

# Baseline results indicate poor glycemic control and delay in initiation and optimization of insulin therapy: results from the improving management practices and clinical outcomes in type 2 diabetes study

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### ABSTRACT

**Introduction:** 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 patients with type 2 diabetes. **Materials and Methods:** A total of 20,653 patients from 885 centers across India were enrolled and treated with premixed insulin therapy as per IIG or routine care. **Results:** Most of the participating centers (81.7%) reported following a diabetes guideline in their practice routinely but only 20.4% targeted HbA1c <7%. Very few of the physicians (2.7%) reported that most of their patients (>75%) achieved an HbA1c <7%. Most of the physicians (39.8%) also agreed that only 10-25% of the patients agree to start insulin therapy at the first counseling. Mean duration of diabetes before initiating insulin in patients using oral anti-diabetic drugs (OADs) was 7 years, indicating a delay in initiating insulin therapy. The difference in mean daily dose of insulin at initiation vs. at 26 weeks was only 0.8 U (25.8 ± 11.3 at initiation compared to 26.6 ± 9.5, respectively,  $p = ns$ ) suggesting lack of treatment optimization. Weekly titration till achieving HbA1c <7% was done in 51.1% of the patients and only 8.9% performed self-titration. **Conclusion:** Baseline glycemic control in these patients was poor and reflects a delay in initiating insulin therapy. Data also reflect a lack of optimization of insulin doses.

**Key words:** IMPACT, baseline glycemic control, insulin dose optimisation

Diabetes mellitus is one of the most common chronic diseases in nearly all countries and continues to increase in numbers and significance, as economic development and urbanization lead to changing lifestyles characterized by reduced physical activity and increased obesity. The

International Diabetes Federation (IDF) estimates that 366 million people had diabetes in 2011; by 2030, this would have risen to 552 million.<sup>[1]</sup> Earlier this year, the Indian Council of Medical Research–India Diabetes (ICMR–INDIAB) study had extrapolated its phase I results to estimate 62.4 million individuals with diabetes and 77.2 million with pre-diabetes in India.<sup>[2]</sup> Majority of the people diagnosed and treated for diabetes are often in poor glycemic and metabolic control. Clinical inertia, defined as “recognition of the problem, but failure to act” is a principal cause of poor glycemic control.<sup>[3]</sup> Recently, the A1chieve® study reported that 11% of the total 66,726 patients with type 2 diabetes (from 28 countries across Asia, Africa, Europe, and Latin America) had not received

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medication for an average of 4.6 years following diagnosis.<sup>[4]</sup> It is widely believed that current treatment trade-offs are another significant barriers to optimal control. Weight gain, hypoglycemia, and increasingly complex treatment regimens for the management of diabetes contribute to poor glycemic control. Insulin initiation, which was traditionally the province of specialists, is increasingly undertaken by primary care. However, significant barriers to appropriate and timely initiation still exist.<sup>[5]</sup>

Although insulin is recognized as providing the most effective treatment in type 2 diabetes, it is also widely considered to be the most challenging and time-consuming. In order to overcome these barriers, the Indian National Consensus Group came up with the Indian insulin guidelines to guide appropriate and timely initiation and intensification of insulin therapy based on the recommendations of 27 experts and further modified by 250 diabetologists and physicians across India.<sup>[5]</sup> Furthermore, to validate this guideline, the improving management practices and clinical outcomes in type 2 diabetes (IMPACT) study was planned to validate the effectiveness of Indian insulin guideline (IIG) versus routine clinical practice (RCP) in patients with type 2 diabetes. It was a prospective, open-label, 26-week, comparative, multi-center study. It has been developed with a view to improve upon the existing practices and thus improve current standards of care. An analysis of results revealed that there was a delay in initiation and intensification of insulin therapy despite poor glycemic control.

The primary objective was to compare safety and efficacy of the Indian insulin guideline (IIG) group versus RCP group in patients with type 2 diabetes. A total of 20,653 patients with type 2 diabetes from 885 centers across India were enrolled and randomly treated with premixed insulin therapy as per IIG or routine care for a period of 26 weeks. Baseline data were recorded at the first visit and the subsequent efficacy and safety parameters were recorded at weeks 13 and 26. Here, we present data reflecting delay in initiating or optimizing insulin therapy despite poor glycemic control.

Most of the participating centers (81.7%) reported following a diabetes guideline in their practice routinely but only 20.4% targeted HbA1c <7%. Very few of the physicians (2.7%) reported that most of their patients (>75%) achieved an HbA1c <7%. Most of the physicians (39.8%) also agreed that only 10-25% of the patients agree to start insulin therapy at the first counseling. Mean duration of diabetes before initiating insulin in patients using oral anti-diabetic drugs (OADs) was 7 years, indicating a delay in initiating insulin therapy. The difference in mean daily dose of insulin at initiation vs. at 26 weeks was only 0.8 U ( $25.8 \pm 11.3$  at initiation compared to  $26.6 \pm 9.5$ , respectively,  $p = ns$ ) suggesting lack of treatment optimization. Weekly titration till achieving HbA1c <7% was done in 51.1% of the

patients and only 8.9% performed titration by themselves. Baseline glycemic control in these patients was poor and reflects a delay in initiating insulin therapy. Data also reflect a lack of optimization of insulin doses.

The treatment of type 2 diabetes is particularly challenging, owing to its progressive nature and perceived complexity of available treatment regimens. Initiation of insulin therapy has traditionally been the domain of specialists, but due to the burgeoning patient population, it is slowly but definitely moving over to the primary care physicians (PCPs). Timely institution and appropriate intensification of insulin therapy can delay the onset and progression of diabetes-related complications. Thus, it is important to instruct both patients and doctors, PCPs in particular, about the need for starting insulin treatment early. The establishment of Indian insulin guidelines is a step forward in this regard, as it sets a precedent for PCPs to follow in their daily practice, thus simplifying complex regimens and increasing acceptability of early institution of insulin therapy among patients. Integrating these guidelines into professional education can further facilitate their implementation.

To conclude, early transition to insulin and a more optimal intensification of treatment may help delay the onset of diabetes complications. Physicians managing diabetes should aim to improve acceptance, persistence, and adherence to insulin therapy by focusing on safety, simplicity, and convenience of therapy.

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