IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 11 Ver. 3 (November. 2018), PP 61-62
www.iosrjournals.org

Dabigatran (Pradaxa) Induced Liver Injury (Case Presentation)

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Abstract: *Dabigatran is a novel antithrombin anticoagulant that was approved by the FDA in 2010 to be used for the prevention of stroke and venous embolism in patients with chronic atrial fibrillation. In this article, we present a case of a 74-year-old Caucasian female who presented to the Emergency Department with acute lower GI bleeding and acute metabolic encephalopathy. The patient INR was 15.4, besides other labs abnormalities. The patient was found to have an acute live injury and acute renal failure that was believed to be induced by the recent start of Dabigatran to treat he Atrial fibrillation (AF). Patient condition improved with stopping the Dabigatran (Pradaxa) immediately, administering FFP, and Hemodialysis.*

Date of Submission: 28-10-2018 Date of acceptance: 14-11-2018

I. Introduction

Dabigatran is a novel antithrombin anticoagulant that was approved by the FDA in 2010 to be used for the prevention of stroke and venous embolism in patients with chronic atrial fibrillation. Dabigatran therapy has been associated with a moderate rate of serum enzyme elevations and rare instances of liver enzyme elevations and jaundice.

II. Case Presentation

This was a 74-year-old Caucasian female who presented to the Emergency Department with acute lower GI bleeding and acute metabolic encephalopathy. History was obtained from the patient's husband and her family members since the patient's altered mental status. They reported a rapid worsening of her symptoms over the two days before presentation. The patient has experienced a change in her cognitive ability, loss of appetite, and bleeding per rectum that was identified by the patient before the presentation. Patient's physical exam findings were Vitals: BP: 89/47, HR: 87bpm, RR: 20/min, Temp: 97.9 F, O2 Sat 100% RA. Look tired, not in distress and pale. Frank red blood in the per-rectal exam. Altered mental status. She has a Known history of Hypertension, Gout, Congestive Heart Failure, Type II Diabetes Mellitus and Atrial Fibrillation. The patient's list of medications (amlodipine 5 mg daily, valsartan 320 mg daily, rosuvastatin 10 mg daily, vitamin D 2000 units daily, and dabigatran 150 mg twice a day was started six weeks before presentation for atrial fibrillation by her cardiologist). The patient was admitted to the Intensive Care Unit (ICU), was started on Fresh Frozen Plasma plus Vita. K, Hemodialysis, IV Insulin, magnesium. The Patient was experiencing Gradual improvement of the INR with Fresh Frozen Plasma (FFP) and Vita. K during her hospital stay. During hospitalization, she experienced Afib. with RVR which was treated medically.

III. Laboratory Result

Table no 1: Shows Blood investigations parameters of the patient with the Dabigatran (Pradaxa) Induced Liver Injury.

CBC		Chemistry		LFTs		Other Labs	
WBC	20.6	Sodium (Na)	123	T.Bili	2.0	Magnesium	1.6
Hgb	11.1	Potassium (K)	7	T.Protein	6	Phosphate	3
Hct	33.3	Chloride (Cl)	98	Alk Phos	70	Calcium	8.4
Plt	264	CO2	14	AST	246	-	-
MCV	97.1	BUN	71	ALT	1111	INR	15.4
Seg	78.1	Creatinine	4.22	Albumin	3.4	PTT	111
Lymph	14.4	Glucose	274	-	-	PT	112

IV. Discussion

The mechanism of liver injury during dabigatran oral anticoagulant therapy is unknown but is likely to be idiosyncratic and perhaps immunologic. Dabigatran undergoes little hepatic metabolism and does not affect CYP 450 activity.A proper history and physical exam are essential. Recent use of Pradaxa is suggestive of drug-induced pathology. There are reports of Dabigatran (Pradaxa) induced Liver injury. The management should include stopping the Dabigatran (Pradaxa) immediately, administering FFP, and Hemodialysis.The improvement of the patient condition of Pradaxa-induced liver injury and the acute kidney injury was after starting the hemodialysis. Known complications of Pradaxa are Lower GI Bleeding, Gastritis-like symptoms, Wound secretion, Hematuria, Increased serum ALT (≥3 x ULN: 2% to 3%), Hematoma andDeath.

V. Conclusion

Given this information, the case is important in that it identifies a patient who presented with clinically severe hepatic dysfunction that onsets with dabigatran use, in the absence of another identifiable cause and that resolved with only withdrawal of dabigatran and starting hemodialysis as strong treatment option especially in case of kidney injury. Although not meeting all criteria for Hy's Law of drug-induced liver injury, the relationship between drug and side effect seems quite distinct. As such, it points to the need for ongoing monitoring of patients receiving this drug for rare cases of drug-induced hepatic dysfunction, especially in patients on other potentially hepatotoxic medications.

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Terad Talmesany M.D. "Dabigatran (Pradaxa) Induced Liver Injury (Case Presentation). " IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 17, no. 11, 2018, pp 61-62.