ISSN(O): 2320-5407 | ISSN(P): 3107-4928

International Journal of Advanced Research

Publisher's Name: Jana Publication and Research LLP

www.journalijar.com

REVIEWER'S REPORT

Manuscript No.: IJAR-57565

Title: Rosuvastatin/Fenofibrate-Induced Gastrointestinal Distress: A Case Report,

Recommendation:
Accept as it is .....
Accept after minor revision.....
Accept after major revision .....YES
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		√		
Techn. Quality			√	
Clarity			√	
Significance		√		

Reviewer's ID: JPR-094

Detailed Reviewer's Report

 # Reviewer's Report

 # Overall Recommendation

****Major Revision****

The manuscript presents a clinically relevant adverse drug reaction associated with rosuvastatin/fenofibrate combination therapy. The topic is important for pharmacovigilance and clinical practice; however, substantial revisions are required to improve scientific rigor, language quality, case documentation, and causality assessment before the manuscript can be considered for publication.

 # Strengths of the Manuscript

1. ****Clinically Relevant Topic**

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

*** The manuscript addresses gastrointestinal adverse effects associated with a commonly prescribed lipid-lowering combination therapy.**

2. **Pharmacovigilance Importance**

*** Reporting ADRs contributes to drug safety monitoring and clinician awareness.**

3. **Clear Temporal Association**

*** Symptoms appeared shortly after drug initiation and improved after discontinuation ("de-challenge"), supporting possible drug causality.**

4. **Practical Clinical Message**

*** The article emphasizes the importance of recognizing GI intolerance and differentiating it from severe complications such as pancreatitis or hepatotoxicity.**

5. **Ethical Compliance**

*** Patient consent, conflict of interest, and data availability statements are included.**

 # Weaknesses of the Manuscript

1. **Insufficient Clinical Details**

*** Important patient data are missing:**

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

*** exact laboratory values,**

*** liver enzyme levels,**

*** lipid profile,**

*** imaging findings,**

*** BMI,**

*** medication history,**

*** alcohol/smoking status,**

*** dietary history.**

2. **Weak Causality Assessment**

*** No formal ADR causality tool was applied:**

*** Naranjo scale absent,**

*** WHO-UMC assessment absent.**

3. **Limited Novelty**

*** GI adverse effects of rosuvastatin/fenofibrate are already documented in literature; therefore, novelty is moderate.**

4. **Language and Grammar Issues**

*** Multiple grammatical errors reduce readability and scientific quality.**

5. **Poor Structure in Case Presentation**

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

*** Timeline of symptom progression is unclear.**

*** Sentences are lengthy and unstructured.**

6. **Lack of Differential Diagnosis**

*** The manuscript does not adequately explain exclusion of:**

*** acute pancreatitis,**

*** intestinal obstruction,**

*** viral hepatitis,**

*** gallbladder disease,**

*** gastritis.**

7. **References Need Correction**

*** Citation formatting is inconsistent.**

*** Some references appear incomplete.**

 # Key Points for Revision

Major Points

1. Improve Case Documentation

Include:

*** baseline lipid profile,**

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

*** exact AST/ALT values,**

*** bilirubin,**

*** serum amylase/lipase,**

*** ultrasound/CT findings if performed,**

*** duration of symptoms,**

*** hospitalization details.**

2. Add ADR Causality Assessment

Include:

*** Naranjo ADR Probability Scale,**

*** WHO-UMC causality classification.**

3. Add Timeline Table

A chronological table would improve clarity:

*** day of drug initiation,**

*** onset of symptoms,**

*** investigations,**

*** discontinuation,**

*** recovery.**

4. Expand Differential Diagnosis

Explain how serious conditions were ruled out.

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

5. Improve Language Editing

The manuscript requires professional English editing.

 # Minor Points

1. Correct spelling:

*** "apetite" → "appetite"**
*** "repored" → "reported"**

2. Improve terminology:

*** "49 years old female" → "49-year-old female"**

3. Avoid repetitive wording:

*** "GI distress" repeated excessively.**

4. Use consistent drug formatting:

*** Rosuvastatin 10 mg/Fenofibrate 160 mg.**

5. References should follow journal style uniformly.

 # Significance of the Study

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

The manuscript has moderate clinical significance because:

*** statin–fibrate combinations are widely prescribed,**
*** GI adverse effects may reduce treatment adherence,**
*** severe presentations can mimic dangerous conditions,**
*** awareness among clinicians can improve early recognition and management.**

The paper is more valuable as a pharmacovigilance and educational case report rather than as a highly novel scientific contribution.

 # Recommendation to the Editor

****Decision: Major Revision****

Reason:

The manuscript contains clinically useful observations but lacks sufficient clinical depth, structured analysis, and language quality for acceptance in its current form. Substantial revision is necessary to strengthen scientific validity and publication quality.

Major Revision Justification

Overall Reviewers Decision: Major Revision

Justification

Although the manuscript discusses a clinically relevant adverse drug reaction, it contains major deficiencies in scientific presentation, case documentation, grammar, causality assessment, and differential diagnosis. The current version lacks sufficient clinical

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

evidence and structured analysis required for publication as a high-quality medical case report.

Line-by-Line Issues and Reasons

Line No.	Issue Identified	Reason for Major Revision
5–7	Background overly generalized without strong supporting evidence	Requires stronger epidemiological data and updated references to justify clinical significance
8	"49 years of female" grammatically incorrect	Scientific writing quality is poor and requires professional language editing
8	"loss of apetite" spelling error	Basic grammatical and spelling issues reduce manuscript quality
9	"within a weeks time" grammatically incorrect	Timeline description lacks clarity and precision
9–10	Brand name "Rosuvas-F 10" used repeatedly	Generic drug names should be preferred in scientific manuscripts
10	"Laboratory investigations were performed" vague statement	Exact investigations and laboratory values are missing
11	"Symptoms resolved promptly" lacks objective evidence	No documented follow-up details or supportive data provided
12–14	Conclusion overstates severity	Life-threatening complications were not demonstrated in this patient
17–20	Introduction contains broad claims	Requires stronger literature support and critical review
21–22	"3.1%" adverse event statistic not adequately contextualized	Needs detailed citation explanation and study population description
23–25	Ethnicity-based susceptibility discussed superficially	Requires stronger evidence and appropriate interpretation
26–27	"de-challenge" emphasized repeatedly	Excessive repetition without formal causality assessment
28	"not a known a case of" incorrect grammar	Major English language revision required
28–29	Past medical history incomplete	Missing BMI, alcohol intake, smoking, dietary habits, previous GI disease
29	Vitamin D mentioned without explanation	Clinical relevance unclear
30–31	Symptom progression poorly	Requires chronological presentation or

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

Line No.	Issue Identified	Reason for Major Revision
	structured	timeline table
31	"decrease in apetite" spelling/grammar issue	Language quality inadequate
31–33	Narrative style informal	Scientific case reports require concise and structured presentation
32	"vomiting , distension" punctuation spacing error	Multiple formatting inconsistencies throughout manuscript
32–34	No hospitalization details mentioned	Severity assessment incomplete
34	"mildly deranged" liver enzymes vague	Exact AST/ALT values required
34	No pancreatic enzyme evaluation reported	Acute pancreatitis not adequately excluded
34–35	ADR reporting statement incomplete	Reference number or pharmacovigilance acknowledgment absent
36–39	Discussion mainly literature repetition	Limited integration with present case findings
37–39	Mechanism explanation speculative	No evidence directly linking mechanism in this patient
40–42	Severe complications discussed without diagnostic evidence	Differential diagnosis inadequately evaluated
41	Pancreatitis mentioned but no amylase/lipase values provided	Important exclusion criteria missing
42	Hepatotoxicity discussed without detailed LFT interpretation	Weak clinical substantiation
43–44	Drug-induced etiology concluded strongly	Formal causality scales absent (Naranjo/WHO-UMC)
45–49	Recommendations generalized	Some recommendations not directly supported by presented case
46	Monitoring recommendations incomplete	No guideline citation provided
47–48	"Educated & Instructed" inappropriate capitalization	Formatting inconsistency
48–49	Asian population recommendation may overgeneralize	Requires cautious interpretation and stronger evidence
51–55	Conclusion lacks novelty	GI adverse effects already well documented in literature

ISSN(O): 2320-5407 | ISSN(P): 3107-4928

International Journal of Advanced Research

Publisher's Name: Jana Publication and Research LLP

www.journalijar.com

REVIEWER'S REPORT

Line No.	Issue Identified	Reason for Major Revision
52	"directly linked" overstates causality	Rechallenge absent; causality remains probable, not definite
54–55	Management strategy oversimplified	Alternative treatment strategies not discussed
58–66	Ethical declarations acceptable but incomplete	Institutional ethics approval not mentioned
68–79	Reference formatting inconsistent	Journal style not followed uniformly
69–70	Reference incomplete	Volume/page/article number missing
71	Author formatting inconsistent	Citation style errors
73–74	Reference numbering merged incorrectly	Major formatting issue
75–76	Citation punctuation inconsistent	Editorial corrections required
Entire Manuscript	Absence of tables/figures	Timeline table and laboratory table strongly recommended
Entire Manuscript	No causality assessment tool used	Major methodological weakness
Entire Manuscript	Limited novelty	Similar GI adverse reactions already reported previously
Entire Manuscript	Language quality poor	Requires substantial English editing before reconsideration

Key Reasons Supporting Major Revision

1. Insufficient Clinical Evidence

The manuscript lacks:

detailed laboratory findings,

imaging reports,

diagnostic exclusion criteria,

objective severity assessment.

2. Weak ADR Causality Assessment

ISSN(O): 2320-5407 | ISSN(P): 3107-4928
International Journal of Advanced Research
Publisher's Name: Jana Publication and Research LLP
www.journalijar.com

REVIEWER'S REPORT

No:

Naranjo Scale,

WHO-UMC causality analysis,

rechallenge data.

3. Poor Scientific Writing Quality

Numerous:

grammatical errors,

spelling mistakes,

formatting inconsistencies,

informal narrative structures.

4. Limited Novelty

The adverse effects described are already recognized in literature, reducing originality.

5. Incomplete Differential Diagnosis

Important competing diagnoses were not adequately ruled out.

Final Recommendation to Editor

Decision: Major Revision

REVIEWERS Reason:

The manuscript presents a clinically relevant adverse drug reaction; however, substantial improvements in clinical documentation, scientific analysis, language quality, causality assessment, and manuscript formatting are required before the article can be considered suitable for publication.