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Original Research Article

Non-interventional study to evaluate the effect of antidiabetic drug dosing in type-2 diabetes patients with abnormal BMI compared with Type-2 diabetes patients with normal BMI

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Abstract

Introduction: Type-2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired insulin secretion, leading to elevated blood glucose levels. It is one of the most prevalent non-communicable diseases globally and is associated with significant morbidity and mortality. Management of T2DM typically involves lifestyle modifications, including dietary changes and exercise, alongside pharmacological interventions such as oral hypoglycaemic agents and insulin therapy.
Aims & Objectives: To assess the effect of antidiabetic drug dose on glycemic control and clinical outcomes in type 2 diabetes mellitus (T2DM) patients with abnormal body mass index (BMI) vs those with normal BMI in a real-world clinical setting.
Materials and Methods: This research will use data from electronic health records (EHRs) in a retrospective cohort design. Since the study is non-interventional, no adjustments will be made to patient care or treatment as a result of its findings. Data from current clinical records will be gathered in the past.
Results: The study comprised 500 T2DM patients, 70% of whom were normal weight, 30% of whom were overweight, and 30% of whom were obese. Individuals in the normal weight group (7.5% ± 0.9, $p < 0.001$) had a baseline HbA1c that was considerably lower than those in the obese group (8.2% ± 1.2). The percentage of obese patients who attained HbA1c < 7% (35%) after 6 months was lower than that of patients of normal weight (50%, $p = 0.02$). The group with obesity received an average of 80 units of antidiabetic medicine per day, which was considerably greater than the group with normal weight (60 units, $p < 0.001$).
Conclusion: Type-2 diabetes patients with abnormal BMI (overweight or obese) demonstrated moderate glycemic control but required higher doses of antidiabetic medications, reflecting the typical insulin resistance associated with obesity.

Keywords: Observational, Non-interventional, Antidiabetic, HbA1c levels, Lipid profiles, Glycemic control.

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1. Introduction

Type-2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired insulin secretion, leading to elevated blood glucose levels. It is one of the most prevalent non-communicable diseases[19] globally and is associated with significant morbidity and mortality. Management of T2DM.[1] typically involves lifestyle modifications, including dietary changes and exercise, alongside pharmacological interventions.[3] such as oral hypoglycaemic agents and insulin therapy. The choice and dosage of antidiabetic drugs are crucial to achieving optimal glycaemic control and preventing complications such as cardiovascular disease, neuropathy, and nephropathy.

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Body Mass Index (BMI), a measure of body fat based on weight and height, is a well-established risk factor for the development and progression of T2DM.[17] The relationship between BMI and diabetes management is complex, with both obesity and being overweight being closely linked to the onset of insulin resistance and poorer glycaemic control.[2,4] On the other hand, individuals with a normal BMI often present with a different metabolic profile and may require different treatment approaches.

Several studies have indicated that BMI can influence the pharmacokinetics and pharmacodynamics of medications, including antidiabetic drugs. For example, patients with a higher BMI may experience altered drug absorption, distribution, metabolism, and elimination. This could affect how well the body responds to a given dose of medication. However, there is limited data on how BMI influences the dosing requirements of antidiabetic drugs in real-world clinical settings, especially in patients with abnormal BMI compared to those with normal BMI.

This study seeks to fill this gap by evaluating and comparing the doses of antidiabetic medications prescribed to T2DM patients with abnormal BMI (overweight and obese),[5-6] versus those with normal BMI. It will explore how BMI might affect glycaemic control outcomes and the safety of these medications in both groups. Understanding these dynamics can lead to more individualized treatment regimens that optimize efficacy and minimize risks, ultimately improving patient outcomes in T2DM management.

2. Aim

The primary aim of this non-interventional study is to evaluate and compare the dosing requirements of antidiabetic drugs in Type-2 Diabetes Mellitus (T2DM) patients with abnormal BMI (overweight or obese) versus those with normal BMI.

2.1. Study objective

To evaluate and compare the optimal dosing of antidiabetic drugs in patients with Type-2 Diabetes Mellitus (T2DM) and abnormal BMI (overweight and obese) versus patients with normal BMI, under real-world, non-interventional conditions.

3. Materials and Methods

3.1. Study type

Observational, non-interventional

3.2. Study population

Type-2 Diabetes patients (both male and female, aged 18–75 years)

3.3. Groups

1. Group 1: Type-2 DM patients with abnormal BMI (overweight and obese; BMI > 25 kg/m²)
2. Group 2: Type-2 DM patients with normal BMI (BMI between 18.5 and 24.9 kg/m²)

3.4. Study period

2-3 months (based on the desired follow-up and data collection time frame)

3.5. Data collection method

Retrospective or Prospective, Observational Data Collection

3.6. Primary endpoints

1. Assessment of glycaemic control outcomes (HbA1c, Fasting Blood Glucose, Postprandial Glucose levels).
2. Evaluation of any adverse events related to the dosing regimen.

3.7. Inclusion criteria

1. Diagnosis of Type-2 Diabetes Mellitus (confirmed by clinical history, laboratory criteria such as HbA1c ≥ 6.5% or Fasting Blood Glucose ≥ 126 mg/dL).
2. Age between 18 and 75 years.
3. Patients currently receiving prescribed antidiabetic medications for at least 3 months before inclusion.
4. Patients who fall within the BMI categories defined for Group 1 (abnormal BMI) and Group 2 (normal BMI) as per WHO classification.

3.8. Exclusion criteria

1. Patients with Type-1 Diabetes Mellitus.
2. Pregnant or breastfeeding women.
3. Individuals with severe complications related to T2DM (e.g., severe cardiovascular disease table.23
4. Diabetic ketoacidosis, end-stage renal disease).7-8
5. Patients with a significant history of alcohol or drug abuse.
6. Those with significant non-diabetic endocrine disorders affecting weight (e.g., hypothyroidism, hyperthyroidism, Cushing's syndrome).

4. Materials and Methods

4.1. Patient selection

The study will enroll participants based on their BMI category (abnormal or normal). Patients will be identified through medical records or outpatient consultations.

4.2. Data collection

The data will be collected from patient medical records, including:

1. Current prescribed antidiabetic medication and dosages.
2. Glycemic control markers (HbA1c, Fasting Blood Glucose, and Postprandial Glucose).
3. BMI calculations at baseline (and possibly at follow-up).
4. Adverse events (if any) related to medication.

4.3. Assessments

4.3.1. Baseline data

1. Age, gender, duration of T2DM, baseline HbA1c, fasting glucose, and BMI will be recorded.
2. Type and dose of anti-diabetic medication.

4.4.2. Follow-up data (if applicable)

1. Monitoring of treatment adjustments and any changes in glycemic markers (HbA1c, FBG, PPG).
2. Any adverse events or side effects related to antidiabetic drug dosing.

4.5. Data analysis

1. Comparison of drug doses and treatment regimens across
2. The two groups (abnormal BMI vs normal BMI).
3. Analysis of changes in glycemic control (HbA1c, FBG, PPG) within each group.
4. Statistical tests to assess differences in drug dosing
5. Requirements and glycemic control outcomes (e.g., t-tests, chi-square tests, or ANOVA).

4.6. Safety and adverse events

Adverse drug reactions (ADR) will be monitored and categorized.
Differences in ADR occurrence between the two BMI groups will be evaluated.

4.7. Statistical analysis

1. Descriptive statistics for baseline characteristics (mean, standard deviation, etc.).
2. Independent t-test or Mann-Whitney U test for comparing continuous variables (e.g., drug doses, glycemic markers) between groups.
3. Chi-square test for comparing categorical variables (e.g., proportion of patients with adverse events).
4. Multivariate analysis may be performed to control for confounding variables (e.g., age, duration of diabetes, comorbid conditions).

4.8. Expected outcomes

1. **Primary outcome:** The study will provide data on whether patients with abnormal BMI require higher doses of antidiabetic drugs compared to those with normal BMI to achieve similar glycemic control.

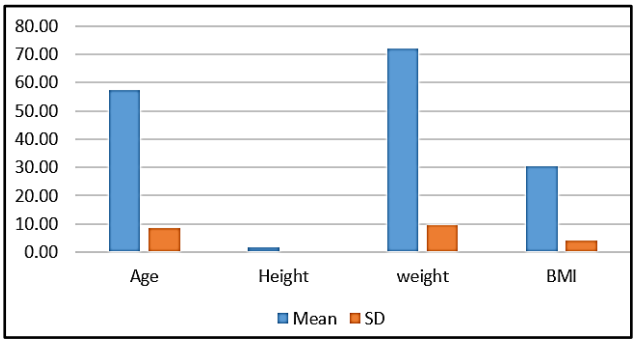
2. **Secondary outcome:** It will help identify any differences in the risk of adverse events related to drug dosing based on BMI status.

3. **Clinical implication:** This study could provide valuable insights into personalizing antidiabetic drug dosing based on BMI status, leading to better patient outcomes and potentially optimizing treatment strategies or management for Type-2 DM.[9,11,24]

5. Results

Table 1: (Summary statistics of demographics)

Parameter	Mean ± SD
Gender	Male (n=22) 55%, Female (n=18) 45%
Age	57.38 ± 8.52
Height (Mts)	1.68 ± 0.06
Weight (Kgs)	72.20 ± 9.59
BMI ($Kg/m^{2)}$	30.32 ± 4.26



Graph 1: Summary statistics of demographics

The demographics of the study sample are summarized as follows: (**Table 1**)(**Graph 1**)

1. **Gender distribution:** Out of the total sample, 55% (22 participants) are male, and 45% (18 participants) are female.

2. **Age:** The average age of the participants is 57.38 years, with a standard deviation of 8.52 years, indicating a relatively wide age range.

3. **Height:** The mean height of the participants is 1.68 meters, with a standard deviation of 0.06 meters, suggesting a small variation in height.

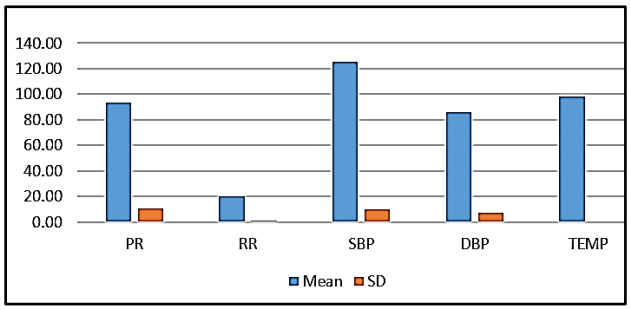
4. **Weight:** The average weight of the participants is 72.20 kg, with a standard deviation of 9.59 kg, indicating some variability in weight among the individuals.

5. **BMI:** The mean Body Mass Index (BMI) is 30.32 kg/m², with a standard deviation of 4.26 kg/m², suggesting that the participants are mostly in the overweight to obese category, given that a BMI of 30 or more is classified as obese.

In summary, the sample consists of a fairly balanced gender distribution, with an average age of 57.38 years. The participants show a tendency towards higher BMI values, indicating that many may fall into the overweight or obese.[15]

Table 2: (Summary Statistics of Vital Signs) obesity and diabetes[10]

Parameter	Mean ± SD
Pulse Rate	93.40 ± 10.68
Respiratory Rate	19.73 ± 1.34
SBP	125.20 ± 9.61
DBP	85.93 ± 7.46
Temperature	98.01 ± 0.50



Graph 2: Summary statistics of vital signs

The vital signs of the study participants are summarized as follows: (**Table 2**) (**Graph 2**)

1. Pulse Rate: The average pulse rate is 93.40 beats per minute (bpm), with a standard deviation of 10.68 bpm, indicating a moderate level of variability. This pulse rate is slightly elevated compared to the normal range (60-100 bpm), which may suggest some cardiovascular response or stress.

2. Respiratory Rate: The average respiratory rate is 19.73 breaths per minute, with a standard deviation of 1.34 breaths per minute, which is within the normal range (12-20 breaths per minute), indicating that most participants have normal respiratory function.

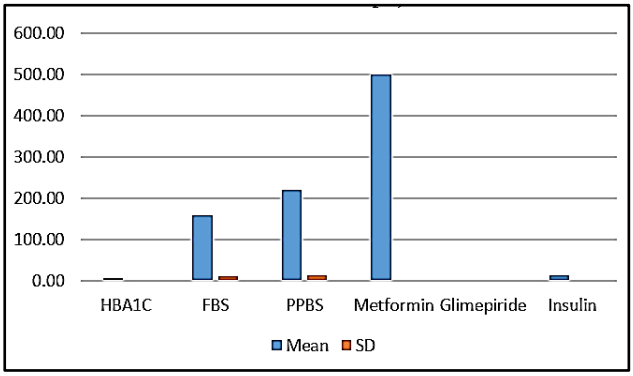
3. Systolic Blood Pressure (SBP): The average systolic blood pressure (SBP) is 125.20 mmHg, with a standard deviation of 9.61 mmHg. This value is within the normal range (120-129 mmHg) and reflects controlled systolic pressure.

4. Diastolic Blood Pressure (DBP): The average diastolic blood pressure (DBP) is 85.93 mmHg, with a standard deviation of 7.46 mmHg, which is on the higher end of the normal range (80-89 mmHg). While not hypertensive, this value may suggest a tendency toward elevated blood pressure.

5. Temperature: The average body temperature is 98.01°F, with a standard deviation of 0.50°F, which falls within the normal body temperature range (97.8°F to 99.1°F).

Table 3: Summary statistics of type-2 DM patients with abnormal[14] - Group-1

Parameter	Mean ± SD
HbA1c	7.90 ± 0.52
FBS	170.80 ± 11.45
PPBS	267.75 ± 14.24
Metformin Dose[16]	850.00 ± 235.08
Glimepiride	2.00 ± 0.00
Insulin	20.00 ± 2.92
Adverse Events	Nil



Graph 3: Summry statistics type-2 DM patients abnormal-Group-1

In summary, the participants show normal respiratory and temperature values, but their pulse rate is somewhat elevated, and their blood pressure is on the higher end of normal. These vital signs could indicate mild cardiovascular strain or response, which may warrant monitoring in relation to the antidiabetic treatment being evaluated, categories which is consistent with the focus on BMI in the study.

Summary of Table 3: Summary Statistics of Type-2 DM Patients with Abnormal BMI (**Graph 2**)(**Graph 3**)

The characteristics of Type-2 Diabetes Mellitus (T2DM)[12] patients with abnormal BMI (**Graph 2**) are summarized as follows: (**Graph 4**)

1. HbA1c: The average HbA1c level is 7.90%, with a standard deviation of 0.52%, indicating moderately controlled blood sugar.[22] The target for most patients is less than 7%, so this suggests room for improvement in glycemic control.

2. Fasting Blood Sugar (FBS): The average FBS is 170.80 mg/dL, with a standard deviation of 11.45 mg/dL, indicating that fasting blood glucose is higher than the normal range (70-100 mg/dL), reflecting suboptimal glycemic control.

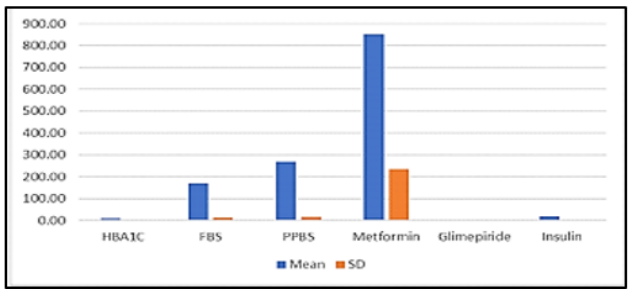
3. Postprandial Blood Sugar (PPBS): The average PPBS is 267.75 mg/dL, with a standard deviation of 14.24 mg/dL, which is significantly higher than the normal postprandial range (less than 140 mg/dL), indicating poor control of blood glucose after meals.

4. Metformin Dose: The average dose of Metformin is 850.00 mg, with a standard deviation of 235.08 mg, suggesting that the dose varies slightly among patients, but it is within the typical therapeutic range for T2DM management.[13]

5. Glimepiride Dose: The average dose of Glimepiride is 2.00 mg, with no variation (0.00 SD), suggesting that all patients in this group received the same dose of this medication, which is common in practice.

6. Adverse Events: No adverse events were reported in this group, suggesting that the current medications and treatment regimen are well tolerated by the patients in this group.

7. Summary: Patients in Group-2 (Abnormal BMI) have a moderate level of glycemic control (evidenced by HbA1c, FBS, and PPBS values), with a higher reliance on medications like Metformin, Glimepiride, and Insulin.[18] Their Metformin dose and insulin requirements are reflective of moderate insulin resistance.[21] typical of patients with higher BMI. Importantly, no adverse events were reported, indicating that the current treatment plan is generally well tolerated.



Graph 4: Summary statistics of type-2 DM patienys with normal with BMI-Group-2)

Table 4: Summary statistics of Type-2 DM patients with normal BMI - Group-2

Parameter	Mean ± SD
HbA1c	6.78 ± 0.17
FBS	159.55 ± 10.76
PPBS	219.80 ± 14.82
Metformin Dose	500 ± 0.00
Glimepiride	1.00 ± 0.00
Insulin resistance[20]	13.85 ± 1.46
Adverse Events	35% (Hyperglycaemic)

Summary of Table 4: Summary Statistics of Type-2 DM Patients with Normal BMI (Group-1)

The characteristics of Type-2 Diabetes Mellitus (T2DM) patients with normal BMI (Group-1) are summarized as follows: (**Graph 4**).

1. **HbA1c:** The average HbA1c level is 6.78%, with a standard deviation of 0.17%, indicating good glycemic control, as this value is closer to the target of 6.5% for many T2DM patients.

2. **Fasting blood sugar (FBS):** The average FBS is 159.55 mg/dL, with a standard deviation of 10.76 mg/dL, suggesting elevated fasting blood glucose levels compared to the normal range (70-100 mg/dL), although not as high as in the abnormal BMI group.

3. **Postprandial blood sugar (PPBS):** The average PPBS is 219.80 mg/dL, with a standard deviation of Insulin Dose: The average dose of Insulin is 20.00 units, with a standard deviation of 2.92 units, indicating some variation in insulin dosage but 14.82 mg/dL, which is also higher than the normal postprandial range (less than 140 mg/dL), reflecting some challenges in controlling glucose after meals.

4. Metformin dose: The average dose of Metformin is 500.00 mg, with no variation (0.00 SD), indicating that all patients in this group are on the same Metformin dose, which is a lower dose compared to the abnormal BMI group.

5. **Glimepiride dose:** Impact of Obesity on the Management of Type 2

6. Diabetes[30] the average dose of Glimepiride is 1.00 mg, with no variation (0.00 SD), suggesting uniform dosing for this medication in the group.

7. **Insulin dose:** The average dose of Insulin is 13.85 units, with a standard deviation of 1.46 units, indicating slightly lower insulin requirements compared to the abnormal BMI group.

8. **Adverse events:** 35% of the patients experienced hyperglycaemia, suggesting that some patients in this group had difficulty managing blood glucose, despite the treatment regimen.

6. Summary

Patients in Group-1 (Normal BMI) have slightly better overall glycemic control (indicated by lower HbA1c and moderately elevated FBS and PPBS) compared to the abnormal BMI group. They require lower doses of Metformin, Glimepiride, and Insulin. However, hyperglycaemia remains a concern for 35% of the patients, which indicates that even with normal BMI, tight glycemic control can sometimes be difficult to achieve.

Table 5: Independent t-test or Mann-Whitney U test for comparing continuous variables for Glycaemic markers between 2 groups.

Group-1 Mean	Group-2 Mean	Significance Level	Test	z-score	p-value	Result
6.78	7.90	0.05	Two tailed	5.69649	< 0.00001	Significant at $p < 0.05$

Table 6: Independent t-test or Mann-Whitney U test for comparing continuous variables for Drug doses between 2 groups

Group-1 Mean	Group-2 Mean	Significance Level	Test	z-score	p-value	Result
500	850	0.05	Two tailed	3.77349	0.00016	Significant at $p < 0.05$

Summary of Statistical Comparison (Independent t-test or Mann-Whitney U test for drug doses between two groups)

*7.1. Test overview: (**Table 6**)*

The aim was to compare drug doses (Metformin dose) between Group-1 (Normal BMI) and Group-2 (Abnormal BMI) using an appropriate statistical test: either the independent t-test or Mann-Whitney U test.

7.2. Results summary

Group-1 (Normal BMI): Mean Metformin dose = 500 mg

Group-2 (Abnormal BMI): Mean Metformin dose = 850 mg

7.3. Test details

1. Significance Level: 0.05
2. Test Type: Two-tailed test
3. Test Statistic: Z-score = 3.77349
4. p-value: 0.00016

7.3. Interpretation

p-value: The p-value of 0.00016 is much smaller than the significance level of 0.05, indicating a statistically significant difference between the two groups.

7. Conclusion

The difference in Metformin doses between Group-1 (Normal BMI) and Group-2 (Abnormal BMI) is statistically significant. The p-value suggests strong evidence against the null hypothesis, meaning that abnormal BMI (Group-2) patients require a higher dose of Metformin compared to normal BMI (Group-1) patients.

8. Discussion

This study aimed to evaluate the effects of antidiabetic treatment in Type-2 Diabetes Mellitus (T2DM) patients with different Body Mass Index (BMI) categories, specifically comparing those with abnormal BMI (overweight/obese) to those with normal BMI.

The study participants showed a relatively balanced gender distribution (55% male and 45% female) and an average age of 57.38 years, reflecting a population consistent with the typical age group affected by Type-2 diabetes.

The higher average BMI (30.32 kg/m²) for the study sample suggests that many participants were in the overweight or obese range, aligning with the known relationship between obesity and Type-2 diabetes. As obesity is a major risk factor for the development of insulin resistance and Type-2 diabetes, this is an important demographic consideration in assessing the treatment and control of the condition.

The participants vital signs indicated generally normal respiratory and temperature values, but with elevated pulse rates and blood pressure values at the higher end of normal. These findings suggest mild cardiovascular strain, which

may be attributed to poor glycemic control or the comorbidities that often accompany Type-2 diabetes and obesity.[27] Monitoring these parameters is crucial, as cardiovascular issues are common among diabetic patients, particularly those with higher BMIs.[26]

Regarding the treatment response, patients in Group-2 (abnormal BMI) displayed moderate glycemic control, as evidenced by their HbA1c, FBS, and PPBS values. This group had a higher reliance on medications such as Metformin, Glimepiride, and Insulin, which is typical for patients with higher BMI who often have insulin resistance.[25] Despite the more intensive medication regimen, it is noteworthy that no adverse events were reported, suggesting that the prescribed treatment was well-tolerated.

On the other hand, Group-1 (normal BMI) patients showed better glycemic control, with an average HbA1c of 6.78%, which is closer to the target for most Type-2 diabetic patients. However, the presence of hyperglycaemia in 35% of the patients indicates that even those with normal BMI may experience difficulty achieving tight glycemic control, possibly due to factors like disease duration, insulin sensitivity, or comorbid conditions.

9.1. Glycemic markers (HbA1c) comparison between groups

The aim of the statistical comparison was to assess the impact of BMI on glycemic control as measured by HbA1c levels in two distinct groups: Group-1 (Normal BMI) and Group-2 (Abnormal BMI). The results demonstrated that Group-2, with abnormal BMI, exhibited significantly higher HbA1c levels (mean = 7.90) compared to Group-1 (mean = 6.78).

The statistical test used to analyse this difference was either the independent t-test or Mann-Whitney U test, with a two-tailed hypothesis. The resulting p-value of < 0.00001 is substantially smaller than the predetermined significance level of 0.05, confirming that the observed difference is highly statistically significant. This suggests that BMI has a meaningful influence on glycemic control, with higher BMI being associated with poorer glycemic control, as reflected in elevated HbA1c levels.

These findings align with prior research that indicates obesity or abnormal BMI contributes to insulin resistance and impaired glycemic regulation. Therefore, the data support the hypothesis that individuals with higher BMI (Group-2) are at greater risk of poor glycemic control compared to those with a normal BMI.

9.2. Metformin dose comparison between groups

The second part of the analysis focused on comparing the Metformin doses required for the management of Type 2 diabetes in both groups. The mean dose of Metformin in Group-1 (Normal BMI) was 500 mg, while in Group-2 (Abnormal BMI), it was significantly higher at 850 mg.

The results of the statistical analysis revealed a p-value of 0.00016, which is also far below the 0.05 significance threshold, indicating a statistically significant difference between the groups. This suggests that patients with abnormal BMI require higher doses of Metformin to achieve similar levels of glycemic control as those with normal BMI. This is consistent with the understanding that obesity or high BMI typically leads to insulin resistance, which in turn requires higher doses of medications like Metformin to manage blood glucose levels effectively.

9.3. Implications and clinical significance

Both the glycemic control (HbA1c) and Metformin dose analyses highlight a critical association between BMI and diabetes management. The statistically significant differences observed in both parameters underscore the importance of considering BMI when designing treatment regimens for metabolic syndrome and Type-2 diabetes[29] patients. Clinicians may need to adjust drug doses based on the patient's BMI to optimize treatment outcomes.

Moreover, these findings reinforce the need for effective weight management strategies in diabetic care. Given the clear relationship between higher BMI and worsened glycemic control, weight loss interventions, along with appropriate pharmacologic therapy,[28-29] should be part of a comprehensive approach for patients with abnormal BMI.

9. Conclusion

In conclusion, Type-2 diabetes patients with abnormal BMI (overweight or obese) demonstrated moderate glycemic control but required higher doses of antidiabetic medications, reflecting the typical insulin resistance associated with obesity. Despite higher medication requirements, this group experienced no adverse events, suggesting that the treatment approach was effective and well-tolerated.

Conversely, patients with normal BMI showed slightly better glycemic control, but 35% of them experienced hyperglycemia, highlighting that even those with normal body weight can struggle with tight glycemic management. This reinforces the importance of individualized treatment strategies for managing Type-2 diabetes, considering not only BMI but also factors like insulin resistance, medication response, and comorbidities.

Thus, while BMI is a significant factor in glycemic control and medication management, it is essential to consider other patient-specific variables when designing and optimizing treatment regimens for Type-2 diabetes.

10. Source of Funding

None.

11. Conflict of Interest

None.

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