## **Brief Communication**

## Improving management practices and clinical outcomes in type 2 diabetes study: Prevalence of complications in people with type 2 diabetes in India

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## ABSTRACT

Introduction: Diabetes is the fourth leading cause of disease-related death and almost 80% of diabetes-related deaths occur in developing countries. Optimal glycemic control, in particular HbA1c level less than 7% with effective management of dyslipidemia and hypertension can reduce development of diabetes-related complications. Delay in initiating/or optimizing appropriate anti-diabetic therapy including insulin could be a possible cause of the increase in complications. Method: Improving management practices and clinical outcomes in type 2 diabetes (IMPACT) was a prospective, open-label, 26-week, comparative, multi-center study to compare efficacy and safety of the Indian insulin guideline (IIG) group versus routine clinical practice (RCP) group in type 2 diabetes patients. A total of 20,653 subjects from 885 centers across India were enrolled. Results: A total of 4695 patients (22.7%) (IIG, 4113 [22.6%]; RCP, 582 [23.5%]) had macrovascular complications and 8640 patients (41.8%) (IIG, 7486 [41.2%]; RCP, 1154 [46.6%]) had microvascular complications. Of 4695 patients with macrovascular complications, 2850 patients (60.7%) had coronary heart disease followed by 1457 patients (31.0%) with peripheral vascular disease. Of all the microvascular complications recorded, 5627 patients (65.1%) had peripheral neuropathy followed by 3313 patients (38.3%) with retinopathy. Conclusion: The rates of complications were high in patients with type 2 diabetes at the time of being initiated on insulin therapy in India.

Key words: Diabetes complications, treatment delay, insulin

Demographic and economic changes are important factors for the increase in prevalence of diabetes observed in the last decade. Ageing, risk factors such as obesity and sedentary lifestyle, and improved longevity of the population have evolved in the Indian population and consequently increased the incidence of diabetes as well. It has also been argued that the previous modeled estimates have generally been underestimating the prevalence of

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diabetes worldwide. Combined with greater urbanization and implicated risk factors, this alarming trend can lead to an enormous increase in the number of people with diabetes in India. It is being hypothesized that certain ethnic characteristics of the Indian (and Asian) populations should decide the best form of anti-diabetic (and insulin) therapy rather than blanket recommendations from various professional bodies.<sup>[1]</sup> An early intensive glycemic control reduces the risk of diabetic complications and has longterm influence of early metabolic control on clinical outcomes. This phenomenon has recently been defined as "metabolic memory." The emergence of the metabolic memory suggests the need for early aggressive treatment aiming to "normalize" metabolic control and reduce cellular reactive species and glycation in order to minimize long-term diabetic complications.

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Despite improvements in lipid and blood pressure control in recent years, achieving good glycemic control remains challenging. Significant barriers to appropriate and timely insulin initiation still exist, and the prospect of intensifying to more complex insulin regimens and the need for more frequent blood glucose monitoring may be daunting for both patients and healthcare professionals alike. Patients' ability to adhere to therapy is known to be a significant problem in the treatment of chronic illnesses, and particularly in conditions such as diabetes, where patients may be asymptomatic for many years, and only develop significant morbidity in the longer term. In 2009, the Indian National Consensus Group (INCG) published the "Premix Insulin: Initiation and Continuation Guidelines for Management of Diabetes in Primary Care" guideline.[3] This was probably one of the first guidelines on insulin therapy in India providing a simple guide for initiation and intensification of insulin therapy. Subsequently, the improving management practices and clinical outcomes in type 2 diabetes (IMPACT) study were planned with the objective of validating this guideline and providing insights for further improvement and revision.

As its primary objective, the IMPACT study intended to compare the safety and efficacy of the Indian insulin guideline (IIG) group versus routine clinical practice (RCP) group in type 2 diabetes patients. It was a prospective, open-label, 26-week, comparative, multi-center study. A total of 20,653 patients from 885 centers across India were enrolled. They were randomly assigned to receive premixed insulin therapy according to either of two practices of care for the next 26 weeks: treatment based on the IIG or the RCP. Baseline data were recorded at the first visit and the subsequent safety and efficacy parameters were recorded at weeks 13 and 26. Here, we present the prevalence of complications in patients with type 2 diabetes based on this study.

A total of 4695 patients (22.7%) (IIG, 4113 [22.6%]; RCP, 582 [23.5%]) had macrovascular complications and 8640 patients (41.8%) (IIG, 7486 [41.2%]; RCP, 1154 [46.6%]) had microvascular complications. In 4695 patients with macrovascular complications, 2850 patients (60.7%) had coronary heart disease followed by 1457 patients (31.0%) with peripheral vascular disease. The records from microvascular complications indicated that 5627 patients (65.1%) had peripheral neuropathy followed by 3313 patients (38.3%) with retinopathy. The results showed that rates of complications were higher in patients with type 2 diabetes at the time of being initiated on insulin therapy in India. Reasons for this are not difficult to understand.

Clinical inertia, defined as failure to start therapy despite the recognition of the problem and awareness of the benefits of the therapy, contributes greatly to this. Unequivocal evidence points in favor of early insulin initiation and appropriate intensification for optimal metabolic control. [2,4] The morbidity and mortality related to diabetes are more often than not attributed to its related complications and these can adversely affect the already scarce resources in a developing country like India. Optimal glycemic control, in particular HbA1c <7% with effective management of dyslipidemia and hypertension can reduce development of diabetes-related complications. [5]

Recently, a major step has been taken to address this issue, with establishment of the INCG guideline. The INCG guideline was established with the aim of providing primary care physicians a simplified regimen based on the patients' and physicians' needs and expectations. This guideline recommends the use of premix insulin regimen for its convenience, safety, and efficacy. Furthermore, this guideline needs to be revised based on changing needs and requirements. Also incorporating this guideline into professional education and disseminating the information to a wider audience, including patients and physicians, can help in its successful implementation. Besides, registries need to be established to keep track of patients afflicted with diabetes-related complications and to provide them with adequate medical information and social support. Adapting clinical practice audit tools may support better analysis and help providers identify patterns and gaps in clinical delivery. Clinical audit tools can present timely and relevant information, so clinicians are better informed (on their own practice) and can more consistently perform screening and prevention. These changes along with an easy-to-implement clinical guideline in India can have a big impact on improving diabetes care and assist in reducing the risk of complications.

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