Clinical experience with insulin detemir, biphasic insulin aspart and insulin aspart in people with type 2 diabetes: Results from the Qatar cohort of the A\textsubscript{1}chieve study

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ABSTRACT

Background: The A\textsubscript{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 from Qatar. Results: A total of 91 patients were enrolled in the study. Two insulin analogue regimens were used in the study. Study patients had started on or were switched to biphasic insulin aspart (n = 88), insulin detemir (n = 2), and other insulin combinations (n = 1). At baseline glycaemic control was poor for both insulin naïve (mean HbA\textsubscript{1c}: 10.9%) and insulin users (mean HbA\textsubscript{1c}: 9.1%) groups. After 24 weeks of treatment, all the study groups showed improvement in HbA\textsubscript{1c} (insulin naïve: −1.8%, insulin users: −1.3%). Major hypoglycaemia did not occur in the study patients. SADRs were reported in 1.4% of insulin users. Conclusion: Starting or switching to insulin analogues was associated with improvement in glycaemic control with a low rate of hypoglycaemia.

Key words: A\textsubscript{1}chieve study, insulin analogues, type 2 diabetes mellitus, Qatar

INTRODUCTION

Diabetes prevalence in Qatar is estimated to be 14.1%, with 216 thousand people with diabetes.\textsuperscript{[1]} Fear of hypoglycaemia and gain in body weight are barriers for initiation of insulin therapy.\textsuperscript{[2]} Modern insulin analogues are a convenient new approach or tool to glycaemic control, associated with low number of hypoglycaemia and favourable weight change.\textsuperscript{[3]} A\textsubscript{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.\textsuperscript{[4]} This short communication presents the results for patients enrolled from Qatar.

MATERIALS AND METHODS

Please refer to editorial titled: The A\textsubscript{1}chieve study: Mapping the Ibn Battuta trail.

RESULTS

A total of 91 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 (96.7%) were started on or were switched to biphasic insulin aspart. Other groups were insulin detemir (n = 2) and other insulin combinations (n = 1).

After 24 weeks of treatment, overall hypoglycaemia reduced from 1.1 to 0.6 events/patient-year in insulin user group.
Compared to baseline, no change in hypoglycaemia was noted in insulin naïve group (0.0 events/patient-year). No hypoglycaemic episode in insulin naïve group even at 24 weeks suggests low event rate than insulin users at baseline. Major hypoglycaemic events or episodes did not occur in the study patients. SADRs were reported in 1.4% of insulin users. Blood pressure decreased and overall lipid profile improved in the total cohort, but the findings were 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]. 10% of insulin users achieved HbA1c < 7.0% at week 24.

### Biphasic insulin aspart ± OGLD

Of the total cohort, 88 patients started on biphasic insulin aspart ± OGLD, 21 (23.9%) were insulin naïve and 67 (76.1%) were insulin users. After 24 weeks of treatment, hypoglycaemic episodes or events reduced from 1.2 to 0.6 events/patient-year in insulin user group while hypoglycaemia remained nil similar to baseline in insulin naïve group. Body weight increased for both insulin naïve and user groups [Tables 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].

### Insulin detemir ± OGLD

Of the total cohort, 2 patients started insulin detemir ± OGLD, of which 1 (50%) was insulin naïve and 1 (50%) was insulin user. Starting or switching to insulin detemir was associated with no hypoglycaemic event in both the groups. All parameters of glycaemic control improved from baseline to study end in those who started on or were switched to insulin detemir ± OGLDs for insulin user group.

| Table 1: Overall demographic data |
|----------------------------------|
| Parameters | Insulin naïve | Insulin users | All |
| Number of participants | 22 | 69 | 91 |
| Male N (%) | 16 (72.7) | 34 (49.3) | 50 (54.9) |
| Female N (%) | 6 (27.3) | 35 (50.7) | 41 (45.1) |
| Age (years) | 45.1 | 52.0 | 50.4 |
| Weight (kg) | 75.4 | 83.1 | 81.2 |
| BMI (kg/m²) | 26.7 | 30.6 | 29.4 |
| Duration of DM (years) | 7.2 | 13.7 | 12.1 |
| >2 OGLD | - | 1 |
| HbA1c | 10.9 | 9.1 | 9.8 |
| FPG (mmol/L) | 16.0 | 11.9 | 13.4 |
| PPPG (mmol/L) | 20.0 | 19.2 | 19.5 |
| Macrovascular complications, N (%) | 2 (9.1) | 16 (23.2) | 18 (19.8) |
| Microvascular complications, N (%) | 7 (31.8) | 41 (59.4) | 48 (52.7) |
| Pre-study therapy, N (%) | | | |
| Insulin users | 69 (75.8) | | |
| OGLD only | 22 (24.2) | | |
| No therapy | - | | |
| Baseline therapy, N (%) | | | |
| Insulin detemir±OGLD | 2 (2.2) | | |
| Biphasic insulin aspart±OGLD | 88 (96.7) | | |
| Others | 1 (1.1) | | |

| Table 2: Overall safety data |
|------------------------------|
| Parameter | N | Baseline | Week 24 | Change from baseline |
| Hypoglycaemia (insulin naïve), events/patient-year | | | | |
| All | 22 | 0.0 | 0.0 | 0.0 |
| Nocturnal | | 0.0 | 0.0 | 0.0 |
| Major | | 0.0 | 0.0 | 0.0 |
| Hypoglycaemia (insulin users), events/patient-year | | | | |
| All | 69 | 1.1 | 0.6 | −0.5 |
| Nocturnal | | 0.0 | 0.3 | 0.3 |
| Major | | 0.2 | 0.0 | −0.2 |
| Body weight, kg | | | | |
| Insulin naïve | 13 | 76.8 | 79.1 | 2.2 |
| Insulin users | 69 | 82.2 | 84.2 | 2.0 |
| Lipids and BP (insulin naïve) | | | | |
| LDL-C, mean (mmol/L), (N, % <2.5 mmol/L) | 16 | 2.5 (6, 37.5) | 2.5 (3, 25.0) | 0.0 |
| HDL-C, mean (mmol/L), (N, % >1.0 mmol/L) | 15 | 1.2 (9, 60.0) | 1.2 (8, 66.7) | 0.0 |
| TG, mean (mmol/L), (N, % <2.3 mmol/L) | 15 | 1.6 (12, 80.0) | 1.5 (13, 100) | −0.1 |
| SBP, mean (mmHg), (N, % <130 mmHg) | 21 | 129.1 (5, 23.8) | 125.8 (9, 64.3) | −3.3 |
| Lipids and BP (insulin users) | | | | |
| LDL-C, mean (mmol/L), (N, % <2.5 mmol/L) | 37 | 2.4 (13, 35.1) | 2.5 (9, 39.1) | 0.1 |
| HDL-C, mean (mmol/L), (N, % >1.0 mmol/L) | 36 | 1.1 (26, 72.2) | 1.4 (15, 65.2) | 0.3 |
| TG, mean (mmol/L), (N, % <2.3 mmol/L) | 37 | 1.9 (30, 81.1) | 1.6 (20, 83.3) | −0.3 |
| SBP, mean (mmHg), (N, % <130 mmHg) | 64 | 142.1 (12, 18.8) | 138.5 (6, 26.1) | −3.7 |

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
Our study reports improved glycaemic control following 24 weeks of treatment with any of the insulin analogues (biphasic insulin aspart; insulin detemir) with or without OGLD. An increase in body weight was observed for the overall cohort. Major hypoglycaemia did not occur in any of the study patients. SADRs were reported in 1.4% of insulin users. 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 Qatar.

**REFERENCES**

1. IDF Diabetes Atlas. 5th ed. Available from: http://www.idf.org/atlasmap/atlasmap [Last accessed on 2013 June 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.

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