metabolism, blood pressure, and body weight were evaluated in Japanese patients with type 2 diabetes. In total, 202 patients with type 2 diabetes were treated with liraglutide (113 men, 89 women; age, 57.3 ± 12.8 years). The patients were divided into the following two groups: a liraglutide monotherapy group (147 patients) and a liraglutide-sulfonylurea combination therapy group (55 patients). Clinical parameters were measured before and after liraglutide administration, and their changes were evaluated. In both groups, HbA1c (NGSP; %) decreased significantly after 12 and 24 weeks of treatment ($P < 0.0005$). Furthermore, body weight also decreased significantly after 12 and 24 weeks ($P < 0.05$) in both groups. Adverse events after starting liraglutide occurred in 45 patients (22.3%), and 23 patients (11.4%) discontinued treatment. Since HbA1c improved significantly and body weight decreased significantly in both groups, liraglutide has two advantages for the treatment of patients with diabetes: it improves glycemic control, and it significantly decreases body weight. Consequently, liraglutide is indicated in obese patients with non-insulin-dependent type 2 diabetes.

PCS-20-2

Comparison of Liraglutide and Exenatide with Continuous Glucose Monitoring (CGM) Among Different Types of Diabetes

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OBJECTIVE: Liraglutide (Lira) and exenatide (Ex) have a definite structural difference. We compared the effects of Lira and Ex on diurnal glycemic properties evaluated by Continuous glucose monitoring (CGM) among patients with type 2 diabetes (T2D), diabetes associated with cirrhosis (LC; $n = 7$), and steroid-induced diabetes (ST; $n = 2$).

METHODS: Fourteen patients were hospitalized and given insulin therapy. After glycemic control had been achieved, Lira 0.6 mg daily or Ex 5 μg twice daily were randomly administered for two consecutive days per each in crossover manner, and blood glucose levels (BG) were monitored by CGM. A day was divided into four equal time periods started from 6 a.m., and each period, postprandial period (2 h after meals) and a whole day were compared by calculating area-under-the-curve (AUC).

RESULTS: Lira administration brought three peaks of BG, but only two peaks were observed in Ex by CGM analyses. The 2-h AUC of BG after breakfast and dinner were higher in Lira, whereas that of after lunch and the AUC of midnight were higher in Ex. The AUC of WD with Lira administration was significantly lower only in LC. The mean BG was lower in Lira, but the duration of hypoglycemia was longer in Ex.

CONCLUSION: Our results showed that (1) Lira had a higher efficacy to control midnight glycemia than Ex, (2) Ex had a higher efficacy to control postprandial glycemia after breakfast and dinner, and that (3) Lira is more suitable for patients with LC than Ex.

PCS-20-3

Lixisenatide in Asian Patients with Type 2 Diabetes (T2DM) Uncontrolled on Metformin ± Sulfonylurea (SU): GetGoal-M Asia

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OBJECTIVE: To evaluate once-daily (QD) lixisenatide in Asian patients with T2DM insufficiently controlled on metformin ± SU.

METHODS: This 24-week, multicenter, double-blind study, conducted in China, Malaysia, Thailand, and Hong Kong, randomized patients to lixisenatide 20 μg QD ($N = 196$) or placebo ($N = 195$), with a 1-step dose increase regimen (NCT01169779). The primary endpoint was absolute HbA_{1c} change from baseline to Week 24.

RESULTS: Mean ± SD age was 54.8 ± 10.4 years; diabetes duration 6.6 ± 4.7 years; BMI 26.9 ± 3.8 kg/m^2; HbA_{1c} 8.0 ± 0.7%; 44.6% were receiving SU. At Week 24, improvements from baseline in HbA_{1c}, 2-h PPG and FPG were all significantly greater with lixisenatide *vs* placebo (Table). The study was completed by 91.3% of lixisenatide- and 94.4% of placebo-treated patients. Lixisenatide was well tolerated, with gastrointestinal events being the most frequent treatment-emergent adverse events.

Efficacy parameters to Week 24 (mITT population; LOCF)			
		Lixisenatide n=195	Placebo n=193
HbA_{1c}	Mean (SD) baseline	7.95 (0.81)	7.83 (0.70)
	LS mean change	−0.83%	−0.47%
	LS mean difference (95% CI) vs placebo	−0.36% (−0.55, −0.16); p=0.0004	
Proportion of patients achieving target HbA_{1c}, ≤6.5%; p vs placebo		32.4%; p=0.0010	18.1%
<7%		53.0%; p=0.0030	38.8%
2-hour PPG, mmol/L	Mean (SD) baseline	16.27 (3.82)	17.34 (4.16)
	LS mean change	−5.61	−1.33
	LS mean difference (95% CI) vs placebo	−4.28 (−5.36, −3.20); p<0.0001	
FPG, mmol/L	Mean (SD) baseline	8.83 (2.12)	8.75 (1.84)
	LS mean change	−0.69	−0.21
	LS mean difference (95% CI) vs placebo	−0.48 (−0.85, −0.11); p=0.0109	
Body weight, kg	Mean (SD) baseline	73.57 (14.03)	72.94 (13.61)
	LS mean change	−1.50	−1.24
	LS mean difference (95% CI) vs placebo	−0.27 (−0.78, 0.24); p=0.2980	
Safety to Week 24 (safety population)			
		Lixisenatide n=196	Placebo n=194
Patients with any TEAE, n (%)		126 (64.3)	92 (47.4)
Patients with any serious TEAE, n (%)		3 (1.5)	4 (2.1)
Patients with any gastrointestinal TEAEs, n (%)		57 (29.1)	18 (9.3)
Nausea		32 (16.3)	5 (2.6)
Vomiting		15 (7.7)	2 (1.0)
Diarrhea		7 (3.6)	2 (1.0)
Patients with symptomatic hypoglycemia[a], n (%)		11 (5.6)	5 (2.6)
Patients with severe symptomatic hypoglycemia, n (%)		0	0

[a]Event with clinical symptoms with either plasma glucose <3.3 mmol/L or prompt recovery after oral carbohydrate, intravenous glucose or glucagon administration if no plasma glucose measurement was available; SD=standard deviation; mITT=modified intent to treat (patients with baseline and at least one post-baseline measurement); LOCF=last observation carried forward; HbA_{1c}=glycated hemoglobin; SD=standard deviation; CI=confidence interval; PPG=postprandial glucose; FPG=fasting plasma glucose; TEAE=treatment emergent adverse event

CONCLUSIONS: Over 24 weeks, lixisenatide significantly improved HbA_{1c} from low baseline levels, with a particularly pronounced effect on PPG, and was well-tolerated in Asian patients with T2DM uncontrolled on metformin ± SU.

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PCS-20-4

Liraglutide Added to Insulin Therapy in Poorly-Controlled Japanese Type 2 Diabetes

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BACKGROUND AND AIMS: We investigated the effects of 12 months treatment with liraglutide added to insulin on glycemic control, insulin dose and body weight reduction in poorly-controlled insulin-treated Japanese type 2 diabetic patients. This study is currently in process, so we report preliminary data in this abstract.

MATERIALS AND METHODS: Twelve poorly controlled Japanese type 2 diabetic patients (seven men, mean age 57.8 ± 13.4 years, BMI 28.4 ± 4.1 kg/m^2, diabetes duration 18.9 ± 9.7 years) with insulin therapy were studied. They were initiated liraglutide at 0.3 mg/day, reducing to half dose of their insulin administration. Maximal dose of liraglutide is 0.9 mg/day in Japan.

RESULTS: After 3 months, glycemic control was improved (HbA1c 8.9 ± 0.9–7.9 ± 1.2%, $P < 0.05$) and marked reduction of insulin dose (42.2 ± 21.2–16.6 ± 14.2 U/day, $P < 0.001$) and body weight (77.0 ± 15.5–73.9 ± 15.1 kg, $P < 0.05$). Changes of these parameters were sustained up to 6 months. After 6 months, serum C-peptide and SUIT index ware increased (C-peptide: 1.17 ± 0.29–1.49 ± 0.44 ng/mL, $P < 0.05$, SUIT index: 17.7 ± 7.5–28.4 ± 15.4, $P < 0.05$). Only two patients complained nausea and vomiting at first period and all patients have continued the study until now. No episodes of major hypoglycemia and acute pancreatitis were reported during the study. Nine patients have finished the study at present.

CONCLUSION: For poorly-controlled Japanese type 2 diabetic patients with insulin treatment, liraglutide combination therapy with insulin provided improved glycemic control and sustained weight loss for up to 6 months. Their β-cell function was improved and insulin dose was markedly reduced.

PCS-20-5

Clinical Use of GLP-1 Analogue (Exenatide) in Obese Type 2 DM Taiwanese

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OBJECTIVE: The prevalence of obesity rises in T2DM and high BMI (Body Mass Index) is harmful for health and life quality. We apply the novel T2DM medication GLP-1 analogue (exenatide) to patients with poor HbA1C (over 8%) under original therapy and with BMI over 27 kg/m^2.

METHODS: Patients received exenatide 5 μg twice daily for 1 month and then 10 μg twice daily for 2 months combined with titrating OAD (oral antidiabetic drug).

RESULTS: Fifteen patients were enrolled. Female is predominant (13, 86.7%). The average age is 45.2 years old. The average T2DM duration is 6.3 years. BMI before exenatide is 32.4. Baseline HbA1C is 9.1%. The average OAD (oral antidiabetic drug) for those without insulin therapy is 2.8 kinds. After exenatide 5 μg for 1 month, HbA1C decreases to 8.9% and body weight reduction is 1.2 kg. And after two more months of exenatide 10 μg, HbA1C decreases to 8.5% and body weight reduction is 2.4 kg from baseline. Ten patients (66.7%) achieved both HbA1C improvement with body weight reduction. Side effects were reported in 66.7% cases. The most common side effect is nausea (40%). But most side effects were tolerable and decreased over time. Only one case (6.7%) withdrew due to severe dizziness to 10 μg dose.

CONCLUSION: Exenatide offered both HbA1C improvement as well as body weight reduction in obese T2DM Taiwanese.

PCS-20-6

Withdrawn

PCS-21-1

Linagliptin Therapy Shows Similar Long-Term Safety and Efficacy to Metformin in Japanese Patients with Type 2 Diabetes

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OBJECTIVES: To evaluate safety and efficacy of oral linagliptin *vs* metformin, in Japanese patients with type 2 diabetes (T2DM) and insufficient glycemic control despite background oral antidiabetic drug (OAD) monotherapy.

METHODS: Five hundred and seventy-four patients, HbA1c ≥7% to ≤10%, entered this 52-week, open-label, multicenter, parallel-group trial. Patients on sulfonylurea (SU) or α-glucosidase inhibitor (A-GI) were randomized to add-on linagliptin (once daily, 5mg) or metformin (bid/tid, maximum 2250 mg/day). Additionally, patients on biguanide, glinide, or glitazone received add-on linagliptin.

RESULTS: At week 52, add-on linagliptin and metformin (mean dose, mg/day: 709.02 [A-GI group], 653.23 [SU]) significantly reduced mean HbA1c levels (*vs* baseline: from 7.9% through 8.1%), in all groups. Add-on linagliptin was as effective as metformin after 52 weeks: adjusted mean change from baseline HbA1c: −0.66% (95% confidence interval, CI, −0.81, −0.51) for linagliptin + SU ($n = 123$) *vs* −0.84% (CI, −1.02 to −0.65) for metformin + SU ($n = 62$), non-significant treatment difference, 0.18% (CI, −0.03 to 0.39); corresponding results were −0.92% (CI, −1.10 to −0.73) for linagliptin + A-GI ($n = 61$) *vs* −1.00% (CI, −1.17 to −0.83) for metformin + A-GI ($n = 61$), non-significant treatment difference, 0.09% (CI, −0.13 to 0.30). Adverse events: mostly mild/moderate, similar rates across all groups. Hypoglycemic event rates: similar for linagliptin and metformin (A-GI groups: 2% *vs* 3%; SU groups: 14% *vs* 16%, respectively).

CONCLUSION: Once-daily linagliptin provides well-tolerated, effective therapy with significant HbA1c reductions, similar to metformin, over 52 weeks in Japanese patients with inadequately controlled T2DM despite OAD monotherapy.

PCS-21-2

Vildagliptin is Effective Even with 50 mg per Day for Japanese Type 2 Diabetic Patients

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OBJECTIVE: To reveal the effectiveness of vildagliptin on Japanese type 2 diabetic patients.

METHODS: Eligibles were type 2 diabetic patients who started their therapy with vildagliptin in our hospital and who continued it more than 26 weeks. Usage of vildagliptin was classified depending on the following situations: (1) add-on to diet therapy, (2) add-on to other oral anti-diabetic drugs (OAD), (3) add-on plus discontinuation of some OADs, (4) add-on plus discontinuation of all other OADs, and (5) switch from insulin therapy.

RESULTS: Analyzed were 142 patients. Their mean age, diabetic duration, HbA1c, and BMI were 67.9 ± 10.8 years old, 12.0 ± 10.5 years, 7.4 ± 1.2%, and 22.5 ± 5.5 kg/m^3. Data are mean ± SD HbA1c changed from baseline to week 26, 7.6 ± 1.6–6.5 ± 0.6, 8.5 ± 0.7–7.5 ± 1.2, 7.7 ± 0.8–7.6 ± 1.1, 6.9 ± 0.8–6.8 ± 0.7, and 7.0 ± 1.3–7.2 ± 1.7 in situation (1), (2), (3), (4), and (5), respectively. In situation (1) and (2), HbA1c was reduced by 1.0%. And there was no significant change in situation (3), (4), and (5). Vildagliptin in 50 mg per day was administered to 90 of 142 (63.4%) patients. There was no significant change in HbA1c reduction ($P = 0.51$) between the 50 mg dose group (△ 0.7%, $n = 41$) and the 100 mg dose group (△ 1.0%, $n = 18$) in situation (1) and (2). And no significant change was either observed in HbA1c reduction ($P = 0.39$) between the 50 mg dose group (△ −0.1%, $n = 49$) and the 100 mg dose group (△ 0.1%, $n = 34$) in situation (3), (4), and (5).

CONCLUSION: Vildagliptin was effective even with 50 mg per day for Japanese type 2 diabetic patients in clinical practice.