



CODEN [USA]: IAJ PBB

ISSN : 2349-7750

**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**

SJIF Impact Factor: 7.187

<https://doi.org/10.5281/zenodo.21905415>Available online at: <http://www.iajps.com>

A Case Report

**CASE REPORT: SIMVASTATIN ASSOCIATED
THROMBOCYTOPENIA - A RARE AND REVERSIBLE
ADVERSE DRUG REACTION**Nissy Mariam Reji ¹, Dr. S. K. Mathew ², Dr. Dhanu Josey ³¹ PharmD Intern, Nazareth College of Pharmacy, Othara, Thiruvalla.² Emeritus Professor, Department of General Medicine, Believer's Church Medical College Hospital, Thiruvalla.³ Clinical Specialist, Department of General Medicine, Believer's Church Medical College Hospital, Thiruvalla.**Abstract:**

Thrombocytopenia is characterized by a platelet count less than 150,000/ μ L and it can be caused by adverse drug effects, increased platelet destruction or reduced production. Drug induced thrombocytopenia (DITP) is an uncommon yet potentially hazardous side effect.

We report a case of a 52-year-old male who had low platelets for the past five months, which was later determined to be caused by simvastatin ADR, upon discontinuation of simvastatin the patient's platelet levels improved. HMG-CoA reductase inhibitors like simvastatin are used to lower cholesterol and lower the risk of cardiovascular events like myocardial infarction and stroke.

Keywords: Drug induced thrombocytopenia, simvastatin, HMG-CoA reductase inhibitors.

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Please cite this article in press Nissy Mariam Reji et al., **Case Report: Simvastatin Associated Thrombocytopenia - A Rare And Reversible Adverse Drug Reaction**, Indo Am. J. P. Sci, 2026; 13(08).

INTRODUCTION:

Thrombocytopenia is defined as a platelet count below 150,000/ μ L and can be categorized as mild (100,000–150,000/ μ L), moderate (50,000–99,000/ μ L), or severe (<50,000/ μ L). It may be occur due to decreased platelet production from bone marrow, increased peripheral destruction, splenic sequestration, or dilutional causes.

Drug induced thrombocytopenia (DITP) is an important and often reversible cause of low platelet count. Drug induced thrombocytopenia is a relatively common clinical disorder. DIT disorders can be a consequence of decreased platelet production (bone marrow suppression) or accelerated platelet destruction (especially immune mediated destruction). The primary treatment of drug induced thrombocytopenia is to discontinue the suspected causative agent.

DITP can be idiosyncratic or immune-mediated reaction. In many cases, it is immune-mediated, involving drug-dependent antibodies that bind to platelet surface glycoproteins in the presence of the offending medication, leading to accelerated platelet clearance. More than 300 drugs have been implicated in DITP, including antibiotics, anti-epileptics, antiplatelet agents, and cardiovascular drugs.

Simvastatin (sim' va stat' in) is an orally available inhibitor of hepatic 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, the major rate-limiting enzyme in cholesterol synthesis. Like other members of its class (the “statins”), simvastatin lowers total serum cholesterol and particularly low density lipoprotein (LDL) concentrations, thereby reducing the risk of atherosclerosis and its complications – myocardial infarction and stroke. Simvastatin was approved for use in the United States in 1991 and is still widely used with more than 40 million prescriptions being filled yearly. Current indications for simvastatin are hypercholesterolemia and reduction in risk for death from coronary, cerebrovascular and peripheral artery disease in patients with these diseases. Here, we present a case

of simvastatin-induced thrombocytopenia in a patient with type 2 diabetes mellitus and DLP.

CASE PRESENTATION:

A 52 year old male come to the outpatient department with complaints of persistently low platelet counts that had been unintentionally found over the course of preceding five months during routine examination. He denied having ever experienced any bleeding symptoms, such as gum bleeding, petechiae, epistaxis, haematuria, or gastrointestinal bleeding.

The patient was a known case of Type 2 diabetes mellitus for the past ten years and was on Tablet GLICLAZIDE and METFORMIN. Six months ago, he was diagnosed with Dyslipidaemia and began taking Tablet SIMVASTATIN 20mg (0-0-1). There was no history of recent infections, alcohol intake, autoimmune disease, liver disease, or exposure to other medications that known to cause thrombocytopenia. On general physical examination, the patient was clinically stable with normal vital signs. No pallor, icterus, lymphadenopathy, hepatosplenomegaly, or skin bleeding manifestations.

An isolated thrombocytopenia with a platelet count of 91,000/ μ L was discovered by laboratory testing. HB, total leukocyte count, liver function tests, and renal function tests were within normal limits. Peripheral smear showed reduced platelets with normal morphology and no abnormal cells. Screening test were done to rule out tropical fevers, haematological malignancies and CLD which all found to be normal.

Given the temporal association between simvastatin initiation and the onset of thrombocytopenia, a provisional diagnosis of drug-induced thrombocytopenia was considered. Simvastatin was discontinued, while other medications were continued. The diagnosis of simvastatin-induced thrombocytopenia was confirmed when the platelet count increased gradually to 152,000/ μ L during the follow-up examination.

PARAMETERS	RESULT(BEFORE STOPPING SIMVASTATIN)	RESULT(AFTER STOPPING SIMVASTATIN)	REFERENCE RANGE
HB	13.7g/dL	14g/dL	13-17g/dL
TLC	7,500 cells/ μ L	7,190 cells/ μ L	4,000–11,000 cells/ μ L
PLATELET	91 $\times 10^3$ / μ L	150 $\times 10^3$ / μ L	150–450 $\times 10^3$ / μ L

DISCUSSION:

Simvastatin induced thrombocytopenia is a rare and uncommon adverse drug response (ADR), with very few cases documented (nearly 330 cases were reported in VigAccess). The reaction is often reversible and may be dosage independent when the medication is stopped. In this case when the patient stopped taking Simvastatin, his thrombocytopenia (platelet count: 91,000/mm³) improved to 152,000/mm³, meeting the requirement for definite DITP.

In immune-mediated statin-induced thrombocytopenia, antibodies recognize platelet antigen in a drug-dependent manner, accelerating platelet clearance. The recovery of platelet count after drug withdrawal, the temporal association between drug exposure and thrombocytopenia, and the lack of other explanations are the key clinical factors that determine the diagnosis.

Causality can be assessed by using evaluation techniques such as the Naranjo adverse drug reaction probability scale. Most likely this case would be classified as probable simvastatin induced thrombocytopenia based on the temporal relationship of the event, de-challenge re-challenge reaction, and lack of other explanations.

The mainstay of DITP management is the immediate withdrawal of the offending agent. Most patient

have spontaneous recovery of platelet count within days to weeks. Platelet transfusions, intravenous immunoglobulin or corticosteroid should be reserved for severe thrombocytopenia or active bleeding. In this patient, conservative therapy including discontinuation of Simvastatin alone resulted in an uncomplicated recovery of platelets.

CONCLUSION:

We report a case of simvastatin associated thrombocytopenia in a patient with type 2 diabetes mellitus and dyslipidaemia. Simvastatin induced thrombocytopenia is a rare but reversible side effect. The rise in platelet count following withdrawal of simvastatin is consistent with the diagnosis of drug induced thrombocytopenia. This case emphasizes the importance of considering drug induced thrombocytopenia in patient with unexplained fall in platelet count.

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