

BEST PRACTICES IN:

The A₁chieve Resource Centre:
Region-Specific Data From Around the World

Introduction

A₁chieve is the largest observational study of insulin analogue therapy ever conducted. The study enrolled a total of 66,726 patients with type 2 diabetes from 28 countries across Asia, Africa, Europe, and Latin America and evaluated the safety and effectiveness of three Novo Nordisk insulin analogues in routine clinical practice. The study collected a wealth of region-specific data on the use of insulin analogues in the management of patients with type 2 diabetes at various stages of disease progression. Those data are now available to clinicians and researchers worldwide via the A₁chieve Resource Centre at www.a1chieve.com. The Centre provides an unprecedented level of detailed data and customizable downloadable reports on the tolerability and effectiveness of insulin analogues and patient outcomes.

A₁chieve Study Objectives

In randomized clinical trials, insulin analogues have demonstrated an ability to improve glycemic control with a significant reduction in the risk of hypoglycemia or without increasing body weight compared to human insulin preparations.¹ However, the results achievable in randomized trials are often not generalizable to other populations and circumstances. In randomized trials, treatment is provided to carefully selected patients in highly structured, monitored, and controlled clinical settings. Such factors are not reproducible in routine clinical practice, and the results of clinical trials, therefore, may not adequately reflect the outcomes achievable in other environments, especially in impoverished and newly developed countries. The A₁chieve study was designed to specifically gather data on the safety and effectiveness of insulin analogues outside the clinical trial setting in non-Western, newly developed countries and countries with limited resources. There are 234 million people with diabetes living in the 28 countries that participated in the A₁chieve study. This is nearly 64% of a total of 366 million people with diabetes worldwide.² Thus, the insight and understanding into the epidemiology of diabetes in those countries, usually quite scarce on data, are of great importance for the medical community.

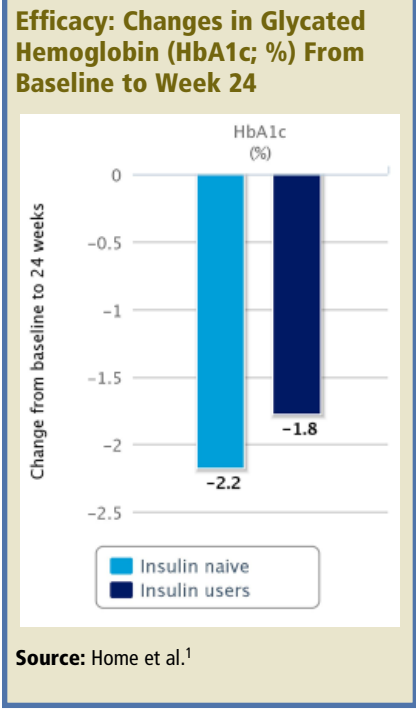
Table. Regions/Countries in A₁chieve

Region	Countries Within Region
China	—
South Asia	Bangladesh, India, Pakistan
East Asia	Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan
North Africa	Algeria, Morocco, Tunisia, Libya
Middle East/Gulf	Egypt, Iran, Jordan, Turkey, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
Latin America	Argentina, Mexico
Russia	—

Source: Home et al.¹

into seven more-specific geographic regions: China, South Asia, East Asia, North Africa, the Middle East/Gulf, Latin America, and Russia (Table).

Figure 1.



rates. There were also regional patterns of change in systolic blood pressure and levels of serum triglycerides and low-density lipoprotein cholesterol. The data are of immense interest when it comes to studying different patient profiles and choice of a particular insulin or insulin regimen that consider various genotypic and phenotypic variations across the globe. Identifying, analyzing, and understanding the details of region-specific data and differences among regions are now possible with the A₁chieve Resource Centre.

The A₁chieve Resource Centre

The A₁chieve Resource Centre comprises the online A₁chieve database. It is published on the Web site of the journal *Diabetes Research and Clinical Practice* with the support of Novo Nordisk. It is a free-access, multipurpose Web site: A₁chieve study results are presented and disseminated through the Web site in the form of downloadable journal articles, videos, and other media, and physicians and researchers can use the Web site to view and generate custom reports from the A₁chieve database. The Web site provides background information about the trial’s methods, outcomes, and investigators and includes a glossary, but the key, unique interactive feature is the Reports Generator.

Reports Generator

The A₁chieve Reports Generator enables users to view and extract demographic, efficacy, and safety data for the entire study cohort or for specific regions. Study outcomes may also be viewed and extracted in their entirety or according to specific end points (eg, Figures 1-3). This information may be further refined according to region and

Study Design and Patient Enrollment

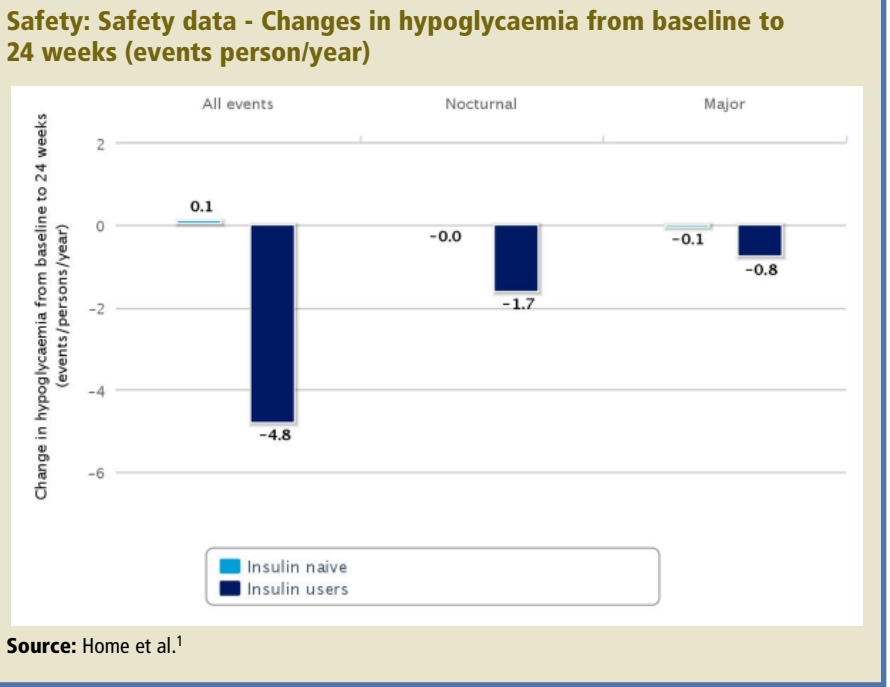
A₁chieve was a 24-week, non-interventional, international, prospective, multicenter observational study. The study enrolled 66,726 patients with type 2 diabetes who had started therapy with basal insulin detemir (Levemir®), bolus insulin aspart (NovoRapid®), and biphasic insulin aspart 30 (NovoMix® 30), alone or in combination. Patients taking any additional prior or current medications were eligible for inclusion. The study was conducted at 3,166 centers in 28 countries in Asia, Africa, Latin America, and Europe. These broad regions were subdivided

Results

Results from the study were published in the journal *Diabetes Research and Clinical Practice* in December 2011. Overall, insulin analogues produced substantial improvements in blood glucose levels. Baseline glycated hemoglobin (HbA_{1c}) was 9.5%. At 6 months, there was a 2.1% improvement (decrease) for the entire cohort (to 7.4%, *P*<0.001). For patients with no prior insulin use, there was a 2.2% improvement and for those with previous insulin use, a 1.8% improvement in HbA_{1c} levels (Figure 1).¹ Overall, hypoglycaemia did not increase in those new to insulin, and fell in those switching insulins (Figure 2).¹ Insulin analogue therapy was also associated with a significant improvement in health-related quality of life measured using the EQ-5D questionnaire at baseline and 24 weeks (increase from 63.4 points to 77.2 points, *P*<0.001) (Figure 3).³

These clinical and quality-of-life outcomes were consistent across the seven study regions. However, there were geographic differences in starting insulin doses, reductions in HbA_{1c} levels, and overall hypoglycemia

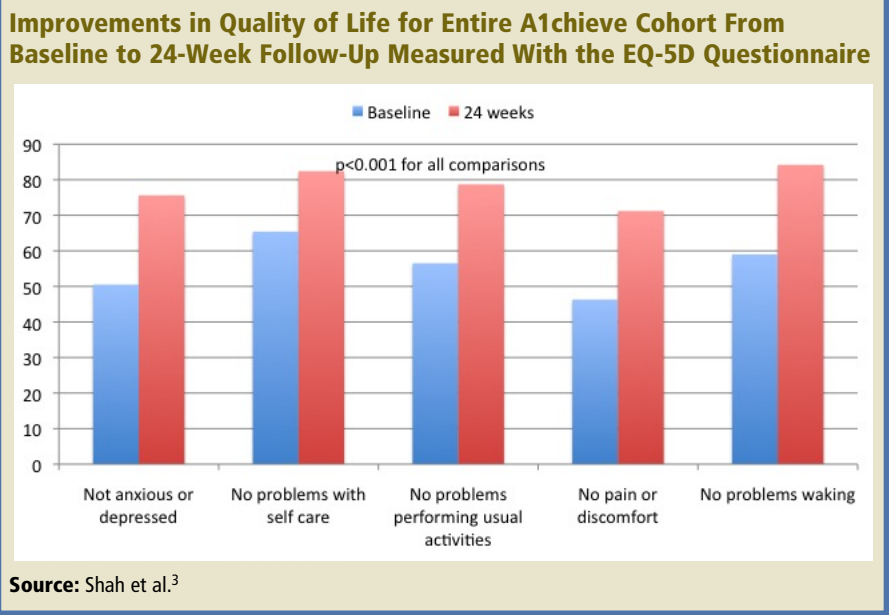
Figure 2.



specific end points for that region. For example, users can view all the results for South Asia simultaneously and visually compare these data with all the results from Russia. Or, if greater specificity is needed, the lipid and blood pressure data or patient satisfaction data, for example, could be compared between the two regions. To fit to local practice, the results can be displayed according to different measurement units as well: mmol/L or mg/dL for blood glucose, percent or mmol/mol for HbA_{1c}, and mmol/L or mg/dL for lipid profiles.

Information of interest to individual users can then be extracted and converted to customized takeaway reports. By following the “Create Custom Report” link on the Reports Generator page, users are taken to sets of individual thumbnail images, organized by region, that provide graphic representations of the study results. To create a report, the thumbnails can be dragged to the “drop zone.” Once in the “drop zone,” the user can arrange the order of the images by dragging them to the desired location. In this way, users may create side-by-side visual comparisons of changes in body weight among patients in Latin America and North Africa, for example, or view changes in weight from all seven regions. By creating a free account with a username and password, users may store their custom reports on the Web site. Reports may also be exported to portable document format (PDFs) or PowerPoint slides.

Figure 3.



Conclusions

A₁chieve study results demonstrated that starting Novo Nordisk insulin analogue therapy in patients who are new to insulin therapy or in those using other insulin preparations provides an opportunity to improve glycemic control with significant reduction in the risk of hypoglycemia and without any clinically significant weight gain. It also showed that, at various stages of type 2 diabetes, use of Novo Nordisk insulin analogues was associated with improvement in patients’ quality of life across all the regions. Data on patient demographics, including data on diabetes complications and use of various treatments across the participating countries, are scarce, and it is of significant clinical value to make these data available to the medical community. The online A₁chieve Resource Centre, to a good extent, will allow physicians and researchers to have access to these data in a user-friendly manner. Considering the large set of data that gets poured into medical literature in the current times, such innovative approaches like the A₁chieve online Resource Centre will be of increasing interest going forward.

References

- Home P, El Naggar N, Khamseh M, et al. An observational non-interventional study of people with diabetes beginning or changed to insulin analogue therapy in non-Western countries: The A1chieve study. *Diab Res Clin Pract.* 2011;94:352-363.
- International Diabetes Federation (IDF). *Diabetes Atlas*. 5th ed. Brussels, Belgium: IDF; 2011.
- Shah S, Zilov A, Malek R, Soewondo P, Bech O, Litwak L. Improvements in quality of life associated with insulin analogue therapies in people with type 2 diabetes: Results from the A1chieve observational study. *Diab Res Clin Pract.* 2011;94:364-370.

This supplement was produced by the customized publication department of IMNG Medical Media, an Elsevier company. Neither the editor of CLINICAL ENDOCRINOLOGY NEWS, the Editorial Advisory Board, nor the reporting staff contributed to its content. The opinions expressed in this supplement are those of the faculty and do not necessarily reflect the views of the Publisher.

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