Original Article

Clinical experience with insulin detemir, biphasic insulin aspart and insulin aspart in people with type 2 diabetes: Results from the Casablanca cohort of the A_1chieve study

Ahmed Farouqi, Asmae Chadli

Departments of Diabetes, Endocrinology and Nutrition, Ibnou Rochd University Hospital, Casablanca, Morocco

ABSTRACT

Background: The A_1chieve, a multicentric (28 countries), 24-week, non-interventional study evaluated the safety and effectiveness of insulin detemir, biphasic insulin aspart and insulin aspart in people with T2DM (n = 66,726) in routine clinical care across four continents. **Materials and Methods:** Data was collected at baseline, at 12 weeks and at 24 weeks. This short communication presents the results for patients enrolled from Casablanca, Morocco. **Results:** A total of 495 patients were enrolled in the study. Four different insulin analogue regimens were used in the study. Study patients had started on or were switched to biphasic insulin aspart (n = 231), insulin detemir (n = 151), insulin aspart (n = 19), basal insulin plus insulin aspart (n = 53) and other insulin combinations (n = 41). At baseline glycaemic control was poor for both insulin naïve (mean HbA_1c: 10.2%) and insulin user (mean HbA_1c: 9.4%) groups. After 24 weeks of treatment, both groups showed improvement in HbA_1c (insulin naïve: –2.3%, insulin users: –1.8%). Major hypoglycaemia was observed in the insulin naïve group after 24 weeks. SADRs were reported in 1.2% of insulin naïve and 2.1% of insulin user groups. **Conclusion:** Starting or switching to insulin analogues was associated with improvement in glycaemic control with a low rate of hypoglycaemia.

Key words: A_1chieve study, Casablanca, insulin analogues, type 2 diabetes mellitus

Introduction

Diabetes prevalence in Morocco is estimated to be 6.4%.[1] Fear of hypoglycaemia and gain in body weight are barriers for initiation of insulin therapy.[2] Modern insulin analogues are a convenient new approach or tool to glycaemic control, associated with low number of hypoglycaemia and favourable weight change.[3] A_1chieve, a multinational, 24-week, non-interventional study, assessed the safety and effectiveness of insulin analogues in people with T2DM (n = 66,726) in routine clinical care.[4] This short communication presents the results for patients enrolled from Casablanca, Morocco.

Access this article online	
Quick Response Code:	Website: www.ijem.in
	DOI: 10.4103/2230-8210.122042

Materials and Methods

Please refer to editorial titled: The A_1chieve study: Mapping the Ibn Battuta trail.

Results

A total of 495 patients were enrolled in the study. The patient characteristics for the entire cohort divided as insulin-naïve and insulin users is shown in the Table 1. Glycaemic control at baseline was poor in this population. The majority of patients (46.7%) started on or were switched to biphasic insulin aspart. Other groups were insulin detemir (n = 151), insulin aspart (n = 19), basal insulin plus insulin aspart (n = 53) and other insulin combinations (n = 41).

Corresponding Author: Prof. Ahmed Farouqi, Ibnou Rochd University Hospital, Casablanca, Morocco. Email id: afarouqi@fmpc.ac.ma

After 24 weeks of treatment, overall hypoglycaemic events or episodes reduced from 11.7 events/patient-year to 5.0 events/patient-year in insulin user group whereas overall hypoglycaemia increased from 3.5 events/patient-year to 3.8 events/patient-year in the insulin naïve group. However, this hypoglycaemia incidence in insulin naive group at 24 weeks was still lower than that observed in insulin users at baseline. Major hypoglycaemic events or episodes occurred in the insulin naïve group. SADRs were reported in 1.2% of insulin naïve and 2.1% of insulin user groups. Blood pressure and quality of life improved after 24 weeks. Although lipid profile improved in the total cohort, but the finding was limited by number of observations [Tables 2 and 3].

All parameters of glycaemic control improved from baseline to study end in the total cohort [Table 4].

Table 1: Overall demographic data

Parameters	Insulin naïve	Insulin users	All
Number of participants	253	242	495
Male *N* (%)	115 (45.5)	107 (44.2)	222 (44.8)
Female *N* (%)	138 (54.5)	135 (55.8)	273 (55.2)
Age (years)	57.5	55.5	56.5
Weight (kg)	71.2	75.1	73.1
BMI (kg/m^2)	26.3	27.5	26.9
Duration of DM (years)	9.2	13.2	11.2
No therapy			22
>2 OGLD	4	1	5
HbA_1c	10.2	9.4	9.9
FPG (mmol/L)	14.3	11.9	13.2
PPPG (mmol/L)	18.5	16.0	17.4
Macrovascular complications, *N* (%)	56 (22.1)	56 (23.1)	112 (22.6)
Microvascular complications, *N* (%)	136 (53.8)	133 (55.0)	269 (54.3)
Pre-study therapy, *N* (%)			
Insulin users			242 (48.88)
OGLD only			231 (46.66)
No therapy			22 (4.44)
Baseline therapy, *N* (%)			
Insulin detemir±OGLD			151 (30.5)
Insulin aspart±OGLD			19 (3.8)
Basal+insulin aspart±OGLD			53 (10.7)
Biphasic insulin aspart±OGLD			231(46.7)
Others			41 (8.3)

BMI: Body mass index, OGLD: Oral glucose-lowering drug, HbA_1c: Glycated hemoglobin A_1c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose, DM: Diabetes mellitus

Biphasic insulin aspart ± OGLD

Of the total cohort, 231 patients started on biphasic insulin aspart ± OGLD, of which 121 (52.4%) were insulin naïve and 110 (47.6%) were insulin users. After 24 weeks of treatment, hypoglycaemic events or episodes reduced from 11.1 events/patient-year to 2.9 events/patient-year in insulin user group whereas hypoglycaemia increased from 1.3 events/patient-year to 3.2 events/patient-year in insulin naïve group. Quality of life improved at the end of the study [Tables 5 and 6].

All parameters of glycaemic control improved from baseline to study end in those who started on or were

Table 2: Overall safety data

Parameter	*N*	Baseline	Week 24	Change from baseline
Hypoglycaemia (insulin naïve), events/participant-year				
All	253	3.5	3.8	0.3
Nocturnal		0.9	1.6	0.7
Major		0.7	0.1	−0.6
Hypoglycaemia (insulin users), events/participant-year				
All	242	11.7	5	−6.7
Nocturnal		4.7	1.2	−3.5
Major		2.2	0.0	−2.2
Body weight, kg				
Insulin naïve	185	70.9	74.3	3.4
Insulin users	166	75.1	76.2	1.1
Lipids and BP (insulin naïve)				
LDL-C, mean (mmol/L), (*N*, % <2.5 mmol/L)	102	3.3 (23, 22.5)	2.6 (22, 40.7)	−0.7
HDL-C, mean (mmol/L), (*N*, % >1.0 mmol/L)	96	1.2 (73, 76.0)	1.2 (43, 86.0)	0.0
TG, mean (mmol/L), (*N*, % <2.3 mmol/L)	114	1.9 (83, 72.8)	1.6 (55, 88.7)	−0.3
SBP, mean (mmHg), (*N*, % <130 mmHg)	245	135.6 (73, 29.8)	132.0 (68, 35.1)	−3.6
Lipids and BP (insulin users)				
LDL-C, mean (mmol/L), (*N*, % <2.5 mmol/L)	105	3.2 (23, 21.9)	2.7 (13, 33.3)	−0.5
HDL-C, mean (mmol/L), (*N*, % >1.0 mmol/L)	93	1.3 (76, 81.7)	1.4 (36, 94.7)	0.1
TG, mean (mmol/L), (*N*, % <2.3 mmol/L)	110	1.6 (95, 86.4)	1.6 (37, 90.2)	0.0
SBP, mean (mmHg), (*N*, % <130 mmHg)	235	133.2 (73, 31.1)	131.0 (63, 35.2)	−2.2
Quality of life, VAS scale (0-100)				
Insulin naïve	200	62.7	78.3	15.6
Insulin users	179	66.0	77.3	11.3

BP: Blood pressure, LDL-C: Low-density lipoprotein cholesterol, HDL-C: High-density lipoprotein cholesterol, TG: Triglycerides, SBP: Systolic blood pressure, VAS: Visual analogue scale

switched to biphasic insulin aspart for both insulin naïve and insulin user groups [Table 7].

Basal + insulin aspart ± OGLD

Of the total cohort, 53 patients started on basal + insulin aspart ± OGLD, of which 10 (18.9%) were insulin naïve and 43 (81.1%) were insulin users. After 24 weeks, hypoglycaemic events reduced from 29.9 events/patient-year to 0.0 events/patient-year in insulin naive group and from 14.5 events/patient-year to 8.1 events/patient-year in insulin user group. Quality of life improved after 24 weeks [Tables 8 and 9].

All parameters of glycaemic control improved from baseline to study end in those who started on or were switched to basal + insulin aspart ± OGLDs for both insulin naïve and insulin user groups [Table 10].

Insulin detemir ± OGLD

Of the total cohort, 151 patients started on insulin detemir ± OGLD, of which 111 (73.5%) were insulin naïve and 40 (26.5%) were insulin users. After 24 weeks of starting or switching to insulin detemir, hypoglycaemia reduced from 13.7 events/patient-year to 3.7 events/patient-year in insulin user group while hypoglycaemic events increased from 3.9 events/patient-year to 4.7 events/patient-year

Table 3: Insulin dose

Insulin dose, U/day	*N*	Pre-study	*N*	Baseline	*N*	Week 24
Insulin naïve	0	0.0	253	28.7	207	34.2
Insulin users	242	41.5	242	42.5	184	49.2

Table 4: Overall efficacy data

Parameter	*N*	Baseline	Week 24	Change from baseline
Glycaemic control (insulin naïve)				
HbA_1c, mean (%)	124	10.2	7.9	−2.3
FPG, mean (mmol/L)	170	14.3	8.1	−6.2
PPPG, mean (mmol/L)	108	18.5	10.2	−8.3
Glycaemic control (insulin users)				
HbA_1c, mean (%)	112	9.4	7.6	−1.8
FPG, mean (mmol/L)	139	11.9	7.5	−4.4
PPPG, mean (mmol/L)	87	16.0	10.1	−5.9
Achievement of HbA_1c <7.0% at week 24				
Insulin naïve (% of patients)	159	21.4		
Insulin users (% of patients)	140	20.7		

HbA_1c: Glycated haemoglobin A_1c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose

Table 5: Biphasic insulin aspart±oral glucose-lowering drug safety data

Parameter	*N*	Baseline	Week 24	Change from baseline
Hypoglycaemia, events/patient-year				
Insulin naïve	121	1.3	3.2	1.9
Insulin users	110	11.1	2.9	−8.2
Body weight, kg				
Insulin naïve	86	69.1	74.1	5.0
Insulin users	76	74.8	77.0	2.2
Quality of life, VAS scale (0-100)				
Insulin naïve	92	64.1	81.1	17.0
Insulin users	82	65.6	79.4	13.9

VAS: Visual analogue scale

Table 6: Insulin dose

Insulin dose, U/day	*N*	Pre-study	*N*	Baseline	*N*	Week 24
Insulin naïve	0	0	121	35.3	95	40.2
Insulin users	110	41.8	110	45.0	86	50.1

Table 7: Biphasic insulin aspart±oral glucose-lowering drug efficacy data

Parameter	*N*	Baseline	Week 24	Change from baseline
Glycaemic control (insulin naïve)				
HbA_1c, mean (%)	51	10.5	7.8	−2.7
FPG, mean (mmol/L)	78	14.4	8.1	−6.3
PPPG, mean (mmol/L)	48	19.4	10.2	−9.2
Glycaemic control (insulin users)				
HbA_1c, mean (%)	55	9.6	7.6	−2.0
FPG, mean (mmol/L)	67	12.3	7.5	−4.8
PPPG, mean (mmol/L)	43	16.0	10.1	−5.9

HbA_1c: Glycated haemoglobin A_1c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose

Table 8: Basal+insulin aspart±oral glucose-lowering drug safety data

Parameter	*N*	Baseline	Week 24	Change from baseline
Hypoglycaemia, events/patient-year				
Insulin naïve	10	29.9	0.0	−29.9
Insulin users	43	14.5	8.1	−6.4
Body weight, kg				
Insulin naïve	9	72.7	73.7	1.0
Insulin users	29	77.6	78.3	0.7
Quality of life, VAS scale (0-100)				
Insulin naïve	9	73.3	83.9	10.6
Insulin users	32	70.4	77.2	6.8

VAS: Visual analogue scale

Table 9: Insulin dose

Insulin dose, U/day	*N*	Pre-study	*N*	Baseline	*N*	Week 24
Insulin naïve	0	0	10	42.1	9	49.0
Insulin users	43	47.3	43	54.7	32	59.3

in insulin naïve group. Quality of life also improved after 24 weeks [Tables 11 and 12].

All parameters of glycaemic control improved from baseline to study end in those who started on or were switched to insulin detemir ± OGLDs for both insulin-naïve and insulin user groups [Table 13].

Insulin aspart ± OGLD

Of the total cohort, 19 patients started on insulin aspart ± OGLD and all of them were insulin users. After 24 weeks of treatment, hypoglycaemic events increased from 10.3 events/patient-year to 13.9 events/patient-year. Quality of life improved at 24 weeks [Tables 14 and 15].

All parameters of glycaemic control improved from baseline to study end in those who started on or were switched insulin aspart ± OGLDs for insulin user group [Table 16].

Table 10: Basal+insulin aspart±oral glucose-lowering drug efficacy data

Parameter	*N*	Baseline	Week 24	Change from baseline
Glycaemic control (insulin naïve)				
HbA_1c, mean (%)	5	10.9	7.3	−3.6
FPG, mean (mmol/L)	8	15.9	7.8	−8.1
PPPG, mean (mmol/L)	6	18.7	8.3	−10.4
Glycaemic control (insulin users)				
HbA_1c, mean (%)	16	9.6	7.6	−2.0
FPG, mean (mmol/L)	28	12.3	8.2	−4.1
PPPG, mean (mmol/L)	16	17.3	9.6	−7.7

HbA_1c: Glycated haemoglobin A_1c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose

Table 11: Insulin detemir±oral glucose-lowering drug safety data

Parameter	*N*	Baseline	Week 24	Change from baseline
Hypoglycaemia, events/patient-year				
Insulin naïve	111	3.9	4.7	0.8
Insulin users	40	13.7	3.7	−10.0
Body weight, kg				
Insulin naïve	82	73.2	75.2	2.0
Insulin users	30	75.9	75.1	−0.8
Quality of life, VAS scale (0-100)				
Insulin naïve	91	60.2	75.2	15.1
Insulin users	31	66.6	74.9	8.3

VAS: Visual analogue scale

Table 12: Insulin dose

Insulin dose, U/day	*N*	Pre-study	*N*	Baseline	*N*	Week 24
Insulin naïve	0	0	111	18.9	94	25.8
Insulin users	40	29.5	40	23.0	32	30.3

Conclusion

Our study reports improved glycaemic control and quality of life following 24 weeks of treatment with any of the insulin analogues (Biphasic insulin aspart; Basal + insulin aspart; Insulin detemir; Insulin aspart) with or without OGLD. Major hypoglycaemia was observed in the insulin naïve group after 24 weeks. SADRs were reported in 1.2% of insulin naïve and 2.1% of insulin user groups. Overall, increase in weight was noted for both insulin naïve and

Table 13: Insulin detemir±oral glucose-lowering drug efficacy data

Parameter	*N*	Baseline	Week 24	Change from baseline
Glycaemic control (insulin naïve)				
HbA_1c, mean (%)	65	9.9	8.1	−1.8
FPG, mean (mmol/L)	77	13.6	7.9	−5.7
PPPG, mean (mmol/L)	52	17.8	10.6	−7.2
Glycaemic control (insulin users)				
HbA_1c, mean (%)	19	9.1	7.6	−1.5
FPG, mean (mmol/L)	28	10.0	6.9	−3.1
PPPG, mean (mmol/L)	14	14.1	9.8	−4.3

HbA_1c: Glycated haemoglobin A_1c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose

Table 14: Insulin aspart±oral glucose-lowering drug safety data

Parameter	*N*	Baseline	Week 24	Change from baseline
Hypoglycaemia, events/patient-year				
Insulin users	19	10.3	13.9	3.6
Body weight, kg				
Insulin users	15	69.8	70.1	0.3
Quality of life, VAS scale (0-100)				
Insulin users	15	68.1	80.7	12.6

VAS: Visual analogue scale

Table 15: Insulin dose

Insulin dose, U/day	*N*	Pre-study	*N*	Baseline	*N*	Week 24
Insulin users	19	42.7	19	19.9	15	48.4

Table 16: Insulin aspart±oral glucose-lowering drug efficacy data

Parameter	*N*	Baseline	Week 24	Change from baseline
Glycaemic control (insulin users)				
HbA_1c, mean (%)	11	9.3	7.6	−1.7
FPG, mean (mmol/L)	7	12.4	7.5	−4.9
PPPG, mean (mmol/L)	10	15.1	10.3	−4.8

HbA_1c: Glycated haemoglobin A_1c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose

insulin user groups. Though the findings are limited by number of patients, still the trend indicates that insulin analogues can be considered effective and possess a safe profile for treating Type 2 diabetes in Casablanca, Morocco.

References

1. IDF Diabetes Atlas. 5th ed.. 2011. Available from: http://www.idf.org/atlasmap/atlasmap [Last accessed date 2013 Jun 10].
2. Korytkowski M. When oral agents fail: Practical barriers to starting insulin. Int J Obes Relat Metab Disord 2002;26 Suppl 3:S18-24.
3. Hirsch IB. Insulin analogues. N Engl J Med 2005;352:174-83.
4. Shah SN, Litwak L, Haddad J, Chakkarwar PN, Hajjaji I. The A1chieve study: A 60 000-person, global, prospective, observational study of basal, meal-time, and biphasic insulin analogs in daily clinical practice. Diabetes Res Clin Pract 2010;88 Suppl 1:S11-6.

Cite this article as: Farouqi A, Chadli A. Clinical experience with insulin detemir, biphasic insulin aspart and insulin aspart in people with type 2 diabetes: Results from the Casablanca cohort of the A$_1$chieve study. Indian J Endocr Metab 2013;17:S408-12.

Source of Support: Nil, **Conflict of Interest:** None declared.