

## Research Article

### Safety and Efficacy of different Classes of Insulin as Add on Therapy of oral hypoglycemic agents in uncontrolled Type 2 Diabetes

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#### Abstract

**Aim:** This study aims to evaluate the safety and efficacy of insulin as an adjunct therapy to one or more oral hypoglycaemic agents in patients with uncontrolled type 2 diabetes (T2D).

**Objectives:** Assess the impact of insulin therapy on achieving target blood glucose and glycated hemoglobin (HbA1c) levels. Examine the long-term effects of combining insulin therapy with oral hypoglycaemic agents on cardiovascular outcomes and overall mortality. Evaluate patient adherence to insulin therapy, considering factors influencing compliance such as dosing regimen, injection technique, and lifestyle adjustments.

**Results:** The study involved 350 patients (183 females and 167 males) receiving various diabetes treatments: 230 on oral hypoglycaemics, 23 on insulin, and 68 on a combination of therapies. A significant HbA1c reduction from 7.71% to 5.33% was observed. Mean FBS, post-FBS, and PPBS were 166.57, 172.86, and 248.57 mg/dL, indicating improved glycaemic control.

**Conclusion:** This study highlights the need for improved strategies to enhance compliance and adherence to treatment, address social habits, and manage weight effectively. By optimising insulin therapy alongside oral hypoglycaemics, healthcare providers can significantly improve glycaemic control and overall health outcomes in patients with uncontrolled T2D.

**Keywords:** Type 2 diabetes, insulin, oral hypoglycaemic drugs, adherence.

#### Introduction

Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces [JH1]. This leads to an increased concentration of glucose in the blood (hyperglycaemia). In poorly controlled diabetes, there is a requirement for intensified and multidrug regimens. Ultimately, oral agents alone cannot be the mainstay treatment for Glycaemic control in many individuals, and the addition of insulin must supplement therapy [1]

#### Classification Of Diabetes:

There are 2 major types of diabetes mellitus:

**Type I** - Insulin-Dependent Diabetes Mellitus (IDDM)/juvenile onset diabetes mellitus: There is beta cell destruction in pancreatic islets; the majority of cases are autoimmune (type 1A),

antibodies that destroy cells are detectable in blood, but some are idiopathic (type1B) - no Beta cell antibody is found. In all type 1 cases, circulating insulin levels are low or very low, and patients are more prone to ketosis [2].

**Type II** - Noninsulin-Dependent Diabetes Mellitus (NIDDM) or maturity-onset diabetes mellitus: It affects individuals who are overweight (BMI > 25 kg/m<sup>2</sup>) and have at least one other risk factor. The recommended screening tests include fasting plasma glucose, HbA1c, or a 2-hour Oral Glucose Tolerance Test (OGTT). Adults without risk factors should begin screening at age 45, as age alone is a risk factor for type 2 DM [3].

**Insulin:** Insulin is a vital natural treatment for type 1 diabetes, as it is characterised by a complete absence of insulin secretion. In type 2 diabetes, insulin deficiency is relative, and endogenous insulin levels are often very high. Insulin is frequently prescribed in type 2 diabetes when blood glucose targets are not achieved despite maximum doses and combination therapy with oral hypoglycaemic drugs. Insulin acts as a growth factor, stimulating the proliferation of both normal and malignant cells [2]

**Oral Antidiabetic Agents:** The majority of patients are overweight or obese at diagnosis and will be unable to achieve or sustain near normoglycemia without oral antidiabetic agents[7,11,14]; a sizable proportion of patients will eventually require insulin therapy to sustain long-term glycemia control either as monotherapy or in conjunction with oral antidiabetic therapy [5,6,8,9,10,12,13]

## Material And Methods

The present observational study was conducted over a period of six months at Dr. Praveen’s Super Speciality Centre, located in Balasamudram, Hanam Konda, Warangal, Telangana, India (Pincode - 506001). A total of 350 patients diagnosed with type 2 diabetes mellitus (T2DM) were included in the study. The inclusion criteria comprised patients aged between 18 to 60 years with a confirmed diagnosis of T2DM. All participants were assessed using standard

diagnostic tests including glyated haemoglobin (HbA1c), fasting blood sugar (FBS), and postprandial blood sugar (PPBS) levels. Patients diagnosed with type 1 diabetes mellitus and individuals outside the specified age range were excluded from the study.

## Results

### GENDER DISTRIBUTION

Gender	Count	Percentage
Female	183	52.30%
Male	167	47.70%

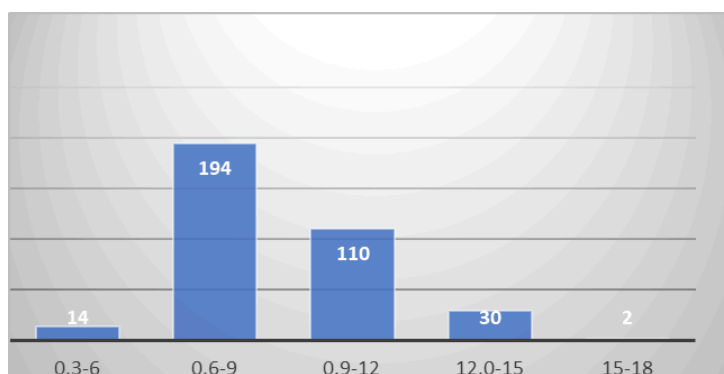
**Table 1: showing gender distribution, there are marginally more females (52.28%) than males (47.72%) in the sample**

### AGE DISTRIBUTION COMPARISON

Age Range	Count	Percentage
20-30	32	9.15%
31-40	50	14.31%
41-50	96	27.52%
51-60	99	28.37%
61-70	53	15.18%
71-80	15	4.30%
81-90	4	1.15%
91-100	1	0.29%

**Table 2: Showing age distribution: The most common age groups are 51-60 (28.37%) and 41-50 (27.52%) and least common age groups are 91-100 (0.29%) and 81-90 (1.15%).**

## HbA1c LEVELS



**Figure 1: Showing HbA1c levels. It shows the level of HbA1c values of the participants before the combination.**

## POST HbA1c LEVELS

Post HbA1c Range	Count	Percentage
0.3-6	1	0.30%
6.0-9	266	82.10%
9.0-12	76	23.40%
12.0-15	7	2.20%
15-18	0	0.00%

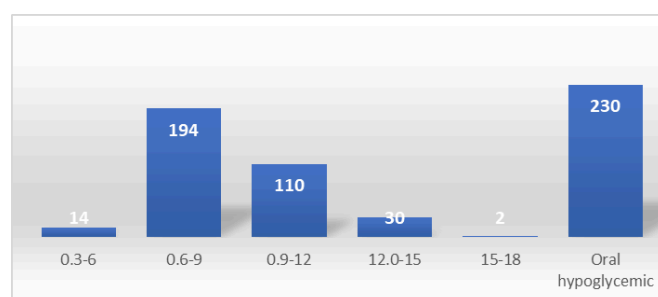
**Table 3: showing the post-HbA1c levels. After combining insulin therapy with oral hypoglycaemic agents, HbA1c values were significantly decreased, highlighting the effectiveness of the treatment strategy in improving glycaemic control.**

## DIABETES MANAGEMENT

Oral hypoglycaemic	230
Insulin	23
Insulin+ oral hypoglycaemic	68

**Table 4: showing diabetes management. It shows that the participants involved in the study of oral, insulin, and combination therapy have been included.**

## ORAL HYPOGLYCEMIC WITH HbA1c



**Figure 2 shows the levels of combination included with oral hypoglycaemic and HbA1c levels are more.**

## POST ORAL HYPOGLYCEMIC WITH POST HbA1c

Post HbA1c	Count
0.3-6	1
0.6-9	266
0.9-12	76
12.0-15	7
15-18	0
Oral hypoglycaemic	230

**Table 5: showing post-OHA with post-HbA1c, shows that the study includes the post oral hypoglycaemic levels, which have more decreased levels**

**INSULIN**

HbA1c	Count
0.3-6	14
0.6-9	194
0.9-12	110
12.0-15	30
15-18	2
Insulin	23

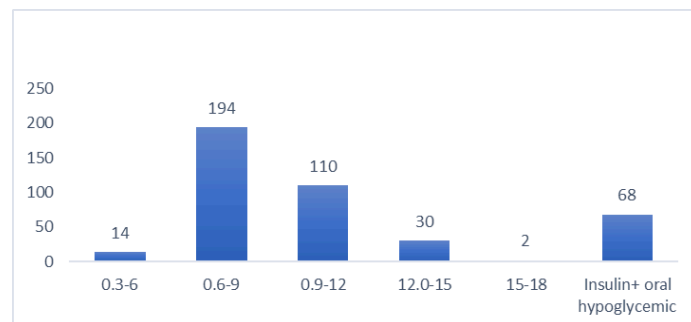
**Table 6: showing the insulin levels, which show more increased levels in the included study**

**POST INSULIN**

Post HbA1c	Count
0.3-6	1
0.6-9	266
0.9-12	76
12.0-15	7
15-18	0
Insulin	23

**Table 7: showing the post-insulin levels, the study shows that the post-insulin levels of participants are decreased compared to the above**

**INSULIN + ORAL HYPOGLYCEMIC**



**Figure 3: shows the combination of insulin with oral hypoglycaemic agents in the study, showing the amount of levels**

**POST-INSULIN WITH ORAL HYPOGLYCEMIC LEVELS**

Post HbA1c	Count
0.3-6	1
0.6-9	266
0.9-12	76
12.0-15	7
15-18	0
Insulin+ oral hypoglycaemic	68

**Table 8: showing post-insulin + oral hypoglycaemic levels, shows that the study includes an increased count of therapy provided.**

## FBS

FBS	Count
0-100	53
100-200	214
200-300	62
300-400	15
400-500	5
500-600	1

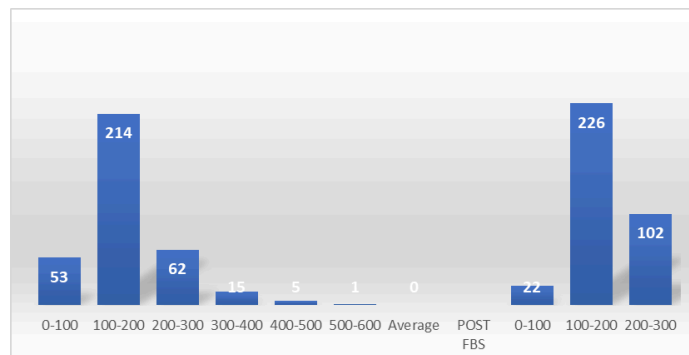
**Table 9:** showing FBS levels, the study included participants with FBS levels according to the levels of insulin and combination.

## PPBS

PPBS	Count
0-100	6
100-200	107
200-300	150
300-400	65
400-500	18
500-600	3
600-700	1

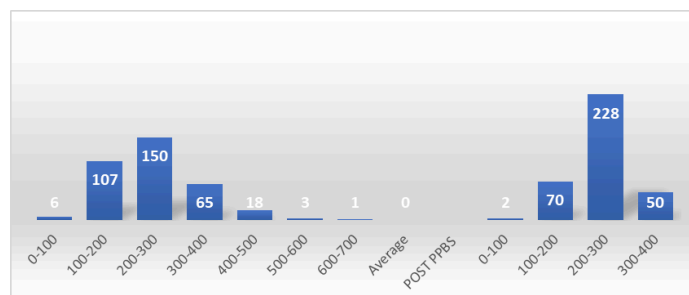
**Table 10:** showing PPBS levels, the study included the participants with the levels of PPBS, with the combination and shows the decreased count of levels.

## COMPARISON OF FBS LEVELS



**Figure 4:** shows the FBS levels, that compared to the FBS levels of both the sample attended at the start and the end of the report.

## COMPARISON OF PPBS LEVELS



**Figure 5:** The study shows that the comparison of PPBS levels in patients with two different levels. That shows the decreased levels of PPBS values

## COMPLIANCE

Compliance	Count
Yes	170
No	179

**Table 11: showing the levels of compliance of the participants in the above table with an increase in values**

**ADHERENCE**

Adherence	Count
Yes	145
No	205

**Table 12: showing the levels of adherence in the participants according to the knowledge of the importance in the therapy**

**Discussion:**

The findings of this study underscore the importance of a comprehensive approach to diabetes management. While insulin therapy effectively reduced HbA1c levels, challenges remain in managing post-prandial blood sugar and ensuring long-term adherence [4]. The prevalence of social habits like smoking and alcohol use necessitates integrated interventions, combining medication with lifestyle modifications to improve overall health outcomes. Compliance and adherence to therapy were significant issues, with only 48% of patients showing consistent adherence. This highlights the need for better patient education, support systems, and monitoring to improve long-term health outcomes. [5] In terms of weight management, the data suggest that insulin therapy may contribute to weight gain, necessitating interventions focused on diet, exercise, and lifestyle changes. With most patients falling into the overweight category, weight control must be a priority to reduce the risk of further complications[6].

**Conclusion:**

This study highlights the critical role of insulin

therapy to improve glycaemic control in patients with uncontrolled T2D. While the results are promising, significant gaps remain in patient compliance, weight management, and the control of post-prandial blood sugar levels. Addressing these challenges through tailored interventions, patient education, and lifestyle changes could further enhance long-term diabetes management outcomes. This study reinforces the importance of using insulin as adjunct therapy to optimize treatment outcomes and improve quality of life for patients with uncontrolled T2D.

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