Editorial Article

The Use of Insulin Analogues in Clinical Practice in Type 2 Diabetes Mellitus: Results from the Egyptian Sub-Group of the A1chieve Observational Study.

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Aim:

A_1chieve[1] was a prospective, multinational, non-interventional study conducted with the aim to bridge the gap of available information regarding the safety and efficacy of insulin analogues in routine clinical practice in developing and newly developed countries. Our focus in this abstract is to highlight the safety and efficacy of insulin analogues in an Egyptian cohort of the A_1chieve[1] study.

Methods:

A total of 412 Egyptian patients with type 2 diabetes mellitus (T2DM) initiating biphasic insulin aspart 30, insulin detemir, and insulin aspart alone or in combination, following prior therapy with oral antidiabetics or other insulins, were included in this 6-month observational study.

The primary outcome was the evaluation of serious adverse drug reactions including major hypoglycaemic events. The secondary outcomes were changes in hypoglycaemic events and the following efficacy parameters: HbA_{1c}, fasting plasma glucose (FPG), postprandial plasma glucose (PPPG), systolic blood pressure (SBP), body weight and lipid profile. Quality of life (QoL) was determined using the EQ-5D* questionnaire that evaluates patient concerns with regard to mobility, self-care, usual activity, pain/discomfort and anxiety.

Results:

This analysis included 172 insulin-naïve patients and 240 prior insulin usershaving mean age ± SD 52.8 ± 9.7 years, mean BMI 30.2 ± 4.9 kg/m^2 and mean diabetes duration 10.5 ± 6.8 years. Mean baseline data were reported as follows: HbA_{1c} 9.2 ± 1.8%, FPG 205.7 ± 78.8 mg/dL, post-breakfast PPPG 282.2 ± 92.7 mg/dL and SBP 134.6 ± 16.4 mmHg. Parameters derived from the baseline data in Egypt were comparable to North Africa, Middle East + Gulf and the global A_1chieve data with the exception of mean body weight that was higher in Egypt (87.6 ± 14.1 kg) and Middle East + Gulf (84.4 ± 15.4 kg) compared to the global A_1chieve data (73.3 ± 14.8 kg).

Keywords: Egypt, type 2 diabetes, insulin analogues, A_1chieve study, observational study.

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Physicians reported that 91.5% of Egyptian patients initiated insulin analogues to improve glycemic control. The mean pre-study insulin dose in prior insulin users was 56.4 ± 28.6 U/day and the starting dose was 62.4 ± 28.0 U/day titrated up to 65.8 ± 29.4 U/day. In insulin-naïve patients the mean insulin analogue dose was titrated up to 35.9 ± 23.9 U/day at Week 24. The highest insulin doses at pre-study (66.7 ± 32.3 U/day), baseline (79.6 ± 28.5 U/day) and Week 24 (82.0 ± 29.0 U/day) were reported in prior insulin users receiving insulin aspart + basal insulin.

Overall hypoglycaemia reduced significantly in the entire cohort from baseline to Week 24 (7.67 vs. 1.97 events/patient-year) with no major hypoglycaemic events at Week 24. At Week 12, 1 event of major nocturnal hypoglycaemia in the insulin aspart + basal insulin group was reported. The proportion of prior insulin users reporting overall hypoglycaemia significantly decreased with all treatments. The highest baseline incidence of overall hypoglycaemia (14.41 events/patient-year) and greatest reduction at Week 24 (1.86 events/patient-year) was reported in prior insulin users receiving insulin aspart + basal insulin (change in proportion of patients affected, $p < 0.0001$). Nocturnal hypoglycaemia decreased in prior insulin users receiving biphasic insulin aspart 30 (3.40 to 0.34 events/patient-year; change in proportion of patients affected, $p = 0.01$) and insulin detemir (3.58 to 0 events/patient-year; change in proportion of patients affected, $p = 0.01$). An increase in overall hypoglycaemia was reported in insulin-naïve patients on biphasic insulin aspart 30 (0.28 events/patient-year at baseline vs 1.81 events/patient-year at Week 24) and insulin aspart + basal insulin (2.36 events/patient-year at baseline vs. 7.22 events/patient-year at Week 24); however, the increase in the proportion of patients affected was not significant ($p > 0.3$). This increase was primarily attributed to the occurrence of minor hypoglycaemic events. Nocturnal hypoglycaemia in insulin-naïve patients decreased from 0.87 to 0 events/patient-year in the insulin detemir group (change in proportion of patients affected, $p = 0.12$), while an increase from 0 to 2.89 events/patient-year was reported with insulin aspart + basal insulin (change in proportion of patients affected, $p = 0.19$). The highest baseline hypoglycaemia and consequently the greatest reduction at Week 24 were reported in Egypt and North Africa compared to Middle East + Gulf and global A1chieve data.

In the entire Egyptian cohort, significant reductions in HbA_{1c} (-1.7 ± 1.8%), FPG (-73.9 ± 82.9 mg/dL), post-breakfast PPPG (-110.7 ± 103.7 mg/dL) and SBP (-5.1 ± 16.4 mmHg) were observed ($p < 0.001$). These results were consistent with those reported in North Africa and Middle East + Gulf as well as the global A1chievedata.The change from baseline in HbA_{1c} (-2.4 ± 1.5%), FPG (-99.0 ± 78.0 mg/dL), PPPG (-139.1 ± 96.1 mg/dL) and SBP(-8.6 ± 19.6 mmHg) was more profound in insulin-naïve patients on biphasic insulin aspart 30 compared to other groups. Lipid parameters improved significantly in the entire Egyptian cohort while body weight changed minimally. These findings were in line with data from North Africa, Middle East + Gulf and the global A1chieve data.

QoL improved significantly in Egyptian patients (change in visual analogue scores* 15.1 ± 16.1 points, $p < 0.001$). Pain/discomfort was the QoL parameter that recorded the greatest changein patients experiencing no problems from baseline (40.4%) to Week 24 (64.2 %, $p < 0.0001$)followed by usual activity (59.2% at baseline vs. 76.5% at Week 24, $p < 0.0001$) and anxiety (57.1% at baseline vs. 74.3% at Week 24, $p < 0.0001$).

*The current QoL was measured on a standard 20 cm visual analogue scale. The EQ-5D VAS scores range from 0 to 100 (worst imaginable to best imaginable health). Each health-state dimension can be converted to a single utility value using an EQ-5D value set, the UK VAS set in the A1chieve study, and is anchored by '1.00' representing full health and '0.00' representing the state 'dead'.

Table I. Baseline and 24-week data for effectiveness outcomes in the entire cohort and by pre-study insulin type- Egyptian data

Parameter		Entire cohort (n = 412)	Insulin-naïve (n = 172)	Prior insulin users (n = 240)
HbA_{1c}, %	Baseline	9.2 (1.8)	9.2 (1.9)	9.2 (1.8)
	Week 24	7.6 (1.5)	7.2 (1.0)	7.8 (1.7)
	Change	-1.7 (1.8)	-2.0 (1.6)	-1.4 (1.9)
	p	<0.001	<0.001	<0.001
FPG, mg/dL	Baseline	205.7 (78.8)	200.3 (72.6)	209.4 (82.9)
	Week 24	131.8 (49.3)	118.5 (32.2)	141.2 (56.7)
	Change	-73.9 (82.9)	-81.9 (73.8)	-68.2 (88.4)
	p	<0.001	<0.001	<0.001
PPPG, mg/dL post-breakfast	Baseline	282.2 (92.7)	283.4 (85.0)	281.4 (98.1)
	Week 24	171.6 (54.8)	164.2 (53.1)	176.9 (55.6)
	Change	-110.7 (103.7)	-119.2 (95.5)	-104.5 (109.1)
	p	<0.001	<0.001	<0.001
Body weight, kg	Baseline	87.6 (14.1)	87.5 (12.7)	87.6 (15.1)
	Week 24	87.5 (13.5)	87.3 (12.0)	87.6 (14.5)
	Change	-0.1 (3.2)	-0.2 (3.1)	-0.1 (3.3)
	p	0.537	<0.001	<0.812
SBP, mmHg	Baseline	134.6 (16.4)	134.2 (16.6)	134.9 (16.3)
	Week 24	129.5 (13.7)	128.0 (10.8)	130.5 (15.3)
	Change	-5.1 (16.4)	-6.2 (15.4)	-4.4 (17.1)
	p	<0.001	<0.001	<0.001
Total cholesterol, mg/dL	Baseline	203.5 (44.2)	204.3 (39.7)	202.9 (47.5)
	Week 24	183.5 (36.6)	181.9 (35.4)	184.7 (37.6)
	Change	-20.1 (51.0)	-22.4 (45.7)	-18.3 (54.9)
	p	<0.001	<0.001	<0.001
Triglycerides, mg/dL	Baseline	185.2 (92.4)	192.6 (96.2)	179.6 (89.4)
	Week 24	155.5 (59.0)	155.7 (61.0)	155.4 (57.6)
	Change	-29.7 (77.0)	-36.9 (77.2)	-24.2 (76.6)
	p	<0.001	<0.001	<0.001
HDL cholesterol, mg/dL	Baseline	43.0 (11.1)	43.7 (11.9)	42.4 (10.5)
	Week 24	45.3 (12.5)	44.8 (5.9)	45.8 (15.8)
	Change	2.4 (14.3)	1.0 (11.3)	3.4 (16.2)
	p	0.03	0.421	0.041
LDL cholesterol, mg/dL	Baseline	122.6 (35.5)	123.8 (36.5)	121.8 (34.9)
	Week 24	112.7 (29.6)	114.1 (28.6)	111.6 (30.4)
	Change	-10.0 (36.4)	-9.6 (37.6)	-10.2(35.7)
	p	<0.001	0.028	0.006

Data reported as mean (SD)

Table II. Rates of hypoglycaemia in the entire cohort and by pre-study insulin therapy type-Egyptian data

Parameter		Entire cohort	Insulin-naïve	Prior insulin users
Overall	Baseline	7.67/23.8	1.74/7.0	11.92/35.8
	Week 12	1.61/7.8	1.39/5.7	1.77/9.2
	Week 24	1.97/8.2	1.43/5.8	2.35/10.0
	P	<0.0001	0.822	<0.001
Minor	Baseline	7.16/22.6	1.59/7.0	11.16/33.8
	Week 12	1.58/7.5	1.39/5.7	1.71/8.8
	Week 24	1.97/8.2	1.43/5.8	2.35/10.0
	P	<0.0001	0.822	<0.001
Nocturnal	Baseline	1.89/9.2	0.60/2.9	2.82/13.8
	Week 12	0.30/2.1	0.25/1.3	0.34/2.6
	Week 24	0.28/2.1	0.17/1.3	0.35/2.7
	P	<0.0001	0.45	<0.001
Major	Baseline	0.50/2.2	0.15/0.6	0.76/3.3
	Week 12	0.03/0.3[a]	0/0	0.06/0.4[a]
	Week 24	0/0	0/0	0/0
	p	0.004	1	0.0077

Data reported as event per patient-year/percent with event
p-value is for difference in percent of patients with at least one event at Week 24
[a]1 event of major nocturnal hypoglycaemia reported in 1 patient

Table III - Baseline and 24-week data for effectiveness outcomes by insulin analogue regimen started- Egyptian Data

		Insulin-naïve				Prior insulin users			
		Biphasic insulin aspart 30	**Insulin detemir**	**Insulin aspart alone**	**Insulin aspart +basal**	**Biphasic insulin aspart 30**	**Insulin detemir**	**Insulin aspart alone**	**Insulin aspart +basal**
Insulin dose, U/day	n	47	105	1	11	84	40	0	46
	Prestudy	-	-	-	-	53.5 (26.2)	33.3 (22.7)	-	66.7 (32.3)
	Baseline	44.7 (13.8)	17.8 (9.2)	15.0 (0)	69.3 (20.1)	60.6 (23.1)	25.5 (11.6)	-	79.6 (28.5)
	Week 24	48.5 (15.9)	23.3 (14.7)	35.0 (0)	70.8 (27.7)	67.6 (26.8)	27.0 (11.9)	-	82.0 (29.0)
HbA_{1c}, %	n	37	82	1	9	58	35	0	38
	Baseline	9.8 (1.8)	8.8 (1.7)	8.3 (0)	9.1 (2.8)	9.4 (1.5)	8.7 (1.9)	-	9.4 (1.8)
	Week 24	7.4 (0.9)	7.0 (1.0)	8.5 (0)	6.8 (0.7)	7.8 (1.3)	7.9 (2.0)	-	7.5 (1.2)
	Change	-2.4 (1.5)	-1.8 (1.6)	0.2 (0)	-2.3 (2.4)	-1.6 (1.6)	-0.8 (2.1)	-	-1.9 (1.7)
	p	<0.001	<0.001	<0.001	0.021	<0.001	0.029		<0.001
FPG, mg/dL	n	43	95	1	8	76	39	0	41
	Baseline	221.3 (66.5)	185.1 (66.7)	171.0 (.)	231.8 (99.8)	207.7 (73.8)	181.8 (80.8)	-	211.3 (92.7)
	Week 24	122.3 (39.6)	114.6 (27.0)	191.0 (.)	120.5 (28.2)	133.1 (42.2)	132.9 (45.6)	-	137.9 (46.7)
	Change	-99.0 (78.0)	-70.5 (65.5)	20.0 (.)	-111.3 (111.6)	-74.6 (69.7)	-48.9 (87.7)	-	-73.4 (96.3)
	p	<0.001	<0.001	<0.001	0.0026	<0.001	<0.001		<0.001
PPPG, mg/dL	n	43	94	1	8	75	37	0	39
	Baseline	303.3 (73.3)	270.4 (88.8)	372.0 (.)	311.0 (101.1)	282.4 (86.7)	255.4 (93.9)	-	280.6 (112.1)
	Week 24	164.2 (59.0)	164.0 (50.3)	299.0 (.)	146.6 (32.0)	173.5 (45.6)	182.3 (54.5)	-	167.4 (45.7)
	Change,	-139.1 (96.1)	-106.5 (92.5)	-73.0 (.)	-164.4 (113.6)	-108.9 (88.7)	-73.1 (105.4)	-	-113.2 (114.8)
	p	<0.001	<0.001	<0.001	0.005	<0.001	<0.001		<0.001
Body weight, kg	n	40	93	1	9	73	39	0	41
	Baseline	89.0 (14.6)	87.2 (11.5)	61.0 (-)	88.1 (13.7)	89.2 (14.4)	89.2 (16.5)	-	88.6 (15.5)
	Week 24	88.6 (13.8)	87.0 (11.0)	64.0 (-)	88.9 (13.2)	89.6 (13.8)	88.9 (15.6)	-	88.2 (15.0)
	Change	-0.4 (3.4)	-0.2 (3.1)	3.0 (0)	0.7 (3.0)	0.4 (4.3)	-0.3 (2.4)	-	-0.5 (2.6)
	p	0.45	0.594	<0.001	0.479	0.434	0.408		0.249
SBP, mmHg	n	43	94	1	9	77	37	0	42
	Baseline	137.3 (20.2)	133.4 (15.0)	140.0 (-)	135.0 (18.4)	138.3 (14.4)	128.8 (11.4)	-	130.7 (19.0)
	Week 24	128.7 (10.9)	127.8 (11.0)	140.0 (-)	130.6 (10.7)	131.3 (18.4)	130.1 (14.1)	-	128.2 (11.2)
	Change	-8.6 (19.6)	-5.6 (13.2)	0.0 (-)	-4.4 (18.3),	-7.0 (19.1)	1.4 (12.5)	-	-2.5 (13.3)
	p	0.006	<0.001	<0.001	0.486	0.002	0.515		0.229
Total cholesterol, mg/dL	n	16	65	1	5	42	28	0	23
	Baseline	229.8 (26.6)	198.0 (40.2)	182.0 (.)	208.2 (52.5)	209.8 (50.6)	202.9 (40.9)	-	182.2 (38.5)
	Week 24	171.9 (59.0)	181.8 (23.3)	320.0 (.)	185.2 (25.6)	184.1 (42.2)	185.6 (33.7)	-	179.2 (28.0)
	Change	-57.9 (62.2)	-16.2 (32.1)	138.0 (.)	-23.0 (52.0)	-25.7 (54.7)	-17.3 (43.1)	-	-3.0 (37.2)
	p	0.002	<0.001	<0.001	0.379	0.004	0.043		0.702
Triglycerides, mg/dL	n	16	65	1	5	42	29	0	23
	Baseline	238.3 (102.6)	183.2 (94.4)	148.0 (.)	159.6 (93.8)	186.6 (74.6)	179.6 (87.6)	-	148.1 (101.9)
	Week 24	149.1 (56.6)	157.8 (63.5)	171.0 (.)	125.4 (50.9)	160.1 (54.1)	158.2 (63.2)	-	133.1 (56.4)
	Change	-89.2 (101.2)	-25.4 (69.3)	23.0 (.)	-34.2 (43.9)	-26.5 (76.2)	-21.4 (68.8)	-	-15.0 (65.3)
	p	0.003	0.004	<0.001	0.156	0.03	0.105		0.282
HDL cholesterol, mg/dL	n	9	60	1	5	32	26	0	21
	Baseline	47.6 (20.3)	43.3 (10.8)	35.0 (.)	45.2 (6.2)	40.6 (7.7)	44.1 (13.0)	-	43.7 (9.6)
	Week 24	43.3 (5.7)	45.1 (5.6)	38.0 (.)	46.0 (10.1)	46.0 (17.2)	46.5 (21.0)	-	47.1 (12.4)
	Change	-4.2 (19.0)	1.8 (10.4)	3.0 (.)	0.8 (6.8)	5.3 (16.2)	2.4 (23.4)		3.4 (9.6)
	p	0.523	0.199	<0.001	0.804	0.073	0.601		0.118
LDL cholesterol, mg/dL	n	9	59	1	5	32	26	0	20
	Baseline	155.3 (17.8)	117.8 (36.2)	117.0 (.)	140.8 (46.7)	127.8 (44.3)	119.2 (28.9)	-	108.3 (25.7)
	Week 24	126.0 (25.1)	109.8 (24.1)	248.0 (.)	119.8 (20.8)	109.6 (31.7)	111.4 (28.8)	-	105.1 (29.7)
	Change	-29.3 (34.4)	-8.0 (32.0)	131.0 (.)	-21.0 (56.8)	-18.1 (34.1)	-7.8 (31.1)	-	-3.2 (34.7)
	p	0.034	0.061	<0.001	0.455	0.005	0.214		0.683

Data reported as mean (SD)

Table IV. Rates of hypoglycaemia in the entire cohort and by pre-study insulin regimen type-Egyptian data

		Insulin-naive				Prior insulin users			
		Biphasic insulin aspart 30	**Insulin detemir**	**Insulin aspart alone**	**Insulin aspart +basal**	**Biphasic insulin aspart 30**	**Insulin detemir**	**Insulin aspart alone**	**Insulin aspart +basal**
Overall	Baseline	0.28/2.1	2.10/8.6	0/0	2.36/9.1	10.21/29.8	11.38/30.0	0/0	14.41/45.7
	Week 12	0.89/4.5	1.35/4.2	0/0	5.20/30.0	1.63/8.8	0.65/5.0	0/0	2.42/11.6
	Week 24	1.81/7.0	0.55/3.2	0/0	7.22/22.2	2.70/13.0	0.67/2.6	0/0	1.86/ 4.8
	p[a]	0.3451	0.1399	-	0.5658	0.0126	0.0015	-	<0.0001
Minor	Baseline	0.28/ 2.1	1.86/8.6	0/0	2.36/9.1	9.29/28.6	10.73/25.0	0/0	12.72/41.3
	Week 12	0.89/4.5	1.35/4.2	0/0	5.20/30.0	1.63/8.8	0.65/5.0	0/0	2.12/9.3
	Week 24	1.81/7.0	0.55/3.2	0/0	7.22/22.2	2.70/13.0	0.67/2.6	0/0	1.86/4.8
	p[a]	0.3451	0.1399	-	0.5658	0.02	0.0069	-	<0.0001
Nocturnal	Baseline	0/0	0.87/3.8	0/0	0/0	3.40/14.3	3.58/17.5	0/0	2.83/13.0
	Week 12	0/0	0.27/1.0	0/0	1.30/10.0	0.16/1.3	0.65/5.0	0/0	0.60/4.7[a]
	Week 24	0/0	0/0	0/0	2.89/22.2	0.34/2.6	0/0	0/0	0.31/2.4
	p[a]	-	0.1231	-	0.1895	0.0104	0.0117	-	0.1127
Major	Baseline	0/0	0.25/1.0	0/0	0/0	0.93/2.4	0.65/ 5.0	0/0	1.70/8.7
	Week 12	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0.30/2.3[a]
	Week 24	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
	p[a]	-	1	-	-	0.4978	0.4937	-	0.118

Data reported as event per patient-year/percent with event p-value is for difference in percent of people with at least one event
[a]1 event of major nocturnal hypoglycaemia reported in 1 patient at Week 12

Table V. Baseline and 24-week data for effectiveness and safety outcomes by entire cohort

Parameter		**Egypt (n = 412)**	**North Africa (n = 4033)**	**Middle East + Gulf (n = 14,896)**	**Global study (n =44,661)**
HbA1c, %	Baseline	9.2 (1.8)	9.5 (1.8)	9.6 (1.7)	9.5 (1.7)
	Week 24	7.6 (1.5)	7.9 (1.4)	7.4 (1.1)	7.4 (1.1)
	Change	-1.7 (1.8)	-1.6 (1.9)	-2.2 (1.6)	-2.1 (1.7)
	p	<0.001	<0.001	<0.001	<0.001
FPG, mg/dL	Baseline	205.7 (78.8)	205.1 (75.4)	204.1 (66.3)	197.2 (63.6)
	Week 24	131.8 (49.3)	142.5 (50.0)	126.7 (33.3)	128.6 (35.0)
	Change	-73.9 (82.9)	-62.7 (85.4)	-77.4 (64.9)	-68.6 (63.1)
	p	<0.001	<0.001	<0.001	<0.001
PPPG, mg/dL post-breakfast	Baseline	282.2 (92.7)	265.9 (84.3)	277.5 (82.1)	272.5 (79.4)
	Week 24	171.6 (54.8)	187.2 (63.4)	166.4 (43.8)	175.6 (52.2)
	Change	-110.7 (103.7)	-78.7 (99.7)	-111.1 (81.1)	-96.9 (80.6)
	p	<0.001	<0.001	<0.001	<0.001
Body weight, kg	Baseline	87.6 (14.1)	75.4 (13.3)	84.4 (15.4)	73.3 (14.8)
	Week 24	87.5 (13.5)	76.2 (12.8)	84.0 (14.4)	73.3 (14.1)
	Change	-0.1 (3.2)	0.9 (3.9)	-0.4 (4.4)	0.1 (3.7)
	p	0.537	<0.001	<0.001	<0.001
SBP, mmHg	Baseline	134.6 (16.4)	133.1 (18.2)	134.9 (17.3)	134.2 (17.8)
	Week 24	129.5 (13.7)	131.0 (19.2)	128.5 (13.2)	127.9 (13.5)
	Change	-5.1 (16.4)	-2.1 (20.9)	-6.4 (16.5)	-6.3 (17.1)
	p	<0.001	<0.001	<0.001	<0.001
Total cholesterol, md/dL	Baseline	203.5 (44.2)	181.9 (45.9)	205.5 (45.6)	205.4 (49.5)
	Week 24	183.5 (36.6)	174.4 (39.0)	181.8 (32.0)	185.4 (37.6)
	Change	-20.1 (51.0)	-7.6 (46.9)	-23.7 (43.9)	-20.0 (45.3)
	p	<0.001	<0.001	<0.001	<0.001
Triglycerides, mg/dL	Baseline	185.2 (92.4)	146.3 (83.0)	193.3 (89.5)	184.2 (95.1)
	Week 24	155.5 (59.0)	136.1 (59.6)	161.9 (59.5)	155.7 (64.4)
	Change	-29.7 (77.0)	-10.1 (76.5)	-31.4 (81.5)	-28.4 (83.5)
	p	<0.001	<0.001	<0.001	<0.001
HDL cholesterol, mg/dL	Baseline	43.0 (11.1)	43.1 (15.9)	42.2 (12.9)	44.4 (15.5)
	Week 24	45.3 (12.5)	44.3 (15.1)	43.5 (11.2)	46.5 (15.4)
	Change	2.4 (14.3)	1.2 (19.4)	1.4 (13.4)	2.1 (15.5)
	p	0.03	0.046	<0.001	<0.001
LDL cholesterol, mg/dL	Baseline	122.6 (35.5)	111.5 (47.9)	122.1 (38.1)	121.2 (40.6)
	Week 24	112.7 (29.6)	106.1 (42.2)	106.0 (29.5)	106.5 (33.4)
	Change	-10.0 (36.4)	-5.4 (56.6)	-16.1 (38.8)	-14.6 (40.5)
	p	<0.001	0.003	<0.001	<0.001

Data reported as mean (SD)

Table VI. Rates of hypoglycaemia by entire cohort

Parameter		Egypt (n = 412)	North Africa (n = 4033)	Middle East + Gulf (n = 14,896)	Global study (n =44,661)
Overall	Baseline	7.67/23.8	8.14/18.6	3.94/10.1	3.11/8.9
	Week 12	1.61/7.8	4.94/16.2	2.18/8.0	1.85/6.7
	Week 24	1.97/8.2	4.09/13.6	2.1/7.6	1.61/5.9
	P	<0.0001	<0.001	<0.001	<0.0001
Minor	Baseline	7.16/22.6	6.96/18.0	3.36/9.5	2.79/8.5
	Week 12	1.58/7.5	4.85/16.2	2.16/8.0	1.84/6.7
	Week 24	1.97/8.2	4.03/13.4	2.09/7.6	1.60/5.8
	P	<0.0001	<0.001	<0.001	<0.0001
Nocturnal	Baseline	1.89/9.2	3.23/11.4	1.07/4.6	0.93/4.0
	Week 12	0.30/2.1	1.35/5.7	0.56/2.8	0.42/2.0
	Week 24	0.28/2.1	1.26/5.3	0.57/2.9	0.36/1.8
	P	<0.0001	<0.001	<0.001	<0.0001
Major	Baseline	0.50/2.2	1.18/5.3	0.58/2.5	0.33/1.5
	Week 12	0.03/0.3[a]	0.09/0.4	0.02/0.1	0.01/0.06
	Week 24	0/0	0.06/0.2	0.01/0.1	0.01/0.03
	p	0.004	<0.001	<0.001	<0.0001

Data reported as event per patient-year/percent with event

p-value is for difference in percent of patients with at least one event at Week 24

[a]1 event of major nocturnal hypoglycaemia reported in 1 patient

Serious adverse event report

At Week 12, 1 prior insulin user receiving insulin aspart (80 IU) + basal insulin (insulin detemir 30 IU) experienced 1 event of major nocturnal hypoglycaemia.

Conclusions:

Insulin analogue therapy resulted in improved glycaemic control and a significant overall decrease in hypoglycaemia without any major concerns of safety in Egyptian T2DM patients. These results provide evidence that initiating or switching to insulin analogues could be beneficial in long-term T2DM management irrespective of prior insulin use.

Reference:

1. **Home P, Naggar NE, Khamseh M, et al.** An observational non-interventional study of people with diabetes beginning or changed to insulin analogue therapy in non-Western countries: the A1chieve study. Diabetes Res Clin Pract 2011;94(3):352-63.