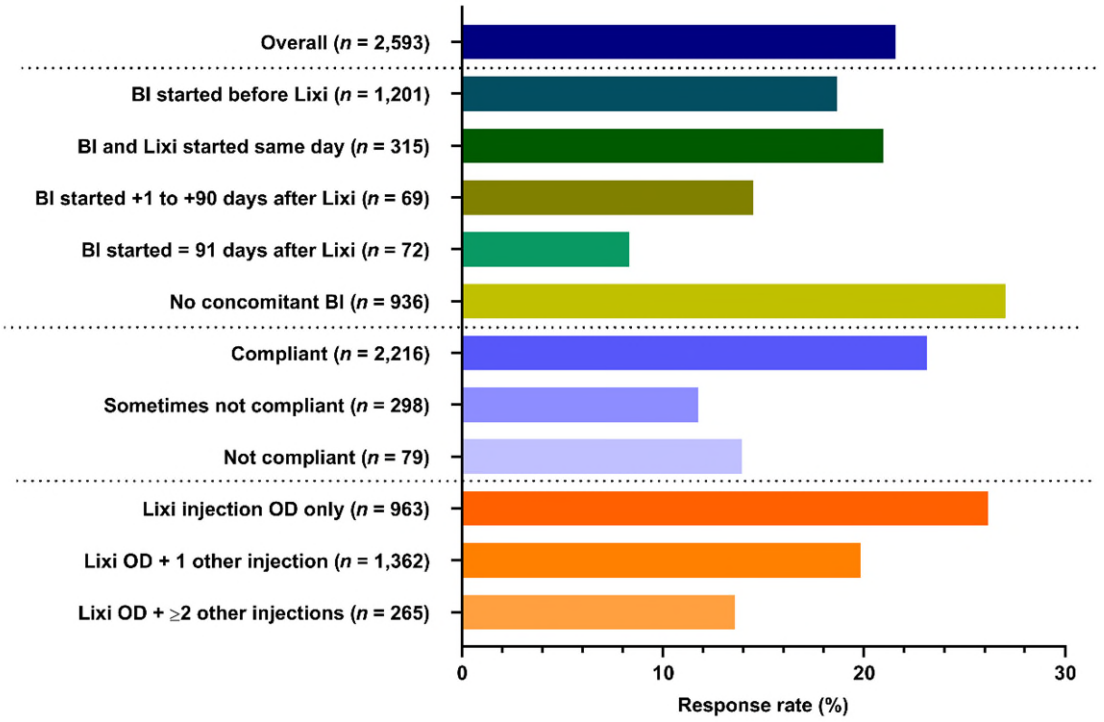
[b]More than one reason for exclusion from analysis could apply to an individual

[c]Compliance status at 6 months after the start of administration of lixisenatide

[d]Number of injections per day at the start of lixisenatide administration, where ≥2 daily refers to other injected diabetic medications

BI basal insulin, *eCRF* electronic case report form, *Lixi* lixisenatide, *OD* once daily, *T2D* type 2 diabetes

Supplementary Fig. S3 The proportion of participants in each subgroup with treatment response. Treatment response was defined as an HbA1c of <7.0% [<53 mmol/mol] at week 156 (LOCF analysis in the effectiveness analysis population). Of the 3 participants for whom daily injection number data were missing (not shown), 1 demonstrated a response to treatment



BI basal insulin, *HbA1c* glycated hemoglobin, *Lixi* lixisenatide, *LOCF* last observation carried forward, *OD* once daily