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Research Article

Therapeutic Escalation, Treatment Intensification, and Modification Patterns in Patients Receiving Antidiabetic Therapy

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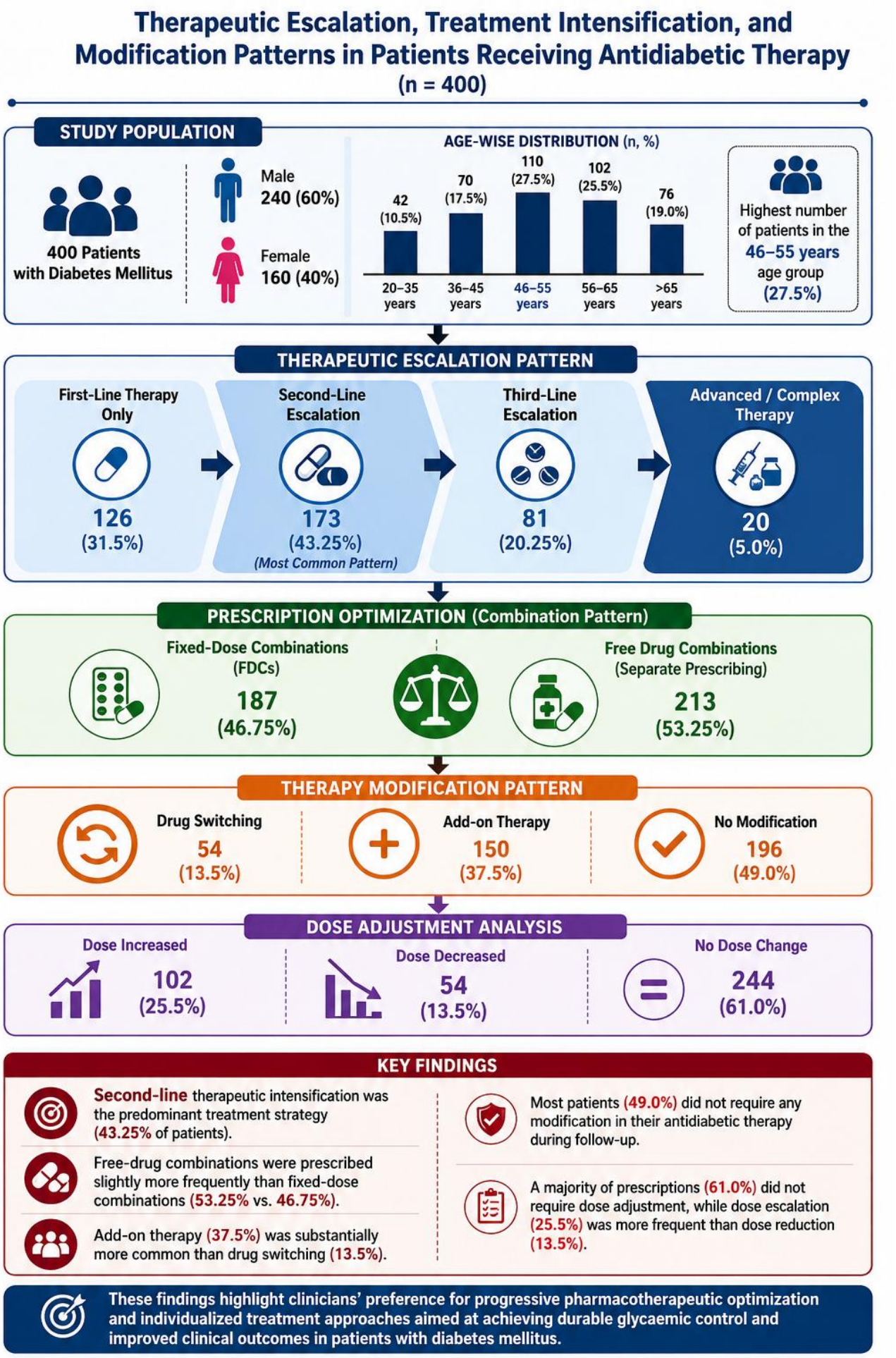
Abstract

Background: The progressive nature of type 2 diabetes mellitus frequently necessitates therapeutic intensification, treatment modification, and regimen optimization to achieve sustained glycaemic control and minimize long-term complications. Evaluating patterns of therapeutic escalation provides valuable insights into real-world prescribing practices and disease management strategies. **Objective:** To assess therapeutic escalation, treatment intensification, dose modification, and prescription adaptation patterns among patients receiving antidiabetic therapy in routine clinical practice. **Methods:** A cross-sectional observational study was conducted involving 400 patients receiving antidiabetic treatment. Demographic characteristics, therapeutic escalation status, utilization of fixed-dose and free-drug combinations, drug-switching practices, add-on therapy patterns, and dose-adjustment trends were systematically evaluated using structured prescription review and patient record analysis. Descriptive statistical methods were employed to summarize treatment modification patterns. **Results:** Male patients predominated the study population (60.0%), with the highest representation observed in the 46–55-year age category (27.5%). Therapeutic escalation analysis demonstrated that second-line intensification constituted the most prevalent treatment strategy (43.25%), followed by first-line therapy maintenance (31.5%), third-line escalation (20.25%), and advanced or complex therapeutic regimens (5.0%). Free-drug combinations were prescribed slightly more frequently than fixed-dose combinations (53.25% vs. 46.75%). Nearly half of the patients (49.0%) exhibited no treatment modification during follow-up, whereas add-on therapy (37.5%) was substantially more common than drug switching (13.5%). Dose-adjustment evaluation revealed that 61.0% of prescriptions remained unchanged, while dose escalation and dose reduction were observed in 25.5% and 13.5% of patients, respectively. **Conclusion:** The findings underscore a substantial reliance on second-line therapeutic intensification and add-on treatment strategies in contemporary diabetes management. The predominance of regimen augmentation over drug substitution highlights clinicians' preference for progressive pharmacotherapeutic optimization, emphasizing individualized treatment approaches aimed at achieving durable glycaemic control and improved clinical outcomes.

Keywords: Type 2 Diabetes Mellitus; Therapeutic Escalation; Treatment Intensification; Antidiabetic Therapy; Prescription Patterns; Add-on Therapy.

Graphical Abstract



INTRODUCTION

Diabetes mellitus represents one of the most challenging chronic metabolic disorders worldwide and continues to impose a substantial burden on healthcare systems, patients, and society. The International Diabetes Federation (IDF) estimates that more than 537 million adults were living with diabetes globally in 2021, with projections suggesting a continued increase in prevalence over the coming decades.[1] The progressive deterioration of pancreatic β-cell function, coupled with worsening insulin resistance, often necessitates ongoing therapeutic adjustments to maintain optimal glycaemic control and prevent diabetes-related complications.[2]

Current evidence-based treatment guidelines emphasize individualized pharmacotherapeutic approaches that evolve according to disease duration, glycaemic status, comorbidities, cardiovascular risk profiles, and patient-specific treatment goals.[3] Metformin remains the preferred first-line pharmacological agent for most individuals with type 2 diabetes mellitus; however, many patients eventually require treatment intensification through the addition of other oral antidiabetic agents or injectable therapies to achieve target glycated haemoglobin (HbA1c) levels.[4]

Therapeutic escalation and treatment intensification constitute essential components of diabetes management. Inadequate glycaemic control despite initial therapy often prompts clinicians to initiate second-line or third-line treatment strategies, including sodium-glucose cotransporter-2 (SGLT-2) inhibitors, dipeptidyl peptidase-4 (DPP-4) inhibitors, sulfonylureas, glucagon-like peptide-1 receptor agonists (GLP-1 RAs), and insulin-based regimens.[5] The selection of these therapies is increasingly influenced by emerging evidence regarding cardiovascular protection, renal preservation, hypoglycaemia risk, weight effects, and overall patient-centred outcomes.[6]

Treatment modification in diabetes management extends beyond therapeutic escalation and frequently includes dose adjustments, drug substitution, regimen simplification, and the incorporation of add-on therapies. These modifications are often driven by inadequate therapeutic response, adverse drug reactions, treatment affordability, patient adherence concerns, and evolving clinical requirements.[7] Fixed-dose combinations (FDCs) have gained considerable popularity because they reduce pill burden, improve treatment adherence, and potentially enhance long-term therapeutic outcomes. Nevertheless, free-drug combinations continue to be widely prescribed owing to their flexibility in individualized dose titration and regimen customization.[8]

Several studies have highlighted the phenomenon of therapeutic inertia; wherein appropriate treatment intensification is delayed despite suboptimal glycaemic control. Such delays contribute significantly to the development of microvascular and macrovascular complications, increased healthcare expenditure, and diminished quality of life.[9] Consequently, understanding real-world prescribing patterns, therapeutic escalation pathways, and treatment modification strategies has become increasingly important for optimizing diabetes care and ensuring alignment with contemporary clinical guidelines.[10]

Evaluation of treatment intensification patterns provides valuable insights into physician prescribing behaviour, medication utilization trends, and the practical implementation of evidence-based recommendations in routine clinical settings. Furthermore, assessment of dose-adjustment practices, drug-switching patterns, and combination therapy utilization may facilitate the identification of opportunities for improving pharmacotherapeutic outcomes and promoting rational prescribing.[11]

Therefore, the present study was undertaken to evaluate therapeutic escalation, treatment intensification, dose modification, drug-switching practices, and prescription adaptation patterns among patients receiving antidiabetic therapy. The findings are expected to contribute to a better understanding of contemporary diabetes management strategies and support efforts aimed at optimizing individualized pharmacotherapy and achieving sustained glycaemic control.

MATERIALS AND METHODS

Study Design and Setting

A prospective observational study was conducted to evaluate therapeutic escalation, treatment intensification, dose modification, and prescription adaptation patterns among patients receiving antidiabetic therapy. The study was carried out in the Department of General Medicine and associated outpatient diabetic clinics of a tertiary care teaching hospital over a period of 12 months. The study was designed to assess real-world prescribing practices and treatment modification trends in patients with diabetes mellitus receiving routine clinical care.

Study Population

A total of 400 patients diagnosed with diabetes mellitus and receiving antidiabetic therapy were enrolled in the study. Eligible participants were recruited consecutively during their routine clinical visits and follow-up consultations.

Inclusion Criteria

- Adult patients aged ≥18 years.
- Patients diagnosed with type 2 diabetes mellitus according to established diagnostic criteria.
- Patients receiving one or more antidiabetic medications for a minimum duration of three months.
- Patients willing to provide informed consent for participation.

Exclusion Criteria

- Patients with gestational diabetes mellitus.
- Patients with type 1 diabetes mellitus.

• Critically ill patients requiring intensive care management.

• Patients with incomplete medical records or insufficient prescription data.

• Patients unwilling to participate in the study.

Data Collection

Data were collected using a structured data collection form specifically designed for the study. Information was obtained from patient case records, prescription charts, laboratory reports, and direct patient interviews. The collected variables included demographic characteristics, age, gender, duration of diabetes, antidiabetic medications prescribed, therapeutic modifications, dose adjustments, and treatment intensification strategies.

Assessment of Therapeutic Escalation

Therapeutic escalation was categorized according to the complexity and progression of pharmacotherapy:

• First-line therapy only: Patients maintained on initial antidiabetic treatment without intensification.

• Second-line escalation: Addition or substitution of a second pharmacological agent due to inadequate glycaemic control.

• Third-line escalation: Introduction of a third antidiabetic agent following failure of dual therapy.

• Advanced or complex therapy: Utilization of multidrug regimens and/or insulin-based intensive treatment strategies.

Evaluation of Prescription Patterns

Prescriptions were reviewed to determine the utilization of:

• Fixed-dose combinations (FDCs).

• Free-drug combinations prescribed as separate formulations.

The frequency and distribution of each prescribing approach were recorded and analyzed.

Assessment of Treatment Modification

Treatment modification patterns were evaluated throughout the study period and categorized as:

• No modification.

• Drug switching (replacement of one antidiabetic agent with another).

• Add-on therapy (addition of a new antidiabetic medication to an existing regimen).

Evaluation of Dose Adjustment Patterns

Dose modifications were assessed by comparing baseline and follow-up prescriptions. Dose adjustment status was classified as:

• No dose change.

• Dose escalation (increase in prescribed dosage).

• Dose reduction (decrease in prescribed dosage).

The frequency of each category was documented and analysed.

Outcome Measures

Primary Outcome

To assess therapeutic escalation and treatment intensification patterns among patients receiving antidiabetic therapy.

Secondary Outcomes

• To evaluate prescription adaptation practices involving fixed-dose and free-drug combinations.

• To assess drug-switching and add-on therapy patterns.

• To determine the prevalence of dose modifications during routine diabetes management.

• To identify real-world trends in antidiabetic prescribing practices.

Statistical Analysis

The collected data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) software version 32.0. Descriptive statistics were employed to summarize demographic characteristics and treatment-related variables. Categorical variables were expressed as frequencies and percentages. The results were presented using tables and graphical representations wherever appropriate. A p-value of <0.05 was considered statistically significant for inferential analyses.

RESULTS

Table 1. Age-wise and Gender-wise Distribution of Study Participants (n = 400)

Age Group (Years)	Male n (%)	Female n (%)	Total n (%)
20–35	24 (6.0)	18 (4.5)	42 (10.5)
36–45	41 (10.25)	29 (7.25)	70 (17.5)
46–55	66 (16.5)	44 (11.0)	110 (27.5)
56–65	61 (15.25)	41 (10.25)	102 (25.5)
>65	48 (12.0)	28 (7.0)	76 (19.0)
Total	240 (60.0)	160 (40.0)	400 (100)

This table shows the distribution of study participants according to age and gender. Male participants were higher than female participants in all age groups. The highest number of patients was observed in the 46–55 years age group.

Table 2. Therapeutic Escalation Pattern Among Study Participants (n = 400)

Therapy Category	Frequency (n)	Percentage (%)
First-line therapy only.	126	31.5
Second-line escalation	173	43.25
Third-line escalation	81	20.25
Advanced/complex therapy	20	5

This table presents the pattern of therapeutic escalation among diabetic patients included in the study. Second-line therapeutic escalation was the most commonly observed treatment approach, followed by first-line therapy alone. Advanced or complex therapy was required in a smaller proportion of patients.

Table 3. Fixed Dose Combination Versus Free Drug Combination Pattern (n = 400)

Prescription Pattern	Frequency (n)	Percentage (%)
Fixed-dose combinations	187	46.75
Free drug combinations	213	53.25

This table compares the prescribing frequency of fixed-dose combinations (FDCs) and separately prescribed free drug combinations among the study participants. Free drug combinations were prescribed slightly more frequently than fixed-dose combinations.

Table 4. Drug Switching and Add-on Therapy Pattern (n = 400)

Modification Pattern	Frequency (n)	Percentage (%)
No modification	196	49
Drug switching	54	13.5
Add-on therapy	150	37.5

This table presents the pattern of modifications made to antidiabetic therapy during treatment follow-up among the study participants. No modification in therapy was observed in nearly half of the patients, while add-on therapy was more common than drug switching.

Table 5. Frequency of Dose Adjustments in Antidiabetic Prescriptions (n = 400)

Dose Adjustment Status	Frequency (n)	Percentage (%)
No dose change	**244**	**61**
Dose increased	**102**	**25.5**
Dose decreased	**54**	**13.5**

This table presents the frequency of dose modifications made during the review of antidiabetic therapy among the study participants. Most prescriptions did not require dose adjustment, whereas dose escalation was observed more frequently than dose reduction.

DISCUSSION

The present study evaluated therapeutic escalation, treatment intensification, prescription modification, and dose-adjustment patterns among patients receiving antidiabetic therapy in routine clinical practice. The findings demonstrated that second-line therapeutic escalation was the most frequently adopted treatment strategy (43.25%), followed by maintenance on first-line therapy (31.5%), third-line escalation (20.25%), and advanced therapeutic regimens (5.0%). These observations reflect the progressive nature of type 2 diabetes mellitus and the need for timely pharmacotherapeutic intensification to achieve and maintain glycaemic targets.

The predominance of second-line escalation observed in the present study is consistent with the findings reported by **Kalyani et al.**[12], who emphasized that progressive β-cell dysfunction often necessitates the addition of second-line agents following metformin monotherapy. Their review highlighted that most patients with type 2 diabetes eventually require therapeutic intensification due to inadequate glycaemic

control. Similarly, the high utilization of second-line therapies in the present study suggests adherence to contemporary treatment recommendations advocating early escalation when glycaemic goals are not achieved.

The observed pattern of therapeutic intensification also aligns with the findings of **Davies et al.[13]**, whose consensus report from the **American Diabetes Association** and **European Association for the Study of Diabetes** emphasized individualized treatment intensification based on patient-specific factors including cardiovascular disease, chronic kidney disease, obesity, and hypoglycaemia risk. The substantial proportion of patients receiving second- and third-line therapies in the present study indicates increasing implementation of evidence-based individualized diabetes management strategies.

Nearly half of the patients (49.0%) experienced no modification in their treatment regimen, while add-on therapy (37.5%) was considerably more frequent than drug switching (13.5%). These findings are comparable to those reported by **Alabkal et al.[14]**, who demonstrated that clinicians often prefer regimen augmentation rather than replacement of existing medications when glycaemic control remains suboptimal. Their systematic review suggested that add-on therapy allows preservation of therapeutic benefits from existing agents while addressing unmet glycaemic needs through complementary mechanisms of action. The higher prevalence of add-on therapy in the current study therefore reflects rational prescribing practices and guideline-directed care.

The preference for add-on therapy over drug substitution is further supported by findings from **Khunti et al.[15]**, who identified therapeutic inertia as a major challenge in diabetes management. Their study demonstrated that clinicians frequently delay appropriate intensification despite persistent hyperglycaemia. Compared with their findings, the relatively high proportion of patients receiving treatment augmentation in the present study may indicate improved recognition of the importance of timely therapeutic escalation and may reflect greater adherence to current diabetes management recommendations.

Regarding prescription adaptation practices, free-drug combinations (53.25%) were prescribed slightly more frequently than fixed-dose combinations (46.75%). Similar observations were reported by **Kalra et al.[16]**, who noted that although fixed-dose combinations improve convenience and adherence, many physicians continue to prefer free-drug combinations because they offer greater flexibility for dose titration and individualized therapeutic adjustments. The results of the present study support this observation, suggesting that clinicians prioritize treatment customization in patients requiring progressive intensification.

The findings concerning combination therapy are also consistent with the work of **Riddle et al.[17]**, who reported that individualized combination regimens are increasingly necessary as diabetes progresses. Their research emphasized that treatment success depends not only on the number of medications prescribed but also on the strategic selection of agents with complementary mechanisms. The frequent utilization of combination therapy observed in the present study reflects this evolving therapeutic approach.

Dose-adjustment analysis revealed that 61.0% of patients experienced no dosage change, while dose escalation (25.5%) occurred more frequently than dose reduction (13.5%). Comparable findings were reported by **Aroda et al.[18]**, who observed that dose escalation remains a common strategy for optimizing glycaemic control before introducing additional pharmacological agents. The greater frequency of dose increases in the present study may therefore represent attempts by clinicians to maximize therapeutic efficacy before progressing to more complex treatment regimens.

The lower proportion of dose reductions observed in the current study is consistent with the findings of **Buse et al.[19]**, who reported that dose reduction generally occurs in response to adverse effects, hypoglycaemia, declining renal function, or achievement of glycaemic targets. The relatively limited occurrence of dose reduction in the present population may indicate that most patients required ongoing intensification rather than de-escalation of therapy.

The demographic distribution observed in this study, with a predominance of male patients (60.0%) and the highest representation within the 46–55-year age group, is similar to findings reported by **International Diabetes Federation reports[20,21,22,23]** which indicate that middle-aged adults constitute a substantial proportion of the global diabetes burden. This age group often represents the stage at which progressive disease necessitates treatment intensification and combination pharmacotherapy.

The present findings collectively demonstrate that contemporary diabetes management increasingly relies on progressive therapeutic escalation, add-on therapy, and individualized treatment modification. These observations are consistent with recent guideline recommendations and real-world evidence supporting early intensification strategies to prevent long-term complications. The preference for regimen augmentation over drug switching, together with substantial utilization of combination therapy, highlights clinicians' efforts to achieve durable glycaemic control through patient-centered pharmacotherapeutic optimization.

Overall, the results corroborate previous studies by **Kalyani et al.[12], Davies et al.[13], Alabkal et al.[14], Khunti et al.[15], Kalra et al.[16], Riddle et al.[17], Aroda et al.[18], Buse et al.[19], and IDF reports[20]**, confirming that therapeutic escalation and treatment intensification remain central components of effective type 2 diabetes management. The study further contributes real-world evidence regarding prescribing behaviors and treatment adaptation practices in routine clinical settings, emphasizing the importance of individualized and timely pharmacological intervention.

CONCLUSION

The present study provides valuable real-world insights into therapeutic escalation, treatment intensification, prescription modification, and dose-adjustment practices among patients receiving antidiabetic therapy. The findings demonstrated that second-line therapeutic escalation represented the most commonly adopted treatment strategy, highlighting the progressive nature of type 2 diabetes mellitus and the frequent need for pharmacotherapeutic intensification to maintain adequate glycaemic control. Add-on therapy was considerably more prevalent than drug switching, indicating a clinical preference for regimen augmentation rather than replacement of existing therapies. Furthermore, free-drug combinations were prescribed slightly more frequently than fixed-dose combinations, reflecting the importance of individualized dose titration and treatment flexibility in routine clinical practice.

The predominance of dose escalation over dose reduction further emphasizes the ongoing need for treatment optimization in patients with inadequately controlled diabetes. Overall, the study findings suggest that contemporary diabetes management is increasingly aligned with evidence-based recommendations that advocate timely treatment intensification and patient-centred therapeutic decision-making. Continuous evaluation of prescribing patterns may facilitate the identification of opportunities to reduce therapeutic inertia, improve glycaemic outcomes, and enhance long-term diabetes care.

Strengths of the Study

- Large sample size involving 400 patients receiving antidiabetic therapy.
- Evaluation of multiple aspects of treatment optimization, including therapeutic escalation, prescription adaptation, drug switching, add-on therapy, and dose modifications.
- Reflection of real-world prescribing practices in routine clinical settings.
- Comprehensive assessment of treatment intensification patterns among patients with type 2 diabetes mellitus.
- Findings provide practical evidence supporting individualised diabetes management strategies.

Limitations of the Study

- The study was conducted at a single tertiary care centre, which may limit generalizability to other healthcare settings.
- Clinical outcomes such as HbA1c reduction, cardiovascular outcomes, and diabetes-related complications were not evaluated.
- Medication adherence and patient-reported outcomes were not assessed.
- Economic factors influencing treatment modification decisions were not analyzed.
- The observational design precludes establishment of causal relationships between treatment modifications and clinical outcomes.

Future Recommendations

- Multicentre prospective studies should be conducted to validate the observed treatment intensification patterns across diverse populations.
- Future investigations should assess the relationship between therapeutic escalation and long-term glycaemic outcomes.
- Evaluation of patient adherence, quality of life, and treatment satisfaction may provide additional insights into diabetes management.
- Pharmacoeconomic analyses should be incorporated to determine the cost-effectiveness of various intensification strategies.
- Research focusing on reducing therapeutic inertia and promoting guideline-directed treatment optimization is warranted.

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Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this study.

Ethical Approval

The study protocol was reviewed and approved by the Institutional Ethics Committee prior to initiation of the study. All procedures were conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and subsequent amendments.

Informed Consent

Written informed consent was obtained from all participants before enrolment into the study.

Abbreviations

ADA – American Diabetes Association

DPP-4 – Dipeptidyl Peptidase-4

EASD – European Association for the Study of Diabetes

FDC – Fixed-Dose Combination

GLP-1 RA – Glucagon-Like Peptide-1 Receptor Agonist

HbA1c – Glycated Hemoglobin

IDF – International Diabetes Federation

SGLT-2 – Sodium-Glucose Cotransporter-2

SPSS – Statistical Package for the Social Sciences

T2DM – Type 2 Diabetes Mellitus

WHO – World Health Organization

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