Original Article

Clinical experience with insulin detemir, biphasic insulin aspart and insulin aspart in people with type 2 diabetes: Results from the Maharashtra cohort of the A₁chieve study

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ABSTRACT

Background: The A₁chieve, 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 Maharashtra, India. **Results:** A total of 3069 patients were enrolled in the study. Four different insulin analogue regimens were used in the study. Patients had started on or were switched to biphasic insulin aspart (n = 2115), insulin detemir (n = 461), insulin aspart (n = 333), basal insulin plus insulin aspart (n = 92) and other insulin combinations (n = 61). At baseline glycaemic control was poor for both insulin naïve (mean HbA₁c: 8.8) and insulin user (mean HbA₁c: 9.1%) groups. After 24 weeks of treatment, both the groups showed improvement in HbA₁c (insulin naïve: -1.4%, insulin users: -1.4%). SADRs including major hypoglycaemic events or episodes did not occur in any of the study patients. **Conclusion:** Starting or switching to insulin analogues was associated with improvement in glycaemic control with a low rate of hypoglycaemia.

Key words: A,chieve study, insulin analogues, Maharashtra, type 2 diabetes mellitus

INTRODUCTION

62.4 million Indians were reported to have type 2 diabetes mellitus (T2DM) putting India on the forefront of diabetic epidemic across globe. [1,2] Fear of hypoglycaemia and gain in body weight are barriers for initiation of insulin therapy. [3] Modern insulin analogues are a convenient new approach or tool to glycaemic control, associated with low number of hypoglycaemia and favourable weight change. [4] A 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.^[5] This short communication presents the results for patients enrolled from Maharashtra, India.

MATERIALS AND METHODS

Please refer to editorial titled: The A1chieve study: Mapping the Ibn Battuta trail.

RESULTS

A total of 3069 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 (68.92%) started on or were switched to biphasic insulin aspart. Other groups were insulin determin (n = 461), insulin aspart (n = 333), basal



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insulin plus insulin aspart (n = 92) and other insulin combinations (n = 61).

Parameters Insulin naïve Insulin users All users Number of participants 2572 497 3069 Male N (%) 1444 (56.2) 332 (66.9) 1776 (57.9 Female N (%) 1127 (43.8) 164 (33.1) 1291 (42.2 Age (years) 51.5 54.4 52.0 Weight (kg) 69.2 70.2 69.4 BMI (kg/m²) 26.7 26.4 26.6 Duration of DM (years) 6.3 10.5 7.0 No therapy 119 >2 OGLD 94 57 151 HbA₁c 8.8 9.1 8.9 FPG (mmol/L) 11.5 9.7 11.3 PPPG (mmol/L) 16.8 14.1 16.4 Macrovascular complications, N (%) 544 (36.1) 214 (46.4) 758 (38.6) complications, N (%) 1109 (73.7) 366 (79.4) 1475 (75.6)	
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complications, N (%)	.0)
Pre-study therapy, N (%)	
Insulin users 497 (16.19	9)
OGLD only 2453 (79.9	93)
No therapy 119 (3.88	3)
Baseline therapy, N (%)	
Insulin detemir±OGLD 461 (15.02	2)
Insulin aspart±OGLD 333 (10.85	
Basal+insulin aspart±OGLD 92 (3.0))
Biphasic insulin aspart±OGLD 2115 (68.9	92)
Others 61 (1.99))
Missing 7 (0.23))

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

After 24 weeks of treatment, overall hypoglycaemic events reduced from 0.2 events/patient-year to 0.0 events/patient-year in insulin naive group and from 2.8 events/patient-year to 0.3 events/patient-year in insulin user group. The hypoglycaemia incidence in insulin naive group at 24 weeks was lower than that observed in insulin users at baseline. SADRs including major hypoglycaemic events did not occur in any of the study patients. Blood pressure decreased while overall lipid profile and quality of life improved at week 24 in the total cohort [Table 2 and 3].

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

Biphasic insulin aspart ± OGLD

Of the total cohort, 2115 patients started on biphasic insulin aspart \pm OGLD, of which 1845 (87.2%) were insulin naïve and 270 (12.8%) were insulin users. After 24 weeks of starting or switching to biphasic insulin aspart, hypoglycaemic events reduced from 0.2 events/patient-year to 0.0 events/patient-year in insulin naïve group and from 2.2 events/patient-year to 0.1 events/patient-year in insulin users group. Quality of life improved at the end of the study [Table 5 and 6].

All parameters of glycaemic control improved from baseline to study end in those who started on or were switched to biphasic insulin aspart for both insulin naïve and insulin user groups [Table 7].

Table 2: Overall safety data								
Parameter	N	Baseline	Week 24	Change from baseline				
Hypoglycaemia (insulin naïve), events/patient-year								
All	2572	0.2	0.0	-0.2				
Nocturnal		0.1	0.0	-0.1				
Major		0.0	0.0	0.0				
Hypoglycaemia (insulin users), events/patient-year								
All	497	2.8	0.3	-2.5				
Nocturnal		1.1	0.1	-1.0				
Major		0.7	0.0	-0.7				
Body weight, kg								
Insulin naïve	2158	69.0	69.1	0.2				
Insulin users	374	69.6	69.7	0.1				
Lipids and BP (insulin naïve)								
LDL-C, mean (mmol/L), $(N, \% < 2.5 \text{ mmol/L})$	357	2.3 (42, 11.8)	2.4 (8, 47.1)	0.1				
HDL-C, mean (mmol/L), $(N, \% > 1.0 \text{ mmol/L})$	357	1.1 (303, 84.9)	1.1 (14, 82.4)	0.0				
TG, mean (mmol/L), $(N, \% < 2.3 \text{ mmol/L})$	424	1.9 (120, 28.3)	1.8 (14, 82.4)	-0.1				
SBP, mean (mmHg), (<i>N</i> , % < 130 mmHg)	2399	131.5 (813, 33.9)	125.7 (1440, 67.4)	-5.8				
Lipids and BP (insulin users)								
LDL-C, mean (mmol/L), (N, % < 2.5 mmol/L)	124	2.7 (42, 33.9)	2.7 (20, 50.0)	0.0				
HDL-C, mean (mmol/L), $(N, \% > 1.0 \text{ mmol/L})$	123	1.2 (91, 74.0)	1.2 (35, 89.7)	0.0				
TG, mean (mmol/L), (N, % < 2.3 mmol/L)	123	1.7 (93, 75.6)	1.5 (40, 100)	-0.1				
SBP, mean (mmHg), (<i>N</i> , % < 130 mmHg)	483	136.0 (97, 20.1)	131.1 (160, 42.7)	-4.9				
Quality of life, VAS scale (0-100)		(, , , , , ,	(11, 11, 11, 11, 11, 11, 11, 11, 11, 11					
Insulin naïve	2089	42.6	78.4	35.8				
Insulin users	351	50.3	75.7	25.4				

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

Basal + insulin aspart ± OGLD

Of the total cohort, 92 patients started on basal + insulin aspart ± OGLD, of which 41 (44.6%) were insulin naïve and 51 (55.4%) were insulin users. After 24 weeks of starting or switching to basal + insulin aspart, hypoglycaemic events reduced from 0.8 events/patient-year to 0.0 events/patient-year in insulin user group, while hypoglycaemia was nil in insulin naïve

Table 3: Insulin dose										
Insulin dose, U/day	N	Pre-study	N	Baseline	N	Week 24				
Insulin naïve Insulin users	0 497	0.0 28.4	2565 497	25.1 28.4	2328 423	24.2 26.9				

Table 4: Overall efficacy data							
Parameter	N	Baseline	Week 24	Change from baseline			
Glycaemic control							
(insulin naïve)							
HbA₁c, mean (%)	1877	8.8	7.4	-1.5			
FPG, mean (mmol/L)	2156	11.5	7.0	-4.5			
PPPG, mean (mmol/L)	1433	16.8	9.8	-7.0			
Glycaemic control							
(insulin users)							
HbA,c, mean (%)	351	9.1	7.7	-1.4			
FPG, mean (mmol/L)	331	9.7	7.1	-2.6			
PPPG, mean (mmol/L)	239	14.1	10.1	-4.0			
Achievement of HbA,c							
<7.0% at week 24							
Insulin naïve	2162	15.7%					
(% of patients)							
Însulin users	388	12.9%					
(% of patients)							

 $\mathsf{HbA}_1\mathsf{c}$: Glycated haemoglobin $\mathsf{A}_1\mathsf{c}$, FPG: Fasting plasma glucose,

PPPG: Postprandial plasma glucose

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

drug safety data				
Parameter	N	Baseline	Week 24	Change from baseline
Hypoglycaemia,				
events/patient-year				
Insulin naïve	1845	0.2	0.0	-0.2
Insulin users	270	2.2	0.1	-2.1
Body weight, kg				
Insulin naïve	1586	68.5	68.8	0.3
Insulin users	209	68.8	69.0	0.2
Quality of life,				
VAS scale (0-100)				
Insulin naïve	1546	42.4	78.4	36.0
Insulin users	215	49.7	76.1	26.3

VAS: Visual analogue scale

Table 6: Insulin dose									
Insulin dose, U/day	N	Pre-study	N	Baseline	N	Week 24			
Insulin naïve	0	0.0	1845	25.2	1683	25.1			
Insulin users	270	28.4	270	28.1	239	28.1			

group, similar to baseline. Quality of life improved after 24 weeks of treatment [Table 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, 461 patients started on insulin detemir ± OGLD, of which 399 (86.6%) were insulin naïve and 62 (13.4%) were insulin users. After 24 weeks of starting or switching to insulin detemir, hypoglycaemic events reduced from 0.2 events/patient-year to 0.0 events/patient-year in insulin naïve group and from 2.7 events/patient-year to 0.0 events/patient-year in insulin users. Body weight decreased and quality of life improved at 24 weeks [Table 11 and 12].

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

Parameter	N	Baseline	Week 24	Change from baseline
Glycaemic control (insulin naïve)				
HbA₁c, mean (%)	1360	8.8	7.4	-1.5
FPG, mean (mmol/L)	1563	11.6	7.0	-4.6
PPPG, mean (mmol/L) Glycaemic control	1037	16.7	9.6	-7.1
(insulin users)				
HbA₁c, mean (%)	194	9.1	7.7	-1.4
FPG, mean (mmol/L)	184	9.7	7.2	-2.5
PPPG, mean (mmol/L)	140	14.2	9.9	-4.3

 $\mathsf{HbA}_1\mathsf{c}$: Glycated haemoglobin $\mathsf{A}_1\mathsf{c}$, 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	41	0.0	0.0	0.0
Insulin users	51	0.8	0.0	-0.8
Body weight, kg				
Insulin naïve	36	68.9	69.4	0.5
Insulin users	41	71.0	71.4	0.4
Quality of life,				
VAS scale (0-100)				
Insulin naïve	35	43.5	78.0	34.5
Insulin users	33	45.7	75.5	29.8

VAS: Visual analogue scale

Table 9: Insulin dose									
Insulin dose, U/day	N	Pre-study	N	Baseline	N	Week 24			
Insulin naïve	0	0.0	41	44.1	38	30.0			
Insulin users	51	32.2	51	39.2	43	31.5			

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

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

N	Baseline	Week 24	Change from baseline
35	9.3	8.3	-1.0
35	12.6	8.5	-4.2
29	18.5	12.4	-6.1
37	8.9	7.7	-1.2
29	10.0	6.4	-3.6
11	15.6	10.7	-4.9
	35 35 29 37 29	35 9.3 35 12.6 29 18.5 37 8.9 29 10.0	35 9.3 8.3 35 12.6 8.5 29 18.5 12.4 37 8.9 7.7 29 10.0 6.4

HbA₁c: Glycated haemoglobin A₁c, FPG: Fasting plasma glucose,

PPPG: Postprandial plasma glucose

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

Saicty data				
Parameter	N	Baseline	Week 24	Change from baseline
Hypoglycaemia, events/patient-year				
Insulin naïve	399	0.2	0.0	-0.2
Insulin users	62	2.7	0.0	-2.7
Body weight, kg				
Insulin naïve	330	71.2	71.1	-0.1
Insulin users	32	71.5	71.2	-0.3
Quality of life,				
VAS scale (0-100)				
Insulin naïve	317	41.3	79.2	37.9
Insulin users	32	54.2	75.3	21.1

VAS: Visual analogue scale

Table 12: Insulin dose										
Insulin dose, U/day	N	Pre-study	N	Baseline	N	Week 24				
Insulin naïve Insulin users	0 62	0.0 20.9	399 62	19.0 15.5	358 42	19.3 16.5				

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

cilicacy data				
Parameter	N	Baseline	Week 24	Change from baseline
Glycaemic control				
(insulin naïve)				
HbA₁c, mean (%)	282	8.9	7.3	-1.5
FPG, mean (mmol/L)	338	11.6	6.8	-4.8
PPPG, mean (mmol/L)	198	17.0	9.5	-7.5
Glycaemic control				
(insulin users)				
HbA₁c, mean (%)	31	9.2	7.5	-1.7
FPG, mean (mmol/L)	28	9.8	7.1	-2.7
PPPG, mean (mmol/L)	19	13.8	10.5	-3.3

 $\mathsf{HbA}_1\mathsf{c} \text{: Glycated haemoglobin A}_1\mathsf{c}, \mathsf{FPG} \text{: Fasting plasma glucose,}$

PPPG: Postprandial plasma glucose

insulin detemir ± OGLDs for both insulin-naïve and insulin user groups [Table 13].

Insulin aspart + OGLD

Of the total cohort, 333 patients started on insulin aspart ± OGLD, of which 242 (72.7%) were insulin naïve and 91 (27.3%) were insulin users. After 24 weeks of treatment starting or switching to insulin aspart a decrease in hypoglycaemic events was observed in both insulin naïve (from 0.5 events/patient-year to 0.0 events/patient-year) and insulin user (from 5.6 events/patient-year to 1.5 events/patient-year) groups. A decrease in body weight and improvement in quality of life was observed at the end of the study [Table 14 and 15].

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

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. All four insulin regimens showed a decrease in FPG and PPPG; however this improvement was higher in insulin naïve compared to insulin users. SADRs including major hypoglycaemic events or episodes did not occur in any of the study patients. A small weight reduction was noted for insulin detemir and insulin aspart groups. Though

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

Saicty data				
Parameter	N	Baseline	Week 24	Change from baseline
Hypoglycaemia, events/patient-year				
Insulin naïve	242	0.5	0.0	-0.5
Insulin users	91	5.6	1.5	-4.1
Body weight, kg				
Insulin naïve	174	69.3	69.2	-0.1
Insulin users	70	70.4	70.3	-0.1
Quality of life,				
VAS scale (0-100)				
Insulin naïve	163	45.7	76.8	31.1
Insulin users	62	54.1	74.8	20.7

VAS: Visual analogue scale

Table 15: Insulin dose							
Insulin dose, U/day	N	Pre-study	N	Baseline	N	Week 24	
Insulin naïve Insulin users	0 91	0.0 28.7	242 91	28.1 28.8	209 77	24.0 25.3	

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

Parameter	N	Baseline	Week 24	Change from baseline
Glycaemic control (insulin naïve)				
HbA₁c, mean (%)	169	8.9	7.5	-1.4
FPG, mean (mmol/L)	187	10.6	7.3	-3.3
PPPG, mean (mmol/L) Glycaemic control	147	16.6	10.7	-5.9
(insulin users)				
HbA₁c, mean (%)	69	9.3	7.8	-1.5
FPG, mean (mmol/L)	69	9.6	7.4	-2.2
PPPG, mean (mmol/L)	60	13.4	10.4	-3.0

HbA₁c: Glycated haemoglobin A₁c, FPG: Fasting plasma glucose,

PPPG: Postprandial plasma glucose

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 Maharashtra, India.

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