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(CASE REPORT)

ELTROMBOPAG ASSOCIATED CEREBRAL VENOUS SINUS THROMBOSIS IN A CHILD WITH IMMUNE THROMBOCYTOPENIA PURPURA: A CASE REPORT

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ABSTRACT

Immune thrombocytopenia purpura (ITP) is initially treated with steroids, but TPO-RAs such as Eltrombopag are used for chronic cases. Although thromboembolic events associated with Eltrombopag have been reported in approximately 2–6% of treated patients, cerebral venous thrombosis is an uncommon and potentially serious manifestation. This case reports a 10-year-old female with ITP who developed dural sinus thrombosis on Eltrombopag initiation. Withdrawal of the drug and initiation of anticoagulants showed improvements highlighting the need for regular monitoring of platelet counts. Based on the Naranjo Adverse Drug Reaction Probability Scale and the WHO–UMC Causality Assessment Scale, the causality of the adverse drug reaction was classified as probable (Score=7).

Keywords: Dural sinus thrombosis, Cerebral Venous Thrombosis, Eltrombopag, Immune Thrombocytopenia Purpura, Anticoagulants

1 INTRODUCTION

According to the World Health Organization (WHO), adverse drug reactions (ADRs) are defined as "Any response to a drug that is noxious and unintended, and that occurs at doses typically used in humans for the prophylaxis, diagnosis, or therapy of disease or the modification of physiological function.

Immune thrombocytopenia (ITP) is a type of platelet disorder that develops when your blood does not clot as it should because of a low platelet count. (1) Individuals often present with symptoms of bleeding including petechiae, purpura, hematoma, epistaxis or hemoptysis.

In children the ASH guideline panel suggests corticosteroids i.e., suggests prednisone (2 - 4 mg/kg/day; maximum, 120 mg daily, for 5-7 days) rather than dexamethasone (0.6 mg/kg/day; maximum, 40 mg/kg/day, for 4 days) as first line treatment while for patients where corticosteroids are contraindicated or otherwise not preferred, intravenous immunoglobulin or anti-D immunoglobulin2 is suggested. Second-line therapies include Thrombopoietin receptor agonist (Eltrombopag or Romiplostim), Rituximab and Splenectomy. (2) Dapsone, azathioprine, mycophenolate mofetil,

and cyclophosphamide are older, cost-effective immunomodulators used when primary second-line choices fail, or as customized second- or third-line options depending on resource availability and patient profile. (3)

Eltrombopag, as the earliest nonpeptide and small molecule oral TPO-RA, can be administered orally and belongs to the current second-line treatment options for ITP. (4)

The treatment goal is to prevent bleeding symptoms by maintaining an adequate platelet level. Prednisolone, dexamethasone, and methylprednisolone are considered the first-line treatment. In an emergency setting, intravenous immunoglobulin and anti-D are also effective, but their effect of raising platelet level become transient. (5)

This case report details the sinus thrombosis associated with the use of Eltrombopag in a 10-year-old female with Immune thrombocytopenia purpura.

2 CASE PRESENTATION

A 10-year-old female weighing 50kg with known case of Immune thrombocytopenia purpura presented with complaints of headache for 1 week duration along with 1 episode of vomiting on the day of hospital admission. She had no history of fever, cough, vomiting, loose stools, chest pain, palpitations or any bleeding manifestations. Her physical examination was unremarkable. Her contrast MRI Venogram Brain showed absent contrast opacification of the right distal transverse, entire sigmoid sinus and proximal IJV suggestive of thrombosis. Linear non lumen occluding filling defect in the posterior superior sagittal sinus and is surrounded by contrast. Features are suggestive of dural sinus thrombosis.

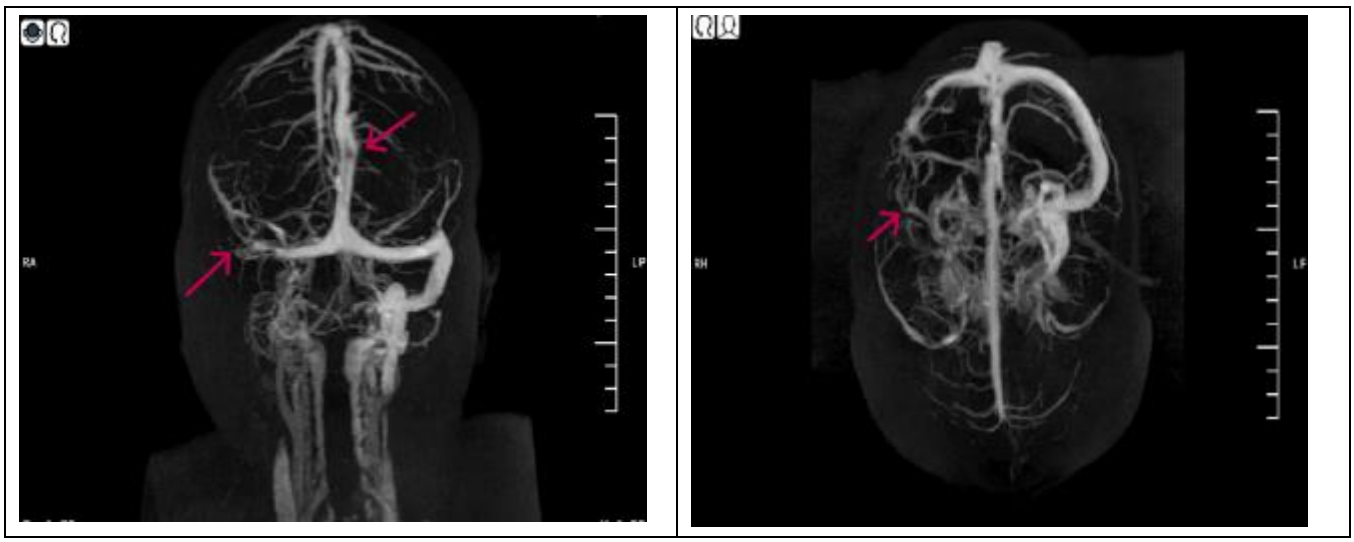

Figure 1 and 2: Absent contrast opacification of the right distal transverse, entire sigmoid sinus and proximal IJV suggestive of thrombosis. Linear non lumen occluding filling defect in the posterior superior sagittal sinus and surrounded by contrast.

Reference: PACS Believers Church Medical College Hospital

She was initiated on T. Prednisolone 50mg once daily (1 mg/kg) and T. Eltrombopag 50mg once daily for the past 5 months since the diagnosis of ITP. Her steroids were on a tapering dose. 2 months later she was also started on T. Azathioprine 50mg once daily due to decreasing platelet counts.

On presentation the blood investigations showed platelet count of 3.29 lakh/µL. While her platelet count was 0.12 lakh/µL prior to starting Eltrombopag 5 months back which then showed an increasing trend. Hence Eltrombopag was discontinued. Further contrast cerebral venograms showed improvement. She was initiated on Inj. Enoxaparin 60mg twice daily at the time of hospital admission and then switched to T. Rivaroxaban during discharge.

The patient was advised to follow up on OPD basis and monitor for any symptoms and platelet monitoring. Later on, her steroids were tapered and stopped and Azathioprine was switched to Dapsone.

We used WHO-UMC and Naranjo scale to determine the causality of this case and categorized it under probable/likely (score = 7). This adverse drug reaction was reported in the vigiflow for further analysis by National Coordination Center (NCC) under the Pharmacovigilance programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) Ghaziabad.

3 DISCUSSION

Immune thrombocytopenia (ITP) is a syndrome in which platelets become coated with autoantibodies to platelet membrane antigens, resulting in splenic sequestration and phagocytosis by mononuclear macrophages. The resulting shortened life span of platelets in the circulation, together with incomplete compensation by increased platelet production by bone marrow megakaryocytes, results in a decreased number of circulating platelets. (6)

Dural sinus thrombosis is a rare but serious adverse effect of Eltrombopag in patients with ITP. The diagnosis is often confirmed by an MRI, which shows filling defects in cerebral sinuses. Eltrombopag is an oral TPO-RA indicated for ITP refractory to steroids, immunosuppressants, or splenectomy, especially in patients at risk of bleeding. (7) Thrombopoietin receptor agonists (TPO-RAs) are hematopoietic growth factors that bind to the thrombopoietin receptors on megakaryocytes and hematopoietic stem cells, inducing the activation of Janus kinase/signal transducer and activator of transcription (JAK-STAT), mitogen-activated protein kinase pathway (MAPK), and phosphatidylinositol 3-kinase (PI3K-AKT) pathways. (3) Although effective, Eltrombopag has been linked to thromboembolic events, with cerebral venous thrombosis (CVT) being a rare complication.

Some other common adverse effects include nasopharyngitis, upper respiratory tract infection, thromboembolic events, alopecia, skin rash, abdominal pain, diarrhea, nausea, toothache, vomiting, xerostomia and urinary tract infection.

Management involves discontinuing Eltrombopag and initiating anticoagulant therapy with warfarin or low-molecular-weight heparin, followed by oral anticoagulants which shows a gradual clinical recovery. This management showed significant improvement in our patient following discontinuation of Eltrombopag and initiation of anticoagulants. Careful medication adjustment and close monitoring are crucial to avoid further complications. The decision to rechallenge Eltrombopag is controversial. Physicians should watch for symptoms such as headaches, blurry vision, fainting, losing control of a part of your body, and seizures in ITP patients being treated with TPO Ras.

Most reported cases suggest the need for close monitoring of platelet counts and symptoms suggestive of thrombosis in patients on TPO-Ras during the course of treatment. Early detection and prompt treatment and drug withdrawal are essential.

Abbreviations

- ITP: Immune thrombocytopenia
- TPO-RAs: Thrombopoietin Receptor Agonists
- CVT: Cerebral Venous Thrombosis
- OPD: Outpatient Department
- JAK-STAT: Janus kinase/signal transducer and activator of transcription pathway
- MAPK: mitogen-activated protein kinase pathway
- PI3K-AKT: phosphatidylinositol 3-kinase pathways

4 CONCLUSION

Dural sinus thrombosis is a rare but serious adverse effect of Eltrombopag in patients with ITP. Careful use and close monitoring are essential in prevent this event. Indications of initiation and tapering must be considered before TPO-RAs administration. Clinicians should maintain a high index of suspicion for cerebral venous thrombosis in children receiving Eltrombopag who present with persistent headache or vomiting despite improving platelet counts. Early detection and prompt treatment and drug withdrawal are essential to prevent thromboembolic events.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

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Disclosure of conflict of interest

There are no conflicts of interest.

Statement of informed consent

The authors certify that they have obtained all appropriate patient consent forms. The patient has consented to the reporting of clinical information in the journal. The patient understands that his name and initials will not be published and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

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