

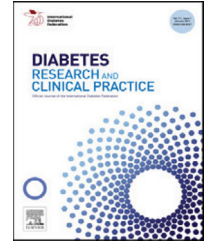


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**International
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Editorial

Observational research: an integral part of enhancing diabetes management in south-east Asia

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1. The diabetes burden

The prevailing burden of the diabetes epidemic and its associated complications poses a substantial threat to socio-economic development worldwide. This crisis is magnified in developing and recently-developed nations including countries in south-east Asia. Estimates from the International Diabetes Federation suggest an inverse relationship between the economic status of a country and the rise of diabetes; with lower-income countries facing the greatest increase in the prevalence of diabetes [1]. In recent years, the Association of Southeast Asian Nations (ASEAN) has faced an exponential increase in the prevalence of diabetes and associated mortality rate. The current diagnosed and undiagnosed diabetes prevalence in four countries from the ASEAN region and corresponding diabetes-related mortality is presented in Figure 1 [2]. Indonesia with a reported diabetes prevalence of 7.3% in 2011 and a projected prevalence of 11.8% by 2030 ranks among the most affected 10 countries worldwide for adults of 20 to 79 years of age [1]. Although this rise is frequently attributed to population growth, ageing populations, excess calorie intake, and physical inactivity, better disease management contributing to better life expectancy with diabetes will also play a part. Nevertheless there is great scope for further improving this to contain the late adverse outcomes which cause so much of the ill health due to diabetes, and a majority of health-care costs.

A shortcoming of ASEAN clinical practice guidelines is that they are often mapped by necessity to data available from western countries [3]. The establishment and implementation of clinically meaningful strategies customized to each country would logically require direction from more local data in routine clinical care settings. However, availability of such data is limited due to a scarcity

in the number of clinical trials conducted in the ASEAN region.

2. The need for observational research

Required data should be obtained using a balanced study design assessing the benefits and harms of treatment simultaneously. Under these circumstances, the observational study approach can be more practical than randomized controlled trials (RCTs). Observational research on medical interventions is more valuable post-approval when large datasets of typical real-life patient populations are involved. The frequency of adverse events reported in RCTs is usually limited by the small numbers of participants and by restrictive inclusion criteria of relatively healthy people. People with significant comorbidity are routinely excluded from RCTs but community-based practitioners have to cater to the needs of all patients irrespective of medical history. Furthermore, in clinical practice, therapies will by definition be used according to the local physician and patients needs and customs, while in RCTs use is generally driven by the protocol employed, with discontinuation of therapy or dose limitation discouraged. This is in contrast to routine clinical care where medication adherence is a major determinant of health outcomes for both oral and injection therapies [4]. Evidently observational study results will still be sensitive to the demographical and clinical characteristics of the population studied, but often offer opportunities for co-evaluation of measures such as baseline characteristics, health economic factors, surrogate and actual outcomes, and health-related quality of life.

3. The importance of A₁chieve in the ASEAN region

The multinational, prospective, non-interventional A₁chieve trial [5] is an example of such a study. It was conducted to

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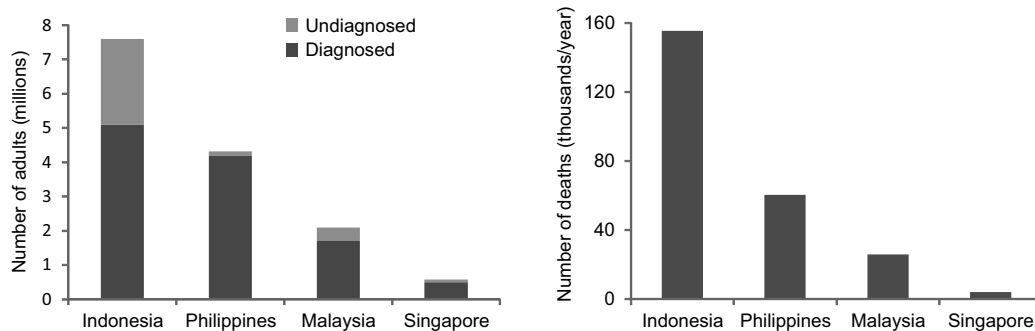


Fig. 1 – Number of adults with diagnosed and undiagnosed diabetes in selected countries in the ASEAN region in 2012, and annual mortality estimates. Data from IDF Diabetes Atlas [2].

determine the clinical experience associated with insulin analogue use in local clinical care across 28 non-western nations, including many less well resourced countries, across six continents. Complete study results are now available online under www.A1chieve.com. The advantages of the multinational A₁chieve study are revealed by the key statistics it has divulged on the current status of type 2 diabetes management in developing countries at baseline. People with type 2 diabetes from Indonesia, Malaysia, Philippines and Singapore were the representative nations of the ASEAN belt. The general observation at baseline was that people entered the study with grossly inadequate control of blood glucose levels. The average HbA_{1c} level in the entire ASEAN cohort of 5029 participants was 9.7% (82 mmol/mol) while fasting plasma glucose and postprandial plasma glucose levels were 12.0 mmol/L (216 mg/dL) and 15.9 mmol/L (286 mg/dL), respectively.

Despite this poor state of glycaemic control and average diabetes duration of 7.2 years, the majority of participants starting analogue therapy ($n = 3635$) had not received insulin therapy previously. Clearly, the approach to diabetes care in these areas was sub-optimal. This may relate to factors such as fear of hypoglycaemia, weight gain, injections themselves, and/or perceived negative impact on quality of life, any or all of which may have delayed beginning insulin. However, it is known that nearly all people with type 2 diabetes will eventually require insulin, unless they die early or make major and permanent lifestyle changes.

The development of insulin analogues was intended to improve the benefit:harm risk of insulin therapy. The A₁chieve study evaluated the clinical experience with insulin analogues (biphasic insulin aspart 30, insulin detemir and insulin aspart) in a non-interventional local setting so that the results can be easily extrapolated to general patient populations in each country involved, and indeed beyond. The importance of an observational study like A₁chieve is

thus justified by its contribution to increasing patient and physician awareness of the gains, and any losses, from the deployment of these therapeutic options designed to bolster diabetes management.

Conflict of interest statement

Philip Home or institutions with which he is associated receive funding from Novo Nordisk and other insulin manufacturers for his research, advisory and educational activities.

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