Use of iGlarLixi for the management of type 2 diabetes in Japanese clinical practice: prior treatment subgroup analysis of the SPARTA Japan study

Supplementary Material

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Supplementary Table S1 Ethics committees that approved the SPARTA Japan study

Institution	Ethics committee[a]
Ayame Internal Medicine	Sone Clinic
Ehime Rosai Hospital	Ehime Rosai Hospital
Gastroenterology Clinic of Muraki Internal Medicine	Sone Clinic
General Inuyama Central Hospital	General Inuyama Central Hospital
Hamamatsu Medical Center	Hamamatsu Medical Center
Hayaishi Hospital	Sone Clinic
Hyogo Central Hospital	Hyogo Central Hospital
Iwamoto Internal Medicine Clinic	Sone Clinic
Jinnai Hospital	Jinnai Hospital
Josai Hospital	Sone Clinic
Kansai Rosai Hospital	Kansai Rosai Hospital
Kasugai Municipal Hospital	Kasugai Municipal Hospital
Kikuchi Internal Medicine Clinic	Sone Clinic
Kokubo Clinic	Sone Clinic
Kurihara Internal Medicine	Sone Clinic
Miyachi Internal Medicine	Sone Clinic
Morinoki Clinic	Sone Clinic
Nagoya City University Hospital	Nagoya City University Hospital
Nishikawa Clinic	Sone Clinic
Ohama Daiichi Hospital	Ohama Daiichi Hospital
Osaka Municipal Comprehensive Medical Center	Osaka Municipal Comprehensive Medical Center
Primula Clinic	Sone Clinic
Saitama Medical Center, Jichi Medical University	Saitama Medical Center, Jichi Medical University
Sei Internal Medicine Clinic	Sone Clinic
Shizuoka Saisei General Hospital	Shizuoka Saisei General Hospital

Suzuki Internal Medicine/Diabetes Clinic	Sone Clinic
Wu Medical Center	Wu Medical Center

[a]Sone Clinic, Tokyo, Japan acted as a central ethics committee for some institutions

Supplementary Table S2 Changes in mean insulin glargine/lixisenatide (iGlarLixi) dose from initiation to 6 months, in the full analysis set (FAS) and in pre-treatment subgroups.

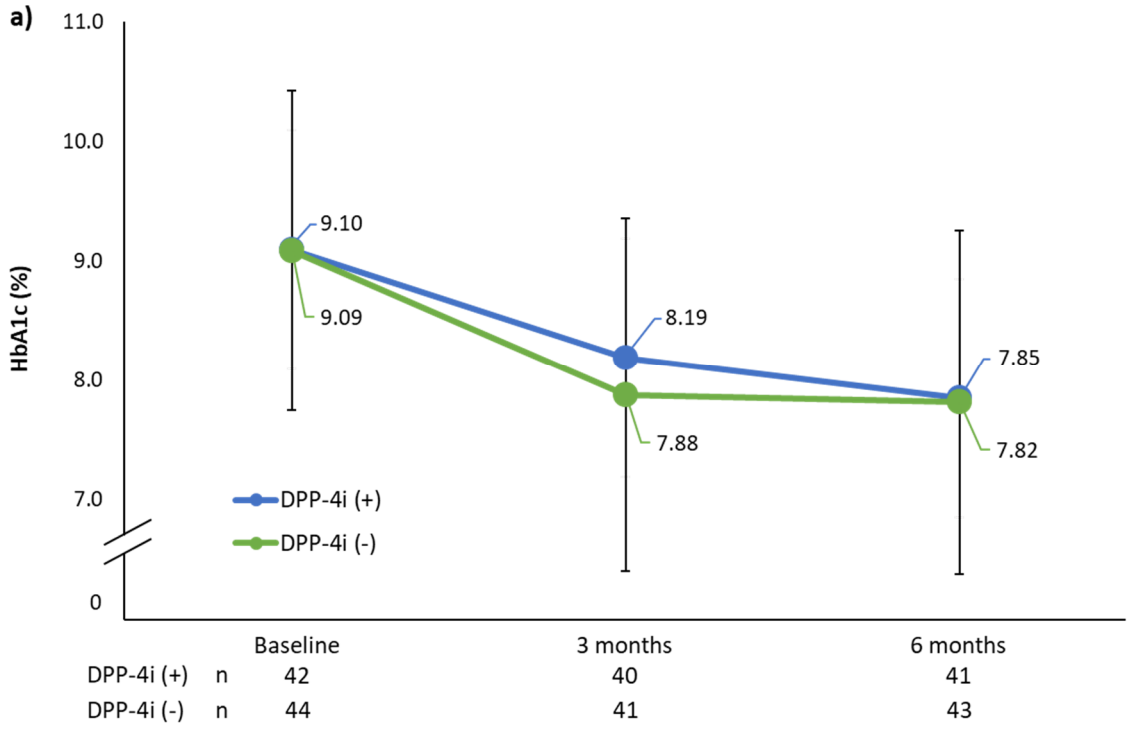
	FAS (N=432)	Post OAD (n=86)	Post GLP-1 RA (n=39)	Post BOT (n=84)	Post GLP-1RA + BI (n=67)	Post MDI	
						Bolus insulin (+) (n=39)	Bolus insulin (-) (n=22)
iGlarLixi dose, dose steps/day, mean (SD)							
Baseline	8.6 (4.3)	5.7 (2.8)	7.2 (3.6)	9.2 (4.0)	12.2 (5.2)	8.8 (3.5)	7.7 (3.2)
6 months	12.2 (5.1)	9.8 (4.7)	13.0 (4.8)	12.8 (4.9)	15.2 (4.6)	12.2 (5.3)	9.9 (4.7)
Change from baseline	3.6 (4.5)*	4.2 (4.5)*	5.8 (4.4)*	3.6 (4.5)*	3.0 (4.3)*	3.4 (5.1)*	2.2 (3.5)*

*p<0.01 vs starting dose

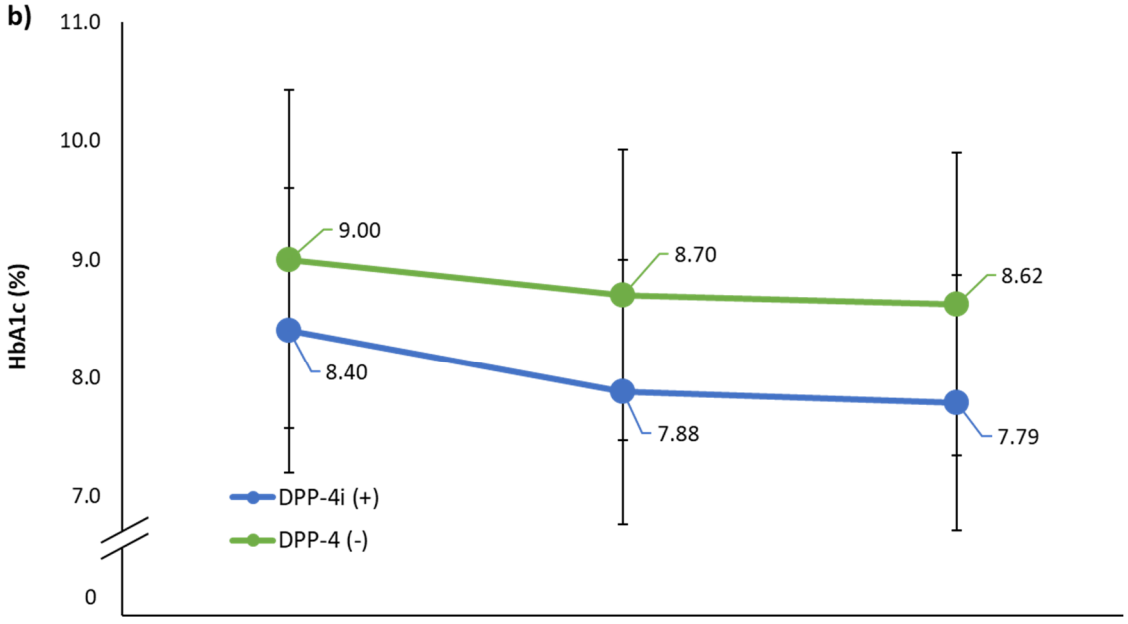
BI basal insulin, *BOT* basal insulin-supported oral therapy, *FAS* full analysis set, *GLP-1 RA* glucagon-like peptide-1 receptor agonist, *MDI* multiple daily injections, *OADs* oral antidiabetic agents, *SD* standard deviation

Supplementary Fig. S1 Mean ± SD glycated haemoglobin (HbA1c) at baseline and 3 and 6 months after initiation of insulin glargine/lixisenatide (iGlarLixi) in **(a)** participants who were previously suboptimally controlled on oral antidiabetic drugs (OADs), stratified by whether or not they received dipeptidyl peptidase-4 inhibitors (DPP-4is) before initiation of iGlarLixi; **(b)** participants who switched from combination therapy of OADs and insulin (basal-supported oral therapy [BOT]), stratified by whether or not they received DPP-4is before initiation of iGlarLixi; and **(c)** participants who switched from BOT, stratified by baseline daily basal insulin dose (<10 vs ≥10 U/day).

SD standard deviation

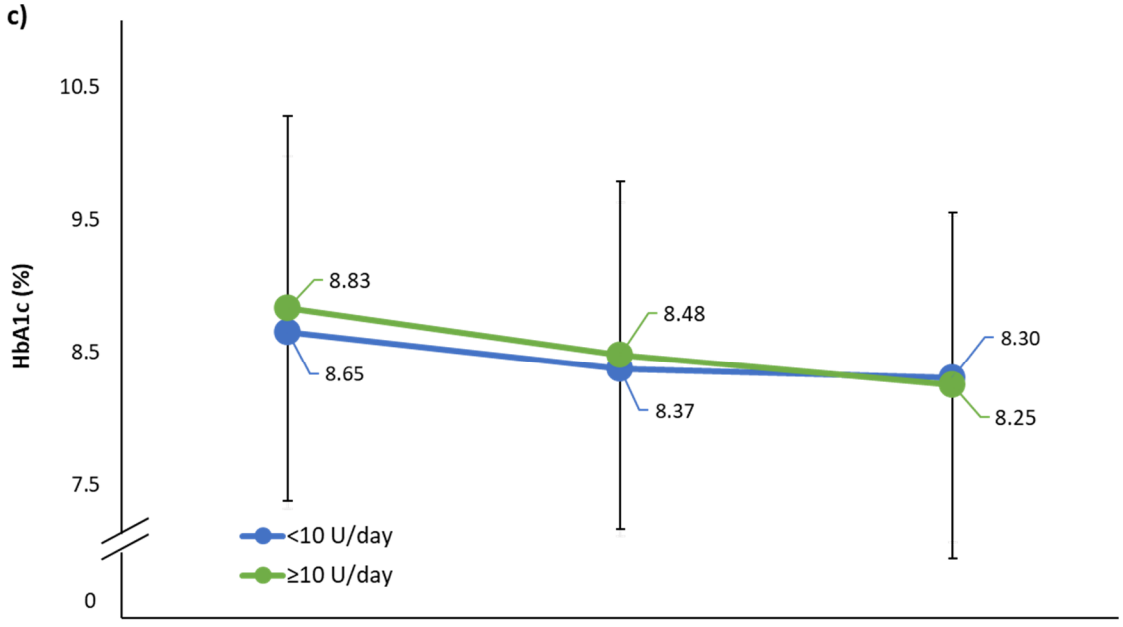


b)



		Baseline	3 months	6 months
DPP-4i (+)	n	26	26	26
DPP-4i (-)	n	59	58	58

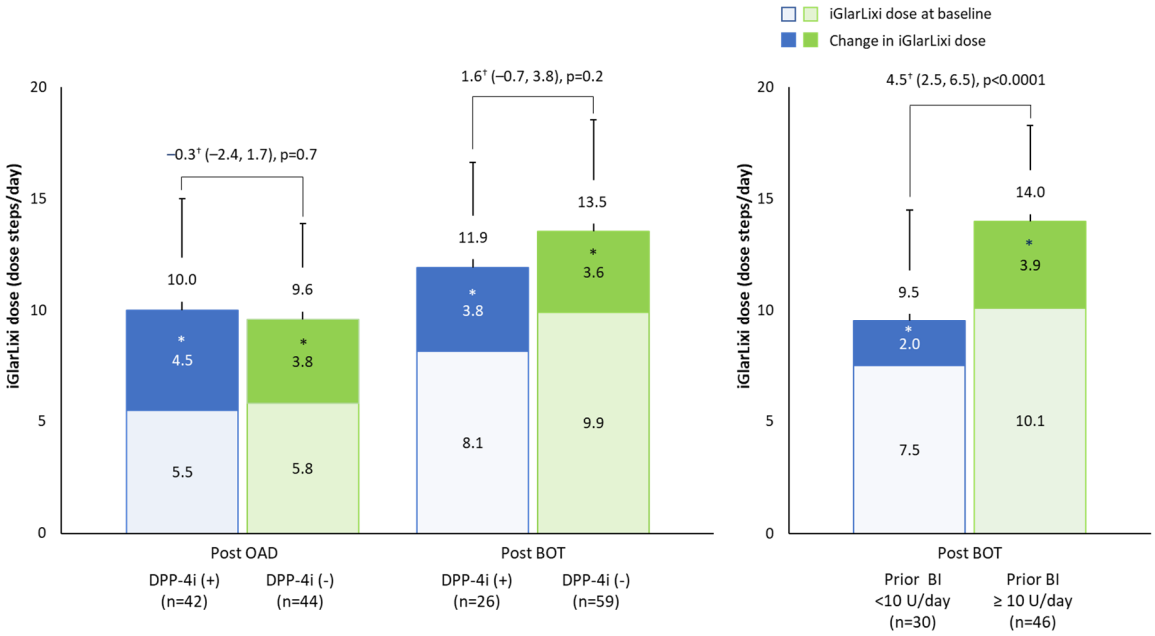
c)



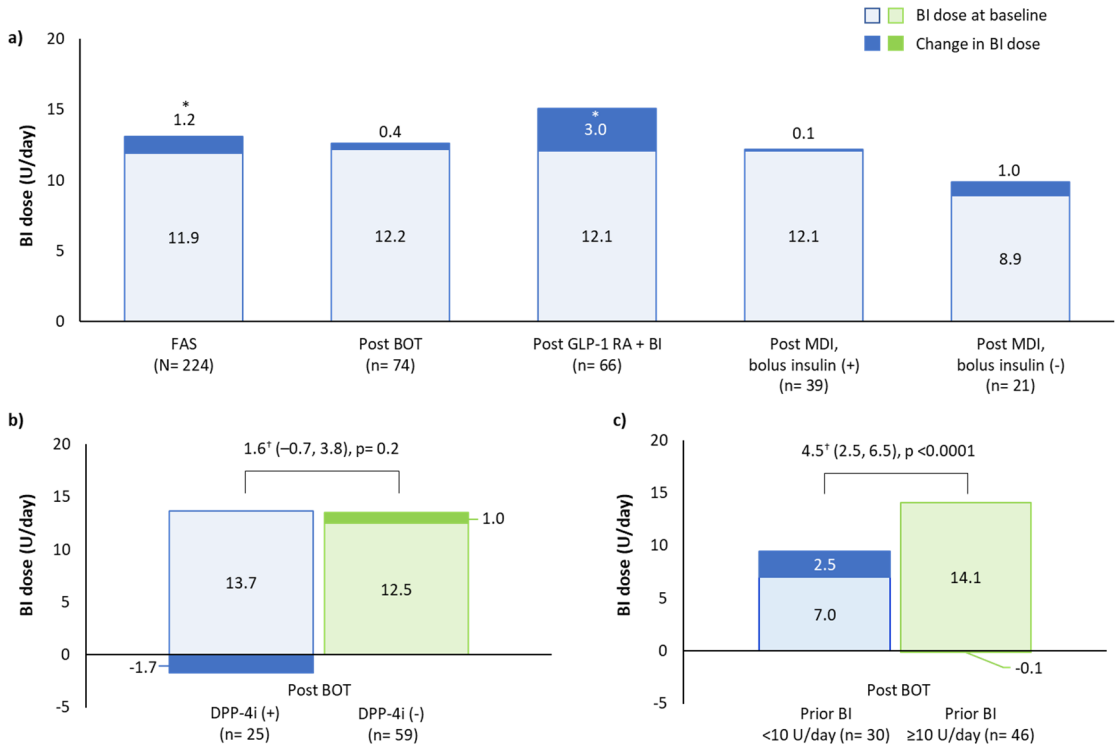
		Baseline	3 months	6 months
<10 U/day	n	30	28	30
≥10 U/day	n	46	46	45

Supplementary Fig. S2 Change in mean ± SD insulin glargine/lixisenatide (iGlarLixi) dose from baseline to 6 months in participants who: were previously suboptimally controlled on oral antidiabetic drugs (OADs), stratified by whether or not they received dipeptidyl peptidase-4 inhibitors (DPP-4is) before initiation of iGlarLixi; switched from combination therapy of OADs and insulin (basal-supported oral therapy [BOT]), stratified by whether or not they received DPP-4is before initiation of iGlarLixi; and switched from BOT, stratified by baseline daily basal insulin dose (<10 vs ≥10 U/day).*p<0.01, paired t-test (vs. initial dose); †regression coefficient (95% CI), univariate analysis

SD standard deviation



Supplementary Fig. S3 Change in mean basal insulin dose from baseline to 6 months, in participants who were previously treated with insulin in **(a)** the full analysis set and by prior treatment subgroup (where applicable); **(b)** participants who switched from combination therapy of oral antidiabetic drugs and insulin (basal insulin-supported oral therapy), stratified by whether or not they received dipeptidyl peptidase-4 inhibitors before iGlarLixi initiation; and **c)** participants who switched from basal insulin-supported oral therapy, stratified by baseline daily basal insulin dose (<10 vs ≥10 U/day).*p<0.001, paired t-test (vs baseline); †regression coefficient (95% CI), univariate analysis*BI* basal insulin, *BOT* basal insulin-supported oral therapy, *DPP-4i* dipeptidyl peptidase-4 inhibitor, *FAS* full analysis set, *GLP-1 RA* glucagon-like peptide-1 receptor agonist, *MDI* multiple daily injections



Supplementary Fig. S4 Change in bolus insulin dose from baseline to 6 months in participants who switched from multiple daily injections (MDI), stratified into those who continued bolus insulin after the initiation of iGlarLixi 'bolus insulin (+)'; and those who did not 'bolus insulin (-)'.

ns not significant (paired t-test, vs baseline)