

**A Prospective, Multicentric, Randomized, Open-Label Comparison
of a Long-Acting Basal Insulin Analog Glargine plus Glulisine with
Premixed Insulin in Adult Patients with Type 2 Diabetes Mellitus**

THESIS SUBMITTED FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY



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SUMMARY AND CONCLUSION

Our randomised controlled study showed a marginally better effectiveness of Glargine + Glulisine insulin compared with premixed insulin in reducing HbA1c in insulin naïve Asian Indian T2D patients uncontrolled with OADs. The results showed that Glargine + Glulisine were effective for initiating insulin. However the dose required is higher than that of premixed insulin. An additional observation was that less episodes of hypoglycemia occurred with Glargine + Glulisine with premixed insulin. There was no clinically significant change in body weight in both groups. The increase in dose and additional injections are due to the higher baseline HbA1c levels among the study group. The patients who had lower HbA1c level at baseline had good glycemic control with less dose and single injection of insulin. This clearly shows that early initiation of insulin therapy will lead to good glycemic control which will reduce the development of complications.

In conclusion, among the subjects initiated on Glargine + Glulisine (basal plus regimen of insulin) there was a significant reduction of HbA1c. The episodes of symptomatic hypoglycemia were less compared with the Premixed insulin analogue. There was no clinically significant change in body weight in both groups.

IMPACT OF THE STUDY

Based on this study we recommend the following points

- ✓ Initiation of the basal plus regimen in the early phase of the disease will have good glycemic control with a lower dose.
- ✓ Initiation of the basal plus regimen in the late stage of the disease will lead to the basal-bolus regimen and also require a higher dose to control the glucose level.
- ✓ While initiating premixed insulin, the physician should be aware that it can cause hypoglycemia.
- ✓ The main disadvantage with premixed insulin compared to basal plus insulin is the titration of the dose of both short-acting and intermediate or long-acting insulin. Since it is premixed, it is not possible to adjust the dose according to the patients need. In basal plus therapy, the injections are given separately. Therefore it is easy to adjust the dose of short or long-acting insulin.
- ✓ Patient education is needed for better understanding regarding the progressive nature of T2D, its complications and the need for intensification of treatment at an early stage to prevent the vascular complications.