Indian Insulin Guidelines: A Year Later and the Road Ahead

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Abstract

There are various regimens available for prescribing insulin, which include but are not limited to basal bolus, split mixed, premix, and prandial therapy. Basal bolus, although termed ideal for people with type 1 diabetes, is often perceived as complex for management of T2DM. In order to provide primary care physicians with a simple algorithm for initiation and titration of insulin therapy, the Indian National Consensus Group (INCG), formulated a guideline on premixed insulin therapy, which was published in 2009. They recommended premixed insulin as simple, safe, easy to start and stay, and a more physiological option for treating type 2 diabetes. The Indian insulin guideline has evoked a good deal of participation and has been discussed at various forums including national conferences, continuing medical education programs, and institutional seminars. The initial feedback on the utility of the guideline from the medical fraternity has been very encouraging.

Type 2 diabetes mellitus (T2DM) is a chronic progressive disorder and its prevalence is reaching great proportions in the Asian and Indian populations at an alarming rate. According to the latest IDF estimates, 50.8 million people in India will be diagnosed with diabetes in 2010 and the figure will increase to approximately 75 million in 2025 and almost 80 million by 2030. This steep rise in prevalence is a cause of great concern as the long-term complications (microvascular and macrovascular) of T2DM will put an enormous social and economic burden on the healthcare resources of the country.

Optimum glycemic control is the key to successful management of patients with diabetes. Reduction in HbA1C levels results in a significant reduction in microvascular complications and shows a trend towards reducing macrovascular complications. However, at present, optimal glycemic control is far from satisfactory as more than two-thirds of people with diabetes do not achieve the target HbA1C goals. While the therapeutic strategies to reduce glycemic burden are plentiful, insulin remains the most definitive option in the armamentarium for the management of diabetes. Exogenous insulin replacement is required for type 1 diabetes (due to absence of endogenous insulin secretion) and in patients with T2DM as well due to progressive decline of β-cell mass.

There are various regimens available for prescribing insulin, which include but are not limited to basal bolus, split mixed, premix, and prandial therapy. Basal bolus, although termed ideal for people with type 1 diabetes, is often perceived as complex for management of T2DM. In order to provide primary care physicians with a simple algorithm for initiation and titration of insulin therapy, the Indian National Consensus Group (INCG), which included 27 experts, formulated a guideline on premixed insulin therapy, which was published in 2009. They recommended premixed insulin as simple, safe, easy to start and stay, and a more physiological option for treating type 2 diabetes. The Indian insulin guideline has evoked a good deal of participation and has been discussed at various forums including national conferences, continuing medical education programs, and institutional seminars. The initial feedback on the utility of the guideline from the medical fraternity has been very encouraging.

Developing this guideline has been a painstaking effort at all levels! However, the real challenge lies in developing a locally relevant implementation strategy. The guideline has effectively taken care of local perspectives through the active involvement of 250 diabetologists and physicians across the country. An accepted notion is that this guideline will equip the primary care physicians with a simple and doable algorithm for initiating insulin in their clinical practice. Proper implementation involves local launch meetings to disseminate ideas and endorse its integration into local professional education activities. Some of the key barriers to the practical implementation of any guideline are the lack of endorsement by and the involvement of key stakeholders, and a dearth of resources.

To review the future course, the INCG core committee met in December 2009 and felt a need to validate the effectiveness and impact of the Indian insulin guideline in real-life practice. A positive move in this particular direction is the Improving Management Practices and Clinical Outcomes in Type 2 Diabetes: IMPACT Study. This 26-week multicenter, open label, randomized, prospective study aims to evaluate the effectiveness of the Indian insulin guideline versus routine clinical practice in patients with type 2 diabetes. According to the core steering committee of the study, it is the first prospective study on the validation of a diabetes guideline in the world and one of the largest prospective studies in diabetes involving more than 25000 participants.
patients and 1200 study sites. An important feature of this study is to address the issue of physician perception on the use of the guideline versus routine clinical practice for management of type 2 diabetes in real-life practice.

The study will help generate data on routine clinical practice trends with guideline based initiation and intensification of a premix insulin regimen in the management of type 2 diabetes. This data will be utilized for developing a modern version of the Indian insulin guideline as agreed by the INCG.

Local investigators’ meetings have been an important means of publicizing the guideline, disseminating the philosophy and momentum of the guideline initiative, and bringing to a wider audience the knowledge of the quality of the guideline, and its endorsement by others.

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Most of these meetings have been hosted and coordinated by respected local opinion leaders. Integrating the guideline into the local professional education and patient-related activities will be an offshoot of the successful validation of this guideline. Validation is often defined as the documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results. Quality is designed and built into the processes, methods, and premises, whereas functionality, consistency, and reproducibility are confirmed by validation. The IMPACT study intends to achieve this objective and set the ground for successful implementation of the Indian insulin guideline.

References