Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2037
Original Article

Evaluating gastrointestinal side effects and discontinuation rates of semaglutide in routine clinical practice: A prospective observational study.

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Abstract

Background:

Semaglutide, a GLP-1 receptor agonist, has demonstrated significant efficacy in glycemic control and weight reduction in Type 2 Diabetes Mellitus (T2DM). However, gastrointestinal (GI) side effects remain a common barrier to long-term adherence in real-world clinical practice. This study aimed to evaluate the prevalence, severity, and impact of gastrointestinal (GI) adverse events on discontinuation rates among patients initiated on semaglutide therapy.

Methods:

A prospective observational study was conducted on 100 adult T2DM patients prescribed semaglutide in a routine outpatient setting. Data on demographics, GI side effects (nausea, vomiting, diarrhea, constipation), severity grading (mild, moderate, severe), dose adjustments, and discontinuation rates were collected over a 12-week follow-up period. Descriptive statistics were applied to analyze frequency distributions.

Results:

The mean age of participants was 54.6 ± 10.8 years, with 52% being male. GI side effects were reported in 43% of patients. Nausea (28%) was the most common symptom, followed by vomiting (12%), diarrhea (10%), and constipation (6%). Multiple GI symptoms occurred in 14% of patients. Among affected individuals, 58.1% experienced mild symptoms, 27.9% required dose reduction for moderate symptoms, while 14% discontinued due to severe intolerance. The overall discontinuation rate was 9%, with GI side effects accounting for 6% of treatment cessations. Dose reductions were performed in 18% of patients, with 66.7% of them successfully continuing therapy post-titration.

Conclusion:

Gastrointestinal side effects are common but generally mild to moderate with semaglutide therapy. Proactive management, including gradual dose escalation and patient education, can mitigate side effects and improve adherence. Despite initial intolerance, most patients can continue therapy with appropriate interventions.

Recommendations:

Routine counseling, slow titration schedules, and early side-effect management strategies are crucial to optimize semaglutide adherence in clinical practice.

Keywords: *Semaglutide, Gastrointestinal Side Effects, Discontinuation Rate, Glucagon-Like Peptide-1 Receptor Agonists, Type 2 Diabetes Mellitus, Drug Tolerability.*
Submitted: *June 07, 2025* ***Accepted:*** *August 10, 2025* ***Published:*** *September 01, 2025*

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INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a global health challenge characterized by progressive beta-cell dysfunction and insulin resistance, necessitating comprehensive therapeutic strategies for optimal glycemic control. Among the emerging therapeutic options, Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) have gained prominence due to their dual benefits of glycemic regulation and weight reduction, along with cardiovascular and renal protective effects [1,2].

Semaglutide, a long-acting GLP-1 RA, has demonstrated superior efficacy in lowering HbA1c and promoting significant weight loss when compared to other incretin-based therapies. Pivotal trials, including the SUSTAIN and STEP programs, have established its robust clinical efficacy in both diabetic and non-diabetic populations [2,5]. However, gastrointestinal (GI) side effects such as nausea, vomiting, diarrhea, and constipation remain the most commonly reported adverse events associated with semaglutide, often emerging as a primary barrier to long-term adherence [1,2].

While randomized controlled trials (RCTs) provide critical insights under controlled environments, the real-world tolerability of semaglutide may vary significantly due to differences in patient demographics, dietary patterns, comorbid conditions, and clinical practice environments [3,4]. Current Indian data on semaglutide's GI safety profile is limited, and regional dietary habits, particularly high-fiber and spicy diets, may influence the severity and persistence of GI symptoms.

Understanding the incidence, severity, and clinical impact of semaglutide-induced GI adverse events in routine outpatient practice is essential to inform clinicians on proactive management strategies. Furthermore, evaluating real-world discontinuation rates is crucial for optimizing therapeutic adherence and ensuring sustained glycemic outcomes in the Indian T2DM population [5]. This study aimed to evaluate the prevalence, severity, and clinical impact of gastrointestinal side effects and their association with therapy discontinuation in patients initiated on semaglutide in a routine outpatient setting.

Methodology

Study Design and Setting

This was a prospective observational cohort study conducted at the Department of General Medicine, Konaseema Institute of Medical Sciences and Research Foundation (KIMS & RF), Amalapuram, in collaboration with Sasi Gastro and Liver Care, Amalapuram, Andhra Pradesh. Adults with type 2 diabetes mellitus (T2DM) newly initiated on semaglutide were consecutively enrolled and followed for 12 weeks at prespecified visits (baseline, 4, 8, and 12 weeks). The study was carried out over a 12-month period from June 2024 to May 2025 in a routine outpatient clinical practice setting. No randomization or control arm was used; the objective was to describe the prevalence and severity of gastrointestinal (GI) adverse events (AEs) and their association with dose modification or discontinuation in real-world care.

Study Population

A total of 100 adult patients diagnosed with Type 2 Diabetes Mellitus (T2DM), aged 18 years and above, who were newly initiated on semaglutide therapy, were included in the study. Patients were selected by consecutive sampling during their routine outpatient visits to ensure a real-world representation.

Inclusion Criteria

Adults aged ≥18 years.
Diagnosed with Type 2 Diabetes Mellitus.
Newly prescribed semaglutide therapy.
Willing to provide written informed consent.

Exclusion Criteria

Patients with significant pre-existing gastrointestinal disorders (e.g., inflammatory bowel disease, active peptic ulcer disease).
History of prior intolerance to GLP-1 receptor agonists.
Pregnant or lactating women.
Patients are unwilling to participate or follow up.

Data Collection and Variables Assessed

Demographic data (age, gender), clinical history (duration of diabetes, comorbidities), and concomitant medications were recorded at baseline. Patients were monitored for gastrointestinal side effects, specifically:
Nausea
Vomiting
Diarrhea
Constipation
The severity of GI symptoms was categorized as follows:
Mild: Tolerable symptoms not requiring medical intervention or therapy alteration.
Moderate: Symptoms necessitating dose reduction or symptomatic treatment.
Severe: Symptoms leading to discontinuation of semaglutide therapy.

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Follow-Up and Monitoring

Patients were followed up at **4 weeks, 8 weeks, and 12 weeks** after semaglutide initiation. During these visits, the occurrence, progression, or resolution of GI side effects was documented. Adjustments in semaglutide dosing, supportive treatments administered, and therapy discontinuation (if any) were recorded meticulously. Dose titration strategies were individualized based on patient tolerability and clinical judgment.

Sample Size

The sample size was calculated using the single-proportion formula:

$n = (Z_{1-\alpha/2})^2 \times p\,(1 - p) / d^2$

Assumptions:

Anticipated prevalence of any GI AE, p = 0.40 (based on published tolerability data with semaglutide in real-world/clinical settings) [2,6,8,11].

Two-sided confidence level 95%: $Z_{1-\alpha/2} = 1.96$.

Absolute precision (margin of error), d = 0.10.

Calculation:

$n = (1.96)^2 \times 0.40 \times 0.60 / (0.10)^2$

$n = 92.2$

Final Sample Size:

Accounting for ~10% potential attrition/incomplete follow-up, the target sample became approximately 102. Given clinic flow and operational feasibility, the sample size was rounded to 100 patients, which provides near-identical precision for the primary descriptive objective and aligns with real-world cohort reporting standards

Bias

Efforts were undertaken to minimize potential sources of bias. Selection bias was reduced by enrolling all eligible, consenting adults consecutively without exclusions for socioeconomic or disease severity. Information bias was addressed by prospectively recording gastrointestinal adverse events (AEs) at each follow-up using a standardized proforma with predefined terms and uniform severity grading, with staff trained before enrolment. Recall bias was minimized by short recall windows and contemporaneous documentation. Observer and data-entry bias were limited by double entry and cross-checking with source verification. As this was a descriptive cohort, causal inference was avoided; potential confounders were documented to permit stratified summaries if necessary.

Statistical Analysis

Data were collected using a pre-structured proforma. Categorical variables such as the incidence of side effects, severity grading, and discontinuation rates were expressed as frequencies and percentages. Continuous variables like age and duration of diabetes were summarized as mean ± standard deviation (SD). Statistical analysis was performed using descriptive statistics to highlight the prevalence and patterns of adverse events in this cohort.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee of KIMS & RF, Amalapuram. All participants provided written informed consent after a thorough explanation of the study objectives, procedures, and confidentiality assurances.

RESULTS

Participant Flow

During the study period, 118 adults with T2DM were screened for eligibility. Of these, 10 patients were excluded due to pre-existing gastrointestinal disorders (n=6), prior intolerance to GLP-1 receptor agonists (n=2), or unwillingness to provide informed consent (n=2). A further 8 patients were lost before initiation (did not return for baseline evaluation). Thus, 100 patients were confirmed eligible, initiated on semaglutide, and included in the study cohort. Of these, 94 patients (94%) completed the 12-week follow-up, while 6 patients (6%) discontinued therapy due to severe GI adverse events. Data from all 100 patients were analyzed, with discontinuations classified as treatment cessations in outcome reporting (Figure 1).

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Original Article

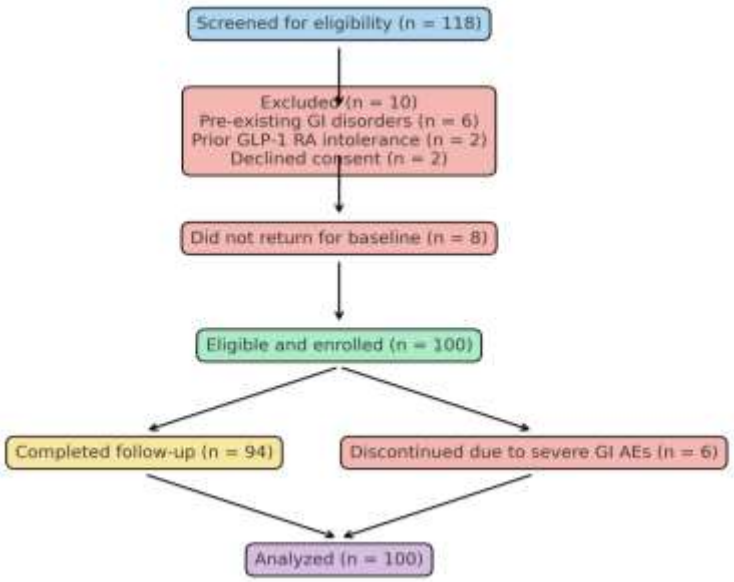

Figure 1. Participant Flow Diagram

A total of 100 patients initiated on semaglutide therapy were included in this study. The mean age of participants was 54.6 ± 10.8 years, with a slight male predominance (52% male; 48% female). The mean duration of Type 2 Diabetes Mellitus among the study population was 7.3 ± 4.2 years (Table 1).

Table 1: Demographic Characteristics of Study Participants (n=100)

Parameter	Value
Sample Size	100
Mean Age (years)	54.6 ± 10.8
Gender – Male	52 (52%)
Gender – Female	48 (48%)
Mean Duration of Diabetes (years)	7.3 ± 4.2

Gastrointestinal (GI) side effects were reported in 43% of patients during the treatment period. Among these, nausea was the most prevalent symptom, observed in 28% of patients, followed by vomiting (12%), diarrhea (10%), and constipation (6%). Additionally, 14% of patients experienced a combination of multiple GI symptoms (Table 2).

Table 2: Gastrointestinal Side Effects Profile (n=100)

Gastrointestinal Side Effect	Frequency (n)	Percentage (%)
Nausea	28	28%
Vomiting	12	12%
Diarrhea	10	10%
Constipation	6	6%
Multiple GI Symptoms	14	14%

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The severity assessment of GI adverse events revealed that 58.1% of affected patients (n=25) experienced mild symptoms that did not necessitate any therapy alteration. 27.9% (n=12) had moderate symptoms requiring dose reduction, while 14% (n=6) experienced severe GI intolerance leading to treatment discontinuation (Table 3).

Table 3: Severity of GI Side Effects among Affected Patients (n=43)

Severity	Frequency (n)	Percentage (%)
Mild (No Therapy Alteration)	25	58.1%
Moderate (Required Dose Reduction)	12	27.9%
Severe (Led to Discontinuation)	6	14.0%

The overall discontinuation rate in the cohort was 9%. Specifically, 6 patients (6%) discontinued semaglutide due to severe GI side effects, while 3 patients (3%) ceased therapy for other reasons such as dizziness or personal preference. Dose adjustments were required in 18% of patients to improve tolerability, out of which 12 patients (12%) successfully continued therapy after titration (Table 4).

Table 4: Discontinuation and Dose Adjustment Rates (n=100)

Outcome	Frequency (n)	Percentage (%)
Discontinuation due to GI Side Effects	6	6%
Discontinuation due to Other Reasons	3	3%
Total Discontinuation Rate	9	9%
Patients Requiring Dose Reduction	18	18%
Successful Continuation after Dose Titration	12	12%

Most GI adverse events were transient, with symptoms subsiding within 8 weeks of therapy initiation. At 12 weeks follow-up, persistent mild GI symptoms were reported in only 10% of patients, suggesting that early symptom management strategies may enhance long-term adherence.

DISCUSSION

In this prospective observational cohort study, gastrointestinal (GI) adverse effects were reported in 43% of patients initiated on semaglutide. Nausea (28%) was the most common adverse event, followed by vomiting (12%), diarrhea (10%), and constipation (6%). The overall treatment discontinuation rate due to GI intolerance was 6%. Most adverse events (86%) were mild to moderate and could be managed with dose adjustments, patient education, or supportive care, highlighting the importance of active symptom management during therapy initiation.

These findings are consistent with published real-world and clinical trial data on semaglutide tolerability. Similar rates of nausea and vomiting have been documented in real-world cohorts evaluating oral semaglutide [6], while the evolution study demonstrated that GI intolerance accounted for early therapy discontinuations during dose titration [7]. Evidence from observational and interventional studies further supports that GI symptoms typically emerge within the first few weeks of therapy and decline in frequency with continued use [8]. The higher occurrence of multiple concurrent GI symptoms in our study (14%) compared to Western data may reflect the influence of regional dietary practices, particularly high-fiber and spicy diets, which could exacerbate GI motility and symptom burden [9,10].

The predominance of nausea and vomiting observed here is in line with pharmacovigilance analyses that identified these as the leading adverse events associated with semaglutide [11]. Expert consensus recommendations emphasize that structured patient counseling, anticipatory guidance on potential adverse events, and individualized titration schedules significantly improve drug tolerability [12]. The results reaffirm these strategies, demonstrating that most patients could successfully continue semaglutide therapy after a temporary dose reduction. The observation that 12% of patients benefited from dose adjustment and subsequently maintained treatment underscores the importance of flexible dosing and personalized care pathways.

From a clinical perspective, these results emphasize that semaglutide, despite its known gastrointestinal side effects, remains a valuable therapeutic option for type 2 diabetes mellitus (T2DM) in real-world practice. The relatively low discontinuation rate indicates that with appropriate support, the majority of patients can tolerate therapy. These findings

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are particularly relevant in India, where patient education, dietary counseling, and proactive follow-up may play a vital role in improving adherence. Early recognition and management of GI symptoms could enhance both treatment persistence and clinical outcomes, thereby maximizing the cardiovascular, metabolic, and weight-related benefits of semaglutide.

Generalizability

The generalizability of these findings is supported by the real-world design, inclusion of consecutively enrolled patients, and minimal exclusion criteria, which together provide a representative cohort of Indian patients with T2DM. The setting in routine outpatient clinics reflects everyday practice and enhances external validity. However, caution should be exercised in extrapolating these results to other regions with different dietary habits, healthcare infrastructures, and patient characteristics. Studies in Western populations have reported lower rates of multiple concurrent GI symptoms, suggesting that cultural and dietary factors may significantly modify tolerability. Thus, while study findings are highly relevant to South Asian populations, additional multicentric research across diverse geographic and demographic settings would further validate the external applicability.

Conclusion

Semaglutide remains a highly effective therapeutic option for glycemic control and weight management in patients with Type 2 Diabetes Mellitus. However, gastrointestinal side effects, particularly nausea and vomiting, are common during the initial treatment phase and pose challenges to long-term adherence. Our study highlights that most adverse events are mild to moderate and can be effectively managed with gradual dose escalation, patient education, and supportive care. The overall discontinuation rate due to GI intolerance was relatively low, underscoring the importance of proactive symptom management strategies. Early intervention, flexible dosing, and structured follow-up are key to maximizing patient retention and clinical outcomes in real-world practice.

Limitations

This study has some limitations. The sample size was modest and limited to a single-center observational cohort, which may restrict the precision of subgroup analyses. The reliance on patient-reported symptoms introduces the potential for reporting bias, although efforts were made to standardize data collection and minimize recall errors. Furthermore, the absence of a comparator arm prevents direct causal inference. Nonetheless, the strength of this study lies in its prospective design, systematic documentation of adverse events, and focus on real-world patients, making the results clinically meaningful.

Recommendations

To enhance semaglutide tolerability and adherence in routine clinical practice, it is essential to adopt individualized dose titration schedules, ensuring a gradual escalation to minimize gastrointestinal side effects. Pre-treatment counseling regarding potential adverse events, dietary modifications, and symptom anticipation can empower patients to better tolerate initial discomfort. Clinicians should prioritize early follow-up visits to monitor tolerability and adjust doses proactively. Implementing supportive therapies such as antiemetics and hydration advice during the initiation phase can further reduce discontinuation rates. Multidisciplinary collaboration involving diabetologists, dietitians, and patient educators is vital to optimize long-term therapeutic outcomes with semaglutide.

Acknowledgements

The authors express their sincere gratitude to the Department of General Medicine, KIMS & RF, Amalapuram, and Sasi Gastro and Liver Care, Amalapuram, for their continuous support throughout the study. We extend heartfelt thanks to all the patients who participated and cooperated in this research. Special appreciation is due to the clinical and nursing staff for their assistance in data collection and patient follow-up, which was crucial for the successful completion of this study.

Abbreviations

T2DM – Type 2 Diabetes Mellitus
GI – Gastrointestinal
GLP-1 RA – Glucagon-Like Peptide-1 Receptor Agonist
KIMS & RF – Konaseema Institute of Medical Sciences and Research Foundation

Source of funding

The study had no funding.

Conflict of interest

The authors declare no conflict of interest.

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https://doi.org/10.51168/sjhrafrica.v6i9.2037
Original Article

Author contributions

MPK-Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **NOAS**-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript, revision of the manuscript.**PPRRP**-Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation.

Data availability

Data is available on request

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PUBLISHER DETAILS:

Student's Journal of Health Research (SJHR)
(ISSN 2709-9997) Online
(ISSN 3006-1059) Print
Category: Non-Governmental & Non-profit Organization
Email: studentsjournal2020@gmail.com
WhatsApp: +256 775 434 261
Location: Scholar's Summit Nakigalala, P. O. Box 701432, Entebbe Uganda, East Africa