Original Article

Clinical experience with biphasic insulin aspart in people with type 2 diabetes: Results from the Libya cohort of the A$_1$chieve study

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ABSTRACT

Background: The A$_1$chieve, 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 in biphasic insulin aspart sub group from Libya. **Results:** A total of 179 patients were enrolled in the biphasic insulin aspart subgroup. All the patients were prior insulin users. At baseline glycaemic control was poor (mean HbA$_1$c: 9.3%). After 24 weeks of treatment there was an improvement in HbA$_1$c (–0.9%). Hypoglycaemic events reduced from 7.2 events/patient-year to 3.7 events/patient-year in 24 weeks. SADRs did not occur in any of the study patients. **Conclusion:** Starting or switching to biphasic insulin aspart was associated with improvement in glycaemic control with a low rate of hypoglycaemia.

Key words: A$_1$chieve study, biphasic insulin aspart, Libya, type 2 diabetes mellitus

Introduction

The incidence of diabetes in Libya is estimated to be 8.9%.[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$_1$chieve, 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 in biphasic insulin aspart sub group from Libya.

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Materials and Methods

Please refer to editorial titled: The A$_1$chieve study: Mapping the Ibn Battuta trail. The study was started with an aim to collect data on all the insulin analogue viz insulin detemir, biphasic insulin aspart and insulin aspart. However, due to ongoing revolution, the complete data could not be collected. Here we present the data for biphasic insulin aspart subgroup.

Results

A total of 316 patients were enrolled in the study. The majority of patients (189) were started on or were switched to Biphasic insulin aspart. Other groups were insulin detemir (n = 58), basal + insulin aspart (n = 44) and other insulin combinations (n = 25). Being the biggest treatment group, this communication describes the results for patients treated with insulin therapy before and then switched to biphasic insulin aspart.

The patient characteristics for biphasic insulin aspart

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Table 1: Overall demographic data

Parameters	Insulin naïve
Number of patients	179
Male *N* (%)	82 (45.8)
Female *N* (%)	97 (54.2)
Mean age (years)	53.9
Mean weight (kg)	84.5
Mean BMI (kg/m^2)	31.7
Mean duration of DM (years)	11.6
Mean HbA$_1$c	9.3
Mean FPG (mmol/L)	10.6
Mean PPPG (mmol/L)	12.8
Macrovascular complications, *N* (%)	28 (15.6)
Microvascular complications, *N* (%)	98 (54.7)

BMI: Body mass index, HbA$_1$c: Glycated haemoglobin A$_1$c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose, DM: Diabetes mellitus

Table 2: Overall safety data

Parameter	*N*	Baseline	Week 24	Change from baseline
Hypoglycaemia, events/patient-year				
Insulin users	179	7.2	3.7	−3.5
Bodyweight, kg				
Insulin users	118	84.2	85.0	0.8
Quality of life, VAS scale (0-100)				
Insulin users	86	74.6	79.3	4.6

VAS: Visual analogue scale

Table 3: Insulin dose

Insulin dose, U/day	*N*	Pre-study	*N*	Baseline	*N*	Week 24
Insulin users	179	50.1	179	47.6	131	58.8

Table 4: Overall efficacy data

Parameter	*N*	Baseline	Week 24	Change from baseline
Glycaemic control				
HbA$_1$c, mean (%)	104	9.3	8.3	−0.9
FPG, mean (mmol/L)	102	10.6	8.9	−1.7
PPPG, mean (mmol/L)	28	12.8	10.8	−2.1

HbA$_1$c: Glycated haemoglobin A$_1$c, FPG: Fasting plasma glucose, PPPG: Postprandial plasma glucose

subgroup are shown in the Table 1. Glycaemic control at baseline was poor in this population.

Safety data

179 patients started on biphasic insulin aspart ± OGLD, and all the patients were on insulin therapy prior to the study. After 24 weeks of switching to biphasic insulin aspart, hypoglycaemic events reduced from 7.2 events/patient-year to 3.7 events/patient-year [Tables 2 and 3].

Efficacy data

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

Conclusion

Our study reports improved glycaemic control following 24 weeks of treatment with biphasic insulin aspart with or without OGLD. Hypoglycemic events decreased from baseline and SADRs did not occur in any of the study patients. A small increase in body weight was observed. Though the findings are limited by number of patients, still the trend indicates that biphasic insulin aspart can be considered effective and possess a safe profile for treating type 2 diabetes in Libya.

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