Rosuvastatin/Fenofibrate-Induced Gastrointestinal Distress: A Case Report.

Abstract

Background: The combination of rosuvastatin and fenofibrate is highly effective for mixed dyslipidemia but is associated with a range of gastrointestinal (GI) side effects. While nausea and vomiting are common, severe abdominal distension can mimic serious conditions like acute pancreatitis or hepatotoxicity.
Case Presentation: We report the case of a patient N.R. 49 years of female who presented with loss of apetite, persistent nausea, vomiting, and significant abdominal distension within a weeks time after initiating **Rosuvas-F 10** (Rosuvastatin 10mg / Fenofibrate 160mg). Laboratory investigations were performed to rule out systemic complications. Symptoms resolved promptly within 3-7 days of drug discontinuation ("de-challenge").
Conclusion: This case highlights the importance of monitoring GI tolerance in patients on combination statin-fibrate therapy. It underscores the need for clinical vigilance to differentiate common dyspeptic side effects from rare, life-threatening complications.

Introduction

The management of mixed dyslipidemia has been revolutionized by the advent of fixed-dose combinations, such as **Rosuvas-F 10** (1). By simultaneously targeting elevated LDL-C and triglycerides, this dual-action therapy offers a potent solution for reducing cardiovascular risk. However, the clinical efficacy of these agents is occasionally overshadowed by gastrointestinal (GI) adverse events, which remain a primary barrier to medication adherence. Research indicates that GI disorders are the most frequent adverse events for this combination, with nausea reported in approximately 3.1% of cases (1,2).

Certain populations are notably more susceptible; women have shown a significantly higher susceptibility to experiencing nausea and diarrhea on this therapy compared to men (1). Additionally, patients of **Asian descent** may experience higher plasma exposure to rosuvastatin even at standard doses, potentially intensifying dose-related GI distress (3,4). This case report details a symptomatic presentation of severe GI distress following the initiation of Rosuvas-F 10, emphasizing the importance of early recognition and the "de-challenge" process.

Case Presentation: N.R. 49 years old female not a known a case of Hypertension, diabetes or hypothyroidism doctor by profession after discussing with physician started this drug along with vitamin D 60k units weekly for newly detected dyslipidemia. But after three to five days of initiation of treatment she started with some abdominal discomfort and decrease in apetite but she ignored it and continued with the treatment. After few days she started with nausea followed by vomiting , distension of abdomen and generalized weakness. Drug was stopped immediately and patient got back to normal gradually within few days except for weakness which took quite a long time. Her investigations were normal except for liver enzymes which were mildly deranged. ADR was repored to pharmacovigilance center, department of pharmacology, GMC Udhampur

Discussion: While generally well-tolerated, GI adverse events like nausea, vomiting, and distension appear in 1% to 10% of patients on this combination (1). The mechanism for statin-induced GI distress is often attributed to localized effects on the intestinal mucosa, while fenofibrate may increase the lithogenicity of bile, potentially leading to gallbladder irritation (3,5).

In cases presenting with severe vomiting and distension, clinicians must distinguish between common dyspepsia and rare complications. Drug-induced pancreatitis, though rare (<0.1%), has been linked to both agents (4). Furthermore, persistent nausea can be an early indicator of liver injury, occurring in approximately 1 in 10,000 patients (2). In this patient, the rapid onset of symptoms following initiation and subsequent resolution upon discontinuation strongly suggests a drug-induced etiology.

Recommendations for Clinical Practice: Advise patients to take the tablet with or immediately after a main meal to reduce stomach upset . Monitoring **of** Liver Function Tests (LFTs) before initiation and periodically thereafter (4). **Patient should be** Educated & Instructed to immediately report "red flags" such as severe upper abdominal pain (potential pancreatitis) or dark urine (potential rhabdomyolysis) (2). Alternative Dosing For high-risk demographics (e.g., Asian patients), consider starting with a lower-dose monotherapy before transitioning to fixed-dose combinations (3,4).

Conclusion

The development of nausea, vomiting, and abdominal distension in this patient was directly linked to the initiation of **Rosuvas-F 10**. Although these are documented side effects, their concurrent presentation can be distressing and may lead to poor adherence. Prompt recognition and discontinuation of the offending agent remains the primary management strategy for drug-induced GI distress.

Declarations:

Written informed consent was obtained from the patient for the publication of this case report and any accompanying laboratory data or images.

Conflict of Interest

The authors declare that they have no competing interests. There was no financial support or grant funding received for the preparation or publication of this case report.

Data Availability

The data supporting the findings of this case report are included within the article. Further details regarding the clinical history are available from the corresponding author upon reasonable request.

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