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Editorial

Significance of observational data on type 2 diabetes management in North Africa

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1. Introduction

The randomized controlled trial (RCT) methodology is often considered to reveal the most accurate data on a product's safety and effectiveness. However, the value of an RCT post-approval is limited as clinical trial cohorts rarely represent the general patient population in real-life settings. Observational studies on the other hand yield better evaluations for safety and effectiveness in routine clinical care. It provides a snapshot of the patients' daily life and highlights the barriers and constraints routinely faced by patients and physicians alike. Observational studies have the key advantage of garnering data from community-based practitioners who have a better understanding of the population needs as opposed to the exposure that clinical trial specialists generally have. The results from RCTs are controlled by restrictive inclusion/exclusion criteria whereas treatment in clinics cannot be governed on selected groups of patients. Furthermore, the evidence on harms for medical interventions is primarily obtained from observational research. A study by Papanikolaou et al. comparing the evidence of harms from randomized versus non-randomized studies demonstrated that results from the latter were more conservative than randomized studies [1]. This suggests that data from both types of study designs should be weighed judiciously prior to defining a product's safety profile. In situations when two approved drugs have to be compared under routine clinical care, an observational study would be more appropriate than a controlled trial. Observational principles also ensure the best consequences in studies on epidemiology, pharmacoepidemiology, statistics, health economics and outcomes research and health surveys.

2. Observational studies in developing nations

Owing to several such advantages, observational studies have now gained credibility as an integral part of drug development and safety surveillance. The importance of observational data is more pronounced in developing countries as the number of RCTs conducted is very low. It has been noted that due to a lack of local data, healthcare policies in these less well-resourced countries are based on guidelines from the developed nations. Implementation of these guidelines frequently becomes challenging due to ethnic, economic and clinical care differences between developing and developed nations. Therefore, it is necessary to cater to the local clinical practice while formulating healthcare guidelines. Apart from the standard therapeutic safety and effectiveness outcomes, healthcare practitioners often require supportive data improvements in treatment adherence and patients' quality of life among others. Furthermore, availability of epidemiological details as well as the cost-effectiveness of therapy would ultimately enhance clinical outcomes. Observational studies are powered to reveal such vital statistics in the general population at baseline itself thus acting as enablers for optimum treatment strategies.

3. The diabetes epidemic in North Africa

The management of widespread chronic diseases such as type 2 diabetes (T2D) warrants results that reflect therapeutic effectiveness in patients irrespective of their background, concomitant medications and comorbid disease states. In recent years, the North African belt has seen an overwhelming rise in the prevalence of diabetes. The incidence of diabetes in relation to the population across North African nations is depicted in Fig. 1 [2]. The International Diabetes Federation also estimates that the Middle East–North Africa region is expected to have the second largest proportional increase in adults with diabetes by the year 2030, preceded only by the rest of Africa [3].

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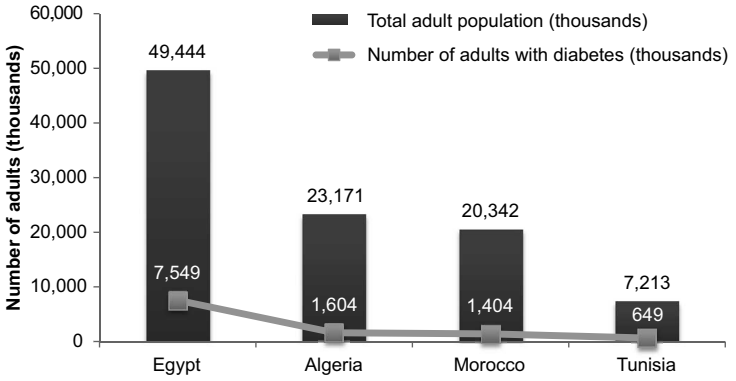

Fig. 1 – Number of adults with diabetes relative to the total adult population in North African countries.

To accommodate this epidemic growth of diabetes, the region requires immediate infrastructure development with appropriate diagnostic and therapeutic tools for T2D management. However, integrated diabetes management plans such as the National Diabetes Plan for Middle East–North Africa face several challenges due to the region's extensive geography, access to medicine and healthcare and risk factors including smoking, hypertension and obesity [4]. Currently, the number of data sources derived from studies in this region is very limited and inconclusive. As a result, availability of country-specific data would naturally become the driver to bring about significant improvements in the management of T2D.

4. Management of type 2 diabetes in North Africa

The prospective, open-label, non-interventional A_1chieve study was the first of its kind conducted in 28 developing countries, worldwide, to determine the safety and effectiveness of insulin analogues in T2D patients as well as to shed light on the status of T2D management in these countries [5]. Complete study results are available online under www.A1chieve.com. At baseline alone, this study has exposed a wealth of information on the therapies adopted to control T2D. It was observed that the majority of T2D patients presented with poorly controlled diabetes at baseline. The North African cohort of the A_1chieve study comprised 4039 patients recruited from 231 centres across Algeria, Libya, Morocco and Tunisia between March 2009 and December 2010. Although the average diabetes duration was 11.5 years, 1969 patients had not received prior insulin therapy. Also, the mean baseline glycated haemoglobin (HbA_{1c}) level was 9.5% (80 mmol/mol) [5]. The mean HbA_{1c} level observed was a long shot from the recommendations of evidence-based guidelines that suggest that a target HbA_{1c} level <7.0% is imperative to reducing the risk of long-term complications [6]. The poor glycaemic control could be correlated to the significant delay in insulin initiation that was reported. This conservative treatment approach by physicians may have been influenced by the lack of awareness or reluctance in initiating insulin therapy due to fears of hypoglycaemia, weight gain and effects on health-related quality of life [7]. Patients on the other hand may have been unaware on the importance of achieving glycaemic goals via adequate life style changes and therapy compliance.

Despite the innovation and tools currently available for the management of type 2 diabetes in the Maghreb, the results are well below the recommended goals. All uncertainties identified in the diabetologic practice have a common denominator, i.e., the lack of therapeutic education covering almost all material, human or psychological areas of diabetes management. Therapeutic education is the real linker between therapy compliance and physician recommendations. Continuous training and clinical awareness on the part of practitioners could be the key to positively modify attitudes of clinical inertia that are sometimes unjustified.

The impact of an observational study is best defined under these circumstances. The A_1chieve study not only reveals the existing status of T2D management but also provides options for practitioners to resort to more clinically significant therapies that would benefit their patients at large. Overcoming the daunting task of managing T2D in routine clinical care could thus be guided, if not simplified, by investing in observational research.

Conflict of interest statement

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