**Switching from basal or basal-bolus insulin to biphasic insulin aspart 30: Results from the Indian cohort of the A1chieve study**

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**ABSTRACT**

**Aim:** To determine the safety and efficacy of biphasic insulin aspart 30 (BIAsp 30) therapy in the Indian patients with type 2 diabetes previously on basal or basal-bolus insulin therapies. **Materials and Methods:** Patients switching from insulin glargine, neutral protamine Hagedorn (NPH) insulin, or basal-bolus insulin to BIAsp 30 in the Indian cohort of the A1chieve study were included. Safety and efficacy of treatment was evaluated over 24 weeks. **Results:** A total of 422 patients (pre-study basal-bolus insulin, 49; NPH insulin, 157; insulin glargine, 216) switched to BIAsp 30. Pre-study insulin doses were 0.61 ± 0.26 U/kg, 0.34 ± 0.2 U/kg and 0.40 ± 0.21 U/kg and the mean week 24 BIAsp 30 doses were 0.50 ± 0.21 U/kg, 0.35 ± 0.15 U/kg and 0.42 ± 0.16 U/kg in the prior basal-bolus insulin, NPH insulin and insulin glargine groups, respectively. No serious adverse drug reactions, major or nocturnal hypoglycemia were reported. The proportion of patients experiencing overall hypoglycemia was significantly lower from baseline (5.6%) to week 24 (1.0%) in the pre-study insulin-glargine group and appeared to be lower in pre-study NPH insulin and basal-bolus insulin groups. Glycemic control improved significantly from baseline week 24 in the pre-study NPH insulin and insulin-glargine groups (P < 0.001), while it appeared to improve in the pre-study basal-bolus group. Quality of life was positively impacted after 24 weeks in all 3 groups. **Conclusion:** The switch from basal or basal-bolus insulin to BIAsp 30 was safe, well tolerated and improved the glycemic control in this Indian cohort.

**Key words:** Basal-bolus insulin, basal insulin, biphasic insulin aspart 30

**INTRODUCTION**

The insulin analog, biphasic insulin aspart 30 (BIAsp 30), constitutes 30% soluble rapid-acting insulin aspart and 70% protaminated intermediate-acting insulin aspart. This constitution enables the benefits of achieving basal insulin levels between meals and prandial glucose control at mealtime with a single injection. This dual mechanism of action promotes the maintenance of both fasting plasma glucose (FPG) and post-prandial plasma glucose (PPPG) levels that are intrinsic to overall glycated hemoglobin (HbA1c) control.¹ The PPPG levels are strongly correlated to the increased risk of cardiovascular diseases.²,³ Also, macrovascular disease, retinopathy, cancer, impaired cognitive function in the elderly, stress, inflammation, myocardial and endothelial dysfunction could be a consequence of uncontrolled PPPG levels.⁴,⁵ Hence, therapeutic regimens that can specifically control PPPG are often instrumental in preventing the risk of long-term complications in type 2 diabetes (T2D). In contrast to basal insulins, such as neutral protamine Hagedorn (NPH) insulin and insulin glargine, BIAsp 30 offers a pharmacokinetic profile that more closely mimics physiological insulin secretion. As a result, PPPG control with BIAsp 30 has been proven to be superior to basal-insulin therapy in randomized controlled trials.⁶-⁸ Furthermore, these studies also suggest that HbA1c control with BIAsp 30 is comparable or superior to basal levels of insulin. This efficiency in glycemic control was associated with an
overall low risk of hypoglycemia, except for nocturnal events. The clinical safety and effectiveness of BIAsp 30 has also been established in multinational observational studies, IMPROVE and PRESENT, including T2D patients irrespective of their pre-study therapy.

The safety and effectiveness of initiation or switching to BIAsp 30 was examined in the 24-week, open-label, prospective, non-interventional Achieve study conducted in 28 developing countries, worldwide. Developing countries including the Indian sub-continent are now facing multifaceted crises to control the rising prevalence of T2D. Urbanization, socioeconomic transition and lifestyle changes have contributed to an exponential increase in the number of people with T2D in this region. According to the International Diabetes Federation, India with 63.0 million diabetes cases ranks second in the list of top 10 countries for diabetes cases worldwide. This number is expected to cross 100 million cases by the year 2030. These figures call for an imperative need to devise strategic T2D management options in routine clinical practice. Local data such as that reported in the AChieve study, could enable healthcare providers to make informed therapeutic decisions. Furthermore, sub-analyses that reflect the effectiveness of pre-study therapy provide data that is targeted to specific groups of patients. This sub-analysis was specifically conducted to assess the safety and efficacy of BIAsp 30 in Indian T2D patients switching from a basal-bolus or basal-insulin therapy. The results of this analysis would also be useful while implementing the recommendation of the Indian National Premixed guidelines that recommend premixed insulin as a preferred mode of initiating and intensifying therapy.

Materials and Methods

Study design
The AChieve study was an international, open-label, prospective, non-interventional study to determine the safety and effectiveness of BIAsp 30 (NovoMix 30®, Novo Nordisk), insulin detemir (Levemir®, Novo Nordisk) and insulin aspart (NovoRapid®, Novo Nordisk), alone or in combination, in routine clinical care. In this sub-analysis, T2D patients from India who switched from basal-bolus insulin therapy or basal insulin (NPH insulin or insulin glargine) to biphasic insulin aspart 30 were included. Patients were recruited at 621 centers in India between May 2009 and December 2010. Insulin therapy was switched at the consulting physicians’ discretion and subsequent changes in dose, frequency and use of oral glucose-lowering drugs (OGLDs) were directed by the physician in routine clinical care. There were no pre-defined study procedures and all assessments were made by the physicians. This study was approved by the local ethics committee. The study drug was commercially available and prescribed in accordance with local regulations.

Patients
Patients in the Indian cohort of AChieve who switched from basal-bolus insulin, NPH insulin or insulin glargine to BIAsp 30 were included in this sub-analysis. The concurrent use of OGLDs was permitted throughout the study. Patients who had received any of the study drugs up to 4 weeks prior to enrollment or those having hypersensitivity to the study drug were excluded. Women who were pregnant, breast-feeding or looking to conceive were not eligible for the study participation. All patients signed informed consent to participate in this study.

Outcomes
The primary safety outcome was the incidence of serious adverse drug reactions (SADRs), including major hypoglycemia related to BIAsp 30, from baseline to Week 24. Secondary safety outcomes included changes in the frequency of hypoglycemic events in the last 4 weeks prior to baseline and final visits, changes in nocturnal hypoglycemia during this period and the number of serious adverse events (SAEs). Efficacy outcomes included baseline to Week 24 changes in HbA1c, FPG and post-breakfast PPPG. Changes in body weight, lipid profile and systolic blood pressure (SBP) were also assessed. All laboratory parameters were certified by the National Glycohemoglobin Standardization Program and were subject to local standardization. Quality of life (QoL) was evaluated using the standard EQ-5D questionnaire and subsequently measured on a 20-cm visual analog scale (VAS).

Statistical analysis
Detailed statistical analyses of the AChieve study have been discussed elsewhere. Continuous and discrete variables were summarized using descriptive statistics and frequency tables (n [%]), respectively. All statistical analyses were conducted using two-sided tests at a pre-specified 5% significance level. The paired t-test was used to analyze the changes in HbA1c, FPG, PPPG, SBP, blood lipids, body weight, and QoL from baseline to Week 24. The McNemar’s test was used to analyze changes from baseline to end of study in the proportion of patients reporting at least one hypoglycemic event. P values are not reported for parameters when the number of patients evaluated was less than 100. All data were analyzed by Novo Nordisk using SAS (Version 9.1.3).

Results
Patient characteristics
A total of 422 Indian patients switched from a pre-study basal or basal-bolus therapy to BIAsp 30. Of these,
49 patients were on basal-bolus insulin, 157 patients were on NPH insulin and 216 patients were on insulin glargine at pre-study. Demographic and baseline characteristics of all patients are listed in Table 1. At baseline, metformin was the most common OGLD used in patients on prior to insulin glargine (85.6%) and basal-bolus therapy (81.0%), while sulphonylureas were the most commonly used OGLDs in patients on prior to NPH-insulin therapy (73.5%).

The physicians’ reason to switch therapy to BIAsp 30 was to improve glycemic control in 98.7% patients on prior NPH insulin, 94.4% patients on prior insulin glargine and 83.7% patients on prior basal-bolus therapy.

Insulin dose and dosing frequency
Among the 3 groups, the pre-study insulin dose was the highest in patients on prior basal-bolus therapy (mean ± SD 0.61 ± 0.26 U/kg), while patients on NPH insulin and insulin glargine were on mean doses of 0.34 ± 0.2 U/kg and 0.40 ± 0.21 U/kg, respectively. The average BIAsp 30 doses at baseline and Week 24 are reported in Table 2. In the prior basal-bolus insulin group, 59.2% patients were on > thrice-daily dosing at pre-study. At baseline and Week 24, the majority of patients from this group were on BIAsp 30, twice daily. NPH insulin was administered twice daily at the pre-study in 65.6% patients and once daily in 33.1% patients, whereas BIAsp 30 was administered twice daily at baseline and Week 24 in 90.4% and 83.1% patients, respectively. Insulin glargine was administered once daily in 50.5% and twice daily in 49.5% patients at pre-study. At baseline and Week 24, majority of the patients (>90%) from this group were on BIAsp 30, twice daily [Table 2].

SADRs, SAEs and hypoglycemia
No SADRs or SAEs were reported during the 24 week evaluation period. The proportion of patients affected by hypoglycemia decreased significantly from baseline to Week 24 in patients on prior insulin glargine (5.6% vs. 1.0%, P = 0.0039). The proportion of patients affected by hypoglycemia was 8.3% at baseline compared with 1.5% at Week 24 in the group on prior NPH insulin therapy (P = 0.0578), while patients on pre-study basal-bolus insulin experiencing hypoglycemia was 28.6% at baseline and 2.8% at Week 24. No major or nocturnal hypoglycemia was reported at Week 24 in all groups. The proportion of patients affected by at least 1 minor hypoglycemia event at Week 24 (1.0%) was significantly lower compared with baseline (4.6%) in the pre-study insulin-glargine group (P < 0.05) whereas the decrease was not significant in patients on pre-study NPH insulin. The proportion of patients experiencing minor hypoglycemia in the pre-study basal-bolus insulin group was 26.5% at baseline and 2.8% at Week 24 [Table 3].

Glucose control
The effect of BIAsp 30 on glucose control parameters is presented in Table 4. In the pre-study basal-bolus insulin group, HbA₁c, FPG and PPPG appeared to be lower at Week 24 compared with the mean baseline levels. Patients on pre-study NPH insulin and insulin glargine experienced a significant decrease in HbA₁c, FPG and PPPG levels from baseline to Week 24 (P < 0.001).

At Week 24, 10 patients in the pre-study basal-bolus insulin group reported HbA₁c <7.0% compared with 1 patient reporting this target at baseline. A total of 24 patients switched

Table 1: Demographic and baseline characteristics

|                | Basal-bolus insulin (n=49) | NPH insulin (n=157) | Insulin glargine (n=216) |
|----------------|-----------------------------|---------------------|--------------------------|
| Male/female, % | 61.2/38.8                   | 60.5/39.5           | 66.2/33.8                |
| Age*, years    | 55.0±11.6                   | 55.9±9.0            | 54.5±9.2                 |
| Body weight*, kg| 70.8±13.9                   | 67.4±12.0           | 72.6±13.9                |
| Body mass index*, kg/m² | 26.6±5.0                   | 27.7±4.6            | 27.9±5.2                 |
| Duration of diabetes*, years | 12.7±6.9                   | 7.9±5.2             | 9.3±4.5                  |
| Duration on insulin*, years  | 3.4±3.3                    | 2.8±2.6             | 3.6±2.8                  |
| HbA₁c*, %      | 9.2±1.4                     | 9.2±1.3             | 9.5±1.7                  |

Table 2: Insulin dose and dosing frequency at pre-study, baseline and week 24

|                | Basal-bolus insulin | NPH insulin | Insulin glargine |
|----------------|---------------------|-------------|------------------|
| Insulin dose*, U/kg | n=48               | 156         | 213              |
| Pre-study        | 0.61±0.26           | 0.34±0.22   | 0.40±0.21        |
| Baseline         | 0.47±0.21           | 0.38±0.18   | 0.40±0.15        |
| Week 24          | 0.50±0.21           | 0.35±0.15   | 0.42±0.16        |
| Daily dose frequency |                 |             |                  |
| Pre-study (n %)  | 49                  | 157         | 216              |
| Once             | 52 (33.1)           | 109 (50.5)  |
| Twice            | 6 (4.1)             | 103 (65.6)  |
| Thrice           | 14 (28.6)           | 2 (1.3)     |                  |
| Thrice           | 29 (59.2)           | -           |                  |
| Baseline (n %)   | 49                  | 157         | 216              |
| Once             | 2 (4.1)             | 15 (9.6)    | 18 (8.3)         |
| Twice            | 44 (89.8)           | 142 (90.4)  | 196 (90.7)       |
| Thrice           | 3 (6.1)             | -           | 2 (0.9)          |
| >Thrice          | -                   | -           | 1 (0.5)          |

*Data are mean±SD. NPH: Neutral protamine Hagedorn
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Systolic blood pressure was significantly lower at Week 24 compared with baseline (125.7 ± 11.1 vs. 131.9 ± 18.1 mmHg, P < 0.001) in the pre-study insulin-glargine group. SBP in patients on pre-study basal-bolus insulin and NPH insulin appeared to decrease by 9.9 ± 11.5 mmHg (136.3 ± 14.4 mmHg at baseline vs. 126.4 ± 10.4 mmHg at Week 24), respectively. The changes in the lipid profile of patients in all 3 groups are reported in Table 4.

Quality of life
In patients on prior NPH insulin EQ-5D VAS scores improved from 59.0 ± 9.1 points at baseline to 69.9 ± 8.5 points (P < 0.001) at Week 24 and in the pre-study insulin-glargine group VAS scores increased from 55.2 ± 9.3 points at baseline to 69.1 ± 8.3 points at Week 24 (P < 0.001). In the pre-study basal-bolus insulin group, EQ-5D VAS scores appeared to be higher at Week 24 (76.6 ± 5.8 points) compared with baseline (59.6 ± 11.3 points).

DISCUSSION

This sub-analysis of the Indian cohort from the Achieve study assessed the safety and effectiveness of switching to BIAsp 30 from prior basal or basal-bolus therapies. The mean baseline HbA₁c level was 9.2% in the pre-study basal-bolus and NPH-insulin groups, whereas the pre-study insulin-glargine group presented with a mean HbA₁c level of 9.5%. Results from the DiabCare India 2011, conducted in 6000 patients, also indicate that the average HbA₁c level from pre-study NPH insulin reported HbA₁c <7.0% after 24 weeks of BIAsp 30 therapy, whereas 2 patients reported HbA₁c <7.0% at baseline. In the pre-study insulin-glargine group, HbA₁c <7.0% was reported in 18 patients at Week 24 compared with 6 patients at baseline.

**Table 3: Baseline and 24-week data for hypoglycemia**

| Hypoglycemia | Basal-bolus insulin | | Insulin glargine | |
|--------------|---------------------|----------|-----------------|----------|
| Hypoglycemic events/patient-year | 12.73 | 28.6 | 4.64 | 8.3 | 1.14 | 5.6 |
| %* | 0.36 | 2.8 | 0.30 | 1.5 | 0.19 | 1.0 |
| P | - | - | 0.0578 | - | 0.0039 | - |
| Minor | | | | | | |
| Baseline | 10.88 | 26.5 | 3.06 | 7.6 | 0.90 | 4.6 |
| Week 24 | 0.36 | 2.8 | 0.30 | 1.5 | 0.19 | 1.0 |
| P | - | - | 0.0956 | - | 0.0114 | - |
| Nocturnal | | | | | | |
| Baseline | 4.51 | 18.4 | 1.66 | 4.5 | 0.48 | 3.2 |
| Week 24 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| P | - | - | 0.1573 | - | 0.0082 | - |
| Major | | | | | | |
| Baseline | 1.86 | 8.2 | 1.57 | 3.8 | 0.24 | 1.9 |
| Week 24 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| P | - | - | 0.1573 | - | 0.0455 | - |

NPH: Neutral protamine hagedorn insulin, *Percent of patients with at least 1 event. †P value not presented as n<100. P value calculated using McNemar’s test for proportion of patients experiencing hypoglycemia from baseline to week

**Table 4: Baseline and 24-week data for glucose-control parameters**

| Parameter | Basal-bolus | NPH | IGlar |
|-----------|-------------|-----|-------|
| HbA₁c, % | n = 35 | 124 | 195 |
| Baseline | 9.2 ± 1.4 | 9.2 ± 1.3 | 6.9 ± 1.7 |
| Week 24 | 7.4 ± 0.7 | 7.6 ± 1.0 | 8.0 ± 1.1 |
| Change | -1.8 ± 1.3 | -1.6 ± 1.1 | -1.6 ± 1.4 |
| P | - | <0.001 | <0.001 |
| FPG, mg/dL | n = 33 | 118 | 189 |
| Baseline | 187.7 ± 63.4 | 183.2 ± 44.9 | 188.7 ± 52.1 |
| Week 24 | 109.4 ± 18.9 | 143.2 ± 36.7 | 143.2 ± 37.4 |
| Change | -78.3 ± 68.5 | -40.0 ± 43.3 | -45.6 ± 44.7 |
| P | - | <0.001 | <0.001 |
| PPPG, mg/dL | n = 29 | 112 | 177 |
| Baseline | 291.7 ± 105.2 | 287.9 ± 56.1 | 283.8 ± 67.0 |
| Week 24 | 159.9 ± 29.9 | 243.4 ± 67.7 | 223.5 ± 64.3 |
| Change | -131.8 ± 119.8 | -44.5 ± 68.1 | -60.3 ± 63.0 |
| P | - | <0.001 | <0.001 |

FPG: Fasting plasma glucose, HbA₁c: Glycated hemoglobin A1c, PPPG: Postprandial plasma glucose. *P value not presented at n<100. Data are mean±SD

from pre-study NPH insulin reported HbA₁c <7.0% after 24 weeks of BIAsp 30 therapy, whereas 2 patients reported HbA₁c <7.0% at baseline. In the pre-study insulin-glargine group, HbA₁c <7.0% was reported in 18 patients at Week 24 compared with 6 patients at baseline.

**Body weight, SBP and lipids**
From baseline to Week 24, the mean change in body weight in the pre-study basal-bolus insulin group was 0.6 ± 2.2 kg. Patients on pre-study NPH insulin reported a mean weight change of 1.0 ± 5.6 kg (P = 0.052) from baseline to Week 24 whereas patients on pre-study insulin glargine reported a decrease of 0.6 ± 3.8 kg (P = 0.021) [Table 5].
Table 5: Baseline and 24-week data for blood lipids, body weight and SBP

|                      | Basal-bolus insulin | NPH insulin | Insulin glargine |
|----------------------|---------------------|-------------|------------------|
| n                    | -                   | 40          | 87               |
| Total cholesterol, mmol/L | 5.5±0.7             | 5.1±1.0     | 4.8±0.9          |
| Triglycerides, mmol/L  | 2.2±1.1             | 2.1±0.4     | 2.1±0.4          |
| HDL cholesterol, mmol/L | 1.7±0.6             | 1.9±0.4     | 1.9±0.6          |
| LDL cholesterol, mmol/L | 3.2±1.3             | 3.3±0.7     | 3.0±0.8          |
| Body weight, kg       | 69.6±12.5           | 67.8±11.6   | 71.5±11.1        |
| SBP, mmHg             | 70.2±11.8           | 68.8±10.4   | 70.8±10.4        |

Weight gain is often an undesired effect of improved glucose control. In this sub-analysis, body weight decreased significantly in patients on prior insulin glargine whereas the change in body weight was not significant in the pre-study NPH insulin basal-bolus groups. Additionally, a significant decrease in SBP was also noted in the pre-study insulin glargine group. SBP appeared to improve in the pre-study NPH insulin and basal-bolus groups. Lipid profile results were not entirely conclusive due to the small group of patients evaluated. Diabetes and its complications act as a major retardant to the patients’ health-related QoL. Switching to BIAsp 30 exerted a positive effect on the overall QoL in all three groups.

The A1c achieve study results are subject to the limitations of non-interventional studies, including the lack of a control and non-standardized study procedures. It is also possible that the recall bias may have resulted in the under-reporting of hypoglycemia or other adverse events. Nevertheless, the results obtained could be extrapolated to optimize treatment strategies in routine clinical care. In conclusion, the switching from basal or basal-bolus therapy to BIAsp 30 could be a safe and effective alternative therapeutic option in patients with uncontrolled T2D.

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In this cohort, patients switching from pre-study NPH insulin and insulin glargine to BIAsp 30 experienced a significant improvement in HbA1c, FPG and PPPG. Although the number of patients on pre-study basal-bolus therapy was too small to yield conclusive results, glycemic control in these patients also appeared to improve after 24 weeks of BIAsp 30 therapy. Notably, no major BIAsp 30 dose titration was required to improve glycemic control for this 24-week evaluation period in all three groups. The effectiveness of treatment was associated with no nocturnal or major hypoglycemia reported during treatment with BIAsp 30. The proportion of patients experiencing hypoglycemia overall decreased significantly in the pre-study insulin glargine group and appeared to decrease in the NPH and basal-bolus groups. Also, after 24 weeks of BIAsp 30 therapy only minor hypoglycemic events were reported. Previously, patients who switched form a basal insulin to BIAsp 30 in randomized controlled trials and the IMPROVE study have also reported similar results concerning the safety and efficiency of glycemic control with BIAsp 30.[6-9]
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