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An analysis of the short- and long-term cost-effectiveness of starting biphasic insulin aspart 30 in insulin-naïve people with poorly controlled type 2 diabetes

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ABSTRACT

Aim: This study aimed to assess the cost-effectiveness of starting insulin therapy with biphasic insulin aspart 30 (BIAsp 30) in people with type 2 diabetes inadequately controlled on oral glucose-lowering drugs in Saudi Arabia, India, Indonesia, and Algeria.

Methods: The IMS CORE Diabetes Model was used to evaluate economic outcomes associated with starting BIAsp 30, using baseline characteristics and treatment outcomes from the A_1chieve study. Time horizons of 1 and 30 years were applied, with country-specific costs for complications, therapies, and background mortality. Incremental cost-effectiveness ratios (ICERs) are expressed as cost per quality-adjusted life-year (QALY) in local currencies, USD, and fractions of local GDP per capita (GDPc). Cost-effectiveness was pre-defined using the World Health Organization definition of <3.0 times GDPc. Comprehensive sensitivity analyses were performed.

Results: In the primary 30-year analyses, starting BIAsp 30 was associated with a projected increase in life expectancy of >1 year and was highly cost-effective, with ICERs of −0.03 (Saudi Arabia), 0.25 (India), 0.48 (India), 0.47 (Indonesia), and 0.46 (Algeria) GDPc/QALY. The relative risk of developing selected complications was reduced in all countries. Sensitivity analyses including cost of self-monitoring, treatment costs, and deterioration of glucose control with time showed the results to be robust. In a 1-year analysis, ICER per QALY gained was still cost-effective or highly cost-effective.

Conclusion: Starting BIAsp 30 in people with type 2 diabetes in the A_1chieve study was found to be cost-effective across all country settings at 1- and 30-year time horizons, and usefully increased predicted life expectancy.

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1. Introduction

The worldwide prevalence of diabetes is steadily increasing, and is expected to reach 592 million by 2035 [1]. Global diabetes-related expenditure, estimated at USD548 billion in 2013, is expected to increase to USD627 billion by 2035 [1]. The International Diabetes Federation estimates that 80% of people with diabetes live in low- and middle-income countries where local health-care systems are often not equipped to deal with the economic burden of diabetes [2]. Newly developed countries also have high diabetes prevalence.

In developing and recently developed countries, many people with diabetes are diagnosed late and may already have diabetes-related complications, resulting in significant costs for individuals and families where government-funded healthcare social security is low or absent. People of working age are especially affected, with consequences for the economic potential of the countries [1]. Successful management of diabetes includes control of high glucose levels [2,3]. However, many people with type 2 diabetes mellitus (T2DM) are not achieving the generally recommended levels for good glycaemic control ($HbA_{1c} < 7.0\%$ [<53 mmol/mol]) [2–5].

Analyses of randomised clinical trials (RCTs) [6,7] and data from non-interventional studies [4,5,8] confirm that beginning insulin analogues in people taking glucose-lowering drugs (OGLDs) alone is associated with clinically significant improvements in glucose control while improving quality of life. Furthermore, there is evidence to support biphasic insulin aspart 30 (BIAsp 30) as a cost-effective treatment option in a number of western and developed countries [9–11].

Evaluation of how health-care funds should be spent to maximise health benefits requires assessment of the economic impact of diabetes interventions. Because of the progressive nature of diabetes and the complexity of the clinical outcomes, health-economic (HE) data modelling is helpful in estimating the effects of an intervention on health consequences and costs. These models can bring together data from a variety of different sources including RCTs, observational studies, case registries, public health statistics, and quality-of-life surveys, simulating disease progression and related costs through time in a population. In rapidly developing and recently developed countries where health-care costs are diverse, data from observational studies can be of use in HE modelling by reflecting actual outcomes in clinical practice, especially where there is a paucity of RCT data for these populations [12–14].

A_1chieve was a very large observational study conducted in countries across Asia, Africa, Eastern Europe, and Latin America, designed to evaluate the safety and clinical effectiveness of insulin analogues in people with T2DM in clinical practice [4]. It thus provides an opportunity to explore how the insulin analogues performed in diverse, heterogeneous populations and to conduct cost-effectiveness analyses in non-western populations. In turn, this may help the evolution of diabetes guidelines and enable the optimal allocation of scarce health-care resources. Furthermore, the prospective use of the globally validated EQ-5D instrument provides a unique opportunity to base the health-related quality of life (HRQoL) data used as input in the HE model on answers from the same population as the clinical outcomes are observed. The aim of the present analysis is to assess the long- and short-term cost-effectiveness of starting BIAsp 30 in people with T2DM poorly controlled on OGLDs applying the specific EQ-5D and clinical outcome data collected during the A_1chieve study.

2. Participants and methods

2.1. A_1chieve data collection

A_1chieve was a 24-week, international, non-interventional, observational study in insulin-naïve and insulin-experienced people with T2DM from 28 countries starting treatment with BIAsp 30, insulin detemir, or insulin aspart (all Novo Nordisk, Copenhagen, Denmark) ± OGLDs in routine clinical practice. Details of the study design and methods and global primary data have been published elsewhere [4,15]. In summary, data were collected on clinical effectiveness and adverse events at routine clinical visits (baseline, 12 and 24·weeks). Participants were asked to complete the EQ-5D questionnaire, used for self-assessment of HRQoL, at baseline and week 24 [15].

2.2. Simulation cohort

The cost-effectiveness analysis used clinical data from the A_1chieve study for the measurement of health outcomes. Data were included for people being treated for diabetes with OGLDs alone at pre-study and starting BIAsp 30 at baseline, in most cases keeping at least part of the OGLD treatment. To secure reliable estimates and for the analysis to be representative for the average population, only countries where more than 100 insulin-naïve people started BIAsp 30 were included. An HbA_{1c} result at both baseline and end of study was also required. These criteria result in study populations from Saudi Arabia ($n = 901$), India ($n = 7546$), and Indonesia ($n = 153$), and three North African countries grouped together (Algeria, Tunisia, and Morocco; $n = 279$), analysed using economic data from Algeria. The prevalence of diabetes has risen dramatically in these neighbouring countries in recent years and they have experienced similar rapid economic development and changes in lifestyle that endorse their assignment as a single population, defined specifically by treatment choice, for this analysis [16]. Baseline characteristics of the defined populations, and changes in blood-glucose control, body mass index, plasma lipids, systolic blood pressure, hypoglycaemia, and EQ-5D-based HRQoL are shown in Table 1.

The clinical and economic costs of starting BIAsp30 (with or without changes to OGLDs) in each country were projected over a 30-year time horizon for the base-case using the IMS CORE Diabetes Model (version 8.5; Basel, Switzerland) [17,18]. Baseline and clinical data from the A_1chieve cohorts were used together with economic data including annual diabetes management costs (medications and surveillance tests) and relevant co-morbid medical conditions taken from the published literature [19–22]. The costs of BIAsp30 and OGLDs were sourced from local Novo Nordisk affiliates. Both costs and effects were discounted at an annual rate of 3.0% according to World Health