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ACECLOFENAC-INDUCED ANAPHYLACTIC SHOCK: A RARE BUT LIFE-THREATENING ADVERSE DRUG REACTION

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ABSTRACT

Aceclofenac is a widely prescribed nonsteroidal anti-inflammatory drug (NSAID) used in the management of pain and inflammatory disorders. Although generally considered safe and well tolerated, rare but severe hypersensitivity reactions such as anaphylactic shock may occur and can be life-threatening without prompt treatment. We report the case of a 39-year-old female who developed acute abdominal pain, irritability and hypotension shortly after ingesting oral aceclofenac for pain relief. On presentation, her blood pressure was 90/60 mmHg with maintained oxygen saturation. Laboratory investigations showed mild leukocytosis and elevated inflammatory markers, and she had no prior history of drug allergy. The close temporal association between drug intake and symptom onset suggested aceclofenac-induced anaphylaxis. Immediate discontinuation of the drug was undertaken, and the patient was treated with intramuscular adrenaline as first-line therapy, followed by intravenous corticosteroids, antihistamines and supportive care, resulting in rapid hemodynamic stabilization and complete recovery. Causality assessment using WHO–UMC criteria categorized the reaction as Probable/Likely, and the Naranjo Adverse Drug Reaction Probability Scale also indicated a Probable association. This case emphasizes the importance of early recognition, prompt adrenaline administration, structured causality assessment and pharmacovigilance reporting to prevent recurrence and improve patient safety.

KEYWORDS: Aceclofenac; Adverse drug reaction; Anaphylactic shock; Naranjo scale; WHO–UMC causality assessment.

INTRODUCTION

Aceclofenac is a phenylacetic acid derivative nonsteroidal anti-inflammatory drug (NSAID) with marked anti-inflammatory and analgesic properties. It is a potent inhibitor of cyclooxygenase (COX), a key enzyme in the synthesis of prostaglandins and thromboxanes, with selectivity for the COX-2 over COX-1 isoform. Aceclofenac was first approved in the EU in 1990 and launched in Spain in 1992. Since then, it has been approved for use in 69 countries worldwide and has an estimated exposure of about 171 million patients treated.[1]

Mechanism of action (MOA)

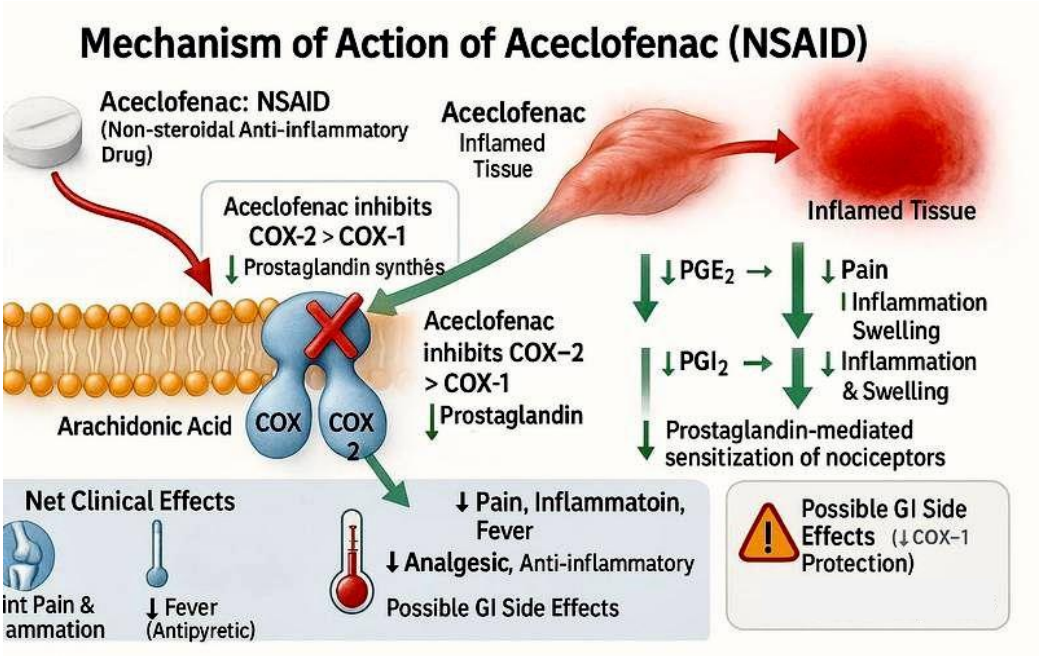

Fig. 1: Schematic representation of the mechanism of action of aceclofenac.[2]

Dose of Aceclofenac

- **Adult dose**: 100 mg orally twice daily
- **Special populations**: Not recommended during pregnancy or breastfeeding.[3]

Therapeutic uses of Aceclofenac

1. Anti-inflammatory and Analgesic Uses

- Management of acute and chronic inflammatory conditions.
- Relief of mild to moderate pain.

2. Rheumatic and Degenerative Disorders

- Rheumatoid arthritis: reduces joint inflammation, pain, swelling, and morning stiffness.
- Osteoarthritis (especially knee OA): effective symptom control with good tolerability.
- Ankylosing spondylitis: alleviates pain and inflammation.

3. Musculoskeletal Conditions

- Acute and chronic low back pain.
- Degenerative spinal disorders.

4. Gynecological Indications

- Treatment of primary dysmenorrheal.

5. Dental and Post-operative Pain

- Control of post-extraction and post-surgical dental pain.
- Management of post-operative orthopedic pain.

6. ENT and Infectious Conditions

- Symptomatic relief in acute viral pharyngoamygdalitis.

7. Long-term Use

- Suitable for short-term analgesia and long-term management of chronic inflammatory diseases due to favorable tolerability.[4]

Adverse effects

- Gastrointestinal adverse effects (most common; generally mild and reversible)
- Dizziness
- Vertigo
- Paraesthesia
- Tremor[5]

ANAPHYLACTIC SHOCK

Anaphylaxis is a systemic, type I hypersensitivity reaction that occurs in sensitized individuals resulting in mucocutaneous, cardiovascular and respiratory manifestations and can often be life threatening.[6]

Epidemiology

The anaphylaxis is a rare life-threatening hypersensitivity reactions.

- **Europe:** Incidence ranges from 1.5–7.9 per 100,000 person-years.
- **Turkey:** Incidence is 1.95 per 100,000 person-years, based on hospital admissions.
- **United States:**

✔ **Males:** 6.6 per 100,000 per year.

✔ **Females:** 8.7 per 100,000 per year.[7]

Etiopathogenesis

- **Medications:** Non-steroidal anti-inflammatory drugs, aspirin, antibiotics, opioid analgesics, insulin, protamine, general anesthetics, streptokinase, blood products, progesterone, radio contrast media, biologic agents and immunotherapy.
- **Foods:** Peanuts, treenuts, fish, shellfish, milk and eggs.
- **Hymenoptera venom:** Yellow jackets, hornets, wasps, honey bees and fireants
- **Miscellaneous:** Latex, exercise, gelatin, menstruation, seminal fluid, dialysis membranes.[6]

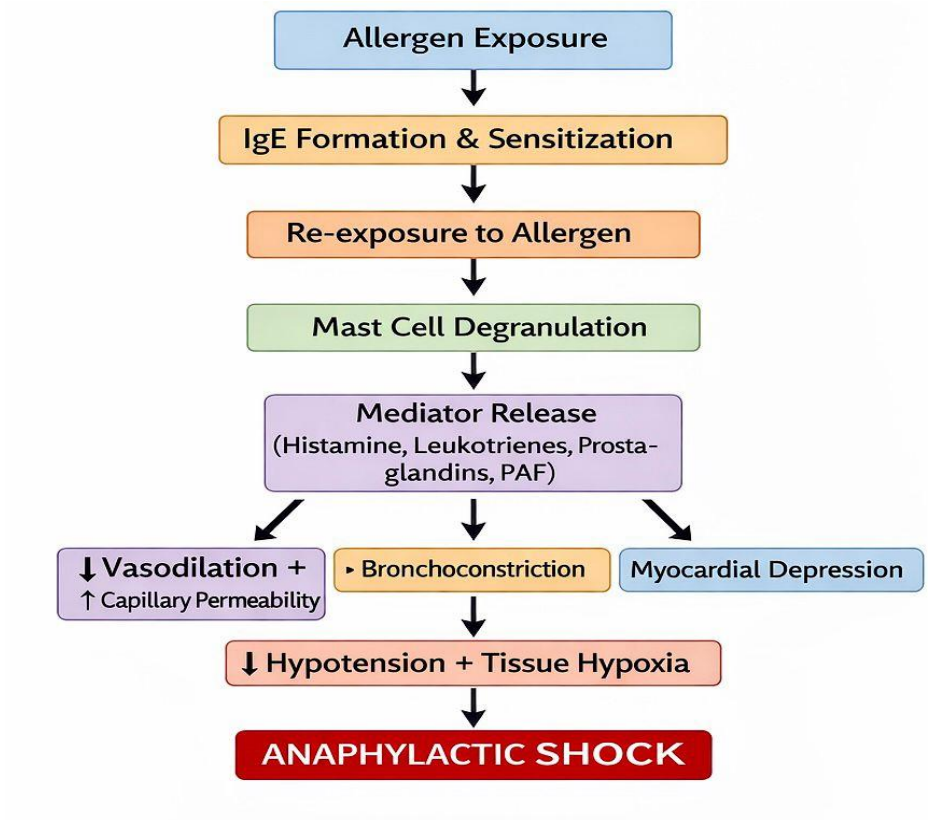

Fig. 2: Pathophysiological Cascade in Anaphylaxis.[8]

Clinical manifestations

- **Cutaneous:** Urticaria, Angioedema, Pruritus and Flushing.
- **Respiratory:** Dyspnea, Throat tightness, Wheezing, Rhinitis, Laryngeal edema and Hoarseness.
- **Oral and Gastrointestinal:** Intraoral angioedema, Emesis, Nausea, Abdominal cramps, Dysphagia, Oral pruritus and Diarrhea.
- **Cardiovascular:** Tachycardia, Pre syncope, Hypotension, Syncope, Shock, Chest pain, Bradycardia and Orthostasis.[6]

Diagnosis

Allergen tests used for the diagnosis of anaphylaxis include :

- Skin testing
- ✔ Prick test
- ✔ Intradermal testing
- ✔ Prick and intradermal
- ✔ Patch
- Serum tryptase, during anaphylaxis.
- Serum tryptase, baseline-after 24 h IgE.
- Methylhitamine level in urine.[7]

Treatment

Table 1: Pharmacological Management of Anaphylactic Shock.[6]

Therapy	Indication	Dosage	Goals
AIRWAY / CUTANEOUS REACTIONS			
Epinephrine (IM)	Bronchospasm, laryngeal edema, hypotension, urticaria, angioedema	0.3–0.5 mL of 1:1,000 solution IM, every 10 minutes as needed	Maintain airway patency, reduce fluid extravasation
Oxygen	Hypoxemia	Up to 100%	Maintain $SaO_2 > 90\%$
Albuterol	Bronchospasm	0.5 mL of 0.5% solution in 2.5 mL isotonic saline via nebulizer **or** 2 puffs by MDI every 15 min (up to 3 doses)	Maintain airway patency
Diphenhydramine	Urticaria	1–2 mg/kg or 25–50 mg parenterally	Reduce pruritus, antagonize histamine effects
Methylprednisolone	Bronchospasm	125 mg IV every 6 hours	Reduce late-phase reactions
CARDIOVASCULAR REACTIONS			
Epinephrine (IV)	Hypotension	1:10,000 solution IV at 1 µg/min initially, then 2–10 µg/min	Maintain systolic BP > 90 mm Hg
Intravenous fluids	Hypotension	1 L isotonic saline (0.9% NS) every 20–30 min as needed	Maintain systolic BP > 90 mm Hg
Ranitidine	Hypotension	50 mg in 20 mL D_5W infused over 10–15 min	Adjunct to epinephrine & IV fluids to maintain BP
SECONDARY THERAPY			
Norepinephrine	Hypotension	4 mg in 1 L D_5W at 2–12 µg/min	Maintain systolic BP > 90 mm Hg
Glucagon	Refractory hypotension	1 mg in 1 L D_5W at 5–15 µg/min	Increase heart rate & cardiac output

CASE PRESENTATION

A 39-year-old female patient was admitted to vijayanagara institute of medical science (VIMS), Ballari (Karnataka) with chief complaints of altered sensorium in the form of irritability and abdominal pain since night followed by intake of Tab. Aceclofenac 500mg for relieving of pain.

PAST HISTORY – Nothing significant.

FAMILY HISTORY – Nothing significant.

ON EXAMINATION

- BP - 90/60 mmHg.
- PR –60 bpm.
- SPO_2 - 98% decreased at RA.
- GRBS - 112mg/dl.
- Patient was conscious and oriented.
- B/L NVBS +VE
- S1 S2 heard.
- P/A was soft and non-tender.

Laboratory investigations

PARAMETERS	RESULT	REFERENCE RANGE
Total WBC	11500	4000-11000 cells/cumm
Neutrophiles	37	40-70%
Lymphocytes	48	20-40%
RBC Count	5.10	5.5-6.5 million/cumm
Platelet count	5.45	1.5-4.5 lakh/cumm
PCV	44.9	45-55%
MCH	26.4	27-34pg
MCHC	30.0	31-36%
RDW-CV	15.4	11.5-14.5%
CRP	7.2	0-6mg/l
Globulin	3.9	2.5-3g/dl
A/G Ratio	0.9	1.2-1.5
ALP	162	20-140U/L

- **Other investigations**

1. **Chest X-ray**:- Mild cardiomegaly.

Treatment chart

SL.NO	NAME OF MEDICATIONS	DOSE	ROUTE	FREQUENCY
1.	INJ.HYDROCORT	100mg	IV	BD FOR 1 DAY
2.	TAB.CETIRIZINE	10mg	PO	BD FOR 1 DAY
3.	INJ.CHLORPHENIRAMINE MALEATE	2CC	IM	OD FOR 1 DAY
4.	INJ.PANTOPRAZOLE	40mg	IV	OD FOR 1 DAY
5.	INJ.ADRENALINE	0.5CC	IM	GIVEN STAT
6.	INJ.DEXAMETHASONE	4CC	IV	GIVEN STAT

DISCUSSION

Aceclofenac is a very commonly used NSAID for pain and inflammation and is generally considered safe. However, like other NSAIDs, it can rarely trigger severe hypersensitivity reactions such as anaphylaxis. Anaphylactic shock is a medical emergency because it can progress rapidly and become fatal if treatment is delayed. In this patient, symptoms developed soon after taking aceclofenac and she presented with hypotension and systemic complaints. This strong time relationship between drug intake and symptom onset makes aceclofenac the most likely trigger. Even though many cases of anaphylaxis show obvious skin symptoms like rashes or swelling, it is important to remember that some patients may mainly present with cardiovascular features such as low blood pressure and altered sensorium, as seen in this case. One of the most important aspects of this case was the clear clinical improvement after immediate withdrawal (dechallenge) of aceclofenac. Stopping the suspected drug early is crucial because continued exposure can worsen the reaction and increase the risk of shock. The patient's recovery after dechallenge, along with prompt emergency management, supports the diagnosis of aceclofenac-induced anaphylactic shock. The patient improved significantly after receiving intramuscular adrenaline, which is the first-line and most life-saving treatment in anaphylaxis. Additional medications such as antihistamines and corticosteroids were given as supportive therapy to control symptoms and reduce the risk of recurrence. The favourable outcome in this case highlights how early recognition, immediate dechallenge, and timely adrenaline administration can lead to rapid stabilization and recovery. This case serves as an important reminder that even routine and frequently prescribed drugs like aceclofenac can occasionally cause life-threatening reactions. Proper documentation, patient counselling to avoid re-exposure, and reporting to pharmacovigilance systems are essential to prevent recurrence and improve drug safety monitoring.

CONCLUSION

Aceclofenac-induced anaphylactic shock is a rare but potentially fatal adverse drug reaction. This case highlights the importance of early clinical suspicion, immediate discontinuation (dechallenge) of the suspected drug and prompt administration of intramuscular adrenaline to achieve rapid clinical recovery. Clinicians should remain vigilant for severe hypersensitivity reactions even with commonly prescribed NSAIDs and patients must be counselled to avoid re-exposure. Reporting such events is essential to strengthen pharmacovigilance and improve patient safety.

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