

# Evaluation of Adverse Drug Reactions Associated with Monocef(ceftriaxone) in a 65-Year-Old Male with Hypertension and COPD: A Case Study

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## Abstract:

A 65-year-old male with a history of hypertension and chronic obstructive pulmonary disease (COPD) was admitted with complaints of cough, shortness of breath, fever, and fatigue. Initial treatment included multiple medications, among which Monocef (Ceftriaxone) was suspected to cause adverse drug reactions, specifically loose stools. Two days into treatment, the patient developed loose stools, which resolved after the discontinuation of Monocef (Ceftriaxone). Using the Naranjo Adverse Drug Reaction Probability Scale, the reaction was determined to be probable (score of 6). The patient's condition improved over the course of four days, and he was discharged in stable condition on the fifth day. This case highlights the importance of monitoring for adverse drug reactions in elderly patients with comorbidities, as well as adjusting treatment based on observed symptoms.

**Key words:** 65-year-old male; adverse drug reaction (ADR); naranjo scale; ceftriaxone; loose stools

## Introduction

Monocef 1 gm Injection contains ceftriaxone, which is a broad-spectrum cephalosporin antibiotic effective against various bacterial infections, including infections of the brain (e.g., meningitis), lungs (Pneumonia), ear, urinary tract, skin and tissues, joints, blood and heart. Research indicates that ceftriaxone is crucial in treating gonorrhoea, particularly with increasing resistance; a single 1 g dose can effectively eradicate most ceftriaxone-susceptible and some resistant strains [1]. The preparation of ceftriaxone for injection involves careful manufacturing processes to minimize impurities, which can affect its stability and compatibility with other solutions, such as calcium-containing ones [2][3]. Additionally, ceftriaxone functions by inhibiting bacterial cell wall synthesis, leading to cell death, and is often combined with sulbactam to enhance its efficacy against beta-lactamase-producing bacteria [5]. The pharmacokinetics of ceftriaxone, including its concentration at the surgical site, supports its use in various clinical settings, ensuring effective treatment outcomes [4].

The higher the score, the more likely the adverse drug reaction (ADR) is considered to be caused by the drug. Questions with a score [6], The Naranjo Adverse Drug Reaction Probability Scale is a tool used to determine the likelihood that an adverse drug reaction (ADR) is related to

a specific medication. It scores various factors, leading to a total score that categorizes the relationship between the drug and the ADR as certain, probable, possible, or doubtful. Naranjo Scale Interpretation as

- 1. Certain** (Score of nine or more): The ADR is clearly related to the drug.
- 2. Probable** (Score of five to eight): There is evidence to suggest that the ADR is likely due to the drug.
- 3. Possible** (Score of one to four): The ADR may be related, but the evidence is not strong.
- 4. Doubtful** (Score of zero or less): The ADR is unlikely related to the drug.

The Naranjo Scale is a widely used tool for assessing the causality of adverse drug reactions (ADRs), categorizing them into four levels: certain, probable, possible, and doubtful based on a scoring system. A score of nine or more indicates a "Certain" relationship, suggesting the ADR is clearly linked to the drug. Scores between five and eight classify the ADR as "Probable," [9-10] indicating a likely connection. Scores of one to four denote a "Possible" relationship, where evidence is

insufficient, while a score of zero or less suggests a "Doubtful" association, implying the ADR is unlikely related to the drug [7]. However, inter-rater agreement between the Naranjo algorithm and the WHO-UMC system has shown minimal concordance, highlighting the need for improved methodologies in causality assessment [8]. Additionally, automated algorithms, including Bayesian approaches, are being explored to enhance the efficiency of ADR screening [8].

## Case Report

A 65-year-old male presented with a week-long history of cough, shortness of breath, fever, tiredness for four days, but no vomiting, abdominal pain, or prior allergies. The patient had a medical history of hypertension and chronic obstructive pulmonary disease (COPD). The initial treatment included Monocef(ceftriaxone) 1gm BD, capsule doxycycline 100mg BD, injection Pentocid 40mg BD, inj. Paracetamol 1gm BD, Tablet Montek Lc levocetirizine and montelukast and inhaler Seroflo 250 (salmeterol and fluticasone propionate), injection diclofenac sodium 75 TID, tablet amlodipine 5mg BD, tablet paracetamol 650mg BD. After two days, the patient experienced three episodes of loose stools per day and body pain. The doctor adjusted the medication by stopping Dolo and Monosave and starting Paracetamol and Providec, along with Magnus. Following these changes, the patient's loose stools resolved, but body pain and underlying conditions like bilateral pneumonia, COPD, and hypertension persisted.

## Discussion

To evaluate the likelihood that Monocef(ceftriaxone) caused the loose stools in this patient using the Naranjo Adverse Drug Reaction Probability Scale, we can go through the scale's questions and assign scores accordingly.

### Naranjo Scale Assessment for Monocef(ceftriaxone):

#### 1. Are there previous conclusive reports on this reaction?

Answer: No. (Score: 0)

#### 2. Did the adverse event appear after the suspected drug was administered?

Answer: Yes, loose stools occurred after starting Monocef. (Score: 2)

#### 3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?

Answer: Yes, the loose stools resolved after stopping Monocef. (Score: 1)

#### 4. Did the adverse reaction reappear upon re-exposure to the drug?

Answer: Not applicable; the patient was not re-exposed. (Score: 0)

#### 5. Are there alternative causes (other than the drug) that could have caused the reaction?

Answer: No, other causes are less likely given the timeline. (Score: 2)

#### 6. Did the reaction occur after the drug was given at a recommended dose?

Answer: Yes. (Score: 1)

#### 7. Was the patient previously aware of the potential for the reaction?

Answer: No previous allergy now as told. (Score: 0)

**we have total score calculation were found to be:**  $0 + 2 + 1 + 0 + 2 + 1 + 0 = 6$  (that is probable).

**Interpretation:** With a total score of six, according to the Naranjo Scale, this indicates that the ADR is Probable [Naranjo CA, et al]. This suggests that it is likely that Monocef(ceftriaxone) caused the loose stools. In this case, a 65-year-old male presented with cough, shortness of breath, fever, and fatigue, along with a medical history of hypertension and chronic obstructive pulmonary disease. After receiving multiple medications, the patient developed loose stools, which occurred shortly after starting Monocef(ceftriaxone). Using the Naranjo Adverse Drug Reaction Probability Scale, the assessment yielded a total score of six, indicating that the loose stools were Probable to be caused by Monocef(ceftriaxone). The reaction improved after discontinuation of Monocef(ceftriaxone), supporting the likelihood of the drug's role in this adverse effect. Ultimately, while the loose stools resolved, the patient continued to experience underlying conditions, including bilateral pneumonia, COPD, and hypertension. Monitoring and appropriate management of these conditions remain necessary.

## Result

A 65-year-old male, admitted from the general ward with a history of hypertension and chronic obstructive pulmonary disease (COPD), presented with cough, shortness of breath, fever, and fatigue. The patient was treated with a combination of medications, including Monocef(ceftriaxone). After two days, the patient developed loose stools and body pain, prompting a change in medication by the attending physician. Monocef(ceftriaxone) was discontinued, and the loose stools resolved afterwards. Using the Naranjo Adverse Drug Reaction Probability Scale, the assessment yielded a score of 6, suggesting a Probable relationship between Monocef(ceftriaxone) and the development of loose stools. The resolution of symptoms following the discontinuation of Monocef(ceftriaxone) further supports this connection. The patient's underlying conditions, such as bilateral pneumonia, COPD, and hypertension, persisted, requiring continued monitoring and treatment. This case underscores the need for careful observation of ADRs, especially in elderly patients with multiple comorbidities. Further management should focus on optimizing treatment for the patient's primary health issues while minimizing drug-related side effects.

## Conclusion

The adverse reaction to Monocef(ceftriaxone) which was likely responsible for the loose stools, was effectively managed by stopping the drug. The patient's underlying conditions—COPD, hypertension, and pneumonia were monitored, and he responded well to treatment. His recovery and eventual discharge highlight the importance of careful medication management in elderly patients with comorbidities.

**Ethical approval and informed consent:** Our institute doesn't impose ethical approval for case study reports. Nevertheless, written informed consent for the publication of this case report was obtained from the patient the identification details (Name and address) of the patient were kept in privacy as requested. The patient understood that any information that disclosed her identification would not be published.

**Declaration of conflicting interests:** No potential conflicts.

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