



AMLODIPINE INDUCED ANKLE EDEMA

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ABSTRACT Amlodipine is a calcium channel blockers which is used in the treatment of hypertension, angina and coronary artery disease. Amlodipine has lot of therapeutic uses but along with it there is occurrence of adverse drug reactions (ADRs) to it. The mechanism of action of the drug is it inhibits trans membrane influx of extracellular calcium ions across membranes of myocardial cells and vascular smooth muscle cells without changing serum calcium concentrations; this inhibits cardiac and vascular smooth muscle contraction, thereby dilating main coronary and systemic arteries. A female patient of age 32 years was admitted in the hospital with chief complaints of swelling of ankle and legs, dizziness, headache. Patient in past medical history identified with known case of hypertension and on medication 5mg of amlodipine twice daily since 1 week. Based on the above information suspected in as a probable adverse drug reaction. (Swelling of ankle and legs). patient is referred to physician to confirm the adr. On analysis of the case amlodipine is the drug given 5mg BD literature supports the above ADR. To know the effect we advised dechallenge test i.e. drug was withdrawn from treatment regimen and prescribed with an alternative regimen. In recent years there is increased number of amlodipine prescriptions. The case report there is probable relation between the amlodipine and swelling of ankle and legs. The case report is to highlight the use of amlodipine and also to create awareness regarding the edema and careful management of all the patients who receives the drug amlodipine. Better Pharmacovigilance can also prevent the above adverse drug reactions

KEYWORDS : Adverse Drug Reactions, Coronary Artery Disease, Dizziness.

INTRODUCTION:

Amlodipine is a calcium channel blockers which is used in the treatment of hypertension, angina and coronary artery disease. Amlodipine has lot of therapeutic uses but along with it there is occurrence of adverse drug reactions (ADRs) to it which can negatively impact the quality of life of patients as well as increase health care cost. Thus knowledge of amlodipine adrs is important to achieve safer treatment outcomes^[1].

Amlodipine blocks calcium from entering certain tissues and arteries. This makes it easier for them to relax so that blood can flow more easily to your heart. This in turn helps lower your blood pressure, and reduces your risk of heart attack or stroke^[2]. The mechanism of action of the drug is it inhibits Tran's membrane influx of extracellular calcium ions across membranes of myocardial cells and vascular smooth muscle cells without changing serum calcium concentrations; this inhibits cardiac and vascular smooth muscle contraction, thereby dilating main coronary and systemic arteries. Increases myocardial oxygen delivery in patients with vasospastic angina. Absorption is Bioavailability: 64-90%, Onset: 24-96 hours, Duration: 24 hours (antihypertensive effect), Peak plasma time: 6-12 hours Steady-state plasma levels are reached after 7-8 days of consecutive dosing Distribution is Protein bound: 93-98%; Volume of Distribution: 21 L/kg Metabolism: Extensively metabolized in liver by CYP3A4; Metabolites: Pyridine analogue (inactive); Elimination: Half-life: 30-50 hours; Excretion: Urine (10% [parent]; 60% [inactive metabolites])^[3]

CASE REPORT:

A female patient of age 32 years was admitted in the hospital with chief complaints of swelling of ankle and legs, dizziness, headache. Patient in past medical history identified with known case of hypertension and on medication 5mg of amlodipine twice daily since 1 week. Based on the above information suspected in as a probable adverse drug reaction. (Swelling of ankle and legs). patient is referred to physician to confirm the adr.

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CAUSALITY ASSESSMENT:

To evaluate the relation between the drug and reaction we performed causality assessment by using scales like WHO causality assessment scale, Naranjo's scale and observed ADR^[4,5, and 6]

Table 1: causality assessment of suspected ADR

ADR SCALE	WHO- CAS	NARANJO'S SCALE
ASSESSMENT	Probable	Probable

Table: 2 Analysis of observed ADR

SEVERITY ASSESSMENT	MODERATE LEVEL 4(a)
Preventability	Probably preventable
Predictability	Type – A

DISCUSSION:

The symptoms experienced by the patient on questioning understandable that adverse reaction in terms of pharmacokinetics, narrow therapeutic index and individual variability in metabolism and elimination, prolonged use of the medication at high dose. The patient developed adverse reaction after prolonged use of medication for 8 weeks. The patient was presented with symptoms of swelling of legs and ankle treatment with the amlodipine. The patient was improved after withdrawal of amlodipine and given with the supportive care for the adverse drugs reaction.

During the treatment course as a clinical pharmacist we have identified adverse reaction as follows: the patient under the medication with amlodipine adverse drug reaction has been identified based on literature reviews, on examination and other investigations. We concluded the condition due to drug carbamazepine performed causality assessment, severity, preventability, predictability. After identification we withdrawn the drug carbamazepine and provided appropriate treatment along with supportive care.

CONCLUSION:

In recent years there is increased number of amlodipine prescriptions.

The case report there is probable relation between the amlodipine and swelling of ankle and legs. The case report is to highlight the use of amlodipine and also to create awareness regarding the edema and careful management of all the patients who receives the drug amlodipine. Better Pharmacovigilance can also prevent the above adverse drug reactions

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